

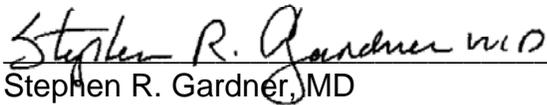
**PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS
SUBMITTED BY
THE JOINT PHARMACIST ADMINISTERED VACCINES COMMITTEE
AND
REVIEWED, REVISED AND APPROVED BY
THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS**

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PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

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PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

I. Introduction

To help increase the vaccination rates in South Carolina, the South Carolina General Assembly enacted an amendment to the Pharmacy Practice Act that authorizes the Board of Medical Examiners to determine whether a specific vaccine is appropriate for administration by a licensed pharmacist without a written order or prescription of a practitioner. If a vaccine is approved for administration, the Board of Medical Examiners shall issue a written protocol for the administration of vaccines by licensed pharmacists without an order or prescription of a practitioner.

II. Authorization

Subject to the requirements of this Protocol, pharmacists meeting the qualifications specified in Section III below and applicable law and regulation may:

- (a) determine the vaccination needs in accordance with the current schedule recommended by the Advisory Committee on Immunization Practices of the US Centers for Disease Control (CDC) and Prevention (ACIP)¹;
- (b) screen all patients for contraindications and precautions for vaccine(s) needed using screening questions for all vaccines (Appendix C), live vaccines (Appendix D), and vaccine-specific screening as set forth in other Appendices as stipulated in this Protocol;
- (c) administer vaccines according to directions provided in section XII of this Protocol; and
- (d) administer epinephrine and diphenhydramine in response to acute allergic reactions precipitated by vaccination as delineated in this Protocol.

III. Qualifications

A pharmacist or pharmacy intern supervised by a pharmacist seeking authorization to administer vaccines pursuant to this Protocol shall meet the following qualifications:

- (a) Licensure -The pharmacist must be licensed and in good standing with the South Carolina Board of Pharmacy. The pharmacy intern must be certified and in good standing with the South Carolina Board of Pharmacy.
- (b) Basic Life Support (BLS) or Cardiopulmonary Resuscitation (CPR) Certification -The pharmacist and pharmacy intern must complete one of the certification courses listed below, possess a valid course completion card, and the certification must be renewed every 2 years:
 1. The American Heart Association BLS for Healthcare Providers Course or
 2. The American Red Cross Adult and Pediatric CPR/AED Course.
- (c) Training -The pharmacist and pharmacy intern must complete an approved pharmacy-based immunization training program that is accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current CDC guidelines and must include study materials, hands-on training, and techniques for administering vaccines and must provide instruction and experiential training in the following content areas:
 - (1) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

¹ In the event of a conflict between information provided in package inserts and ACIP recommended guidelines, pharmacists administering vaccines pursuant to this Protocol should adhere to ACIP guidelines.

- (2) standards for vaccination practices;
- (3) basic immunology and vaccine protection;
- (4) vaccine-preventable diseases;
- (5) recommended immunization schedules;
- (6) vaccine storage management;
- (7) biohazard waste disposal and sterile techniques;
- (8) informed consent;
- (9) physiology and techniques for vaccine administration;
- (10) pre-vaccine and post-vaccine assessment and counseling;
- (11) vaccine record management;
- (12) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
- (13) understanding of vaccine coverage by federal, state, and local entities;
- (14) needle stick management.

A list of approved programs is specified in Appendix A.

- (d) Continuing Education -The pharmacist must complete at least one hour of CME category I, or ACPE-approved continuing education related to the administration of vaccines as part of his or her annual license requirements.
- (e) Liability Insurance -The pharmacist must maintain liability insurance that covers the administration of vaccines.

IV. Limitations on Pharmacy-based Vaccination

- (a) Age -The administration of the non-influenza vaccines without a written order or prescription pursuant to this Protocol must not be to any persons under the age of eighteen (18) years. The administration of influenza vaccines without a written order or prescription pursuant to this Protocol may not be to any persons under the age of twelve (12) years.
- (b) Delegation -A pharmacist may not delegate the administration of vaccines to a pharmacy technician or any other person who is not a pharmacist or pharmacy intern meeting the requirements set forth in III (a), (b) and (c) of this Protocol and any other applicable law and regulation. The qualified pharmacy intern must be under the direct supervision of the pharmacist.
- (c) Patient Specific Factors- Potential vaccinees with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary care practitioner.

V. Protocol, Facility and Equipment

Pharmacists who administer vaccines under this Protocol shall maintain a current copy of this Protocol at each location at which a pharmacist administers a vaccine, and an appropriate area for administering vaccines with the supplies and equipment listed in Appendix B.

VI. Informed Consent

Before receiving the vaccine, the vaccinee (or his or her legal representative) must be given information about the risks and benefits associated with vaccination.

- (a) Consent Form -Any pharmacist administering vaccines pursuant to this Protocol must document the vaccinee or the vaccinee's legal representative's informed consent in writing prior to administration of a vaccine. Either the pharmacist or the qualified pharmacy intern and the

supervising pharmacist must be identified on the consent form. The required consent form language is provided in Appendix E.

- (b) Vaccine Information Statements - Each vaccinee, or his or her legal representative, must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine provided. The vaccinee or legal representative must be given the opportunity to read the VIS prior to administration of the vaccine, and the pharmacist must provide answers to any questions raised. Non-English speaking persons must receive a copy of the VIS in their native language, if available.

VII. Pharmacy-based Vaccination Record

A pharmacist or qualified pharmacy intern supervised by a pharmacist administering a vaccine pursuant to this Protocol must create a vaccination record for each vaccinee, and must maintain this record for a period of at least ten (10) years for patients at least 18 years old and at least thirteen (13) years for patients less than 18 years old. This vaccination record must be readily accessible and shall include the following:

- (a) The name, address, date of birth, gender and telephone number of the vaccinee;
- (b) A copy of the vaccinee's responses to eligibility questionnaires;
- (c) The name, dose, manufacturer, and lot number of the vaccine administered;
- (d) The date of the administration of the vaccine and the injection site;
- (e) A signed and dated consent form by which the vaccine recipient acknowledges receipt of the VIS and consents to the administration of the vaccine;
- (f) A record of any adverse events or complications that arose following vaccination;
- (g) The name, address, license number, and telephone number of the administering pharmacist or the pharmacist supervising the administering pharmacy intern; and
- (h) A copy of the notification letter sent to the vaccinee's designated primary care practitioner of any vaccine administered.

VIII. Reporting Requirements

- (a) Personal Immunization Record -The pharmacist must encourage all vaccinees to carry a personal immunization record card in their wallet. The pharmacist must provide and record the date of vaccination on the vaccinee's personal immunization record card.
- (b) Medical Home Notification -Vaccinees must be informed regarding the importance of having a medical home and receiving other preventive medical services. When a vaccinee receives a vaccine, this shall be reported to their designated primary care practitioner. The required language is provided in the reporting form in Appendix F.
- (c) Immunization Registry – A pharmacist administering vaccinations without an order or prescription of a practitioner shall report administration of all vaccinations to the South Carolina Immunization Registry in compliance with regulations established by the Department of Health and Environmental Control as the department may require; provided, however, that the phase-in schedule provided in Regulation 61-120 for reporting vaccinations does not apply to vaccinations administered pursuant to S.C. Code Ann. Section 40-43-190(B).
- (d) Adverse Event Reporting -The pharmacist shall report any clinically significant event that occurs following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS), even if it is not certain that the event was caused by the vaccine. Clinically significant events include, but are not limited to: death, hypersensitivity reactions, and those events described in the manufacturer's package insert as contraindications to additional doses of vaccine.

IX. Vaccination Safety

- (a) Infection Control and Sterile Technique -Pharmacists and qualified pharmacy interns administering vaccines must follow appropriate precautions to minimize risk for spread of disease. Hands must be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water between each contact. Gloves must be worn if the pharmacist administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on his or her hands. Needles used for injections must be sterile and disposable to minimize the risk for contamination.
- (b) Prevention of Needle-stick Injuries -To prevent inadvertent needle-stick injury or reuse, needles and syringes must be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices should be used to reduce the risk for injury.
- (c) Hepatitis B Vaccine -Pharmacists and qualified pharmacy interns who administer vaccines shall receive the hepatitis B vaccine series unless: (1) the pharmacist has previously received the complete hepatitis B vaccination series, (2) antibody testing has revealed that the pharmacist or qualified pharmacy intern is immune, (3) the vaccine is contraindicated for medical reasons, or (4) the pharmacist or qualified pharmacy intern signs a Hepatitis B Vaccine Declination statement.
- (d) Occupational Safety and Health Administration (OSHA) Compliance -Pharmacists must document compliance with OSHA regulations and applicable state law and regulations regarding the storage and disposal of injection supplies and the disposal of, and prevention of exposure to, biological hazards.

X. Management of Adverse Events

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, vaccinees must be carefully screened for precautions and contraindications before the vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g. soreness, itching) to severe and life threatening (e.g. anaphylaxis). If reactions occur, the pharmacists must be prepared with procedures for their management. The procedures for managing adverse reactions are set forth in Appendix G.

XI. Supply Considerations

The supply of vaccines and the timing of distribution cannot be guaranteed. If supplies of the vaccines are delayed or limited, the pharmacist must comply with state and national guidance and directives for the tiered use of vaccines, and must cooperate with health officials and local practitioners to insure that limited supplies of vaccines are targeted to and reserved for those persons at higher risk for disease and disease-related complications.

XII. Vaccines

Pharmacists may administer US Food and Drug Administration (FDA) approved formulations of the vaccines listed below, alone or in combination, without an order from a licensed practitioner provided they follow all requirements set forth in this Protocol, assess patient eligibility according to indications, precautions, and contraindications recommended in current guidelines from the ACIP, and adhere to dosing and administration information provided by the package inserts and ACIP recommended guidelines. Pharmacists must make every effort to assure that vaccination series are completed.

1. Haemophilus Influenzae
2. Hepatitis A
3. Hepatitis B
4. Human Papillomavirus
5. Influenza
6. Measles, Mumps, Rubella
7. Meningococcal (MCV4 and MenB)
8. Pneumococcal (PPSV23 and PCV13)
9. Tetanus and diphtheria/Tetanus, diphtheria, and pertussis (Td/Tdap)
10. Varicella
11. Zoster

APPENDIX A

APPROVED PHARMACY-BASED IMMUNIZATION TRAINING PROGRAMS

The Pharmacy Practice Act requires that pharmacists and pharmacy interns seeking authorization to administer vaccines complete an accredited training course. The course must comply with current CDC guidelines, as those guidelines may be revised from time to time, and must include study materials, hands-on training, and techniques for administering vaccines, and must provide instruction and experiential training in the following content areas:

- (a) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
- (b) standards for adult immunization practices;
- (c) basic immunology and vaccine protection;
- (d) vaccine preventable diseases;
- (e) recommended vaccination schedules;
- (f) vaccine storage management;
- (g) biohazard waste disposal and sterile techniques;
- (h) informed consent;
- (i) physiology and techniques for vaccine administration;
- (j) pre-vaccine and post-vaccine assessment and counseling;
- (k) vaccine record management;
- (l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
- (m) understanding of vaccine coverage by federal, state, and local entities; and
- (n) needle stick management.

A pharmacist or qualified pharmacy intern may demonstrate satisfaction of the training criteria for this Protocol by submission of the following:

- (a) A certificate of achievement for the American Pharmacists Association's "Pharmacy-based Immunization Delivery" training program; or
- (b) A certificate of achievement for the Ohio Pharmacists Association Immunization Training Program; or
- (c) A certificate of achievement for completion of alternative training programs jointly pre-approved by the South Carolina Board of Pharmacy and the South Carolina Board of Medical Examiners.

APPENDIX B

REQUIRED SUPPLIES AND EQUIPMENT

The following items must be available in the area where vaccines are administered:

- (1) A current copy of this Protocol.
- (2) A supply of the most current federal VIS for vaccines being administered, or electronic access to these statements.
- (3) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (i.e., EpiPen). If an EpiPen is to be stocked, at least four adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available.
- (4) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules or liquid.
- (5) Syringes: 1-mL and 3-mL, 22g and 25g, 1-inch, and 1 ½-inch needles for epinephrine and diphenhydramine.
- (6) Alcohol swabs and bandages.
- (7) Blood pressure monitoring device or stethoscope and sphygmomanometer (with pediatric, adult and extra-large cuffs).
- (8) Adult and pediatric size pocket masks with one-way valve.
- (9) Flashlight with extra batteries (for examination of mouth and throat).
- (10) Time-keeping device with ability to count seconds.
- (11) Telephone access.
- (12) Equipment to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine, such as a mat or a reclining chair.

APPENDIX C

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

Below is a list of general screening questions a pharmacist or qualified pharmacy intern must ask a patient prior to administration of any vaccine. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and manufacturer's package inserts. Pharmacists must document relevant responses and explanations provided in response to the screening questions.

1. Are you sick today? If yes, ask these additional questions:
 - Do you have a new fever?
 - Do you have a cough?
 - Do you have diarrhea?
 - Have you been vomiting?
2. Have you ever fainted or felt dizzy after receiving a vaccine?
3. Have you ever had a reaction after receiving a vaccine?
4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?
5. Do you have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?
6. Do you have allergies to latex, medications, food or vaccines? (Examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)
7. Have you ever had a seizure disorder for which you are on seizure medications, a brain disorder, Guillain-Barré syndrome or other nervous system problems?
8. For women: Are you pregnant or considering becoming pregnant in the next month?

Precaution

Precaution must be taken before administering any vaccine to potential vaccinees with moderate or severe acute illness, with or without fever. Vaccination should be delayed until the illness has resolved.

Referrals

Potential vaccinees with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary care practitioner.

APPENDIX D

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF LIVE VACCINES

Below is a list of screening questions a pharmacist must ask a patient prior to administration of a live vaccine (in addition to the questions listed in Appendix C). This is a list of general questions. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to ACIP guidelines.

1. Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actemra, Cytoxan, Rituxan, adalimumab, infliximab or etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?
2. Have you received any vaccinations or skin tests in the past four weeks?
3. Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?
4. Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

APPENDIX E

CONSENT FOR VACCINE ADMINISTRATION

This pharmacy is providing necessary vaccines to you in a safe and convenient setting in order to promote adherence to current immunization guidelines recommended by the CDC and ACIP. It does not take the place of an ongoing relationship with your primary care provider to address ongoing medical issues and other types of preventive care. We are providing your primary care provider with records of the vaccine(s) administered here so that your medical records may be complete, but be sure to take your personal record with you to your next appointment as well.

Please review the statement below confirming your consent for vaccination and provide the information requested.

I have read, or had explained to me, the Vaccine Information Statement for the [NAME OF] vaccine. I understand the risks and benefits, and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I wish to receive the [NAME OF] vaccine and hereby give consent for [PHARMACIST OR PHARMACY INTERN AND SUPERVISING PHARMACIST NAME(S)] to administer the [NAME OF] vaccine and communicate the administration of the vaccine to my primary care practitioner, who is listed below.

Vaccine recipient's name

Vaccine recipient's date of birth

Vaccine Recipient's (or legal representative's) signature

Date

VIS Date

Vaccine recipient's designated primary care practitioner

APPENDIX F

NOTIFICATION LETTER

Dear Healthcare Provider at [vaccinee's primary care clinic]:

We have recently provided vaccination services to one of your patients. A personal immunization record card was filled out and given to the patient. We want to make certain that you also have this information so that you can update your patient's medical record. Please contact us if you have any questions about this information.

Vaccinee's name: _____

Vaccinee's Date of Birth: _____

The vaccine that was given on _____ is listed below.

Vaccine Given: _____

Dose: _____

Method: IM / SQ

Location: Right / Left Arm

Lot #: _____

Manufacturer: _____

Expiration Date: _____

Administering Pharmacist or Pharmacy Intern

Pharmacist Supervising Administering Pharmacy Intern
(If applicable)

Contact Information for Administering or Supervising Pharmacist

APPENDIX G

PROCEDURES FOR MANAGEMENT OF ADVERSE REACTIONS TO VACCINES

Anaphylactic Reactions

Signs and symptoms of anaphylactic reaction include:

- the sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives);
- angioedema (swelling of the lips, face, or throat);
- bronchospasm (wheezing);
- shortness of breath;
- shock;
- abdominal cramping; or
- cardiovascular collapse.

The following procedures should be used to manage anaphylactic reactions following vaccination:

- (1) If itching and swelling are confined to the injection site where the vaccination was given, observe the vaccinee closely for at least 30 minutes, watching for the development of generalized symptoms.
- (2) If symptoms are generalized, activate the emergency medical system (e.g., call 911) immediately. This should be done by a second person, while the pharmacist assesses the level of consciousness, circulation, airway and breathing of the vaccinee.
- (3) Place vaccinee in a recumbent position and elevate legs.
- (4) The first-line therapy in anaphylaxis is epinephrine. There are no contraindications to epinephrine in the setting of anaphylaxis.
 - (a) Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01mL/kg/dose (adult dose ranges from 0.3mL to 0.5mL, with a maximum single dose of 0.5mL), as indicated:

Ampules or vials of solution:

Weight (lbs)	Weight (kg)	Epinephrine Dose
22-44 lbs	10-20 kg	0.15mg (or mL)
45-88 lbs	21-40 kg	0.30mg (or mL)
89-110 lbs	41-50 kg	0.45mg (or mL)
111 lbs+	51 kg+	0.50mg (or mL)

Prefilled devices (i.e., EpiPen Jr. / EpiPen):

Weight (lbs)	Weight (kg)	Epinephrine Dose
33-66 lbs	15-30 kg	EpiPen®Jr - 0.15mg
>66 lbs	>30 kg	EpiPen® - 0.30mg

The site of injection can be gently massaged to facilitate absorption.

- (b) If EMS has not arrived and symptoms are still present, the dose of epinephrine may be repeated every 5 to 15 minutes for up to 3 doses, depending on the patient's response.

- (5) Antihistamines may be given for hives or itching. Administer diphenhydramine either orally or by intramuscular injection. The standard dose is 1-2 mg/kg every 4-6 hours, up to 100 mg maximum single dose for adults, and 50 mg maximum single dose for children and adolescents. Do not attempt to give oral medications to a vaccinee who is not fully alert and able to swallow safely. Refer to the dosing chart below:

Age Group	Weight (lbs)	Weight (kg)	Diphenhydramine Dose (Injectable dose based on 50 mg/ml solution)
1-6 months	9-15 lbs	4-7 kg	5 mg (0.1 mL)
7-36 months	16-31 lbs	8-14 kg	10-15 mg (0.2-0.3mL)
37-59 months	32-42 lbs	15-19 kg	20 mg (0.4mL)
5-12 yrs.	43-99 lbs	20-45 kg	30-40 mg (0.6-0.8mL)
13 yrs. and older	100+ lbs	46+ kg	50-100 mg (1-2 mL)

- (6) Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.
- (7) Stay with vaccinee until EMS arrives.
- (8) If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.
- (9) Keep vaccinee in supine position unless he or she is having breathing difficulty. If breathing is difficult, vaccinee's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
- (10) Record all vital signs, medications administered to the vaccinee (including the time, dosage, response, and the name of the person who administered the medication), and other relevant clinical information contemporaneously in an adverse reaction medication log to be maintained by the pharmacy, a copy of which may be provided to EMS and/or the vaccinee's primary care provider. An Adverse Reaction Medication Log form is attached hereto as Appendix G-1.
- (11) Notify the vaccinee's primary care practitioner as soon as possible. All vaccinees experiencing anaphylactic reactions must be referred for evaluation, even if symptoms resolve completely.

References

Immunization Action Coalition. *Medical Management of Vaccine Reactions in Adult Patients*. Retrieved from <http://www.immunize.org/catg.d/p3082.pdf>. January 30, 2016.

Immunization Action Coalition. *Medical Management of Vaccine Reactions in Children and Teens*. Retrieved from <http://www.immunize.org/catg.d/p3082a.pdf>. January 30, 2016.

APPENDIX G-1

Adverse Reaction Medication Log

Date and Time of Adverse Reaction: _____

Name and Date of Birth of Individual Receiving Vaccine:

Name of Vaccine(s) Given: _____

Describe Adverse Reaction of the Vaccine(s): (example: Shortness of breath, Angioedema, Chest Pain, Syncope, Rash, etc.).

Describe Interventions (include medications and dosage, CPR, etc.) for Adverse Reaction:

Disposition: (home, EMS, etc.)

Signature of Administering Pharmacy Intern (if applicable)

Date: _____

Signature of Administering or Supervising Pharmacist

Date: _____

APPENDIX H

HUMAN PAPILLOMAVIRUS (HPV)

Below is general information a pharmacist should be familiar with prior to the administration of these vaccines. Vaccine- specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines.

Special Clinical Considerations

I. Formulations

- a. Cervarix Human Papillomavirus Bivalent (16 and 18) Vaccine Recombinant
 - i. Females age 9 – 26
 - ii. **Not approved for males**
- b. Gardasil[®] Human Papillomavirus Quadrivalent (6, 11, 16 and 18) Vaccine Recombinant
 - i. Females and Males age 9 – 26
- c. Gardasil[®]9 Human Papillomavirus 9- valent (6, 11, 16, 18, 31, 33, 45, 52 and 58) Vaccine, Recombinant – expected to replace Gardasil, yet both are available in US at least through 2015
 - i. Females and Males age 9 – 26

II. Administration Intervals

- a. All three vaccines should be administered in a 3- dose schedule, with the second dose administered 1 to 2 months after the first dose and the third dose 6 months after the first dose. The minimum interval between the first and the second doses of vaccine is 4 weeks. The minimum interval between the second and the third doses is 12 weeks. The minimum interval between the first and third dose is 24 weeks.
- b. If a dose is missed, the patient **does not have to start over**. The series should be continued where the patient left off to complete the series.

Special Counseling Information

III. Patient should be advised:

- a. Patients should seek routine annual examinations with their primary care provider, to include age-appropriate sexual health counseling.
- b. Women should obtain cervical cancer screening per standard of care:
 - i. Cervical cancer screening via Papanicolaou (Pap) testing should start at age 21; and
 - ii. Cervical cancer screening via Pap and HPV co-testing should begin at age 30;
- c. Vaccines will not protect against disease from all HPV types;
- d. Vaccines will not protect patient against HPV that the patient already has; and
- e. Vaccines are not a treatment for HPV infection.

IV. References:

- a. Centers for Disease Control and Prevention. (2015). *Use of 9- valent human papillomavirus (HPV) vaccine: Updated HPV vaccination recommendations of the advisory committee on immunizations practices*. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm?s_cid=mm6411a3_w
- b. GlaxoSmithKline. (2015). *Cervarix: Highlights of prescribing information*. Retrieved from https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Cervarix/pdf/CERVARIX-PI-PIL.PDF
- c. Merck & Co, Inc. (2011). *Gardasil: Highlights of prescribing information*. Retrieved from http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf
- d. Merck & Co, Inc. (2014). *Gardasil 9: Highlights of prescribing information*. Retrieved from https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf

APPENDIX I

PNEUMOCOCCAL VACCINES

Below is general information a pharmacist should be familiar with prior to the administration of these vaccines. Vaccine-specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines.

I. Formulations

Two pneumococcal vaccines are currently licensed for use in the United States: the 13-valent pneumococcal conjugate vaccine (PCV13, Prevnar 13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23, Pneumovax 23). ACIP currently recommends that a dose of PCV13 be followed by a dose of PPSV23 in all adults aged ≥ 65 years who have not previously received pneumococcal vaccine and in persons aged ≥ 2 years who are at high risk for pneumococcal disease because of underlying medical conditions. Please refer to the current ACIP guidelines for updated administration recommendations.

II. Recommendations

As of September 2015, the ACIP recommended intervals for sequential administration of PCV13 and PPSV23 vaccines in immunocompetent patients are outlined below.

- a. In pneumococcal vaccine-naïve persons ≥ 65 years, a single dose of PCV13 should be administered first, followed by a single dose of PPSV23 after at least 12 months have elapsed since PCV13 administration.
- b. In persons who received PPSV23 previously at age ≥ 65 years, a single dose of PCV13 should be administered after at least 12 months have elapsed since PPSV23 administration.
- c. In persons who received PPSV23 before age 65 years, who are now ≥ 65 years, a single dose of PCV13 should be administered first, after at least 12 months have elapsed since PPSV23 administration. This is followed by a single dose of PPSV23 after at least 12 months have elapsed since PCV13 administration. A minimum of 5 years should elapse between administrations of PCV23.

III. Vaccine Administration

- a. Pneumococcal polysaccharide (PPSV23)
 - i. A single dose of 0.5 mL may be administered intramuscularly or subcutaneously only.
 - ii. Concomitant administration of routine adult vaccines is allowable in accordance with current ACIP recommendations.
 - iii. Administration to children < 2 years of age is not recommended due to lack of immunogenic response.
 - iv. Please refer to package insert information for complete administration information.

- b. Pneumococcal 13-valent conjugate (PCV13)
 - i. Persons > 5 years of age are recommended to receive a 0.5mL injection as a single dose in accordance with current ACIP recommendations.
 - ii. Children ages 6 weeks to 5 years are recommended to receive a four-dose vaccination series in accordance with current ACIP recommendations.
 - iii. Concomitant administration of routine adult vaccines is allowable in accordance with current ACIP recommendations.
 - iv. Please refer to package insert information for complete administration information.

IV. Warnings and Precautions

- a. Medication errors secondary to erroneous administration of incorrect formulations has been reported. Please use careful evaluation of age-appropriate administration schedules as outlined by current ACIP recommendations and formulation selection prior to administration.
- b. PPSV23 and PCV13 should not be administered intravenously.
- c. PPSV23 and PCV13 should not be administered concomitantly.
- d. Caution should be exercised prior to vaccinating patients with severe immunocompromised states, those that are pregnant and those with other significant co-morbid conditions.
- e. Please refer to the current ACIP recommendations and package insert information for complete warnings and precautions.

V. References

- a. Centers for Disease Control and Prevention. Pneumococcal ACIP Vaccine Recommendations. <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html>. Accessed 20 September 2015.
- b. Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine). Package Insert. Pfizer Inc., Philadelphia, PA. Updated 2015. Available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf> Accessed 20 September 2015.
- c. Pneumovax 23 (pneumococcal vaccine polyvalent vaccine) Package Insert. Merck & Co., Inc. Whitehouse Station, NJ. Updated May 2014. Available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM257088.pdf>. Accessed 20 September 2015.
- d. Kobayashi M, Bennett NM, Gierke R, et al. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep 2015 Sep 4;64(34):944-7. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm>. Accessed 20 September 2015.

VI. Table 1. Current ACIP Recommendations for Sequential Administration of Pneumococcal Vaccines (September 2015)

