POLICY FOR ADMINISTRATION OF VACCINES BY EMS PERSONNEL
SUBMITTED BY
THE DIVISION OF PREHOSPITAL MEDICINE RESEARCH
AND
REVIEWED, REVISED AND APPROVED BY
THE SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

ESTABLISHED December 2020

L. Brannon Traxler, MD, MPH
Public Health Director - Interim

Edgard DesChamps, III, MD
State EMS Medical Control Physician
Chair, EMS Advisory Board

Arnold Alier, EdD, NRP
Division Director of Prehospital Medicine Research

This page was intentionally left blank

Table of Contents

I. Introduction

EMS personnel are involved in numerous community and public health initiatives, such as working with health care systems to provide non-emergent care and follow up to certain patient populations as well as providing immunizations, illness and injury prevention programs, and other health initiatives. To help increase the vaccination rates in South Carolina, the South Carolina General Assembly enacted an amendment to the Contagious and Infectious Diseases, S.C. Code Ann. Section 44-29-40 (The Act) and The South Carolina Immunization Registry (The Regulation) that authorizes SCDHEC: Bureau of EMS in conjunction with the Bureau of Public Health Preparedness and the Division of Immunization to determine specific vaccines are appropriate for administration by certified South Carolina EMS personnel. Only vaccines identified by state protocol are approved for administration by SC certified personnel without an order or prescription from the individual's medical practitioner.

Agencies who employee personnel meeting the qualifications specified in Section II 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]; and
(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; and
(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 policy.

---

[1] In the event of a conflict between information provided in package inserts and ACIP recommended guidelines, the individual administering vaccine(s) pursuant to this Protocol should adhere to ACIP guidelines.

II. Agency Pre-Requirement requirements

The Bureau of EMS acknowledges the diverse availability of licensed agencies. At a minimum, agencies who are interested must:

(a) have a current Advanced Life Support Ambulance or Advanced EMT Rapid Responder unencumbered agency license; and
(b) a signed Adult Vaccine Initiative (AVI) Memorandum of Agreement (MOU); and
(c) a current and signed Adult Immunization protocol/authorization from agency's local Medical Control Physician (MCP) licensed by the SC Board of Medical Examiners; and
(d) a current signed Anaphylaxis and/or Allergic Reaction protocol from agency's local MCP; and
(e) become an authorized user of the immunization registry; and
(f) report any adverse reaction(s) in the Vaccine Adverse Event Reporting System (VAERS), or its successors.

III. Qualifications

Personnel seeking authorization to administer vaccines pursuant to this policy shall meet the following qualifications:

(a) Certification – Personnel must possess an unencumbered South Carolina credential and maintain all certification requirements as stated in Regulation 61-7 §902 or Regulation 61-7 §903:

1. approved healthcare provider Basic Life Support (BLS) Credential; and / or
2. approved Advanced Cardiac Life Support (ACLS) Credential; and
3. a current NREMT Credential; and
4. current National and State criminal background requirement(s)

(b) Training – All participating EMS professional must complete an approved Prehospital immunization training program that is accredited by the Commission on Accreditation For Prehospital Continuing Education (CAPCE®), CDC, or a similar health authority or professional body approved by SCDHEC: Bureau of EMS.

1. Immunization 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:
    - signs and Symptoms of the virus(es);
    - risk factors and/or environmental concerns;
        - such as homelessness
        - natural disaster (i.e. flooding)
    - basic immunology and the need for vaccine protection;
    - vaccine-preventable diseases;
    - recommended immunization schedules;
    - mechanisms of action for vaccines (Live, inactive or combination);
    - immunization considerations/contraindications;
    - patient education and/or CDC Vaccine Information Statement (VIS);
    - drug interactions;
    - intramuscular (IM) injections;
        - Review injection site(s)
        - needle depth,
        - needle gauge(s), and
        - volume(s) associated with site(s).
    - vaccine storage management; link below
        - https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
    - pre-vaccine and post-vaccine assessment and counseling;
    - required monitoring after vaccine administration;
    - management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
        - https://vaers.hhs.gov/reportevent.html
    - biohazard waste disposal and sterile techniques;
    - needle stick management; and
    - vaccine record management.

2. Successful completion of the didactic portion documented with a successful proficiency quiz of 80% or above (Appendix I).

(c) Continuing Education – Each participating provider must complete at least two hours of didactic State Content or CAPCE® approved continuing education related to the administration of vaccines as part of their biannual NREMT recertification requirements. At minimum, the provider must display a satisfactory clinical performance and/or competency annually by their Local MCP or their authorized agent [such as, agency Training Officer].

[2] An individual who has gained a NREMT credential on or after October 1, 2006, must maintain their NREMT credential to be certified, recertified, and maintain their South Carolina certification.

IV. Limitations on Prehospital-based Vaccination(s)

(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 provider may not delegate the administration of vaccines to a student of any level, or any other person who is a provider who has not met and/or completed the requirements set forth in section II, III and any other applicable law and regulation. The authorized provider must be under and shall maintain local MCP direction.

(c) Patient Specific Factors – Potential vaccines with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barre syndrome should be referred to their primary care practitioner. Completion of prescreen questionnaire(s) assist in determining the appropriate administration of vaccines (Appendix D, E).

V. Protocol, Facility and Equipment

The facility and/or immunization location must be clean, well-lit, and environmentally comfortable with the ability to maintain patient confidentiality. Providers who administer vaccines under this policy shall maintain a current copy of the applicable Protocol(s) which must be readily available when administering vaccines. The minimum protocols needed for immunization administration are listed in Appendix A. The minimum equipment needed for immunization administration is listed in Appendix B.

VI. Patient Education Materials

(a) Vaccine Information Statements – Each vaccine recipient, or their legal representative, must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine provided. The vaccine recipient or legal representative must be given the opportunity to read the VIS ***prior*** to administration of the vaccine, and the provider must provide answers to any questions raised.

- https://www.cdc.gov/vaccines/hcp/vis/index.html

(b) Non-English Speaking – Persons must have an interpreter available and receive a copy of the VIS in their native language, if available.

VII. Informed Consent

Before receiving the vaccine, the vaccine recipient, or their legal representative, must be given information about the risks and benefits associated with vaccination.

(a) Consent Form -Any provider administering vaccines pursuant to this Protocol must document the vaccine recipient, or their legal representative's informed consent in writing prior to administration of a vaccine. The provider and the supervising Medical Control Physician must be identified on the consent form. The required consent form language is provided in Appendix F.

VIII. Prehospital-based Vaccination Record

The Provider administering a vaccine pursuant to this policy must create a vaccination record for each vaccine recipient. An electronic Patient Care Report (ePCR) does not need to be completed for an immunization. However, the completion of current DHEC documentation is required. The vaccination record must be maintained for a period of no less than 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 agency name, agency address, Provider's certification [SC] number, and agency telephone number; and
(h) A copy of the notification letter sent to the vaccinee's designated primary care practitioner, if identified, of any vaccine administered (Appendix G).

IX. Reporting Requirements

(a) Personal Immunization Record – The Provider must encourage all vaccinees to carry a personal immunization record card in their wallet. The Provider 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 G.
(c) Immunization Registry – A Provider administering vaccinations without a written order or prescription from the vaccinee's local primary care 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 provider 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. The Procedures for Adverse Reaction(s) Management is provided in Appendix H.

X. Vaccination Safety

(a) Infection Control and Sterile Technique – Providers administering vaccines must follow Universal 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 when the Provider is preparing and administering the vaccine. 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 injuries, needles and syringes must be discarded immediately after use in a labeled, puncture-proof biohazard container. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices are suggested to reduce the risk for injury.

(c) Occupational Safety and Health Administration (OSHA) Compliance – Agencies/providers must document compliance with Federal Bloodborne Pathogens (BBP) standard found at 29 CFR 1910.1030 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.

- Such as, established an infectious waste generator

XI. 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 (Appendix D) and contraindications (specific for each vaccine) 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 provider must be prepared with medication, equipment and procedures for their management. The procedures for managing adverse reactions are set forth in Appendix G.

- Reporting is required to be into the VACCINE Adverse Event Reporting System; www.vares.hhs.gov

XII. Supply Considerations

The supply of vaccines and the timing of distribution cannot be guaranteed. If supplies of the vaccines are delayed or limited, the provider 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.

XIII. Vaccines

Provider may administer US Food and Drug Administration (FDA) approved formulations of the vaccines listed on the Prehospital Immunization Formulary (Appendix B). Providers must follow the current guidelines from the ACIP, adhere to dosing and administration information provided by the package inserts and ACIP recommended guidelines. Providers must make every effort to assure that vaccination series are completed.

APPENDIX A: MINIMUM REQUIRED PROTOCOLS

Universal Patient Care

Allergic Reaction / Anaphylaxis

Syncope

APPENDIX B: APPROVED PREHOSPITAL VACCINES

Hepatitis A

Influenza

COVID-19

APPENDIX C: 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 D: GENERAL SCREENING QUESTIONNAIRE

Below is a list of general screening questions a provider 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. Providers 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 E: SCREENING QUESTIONNAIRE OF LIVE VACCINES

Below is a list of screening questions a provider 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, Actermra, 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 F: CONSENT FOR VACCINE ADMINISTRATION

This Agency 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 [PROVIDER AND SUPERVISING MEDICAL CONTROL PHYSICIAN 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 (If known)

APPENDIX G: NOTIFICATION LETTER

Dear Healthcare Provider at [_____]:

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 EMS Provider

_____
Medical Control Physician (Name)

_____
Contact Information for EMS Agency

APPENDIX H: PROCEDURES FOR ADVERSE REACTIONS MANGEMENT

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:

(a) If itching and swelling are confined to the injection site where the vaccination was given, observe the vaccinee closely for no less than thirty (30) minutes, watching for the development of generalized symptoms.

(b) If symptoms are generalized, activate the emergency medical system (e.g., call 911) immediately. This should be done by a second person if available, while the provider assesses the level of consciousness, circulation, airway and breathing of the vaccinee.

(c) Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.

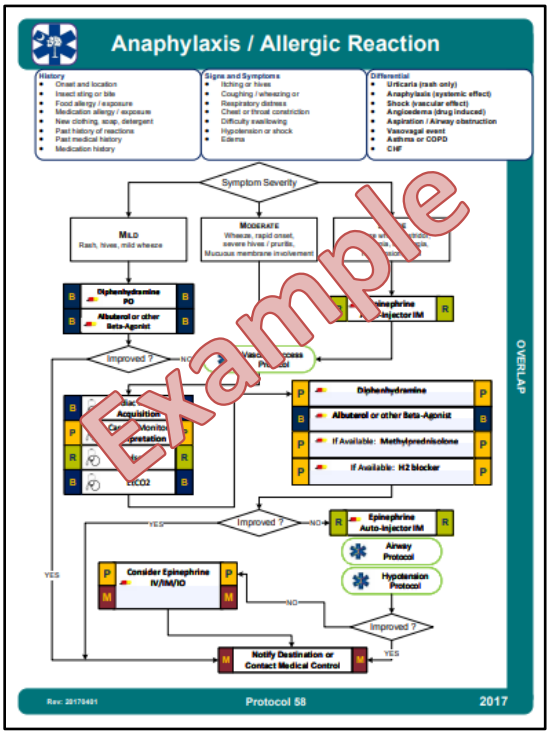
(d) Review your local allergic and/or anaphylactic reaction protocol for intervention(s).

(e) An Adverse Reaction Medication Log form is attached hereto as Appendix G-1.

(f) Reporting is required to be entered into the VACCINE Adverse Event Reporting System;

- www.vares.hhs.gov

(g) Notify the vaccinee's primary care practitioner as soon as possible. All vaccinees experiencing anaphylactic reactions must be referred for medical evaluation, even if symptoms resolve completely.



APPENDIX H.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.)

_____

_____ Date: _____
Signature of Administering EMS Professional

_____ Date: _____
Signature of Medical Control Physician

APPENDIX I: PROFICIENCY QUIZ

- Locally generated by the Agency providing immunizations
- Must be separate and apart for each vaccine being administered to include storage, dosages, temperature requirements, side effects, etc.
- Must be kept with competencies for a period of no less than 3 years.