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Title: Vaccine Administration	**Policy #**: IDOH Immunization Division Policy 23
Effective dates: 01-Jan-25 to 31-Dec-25	**Approvals**: Dave McCormick Dave McCormick, Immunization Director January 1, 2025 Date

Purpose

The Immunization Division has a policy for the safe administration of vaccines that are included in the routine schedules for children and adults. Providers should follow their own internal policies for the administration of vaccines or medications if such a policy is available and should follow applicable state and federal regulations pertaining to the administration of vaccines. This policy applies to all providers who are actively enrolled in any Indiana publicly funded vaccine program but does not apply to the administration of vaccines outside the routinely recommended schedules. If a vaccine is given outside of the routinely recommended schedule, it must be reported to the Vaccine Adverse Event Reporting System (VAERS) and the vaccine manufacturer.

VAERS forms can be completed online at: http://vaers.hhs.gov/index. A paper form is also available on the website which can be mailed or faxed to VAERS.

Administering vaccines correctly promotes optimal vaccine efficacy and reduces the chance of an adverse reaction or injury.

Rights of Medication Administration

When vaccines are administered, the "Rights of Medication Administration" should be applied. These rights include the:

- Right patient

- Right vaccine or diluents
- Right vaccine storage and handling
- Right time (the correct age, the correct interval, and before vaccine or diluent expires)
- Right dosage
- Right route, needle gauge, length and technique
- Right site
- Right documentation

Staff Training and Education

Prior to administering vaccines, all health care providers should receive competency-based training and education on vaccine administration. This includes a skills check for the administration of vaccines. All staff should be well-versed in the vaccine formulary used at their practice. Continuing education for staff should be provided as needed to update staff on the use of new vaccines, new schedules, and new or revised recommendations.

Patient Safety and Education

All patients should be screened for contraindications and precautions prior to administering each dose of vaccine. The CDC's Pink Book (Appendix A) has several tables detailing known contraindications and precautions for commonly used vaccinations. Several sample screening questionnaires are available from the Immunization Action Coalition at www.immunize.org/handouts/screening-vaccines.asp.

The National Childhood Vaccine Injury Act (NCVIA) of 1986 (Public Law 99-660) requires all health care providers who administer vaccinations to offer a copy of the vaccine information statement (VIS) produced by the Centers for Disease Control and Prevention (CDC) to the parent or legal representative of the child the provider intends to vaccinate. A copy of the VIS should be provided before the administration of every dose of vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine. If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines. All available VISs can be downloaded from the Immunization Action Coalition website, www.immunize.org/vis, or from the CDC website, https://www.cdc.gov/vaccines/hcp/vis/index.html.

Upon administration of the vaccine, the provider needs to document VIS edition date and the date the materials were provided in the patient's medical record.

Infection Control

Health care providers should follow standard precautions to minimize the risk of spreading disease. More information about these standards is available at https://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html.

Standard precautions include thoroughly washing hands with soap and water or cleansing with an alcohol-based antiseptic before vaccine preparation, between patients, and any time hands become soiled. Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccines unless the vaccine is likely to come into contact with potentially infectious body fluids or if the person administering the vaccine has open lesions on his/her hands. If worn, gloves should be discarded between patients.

Used needles should not be recapped, cut or detached from the syringe before disposal. All used sharps should be placed in a puncture proof container to prevent accidental injury or reuse.

All needle-stick injuries should be washed thoroughly with soap and water and reported immediately to the site supervisor to obtain necessary medical treatment.

Medical Reactions to Vaccination

Health care providers should have adequate supplies at their location to effectively manage any medical emergencies following routine vaccination. Each provider of immunizations should have an emergency medical management protocol that is signed by the agency medical director or local health officer.

Emergency Kit

At a minimum, an emergency kit should include the following supplies:

Medical Supplies

- Stethoscope
- Blood pressure cuffs
    - Consider sizes needed for patient population
- Tongue depressors
- Pediatric and adult oral airways
- Flashlight
- Tourniquet

- Alcohol wipes
- Pediatric and adult pocket masks with one-way valve
- Syringes for epinephrine and diphenhydramine (Benadryl)

First-line Medication

- Epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials, or pre-filled syringes
- Epinephrine autoinjectors (EpiPen®) – multiple
    - Adult: 0.30 mg (for patients weighing more than 30 kg [approximately 66 lbs.])
    - Pediatric: 0.15 mg (for patients weighing between 15 kg and 30 kg [between 33 lbs. and 66 lbs.])

Second-line Medication

- Diphenhydramine (Benadryl) and/or
    - Injectable (50 mg/mL solution)
    - Oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets)
- Hydroxyzine (e.g., Atarax, Vistaril)
    - Oral (10 mg/5 mL or 25 mg/5 mL liquid, 10 mg or 25 mg tablets, or 25 mg capsules)

Procedure Details for Administering Vaccine

Health care providers should always review the manufacturer's package insert for additional guidance and information related to the administration of the vaccine. Vaccines differ in presentation, packaging and instructions for correct administration. The recommended route of administration is based on clinical trials, practical experience and theoretical considerations. This information is included in the manufacturer's product information for each vaccine. Several vaccines are prepared in a lyophilized (freeze-dried) powder that requires reconstitution with a liquid diluent. Vaccines should be reconstituted according to manufacturer guidelines using only the specific diluent supplied by the manufacturer for that vaccine.

Vaccine should be drawn from the vial into the syringe at the time of administration. An individual should only administer a vaccine he or she has prepared and drawn up. Syringes, other than those filled by the manufacturer, are designed for immediate administration and not for vaccine storage. Do not pre-draw doses before they are needed. Pre-drawing vaccine into syringes is a quality control and patient safety issue for many reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to differentiate, and there is no stability data available for vaccines stored in plastic syringes. Other problems associated with this practice are wasted vaccine and possible bacterial growth in vaccines that do not contain a preservative.

As an alternative to pre-filling syringes, CDC recommends use of manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration. Once a manufacturer prefilled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The syringe should be used that day or discarded at the end of the clinic day. For single-dose vials (SDV), activation occurs when the cap is removed. SDV should also be discarded at the end of the clinic day if the protective cap has been removed. When using pre-filled syringes, it is not necessary to expel the air pocket out of the syringe prior to administering the vaccine.

The type of vaccine, lot number, and date of filling should be labeled on each syringe, and the doses should be administered as soon as possible. Some vaccines that are reconstituted must be administered immediately following reconstitution (see section pertaining to vaccines with diluent).

Prior to administering vaccinations, health care professionals should always:

1. Verify the vaccine is stored in the appropriate storage unit (refrigerator vs. freezer).
2. Check the expiration date of the vaccine and diluents (if applicable) on the vial or box. Never use expired vaccine or diluents.
    a. Vaccine can be used through the last day indicated on the vaccine packaging. For vaccines with a mm/yy expiration date, the vaccines can be used through the last day of the month.
    b. The expiration date for certain vaccines changes once the vaccine vial is opened or the vaccine is reconstituted.
3. Inspect the vaccine vial or syringe and diluent for signs of damage or contamination.
4. If vaccine is presented in a vial, remove the protective vial cap and swab the vial stopper with a new alcohol prep pad prior to drawing up the contents into the syringe.

To reconstitute vaccine:

1. Select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine.
    a. Exceptions: Rotavirus vaccine is an orally administered vaccine, read package insert for instructions for reconstitution. Live attenuated influenza vaccine (FluMist®) is administered via the intranasal route.
2. Check the labels of both the lyophilized vaccine and diluents to verify they are the correct products to mix together and that the diluent is the correct volume.
3. Insert the needle of the syringe into the diluent vial and withdraw the entire contents.

4. Inject the diluent into the lyophilized vaccine vial.
5. Rotate or gently agitate the contents in the vial to dissolve the powder.
6. Check the appearance of the reconstituted vaccine to ensure it matches the description in the package insert. If the appearance does not match the description, do NOT use the vaccine.
7. Administer the vaccine within the timeframes indicated by the manufacturer. Please note that some vaccines must be administered within 30 minutes of reconstitution.
8. If using a multi-dose vial, clearly mark the vial with the date and time of reconstitution.

Procedure Details

Administering Vaccine by Injection (IM or SC)*

1. Cleanse area of injection using a new alcohol swab.
2. Stabilize tissue in area of injection to ensure vaccine is administered according to the correct route. Insert the needle at a 90-degree angle (IM) or 45-degree angle (SC) to the skin with a quick thrust.
3. Push down on plunger and inject the entire contents of the syringe. Do not aspirate.
4. Remove the needle and apply pressure to the injection site with a dry cotton ball or gauze. Hold in place for several seconds.
5. Cover the injection site with a bandage if there is bleeding.
6. Place used syringe in sharps container.
7. If administering multiple vaccines in the same extremity, separate the injection sites by at least one (1) inch.

Administering Intranasal Live Attenuated Influenza Vaccine

1. Remove rubber tip protector. Do not remove the dose-divider clip at the other end of the sprayer.
2. Ask patient to keep head in upright position and breathe normally. Do not tip their head back.
3. Place the tip of the applicator slightly inside the nostril.
4. Depress plunger rapidly until the dose divider clip prevents further administration of the vaccine.
5. Remove applicator from nostril.
6. Pinch to remove dose-divider clip from the plunger.
7. Place the tip of the applicator slightly inside the other nostril.
8. Depress plunger rapidly to deliver remaining vaccine.
9. Dispose of applicator in sharps container.

Administering Rotavirus Vaccine

1. Follow manufacturer's instructions for vaccine preparation.

2. Insert applicator tip inside the infant's mouth. Avoid eliciting the gag reflex.
3. Administer the liquid slowly down one side of the inside cheek toward the back of the mouth until fully administered.
4. Dispose of applicator in sharps container.

Common injectable vaccines and their routes of administration

- **Intramuscular (IM)**
  - Meningococcal Serogroup B (Trumenba or Bexsero)
  - Pneumococcal Conjugate (PCV13, PCV15, PCV20)
  - Influenza, inactivated (IIV3/IIV4)
  - Zoster, Recombinant (Shingrix)
  - COVID-19
  - DTaP-HepB-IPV (Pediarix)*
  - DTaP-IPV-Hib (Pentacel)*
  - DTaP-IPV (Kinrix, Quadracel)*
  - HepA-HepB (Twinrix)*
- **Subcutaneous (SC)**
  - Measles, mumps, rubella (MMR)
  - Varicella (VAR)
  - Zoster, Live (Zostavax)
  - MMRV (ProQuad)*
- **Intramuscular (IM) or subcutaneous (SC)**
  - Polio, inactivated (IPV)
  - Pneumococcal polysaccharide (PPSV23)

*Combination vaccine.

Route, Needle Size and Site for Commonly Used Vaccines

- **Subcutaneous (SC)**
  - Administration:
    - Pinch up fatty tissue and insert needle at 45-degree angle
  - Needle size:
    - 5/8-inch needle; 23-25 gauge
  - Injection site:
    - Infants (under 12 months): Administer injection in fatty tissue of thigh
    - Children and adults: Administer injection into fatty tissue surrounding the triceps muscle

- **Intramuscular (IM)**
  - Administration:
    - Pull skin taut to stabilize injection site. Insert needle at a 90-degree angle
  - Needle size:
    - One-inch needle; 22-25 gauge. The needle must be long enough to reach muscle mass.
  - Injection site:
    - Young children and infants:
      - Administer injection in vastus lateralis muscle on the anterolateral aspect of thigh
      - The deltoid may be used in children under three (3) years of age
    - Teens and adults:
      - Administer injection in deltoid muscle of upper arm
      - Do NOT administer vaccines in the buttock
  - Other considerations:
    - A 5/8-inch needle may be considered when administering IM injections to premature infants and to individuals less than 130 pounds when given in the deltoid muscle
- **Oral (Rotavirus)**
  - Administration:
    - Use oral applicator and administer the dose inside of the cheek
  - Other considerations:
    - Administer oral vaccines first
    - **If the child spits up or vomits after receiving the vaccine, do not repeat the dose**
- **Intranasal**
  - Administration:
    - Administer nasal spray in nares
  - Other considerations:
    - FluMist® is the only U.S. licensed vaccine administered through the intranasal route
    - Administer to individuals two (2) to 49 years of age
    - **If the patient sneezes after the vaccine is administered, do not repeat the dose**

Documenting Vaccination

Following the administration of vaccinations, it is important to document the administration of each vaccination in the patient's medical record. This documentation must include the:

- Date (MM/DD/YYYY) the vaccine was administered
- Manufacturer, lot number and expiration date
- Vaccination site and route
- Name and title of the person administering the vaccine as well as the address of the facility where the permanent record will reside
- Edition date for VIS and date provided to patient

In the patient's medical record, document the reasons for delaying or missing vaccination, including medical contraindications and patient/parent refusal.

Providers are advised to document this information on a personal immunization record and in the Children and Hoosier Immunization Registry Program (CHIRP). Medical providers are required to document a complete record in the registry for persons 18 years of age and younger. *This requirement went into effect on July 1, 2015.*

Adverse Events

The NCVIA also requires health care providers to report suspected adverse events that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS). Providers should report adverse events even if there is uncertainty that the vaccine caused the event. The report should include the:

- Type of vaccine received
- Timing of vaccination
- Onset date/time and a description of adverse event
- Concurrent illnesses and/or medications
- Patient's history of adverse events following vaccination
- Patient's demographic information

VAERS forms can be completed online at: http://vaers.hhs.gov/index. A paper form is also available on the website which can be mailed or faxed to VAERS.

Adverse events should also be documented in CHIRP.

Pain and Fever Control

One of the main reasons individuals refuse vaccination is due to the fear of pain from the needle-stick. There are several evidence-based strategies that can be used to decrease pain and fever associated with immunizations including:

- The use of antipyretics (non-aspirin containing) to decrease fever if it occurs after vaccination. Do not administer antipyretics before or at the time of vaccination.
- Age-appropriate distraction techniques (playing music, reading books, deep breathing, etc.)
- Ingestion of sweet-tasting liquids or breast-feeding in infants up to 12 months of age
- Injecting the most painful vaccines last (MMR, PCV13, or HPV)
- Rubbing the skin near the injection site (demonstrated to be effective in children four [4] years and older)
- **Do not aspirate IM injections**

References

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Kroger A, Wolfe S, eds. Washington D.C. Public Health Foundation, 2021. http://www.cdc.gov/vaccines/pubs/pinkbook/index.html.

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