April 14, 2021

Ideas for COVID-19 Vaccination Safety Policies Procedures

> Information from the Centers for Disease Control (CDC) is correct as of March 12, 2021. Please check the CDC's website for updates and changes.

Adverse Event Reporting

In the unfortunate event of an immediate reaction or anaphylaxis requiring medical management and stabilization or transfer, the physician or practice will need to complete a Vaccine Adverse Event Reporting System (VAERS) report. The Food and Drug Administration (FDA) requires reporting as part of the emergency use authorization of the COVID-19 vaccines. Health care professionals and practitioners as well as patients and patients' representatives can submit a report to VAERS. Health care professionals and practitioners must report the following to VAERS:

- any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within a specified timeframe, and
- an adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

FDA-Approved Vaccine Information for Patients

Vaccine information sheets (VIS) should be distributed to patients or their representatives **prior** to the vaccination process. Currently, there are no VIS for the COVID-19 vaccines approved by the FDA for emergency use. The emergency use authorization requires patients and their representatives/caregivers receive vaccine-specific emergency use information before vaccination. To comply with the emergency use information requirement, the FDA provides emergency use fact sheets for the Moderna, Janssen (Johnson & Johnson), and Pfizer-BioNTech COVID-19 vaccines. The Centers for Disease Control and Prevention (CDC) also provides FDA-approved information for the Moderna, Pfizer BioNTech, AstraZeneca, and Janssen COVID-19 vaccines.

Immunization Schedules

The CDC updated the child and adolescent immunization schedule and the adult immunization schedule for 2021, but neither includes information on the immunization schedule for COVID-19 vaccinations. See the vaccine manufacturers' instructions for dosing and timing of the first and second vaccinations.

Multidose Vials

The PfizerBioNTech, Moderna, and AstraZeneca COVID-19 vaccines are supplied in multidose vials. The vials must be stored and accessed in a clean medication preparation area to prevent contamination. For a multidose vial that has been opened or accessed, which includes needle puncture, write the date of opening on the vial and discard the vial when the manufacturer specifies.[1]

Post Vaccination Observation Periods

Implement post-vaccination observation periods to allow for immediate medical intervention in case of a reaction and to reduce the risk that a patient leaving the clinic could suffer a reaction while driving. Develop a vaccination procedure that specifies who will instruct the patient about the length of the observation period, where the patient will wait during the period, and how the practice will manage a reaction or anaphylaxis. The CDC recommends the following observation periods:[2]

- a minimum of 30 minutes if the patient has a history of an immediate allergic reaction of any severity to another vaccine or injection or has a history of anaphylaxis for any reason;
- a minimum of 30 minutes if another type of COVID-19 vaccine is contraindicated, for example, if an mRNA COVID-19 vaccine is contraindicated and the patient is receiving a Janssen vector vaccine; and
- a minimum of 15 minutes for all other patients.

The CDC recommends stocking the following supplies:

- at least three doses of epinephrine in prefilled syringes or autoinjectors;
- an H1 antihistamine, such as diphenhydramine or cetirizine;
- a blood pressure monitor; and
- a clock, watch, or other timing device.[3]

Standing Orders

Standing orders may prevent medication and vaccination errors and facilitate the medical management of vaccine reactions. If your practice is not using standing orders, the Immunization Action Coalition's (IAC) 10 Steps to Implementing Standing Orders for Immunization in your Practice Setting can guide you through the process. The IAC offers standing orders templates for adverse reactions in adults and children. If your practice is using standing orders, but wants to improve the process, review the IAC's Using Standing Orders for Administering Vaccines: What You Should Know.

Sharps Safety

Physicians and practices should ensure "sharps" disposal containers are in every room of the practice. Physicians and practice administrators should also remind staff to use sharps containers and never throw away loose needles or sharps in trash cans, recycling bins, sinks, or toilets. The FDA says the safest way to dispose of needles or sharps is in an approved container.[4] If a container is not available and needle recapping is necessary, practices should encourage the use of mechanical recapping devices, practice-approved needle clippers, or the FDA's one-handed scoop needle recapping method.[5]

The U.S. Food and Drug Administration One-Handed Needle Recapping Method

1. Place the cap on a flat surface, like the table or counter, with something firm to "push" the needle cap against.
2. Holding the syringe with the needle attached in one hand, slip the needle into the cap without using the other hand.
3. Push the capped needle againt a firm object to "seat" the cap onto the needle firmly using only one hand.

Verifying Competency for Vaccination Administration

Physicians and practice administrators should confirm the credentials and competency of practice staff to administer vaccinations of any kind. Check the practice's employment and/or credentials/competency files to ensure registered nurses, licensed practical or vocational nurses, and medical assistants are qualified to administer vaccines and, if required, are supervised by the appropriate level health care professional. The documentation will fortify the defense of a related medical professional liability claim.

[1] See the CDC's frequently asked questions and answers about multidose vials at Questions about Multi-dose vials | Injection Safety | CDC.

[2] The CDC also lists early clinical signs and symptoms of anaphylaxis and recommends clinical steps to manage anaphylaxis at Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC.

[3] See the CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination, updated February 10, 2021, for more information.

[4] See the FDA's 2018 publication What to Do if You Can't Find a Sharps Disposal Container | FDA

[5] *Id.*

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