COVID-19 Vaccine Update

Webinar 5

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Presentation By:

Allie Staton, PharmD

Vaccine Confidence Strategist

Immunize Arkansas

Email: allie@immunizear.org

ImmunizeAR

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WEBINAR

- If you have a question during the webinar, please post your question in the chat.
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- If you have a question after the webinar, please email Allie Staton.
  - allie@immunizear.org

OBJECTIVES

At the end of this webinar, learners will be able to:

- Interpret current COVID-19 vaccine guidelines.
- Recommend appropriate vaccines to patients and community members.
- Discuss current COVID-19 vaccine guidelines and recommendations.

TOPICS

- Review common COVID-19 vaccine administrations errors
- Discuss how to report vaccine administration errors
- Discuss how to avoid vaccine administration errors

CURRENTLY AVAILABLE PRODUCTS

COVID-19 VACCINE PRODUCT REVIEW

Pfizer	Moderna	Janssen / J&J	Novavax
mRNA	mRNA	Adenovirus Vector	Protein Subunit
6 months and older	6 months and older	18 years and older	12 years and older
Products Monovalent: - 6 months thru 4 years - 5 years thru 11 years - 12 years and older Bivalent: - 6 months thru 4 years - 5 years thru 11 years - 12 years and older	**Products** Monovalent: - 6 months thru 5 years - 6 years thru 11 years - 12 years and older Bivalent: - 6 months thru 5 years - 6 years and older *half-dose for 6 years thru 11 years	**Products** Monovalent: - 18 years and older	**Products** Monovalent: - 12 years and older

COMMON VACCINE ADMINISTRATION ERRORS

COMMON ERRORS

Common vaccine administration errors include:

- Doses administered too early (e.g., before the minimum age or interval)
- Wrong vaccine
- Wrong dosage
- Vaccine administered outside the approved age range
- Expired vaccine or diluent administered
- Improperly stored vaccine administered
- Vaccine administered to a patient with a contraindication
- Wrong diluent used to reconstitute the vaccine or only the diluent was administered

https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

CDC INTERIM CLINICAL CONSIDERATIONS FOR COVID-19 VACCINES

Appendices

- Guidance for use of Janssen COVID-19 Vaccine (Appendix A)
- People who received COVID-19 vaccine outside the United States (Appendix B)
- People who received COVID-19 vaccine as part of a clinical trial (Appendix C)
- Vaccine administration errors and deviations (Appendix D)
- Triage of people with a history of allergies or allergic reactions (Appendix E)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Appendix D. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that might cause or lead to inappropriate use of vaccine or patient harm.

The FDA-issued Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.
- Follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine product. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes to this Appendix).
    - For doses recommended to be repeated, some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech) or Novavax COVID-19 Vaccine, particularly in groups at increased risk for myocarditis and pericarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following COVID-19 vaccination should be taken into consideration when recommending a longer interval. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks if the interval is not sooner than the minimal interval noted in this table.

Table D. Interim recommendations for COVID-19 vaccine administration errors and deviations

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (recipients younger than age 6 months)	• Do not give another dose at this time.*
	• Recipients transitioning from age 4 years to 5 years during the primary series who start a 3-dose Pfizer-BioNTech primary series with the product for ages 6 months–4 years (maroon cap and label border) and incorrectly receive the product for ages 5–11 years (orange cap and label) for either dose 2 or 3	• Do not repeat primary series dose 2 or 3. • If the error occurred with dose 2, administer the bivalent Pfizer-BioNTech product for ages 6 months–4 years (maroon cap and label border) for the third primary series dose at least 8 weeks after the second primary series dose.

Product and dosage	• Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	• Do not repeat dose.[†‡]
	• Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).[‡§] • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
	• Bivalent vaccine incorrectly administered for the primary series	• Bivalent Pfizer-BioNTech vaccine: Do not repeat dose. • Bivalent Moderna vaccine: Repeat 1 monovalent dose immediately (no minimum interval)[§] because administration of the booster dose will result in a lower-than-authorized dose.
	• Children ages 6 months–4 years who receive a monovalent Pfizer-BioNTech vaccine for the third primary series dose	• Do not repeat dose.
	• Monovalent vaccine incorrectly administered for a booster dose (if bivalent booster indicated)	• In general, do not repeat dose. • However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference. In this case, space the repeat dose after the dose given in error by at least 2 months.

Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer for information on the stability of the vaccine.[¶] If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
	• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for information on the stability of the vaccine.[¶] If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]
Intervals	• Any COVID-19 dose administered prior to the minimum interval[#]	• Repeat dose. Space repeat dose after the dose given in error by at least the minimum interval (Table 2 and Table 3).[§]
	• Any COVID-19 vaccine dose administered at any interval after the recommended interval	• Do not repeat dose. There is no maximum interval. • This deviation from CDC guidance does not require VAERS reporting.

Mixed primary series	• COVID-19 vaccines from different manufacturers administered as part of a 2- or 3-dose primary series	• Do not repeat dose. • Any combination of Moderna, Novavax, or Pfizer-BioNTech vaccines is considered a complete primary series provided the indicated number of doses is administered. • If Janssen vaccine is administered, this counts as a single-dose series and no more primary series doses are indicated. • Children ages 6 months–4 years who received 1 monovalent Moderna vaccine and 1 monovalent Pfizer-BioNTech vaccine for the first 2 doses of an mRNA COVID-19 vaccine primary series should follow a 3-dose schedule. A third dose of either a monovalent Moderna vaccine or a bivalent Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose to complete the 3-dose primary series. One bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) may be administered at age 5 years.

Diluent (Pfizer-BioNTech COVID-19 Vaccine formulation only [orange cap and maroon cap])	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the authorized dose immediately (no minimum interval).
	• No diluent, resulting in higher than authorized dose	• Do not repeat dose.† Inform the recipient of the potential for local and systemic adverse events.
	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% sodium chloride)	• Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§
	• Vaccine is mixed with too little diluent	• Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.†
	• Vaccine is mixed with too much diluent	• Repeat dose immediately (no minimum interval).§
	• Single-use vial of diluent is used to mix multiple vials of vaccine	• Do not repeat dose. Inform patient of the potential for bacterial infection.
Diluent (Pfizer-BioNTech COVID-19 formulation that should not be mixed with diluent, i.e., gray cap)	• Vaccine is mixed with any diluent (i.e., any type or volume of diluent)	• Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§

REPORTING VACCINE ADMINISTRATION ERRORS

Reporting is REQUIRED for COVID-19 vaccine administration errors.

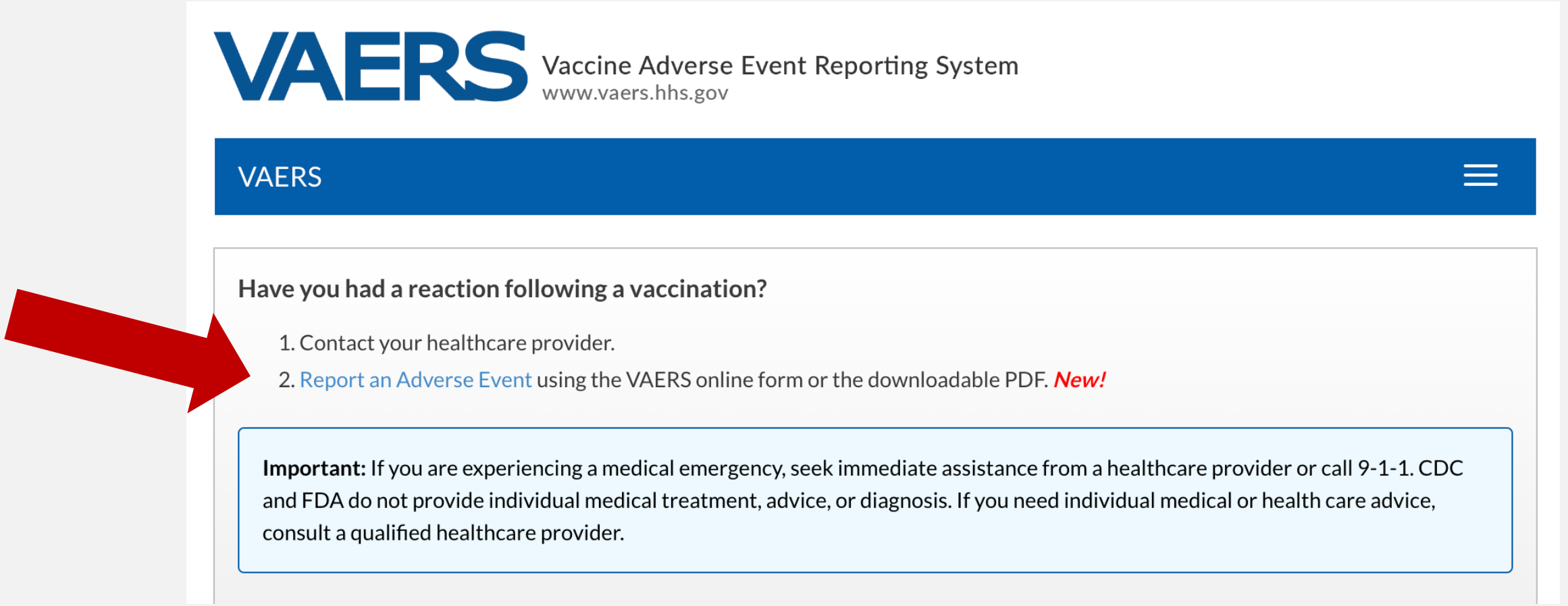
Reporting of vaccine adverse events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by FDA and the provider agreement for the CDC COVID-19 Vaccination Program to report the following that occur after COVID-19 vaccination under BLA or EUA:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events , irrespective of attribution to vaccination
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, CDC has developed a new voluntary, smartphone-based tool, v-safe, to provide near real-time health check-ins after patients receive COVID-19 vaccination.



https://vaers.hhs.gov/index.html

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

VAERS

Home / Report an Adverse Event / en Español

Report an Adverse Event to VAERS

Two Ways to Submit an Online Report to VAERS

Option 1 - Report Online to VAERS

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

REQUIRED

Checklist

What will I need to fill out the report?

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

Full checklist

Report an Adverse Event - Patient Information

Instructions | en Español

Report an Adverse Event - Vaccine Information

Instructions | en Español

Report an Adverse Event - Reporter Information

Instructions | en Español

Report an Adverse Event - Additional Information

Instructions | en Español

Report an Adverse Event - Facility Information

Instructions | en Español

Note: Fields marked with an * are essential and should be completed.

Item 2

* Date of birth (mm/dd/yyyy or mm/yyyy)

mm/dd/yyyy

Item 3

* Sex:

○ Male ○ Female ○ Unknown

Item 4

* Date of vaccination (mm/dd/yyyy or mm/yyyy)

mm/dd/yyyy

Item 18

* Describe the adverse event(s), treatment, and outcome(s): (symptoms, signs, time course, etc.)

Type in all information about the administration error here

AVOIDING VACCINE ADMINISTRATION ERRORS

Traditionally, medication errors are thought to be caused by mistakes. This “blame-seeking” approach fails to address the root cause, potentially causing the error to recur. An environment that values the reporting and investigation of errors (and “near misses”) as part of risk management and quality improvement should be established. Health care personnel should be encouraged to report errors and trust that the situation and those involved will be treated fairly without fear of punishment and ridicule. Error reporting provides opportunities to discover how the errors occur and to share ideas to prevent or reduce those errors in the future. When a vaccine administration error occurs, health care providers should determine how it happened and put strategies in place to prevent it in the future.

Guidance for handling some common vaccine administration errors is included in ACIP’s *General Best Practice Guidelines for Immunization*. Some vaccine administration errors require revaccination, but others do not.

YOU CALL THE SHOTS

Vaccine Administration: Preventing Vaccine Administration Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm.[1] Vaccine administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system. Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors as part of risk management and quality improvement.

Vaccine administration errors may be due to causes such as:

- Insufficient staff training
- Distraction
- Changes in recommendations
- Lack of standardized protocols
- Patient misidentification
- Using nonstandard or error-prone abbreviations
- Easily misidentified products (e.g. DTaP, DT, Tdap, Td)

If an error occurs, determine how it occurred and take the appropriate actions to put strategies in place to prevent it from happening in the future. The following table outlines common vaccine administration errors and possible preventive actions you can take to avoid errors.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf

Error(s)	Possible Preventive Actions
Wrong vaccine, route, site, or dosage (amount); or improperly prepared.	Circle important information on the packaging to emphasize the difference between the vaccines.
	Include the brand name with the vaccine abbreviation whenever possible (e.g., PCV13 [Prevnar13]) in orders, medical screens, etc.
	Separate vaccines into bins or other containers according to type and formulation. Use color-coded identification labels on vaccine storage containers.
	Store look-alike vaccines in different areas of the storage unit (e.g., pediatric and adult formulations of the same vaccine on different shelves in the unit).
	Do not list vaccines with look-alike names sequentially on computer screens, order forms, or medical records, if possible.
	Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines are stored.
	Consider purchasing products with look-alike packaging from different manufacturers, if possible.
	Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or administered.
	Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name.
	Do not administer vaccines prepared by someone else.
	Triple-check work before administering a vaccine and ask another staff member to check.
	Keep reference materials on recommended sites, routes, and needle lengths for each vaccine used in your facility in the medication preparation area.
	Clearly identify diluents if the manufacturer's label could mislead staff into believing the diluent is the vaccine itself.
	Integrate vaccine administration training into orientation and other appropriate education requirements.
	Provide education when new products are added to inventory or recommendations are updated.
	Use standing orders, if appropriate.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf

Error(s)	Possible Preventive Actions
Wrong patient	Verify the patient's identity before administering vaccines.
	Educate staff on the importance of avoiding unnecessary distractions or interruptions when staff is administering vaccine.
	Prepare and administer vaccines to one patient at a time. If more than one patient needs vaccines during the same clinical encounter (e.g., parent with two children), assign different providers to each patient, if possible. Alternatively, bring only one patient's vaccines into the treatment area at a time, labeled with vaccine and patient name.
Documentation errors	Do not use error-prone abbreviations to document vaccine administration (e.g., use intranasal route [NAS] to document the intranasal route—not IN, which is easily confused with IM).
	Use ACIP vaccine abbreviations.
	Change the appearance of look-alike names or generic abbreviations on computer screens, if possible.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf

Improperly stored and/or handled vaccine administered (e.g., expired vaccine given)	Integrate vaccine storage and handling training based on manufacturer guidance and/or requirements.
	Rotate vaccines so those with the earliest expiration dates are in the front of the storage unit. Use these first.
	Remove expired vaccines/diluents from storage units and areas where viable vaccines are stored.
	Isolate vaccines exposed to improper temperatures and contact the state or local immunization program and/or the vaccine manufacturer.
Scheduling errors (e.g., vaccine doses in a series administered too soon)	Use standing orders, if appropriate.
	Create procedures to obtain a complete vaccination history using the immunization information system (IIS), previous medical records, and personal vaccination records.
	Integrate vaccine administration training, including timing and spacing of vaccines, into orientation and other appropriate education requirements.
	For children, especially infants, schedule immunization visits after the birthday.
	Post current immunization schedules for children and adults that staff can quickly reference in clinical areas where vaccinations may be prescribed and administered.
	Post reference sheets for timing and spacing in your medication preparation area. CDC has vaccine catch-up guidance for DTaP, Tdap, Hib, PCV13, and polio vaccines to assist health care personnel in interpreting the catch-up schedule for children.
	Counsel parents and patients on how important it is for them to maintain immunization records.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf

RESOURCES

- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- https://vaers.hhs.gov/index.html
- https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
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