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A Brief Case for Safety: Preventing Errors Associated with Vaccine Management

Scenario

Deandre, the health center clinical director, reviews the upcoming schedule for the week and notices a sharp increase in patient volume and vaccine appointments due to recent wellness campaigns and influenza season approaching.

In response to the increased volume, Deandre prioritizes vaccine safety by ensuring all staff demonstrate understanding of organizational vaccination policies. She also meets with the safety committee to analyze a recent vaccine-related event, in which a child mistakenly received an adult booster form of diphtheria, tetanus, and pertussis toxoids, instead of the pediatric formulation.

The safety committee's root-cause analysis of the event suggested that similarities between the nonproprietary names and vaccine abbreviations for the DTaP vaccine (diphtheria, tetanus, and acellular pertussis) and the Tdap vaccine (tetanus, diphtheria, and acellular pertussis) may have contributed to the confusion. Tdap and DTaP protect against the same illnesses but are indicated for different age groups. To prevent future errors, the health center separated the pediatric and adult vaccine formulations and added color-coded labels to shelving and individual vials, creating a stronger visual distinction between the pediatric and adult products.

The Bottom Line

Vaccine management should be a part of any organization's risk and safety plan. Each year, millions of vaccines are given to children and adults in the United States to protect against infectious diseases and illnesses; however, the World Health Organization and the ECRI-affiliated Institute for Safe Medication Practices warn that errors

associated with wrong vaccine, wrong dose administered, wrong diluent used for reconstitution or diluent-only administered, and expired vaccines may create greater concern than risks caused by the vaccines themselves. These types of errors often stem from storage and handling failure modes; therefore; all staff who handle or administer vaccines should be familiar with policies and procedures in the facility. The Centers for Disease Control and Prevention (CDC) recommends that facilities develop and maintain clearly written, detailed storage and handling procedures that are reviewed and updated annually. Health centers and free clinics can use the following checklist to help prepare for immunization activities and prevent errors associated with vaccines.

Target 1. Provide staff with a structured orientation and training program on vaccine protocol and safety.

- Implement a competency-based training program, such as the CDC's You Call the Shots (see "Vaccine Storage and Handling" module) or Keys to Storing and Handling Your Vaccine Supply, for all staff involved in immunization activities. The training should be offered as part of new-hire orientation, annually as a refresher, whenever new vaccines are added to the inventory, and whenever vaccine recommendations are updated.
- Document all training completed with dates and participant names.
- Keep policies and procedures near vaccine storage areas and ensure that staff know where to find them.
- Post reminders throughout the health center or free clinic about the "7 rights" of vaccine administration to emphasize safety practices and proper documentation and to create greater awareness for choosing the correct vaccine (and diluent, if applicable), choosing age-appropriate dosage, and checking expiration dates.
- Ensure compliance with state-specific scope-of-practice laws for medical assistants and other unlicensed healthcare staff as they pertain to immunization activities.

- Educate staff about the Vaccine Adverse Event Reporting System (VAERS) and encourage complete reporting of adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event. Learn more about vaccine safety monitoring from the CDC's safety monitoring webpage.

Target 2. Implement best practices for vaccine inventory management, including proper storage, labeling, and temperature monitoring.

- Designate a primary vaccine coordinator, as well as a backup staff member, who will be responsible for ensuring all vaccines are stored and handled correctly. Responsibilities may include ordering and receiving the vaccine supply, documenting inventory, organizing the storage areas, conducting daily temperature audits, and responding to out-of-range recordings.
- Maintain proper temperature of vaccines. Use best temperature-monitoring practices for refrigerated vaccines and for frozen vaccines, using calibrated thermometers, temperature-monitoring devices, and temperature control logs. Vaccines exposed to temperatures outside of recommended ranges may be reduced in potency and protectiveness. To reduce errors, institute the following:
    - Record minimum and maximum temperatures for the refrigerator and freezer, along with the date, time, and initials of the person who checked the temperature, twice daily (at the start and end of every workday). Maintain temperature logs for three years.
    - Use outlet covers and "Do Not Unplug" warning signs on refrigerators and freezers.
    - Take immediate action for temperatures out of range by notifying staff and labeling the exposed vaccines, and document the date and time, storage unit temperature, room temperature, and inventory of affected vaccine on your facilities' temperature excursion record. Place exposed vaccines in a separate container apart from other vaccines, but do not discard.

    - Consult with the state or local health department and contact your immunization program and/or the appropriate vaccine manufacturer if vaccines are exposed to improper storage conditions, to determine whether they can still be used.
- Display a vaccine storage chart that describes where and how to store specific vaccines and diluents and consider storing products used for reconstitution with their corresponding vaccines (e.g., put a vaccine and its diluent together in a sealable plastic bag, purchase unit-dose vaccines that are packaged with their diluents).
- Avoid storing vaccines and diluents with similar names or similar packaging near each other and use vaccine labels to safely and effectively organize vaccines within the storage area.
- Separate pediatric and adult formulations of a vaccine; label the containers to facilitate age-specific selection. For example, use shelf labels to direct staff to the location of each formulation, and place warning labels on products (e.g., "Adult" or "Pediatric").
- Provide staff with an approved list of vaccine acronyms and abbreviations.
- Store vaccines separately from other medications and biologic agents and never store food or beverages in refrigerators or freezers with vaccines.
- Check for expired doses and rotate vaccine and diluent stock at least weekly or when the facility receives a vaccine delivery, placing products with the earliest expiration dates to the front of the storage unit, facilitating easy access. Expired vaccines and diluents should be removed immediately to avoid inadvertently administering them.
- Conduct focused medical record reviews to ensure that required vaccination procedures and documentation are being followed.

Target 3. Follow standard guidelines for vaccine preparation.

- Consider using job aids, including a vaccine preparation and administration table, as well as implementing a self-check tool when preparing vaccines for administration.

- Always refer to product information or package inserts for detailed instructions on reconstituting specific vaccines and important information on the appropriate diluent and expiration time after a vaccine package has been opened or a vaccine has been reconstituted.
- Prepare vaccines only when you are ready to administer them and label syringes after preparation.
- Administer only vaccines that you have prepared yourself.
- When conducting large immunization events, use manufacturer-supplied prefilled syringes, if possible, as they are designated for both storage and administration.
- However, otherwise avoid prefilling syringes, as this increases the risk for administration errors or wasted vaccine and may cause bacterial growth in vaccines that do not contain a preservative. Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage.

Target 4. Involve patients, caregivers, and parents of pediatric patients when administering vaccines.

- Verify the vaccination schedule and the patient's age in the health record or state immunization information system to avoid doses administered too soon, as well as errors associated with age-specific formulations.
- Provide patients and parents or caregivers with vaccine information statements (VISs), which include age requirements, and review before each vaccination.
- Read the name of the vaccine and the expiration date aloud, with simultaneous confirmation from the patient, parent, or caregiver.
- Document the name of the vaccine administered, product lot number, dose, route, date, and time the vaccine was administered, as well as the name of the individual who administered the vaccine and whether the VIS was given during the informed consent discussion.
- Consider having both the person administering the vaccine and the patient, parent, or caregiver sign and date the immunization record.

Want to learn more? See Immunizations and Safe Injection Practices in the Infection Control Toolkit, the Get Safe! A Brief Case for Safety: Strategies to Increase Pediatric Vaccination Rates in Your Practice, and the Get Safe! A Brief Case for Safety: Vaccine Awareness and Administration.

All resources are provided for FREE by ECRI on behalf of HRSA. Don't have access or want to attend a free, live demonstration of the Clinical Risk Management Program website? Email Clinical_RM_Program@ecri.org or call (610) 825-6000 ext. 5200.

Additional resources include the CDC Vaccine Storage and Handling Toolkit, the American Academy of Pediatrics Immunization Training Guide and Practice Procedure Manual, and Understanding the Vaccine Adverse Event Reporting System (VAERS). An addendum to the Vaccine Storage and Handling Toolkit that specifically addresses COVID-19 vaccines is being developed at the time of this publication in addition to other training materials.

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