**PB5**

**Welcome to today's session of the *Epidemiology and Prevention of Vaccine-Preventable Diseases* webinar series for 2019. I'm JoEllen Wolicki, a nurse educator in the Immunization Services Division of CDC's National Center for Immunization and Respiratory Diseases. I'll be the moderator for today's session. Here are our learning objectives. At the conclusion of this session, the participant will be able to describe the different forms of immunity; describe the different types of vaccines; for each vaccine-preventable disease, identify those for whom routine immunization is recommended; for each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease; describe an emerging immunization issue; locate resources relevant to current immunization practice; and implement disease detection and prevention in health care services, for example, smoking cessation, weight reduction, diabetes screening, blood pressure screening, and immunization services to prevent health problems and maintain health. Today's webinar will cover vaccine storage, handling, and administration. Our presenter is Commander Tina Objio, a nurse educator in the Immunization Services Division of the National Center for Immunization and Respiratory Diseases. Continuing education or CE is available only through the CDC Training and Continuing Education online system. The web address is shown on your screen. Once in the system, search for the relevant course number listed on the screen. If you are watching this webinar live, CE credit for the session will expire on August 19, 2019. If you are watching the enduring archived version, CE credit expires on June 1, 2020. When obtaining CE for today's live program, you will be required to provide an access code. We will tell you the access code later in this program. The access code will only be provided during the presentation. CE requirements prohibit us from sharing this code at any other time. If you are not familiar with CDC's CE system, detailed, written instructions on how to get CE are available in the resources pod. CDC, our planners, and content experts and their spouses and partners wish to disclose they have no financial interest in or other relationships with manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. Presenters will not include any discussion of the unlabeled use of a product or a product under investigational use. CDC does not accept any commercial support. If you have a question during this presentation, please type your question into the Q and A pod on your screen. I will collect these questions during the presentation and we will address them during the question and answer period that follows the presentation. I would now like to turn today's session over to Ms. Objio for her presentation.**

Thank you, Ms. Wolicki. If you're following along in the 13th edition of *Epidemiology and Prevention of Vaccine-Preventable Diseases*, the Pink Book, there have been some updates since the Pink Book was published. However, the information presented on these slides is current. We'll start with vaccine storage and handling. Do storage and handling matter? Yes, they do. Analysis of data from the Vaccine Adverse Event Reporting System, or VAERS, which was briefly discussed in an earlier presentation in this series, suggests that vaccine storage and handling errors are by far the number one vaccine-related error, but what does that mean in the practical sense for providers who administer vaccines or patients who receive them?

A product that has not been stored properly may not work. If it does not work, then the whole purpose, which is to generate an immune response to vaccine-preventable disease, is defeated.

Confidence in a provider and practice can impact future vaccine decision-making. If you have to recall a patient or many patients for revaccination because you've just learned that a product was stored out of range and is not viable, that can create a problem and if the error involves children, you may have upset parents to deal with.

Cost is another factor. We usually account for provider or staff time in product cost if we want to calculate the cost on our end, but there's also a cost to the parent bringing the child back in. They may be missing work and the child may be missing valuable learning time at school and so on. This error can trickle down to impact many people. The key to remember is that this is avoidable and we're going to talk more about how to avoid storage and handling errors.

Let's begin with recommendations. CDC's Vaccine Storage and Handling Toolkit brings together best practices from multiple sources and scientific studies. Other materials are generally updated based on the toolkit. This includes *You Call the Shots* training and other tools and resources.

Let's talk about the foundation of storage and handling, the cold chain. The cold chain starts with the manufacturer and ends at the point you're administering the vaccine. As soon as a vaccine delivery arrives, the responsibility for the cold chain shifts to you and remains with you until the vaccine has been given to the patient. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, freezing temperatures, or light at any step in the cold chain. Once lost, potency cannot be restored. Vaccines that are too warm or too cold can have reduced or destroyed potency, so don't forget to monitor both ends of the temperature range.

An effective cold chain relies on three main elements: a well-trained staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management. On the right, I'm showing an image associated with one of our trainings that highlights keys to vaccine storage and handling. This training provides a great opportunity to review some important concepts and get free CE.

Let's talk a little more about staff and training. All staff members who receive vaccine deliveries, as well as those who handle or administer vaccines, should be trained in vaccine-related practices and be familiar with your facility's storage and handling SOPs. If you're a VFC provider or have vaccines purchased with public funds, your program may have specific requirements related to training, policies, and procedures.

Storage and handling plans and SOPs should contain plans and information for three major areas: general information such as manufacturer and equipment service provider contact information, as well as duty descriptions, regularly used forms, and staff training requirements; routine storage and handling SOPs such as ordering and temperature monitoring instructions; and emergency vaccine storage handling and transport SOPs. These should outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions. Worksheets and checklists to assist you in developing your organization's routine and emergency SOPs are located in the resources section of the toolkit.

In addition to these Pink Book Webinars, *You Call the Shots* training is available online with free CE and is a great resource for vaccine-specific staff training and other principles, including storage and handling. Staff training should be completed as part of new employee orientation, annually, when new vaccines are added, and when recommendations change.

The vaccine coordinator has a lot of responsibilities. In the toolkit, we've provided a list of duties to include such as ordering vaccines, training, and responding to temperature excursions, but your organization may have additional duties based on the setup. The primary coordinator should have an alternate to help with duties and cover in the absence of the primary and duties can be delegated to train staff so long as the coordinator continues to monitor and oversee those duties to ensure they are correctly completed and documented.

Let's talk about equipment. This can be an area of frustration because it involves resources, which we know can be limited, so in the toolkit, we aim to provide options when possible, highlighting what is preferred but still allowing for some acceptable options with guidance for use.

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines and are preferred. Pharmaceutical-grade units are designed to store biologics, including vaccines, and are a preferred option for providers who need to do both. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

Purpose-built or pharmaceutical-grade units can be designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large. Household-grade units can be an acceptable alternative to pharmaceutical-grade and purpose-built vaccine storage units. Household-grade units are primarily designed and marketed for home use. The freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

Compact-style, purpose-built units for biologics can be used to store vaccines. Be sure to ensure there is enough space for stock at the busiest time of year, such as flu season. These units should not be confused with dormitory-style units, which are also small, but do not adequately maintain temperatures needed for vaccine storage. Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances. These units have a single exterior door and an evaporator plate cooling coil, usually located in an icemaker/freezer compartment. Even when used for temporary storage, these units are high risk to freeze and potentially destroy vaccine.

No matter what type of unit you have, refrigerators should maintain temperatures between 2 degrees Celsius and 8 degrees Celsius, or 36 degrees Fahrenheit and 46 degrees Fahrenheit. Freezers should maintain temperatures between -50 degrees Celsius and -15 degrees Celsius, or -58 degrees Fahrenheit and +5 degrees Fahrenheit. Refer to the owner's manual for instructions on how to operate the thermostat. Measure and monitor unit temperatures with a temperature monitoring device—not based on any thermostat markings or readings, which can vary by unit.

CDC recommends a specific type of temperature monitoring device, or TMD, called a “digital data logger” or “DDL.” A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range, referred to as a “temperature excursion.” Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. It can also be set to alarm for out-of-range temperatures. Data are collected, which can be helpful for management of a temperature excursion or the unit generally.

Many DDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend to reflect only air temperature.

You should have one TMD, preferably a DDL, for each storage unit and transport unit, including any that may be used in an emergency, plus a backup DDL for use in case one breaks.

Certain types of TMDs have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they're checked, may fail to detect temperatures outside the recommended range.

Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline. TMDs can experience a drift over time, affecting their accuracy. This testing ensures that accuracy of the device continues to conform to nationally accepted standards. Their certificate of calibration should include a number of items shown on the slide.

Storage unit temperatures can be monitored in one of two ways, depending on the type of temperature monitoring device being used. If using a DDL with a buffered probe, which is recommended, or other device that measures min/max temperatures, check and record the storage unit min/max at the start of each workday. This is a requirement for VFC providers, but VFC programs may have even more specific requirements. The min/max recorded should be those obtained since the last workday when the min/max were reset.

If the device does not display min/max, then check and record the current temperature a minimum of two times at the start and end of the workday. This should be done even if there is an alarm.

Use a log sheet to have staff record the temperature, date, time, name or initials of the person recording, and any actions taken for temperature excursion or any other notes per organizational SOPs. Immunization Action Coalition, or IAC, has developed temperature monitoring logs that are useful that can be found on their website.

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Your vaccines are either on their way to not working or have already been rendered ineffective, depending on the circumstances of the excursion, so you must act immediately. Failure to act means that patients could get vaccines that don't work and then what is the point?

Any temperature reading outside the recommended ranges in the manufacturer's package insert is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable. There are detailed instructions on temperature excursions in the toolkit. The key is that you must act immediately and follow through the entire process in order to ensure you have resolved the situation.

We get a lot of questions from providers who want to know if they can still use a product after an excursion. Those questions should be directed to the manufacturer, as they have done the studies and know the limits their product can withstand. Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

There are a lot of things you can do to reduce the risk of errors and temperature excursions. Store each type of vaccine or diluent in its original packaging and in a separate labeled container. Avoid danger zones in a household-style unit, which include the very top, bottom, door, shelves, and deli/fruit/veggie doors. Avoid placing or storing any item other than vaccines, diluents, and water bottles inside storage units. If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines. Potentially contaminated items like blood or urine should be properly contained and stored below vaccines to avoid the risk of contamination from drips or leaks. The freezer of a household-grade unit may be used for non-vaccine medical storage so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored. Use products that expire sooner first and get already expired products out of the unit. Place water bottles on the top shelf and floor and in the door racks in household-grade units. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or power failure. Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Proper vaccine inventory management is essential for vaccine ordering and stock rotation and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they're managed properly is important.

Maintaining the cold chain is the first step in vaccine inventory management. All staff members who might receive vaccines should be trained to immediately notify the vaccine coordinator, alternate, or trained designee about vaccine arrival. Vaccines must always be immediately checked and stored when they arrive. Check for damage and receipt of order, including diluents. Check expiration dates and place vaccines in the storage unit accordingly. Immediately check the cold chain monitor in the shipping container, if one was included, for any indication of a temperature excursion during transit. Even if there was a temperature excursion, store the affected vaccine in the storage unit at the appropriate temperature and mark it "do not use." If there are any issues with the delivery, be sure to notify the manufacturer, VFC program, or other relevant parties, as appropriate, to ensure the situation is documented and steps can be taken to remedy the problem.

Use a stock record to account for and document every dose of vaccine. A stock record of inventory can be in either paper or electronic form and should include information from delivery to use in order to account for your stock. State and local programs that have an immunization information system with vaccine inventory accounting functions will usually require VFC providers to use the IIS to track their inventory.

Rotate stock so that vaccines that will expire first are used first. Never leave expired vaccine in the unit. It cannot be used and should be disposed of according to policy. If you're a VFC provider, contact your immunization program to find out if expired vaccines purchased with public funds can be returned.

Overstocking can create issues, including waste of unused vaccine, storage space problems, and higher volume of loss in the event of storage unit failure. Most facilities keep about four weeks of inventory on hand and reorder based on patient needs after checking stock count. Vaccine orders usually arrive within one to two weeks, but there can be delays, so keep this in mind when planning orders.

Sometimes, unused vaccine, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. The immunization program and/or the vaccine manufacturer may be able to provide this type of information. Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccines predrawn by providers—these usually cannot be returned and should be discarded according to your state requirements.

As for empty vaccine vials, most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your state requirements regarding disposal. Medical waste disposal requirements may vary from state to state because they are set up by state environmental agencies. The immunization program and state environmental agency are good resources for specific disposal information and guidance.

Vaccine transport, as described in this section, involves the movement of vaccine between providers or other locations over a shorter distance and time frame and is appropriate for events such as an emergency, offsite clinic, or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine transport to offsite or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised because of a power loss. Depending on the situation, some transport recommendations may be the same, but there are also some differences. On the right is an image of an inexpensive emergency vaccine transport system. This system uses conditioned frozen water bottles to keep refrigerated vaccines cool.

Vaccines from your supply should not be routinely transported, but there are situations when transport is necessary, such as an offsite clinic or in an emergency. This table shows different transport systems that can be used. Please note that some can be used for emergency transport only.

The total time for transport alone or transport plus clinic workday should be a maximum of eight hours. For example, if transport to an offsite clinic is one hour each way, the clinic may run for up to six hours.

All of the recommended systems require you to use a temperature monitoring device, preferably a DDL with a buffered probe, to ensure your vaccines stay in range for the whole transport process.

Improper packing for transport is as risky for vaccines as a failed storage unit, so having detailed transport SOPs is critical to ensuring vaccine viability. If your organization transports vaccine for any reason, include vaccine packing and transport protocols in your routine and emergency storage and handling SOPs. If an emergency can be anticipated, like a weather event, suspend vaccination activities before the onset of the emergency conditions to allow more time for packing and transport. Be sure transport protocols include information about the vehicle that is to be used and other considerations for keeping the vaccine transport unit from getting excessively hot or cold during movement.

Regardless of if the transport is for an emergency or other situation such as an offsite clinic, use a continuous temperature monitoring device, preferably a digital data logger, for monitoring and recording temperatures while transporting vaccines. Place the buffered probe directly with the vaccines. Keep the display on top so you can easily see the temperature.

In addition to what has been discussed for vaccine transport, which included emergency vaccine transport, there are some additional things to keep in mind during emergencies.

Establish a working agreement with at least one alternative storage facility, even if you have a generator as backup. Make sure you have 24-hour access to this facility. If you just have a broken storage unit and have a backup unit or other units in use with free space, you can transfer your vaccine stock while you repair a broken unit. Having an onsite generator prevents the need to transport vaccines to an alternative storage facility during a power outage. Keep sufficient fuel on hand to continuously run a generator for at least 72 hours.

If you cannot find an alternative vaccine storage facility within a reasonable distance or if you cannot reach your alternative facility, keep your vaccine storage units closed. They should maintain appropriate temperatures for some time because they're usually well insulated. Your TMD should alert you to the temperature starting to change. Temporary storage containers should also remain closed and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

If you have a power outage, you may need to quickly determine what the situation is in order to figure out next steps. If you find that the outage will be short, you may want to just keep your vaccines in their current storage units. Keep the doors closed and monitor for temperature changes using the DDL from the outside display. If this is likely to be a long outage, you should implement emergency SOPs and get your vaccines moved to a safe location per your protocols.

Vaccine preparation is the final step in the cold chain before administration and is as important as managing the vaccines within the storage units. Prepare vaccines in a designated area away from any space where potentially contaminated items are placed. Only prepare vaccines when you're ready to administer them and prepare your own vaccines for administration. Don't use something prepared by another person. This is a quality control and patient safety issue and best practice standard of medication administration. Verify all parts of the process, ensuring you are following medication administration best practices. Vaccines, although safe, should be treated like other medications because people can have true contraindications, like history of anaphylactic reaction to vaccine or component, and staff can make errors like administering the wrong vaccine. Always check expiration dates and confirm that you've selected the correct vaccine.

Predrawing is generally not recommended, but if you must predraw, such as at a mass immunization event, here is some guidance. Predrawn syringes must be stored at the manufacturer-recommended temperatures throughout the clinic day. Set up a separate administration station for each vaccine type to prevent medication errors. Draw up vaccines only after arriving at the clinic site or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for vaccine storage. Each person administering vaccines should draw up no more than one multidose vial or 10 doses at one time. Monitor patient flow to avoid drawing up unnecessary doses. Predraw reconstituted vaccine into a syringe only when you're ready to administer it. If a predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused, reconstituted vaccine can only be stored in the vial for a specified amount of time. Never transfer predrawn, reconstituted vaccine back into a vial for storage. Discard any remaining vaccine and predrawn syringes at the end of the workday or sooner as per manufacturer guidance. As an alternative to predrawing vaccines, use manufacturer-filled syringes for large vaccination clinics when possible.

Now let's talk about vaccine administration. Not only is it critical that vaccines are stored and handled properly, but they must also be administered correctly to ensure the vaccination is as safe and effective as possible. Vaccinators should follow professional standards for medication administration and the guidance provided by vaccine manufacturers. CDC also has a website for providers on evidence-based safe injection practices. The link to this website is included on the slide.

Improper administration of vaccines can prevent the vaccines from providing optimal protection and may even lead to adverse reactions and injuries. All personnel, including temporary staff, that will administer vaccines should receive comprehensive, competency-based training on vaccine administration during their orientation, at annual updates, and when there are new recommendations or new vaccines are added to the facility's inventory. Knowledge and skill should be assessed before someone is allowed to administer vaccines to patients. If you need an immunization skills checklist, we have included a link to one on the Immunization Action Coalition website.

The patient's immunization history should be reviewed at every health care visit. When the patient arrives, providers should obtain a complete immunization history and compare the patient's immunization records, the medical record, and immunization information system or registry data if one is available. Use the current immunization schedule based on the age of the patient to determine all recommended vaccines that are needed. Also assess for any vaccines that are indicated based on health status, occupation, or other risk factors. If a documented immunization history is not available, administer the vaccines that are indicated. With the exception of self-report for influenza and pneumococcal polysaccharide vaccine, providers should only accept written, dated records.

All patients should be screened for contraindications and precautions prior to administering any vaccine, even if the patient has previously received that vaccine. If you do not have screening questionnaires, we've included links to screening forms available on the Immunization Action Coalition website. Use vaccine information statements and other resources to discuss vaccine benefits and risks and disease risks with parents and patients. After-care instructions should include information and strategies for dealing with side effects and for determining when medical attention should be sought. We've also included links to a few resources that can be used with parents when providing after-care instructions.

When determining patient positioning and restraint, consider the patient's comfort and safety as well as their age, activity level, and the site where you'll be administering the vaccine. If you can get the parent involved, this has been shown to increase a child's comfort. Encourage parents to hold their child while the vaccine is being administered but, if the parent isn't comfortable, have someone else assist. This slide shows some suggested positioning techniques. Studies have shown that children are less fearful and experience less pain if they're sitting up rather than lying down when vaccines are administered. This seems to reduce anxiety, which, in turn, reduces the perception of pain.

All providers who administer vaccines to older children, adolescents, and adults should be aware of the risk of syncope or fainting after vaccination, which could lead to patient injury, so make sure the person who is being vaccinated is always seated or lying down. Be aware of symptoms that precede fainting, like weakness, dizziness, and if the patient looks pale and, of course, provide supportive care and take appropriate measures to prevent injuries if the patient does faint. The Advisory Committee on Immunization Practices, or ACIP, also recommends that providers consider observing the patient with the patient seated or lying down for 15 minutes after vaccination.

The pain associated with vaccine injections is a source of distress for children, their parents, and those administering the injections. If not addressed, this pain can lead to preprocedural anxiety in the future, needle fears, and avoiding health care, including not adhering to vaccination schedules. It's estimated that up to 25% of adults have a fear of needles, with most fears developing in childhood, and about 10% of the population avoids vaccination and other needle procedures because of needle fears. We've divided pain management strategies into the five Ps: pharmacological, physical, psychological, procedural, and process intervention. The first two are shown here and the next three are shown on the next slide. Pharmacological strategies include topical numbing agents and physical strategies include positioning and tactile stimulation.

Several of the practice recommendations relating to the injection procedure can be implemented easily because they don't require planning or additional resources. For example, selecting appropriate positioning does not usually require any advance planning. A few practice recommendations, such as breastfeeding or administration of sugar water for infants and application of topical anesthetics and psychological interventions, require some planning and possibly additional resources. Health care providers are encouraged to discuss these additional options with parents and children and to select the strategies best suited to individual children. Pain relief is enhanced when individual strategies are combined. Therefore, health care providers are encouraged to use a mix of strategies. Here's a job aid that can be shared with staff, outlining these and other measures to decrease procedural pain.

I'm sure we all know that we need to take every precaution to prevent infection when performing any procedure, so just as a reminder, hand hygiene should be performed before preparing vaccines, between patients, and anytime hands become soiled. Occupational Safety and Health Administration, or OSHA, regulations do not require gloves to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. If gloves are worn, they should be changed and hands cleaned after removing gloves. CDC has additional information on hand hygiene in health care settings. The link is at the bottom of this slide and, of course, puncture-proof biohazard containers should be used for discarding injection supplies.

Here are a few “nevers” when preparing vaccines. Never combine separate vaccines into a single syringe. Never transfer vaccine from one syringe to another and never draw partial doses of vaccine from separate vials to obtain a full dose.

Rotavirus vaccines, oral typhoid vaccine, and an oral cholera vaccine are the only US-licensed vaccines that are administered by the oral route. For children, oral vaccines should generally be given before administering injections or performing other procedures that might cause discomfort because it can be difficult to administer an oral vaccine if an infant or small child is crying. The Rrotavirus liquid should be administered slowly down the inside of the cheek between the cheek and the gum toward the back of the infant's mouth.

Live, attenuated influenza vaccine is the only vaccine administered by the intranasal route. The images to the right show both oral vaccine administration for an infant, as well as live, attenuated influenza vaccine administration in a child. These images were taken from the vaccine administration resources page, which houses several short vaccine administration training videos. The link to this training is provided on the slide.

Subcutaneous injections are administered into the fatty tissue found below the dermis and above muscle tissue. The recommended sites are the thigh for infants younger than 12 months of age and the upper outer triceps of the arm for persons one year of age and older. If necessary, the upper outer triceps area can be used for infants. A 5/8-inch, 23- to 25-gauge needle should be used. To avoid reaching the muscle, the fatty tissue is pinched up and the needle is inserted at a 45-degree angle.

Intramuscular injections are administered into the muscle tissue below the dermis and subcutaneous tissue. To avoid injection into subcutaneous tissue, the skin is spread taut between the thumb and forefinger, which isolates the muscle. Another technique used mostly for pediatric and geriatric patients is to grasp the tissue and bunch up the muscle; then the needle is inserted fully into the muscle at a 90-degree angle. Because there are no large blood vessels in the recommended sites, aspiration before injection of vaccines is not necessary. Also, some safety-engineered syringes do not allow for aspiration. The needle gauge is typically a 22- to 25-gauge needle. The needle should be long enough to reach the muscle and prevent vaccine from seeping into subcutaneous issue, but not so long that the needle would strike underlying nerves, blood vessels, or bone. It is important for the health care provider to be familiar with the anatomy of the area where the vaccine will be injected.

For the majority of infants, the anterolateral aspect of the thigh or vastus lateralis muscle is the recommended site because it's a large muscle. For the majority of infants, a 1-inch, 22- to 25-gauge needle is sufficient to penetrate the muscle. For a neonate, which is defined as the first 28 days of life, and for preterm infants, a 5/8-inch needle is usually long enough if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90-degree angle.

For toddlers, the vastus lateralis muscle in the anterolateral thigh is the preferred site. The needle should be at least 1 inch long. The deltoid muscle can be used if there is enough muscle tissue. A 5/8-inch needle is adequate for the deltoid muscle and if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90-degree angle.

The deltoid muscle is preferred for children 3–18 years of age. The needle size for deltoid injections can range from 22- to 25-gauge and from 5/8 to 1 inch depending on technique. A 5/8- or 1-inch needle is required for most young children in this age range. In general, a 1-inch needle is needed for older children and adolescents. The vastus lateralis muscle in the anterolateral thigh is an alternative site if the deltoid site cannot be used and a 1-inch or 1-1/4-inch needle will be long enough for most older children and adolescents.

For adults, the deltoid muscle is recommended for routine intramuscular vaccinations, but the anterolateral thigh can also be used. There's a chart in the Pink Book on page 96 based on gender and weight to assist in selecting needle length. It's important to use the route of administration recommended by the vaccine manufacturer. There are only two vaccines that can be administered by either the subcutaneous route or the intramuscular route. They are PPSV23, the pneumococcal polysaccharide vaccine, and IPV, the inactivated polio vaccine.

Shoulder injury related to vaccine administration is a vaccine administration error that we have seen in increasing reports to the Vaccine Adverse Event Reporting System and claims to the Vaccine Injury Compensation Program in recent years. In March 2017, shoulder injury related to vaccine administration was added to the vaccine injury table. Shoulder injuries related to vaccine administration are injuries to the musculoskeletal structure of the shoulder, including the ligaments, bursa, and tendons. The injury is thought to occur as a result of the unintended injection of vaccine antigen and/or trauma from the needle going into and around the underlying bursa of the shoulder. Symptoms include shoulder pain and limited mobility after the injection.SIRVA is much more common in adults than children.

Follow proper injection technique and best practices when administering vaccines. Identify the site correctly using proper landmarks. Use the correct needle length based on the age, size of the patient, and injection technique.

CDC's vaccine administration web page contains additional vaccine administration information and materials.

If multiple vaccines are administered at a single visit, it is best to administer each vaccine at a different anatomic site if possible. For infants and younger children, if more than two vaccines are injected in a single limb, the thigh is preferred because it's a larger muscle. For older children and adults, the deltoid muscle can be used for more than one intramuscular injection. The injection sites should be separated by one to two inches. This way, if one of the vaccines causes a local reaction, you have a better chance of knowing which vaccine caused it. Vaccines that are the most reactive should be administered in different limbs if possible. If you have combination vaccines in stock, they can reduce the number of injections. If a vaccine and an immune globulin preparation are administered at the same time, separate limbs should be used. The location of all injection sites should be documented in the patient's medical record. Health care providers should consider using a vaccination site map so that all persons administering vaccines routinely use the same anatomic site for each different vaccine.

Documentation is an important part of any immunization visit. This can be useful for ensuring people get the vaccines they need when they need them without duplication and it can also help in the event that you need to review records, such as a product recall or internal tracking of organizational performance.

VAERS data show the top vaccination errors are storage and handling errors and second to these are administration errors, so it’s important to take a minute to discuss errors.

As hard as we try to prevent errors, we’re human and we’re going to make mistakes sometimes. The first step to preventing errors is to establish an environment where you work that values reporting and investigating errors. This is critical to good risk management and quality improvement. ou don’t want your staff to fear reporting an error. This is often referred to as “establishing a just culture.” Be familiar with and use best practice guidelines for storing, handling, preparing, and administering vaccines. If a temperature excursion occurs, isolate the affected vaccine and take immediate action to correct the situation. Promptly remove expired vaccines from your storage unit.

Only administer vaccines that you have prepared and triple-checked. Be familiar with current recommended immunization schedules. Recommendations change as new data become available and new vaccines enter the market. Immunization recommendations can change as often as three times per year because the Advisory Committee on Immunization Practices meets three times per year. After final approval, the most current vaccine recommendations will be published and posted on the ACIP web page under “recommendations.” Use standing orders when possible. We’ve included a link to information about standing orders available on the Immunization Action Coalition website.

So what you’re to do if there is an administration error. The patient or parent should be notified of the error. You want to assess the status of the patient and, hopefully, there are no adverse events associated with the error. Of course, the patient or parent will want to know what’s next. Do they have to be revaccinated? So be sure you know what action to take. Not all errors require revaccination, so be sure to consult available resources to find out if it is necessary or not. Documentation is also important. Even if it was an error, the vaccine administered will need to be recorded. Other documentation will depend on your facility’s requirement for documentation related to an error. There may be an incident report that needs to be completed.

The Vaccine Adverse Event Reporting System, VAERS, accepts all reports, including reports of vaccination errors. Please report clinically important adverse events that occur after vaccination of adults and children, even if you’re not sure whether the vaccine caused the adverse event or the error would be preventable with public health action or education. That concludes the content portion. I’m going to turn things back over to Ms. Wolicki for a moment before we take a few questions.

Thank you very much, Ms. Objio, for a very informative presentation. On the screen you can now see the continuing education information, including the access code for today’s webinar. The access code is Handling with a capital “H.” The access code applies to the live program only. Things to remember about the access codes— number one and most important, please write the access code down now. The access code cannot be given out at any time other than during this presentation—not by email request or any other means. Number two, the access code is case-sensitive, so that capital “H” is very important. There is no access code for the enduring archived program. Let me repeat the access code. It is Handling with a capital “H” and, as a reminder, the resources pod on your screen contains the instructions for CE.

Now let’s take the remaining time to review some of the questions we received during the program. So someone has a question about single-dose vials and the question is some single-dose vials contain more than 0.5 mL. Should we administer the recommended dose of vaccine or the entire vial, even if it contains more than the recommended dose?

We get this question quite a bit. Generally, the entire volume should be used, even if it’s a little more than the 0.5 mL. Discarding the excess vaccine is not required or recommended, but there is an exception. This exception is for recombinant zoster vaccine, or Shingrix. The RZV adjuvant vial may contain up to 0.75 mL of liquid. All of the adjuvant solution should be withdrawn and used to reconstitute the lyophilized or powder vaccine component and then after mixing, withdraw the recommended 0.5 mL dose and discard any reconstituted vaccine left in the vial.

**Thanks, because that’s really important to let people know because we do get that question a lot. We have a question about someone who has a lot of vaccine in their stock. So we have a number of different vaccines in our stock and the space in the storage unit is very limited. Can we put the probe for our digital data logger in the bottom of the fridge where the food drawer was located to make space for a few more vaccines?**

The answer to that is no. The reason we recommend you avoid storing vaccines in the deli, fruit, or vegetable drawers or in the door of the household-grade unit is because the temperatures in these areas are not stable and they can differ from those inside of the main part of the unit where we recommend vaccines are stored. The buffered probe of the digital data logger should be placed—or the probe that you have—should be placed where your vaccines are located. If you place the probe in an area of the refrigerator where we know temperature fluctuations can occur, you may be adjusting your fridge based on the temperature in the drawer area as opposed to the temperature in the vaccine storage area. And then later, if you found out that you’ve been incorrectly measuring temperature, and your vaccine storage area was actually several degrees out of range, you’d be looking at activating a temperature excursion protocol and that means determining if vaccine was viable and doses were valid for a whole lot of patients, potentially for the entire duration that the probe was in the incorrect location and the temperature in the vaccine storage area was out of range.

**Thanks. That’s a lot of really good information. Here’s a question we received about the Vaccine Adverse Event Reporting System. Does the VAERS report have to be submitted by the health care provider only or is the patient responsible to report? Whose responsibility is it?**

That’s an excellent question and, actually, if you go to the VAERS page, it contains a lot of great information, but. very simply, I will answer that question in that anybody can submit a VAERS report. The provider can submit it. The patient can submit it. I’ve even heard that pharmaceutical companies have submitted to VAERS. So the answer to that is anybody can submit a report to VAERS.

**Here’s a question we get pretty frequently. When we have storage and handling guidance, who takes precedence? So our ACIP storage and handling recommendations or is it the state-level guidance that takes precedence over each other?**

Storage and handling recommendations are the general guidance based on science and best evidence and often what happens is the state-level guidance will exceed what is stated in the Storage and Handling Toolkit and that is perfectly acceptable. Sometimes there are requirements by VFC or other program requirements and they may stipulate something a little bit stricter than what’s stated in CDC’s Vaccine Storage and Handling Toolkit and, sometimes, we’ll get people who will write in and ask us if that’s ok and, of course, the answer to that is you should follow the VFC or program-specific guidance. Now if you have a question and you think something is not being met or it’s under what’s stated in CDC’s Vaccine Storage and Handling Toolkit, certainly reach out to your program or you could write us at NIP-INFO and we’d be happy to try to help you through that or talk to you about the situation.

**Great. We have time for one last question. This one is another one that I’ve been getting a lot lately. Why are some vaccinations given subcutaneously while others must be given intramuscularly?**

Generally, vaccines containing an adjuvant, which is a component of the vaccine that’s in there to enhance the response to the antigen—those are administered IM, intramuscularly, to help to try to avoid irritation, inflammation, sometimes skin discoloration, or that hard area, the induration that can develop. So this includes most of the inactivated vaccines, with a few exceptions. I think those are IPV and pneumo, which, like we said in the presentation, those can be given either subcutaneously or IM. The other thing is that vaccine efficacy can also be reduced if vaccine is not given via the recommended route per the manufacturer instructions.

Thank you. We did have a number of questions today that we don’t have time to get to. I want to remind everybody that we will post answers to these questions on the web page for today’s webinar, along with the resources document and a copy of the slides. I’d like to review some of the continuing education information one last time. Please go to the web page shown on the screen to obtain CE credit. You can search for today’s live CE event course number, which is WC2645-071719. The numbers after the dash are today’s date and differentiate this presentation from others in the series. CE credit for the live course will expire on August 19, 2019. The access code again for today’s live session is Handling with a capital “H.” If you are watching the archived version of the webinar, search for the course number, which is WD2645-071719, slightly different from the live webinar course number. CE for the enduring archived program lasts until June 1, 2020, and no access code is needed.

**For help with the online system, please dial 1-800-41-TRAIN, or 1-800-418-7246, from 8 am until 4 pm Eastern time, or you can email** **ce@cdc.gov****. If you have any additional questions about content presented today, email us at** **NIPINFO@cdc.gov** **and we’ll respond as quickly as possible. A comprehensive list of resources for all of the Pink Book webinars in this series is pictured here on the slide, and they can be found in the resources pod and on the web page for this session. Additional resources with links are outlined on this slide, including the Pink Book. It’s available online or if you want a hard copy, you may purchase it at the link for the Public Health Foundation Learning Resource Center. Our CDC vaccines and immunizations home page is highlighted with resources for patient education. That concludes today’s program. I want to thank Ms. Objio for the presentation today and for answering your questions. Please join us for the next session in this series and next week we’ll be discussing DTaP and Tdap. Thank you very much for joining us today and have a great day.**

**END.**