

NWX-DISEASE CONTROL & PREVENTI

**Moderator: Dale Babcock
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11:00am CT**

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen only mode. During the question and answer session you may press star one on your touchtone phone if you would like to ask a question.

Today's conference is being recorded. If you have any objections, you may disconnect at this time. I'd now like to turn the meeting over to Dr. (Andrew Kroger). You may begin.

Dr. (Andrew Kroger): Thank you very much. Welcome to Current Issues in Immunization Netonference. I'm (Andrew Kroger), a medical officer in the Immunization Services Division of the National Center for Immunization and Respiratory Diseases, or NCIRD, at the CDC and I will be the moderator for today's session.

To participate in today's program, you need a telephone connection and a separate internet connection. The learning objectives for the session are to describe an emerging immunization issue; to list a recent immunization recommendation made by the Advisory Committee on Immunization Practices, or ACIP; to locate resources relevant to current immunization

practice; and to obtain, assess, and apply patient information to determine the need for immunization.

Today is July 29, 2015. We have one topic for today's Netconference Ms. (Donna Weaver), nurse educator in the Communication and Education Branch in the Immunization Services Division of NCIRD CDC will discuss vaccine storage and handling and vaccine administration as presented in the CDC textbook Epidemiology and Prevention of Vaccine-Preventable Diseases, also known as the Pink Book whose thirteenth edition was published this year.

A question and answer session will follow today's presentation and we'll also offer another question and answer session on Thursday, August 6, at 10am Eastern Daylight Time.

Please make note of the following information. If you have technical trouble, please dial star zero on your telephone. If you'd like to ask a question when we get to that segment, please press star one on the phone. Continuing education or CE credit is available only through the CDC ATSDR training and continuing education online system at www2a.cdc.gov.TCEonline/. CE credit for this session today expires on August 31, 2015.

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So I will now turn the microphone over to Ms. (Weaver). You may begin.

(Donna Weaver): Well thank you Dr. (Kroger). Good afternoon everyone. It's a pleasure to present to you from here in Atlanta. Our topic today is vaccine storage and handling and administration. And if you're following along in the thirteenth edition of the pink book, the storage and handling slides I'm using are similar to the ones in chapter five, which starts on page sixty-three. This chapter provides an overview of best practice guidance for storage and handling.

I won't be able to cover every slide in this chapter given time constraints but you will find more detail in the Pink Book and we will also be posting these slides and a transcript on the Web site for this webinar series next week.

CDC's Vaccine Storage & Handling Toolkit located on the link you see on the slide contains comprehensive information on best practices and CDC storage and handling recommendations. Manufacturers' product information and package inserts include the most current information about the storage and handling of specific vaccines. And participants in the Vaccines for Children -- or VFC -- program or those who have any vaccines purchased with public funds should consult their state or local immunization program for specific program requirements.

Sometimes I'm asked what we mean by the vaccine storage and handling cold chain. It is the temperature-controlled environment that must be maintained to ensure that vaccines are stored properly from the time they're manufactured until they're administered to patients. The responsibility for maintaining the cold chain is shared among manufacturers, distributors, public health staff, and healthcare providers. And as you can see on this slide, the majority of the responsibility for maintaining the vaccine cold chain occurs at the provider level.

There are three essential components for managing the cold chain that every facility should have, and they are well-trained staff, the appropriate equipment for storing and monitoring vaccines, and efficient vaccine management procedures. Every facility should have policies and procedures in place that clearly spell out the storage and handling of vaccines. There should be a routine plan for daily management of your vaccine supply and also an emergency plan that spells out what to do to protect your vaccine supply in the event of an emergency.

If you do not have these plans in place, there is more detail in the Pink Book and CDC's storage and handling toolkit also provides guidance and checklists to help you in developing comprehensive detailed plans. These plans should be kept near your vaccine storage units and you want to be sure your staff knows where to find them and that they're familiar with them.

Also be sure that custodial and security staff are familiar with emergency notification procedures.

There should be one person in your facility who takes primary responsibility for vaccine storage and handling management, but there should also be at least one backup person who can take over in the absence of the primary coordinator. They both should be fully trained in all aspects of your routine and emergency policies and procedures. We also recommend that a physician partner or member of management be directly involved in seeing that these policies and procedures are carried out.

In addition to the coordinators and management, anyone who will receive deliveries, handle or administer vaccines, and have access to vaccine storage units should receive training and be familiar with the storage and handling

policies and procedures. Training is an important part of new employee orientation but it doesn't stop there.

Be sure that not only new staff know how to store and handle your vaccine supply but also any temporary staff. And we all need a review and update periodically, so all staff should receive annual training and an update whenever there are new recommendations for storage and handling or when new vaccines are added to your inventory.

Now, I want to be sure you're aware of CDC's storage and handling training products. We have an online training course called You Call the Shots which contains several modules including one on the Vaccines for Children or VFC program and another module on vaccine storage and handling. We offer continuing education credit for a variety of healthcare professions for these modules. I know some immunization programs require that their VFC providers complete these two modules annually.

And we also have an online training video called *Keys to Storing and Handling Your Vaccine Supply*. And there's also continuing education credit available with this video. We actually won an award for this video. It's interactive. It gives you an opportunity to test your vaccine storage and handling knowledge.

And don't forget about your state immunization program. Many of them have developed their own storage and handling training products.

Another issue that can sometimes cause problems and expensive loss of vaccines is improperly handling vaccine deliveries. Try to arrange for deliveries when the vaccine coordinator or backup person is available and

notify them immediately when the shipment arrives. Examine deliveries right away and store vaccines at the proper temperatures immediately upon arrival.

Examine the shipping container and its contents for any evidence of damage during shipment. Cross check the contents with the packing slip to be sure they match. Check heat and cold temperature monitors or indicators if either are included in the shipping container and follow the instructions on the monitors for reading and reporting.

If a monitor indicates a possible temperature excursion during shipping, the vaccines in question should be properly stored separate from other vaccines and marked "Do NOT Use." Then, according to your policies, the immunization program, distributor, or vaccine manufacturer should be consulted for guidance.

So now let's move on from the first element, well-trained staff, to the second which is the appropriate equipment for storing vaccines. We know from testing done by the National Institute of Standards and Technology, or NIST, that vaccine storage temperatures are best maintained in separate stand-alone refrigerators and freezers or pharmaceutical grade storage units.

So these are the types of units that CDC recommends for storing your vaccines. When vaccine are exposed to temperatures outside the recommended ranges, the losses can be very costly not only in vaccines and replacements but also in staff resource's and confidence in your facility if patients have to be recalled for revaccination.

So it is less costly in the long run to use good equipment that will maintain the appropriate temperatures.

Household combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. Most of these types of units have cold spots and temperature fluctuations in the refrigerator portion of the unit. Risk of freeze damage to refrigerated vaccines is increased because air from the freezer is circulated for cooling into the refrigerator.

If your current storage unit is a combination unit that has both a freezer compartment and refrigerator compartment, we recommend that you only use the refrigerator compartment for storing vaccines.

You know, we used to always worry about vaccines getting too warm, but actually more damage can be done if refrigerated vaccines are exposed to freezing temperatures. CDC recommends that if you stock varicella-containing vaccines, you should use a separate stand-alone freezer to store these vaccines. Do not risk exposing your refrigerated vaccines to the freezing temperatures required for varicella, MMRV, and zoster vaccines.

CDC does not recommend the use of dormitory style units at all, not even for temporary storage of vaccines. And VFC does not allow them to be used at all. NIST testing has shown that this type of unit is consistently unreliable in maintaining the recommended temperatures for both refrigerated and frozen vaccines.

Now, just because a storage unit is small does not mean that it is a dormitory style unit. See the green arrow. That little freezer area is not sufficient to maintain the appropriate freezer temperatures necessary for varicella-containing vaccines, but it can have a detrimental effect on refrigerator temperature. An under- or on-the-counter stand-alone refrigerator or freezer unit can be used to store vaccines as long as it's large enough to maintain the

proper temperatures for the largest vaccine stock that you handle at any time during a year.

For monitoring storage unit temperatures, CDC recommends only using calibrated continuous temperature monitoring devices that have a certificate of traceability and calibration testing, which is also known as a report of calibration. Now this calibration or report of calibration is required for providers who receive VFC vaccines or vaccines purchased with public funds.

Calibration testing should be performed every one to two years or according to the manufacturer's suggested timeline to ensure that the device is recording accurate temperatures. CDC is also recommending using digital data loggers that will provide continuous temperature monitoring of the storage unit. Be sure your staff is trained on how to set up and properly use whatever type of device you have or as recommended by your state immunization program.

Now this slide includes the data logger characteristics that CDC recommends, and we've heard from several providers that once they get used to using these devices they really like them because they have better data about what is going on in the storage units. Some providers have reported that when they have a short temperature excursion the data logger provided very specific data they could report to the manufacturer and that it saved them from having to discard vaccine that was still good.

Now there are a variety of continuous temperature monitoring devices on the market and your state immunization program may have more specific guidance on temperature monitoring equipment.

CDC recommends that you document the temperature in the unit once in the morning and once before closing for the day. If your device does display the

minimum and maximum temperatures - and by this we mean the minimum temperature that the unit reached and the maximum temperature that the unit reached in the last twenty-four hours since you last reset the device - then you may record the min/max temperature once daily before resetting the device. This information along with the room temperature can be very helpful if there has been a temperature excursion. Temperature data should be kept for three years or according to state record retention requirements.

Always be sure to take immediate action if there is a temperature excursion, and of course by this we mean that there's been an out-of-range temperature. Do not immediately discard the vaccines. Store them properly separate from any vaccines that are not in question and mark them "Do NOT Use." Then according to your policies, contact the immunization program, the vaccine manufacturer, or both for guidance.

Now there's an image of CDC's temperature excursion checklist on this slide. It's available in CDC's storage and handling toolkit. So if you have an excursion, you can use this checklist to collect and document the information that you'll need when you call the manufacturer or the state immunization program for guidance.

Now when preparing to store a particular vaccine, always check the manufacturer's product information or package insert for storage and handling information specific to that product. Avoid storing vaccines near walls, coils, cooling vents, the top shelf, the ceiling or floor, or back of the unit because these areas are more likely to have temperature variances.

Keeping vaccines and diluents in the original packaging until ready to use helps maintain the temperature and avoid unnecessary exposures to light, and it can help prevent administration errors. You can stack vaccines and diluents

in rows of the same type with rows separated by two to three inches to promote good air flow in the unit.

And you can store vaccines and diluents in their packaging in uncovered storage bins to help keep things organized and separated. Do not store vaccines in the doors or deli, vegetable, or fruit crisper drawers. Store pediatric and adult formulations on different shelves and do not store sound-alike and look-alike vaccines next to each other. We recommend you use labels with vaccine types, age, and gender indications or color-coding to help prevent errors.

Also, if you are a VFC provider you need to consult your state immunization program for guidelines on storing VFC and privately purchased vaccines.

Be sure that you store diluents according to the manufacturer's instructions. If a diluent should be refrigerated, the best thing is to store it with the corresponding vaccine because the diluent may also contain vaccine. And never freeze any diluents. Label diluents to avoid inadvertently using the wrong diluent. Now I've included an excellent job aid about diluents from the Immunization Action Coalition and the link where you can download it.

Be proactive and take preventive measures to protect your vaccines. Plug the storage unit directly into the wall. Do not use a multi-outlet power strip. Do not use power outlets with built in circuit switches and do not use power outlets that can be activated by a wall switch. Plug only one unit into an outlet and use a plug guard or a safety lock plug.

Install a temperature alarm and label circuit breakers and electrical outlets. Post warning signs that include emergency contact information and use water bottles in the refrigerator and frozen water bottles or frozen coolant packs in

the freezer to help maintain the temperature. You should also perform daily inspection of your storage unit and if other biologics must be stored in the same unit, then they should be stored below the vaccines to avoid contamination. Ideally, they should be stored in a separate unit. And never store food and beverages in the same unit with vaccines.

And also I mentioned this earlier, but it definitely warrants repeating, and that's to take immediate corrective action when there is a problem.

You want to conduct a vaccine inventory monthly to ensure adequate supplies to meet demands. Include vaccine diluents in the inventory and determining factors for the amount of vaccine and diluents to be ordered include what's the projected demand, storage capacity, and your current vaccine supply. Avoid overstocking vaccine supplies because this can lead to vaccine wastage or having outdated vaccine on hand.

Unfortunately, we hear reports of administration of expired vaccine. So always check vaccine and diluent expiration dates a minimum of weekly and, of course, when you get ready to administer it. You should rotate stock so that vaccines and diluents with the soonest expiration dates are used first to avoid waste from expiration. And get expired vaccines out of your storage units.

Some multidose vials have an expiration date that includes the month, day, and year. Others only have the month and year. If month, day, and year are included, then the vaccine can be used until the end of the day noted on the product. If only the month and year are given, the vaccine can be used through the last day of that month. And of course, this only applies as long as the vaccine is stored and handled properly and is normal in appearance.

There are a few exceptions to the printed expiration date. One exception is for vaccines that have to be reconstituted with a diluent. The clock is ticking once the vaccine is reconstituted, so always check the manufacturer's product information or package insert for information on how long the vaccine can be kept after it is reconstituted. The time limit is not the same for all vaccines and, of course, the best practice is to only reconstitute the vaccine when you are ready to use it. And don't draw it up in a syringe until ready to use.

Another exception applies to some multidose vials. Some manufacturer package inserts will include information that once the vial is opened it can only be used for a certain number of days regardless of the expiration date on the package. Here's an example that says once entered, the multidose vial of this product should be discarded after twenty-eight days even if there are still residual contents in the vial.

Now the third exception usually occurs after a temperature excursion. When you call the manufacturer for guidance, depending on the information provided, they may say the vaccine can still be used but they will give you a shortened expiration date.

These exceptions are referred to as a "beyond use date" or BUD, and in the case of reconstituted vaccines it may be a "beyond use time." If there is a change in the amount of time or the date by which the vaccine must be used or discarded, it should be documented on the vaccine label along with the initials of the person making the change.

Now we get a lot of questions about vaccine transport. CDC and vaccine manufacturers do not recommend transport of vaccines unless it is an emergency and the vaccines have to be moved to preserve them. If you

operate satellite or off-site immunization clinics, you really should have the vaccines delivered directly to that facility.

But if you must transport vaccine other than for an emergency, limit the amount to just what you will need for that work day. And CDC now recommends that transport and clinic time together should not exceed a total of eight hours before the vaccines are returned to the primary storage unit.

CDC's best practice recommendation is that you use portable refrigerators and freezers or qualified containers and pack outs with calibrated continuous temperature monitoring devices to transport vaccines. We're working on an emergency transport job aid for refrigerated vaccines that should be available on our Web site in a few weeks. We just have to get it through the clearance process and then we'll have it posted on our Web site.

The vaccine manufacturer does not recommend transporting varicella-containing vaccines to off-site facilities. If these vaccines must be transported, refer to the guidelines in CDC's vaccine storage and handling toolkit.

Now when you remove the dust cover and expose the rubber diaphragm or stopper on a single-dose vial, you should use that vaccine or discard it at the end of the workday. You cannot always tell if the diaphragm or stopper has been punctured by someone else if the cover is off, and single-dose vials do not contain a preservative.

Once a manufacturer-filled syringe is activated and the sterile seal is broken, that's when the cap is removed from the needle or when a needle is added to the syringe, it should be used that day or discarded at the end of the workday. Manufacturer-filled syringes are like single-dose vials. They do not contain a preservative and cannot be stored once the sterile seal is broken.

When preparing vaccines, do not draw vaccines into a syringe until ready to use it. Pre-drawing increases the risk for administration errors, wasting vaccine, and possible bacterial growth in the vaccines that do not contain a preservative. Administration syringes are not designed for storage. Consider using manufacturer-filled syringes for large immunization events because they are designed for both storage and administration.

Any vaccine pre-drawn into a syringe by a provider should be used that day or discarded at the end of the clinic day. If it is a reconstituted vaccine, you should not draw it into the syringe until ready to use it. And I know that the nurses out there know that you should only administer vaccines that you have prepared.

If you are working a busy immunization clinic and absolutely must pre-draw like a mass flu clinic, don't draw up more than a total of ten doses or one multidose vial at a time. Contact your immunization program and/or vaccine manufacturer for policies regarding disposal of unopened vials, expired vials, unused doses, and potentially compromised vaccines.

Now open vials, activated manufacturer filled syringes, vaccines pre-drawn by a provider, and broken vials and syringes are not returnable and should be appropriately discarded. Requirements for medical waste disposal are regulated by state environmental agencies. So contact your immunization program or state environmental agency to ensure that your vaccine disposal procedures and any related documentation are in compliance with state and federal regulations.

So now let's move on to vaccine administration. And if you're following along in the Pink Book, this is chapter six which begins on page seventy-nine.

Proper vaccine administration is a critical component of a successful immunization program. It is a key part of ensuring that vaccination is as safe and effective as possible. Professional standards for medication administration and guidance from the vaccine manufacturer should be used in conjunction with evidence-based safe injection practices. I've included a link to CDC's safe injection practices for providers Web site on the bottom of the slide.

Now improper administration of vaccines may result in injuries or prevent the vaccines from providing optimal protection. All personnel who will administer vaccines should receive comprehensive competency-based training regarding vaccine administration policies and procedures before administering vaccines. And providers should validate staff's knowledge and skills regarding vaccine administration with a skills checklist. If you need an immunization skills checklist, I've included a link to one that the California Immunization Program has developed.

Competency-based training should be integrated into existing staff education programs such as new staff orientation and annual education requirements. Just as with vaccine storage and handling, staff should receive ongoing education. For example, when vaccine administration recommendations are updated or when new vaccines are added to the facility's inventory.

An accountability check should be put in place to ensure policies and procedures are followed. Training should also be offered to your temporary personnel; for example, if you have temporary staff that comes on at busy times like for flu clinics or when you're getting ready - a lot of kids are coming in before school.

So the patient's immunization history should be reviewed at every healthcare visit. When the patient arrives, providers should obtain a complete immunization history and compare the patient's immunization record to the medial record and immunization information system or registry data if that's available. Use the current immunization schedule based on the age of the patient to determine all recommended vaccines that are needed. Assess for all routinely recommended vaccines as well as 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 based on the person's age, their medical condition, and other risk factors. With the exception of influenza and pneumococcal polysaccharide vaccine -- or PPSV23 -- providers should only accept written dated records as evidence of vaccinations. Self-reported doses of influenza vaccine and PPSV23 are acceptable. This prevents missing an opportunity to vaccinate while the patient or parent searches for the immunization record.

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 good screening questionnaires, I've included links to screening forms available on the Immunization Action Coalition Web site.

Use vaccine information statements and other resources to discuss vaccine benefits and risks and disease risks with parents and patients. And we have a wealth of information on our CDC Web site to help you with those discussions.

Aftercare instructions should include information and strategies for dealing with side effects such as injection site pain, fever, fussiness (especially with infants), and for determining when medical attention should be sought. I've

also included a link to a resource for things parents can do before, during, and after vaccines are administered to comfort their child.

When determining patient positioning and restraint, consider the patient's comfort, their safety, their age, their activity level, and the site of administration. Parent participation has been shown to increase the child's comfort. When vaccines are being administered to infants and small children, the parent or guardian should be encouraged to hold the child during administration and the parent or guardian should be instructed on how to help the child stay still so the vaccine can be administered safely.

Now if they are uncomfortable, another person may assist or the patient may be positioned safely.

While definitive guidelines for positioning patients during vaccination have not been established, some recommendations have been suggested. Research supports the belief that children are less fearful and experience less pain when receiving an injection if they are sitting up rather than lying down. The exact mechanism behind this phenomenon is unknown. It may be that the child's anxiety level is reduced, which in turn reduces the child's perception of pain.

All providers who administer vaccines to older children, adolescents, and adults should be aware of the potential for syncope or fainting after vaccination and the related risk of injury caused by falls. Clinicians should make sure the person who is being vaccinated is always seated or, in this case, they may lay down. Be aware of symptoms that precede fainting such as weakness, dizziness, and being pale in appearance. And provide supportive care and take appropriate measures to prevent injuries if such symptoms do occur.

Now, the Advisory Committee on Immunization Practices -- or ACIP -- also recommends that providers consider observing the patient with the patient seated or, if they feel better lying down for fifteen minutes after vaccination. Patients are much more likely to faint than they are to have an allergic reaction. If you do good screening, allergic reactions are really quite rare.

Now, concern and anxiety about injections are common for all ages. Fear of injections and needle stick pain are often cited as reasons why children and adults, including healthcare personnel, refuse vaccines. It's been estimated that up to 25% of adults have a fear of needles with most fears developing in childhood. Decreasing pain associated with immunizations during childhood may help to prevent this distress and future healthcare avoidance behaviors.

The pain is subjective and it's influenced by multiple factors, including a person's age, their anxiety level, their previous healthcare experiences, and their culture. Although pain from immunizations is to some extent unavoidable, there are some things that parents and healthcare providers can do to help when children and adults need vaccines.

Several evidence-based strategies to ease the pain associated with the injection process are included on this slide and there's more detail about these strategies included in the Pink Book.

Now, healthcare providers should follow appropriate precautions to minimize the risk of spreading disease during the administration of vaccines. Hand hygiene should be performed before vaccine preparation, between patients, and any time hands become soiled.

The 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 hand. If gloves are worn, they should be changed and hand hygiene performed between patients.

Use a separate two milliliter or three milliliter sterile syringe for each injection. Use safety-engineered needles or syringes or needle-free injection devices to reduce risk for injury. And used needles should never be recapped. Needle selection depends on the route, the patient's size, and the injection technique.

Always inspect the vaccine and diluent vials for damage or signs of contamination. You should not only check the expiration date on the vaccine and diluent, but some syringes and needles have expiration dates.

Now we mentioned this earlier but it's worth repeating -- always use only the diluent supplied by the manufacturer for that specific vaccine, and agitate the vial to be sure the vaccine is re-suspended and thoroughly mixed.

Here are a few never's when preparing vaccines. Never combine vaccines into a single syringe except when specifically approved by the FDA and packaged for that specific purpose. Never transfer a vaccine from one syringe to another. And never draw partial doses of vaccine from separate vials to obtain a full dose.

Rotavirus and oral typhoid are the only US licensed vaccines that are administered by the oral route. RV1, or Rotarix, requires reconstitution prior to oral administration. RV5, or RotaTeq, is provided in liquid form and oral typhoid vaccine is supplied in capsules.

For children, oral vaccines should generally be administered prior to administering injections or performing other procedures that might cause discomfort. Administer the liquid slowly down one side of the inside of the cheek (between the cheek and gum) toward the back of the infant's mouth.

Now, LAIV -- the live attenuated influenza vaccine -- is currently the only vaccine administered by the intranasal route. Insert the tip of the sprayer and spray half the dose in one nostril. Then remove the dose divider clip and administer the other half-dose in the other nostril.

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 twelve months of age, and the upper outer triceps of the arm for persons one year of age and older.

Now, if necessary, the upper outer triceps area can be used to administer subcutaneous injections to infants. Typically, a 5/8 inch, twenty-three to twenty-five gauge needle should be used. And to avoid reaching the muscle, pinch up the fatty tissue. Insert the needle at a forty-five degree angle, and inject the vaccine into the tissue.

Intramuscular injections are administered into muscle tissue below the dermis and subcutaneous tissue. To avoid injection into subcutaneous tissue, the skin at the selected site is spread taut between the thumb and forefinger, isolating the muscle. Another technique acceptable 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 ninety degree angle to inject the vaccine into the tissue. 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.

For the majority of infants, the anterolateral aspect of the thigh is the recommended site for injections because it provides a large muscle mass. The muscles of the buttock are not routinely used for administration.

For the majority of infants, a one inch, twenty-two to twenty-five gauge needle is sufficient to penetrate muscle in an infant's thigh. For neonates (those in the first twenty-eight days of life) and for pre-term infants, a 5/8 inch needle may be adequate if the skin is stretched flat between the thumb and forefinger and the needle inserted at a ninety degree angle to the skin.

For toddlers, the vastus lateralis muscle in the anterolateral thigh is preferred. The needle typically should be at least one inch long. The deltoid muscle can be used if the muscle mass is adequate. A 5/8 inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger and the needle inserted at a ninety degree angle to the skin. Otherwise, a one inch needle is recommended.

The deltoid muscle is preferred for children three through eighteen years of age. The needle size for deltoid injections can range from twenty-two to twenty-five gauge and from 5/8 to one inch, depending on technique and the size of the patient. Most young children in this age range require 5/8 or one inch needles. In general, older children and adolescents require a one inch needle.

Now, one study found that obese adolescents may need a one and a half inch needle in order to reach muscle tissue. If there is any doubt, knowledge of body mass may be helpful in estimating the appropriate needle length. The

vastus lateralis muscle in the anterolateral thigh is an alternative site if the deltoid sites cannot be used, and a one inch needle is generally sufficient to reach muscle tissue in most older children and adolescents in the thigh.

For adults, the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh also can be used. Now there's a chart in the Pink Book that's based on gender and weight to assist in selecting needle length and to ensure that the vaccine reaches muscle tissue. As with adolescents, the vastus lateralis muscle in the anterolateral thigh is an alternative site if the deltoid muscle cannot be used, but there's a lot of clinical judgment that has to go on and evaluation of the individual patient that's in front of you when deciding about site and needle length.

Now Fluzone intradermal is the only US licensed vaccine that is administered by the intradermal route. This Fluzone formulation is not the same as intramuscular formulations of inactivated influenza vaccine. Other inactivated formulations should not be administered by the intradermal route. The site of administration is the deltoid region of the upper arm. The patient should be seated with the arm bent at the elbow and the hand on the hip to ensure that the site of administration is prominent.

A manufacturer-prefilled microinjection syringe is used to administer a 0.1 milliliter dose into the dermal layer of the skin. The needle is inserted perpendicular to the skin into the deltoid region of the upper arm without aspirating. Because the needle is very short, the vaccine will be delivered just under the skin into the dermal layer. Now this vaccine should not be administered into the volar aspect of the forearm using the intradermal technique that's used for tuberculin skin tests. Don't use that for this vaccine.

Now these are images of errors that have been reported to us regarding the injection sites. If the vaccine is administered too high, this can cause pain and permanent injury. There's even a term for this -- SIRVA -- S-I-R-V-A, or shoulder injury related to vaccine administration -- which is now recognized by the Vaccine Injury Compensation Program.

If an intramuscular injection meant for the deltoid is administered too low, then it will not reach the muscle. And we have a saying around here -- "there are no butt's in vaccines". The buttock is not a recommended site for vaccine administration because of proximity to the sciatic nerve and because there is a greater chance that a vaccine that should be delivered into muscle will end up in subcutaneous tissue. Both of these concerns can lead to increased risk of injury and an exaggerated local reaction.

So it's very important that providers who administer vaccines know the recommended sites for vaccine administration and use proper landmarks to identify these sites.

Now 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 the preferred site because of the greater muscle mass.

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 inch or more and, if possible, so that any local reactions can be differentiated, that you don't get an overlap in local reactions.

Vaccines that are the most reactive such as tetanus toxoid-containing and the pneumococcal conjugate (PCV13) vaccine should be administered in different

limbs, if possible. And of course, use of combination vaccines can reduce the number of injections.

Now if a vaccine and an immune globulin preparation are administered simultaneously - for example, if you have to give Td or Tdap and tetanus immune globulin or TIG, or hepatitis B vaccine and HBIG -- hepatitis B immune globulin -- then they should be administered at separate sites. For example, if you're giving a baby HBIG and hepatitis B, give the hepatitis B vaccine in one thigh and the HBIG in the other thigh.

The location of all injection sites should be documented in the patient's medical record. Healthcare providers should consider using a vaccination site map so that all persons administering vaccines routinely use the same anatomic sites for each different vaccine.

Now there's a link on the slide to several job aids that have been developed by the Michigan Immunization Program that are very helpful when more than one vaccine is being administered.

All vaccines administered should be fully documented in the patient's permanent medical record. Healthcare providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the recipient indicates the date of administration, the vaccine manufacturer, the vaccine lot number, the name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside, and Vaccine Information Statements. You want to document the date that's printed on the VIS as well as the date that the VIS was given to the patient, parent, or guardian.

Now, also, best practice documentation guidelines would include, of course, vaccine type, route, dosage -- meaning the volume, and the site. And we have standard ACIP abbreviations that are available on our Web site that we recommend be used basically so that everybody is using the same language and we know what vaccines have been given.

Now time is limited for today's presentation, but I do want to point out that the vaccine administration chapter in the Pink Book does include strategies to prevent errors. So I hope you will take a look.

And with that, I'm going to turn things back over to Dr. (Kroger) so that we can take your questions. Thank you for your attention.

Dr. (Andrew Kroger): Thank you very much, Ms. (Weaver). We're now going to move on to the question and answer portion and I'm going to give you some information about that. As well, I want to go through a couple of slides -- one on continuing education credits that you need to have before we do any questions and answers. And I will remind folks on the phone that to ask a question, please dial star one to get in the queue for the operator.

We are going to have a recast of this program available on the, internet on our Web site at www.cdc.gov/vaccines/ed/ciinc next week. That is the week of August 3. The slides will be there as will the audio portion and other resource information.

Now for continuing education information, this is important. Again, the Web site you have seen before but it's worth noting. It's www2a.cdc.gov/TCEonline/. The course number for this program is date-specific, and the letter is E as in Edward, C as in cat, 2064, "dash" 072915. That's today's date, 0723915 - July 29, 2015.

You need that for completing your CE requirements and you need the verification code, which is storage29 -- no space. And that's for today's program only. The CE credit for the program expires in approximately one month - August 31, 2015.

I'm going to repeat this information at the end of the question and answer period. So we did want to make sure that you did see this verification code and the code number that you need for CE's.

So now let me turn the line back over to our operator and have our participants ask the questions they wish to ask. Operator?

Coordinator: At this time, if you'd like to ask a question you may press star one. Please remember to unmute your phone and record your first or last name clearly when prompted. In the event that you would like to withdraw your question, press star two. One moment please for our first question.

Our first question comes from (). Okay, one moment. She's disconnected. One moment for the next question. Next question comes from ().

(): Yes. I just have a question on meningitis. Menactra and Menveo - you know we give it two doses at eleven years old and before the children go off to college at sixteen. Doctor, would you recommend that we also give meningococcal B since it covers a different type of serial type?

Dr. (Andrew Kroger): I'll take that question. This is (Andrew Kroger). So CDC has recommendations for the use of the quadrivalent vaccine, as you mentioned Menactra and Menveo. A dose is recommended at eleven to twelve for dose number one and then a dose, generally, after sixteen years of age. And ACIP

has recently voted on permissive use of the meningococcal B vaccine. This is back in June, and so we haven't published our official recommendations on that yet but providers may also use either one of the meningococcal B vaccines as well. And there aren't interactivity issues or interaction issues between the B and the quadrivalent vaccine. –We're going to have more recommendations coming on that. But yes, ACIP did recently vote for meningococcal B vaccine.

So I think - does that get to your question?

Q): Yes. I just wanted to know your take on it because I think the meningococcal B vaccine that - you can give it between the ages of sixteen to nineteen based on VFC recommendation, and I think that FDA recommendation is age ten to twenty-five years old and it's given in three doses. So I wanted to know since they covered different types of the serotypes, I would think Menactra is covered. The ACYW and the B is only for the B. would you recommend that we give both or do you recommend that we give it whatever the doctor decides since they cover different types?

Dr. (Andrew Kroger): So we have a full recommendation for the quadrivalent and we're still waiting - ACIP voted on a permissive recommendation for the meningococcal B vaccine. And I will add just for clarification proposes that the B vaccine is permissively recommended sixteen to twenty-three years of age. So there were no interaction issues with that second dose of the quadrivalent.

We do have a recommendation as well for the meningococcal B vaccination for high risk ten years and older. So - but again, for those high risk persons, yes. Both are recommended and it is a full recommendation for the use of both vaccines.

():
Okay. Thank you so much and thanks for holding this lecture. I really do appreciate it.

Dr. (Andrew Kroger): Thank you. And we'll take the next - let me remind our listeners. If they have a question related to today's presentation, we'll take the next question now.

Coordinator: Next question comes from ().
from West Virginia.

():
Yes, this is () from West Virginia. My question is regarding vaccine storage and handling. We have many providers are still using the household double-door, double thermostat refrigerator/freezer. And they're using the freezer for frozen vaccines even though the CDC recommends to not use them. And we do the same thing as the CDC. Are there any plans to change this to a requirement?

(Donna Weaver): Well, we have been trying to get people to transition over to the stand-alone units when they buy new units because there really is concern. If they're trying to store both in a combination unit, then you're really putting your refrigerated vaccines at risk. We really do recommend that if they want to keep the household unit and keep using it, then use it for the refrigerated vaccines.

But then depending on how much supply they have of the varicella-containing vaccines maybe they just have to get a small freezer unit. But at this point, unless individual states are making specific requirements, it's still in a transition state that we're making this recommendation that people switch over as they buy new equipment.

():
Thank you. I have one more question. Regarding the new vaccine Men B and the VIS. We still don't have a VIS here. How does the provider give the vaccine without VIS, without the documentation of the date that the VIS was given nor the VIS date? How is that going to happen?

Dr. (Andrew Kroger): This is (Andrew Kroger). So we don't have recommendations for meningococcal B routine use yet, and the VIS is currently in clearance right now. So we hope to have it shortly, and we anticipate published recommendations for routine use of that vaccine shortly as well.

(Donna Weaver): Until then, typically what's recommended until a VIS comes out is that you can use the manufacturer's information that they provide for the vaccine and information also from the package insert. And document that that has been used.

():
Do you have a date when the VIS is going to be out?

(Donna Weaver): No. We don't have a hard date. It depends on clearance and then also the fact that the last part of the permissive recommendations have not been published yet. But they're definitely working on it. I can tell you that.

():
Thank you.

Dr. (Andrew Kroger): Thank you.

Coordinator: Our next question comes from ().

():
Yes, hi. Can you hear me?

(Donna Weaver): We can.

() : Okay. I'm from Baltimore, Maryland and I'm calling to ask a question on the documentation. Currently we have an EMR system -- electric medical record - - and we record the lot number and the initials of the manufacturer with the lot number, but we don't have a column that actually puts in the manufacturer's name. Is that an acceptable process?

(Donna Weaver): You can use a log. You can keep a log in addition so that you can write down the actual manufacturer. Just use that as a supplement to your EMR.

() : Okay. Thank you.

Coordinator: Our next question comes from (). (), you have an open line. Okay. Our next question comes from ().

() : Hello. My question is regarding transportation of vaccines. Sometimes we have multiple flu clinics going on at different sites, and at times we have used the portable coolers with ice packs. Is that recommended and how long do you think we can keep vaccines in these containers?

(Donna Weaver): Well, I think I had mentioned during the presentation that if you're going to transport vaccines, you should always take the amount that you're going to need for that day. And from the time that you take it out of the primary storage until you return it to the primary storage, CDC recommends that that full time not exceed eight hours.

We also recommend that if at all possible you use portable refrigerators and freezers or qualified pack outs that also will then tell you what type of cooling supplies come with that qualified pack out.

The other thing is if you have to use a cooler, to use a hard-sided cooler that has sides as close to two inches as you can get it; and then that you use coolant packs in there to help protect the vaccine. We don't recommend that for refrigerated vaccines that you're putting frozen bottles or frozen gel packs or anything like that in there.

You really should be using qualified pack outs. And we hope, again, that we'll have more information coming on that before too long, but I'd also recommend that you check with your state immunization program on what they recommend because sometimes it really depends on where you are. But for routine transport, we don't recommend that you reuse the manufacturer containers or the manufacturer's packing materials.

Dr. (Andrew Kroger): Thank you very much. We'll take another question.

Coordinator: Next question comes from ().

(): Hi. Thank you. Just a couple questions regarding storage. The CDC specifically recommends water bottles on the wall of the refrigerator. Why not using also acceptable gel packs as part of that cold insulation barrier? Is that something that is not recommended? And if so, why?

(Donna Weaver): Well, the only recommendation I've seen in the refrigerator is for the water bottles. And I don't know if there's data on the use of gel packs there. And then for the freezer, you can use frozen water bottles or frozen coolant packs. In the refrigerator, trying to use those gel packs sometimes they can slip down in between the shelves and it just seems to be a more stable situation if you can use the water bottles on the top shelf, in the door, and on the floor of the unit.

And that's what's been - to my knowledge and to this date, that's what has been tested and found to be the most effective.

():
Okay. The other question I have - I believe the woman's name was () regarding transporting of vaccines to flu clinics. And you referenced something called a qualified pack out. Can you define what a qualified pack out is since you did specifically say that you shouldn't use the manufacturer's shipping materials or their refrigerator or, basically, gel packs -- as I'm assuming -- to transport? I'm kind of unclear what a qualified pack out would be if you don't recommend using those containers that the manufacturer shipped the vaccine in.

(Donna Weaver): They're working on trying to develop more specific guidance on that, I think some of the states are aware of them. You've got to have at least a hard-sided container. And you've got to have barrier between the vaccines and the cooling materials.

And if you're using coolant packs, they should be conditioned so that they're not frozen. You'll need to have it layered with a barrier using bubble wrap - don't use the peanuts- or some type of barrier in there like bubble wrap in between the vaccine and the coolant that you're using.

And then also, that you have a calibrated thermometer that's closest to the vaccines. And then you layer like that. And then also have a temperature log because during the time that you're gone the vaccines should be monitored hourly. And if the facility you're going to has a refrigerator that you can put it in that can maintain the recommended temperature, then it's better to get it out of the cooler if you can.

But for routine transport like that - they do not want you reusing their materials.

(): Okay.

(Donna Weaver): They can be used if - at least the container can be used if it's absolutely necessary in an emergency to move that vaccine, but not just for routine off-site clinics. And there's a little more detail about this in our vaccine storage and handling toolkit. And we're also getting ready to update that. So hopefully we'll have more detailed information in there on that for you.

(Mark Glaraglaco): Okay. And hopefully this will be released prior to the upcoming flu season because I know manufacturers will start shipping vaccine in late August.

(Donna Weaver): Yes, well we're working on the updates to the storage and handling toolkit now.

(Mark Glaraglaco): Okay, thank you very much.

(Donna Weaver): Yes, sir.

Dr. (Andrew Kroger): Why don't we take one last question?

Coordinator: Next question comes from ().

(): Hi. We're a small group watching the program today. We had a question about whether or not you could quickly review the expiration exceptions?

(Donna Weaver): Okay. Well, you've got the expiration date that's on the label, but if it's a vaccine that has to be reconstituted, then that time is going to change once it's

reconstituted. That depends on the individual vaccine. It may be thirty minutes. It may be eight hours. It may be twenty-four hours. It just really depends on the vaccine, and that's while the vaccine is reconstituted and in the vial that it can be stored during that time.

The other was for multidose vials. Some multidose vials when you look at the package insert they will have a beyond use date that regardless of what it says on the outside of the multidose vial, once you open it if it says, for example, once this is opened you can only use it for twenty-eight days, then that changes the expiration date.

And then the other situation most often where I have seen this is like with varicella-containing vaccines, but it could apply to other vaccines also. If you have a temperature excursion and you call the vaccine manufacturer and you're able to give them enough information that they can make a decision that the vaccine can still be used, but they say we're going to have to shorten the expiration date on it.

So those would be the three exceptions -- reconstitution, if a multidose vial has a beyond use date once it's opened, and then the other one is if there's an excursion and the manufacturer gives you a shorter expiration date.

(): Thank you.

Dr. (Andrew Kroger): Thank you very much. That's all the time we can devote to questions right now. So now before we close, I'm going to repeat some continuing education information.

We are going to have -- as we've been doing and will continue to do -- a session at ten AM next Thursday Eastern Time - an hour-long session. So we will do that.

For CE information, please go to www2a.cdc.gov/TCEonline/. The course number for this course is EC2064, "dash" 072915. And please note that that course number - it's a date-specific extension on that course number -- 072915. The verification code is storage29 -- S-T-O-R-A-G-E 29 without a space. You're going to need that verification code, so write it down.

CE credit expires August 31, 2015 for this program. For help with the online system, which is very easy to use, you dial 1-800-41-TRAIN. As an alternative, you can email CE@cdc.gov.

You can email immunization questions to us if you did not get to ask them today, and if you cannot participate in the Q and A session a week from tomorrow. And so the email that you can send your questions to is NIPinfo@cdc.gov. And we'll try to respond to those as quickly as possible.

You can also call immunization questions to 1-800-CDCINFO from 8:00 am to 8:00 pm Eastern Time Monday through Friday.

Some additional resources that you can use - you already know about the Pink Book, and the Web site for the Pink Book is there. It's available online or you can purchase a hard copy. And the instructions on how to do that are at that first Web site. Our CDC vaccine home page is cdc.gov/vaccines/defaults.htm.

And then the resource guide for healthcare providers listed there under the resources Web site. And we also have a Twitter handle. It's a Twitter account.

It's at cdcizlearn -- L-E-A-R-N. So this is for you if you wish to tweet us about something that you're concerned about.

So that concludes our program for today. I want to thank Ms. (Donna Weaver) for the presentation covering many topics in great detail and for answering your questions. Thank you very much and have a great day from Atlanta. Goodbye.

Coordinator: This concludes today's conference. Thank you for joining us. You may now disconnect.

END