STAY SAFE MN

Transcript: Immunization Basic Principles for COVID-19 Vaccine

2/8/2021

Welcome to Immunization Basic Principles for COVID-19 Vaccine. This presentation is not a substitute for competency-based hands-on training. This presentation will proceed automatically, but you can pause or go back if needed. Also, there will be CEU credit available upon completion. The links for the CEU certificate and additional resource documents are available below this video on the webpage.

By the end of this training, you will be better able to describe basic components of a vaccination program, discuss general vaccination principles, list the "Seven Rights" of vaccine administration and discuss elements of each, and describe core storage and handling practices.

This training is intended to review some of the basic principles of a comprehensive immunization program. If you are new to vaccinating in your role, this will be a good introduction. If you have not been vaccinating recently, this will provide a good review.

Anyone administering vaccines needs comprehensive, competency-based training including hands-on demonstration and practice of vaccine administration. The Immunization Action Coalition has one example of a skills-based checklist that you can use to develop your training program. This training is not a substitute for hands-on training, rather supplemental information. The link to the Immunization Action Coalition is in the resource document located below this video on the webpage and provides many resources for clinics about immunizations.

This training has three sections. The first is principles of immunization, the second is vaccine administration, and the third is storage and handling.

There are many components of an immunization program that include more than just giving the shot. A comprehensive program requires ensuring that the vaccine is safe and effective, given properly to the right person at the right time, and documented in the medical record. In order to administer vaccines, things that need to be considered include legal, schedule, screening, administration, documentation, and storage and handling components.

Most vaccines go through a Food and Drug Administration or FDA approval process before they are licensed for use in the United States. Because of the pandemic, these vaccines are being released under an Emergency Use Authorization or EUA. Although we do not have enough information for full approval, we do have information that the vaccines are safe and effective at preventing disease. Also, the public health emergency allows for the ability for some groups, such as pharmacists, to expand their ability to order and administer vaccines.

The EUA requires manufacturers to provide information on their vaccines. The fact sheet for health care providers contains the information we usually find in the package insert that comes in every box of

vaccine. It includes information about how to handle the vaccine and specifics about storage and temperature requirements.

The manufacturers also need to provide a Fact Sheet for recipients which is like our usual Vaccine Information Statement that must be given with other vaccines. It is a federal requirement that this information is given to people before they receive their vaccine either in a paper or electronic format. The EUA Fact Sheets are linked from the MDH vaccine page, the CDC vaccine page and the FDA COVID Vaccine EUA page. Translations are available in many different languages on the FDA's website.

The best protection from the vaccine is when the schedule is followed as recommended. Many of the COVID-19 vaccines require 2 doses. The manufacturer includes the recommended interval in the fact sheet for health care providers. It is important to schedule people when they are due for the vaccine. There is a 4-day grace period when giving the second dose vaccine, but if needed you can give it a couple days earlier. Giving the second dose at the recommended time provides the best protection as soon as possible, but if the second dose is delayed for some reason, just give it as soon as you can. There is no need to start over or give additional doses.

All vaccines have contraindications, which are specific reasons that we should not give the vaccine. Anaphylaxis, or a very severe allergic reaction, is almost always a contraindication for getting another dose of the vaccine. Vaccines also have precautions, which are reasons to stop and think about whether this vaccine currently is the best for this person. All people receiving vaccines should be screened by a nurse or pharmacist to determine if vaccination is appropriate at this time. This doesn't mean they can't get the vaccine; it just means there is a need to take factors into consideration. These contraindications and precautions are listed in the EUA Fact Sheet specific for each vaccine.

Adverse reactions can be categorized into three general categories. The first category is local reactions which are the most common and can result in arm soreness, redness at the injection site, and swelling in the armpit. They are usually mild and self-limited. The second category includes systemic symptoms such as fever, muscle and joint pain, chills, feeling tired, and headache. These systemic symptoms appear to be more common with the COVID vaccines, so it can be helpful to let people know ahead of time. The third category of adverse reactions is that of an allergic reaction, in particular anaphylaxis, which can be life threatening. Fortunately, these are rare.

Encourage patients to call if they are experiencing concerning symptoms after vaccination but remember not everything that happens is due to the vaccine. If patients have a significant event such as fainting or hospitalization following vaccination, complete a report in the Vaccine Adverse Event Reporting System or VAERS. This allows the FDA and CDC to learn more about any serious problems that may be related to the vaccine. For COVID-19 vaccines, the CDC has a special program that recipients can sign up for called v-safe. It sends them a text message to see if they have any symptoms and follows-up with them as needed. Information and links to VAERS and v-safe can be found on the MDH COVID Vaccine website.

This next section will discuss general principles related to vaccine administration.

First, we need to make sure we follow the Seven Rights of Vaccine Administration. What they are? The right patient, the right vaccine and diluent when applicable, the right time including the correct age and interval, as well as before the product expires, the right dose, the right route including the correct needle gauge and length and technique, the right site, and the right documentation. These 7 rights of vaccine administration need consideration for all patients when vaccine is prepared and administered.

Another check you should do is what is called the “three checks”. Check the vaccine product label 3 times! When removing vaccine from storage, when withdrawing the vaccine, and when disposing the syringe or placing the vial back in storage. Be sure to visually inspect the vaccine and diluent to determine if it is damaged, contaminated, or discolored. Only use vaccine that has particulates described by the manufacturer as acceptable. Only use vaccine that appears normal and has been stored and handled properly.

The CDC’s One and Only Campaign aims to eliminate infections that result from unsafe injection practices. Always use one needle, one syringe, one time. For vaccines that are administered intramuscular or IM, use either a 1 milliliter or 3 milliliter syringe. Since vaccines are less viscous or thick so smaller gauge needles can be used such as 22 to 25 gauge needles. There are resources available that help you choose the right needle length for your patients. Some syringes and needles have expiration dates, so do not use them if expired. For COVID-19 vaccines, the federal government is providing ancillary kits that contain needles, syringes, alcohol prep pads, surgical masks and face shields, and COVID-19 vaccination cards.

When preparing vaccine and diluent, check their expiration dates and never administer if expired. When the expiration date has a month, day, and year, the vaccine may be used through the end of that day. For example, if the expiration date was January 16, 2020, the vaccine could be used through the end of that day and discarded. It cannot be used starting January 17th. If a vial has just a month and year, the vaccine may be used up to and including the last day of that month. If the expiration date was January 2020, the vaccine could be used through the month of January. It could not be used beginning February 1st.

Sometimes vaccines must be used before the expiration date by an earlier date known as the “beyond use date” or BUD. Once a vial is pierced, it must be used with a specific timeframe per vaccine manufacturer’s information. The BUD is calculated based on the date and time the vial is first entered. Some multi-dose vials do not contain preservatives and must be used sooner, sometimes within hours, before the expiration date listed on the vial. The BUD replaces the expiration date and is written on the vial or on a label placed on the vial along with the name or initials of the person making the change.

Some vaccines require reconstitution. Another term often used for this is dilution. Each diluent is specific to its corresponding vaccine in pH, volume, chemical balance, and sterility. If the wrong diluent is used, the vaccine dose is considered invalid and will need to be repeated. Reconstitute vaccine just prior to administration. Follow the Fact Sheet for Health care Providers specific instructions if the COVID-19 vaccine product being used requires dilution and how to calculate the new expiration or beyond-use date.

When preparing vaccines, use aseptic technique. This means preparing the vaccine in a manner that prevents bacterial contamination and infection. After performing hand hygiene, prepare vaccine in a clean area just prior to administration. Use a new needle and syringe for each injection. Vials have a protective dust cover. Once removed, clean the stopper with a sterile alcohol wipe. Only administer vaccines that you have prepared. Never draw partial doses of vaccine from separate vials to make a full dose and never transfer vaccine from one syringe to another.

Vaccine vials are either single dose or multiple dose. Briefly, single dose vials and single dose manufactured syringes should be clearly labeled for single use as they are used on a single patient for a single injection. They typically do not have an antimicrobial preservative, so you would discard the vial and not save any leftover vaccine. Multi-dose vials can be used for more than one patient if aseptic technique is followed. These vials may or may not have an antimicrobial preservative. Follow the EUA Fact Sheet for Healthcare Providers for when to discard multi-dose vials once entered. For example, the

COVID-19 messenger RNA vaccines, such as Moderna and Pfizer, the multidose vials have a BUD of 6 hours once the vial is entered or pierced because they contain no antimicrobial preservative.

There are a few general vaccine injection principles to consider. Aspiration is not needed for vaccines because the locations where vaccines are given have no major blood vessels. In general, multiple injections given in the same extremity need to be **at least** 1" apart. Injections may be given through a tattoo. Avoid lumps, swelling, bruises, redness, warmth, and wounds.

Intramuscular or IM injections must go into the muscle. There are two techniques for administering intramuscular injections. In the first technique, the skin is spread between the thumb and forefinger to isolate the muscle. This avoids injecting into the subcutaneous tissue.

Another technique, acceptable mostly for geriatric patients, is to grasp the tissue and "bunch up" the muscle. Insert the needle and syringe at a 90-degree angle!

There are two recommended sites for administering IM injections; the deltoid muscle in the upper arm and the vastus lateralis muscle in the anterolateral thigh. These sites are not near major blood vessels or nerves. For COVID-19 vaccines, most will be given in the deltoid muscle. The vastus laterals is used for adults when needed, such as those who cannot receive injections in their arms.

Shoulder injury related to vaccine administration or SIRVA happens when a vaccine administrator gives an IM injection in the upper arm too high that enters the tissues and structures lying under the deltoid muscle of the shoulder. Symptoms typically include a rapid onset of severe, long-lasting shoulder pain that may result in limited range of motion. SIRVA should be reported to VAERS as a vaccine administration error. Be sure to inject the vaccine into the belly of the muscle. Feel for the acromion process which is the bony part at the top of the shoulder. Place 2-3 fingers below the bony part and look for the center of the deltoid muscle above the armpit. This is where you will inject the vaccine at a 90-degree angle. Practice locating the correct site on a family member or friend.

Let's review general guidelines for safe vaccine administration. Always use strict aseptic practices while preparing and administering injectable vaccines. Hands should be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water before preparing vaccines for administration and between each patient contact. To avoid falls, patients should be seated or lying down. Swab the area to be injected with a sterile alcohol wipe in a circular motion, starting in the center and working outward. Let it dry. Insert the needle at the proper angle smoothly and quickly.

To continue, inject the vaccine – slowly but smoothly. Hold the syringe steady once the needle is in the tissue as moving it around the tissue may cause damage. Withdraw the needle smoothly at the same angle it was inserted. Apply gentle pressure to the site with either an alcohol pad or a sterile gauze pad. Apply a bandage if the site is bleeding.

CDC recommends an observation period following vaccination with COVID-19 vaccines. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. All other persons should be observed for 15 minutes. Be sure to have an area where persons who have received the vaccine are visible and can safely distance from others.

It is important to maintain good practices so you as the employee stay safe. Perform hand hygiene before preparing vaccine, when entering patient care area, and after vaccine administration. Occupational Safety and Health Administration or OSHA regulations do not require gloves to be worn when administering vaccinations, unless persons administering them have open lesions on their hands

or may have contact with a person's body fluids. When wearing gloves, remove them and perform hand hygiene between patients. If your needle or syringe has a safety feature, be familiar with how it works and activate it as you complete the vaccination. To avoid needle sticks injuries, dispose of used needles and syringes immediately in a readily available sharps container and never recap used needles.

Be prepared for emergencies. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur following vaccine administration. Emergency equipment includes epinephrine in prefilled syringes or autoinjector, an H1 antihistamine such as diphenhydramine, blood pressure cuffs, stethoscopes, and a timing device to check a pulse. Other items to consider but are not required include a pulse oximeter, oxygen, intravenous fluids, intubation kit, adult-sized pocket mask with a one-way valve, a bronchodilator like albuterol and other antihistamines. Part of being prepared is for you to maintain your CPR certification.

Providers should follow their usual documentation processes in the patient's permanent medical record. Refer to the slide and the provider guide for information you should document. Give the patient or caregiver a completed COVID-19 Vaccination Record Card that includes the name of the vaccine given, the date administered, and name and location of the administering clinic.

The Minnesota Immunization Information Connection or MIIC, is Minnesota's confidential system that stores immunization records. This data is associated with the organization that reports it to MIIC. As a vaccinator, part of your role is to access MIIC to see what immunizations your patient has had and what immunizations are due. You need to register to become a MIIC user. This can be done by following guidance on MIIC's website. MIIC has many features. It is also used to report nonviable vaccine. For COVID-19 vaccine, administered doses must be submitted to MIIC within 24 hours of administration.

Vaccine errors do occur. You are doing your part to prevent errors by being as knowledgeable as possible. Most common errors: Doses given too early, wrong vaccine, wrong dose, wrong route, vaccine given outside recommended age, expired vaccine or diluent, and wrong diluent used for reconstitution. So, what can you do? Continue educating yourself. Have vaccine resources readily available; follow the 7 rights of vaccine administration and the 3 Checks. Rotate vaccines so those expiring soonest are out in front in your storage unit. Report errors as part of risk management and quality improvement, so strategies can be implemented to prevent such errors in the future. Lastly, double-check your work with someone else.

There are principles of vaccine storage and handling that everyone should know, not just the vaccine coordinator and immunization manager. These are best practices for keeping your vaccine safe and effective.

The vaccine coordinator is responsible for all parts of the immunization program including knowing about training, vaccine schedules, administration of vaccine and proper storage and handling. Every site should also have a back-up coordinator who can help during times the primary coordinator is away. The coordinator should be able to answer questions about vaccines or know how to find the answers.

The Minnesota Department of Health has developed several resources for vaccine coordinators giving COVID-19 vaccines. All vaccine coordinators and back-ups are required to complete our on-demand trainings on COVID-19 vaccine. We also recommend others at your site who will administer vaccine complete the trainings, but it is not required. The trainings follow our COVID-19 Vaccine Provider Guide which contains information about the COVID-19 vaccines and should be used as a reference to answer many of your questions.

Why is vaccine storage so important? We don't want to waste vaccine. Vaccines can be very expensive. They must be stored in the proper temperature range, so people receive safe and effective vaccine. Vaccines exposed to either too warm or too cold of temperatures can be spoiled and will no longer protect people against disease.

Keeping the vaccine in the proper temperature range is called the cold chain. Starting with the manufacturer of the vaccine, through transporting and distribution, continuing in your office, all the way until that dose is actually given to the patient. Too hot or too cold anywhere along the cold chain puts the vaccine at risk for not being effective.

Receiving vaccine shipments is an important role in the cold chain. When you receive vaccine, make sure it is what you ordered and no vaccine is damaged. If you have any concerns that the vaccine has not been at the proper temperature, call the distributor number on the packing slip. Vaccine should be unpacked and put away promptly in a storage unit that is within the recommended temperature range. Don't risk forgetting to put it away and having it be spoiled. Keep vaccine with the earliest expiration date in front.

One of the COVID vaccines needs to be stored at ultra-cold temperatures. Many sites don't have special freezers that can get that cold, so the vaccine can be stored in the shipper box for a limited time. If you are getting this vaccine and storing it in the shipper, more information can be found in the Provider Guide and on the Pfizer website.

The kind of storage unit you use to store your vaccine is important. A pharmaceutical grade unit is the best, it has good air circulation and consistent temperatures. If you must store vaccine in a household unit, use only the refrigerator section. Household units look like they belong in a kitchen. Combination household units can get too cold in the refrigerator section if you have the freezer section cold enough for vaccines. Dormitory units are the small ones with a little freezer inside the refrigerator – these can never be used for vaccine storage.

You should know what the proper temperature range for vaccine storage is in your clinic. Refrigerated vaccines should be stored between 36 to 46 degrees Fahrenheit, or 2 to 8 degrees Celsius. Freezer temperatures should be colder than 5 degrees Fahrenheit or -15 degrees Celsius. Any temperatures warmer or colder than that are considered out of range. 'Protect Your Vaccines!' magnets can be ordered from MDH on the immunization page to remind you of the proper temperatures and what to do about out-of-range temperatures.

All storage units should be monitored for maintaining the proper temperature. This should be a device that continually records the temperature which allows us to know if and when the temperature has been out of range. The device may be a data logger which requires you to unplug it and download the data onto your computer. Or you may have a continuous temperature monitoring system where data is transmitted to your computer and can be set up to alert staff if the temperature is out of range.

Any temperature monitoring device needs to be checked daily, the minimum and maximum temperature, date, time and initials of person checking should be documented on your temperature log. Some continuous temperature monitoring systems can document this electronically. This is also a time to really pay attention to the storage unit – for example, is it making noises? Is the door shutting all the way? Is there a puddle on the floor? Is there food in the unit? Often this visual inspection can prevent a problem from happening before the temperature is out of range. The daily temp checks should be done by the on-site staff, not someone remotely looking at temperatures at a central location.

Documenting the minimum and maximum temperature alerts you to when the unit may have been out of range overnight or over the weekend. If the unit is routinely getting too warm or too cold at night, it's time to do a little further evaluation of the unit and possibly adjust the temperature.

It is also important to organize your storage unit. The center of the unit is usually the most stable temperature, try to keep your vaccines in the middle of the unit. The temperature probe should be in the middle with the vaccines. Keep vaccines in their original packaging to protect them from light, keep them organized and make it easier to read the label.

Water bottles can be used to help keep your vaccines safe. In the fridge, put water bottles in the back and sides to help keep vaccine in the middle and away from the cold spots. In the freezer they also help to maintain a stable temperature should your storage fail or there is a power outage. You can also use **conditioned** water bottles to transport vaccine as outlined in CDC's Storage and Handling Toolkit. Do not use the gel packs that come with the vaccine shipment in the freezer as they get too cold and can freeze your vaccine if put in a cooler.

One of the biggest problems is when storage units have out of range temperatures, and no one acts! If the current temp, or the minimum or maximum is out of range it is time to act. Call MDH or the CDC – the numbers are included in the Provider Guide. Vaccines exposed to out-of-range temperatures may be spoiled, if you use them you may need to re-vaccinate your patient. Mark the vaccine, 'DO NOT USE.' Gather information about temperature and time out of range. The Storage and Handling Mishap Checklist has the action steps and a place to document your response. If you don't remember anything else from this presentation, please remember this! Better to call than give bad vaccine.

Every site should have a plan for what to do with vaccine in the event of a power outage or unit failure. You should have supplies to pack and transport your vaccine and know where to take it. The emergency plan and supplies should be in a readily available area.

In review, vaccine administration requires a coordinated process. Understanding these components helps you make sure that your vaccine is safe and effective.

Let's review with a few questions.

Question one of three: Vaccine schedule: Someone comes to your clinic although they are due for their second COVID-19 vaccine dose tomorrow. Can you give the dose today or do they need to come back tomorrow? A. give today. B. return tomorrow.

Question 1 answer is A: give today. The second COVID vaccine dose can be given up to 4 days early.

Question 2 of 3. Multi-dose vials: After reconstitution, your Pfizer BioNTech multi-dose vial or MDV may contain up to six 0.3ml doses. You are drawing up the sixth syringe and only have a 0.2ml dose. What should you do? A. Take another MDV, reconstitute it, and add 0.1ml to the syringe with 0.2 ml to make a full dose. B. Administer the 0.2ml dose. C. Discard the needle and syringe with the 0.2ml and start over with a new reconstituted MDV, needle, and syringe.

Question 2 Answer is C. Discard the needle and syringe with the 0.2ml and start over with a new reconstituted MDV, needle, and syringe. Never pool vaccine from different vials to make a full dose.

Question 3 of 3. Temperature monitoring: You come to work in the morning and your refrigerator is too cold. What should you do? A. write down the min/max temperature and start your day. B. mark vaccine

“do not use” and call MDH for information about what to do. C. Open the door until the temperature goes up.

Question 3 the Answer: is Mark the vaccine “do not use” can call MDH for information about what to do. Vaccine that has been too cold may no longer work to protect your patient. Always call to find out if vaccine is okay before using.

Thank you for watching this presentation and all the good work you do vaccinating Minnesotans! Select the link below this presentation on the website for the resources, evaluation, and your CEU certificate.

COVID-19 Vaccination Administration Storage and Handling Resources

- Minnesota Department of Health
  - COVID-19 Vaccine (https://www.health.state.mn.us/diseases/coronavirus/vaccine/index.html)
  - How to Administer IM (Intramuscular Injections) and How to Administer (Subcutaneous) Injections (https://www.health.state.mn.us/people/immunize/hcp/admim.pdf) (PDF)
- Minnesota Immunization Information Connection
  - New to MIIC? Visit: Participating in MIIC (https:/www.health.state.mn.us/people/immunize/miic/participate/index.html)
  - Questions about your organization's MIIC account? Email: health.miichelp@state.mn.us
  - Want to learn more about using MIIC? Check out: MIIC User Guidance and Training Resources (https://www.health.state.mn.us/people/immunize/miic/train/index.html), or call the MIIC Help Desk
- Centers for Disease Control and Prevention
  - COVID-19 Vaccination (https://www.cdc.gov/vaccines/covid-19/index.html)
  - One and Only Campaign (https://www.cdc.gov/injectionsafety/one-and-only.html)
  - Vaccine Storage and Handling Toolkit (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
  - U.S. COVID-19 Vaccine Product Information (https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)
- Immunization Action Coalition
  - Clinic Tools (https://www.immunize.org/clinic/administering-vaccines.asp)
- Other
  - Perry, Potter, & Ostendorf (2018). *Clinical Nursing Skills & Techniques*, (9th Ed), pp. 576-577. St. Louis, MO: Elsevier.
  - Vaccine Provider email: health.covid.vaccine@state.mn.us

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