

Excerpt from "The Immunization Encounter: Critical Issues"
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Vaccine Storage and Handling Segment

ATKINSON:

Proper storage and handling procedures are critical to a safe and effective vaccination program. Inattention to vaccine storage conditions can lead to damaged vaccine and reduced protection.

Most live vaccines, in particular MMR, varicella and yellow fever vaccines, are sensitive to light and increased temperatures. Inactivated vaccines can be damaged by exposure to freezing temperatures. Some products may show physical evidence of altered integrity, like clumping in the solution that doesn't go away when the vial is shaken. But other vaccines may look perfectly normal, giving no indication of loss of potency.

All staff working with vaccines in an office or clinic setting should be familiar with proper storage and handling to minimize the risk of damage to your vaccine supply. During this segment we will cover general guidelines for proper vaccine storage and handling. Specific storage and handling recommendations for each vaccine are available in the manufacturer's package insert and several other resources, which will be included on the resource web page for this broadcast. Judy?

SCHMIDT:

Thanks, Bill . There are few immunization issues more important than the appropriate storage and handling of your vaccine supply. This is also one of the most common vaccine delivery problems that we encounter at the National Immunization Program. A vaccine storage or handling failure can affect large numbers of your patients, and result in embarrassment, expense, and potential liability for your practice.

Every facility that stores vaccines should develop and maintain a detailed written protocol on vaccine storage and handling. This protocol should include information for accepting vaccine deliveries and guidelines for storage and handling. Each facility should assign one person primary responsibility for ensuring that vaccines are carefully handled in a safe, documented manner.

Since no one works every single day, a back-up person should also be designated. All office staff working with vaccines should be familiar with storage and handling guidelines. Post temperature guidelines for vaccines on or near the refrigerator and freezer where vaccines are stored.

Your responsibility for proper vaccine storage and handling begins the moment the vaccine arrives. Vaccine shipments should be examined on arrival. Examine the shipping container and its contents for any evidence of damage during transport. Cross-check the contents with the packing slip to be sure they match. Finally, check the shipment date to determine how long the package was in transit to you. If the interval between shipment from the supplier and arrival of the product at your office was more than 48 hours, it could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity.

Each shipment should be recorded on an inventory log. This log should include the name of each vaccine; the number of doses for each vaccine received; the date it was received; the condition of the vaccines upon arrival; the name of the vaccine manufacturers; the lot numbers; and the expiration dates for each vaccine

If there are any discrepancies with the packing slip or concerns about the vaccine shipment, store the vaccine under proper conditions and mark, "Do NOT Use" until the integrity of the vaccine is determined. You will then need to contact the manufacturer or your state immunization program for further guidance. Who you contact will depend on who shipped the vaccine to you and on your agency or state policy.

In order to store vaccines correctly in your office, you must have the right equipment. Vaccines must be stored in a properly functioning household- or commercial- style refrigerator- freezer unit. The refrigerator and freezer compartments must have separate doors. This is particularly important if you stock varicella vaccine.

We discourage the use of small single door refrigerators like this. This type of unit may be OK for storing small quantities of inactivated vaccines, if the refrigerator compartment can maintain a constant temperature. But the freezer compartments of these units are incapable of maintaining temperatures cold enough to store varicella vaccine, so they are totally unacceptable for offices that use varicella vaccine. You have a lot of money invested in your vaccines. So do the right thing,

and invest in a quality refrigerator freezer to store them in. Use the dorm refrigerator to store your salads and snacks.

The refrigerator and freezer compartments should have their own thermometers. The thermometers should be placed in the central part of the storage compartment, not against the wall. There are several types of thermometers you can use. Here are 3 types of certified calibrated thermometers. The thermometer on the left in biosafe liquid is available for refrigerators and freezers. The one in the center is a continuous graphic thermometer, which records temperatures on graph paper. The thermometer on the right records the upper and lower extremes of temperature during the observation period. This is referred to as a minimum- maximum thermometer. These thermometers provide a means of establishing if vaccines have been exposed to potentially harmful temperatures. Get the best thermometer you can afford.

Temperature readings should be taken and recorded on a temperature log like this, twice each day, once when the office or clinic opens and again at the end of the day. Also, the back-up person should review the log on a weekly basis to assure proper temperature recording. The date and time of any mechanical malfunction or power outage should also be noted. Some temperature logs have a place to record this information on the back of the temperature log. Temperature logs should be kept on file for a minimum of three years.

One very important point to remember is that it's not enough to just record the temperature of the refrigerator and freezer units twice daily. If a temperature outside of the recommended range is found, then IMMEDIATE action should be taken to correct the problem. It may be a problem that can be solved easily, such as a door that was left open, or a unit was unplugged. On the other hand, there may be a more serious problem with the unit- after all, all refrigerators eventually fail. It could also be a power failure or some type of emergency or disaster situation that will require alternative storage for the vaccine until the situation is corrected. It's very important that staff know whom to contact in case of a malfunction or disaster. If the problem is short- term, usually 2 hours or less, you can probably maintain the temperature in the unit by adding ice or ice packs and keeping the door closed. If there is an extended period of time before the situation can be corrected, then you should move the vaccine to another cooling unit.

It's a good idea to have an agreement with another clinic, hospital or agency where you can store your vaccine in an

emergency. If the vaccine can be moved to this site within 30 minutes, it can be transported in insulated containers or coolers. If the location is more than 30 minutes away and you have a large quantity of vaccine, you should consider renting a refrigerated truck to transport your vaccine. Also, remember whenever there is a question about the integrity of the vaccine, contact the vaccine manufacturer and/or your state immunization program for guidance.

The BEST recommendation we can make is to take precautions to PREVENT problems. In addition to the twice daily monitoring of the refrigeration unit, install a plug guard or safety lock plug to reduce the chance of someone inadvertently unplugging the unit. Post warning signs above the plug and on the storage unit to remind staff not to unplug the unit. Label fuses and circuit breakers with information that clearly identifies power to the vaccine storage unit, and the immediate steps to be taken if power is interrupted. Install a temperature alarm that is audible and, if possible, connected to a remote or automated telephone system.

Here's a simple technique that will tell you if your freezer has thawed. Fill a plastic cup with water, freeze it, and place a penny on TOP of the frozen ice in the cup. Place the cup in the middle of the freezer compartment. Check the placement of the penny each morning when you record the freezer temperature. If the penny is IN the ice you know the freezer temperature was not maintained while the office was closed. You will need to talk to the manufacturer or state immunization program before using any of the vaccine stored in the freezer.

Another point to remember is to learn from previous situations or mistakes. Whenever there is a violation of the vaccine handling protocol or another vaccine storage problem, document the occurrence. Use the experience as a learning opportunity for all clinic or office personnel and when training new staff so that a similar situation can be avoided in the future. Donna, will you tell us more about storing vaccines?

WEAVER:

Thank you Judy. It's critical that your vaccine supply be stored carefully. All vaccines, with the exception of varicella and yellow fever vaccines, should be stored in the refrigerator section.

The refrigerator must maintain a temperature between 35 and 46 degrees Fahrenheit. That's 2 to 8 degrees Celsius. We suggest

that you set your refrigerator temperature to an average of 40 degrees Fahrenheit, or 5 degrees Celsius. This will allow your refrigerator to fluctuate within the recommended range of 35 to 46 degrees Fahrenheit. Your freezer must maintain an average temperature of 5 degrees Fahrenheit, or minus 15 degrees Celsius or colder. This temperature is necessary to assure proper storage of varicella vaccine. Lyophilized, or freeze dried, vaccines are in a powder form and must be reconstituted before use. Vaccine diluents can be stored in the refrigerator or at room temperature. Do NOT freeze vaccine diluent.

Vaccine should be stored in the middle of the refrigerator compartment away from the walls and coils. This allows air to freely circulate around and through the vaccine stacks and provide even cooling to all stored vaccine. To avoid confusion, the vaccine should be stacked in rows with vaccine of the same type. Bottles or jugs of water stored next to the walls or on an empty shelf will help maintain an even temperature in the refrigerator compartment.

Vaccine stored in the freezer compartment should also be located in the center of the compartment and away from sides of the unit. Ice trays or ice packs can be used in the freezer to help maintain an even temperature.

Never store vaccines in the door of the refrigerator or freezer, or on the bottom or near peripheral areas of the unit. There is greater temperature fluctuations in these areas, and temperature fluctuations are bad for vaccine.

Check and rotate vaccine stock weekly so that vaccines with the shortest expiration dates are in the front to be used first. If the expiration date on the vial is identified only as month and year, the vaccine does not expire until the LAST day of the month indicated on the vial.

Expired vaccine - even if only one day after the expiration date- should NEVER be administered. Promptly remove expired vaccine from the refrigerator or freezer and dispose of it appropriately. If the expired vaccine is VFC vaccine, you should contact your state immunization program so that the expired vaccine can be accounted for.

Keep opened vials of vaccine in a tray, so that they are readily identifiable. Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.

Pediatric DT, adult hepatitis B, influenza, meningococcal, pneumococcal polysaccharide, IPV, Td and tetanus toxoid are manufactured in multi-dose and single dose vials. A multi dose vial of vaccine contains a bacteriostatic agent, usually thimerosal. This vaccine can be used until the date of expiration unless it becomes visibly contaminated. Single dose vials do not contain a bacteriostatic agent and are meant for one time use only. Once opened, they must be discarded after 24 hours.

Once a lyophilized vaccine has been reconstituted, the clock is running. Reconstituted vaccines must be used within a specified time frame or they must be discarded. Varicella and ActHIB brand of Hib vaccine must be used within 30 minutes. Yellow fever vaccine must be used within one hour of reconstitution. MMR must be used within 8 hours, and PedvaxHIB must be administered within 24 hours. Vaccines reconstituted beyond these limits should NOT be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

Varicella vaccine that has not been reconstituted can be stored in the refrigerator compartment for up to 72 hours. If not used within 72 hours at refrigerator temperature, it must be discarded. Varicella vaccine should not be refrozen.

We are often asked about prefilling syringes, or drawing up vaccine into syringes in advance of the need for it. We STRONGLY discourage this practice. Loading vaccine into syringes before you are ready to use it increases the risk for medication errors, vaccine contamination, and vaccine wastage. When time and staff are limited and demand is high, most commonly-used vaccines are available in prefilled syringes from the manufacturer. Manufacturer prefilled syringes are prepared under sterile conditions that meet standards for proper handling and storage and they are individually labeled. Varicella, MMR, and yellow fever vaccines must NEVER be drawn up ahead of time. But there may be situations in which a single vaccine is going to be administered- such as a large influenza campaign- and manufacturer's prefilled syringes are not available. In these situations, each person giving injections may choose to prefill a few syringes shortly before administration.

In keeping with nursing medication administration guidelines, we recommend that the person who prepares the medication should be the same person who administers the medication. We recommend that any prefilled syringes should be properly stored and should be used on the same day they are filled. Label each syringe

carefully, and keep the filled syringes cool.

Vaccines should always be stored in the refrigerator or freezer until they are needed. Even if you anticipate using vaccines throughout the day, do not leave them sitting out on a medicine tray or counter.

If your clinic situation permits, open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control. We also recommend that all opened vaccine vials be kept in a tray in the refrigerator separate from other medications and biologics to avoid medication errors. Do NOT store food and beverages in the same refrigerator or freezer with vaccines. This practice leads to more frequent opening of the unit and greater chance for temperature instability and excessive exposure to light. It's advisable to keep MMR, varicella and yellow fever vaccines in their boxes with the top on until ready to use to avoid unnecessary light exposure. If other medications and biologics MUST be stored in the same unit with vaccine, then store the vaccines on a different shelf. This will help reduce the chance of a medication error, or contamination of the vaccine in the event the other medications or biologics spill.

Occasionally vaccines must be transported between clinics or administered at sites where there is no permanent storage unit. In these situations, you must still maintain appropriate storage temperatures. Always use insulated containers for vaccine transport. A thermometer must be placed in each container so that the temperature can be monitored and documented hourly. Craft paper, newspaper, or bubble wrap should be used to keep the vaccine from coming in direct contact with the ice and inadvertently freezing. Varicella vaccine can only be transported and temporarily stored using dry ice. Other vaccines should be stored in separate containers with regular ice. And remember NEVER touch dry ice without wearing heavy-duty gloves and eye protection.

Inventory control is an important quality control measure. Conduct a monthly vaccine inventory. This helps you avoid running out of vaccine or over-ordering. If you work in a satellite clinic, avoid stocking excessive amounts of vaccine because of the possibility of a power failure. Whenever conducting a monthly inventory, check the expiration dates. Rotate your stock to assure that the vaccine with the earliest expiration date is being used first to minimize waste. NEVER use expired vaccine. If a dose of expired vaccine is given by mistake, the dose should be

repeated.

Sometimes vaccine just seems to disappear. To avoid the inappropriate removal of vaccine, limit access to the vaccine storage refrigerator to authorized personnel. When the unit is not being used, keep it closed and locked.

We recently had the opportunity to talk with Jean Popiak, one of our vaccine management experts here at the National Immunization Program. We asked Jean to share with us some of the most common errors in vaccine storage and handling.

POPIAK:

As a state vaccine manager and now with the National Immunization Program, I have seen my share of costly vaccine management errors. Here is my Top Ten list of vaccine storage and handling no-no's, boo-boo's, transgressions, errors, offenses, violations, treasonistic acts, and absurdities.

Number 10: Only one person in the office is responsible for vaccine. Now let's face it, everyone gets sick or takes a vacation. It's important to train a backup person to learn your job, specifically when it comes to storage and handling of vaccines. Your backup should be well versed in recording refrigerator and freezer temperatures and recording them properly. Your backup should also know what to do in case of an equipment problem or power outage, but more on that later.

Number 9: Vaccine stored in the wrong part of the refrigerator like the vegetable bins, plastic containers, the door or the bottom of the refrigerator. This is a major vaccine no-no. The temperature in these areas will be higher than the temperature in the body of the refrigerator. Take the vegetable bins and loc-tight plastic containers out of the refrigerator. Also, don't store vaccine on the bottom of the refrigerator. The refrigerator motor is there, and it's the warmest location in the refrigerator. Place the vaccines on the shelves in open, labeled containers, so that air can circulate around the vaccine. And, remember, don't store vaccine in the refrigerator or freezer doors because the temperature will fluctuate.

Number 8: No emergency plans for a power outage or natural disaster. Every practice should have a written Disaster Recovery Plan. The most important item in this plan is to identify a location with a backup generator to take your vaccine to in the event of a power outage or natural disaster. Consider contacting your local hospital, Red Cross, elder care facility and contact

them now! An example of a mock Disaster Recovery Plan is available on the NIP broadcast resource website - you can just fill in the blanks. What you want to do is pre-arrange everything that way, when you take vacation, your backup person - remember the backup person? - will know what to do.

Number 7: Discarding multi-dose vials after they are opened for 30 days. This issue has been around for years. All multi-dose vials of vaccine have preservatives in them. Unless you see contamination in the vial, the vaccine should be used until the expiration date.

Number 6: Leaving the refrigerator or freezer door open overnight. This baffles me. In all my years, I've never left my home refrigerator or freezer door open overnight. Yet this happens every week in an office. To prevent this, check the seals on the doors, and if there is ANY indication the door seal may be cracked or not sealing properly, have it replaced. The cost of replacing a seal is much cheaper than the cost of replacing a box of pneumococcal conjugate or varicella vaccine.

Number 5: Storing varicella vaccine in a dorm-style refrigerator. Varicella must be stored in a refrigerator with a separate freezer door. No matter how hard you try to adjust the temperature to +5 F in a dorm-style refrigerator's freezer, there is no possible way to keep the refrigerator portion between 35 - 46 F! I've seen the freezer section enclosed with in everything from aluminum foil to cardboard. It doesn't keep the freezer section frozen. BUT you WILL freeze the vaccine in the refrigerator.

Number 4: Recording temperatures once per day. Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning of the day to determine if the unit is getting too cold overnight and at the end of the day to determine if the unit is not holding a constant temperature throughout the day. This is an all-inclusive temperature log. Note that it has space for refrigerator temperatures AND freezer temperatures, to be documented twice per day. Some temperature logs also have a space for room temperature. This is good information to know if there is a problem with the refrigerator. Also note that the correct temperature range is noted on the temperature log: 35 to 46 F or 2 to 8 C for the refrigerator, and colder than +5 F or -15 C for the freezer.

Number 3: Recording temperatures for only the refrigerator or

freezer. If your facility administers varicella vaccine, you should have a thermometer in the refrigerator AND the freezer. That means two thermometers. Not one thermometer that you can move from refrigerator to freezer and back, but two thermometers.

Here are examples of calibrated, certified accurate thermometers. Rather than buying a cheap thermometer that doesn't accurately measure the temperature six months after you purchase it, consider a quality thermometer that will last for years.

Number 2: Throwing away temperature logs at the end of every month or year. It's important that you keep temperature logs for 3 years. As the refrigerator ages, you can track recurring problems. If temperatures have been documented out of range, you can determine how long this has been happening and take appropriate action. It's also a great way to prove to your boss you need a new refrigerator!

And the Number 1 Storage and Handling faux pas is: Documenting out of range temperatures on vaccine temperature logs and not taking action. Documenting temperatures is not enough. Processing the information is just as - or even more important! Your job is not done if you document 28 F consistently in the refrigerator. This temperature log shows the correct temperature range to be 35 to 46 F. Here are some hints on what you should do if the temperature is out of range. To begin with, notify your supervisor. Someone else should be aware of the problem. Attempt to adjust the thermostat. Check the condition of the unit for problems. Are the seals tight? Is there excessive lint on the coils? After you have made the adjustment, document the date, time, temperature, what the problem was, the action you took, and the results of this action. Recheck the temperature every two hours. Call maintenance or a repairman if the temperature is still out of range. And move contents to your designated location, which will be found in your Disaster Recovery Plan.

Those are the Top Ten vaccine storage and handling errors. We've now come full circle. See how everything fits together?

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