

Net Conference Jan. 15, 2004
Vaccine Storage and Handling
FINAL SCRIPT

The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can adversely affect their potency and reduce the protection they provide.

Today, I'd like to review the basic guidelines for vaccine storage and handling. But first, I want to share a few true stories with you that I think will illustrate some of the problems occurring in the field, the consequences of those errors, and the reasons why proper S&H practices are so important.

A certain clinic closed for the Christmas holidays one year. The employee in charge of the vaccines, with the best of intentions but limited storage and handling knowledge, inappropriately placed all the vaccines in the freezer for "safe keeping". When the clinic re-opened one week later, staff contacted the State Health Department for advice on how long to defrost the vaccines before administration. As a result of this mistake, \$50,000 worth of vaccine was lost.

Another clinic discovered that for a long period of time they had been inappropriately exposing their vaccines to freezing temperatures. As a result, they may have given damaged or inactivated vaccine to potentially 3,400 people. This mistake cost an estimated \$300,000, including the cost of revaccination.

Finally, a refrigerator at a State Health Department vaccine distribution center set off the temperature alarm. Fifty-three minutes later, the security company contacted the designated public health employee. Forty-four minutes after being contacted, the employee arrived at the distribution center. On his arrival, the refrigerator temperature was -10 degrees Celsius, which was far below the required temperature range of 2-8 C. Sixty-three thousand doses of Td were lost, valued at almost half a million dollars.

I think these stories illustrate HOW IMPORTANT vaccine S&H is. Vaccines are fragile and must be kept at the temperatures recommended by the vaccine manufacturers at all times.

Storage and handling errors are not only expensive mistakes, they also result in the failure to protect patients due to the use of compromised vaccine, and in the loss of patient confidence in your practice when repeat doses are required. Don't make these easily avoidable mistakes! It is better to NOT VACCINATE than to administer a dose of vaccine that has been mishandled.

Live vaccines can tolerate freezing temperatures. In fact, both varicella vaccine and live attenuated influenza vaccine (or LAIV), must be stored in a continuously frozen state at

the recommended freezer temperatures until administration. MMR vaccine is usually stored in the refrigerator, but it can also tolerate freezing temperatures. Live virus vaccines deteriorate rapidly after they are removed from the freezer (or from the refrigerator in the case of MMR).

On the other hand, inactivated vaccines are damaged when exposed to freezing temperatures, and should not be used. However, they can tolerate short periods of time outside of the refrigerator, although the potency is also adversely affected over time.

An estimated 17% to 37% of providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold than too warm. Out-of-range temperature readings require IMMEDIATE action. It is estimated that more than \$100 million worth of vaccine is exposed to freezing temperatures each year in the United States.

Vaccines must be stored properly from the time they are manufactured until they are administered to your patients. The cold chain begins with the manufacturer and continues with the transfer of vaccine to the distributor, transfer from the distributor to the provider's office, and administration to the patient. Proper storage temperatures must be maintained at every link in the chain.

All healthcare providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed. Each office should:

- develop and maintain a detailed written storage and handling protocol,
- assign storage and handling responsibilities to one person,
- designate a back-up person, and
- ensure that both of them are provided with training on vaccine storage and handling.

When you receive your vaccine shipment, it should be examined. Crosscheck the contents with the packing slip to be sure they match. Check the vaccine expiration dates to ensure that you have not received any vaccine that is already expired. Examine the contents for any signs of damage (including physical damage to the package or vials, as well as heat or cold damage), and determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival of the product at the provider's office was more than 48 hours, it could mean the vaccine was exposed to excessive heat or cold that might alter the integrity of the vaccine.

If there are any discrepancies with the packing slip, or concerns about the vaccine shipment, mark the vaccine as "DO NOT USE" and store it under proper conditions until the integrity of the vaccine is determined. You'll need to contact the manufacturer or 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.

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 the shipment 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.

Vaccine storage units must be selected carefully and used properly. Refrigerators without freezers, and stand-alone freezers, are usually better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate door. Any refrigerator or freezer used for vaccine storage:

- must be able to maintain the required temperature range year-round,
- must be large enough to hold the year's largest inventory, and
- must be dedicated to the storage of biologics. Food and beverages should NOT be stored in vaccine storage units.

NIP discourages the use of small single-door (dorm-style) 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. However, the freezer compartment in this type of unit is incapable of maintaining the required temperature range for varicella vaccine and LAIV, and therefore cannot be used to store these vaccines

Most vaccines require storage temperatures of 35o to 46oF (which is 2o to 8oC), with a desired average temperature of 40oF (or 5oC). Both varicella vaccine and LAIV must be stored in a continuously frozen state at 5oF, which is -15oC, or colder. If you're using both the refrigerator and freezer to store vaccines, be careful not to make the freezer so cold that the refrigerator temperature drops below the recommended temperature range.

Proper temperature monitoring is key to proper cold chain management. Check the temperatures twice a day...once in the morning, and once before you leave at the end of the work day. Post a temperature log, similar to this one, on the door of the refrigerator or freezer and record the temperature readings twice daily.

It is important to keep temperature logs for at least 3 years, unless state statutes or rules require a longer period. As the refrigerator or freezer ages, you can track recurring problems or identify how long problems have existed.

While it's important to document the temperatures, it's not enough. Equally important is taking immediate action when the temperatures fall outside the recommended ranges. Remember, any mishandled vaccines should NOT be administered.

Both the refrigerator and freezer compartments should have their own thermometers. The thermometers should be placed in the center of the compartment away from the coils, walls, floor, and fans in order to get a true reading of the temperature. If it is not possible to place the thermometer away from a fan venting on the top shelf of the refrigerator, place the thermometer on the second (middle) shelf, in the center of the refrigerator compartment.

Here are some examples of thermometers that can be used. If you are using a continuous recording thermometer, even though it is recording the temperatures for you, it should still be checked twice each day to make sure the temperatures are in range. All thermometers are calibrated during manufacturing. Calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency, like the National Institute of Standards and Technology, or the American Standards of Technology and Measurement.

This certification, which is different than the manufacturer's warranty, is recorded on an official report from the manufacturer, like the one shown here, and provided with the instrument when purchased.

To keep the refrigerator and freezer cold, the unit must be in good working condition, and it must have power at all times. In order to prevent problems:

- Your refrigerator should have a plug guard or a safety-lock plug so that it cannot be pulled out accidentally.
- Post a warning sign (like this one) at the plug and on the refrigerator.
- Label the fuses and circuit breakers to alert janitors and electricians not to unplug the vaccine storage unit or turn the power off.
- And finally, you may want to install a temperature alarm to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.

You can help stabilize the temperature in the refrigerator by keeping containers of water inside. This liquid bulk helps keep the temperature stable, particularly when the refrigerator is being opened and closed all day long. The same principle applies to the freezer. Store extra cold packs or blue ice in the freezer. Not only will they help keep the temperature stable with frequent opening and closing of the door, they will also help keep the temperature stable in the event of a power failure.

Avoid letting the refrigerator or freezer doors stand open unnecessarily. Not only does this affect the temperature of the unit, it also exposes the vaccines to light (which can affect the potency of MMR and varicella vaccines). Providers should also never store vaccines in the door of the freezer or the refrigerator; the temperatures in the doors are not stable. Finally, you'll notice in this picture that the vegetable bins have been removed. There are 2 reasons for this:

- 1) it avoids the temptation to store things in them (e.g. food, beverages, or vaccines – vaccines should never be stored near the floor because the temperature is different here than that in the body of the refrigerator); and

- 2) this is a good place to store extra containers of water to help stabilize the temperature.

Multi-dose vials of vaccine contain a bacteriostatic agent and can be used until the date of expiration, unless they become visibly contaminated. Single-dose vials do NOT contain a bacteriostatic agent. Once opened, they must either be used or discarded at the end of the clinic day. With regards to reconstituted vaccine, once vaccines are reconstituted with a diluent, their shelf life is limited and they should be kept cold. The life of each reconstituted vaccine varies from product to product. Check the package insert for specific time limits.

We are frequently asked about pre-filling or drawing up doses of vaccine before they are actually needed. The National Immunization Program strongly discourages filling syringes in advance because this increases the risk for administration errors. Once in the syringe, it is difficult to tell which vaccine is which. Pre-filling syringes also leads to vaccine wastage. Unused syringes you have pre-filled must be discarded at the end of the clinic day. Finally, pre-filling syringes may result bacterial growth in the vaccines that don't contain preservatives (such as vaccines supplied in single-dose vials)

As an alternative to pre-filling syringes yourself, consider using manufacturer-supplied pre-filled syringes for large immunization clinics (e.g. flu clinics). Syringes (other than those filled by manufacturer) are designed for immediate administration and NOT for vaccine storage. However, if you have a reason to draw up more than one dose of vaccine, you should only pre-fill a few syringes at a time which you will administer, while someone else is pre-filling a few syringes he or she will administer.

To reiterate: any syringes of vaccine, NOT pre-filled by the manufacturer, should be discarded at the END OF CLINIC DAY.

Vaccine inventory control is a critical part of vaccine quality management. As part of inventory control, providers should count their vaccine supply on a monthly basis to be sure they have enough to meet their needs. However, avoid stocking excessive vaccine supplies, as this leads to vaccine wastage when old vaccines become outdated. Also include diluents in the stock control procedures and ensure adequate diluent supplies are available. Vaccines may only be reconstituted with the specified diluent. Diluents are not interchangeable. Providers should monitor the expiration dates of their vaccine and diluent supplies and rotate stock to avoid waste. Expired vaccine and diluent should never be used. Providers can also help protect their vaccine supply by limiting access to authorized personnel only.

It is critical that every clinic have a written emergency vaccine retrieval and storage plan. The most important part of this plan is to identify a location with a backup generator where providers can move their vaccine in the event of an emergency, such as an equipment failure, power outage, or natural disaster. Consider contacting the local hospital, Red Cross, or long-term care facility as a backup site. Information to assist in developing a written plan is available on the NIP website shown on the screen.

There are also other useful storage and handling resources available on the NIP website. Additionally, the Immunization Action Coalition website has an online catalog that contains a number of useful documents you can download (e.g. temperature logs in Fahrenheit and Celsius)

There is also an excellent “Checklist for Safe Vaccine Handling and Storage” available in the IAC online catalog, listed under “staff materials”. The checklist contains twenty of the most important actions clinics should take to safeguard their vaccine supply. This checklist is a GREAT training tool for staff.

Another excellent resource in the IAC online catalog is a one page list entitled “Don’t Be Guilty of These Errors in Vaccine Storage and Handling”. It reviews the top ten reported vaccine storage and handling errors. This error list and the checklist can be posted on your refrigerator so that everyone who uses vaccines in your clinic will be aware of proper storage and handling guidelines, as well as problems and errors to avoid.

Other helpful tools will also soon be available from CDC. A revised version of the “Ice, Champagne, and Roses” video, now entitled “How to Protect Your Vaccine Supply”, will be available from CDC in the next few months. In addition, a companion CD containing more detailed vaccine storage and handling information will also be available.

In order for patients to be protected by vaccines, vaccines must be stored and handled with care. With a few simple steps and good practices to maintain proper vaccine S&H, we can ensure that the full benefit of immunization is realized.