# Vaccine Cold Chain

## Part 1. Proper Handling and Storage of Vaccine

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ABSTRACT

The Centers for Disease Control and Prevention reports that professionals in clinic settings may not be adequately storing and handling vaccine, leading to insufficient immunity of vaccinated individuals. This article provides information about proper cold chain storage and handling of vaccine and offers resources to begin, or reinforce, proper procedures in the occupational health unit to secure an effective immunization program.

On arriving at work, the occupational and environmental health nurse methodically completed the routine of preparing to open the occupational health unit for the day. However, on entering the treatment room, she found herself standing in a puddle of water streaming from the vaccine freezer. On further inspection, she discovered the switch of the surge-protected power bar, to which both the vaccine freezer and the refrigerator were connected, was in the "off" position. Thousands of dollars of vaccine were in peril. What should the occupational and environmental health nurse do next? What are the implications for the employees who receive the vaccine and the effectiveness of the occupational health immunization program?

Cold chain, sometimes referred to as vaccine cold chain, is a system designed to protect and maintain vaccine viability. The cold chain has three main components: transport and storage equipment, personnel training, and efficient management procedures. This article appears in two parts. Part 1 discusses the importance of the cold chain and the need to adhere to procedures when transporting, shipping, receiving, and storing vaccine to maintain vaccine safety and effectiveness. Guidelines, emergency plans, and equipment monitoring and maintenance are addressed, along with cold chain failures and their remedy. Training of personnel about cold chain procedures and available resources will be detailed in Part 2. Furthermore, elements important to efficient and effective management will be discussed so that consistent oversight can be provided and cost implications considered. The role of the vaccine coordinator is emphasized throughout both Part 1 and Part 2.

As early as 200 B.C., a method of inoculation was used to create immunity against smallpox. It involved drainage from the lesions of individuals infected with smallpox be-

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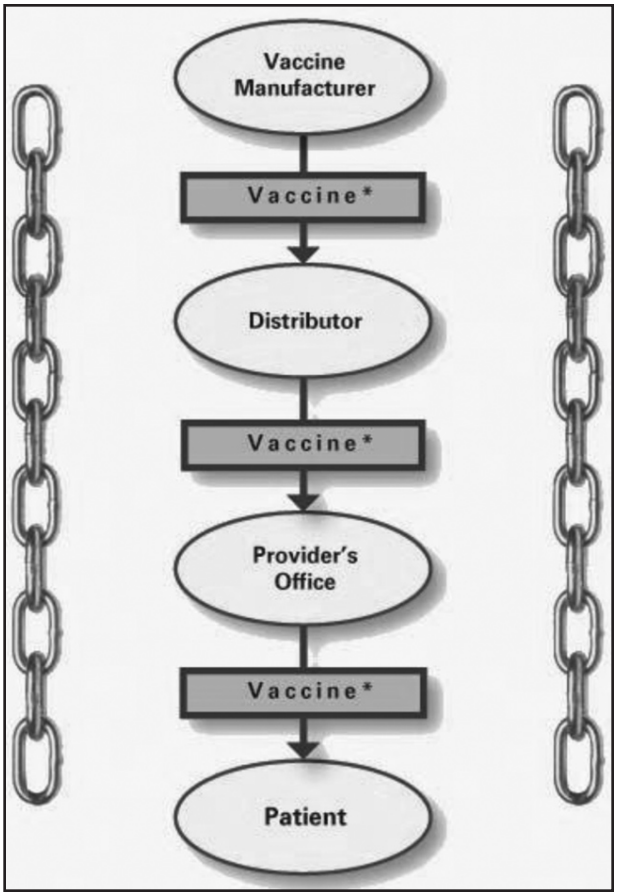


**Figure 1. Links in the cold chain. [Source: Centers for Disease Control and Prevention. (2008). *CDC: Vaccine storage and handling toolkit* (Fact sheet). Retrieved from www2a.cdc.gov/vaccines/ed/shtoolkit.]**

ing applied to fresh cuts on the skin of healthy individuals, leading to immunity of the exposed individuals. However, this method resulted in exposed individuals contracting the disease. Although this was usually a milder version of the disease, the risk of disease spread increased and some individuals died of the disease (Morgan & Parker, 2007).

Work-related health hazards have also played a significant role in vaccine development. In 1796, a British physician, Dr. Edward Jenner, observed that workers with cowpox disease, from a separate species closely related to the smallpox virus (Koplow, 2003), had less risk of developing smallpox. Cowpox disease, a mild viral infection causing lesions on the skin of cow udders and teats, spread to dairymaids through their contact with the lesions during the milking process; however, the dairymaids did not contract smallpox.

Dr. Jenner injected fluid from cowpox lesions on a dairymaid's hands into a young boy. The boy developed strong immunity against smallpox without dangerous exposure to the smallpox virus (Immunization Action Coalition [IAC], 2007; Koplow, 2003). This discovery led to safe and aggressive vaccination programs and in 1980, naturally occurring smallpox was considered eradicated throughout the world (World Health Organization [WHO], 2002). As early as 1798, the Marine Health Service protected shipmen and other marine workers from smallpox, cholera, and yellow fever with immunization (IAC, 2007); the Marine Health Service was the first public health agency to do so.

Vaccination is considered the most cost-effective method of preventing infectious diseases and is central to disease prevention and elimination (Centers for Disease Control and Prevention [CDC], 2007). In fact, immunization of all Americans for vaccine-preventable diseases is of major importance in the *Healthy People 2010* and *2020* documents (U.S. Department of Health and Human Services, 2009).

## THE COLD CHAIN

To maintain an effective vaccination program, vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold reduces their potency, increasing the risk that recipients will not be protected against vaccine-preventable diseases. The system used to effectively distribute and maintain vaccines is called the cold chain (sometimes referred to as vaccine cold chain). The cold chain has three main components: transport and storage equipment, trained personnel, and efficient management procedures. All three elements must combine to ensure safe vaccine transport and storage (Fig. 1) (CDC, 2008). Cold chain is similar to the process used to transport foods needing cold storage while in route from producers to consumers (CDC, 2008).

The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the recipient (Fig. 1). Proper storage temperatures must be maintained at each link in the chain or the vaccine may be damaged and become ineffective.

The WHO (1998) developed guidelines for cold chain storage in the early 1990s, outlining the importance of proper vaccine storage and handling, appropriate methods of immunization, adequate equipment options, and suggestions for alternative equipment. The issues of international concern were primarily related to how vaccines were stored and the lack of sterile equipment in developing countries (WHO, 1998). Refrigeration that relied on electricity was not accessible and gasoline or kerosene generators were a poor substitute with many mechanical problems. Following numerous well-documented incidents of improperly stored and handled vaccine (CDC, 2004, 2008), the CDC created a vaccine storage and handling "toolkit" that describes the vaccine cold chain and provides guidelines for managing vaccines appropriately (CDC, 2008).

## COMPONENTS OF THE COLD CHAIN

### *Transportation and Storage of Vaccine*

Maintenance of proper temperatures for vaccines is imperative to ensure their effectiveness. A vaccine coordinator, who, if employed, is often the occupational and environmental health nurse, should be assigned to ensure proper cold chain adherence during the transport, shipping, and receipt of vaccines. Written guidelines provide

necessary information to protect and maintain the effectiveness of vaccine and should include standard operating procedures (SOPs) for reference (Sidebar), vaccine personnel training and evaluation of staff performance, and procedures for proper storage and handling (CDC, 2008).

Manufacturers have determined that all vaccines are sensitive biological substances that can lose their potency when exposed to temperatures outside the recommended storage range (WHO, 1998). A properly packed cooler that maintains the vaccine temperature within the prescribed acceptable range can reduce the effect of the external temperature on the internal temperature of the cooler (CDC, 2008).

The correct number and placement of ice packs inside the cooler is important because too few ice packs can fail to maintain the internal cooler temperature and too many ice packs have the potential to freeze the vaccine. The CDC has developed a chart providing details for ice pack use in different climates (Table 1). Placement of ice packs is also critical to protect the vaccine from freezing. A barrier such as bubble wrap, crumpled brown wrap, or Styrofoam® peanuts should be placed between the vaccine and the cold packs. A certified thermometer should be included in the transport container for hourly monitoring of the internal cooler temperature by vaccine transport personnel. The thermometer should be placed next to the vaccine, not adjacent to the cold pack. Contents should be layered bottom to top in the following order: refrigerated cold packs, barrier material, vaccine, thermometer, and another barrier layer. Vaccine should remain in its original packaging and doses should not be prepared in advance. The vaccine name, number of vials, date, time, and recorded temperatures should be displayed legibly on the outside of the cooler. The U.S. Food and Drug Administration prohibits transport of partially used vaccine across state lines. Vaccine should never be transported inside the trunk of a vehicle because the temperature inside the trunk cannot be controlled as well as the temperature inside the vehicle; nor should the vaccine be left unattended in the vehicle because the temperature may become either warmer or cooler, altering the internal temperature of the cooler (CDC, 2008).

Occupational and environmental health nurses may have occasion to hand carry or transport vaccine to locations such as off-site clinics. Vaccine must be transported in properly insulated containers. Styrofoam® with 2-inch thick walls and validated hard-sided coolers are sufficient

## Key Elements of Standard Operating Procedures for Vaccine Storage and Handling

- Summary of the storage requirements for each vaccine
- Descriptions of roles and responsibilities of vaccine coordinators
- Protocol for transporting and receiving shipments
- Protocol for administering vaccine
- Protocol for troubleshooting
- Sample forms used in the vaccine program

Note. *Source: Centers for Disease Control and Prevention. (2008).* CDC: Vaccine storage and handling toolkit [Fact sheet]. *Retrieved from www2a.cdc.gov/vaccines/ed/shtoolkit.*

Table 1

## Refrigerated/Frozen Pack Needs for Different Climates

| *Outside Temperature* | *Number of Faces[a] Covered With Packs* | *Temperature of Packs* | *Comment[b]* |
|---|---|---|---|
| > 75°F to 110°F (> 24°C to 43°C) | 2[c] | 23°F (-5°C) | Up to 48 hours of delivery with 10 hours at 110°F (43°C) |
| 32°F to 75°F (0°C to 24°C) | 2[c] | 23°F (-5°C) | Up to 48 hours of delivery |
| | 4 | 41°F (+5°C) | Up to 24 hours of delivery |
| < 32°F (< 0°C) | 4 to 6[d] | 50°F (+10°C) | About 24 hours of exposure to mix of outdoor and heated areas |
| 0°F (-18°C) or colder | 6[d] | 68°F (+20°C) | Prolonged, 24 to 48 hours of continuous exposure to 0°F (-18°C) |

Note. *[a]Faces would include the interior surfaces of the box, including the walls, floor, and lid (above the vaccines and insulating material). [b]Applies when high-quality insulated boxes with walls of 1¾ to 2¼ inches of expanded polystyrene, 1 inch of isocyanurate, or 3 inches of polyurethane insulation were used. [c]Three for medium-sized box tested by the Centers for Disease Control and Prevention (10 × 10 × 7 inches—interior dimensions). [d]Essentially the entire surface area is covered with packs. [Source: Centers for Disease Control and Prevention. (2008).* CDC: Vaccine storage and handling toolkit *(Fact sheet). Retrieved from www2a.cdc.gov/vaccines/ed/shtoolkit.]*

for short-term transport. Shipping containers that housed the vaccine from the vaccine manufacturer can also be saved and used for transport off-site. Thin-walled Styrofoam® containers and soft-sided coolers are not sufficient to maintain the vaccine cold chain during transport (CDC, 2008).

### *Shipping*

Occupational and environmental health nurses may also need to ship vaccines to other clinics due to inventory shortages. When shipping is necessary, vaccine cold chain requirements must be maintained (i.e., proper packing with ice packs and barrier materials and temperature monitoring and recording). Containers capable of maintaining the acceptable temperature range for 48 hours should be used. Refrigerated ice packs with a barrier of bubble wrap, Styrofoam® peanuts, or crumpled brown wrapping paper placed between the ice packs and the vaccine should be used to thwart freezing (CDC, 2008).

When shipping a vaccine, it is important to determine whether the vaccine has been exposed to temperatures outside the recommended range, potentially rendering the vaccine ineffective. Cold chain monitors (CCMs) are used to monitor vaccine temperatures during shipping. Three basic types of CCMs are available: one indicates if the vaccine reached temperatures above 50°F or 10°C, one indicates if the vaccine reached temperatures of 32°F or 0°C, and one indicates the vaccine temperature continuously during the entire shipping process.

Heat indicator CCMs are for single use, are temperature sensitive, and should be placed in the refrigerator prior to use to ensure that the dye is in a solid state before activation. A heat indicator CCM releases a colored dye into the windows of the device when the activation temperature has exceeded the set range (indicated on the device). The dye gradually moves through the windows over time. If the temperature drops below the threshold again, the dye stops moving but does not disappear; therefore, the indicator also shows the length of time, in hours or days, that the temperature has exceeded the desired range. When ready for use, the heat indicator CCM is removed from the refrigerator and placed in the environment being monitored. If the environment being monitored is above the temperature threshold of the indicator, the heat indicator CCM will activate prematurely; therefore, the indicator must be attached directly to the vial or the vaccine box promptly. Freeze indicator CCMs are also for single use and release a colored liquid dye when exposed to freezing temperatures (32°F or 0°C). However, they do not indicate the length of time the vaccine is exposed to the undesired temperature range. Some types of freeze indicators require preconditioning (CDC, 2008).

Digital data loggers are small, programmable, battery-operated, electronic devices available in single- and multi-use models. These devices have external lights alerting the user when the appropriate temperature occurs and when a temperature either too hot or too cold has occurred. The vaccine shipment must not be approved for further use until the temperature data have been interpreted. The digital data logger requires a special software program that interprets the data and reveals if the vaccine has reached temperatures outside the recommended range (CDC, 2008).

When shipping a vaccine, it is critically important to review the vaccine insert carefully, noting the manufacturer's recommended temperature range. At least 6 pounds of dry ice should be used for vaccine that must remain frozen. Dry ice should not be used for vaccine that is to remain unfrozen. Live vaccines generally tolerate freezing well and deteriorate rapidly when removed from the freezer. Consequently, occupational and environmental health nurses should administer the vaccine immediately after removing it from the freezer (CDC, 2009a).

When shipping expired vaccine back to the manufacturer for a refund or disposal, occupational and environmental health nurses should contact the vaccine manufacturer for shipping instructions and authorization. Cold chain monitoring is unnecessary for expired vaccine. Vaccine that is damaged or expired is considered medical waste and must be properly disposed of in accordance with state regulations (CDC, 2008).

### *Receiving*

As vaccine arrives, it must be carefully inspected to ensure that the cold chain has been maintained. The shipment must be received, inspected, and properly stored as soon as it arrives. Once the vaccine arrives, the container and its contents should be examined for any damage (e.g., broken or fractured glass). A shipping time of less than 48 hours is necessary to ensure that the vaccine temperature has been within the acceptable range; ice packs and dry ice are ineffective after this time period. Vaccine vials should be inspected for expiration date. The CCMs should be checked to ensure the temperatures were maintained during shipping. Cold packs or dry ice should be inspected for coldness and to ensure a barrier exists between the packs and the vaccine. The CDC stresses that visual inspection is ineffective to ensure vaccine potency. If any question arises as to whether the vaccine was compromised during shipping, the vaccine should be clearly marked DO NOT USE and kept separated from other vaccines until its integrity can be determined (CDC, 2008).

### *Guidelines for Storage*

An individual, usually the occupational and environmental health nurse, should be assigned as primary vaccine coordinator, with a second coordinator assigned to monitor the vaccine storage and handling issues if the primary vaccine coordinator is unavailable. The occupational and environmental health nurse should have written guidelines on proper vaccine storage and handling for vaccine staff. The guidelines should be prominently located and easily accessible to those administering or storing vaccines. These guidelines should include:

- Contact information for the vaccine coordinators.
- Contact information for resources or vendors (e.g., vaccine manufacturers; refrigerator, freezer, and maintenance companies).
- Descriptions of the roles and responsibilities of the vaccine coordinators.

- Summaries of storage requirements for vaccines.
- Instructions for monitoring the temperature of vaccine storage units, including placement of vaccine within the storage units.
- Instructions for transporting and receiving vaccine shipments.
- Instructions for managing vaccine inventory.
- Instructions for properly disposing of vaccine and supplies.
- Instructions for administering vaccine.
- Instructions for troubleshooting.
- Sample forms used in the vaccine program (CDC, 2008).

The IAC (2008) has developed a checklist for safe vaccine handling and storage (Fig. 2).

### *Emergency Plan*

A written emergency plan in case of equipment failure, natural disaster, or major power outage should be available. An occupational health clinic with a large vaccine inventory could be at risk of financial loss if vaccine is compromised and must be discarded. A well-written emergency plan to manage vaccine storage can ensure the security of this investment. Occupational and environmental health nurses should consider establishing a working agreement with an agency such as a hospital that has a generator and the ability to monitor vaccine when weather alerts are in effect (CDC, 2008).

The emergency plan, prepared well in advance, should be prominently located, be freely accessible, and include:

- Contact information for the vaccine coordinators.
- Protocol for the role of the vaccine coordinators—track inclement weather, maintain notification systems, store vaccine appropriately during a disaster or power outage, ensure 24-hour access to the building and storage unit, and ensure that fuel is available for at least 72 hours if the facility has a generator.
- Specifications of vaccine storage units (i.e., types of storage units, including brand names, models, and serial numbers).
- Names and addresses of potential alternate vaccine storage facilities (i.e., hospital, long-term care facility, American Red Cross, or packing plant) and contact information.
- Guidelines for appropriate storage of vaccine at alternate facilities.
- Written guidelines with directions for drivers transporting vaccine to and from alternate storage facilities.
- Guidelines describing proper packing materials and how to properly pack vaccine for transport.

For small occupational health clinics with no resources for computerized notifications or supplemental generators, occupational and environmental health nurses should consider maintaining a minimal inventory of vaccine to reduce potential loss in the event of such emergencies (CDC, 2008).

### *Storage Equipment*

Proper storage equipment is essential to ensuring that vaccine temperature is maintained. Necessary equipment for routine storage and handling of vaccines includes refrigerators and freezers, calibrated thermometers, and alarms. In addition, the amount of inventory needing to be stored must be considered when selecting equipment (CDC, 2008).

A combined refrigerator-freezer must have separate external doors to ensure temperatures are properly maintained. The unit must have the capacity to store the largest inventory anticipated, frozen packs in the freezer, and water bottles in the refrigerator. A dormitory-style unit, a small combined refrigerator-freezer with one external door, is insufficient for storing vaccine permanently because proper temperature regulation is not possible. The selected refrigerator-freezer must have a temperature regulator that can be adjusted to appropriate temperature ranges. The temperature of the refrigerator unit should be maintained between 35ºF and 46ºF (2ºC and 8ºC), and the temperature of the freezer unit should be 5ºF (-15ºC) or colder. Occupational and environmental health nurses should monitor the temperatures of both the freezer and the refrigerator twice daily: once in the morning and once before the end of the work shift (CDC, 2008).

The National Center for Immunization and Respiratory Diseases recommends the use of certified calibrated thermometers for monitoring storage unit temperatures. Thermometers are calibrated during manufacture and again from an appropriate agency (e.g., the National Institute of Standards and Technology or the American Society for Testing and Materials). These thermometers generally receive a 2-year certification. The certificate should be maintained for reference (CDC, 2008), and occupational and environmental health nurses should monitor for their expiration. Occupational and environmental health nurses should evaluate different types of thermometers and temperature recorders to determine which will work best. Table 2 details types of thermometers used to monitor vaccine temperatures (CDC, 2003).

Labels assist workers in properly storing and handling vaccine. Labels placed on external refrigerator doors provide instructions about the correct storage location for each vaccine in the inventory and inform workers not to store food or beverages in designated vaccine refrigerators and freezers. In addition, vaccines should be stored in separate labeled bins in refrigerator-freezer units to reduce the risk of retrieving the wrong vaccine (CDC, 2008).

### *Cold Chain Violation*

Vaccine cold chain violations include storing vaccine outside the required temperature range, improperly monitoring temperatures to maintain vaccine safely, using improper storage containers or improper locations inside a refrigerator, equipment failure, and inadequately training personnel (CDC, 2008, 2009a). Cold chain violation is the leading cause of vaccine waste, leading to excessive cost, lack of consumer trust, and potentially unprotected or harmed recipients (CDC, 2009a). According to the CDC (2008), millions of dollars of vaccine are lost each year due to improper storage and handling. For example,

Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all? Reviewing this list can help you improve your clinic's vaccine management practices.

| Yes | No | | |
|---|---|---|---|
| _____ | _____ | 1. | We have a designated person in charge of the handling and storage of our vaccines. |
| _____ | _____ | 2. | We have a back-up person in charge of the handling and storage of our vaccines. |
| _____ | _____ | 3. | A vaccine inventory log is maintained that documents:<br>_____ Vaccine name and number of doses received<br>_____ Date the vaccine was received<br>_____ Arrival condition of vaccine<br>_____ Vaccine manufacturer and lot number<br>_____ Vaccine expiration date |
| _____ | _____ | 4. | Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer. |
| _____ | _____ | 5. | We do NOT store any food or drink in the refrigerator or freezer. |
| _____ | _____ | 6. | We store vaccines in the middle of the refrigerator or freezer, and NOT in the door. |
| _____ | _____ | 7. | We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date. |
| _____ | _____ | 8. | We check vaccine expiration dates and we first use those that will expire soonest. |
| _____ | _____ | 9. | We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer. |
| _____ | _____ | 10. | We always keep a thermometer in the refrigerator. |
| _____ | _____ | 11. | The temperature in the refrigerator is maintained at 35–46°F (2–8°C). |
| _____ | _____ | 12. | We keep extra containers of water in the refrigerator to help maintain cold temperatures. |
| _____ | _____ | 13. | We always keep a thermometer in the freezer. |
| _____ | _____ | 14. | The temperature in the freezer is maintained at +5°F (-15°C) or colder. |
| _____ | _____ | 15. | We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures. |
| _____ | _____ | 16. | We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day—first thing in the morning and at clinic closing time—and we know whom to call if the temperature goes out of range. |
| _____ | _____ | 17. | We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet. |
| _____ | _____ | 18. | In the event of a refrigerator failure, we take the following steps:<br>_____ We assure that the vaccines are placed in a location with adequate refrigeration.<br>_____ We mark exposed vaccines and separate them from undamaged vaccines.<br>_____ We note the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines.<br>_____ We follow the vaccine manufacturer's or health department's instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department. |
| _____ | _____ | 19. | We have obtained a detailed written policy for general and emergency vaccine management from our local or state health department. |
| _____ | _____ | 20. | If all above answers are "yes," we are patting ourselves on the back. If not, we have assigned someone to implement needed changes! |

**Figure 2. Checklist for safe vaccine handling and storage. [Source: Immunization Action Coalition. (2008). *Checklist for vaccine handling and storage.* Retrieved from www.immunize.org/catg.d/p3035.pdf.]**

$392,717 was lost in San Francisco Bay County in 2006 and $4 million in New Mexico in 2007 due to improper storage and management of vaccine (Backer, Hammer, & Vantine, n.d.). During the 2009 H1N1 pandemic, thousands of doses of H1N1 vaccine were lost due to refrigerator malfunction at a Pennsylvania public school (WPXI News, 2009).

Cold chain violations can significantly increase the

Table 2

**Comparison of Thermometers Used to Monitor Vaccine Temperatures**

| | *Type of Thermometer* | | | | | |
|---|---|---|---|---|---|---|
| ***Characteristic*** | ***Fluid-Filled Bio Safe Liquid*** | ***Bi-Metal Stem*** | ***Minimum-Maximum*** | ***Digital*** | ***Chart Recorder*** | ***Digital Data Logger*** |
| Expense | Moderate | Moderate | Moderate | Moderate | Moderate | High |
| Continuous read | No | No | No | No | Yes | Yes |
| Available in digital | Yes | No | Yes | Yes | Yes | Yes |
| Difficult to read | Yes | Yes | Yes | No | Yes | No |
| Requires software | No | No | No | No | No | Yes |
| Requires paper change | No | No | No | No | Yes | No |

Note. *Sources: Centers for Disease Control and Prevention. (2003). Notice to readers: Guidelines for maintaining and managing the vaccine cold chain.* Morbidity and Mortality Weekly Report, 52*(42), 1023-1025. Retrieved from www.cdc.gov/mmwr/preview/mmwrhtml/mm5242a6.htm. Dickson Data. (2010).* Vaccine storage education guide. *Retrieved from www.dicksondata.com/article/article_30.php#compair.*

cost from lost vaccine in an occupational health unit. An occupational health unit can easily store significant quantities of vaccine costing thousands of dollars. For example, according to the CDC (2009b) price list for vaccine, 50 seasonal influenza immunizations, 20 nasal influenza immunizations, 10 tetanus with diphtheria boosters, and 10 hepatitis B immunizations total nearly $2,000. Potential legal liability due to lack of immunity to vaccine-preventable illnesses or complications from contaminated vaccine are additional costs. In addition, loss of confidence by the employer and employees can potentially destroy a valuable program for workers (CDC, 2008).

Participants in the Vaccines for Children programs were mandated to replace dormitory-style refrigerators with approved refrigerators by December 31, 2009, because of their unreliability in storing vaccines properly, and thus potential to cause vaccine damage (CDC, 2008; Lacen, 2008). This should be considered a best practice for all occupational health clinics. Cold chain failure requires immediate action. Staff must follow the procedures outlined in the Sidebar (CDC, 2008).

The vaccine manufacturer determines the vaccine's viability based on the information reported. Vaccines that are deemed viable are returned to vaccine inventory and stored in appropriate temperature conditions. Vaccines that are deemed viable with a new, shorter expiration date must be labeled with the new date, returned to vaccine inventory, stored in an appropriate area, and administered first. Vaccines that are deemed not viable are bagged, packaged, and returned to the manufacturer.

In addition to the vaccine manufacturer, the vaccine coordinator must be notified of a vaccine cold chain failure. The vaccine coordinator is responsible for ensuring that vaccines are handled appropriately and procedures for vaccine cold chain maintenance and failure are properly documented (CDC, 2008).

**Procedures in the Event of a Vaccine Cold Chain Failure**

To reduce the possibility of further vaccine damage, immediately relocate vaccine to a safe storage area that has appropriate temperature.

Label vaccines as DO NOT USE until after further investigation about their viability.

Keep affected vaccines separated from unaffected vaccines until validation on the viability of the vaccines is determined. Affected vaccines might have lost some of their potency, affecting expiration dates.

Contact the vaccine manufacturer immediately to report the quantity of vaccine affected, temperature of the area where the vaccine was stored, and time vaccine was exposed to inappropriate temperature conditions.

Note. *Source: Centers for Disease Control and Prevention. (2008).* CDC: Vaccine storage and handling toolkit [Fact sheet]. *Retrieved from www2a.cdc.gov/vaccines/ed/shtoolkit.*

## CONCLUSION

Employers and employees have an unparalleled trust in occupational and environmental health nurses and expect and deserve diligence in the delivery of safe, potent vaccines at work. With that trust, occupational and environmental health nurses can positively influence the economics and health of an organization. To that end, the vaccine cold chain procedures that have been developed must be closely followed in the occupational health clinic.

The loss due to vaccine cold chain violations in occupational health clinics could be catastrophic, as limited

## IN SUMMARY

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### Part 1. Proper Handling and Storage of Vaccine

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1. From the vaccine manufacturer to vaccination of the individual, the importance of vaccine cold chain procedures cannot be overstated.

2. In the occupational health setting, an effective vaccine program is important for disease prevention among workers.

3. A vaccine coordinator should be assigned to develop proper cold chain procedures for transporting, shipping, and receiving vaccines. The coordinator is responsible for monitoring compliance with procedures to prevent and control cold chain violations.

vaccine must be replaced and more employees are at risk for illness and death. More importantly, the loss created by vaccine cold chain violation is broad, including loss of production for the company, loss of income for workers, and a generalized societal mistrust of vaccine programs.

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# Vaccine Cold Chain: Part 1. Proper Handling and Storage of Vaccine

This issue of the AAOHN JOURNAL contains a Continuing Nursing Education Module on "Vaccine Cold Chain: Part 1. Proper Handling and Storage of Vaccine." 1.0 contact hour of continuing nursing education credit will be awarded by AAOHN upon successful completion of the posttest and evaluation.

A certificate will be awarded and the scored test will be returned when the following requirements are met by the participant: (1) The completed answer sheet is received at AAOHN on or before July 31, 2011; (2) A score of 70% (7 correct answers) is achieved by the participant; (3) The answer sheet is accompanied by a check or money order for $15.00 ($20.00 non-members), or purchase online for $10.00 ($15.00 non-members) at www.aaohn.org. Expect up to 4 weeks for delivery of the certificate.

Upon completion of this lesson, the occupational health nurse will be able to:

1. Describe the components of the vaccine cold chain.

2. Discuss the importance of the cold chain for safe and effective vaccines.

3. Explain the methods for transporting, shipping, receiving, and storing vaccines.

4. Identify the role of the occupational health nurse in emergency planning for cold chain failures.

AAOHN is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

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Contact hour credits received for successful completion of the posttest and evaluation may be used for relicensure, certification, or re-certification.

*Directions:* Circle the letter of the best answer on the answer sheet provided. (Note: You may submit a photocopy for processing.)

**1. All of the following are main components of the vaccine cold chain except:**
A. Transport and storage equipment.
B. Trained personnel.
C. Disease-preventable immunization.
D. Efficient management procedures.

**2. If the outside temperature is greater than 75°F to 110°F, the number of faces covered with packs is:**
A. 2.
B. 4.
C. 6.
D. 8.

**3. Going from bottom to top, a cooler is layered with this first:**
A. Barrier material.
B. Refrigerated cold packs.
C. Vaccine.
D. Thermometer.

**4. Which of the following is used for the short-term transport of an insulated container?**
A. Soft-sided cooler.
B. Thin-walled Styrofoam®.
C. Validated hard-sided cooler.
D. Styrofoam® with 1-inch thick walls.

**5. Containers capable of maintaining the acceptable temperature range for ___ hours should be used.**
A. 6.
B. 12.
C. 24.
D. 48.

**6. All of the following are characteristics of freeze indicator cold chain monitors except:**
A. Single use.
B. Indicate the length of time the vaccine is exposed to undesired temperature ranges.
C. Release a colored liquid dye when exposed to freezing temperatures.
D. Some types require preconditioning.

**7. When shipping vaccine that must remain frozen, occupational and environmental health nurses use at least ___ pounds of dry ice.**
A. 2.
B. 4.
C. 6.
D. 8.

**8. The Immunization Action Coalition (Centers for Disease Control and Prevention, 2008), recommends checking the temperature of the refrigerator and freezer:**
A. Daily.
B. 2 times per day.
C. 3 times per day.
D. 4 times per day.

**9. The emergency plan for managing vaccine storage and security includes that fuel be available for at least __ hours if the facility has a generator.**
A. 40.
B. 52.
C. 60.
D. 72.

**10. Which of the following is the priority action for occupational and environmental health nurses following a cold chain failure?**
A. Immediately relocate vaccine to a safe storage area.
B. Keep affected vaccine separated from unaffected vaccine.
C. Label vaccine as DO NOT USE.
D. Report to the vaccine manufacturer.

# Vaccine Cold Chain: Part 1. Proper Handling and Storage of Vaccine

## August 2010

(Goal: To gain ideas and strategies to enhance personal and professional growth in occupational health nursing.)

**Mark one answer only!**
**(You may submit a photocopy of the answer sheet for processing.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1.** | A | B | C | D | **6.** | A | B | C | D |
| **2.** | A | B | C | D | **7.** | A | B | C | D |
| **3.** | A | B | C | D | **8.** | A | B | C | D |
| **4.** | A | B | C | D | **9.** | A | B | C | D |
| **5.** | A | B | C | D | **10.** | A | B | C | D |

## *EVALUATION (must be completed to obtain credit)*

Please use the scale below to evaluate this continuing education module.

| | 4 - To a great extent | 3 - To some extent | 2 - To little extent | 1 - To no extent |
|---|---|---|---|---|
| 1. As a result of completing this module, I am able to: | | | | |
| A. Describe the components of the vaccine cold chain. | 4 | 3 | 2 | 1 |
| B. Discuss the importance of the cold chain for safe and effective vaccines. | 4 | 3 | 2 | 1 |
| C. Explain the methods for transporting, shipping, receiving, and storing vaccines. | 4 | 3 | 2 | 1 |
| D. Identify the role of the occupational health nurse in emergency planning for cold chain failures. | 4 | 3 | 2 | 1 |
| 2. The objectives were relevant to the overall goal of this independent study module. | 4 | 3 | 2 | 1 |
| 3. The teaching/learning resources were effective for the content. | 4 | 3 | 2 | 1 |
| 4. How much time (in minutes) was required to read this module and take the test? | 60 | 70 | 80 | 90 |

*Please print or type: (this information will be used to prepare your certificate of completion for the module).*
*DEADLINE: JULY 31, 2011. Allow up to 4 weeks for processing.*

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