Interlibrary Loans and Journal Article Requests

Notice Warning Concerning Copyright Restrictions:

The copyright law of the United States (Title 17, United States Code) governs the making of photocopies or other reproductions of copyrighted materials.

Under certain conditions specified in the law, libraries and archives are authorized to furnish a photocopy or other reproduction. One specified condition is that the photocopy or reproduction is not to be *"used for any purpose other than private study, scholarship, or research."* If a user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of "fair use," that user may be liable for copyright infringement.

Upon receipt of this reproduction of the publication you have requested, you understand that the publication may be protected by copyright law. You also understand that you are expected to comply with copyright law and to limit your use to one for private study, scholarship, or research and not to systematically reproduce or in any way make available multiple copies of the publication.

The Stephen B. Thacker CDC Library reserves the right to refuse to accept a copying order if, in its judgment, fulfillment of the order would involve violation of copyright law.

Terms and Conditions for items sent by e-mail:

The contents of the attached document may be protected by copyright law. The CDC copyright policy outlines the responsibilities and guidance related to the reproduction of copyrighted materials at CDC. If the document is protected by copyright law, the following restrictions apply:

- You may print only one paper copy, from which you may not make further copies, except as maybe allowed by law.
- You may not make further electronic copies or convert the file into any other format.
- You may not cut and paste or otherwise alter the text.

Vaccine Cold Chain

Part 2. Training Personnel and Program Management

by Bonnie Rogers, DrPH, COHN-S, LNCC, FAAN, Kim Dennison, RN, BSN, COHC, Nikki Adepoju, BSN, RN, Shelia Dowd, BSN, RN, COHN-S/CM, and Kenneth Uedoi, BSN, RN, COHC, CEN, COHN-S

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. Part 2 of this article provides information about the importance of adequate personnel training and program management policies and procedures needed to implement and maintain an effective vaccine cold chain 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 discussed 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 (Rogers, Dennison, Adepoju, Dowd, & Uedoi, 2010). Guidelines, emergency plans, and equipment monitoring and maintenance were addressed, along with cold chain failures and their remedy. Training of personnel about cold chain procedures and available resources are detailed in Part 2. Furthermore, elements important to efficient and effective management are 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.

ABOUT THE AUTHORS

Dr. Rogers is Professor and Director, North Carolina Occupational Safety and Health Education and Research Center and OHN Program, University of North Carolina, School of Public Health, Chapel Hill, NC. Ms. Dennison is Occupational Health Nurse and Educator, Michigan Laborers' Training and Apprenticeship Institute, Perry, MI. Ms. Adepoju is Nursing Program Director, University of the District of Columbia Nursing Certificate Programs, Washington, DC. Ms. Dowd is Disability Case Management Supervisor, Southern Nuclear Company, Birmingham, AL. Mr. Uedoi is Occupational Health Nurse, Hawaii Army National Guard, Kapolei, HI.

The authors disclose that they have no significant financial interests in any product or class of products discussed directly or indirectly in this activity, including research support.

Address correspondence to Bonnie Rogers, DrPH, COHN-S, LNCC, FAAN, Professor, University of North Carolina at Chapel Hill, 1700 MLK Blvd. CB#7502, Chapel Hill, NC 27599-7502. E-mail: rogersb@email.unc.edu.

Received: March 8, 2010; Accepted: June 7, 2010; Posted: August 23, 2010.

doi:10.3928/08910162-20100816-02

COLD CHAIN TRAINING PROGRAM

For all staff who administer or handle vaccines, it is essential to provide comprehensive training about proper vaccine handling and storage, the importance of maintaining the vaccine cold chain, and the procedures to follow if there is a break in the cold chain (Centers for Disease Control and Prevention [CDC], 2008). All new personnel must receive training as part of their orientation. In the workplace, the occupational and environmental health nurse, as the primary vaccine coordinator, assumes the major training role and must possess knowledge and skills about vaccine cold chain at the worksite. Although the CDC (2008) recommends annual training, an ongoing educational process throughout the year should be considered due to the health and financial implications

Table

Essential Elements of Vaccine Cold Chain Training in the Workplace

- Cold Chain
  - What is cold chain?
    - System to keep and distribute vaccines in good condition
  - Components of cold chain
    - Transport and storage equipment
    - Trained personnel
    - Efficient management procedures
  - Importance of maintaining cold chain
    - Ensure vaccine potency
    - Avoid cold chain failure
- Vaccine Personnel
  - Role and responsibility of the primary and back-up coordinators
    - Monitor vaccine storage and handling
    - Develop handling guidelines, inventory management, temperature monitoring, and emergency plans
    - Train all personnel who handle and administer vaccine in the workplace about the importance of maintaining cold chain procedures to follow in the event of a break in cold chain
  - Role and responsibility of other staff
    - Become familiar with the workplace policy and procedure for vaccine storage and handling practices
- Vaccine Storage and Handling Guideline
  - Routine guidelines for vaccine management
    - Ordering and controlling inventory
    - Storing vaccines and monitoring storage conditions
    - Minimizing vaccine waste
    - Vaccine shipping, including receiving, packing, and transporting
  - Emergency guidelines for vaccine management
    - Designated personnel responsible for preparing and transporting vaccine
    - How to pack vaccine for transport
    - Worksheet to document vaccine involved in power or equipment failure
- Vaccine Storage Equipment
  - Importance of selecting and requirements for appropriate vaccine storage equipment
    - Care and maintenance for vaccines storage
    - National Institute of Standards and Technology; American Society for Testing and Materials-certified thermometer inside storage equipment
    - Storage equipment dedicated for storing vaccines only
- Vaccine Storage Practices
  - Importance of proper vaccine storage practices
  - Aspects to consider when storing vaccines
    - Appropriate vaccine and diluent storage conditions
      1. Live vaccines
      2. Inactivated vaccines
      3. Vaccine light sensitivity
      4. Freeze-dried vaccines and diluents
    - Vaccine storage locations and positioning
      1. Freezer
      2. Refrigerator
      3. Vaccine spacing
      4. Vaccine packaging
    - Vaccine labeling and reading
    - Storage containers for vaccines
      1. Vaccine boxes
      2. Trays and containers
    - Storage of non-vaccine products
      1. Food and beverages
      2. Medications and other biological products

Temperature Monitoring
- Significance of temperature reading
- How to read thermometers
- How to respond to out-of-range temperatures
- How and where to document actions taken for out-of-range temperatures
- How to maintain, review, and store temperature logs
- Noting failures and room temperatures
- Using an alarm system

Storage Troubleshooting
- Handling inappropriate vaccine storage conditions
- Handling malfunctioning vaccine storage unit
    1. Vaccine storage unit extreme temperature conditions
    2. Vaccine storage unit working condition
- Refrigerator and freezer door problem
    - How to check and adjust door seal and dropped door seals
- Thermometer problems
    - How to check placement, working condition, and accuracy of thermometer
- Power outages
    1. Temperature considerations for vaccines
    2. Power outage procedures to follow
- Imminent emergency

Vaccine Inventory Management
- Vaccine access/limitation
- Expiration dates
    1. How to interpret expiration dates
    2. How to handle expired and mishandled vaccines
- Vaccine stock rotation
- Inventory accounting
    1. Importance of inventory accounting
    2. Vaccine inventory protocol and procedure
- Vaccine stock calculation and vaccine ordering
    1. Importance of stock calculation and ordering
        - To avoid stockpiling
        - Buildup of excess vaccine inventory
    2. How to maintain accurate records for vaccines

Vaccine Shipments
- Process for vaccine shipments
    - Standard operating procedures for vaccine shipments
    - Receiving and unpacking vaccine shipments
    - Policy and procedure to maintain vaccine cold chain during transport to:
        1. Off-site clinics
        2. Emergency storage locations
    - Process for shipping vaccines to:
        1. State health department
        2. Vaccine manufacturer

Preparation and Disposal
- Preparation for vaccine administration
    - Proper procedure for vaccine administration
        1. Ensure that cold chain is maintained
        2. Ensure that vaccine is not inappropriately exposed to light
- Disposal of vaccines and diluents
    - Importance of proper disposal of vaccines and diluents
    - Policies for disposition of vaccines
        1. Unopened vaccine vials
        2. Expired vials
        3. Unused doses
        4. Doses drawn but not administered
        5. Potentially compromised vaccines due to inappropriate storage 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.*

of vaccine failure and loss. Other activities such as distributing current fact sheets, conducting lunch and learn sessions, or using e-mail to update information can effectively support the program.

To ensure compliance with vaccine cold chain maintenance, the CDC (2008) has developed a vaccine toolkit that can be used as a training guide for vaccine personnel at the workplace. Based on the content of the toolkit, the Table details the essential elements to be covered in a typical vaccine cold chain training program. In any training program, the terminology and procedures should be fully explained and staff should have an opportunity to ask questions for clarification. Demonstrations or application of information, such as monitoring and recording temperatures and making adjustments, should be included. Educational sessions for vaccine personnel also provide an opportunity for them to discuss and clarify their roles in implementing the program and provide evidence of problems that have occurred and the corrective actions taken. The ultimate purpose of training is to avoid situations that can cause a vaccine cold chain failure, with emphasis on how to prevent repeated errors. It should be stressed that vaccine staff know that immediate action must be taken to correct inappropriate storage and handling conditions. Information about the vaccine cold chain program can also be shared with employees through such communications as newsletters, posters, or fact sheets so they have an understanding of vaccine safety and potency. In addition, employers must have basic knowledge about the requirements for an effective program and policies needed to manage the program, including developing and implementing a system for training and attendance, and how to handle problems should they arise.

Resources

The National Center for Immunization and Respiratory Disease (NCIRD) has developed numerous resources, including general vaccine storage and handling guidelines, multimedia training resources, and practice resources such as how to use and read thermometers, as training tools for personnel. The vaccine storage and handling toolkit has videos, challenge games, and written resources on vaccine cold chain management. The Immunization Action Coalition (IAC) has educational print materials such as vaccine administration and documentation fact sheets, handling and storage guidelines, and vaccine information statements for health care professionals. These resources are evidence-based practice tools that can be used as part of a vaccine training program in the workplace.

Common vaccine storage and handling errors (Sidebar) can be costly for the organization. Vaccine personnel need to be aware of frequent vaccine storage and handling errors and how to avoid them. Staff should have an opportunity to discuss why errors occur, what errors they have observed, and recommendations to reduce or eliminate errors.

Continuing Training

The CDC recommends continuing training for all vaccine personnel (CDC, 2008). An annual training and refresher course should be conducted by the primary vaccine coordinator (Rogers et al., 2010) to ensure all vaccine personnel are updated on best practices for vaccine storage and handling. Training should include current information regarding vaccine storage and handling practices from the CDC and the World Health Organization (WHO). Training logs should be used to evaluate vaccine personnel on work performance related to proper vaccine storage and handling practices (Rogers et al., 2009).

EFFICIENT MANAGEMENT

The WHO (2009) states that program planning and management is a main component of a well-functioning immunization program system. In vaccine cold chain, efficient management is essential to ensuring consistent oversight and control of vaccine stock and storage. Efficient management includes the elements of inventory management, equipment maintenance, access control considerations, power supply, and quality improvement activities.

Inventory Management

The CDC (2008) and the WHO (2002) provide guidelines for inventory management and recordkeeping systems. According to the CDC (2008), proper inventory management includes vaccine access, expiration dates, stock rotation, inventory accounting, stock calculations, and vaccine ordering. In addition, the reader is alerted that state and local health departments may have policies and additional requirements that need to be observed when developing an inventory management and recordkeeping system.

Vaccine access must be limited to authorized and trained personnel only. This will protect the vaccine supply from inappropriate handling and removal of vaccines by untrained personnel (CDC, 2008).

Vaccines and diluents must not be used after the expiration date printed on all boxes, vials, and pre-loaded syringes. The expiration date does not apply to vaccines that may have been compromised due to cold, heat, or light exposure; these vaccines should not be used. The CDC (2008) recommends attempting to use or transfer vaccine due to expire within 120 days. If this cannot be done, the vaccine supplier should be contacted because the supplier may take vaccine stock back for credit or may transfer the stock to another facility that can use the vaccine prior to expiration.

The treatment of expiration dates on opened multidose vials can vary (CDC, 2007b; WHO, 2002). However, the CDC does not recommend an adjusted expiration date unless otherwise stated by the manufacturer. If questions arise, guidance can be obtained from state or local health authorities.

Vaccines that require reconstitution may have specific rules for expiration after reconstitution that are provided by the vaccine manufacturer. For example, lyophilized varicella vaccine should be used within 30 minutes after reconstitution; measles, mumps, and rubella vaccine should be used within 8 hours after reconstitution; and

Common Vaccine Storage and Handling Errors

Designating only one person in the office to be responsible for storage and handling of vaccines, instead of a minimum of two.

There should be a back-up person familiar with all aspects of vaccine storage and handling who knows what to do in case of equipment failure.

Recording temperatures only once per day.

Twice daily recording is required to ensure proper temperatures are maintained, even if using a continuous graphing recording thermometer or a digital logger.

Recording temperatures for only the refrigerator or the freezer.

There should be twice daily recording of temperatures for both the refrigerator and the freezer with a National Institute of Standards and Technology-certified thermometer, especially if live and inactivated vaccines are stored in the storage equipment.

Documenting out-of-range temperatures on vaccine temperature logs but not taking action.

Immediate action should be taken to correct improper vaccine storage conditions to ensure protection and potency of the vaccines, in addition to detailed documentation of the event.

Discarding temperature logs at the end of every month.

The Centers for Disease Control and Prevention recommends maintaining an ongoing file of temperature logs and storing completed logs for 3 years.

Refrigerating vaccine in a manner that could jeopardize its quality.

Vaccines should be stored according to manufacturers' recommendations. Vaccines that require refrigeration should be stored in the middle of the refrigerator compartment, away from the walls, coils, floor, and cold air vent. Vaccines that require freezer storage should be stored in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.

Storing frozen vaccines in a dorm-style refrigerator.

Vaccines should be stored in a freezer with its own external doors separate from the refrigerator. Dorm-style refrigerators are inadequate.

Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.

Refrigerator and freezer doors must be closed and secured at all times to maintain appropriate storage conditions for vaccines. Only trained vaccine personnel should have access to vaccine supply.

Discarding multi-dose vials 30 days after they are opened.

Reconstituted multi-dose vials must be discarded within the defined time period as specified by the manufacturer. Almost all multi-dose vials contain a preservative and can be used until the expiration date, unless there are visible signs of vaccine contamination.

Not having emergency plans for a power outage or natural disaster.

An emergency plan for power outages and a natural disaster must be established for all vaccine personnel. The emergency plan should include an action plan on what to do in the event of equipment malfunction, power failure, natural disaster, and other emergency that may compromise appropriate vaccine storage conditions.

Storing food and drinks in the vaccine refrigerator.

There should be a designated vaccine storage unit. Storage of food and beverages in the vaccine refrigerator will result in frequent opening of the refrigerator and destabilization of the temperature.

Note. *Source: Immunization Action Coalition. (2008).* Don't be guilty of these errors in vaccine storage and handling. *Retrieved from www.immunize.org/catg.d/p3036.pdf.*

meningococcal polysaccharide vaccine should be used within 35 days. However, vaccine personnel should be aware of stricter standards imposed by state or local authorities.

The efficient stock rotation principle is meant to promote use, control waste, and contain costs. Efficient stock rotation follows the first expiration first out (FE-FO) principle (CDC, 2007b; WHO, 1998). Stock that is nearing

Instructions: At the end of each stock record page and at the end of each month, conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of the discrepancy cannot be discovered and corrected, make a note of this. Start a new stock record page by recording the physical count from the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines and weekly accounts of doses used.

Vaccine Type: PPV **Month and Year:** January 2008

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
01/2/08	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
01/9/08										1	1
01/16/08	LST	✔	Pneumovax 23	Merck	M	0395B	2/18/09	N/A	5	3	3
01/22/08										1	2
01/29/08										0	2
								Vaccine Totals	7	5	2 ††

* The initials of the person who unpacked and checked the vaccine and/or diluent upon arrival.

** ✔= vaccine arrived in good condition;
X = condition of vaccine questionable and state health department immunization program and vaccine manufacturer contacted. Document details/outcome on reverse side of Stock Record.

*** S = single-dose vial;
M = multidose vial;
Y = manufacturer-filled syringe.

† Includes number of doses administered, wasted, spoiled, expired, or transferred.

†† Enter the sum of 'Total Doses Received/Balance Forward' minus 'Total Doses Used'

Physical Stock Check (In Doses)	2
Difference ("Balance" minus "Physical Stock Check")	0
Balance Carried Forward (In Doses)	2

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

expiration should be kept in a designated area near the front of the storage area, be easily accessible, and not be on refrigerator door shelves or in vegetable bins. Opened multi-dose vials should be clearly labeled, dated, and identified.

The WHO (2002) also cautions vaccine management program personnel to be aware that diluents shipped with vaccines may have different expiration dates. For example, a vaccine might expire within a year after arrival, but its packaged diluent may have a 2-year life span. Thus, diluents should be maintained and monitored in the same manner as vaccines using the FE-FO principle. Inattention to the expiration dates of diluents may lead to failure by not using older diluents prior to expiration. Diluents do not require refrigeration, and may be stored on refrigerator door shelves or in vegetable bins. This practice also minimizes the risk of vaccines being inappropriately stored in refrigerated areas (i.e., doors) where temperatures can be unstable.

Inventory accounting monitors stock levels to ensure efficient use and ordering of vaccines. Proper stock levels should account for the expected number of vaccines to be administered, the amount of vaccine that can be stored safely, and the time interval from order to receipt of new shipments. A stock recordkeeping form should be used to streamline and standardize the monitored information (CDC, 2008), including information about the receipt of the vaccines, vaccine information, and a running inventory count. The receipt information should include the date received, integrity of the contents, initial temperature, and names of the individuals who unpacked and verified the vaccine cold chain integrity. The vaccine information should include vaccine manufacturer, lot numbers, and expiration dates of each batch. A sample stock record is shown in the Figure.

The occupational and environmental health nurse must recognize that similar vaccines might have differing lot numbers and expiration dates; each batch must be tracked separately. Inventory counts for each vaccine and diluent should be continuously maintained to monitor vaccine stock by accurately tracking vaccine acquisition and use. The CDC (2008) recommends validating the running count by cross-referencing the actual vaccine stock count against the recordkeeping form. This

should be completed every month and prior to ordering new stock. At the end of the year, the total stock usage should be evaluated to assist with determining projected annual usage. The CDC also suggests the use of tally sheets to track vaccine administration without adjusting the stock recordkeeping form for each individual dosage.

Efficient vaccine ordering and requisitioning is a complex topic that considers vaccine forecasting, frequency of ordering, storage space, and planning (WHO, 2009). Forecasting vaccine expected usage and ordering frequency is essential to ensuring adequate stock levels while minimizing overstocking and waste. A small health clinic may order vaccine quarterly, whereas a larger operation may order vaccine bimonthly (CDC, 2007a). Stock levels should correlate with the expected usage during that period. For example, if reorders occur every quarter, then 90 days of stock should remain on hand. Reordering should occur at least 30 days in advance of anticipated stock shortages (CDC, 2008). Limiting stock levels to operational needs will minimize waste in the event of vaccine cold chain failures. An example of an inappropriate procedure would be ordering stock for annual use when only 3 months of vaccine needs to be kept on hand. A vaccine cold chain failure could needlessly compromise a year's worth of vaccine inventory, whereas an efficient stock level would risk only 3 months of inventory. Excessive stock levels increase the chance of exceeding expiration dates and create a greater cost burden in the event of vaccine cold chain failures. The WHO forecasting and planning tools are excellent sources to review when considering stock level usage (WHO, 2009).

When planning for vaccine and diluent stock levels, stock levels should not exceed the on-hand storage space capacity of refrigeration systems. The physical volume of storage space required should be considered when ordering vaccines and diluents (WHO, 2002). For example, imagine ordering 500 doses of the H1N1 vaccine but having a refrigeration capacity for only 250 doses; or ordering 100 doses of tetanus vaccine from a new manufacturer and expecting multi-dose vials but receiving single-use syringes that occupy more space. The WHO (2009) vaccine logistics website has compiled storage space requirements for various vaccines and vaccine manufacturers that can also estimate the physical storage space prior to ordering.

Equipment Maintenance

Equipment maintenance ensures consistent and reliable functioning of refrigeration equipment to facilitate vaccine cold chain (CDC, 2008). Refrigerators, freezers, portable coolers, ice packs, and thermometers should be routinely inspected and cleaned. Policies and procedures for correcting and servicing defective equipment should also be accomplished in advance.

Routine inspection of equipment is intended to determine that equipment is working properly and identify or mitigate potential problems (CDC, 2008). Refrigerators and freezers should have doors that close fully and passively, are unobstructed, and have rubber seals that are intact, pliable, and secure. The CDC (2008) suggests holding a piece of paper below the door seal and lightly pulling. An adequate seal should hold the paper in place.

Ice buildup in freezers may impinge on closing the door fully and potentially affect temperature regulation. Many modern refrigerators rely on cold air from the freezer compartment to cool the refrigeration compartment. Ice buildup on or near the adjoining fan may adversely impact the temperature in the refrigerator compartment. Refrigerator coils should be vacuumed or lightly brushed weekly to ensure proper heat transfer and cooling ability. Frost-free freezers have drain pans that collect water during the defrost cycles. They should be cleaned at least monthly to minimize odors and the potential for mold growth. Routine refrigerator/freezer maintenance should also be performed to identify and correct problems such as out-of-range temperatures. Melting ice and leaking water might be an indication of a problem with temperature regulation. Refrigerators that are equipped with door ajar alarms should be tested monthly. Problems that cannot be reliably corrected should be referred for prompt servicing by authorized appliance technicians (CDC, 2008). A logbook should be used to record and track installation date, repair dates, and routine maintenance.

Refrigerators should be properly located so that they have adequate air clearance for heat transfer (i.e., at least 1 to 2 inches below the unit and 4 inches behind the coils) (WHO, 2002). Refrigeration equipment should not be placed in areas subject to wide temperature variations, such as near intermittent direct sunlight or near variable heating or cooling equipment. The ambient room temperature should not exceed 109°F or 42°C or vary outside stable temperature ranges (WHO, 2002).

Preventive maintenance and inspections of portable coolers should address serviceability and cleanliness. These coolers should be inspected and cleaned before and after each use. Cooler replacement is recommended when the seals or integrity of these units are compromised or questionable. Coolers should seal securely and ice packs should not leak.

Thermometer quality control involves inspection, proper placement, and preventive maintenance. Placement of the thermometer within the refrigeration compartment should be in the center of the unit, away from the walls, door, floor, ice, and fan. The thermometer should be easily visible to facilitate inspections and minimize the time the refrigeration unit is open during inspections. If needed, the thermometer can be suspended from the unit ceiling or elevated on a non-heat-conducting box to the center of the compartment. Consider immobilization of thermometers to ensure that staff members do not inadvertently relocate or dislodge them. Liquid column thermometers must remain bubble free or they will be inaccurate (CDC, 2008).

Access Control Considerations

Limited vaccine access ensures that vaccine and refrigeration equipment are accessed only by appropri-

ately trained individuals. Only the vaccine coordinators should adjust the temperature settings. Access to vaccine storage should be restricted by policy or physical means (i.e., door locks) to prevent inadvertent access by non-trained individuals such as repair, maintenance, janitorial, or clerical personnel. Locks can be placed directly on the refrigeration unit or on the door of the room where the refrigeration unit is located to limit access. Keys to these locks should not be available to unauthorized personnel.

Power Supply

The power supply for the vaccine refrigeration unit should be securely controlled to ensure a continuous and uninterrupted power source for effective temperature regulation (CDC, 2008). Power at the point of usage, power interruptions, and power supply must all be managed. At the point of usage, ground fault circuit interrupter outlets should not be used because they can be accidentally tripped off or shut off, resulting in a loss of power (CDC, 2008). Outlets controlled by wall switches should not be used to prevent accidental shut-off by personnel looking for a correct light switch. Circuit breakers should be clearly labeled "Do Not Turn Off" at the circuit panel. These circuit breaker labels should include instructions to contact the vaccine coordinator in the event of power interruption. Likewise, refrigerator plugs should be labeled "Do Not Unplug" (CDC, 2008). Safety outlets that cannot be easily unplugged are ideal. If available, outlets should have back-up generator service in the event of power outages. Non-typical refrigeration systems such as solar power and fossil fuels are recommended by the WHO (2002) if non-typical conditions exist.

Quality Improvement Activities

Evaluation of vaccine cold chain policies and procedures should improve the process and outcome of vaccine cold chain management. Efficient management is a process that improves and evolves over time so process improvement activities are accomplished. Two key opportunities for improvement are to analyze when vaccine cold chain failure occurs and when vaccines expire without use. Stock recordkeeping, rotation, and requisitions can be analyzed for potential explanations of vaccine and diluent expirations.

Vaccine cold chain failures could be the result of equipment failure, power supply interruption, or lack of policies and procedures. With such a wide variety of causes, a root cause analysis should be pursued. If the problem is due to equipment failure, then a cause might be improper care and maintenance of the refrigeration equipment, whereas the root cause might be lack of maintenance tracking or maintenance procedure implementation. An analysis of a power supply interruption could show that a maintenance worker decided to work on power outlets and turned off the power for the weekend. A root cause might be improper labeling at the circuit breaker. In both of these situations, proper training is essential.

Excess vaccine waste could be due to vaccine cold chain failures, expired vaccine, inefficient stock rotation, or inaccurate recordkeeping of vaccine stock levels. The CDC does not define what level of vaccine waste is excessive, but the WHO (2003) provides guidance on estimating and reducing vaccine waste. Consider an example of 1,000 expired doses of live-attenuated influenza vaccine (LAIV) resulting in a loss of more than $10,000. Was the FE-FO principle used? Was the recordkeeping tally incorrect? Was an excess of vaccine ordered by accident (i.e., expecting 200 single doses and instead receiving 200 multi-dose vials)? Were staff unfamiliar with a new formulation, not realizing that the LAIVs have a shorter shelf life? Were personnel untrained in vaccine cold chain requirements, leaving the shipment box in the mailroom over the weekend? Quality improvement systems should be implemented to minimize errors.

IMPACT OF EXCESSIVE COST TO EMPLOYERS FOR VACCINE LOSS

In the lean production environments of 2010 and forward, wasted vaccine can be the demise of an occupational health program within a company. Researchers report that the number of days lost to illness with influenza is between 2 and 6 per episode (Keech & Beardsworth, 2008). For an employee paid $10 per hour, a total of $160 to $480 per episode of paid sick leave would occur without considering lost production. If the employee is not compensated for days off due to illness, that loss of income is also significant for the worker's family. Job satisfaction and productivity are also known to increase when employers provide on-site vaccination (Olsen, Steinberg, & Ley, 2005).

If vaccine cold chain errors are discovered after employees are vaccinated, the costs grow. Workers are not protected against vaccine-preventable illnesses and confidence in the workplace vaccination process is lost. In addition, potential litigation risks may also increase, especially if an employee is harmed due to contamination of the vaccine by improper vaccine cold chain procedures (CDC, 2008).

IMPORTANCE OF THE OCCUPATIONAL AND ENVIRONMENTAL HEALTH NURSE'S ROLE IN MAINTENANCE OF VACCINE COLD CHAIN TECHNIQUES

In the occupational health setting, the occupational and environmental health nurse usually works independently and has many responsibilities. Advocating for employees and being responsive to employer needs can be challenging. However, studies have shown that workplace immunization programs can effectively protect 65% to 80% of the workers immunized (Nichol, 2003), saving loss-time costs and ultimately improving community health (Keech & Beardsworth, 2008). The National Business Group on Health (2009) estimates that one tetanus booster given every 10 years equals $143,138 per year of life saved in the United States.

Immunization programs in the workplace can pro-

IN SUMMARY

Vaccine Cold Chain

Part 2. Training Personnel and Program Management

Rogers, B., Dennison, K., Adepoju, N., Dowd, S., & Uedoi, K.

AAOHN Journal 2010; 58(9), 391-400.

1. A comprehensive training program about vaccine cold chain procedures is essential to secure effective vaccine.
2. Essential resources for effective vaccine training are provided by several sources (e.g., Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Disease).
3. Management procedures are needed to support quality, control costs, and provide safe, effective vaccine.

vide opportunities for many members of the community to be vaccinated. However, employers are sometimes concerned with providing at-work vaccinations. These concerns can be easily alleviated by the occupational and environmental health nurse in several ways: scheduling vaccination clinics at locations and times that minimize employee time away from production, offering efficient clinics free from vaccine cold chain violations, and educating the employer about the financial rewards (and increased worker satisfaction) of on-site vaccination clinics (Keech & Beardsworth, 2008).

Workers who travel internationally require many more immunizations than do domestic workers. In the occupational health clinic, the greater the number of vaccines and the more complex the vaccination regimen, the greater the risk of error (CDC, 2000). A well-documented, organized, and strict routine for immunizations lessens the risk of violation to cold chain and other errors (CDC, 2000). The convenience of receiving vaccinations at the worksite also increases compliance with required vaccinations for travel.

The occupational and environmental health nurse plays a significant role in educating employees and employers about vaccine-preventable disease risks, increasing vaccination rates, and decreasing costs. Providing information to workers can also lead to family members being vaccinated.

CONCLUSION

Employers and workers 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.

As the primary vaccine coordinator, the occupational and environmental health nurse is directly responsible for training all personnel regarding proper cold chain procedures, accurate recordkeeping, and the integrity of the vaccines given. Seasonal influenza kills nearly 40,000 individuals in the United States each year (CDC, 2009); pandemic preparedness at the workplace could significantly reduce the number of lives lost or determine if illness occurs at all.

The loss due to vaccine cold chain violations in occupational health clinics could be catastrophic, as limited 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. An effective vaccination program, on the other hand, is another tool for the occupational and environmental health nurse in preventing disease and improving worker productivity.

REFERENCES

Centers for Disease Control and Prevention. (2000). *Adult immunization programs in nontraditional settings: Quality standards and guidance for program evaluation.* Retrieved from www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a1.htm

Centers for Disease Control and Prevention. (2007a). *Vaccines and immunizations: Immunization program operations manual.* Retrieved from www.cdc.gov/vaccines/vac-gen/policies/ipom/default.htm

Centers for Disease Control and Prevention. (2007b). *Vaccine management: Recommendations for storage and handling of selected biologicals.* Retrieved from www.cdc.gov/vaccines/pubs/downloads/bk-vac-mgt.pdf

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

Centers for Disease Control and Prevention. (2009). *Seasonal influenza (flu): Questions and answers regarding estimating deaths from seasonal influenza in the United States* [Fact sheet]. Retrieved from www.cdc.gov/flu/about/disease/us_flu-related_deaths.htm

Immunization Action Coalition. (2008). *Don't be guilty of these errors in vaccine storage and handling.* Retrieved from www.immunize.org/catg.d/p3036.pdf

Keech, M., & Beardsworth, P. (2008). The impact of influenza on working days lost: A review of the literature. *Pharmacoeconomics, 26,* 911-924.

National Business Group on Health. (2009). *Tetanus (immunization): Evidence statement.* Retrieved from www.businessgrouphealth.org/preventive/topics/tetanus.cfm

Nichol, K. L. (2003). *The efficacy, effectiveness and cost-effectiveness of inactivated influenza virus vaccines.* Retrieved from http://download.thelancet.com/flatcontentassets/H1N1-flu/vaccination/vaccination-22.pdf

Olsen, G. W., Steinberg, M. E., & Ley, C. A. (2005). Worksite influenza immunization programs: Insight into the implementation and cost-benefit. *AAOHN Journal, 53*(3), 105-110.

Rogers, B., Dennison, K., Adepoju, N., Dowd, S., & Uedoi, K. (2010). Vaccine cold chain: Part 1. Proper handling and storage of vaccine. *AAOHN Journal, 58*(8), 337-344.

Rogers, B., Meyer, D., Summey, C., Scheessele, D., Atwell, T., Ostendorf, J., et al. (2009). What makes a successful hearing conservation

program? *AAOHN Journal, 57*(8), 321-336.
World Health Organization. (1998). *Safe vaccine handling, cold chain and immunizations: A manual for the newly independent states* [Fact sheet]. Retrieved from www.who.int/vaccines-documents/DocsPDF/www9825.pdf
World Health Organization. (2002). *Guideline for establishing or improving primary and intermediate vaccine stores* [Fact sheet]. Retrieved from www.who.int/vaccines-documents/DocsPDF02/www715.pdf
World Health Organization. (2003). *Monitoring vaccine wastage at country level: Guidelines for programme managers.* Retrieved from http://whqlibdoc.who.int/hq/2003/WHO_V&B_03.18.pdf
World Health Organization. (2009). *Immunization service delivery and accelerated disease control: Vaccine management and logistics.* Retrieved from www.who.int/immunization_delivery/systems_policy/logistics/en/index5.html