Vaccine Storage In The Physician's Office: A Community Study

Erika Woodyard, MD, Lance Woodyard, and William A. Alto, MD

Background: **A survey was conducted of 26 physician offices and the County Health Department to determine the quality of vaccine storage.**

Methods: **All refrigerators were examined for secure electrical supply, firmly shut door, storage of inappropriate items, and expired vaccines. A maximum-minimum thermometer was then placed in the middle of the storage area for 24 hours, and temperatures were recorded.**

Results: **Of the 27 sites, only two had refrigerator temperatures in which both maximum and minimum temperatures fell within the acceptable range of 2° to 8°C. Sixty-three percent fell below minimum, 59 percent were above maximum, and 93 percent fell either below or above or both. Eight of the offices had a designated cold chain monitor, but there was no correlation with appropriate monitoring and storage of vaccines. Nine of the offices had permanent thermometers, but no correlation could be found between these sites and appropriate storage temperatures.**

Conclusions: **A majority of vaccines in the community have been exposed to conditions that could reduce or destroy their potency. Physicians must educate their personnel in proper storage techniques of vaccines to ensure the potency of these vaccines. (J Am Board Fam Pract 1995; 8:91-4.)**

During the last decade there has been an increased emphasis by health providers on improving the delivery of vaccinations to infants, children, and teenagers. In the next decade, millions of dollars will be spent on increasing immunization coverage as the country moves toward the disease-prevention goals presented in *Healthy People 2000*.[1] Some of this energy should be directed toward preserving the cold chain, as vaccinations might not be effective if the process of their delivery and storage at clinics is compromised.[2] Recent research from general practices in Great Britain and the national cold chain system in Hungary reveals multiple weak spots in the cold chain of vaccine storage, including limited awareness of codes, improper storage conditions, and storage of outdated vaccines.[3-5] A concern has arisen that these weak links in the cold chain are present in the United States as well despite the recent heightened awareness of proper vaccine storage.[6,7] Are our immunization clinics and private physician's offices monitoring for breaks in the cold chain? Do we delegate this care to a designated cold chain monitor? Are temperature guidelines known and followed? Are monitors aware that freezing or heat can adversely affect a given vaccine?

Vaccines have recommended storage temperature guidelines, and failure to ensure an optimal temperature could expose them to a possible decrease or loss of potency. Vaccine manufacturers will assist physicians in clinical decision making regarding the potency of vaccines stored under nonideal temperatures. In general, all vaccines, except oral polio and unreconstituted measles, mumps, and rubella (MMR), cannot be frozen without damage. All vaccines except polio are stable for several days at room temperature.[2]

The specific freezing points of vaccines are not readily available. Manufacturers recommend against storage at less than 2°C and advise discarding any vaccine that was stored at less than 0°C. Oral polio virus vaccine should be stored at less than 0°C, but it may be thawed and refrozen several times under specific conditions. Physicians are urged to contact the manufacturers for more details. Current recommendations are that diphtheria, tetanus toxoid, pertussis, measles, mumps, rubella, and *Hemophilus influenza* vaccines be stored between 2° and 8°C.[2] To ensure that this temperature is maintained, 1 person in the office should be a designated cold chain monitor and

Submitted, revised, 18 October 1994.

From the St. Mary's Family Practice Residency, Grand Junction, Colorado (EW, LW, WAA). Address reprint requests to William Alto, MD, Maine Dartmouth Family Practice Residency, PO Box 341, Fairfield, ME 04937-0341.

Lederle-Praxis Biologicals provided maximum-minimum thermometers.

properly educated concerning vaccine storage.[8,9] This person should check and record daily maximum and minimum storage temperatures, guard against inappropriate uses of the refrigerator, and monitor the expiration dates of vaccines.

This study was undertaken to determine the quality of vaccine storage in family practice and pediatric offices and at the County Health Department in one community. The results provide a base line for future interventions to improve the cold chain.

Methods

A list of community physician offices was obtained from the telephone directory to include all primary care physicians in the Grand Valley of Colorado. A total of 28 offices were participating in childhood immunization programs. A physician at each office was contacted and a request was made to administer a questionnaire to the person in charge of the care of vaccines and to monitor the storage temperature of the vaccine refrigerator for a 24-hour period. Of the 28 offices contacted, only one declined to participate.

An investigator then scheduled a day to visit the office. The person who took care of vaccine storage (cold chain monitor, nurse, medical office assistant) was administered a brief verbal questionnaire. Included were questions concerning possible designation of an office cold chain monitor, inventory techniques of incoming vaccines as well as vaccines on site, and what the office considered to be an ideal storage temperature. The vaccine storage refrigerator and its contents were examined. A maximum-minimum thermometer probe was placed as close as possible to the center of the refrigerator and monitored until it read between 2° to 8°C. The probe remained for at least 24 hours after which the investigator returned to the office site and maximum and minimum temperatures were recorded. Two identical thermometers were used to facilitate data collection. They were checked for accuracy by calibration from −10° to 20°C using a standard laboratory thermometer as reference. Accuracy was ±1°C. There was no known power outage during this study. Temperatures were recorded during weekdays so that the refrigerator was actively in use. Freezer temperature for storage of the oral polio virus vaccine was not monitored. One office did not have a freezer; it also did not store oral polio virus.

Results

Eight of 27 offices (30 percent) had a designated cold chain monitor. Nine of 27 offices (33 percent) had a refrigerator thermometer. Two thermometers were never read, six were read daily, and one was read weekly. Of the eight offices with a designated monitor, seven offices had a refrigerator thermometer, and temperatures were monitored on a daily or weekly basis.

Respondents in 13 offices said that 2° to 8°C is the ideal storage temperature for most childhood vaccines. Fourteen responded either incorrectly or did not know. All respondents knew that heat can harm vaccine potency; 5 answered "false" to the statement, "Freezing can harm certain vaccines." ("True" is the correct answer.)

Twenty-six refrigerators contained items other than vaccines, including food in 11 and blood products in 6.

Six refrigerators had automatic defrost features. The remainder were defrosted by office personnel every month to every 4 years. Two offices reported defrosting when the temperature became unstable, and both of these offices had refrigerator temperatures that exceeded the acceptable range.

Seventeen percent of the refrigerators had a permanent electrical hookup, ensuring against accidental disconnection and compromise of the cold chain. All refrigerator doors were found to shut firmly; however, one door was ajar at the onset of the inspection.

One person stated that the office had a written protocol should the refrigerator temperature exceed the specified range. Although all of the monitors reported that they discarded vaccine vials not used within the manufacturer's recommended time, 10 offices had refrigerators that contained expired vaccines, including several vaccines that were more than 1 year out of date and in one instance more than 2 years out of date.

Of the 27 sites, only two were found to have refrigerator temperatures in which both maximum and minimum temperatures fell within the acceptable range of 2° to 8°C (Figure 1). Neither of these offices had a cold chain monitor. Sixty-three percent of office refrigerators had temperatures that fell below the minimum, and 50 percent were higher than the maximum; 93 percent registered either above or below or both. Twenty-six percent fell below 0°C, severely compromising the po-

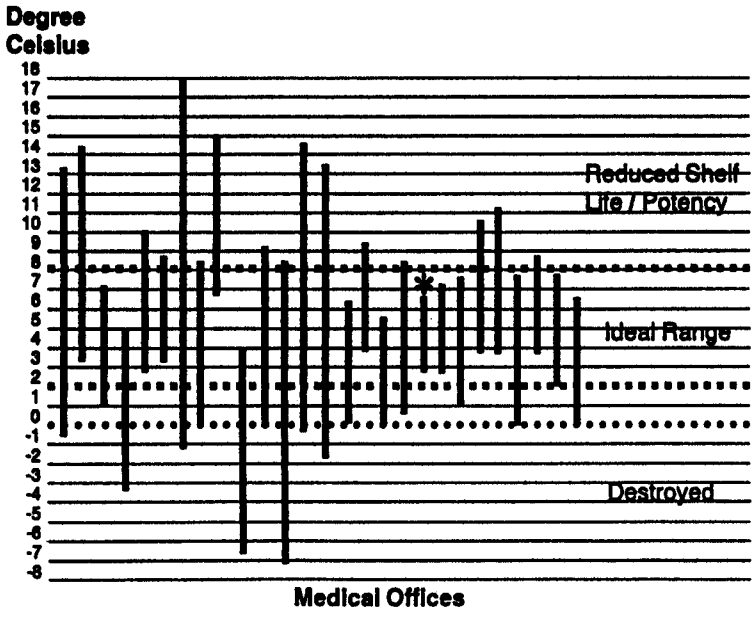

Figure 1. Vaccine storage temperature ranges at 27 medical offices.
***Almost all vaccines were out of date.**

tency of the vaccine. Eight of the offices had a designated cold chain monitor, but no correlation (r=0) could be found between these sites and appropriate monitoring and storage of vaccines. Nine of the offices had permanent thermometers, but there was no correlation (r=0) between these sites and appropriate storage temperatures of vaccines.

Discussion

The results of this study show that vaccine storage in our community was inadequate, and cold chain monitors were not monitoring effectively. The primary care physicians and their staff in this community were in need of education in the preservation of the cold chain of vaccines. By following some very general guidelines, vaccines could be subjected to less frequent or extreme temperature variation. Table 1 is suitable for posting near the vaccine refrigerator.

One person in each office should be assigned the duties of the cold chain monitor.[7,8] That person would learn requirements of vaccine storage and regularly inspect incoming and stored vaccines for expiration dates. Each office should obtain two maximum-minimum thermometers for each vaccine refrigerator in the office: one for the freezer compartment and the other placed as closely as possible to the center of the refrigerated storage area. The cold chain monitor should examine and log refrigerator temperatures daily to assess any possible breaks in the required temperature range. Vaccines that have been inappropriately frozen must be discarded. A cold chain monitor could ensure that the refrigerator is used properly. Storage of any items other than vaccines should be limited. The more the refrigerator door is opened and closed, the more likely there will be wide fluctuations in temperature quite possibly exceeding the acceptable range. The refrigerator should also be monitored on a timely basis for defrosting and for the condition of the door seals. A permanent electrical hookup is necessary to avoid inadvertent disconnection.

This study monitored vaccines only from the time of arrival at the physician's office to the time of administration to the patient. In our community vaccines are shipped without temperature indicators and could well have been damaged before reaching the physician's office.[10,11] This important issue requires further study. Although the physician might have less direct control over what happens to vaccines before arrival at the office, there are numerous ways to monitor storage of vaccines on site to ensure that the extensive amount of time and money spent in promoting a healthy

Table 1. Rules for Care of Vaccines.

1. Designate a cold chain monitor and an alternate person to assume responsibility when the monitor is away.
2. Place a maximum-minimum thermometer as close as possible to the center of refrigerator and freezer storage areas.
3. Check refrigerator and freezer temperatures daily and record them on a graph. The correct temperatures are 2–8°C in the refrigerator and <0°C in the freezer.
4. Keep the freezer free of excessive ice buildup. Check weekly. Store vaccines properly when defrosting freezer.
5. Check all vaccines on arrival for evidence of heat damage or freezing. Ask the supplier to include a temperature indicator within the shipment packing.
6. Monitor vaccine expiration dates monthly. Expired or damaged vaccines should be discarded.
7. Do not use the refrigerator for storage of items other than vaccines and medications.
8. Provide the refrigerator with a permanent electrical hookup.
9. Close the refrigerator door promptly.

childhood through timely vaccination schedules is worthwhile and efficacious. Although this study was small, the results could apply to other locations. A state or regional cold chain study would help to determine whether improper vaccine storage is a concern and whether children remain at risk for immunization-preventable diseases.

We thank the pediatricians and family physicians in Grand Junction and vicinity who participated in this study.

References

1. US Public Health Service. Healthy people 2000: national health promotion and disease prevention objectives. Washington, DC: US Government Printing Office, 1990. DHHS publication PHS 91-50212.
2. WHO news and activities. Stability of vaccines. Bull World Health Organ 1990; 68:118-20.
3. Thakker Y, Woods S. Storage of vaccines in the community: weak link in the cold chain? BMJ 1992; 304:756-8.
4. Haworth EA, Booy R, Stirzaker L, Wilkes S, Battersby A. Is the cold chain for vaccines maintained in general practice? BMJ 1993; 307:242-4.
5. Expanded programme on immunization. Cold chain evaluation. Wkly Epidemiol Rec 1990; 65:181-4.
6. Casto DT, Brunell PA. Safe handling of vaccines. Pediatrics 1991; 87:108-12.
7. Bishai DM, Bhatt S, Miller LT, Hayden GF. Vaccine storage practices in pediatric offices. Pediatrics 1992; 89:193-6.
8. Lugosi L, Battersby A. First European study using cold chain monitors. World Health Forum 1990; 11:200-1.
9. *Idem*. Transport and storage of vaccines in Hungary: the first cold chain monitor study in Europe. Bull World Health Organ 1990; 68:431-9.
10. Cheyne J. Vaccine delivery management. Rev Infect Dis 1989; 11:S617-22.
11. Briggs H, Ilett S. Weak link in vaccine cold chain. BMJ 1993; 306:557-8.