



ASSOCIATION OF IMMUNIZATION MANAGERS

AIM Statement on Vaccine Storage and Management

Introduction:

The effectiveness of vaccines depends on proper storage and handling. If vaccines are not stored properly, they may lose potency and no longer protect people from vaccine preventable diseases.

Background:

Policies and practices guiding vaccine storage and handling are at a critical juncture. The Health and Human Services Office of Inspector General (OIG) released the report, Vaccines for Children: Vulnerabilities in Vaccine Management in June 2012. The report highlights problems with the storage and handling of vaccines. The findings emphasize the urgency of addressing vaccine storage and handling practices. We must reconsider current approaches to deciding whether or not to use vaccines after exposure to out of range temperatures. Best practices for vaccine storage and handling must include guidance about using new technologies for temperature monitoring and vaccine storage. Recommendations must include clear guidance about optimal storage equipment for vaccines.

Standard primary prevention measures reduce the costs and the risks that may result from improper storage conditions. The first step is investing in equipment that reliably monitors and maintains the right temperature throughout a storage unit. Properly used monitoring and alarm devices can alert providers to a problem before the vaccine is lost. These systems, when used by well-trained staff, minimize vaccine losses and the financial burden of replacing vaccine and revaccinating patients. Ultimately, best practice standards, coupled with reliable equipment for storing and monitoring vaccines assure health care providers and patients that vaccines will protect them effectively.

Statement:

The Association of Immunization Managers (AIM) offers this position statement on vaccine storage and handling to characterize our position on a range of policy issues about the proper storage, handling and management of vaccines.

The state and territorial health agencies funded by CDC that oversee immunization programs for their areas (known as “grantees”), the federal Vaccines for Children (VFC) Program and all immunization providers need clear, easily understood and standardized best practice guidelines and recommendations for vaccine storage and handling. The guidance must be succinct, readily understood and usable by all levels of clinic staff. All grantees should be able to implement the guidelines. The critical areas of focus identified by AIM, and AIM’s position are included in the following pages.

Temperature Monitoring

- **Temperature monitoring** - Providers should use continuous recording electronic temperature monitoring equipment programmed to log temperatures at appropriate intervals to ensure damaging temperature changes are detected.
- **Specifications for monitoring and alarm systems** - Grantees and providers need easily understood, standardized best practice guidance on the specifications for temperature monitoring and the use of alarm systems. Guidance should be designed to capture critical problems in time to prevent vaccine waste while minimizing false alarms.
- **Temperature monitoring equipment** -The probes in temperature monitoring equipment should be set in glycol, glass beads or other appropriate buffer against recording frequent air temperature changes. Ideally thermometers should have digital displays, be programmable for acceptable ranges and signal if temperatures go out of range.
- **Management of inconsequential out of range temperatures** - The guidance should include how to recognize and manage routine temperature fluctuations detected by continuous monitoring.
- **Management of out of range temperatures** - The guidance should recommend equipment and temperature monitoring specifications that minimize the risk of freeze damage.
- **Frequencies for recording temperatures** - We need scientific studies to learn the ideal frequency of capturing storage unit temperatures with continuous monitoring devices. The studies should include different storage conditions (e.g., real practice conditions in addition to controlled laboratory studies). The studies should include different types of thermometers, probes and storage units. The studies should be designed to inform guidance for providers to optimize their ability to capture critical problems in time to prevent vaccine waste while minimizing false alarms from routine changes (such as the defrost cycle).
- **Verifying the Accuracy of Thermometers** - Grantees should have clearly defined options for confirming thermometer accuracy. The guidance should include how to validate accuracy with a reference thermometer, how frequently validation should be done, standards for

confirming the accuracy of thermometers that do not need re-calibration and standards for thermometers that do need re-calibration.

- **Future Temperature Monitoring Devices** - Every vaccine vial shipped and stored in the United States should include a visual indicator that will signal when a vaccine has been too warm or too cold for long enough that it should not be used.

Practice Guidelines and Policy Formation

- **Development of Practice Guidelines:** Grantees and providers need easily understood protocols and guidance on the specifications and use of monitoring and alarm devices.
- **Formation of a best practice standards workgroup:** AIM recommends the formation of subject matter expert workgroups to develop the protocols and best practice recommendations called for in this paper. The standards of practice would not be required, but individual immunization programs could choose to implement additional or different strategies based on their own unique requirements and needs.

The Modeling of Immunization Registry Operations (MIROW) Workgroup provides a model for the workgroups.

- **Members:** The workgroup should include subject matter experts from grantees, CDC, vaccine manufacturers, national organizations and others.
- **Initial topics:** Follow up on equipment specifications developed by the CDC's International Vaccine Thermostability Working Group, use of continuously recording monitoring devices and frequency of temperature monitoring.
- **Support:** The CDC should fund and support AIM-coordinated best practice standards workgroups in the same fashion as the MIROW Workgroups.
- **Implementation of best practices:** AIM would work with the CDC to develop and make the standards available. AIM would promote the standards and Grantees would incorporate the standards in their overall strategy for assuring vaccine security.
- **Updating recommendations** – The AIM-coordinated best practice standards work groups, in partnership with CDC, would update the guidance when research studies provide new information about improving practices for vaccine storage and handling.

Vaccine Storage Equipment

- **Vaccine Storage Equipment** - Vaccine storage units should use continuous temperature monitoring tools and equipped with alarms. The units should be stand-alone refrigerators and stand-alone freezers. Grantees should use a staged approach for implementing new requirements to allow adequate time and absorb the associated costs.
- **Dormitory-style refrigerators** – Providers should never use dormitory-style refrigerators for vaccine storage.

- **Costs for VFC providers** – Investing in new equipment is costly. Providers may need ways of defraying these costs to stay in the VFC Program, and assure vaccine access for VFC eligible children. CDC, AIM and other partners should explore permanently increasing the allowed vaccine administration fee, tax credits and incentive programs.
- **Uniformity for responding to non-compliance** – CDC should work with AIM and develop standardized protocols for following up with providers who are out of compliance with the storage and handling requirements. While standards are needed, flexibility also is necessary to allow grantees to address unique situations.
- **Training** – All personnel who handle, administer, or monitor vaccines, or manage vaccine storage and handling, must complete a standard training program developed or endorsed by CDC. AIM recommends the following training requirements:
 - **Clinic staff:** Initial training on vaccine storage and handling and routine refresher training each year. Staff also should be trained when providers stock new vaccines and when storage and handling guidelines change. Documentation should be required: continuing education credits and certificates of completion should be available.
 - **Certification requirements:** Require that certificates of completion for the approved online vaccine storage and handling course be provided by two or more vaccine contact staff annually as part of provider re-enrollment. Consider more extensive training and certification requirements for new VFC Program enrollees.
 - **Site Visit Reviewers:** Require annual certification for all staff conducting VFC site visits.

Temperature Excursions

- **Temperature Excursion Information from Vaccine Manufacturers:** Manufacturers should provide clear, consistent, written guidance about temperature stability and using vaccines exposed to out-of-range temperatures.
- **Incorporation of complete storage guidance:** Manufacturers should include significantly expanded stability data in package inserts and shipping information.
- **Updating of product information:** Manufacturers should update product information with new information about allowable storage temperatures when they have data to support expanded allowable temperatures. They should pay special attention to allowances for warmer temperatures. This would allow providers to set vaccine storage unit temperatures at higher average temperatures, providing a greater safety margin to prevent damaging freezing events.
- **Stability data** - The Food and Drug Administration (FDA) should require manufacturers to provide a wider range of temperature stability data as part of the licensure process for new

vaccines. The CDC and FDA should lead efforts to address the legal and regulatory barriers to this.

- **Vaccine Transport** – CDC should provide practical, clear guidance for transporting vaccine without damaging it. Providers may need to transport vaccine during emergencies, power outages, or to ensure short-dated vaccine is used before expiration.

CDC policy

- **Implementing Changes** – CDC should work with AIM as policies are developed. CDC should involve grantees early in the process, as described above, and allow enough lead-time for communicating and implementing new policies. Time must be allowed to mitigate budgetary impacts of changes. New policies and recommendations should be implemented based on the availability of funding, and any new requirements to the VFC program should be accompanied by appropriate VFC funding.
- **Restitution and Replacement Policies** – CDC should work with AIM to standardize the implementation of grantee VFC vaccine restitution policies for negligent providers. The standard should include templates, clear definitions and guidance for reimbursement or replacement of negligently wasted vaccine. The guidelines should be fair, focusing on vaccine loss due to negligence and corrective action. The guidelines should provide positive reinforcement of providers who respond properly to storage failures and prevent negligence.

Approved by AIM Vaccine Storage and Handling Work Group, October 10, 2012

Approved by AIM Executive Committee, November 8, 2012

Approved by AIM General Membership, November 27, 2012