ASSOCIATION OF IMMUNIZATION MANAGERS

AIM Statement on Vaccine Storage and Management

Voted on by AIM Executive Committee

Introduction:

The effectiveness of vaccines depends on proper storage and handling from manufacture to administration. If vaccines are not stored properly, they may lose potency or become inactivated, and will not provide expected protection from vaccine preventable diseases.

Background:

The Health and Human Services Office of Inspector General (OIG) released the report, Vaccines for Children: Vulnerabilities in Vaccine Management in June 2012 highlighting problems with the storage and handling of vaccines in provider offices. Since 2012, CDC has changed many program requirements and recommendations for the proper storage and handling of vaccines. Among other things, the new requirements and recommendations included guidance on acceptable continuous temperature monitoring devices, availability of calibrated back-up thermometers, features of storage units, definitions of temperature excursions, and training requirements for provider office staff to increase uniformity for responding to storage problems.

Investments in proper vaccine storage, handling and inventory management reduce the costs and risks that result from improper storage conditions. This includes investing in equipment that reliably monitors and maintains the right temperature throughout a storage unit and implementation of temperature monitoring and alarm devices that can alert providers to a problem before the vaccine is compromised. These systems, when used by well-trained staff, minimize vaccine losses and the financial burden of replacing vaccine and revaccinating patients. Ultimately, clear and thorough guidance, coupled with reliable equipment for storing and monitoring vaccines assures 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 “awardees”), 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 based upon science and realistic expectations of clinical practice: it should be succinct, readily understood and usable by all levels of clinic staff. All awardees should be able to implement the guidelines and share resources with healthcare providers, as needed. The critical areas of focus identified by AIM, and AIM’s position are included in the following pages.

Temperature Monitoring

• **Establishment of manufacturing standards for vaccine continuous temperature monitoring devices**: Awardees and providers would benefit from standardized specifications for continuous temperature monitoring devices appropriate for use with vaccines, including standardized device features, software (if needed) and standardized output formats capable of being uploaded to Immunization Information Systems (IIS). Products that meet these standards should be readily identifiable by immunization providers and awardees purchasing vaccine monitoring equipment. NSF-International (NSF-I) is a standards-making body already establishing vaccine storage equipment manufacturing standards. NSF-I is well-positioned to establish standards for vaccine temperature monitoring devices and should be asked to do so. Once standards exist, continuous temperature monitoring device manufacturers will be able to seek and obtain NSF-I labeling that immunization providers can look for and trust when making purchases.

• **Temperature monitoring**: Providers should use continuous recording electronic temperature monitoring equipment (digital data loggers) programmed to log temperatures at appropriate intervals to ensure damaging temperature changes are detected while "noise" from insignificant variations is minimized.

• **Specifications for monitoring and alarm systems**: Awardees 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**: If avoidance of air temperature monitoring is desired, guidance should include specifications on the volume and types of appropriate physical or digital buffers to air temperature fluctuations. If air temperatures are measured, alarm parameters should be designed to account for brief air fluctuations and to alarm in ways consistent with buffered temperature monitor probes. Ideally, temperature monitoring equipment should have digital displays, be programmable for acceptable ranges and signal an alarm indication if temperatures go out of range.

• **Use of built-in temperature monitoring systems in storage units**: Awardees and providers need specific scientific guidance on the appropriate use of and calibration of built in temperature monitoring systems within storage units. For example, when and why is an external digital data logger recommended or required in addition to such systems.

• **Management of inconsequential out of range temperatures**: Guidance should include how to recognize and manage routine insignificant temperature fluctuations detected by sensitive continuous monitoring devices. This is necessary to minimize unnecessary work by providers and awardees to follow-up trivial temperature excursions and to avoid suspending clinic immunization services when trivial fluctuations in temperature are detected as a part of normal operations, such as when conducting a physical inventory.

• **Management of out of range temperatures**: Guidance should recommend equipment and temperature monitoring specifications that minimize the risk of freeze damage or unintentional warming. Guidance should be evidence-based, clear and complete for managing vaccine once it has

been exposed to out of range temperatures. Manufacturers provide guidance on the viability of vaccine exposed to out of range temperatures. Evidence based guidance should be available to awardees and providers about when to consider revaccination of patients to whom exposed vaccines have been administered, recognizing that there may be different parameters for not continuing to use a vaccine and for repeating a dose in a patient.

• **Frequencies for recording temperatures with continuous monitoring devices**: The National Institute of Standards and Technology (NIST) can evaluate the ideal temperature recording frequency for continuous monitoring devices. Guidance to awardees and providers should include the ideal frequency of capturing storage unit temperatures with continuous monitoring devices. Guidance should address different types of thermometers, probes and storage units and allow for providers to capture critical problems in time to prevent vaccine waste while minimizing the burden of false alarms from routine changes (such as the freezer defrost cycle).

• **Future Temperature Monitoring Devices**: AIM recognizes that vaccine storage monitoring and training is carefully supervised and enforced only in the federal Vaccines for Children (VFC) Program and not in practices that vaccinate children and adults outside of VFC. Because every person deserves to receive vaccine that has been appropriately stored up till the moment of use, every vaccine vial or unit of packaging shipped and stored in the United States should include a digital or chemical visual indicator that will signal when a vaccine has been too warm or too cold for long enough that it should not be used in a patient. Future digital temperature monitoring devices should include user-friendly options for displaying data, including graphs, to visualize temperature trends over time.

Practice Guidelines and Policy Formation

• **Development of Practice Guidelines**: Awardees and providers need practical, easily understood protocols and guidance on the specifications and use of monitoring and alarm devices. Once NSF-I manufacturing standards are in effect for vaccine storage equipment, awardees and providers should be encouraged to use NSF-I certified vaccine storage equipment.

• **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, including the use of NSF-I committees for equipment manufacturing standards where appropriate. 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 workgroups related to development and implementation of recommendations.

- **Members:** Workgroups should include subject matter experts from awardees, CDC, vaccine and equipment manufacturers, national professional organizations representing immunization providers and others.

- **Topics:** Make recommendations for awardee and provider implementation of NSF-I vaccine storage equipment manufacturing guidelines, once established. Champion establishment of

NSF-I standards for vaccine monitoring and alarm equipment. Prioritize areas in need of clearer policy related to temperature excursions, vaccine transport, and revaccination (for example). Establish desirable future developments in vaccine storage to further simplify and improve the quality and consistency of the vaccine cold chain.

O **Support:** The CDC should fund and support AIM-coordinated best practice standards workgroups in the same fashion as the MIROW Workgroups.

O **Implementation of best practices**: AIM would work with the CDC to develop and make their standards and NSF-I standards available. AIM would promote the standards and awardees would incorporate the standards in their overall strategy for assuring vaccine security.

O **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 comply with NSF-I manufacturing standards, once established. Properly calibrated, external continuous temperature monitoring tools and alarms are recommended. The units should be stand-alone refrigerators and stand-alone freezers or combination units purpose-built for vaccine storage and in compliance with NSF-I standards. Awardees should use a staged approach for implementing new requirements to allow adequate time and absorb the associated costs.

• **Dormitory-style refrigerators**: Since the 2012 edition of this statement, CDC has changed the requirements for refrigerators so that providers are never allowed use dormitory-style refrigerators for vaccine storage. This should continue.

• **Costs for VFC providers**: Investing in new equipment is costly to immunization providers, but taxpayers will reap savings through reduced waste of federal vaccines. Many providers 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 paid by Medicaid, 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 awardees to address unique situations.

• **Warranties for Storage Equipment**: Warranties are recommended to help providers in situations where vaccine waste or loss occurs; keep in mind that vaccine loss for a VFC Provider will likely include private-stock vaccine. Best practice standards groups should address improved manufacturer warranties for storage equipment and monitoring devices, as well. Warranties and insurance are options providers should consider to protect themselves from financial harm as a result of storage unit failures.

• **Length of calibration certification of temperature monitoring devices**: There is a need for improvement in the process of maintaining proof of accurate calibration of temperature monitoring equipment. NSF-I may be the appropriate group to bring together manufacturers, NIST, CDC and other stakeholders for developing more practical and cost-effective standards for maintenance of calibration of temperature monitoring devices.

• **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, such as "You Call The Shots". AIM recommends the following training requirements:

O **Clinic staff**: Initial training on vaccine storage and handling and routine annual refresher training each year. Staff also should be trained when providers stock new vaccines with different requirements and when storage and handling guidelines change. Documentation should be required: continuing education credits and certificates of completion should be available to participants to encourage them and to document completion. CDC and professional organizations should encourage adoption of these standards by all immunization providers through CME or other professional incentives, such training should not be limited to VFC Program participants.

O **Temperature Monitoring Training:** Staff who have been assigned to check and assess temperatures should have standardized training that includes a record of completion on how to use temperature monitoring devices, acceptable temperature ranges for vaccine and should know proper procedures to follow if out of range temperatures are identified. There should be a Celsius standard for temperature monitoring, since rounding of temperature conversions to Fahrenheit results in a narrower range of acceptable temperatures on the Fahrenheit scale.

O **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.

O **Site Visit Reviewers:** Require annual certification for all staff conducting VFC compliance visits.

<u>Temperature Excursions</u>

•**Temperature Excursion Guidance from Vaccine Manufacturers**: Manufacturers should provide clear, consistent, written guidance about temperature stability and using vaccines exposed to out-of-range temperatures.

•**Temperature Excursion Guidance from CDC**: The CDC should provide written, evidence-based general guidance on action steps for temperature excursions, such as job aids for clinic staff.

•**Updating of product information**: Manufacturers should update product information with new information about allowable storage temperatures, and expand the recommended temperature range

beyond 2-8 Celsius when they have data to support that decision. They should pay special attention to making allowances for warmer temperatures. This would allow providers to set vaccine storage unit temperatures at slightly 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, including frozen vaccine, without damaging it as well as guidance on appropriate transport containers, whether commercially-available or created from available supplies within a clinic. Providers may need to transport vaccine during emergencies, power outages, and sometimes to ensure vaccine is used before expiration. CDC has provided this guidance for emergency situations, but further information is needed to address non-emergency situations and off-site clinics with guidance on commercially-available materials. NSF-I may be considered as a route for establishing vaccine transport container manufacturing guidelines.

CDC Policy

•**Implementing Changes**: CDC should work with AIM as policies are developed. CDC should involve awardees 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 awardee 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. In the absence of a mandatory restitution policy for the federal VFC program, options other than zero restitution or complete restitution (a state-specific capped restitution penalty) should be permitted by CDC. Anticipatory guidance to help providers avoid situations that will require restitution or replacement due to the increasingly technical nature of vaccine storage equipment and monitoring is also needed.

•**Management of burden of new requirements:** CDC should measure the program burden (staff time, new FTEs, loss of VFC providers from the program) caused from managing temperature excursions, restitutions and other activities stemming from the increase in storage and handling requirements with the goal of providing appropriate tools and funding to programs specifically to cover additional staff needed to implement new requirements and respond to temperature excursions.

•**Encouraging New Technology**: CDC policy and recommendations should not only utilize current technology but also encourage the development of new technology to improve vaccine storage and handling practices. Flexibility is needed to allow the use of new, more efficient technology to meet

storage and handling goals. CDC should encourage innovation and have the flexibility to embrace new technologies which demonstrate improvement and address challenges. This type of flexibility will help ensure that VFC providers are able to use the best and most effective technologies to properly store, handle and manage vaccines. New technologies can be phased into policy and practice over time.

Approved by the AIM Executive Committee on December 8, 2016

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