



Department of Health and Human Services (HHS), Office of Inspector General (OIG)
Vaccines for Children Program: Vulnerabilities in Vaccine Management
Response Talking Points

- 1. AIM strongly supports accountability and proper vaccine storage and handling in the VFC program and commends the OIG for its investigation and report.**
 - Stewardship of the nearly \$4 billion public vaccine program is critical.
- 2. OIG findings must be viewed in context of the highly successful and widespread VFC program.**
 - The VFC program has enabled public health to create and ensure vaccine quality assurance in thousands of provider offices.
 - More than 44,000 VFC provider sites vaccinate approximately 50% of young children and 30% of adolescents against 16 diseases each year.
 - Unique public/private partnerships established in VFC allow publicly purchased vaccine to be administered in private physician offices (children are vaccinated in the medical home).
 - Disease rates for most vaccine-preventable diseases are at record lows and childhood immunization coverage rates are at record highs. It is estimated that 94% of the population needs to be vaccinated against measles in order to prevent outbreaks in the community. Prior to the VFC program, measles coverage rate was only 84% and disease outbreaks were common. Due to the implementation of the VFC program, measles coverage rates reached 92% in 2011.
 - The five VFC programs visited are the largest of the 62 VFC programs and may not be representative of other programs.
 - The 45 provider sites visited represent a small percentage (.19%) of the 44,000 participating provider sites.
- 3. The OIG report confirms the need for additional investment in vaccine management and immunization infrastructure.**
 - Dorm style refrigerators must be replaced with purpose built or reliable quality refrigerators designed to maintain vaccines properly, such as those purpose built for storing fragile biologics.
 - Vaccines storage units should be equipped with high quality, temperature monitoring devices, including alarm systems and accurate, reliable and quality assured thermometers.
 - VFC programs need additional resources for staff and training.

- New tools are needed to continuously monitor temperatures of vaccine vials right up to the points of use that will visually indicate when vaccine vials have been compromised by improper hot or cold temperatures.
- Simpler, more efficient procedures (such as barcodes) are needed to manage vaccine inventory and documentation.
- Additional research and clear guidance is needed for proper handling and use of vaccine that has been exposed to out-of-range temperatures for short periods of time (e.g., 3 days or less).
- The resources put towards the VFC program are critically important but should not be taken away from other core public health functions including disease surveillance and outbreak control.

4. Recent investments and improvements in vaccine management demonstrate the commitment of CDC and state and local VFC programs to protect public vaccine supply.

- 2009-2010: Investment of American Recovery and Reinvestment Act (ARRA) funding in purchase of refrigerators and freezers and/or calibrated thermometers for their VFC providers in 16 states.
- 2008: Requirement that all VFC programs develop and implement fraud and abuse policies.
- 2011: Requirement that VFC programs institute VFC compliance questionnaire and follow-up algorithm with all providers.
- 2012: Requirement that VFC programs conduct compliance visits to every provider at least once every 2 years. According to the 2011 VFC management Survey, a total of 26,890 VFC enrolled providers (public and private) received compliance site visits.
- 2008: Policy restricting use of dorm style refrigerators to temporary storage only, new 2012 CDC recommendation against any use of dorm style refrigerators may become VFC policy soon.
- Enactment of additional guidance and policies at state level:
 - California vaccine storage training guide;
 - Alaska guidance on thermometers;
 - Restitution policies requiring providers to pay for spoiled vaccine;
 - Many states, among them California and Minnesota, have banned the use of dorm style refrigerators for any VFC vaccine storage;
 - Several states, including Oregon and Wyoming, are using data loggers in vaccine storage units for 24/7 temperature monitoring.

5. Additional requirements in the VFC program should be balanced against the need to maintain and support the voluntary participation of private providers.

- Private providers are the backbone of the program.
- Providers do not receive funding to purchase refrigerators, freezers or thermometers and other temperature monitoring devices or other vaccine storage equipment, such as alarm systems.

- VFC administration fees do not adequately cover providers' time and resources spent tracking and monitoring vaccines, documenting and reporting vaccine administration, educating parents, and distributing vaccine information statements as required in the VFC program.

6. AIM has a long history of working to improve vaccine storage and handling and will continue to push for quality improvement and increased accountability in VFC.

- Formed Vaccine Storage and Handling Work Group in 2006.
- Conducted survey of VFC programs to identify storage and handling challenges and concerns in 2008.
- Sent letter to CDC in 2008 requesting uniform, science-based recommendations for vaccine storage and handling and standards for refrigerators, freezers, and thermometers.
- In 2009, characterized 318 vaccine storage and failure incidents reported to immunization programs that resulted in vaccine waste in a period of 8 weeks (annualized to 2,067 events).
- Testified before Institute of Medicine on the importance of proper vaccine storage and handling in 2010.
- Met with Food and Drug Administration (FDA) officials in 2010 and requested additional research and guidance on the stability of vaccine exposed to out-of-range temperatures.
- Participated in CDC International Vaccine Stability Work Group since 2010.

7. AIM recommends that CDC work closely with VFC programs, providers and partners to improve vaccine management.

- CDC should convene a meeting of partners including VFC programs, providers, vaccine manufacturers, distributors, etc. to assess challenges, identify opportunities for improvement, and make recommendations for additional action.
- Efforts must recognize the challenges faced by provider offices such as staff turnover, a lack of resources dedicated to staff training and lack of expertise in vaccine management. CDC and the immunization programs should consider developing a short-online training video that could be used to train staff in provider's offices. Consideration should also be given to development of an on-line certification program for any staff member responsible for vaccine storage and administration.