

OIG Vaccine Management Report: Overarching Key Messages for the Public

- The OIG report highlighted that there are some areas where we can do better in the VFC program. It also underscores the importance of maintaining a robust public health system to support quality assessment and improvement in immunization services. VFC providers generally manage their public and private stock vaccines in a similar manner and 90 percent of U.S. children are vaccinated by a provider that participates in the VFC program. Thus, strengthening VFC vaccine storage and handling practices will help improve vaccination services nationally and benefit all children.
- With more than 44,000 participating provider sites, the Vaccines for Children (VFC) Program plays a significant role in reducing barriers and improving access to vaccination for millions of financially vulnerable children and adolescents.
- CDC appreciates the OIG's thorough and careful review of VFC vaccine management and concurs with their recommendations. The review is extremely helpful in terms of giving us insight into how to focus our efforts as we move forward.
- Ensuring the proper storage, handling and oversight of vaccines is a priority for CDC and our partners. The report underscores that **we must do better** at ensuring that vaccines are stored properly and expiration dates are monitored – and that VFC program requirements are being met.
- We understand that parents who hear about this report may have questions about their child's vaccinations. We want you to know:
 - The main concern with improper storage temperatures is that they can make vaccines less effective rather than less safe.
 - Vaccines are carefully researched and monitored in the United States – both before and after they are licensed for use. We have a broad body of knowledge regarding the safety and real world effectiveness of vaccines through clinical studies, disease surveillance and outbreak investigation. In fact, the studies that the vaccine manufacturers do as part of the FDA vaccine approval process are often conducted in provider offices and use vaccines stored in the types of storage units that are widely used by providers in practice today. This extensive experience supports the safety and effectiveness of vaccines stored under "routine use" conditions.
 - There is every indication that vaccines are doing their job at providing protection against disease.
 - We monitor the diseases that vaccines prevent and can see that vaccines are doing their job; we see little vaccine-preventable disease in the U.S.
 - Recent outbreaks of measles and pertussis are not linked to less effective or ineffective vaccines
 - Cases of measles reported in the United States appear to be associated with unimmunized people and travel, not vaccine storage outside of recommended temperature ranges. Likewise, the primary factor in pertussis outbreaks seen in the U.S. appears to be waning immunity.

OIG Vaccine Management Report: Key Messages and Q&A

- While the safety and health of our nation's children have not been compromised by the issues identified by the OIG, the findings still are sobering. CDC and our partners are working with a sense of urgency to address these issues.
- The OIG study was aimed at assessing if VFC providers are meeting their vaccine management requirements, such as storing vaccine at proper temperature ranges and monitoring expiration dates. The OIG did not examine the reasons why these requirements were or were not being met.
- Meeting VFC requirements is a shared responsibility among CDC, all of our state and local health departments, and VFC provider offices. Working together, we will identify and successfully implement solutions.
- Vaccine storage and handling is a complex process that requires the vaccine be properly managed from the manufacturer to the distributor, the distributor to the provider office, and the provider office to the patient. We have made significant strides in improving storage and handling of publicly-purchased vaccine at the manufacturer and distributor levels through implementation of centralized vaccine distribution.
- CDC is in the process of implementing substantial improvements in vaccine ordering and inventory management systems. Through changes in the vaccine ordering systems and processes, CDC is expecting to improve vaccine accounting in provider offices and better forecasting of their vaccine supply needs. As a result, providers will have less expired and soon-to-be expired vaccines to manage.
 - It should be noted that CDC allows providers up to six months to return expired VFC vaccine.
- We will work with our partners, including state health officials, immunization program managers, and professional organizations to research the challenges and barriers providers face in meeting VFC requirements and identify strategies to improve compliance.
- CDC will also work to improve the focus, clarity and utility of our educational materials, guidance documents, program requirements, and support materials for vaccine management, storage, and handling.
- CDC has begun working with key partners and stakeholders to identify other steps that need to be taken to address the findings in the report as well as develop longer-term strategies to help providers strengthen their capacity to appropriately store and handle vaccines.

OIG Vaccine Management Report: Q&As for the Grantees, Partners and Public

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1. What is the VFC program?

The Vaccines for Children (VFC) program is a federally funded vaccine program, administered by the Centers for Disease Control and Prevention (CDC). It provides free vaccines to:

- Uninsured children
- Medicaid eligible children
- American Indian children
- Alaska Native children
- Underinsured children seeking care at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)

More than 44,000 provider sites in all 50 states and U.S territories receive VFC vaccines every year. The program benefits an estimated 40 million children.

2. What is a VFC Grantee? What do Grantees do?

A VFC Grantee is an important partner in the VFC program. Grantees are state/territorial health departments and public health agencies that are funded by CDC that oversee the VFC program for their area. Grantees enroll health care providers in the VFC program to make sure a

wide network of providers is able to vaccinate uninsured children and those whose insurance does not cover vaccines. The VFC program has 61 Grantees and more than 44,000 providers.

3. Why are vaccines important as part of regular health care visits?

Vaccines prevent infectious diseases that once killed or harmed many infants, children, and adults. Without vaccines, children are at risk for getting seriously ill and suffering pain, disability, and even death from diseases like measles and whooping cough. Many vaccine-preventable diseases are rare in the U.S. because we have been vaccinating against them for decades. Because some of these diseases are seen so infrequently in the U.S., some people think they do not need to vaccinate for them. However, vaccine-preventable diseases remain a threat. For example, last year there were more than 15,000 cases of measles in France, with potential for exportation across the globe, including to the U.S. This continuing threat was evident last year with 222 reported measles cases in the U.S, the highest number of cases since 1996 – without a high level of vaccinated people in the U.S. cases could have been much higher.

4. Could the outbreaks of vaccine-preventable disease we are seeing in the U.S. be caused by the storage and handling issues identified in the report?

There is a very low incidence of vaccine-preventable disease among people with age appropriate vaccinations, demonstrating that vaccination is effective. Investigation into the recent outbreaks of measles found the cases to be among unvaccinated people and not associated with vaccines storage outside of recommended temperature ranges. However, CDC is committed to improving vaccine storage and handling.

5. Do the Inspector General's (IG) findings raise concerns about the safety of vaccines being administered to children?

The findings do not raise concerns about the safety of vaccines administered to children. The primary focus of the Inspector General's report was on documentation/oversight issues and proper temperature storage for vaccines. The concern with improper storage temperatures is that they can make vaccines less potent rather than less safe. Post-licensure monitoring supports the safety and effectiveness of vaccines stored under "routine use" conditions.

If parents have questions or concerns regarding their child's vaccinations, they should speak to their child's doctor or health care provider, or call the CDC for information at 1-800-CDC-INFO.

A list of VFC state and territory coordinators can be found at:

<http://www.cdc.gov/vaccines/programs/vfc/contacts-state.htm>.

6. Do I need to get my child revaccinated?

Grantees/states handle recommendations regarding potential revaccination so it is important for providers to contact their grantee for proper guidance. In some cases, states/grantees may recommend revaccination in keeping with CDC's General Recommendations. However,

depending on the particular circumstances, revaccination may or may not be necessary or recommended.

It's important to keep in mind that while it is possible that some children have received less potent vaccines due to exposure to improper temperatures, our data do not suggest that this is a common or widespread problem. Our national monitoring suggests vaccines are performing as expected, and most diseases are at record low levels. Cases of measles reported in the United States appear to be associated with unimmunized people and travel, not vaccine storage outside of recommended temperature ranges. Likewise, the primary factor in pertussis outbreaks seen in the U.S. appears to be waning immunity.

Parents concerned about the potency of the vaccines their child received are encouraged to speak with their providers regarding provider storage and handling of vaccines and whether revaccination is recommended based on the state grantee's recommendations.

If you have questions or concerns regarding your child's vaccinations, please speak with your child's doctor or health care provider, or call the CDC for information at 1-800-CDC-INFO. A list of VFC state and territory coordinators can be found at:

<http://www.cdc.gov/vaccines/programs/vfc/contacts-state.htm>.

7. Do the findings from this report mean the VFC program is not working?

There is clear evidence that U.S. vaccination efforts, including the VFC Program, work extremely well. Efforts to prevent vaccine-preventable diseases in the U.S. are some of the most successful public health programs in the world.

The VFC Program has 61 grantees and more than 44,000 provider sites who work together to provide more than 80 million doses of vaccines every year. With any program of such magnitude there are always opportunities to improve certain areas and CDC takes the recommendations in the report seriously. CDC views the Inspector General's findings as an opportunity to strengthen and further improve what is already a very good program.

8. Why did the Inspector General (IG) conduct this study?

The mission of the Office of the Inspector General is to protect the integrity of the Department of Health and Human Services (HHS) programs (CDC is an agency under HHS). As part of its mission, the IG conducts routine, planned assessments and inspections, as well as investigations. This report is a result of a routine and planned assessment of the Vaccines for Children Program (VFC).

9. When did the Inspector General (IG) conduct this study?

In 2010 the Inspector General selected the five largest VFC Grantees (based on 2010 vaccine order volume) to study. It conducted the study in April and May of 2011.

10. How was the study conducted?

The Inspector General selected 45 VFC providers from the five largest VFC Grantees (based on 2010 vaccine order volume) for the sample. The study evaluated providers' adherence to three VFC program requirement areas:

- Storage equipment
- Vaccine management
- VFC program eligibility screening

For each of the 45 providers selected, the IG conducted:

- Provider site visits
- Interviews with vaccine coordinators
- Observations of VFC provider management practices
- 2 week study of vaccine storage unit temperatures and a review of temperature logs
- Interviews with the five grantees' VFC program staff regarding oversight

11. Will the report name the provider sites that were visited?

No. The report identifies the state and city Grantees in the survey but does not name specific provider sites.

12. What were the report results and recommendations?

The Inspector General report identifies two types of findings: storage and handling of vaccine, and program management issues. Storage and handling issues include improper temperature and unapproved storage units as well as expired vaccine stored alongside non-expired vaccine. Program management issues include a lack of required documentation, program oversight and vaccine management at provider sites.

The Inspector General recommends that CDC continue to work with Grantees to ensure proper storage of vaccines, separation of expired and non-expired vaccines, and adherence to VFC oversight requirements. CDC will work with its partners, including state health officials, immunization program managers, and professional organizations to research and identify strategies to improve compliance with the requirements for equipment and temperature monitoring for proper vaccine storage.

13. Do the findings only relate to the sites visited, or are they applicable across the VFC program?

It is important to note that although the Inspector General's office assessed a small percentage of the VFC grantees and providers, challenges in assuring proper storage and handling practices are not unique to the VFC grantees and provider sites included in this study. CDC takes its stewardship of the VFC program very seriously. Ensuring the proper storage, handling, and oversight of vaccines by all providers, whether they are VGC providers or solely administer

vaccine in their private practices, is a priority for CDC and our partners. Improving the VFC program based on the Inspector General's report is a shared responsibility among CDC, all of our Grantees (not just the five in the report), and VFC provider offices.

14. Are publicly funded vaccines being stored differently than those purchased privately by health care providers?

The investigators found most providers surveyed do not have separate storage facilities for VFC and privately purchased vaccine. CDC believes this is likely true for most providers in the VFC program. Because of shared storage facilities, any changes based on the report will improve vaccination efforts generally regardless of whether federally or privately funded.

15. What do grantees need to achieve compliance?

Grantees need to ensure VFC providers have a good working knowledge of the VFC program guidelines and requirements, and follow them. The guidelines and requirements are in place to ensure the highest quality program to serve our at-risk children.

CDC understands the commitment grantees, providers, and partners all have to the VFC program as well as the time it takes to properly manage the program. CDC is working to identify ways to strengthen the program as well as streamline cumbersome processes and support grantees and providers. While the CDC works to identify these improvements to the program, grantees are encouraged to provide enhanced, regular communications to providers regarding tools and resources available to help providers comply with VFC requirements.

16. What is a cold chain and why is it important for vaccines?

A cold chain is a temperature-controlled supply chain. Vaccines should be shipped and stored within a defined temperature range to ensure potency (the relationship between the vaccine dose and its beneficial effect).

17. What is the VFC cold chain process from vaccine manufacturer to provider?

Manufacturers are required to ship vaccines under temperature controlled conditions that ensure product stability. The CDC distributor is required to validate all steps in the distribution process and include temperature monitors in each shipment. VFC guidelines advise providers to open vaccine shipment containers immediately upon receipt and transfer vaccines to appropriate storage refrigerators.

CDC has recently made significant improvements in the manufacturer-to-provider cold chain process. CDC streamlined the process for most vaccines from 500 distribution centers to a centralized vaccine distribution center that sends vaccines directly to providers. This improvement provides much greater temperature control and oversight during the distribution, and helps ensure products quality is maintained during storage and shipment.

18. What is CDC doing to improve storage and handling for the VFC program?

CDC is undertaking a comprehensive review of all aspects of vaccine storage and handling in the provider setting. This review includes:

- Reviewing and revising CDC's current temperature monitoring recommendations.
- Developing recommendations for storage and handling equipment including temperature monitoring technology and refrigerator and freezer units.
- Developing standardized tools and training for field staff conducting VFC provider visits.
- Reviewing current VFC requirements and developing corrective action guidance for out of compliance providers.
- Considering development of a certification program for vaccine storage and handling.
- Updating CDC's Storage and Handling Guide and Toolkit.
- Providing funding through new PPHF funding announcement \$8.8M to grantees to improve vaccine storage and handling.

19. What is CDC doing about expired vaccines?

Even prior to the report, CDC implemented significant VFC vaccine ordering and distribution changes. These changes improve vaccine forecasting and help to ensure less expired vaccine and wastage. It is important to keep in mind however, that the majority of the expired vaccines the Inspector General found in site visits were influenza vaccine. Manufacturers modify flu vaccine each year, ensuring effectiveness against that year's predicted flu strains. Because it is slightly different from year-to-year, it always expires at the end of each flu season. The site visits for this report took place at the end of the flu season so it was not uncommon to find some expired flu vaccine in the storage units. However, CDC will continue to work with its VFC grantees to encourage providers to return expired VFC vaccines, including flu vaccines, in a timely manner.

20. What resources are available to VFC providers to help them improve?

CDC develops technical assistance, and vaccine storage and handling education products including guidebooks, DVD training courses, and net conferences. Grantees and providers can get a complete list of available resources from CDC and can also visit the CDC's website at <http://www.cdc.gov/vaccines/hcp.htm>. One excellent resource is California's storage and handling guidelines and tools (<http://www.cdph.ca.gov/programs/immunize/Pages/VaccineStorageandHandling.aspx>)