

Special Issue: Vaccine Storage and Handling Report Released

A report was released on June 6, 2012, based on a study conducted by the Office of Inspector General (OIG) entitled *Vaccines for Children Program: Vulnerabilities in Vaccine Management*, which explores vaccine storage and handling and inventory management in the Vaccines for Children (VFC) program. The *OIG Vaccine Management Report* is a result of a routine and planned assessment of the Vaccines for Children Program (VFC). The report highlights results of an April and May 2011 study investigating the five largest VFC programs of the 64 state, city/territorial immunization programs and a sample of 45 physician offices in each jurisdiction. NOTE: Michigan was not one of the states selected for this report. The [Vaccine Management Report is posted at the OIG website](#).

The mission of the Office of the Inspector General (OIG) is to protect the integrity of the Department of Health and Human Services (HHS) programs (CDC is an agency under HHS). HHS OIG is the largest inspector general's office in the Federal Government, with more than 1,700 employees dedicated to combating fraud, waste and abuse and to improving the efficiency of HHS programs. A majority of OIG's resources goes toward the oversight of Medicare and Medicaid – programs that represent a significant part of the Federal budget and that affect this country's most vulnerable citizens. OIG's oversight extends to programs under other HHS institutions, including the Centers for Disease Control and Prevention, National Institutes of Health, and the Food and Drug Administration. As part of its mission, the IG conducts routine, planned assessments and inspections, as well as investigations.

The OIG conducted the study because the Centers for Disease Control and Prevention's (CDC) Vaccines for Children (VFC) program provides free vaccines to eligible children through a network of 61 grantees and 44,000 enrolled providers. In 2010, approximately 82 million VFC vaccine doses were administered to an estimated 40 million children at a cost of \$3.6 billion. VFC providers must meet certain requirements for vaccine management, such as storing vaccines within required temperature ranges and monitoring expiration dates, to ensure that these vaccines provide children with maximum protection against preventable diseases. These requirements are also intended to prevent or decrease VFC fraud, waste and abuse.

The Inspector General (IG) selected a sample of 45 VFC providers from the five largest VFC Grantees (state/city health departments) based on 2010 highest volume of vaccines ordered. 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 program oversight

Box of Refrigerated Influenza Vaccine Exposed to Freezing Temperatures (Note Ice in Circle)



See next page for highlighted findings.

Varicella Vaccine, With an Expiration Date of 04 Dec 2010, Identified During Site Visit on 21 April 2011



Dorm-Style Unit Used for Permanent VFC Vaccine Storage (Note Frost Buildup in Circle)



Findings of the study include:

- The majority of temperatures measured were within required ranges; however VFC vaccine stored by 76 percent of the 45 providers were exposed to inappropriate temperatures for at least 5 cumulative hours during the two week period. Vaccines exposed to inappropriate temperatures can have reduced potency and efficacy.
- Thirteen providers had expired vaccine stored with nonexpired vaccines which increases the risk of administration of an expired vaccine.
- In general, the providers did not meet vaccine management requirements or correctly maintain required documentation
- None of the five selected grantees met all VFC program oversight requirements and results demonstrated that site visits were not effective at assisting providers to meet vaccine management requirements.

Based on the results of the study, OIG recommends that CDC continue to work with grantees and providers to ensure that:

- VFC vaccines are stored according to requirements
- Expired vaccines are identified and separated from nonexpired vaccines
- Grantees better manage providers' vaccine inventories
- Grantees meet program oversight requirements

CDC concurred with the above recommendations and noted that vaccination is one of the most successful public health tools prevention and control of diseases.

Michigan

Some of the steps that Michigan has taken to promote proper vaccine storage and handling include:

- Michigan requires new VFC providers to have a VFC Enrollment Site Visit, temperature log review, and vaccine storage and handling education before healthcare providers can receive public vaccine supply.
- In collaboration with local health departments in the state, 87% of Michigan VFC enrolled provider sites received a VFC Compliance Site Visit last year, exceeding the 50% required by CDC.
- The Michigan VFC program requires vaccine temperature log reviews for every provider site prior to vaccine order approval.
- Michigan uses the Michigan Care Improvement Registry (MCIR) to order, track, and manage vaccine inventories, which includes color coding vaccines soon-to-expire, and recording doses that have been lost or wasted.

Proper vaccine storage and handling maintains the integrity and stability of vaccines administered to patients, prevents inadvertent administration of improperly stored vaccines and avoids unnecessary vaccine wastage. Vaccine storage and handling continues to be a priority for the Michigan Vaccines for Children program, as it is for all providers.

Michigan recommends that all immunization providers - both VFC and non-VFC - review vaccine management practices, including storage and handling of vaccines, inventory management and temperature monitoring per CDC recommendations. Provider sites should have a designated vaccine coordinator and an assigned back-up person that are knowledgeable and responsible for vaccine management. Conducting monthly inventory of vaccines will result in identifying soon-to-expire vaccines so they can be used first and prevent vaccine expiration. Prompt removal of vaccine that has expired must occur to prevent accidental administration. All storage units must have a certified thermometer and temperatures monitored twice daily. Vaccine stored incorrectly, allowed to expire, or wasted leads to costly vaccine replacement in both the private and public sector.

In addition to storage and handling guidance, Michigan has developed nationally recognized provider educational sessions provided free of charge to provider offices by a trained Nurse Educator, which can be obtained by calling your local health department. Job aids and educational materials on vaccine storage and handling can be found at www.michigan.gov/vfc. Additional vaccine storage and handling resources are posted on the AIM website at www.aimtoolkit.org.