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VACCINES FOR CHILDREN PROGRAM: VULNERABILITIES IN VACCINE MANAGEMENT

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EXECUTIVE SUMMARY: VACCINES FOR CHILDREN PROGRAM: VULNERABILITIES IN VACCINE MANAGEMENT
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WHY WE DID THIS STUDY

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 decrease VFC program fraud, waste, and abuse.

HOW WE DID THIS STUDY

Using CDC data, we selected a sample of 45 VFC providers from the 5 grantees with the highest volume of vaccines ordered in 2010. We conducted site visits at these providers' medical practice locations, interviewed their vaccine coordinators, and observed their vaccine management practices. We also independently measured these providers' vaccine storage unit temperatures for a 2-week period. Finally, we interviewed the five grantees' VFC program staff regarding their program oversight.

WHAT WE FOUND

Although the majority of storage temperatures we independently measured during a 2-week period were within the required ranges, VFC vaccines stored by 76 percent of the 45 selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period. Exposure to inappropriate temperatures can reduce vaccine potency and efficacy, increasing the risk that children are not provided with maximum protection against preventable diseases. Thirteen providers stored expired vaccines together with nonexpired vaccines, increasing the risk of mistakenly administering the expired vaccine. Finally, the selected providers generally did not meet vaccine management requirements or maintain required documentation. Similarly, none of the five selected grantees met all VFC program oversight requirements, and grantee site visits were not effective in ensuring that providers met vaccine management requirements over time.

WHAT WE RECOMMEND

We recommend that CDC continue to work with grantees and providers to ensure that (1) VFC vaccines are stored according to requirements, (2) expired vaccines are identified and separated from nonexpired vaccines, (3) grantees better manage providers' vaccine inventories, and (4) grantees meet oversight requirements. CDC concurred with all four of our recommendations and noted that vaccination is one of the most successful public health tools in preventing and controlling disease.

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OBJECTIVE

To determine the extent to which selected Vaccines for Children (VFC) program providers and grantees adhered to the Centers for Disease Control and Prevention's (CDC) requirements for vaccine management.

BACKGROUND

The VFC program is a Medicaid benefit that provides free vaccines to eligible children.[1, 2] The Centers for Medicare & Medicaid Services (CMS) delegates the program's implementation to CDC, which purchases VFC vaccines and distributes them to VFC providers.[3] CMS reimburses CDC for the cost of the vaccines and for program management. In 2010, the program cost $3.6 billion and approximately 44,000 providers participated.[4, 5] These providers ordered approximately 82 million VFC vaccine doses to administer to an estimated 40 million children.[6, 7]

Children eligible to participate in the VFC program may not otherwise be vaccinated because of inability to pay. They include Medicaid-eligible, uninsured, American Indian/Alaska Native, and/or underinsured children who receive care through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).[8, 9] In 2011, approximately 70 percent of VFC-eligible children were enrolled in Medicaid.[10]

Vaccines administered through the VFC program are licensed by the Food and Drug Administration (FDA) and approved for program inclusion by CDC.[11] Licensed vaccines are labeled with required storage temperature

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[1] Omnibus Budget Reconciliation Act of 1993, P.L. 103-66 § 13631.

[2] Social Security Act (SSA), § 1928(a); 42 U.S.C. § 1396s(a).

[3] CMS, *Delegation Memorandum*, June 30, 1994.

[4] Department of Health and Human Services, *CDC Justification of Estimates for Appropriation Committees*, Fiscal Year 2011.

[5] CDC, *VFC: Summary Reports*, 2010. Accessed at http://www2a.cdc.gov/nip/irar/grantee/granteeinfo.asp#grptg on September 27, 2011.

[6] CDC, VFC vaccine dose data, provided by CDC on January 14, 2011.

[7] CDC, national population estimate for 2011, provided by CDC on October 4, 2011.

[8] CDC, *VFC Operations Guide*, Module 1: Overview, p. 1, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[9] SSA, § 1928(b)(2); 42 U.S.C. § 1396s(b)(2).

[10] CDC, national population estimate for 2011, provided by CDC on October 4, 2011.

[11] VFC vaccines must be approved by the Advisory Committee on Immunization Practices. CDC, *VFC: The ACIP-VFC Vaccine Resolutions*, 2010. Accessed at http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm on September 13, 2010.

ranges and expiration dates.[12] Vaccines must be stored within the required ranges to ensure that the vaccines maintain the highest possible level of strength (i.e., potency) and effectiveness (i.e., efficacy). Additionally, vaccines must not be administered after their expiration dates because they may lose potency and efficacy, reducing their ability to provide maximum protection against preventable diseases.[13] VFC vaccines protect children against 16 preventable diseases:

- diphtheria
- *haemophilus influenzae* type b
- hepatitis A
- hepatitis B
- human papillomavirus
- influenza
- measles
- meningococcal disease
- mumps
- pertussis
- pneumococcal disease
- polio
- rotavirus
- rubella (German measles)
- tetanus
- varicella (chickenpox)

See Appendix A for a list of all VFC program-covered vaccines and the required storage temperature ranges.

VFC providers may receive funding for the same program-covered vaccines through other public and private funding sources. Additional public funding sources include the Section 317 grant program and State budgets.[14] Alternatively, providers may purchase these vaccines with their own funds to administer to children who are not VFC-eligible (e.g., individuals with health insurance that covers the cost of the vaccines). Most providers store publicly and privately purchased vaccines in the same freezers and refrigerators. Providers must distinguish publicly purchased vaccines from privately purchased vaccines to ensure that vaccines are administered to the corresponding populations.[15] For

[12] 21 CFR §§ 610.50, 610.53, and 610.60-62. FDA, *Vaccine Product Approval Process*, 2009. Accessed at http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm on November 29, 2010.

[13] Vaccine expiration dates may be extended with FDA approval if the manufacturer verifies the sterility and potency of the vaccine. FDA, *Vaccine Safety Questions and Answers*. Accessed at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm133806.htm on January 24, 2012.

[14] The Section 317 grant program consists of Federal discretionary funds that may be used to purchase vaccines for non-VFC-eligible populations (children and adults). States may also contribute funds to purchase vaccines for these populations. CDC, *VFC Operations Guide*, Module 8: Vaccine Accountability, p. 1, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[15] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, p. 11, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

example, providers must ensure and be able to document that only VFC-eligible children receive VFC-purchased vaccines.[16]

VFC Program Management and Oversight

CDC manages the VFC program through 61 grantees that implement the program at the State and local levels. Grantees include all 50 State health departments as well as public health agencies in 6 metropolitan areas and 5 U.S. territories and protectorates.[17] Each grantee recruits and enrolls providers in its jurisdiction. A variety of provider types participate, including private providers (e.g., individuals or groups), public health departments, FQHCs/RHCs, other public health clinics (e.g., maternal and child health programs), and private hospitals.[18] Approximately 70 percent of VFC providers are private providers.[19]

Provider Vaccine Management Requirements. VFC providers must perform required activities in 10 categories established in the Vaccine Management Module of CDC's *VFC Operations Guide*:[20]

1. Vaccine Storage Equipment
2. Vaccine Storage Practices
3. Temperature Monitoring
4. Vaccine Storage and Handling Plans
5. Vaccine Personnel
6. Vaccine Waste
7. Vaccine Security and Equipment Maintenance
8. Vaccine Ordering and Inventory Management
9. Receiving Vaccine Shipments
10. Vaccine Preparation

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[16] CDC, *VFC Operations Guide*, Module 3: Provider Recruitment and Enrollment, pp. 4-5, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[17] The six metropolitan public health agencies are those of Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio. The five territory and protectorate public health agencies are those of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. CDC, *VFC: State/Territory VFC Coordinators*. Accessed at http://www.cdc.gov/vaccines/programs/vfc/contacts-state.htm on October 24, 2011.

[18] CDC, VFC provider data, provided by CDC on August 22, 2010.

[19] CDC, *VFC/AFIX Activities Query Results*, 2010. Accessed at http://www2a.cdc.gov/nip/irar/grantee/granteeinfo.asp#grptg on October 4, 2011.

[20] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, pp. 6-11, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

Appendix B lists all required vaccine management activities within each category. For example, the Vaccine Storage Equipment category does not allow the use of dormitory (dorm)-style storage units for permanent VFC vaccine storage because such units are not able to reliably maintain temperatures within required ranges.[21]

In addition, the *VFC Operations Guide* establishes documentation requirements for VFC providers. Each provider must maintain the following documents related to vaccine management:[22]

1. training records,
2. documentation demonstrating the provider's process to ensure that VFC vaccines are administered only to the VFC-eligible population,
3. a routine storage and handling plan,
4. an emergency storage and handling plan,
5. a current provider enrollment form,
6. a current provider profile form, and
7. temperature-monitoring logs.

Meeting these requirements enables providers to (1) ensure that vaccines provide children with maximum protection against preventable diseases and (2) reduce the risk of fraud, waste, and abuse in the VFC program.

The *VFC Operations Guide* also reflects FDA's vaccine storage requirements.[23, 24] Specifically, vaccines must be stored within the required temperature ranges from the time they are shipped from the manufacturer until they are administered by the provider.[25] For example, the varicella vaccine, which protects against the virus that causes

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[21] A dorm-style unit is a small combination refrigerator-freezer unit outfitted with a single external door. Two types of storage units are acceptable for storing VFC vaccines: (1) a refrigerator that has a separate freezer compartment with separate exterior door (combined unit) or (2) a stand-alone, single-purpose freezer or refrigerator (stand-alone). CDC, *VFC Operations Guide*, Module 6: Vaccine Management, p. 7, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[22] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, pp. 6-11, and Module 3: Provider Recruitment and Enrollment, pp. 2-3, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011. Certain documents, such as temperature-monitoring logs, must be maintained for at least 3 years.

[23] CDC, *Vaccine Storage and Handling Guide*, September 30, 2011. Accessed at http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf on February 7, 2012.

[24] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, p. 3, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[25] Ibid., pp. 2-3.

chickenpox, must be stored at or below 5 degrees Fahrenheit (°F).[26] Exposure to a temperature above 5°F reduces the vaccine's ability to provide children with maximum protection against chickenpox.

Depending on the type of vaccine, providers must store vaccines in a central area of either a freezer or refrigerator.[27] Cold air circulation is maximized when vaccines are stored in the center of a storage unit, where temperatures are also most stable.[28] In other areas of freezers and refrigerators—such as spaces near walls, coils, floor, vents, and doors—temperatures are not as stable as those in the center of the units.[29] Vaccines requiring refrigeration must be stored between 35°F and 46°F, and vaccines requiring freezer storage must be stored at or below 5°F .[30]

Providers must monitor all vaccine storage temperatures using a certified, calibrated thermometer to ensure that vaccines are not exposed to temperatures outside the required ranges.[31] Additionally, to obtain a temperature reading that is representative of the storage unit, a thermometer must be placed in a central area inside each freezer and refrigerator used to store VFC vaccines.[32]

Providers must also monitor vaccine expiration dates and ensure that expired vaccines are not administered.[33, 34] Providers must notify their respective grantees if vaccines expire and follow grantee guidance on how

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[26] FDA, *Varicella Vaccine Virus Package Insert (Varivax, Frozen)*, February 7, 2012. Accessed at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf on February 13, 2012.

[27] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, p. 9, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[28] CDC, *Vaccine Storage and Handling Toolkit*, Appropriate Vaccine and Diluent Storage Conditions, pp. 2-3. Accessed at http://www2a.cdc.gov/vaccines/ed/shtoolkit/ on December 7, 2009.

[29] Ibid.

[30] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, p. 3, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011. Storage temperature requirements are also listed in degrees Celsius (°C). Refrigerated vaccines must be stored between 2°C and 8°C (which convert to 35.6°F and 46.4°F, respectively) and vaccines requiring freezer storage must be stored at or below -15°C (which converts to 5.0°F).

[31] Ibid., p. 4. A variety of thermometer types may be used, including digital, minimum-maximum, standard fluid-filled, continuous recording, and dial thermometers. CDC, *Vaccine Storage and Handling Toolkit*, Vaccine Storage Equipment, pp. 12-16. Accessed at http://www2a.cdc.gov/vaccines/ed/shtoolkit/ on December 7, 2009.

[32] CDC, *Vaccine Storage and Handling Toolkit*, Vaccine Storage Equipment, p. 16. Accessed at http://www2a.cdc.gov/vaccines/ed/shtoolkit/ on December 7, 2009.

[33] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, pp. 9 and 11, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[34] CDC, *Vaccine Storage and Handling Toolkit*, Vaccine Personnel, p. 1. Accessed at http://www2a.cdc.gov/vaccines/ed/shtoolkit/ on December 7, 2009.

to either return expired vaccines for excise tax credit or dispose of them.[35] Further, providers must remove the expired vaccines from freezers and refrigerators with nonexpired vaccines to prevent them from being mistakenly administered.[36] Finally, providers must notify their respective grantees upon identifying vaccines that will expire before the providers can administer them.[37] Grantees will determine the appropriate action to take to minimize vaccine waste.

Grantee Oversight Requirements. Grantees must meet the oversight requirements in CDC's *VFC Operations Guide*. For example, each grantee is responsible for developing and maintaining a vaccine accountability system that ensures that:[38]

1. VFC vaccines are ordered on the basis of the size of each provider's VFC-eligible population;
2. VFC vaccines are administered only to VFC-eligible children;
3. VFC vaccine loss and waste are minimized and measured; and
4. the VFC program is protected against fraud and abuse.

Grantees must develop a fraud and abuse policy that addresses (1) prevention and detection of fraud and abuse and (2) investigation and resolution of fraud and abuse allegations. The policy must include the following eight activities and describe how they are integrated into the grantees' daily VFC program administrative activities:[39]

1. identifying oversight personnel,
2. developing a fraud and abuse referral procedure,
3. creating an allegation and referral database,
4. developing a procedure for monitoring the program,
5. developing training materials for personnel,

[35] CDC, *VFC Operations Guide*, Module 6: Vaccine Management, pp. 6 and 11, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[36] Ibid., p. 11.

[37] Ibid., p. 9.

[38] CDC, *VFC Operations Guide*, Module 8: Vaccine Accountability, p. 1, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[39] CDC, *VFC Operations Guide*, Module 10: Fraud and Abuse, pp. 4-6, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

6. comparing enrolled providers to exclusion databases,[40]
7. developing a procedure for reporting provider terminations, and
8. creating a protocol to annually review fraud and abuse policies.

When a provider enrolls in the program, its grantee conducts a one-time initial site visit to educate the provider's staff about VFC program requirements and to ensure that the provider has appropriate equipment to implement the requirements.[41] For example, the grantee should ensure that the provider has vaccine storage freezers and refrigerators that meet CDC requirements.[42]

Grantees are also required to conduct periodic site visits of VFC providers. Since January 2011, grantees have been required to visit 50 percent of their providers each year.[43] During these site visits, grantees interview providers and observe the storage of vaccines to complete the VFC Site Visit Questionnaire to evaluate whether providers meet program requirements for vaccine storage, management, and recordkeeping.[44, 45] Grantees must develop corrective action plans for providers whose answers to priority questions on the VFC Site Visit Questionnaire indicate that they are not complying with program requirements. During 2010 site visits, grantees identified vaccine management deficiencies and developed corrective action plans for 57 percent of private providers and 46 percent of public providers.[46] Providers may be suspended or terminated from the

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[40] CDC, *VFC Operations Guide*, Module 9: Quality Assurance, p. 3, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011. The Department of Health and Human Services (HHS) Office of Inspector General (OIG) maintains a database of providers excluded from participating in federally funded health care programs on the "List of Excluded Individuals/Entities." Providers employing persons on this list may not participate in the VFC program.

[41] CDC, *VFC Operations Guide*, Module 3: Provider Recruitment and Enrollment, pp. 2 and 15, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[42] Ibid., p. 15. Grantees should ensure that providers understand the vaccine management requirements in the *VFC Operations Guide*, including requirements regarding vaccine storage equipment.

[43] CDC, *VFC Operations Guide*, Module 9: Quality Assurance, p. 2, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011. At least half of the VFC providers should be visited in 1 year and the remaining half the following year. Prior to January 2011, grantees were required to conduct site visits of 25 percent of VFC providers per year, and there was no requirement specifying which providers were to be visited each year.

[44] CDC created a VFC Provider Site Visit Questionnaire—updated periodically—that grantees must use during their site visits. Priority questions that providers do not meet automatically require corrective action.

[45] CDC, *VFC Operations Guide*, Module 9: Quality Assurance, p. 2, 2011. Accessed at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/vfc-op-guide-all-chaptr-files.pdf on February 2, 2011.

[46] CDC, *VFC/AFIX Activities Query Results*, 2010. Accessed at http://www2a.cdc.gov/nip/irar/grantee/granteeinfo.asp#grptg on October 4, 2011. Percentages are based on the total number of private and public providers with a site visit during 2010.

program if they do not meet requirements after implementing corrective action plans.

VFC grantees must meet the vaccine management requirements in the *VFC Operations Guide.* For example, grantees must train VFC providers on appropriate vaccine ordering, handling, storage, and waste reporting. In addition, grantees must give providers an overall vaccine management plan template to ensure that providers meet CDC's vaccine management requirements. Grantees are also required to ensure that vaccines remain effective by developing standard operating procedures for providers that address vaccine ordering, receiving, storage, handling, inventory management, and disposal. Grantees must also develop their own vaccine management policies and procedures based on CDC's VFC program requirements. For example, grantees must establish their own policies regarding the types of thermometers that providers may use to monitor VFC freezer and refrigerator temperatures.

METHODOLOGY

Sample Selection

The VFC program is implemented through 61 VFC grantees in collaboration with approximately 44,000 providers. The scope of this evaluation did not allow for the review of vaccine management practices of all grantees and providers. Therefore, we selected a purposive sample of 45 providers within 5 grantee jurisdictions to conduct site visits and collect documentation. We selected the five program grantees with the highest VFC vaccine order volumes during fiscal year (FY) 2010: California, Florida, Georgia, New York City, and Texas.[47] These grantees ordered 36 percent of all VFC vaccines during FY 2010. Appendix C lists the VFC vaccine order volume for each of the five selected grantees and the total VFC vaccine order volume for 2010.

We visited nine VFC providers within each grantee jurisdiction. To ensure diversity of providers, we selected providers according to three characteristics: provider type (i.e., private provider, public health department, FQHC/RHC, other type of public health clinic, or private hospital), vaccine order volume (i.e., high or low), and location type

[47] CDC, VFC vaccine dose data, provided by CDC on December 20, 2010.

(i.e., rural or urban).[48, 49] Because we also met with grantee staff, we limited our sample of providers to those within 100 miles of each grantee's office location. Appendix D lists (1) the number of providers within the five selected grantee jurisdictions, (2) their three characteristics, and (3) the number of providers in our sample for each characteristic.

Data Collection

VFC provider site visits and interviews. We conducted site visits of the 45 selected VFC providers to determine whether they met the 10 vaccine management requirements. We notified providers of our site visits 2 weeks in advance and conducted our site visits in April and May 2011.

We conducted structured interviews using standardized data collection instruments. We interviewed each provider's VFC coordinator(s) on the provider's procedures for vaccine management. We also used a standardized data collection instrument to observe VFC vaccine storage practices and review storage and temperature-monitoring equipment to determine whether providers met CDC requirements. Finally, we checked vaccine expiration dates to determine whether VFC vaccines were expired on the days of our site visits.

Independent temperature measurement. We independently measured temperatures of the vaccine storage equipment (i.e., freezers and refrigerators) for the 2-week period following our site visits (2-week period). We used a commercially available calibrated temperature-recording device—TempTale®—that met National Institute of Standards and Technology standards.[50, 51] At each selected provider site, we placed one TempTale® in a VFC vaccine freezer and one in a VFC vaccine refrigerator. Each TempTale® recorded temperatures every 15 minutes for 2 weeks.[52] For providers with more than one freezer and

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[48] Using CDC's Economic Order Quantity, we defined high-volume providers as those who receive at least 800 vaccine doses per year and low-volume providers as those who receive 799 or fewer vaccine doses per year.

[49] Urban areas were located within a core-based statistical area (CBSA) and rural areas were not. CBSAs include both metropolitan statistical areas (i.e., core urban areas with populations of 50,000 or more) and micropolitan statistical areas (i.e., core urban areas with populations between 10,000 and 50,000). U.S. Census Bureau, *Metropolitan and Micropolitan Statistical Areas*, accessed at http://www.census.gov/population/www/metroareas/metroarea.html on September 9, 2010.

[50] We purchased TempTale®4 monitors (TempTale®) and analytic services from a qualified contractor. The TempTale® monitor temperature range is -22.0°F to 158.0°F and the accuracy range is ±2.0°F from -22.0°F to 0°F, ±1.0°F from 0°F to 122.0°F, and ±2.0°F from 122.0°F to 158.0°F.

[51] The National Institutes of Standards and Technology is an agency of the U.S. Department of Commerce that develops measurement and accuracy standards and reference materials. It also provides certification and calibration services to establish conformity and quality across devices.

[52] Four selected providers did not have VFC vaccines in their freezers on the days of our site visits, so we did not place TempTales® in their freezers. We placed TempTales® in a total of 86 freezers and refrigerators during our site visits.

one refrigerator storing VFC vaccines, we selected the freezer and refrigerator with the most VFC vaccines at the time of our visit. To ensure that the TempTale® was measuring the same temperature as the provider's thermometer, we placed the TempTale® next to the probe of the provider's thermometer. For providers with more than one thermometer per unit, we placed the TempTale® next to the thermometer closest to the center of the unit to ensure that the temperature we recorded was representative of the temperature in the unit.

Provider documentation. One week prior to our site visits, we gave the selected providers a list of requested documents. During site visits, we collected these documents, which included the providers' policies and procedures for VFC vaccine storage and management, their overall vaccine management plans, and their routine and emergency storage and handling plans. We also collected training records, documentation used to ensure that VFC vaccines are administered only to VFC-eligible children (for example, sample eligibility screening forms or vaccine-use logs), provider enrollment and profile forms, and temperature-monitoring logs for 2010. We followed up with providers at least once to request documents that were not available during our site visits. Providers also mailed us their temperature-monitoring logs for the 2-week period when we were independently measuring freezer and refrigerator temperatures.

VFC grantee interviews and documentation. We interviewed the staff of each of the five VFC grantees to determine the extent to which the grantees met the VFC oversight requirements, including establishing accountability systems and developing comprehensive fraud and abuse policies. We conducted a structured interview with each grantee and collected documentation—such as training materials, program guidance, and records of their provider site visits—to assess the grantees' provider oversight activities. We collected site visit records only for those providers with a grantee site visit in the 12 months preceding our site visit (i.e., between April 15, 2010, and April 15, 2011). Additionally, because providers may submit their annual enrollment and profile forms to grantees electronically, we also requested these documents from the grantees.

Data Analysis

Vaccine storage temperatures. We analyzed freezer and refrigerator temperatures during the 2-week period to determine the extent to which VFC vaccines were exposed to temperatures outside the required ranges. Specifically, we used the TempTale® data to determine how many freezers

and refrigerators were outside the required temperature ranges for at least 5 cumulative hours during the 2-week period. Temperatures recorded by TempTale® devices were analyzed to the nearest tenth of a degree Fahrenheit. Any temperature higher than 5.0°F was considered out of range for freezers, and any temperature lower than 35.6°F or higher than 46.4°F was considered out of range for refrigerators. These ranges are based on exact Celsius-to-Fahrenheit conversions; however, in this report we have used the rounded temperatures (5°F, 35°F, and 46°F) listed in both CDC and FDA guidance documents.

We determined the longest span of consecutive hours each freezer and refrigerator was outside the required temperature range and the number and cost of vaccines in these units. Cumulative and consecutive hours outside the required temperature ranges were based on number of minutes the TempTale® recorded out-of-range temperatures. We also determined the mean temperature of each freezer and refrigerator that was out of range for at least 5 hours during the 2-week period, as well as the standard deviation, temperature range, storage unit type, and thermometer type(s).

We compared temperature data from each TempTale® to the VFC providers' temperature-monitoring logs for the 2-week period. To do this, we used the temperature recorded by the TempTale® at the time closest to each temperature recorded by the providers for the 2-week period. For example, if a provider recorded a temperature at 9 a.m., we compared it to the TempTale® measurement at the 15-minute interval closest to 9 a.m. Temperatures recorded by providers on monitoring logs were generally rounded to the nearest degree. To maintain accuracy, we did not round our independently measured temperatures for our analysis; however, in this report we have rounded temperatures to the nearest degree. We calculated the absolute value of the difference between the two temperatures and then calculated minimum, maximum, and mean differences for each provider and across all providers.[53]

We also reviewed providers' temperature-monitoring logs for 2010 to determine how often providers indicated that VFC vaccines were exposed to temperatures outside the required ranges for that year. Each provider had approximately 960 opportunities to record out-of-range temperatures during 2010, based on the following assumptions: (1) one freezer and one

[53] Comparison does not apply for four providers without freezers storing VFC vaccines. In addition, we were unable to compare all recorded freezer temperatures for 21 providers to independently measured temperatures because of the temperature log formats. For example, the minimum possible recorded freezer temperature was ≤ 3°F on many providers' temperature logs. In these instances, we assumed the recorded temperature was 3°F and calculated a difference only if the TempTale® temperature for the same time was greater than 3°F. Comparison was not possible for seven providers' freezers.

refrigerator per provider, (2) twice-daily temperature recordings for both the freezer and refrigerator, and (3) 20 days of temperature recordings per month for 12 months.

Vaccine expiration. We determined the number of selected providers that had expired vaccines on the day of each site visit. We calculated the total number and cost of expired vaccines. We also determined how many days the expired vaccines were past expiration and whether they were separated from nonexpired vaccines. Finally, we determined whether providers notify grantees upon identifying VFC vaccines that will expire before the providers can administer them.

Vaccine management practices. We reviewed data from provider interviews and observations, as well as provider-supplied documentation, to determine which of the required activities in the 10 categories the providers had performed. Providers had to perform all required activities within each category for us to conclude that they met the requirements for that category. Additionally, if our observations during the site visits were not consistent either with providers' documentation or with interview answers, we used our observations to determine whether the providers met the requirements. For example, the Vaccine Storage Practices category includes a requirement for providers to rotate VFC vaccine stock by expiration date; for each vaccine type, providers must place vaccines with closer expiration dates in front of those with more distant expiration dates. If providers told us that they rotate vaccines as required but we observed vaccines that were not placed in order by expiration date, we determined that the providers did not meet the requirements in the Vaccine Storage Practices category.

We also determined whether each selected provider had the seven vaccine management documents required by the *VFC Operations Guide*. These seven required documents are listed on page 4 of this report.

Grantee oversight. We reviewed grantee interview responses and supporting documentation to determine the extent to which the five grantees met grantee vaccine accountability requirements established in the *VFC Operations Guide.* These four oversight requirements are listed on page 6.

We also determined the extent to which the selected grantees' fraud and abuse policies addressed eight categories of activities required by the *VFC Operations Guide*. The list of these eight activities begins on page 6.

Grantees had to meet all of the fraud and abuse policy requirements within each category for us to conclude that they met the overall requirement for that category.

In addition, we determined whether each of the five selected grantees provided required vaccine management materials to the nine VFC providers in their jurisdictions, including overall vaccine management plan templates and standard operating procedures. We also compared our site visit results with the grantee site visit results for the 25 providers that had grantee site visits during the 12 months prior to our site visits (between April 15, 2010, and April 15, 2011). We conducted this comparison to determine whether providers corrected grantee-identified deficiencies and continued to meet vaccine management requirements over time. This analysis was based on our findings and grantees' findings on 22 priority questions related to vaccine management. These questions were included both on the grantee VFC Site Visit Questionnaire and in our data collection instruments.

Limitations

Our results apply only to our sample of 5 grantees and 45 providers and are not projectable to the population of 61 VFC grantees or approximately 44,000 providers.

TempTale® measurements and differences between TempTale® measurements and providers' recorded temperatures were not adjusted to account for each device's accuracy range. The accuracy range for TempTale® devices is ±2°F from -22°F to 0°F and ±1°F from 0°F to 122°F. No standard accuracy range was established for the providers' temperature-monitoring devices because of the wide variety of devices used by providers.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

VFC vaccines stored by 76 percent of 45 providers we reviewed were exposed to inappropriate temperatures

Although the majority of storage temperatures we independently measured during a 2-week period were within the required ranges, VFC vaccines stored by 76 percent—34 of 45—of the selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period.[54] We also found that all 45 providers had recorded temperatures that differed from our independently measured temperatures during the 2-week period.

Sixteen of the thirty-four providers had both freezers and refrigerators that exposed VFC vaccines to temperatures outside the required ranges for 5 or more hours during the 2-week period. If the 34 providers' freezer and refrigerator temperatures followed this same pattern for a year, these storage units could expose vaccines to inappropriate temperatures for at least 130 hours over 1 year.[55] On the days of our site visits, the 34 providers had 9,173 VFC vaccine doses, worth approximately $368,820. See Appendix E for cumulative and consecutive hours during which these 34 providers' freezers and refrigerators were outside the required ranges, as well as additional storage temperature information for the 2-week period.

Freezer storage. VFC vaccines stored in 28 of 41 selected providers' freezers were exposed to temperatures above the maximum permitted temperature (5°F) for at least 5 cumulative hours during the 2-week period.[56, 57] Eleven of these providers' freezers were above 5°F for more than 120 hours, representing at least 36 percent of the total 2-week period of our independent temperature measurement. One provider's freezer was above 5°F for 94 percent of the total 2-week period, including a span of 44 consecutive hours. Additionally, three providers' freezers had a maximum temperature of at least 33°F during the 2-week period, and one of these reached 44°F. Exposure to temperatures above 5°F may cause

[54] Eighty-three percent and eighty-seven percent of independently measured freezer and refrigerator temperatures, respectively, were within the required temperature ranges during the 2-week period.

[55] Assuming each freezer or refrigerator was outside the required range for at least 5 hours during all 26 2-week periods for 1 calendar year.

[56] Four selected providers did not have VFC vaccines stored in freezers on the days of our site visits.

[57] The accuracy range for TempTale® devices placed in providers' freezers is ±2°F from -22°F to 0°F and ±1°F from 0°F to 122°F. Eighty-nine percent of our independently measured freezer temperatures were within 1°F of the required range, and 93 percent of our independently measured freezer temperatures were within 2°F.

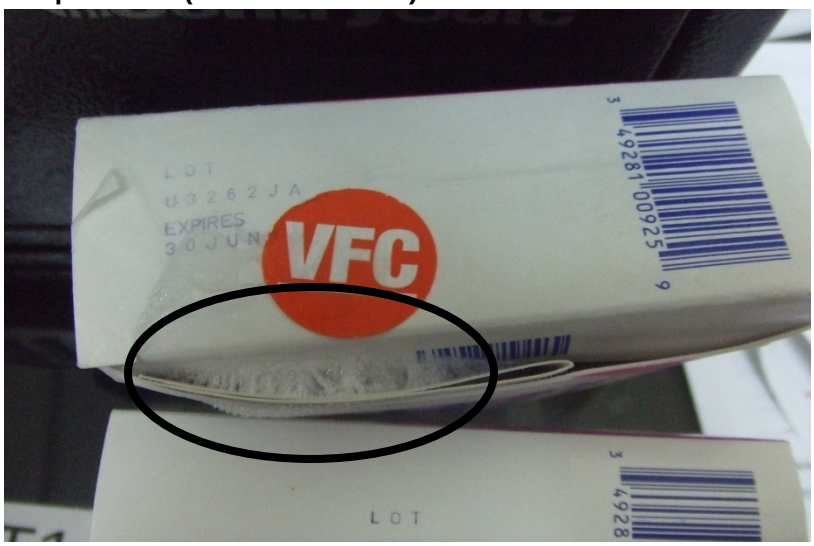
vaccines to lose their ability to provide maximum protection against preventable disease. The 28 providers stored 992 VFC vaccine doses in their freezers on the days of our site visits, worth approximately $67,660.

Refrigerator storage. VFC vaccines stored in 22 of 45 selected providers' refrigerators were exposed to temperatures outside the required range (above 46°F, below 35°F, or both) for at least 5 cumulative hours during the 2-week period.[58] Four providers' refrigerated vaccines were exposed to temperatures above 46°F for at least 5 cumulative hours during the 2-week period, and 19 providers' refrigerated vaccines were exposed to temperatures below 35°F for at least 5 hours. One provider's refrigerated VFC vaccines were exposed to temperatures both above 46°F and below 35°F for at least 5 hours during the 2-week period. The highest and lowest independently measured refrigerator temperatures among the 22 refrigerators were 60°F and 21°F, respectively. Exposing vaccines to high or low temperatures can reduce their potency and efficacy, increasing the risk that the vaccine may not provide children with maximum protection against preventable diseases. The 22 providers stored 8,181 VFC vaccine doses in their refrigerators on the days of our site visits, worth approximately $301,160.

Six providers' refrigerated VFC vaccines were exposed to temperatures outside the required range for more than 120 hours, including one provider's refrigerator that was above 46°F for 265 hours (79 percent) of the total 2-week period. Vaccines of eight providers whose refrigerated vaccines were exposed to temperatures outside the required range for at least 5 hours were exposed to freezing temperatures (i.e., temperatures at or below 32°F) during the 2-week period, and one refrigerator storing VFC vaccines had an average temperature below 32°F for the 2-week period. See Photo 1 for an example of a refrigerated vaccine exposed to freezing temperatures, as demonstrated by the ice on the exterior of the box (circled).

[58] The accuracy range for TempTale® devices placed in providers' refrigerators is ±1°F from 0°F to 122°F. Ninety-two percent of our independently measured refrigerator temperatures were within ±1°F of the required range.

Photo 1: Box of Refrigerated Influenza Vaccine Exposed to Freezing Temperatures (Note Ice in Circle)



All 45 providers recorded temperatures that differed from our independently measured temperatures

All 45 selected providers recorded temperatures that differed from our independently measured temperatures at least once during the 2-week period. These differences indicate that providers' thermometers were not representing accurate temperatures or providers were not accurately recording the temperature readings.

Twenty-five providers recorded at least 1 freezer temperature and 24 providers recorded at least 1 refrigerator temperature that differed from our independent measurement by at least 5ºF. For example, one provider recorded a refrigerator temperature that differed from our independent measurement by 17°F. This provider recorded a temperature of 40°F on the temperature-monitoring log, while the TempTale® recorded a temperature of 23°F for the same time period, well below the temperature necessary to inappropriately freeze the vaccines and reduce their potency and efficacy. On average, providers' recorded freezer and refrigerator temperatures varied from our independently measured temperatures by 4°F and 2°F, respectively.[59]

[59] Comparison does not apply for four providers without freezers storing VFC vaccines. In addition, we were unable to compare all recorded freezer temperatures for 21 providers to independently measured temperatures because of the temperature log formats. For example, the minimum possible recorded freezer temperature was ≤ 3°F on many providers' temperature logs. In these instances, we assumed the recorded temperature was 3°F and calculated a difference only if the TempTale® temperature for the same time was greater than 3°F. Comparison was not possible for seven providers' freezers.

In addition, only 12 of the 45 selected providers' temperature-monitoring logs for 2010 included a temperature outside the required storage ranges. Further, less than 1 percent of these providers' total temperature recordings were outside the required ranges.[60] Three of the twelve providers did not document any actions taken as a result of temperatures' being outside the required ranges. The remaining nine providers documented actions such as notifying the appropriate vaccine manufacturer, notifying the grantee, adjusting the storage unit temperature, and moving the vaccines to another unit until the problem was resolved. If the same pattern of differences we found during the 2-week period between the TempTale®-recorded temperatures and the provider-recorded temperatures existed throughout 2010, VFC vaccines were likely exposed to temperatures outside required ranges more frequently than providers documented.

Sixteen of forty-five providers we reviewed had expired VFC vaccines

According to FDA requirements, providers should not administer expired vaccines because they may not provide maximum protection against preventable diseases.[61] Additionally, providers must remove expired vaccines from freezers and refrigerators containing nonexpired vaccines to prevent mistakenly administering expired vaccine. Thirty-six percent (16 of 45) of selected providers had expired vaccines on the days of our site visits. Expired vaccines were an average of 186 days past their expiration dates on the days of our site visits, ranging from 6 to 673 days past expiration. Thirteen providers stored expired vaccines with nonexpired vaccines, increasing the risk of mistakenly administering the expired vaccine.

We identified 579 expired vaccine doses, worth $14,645, which represents 3 percent of VFC vaccines we observed.[62] If 3 percent of all VFC vaccines ordered during 2010 were allowed to expire, approximately 2.4 million VFC vaccine doses would be subject to waste during the year. See Photo 2 for an example of an expired vaccine identified during one of our site visits.

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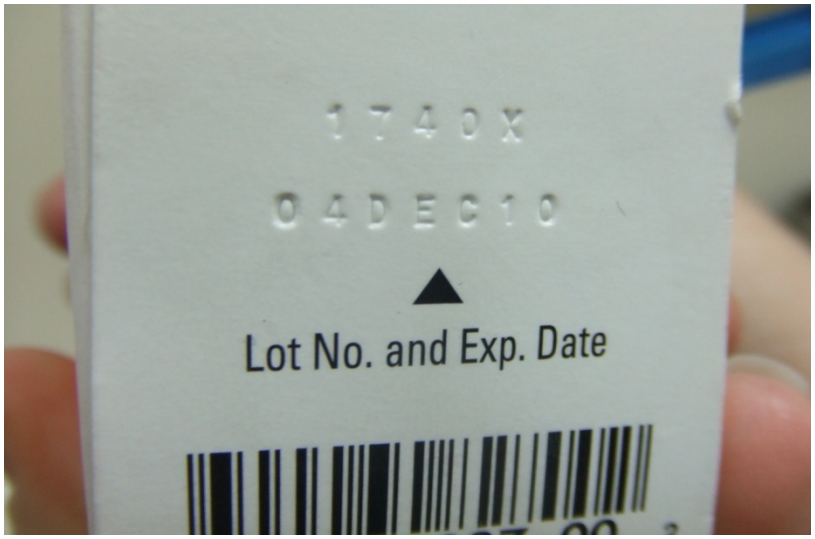
[60] The 12 providers recorded 74 instances of temperatures outside required ranges out of a possible 11,520 instances for 2010.

[61] 21 CFR §§ 610.50, 610.53.

[62] Seventy-three percent of identified expired vaccines were seasonal influenza vaccines. Seasonal influenza vaccines expire at the end of each flu season. Utilization of seasonal influenza vaccines varies from year to year, depending on the severity of the flu season.

Photo 2: Varicella Vaccine, With an Expiration Date of 04 Dec 2010, Identified During Site Visit on 21 April 2011



Providers must also monitor vaccine expiration dates to identify vaccines that they do not expect to administer before expiration. Providers should notify grantees of vaccines that will expire before the providers can administer them. The grantees should then determine the appropriate action to take to prevent vaccine waste. However, 7 of the 45 providers indicated that they do not notify grantees upon identifying vaccines that will expire before they can administer them.

None of the 45 providers we reviewed met the vaccine management requirements in all 10 categories

None of the forty-five selected VFC providers performed all required activities within each of the 10 vaccine management categories established in the *VFC Operations Guide*. As a result, the 20,252 VFC vaccine doses that we observed during site visits may not provide children with maximum protection against preventable disease and may be vulnerable to fraud, waste, and abuse. These doses were worth approximately $800,000. In addition, 38 of 45 selected providers did not have all required VFC documentation.

Forty of the forty-five selected providers did not meet all requirements in at least half of the vaccine management categories

Forty selected providers did not meet all requirements in at least 5 of the 10 requirement categories. The highest number of categories in which any provider met all requirements was 8 (1 provider), and 7 of the 45 selected

providers met all requirements in 2 or fewer categories. Table 1 shows the number and percentage of providers that did not meet the requirements in each category. See Appendix F to see in which of the 10 categories each provider did not meet all requirements.

Table 1: Number and Percentage of Selected Providers That Did Not Meet All Requirements in Vaccine Management Categories

Category of Vaccine Management Requirements	Number of Providers That Did Not Meet All Requirements in Category (n=45)	Percentage of Providers That Did Not Meet All Requirements in Category (n=45)
Vaccine Storage Equipment	43	96%
Vaccine Storage Practices	42	93%
Temperature Monitoring	40	89%
Vaccine Storage and Handling Plans	38	84%
Vaccine Personnel	37	82%
Vaccine Waste	24	53%
Vaccine Security and Equipment Maintenance	18	40%
Vaccine Ordering and Inventory Management	17	38%
Receiving Vaccine Shipments	14	31%
Vaccine Preparation	1	2%

Source: OIG analysis of selected VFC provider documentation and site visit observations, 2011.

Of the 43 providers that did not meet all requirements in the Vaccine Storage Equipment category, 3 were permanently storing VFC vaccines in dorm-style storage units on the days of our site visits.[63] VFC program requirements do not allow the use of dorm-style units for permanent VFC vaccine storage because such units are unable to reliably maintain temperatures within required ranges. The average standard deviation of the temperatures recorded in dorm-style refrigerator units was approximately two times the average standard deviation for all refrigerator types.[64] See Photo 3 for an example of the interior of a dorm-style storage unit that a VFC provider used for permanent VFC vaccine storage. Note frost buildup on the bottom of the freezer compartment (circled).

[63] The three providers were using a total of four dorm-style units to permanently store VFC vaccines.

[64] The average temperature for dorm-style units during the 2-week period was 38°F with a standard deviation of 4°F. In contrast, combined units had an average temperature of 39°F with a standard deviation of 2°F and stand-alone units averaged 40°F with a standard deviation of 1°F. The overall standard deviation for all refrigerators we observed was 2°F. Sensitech analysis of TempTale® data, 2011.

Photo 3: Dorm-Style Unit Used for Permanent VFC Vaccine Storage (Note Frost Buildup in Circle)

Selected providers also did not meet thermometer requirements included in the Vaccine Storage Equipment category. Specifically, thermometers were not always calibrated or centrally placed within the VFC vaccine storage units. For example, 38 providers had at least 1 thermometer that was not calibrated as required in their freezers and/or refrigerators.[65] Our independently measured temperatures showed that VFC vaccines stored by 28 of these 38 providers were exposed to temperatures outside required ranges for at least 5 cumulative hours during the 2-week period. In addition, 14 providers did not have at least 1 centrally placed thermometer in their respective freezers, and 23 providers did not have a centrally placed thermometer in their respective refrigerators. Of these 14 and 23 providers, our independently measured temperatures showed that 8 and 11, respectively, stored vaccines outside the required temperature ranges for at least 5 hours. Without calibrated, centrally placed thermometers, providers cannot ensure that their VFC freezers and refrigerators are maintaining temperatures within the required ranges.

[65] We either did not observe a current (nonexpired) calibration sticker on the providers' thermometers or the providers did not provide documentation demonstrating the thermometers were calibrated as required.

Thirty-eight of forty-five selected providers did not have all required documents

Thirty-eight of forty-five selected VFC providers did not have at least one of seven required VFC program documents. For example, providers must maintain records to demonstrate that relevant staff were trained on how to transport vaccines in an emergency. Without this training, providers may not ensure that vaccines are maintained within the required temperature ranges during an emergency, such as a power outage. Table 2 shows the number and percentage of providers that did not have each of the seven required documents. See Appendix G for the required documents not provided by each of the 45 providers.

Table 2: Number and Percentage of Selected Providers Without Required Documents

Required Document	Number of Selected VFC Providers Without Document (n=45)	Percentage of Selected VFC Providers Without Document (n=45)
VFC vaccine management training records	32	71%
Documentation demonstrating the process to ensure that VFC vaccines are administered only to the VFC-eligible population	15	33%
Routine storage and handling plan	14	31%
Emergency storage and handling plan	12	27%
Current provider enrollment form*	8	18%
Current provider profile form*	8	18%
Calendar year 2010 temperature-monitoring logs	3	7%

* We also reviewed grantee documentation to determine whether providers had current enrollment and profile forms. If a grantee had the document, we considered the provider to have the document for these analyses.

Source: OIG analysis of selected VFC provider documentation, 2011.

None of the five VFC grantees we reviewed met all oversight requirements, and grantee site visits were not effective in ensuring that providers met VFC requirements over time

None of the five selected VFC grantees met all of the oversight requirements we reviewed, including accountability requirements, establishing comprehensive fraud and abuse policies, and providing required vaccine management materials to VFC providers. In addition,

grantee site visits did not ensure that providers met vaccine management requirements over time.

Two of the five selected VFC grantees did not meet two accountability requirements

Two selected VFC grantees each did not meet two of the four vaccine accountability requirements established in the *VFC Operations Guide*. The three remaining grantees met all four vaccine accountability requirements. One of the two grantees that did not meet all four accountability requirements did not ensure that vaccines purchased with VFC funds were administered only to VFC-eligible children or that vaccines were ordered on the basis of the size of a provider's VFC-eligible population. The other grantee did not ensure that vaccine loss and waste were minimized and measured or that the VFC program was protected against fraud and abuse. Grantees that do not implement these four requirements may have an increased risk of fraud, waste, and abuse in their VFC programs.

None of the selected grantees' fraud and abuse policies addressed all required activities

None of the selected grantees' fraud and abuse policies addressed all eight activities needed to establish a comprehensive fraud and abuse mitigation plan. According to the *VFC Operations Guide*, all grantees should have well-defined processes for (1) the prevention and identification of fraud and abuse and (2) the investigation and resolution of suspected cases of fraud and abuse within their VFC programs. None of the selected grantees' fraud and abuse policies addressed the following two activities:
(1) comparing enrolled providers to exclusion databases and
(2) developing a procedure for reporting provider terminations. In addition, four of the five selected grantees' fraud and abuse policies did not include a fraud and abuse referral procedure. Also, four of five grantees did not establish an allegation and referral database in their policies. Table 3 shows the number and percentage of selected grantees whose fraud and abuse policies did not include each of the eight required activities. See Appendix H for the activities not included in each selected grantee's fraud and abuse policy.

Table 3: Number and Percentage of Selected Grantees Whose Fraud and Abuse Policies Did Not Include Each Required Activity

Required Activity	Number of Grantees' Fraud and Abuse Policies Without Required Activity (n=5)	Percentage of Grantees' Fraud and Abuse Policies Without Required Activity (n=5)
Comparing enrolled providers to exclusion databases	5	100%
Developing a procedure for reporting VFC provider terminations	5	100%
Developing a fraud and abuse referral procedure	4	80%
Creating an allegation and referral database	4	80%
Identifying oversight personnel	3	60%
Creating a protocol to annually review fraud and abuse policies	3	60%
Developing a procedure for monitoring the VFC Program	2	40%
Developing training materials for VFC personnel	2	40%

Source: OIG analysis of selected grantees' fraud and abuse policies, 2011.

None of the selected grantees provided required vaccine management materials to all providers

None of the five selected grantees provided required vaccine management materials to all nine selected VFC providers in their respective jurisdictions. These materials are intended to assist VFC providers in meeting the vaccine management requirements in the *VFC Operations Guide*. Grantees must give providers a standardized vaccine management plan template, which providers may use to meet the routine and emergency storage and handling plan requirements. Fourteen selected providers did not have overall vaccine management plans.

In addition, grantees did not provide standard operating procedures to all providers, as required. At least seven of the nine selected providers in each grantee jurisdiction did not provide at least one of the eight written procedures that we requested during our site visits.

Finally, one grantee provided inaccurate guidance to VFC providers in its jurisdiction. This grantee provided a temperature-monitoring log template that instructed providers to maintain the logs for 1 year; however, the *VFC Operations Guide* requires these logs to be maintained for a minimum of 3 years.

Site visits by the selected grantees did not ensure that providers met vaccine management requirements over time

Twenty-five of the forty-five selected VFC providers had a grantee site visit during the 12 months prior to our site visits. However, the results of our site visits for these 25 providers differed from those of the grantees. We determined during our site visits that, on average, these 25 providers did not meet 6 vaccine management requirements, whereas grantees determined that providers did not meet an average of 2 requirements. Overall, we found that 21 of the 25 providers met fewer vaccine management requirements during our site visits than during grantee site visits conducted within the previous 12 months. For example, 2 of these 25 providers were using dorm-style units to store their VFC vaccines when we conducted our site visits. However, the grantees' site visits—including one grantee site visit conducted less than 2 months before our site visit—did not identify these dorm-style units. In addition, five providers did not have routine or emergency handling plans on the days of our site visits. However, the grantee site visit reports noted that these providers did have such plans.[66] We could not determine whether the grantee site visit results were not accurate or whether providers had been in compliance with vaccine storage requirements at the time of the grantee site visits and later stopped following program requirements. In either case, site visits were not effective in ensuring that providers met vaccine management requirements over time.

[66] The time interval between grantees' site visits for these five providers and our site visits ranged from 5 days to 344 days.

CONCLUSION AND RECOMMENDATIONS

Although the majority of storage temperatures we independently measured during a 2-week period were within the required ranges, VFC vaccines stored by 76 percent—34 of 45—of the selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period. If these 34 providers' freezer and refrigerator temperatures followed this same pattern for a year, these storage units could expose vaccines to inappropriate temperatures for at least 130 hours over 1 year. The 34 providers had 9,173 VFC vaccine doses on the days of our site visits, worth approximately $368,820.

Additionally, 16 of 45 selected providers had expired VFC vaccines. Thirteen of these providers did not remove their expired vaccines from freezers or refrigerators containing nonexpired vaccines, increasing the risk that the expired vaccines could be mistakenly administered. Expired vaccines accounted for 3 percent of all VFC vaccines observed on the days of our site visits. If 3 percent of all VFC vaccines ordered during 2010 were allowed to expire, approximately 2.4 million VFC vaccine doses would be subject to waste during the year.

None of the 45 selected providers that we reviewed managed VFC vaccines according to all vaccine management requirements, and 38 providers did not have all required documents. In addition, none of the five VFC grantees that we reviewed met all oversight requirements or provided required vaccine management materials to all selected VFC providers in their jurisdictions. Finally, grantees' site visits to 25 selected providers did not ensure that these providers met vaccine management requirements over time.

To address our findings, we recommend that CDC continue to work with grantees and providers to:

Ensure That VFC Vaccines Are Stored According to Requirements

The *VFC Operations Guide* requires grantees to ensure that VFC providers have appropriate equipment to meet the vaccine management requirements during enrollment site visits. CDC should continue to work with grantees, providers, and professional organizations to ensure that VFC vaccines are stored and temperatures are monitored according to program and FDA requirements. Specifically, grantees should ensure that providers have freezers and refrigerators that can maintain vaccines within

the required temperature ranges, as well as accurate temperature-monitoring devices that are regularly calibrated and centrally placed within freezers and refrigerators. Providers without appropriate equipment, such as those with dorm-style storage units or noncalibrated thermometers, should not receive VFC vaccines.

Ensure That Expired VFC Vaccines Are Identified and Separated From Nonexpired Vaccines

CDC and grantees should continue to work with providers and professional organizations to ensure that VFC providers monitor vaccine expiration dates to identify expired vaccines. In addition, providers should immediately remove expired vaccines from freezers and refrigerators used to store nonexpired vaccines to prevent inadvertent administration of expired vaccines. If expired vaccines are mistakenly administered, they may not provide children with maximum protection against preventable disease. To reduce the likelihood of administering expired vaccines, grantees should ensure that providers immediately report expired vaccines and ensure that providers follow the grantees' guidance on the disposal of expired vaccines. Where possible, grantees should ensure that providers return expired VFC vaccines for excise tax credit.

Ensure That Grantees Better Manage Providers' Vaccine Inventories

CDC and grantees should improve vaccine inventory management systems and procedures to ensure that providers' vaccine orders reflect their needs and reduce vaccine waste. Before approving vaccine orders, grantees should review providers' profile forms; their inventories of current vaccine, including expiration dates; and their doses-administered reports. Further, grantees should ensure that providers notify them upon identifying vaccines that will expire before the providers can use them. To prevent program waste, grantees should consider alternate approaches, such as increasing the use of these vaccines through vaccination drives. Improved inventory systems and procedures for vaccine management can prevent provider stockpiling and excessive inventories of all VFC vaccines, including seasonal flu vaccines.

Ensure That Grantees Meet Oversight Requirements

CDC should review grantees' activities and materials to ensure that they meet oversight requirements. Before distributing vaccines to providers, CDC should review grantees' policies for ensuring accountability and preventing fraud and abuse, as well as the training materials, the written

procedures, and document templates they have developed for providers. CDC should ensure that grantees' templates and training materials focus on: (1) the vaccine management requirements that selected providers met least frequently and that have the greatest impact on vaccine potency and efficacy and (2) VFC program accountability requirements. Finally, CDC should review the reports from grantees' annual site visits to identify grantees' specific needs for provider training. CDC should periodically train grantees' site visit staffs to ensure that grantee site visits to providers result in improved vaccine management and program accountability.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC concurred with all four of our recommendations and noted that vaccination is one of the most successful public health tools in preventing and controlling disease. According to CDC, the United States has achieved 90-percent or greater reduction in most vaccine-preventable diseases through public and private vaccination efforts. Further, CDC noted that 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. Therefore, CDC believes that its efforts to strengthen VFC program storage and handling practices will help improve vaccination services nationally and benefit children vaccinated with both publicly and privately purchased vaccines.

With regard to our first recommendation, CDC stated that it will work with its partners, including State health officials, immunization program managers, and professional organizations, to improve compliance with vaccine storage equipment and temperature-monitoring requirements to ensure proper vaccine storage.

With regard to the second and third recommendations, CDC said that it is implementing significant changes to the VFC vaccine ordering and provider inventory reporting systems. Improvements to these systems and associated processes will result in better vaccine management, reducing the risk of expired vaccines. CDC will also review its guidance and training materials to ensure that program requirements related to managing expired vaccines are communicated to and understood by VFC providers and grantees.

With regard to our fourth recommendation, CDC stated that it will work with VFC grantees and provider organizations to ensure that program requirements are necessary for effective program oversight. In addition, CDC will task working groups with reviewing VFC provider site visit procedures and documentation to ensure that site visits are effective in enforcing program requirements.

We support CDC's efforts to address these issues and encourage it to continue making progress. For the full text of CDC's comments, see Appendix I.

APPENDIX A

Vaccines for Children Program Vaccines and Required Storage Temperatures		
Vaccines That Must Be Stored Between 35°F and 46°F		
Vaccine	**Brand**	**Manufacturer**
Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DtaP)	Daptacel Tripedia	Sanofi Pasteur, Inc.
	Infanrix	GlaxoSmithKline Biologicals
Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus Vaccine Combined (DtaP-Hep B- IPV)	Pediarix	GlaxoSmithKline Biologicals
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (DtaP-IPV)	KINRIX	GlaxoSmithKline Biologicals
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus* b Conjugate (Tetanus Toxoid Conjugate) Vaccine (DtaP-IP-HI)	Pentacel	Sanofi Pasteur, Inc.
Haemophilus b Conjugate (Meningococcal Protein Conjugate) (Recombinant) (Hepatitis B-Hib)	Comvax	Merck & Co., Inc.
Haemophilus b Conjugate (Meningococcal Protein Conjugate) (Hib)	PedvaxHIB	Merck & Co., Inc.
Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (Hib)	ActHIB	Sanofi Pasteur, Inc.
	Hiberix	GlaxoSmithKline Biologicals
Hepatitis A Vaccine, Inactivated	VAQTA	Merck & Co., Inc.
	Havrix	GlaxoSmithKline Biologicals
Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine (Hepatitis A - Hepatitis B)	Twinrix	GlaxoSmithKline Biologicals
Hepatitis B Vaccine (Recombinant)	Engerix-B	GlaxoSmithKline Biologicals
	Recombivax HB	Merck & Co., Inc.
Human Papillomavirus Bivalent (Types 16, 18) Vaccine, Recombinant (HPV)	Cervarix	GlaxoSmithKline Biologicals
Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (HPV)	Gardasil	Merck & Co., Inc.
Influenza Vaccine, Live, Intranasal	FluMist	MedImmune, LLC.
Influenza Virus Vaccine, Trivalent, Types A and B	Fluvirin	Novartis Vaccines and Diagnostics Ltd.
	Fluzone	Sanofi Pasteur, Inc.
Measles, Mumps, and Rubella Virus Vaccine, Live (MMR)	M-M-R II	Merck & Co., Inc.
Meningococcal Polysaccharide (Serogroups A, C, Y, and W-135) Diphtheria Toxoid Conjugate Vaccine	Menactra	Sanofi Pasteur, Inc.
Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Menveo	Novartis Vaccines and Diagnostics, Inc.

continued on next page

Appendix A, continued

Vaccines for Children Program Vaccines and Required Storage Temperatures		
Vaccines That Must Be Stored Between 35°F and 46°F		
Vaccine	**Brand**	**Manufacturer**
Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein) (PCV)	Prevnar 13	Wyeth Pharmaceuticals Inc.
Pneumococcal Vaccine, Polyvalent	Pneumovax 23	Merck & Co, Inc
Poliovirus Vaccine Inactivated (Monkey Kidney Cell) (e-IPV)	IPOL	Sanofi Pasteur, SA
Rotavirus Vaccine, Live, Oral	ROTARIX	GlaxoSmithKline Biologicals
Rotavirus Vaccine, Live, Oral, Pentavalent	RotaTeq	Merck & Co., Inc.
Tetanus and Diphtheria Toxoids	Decavac	Sanofi Pasteur, SA
	MassBiologics	MassBiologics
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)	Adacel	Sanofi Pasteur, Inc.
	Boostrix	GlaxoSmithKline Biologicals
Vaccines That Must Be Stored at or Below 5°F		
Measles, Mumps, Rubella, and Varicella Virus Vaccine Live (MMR-V)*	ProQuad	Merck & Co., Inc.
Varicella Virus Vaccine Live*	Varivax	Merck & Co., Inc.

* These vaccines are also available in refrigerator-stable versions that can be stored in either a freezer or a refrigerator. Refrigerator-stable MMR-V and Varicella vaccines that are first stored in a freezer and subsequently stored in a refrigerator should not be refrozen and must be used within 72 hours.

Sources: FDA, *Vaccines licensed for immunization and distribution in the US with supporting documents*. Accessed at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm on November 29, 2010.

CDC, *CDC vaccine price list*. Accessed at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm on November 29, 2010.

APPENDIX B

Vaccines for Children Program Vaccine Management Requirements for Providers	
Requirement Category	**Required Activities**
Vaccine Storage Equipment	Providers must have appropriate equipment that can store vaccine and maintain proper conditions. For detailed information on refrigerators and freezers, grantees and providers should refer to [the Centers for Disease Control and Prevention's (CDC)] *Vaccine Storage and Handling Toolkit*. Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with separate exterior door, or 2) stand-alone, single-purpose refrigerators and freezers.
	Refrigerators or freezers used for vaccine storage must be able to maintain required vaccine storage temperatures year-round.
	Refrigerators or freezers used for vaccine storage must be large enough to hold the year's largest inventory.
	Refrigerators or freezers used for vaccine storage must have a working thermometer calibrated with certificate in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment; follow manufacturer's recommended schedule for recalibration.
	Refrigerators or freezers used for vaccine storage must be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.)
	A dormitory-style refrigerator (a small combination refrigerator-freezer unit outfitted with a single external door) is **never acceptable for permanent storage** of Vaccines for Children (VFC) vaccines …. At the grantee's discretion, providers may use dormitory-style refrigerators to **temporarily** store a clinic's single-day supply of **refrigerated** vaccines. The freezer portion of a dormitory-style refrigerator must never be used to store any vaccine …. Grantees have the discretion to ban the use of dormitory-style refrigerators among providers altogether, even for temporary storage. However, for grantees choosing to allow the use of dormitory-style refrigerators under limited conditions for short-term (temporary) storage of VFC vaccines, the following conditions must apply: 1. The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient. **2. The unit is never used for storing varicella-containing vaccines.** 3. Only small amounts of inactivated vaccines are maintained in these units. The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day. 4. The vaccine is returned to the main storage unit at the end of each clinic business day, and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business. 5. Each unit has a dedicated calibrated thermometer in place. 6. **Temperatures are visually monitored and documented twice a day on a temperature log specifically for that unit.** Appropriate action is immediately taken when the temperatures are outside the appropriate range. 7. These units must be included and examined during the VFC compliance site visit and corrective actions taken and documented by the grantee if any of the above conditions are not met.
Vaccine Storage Practices	The vaccine storage practices … are the responsibility of the provider/clinic vaccine coordinator or the vaccine coordinator's backup. If delegated to the backup, the designated vaccine coordinator must monitor these activities regularly.
	Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
	Notify the immunization program of any vaccine doses that will expire before they can be administered.
	Only with the approval and direct guidance of the immunization program and only if the cold chain can be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer it before it expires.

Continued on next page

Appendix B, continued

Vaccines for Children Program Vaccine Management Requirements for Providers	
Requirement Category	**Required Activities**
Vaccine Storage Practices (cont'd)	Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
	Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
	Space stored vaccine to allow for cold air circulation around the vaccine.
	Never store vaccines in the door of the storage unit.
	Never store food or drink in the storage unit.
Temperature Monitoring	Temperature monitoring should be the primary responsibility of the provider/clinic vaccine coordinator and back-up. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.
	Post a temperature log on the vaccine storage unit door or nearby in a readily accessible and visible location.
	Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35°F and 46°F. The freezer temperature should be 5°F or lower. Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
	Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the temperature log.
	Maintain an ongoing file of temperature logs, and store completed logs for at least 3 years.
Vaccine Storage and Handling Plans	Providers must have written routine and emergency storage and handling plans. They may develop their own or customize the grantee-supplied storage and handling templates to reflect their office practice …. Both plans should be reviewed and updated as necessary.
	The routine vaccine storage and handling plan should include guidance on routine vaccine management process/practices. Please refer to "Routine Vaccine Storage and Handling Plan Worksheet" in the *Vaccine Storage and Handling Toolkit*.
	The emergency vaccine storage and handling plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. Please refer to "Emergency Vaccine Retrieval and Storage Plan Worksheet" found in the *Vaccine Storage and Handling Toolkit*.
	In any type of power outage: - Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location. - Temperatures and duration of power outage must be monitored; vaccine should not be discarded or administered until the situation has been discussed with public health authorities.
	At a minimum, the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff that have responsibilities specified in the emergency plan.

Continued on next page

Appendix B, continued

Vaccines for Children Program Vaccine Management Requirements for Providers	
Requirement Category	**Required Activities**
Vaccine Personnel	Designate one staff member to be the primary vaccine coordinator and at least one backup vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office.
	The designated vaccine coordinator and backup must be responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended ranges and documenting the temperature on the temperature logs for each storage unit twice a day.
	Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training must be kept and displayed as documentation.
	Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office.
Vaccine Waste	Notify immediately the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines after discovery of the incident. Follow the guidance of the grantee on how to document and report the incident ….
	Implement written protocols for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.
	Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration.
	Return, as directed by the grantee, all spoiled or expired publicly purchased vaccines for excise tax credit.
Vaccine Security and Equipment Maintenance	Post "DO NOT DISCONNECT" notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.
Vaccine Ordering and Inventory Management	Order vaccine in accordance with actual vaccine need.
	Develop and maintain complete, accurate, and separate stock records for both publicly and privately purchased vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock.
Receiving Vaccine Shipments	VFC vaccine shipments received from the distributor contain heat and freeze exposure indicators. VFC direct shipments of frozen vaccine from manufacturers are shipped in specialized boxes and do not contain heat indicators.
	Immediately upon delivery of vaccine, check the vaccine cold chain monitors, if included, and store vaccine according to manufacturers' product specifications.
	Take proper action if either the freeze or heat cold chain monitor was activated. Instructions for reading the monitors are printed on the monitor cards.

Continued on next page

Appendix B, continued

Vaccines for Children Program Vaccine Management Requirements for Providers	
Requirement Category	**Required Activities**
Receiving Vaccine Shipments (cont'd)	Document heat or freeze monitor readings if indicative of out-of-range temperature exposure, and contact the State immunization program for further guidance. Document actions taken based on State immunization program instructions.
	If the provider believes that a vaccine shipment is compromised, temperature monitors are out of range, or a heat monitor is not activated (i.e., turned on), the provider should also contact McKesson Customer Service within 2 hours of vaccine shipment delivery time.
	Develop policies and protocols for maintaining the vaccine cold chain during transport to offsite clinics or emergency storage locations.
Vaccine Preparation	The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention, strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** pre-draw doses before they are needed.
Source: CDC, *VFC Operations Guide*, Module 6: Vaccine Management, pp. 1-12, January 2011.	

APPENDIX C

Five Vaccines for Children Program Grantees With Highest Vaccine Order Volumes

Grantee	Vaccine Doses Ordered	Percentage of Total Vaccine Doses Ordered
California	9,466,260	12%
Texas	8,749,080	11%
Florida	4,301,029	5%
New York City	3,412,996	4%
Georgia	3,244,547	4%
Total Vaccine Doses Ordered for Top Five Grantees	**29,173,912**	**36%**
Total Vaccine Doses Ordered for All Grantees	**81,632,576**	**100%**

Source: Data provided by Centers for Disease Control and Prevention officials, December 20, 2010, and January 14, 2011. Data reflect volume of vaccine orders for fiscal year 2010.

APPENDIX D

Vaccines for Children Program Providers in the Five Selected Grantee Jurisdictions by Sample Selection Characteristics				
Characteristic	**Number of Vaccines for Children (VFC) Providers in Population for Selected Grantees**	**Percentage of VFC Providers in Population for Selected Grantees**	**Number of VFC Providers in Sample**	**Percentage of VFC Providers in Sample**
Provider Type				
Private Practice	8,235	74%	33	73%
Public Health Department	928	8%	4	9%
Federally Qualified Health Center or Rural Health Clinic	823	7%	3	7%
Other Public Health Provider	785	7%	3	7%
Private Hospital	313	3%	2	4%
Grantees' Total Providers by Selected Provider Types[1]	**11,084**	**99%[2]**	**45**	**100%**
Vaccine Order Volume				
Low Volume	5,128	42%	19	42%
High Volume	7,171	58%	26	58%
Grantees' Total Providers by Volumes	**12,299**	**100%**	**45**	**100%**
Location Type				
Rural	336	9%	5	11%
Urban	3,266	91%	40	89%
Grantees' Total Providers by Location Types[3]	**3,602**	**100%**	**45**	**100%**

Source: Data provided by Centers for Disease Control and Prevention officials, December 20-29, 2010.

[1] Total providers by type differs from total providers by volume because we limited our sample to these five provider types. The remaining 1,215 providers were types not included in our sample.

[2] Figures do not sum to 100 because of rounding.

[3] Only providers within 100 miles of the grantees' VFC program office locations were included in our sample.

APPENDIX E

Selected Vaccines for Children Program Providers With Storage Units Outside the Required Temperature Range During a 2-Week Period

Table E-1: Twenty-eight Freezers Above 5°F for at Least 5 Cumulative Hours

Provider	Cumulative Hours Above Required Range	Longest Consecutive Hours Above Required Range	Mean Temperature During Entire 2-Week Period (°F)	Standard Deviation During Entire 2-Week Period (°F)	Temperature Range During Entire 2-Week Period (°F)	Thermometer Type(s)	Unit Type
28	316.5	43.8	8.1	4.3	4.6 – 28.3	Digital, Min-Max Standard Fluid	Combined
27	202.0	23.3	5.6	1.6	1.9 – 16.2	Standard Fluid	Combined
10	195.3	3.0	5.7	2.7	-2.1 – 15.1	Standard Fluid	Combined
36	162.0	2.3	5.6	2.8	2.7 – 22.3	Digital Digital, Min-Max	Combined
20	138.5	20.0	3.4	6.5	-11.4 – 44.3	Dial Digital, Min-Max	Combined
13	133.3	1.3	3.5	3.8	-4.4 – 10.7	Dial	Combined
31	131.3	0.5	2.7	5.2	-6.7 – 11.4	Digital Standard Fluid (2)	Stand-alone
25	130.3	0.5	4.5	1.5	2.2 – 9.5	Digital Standard Fluid	Stand-alone
8	125.3	3.8	2.9	6.0	-7.1 – 14.4	n/a	Stand-alone
3	123.0	12.3	3.0	5.3	-12.8 – 23.6	Standard Fluid	Combined
41	120.3	2.3	-0.2	9.6	-20.7 – 19.8	Standard Fluid	Combined
30	79.8	1.5	2.5	4.5	-7.2 – 33.4	Standard Fluid	Combined
43	65.0	44.0	3.3	2.6	-1.3 – 15.9	Standard Fluid (2)	Combined
24	43.8	2.5	3.7	2.6	-1.9 – 25.8	Digital, Min-Max	Combined
17	43.3	5.0	2.4	3.7	-1.6 – 30.8	Standard Fluid	Combined
5	37.5	3.8	-0.3	4.6	-10.9 – 26.3	Standard Fluid (2)	Combined
23	30.0	14.3	-3.7	9.5	-35.7 – 15.6	Digital, Min-Max Min-Max, Mercury Standard Fluid	Combined

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Appendix E, continued

Selected Vaccines for Children Program Providers With Storage Units Outside the Required Temperature Range During a 2-Week Period

Table E-1 (cont'd): Twenty-eight Freezers Above 5°F for at Least 5 Cumulative Hours

Provider	Cumulative Hours Above Required Range	Longest Consecutive Hours Above Required Range	Mean Temperature During Entire 2-Week Period (°F)	Standard Deviation During Entire 2-Week Period (°F)	Temperature Range During Entire 2-Week Period (°F)	Thermometer Type(s)	Unit Type
11	27.0	10.3	0.7	2.5	-2.9 – 11.4	Dial	Combined
40	24.3	1.3	-2.3	5.5	-14.0 – 25.4	Digital, Min-Max Standard Fluid	Combined
39	19.5	1.3	0.6	2.7	-2.9 – 16.9	Dial Standard Fluid (2)	Combined
44	16.0	1.3	0.6	4.3	-8.8 – 36.1	Digital, Min-Max Standard Fluid	Combined
37	15.3	1.0	1.5	2.2	-3.9 – 16.8	Digital, Min-Max	Combined
6	12.5	1.3	-2.4	3.3	-8.0 – 14.1	Digital, Min-Max Standard Fluid	Combined
7	11.3	0.8	0.2	2.6	-2.6 – 21.7	Dial (2) Digital, Min-Max (2) Standard Fluid	Combined
4	11.0	0	-2.7	2.7	-6.3 – 10.5	Standard Fluid (2)	Combined
12	10.3	1.0	-0.3	3.3	-9.2 – 11.6	Digital, Min-Max	Combined
21	9.0	8.8	-1.8	2.0	-4.2 – 11.6	Standard Fluid	Stand-alone
29	5.0	0.5	-10.1	3.5	-16.2 – 11.5	Digital, Min-Max Digital, part of unit Standard Fluid, Min-Max (2)	Combined

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Appendix E, continued

Selected Vaccines for Children Program Providers With Storage Units Outside the Required Temperature Range During a 2-Week Period

Table E-2: Twenty-two Refrigerators Above 46.4°F, Below 35.6°F, or Both for at Least 5 Cumulative Hours

Provider	Cumulative Hours Above Required Range	Longest Consecutive Hours Above Required Range	Cumulative Hours Below Required Range	Longest Consecutive Hours Below Required Range	Mean Temperature During Entire 2-Week Period (°F)	Standard Deviation During Entire 2-Week Period (°F)	Temperature Range During Entire 2-Week Period (°F)	Thermometer Type(s)	Unit Type
14	264.8	34.0	0	0	47.0	0.9	41.9 – 50.4	Digital, Min-Max Standard Fluid	Combined
36	10.3	2.3	0	0	44.1	0.9	41.9 – 52.2	Digital Digital, Min-Max	Combined
12	5.3	1.5	0	0	43.6	1.6	40.3 – 60.3	Digital, Min-Max	Combined
3	5.0	1.0	15.3	0.5	40.7	2.9	33.1 – 59.0	Standard Fluid	Combined
11	0	0	294.8	10.3	34.3	1.4	32.2 – 40.6	Dial	Combined
18	1.5	1.0	284.3	12.3	30.7	5.1	25.0 – 58.1	Continuous Digital, Min-Max	Pharmacy
20	0	0	171.0	20.0	35.1	2.8	25.1 – 41.2	Dial Digital, Min-Max	Combined
4	0	0	134.3	1.5	36.1	1.4	32.9 – 43.6	Digital, Min-Max	Combined
21	2.8	1.5	123.3	6.5	35.4	5.5	20.7 – 54.4	Dial Digital Standard Fluid	Dorm-style
19	0	0	108.3	1.3	36.7	2.1	31.5 – 44.1	Digital, Min-Max (3)	Combined
41	0	0	91.8	2.0	38.1	3.7	28.4 – 45.2	Standard Fluid	Combined
10	0	0	67.3	0.5	38.1	2.5	32.7 – 44.0	Standard Fluid	Combined
32	1.8	1.8	52.0	0.8	39.6	3.2	33.4 – 48.3	Digital, Min-Max	Combined
5	0	0	50.0	3.8	38.7	2.7	29.9 – 45.2	Standard Fluid (2)	Combined
17	0	0	49.3	0.3	36.4	0.8	34.5 – 40.8	Standard Fluid	Combined
42	1.3	1.3	35.5	7.0	36.2	1.1	33.7 – 49.0	Digital Standard Fluid	Combined
30	0	0	34.3	1.8	38.9	2.4	31.0 – 44.3	Standard Fluid	Combined
28	0	0	31.0	1.0	37.8	1.9	32.4 – 44.9	Dial Digital, Min-Max Standard Fluid	Combined

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Selected Vaccines for Children Program Providers With Storage Units Outside the Required Temperature Range During a 2-Week Period

Table E-2 (cont'd): Twenty-two Refrigerators Above 46.4°F, Below 35.6°F, or Both for at Least 5 Cumulative Hours

Provider	Cumulative Hours Above Required Range	Longest Consecutive Hours Above Required Range	Cumulative Hours Below Required Range	Longest Consecutive Hours Below Required Range	Mean Temperature During Entire 2-Week Period (°F)	Standard Deviation During Entire 2-Week Period (°F)	Temperature Range During Entire 2-Week Period (°F)	Thermometer Type(s)	Unit Type
6	0.3	0.3	25.8	1.3	39.6	2.5	32.1 – 46.7	Digital, Min-Max Standard Fluid	Combined
7	0.8	0.5	18.5	1.0	39.8	2.0	28.7 – 48.9	Digital, Min-Max (2)	Combined
2	3.8	3.0	13.3	0.3	38.7	2.2	34.1 – 59.5	Digital, Min-Max	Combined
27	0	0	12.5	0.3	38.0	1.4	34.2 – 43.7	Standard Fluid	Combined

Sources: Sensitech analysis of TempTale® data and OIG observations, 2011.

APPENDIX F

Vaccines for Children Program Vaccine Management Requirements That Providers Did Not Meet

Provider	Total Categories With Requirements Not Met	Category of Requirements									
		Vaccine Storage Equipment	Vaccine Storage Practices	Temperature Monitoring	Vaccine Storage and Handling Plans	Vaccine Personnel	Vaccine Waste	Vaccine Security and Equipment Maintenance	Vaccine Ordering and Inventory Management	Receiving Vaccine Shipments	Vaccine Preparation
1	9	X	X	X	X	X	X	X	X	X	
2	8	X	X	X	X	X	X	X			X
3	8	X	X	X	X	X	X	X	X		
4	8	X	X	X	X	X	X	X		X	
5	8	X	X	X	X	X	X	X		X	
6	8	X	X	X	X	X	X		X	X	
7	8	X	X	X	X	X	X		X	X	
8	7	X	X	X	X	X	X		X		
9	7	X	X	X	X	X	X	X			
10	7	X	X	X	X	X	X	X			
11	7	X	X	X	X	X	X	X			
12	7	X	X	X	X	X	X			X	
13	7	X	X	X	X	X	X		X		
14	7	X	X	X	X	X	X			X	
15	7	X	X	X	X	X	X		X		
16	7	X	X	X	X	X	X			X	
17	7	X	X	X	X		X	X		X	
18	7	X		X	X	X	X	X	X		
19	7	X		X	X	X	X		X	X	
20	6	X	X	X	X	X	X				
21	6	X	X	X	X	X	X				
22	6	X	X	X	X	X		X			
23	6	X	X	X	X	X				X	

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Appendix F, continued

Vaccines for Children Program Vaccine Management Requirements That Providers Did Not Meet

Provider	Total Categories With Requirements Not Met	Category of Requirements									
		Vaccine Storage Equipment	Vaccine Storage Practices	Temperature Monitoring	Vaccine Storage and Handling Plans	Vaccine Personnel	Vaccine Waste	Vaccine Security and Equipment Maintenance	Vaccine Ordering and Inventory Management	Receiving Vaccine Shipments	Vaccine Preparation
24	6	X	X	X	X	X			X		
25	6	X	X	X	X			X	X		
26	6	X	X	X	X				X	X	
27	6	X	X	X		X	X		X		
28	6	X	X	X		X		X		X	
29	6	X	X	X		X			X	X	
30	6	X	X		X	X		X	X		
31	5	X	X	X	X	X					
32	5	X	X	X	X	X					
33	5	X	X	X	X	X					
34	5	X	X	X	X	X					
35	5	X	X	X	X			X			
36	5	X	X	X		X			X		
37	5	X	X	X		X	X				
38	5	X	X	X		X		X			
39	5	X		X	X	X		X			
40	5		X	X	X	X	X				
41	4	X	X		X			X			
42	4	X	X		X				X		
43	4		X	X	X	X					
44	3	X	X		X						
45	2	X	X								
Total	**N/A**	**43**	**42**	**40**	**38**	**37**	**24**	**18**	**17**	**14**	**1**

Source: OIG observations and analysis of selected VFC provider interview responses and documentation, 2011.

APPENDIX G

Required Vaccines for Children Program Documents Not Provided by Providers

Provider	Total Number of Required Documents Not Provided	Training Records	Documentation Demonstrating the Process To Ensure That Vaccines for Children (VFC) Vaccines Are Administered Only to the VFC-Eligible Population	Routine Storage and Handling Plan	Emergency Storage and Handling Plan	Current Provider Enrollment Form	Current Provider Profile Form	2010 Temperature-Monitoring Logs
18	6	X	X	X	X	X	X	
5	5	X	X	X			X	
4	5	X		X	X	X	X	
20	4	X	X	X	X			
13	4	X		X			X	
15	3	X	X					X
6	3	X				X	X	
7	3	X		X	X			
11	3	X		X	X			
16	3	X		X	X			
19	3	X		X	X			
32	3	X			X			X
14	3	X				X	X	
39	3	X				X	X	
1	3		X	X	X			
12	2	X	X					
21	2	X	X					
22	2	X	X					
23	2	X	X					
25	2	X	X					
31	2	X	X					
36	2	X	X					

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Appendix G, continued

Required Vaccines for Children Program Documents Not Provided by Providers

Provider	Total Number of Required Documents Not Provided	Training Records	Documentation Demonstrating the Process To Ensure That VFC Vaccines Are Administered Only to the VFC-Eligible Population	Routine Storage and Handling Plan	Emergency Storage and Handling Plan	Current Provider Enrollment Form	Current Provider Profile Form	2010 Temperature-Monitoring Logs
40	2	X	X					
43	2	X	X					
10	2	X		X				
27	2	X						X
8	2			X	X			
9	2			X	X			
17	2			X	X			
42	2					X	X	
2	1	X						
24	1	X						
28	1	X						
29	1	X						
33	1	X						
37	1	X						
38	1	X						
41	1		X					
3	0							
26	0							
30	0							
34	0							
35	0							
44	0							
45	0							
Total		**32**	**15**	**14**	**12**	**8**	**8**	**3**

Source: OIG analysis of selected VFC provider documentation, 2011.

APPENDIX H

Activities Missing From Selected Grantees' Vaccines for Children Program Fraud and Abuse Policies

Grantee	Total Activities Not Included	Compare Enrolled Providers to Exclusion Databases	Develop a Procedure for Reporting Vaccines for Children (VFC) Provider Terminations	Develop a Fraud and Abuse Referral Procedure	Create an Allegation and Referral Database	Identify Oversight Personnel	Create a Protocol To Annually Review the Fraud and Abuse Policy	Develop a Procedure for Monitoring the VFC Program	Develop Training Materials for VFC Personnel
1	**6**	X	X	X	X	X	X		
2	**8**	X	X	X	X	X	X	X	X
3	**6**	X	X		X	X	X		X
4	**3**	X	X	X					
5	**5**	X	X	X	X			X	
Total		**5**	**5**	**4**	**4**	**3**	**3**	**2**	**2**

Source: Office of Inspector General analysis of selected grantees' fraud and abuse policies, 2011. Requirements established in the *VFC Operations Guide*, Module 10: Fraud and Abuse.

APPENDIX I

Agency Comments

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

TO: Inspector General, Department of Health and Human Services

FROM: Director, Centers for Disease Control and Prevention

DATE: April 27, 2012

SUBJECT: Office of Inspector General's Draft Report: "Vaccines for Children: Vulnerabilities in Vaccine Management" (OEI-04-10-00430)

The Centers for Disease Control and Prevention (CDC) appreciates the opportunity to review and comment on the Office of Inspector General's draft report "Vaccines for Children: Vulnerabilities in Vaccine Management."

Vaccination is one of the most successful public health tools in preventing and controlling disease. In the United States today, we enjoy the benefits of vaccines that protect against 17 diseases across a person's lifespan. The nation has achieved 90 percent or greater reduction in most vaccine preventable diseases, and some dreadful diseases that were once commonplace have been eradicated or eliminated, such as smallpox and measles. The success of the nation's vaccination program is dependent upon a robust public-private partnership that makes quality vaccination services available to all Americans. The Vaccines for Children (VFC) Program plays a significant role in reducing barriers and improving access to vaccination for financially vulnerable children and adolescents. CDC takes seriously its responsibility to work with its partners to ensure that the successes of the VFC program are sustained.

Vaccine storage and handling is a core but 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. CDC and its partners 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, which will support improvements in vaccine management at the provider office.

Because 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, CDC believes that efforts to strengthen storage and handling practices will help improve vaccination services nationally and benefit children vaccinated with both publicly and privately purchased vaccines.

Among the assessed VFC grantees and provider sites, OIG identified four key findings regarding deficiencies in adherence to CDC requirements for vaccine storage and management. OIG provided the following four recommendations to address these findings:

Office of Inspector General (OIG) Recommendation: Ensure VFC vaccines are stored according to requirements.

CDC Response: CDC concurs with this recommendation and is committed to protecting public investments in life saving vaccines and ensuring proper vaccine storage and handling. We recognize that proper vaccine management is a collaborative effort between the agency, immunization grantees, and the nearly 45,000 participating VFC provider sites.

CDC is committed to the continuous quality improvement of guidance documents, program requirements, and support materials for vaccine management, as well as storage and handling at the provider and grantee level. In addition, 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 equipment requirements and temperature monitoring for proper vaccine storage.

OIG Recommendation: Ensure expired vaccines are identified and separated from viable vaccines.

CDC Response: CDC concurs with this recommendation. CDC is in the process of implementing significant changes in how VFC vaccines are ordered and provider inventories are reported. Through changes in the vaccine ordering systems and processes, CDC is expecting to improve vaccine accounting in the provider office and forecasting of their vaccine supply needs. The end result will be better vaccine management and reduced risk of expired and soon-to-be expired vaccine. With less expired vaccine in the provider office, a lower risk of expired vaccine being comingled with viable stock will exist. CDC will also review its guidance and training materials to ensure program requirements related to expired vaccine management are clear, well-communicated, and understood by grantees and providers.

OIG Recommendation: Ensure grantees establish provider inventory systems and procedures to better manage soon-to-expire vaccines.

CDC Response: CDC concurs with this recommendation. As stated above, CDC is in the process of implementing significant changes in how VFC vaccines are ordered and provider inventories are reported. Through changes in the vaccine ordering systems and processes, CDC is expecting vaccine supply forecasting by providers to improve. The end result will be better vaccine management and reduced risk of expired and soon-to-be expired vaccines. As CDC continues to transform the vaccine ordering and information systems, it will incorporate OIG's recommendations.

OIG Recommendation: Ensure grantees meet oversight requirements.

CDC Response: CDC concurs with this recommendation and is committed to maintaining the integrity of the VFC program through effective management and oversight. CDC also understands the need to minimize the burden of administrative and record keeping requirements on VFC providers. CDC will work with its grantees and provider organizations to ensure program requirements are necessary for effective oversight of the program. In addition, working groups will review VFC provider site visit procedures and documentation to ensure they can be effective in enforcing program requirements.

/S/

Thomas R. Frieden, M.D., M.P.H.

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Office of Inspector General

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