VACCINES FOR CHILDREN (VFC) PROGRAM OVERVIEW

May 11, 2016
Providers’ Best Practices & GPRA Measures Conference
Sacramento, CA
Claudia Aguiluz, Vaccine Management and VFC Program Section
CDPH, Immunization Branch
Presentation Objectives

• Identify recent changes in provider participation requirements for CA VFC Program participants
• Review childhood and adolescent vaccines covered by the VFC Program
• Discuss VFC Program requirements specific to vaccine availability and adolescents; required vs recommended immunizations
• Review key aspects of proper vaccine management as outlined in the Program’s Vaccine Management Plans
VFC PROGRAM OVERVIEW
21<sup>th</sup> Anniversary of the VFC Program

Vaccines for Children
20 years of protecting America’s children

The Vaccines for Children program was established in 1994 to make vaccines available to uninsured children. VFC has helped prevent disease and save lives...big time!

CDC estimates that vaccination of children born between 1994 and 2013 will:

- Prevent 322 million illnesses
- Help avoid 732,000 deaths
- Save nearly $1.4 trillion in total societal costs (that includes $295 billion in direct costs)

[www.cdc.gov/features/vfcprogram]
About CA’s VFC Program

50% of CA’s children 0-18 years of age are eligible to receive VFC supplied vaccines (5M)

4,000 provider offices enrolled in the VFC Program, most of them are pediatric and family practice offices

VFC-Supplied vaccines are provider at no-cost to eligible children 0-18 years of age, including those with no health insurance, American Indian/Alaskan Natives, and Medi-Cal/CHDP eligible children

15,000 calls are received by VFC’s Call center annually, staffed by 6.5 Customer Service Representatives

1/2 Billion dollars worth of vaccines are distributed annually

Over 2,000 QA visits conducted annually by VFC Field Staff

140 storage and handling incidents are reported each month - most of them due to fridge left open at the end of the day

20,000 vaccine orders are processed annually

11 Million doses of vaccines are distributed annually
Your Impact

YOU make it happen
CA Vaccine Distribution 2005-2015

89 Million Doses*

* ^ Partial years

* Excluding flu

California Department of Public Health, Immunization Branch
Vaccines Available Through VFC

• The VFC Program includes all ACIP-recommended vaccines

• New vaccines are quickly incorporated into the program after
  • the negotiation of a federal vaccine price contract;
  • an official vote from ACIP; and
  • An approved VFC Resolution

• CA makes all product, brands and presentations available to enrolled providers.

Resolution No. 6/08-1

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
VACCINES FOR CHILDREN PROGRAM

VACCINES TO PREVENT ROTAVIRUS GASTROENTERITIS

The purpose of this resolution is to add a newly licensed rotavirus vaccine to the Vaccines for Children Program.

VFC resolution 2/06-2 is repealed and replaced by the following:

Eligible Groups
Infants aged 6 weeks to 8 months.

Recommended Schedule for Rotavirus Vaccines

<table>
<thead>
<tr>
<th>Dose</th>
<th>Rotateq® Age</th>
<th>Rotarix® Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>2 months</td>
<td>2 months</td>
</tr>
<tr>
<td>Primary 2</td>
<td>4 months</td>
<td>4 months</td>
</tr>
<tr>
<td>Primary 3</td>
<td>6 months</td>
<td>-----</td>
</tr>
</tbody>
</table>

Dosage Intervals and Ages for Rotavirus Vaccines

<table>
<thead>
<tr>
<th></th>
<th>RV5 (RotaTeq®; Merck)</th>
<th>RV1 (Rotarix®; GSK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses in series</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Recommended ages for doses</td>
<td>2, 4, and 6 months</td>
<td>2 and 4 months</td>
</tr>
<tr>
<td>Minimum age for first dose</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Maximum age for first dose</td>
<td>14 weeks 6 days</td>
<td></td>
</tr>
<tr>
<td>Interval between doses</td>
<td>4 weeks or more</td>
<td></td>
</tr>
<tr>
<td>Maximum age for last dose</td>
<td>8 months 0 days</td>
<td></td>
</tr>
</tbody>
</table>
ACIP-Recommended Pediatric and Adolescent Vaccines

**Pediatric vaccines**
- Diphtheria, Tetanus, Pertussis (DTaP)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
  - *Haemophilus influenzae* type b (Hib)
- Inactivated poliovirus (IPV)
- Influenza (flu)
- Meningococcal B (MenB)
- Measles, Mumps, Rubella (MMR)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)
- Rotavirus (RV)
- Varicella (chickenpox)

**Combination vaccines**
- DTaP-IPV combination vaccine
- DTaP-IPV/Hib combination vaccine
- DTaP-HepB-IPV combination vaccine
- MMR-V (MMR + V)

**Adolescent vaccines**
- Human Papillomavirus (HPV)
- Influenza (flu)
- Meningococcal conjugate (MCV4)
- Meningococcal B
- Tetanus, Diphtheria, Pertussis (Tdap)
Vaccine Requirements vs. Federal Vaccine Recommendations

Table 1: Immunization Requirements for K-12

<table>
<thead>
<tr>
<th>Grade</th>
<th>Requirement</th>
<th>Doses Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-6 years</td>
<td>Polio</td>
<td>4 doses, except that a total of 5 doses is acceptable if at least one dose was given on or after the 4th birthday.</td>
</tr>
<tr>
<td></td>
<td>DTP or combination of DTP and diphtheria-tetanus toxoids</td>
<td>5 doses, except that a total of 4 doses is acceptable if at least one dose was given on or after the 4th birthday.</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps, rubella (MMR)</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td></td>
<td>Measles B1</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td></td>
<td>Varicella</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td>Elementary school, secondary school</td>
<td>7-17 years</td>
<td>4 doses, except that a total of 3 doses is acceptable if at least one dose was given on or after the 2nd birthday.</td>
</tr>
<tr>
<td></td>
<td>Diphtheria and tetanus toxoids and pertussis vaccine given as DTP, DT, or Td, or Tdap</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td></td>
<td>Measles and mumps (mumps not required)</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td></td>
<td>Varicella</td>
<td>1 dose on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.)</td>
</tr>
<tr>
<td>Seventh grade</td>
<td>Tdap</td>
<td>1 dose on or after the 7th birthday.</td>
</tr>
<tr>
<td>Eighth through Twelfth Grades</td>
<td>Any aged 13 through 18 years</td>
<td>2 doses on or after the 7th birthday.</td>
</tr>
<tr>
<td>Any</td>
<td>Tdap</td>
<td>1 dose on or after the 7th birthday.</td>
</tr>
</tbody>
</table>

1 Oral polio vaccine (OPV) or inactivated poliovaccine (IPV) or any combination of these vaccines is acceptable.
2 Applies only to children entering at kindergarten level (or at first grade level if kindergarten skipped) or below on or after August 1, 1997. Applies only to children (of any age) entering or advancing to the seventh grade or on or after July 1, 1999.
3 Applies only to children (of any age) entering or advancing to the seventh grade or on or after July 1, 1999. Children admitted to California schools at the kindergarten level or above before July 1, 2001, are exempt from this requirement.
4 Polio must have received at least one dose of Tdap prior to admission or advancement to the 7th through 12th grades.
5 If DTP was given on or after age 7 years instead of Tdap, this dose may also be counted as a valid dose for this requirement.
6 This requirement is effective July 1, 2011, through June 30, 2012.
VFC Program Requirement: Vaccine Availability

- Providers, including non-traditional providers such as OB/GYNs, pharmacies, and others, are required to offer age-appropriate immunizations to patients served by their practice in accordance with schedules determined by the ACIP in its VFC resolutions.

PCV, Hib, DTaP, RV, IPV...

MCV, HPV, flu, Tdap...
VFC Program Requirement: Vaccine Availability

VFC entitles children to all ACIP vaccines

VFC Providers agree to comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) for the vaccines identified and agreed upon in the Provider Agreement and Provider Profile UNLESS:

In the VFC Provider's medical judgment, and in accordance with accepted medical practice, the VFC Provider deems such compliance to be medically inappropriate for the child;
# 2016 Recommended Immunizations for Children from Birth Through 6 Years Old

<table>
<thead>
<tr>
<th>Age</th>
<th>HepB</th>
<th>RV</th>
<th>DTaP</th>
<th>Hib</th>
<th>PCV</th>
<th>IPV</th>
<th>DTaP</th>
<th>Hib</th>
<th>PCV</th>
<th>IPV</th>
<th>Influenza (Yearly)¹</th>
<th>MMR</th>
<th>Varicella</th>
<th>HepA⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>HepB</td>
<td>RV</td>
<td>DTaP</td>
<td>Hib</td>
<td>PCV</td>
<td>IPV</td>
<td></td>
<td></td>
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<tr>
<td>1 month</td>
<td>HepB</td>
<td>RV</td>
<td>DTaP</td>
<td>Hib</td>
<td>PCV</td>
<td>IPV</td>
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<tr>
<td>2 months</td>
<td></td>
<td>RV</td>
<td>DTaP</td>
<td>Hib</td>
<td>PCV</td>
<td>IPV</td>
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<td>12 months</td>
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<td>18 months</td>
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<td>19–23 months</td>
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<td>2–3 years</td>
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<td>4–6 years</td>
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</tbody>
</table>

**Is your family growing?** To protect your new baby and yourself against whooping cough, get a Tdap vaccine in the third trimester of each pregnancy. Talk to your doctor for more details.

**NOTE:** If your child misses a shot, you don't need to start over, just go back to your child's doctor for the next shot. Talk with your child's doctor if you have questions about vaccines.

**FOOTNOTES:**

¹ Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting an influenza (flu) vaccine for the first time and for some other children in this age group.

² Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 to 18 months later. HepA vaccination may be given to any child 12 months and older to protect against HepA. Children and adolescents who did not receive the HepA vaccine and are at high-risk, should be vaccinated against HepA.

³ If your child has any medical conditions that put him at risk for infection or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.

For more information, call toll free 1-800-CDC-INFO (1-800-232-4636) or visit [http://www.cdc.gov/vaccines](http://www.cdc.gov/vaccines).
Talk to your child’s doctor or nurse about the vaccines recommended for their age.

<table>
<thead>
<tr>
<th>Age</th>
<th>Flu</th>
<th>Tdap</th>
<th>HPV</th>
<th>Meningococcal</th>
<th>Pneumococcal</th>
<th>Hepatitis B</th>
<th>Hepatitis A</th>
<th>Inactivated Polio</th>
<th>MMR</th>
<th>Chickenpox</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-8 Years</td>
<td><img src="Image" alt="Flu" /></td>
<td><img src="Image" alt="Tdap" /></td>
<td><img src="Image" alt="HPV" /></td>
<td><img src="Image" alt="Meningococcal MenACWY" /></td>
<td><img src="Image" alt="Pneumococcal" /></td>
<td><img src="Image" alt="Hepatitis B" /></td>
<td><img src="Image" alt="Hepatitis A" /></td>
<td><img src="Image" alt="Inactivated Polio" /></td>
<td><img src="Image" alt="MMR" /></td>
<td><img src="Image" alt="Chickenpox" /></td>
</tr>
<tr>
<td>9-10 Years</td>
<td><img src="Image" alt="Flu" /></td>
<td><img src="Image" alt="Tdap" /></td>
<td><img src="Image" alt="HPV" /></td>
<td><img src="Image" alt="Meningococcal MenACWY" /></td>
<td><img src="Image" alt="Pneumococcal" /></td>
<td><img src="Image" alt="Hepatitis B" /></td>
<td><img src="Image" alt="Hepatitis A" /></td>
<td><img src="Image" alt="Inactivated Polio" /></td>
<td><img src="Image" alt="MMR" /></td>
<td><img src="Image" alt="Chickenpox" /></td>
</tr>
<tr>
<td>11-12 Years</td>
<td><img src="Image" alt="Flu" /></td>
<td><img src="Image" alt="Tdap" /></td>
<td><img src="Image" alt="HPV" /></td>
<td><img src="Image" alt="Meningococcal MenACWY" /></td>
<td><img src="Image" alt="Pneumococcal" /></td>
<td><img src="Image" alt="Hepatitis B" /></td>
<td><img src="Image" alt="Hepatitis A" /></td>
<td><img src="Image" alt="Inactivated Polio" /></td>
<td><img src="Image" alt="MMR" /></td>
<td><img src="Image" alt="Chickenpox" /></td>
</tr>
<tr>
<td>13-15 Years</td>
<td><img src="Image" alt="Flu" /></td>
<td><img src="Image" alt="Tdap" /></td>
<td><img src="Image" alt="HPV" /></td>
<td><img src="Image" alt="Meningococcal MenACWY" /></td>
<td><img src="Image" alt="Pneumococcal" /></td>
<td><img src="Image" alt="Hepatitis B" /></td>
<td><img src="Image" alt="Hepatitis A" /></td>
<td><img src="Image" alt="Inactivated Polio" /></td>
<td><img src="Image" alt="MMR" /></td>
<td><img src="Image" alt="Chickenpox" /></td>
</tr>
<tr>
<td>16-18 Years</td>
<td><img src="Image" alt="Flu" /></td>
<td><img src="Image" alt="Tdap" /></td>
<td><img src="Image" alt="HPV" /></td>
<td><img src="Image" alt="Meningococcal MenACWY" /></td>
<td><img src="Image" alt="Pneumococcal" /></td>
<td><img src="Image" alt="Hepatitis B" /></td>
<td><img src="Image" alt="Hepatitis A" /></td>
<td><img src="Image" alt="Inactivated Polio" /></td>
<td><img src="Image" alt="MMR" /></td>
<td><img src="Image" alt="Chickenpox" /></td>
</tr>
</tbody>
</table>

More information:
- Pretenders and teens should get a flu vaccine every year.
- Pretenders should get a Tdap vaccine at age 11 or 12 years.
- Both girls and boys should receive 3 doses of HPV vaccine to protect against HPV-related disease. HPV vaccination can start as early as age 9 years.
- All 11-12 year olds should be vaccinated with a single dose of a quadrivalent meningococcal conjugate vaccine (MenACWY). A booster shot is recommended at age 16.
- Teens, 16-18 years old, may be vaccinated with a MenB vaccine.

These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.

These shaded boxes indicate the vaccine should be given if a child is catching-up on missed vaccines.

These shaded boxes indicate the vaccine is recommended for children at increased risk but who wish to get the vaccine after speaking to a provider.
Adolescent Vaccine Distribution

Parents: DID YOU KNOW HPV CAUSES

- Throat and Mouth Cancers
- Cervical Cancer
- Vaginal Cancer
- Anal Cancer
- Penile Cancer

HPV Target Distribution

California Department of Public Health, Immunization Branch
RECENT VFC PROGRAM PARTICIPATION REQUIREMENTS
Why Requirements Matter?

- Requirements are critical in many industries, including agricultural, food, and healthcare.

- Health care regulations and standards are necessary to ensure compliance and to provide safe health care to every individual who accesses the system.

- Health care regulations are developed and implemented not only by all levels of government (federal, state and local) but by private organizations as well.
Why Requirements Matter?

They are important and impact us on a daily basis.

Requirements are critical in many industries, including agricultural, food, and healthcare.

In healthcare, they are necessary to ensure compliance and to provide safe health care.

They are developed and implemented by all levels of government (federal, state and local) and private sector.

While sometimes confusing, and sometimes viewed as burdensome, they are critical to ensuring safe and effective care for those accessing the health care system.
Why Requirements Matter for VFC

- **Entitlement program** - making sure services or goods intended for a population are accessible to them.
  - In VFC, this means making sure vaccines intended to VFC children are available to them.

- **Appropriate management of resources**
  - Vaccines are administered according to schedules, dosages, and have been handled appropriately to protect those receiving them.

- **Stewardship and Accountability**
  - ensuring resources are accounted for, and unnecessary waste is prevented.

- **Federal program**
  - maintaining the integrity of the program is key for its continued success.

- **Knowledge and education** - continuously improves delivery of service, and effective management of areas of the program.
Requirements for participation in the VFC Program are set by CDC and outlined in the Program’s “Participation Agreement”
- Providers must agree with set requirements upon enrollment and on an annual basis thereafter (Recertification)
- Failure to meet recertification requirement leads to suspension of ordering privileges

Agreements and Certification of Capacity
- Important documents for the provider of record
- signing as responsible party to ensure clinic participates in the program according to those requirements
Key Areas of VFC Requirement Changes

- Provider Enrollment & Recertification
- Quality Assurance and Accountability
- Vaccine Management
Roles & Rules of Engagement.. Critical for those in charge
Emphasis on the Provider of Record and Responsibilities

 Provider of Record – Medical Director or equivalent at the office who must sign the enrollment forms and whose responsibilities include:

• Operate within all program requirements
• Account for VFC doses AND be accountable for vaccine loss (negligence)
• Identify, train, and evaluate skill for key staff with vaccine management responsibilities
• Ensure use of appropriate vaccine storage and temperature monitoring equipment
• Develop and implement vaccine management plans (routine and emergency)
• Be present during compliance visits or designate staff to act on his/her behalf on VFC Program related matters, such as signing the visit acknowledgement form, when the POR is unavailable.
Key Practice Staff Educational Requirement

• Provider Education Goals are designed to support providers in meeting VFC requirements outlined on the CDC Provider Agreement.
  • annual training must be provided on key program areas to all enrolled providers annually
  • Training completion must be tracked
  • A condition for continued participation
  • CA's approach: Utilize existing training platform for training and tracking completion of trainings

<table>
<thead>
<tr>
<th>Lessons</th>
<th>Key Clinic Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine Coordinator</td>
</tr>
<tr>
<td>VFC Program Requirements</td>
<td>✓</td>
</tr>
<tr>
<td>Storing Vaccines</td>
<td>✓</td>
</tr>
<tr>
<td>Monitoring Storage Unit Temperatures (NEW)</td>
<td>✓</td>
</tr>
<tr>
<td>Conducting a Vaccine Inventory</td>
<td>✓</td>
</tr>
<tr>
<td>2016 Refrigerator Temperature Log (NEW)</td>
<td>✓</td>
</tr>
<tr>
<td>2016 Freezer Temperature Log (NEW)</td>
<td>✓</td>
</tr>
</tbody>
</table>
New Temperature Monitoring Lesson Required for key practice staff AND clinic staff responsible for temperature monitoring

78% of Vaccine Coordinators share storage and handling activities with other clinic staff
Training and Supervision

• Temperature monitoring is not a purely mechanical exercise.
• Understanding the impact of the activity is critical.
• Responsible staff must know how to react effectively to problems as soon as they arise.
• Training not only is essential to allow adequate time for initial training, but training should be on-going, and verified.
Recognizing that monitoring a unit’s current temperature ONLY, and not MIN or Max temperatures, is a critical gap in temperature monitoring.
Test Your Knowledge

Review the below temperature readings and select the correct answer.

1. Current temp and min/max are within range - no action necessary
   A. Current temp is within range, min/max out of range - take action
   B. Current temp is within range, min/max out of range - no action necessary
   C. Current temp and min/max are out of range - take action

3. Current temp and min/max are within range - no action necessary
   A. Current temp is within range, min/max out of range - take action
   B. Current temp is within range, min/max out of range - no action necessary
   D. Current temp and min/max are out of range - take action

4. Current temp and min/max are within range - no action necessary
   A. Current temp is within range, min/max out of range - take action
   C. Current temp is within range, min/max out of range - no action necessary
   D. Current temp and min/max are out of range - take action
CDC Vaccine Storage and Handling Improvement Project

- Survey Question: What is the MIN temperature on a MIN/MAX thermometer? Select one.

| The number of minutes the unit has stayed at the same temperature | 4 (1%) |
| The temperature of the coldest spot in the unit | 24 (3%) |
| **The coldest temperature in the unit since the thermometer’s memory was cleared or reset** | 503 (72%) |
| The minimum acceptable temperature for vaccine | 157 (23%) |
| Don’t know or Not sure | 8 (1%) |
Enhanced Temperature Monitoring and Documentation

Incremental changes

• Temperature readings and frequency
• Guidance for actions if temperatures are outside ranges
• Documentation of actions taken
• Recording staff member’s names
• Supervisory review of logs
• Checking for triggered alarms
• Online documentation of actions taken
Documentation of Storage and Handling Incidents

- If a cold chain failure is suspected (temperatures outside the recommended temperature range), providers must:
  - Store vaccine under correct temperature storage conditions
  - Label the vaccine “DO NOT USE” so the vaccine is not administered until a response indicating the vaccine is acceptable for use has been received
  - Notify your clinic’s supervisor
  - Report excursion into VFC’s new Storage and Handling Online Triage System (SHOTS)
  - Contact individual vaccine manufacturers for a determination of vaccine viability
Improved use of Vaccine Storage Equipment

Mid 90’s: Any refrigerator.

2009: Stand alone refrigerators, household and purpose built, limited combo unit use.

2000’s: No Dormitory-style refrigerators, household combo unit use ok.

2016: No combo refrigerators, purpose build units standalone units optimal, household standalone units ok.
Improved use of Vaccine Storage Equipment
Advance Temperature Monitoring Equipment

Sticking Point: Temperature Control Vital to Vaccine Viability

- Thermometer in each compartment of the refrigerator
- Use of Min/Max thermometers
- Use of buffered probes
- Use of high accuracy thermometers
- Use of continuous recording devices
Accurate Temperature Monitoring Equipment

- Thermometers are a critical component in ensuring vaccines are stored at the indicated temperatures.

- Accurate and reliable thermometers- A worthwhile investment for any practice
  - Inaccurate/inexpensive units could cost practices thousands of dollars due to inaccurate readings
    - Vaccine loss
    - Patient recall
    - Patient trust
Continuous Temperature Recording Devices

- VFC is transitioning to the use of thermometers that provide continuous recording of min/max temperatures.
  - Digital Data Loggers

- These types of thermometer are preferred because they provide an indication of the length of time a storage unit may have been operating outside recommended temperature ranges.
  - Data readings are downloaded
  - Have varying levels of alarm notifications
  - Are capable of storing thousands of temperature readings

- Traditional min/max thermometer must be reset regularly (after properly recording temperatures) for useful readings.
VFC Program Requirements: Thermometers

All new VFC providers, practices that are open 2 days a week or less, and practices needing to replace their primary or back-up thermometer will be required to purchase and use data loggers to monitor temperatures. Providers conducting mass vaccination clinics also must use data loggers to monitor temperatures during vaccine transport and at the mass vaccination clinic.

*Beginning in 2017, all VFC providers will be required to use data loggers.*
Unacceptable Thermometers

- Fluid-filled biosafe liquid
- bi-metal stem
- food
- household mercury

• have significant limitations in temperature monitoring
• can be difficult to read and only indicate the temperature at the precise time they are read
• temperature fluctuations outside the recommended range are not detected

Chart recorders
- difficult to read
- failure to change the chart paper will result in unusable temperature data
Purchase your unit ASAP

- Vaccines refrigerator/freezers without temperature monitoring cannot store VFC vaccine supply (or store ANY vaccines really!)

- Vaccines in a storage unit without a VFC compliant thermometer, or without temperature monitoring will be deemed non-usable

- Without documentation of the current, minimum, and maximum temperatures it is unclear what the highest and lowest temperatures the vaccines were exposed to.
Temperatures Re-Created?

• 2016 Certification of Capacity to Store and Manage Vaccines Agreement, #7:
  • “The Vaccine Manager shall monitor and record the temperatures (including current, minimum and maximum temperatures) in the refrigerator and freezer twice each day...If temperatures are not monitored and documented, or if temperature logs are falsified, the affected vaccines will be automatically deemed non-viable and will be considered a negligent vaccine loss.”
Thermometer Calibration

- All thermometers (primary and back-up) must be calibrated annually (or every other year when the manufacturer recommends calibration done in a period that is longer than two years), and have a valid Certificate of Traceability and Calibration Testing, also known as a Certification of Calibration.

- A valid Certification of Calibration must be kept on file according to recordkeeping requirements and be readily available for review during VFC visits.

- Calibration should be conducted by an ILAC/MRA accredited laboratory.

- Thermometer no longer accurate within +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced at the next calibration due date.
Certificates of Calibration

Keep these in a safe place!
Site Visits

Enrolled providers agree to site visits from VFC Program staff, including:

1) scheduled compliance visits (CV)
2) unannounced storage and handling visits (USH); and
3) visits for educational and programmatic support
Stewardship and Accountability

3.7 Billion dollars worth of annual vaccine purchase are supported by the VFC Program nationwide

Strong accountability and program stewardship are essential to maintaining a strong VFC program

Difference between free and no cost vaccines….
   Vaccines are free to eligible patients, and provided at no cost to providers. However, they are not free. They have been purchased with federal dollars.
“Lance Rodewald, an immunization expert at the WHO’s China office, said the broader risk was that parents might “lose confidence in vaccines and decline routine vaccination of their children as a result of this incident.”

“The authority said the vaccines in Shanghai are safe, but how do I know that the vaccines are refrigerated during the transport;” he said, holding a green booklet in which his daughter’s vaccines so far were recorded. “The credibility of the government is at stake.”
Stewardship and Accountability

• Scenario….

• If you were running your own startup business…would you be OK with...
  • A $10,000 perishable shipment received and tucked under a desk?
  • Left a $5,000 purchase delivered by UPS outside your door unattended for days?
  • Discovered $1,000 unaccounted each month you balanced your bank account?
Vaccine Restitution

Dose by Dose replacement

• Providers must agree to replace vaccine on a dose-for-dose basis that is purchased with federal funds and deemed non-viable due to provider negligence or misuse.

• Once a provider meets the Program’s criterion for restitution, lost doses must be replaced with doses purchased at private pricing

Example: MMR ($20.11 vs. $62.79 at the private price)
VACCINE MANAGEMENT
Proper Vaccine Storage and Handling...

- Vaccines are one of the most valuable resources in protecting the public’s health.

- Is key in ensuring vaccinated individuals are protected against vaccine preventable diseases.

- It is indeed a shared responsibility, from manufacturers to vaccinators, in ensuring everyone receiving a vaccine dose, receives a dose that has been handled and stored appropriately!
Importance of Temperature Monitoring

• Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range.

• An immediate loss of potency of cold-sensitive vaccines may occur following freezing.

• For vaccines exposed to temperatures above the recommended temperature range, there is some loss of potency with each episode of exposure.

• Repetitive exposure to heat episodes could result in a cumulative loss of potency that is not reversible.

• Once vaccine potency is lost, it cannot be regained.
Despite the success of routine immunization programs, national vaccine supply chains are now strained to effectively manage the surge of new vaccine introductions, adapt to the needs of new delivery strategies, or benefit from new technological advances in cold chain equipment to increase their efficiency and effectiveness.
Different Challenges

Buildings, cold chain equipment and transport systems enable the vaccine and consumables supply chain to function well.

September 2010, Effective Vaccine Management (EVM) WHO Training
REACHING CHILDREN EVERYWHERE

A vaccinator crosses flood areas in the Kosi river in India, to reach communities to be vaccinated.

Dr Madhup

Health staff in Bangladesh transport vaccine carriers on a bike.
The EVM criteria are the nine criteria:

- Information System & supportive Management
- Vaccine Management Policies & procedures
- Distribution
- Capacity
- Stock Management
- Functional infrastructure & system
- Maintenance
- Storage Temperature
- Pre-shipment & arrivals

EVM sets minimum standards for the immunization supply chain.
Principles of Vaccine Management are Universal

2.4 PRINCIPLES OF SAFE VACCINE STORAGE MANAGEMENT

Immunisation service providers must:

- Store vaccines in a purpose-built vaccine refrigerator (see Section 5).
- Nominate a staff member to be responsible for vaccine management, and a back-up staff member to take responsibility in their absence.
- Ensure policies, procedures and protocols are in place for vaccine management in each facility (see Appendix 1).
- Ensure all people involved in vaccine transport, storage and administration are trained in vaccine management to ensure the vaccines remain effective and potent.
- Perform vaccine storage self-audits at least 12 monthly (see Appendix 2).
- Perform temperature monitoring of vaccine refrigerators twice daily (see Section 6).
- Ensure plans are in place for responses to cold chain breaches and power failures in each facility (see Section 8).
- Report temperatures outside the +2°C to +8°C range to your state or territory health department. Do not use or discard vaccine until advice is given (see Appendix 3).
- Follow the guidelines for using ice packs/gel packs and monitoring vaccines in coolers and cold boxes (see Section 9).
Cold Chain

“Cold chain” refers to the process used to maintain optimal temperature conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client.

- The recommended temperature for vaccine storage and handling is, at all times, at +2°C to +8°C.
- Maintaining a temperature of +5°C provides a safety margin for temperature fluctuations.

Cold Chain Break

Vaccines may be inactivated by exposure to excess light, heat or freezing, depending on the nature of the product, the temperature reached and the duration of exposure.

- Damage from successive exposures to temperatures outside of +2°C to +8°C is CUMULATIVE.
- Any loss of vaccine potency is PERMANENT and irreversible which would result in lower levels of protection against disease!
## HOW TO MONITOR TEMPERATURES IN THE VACCINE SUPPLY CHAIN

### Table 1. Vaccine sensitivity to heat

<table>
<thead>
<tr>
<th>Heat sensitivity</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most-sensitive</td>
<td>Oral poliovirus</td>
</tr>
<tr>
<td></td>
<td>Varicella-zoster virus</td>
</tr>
<tr>
<td></td>
<td>Influenza (inactivated, split)</td>
</tr>
<tr>
<td></td>
<td>Inactivated poliovirus</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (live)</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps, rubella</td>
</tr>
<tr>
<td></td>
<td>Cholera (inactivated)</td>
</tr>
<tr>
<td></td>
<td>DTaP</td>
</tr>
<tr>
<td></td>
<td>DTwP</td>
</tr>
<tr>
<td></td>
<td>DTaP-hepatitis B-Hib-IPV (hexavalent)</td>
</tr>
<tr>
<td></td>
<td>DTwP-hepatitis B-Hib (pentavalent)</td>
</tr>
<tr>
<td></td>
<td>Hib (liquid)</td>
</tr>
<tr>
<td></td>
<td>Measles</td>
</tr>
<tr>
<td></td>
<td>Rotavirus (liquid and freeze dried)</td>
</tr>
<tr>
<td></td>
<td>Rubella</td>
</tr>
<tr>
<td></td>
<td>Yellow fever</td>
</tr>
<tr>
<td>Least-sensitive</td>
<td>Bacillus Calmette-Guérin</td>
</tr>
<tr>
<td></td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (inactivated)</td>
</tr>
<tr>
<td></td>
<td>TT, DT, Td</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B</td>
</tr>
<tr>
<td></td>
<td>Hib (freeze dried)</td>
</tr>
<tr>
<td></td>
<td>Meningitis A (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Meningitis C (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
</tr>
<tr>
<td></td>
<td>Typhoid polysaccharide</td>
</tr>
</tbody>
</table>

### Table 2. Vaccine sensitivity to freezing

- *All these vaccines are damaged by freezing*
  - Cholera (inactivated)
  - Influenza (inactivated, split)
  - Hib (liquid)
  - Inactivated poliovirus
  - Human papillomavirus
  - Meningitis C (polysaccharide-protein conjugate)
  - Pneumococcal (polysaccharide-protein conjugate)
  - TT, DT, Td

- *These vaccines are not damaged by freezing*
  - Meningitis A (polysaccharide-protein conjugate)*
  - Rotavirus (liquid and freeze dried)
  - Yellow fever

- Bacillus Calmette-Guérin
- Hib (freeze dried)
- Japanese encephalitis (live and inactivated)
- Measles
- Measles, mumps, rubella
- Oral poliovirus
- Rabies
- Rubella
- Varicella-zoster virus
Same boat, experiencing same issues
2010 OIG Report

Are Doctors Improperly Storing Vaccines?

Vaccines Stored Improperly: Warning for Parents

By KIM CAROLLO
June 6, 2012
Htfd. Healthcare docs may have administered improperly stored vaccines

Hartford Healthcare Medical Group said that more than 5,000 doses of vaccines it administered since last year may not have been stored under the proper temperature.

The medical group said patients who received the shots are not at risk of harm, but it believes the temperatures may have reduced the effectiveness of the vaccines, which were mainly for influenza, pneumonia and tetanus/pertussis.

The 5,000 shots were given to 3,833 patients at locations in Enfield, West Hartford, Storrs and Unionville.

The medical group is reaching out to affected patients and recommending they be revaccinated at no charge.

Those with questions can call 877-707-4442 or visit this website.
Bad refrigerator at Stanford Children's Health medical office means 1,551 kids need re-vaccination

By Tracy Seipel  |  tseipel@mercurynews.com

POSTED: 10/03/2015 05:59:02 AM PDT  |  UPDATED: 7 MONTHS AGO

SAN MATEO -- More than 1,500 pediatric patients will have to repeat their vaccinations after a faulty refrigerator compromised 10 different vaccines stored at a medical office affiliated with Stanford Children's Health, officials said Friday.

Dr. Mark Showen, the lead physician who oversees five other pediatricians at the Peninsula Pediatric Medical Group in San Mateo, said the safest thing to do is to offer new vaccinations -- including shots every four weeks for some -- to everybody who could possibly be affected, from babies to 18 year olds.

He said letters are being mailed Saturday to the patients' families to help them arrange an appointment, and if a patient or their family has not responded by a certain date, they will be re-contacted.
Key Elements in Storage and Handling

- Skilled and trained staff
- Written Routine and Emergency Vaccine Management Plans
- Appropriate vaccine storage units
- Accurate temperature monitoring equipment
- Proper temperature monitoring AND documentation
Skilled and Properly Trained Staff

- Designate a primary and a back-up vaccine coordinator (VC) to oversee storage and handling activities within the clinic
  - A description of the vaccine coordinator’s role is included in this job aid
  - BOTH VCs must be equally trained

- The clinics’ provider of record, or member of management should be directly involved in overseeing vaccine management activities in the clinic
  - Financial implications of vaccine replacement cost AND clinical implications of mishandling of vaccines
Skilled and Properly Trained Staff

- Incorporate training as part of new employee orientation
- Schedule refresher trainings annually
- Complete trainings during VFC Recertification
- Incorporate checks, such as demonstration skills to ensure proper procedures are followed
Written Vaccine Management Plans

- All facilities storing and administering vaccines should have them.
- For VFC Program participants, these plans are a requirement for participation in the VFC Program.
- Routine Plan – include all aspects of vaccine management, from ordering, storage conditions to temperature monitoring.
- Emergency Plan - Outline steps and key contacts in case of an emergency, such as a planned or unplanned power loss.
Written Routine and Emergency Vaccine Management Plans

- Plans help ensure staff training and quality assurance
- All staff managing vaccines must be familiar with the clinic’s location and plan contents
  - Plans must be reviewed and updated annually, or whenever personnel or other changes are made to the plans
  - Review must be documented in the plans
- Treat plans as fire drills-Not only have reviewed the plans, but have exercised them.
Vaccine Transport: WHO Guidance

**Distribution principles - 6**

- Train staff in correct use of icepacks and/or cool water packs
  - To avoid freezing, frozen icepacks must be correctly ‘conditioned’
  - Cool water packs cannot freeze vaccine.
  - Cool water packs are preferred provided their use has been validated by a temperature monitoring study
- Train staff to pack cold boxes correctly
  - Cold boxes must be packed as shown in the manufacturer’s instructions
Temperatures inside vaccine vials placed in the centre of a vaccine carrier packed with four types of water-packs

![Graph showing temperature changes over time for different water-packs.](image)

**Source:** Illustrative data from PATH laboratory tests using a WHO prequalified vaccine carrier (2014).

California Department of Public Health, Immunization Branch.
Transporting Refrigerated Vaccine

Guidelines for vaccine transport and short-term storage

- This procedure will keep all vaccines except varicella and MMRV within the recommended temperature range for up to 12 hours during transport and/or storage outside the primary storage unit (e.g., in the building, inside a car, etc.). If the storage cooler is exposed to temperatures as low as -4°F (e.g., inside a car trunk), this procedure will safeguard vaccines for up to 1 hour.
- If the vaccine will be stored in refrigerators after transport, be sure these refrigerators have maintained temperatures between 35°F and 46°F for at least 3 to 5 days.

Assemble packing supplies and documents

1. **Cooler.** Use a hard-sided cooler. Attach a “Vaccine: Do Not Freeze” label to the cooler.
2. **“Conditioned” cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they’ve “sweated.” Cold packs that are not conditioned can freeze vaccine. **DO NOT USE dry ice.**
3. **Thermometer.** Prepare a VFC-compliant thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine. If you normally use a continuous-read monitoring system, you will need a portable thermometer for vaccine transport.
4. **Packing material.** Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.
5. **Transport Log.** Complete a Refrigerated Vaccine Transport Log (IMM. 1132) to document the duration and temperature monitoring information.

Pack vaccine and prepare for transport

1. **Cold packs.** Spread conditioned cold packs to cover only half of the bottom of the cooler.
2. **Bubble wrap.** Completely cover the vaccine with another 2-inch layer of bubble wrap.
3. **Thermometer.** Completely cover the cold packs with a 2-inch layer of bubble wrap. Then, place the thermometer probe on top of the bubble wrap directly above a cold pack.
4. **Vaccine.** Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.
5. **Cold packs.** Spread “conditioned” cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.
6. **Form & display.** Fill the cooler to the top with bubble wrap. Place the thermometer’s digital display and the Refrigerated Vaccine Transport Log on top. It’s okay if temperatures go above 46°F while packing.

Unpack vaccine

When you reach the destination site, record the temperature in the cooler on the Transport Log before removing the vaccine. If it is:
- Between 35°F and 46°F (2°C and 8°C), unpack the vaccine and put it in the refrigerator.
- Below 35°F (2°C) or above 46°F (8°C), call your VFC Representative or the VFC Program immediately at 877-243-0832. Then label the vaccine “Do Not Use” and place it in the refrigerator.

www.eziz.org

Vaccine Transport: CA Guidance

VACCINE FOR CHILDREN (VFC) PROGRAM
Refrigerated Vaccine Transport Log

Instructions: Complete this log when transporting vaccines to an alternate or back-up refrigerator.

Provider Name: ____________________________

Provider ID: ____________________________

Date: ____________________________

[Table: Vaccine Inventory Information]

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Lot Number</th>
<th>Number of Doses</th>
<th>Expiration Date</th>
<th>Vaccine previously transported? (yes)</th>
<th>Comments</th>
</tr>
</thead>
</table>

| Temperature Monitoring Information |

- Temperature of vaccine in refrigerator prior to transfer: C°F Time
- Temperature of vaccine in cooler before departure: C°F Time
- Temperature of vaccine in cooler upon arrival: C°F Time
- Temperature of back-up refrigerator: C°F Time

Contact the VFC Program (877-243-0832) if temperatures during transport exceed recommended ranges.
Survey Question: Dry ice can be used to transport vaccines between two clinics as long as a calibrated thermometer is used to monitor temperature during the transport.

True  
False  
Don’t Know

<table>
<thead>
<tr>
<th>Response</th>
<th>Total (n=1,087)</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
<td>427 (39%)</td>
</tr>
<tr>
<td>False</td>
<td>504 (46%)</td>
</tr>
<tr>
<td>Don’t know or Not sure</td>
<td>156 (14%)</td>
</tr>
</tbody>
</table>
Vaccine Transport: CA Guidance

Transporting Frozen Vaccines

Guidelines for emergency vaccine transport and short-term storage:

- Routine transport of vaccine stored in the freezer (MMR, MMRV, varicella, Zoster) is not allowed. These vaccines should only be moved when absolutely necessary.
- If vaccine must be transported to an off-site clinic, transport only what is needed for that clinic day.
- If vaccines must be transported, contact your VFC Program Representative or the VFC Program.
- Have an Emergency Vaccine Management Plan that includes the name and address of your back-up site.
- Varicella-containing vaccines should be transported under frozen conditions. Do not freeze diluent for varicella-containing vaccines.
- Complete a Frozen Vaccine Transport Log (PMN-1196) to document the duration and temperature monitoring information.

Pack vaccines and prepare for transport:

Prepare for transport:
- Verify that the destination site has room for your vaccine and that someone will be there when the vaccine arrives.
- Verify that you have all the packing supplies on the above list.
- Complete the Frozen Vaccine Transport Log.

Pack vaccines:
- Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice.
- Stack layers of vaccine boxes directly on top of the frozen ice packs.
- Fill the cooler to the top with insulation material (bubble wrap).
- Spread another layer of frozen ice packs to cover the vaccine.

Vaccine for Children (VFC) Program

Refrigerated Vaccine Transport Log

Instructions: Complete this log when transporting vaccines to an alternate or back-up refrigerator.

Provider Notes:

Vaccine transferred due to:
- Short supply
- Short dated
- Unit shortages
- Building maintenance
- Other

Vaccine Inventory Information

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Lot Number</th>
<th>Number of Doses</th>
<th>Expiration Date</th>
<th>Vaccine received from refrigerator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Temperature Monitoring Information

<table>
<thead>
<tr>
<th>Temperature monitored</th>
<th>C/F</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature of vaccine in refrigerator before transfer</td>
<td>C/F</td>
<td>Time</td>
</tr>
<tr>
<td>Temperature of vaccine in refrigerator before departure</td>
<td>C/F</td>
<td>Time</td>
</tr>
<tr>
<td>Temperature of vaccine in cooler before departure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature of vaccine in cooler before departure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature of back-up refrigerator</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Contact the VFC Program (877-260-8020) if temperatures during transport exceed recommended ranges.

Calif Dept of Public Health, Immunization Branch

California Department of Public Health, Immunization Branch
Appropriate Vaccine Storage Units

- Vaccine storage units must be reliable, maintaining adequate temperatures at all times to protect vaccine supply.
- The VFC Program has specific vaccine storage equipment requirements for participating providers, this includes types of units allowed, and specifications for those units.

<table>
<thead>
<tr>
<th>Office Size</th>
<th>Required Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very High Volume</strong></td>
<td>Pharmacy-grade or biologic-grade refrigerator-only units</td>
</tr>
<tr>
<td>10,000 doses/year</td>
<td>and stand-alone freezer units</td>
</tr>
<tr>
<td><strong>High Volume</strong></td>
<td>Refrigerator-only (11 cubic feet minimum) and stand-</td>
</tr>
<tr>
<td>2,000-10,000 doses/year</td>
<td>alone freezer units</td>
</tr>
<tr>
<td><strong>Medium Volume</strong></td>
<td>Refrigerator-only (11 cubic feet minimum) and stand-</td>
</tr>
<tr>
<td>500-2,000 doses/year</td>
<td>alone freezer units OR</td>
</tr>
<tr>
<td><strong>Low Volume</strong></td>
<td>Pharmacy-grade or biologic-grade under the counter</td>
</tr>
<tr>
<td>Less than 500</td>
<td>units.</td>
</tr>
<tr>
<td>doses/year</td>
<td></td>
</tr>
</tbody>
</table>
Vaccine Storage

Arriving at the final destination
The moment a shipment reaches its destination, a vaccine arrival report is completed to ensure that the type of vaccine, batch numbers, shipping boxes, vial size, quantity and expiration date all correspond to shipping papers. Temperature monitors and vaccine boxes are examined to ensure that the cold chain has been maintained. All documents are checked for compliance with shipping instructions and to ensure that relevant certificates and test protocols are included. Once this has been done, the vaccine arrival report is signed, and the recipient government assumes responsibility to maintain the vaccine in good condition.

Storing the precious cargo
When the vaccines arrive at the national cold storage facility, details of their type, the number of doses, batch number and expiration date are recorded again. The vaccines are regularly checked while in storage and when they leave for distribution.

Newly arrived shipments are immediately stored in giant walk-in freezers or refrigerators where temperatures are monitored and recorded several times a day. Since different vaccines require different storage conditions, staff must ensure the optimal storage conditions for each vaccine. That means that exactly the right temperature range is maintained continuously, from manufacture until the moment of use.
Appropriate Vaccine Storage Units

• Store refrigerated vaccines in a stand-alone refrigerator

• Store frozen vaccines in a stand-alone freezer
  • Below +5 °F (-15 °C)
### Appropriate Vaccine Storage Units: Refrigerator-only units

<table>
<thead>
<tr>
<th>Grade/Type</th>
<th>Comments</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical grade/purpose-built units</td>
<td>Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.</td>
<td>Best</td>
</tr>
<tr>
<td>(stand-alone)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical grade/purpose-built units</td>
<td>Specifically engineered to maintain consistent temperatures throughout the unit. These units have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.</td>
<td>Best</td>
</tr>
<tr>
<td>(combination)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial units*</td>
<td>Usually intended to store food and beverages and are often larger and more powerful than household units. These units are not specifically designed to store biological materials, but may be acceptable under certain conditions.</td>
<td>Good</td>
</tr>
<tr>
<td>(stand-alone)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household*</td>
<td>Usually smaller than commercial units and are intended for use in small offices and in homes, typically for food storage. Like commercial units, they are not designed to store biological materials, but may be acceptable under certain conditions.</td>
<td>OK</td>
</tr>
<tr>
<td>(stand-alone)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*These units may require additional water bottles (refrigerator) or frozen cold packs (freezer) to maintain stable temperatures. Consult your VFC Representative for guidance.
### Unacceptable Vaccine Storage Units

**Unacceptable Storage Units**

These do not meet VFC specifications and may **not** be used to store vaccines.

<table>
<thead>
<tr>
<th>Household combination units</th>
<th>These units have a refrigerator and a freezer with separate exterior doors. These units have one compressor with poor temperature control. They may pose a risk to refrigerated vaccines because cold air from the freezer is vented into the refrigerator and can freeze vaccines. The freezer portions of many combination units are not capable of maintaining the correct temperature for frozen vaccines.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dormitory-style and bar-style combined refrigerator/freezers</strong></td>
<td>These units pose a significant risk of freezing even when used for temporary storage.</td>
</tr>
<tr>
<td><strong>Manual defrost (cyclic defrost) units</strong></td>
<td>These models have an exposed vertical cooling plate at the back of the refrigerator. They have significant temperature variation and risk freezing vaccines.</td>
</tr>
<tr>
<td><strong>Convertible refrigerator-only units</strong></td>
<td>These units have an internal switch that converts an “all-refrigerator unit” to an “all freezer” unit.</td>
</tr>
</tbody>
</table>

Household combination units are no longer accepted for the storage of small supplies of vaccine.
Unit Specifications

Refrigerator Specifications

Refrigerators must:

- Maintain consistent temperatures between 35.0°F and 46.0°F (2.0°C and 8.0°C);
- Be a stand-alone unit;
- Have a capacity of 11 cubic feet or larger, unless it is a pharmacy-grade or biologic-grade under-the-counter unit (applicable for low-volume providers only);
- Have enough space to store all the practice’s refrigerated vaccine inventory throughout the year, including during flu and back-to-school seasons.
- Have enough space to store water bottles to stabilize temperatures;
- Defrost automatically and be free of frost, ice, water, and leaks;
- Seal tightly and close properly;
- Be used primarily for vaccine storage. In limited circumstance, medications or biologic media (not inoculated) may be stored on the shelves below vaccines.
Very High Volume, Biomedical, Pharm
Purpose-Built Vaccine Refrigerator

ADVANTAGES

A digital feedback system achieves narrow tolerances within internal temperatures, thus providing an excellent temperature regulation system for vaccine storage.

Ongoing air circulation ensures that the temperature distribution is even.

A set-point temperature, within a +2°C to +8°C (+35°F to +46°F) range, is maintained.

Evaporator operates at +2°C (+35°F), which prevents vaccine from freezing.

Air circulation is fan forced.

Temperature recovery system is good.

Built to handle ambient temperature changes.

LIMITATIONS

Glass door design required extra effort to protect vaccines from light exposure.

Glass doors do not provide good insulation in the event of a power interruption.
Appropriate Vaccine Storage Units: Freezers

Upright freezer

Chest freezer
Catching up with WHO’s Recommendations

Temperature monitoring principles - 2

- **Storekeepers must know correct vaccine storage conditions**
  - Incorrect storage places vaccine at risk

- **Temperature monitoring should be continuous**
  - Periodic (e.g. twice daily) monitoring only tells you the temperature at the time of inspection. These devices provide continuous monitoring:

  - A thermometer does not:
Thermometer Requirements

Use a VFC-compliant temperature monitoring device in each vaccine storage unit at all times. Have at least one VFC-compliant back-up device for use when primary devices fail or are being recalibrated.

To meet specifications, temperature monitoring devices must:

- Be accurate within +/-1.0°F (+/-0.5°C);
- Be digital, with the digital display placed outside the unit;
- Have a buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum);
- Display current, minimum, and maximum temperatures;
- Have a visual or audible alarm to signal out-of-range temperatures;
- Be calibrated annually (or every other year when the manufacturer recommends calibration done in a period that is longer than two years); and
- Have a valid Certificate of Calibration on file for 3 years and presented upon request.
- Memory stores at least 4,000 readings (specific to data loggers only)

All new VFC providers, practices that are open 2 days a week or less, and practices needing to replace their primary or back-up thermometer will be required to purchase and use data loggers to monitor temperatures. Providers conducting mass vaccination clinics also must use data loggers to monitor temperatures during vaccine transport and at the mass vaccination clinic.
Installing a new temperature monitoring device in your fridge? Play, Practice, and Test

Practice and test before set-up in the unit

1. Test alarm settings to make sure they work
2. Practice resetting temperature readings
3. Train, and verify competency of thermometer use among all staff responsible for temperature monitoring

“DON'T PRACTICE UNTIL YOU GET IT RIGHT.

PRACTICE UNTIL YOU CAN'T GET IT WRONG.”

Pretty... BEAUTIFUL... Things.
Installing a new temperature monitoring device in your fridge?
Temperature Documentation

Read and record refrigerator and freezer (including current, minimum, and maximum) temperatures twice each workday, at the beginning of the day and prior to closing.

Use only current VFC Program temperature logs, available from EZIZ, even if using a continuous temperature recording device or a digital data logger.

Only trained staff may record temperatures. Specify the names of staff who record temperatures on the practice’s Routine Vaccine Management Plan.

Record out-of-range temperature excursions and the action(s) taken. Vaccines stored out of range may be deemed non-viable, and maybe considered a negligent vaccine loss. If temperatures are not monitored and documented for a prolonged period of time, the affected vaccines will be automatically deemed non-viable and this will be considered a negligent vaccine loss.

Supervisors must review and sign completed temperature logs.

Maintain completed temperature logs for three years. Be prepared to present them upon request.
VFC Requirements

• Not intended to be a burden for providers
• Aimed at ensuring vaccine availability for VFC eligible children, preserving program integrity, ensuring safe management and handling of vaccines, ultimately ensuring the protection of children from vaccine preventable diseases
• Try to minimize impact in practices as much as possible
Questions?

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