# 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

# 21th 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 → more than the current population of the entire U.S.A.

help avoid **732,000** deaths → greater than the population of Boston, MA.

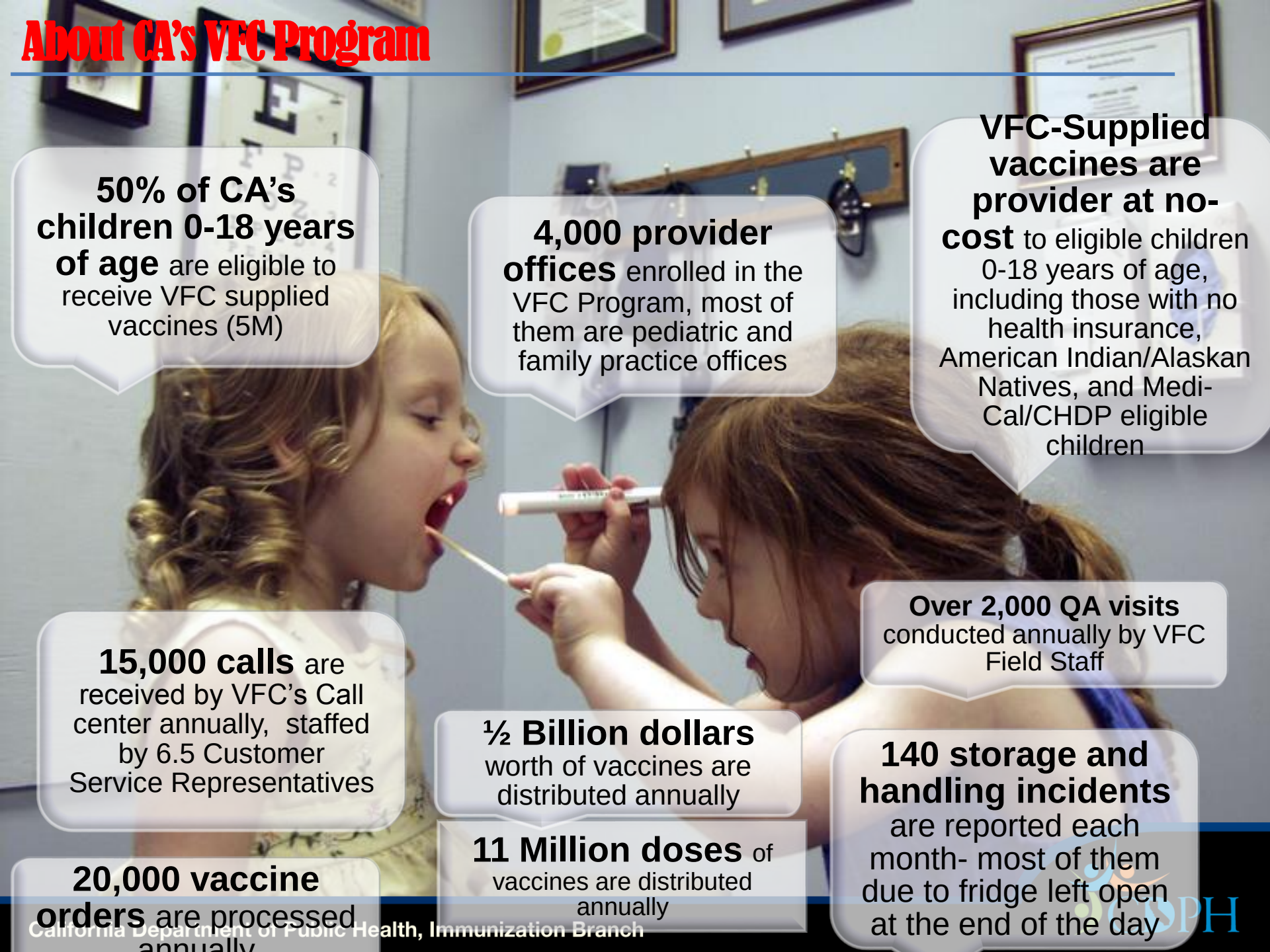
save nearly **$1.4 trillion** in total societal costs *(that includes $295 billion in direct costs)* → or $4,473 for each American

20 Years of Success VFC Vaccines for Children Program

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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

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

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

**½ Billion dollars** worth of vaccines are distributed annually

**11 Million doses** of vaccines are distributed annually

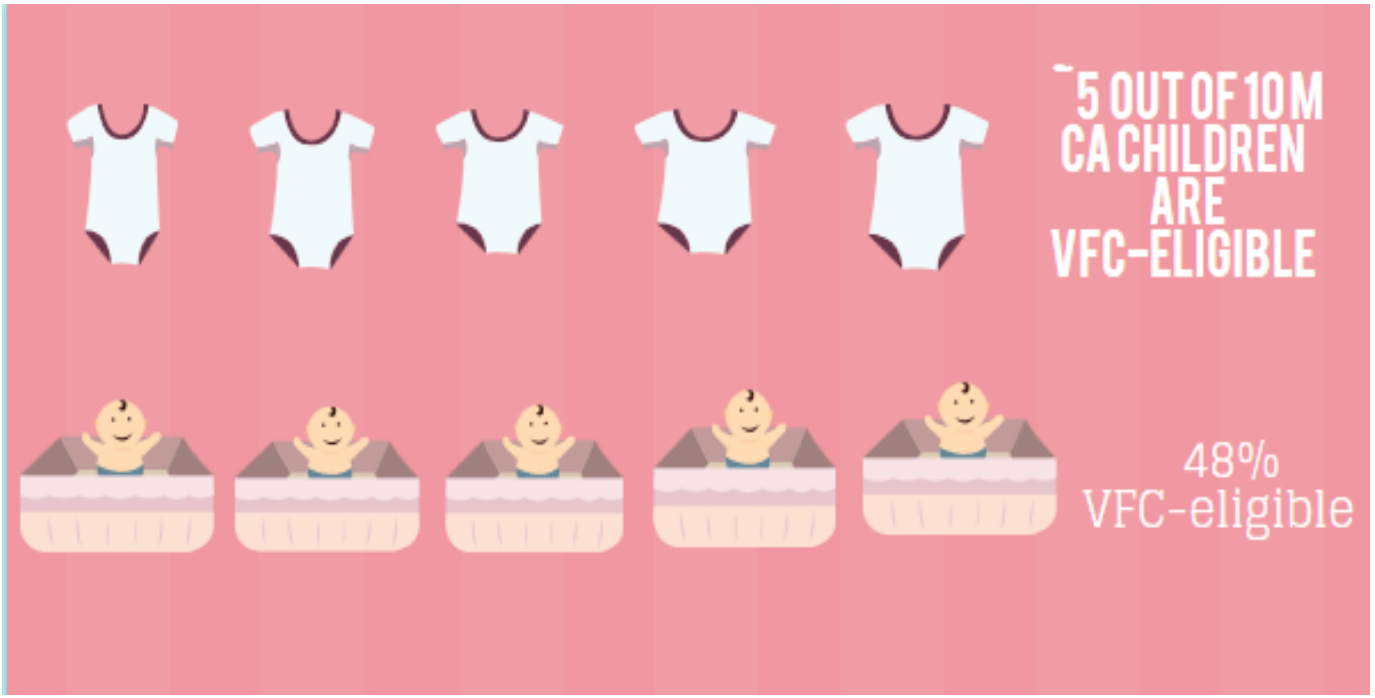
**140 storage and handling incidents** are reported each month- most of them due to fridge left open at the end of the day

**20,000 vaccine orders** are processed annually



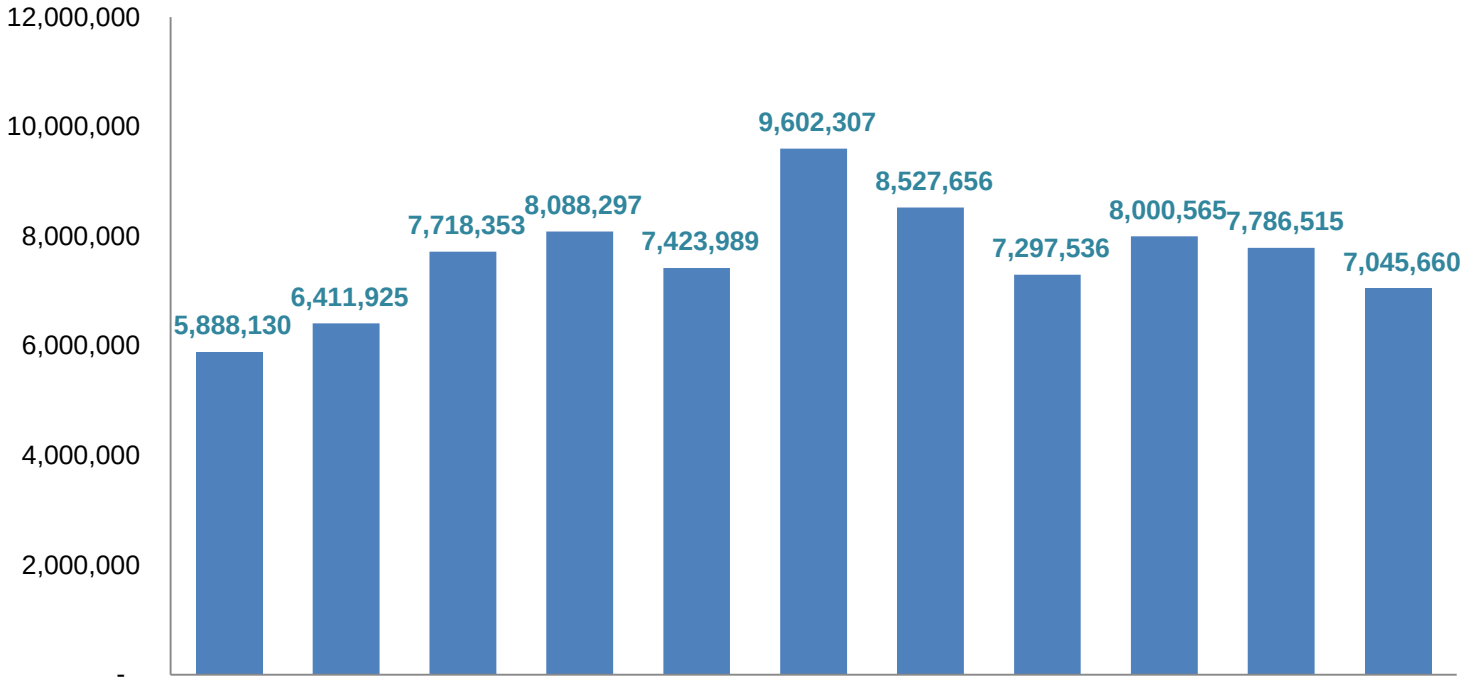
CDPH

# Your Impact




**YOU** make it happen

# CA Vaccine Distribution 2005-2015




**89 Million Doses***

* ^ Partial years

*Excluding Flu

# 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**

| Dose | Rotateq® Age | Rotarix® Age |
|---|---|---|
| Primary 1 | 2 months | 2 months |
| Primary 2 | 4 months | 4 months |
| Primary 3 | 6 months | ------ |

**Dosage Intervals and Ages for Rotavirus Vaccines**

| | RV5 (RotaTeq®; Merck) | RV1 (Rotarix®; GSK) |
|---|---|---|
| Number of doses in series | 3 | 2 |
| Recommended ages for doses | 2, 4, and 6 months | 2 and 4 months |
| Minimum age for first dose | 6 weeks | |
| Maximum age for first dose | 14 weeks 6 days | |
| Interval between doses | 4 weeks or more | |
| Maximum age for last dose | 8 months 0 days | |

# ACIP-Recommended Pediatric and Adolescent Vaccines

**Pediatric vaccines**

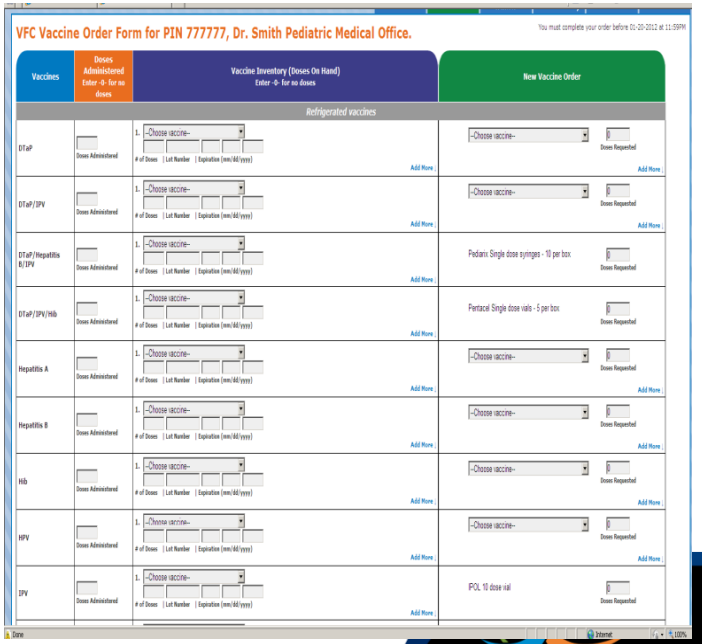
- Diphtheria, Tetanus, Pertussis (DTaP)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- *Haemophilus influenza* type b (Hib)
- Inactivated poliovirus (IPV)
- Influenza (flu)
- Meningococcal B (MenB)
- Measles, Mumps, Rubella (MMR)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)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

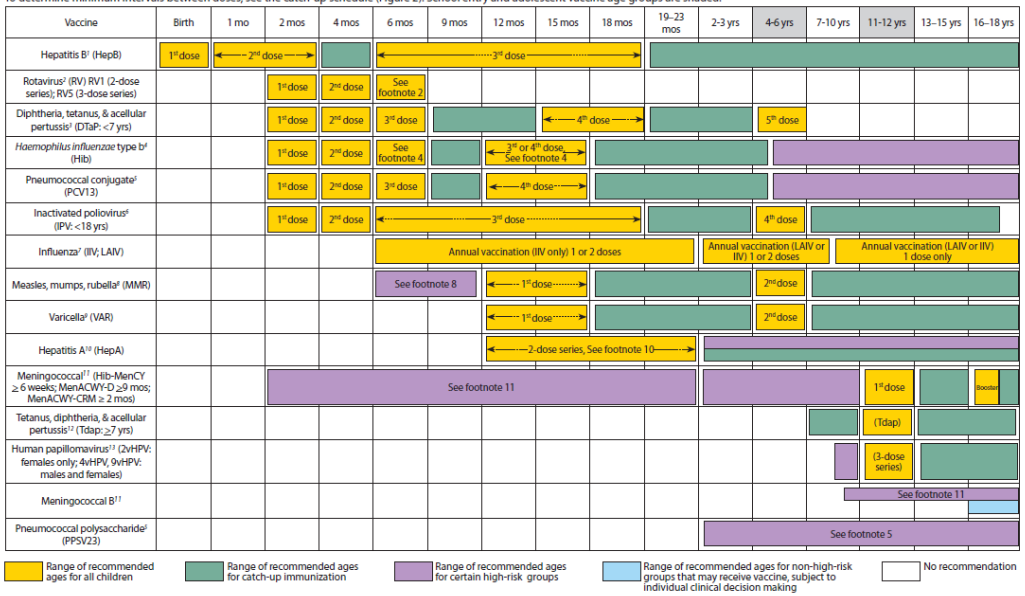


# Vaccine Requirements vs. Federal Vaccine Recommendations

**Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2016.**

**(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).**

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.




This schedule includes recommendations in effect as of January 1, 2016. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

**NOTE: The above recommendations must be read along with the footnotes of this schedule.**

**CALIFORNIA CODE OF REGULATIONS**
**TITLE 17, DIVISION 1, CHAPTER 4**

Subchapter 8. Immunization Against Poliomyelitis, Diphtheria, Pertussis, Tetanus, Measles (Rubeola), Haemophilus influenzae Type B (Hib), and Mumps

***Table 1: Immunization Requirements for K-12***

| Institution | Age | Vaccine | Total Doses Received |
|---|---|---|---|
| Elementary school at kindergarten level and above | 4-6 years | Polio[1] | 4 doses, except that a total of 3 doses is acceptable if at least one dose was given on or after the 4th birthday |
| | | DTP, or combination of DTP and diphtheria-tetanus toxoids | 5 doses, except that a total of 4 doses is acceptable if at least one dose was given on or after the 4th birthday |
| | | Measles, rubella, and mumps | 1 dose of each, separately or combined, on or after the 1st birthday. Pupils entering a kindergarten (or first grade kindergarten skipped) are required to have 2 doses of measles-containing vaccine, both given on or after the first birthday |
| | | Hepatitis B[2] | 3 doses |
| | | Varicella | 1 dose |
| Elementary school, secondary school | 7-17 years | Polio[3] | 4 doses, except that a total of 3 doses is acceptable if at least one dose was given on or after the 2nd birthday |
| | | Diphtheria and tetanus toxoids and pertussis vaccine given as DTP, DT, Td, or Tdap | At least 3 doses. One more dose is required if the last dose was given before the 2nd birthday |
| | | Measles and rubella (mumps not required) | 1 dose of each, separately or combined, on or after the 1st birthday. (See below for additional requirements for 7th grade enrollment, effective 7/1/99.) |
| | | Varicella[4] | 1 dose aged 7 through 12 years for students not admitted to California schools before July 1, 2001. 2 doses for students aged 13 through 17 years not admitted to California schools before July 1, 2001. |
| Seventh Grade | Any | Tdap[5,6] | 1 dose on or after the 7th birthday |
| | | Measles[3] | 2 doses of measles -containing vaccine, both given on or after the first birthday. |
| Eighth through Twelfth Grades[7] | Any pupil under 18 years | Tdap[5,6] | 1 dose on or after the 7th birthday |
| Any | 18 years ad older | None | |

[1] Oral polio vaccine (OPV) or inactivated polio vaccine (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 entering at kindergarten level (or at first grade level if kindergarten skipped) or below on or after August 1, 1997.

[3] Applies only to children (of any age) entering or advancing to the seventh grade on or after July 1, 1999.

[4] Children admitted to California schools at the Kindergarten level or above before July 1, 2001 are exempt from this requirement.

[5] Pupils must have received at least one dose of Tdap prior to admission or advancement into the 7th through 12th grades.

[6] 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.

[7] 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

| Birth | 1 month | 2 months | 4 months | 6 months | 12 months | 15 months | 18 months | 19–23 months | 2–3 years | 4–6 years |
|---|---|---|---|---|---|---|---|---|---|---|
| HepB | HepB | | | HepB | | | | | | |
| | | RV | RV | RV | | | | | | |
| | | DTaP | DTaP | DTaP | | DTaP | | | | DTaP |
| | | Hib | Hib | Hib | Hib | | | | | |
| | | PCV | PCV | PCV | PCV | | | | | |
| | | IPV | IPV | | IPV | | | | | IPV |
| | | | | | Influenza (Yearly)* | | | | | |
| | | | | | | MMR | | | | MMR |
| | | | | | | Varicella | | | | Varicella |
| | | | | | | | HepA§ | | | |

**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.

Shaded boxes indicate the vaccine can be given during shown age range.

**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:**

* 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.

§ 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.

*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.*

SEE BACK PAGE FOR MORE INFORMATION ON VACCINE-PREVENTABLE DISEASES AND THE VACCINES THAT PREVENT THEM.

For more information, call toll free
**1-800-CDC-INFO** (1-800-232-4636)
or visit
**http://www.cdc.gov/vaccines**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
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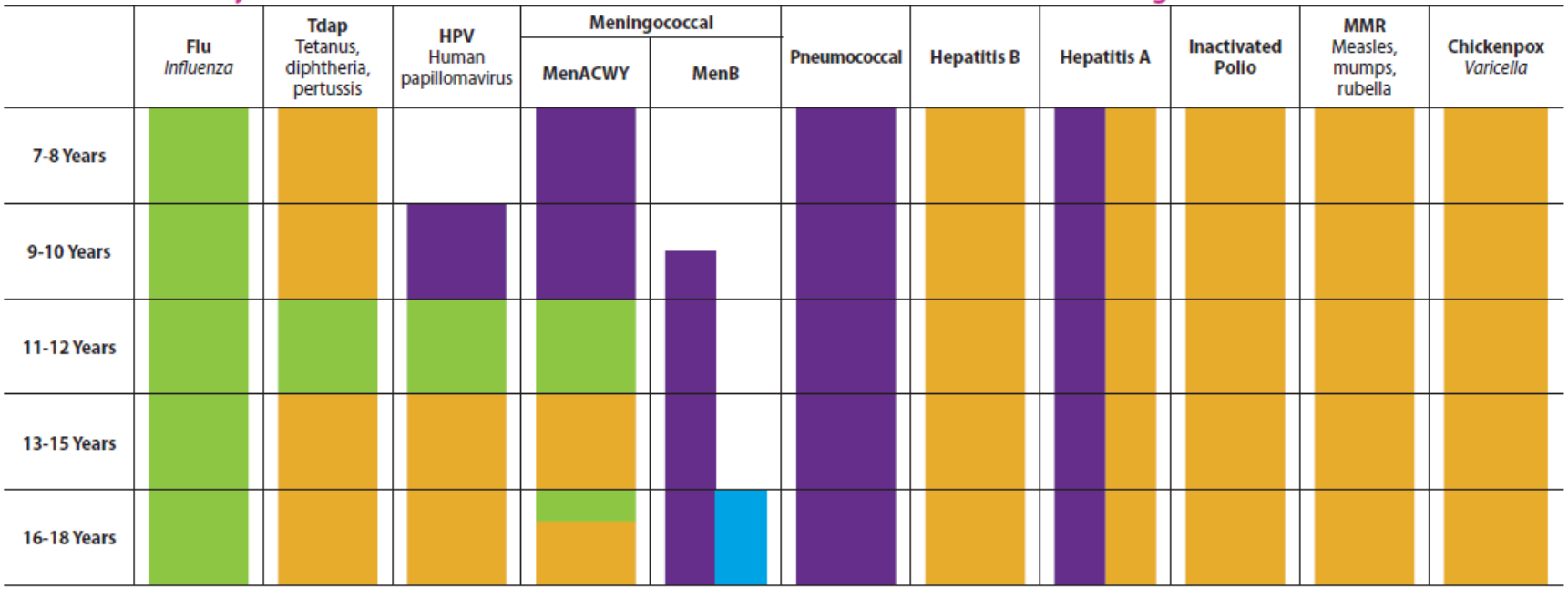
INFORMATION FOR PARENTS

# 2016 Recommended Immunizations for Children 7-18 Years Old

## Talk to your child's doctor or nurse about the vaccines recommended for their age.




**More information:**

- **Flu:** Preteens and teens should get a flu vaccine every year.
- **Tdap:** Preteens and teens should get one shot of Tdap at age 11 or 12 years.
- **HPV:** 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.
- **MenACWY:** 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.**
- **MenB:** 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 with certain health or lifestyle conditions that put them at an increased risk for serious diseases. See vaccine-specific recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html

This shaded box indicates the vaccine is recommended for children not at increased risk but who wish to get the vaccine after speaking to a provider.

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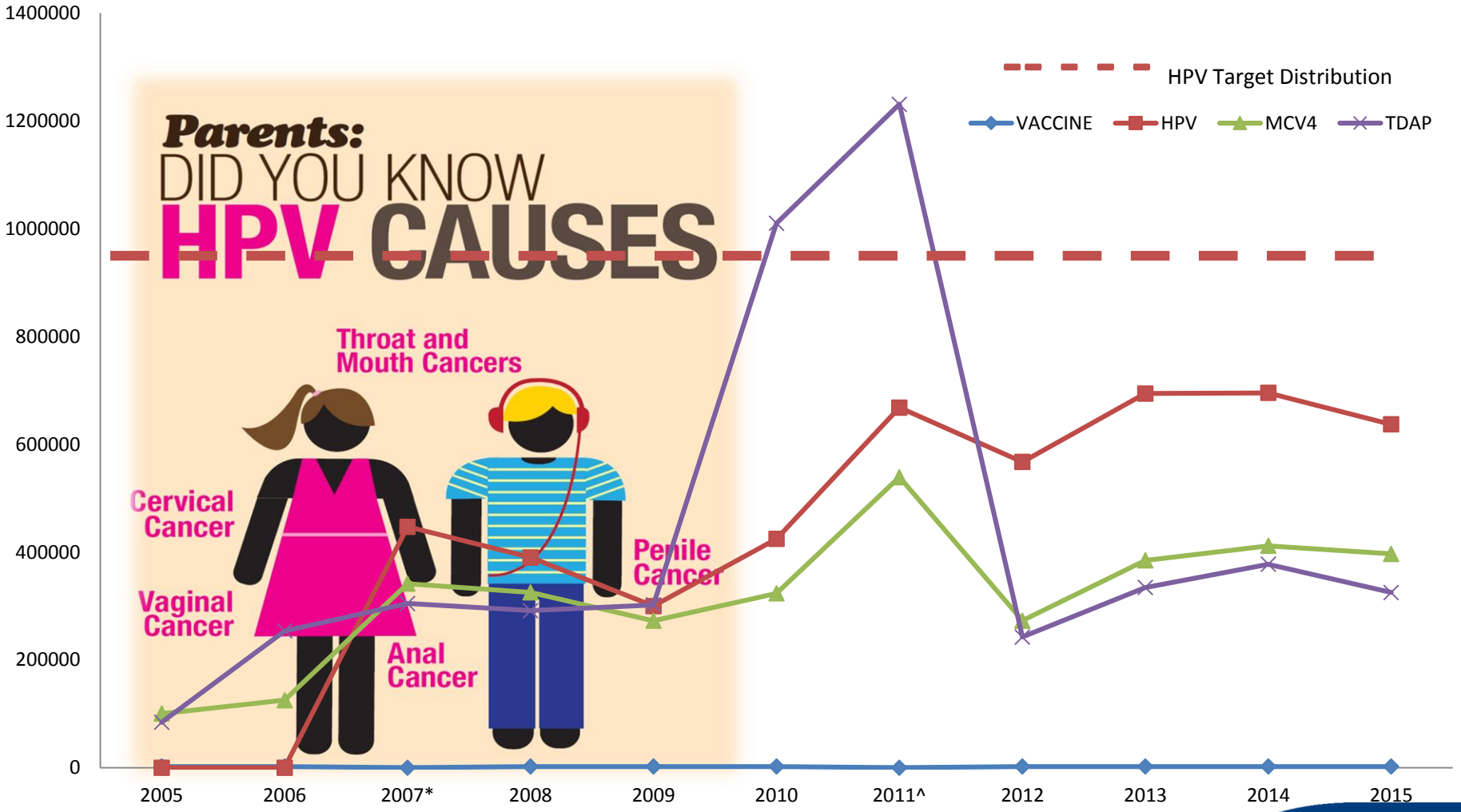
# Adolescent Vaccine Distribution



# 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.

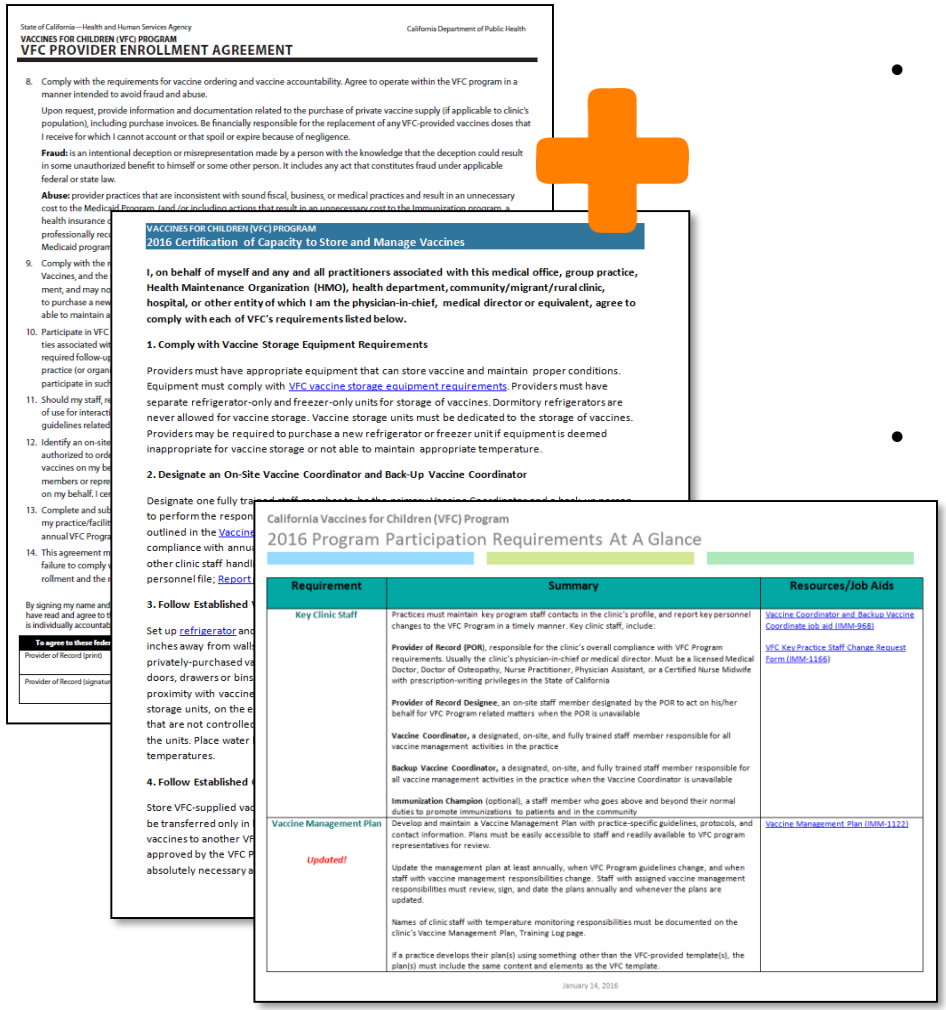

They are developed and implemented by all levels of government (federal, state and local) and private sector.

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

# Provider Agreements, *plus* Certification of Capacity to Store and Manage Vaccines



State of California—Health and Human Services Agency — California Department of Public Health

VACCINES FOR CHILDREN (VFC) PROGRAM

**VFC PROVIDER ENROLLMENT AGREEMENT**

8. Comply with the requirements for vaccine ordering and vaccine accountability. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.

Upon request, provide information and documentation related to the purchase of private vaccine supply (if applicable to clinic's population), including purchase invoices. Be financially responsible for the replacement of any VFC-provided vaccines doses that I receive for which I cannot account or that spoil or expire because of negligence.

**Fraud:** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

**Abuse:** provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid Program, and/or including actions that result in an unnecessary cost to the Immunization program, a health insurance c… professionally rec… Medicaid program…

9. Comply with the r… Vaccines, and the … ment, and may no… to purchase a new… able to maintain a…

10. Participate in VFC … ties associated wit… required follow-up… practice (or organ… participate in such…

11. Should my staff, re… of use for interact… guidelines related…

12. Identify an on-site … authorized to ord… vaccines on my be… members or repre… on my behalf. I cer…

13. Complete and sub… my practice/facilit… annual VFC Progra…

14. This agreement m… failure to comply … rollment and the r…

By signing my name and … have read and agree to t… is individually accountab…

To agree to these terms …

Provider of Record (print)

Provider of Record (signatur…

VACCINES FOR CHILDREN (VFC) PROGRAM

**2016 Certification of Capacity to Store and Manage Vaccines**

**I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization (HMO), health department, community/migrant/rural clinic, hospital, or other entity of which I am the physician-in-chief, medical director or equivalent, agree to comply with each of VFC's requirements listed below.**

**1. Comply with Vaccine Storage Equipment Requirements**

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Equipment must comply with VFC vaccine storage equipment requirements. Providers must have separate refrigerator-only and freezer-only units for storage of vaccines. Dormitory refrigerators are never allowed for vaccine storage. Vaccine storage units must be dedicated to the storage of vaccines. Providers may be required to purchase a new refrigerator or freezer unit if equipment is deemed inappropriate for vaccine storage or not able to maintain appropriate temperature.

**2. Designate an On-Site Vaccine Coordinator and Back-Up Vaccine Coordinator**

Designate one fully trained staff member to be the primary Vaccine Coordinator and a back-up person to perform the respon… outlined in the Vaccine… compliance with annu… other clinic staff handl… personnel file; Report…

**3. Follow Established …**

Set up refrigerator and … inches away from walls … privately-purchased va… doors, drawers or bins… proximity with vaccine… storage units, on the e… that are not controlled… the units. Place water … temperatures.

**4. Follow Established …**

Store VFC-supplied vac… be transferred only in … vaccines to another VF… approved by the VFC P… absolutely necessary a…

California Vaccines for Children (VFC) Program

2016 Program Participation Requirements At A Glance

| Requirement | Summary | Resources/Job Aids |
|---|---|---|
| Key Clinic Staff | Practices must maintain key program staff contacts in the clinic's profile, and report key personnel changes to the VFC Program in a timely manner. Key clinic staff, include:<br><br>**Provider of Record (POR)**, responsible for the clinic's overall compliance with VFC Program requirements. Usually the clinic's physician-in-chief or medical director. Must be a licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Physician Assistant, or a Certified Nurse Midwife with prescription-writing privileges in the State of California<br><br>**Provider of Record Designee**, an on-site staff member designated by the POR to act on his/her behalf for VFC Program related matters when the POR is unavailable<br><br>**Vaccine Coordinator,** a designated, on-site, and fully trained staff member responsible for all vaccine management activities in the practice<br><br>**Backup Vaccine Coordinator,** a designated, on-site, and fully trained staff member responsible for all vaccine management activities in the practice when the Vaccine Coordinator is unavailable<br><br>**Immunization Champion** (optional), a staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community | Vaccine Coordinator and Backup Vaccine Coordinate job aid (IMM-968)<br><br>VFC Key Practice Staff Change Request Form (IMM-1166) |
| Vaccine Management Plan<br><br>*Updated!* | Develop and maintain a Vaccine Management Plan with practice-specific guidelines, protocols, and contact information. Plans must be easily accessible to staff and readily available to VFC program representatives for review.<br><br>Update the management plan at least annually, when VFC Program guidelines change, and when staff with vaccine management responsibilities change. Staff with assigned vaccine management responsibilities must review, sign, and date the plans annually and whenever the plans are updated.<br><br>Names of clinic staff with temperature monitoring responsibilities must be documented on the clinic's Vaccine Management Plan, Training Log page.<br><br>If a practice develops their plan(s) using something other than the VFC-provided template(s), the plan(s) must include the same content and elements as the VFC template. | Vaccine Management Plan (IMM-1122) |

January 14, 2016

- 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

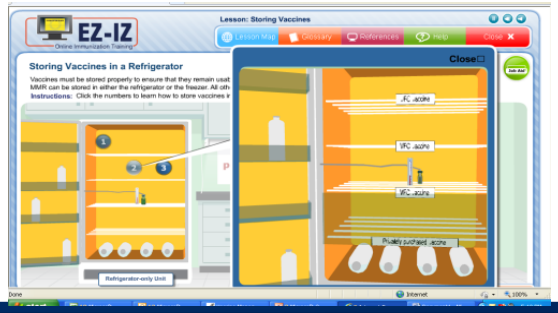
***Provider of Record*** –Medical Director or equivalent at the office who must sign the enrollment forms and whose responsibilities include:

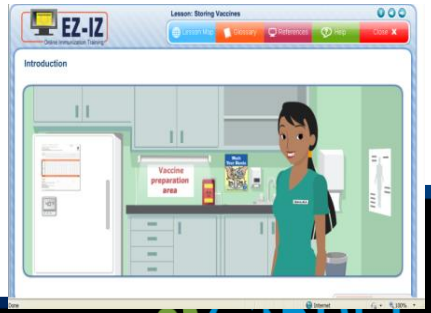
- Operate within all program requirements
- Account for VFC doses AND be accountable for vaccine loss (negligence)
- Identify, train, and evaluate skill for key staff with vaccine management responsibilities
- Ensure use of appropriate vaccine storage and temperature monitoring equipment
- Develop and 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 to 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

| | | Key Clinic Staff | | | |
|---|---|---|---|---|---|
| | | Vaccine Coordinator | Back-up Vaccine Coordinator | Provider of Record | Provider of Record Designee |
| Lessons | VFC Program Requirements | ✓ | ✓ | ✓ | ✓ |
| | Storing Vaccines | ✓ | ✓ | ✓ | ✓ |
| | Monitoring Storage Unit Temperatures *(NEW)* | ✓ | ✓ | ✓ | ✓ |
| | Conducting a Vaccine Inventory | ✓ | ✓ | Optional | Optional |
| Review & Acknowledge | 2016 Refrigerator Temperature Log *(NEW)* | ✓ | ✓ | ✓ | ✓ |
| | 2016 Freezer Temperature Log *(NEW)* | ✓ | ✓ | ✓ | ✓ |



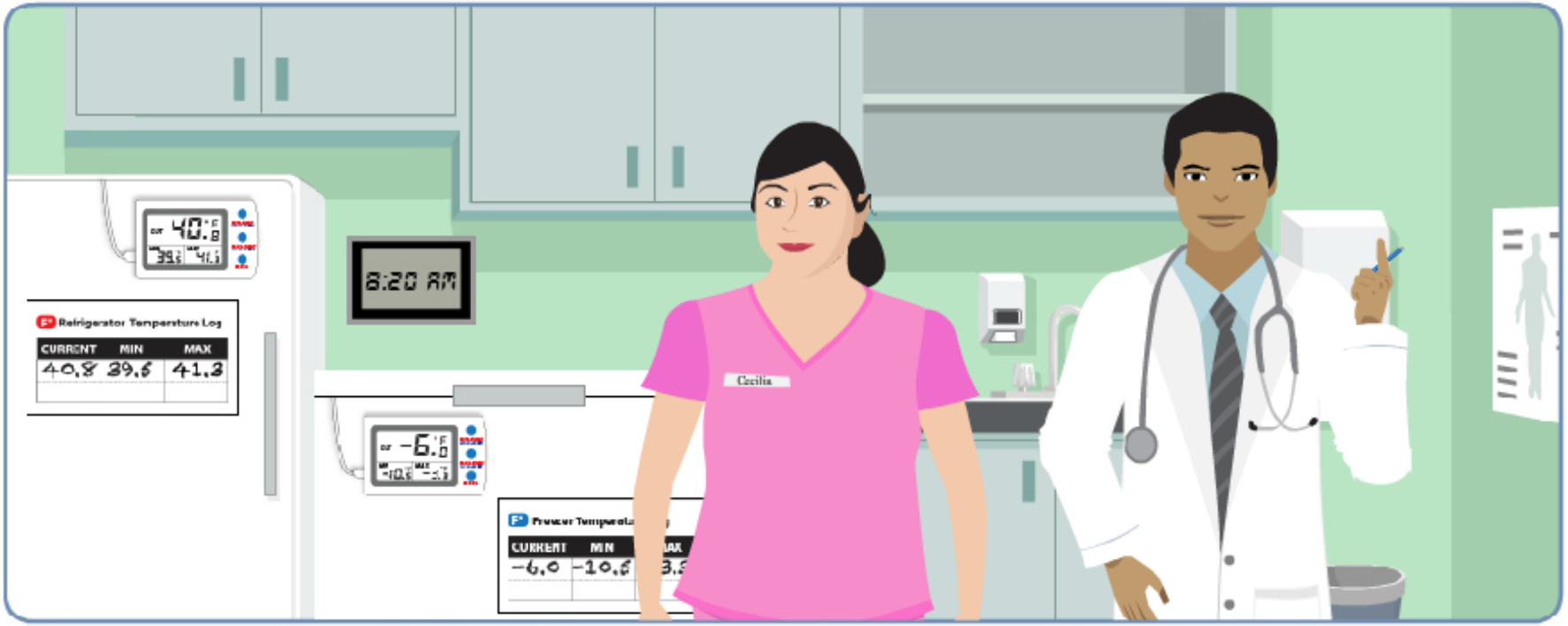



# New Temperature Monitoring Lesson Required for key practice staff *AND clinic staff responsible for temperature monitoring*

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

**EZIZ** Lesson: Monitoring Storage Unit Temperatures

## Welcome to Monitoring Storage Unit Temperatures

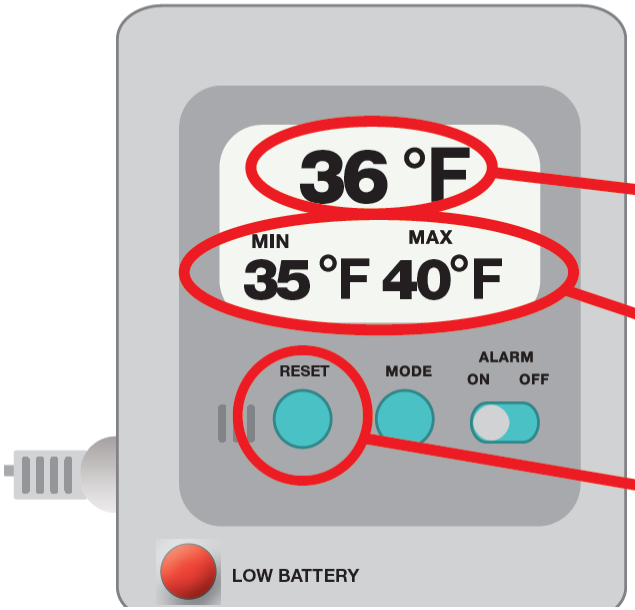


# Training and Supervision


- 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.

# Temperature Monitoring

## 2 Record daily temperatures




**Three Steps - Twice a Day:** Temperatures should be checked and recorded first thing in the morning and before leaving at night.

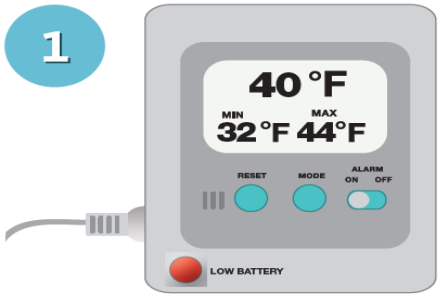
1. **Current Temperature:** The temperature that the refrigerator is right now.
2. **Min/Max:** The coldest and warmest the refrigerator has been since you last reset the thermometer.
3. **Reset:** The button you push after you have checked the Min/Max.

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**



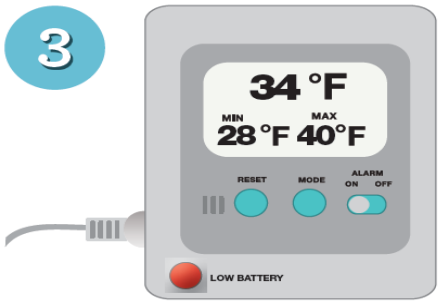

**A.** Current temp and min/max are within range - no action necessary

**B.** 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

**3**



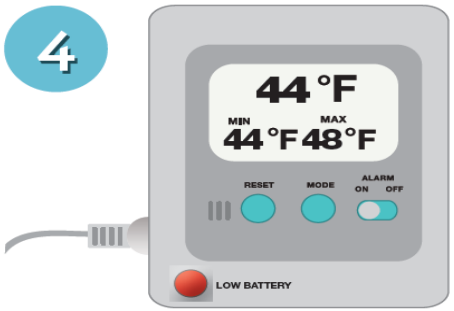

**A.** Current temp and min/max are within range - no action necessary

**B.** 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

**4**



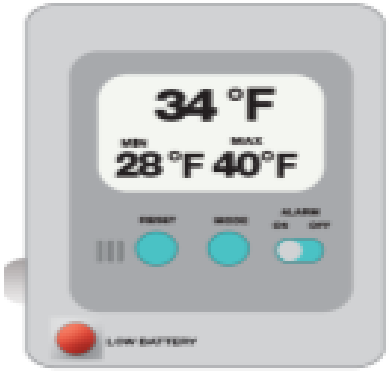

**A.** Current temp and min/max are within range - no action necessary

**B.** 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



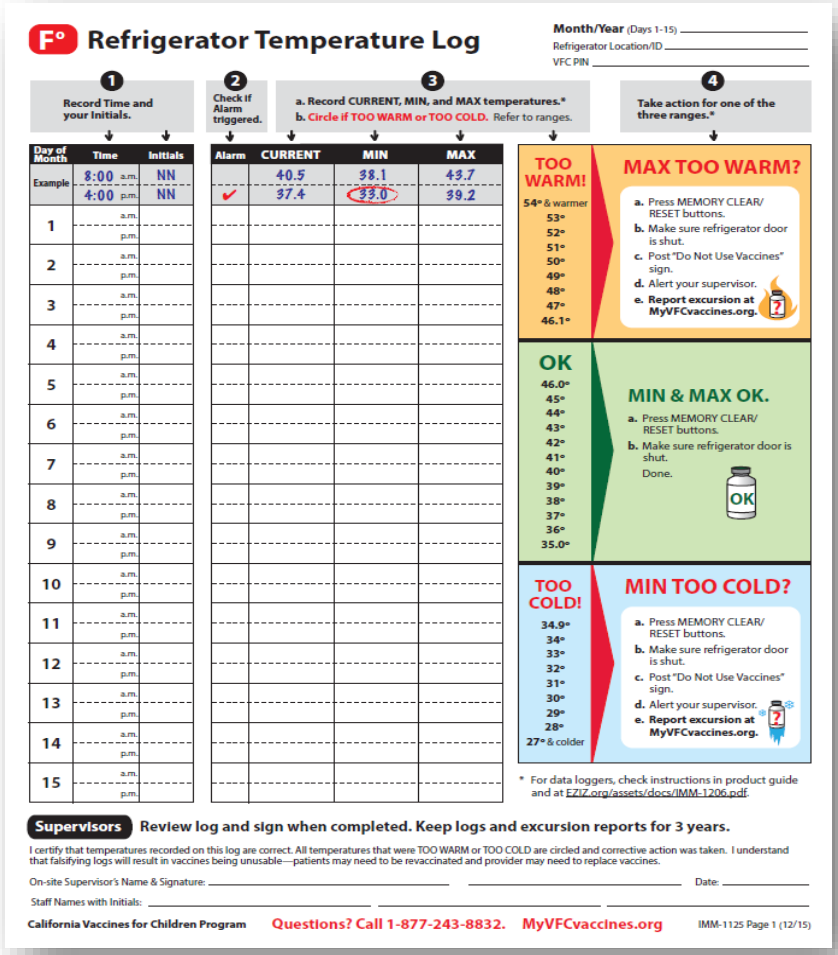

- Survey Question: What is the MIN temperature on a MIN/MAX thermometer? Select one.

| | |
|---|---|
| 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



**F° Refrigerator Temperature Log**

Month/Year (Days 1-15) _____
Refrigerator Location/ID _____
VFC PIN _____

1 Record Time and your Initials. | 2 Check if Alarm triggered. | 3 a. Record CURRENT, MIN, and MAX temperatures.* b. Circle if TOO WARM or TOO COLD. Refer to ranges. | 4 Take action for one of the three ranges.*

| Day of Month | Time | Initials | Alarm | CURRENT | MIN | MAX |
|---|---|---|---|---|---|---|
| Example | 8:00 a.m. | NN | | 40.5 | 38.1 | 43.7 |
| | 4:00 p.m. | NN | ✔ | 37.4 | 33.0 | 39.2 |
| 1 | a.m. p.m. | | | | | |
| 2 | a.m. p.m. | | | | | |
| 3 | a.m. p.m. | | | | | |
| 4 | a.m. p.m. | | | | | |
| 5 | a.m. p.m. | | | | | |
| 6 | a.m. p.m. | | | | | |
| 7 | a.m. p.m. | | | | | |
| 8 | a.m. p.m. | | | | | |
| 9 | a.m. p.m. | | | | | |
| 10 | a.m. p.m. | | | | | |
| 11 | a.m. p.m. | | | | | |
| 12 | a.m. p.m. | | | | | |
| 13 | a.m. p.m. | | | | | |
| 14 | a.m. p.m. | | | | | |
| 15 | a.m. p.m. | | | | | |

**TOO WARM!** 54° & warmer, 53°, 52°, 51°, 50°, 49°, 48°, 47°, 46.1°
**MAX TOO WARM?**
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. **Report excursion at MyVFCvaccines.org.**

**OK** 46.0°, 45°, 44°, 43°, 42°, 41°, 40°, 39°, 38°, 37°, 36°, 35.0°
**MIN & MAX OK.**
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
Done.

**TOO COLD!** 34.9°, 34°, 33°, 32°, 31°, 30°, 29°, 28°, 27° & colder
**MIN TOO COLD?**
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. **Report excursion at MyVFCvaccines.org.**

* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1206.pdf.

**Supervisors** Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccines.

On-site Supervisor's Name & Signature: _____ _____ Date: _____

Staff Names with Initials: _____ _____ _____

California Vaccines for Children Program Questions? Call 1-877-243-8832. MyVFCvaccines.org IMM-1125 Page 1 (12/15)

# 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

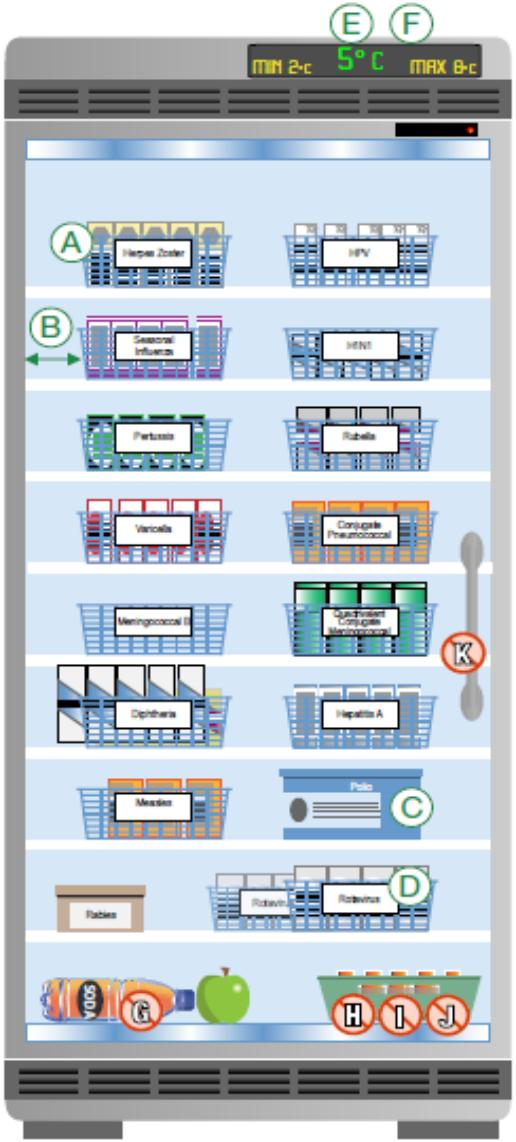
# Improved use of Vaccine Storage Equipment

Mid 90's: Any refrigerator.

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

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

**2016:** No combo refrigerators, purpose build units standalone units optimal, household standalone units ok.



# Improved use of Vaccine Storage Equipment

# Advance Temperature Monitoring Equipment

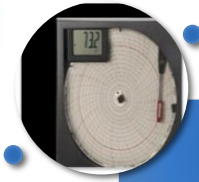
Sticking Point: Temperature Control Vital to Vaccine Viability

BY MICHAL CHOJNACKY ON JANUARY 21, 2016 HEALTH, PHYSICS, PUBLIC SAFETY


Use of continuous recording devices


Use of high accuracy thermometers

Use of buffered probes

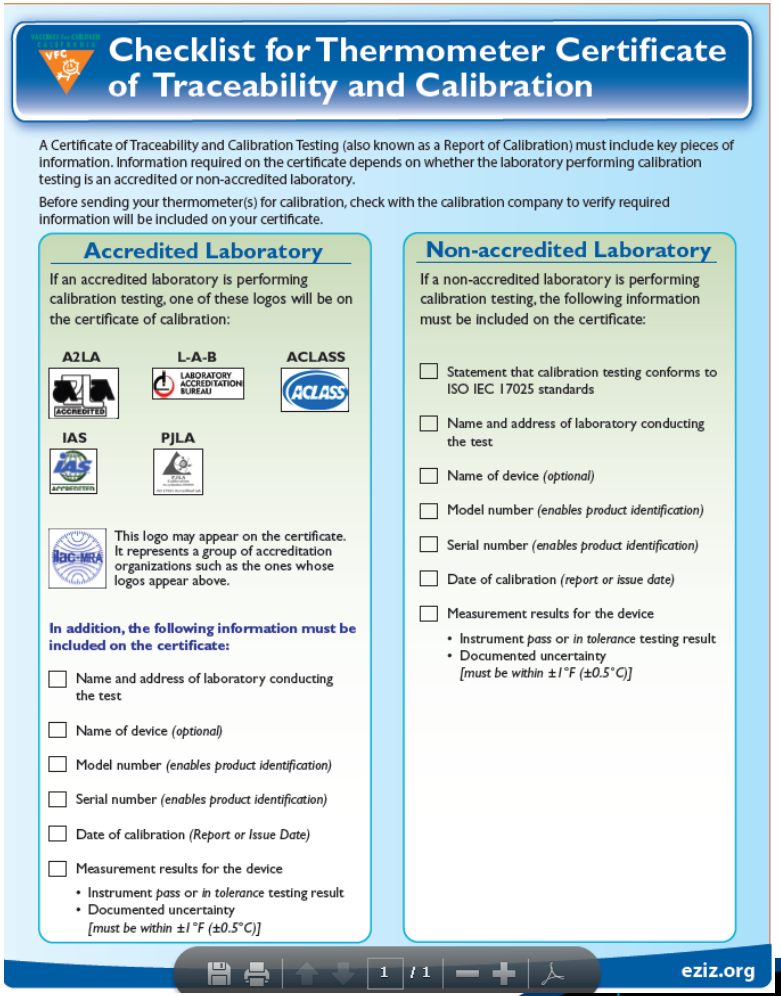


Use of Min/Max thermometers


Thermometer in each compartment of the refrigerator

# 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



## Checklist for Thermometer Certificate of Traceability and Calibration

A Certificate of Traceability and Calibration Testing (also known as a Report of Calibration) must include key pieces of information. Information required on the certificate depends on whether the laboratory performing calibration testing is an accredited or non-accredited laboratory.

Before sending your thermometer(s) for calibration, check with the calibration company to verify required information will be included on your certificate.

### Accredited Laboratory

If an accredited laboratory is performing calibration testing, one of these logos will be on the certificate of calibration:

A2LA · L-A-B · ACLASS · IAS · PJLA

This logo may appear on the certificate. It represents a group of accreditation organizations such as the ones whose logos appear above.

**In addition, the following information must be included on the certificate:**

- ☐ Name and address of laboratory conducting the test
- ☐ Name of device *(optional)*
- ☐ Model number *(enables product identification)*
- ☐ Serial number *(enables product identification)*
- ☐ Date of calibration *(Report or Issue Date)*
- ☐ Measurement results for the device
  - Instrument *pass* or *in tolerance* testing result
  - Documented uncertainty *[must be within ±1°F (±0.5°C)]*

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1 / 1

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# 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.

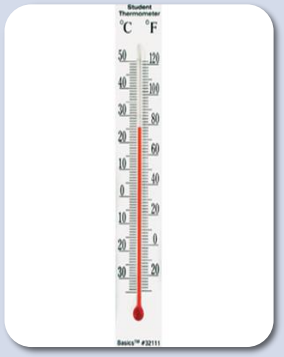
# VFC Program Requirements: Thermometers

**2016**

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.**

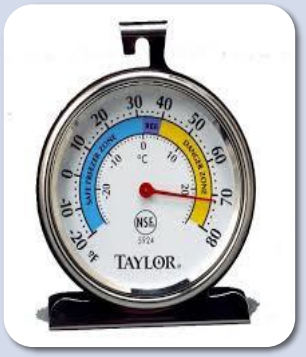
# Unacceptable Thermometers



Fluid-filled

biosafe liquid

bi-metal stem




food

household mercury

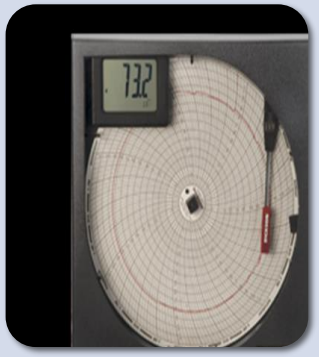


**Chart recorders**

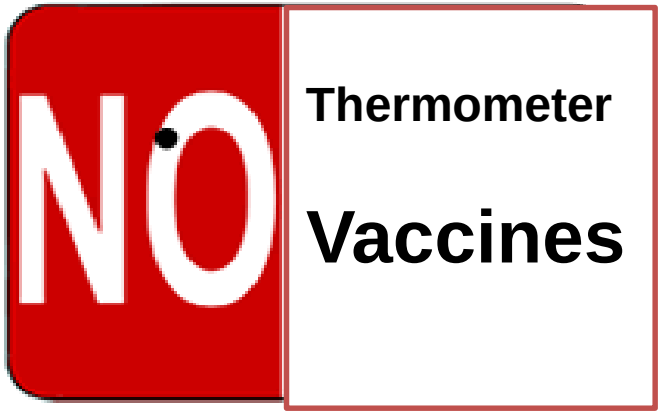
difficult to read

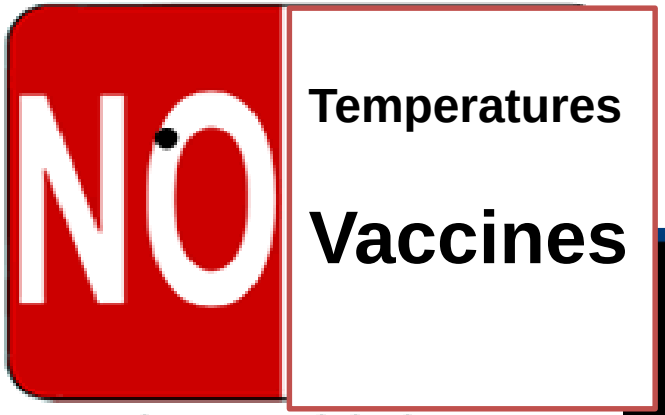
failure to change the chart paper will result in unusable temperature data

- 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

# 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.

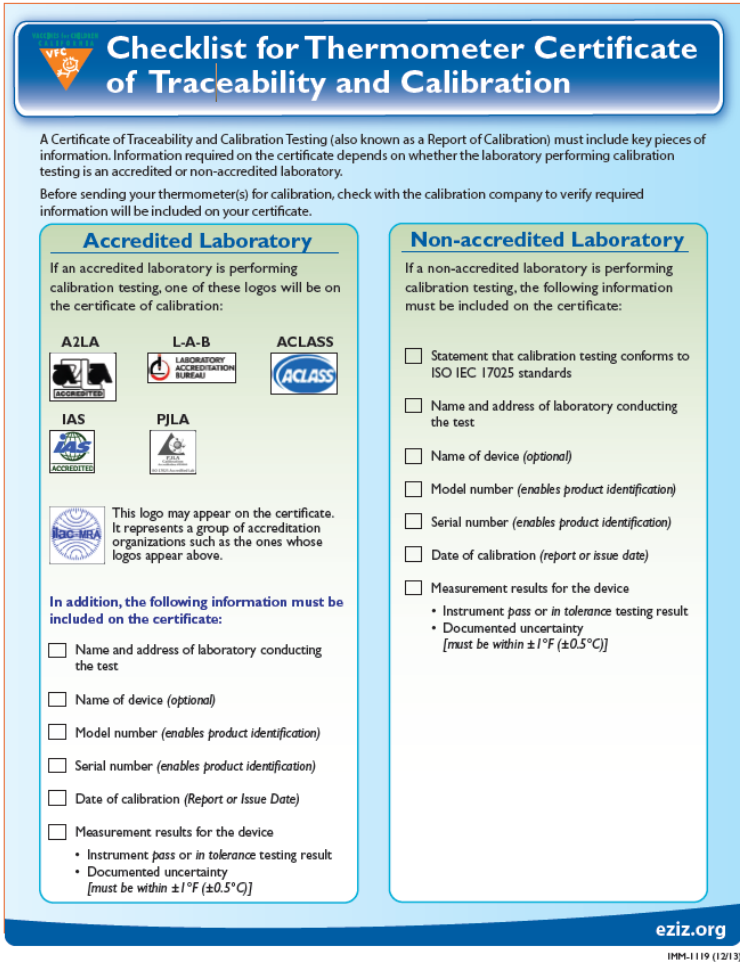



# Temperatures Re-Created?

- 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.



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  - Documented uncertainty *[must be within ±1°F (±0.5°C)]*

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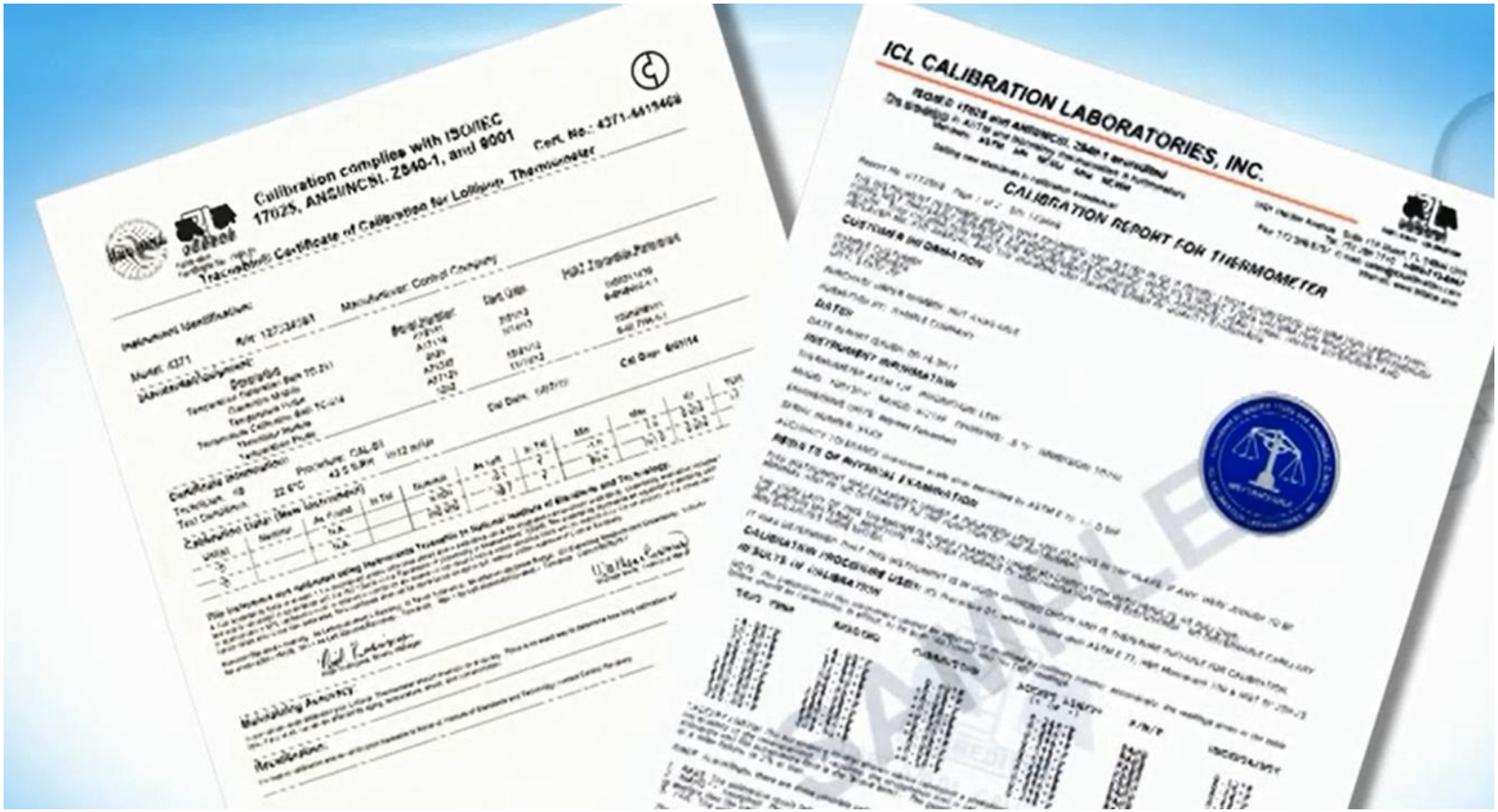
IMM-1119 (12/13)

# 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.

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# China's Vaccine Scandal Reveals System's Flaws

Weak points include close links between vendors and government clinics

A child receives a shot of vaccine against encephalitis B at a health station in Quzhou county, in China's Hebei province. The province's Centers for Disease Control branch is the sole investor in one of the vaccine distributors now under investigation. *PHOTO: EUROPEAN PRESSPHOTO AGENCY*

March 25, 2016 7:44 a.m. ET 32 COMMENTS

SHANGHAI—A scandal over improperly handled vaccines is exposing weaknesses in how vaccines are distributed across China, including close links between vendors and government clinics.

After years of government efforts to build up China's immunization program, the unfolding scandal has undermined many Chinese parents' trust in vaccines' safety and the government's oversight.

Li Ling, a Shanghai mother who took her 2-month-old son to a government clinic in her neighborhood one morning this week, opted to pay 500 yuan ($77) for a shot of an imported vaccine even though she could get the domestic equivalent free.

"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.

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World Health Organization

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## Immunization, Vaccines and Biologicals

### Effective Vaccine Management (EVM) Initiative

**Setting a standard for the vaccine supply chain**

With the rising cost of vaccines and the greater storage capacity now required at every level of the cold chain, countries must maintain lower stock levels, reduce wastage, accurately forecast vaccine requirements, and prevent equipment break-downs. This requires a consistently high standard of supply chain management, which can only be achieved if all the links in the supply chain comply with current standards for storage and distribution.

The Effective Vaccine Management (EVM) initiative provides materials and tools needed to monitor and assess vaccine supply chains and help countries to improve their supply chain performance. Follow the links in the right-hand menu to access EVM-related documents, and follow the links below to access the EVM e-learning website and the EVM assessment website (restricted access).

# A world-wide issue…

"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

## EVM requirement

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

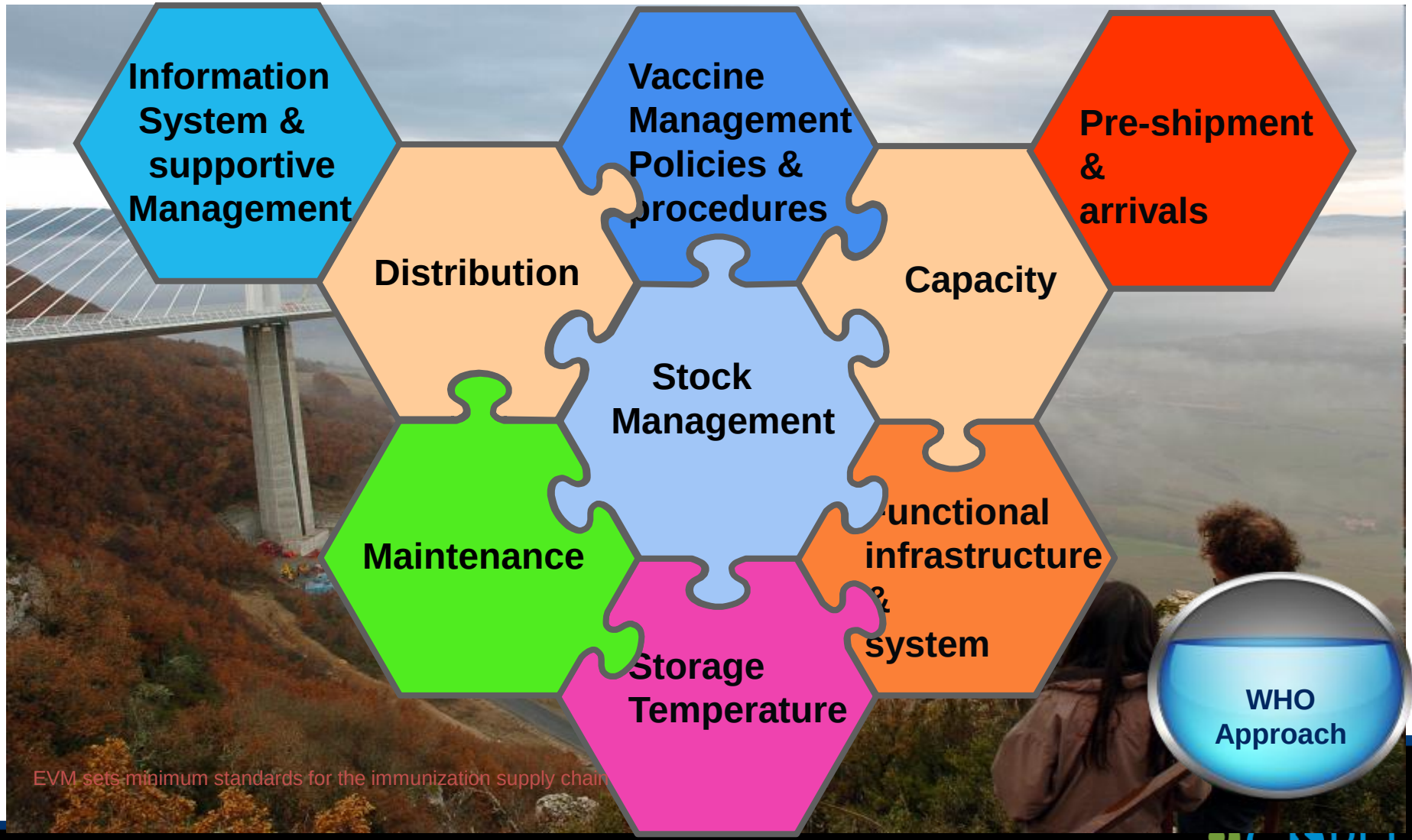
# REACHING CHILDREN EVERYWHERE

Dr Madhup

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

Health staff in Bangladesh transport vaccine carriers on a bike

# The to EVM are the nine criteria



# 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.

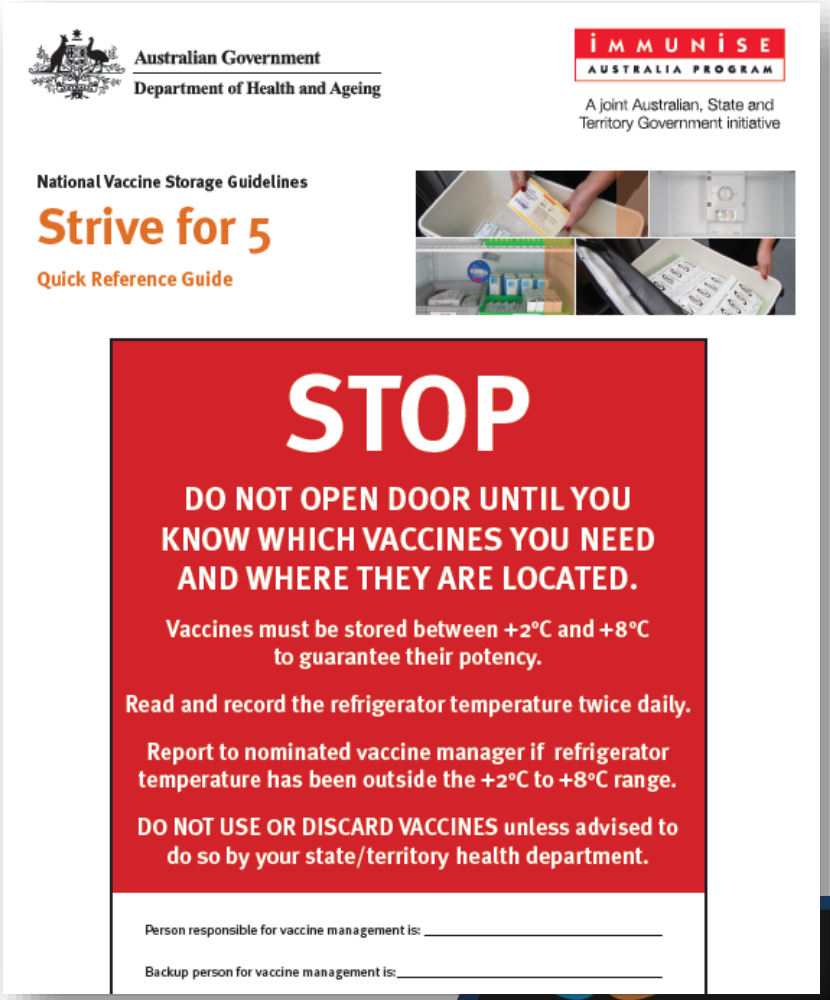
Perform vaccine storage self-audits at least 12 monthly (see Appendix 2).

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).



Australian Government
Department of Health and Ageing

IMMUNISE AUSTRALIA PROGRAM

A joint Australian, State and Territory Government initiative

National Vaccine Storage Guidelines

**Strive for 5**

Quick Reference Guide

**STOP**

DO NOT OPEN DOOR UNTIL YOU KNOW WHICH VACCINES YOU NEED AND WHERE THEY ARE LOCATED.

Vaccines must be stored between +2°C and +8°C to guarantee their potency.

Read and record the refrigerator temperature twice daily.

Report to nominated vaccine manager if refrigerator temperature has been outside the +2°C to +8°C range.

DO NOT USE OR DISCARD VACCINES unless advised to do so by your state/territory health department.

Person responsible for vaccine management is: _____

Backup person for vaccine management is: _____

COLD CHAIN

## You are important!

By maintaining optimal temperatures while transporting, storing and handling vaccines you:

- Ensure the best quality vaccine for your clients
- Assist in preventing vaccine wastage

## 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

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

Table 2. Vaccine sensitivity to freezing

| | Vaccine |
|---|---|
| All these vaccines are damaged by freezing | DTaP<br>DTaP-hepatitis B-Hib-IPV (hexavalent)<br>DTwP<br>DTwP-hepatitis B-Hib (pentavalent)<br>Hepatitis A<br>Hepatitis B<br>Human papillomavirus<br>Meningitis C (polysaccharide-protein conjugate)<br>Pneumococcal (polysaccharide-protein conjugate)<br>TT, DT, Td |
| | Cholera (inactivated)<br>Influenza (inactivated, split)<br>Hib (liquid)<br>Inactivated poliovirus<br>Typhoid polysaccharide |
| These vaccines are not damaged by freezing | **Meningitis A (polysaccharide-protein conjugate)***<br>Rotavirus (liquid and freeze dried)<br>Yellow fever |
| | **Bacillus Calmette-Guérin**<br>**Hib (freeze dried)**<br>**Japanese encephalitis (live and inactivated)**<br>**Measles**<br>**Measles, mumps, rubella**<br>Oral poliovirus<br>**Rabies**<br>**Rubella**<br>**Varicella-zoster virus** |


Same boat, experiencing
same issues

# 2010 OIG Report

Are Doctors Improperly Storing Vaccines?


Vaccines Stored Improperly: Warning for Parents

AUTO START: ON OFF

abc NIGHTLINE By KIM CAROLLO June 6, 2012

- h

JULY 18, 2014

# 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 5,003 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.

RELATED CONTENT

CMG-Grove Hill merger aims to preserve independent-doctor model

Connecticut Children's gets extra $10M from state to shore up finances

Big money pushes urgent care competition, consolidation

ProHealth forms ACO with United Healthcare

Regulators grant initial OK to Waterbury Hospital acquisition

Jacobs introduces national model to maximize victim survival

LATEST HEADLINES

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Lazowski officially joins Holocaust council

UnitedHealth Group 4Q net rises on premium growth

W. Hartford accounting firms merge

Semple tagged to be CT prisons' chief

VIEW ALL

TODAY'S POLL Does your company employ summer interns?

# Recent Headlines-2015

## Bad Refrigerator Sparks Palo Alto Medical Foundation to Issue Vaccination Warning

By Terry McSweeney


The Palo Alto Medical Foundation is warning parents that their children may
vaccinations. Terry McSweeney reports. (Published Tuesday, May 12, 2015)

The Palo Alto Medical Foundation is warning parents that their
to repeat their vaccinations.

A bad refrigerator inside the foundation's Los Gatos office had
vaccines a couple degrees too cold, possibly ruining the vaccin

## 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.

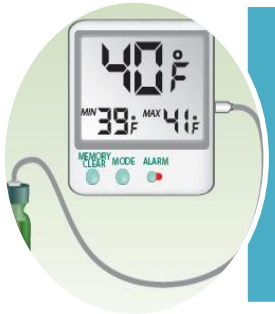
He said letters are being mailed Saturday to the patients' families to help them arrange an appointment, and if a patient or their family has not responded by a certain date, they will be re-contacted.

# Key Elements in Storage and Handling


Skilled and trained staff

Written Routine and Emergency Vaccine Management Plans

Appropriate vaccine storage units

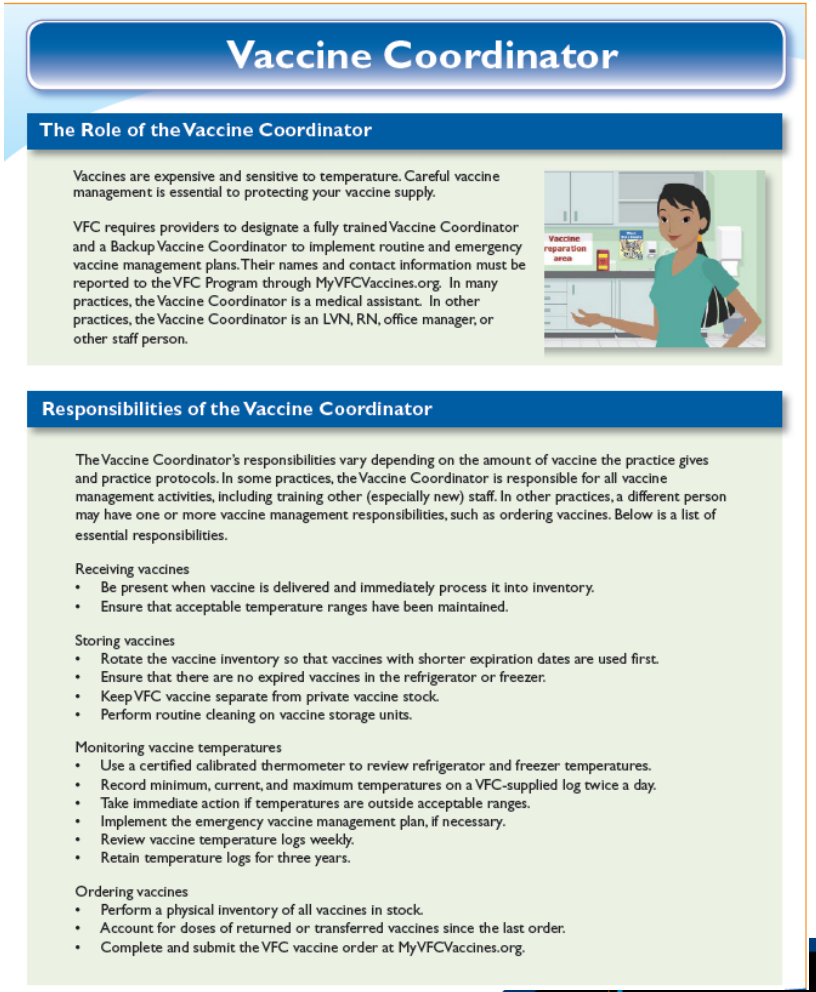




Accurate temperature monitoring equipment

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



## Vaccine Coordinator

### The Role of the Vaccine Coordinator

Vaccines are expensive and sensitive to temperature. Careful vaccine management is essential to protecting your vaccine supply.

VFC requires providers to designate a fully trained Vaccine Coordinator and a Backup Vaccine Coordinator to implement routine and emergency vaccine management plans. Their names and contact information must be reported to the VFC Program through MyVFCVaccines.org. In many practices, the Vaccine Coordinator is a medical assistant. In other practices, the Vaccine Coordinator is an LVN, RN, office manager, or other staff person.

### Responsibilities of the Vaccine Coordinator

The Vaccine Coordinator's responsibilities vary depending on the amount of vaccine the practice gives and practice protocols. In some practices, the Vaccine Coordinator is responsible for all vaccine management activities, including training other (especially new) staff. In other practices, a different person may have one or more vaccine management responsibilities, such as ordering vaccines. Below is a list of essential responsibilities.

Receiving vaccines
- Be present when vaccine is delivered and immediately process it into inventory.
- Ensure that acceptable temperature ranges have been maintained.

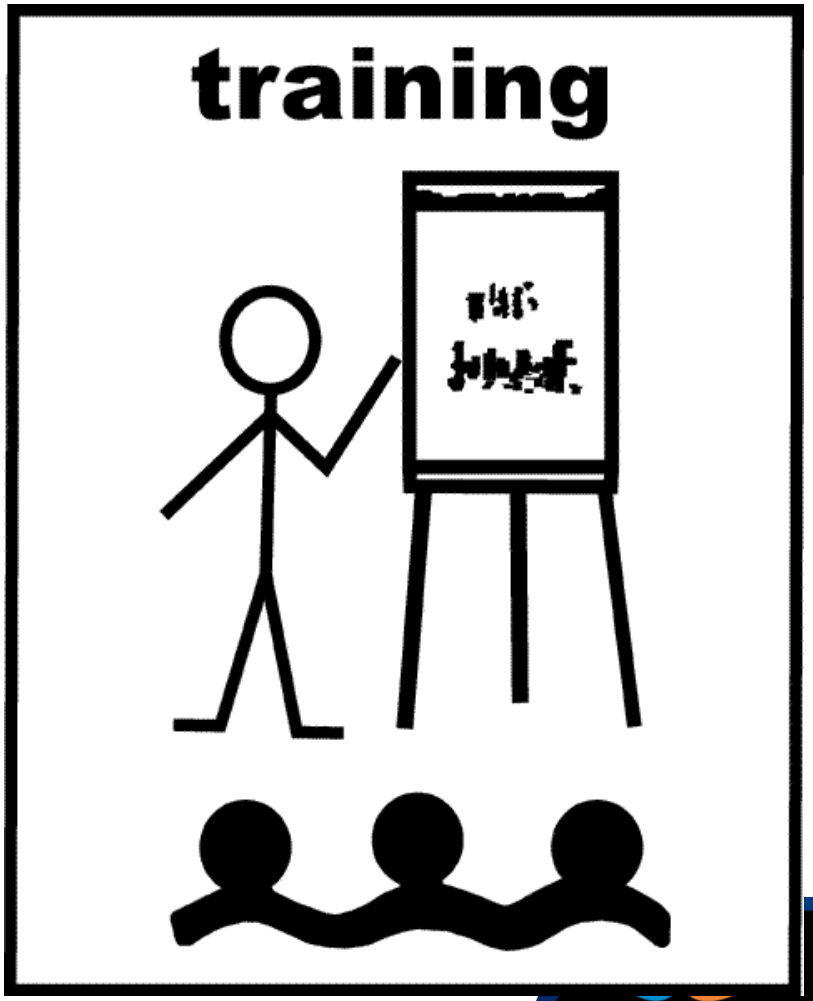
Storing vaccines
- Rotate the vaccine inventory so that vaccines with shorter expiration dates are used first.
- Ensure that there are no expired vaccines in the refrigerator or freezer.
- Keep VFC vaccine separate from private vaccine stock.
- Perform routine cleaning on vaccine storage units.

Monitoring vaccine temperatures
- Use a certified calibrated thermometer to review refrigerator and freezer temperatures.
- Record minimum, current, and maximum temperatures on a VFC-supplied log twice a day.
- Take immediate action if temperatures are outside acceptable ranges.
- Implement the emergency vaccine management plan, if necessary.
- Review vaccine temperature logs weekly.
- Retain temperature logs for three years.

Ordering vaccines
- Perform a physical inventory of all vaccines in stock.
- Account for doses of returned or transferred vaccines since the last order.
- Complete and submit the VFC vaccine order at MyVFCVaccines.org.

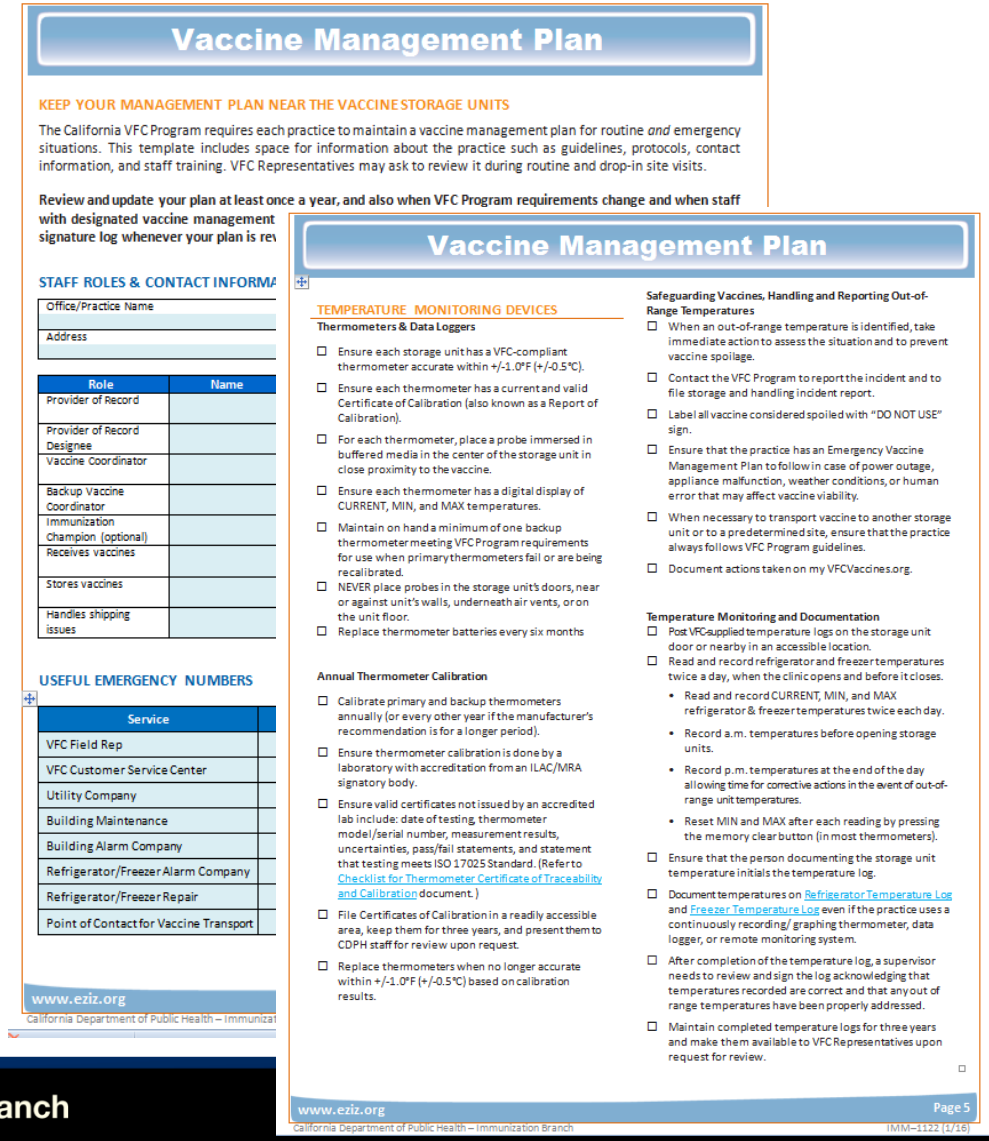
# Skilled and Properly Trained Staff

- 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 planed or unplanned power loss.



## Vaccine Management Plan

KEEP YOUR MANAGEMENT PLAN NEAR THE VACCINE STORAGE UNITS

The California VFC Program requires each practice to maintain a vaccine management plan for routine *and* emergency situations. This template includes space for information about the practice such as guidelines, protocols, contact information, and staff training. VFC Representatives may ask to review it during routine and drop-in site visits.

**Review and update your plan at least once a year, and also when VFC Program requirements change and when staff with designated vaccine management signature log whenever your plan is rev**

STAFF ROLES & CONTACT INFORMA

| Office/Practice Name |
|---|
| Address |

| Role | Name |
|---|---|
| Provider of Record | |
| Provider of Record Designee | |
| Vaccine Coordinator | |
| Backup Vaccine Coordinator | |
| Immunization Champion (optional) | |
| Receives vaccines | |
| Stores vaccines | |
| Handles shipping issues | |

USEFUL EMERGENCY NUMBERS

| Service | |
|---|---|
| VFC Field Rep | |
| VFC Customer Service Center | |
| Utility Company | |
| Building Maintenance | |
| Building Alarm Company | |
| Refrigerator/Freezer Alarm Company | |
| Refrigerator/Freezer Repair | |
| Point of Contact for Vaccine Transport | |

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California Department of Public Health – Immunizat

## Vaccine Management Plan

TEMPERATURE MONITORING DEVICES

**Thermometers & Data Loggers**

- ☐ Ensure each storage unit has a VFC-compliant thermometer accurate within +/-1.0°F (+/-0.5°C).
- ☐ Ensure each thermometer has a current and valid Certificate of Calibration (also known as a Report of Calibration).
- ☐ For each thermometer, place a probe immersed in buffered media in the center of the storage unit in close proximity to the vaccine.
- ☐ Ensure each thermometer has a digital display of CURRENT, MIN, and MAX temperatures.
- ☐ Maintain on hand a minimum of one backup thermometer meeting VFC Program requirements for use when primary thermometers fail or are being recalibrated.
- ☐ NEVER place probes in the storage unit's doors, near or against unit's walls, underneath air vents, or on the unit floor.
- ☐ Replace thermometer batteries every six months

**Annual Thermometer Calibration**

- ☐ Calibrate primary and backup thermometers annually (or every other year if the manufacturer's recommendation is for a longer period).
- ☐ Ensure thermometer calibration is done by a laboratory with accreditation from an ILAC/MRA signatory body.
- ☐ Ensure valid certificates not issued by an accredited lab include: date of testing, thermometer model/serial number, measurement results, uncertainties, pass/fail statements, and statement that testing meets ISO 17025 Standard. (Refer to Checklist for Thermometer Certificate of Traceability and Calibration document.)
- ☐ File Certificates of Calibration in a readily accessible area, keep them for three years, and present them to CDPH staff for review upon request.
- ☐ Replace thermometers when no longer accurate within +/-1.0°F (+/-0.5°C) based on calibration results.

**Safeguarding Vaccines, Handling and Reporting Out-of-Range Temperatures**

- ☐ When an out-of-range temperature is identified, take immediate action to assess the situation and to prevent vaccine spoilage.
- ☐ Contact the VFC Program to report the incident and to file storage and handling incident report.
- ☐ Label all vaccine considered spoiled with "DO NOT USE" sign.
- ☐ Ensure that the practice has an Emergency Vaccine Management Plan to follow in case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
- ☐ When necessary to transport vaccine to another storage unit or to a predetermined site, ensure that the practice always follows VFC Program guidelines.
- ☐ Document actions taken on my VFCVaccines.org.

**Temperature Monitoring and Documentation**

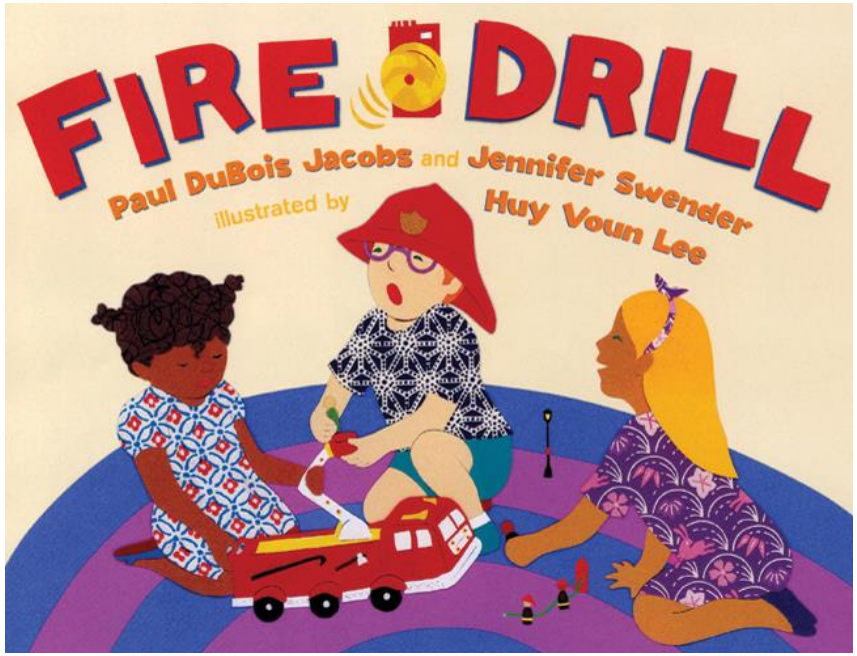
- ☐ Post VFC-supplied temperature logs on the storage unit door or nearby in an accessible location.
- ☐ Read and record refrigerator and freezer temperatures twice a day, when the clinic opens and before it closes.
  - Read and record CURRENT, MIN, and MAX refrigerator & freezer temperatures twice each day.
  - Record a.m. temperatures before opening storage units.
  - Record p.m. temperatures at the end of the day allowing time for corrective actions in the event of out-of-range unit temperatures.
  - Reset MIN and MAX after each reading by pressing the memory clear button (in most thermometers).
- ☐ Ensure that the person documenting the storage unit temperature initials the temperature log.
- ☐ Document temperatures on Refrigerator Temperature Log and Freezer Temperature Log even if the practice uses a continuously recording/graphing thermometer, data logger, or remote monitoring system.
- ☐ After completion of the temperature log, a supervisor needs to review and sign the log acknowledging that temperatures recorded are correct and that any out of range temperatures have been properly addressed.
- ☐ Maintain completed temperature logs for three years and make them available to VFC Representatives upon request for review.

www.eziz.org Page 5

California Department of Public Health – Immunization Branch IMM–1122 (1/16)

# 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.

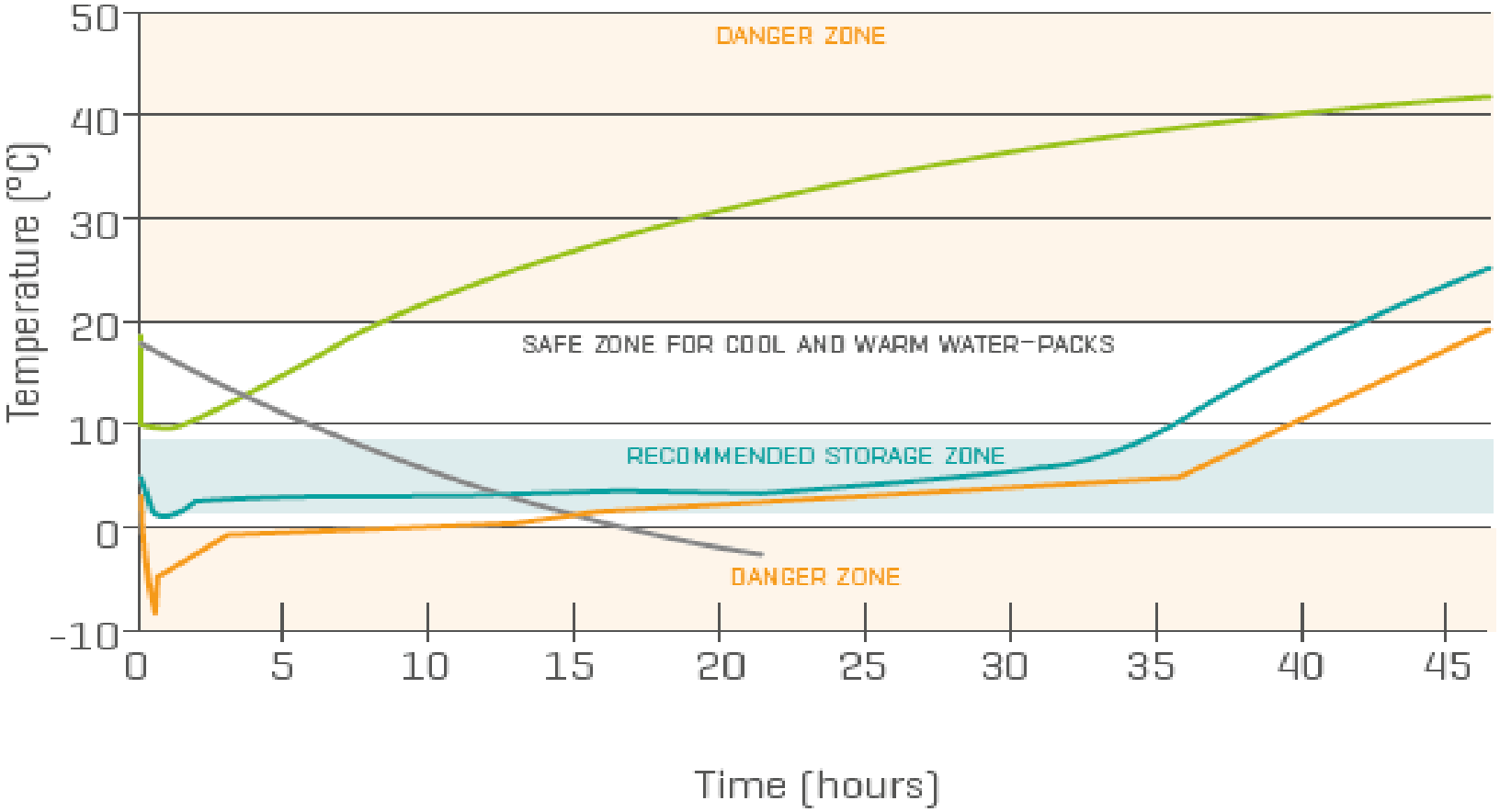


# Vaccine Transport: WHO Guidance

## 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




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

# 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 those 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 "Vaccines: 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 been "sweating." 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 & 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.

**3. Vaccine**

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.

**4. Bubble wrap**

Completely cover the vaccine with another 2-inch layer of bubble wrap.

**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 877-243-8832. Then label the vaccine "Do Not Use" and place it in the refrigerator.

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California Department of Public Health, Immunization Branch IMM-983 (9/14)

# Vaccine Transport: CA Guidance

**VACCINE FOR CHILDREN (VFC) PROGRAM**
Refrigerated Vaccine Transport Log

Date: _____

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

**Provider Name:** _____ **PIN:** _____

**Transferred to:** _____ **PIN:** _____

**Vaccine transferred due to:** ☐ Power outage ☐ Excess supply ☐ Short dated ☐ Unit malfunction ☐ Building maintenance ☐ Other _____

**Vaccine Inventory Information**

| Vaccine | Lot Number | Number of Doses | Expiration Date | Vaccine previously transported? (Yes/No) | Comments |
|---|---|---|---|---|---|
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**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 (877-243-8832) if temperatures during transport exceed recommended ranges.

**Total Transport time:** _____ **Min/Hr**

IMM-1132 (8/14)

**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

| Response | Total (n=1,087) |
|---|---|
| True | 427 (39%) |
| ***False*** | ***504 (46%)*** |
| Don't know or Not sure | 156 (14%) |

# 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 vaccines must be transported to an off-site day 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 (IMM-1116) to document the duration and temperature monitoring information.

**Assemble packing supplies and documents**

Most emergencies happen suddenly. Be sure you are prepared for emergency transport of frozen vaccine by always having the following supplies ready.

1. **Cooler.** Use a hard-sided cooler.
2. **Frozen cold packs.** Keep enough frozen cold packs in your vaccine freezer to make two layers in the transport cooler. You will need 6-8 frozen packs per cooler. NEVER USE DRY ICE.
3. **Thermometer.** Use a VFC-compliant thermometer. If you normally use a continuous-read monitoring system, you will need a portable thermometer for vaccine transport.
4. **Packing materials.** Use any material like bubble wrap to place on top of the frozen cold packs to prevent contents from shifting. Make sure you DO NOT place bubble wrap between the vaccine and frozen packs.
5. **Frozen Vaccine Transport Log.** You must document the total timeframe and temperatures vaccines were exposed to during transport to and from the back-up facility. Put a copy of the log in each cooler that might be used to transport frozen vaccine.
6. **Transporting Frozen Vaccine job aid.** Put one copy in each cooler that might be used to transport frozen vaccine.

### Pack vaccines and prepare for transport

**Prepare for transport**

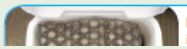
- Verify that the destination site has enough room for your vaccine and that someone will be there when the vaccine arrives.
- Verify that you have all the packing supplies on the above list.
- Complete the Frozen Vaccine Transport Log

**Pack vaccines**

1 Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice.

4 Spread another layer of frozen ice packs to cover the vaccine.

Stack layers of vaccine boxes directly on top of the frozen



Fill the cooler to the top with insulation material (bubble wrap).

## Pack vaccines

Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice.

1

California Department of Public Health, Immunization Branch IMM-1130 (8/14)

## VACCINE FOR CHILDREN (VFC) PROGRAM
Refrigerated Vaccine Transport Log

Date: _____

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

**Provider Name:** _____ **PIN:** _____

**Transferred to:** _____ **PIN:** _____

**Vaccine transferred due to:** ☐ Power outage ☐ Excess supply ☐ Short dated ☐ Unit malfunction ☐ Building maintenance ☐ Other _____

**Vaccine Inventory Information**

| Vaccine | Lot Number | Number of Doses | Expiration Date | Vaccine previously transported? (Yes/No) | Comments |
|---|---|---|---|---|---|
| | | | | | |
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**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 (877-243-8832) if temperatures during transport exceed recommended ranges.

**Total Transport time:** _____ **Min/Hr**

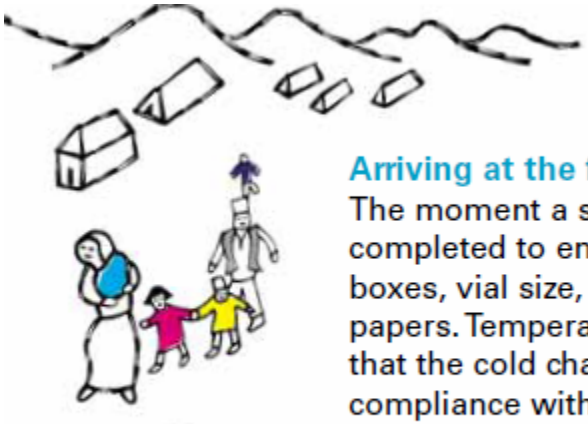
IMM-1132 (8/14)

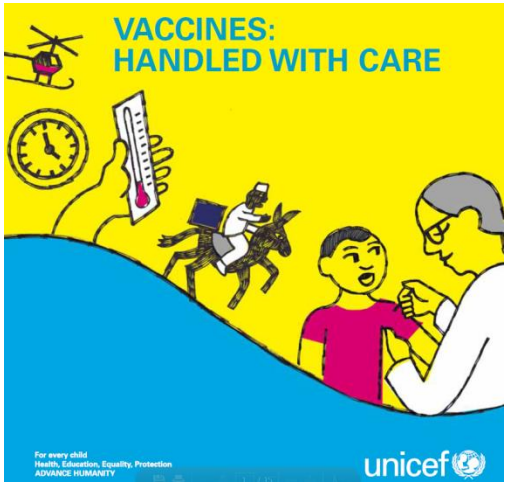
# Appropriate Vaccine Storage Units

- 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

| Office Size | Required Equipment |
|---|---|
| **Very High Volume** 10,000 doses/year | Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units |
| **High Volume** 2,000-10,000 doses/year | Refrigerator-only (11 cubic feet minimum) and stand-alone freezer units |
| **Medium Volume** 500-2,000 doses/year | Refrigerator-only (11 cubic feet minimum) and stand-alone freezer units ***OR*** Pharmacy-grade or biologic-grade under the counter units. |
| **Low Volume** Less than 500 doses/year | |

# 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.

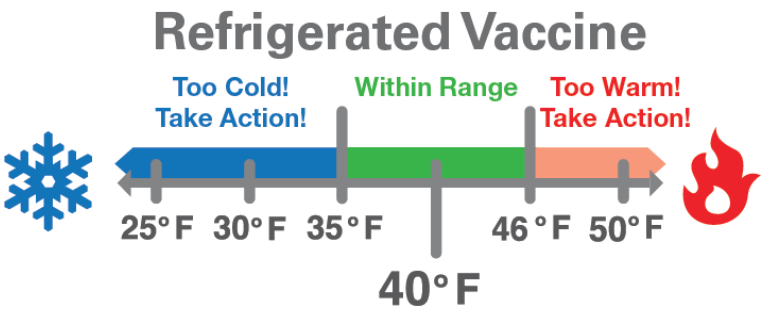
## Storing the precious cargo

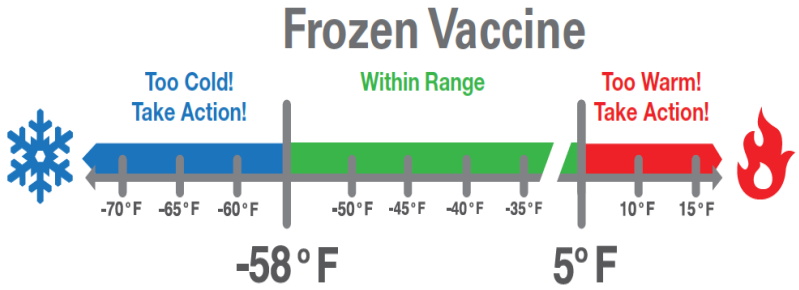
When the vaccines arrive at the national cold storage facility, details of their type, the number of doses, batch number and expiration date are recorded again. The vaccines are regularly checked while in storage and when they leave for distribution.

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)



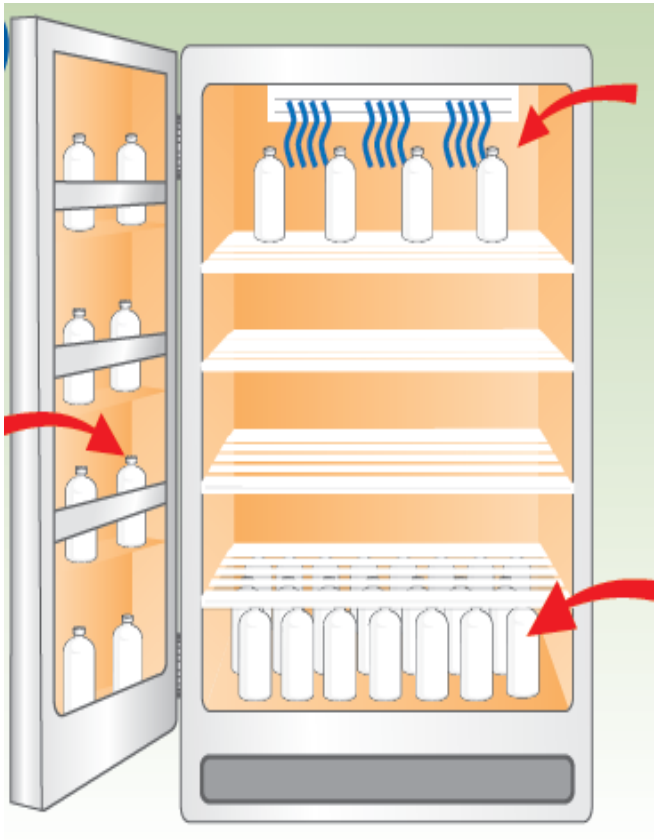



# Appropriate Vaccine Storage Units: Refrigerator-only units

**Acceptable Units**

| Grade/Type | Comments | Rating |
|---|---|---|
| **Pharmaceutical grade/ purpose-built units (stand-alone)** | Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices. | Best |
| **Pharmaceutical grade/ purpose-built units (combination)** | 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. | Best |
| **Commercial units* (stand-alone)** | 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. | Good |
| **Household* (stand-alone)** | 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. | OK |

*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

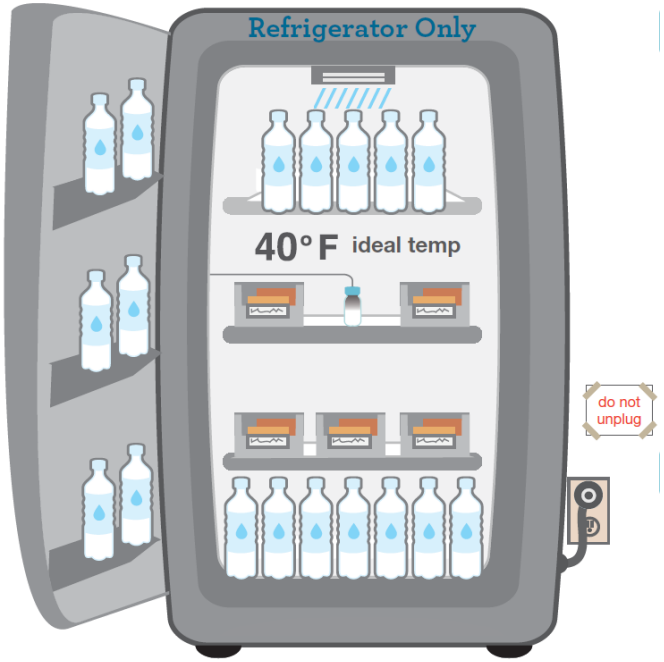
**Unacceptable Storage Units**

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

| | |
|---|---|
| **Household combination units** | 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. |
| **Dormitory-style and bar-style combined refrigerator/freezers** | These units pose a significant risk of freezing even when used for temporary storage. |
| **Manual defrost (cyclic defrost) units** | These models have an exposed vertical cooling plate at the back of the refrigerator. They have significant temperature variation and risk freezing vaccines. |
| **Convertible refrigerator-only units** | These units have an internal switch that converts an "all-refrigerator unit" to an "all freezer" unit. |

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

# Unit Specifications

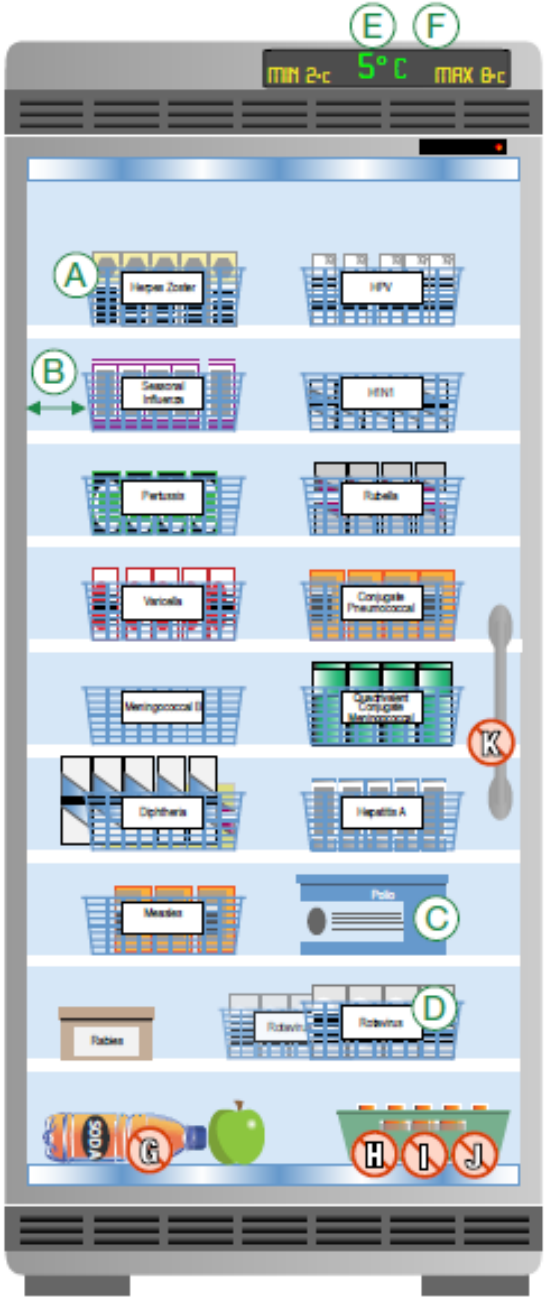



## Refrigerator Specifications

**Refrigerators must:**

- Maintain consistent temperatures between 35.0ºF and 46.0ºF (2.0ºC and 8.0ºC);
- 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.

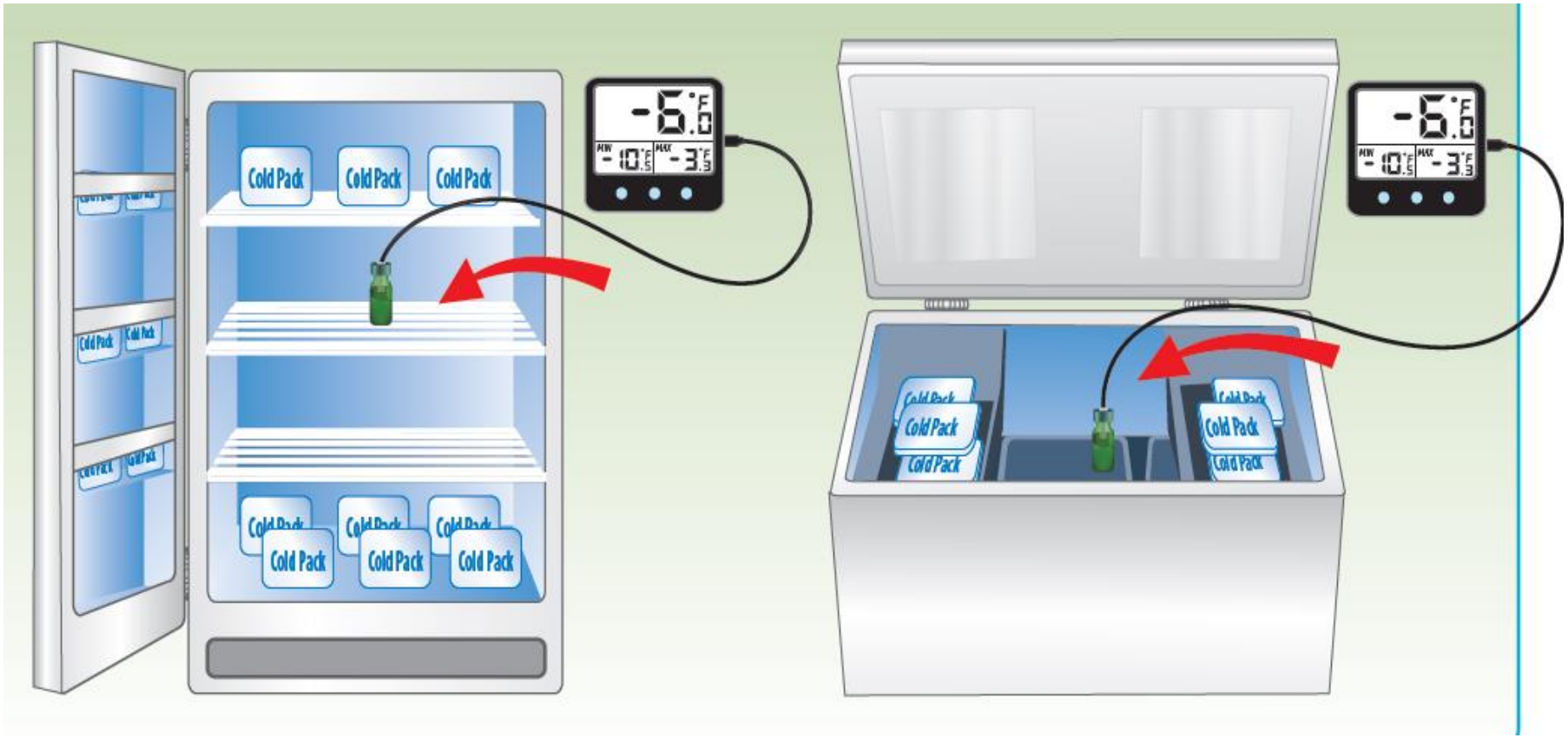
Built to handle ambient temperature changes.

## 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.**

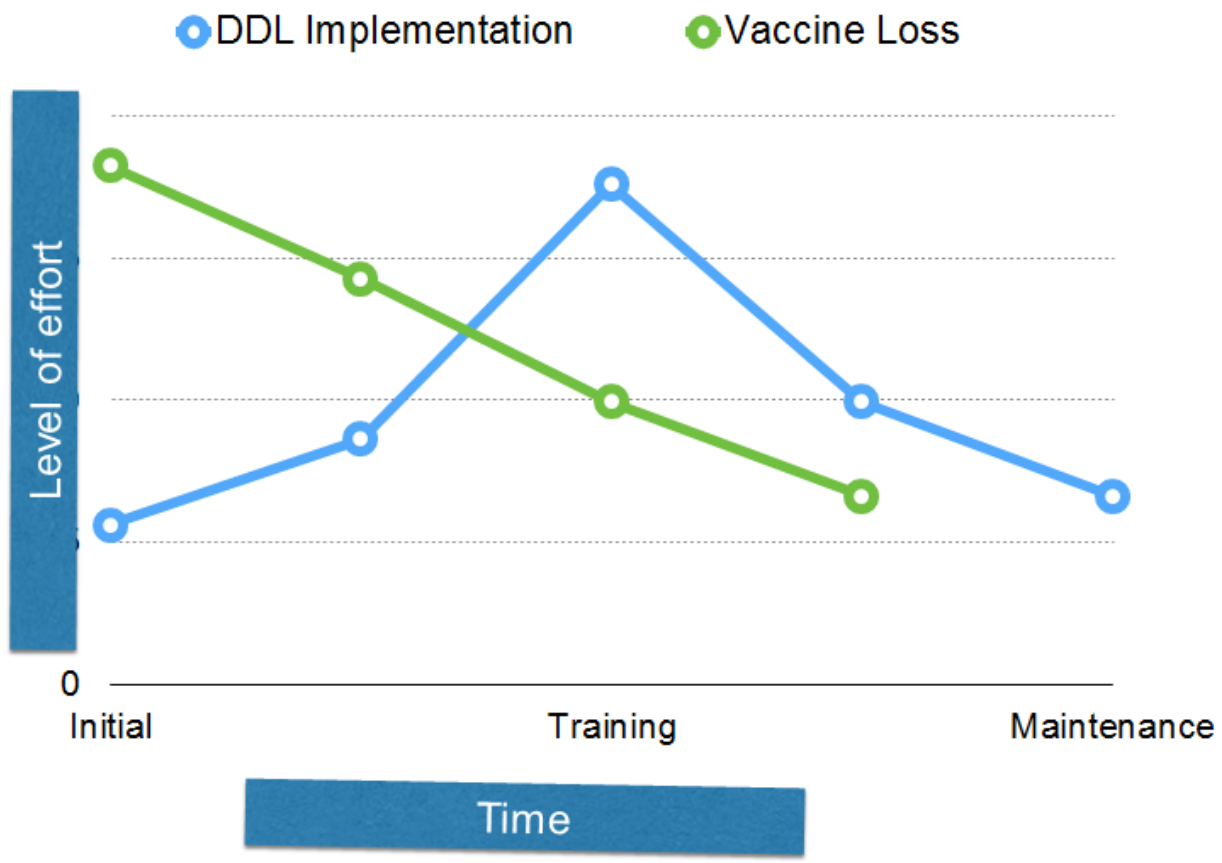
# Installing a new temperature monitoring device in your fridge? Play, Practice, and Test

## 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

# Installing a new temperature monitoring device in your fridge?

**DDL Implementation**



# 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.

# SUMMARY

# 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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