Pennsylvania Vaccines For Children Provider Training

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10/4/2013

Welcome to the VFC Program

Welcome to the Pennsylvania Vaccines for Children Program

How to Contact Us:	Provider Information
Pennsylvania Department of Health Division of Immunizations 625 Forster Street, Room 1026 Harrisburg, Pennsylvania 17120 Phone: 717-787-5681 Toll Free: 1-888-646-6864 Vaccine Orders Fax: 717-441-3800 Email: paimmunizations@pa.gov	**Provider Identification Number (PIN)** **PIN** (contact) (last name) (address) (address 2) (city) (state) (zip code)

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Procedures and Requirements for Enrollment

- Primary and Backup VFC Provider Contact
- PA VFC eligibility
- Vaccine ordering, administration and accountability
- Vaccine receiving, storage and handling
- Procedures and forms
- Current Vaccine Information Statements (VIS)
- Vaccine Adverse Event Reporting System (VAERS)
- Current Recommended Childhood Immunization Schedule
- Vaccine Borrowing
- Vaccine Disaster Recovery plan
- Quality Assurance Site Visits & Follow up
- Resources and Websites
- Immunization documentation and record retention
- The PA Statewide Immunization Information System (PA-SIIS)

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Patient Eligibility Screening

- Who is eligible? Birth through 18 years of age (until the 19th birthday) and Medicaid Enrolled, Uninsured, and/or American Indian or Alaskan native.

- Children with insurance that does not cover immunizations may be referred to a public VFC site, i.e. FQHC (Federally Qualified Health Center), or RHC (Rural Health Clinic).

- Children with primary or secondary Medicaid insurance are eligible for VFC vaccine (Billing Questions call 1-800-537-8862).

- Eligibility screening and documentation must occur at every visit (either on the eligibility form, electronic database, vaccine administration record, or the medical chart (e.g. EMR, EHR).

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Patient Eligibility Screening Record

Patient Eligibility Screening Record
Vaccines for Children Program

1. Initial Screening Date: 0 1 0 5 2 0 1 3
   M M D D Y Y Y Y

2. Child's Name: Smith (Last Name) John (First) C (MI)

3. Child's Date of Birth: 0 1 0 3 2 0 1 3
   M M D D Y Y Y Y

4. Parent/Guardian/Individual of Record: Smith (Last Name) Mary (First) T (MI)

5. Is your facility a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)?
   ☐ Yes ☒ No

6. Primary Provider's Name: Wilson (Last Name) James (First) B (MI)

7. Does this patient qualify for immunization through the VFC program because he/she (check only one) :
   a) Yes, is enrolled in Medicaid ☐
   b) Yes, does not have health insurance ☐
   c) Yes, is an American Indian or Alaska Native ☐
   d) Yes, is underinsured (has health insurance that does not pay for vaccinations)* ☐
   f) No, this child does not qualify for immunizations through the VFC program because he/she does not meet the eligibility criteria. ☐

Date	Is enrolled in Medicaid	Does not have health insurance	Is an American Indian or Alaska Native	Is underinsured (has health insurance that does not pay for vaccinations)*	Does not meet eligibility criteria
02/05/13	X				
03/05/13					X
05/05/13		X			
07/05/13				X	

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Charges & Fees

- VFC eligible patients cannot be denied vaccine due to inability to pay.
- Provider may not charge for vaccines provided through the PA VFC program.
- Providers may charge a fee for administration of PA VFC supplied vaccines (currently capped at $23.14 per vaccine).
- Providers may charge for an office visit in addition to vaccine administration fee, if additional care is provided.
- CHIP eligible children are not eligible for PA VFC vaccine.
- Any billing questions regarding CHIP, call the CHIP Program at 1-800-986-KIDS.
- If a child is enrolled in Medicaid (Medical Assistance, MA) they are automatically eligible for VFC vaccine (Billing questions 1-800-537-8862).

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Charges & Fees (continued)

- Providers must accept MA payment as payment in full for services rendered.
- Medicaid Federal guidelines stated at 42 CFR 433.139 for Coordination of Benefits related to preventive services, which includes payment for immunizations.
- The Code of Federal Regulations directs that Medicaid must pay the full amount for an immunization, which is a $10.00 administration fee, and seek reimbursement from any liable third party.
- Providers should bill MA within 30 days of date of service.

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Administration Fee

- For non-Medicaid VFC eligible children (i.e., Alaska Natives/Native Americans, uninsured and underinsured), the administration fee is based on vaccine dose, **not the number of antigens** contained in a vaccine dose.
- The administration fee charged to a non-Medicaid VFC-eligible child cannot exceed the maximum regional charge (i.e. $23.14 per shot).
- No VFC eligible client may be refused administration of a vaccine due to an accompanying adult's inability to pay an administration fee.
- VFC vaccines may only be used for VFC eligible clients

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CHIPS V/S Medicaid

CHIP vs. Medicaid Insurance Cards: What's the Difference?

Pennsylvania's Children's Health Insurance Program — We Cover All Kids.

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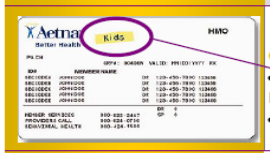
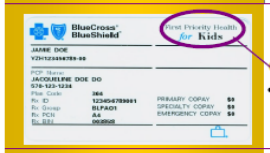
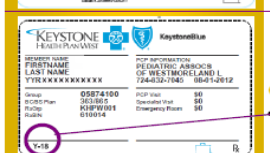
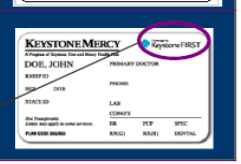
CHIP Patients are not eligible for VFC vaccines		Medicaid patients are eligible for VFC vaccines
	**Aetna Better Health** CHIP Card: • "Kids" logo Medicaid Card: • No logo	
	**Blue Cross Blue Shield** CHIP Card: • "First Priority Health *for* Kids"	Medicaid not offered by this Carrier
	Keystone Health Plan Central CHIP Card: • "Capital Cares 4 Kids" logo	Medicaid not offered by this Carrier
	**Keystone Health Plan West** CHIP Card: • "Y-18"	Medicaid not offered by this Carrier
	Keystone Health Plan East CHIP Card: • "PA Kids" logo Medicaid Card: • "Keystone First" logo	

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Continued: CHIP vs. Medicaid Insurance Cards

Pennsylvania's Children's Health Insurance Program — We Cover All Kids.

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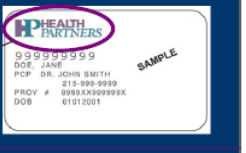
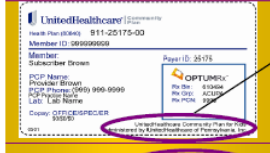
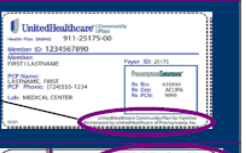
CHIP Patients are not eligible for VFC vaccines		Medicaid patients are eligible for VFC vaccines
	Geisinger Health Plan CHIP Card: • "GHP Kids"	Medicaid not offered by this Carrier
	Health Partners CHIP Card: • "Kidz Partners" Medicaid Card: • HP Health Partners	
	**United Healthcare** • Community Plan for Kids • United Healthcare Community Plan for Families	
	UPMC CHIP Card: • "UPMC *for* Kids" Medicaid Card: • "UPMC *for* You"	

CHIP not offered by the following Medicaid carriers

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Provider Enrollment Form

- Effective March 2013 provider sites transitioned from paper to online enrollment through PA-SIIS.
- Online electronic signature indicates agreement to comply with the requirements stated.
- Provider's not having Internet access will complete a Provider Site Profile/Enrollment form, located in Section 6-Forms of the Provider Handbook & fax the form to (717) 214-7223.
- Submit any changes(Physicians, VFC contacts, Address, Office/Delivery hours) online through PA-SIIS when completing vaccine order **and** contact Division of Immunizations at (717)787-5681.
- If the provider enrollment form is not updated; the vaccine orders will not be processed.

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Checklist for Safe Storage & Handling

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either (YES) or (NO).

Establish Storage and Handling Policies

(YES) (NO) 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.

(YES) (NO) 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.

(YES) (NO) 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.

(YES) (NO) 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

5. We maintain a vaccine inventory log that we use to document the following:

(YES) (NO) a. Vaccine name and number of doses received

(YES) (NO) b. Date we received the vaccine

(YES) (NO) c. Condition of vaccine when we received it

(YES) (NO) d. Vaccine manufacturer and lot number

(YES) (NO) e. Vaccine expiration date

Use Proper Storage Equipment

(YES) (NO) 6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).

(YES) (NO) 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.

(YES) (NO) 8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

(YES) (NO) 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.

(YES) (NO) 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

(YES) (NO) 11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.

(YES) (NO) 12. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).

(**Maintain Correct Temperatures** continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

Technical content reviewed by the Centers for Disease Control and Prevention, July 2011.

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org

(**Maintain Correct Temperatures** continued from page 1)

(YES) (NO) 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.

(YES) (NO) 14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.

(YES) (NO) 15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).

(YES) (NO) 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

(YES) (NO) 17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.

(YES) (NO) 18. We do NOT store any food or drink in any vaccine storage unit.

(YES) (NO) 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.

(YES) (NO) 20. We have removed all vegetable and deli bins from the storage unit.

(YES) (NO) 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).

(YES) (NO) 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.

(YES) (NO) 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

(YES) (NO) 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.

(YES) (NO) 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.

(YES) (NO) 26. The logs show whom to call if the temperature in the storage unit goes out of range.

(YES) (NO) 27. When we change the thermostat setting, we document it in the daily log sheet's note section.

(YES) (NO) 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.

(YES) (NO) 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.

(YES) (NO) 30. We keep the temperature logs on file for at least 3 years.

Take Emergency Action As Needed

31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:

(YES) (NO) a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.

(YES) (NO) b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.

(YES) (NO) c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.

(YES) (NO) d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.

(YES) (NO) e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer (YES) to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

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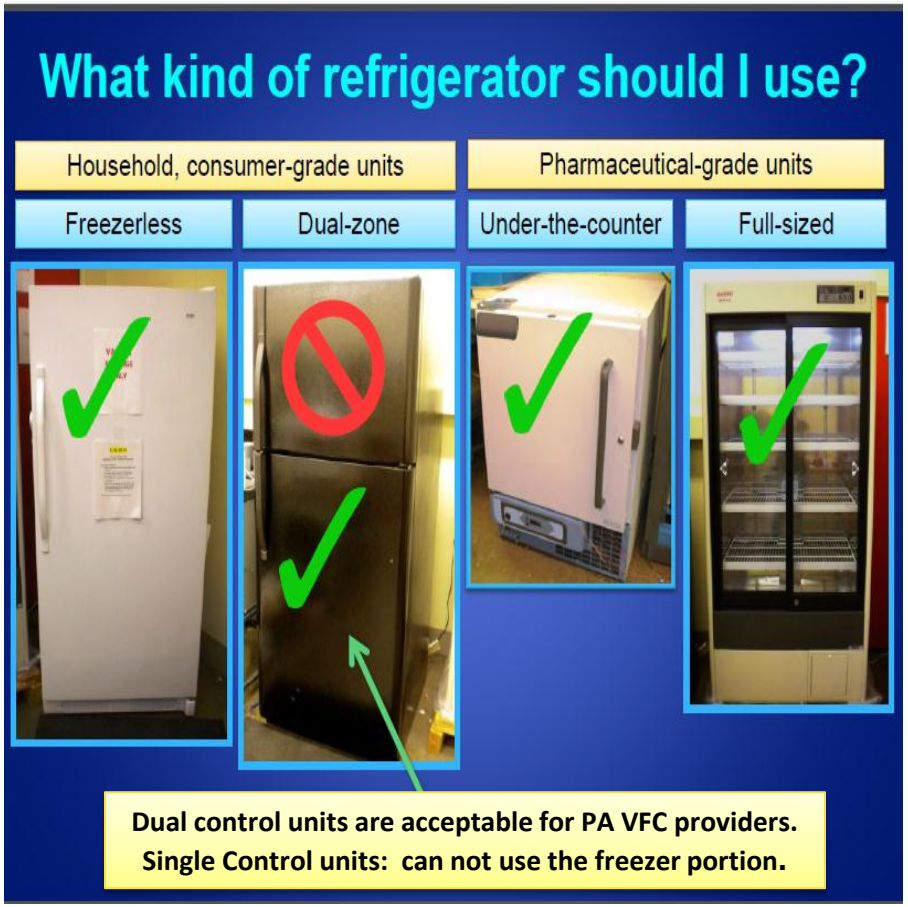
Vaccine Storage & Handling Equipment

- CDC strongly recommends use of stand-alone freezer and stand-alone refrigerators for vaccine storage.



NIST Certified Calibrated Thermometers with biosafe glycol-encased probe

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Calibrated Thermometers

- The best calibration is annual however the Department of Health will accept manufacturer suggestion but not to exceed <u>two</u> years.
- Temperatures must be recorded twice a day
- Temperature logs must be kept for three years
- Recommended Temperatures
  - Freezer: Between -58°F And +5°F (-50°C To -15°C)
    - Aim for 0°F
  - Refrigerator: Between 35°F And 46°F (2°C To 8°C)
    - Aim for 40°F (5°C)

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Single Control Unit

- 90 days grace period to get a stand alone freezer
- Suspension of ordering privileges after 90 days if a stand alone freezer is not in place

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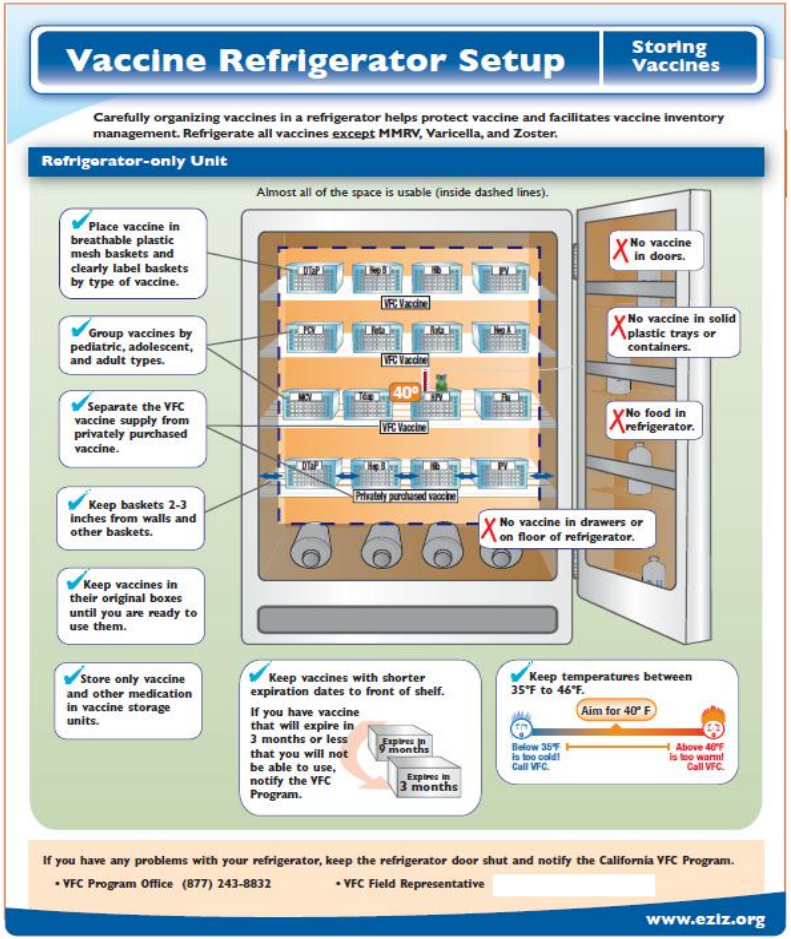
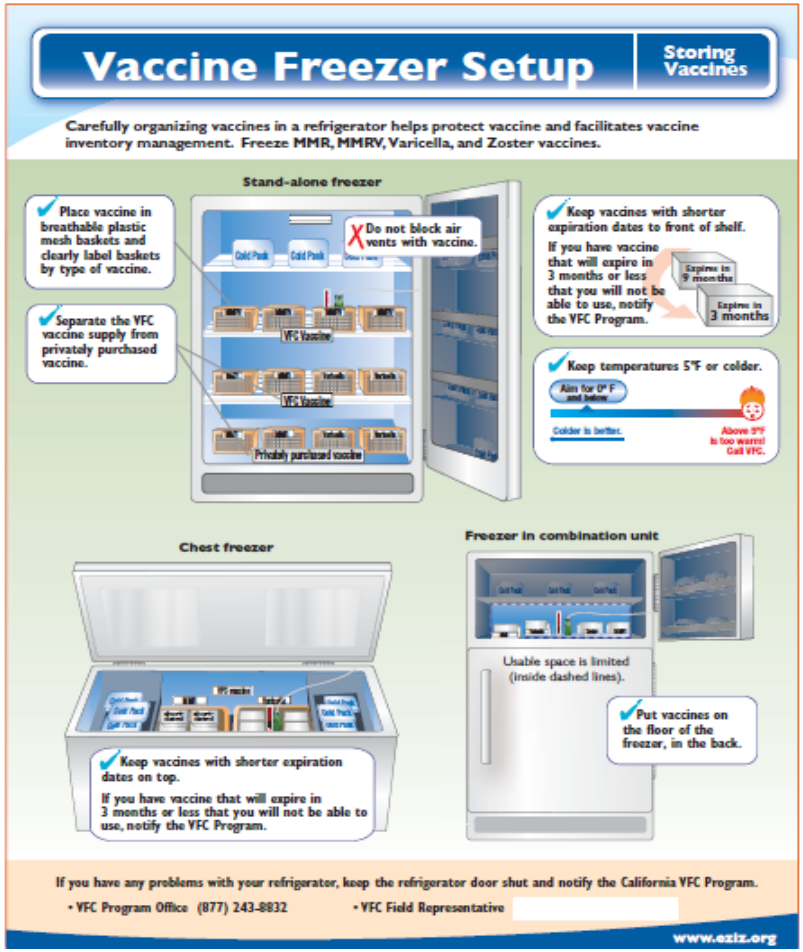
Refrigerator / Freezer Setup





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Vaccine Storage & Handling

Vaccines must be stored and handled correctly to work!

- Once lost, vaccine potency can not be restored
- Loss of vaccine potency may not be visible
- Call the manufacturer if out of range temperatures occur
- Vaccines are expensive!
- It is better to not vaccinate than to administer vaccine that is expired, was mishandled, is the wrong vaccine, or was reconstituted with the wrong diluent

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Vaccine Storage & Handling

- Keep vaccines in original packaging
- Store similarly packaged vaccines in different parts of the refrigerator
- Label VFC vaccine to keep separate from private stock
- Never transport or store diluent at freezer temperature
  - Vials could crack
- For some vaccines the “diluent” contains antigen that should not be frozen (Pentacel®, Menveo®)

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Cold Chain Failure=Incident Report

- An IR is to be completed within 5 days to provide explanation of what occurred and what corrective actions were taken by the provider.
- All forms must be complete to process the report, and suspension time may be increased.
- There is no need to return diluents to McKesson
- Flu vaccine does need sent back to McKesson for Federal Excise Tax

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Vaccine Incident Report

HD0506P (1/11)
HD0507P (1/11)

VACCINE INCIDENT REPORT & WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____
DATE _____

PROVIDER NAME: _____ PIN #: _____

DATE/TIME OF INCIDENT: _____ Phone: _____

ADDRESS: _____
(City) (County) (District)

TYPE OF INCIDENT: _____
(Power outage, equipment failure, failure to properly store, etc.)

REPORTED BY: _____ REPORTED TO: _____
(Include name, title, and work location)

TEMPERATURE DATA:

Date, time and temperature of units prior to the incident:

Refrigerator ____ ____ ____
Date Time Temperature

Freezer: ____ ____ ____
Date Time Temperature

Date, time and temperature of units when aware of the incident:

Refrigerator ____ ____ ____
Date Time Temperature

Freezer: ____ ____ ____
Date Time Temperature

DESCRIPTION OF INCIDENT (Circle all appropriate responses and/or write a narrative giving details of actions taken; attach additional sheet of paper if needed.)

Out of range temperature in fridge or freezer	Fridge or freezer door not closed
Failure to store properly upon delivery	Power failure due to:
Shipping from distributor error due to:	Storage unit malfunction due to:
Transporting to/from another VFC site	Thermometer malfunction due to:
Damaged shipping container due to:	Storage unit unplugged due to:
No/Non sufficient coolant in shipping container	Min/Max Readings if Available_____
Expired	Other/Additional Information:

INCIDENT RESOLUTION (Circle all appropriate responses and/or write a narrative giving details of actions taken after a problem was detected; attach additional sheet of paper if needed.)

Fridge, Freezer, Thermometer repaired replaced Date_____

Manufacturers called immediately (list their instructions on the "Vaccine Worksheets")

Requested Vaccine Return label from VFC Program (do so if need to return vaccine) Yes_____No_____

Other/Additional information:

Page 1

Must complete all four pages of worksheet and an additional two pages of Vaccine Return Form if vaccine is wasted.

Revised March 2013

HD0506P (1/11)
HD0507P (1/11)

VACCINE INCIDENT REPORT & WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____
DATE _____

CORRECTIVE ACTION PLAN (Write a narrative giving details of actions taken to assure that another preventable loss does not occur in the future; attach additional sheet of paper if needed.)

Staff educated re:

Developed protocol re:

Alternate delivery instructions posted

Emergency instructions reviewed/posted in prominent place

Other:

REQUIRED INFORMATION:

1. Was it necessary to waste vaccine because of the incident: Yes_____No_____
   If so, also complete the Vaccine Return Form and the Vaccine Worksheets; be sure to include the manufacturer's instructions and the number of doses wasted, short dated, etc.

2. Were any affected vaccines administered to patients and they now require revaccination: Yes_____No_____

   If so, how many patients need revaccinated: _____
   Patients were notified of need for revaccination Yes___ No ___

3. Are there water bottles stored in the refrigerator crisper bins as recommended: Yes ___ No___

4. Are there ice packs stored along the perimeter of the freezer as recommended: Yes___No___

5. Is a dormitory-style storage unit being used to store vaccines (not permissible): Yes___ No___

6. Type of Storage unit (i.e. Combo unit, medical grade, or stand alone)_____

7. Are there NIST-certified thermometers with current calibration in the middle of each compartment: Yes_____No_____

8. Are temperatures being taken twice daily during operating hours: Yes ___ No___

9. Are any adjustments to the thermometers noted on the temperature logs: Yes____ No___

10. The temperature log submitted with the storage incident. Yes ___ No___

Page 2

Must complete all four pages of worksheet and an additional two pages of Vaccine Return Form if vaccine is wasted.

Revised March 2013

HD0506P (1/11)
HD0507P (1/11)

VACCINE INCIDENT REPORT & WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____
DATE _____

CALL EACH MANUFACTURER OF AFFECTED VACCINE(S) AND ASK FOR THE VACCINE STABILITY SECTION

VACCINE	MANUFACTURER	TELEPHONE NUMBER
DT, DTaP (Tripedia), **DTaP** (Daptacel), **DTaP-IPV-Hib** (Pentacel) **EIPV** (Polio), **Flu** (Fluzone), **Hib** (ActHib), **Meningococcal** (MCV4), **Td** (Decavac), **Tdap** (Adacel))	sanofi pasteur www.us.aventispasteur.com	1-800-822-2463
Flu(Afluria), **Hep A** (Vaqta, **Hep B** (Recombivax), **HepB-Hib** (Comvax), **Hib** (PedvaxHib), **HPV** (Gardasil), **MMR, MMRV** (ProQuad), **Pneumococcal PPV23** (Pneumovax), **Rotavirus** (RotaTeq), **Varicella** (Varivax)	Merck www.merck.com	1-800-672-6372
DTaP (Infanrix), **DTaPHBIP** (Pediarix), **DTaP-IPV** (Kinrix), **Flu** (Fluarix), **Hep A** (Havrix), **Hep B PF** (Engerix), **Hep AB** (Twinrix), **HPV** (Cervarix) **Tdap** (Boostrix), **Rotavirus** (Rotarix)	GlaxoSmithKline www.gsk.com/products/vaccines.jsp	1-888-825-5249
PNU13 (Prevnar PCV13)	Pfizer www.pfizer.com	1-800-572-8221
Fluvirin, Meningococcal (Menveo)	Novartis www.novartisvaccines.com	1-800-244-7668
FluMist (LAIV)	MedImmune www.medimmune.com	1-877-358-6478

Sample documentation below

Vaccine Brand Name	Manufacturer	Lot Number	Expiration Date	Number of Doses	Manufacturer's Recommendation
DTaP (Tripedia)	sanofi pasteur (Aventis)	20034	12/1/2012	3	Spoke with Doreen, vaccine ok as long as it didn't freeze. None wasted.
VARICELLA (Varivax)	Merck	12345	12/1/2012	20	Spoke with Tim, must waste all doses. 20 doses wasted.
DTaHBIP (Pediarix)	GSK	UF064AA	12/1/2012	10	Spoke with Lucy, must use within three months. 10 doses marked with new expiration date.

Please attach additional sheets as needed.

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Vaccine Incident Report

HD0806P (1/11)
HD0807P (1/11)

VACCINE INCIDENT REPORT & WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____
DATE _____

CALL EACH MANUFACTURER OF AFFECTED VACCINE(S) AND ASK FOR THE VACCINE STABILITY SECTION

VACCINE	MANUFACTURER	TELEPHONE NUMBER
DT, DTaP (Tripedia), DTaP (Daptacel), DTaP-IPV-HIb (Pentacel) EIPV (Polio), Flu (Fluzone), HIb (ActHIb), Meningococcal (MCV4), Td (Decavac), Tdap (Adacel)	sanofi pasteur www.us.sanofipasteur.com	1-800-822-2463
Flu(Afluria), Hep A (Vaqta, Hep B (Recombivax), HepB-HIb (Comvax), HIb (PedvaxHIb), HPV (Gardasil), MMR, MMRV (ProQuad), Pneumococcal PPV23 (Pneumovax), Rotavirtus (RotaTeq), Varicella (Varivax)	Merck www.merck.com	1-800-672-6372
DTaP (Infanrix), DTaPHIBP (Pediarix), DTaP-IPV (Kinrix), Flu (Fluarix), Hep A (Havrix), Hep B PF (Engerix), Hep AB (Twinrix), HPV (Cervarix) Tdap (Boostrix), Rotavirtus (Rotarix)	GlaxoSmithKline www.gsk.com/products/vaccines.jsp	1-888-825-5249
PNU13 (Prevnar PCV13)	Pfizer www.pfizer.com	1-800-572-8221
Fluvirin, Meningococcal (Menveo)	Novartis www.novartisvaccines.com	1-800-244-7668
FluMist (LAIV)	MedImmune www.medimmune.com	1-877-358-6478

Sample documentation below

Vaccine Brand Name	Manufacturer	Lot Number	Expiration Date	Number of Doses	Manufacturer's Recommendation
DTaP (Tripedia)	sanofi pasteur (Aventis)	20034	12/1/2012	3	Spoke with Doreen, vaccine ok as long as it didn't freeze. None wasted.
VARICELLA (Varivax)	Merck	12345	12/1/2012	20	Spoke with Tim, must waste all doses. 20 doses wasted.
DTaHIBP (Pediarix)	GSK	UF064AA	12/1/2012	10	Spoke with Lucy, must use within three months. 10 doses marked with new expiration date.

Please attach additional sheets as needed.

Page 3

Must complete all four pages of worksheet and an additional two pages of Vaccine Return Form if vaccine is wasted.

Revised March 2011

HD0806P (1/11)
HD0807P (1/11)

VACCINE INCIDENT REPORT & WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____
DATE _____

Vaccine Brand Name	Manufacturer	Lot Number	Expiration Date	Number of Doses On Hand	Manufacturer's Recommendation	# Keep	#Destroy	#Return

Note: If the vaccine must be wasted, complete and fax the Vaccine Return Form(2 pages) to 717-214-7223. A Vaccine Return ID number will be faxed and a UPS label will be mailed to your facility, allow 7-10 business days to receive the UPS label from McKesson Specialty Distribution.
Record all unopened vials/boxes of non-viable vaccine on page one (including Varicella and Influenza) and then return to McKesson Specialty Distribution. Record all wasted open vials on page two of the return form and then discard those vials of non-viable vaccine according to your Biohazard Waste Disposal process. Fax the completed Vaccine Incident Report & Worksheet and Vaccine Return Form to the Vaccine Manager, Division of Immunizations, (717) 214-7223 within five days of the incident.

Page 4

Must complete all four pages of worksheet and an additional two pages of Vaccine Return Form if vaccine is wasted.

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Vaccine Return Form

VACCINE RETURN AND ACCOUNTABILITY FORM

PENNSYLVANIA DEPARTMENT OF HEALTH

RETURNABLE

Date: _____ * VTrckS Return ID _____ VFC PIN #: _____

Site Name: _____

Person Reporting: _____ Phone: _____ # of Shipping Boxes _____

Does this facility have routine UPS service – please check the appropriate box: ☐ YES ☐ NO

*** This number will be provided to the VFC Contact by phone, fax or e-mail.**

NON-VIABLE VACCINES TO RETURN TO MCKESSON

COMPLETION OF ALL COLUMNS IS REQURED

NDC #**	Vaccine	Manufacturer	Lot #	Expiration Date	# Doses	Reason Code

****The NDC Number can be found on each individual vaccine vial/syringe.**

Non-Viable – Returnable Vaccines Reason Code includes:

A. **Expiration date has passed**

B. **Failure to store or handle properly (e.g. vaccine left out overnight – temperatures out of range) – IF it is a partial vial it is considered wasted and non-viable – non-returnable and should be documented on the non-returnable section.**

C. **Refrigerator or Freezer failure - If it is a partial vial it is considered wasted and non-viable – non-returnable and should be documented on the non-returnable section**

D. **Power outage - If it is a partial vial it is considered wasted and non-viable – non-returnable and should be documented on the non-returnable section**

VACCINE RETURN AND ACCOUNTABILITY FORM

PENNSYLVANIA DEPARTMENT OF HEALTH

NON-RETURNABLE

Date: _____ * VTrckS Return ID _____ VFC PIN #: _____

Site Name: _____

Person Reporting: _____ Phone: _____

ACCOUNTABILITY OF WASTED, NON-VIABLE – NON-RETURNABLE VACCINES

COMPLETION OF ALL COLUMNS IS REQUIRED

NDC #**	Vaccine	Manufacturer	Lot #	Expiration Date	# Doses	Reason Code

****The NDC Number can be found on each individual vaccine vial/syringe.**

Although wasted non-viable/non-returnable vaccines are not returned to McKesson ARS Specialty, the VFC Program must account and document this vaccine. Please complete the Vaccine Return and Accountability Form for Non-Viable/Non-Returnable vaccine and fax this form to (717) 214-7223 – Attention: Vaccine Manager

Properly dispose of all wasted non-viable/non-returnable vaccine.

Wasted – Non-Viable- Non-Returnable Vaccine Reason Code Includes:

A. **Drawn up – and refused**

B. **Broken vial or syringe**

C. **Lost or unaccounted for**

D. **Open/partial vial exposed to out of range temperatures, unit failures or power outages**

E. **Open/partial vial that has passed the expiration date**

F. **All vaccines deemed non-viable/non-returnable must be properly disposed of according to the policy in place at your facility.**

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Thermometer & Vaccine placement

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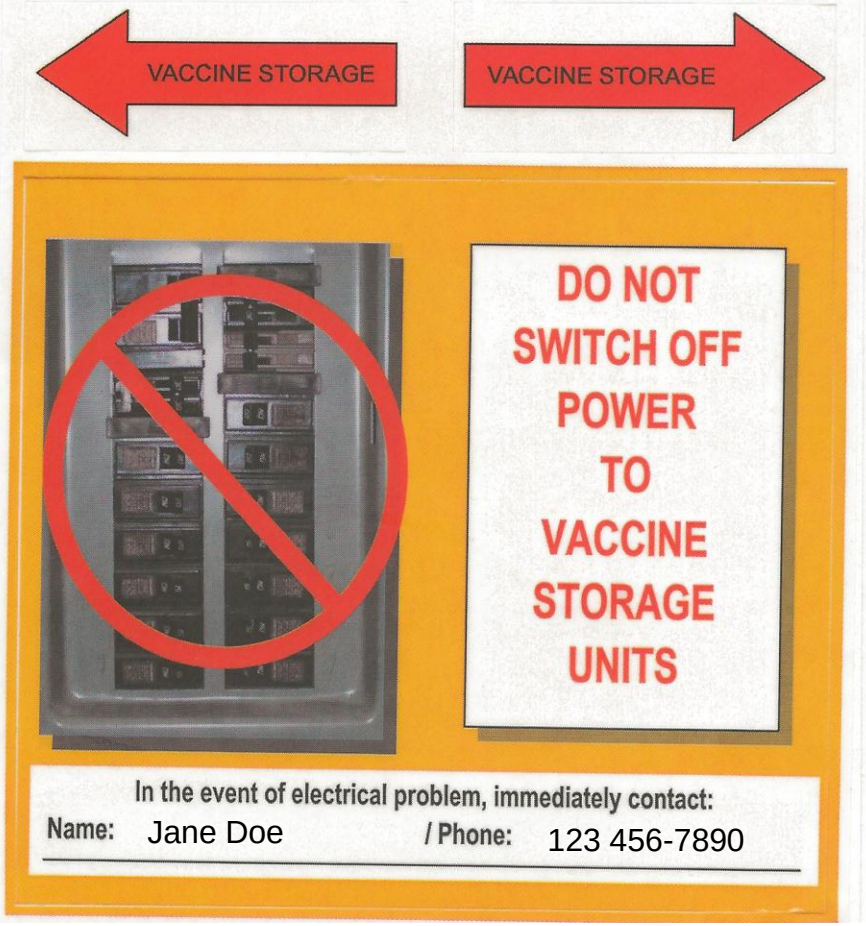
Stickers



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Temperature Logs

FAHRENHEIT TEMPERATURE LOG

Instructions: Place an "x" in the box that corresponds with the temperature (columns), day of the month, and a.m. or p.m. (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes. Document temperatures twice daily and keep temp logs on file for at least three years!

MONTH/YEAR: _____ **PIN #** _____

Refrigerator 35 - 46ºF																					Freezer 5F° to -58º F					
Day of month	Time	Staff Initials		≥49	48	47	46	45	44	43	42	41	40	39	38	37	36	35	34	33	≤32	≥8	7	6	5	4	≤3
1			am																								
2			pm																								
3			am																								
4			pm																								
5			am																								
6			pm																								
7			am																								
8			pm																								
9			am																								
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24			pm																								
25			am																								
26			pm																								
27			am																								
28			pm																								
29			am																								
30			pm																								
31			am																								
			pm																								
				≥49	48	47	46	45	44	43	42	41	40	39	38	37	36	35	34	33	≤32	≥8	7	6	5	4	≤3

TOO WARM

TOO COLD

TOO WARM

CELSIUS TEMPERATURE LOG

Instructions: Place an "x" in the box that corresponds with the temperature (columns), day of the month, and a.m. or p.m. (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes. Document temperatures twice daily and keep temp logs on file for at least three years!

MONTH/YEAR: _____ **PIN #** _____

Refrigerator 2 - 8ºC																			Freezer -15°Cto -50ºC					
Day of month	Time	Staff Initials		≥11	10	9	8	7	6	5	4	3	2	1	0	≤-1	≥-12	-13	-14	-15	-16	≤-17
1			am																			
2			pm																			
3			am																			
4			pm																			
5			am																			
6			pm																			
7			am																			
8			pm																			
9			am																			
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25			am																			
26			pm																			
27			am																			
28			pm																			
29			am																			
30			pm																			
31			am																			
			pm																			
				≥11	10	9	8	7	6	5	4	3	2	1	0	≤-1	≥-12	-13	-14	-15	-16	≤-17

TOO WARM

TOO COLD

TOO WARM

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Vaccine Storage Maintenance Reminder

Vaccine Storage Maintenance Reminder

Certificate of NIST Thermometer ⇨ Date_____

Date_____

Date_____

Date_____

Annual/Biannual Recalibration of NIST thermometers

	Due Date	Completed Date
Refrigerator:	05/28/15	_____
	_____	_____
Freezer:	05/28/15	_____
	_____	_____

Yearly Service of Storage unit (Recommended)

_____	_____
_____	_____
_____	_____
_____	_____

Defrosting Freezer Unit Monthly

January	February	March	April	May	June
July	August	September	October	November	December

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Vaccine Management Plan

PA VFC Vaccine Management Plan and Designated Responsible Staff (Page 1 of 2)

VFC PIN#:_____NAME:_____

1. Update Vaccine Management Plan and Designated Responsible Staff document annually.
2. Each staff member/provider that has direct contact with VFC vaccine must review and sign the updated Vaccine Management Plan and the Disaster Recovery Plan annually and keep posted at the site.
3. VFC vaccine shipments are received and inventoried by_____ [designated person].
4. Upon receipt VFC vaccines are labeled to differentiate them from private vaccine stock.
5. DTap, Td, Tdap, HepA, Hep B, Hib, HPV, Influenza, Meningococcal, MMR, Pneumococcal, Polio and Rotavirus vaccines are stored in the refrigerator with temperatures maintained at 35° to 46°F/2 to 8°C.
6. Frozen vaccines (Varicella, Zostavax, MMRV) must be stored in the freezer with temperatures maintained at 5°F to negative 58°F/negative 15°C to negative 50°C. MMR may be stored in the freezer. Diluents are stored at refrigerator 35°F to 46°F/2 to 8°C or room temperatures 68°F to 77°F/20°C to 25°C.
7. Only freestanding refrigerators and freezers or combined units with two separate external doors and separate temperature controls are used to store VFC vaccine. It is never permissible to use Dormitory style units (freezer section located within the refrigerator section) to store VFC vaccine. (See VFC Handbook)
8. Warning signs are posted to assure vaccine storage units are plugged in at all times and circuit breaker boxes identify vaccine storage unit switches to prevent turning off the power supply without prior notification given to _____ [designated person].
9. Calibrated thermometers with current Certificate of NIST Traceability and Calibration are located in the central compartment of each VFC vaccine refrigerator and freezer storage unit. Thermometers are due for recalibration_____. Certificates are kept and maintained by_____ [designated person/location].
10. Temperature logs are maintained on site for 3 years. Failure to maintain temperature logs will result in suspension of your VFC vaccine ordering privileges.
11. Temperatures are recorded twice a day at the beginning and end of day by _____ [designated person]. Min/max. Temperatures may also be recorded in the AM, if your thermometer has this capability.
12. Document any actions taken for out of range temperatures on the temperature log. Recheck the temperature in 30 minutes and record. If still out of range after 30 minutes, immediately contact the manufacturers for recommendations on the viability of the vaccine.
13. If temperatures are out of range _____ [designated person] will be notified and determine what actions will be taken. Vaccine Incident Report and Worksheets (and Vaccine Return Form if applicable) located in section 6 of the VFC Handbook must be completed and submitted to the VFC Program within 5 days of the incident.
14. Vaccine is stored in the central shelving of the units. No vaccine is permitted in the crisper bins or on the doors/floor of the storage unit. Crisper bins are removed and jugs of water are placed in crisper space. No food or drink is permitted in vaccine storage units.
15. Vaccine vials/syringes must be stored in the manufacturer original packaging.

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PA VFC Vaccine Management Plan and Designated Responsible Staff (Page 2 of 2)

16. Vaccine inventory is reviewed weekly by _____ [designated person].
17. Vaccine stock is rotated with short-dated vaccines used first. Expired vaccines are removed from the storage unit and labeled to be returned to McKesson. The Vaccine Return Form is completed listing all wasted, open, and expired vaccine then submitted to the VFC Program in order to receive the vaccine Return Shipping Label. No opened multidose vials may be returned, dispose of open vials according to your biohazard waste disposal process.
18. Notify your VFC Immunization Nurse for assistance if vaccine will expire within 90 days.
19. Vaccine are ordered in accordance with the assigned EOQ schedule _____[insert EOQ schedule].
20. Vaccine borrowing is documented on Vaccine Borrowing Report Form [in section 6 of VFC Handbook]. This important information is documented and maintained for 3 years for review by the VFC program.
21. Procedures for vaccine relocation in the event of a power outage, mechanical difficulty or emergency are reviewed and updated annually. [attach Site specific Vaccine Disaster Recovery Plan or adapt the sample in Section 6 c VFC Handbook with a detailed plan of the alternative storage site, documentation of temperatures, directions to the site and instructions of how to pack and maintain temperatures in the transport coolers]
22. The Vaccine Storage Maintenance Reminder should be posted on the VFC storage unit and be complet by _____ [designated person].

Designated Responsible Staff

It is the direct responsibility of the staff person designated below to safeguard and ensure the maintenance of vaccines use by this clinic. In addition, all staff members that have direct contact with VFC vaccine must read the Provider Handbook an be familiar with your organization's vaccine management plan. These staff members must also sign and date the form belc indicating they have read the Provider Handbook and this document. If you have questions about any information in this guide, please contact your Immunization Nurse Consultant.

Designated responsible staff person:_____Alternate _____

Read by:	Date

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Vaccine Disaster Recovery Plan

VACCINE DISASTER RECOVERY PLAN
Pennsylvania Department of Health
Vaccines for Children Program

Provider Site Name:_____

Address:_ _____

_____

Phone: _____

Date: _____**Person Completing Form:** _____

This document offers guidance for developing a vaccine disaster recovery plan and protocols for routine vaccine handling and storage. Included are steps to follow when your refrigerator or freezer malfunctions due to mechanical failure or natural disaster.

1. RECOVERY PLAN

Advanced Preparations

Vaccine Coordinators	Title	Telephone Numbers (home, cell, beeper)
Primary		
Backup		

The primary and back-up vaccine contact persons should:

- Develop a written emergency vaccine retrieval and storage plan which includes how to access the facility and storage area. Provide protocols for proper handling of vaccines during transportation using the VFC transport policy guides and the Vaccine Transport Hourly Monitoring form.

CONTACT INFORMATION

Our VFC Program contact is:_____

Phone: _____

Fax: _____

E-mail: _____

Company	Name	Phone Number
Electric power		
Refrigeration repair		
Temperature alarm monitoring		
Security Alarm Contact		
Backup vaccine storage facility		
Transportation to backup storage facility		
Emergency generator repair		
National Weather Service http://www.nws.noaa.gov http://www.nhc.noaa.gov http://www.goes.noaa.gov		
FEMA http://www.fema.gov/index.shtm		
Owner /Building Maintenance Company		

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Vaccine Adverse Event Reporting System

WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

VAERS

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name: _____ Last First M.I.
Address _____ City State Zip
Telephone no. (____) _____

Vaccine administered by (Name): _____
Responsible Physician _____
Facility Name/Address _____ City State Zip
Telephone no. (____) _____

Form completed by (Name): _____
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)* _____ City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm / dd / yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm / dd / yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy Time _____ AM PM

11. Adverse event onset mm / dd / yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. Birth weight _____ lb. _____ oz.
23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project
24. Mfr./imm. proj. report no.
25. Date received by mfr./imm.proj.
26. 15 day report? ☐ Yes ☐ No
27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1 (FDA)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD
POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM
(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
Item 10: and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
Item 13: List ONLY those vaccines given on the day listed in Item 10.
Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
Item 26: This space is for manufacturers' use only.

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Vaccine Borrowing Report

SAMPLE COMPLETED VFC Vaccine Borrowing Report

Guidance:
VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider must assure that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of appropriate stock vaccine (VFC or provider-purchased) due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider or new staff who calculated ordering time incorrectly. The reason cannot be provider planned borrowing from either the private stock or the VFC stock.
Directions for use of this form:
When a provider has borrowed vaccine from one stock to administer to a child who is only eligible to receive vaccine from the other stock, this form must be COMPLETELY FILLED OUT for each borrowing occurrence. **Each vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of vaccine are replaced to the appropriate vaccine stock, that date must be entered on this form. These borrowing reports must be kept as part of the VFC program records and be made available to the VFC staff during the VFC Site Visit.

Vaccine Borrowed	Patient Name/Patient Identifier/ Insurance status (VFC or private)	DOB	Date Borrowed	Reason no appropriate stock vaccine was available (circle one)	Date vaccine returned to appropriate stock
DTaP	Shirley Temple VFC	08/01/20010	10/19/2010	1.Private stock order delayed 2..Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	10/21/2010
IPV	" "	" "	" "	1.Private stock order delayed 2..Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	10/21/2010
DTaP	Mickey Rooney private	08/15/2010	10/19/2010	1.Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4.VFC order non-viable on arrival 3. other (specify)	10/21/2010
IPV	Mickey Rooney private	08/15/2007	10/19/2010	1.Private stock order delayed 2..Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	10/21/2010
				1.Private stock order delayed 2..Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.
"Provider Name: Dr. Sam Who Provider Signature: Dr. Sam Who Date: 02/21/2011

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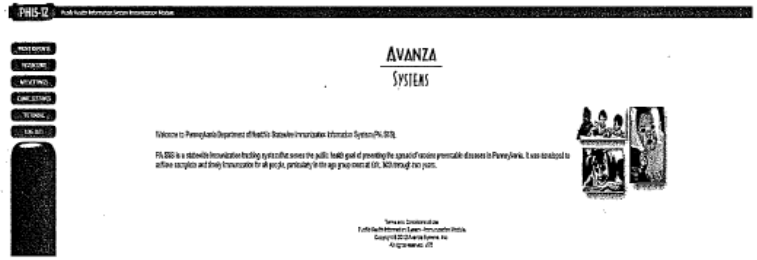
Vaccine Ordering

Initial PA-SIIS User set up prior to placing your first VFC Vaccine order

After logging into the PA-SIIS and accepting the on-line User Agreement you will land on the Avanza home screen as shown below.



Please go directly to My Settings and update your name, Password, Confirm Password and email address as needed. After completing your updates **select *Update*,** then ***OK*** and ***Close My Settings*** and then ***OK*** to return to the Avanza home screen.

EDIT MY SETTINGS

Pennsylvania Statewide Immunization Information System

Production Website: **https://siis.health.state.pa.us/siis**

PA-SIIS Support Site: **www.health.state.pa.us/pasiis**

Phone Number: (717) 783-2548 or (877) 774-4748

Training Manual

Vaccine Ordering And Receiving PA-SIIS Electronic Inventory Shipments

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Vaccine Online Ordering

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PENNSYLVANIA DEPARTMENT OF HEALTH SUPPLIED VACCINE ORDER, INVENTORY & ACCOUNTABILITY FORM

I take full responsibility for the information on this form and attest that there is a current temperature log at this practice site.

Signature of person completing this form: _____

PIN#:	DATE:	Report Period: FROM:	TO:
Name of Physician's Office, Practice, Clinic, etc.:			
Address:		PHONE:	FAX:
City/State/Zip:			ORDER FREQ:

Fax Order to: (717) 441-3800 or e-mail to: paimmunizations@pa.gov

VACCINE	CURRENT INVENTORY						WASTED/EXPIRED VACCINE		NEW VACCINE ORDER				
	DOSES ON HAND	LOT#	EXPIRATION DATE	DOSES ON HAND	LOT#	EXPIRATION DATE	Lot#/Exp Date	Doses	MANUF	BRAND	NDC	PKG DESCRIPTION	DOSES ORDERED
DTaP									Sanofi	Daptacel	49281-0286-10	(10 pk) 1-dose vials	
									GSK	Infanrix	58160-0810-11	(10 pk) 1-dose vials	
									GSK		58160-0810-52	(10 pk) 1-dose syringes	
DTaP/Hep B/IPV									GSK	Pediarix	58160-0811-52	(10 pk) 1-dose syringes	
DTaP/IPV/Hib									Sanofi	Pentacel	49281-0510-05	(5 pk) 1-dose vials	
DTaP/IPV									GSK	Kinrix	58160-0812-11	(10 pk) 1-dose vials	
									GSK		58160-0812-52	(10 pk) 1-dose syringes	
EIPV									Sanofi	IPOL	49281-0860-10	(1 pk) multi-dose vials	
HEP A - Peds									Merck	Vaqta	00006-4831-41	(10 pk) 1-dose vials	
									Merck		00006-4095-09	(6 pk) 1-dose syringes	
									GSK	Havrix	58160-0825-11	(10 pk) 1-dose vials	
									GSK		58160-0825-52	(10 pk) 1-dose syringes	
HEP B - Peds									Merck	Recombivax	00006-4981-00	(10 pk) 1-dose vials	
									Merck		00006-4093-09	(6 pk) 1-dose syringes	
									GSK	Engerix	58160-0820-11	(10 pk) 1-dose vials	
									GSK		58160-0820-52	(10 pk) 1-dose syringes	
HepB-Hib									Merck	Comvax	00006-4898-00	(10 pk) 1-dose vials	
Hib									Merck	PedvaxHIB	00006-4897-00	(10 pk) 1-dose vials	
									Sanofi	ActHIB	49281-0545-05	(5 pk) 1-dose vials	
HPV - Peds									Merck	Gardasil	00006-4045-41	(10 pk) 1-dose vials	
									GSK	Cervarix	58160-0830-52	(10 pk) 1-dose syringes	
Meningococcal Conjugate-Peds									Sanofi	Menactra	49281-0589-05	(5 pk) 1-dose vials	
									Novartis	Menveo	46028-0208-01	(5 pk) 1-dose vials	
MMR - Peds									Merck	MMR-II	00006-4681-00	(10 pk) 1-dose vials	
MMR-V - Peds									Merck	ProQuad	00006-4999-00	(10 pk) 1-dose vials	

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revised 10/23/12

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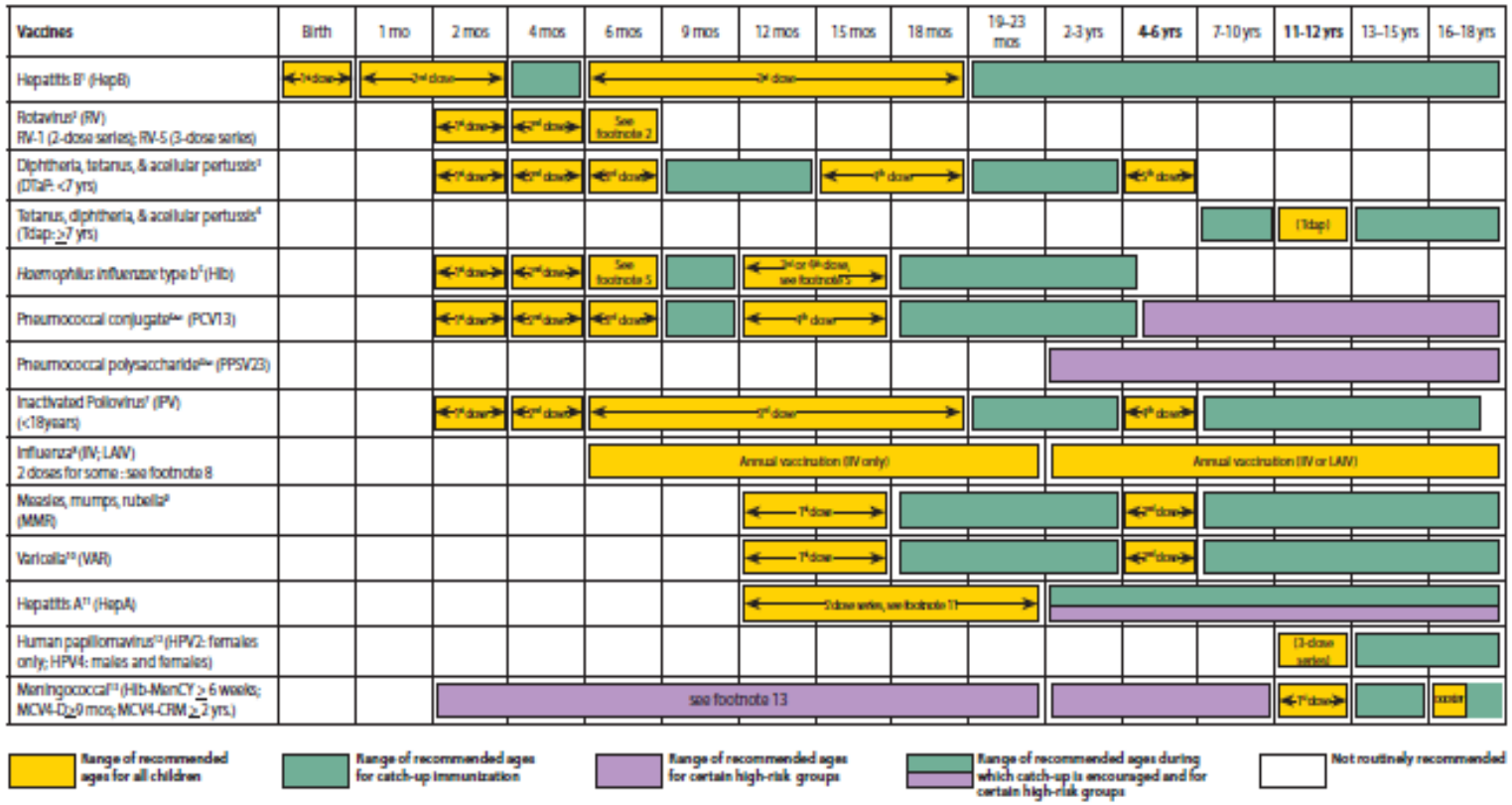
Recommended Immunization Schedule 0 – 18 Years

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – 2013.
(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 in bold.



http://www.cdc.gov/vaccines/schedules/hcp/childadolescent.html

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Standards for Immunization Practices

Summary of Recommendations for Child/Teen Immunization *(Ages birth through 18 years)* (Page 1 of 4)

Vaccine name and route	Schedule for routine vaccination and other guidelines (any vaccine can be given with another)	Schedule for catch-up vaccination and related issues	Contraindications and precautions (mild illness is not a contraindication)
Hepatitis B (HepB) *Give IM*	• Vaccinate all children age 0 through 18yrs. • Vaccinate all newborns with monovalent vaccine prior to hospital discharge. Give dose #2 at age 1–2m and the final dose at age 6–18m (the last dose in the infant series should not be given earlier than age 24wks). After the birth dose, the series may be completed using 2 doses of single-antigen vaccine or up to 3 doses of Comvax (ages 2m, 4m, 12–15m) or Pediarix (ages 2m, 4m, 6m), which may result in giving a total of 4 doses of hepatitis B vaccine. • **If mother is HBsAg-positive:** give the newborn HBIG + dose #1 within 12hrs of birth; complete series at age 6m or, if using Comvax, at age 12–15m. • **If mother's HBsAg status is unknown:** give the newborn dose #1 within 12hrs of birth. If low birth weight (less than 2000 grams), also give HBIG within 12hrs. For infants weighing 2000 grams or more whose mother is subsequently found to be HBsAg positive, give the infant HBIG ASAP (no later than 7d of birth) and follow HepB immunization schedule for infants born to HBsAg-positive mothers.	• Do not restart series, no matter how long since previous dose. • 3-dose series can be started at any age. • Minimum intervals between doses: 4wks between #1 and #2, 8wks between #2 and #3, and at least 16wks between #1 and #3.	**Contraindication** Previous anaphylaxis to this vaccine or to any of its components. **Precautions** • Moderate or severe acute illness. • For infants who weigh less than 2000 grams, see ACIP recs.*
DTaP, DT (Diphtheria, tetanus, acellular pertussis) *Give IM*	• Give to children at ages 2m, 4m, 6m, 15–18m, 4–6yrs. • May give dose #1 as early as age 6wks. • May give #4 as early as age 12m if 6m have elapsed since #3. • Do not give DTaP/DT to children age 7yrs and older. • If possible, use the same DTaP product for all doses.	• #2 and #3 may be given 4wks after previous dose. • #4 may be given 6m after #3. • If #4 is given before 4th birthday, wait at least 6m for #5 (age 4–6yrs). • If #4 is given after 4th birthday, #5 is not needed.	**Contraindications** • Previous anaphylaxis to this vaccine or to any of its components. • For DTaP/Tdap only: encephalopathy not attributable to an identifiable cause, within 7d after DTP/DTaP. **Precautions** • Moderate or severe acute illness. • History of arthus reaction following a prior dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10yrs have elapsed since the last tetanus toxoid-containing vaccine. • Guillain-Barré syndrome (GBS) within 6wks after previous dose of tetanus-toxoid-containing vaccine. • For DTaP only: Any of these events following a previous dose of DTP/DTaP: 1) temperature of 105°F (40.5°C) or higher within 48hrs; 2) continuous crying for 3hrs or more within 48hrs; 3) collapse or shock-like state within 48hrs; 4) seizure within 3d. • For DTaP/Tdap only: Progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.
Td, Tdap (Tetanus, diphtheria, acellular pertussis) *Give IM*	• For children and teens lacking previous Tdap: give Tdap routinely at age 11–12yrs and vaccinate older teens on a catch-up basis; then boost every 10yrs with Td. • Make special efforts to give Tdap to children and teens who are 1) in contact with infants younger than age 12m and 2) healthcare workers with direct patient contact. • For pregnant women lacking previous Tdap, give Tdap in 3rd or late 2nd trimester (i.e., more than 20wks gestation). If not given during pregnancy, give Tdap in immediate postpartum period.	• Children as young as age 7yrs and teens who are unvaccinated or behind schedule should complete a primary Td series (spaced at 0, 1–2m, and 6–12m intervals); substitute a 1-time Tdap for any dose in the series, preferably as dose #1. • Tdap should be given regardless of interval since previous Td.	
Polio (IPV) *Give SC or IM*	• Give to children at ages 2m, 4m, 6–18m, 4–6yrs. • May give dose #1 as early as age 6wks. • Not routinely recommended for U.S. residents age 18yrs and older (except certain travelers).	• The final dose should be given on or after the 4th birthday and at least 6m from the previous dose. • If dose #3 is given after 4th birthday, dose #4 is not needed if dose #3 is given at least 6m after dose #2.	**Contraindication** Previous anaphylaxis to this vaccine or to any of its components. **Precautions** • Moderate or severe acute illness. • Pregnancy.

Special Notes on Hepatitis B Vaccine (HepB)
Dosing of HepB: Monovalent vaccine brands are interchangeable. For people age 0 through 19yrs, give 0.5 mL of either Engerix-B or Recombivax HB.
Alternative dosing schedule for unvaccinated adolescents age 11 through 15yrs: Give 2 doses Recombivax HB 1.0 mL (adult formulation) spaced 4–6m apart. (Engerix-B is not licensed for a 2-dose schedule.)
For preterm infants: Consult ACIP hepatitis B recommendations (*MMWR* 2005; 54 [RR-16]).*

*This document was adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP). To obtain copies of the recommendations, call the CDC-INFO Contact Center at (800) 232-4636; visit CDC's website at www.cdc.gov/vaccines/pubs/ACIP-list.htm; or visit the Immunization Action Coalition (IAC) website at www.immunize.org/acip. This table is revised periodically. Visit IAC's website at www.immunize.org/childrules to make sure you have the most current version.

Technical content reviewed by the Centers for Disease Control and Prevention, January 2012.

www.immunize.org/catg.d/p2010.pdf • Item #P2010 (1/12)

Immunization Action Coalition • 1573 Selby Avenue • Saint Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

http://www.immunize.org/handouts/view-all.asp

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Contraindications for Childhood Immunization

Guide to Contraindications and Precautions[1] to Commonly Used Vaccines* (Page 1 of 2)

Vaccine	Contraindications	Precautions[1]
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Infant weighing less than 2000 grams (4 lbs, 6.4 oz)[2]
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception	• Moderate or severe acute illness with or without fever • Altered immunocompetence other than SCID • Chronic gastrointestinal disease[3] • Spina bifida or bladder exstrophy[3]
Diphtheria, tetanus, pertussis (DTaP) **Tetanus, diphtheria, pertussis (Tdap)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP (for DTaP); or of previous dose of DTP, DTaP, or Tdap (for Tdap)	• Moderate or severe acute illness with or without fever • Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine • Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized **For DTaP only:** • Temperature of 105° F or higher (40.5° C or higher) within 48 hours after vaccination with a previous dose of DTP/DTaP • Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP • Seizure within 3 days after receiving a previous dose of DTP/DTaP • Persistent, inconsolable crying lasting 3 or more hours within 48 hours after receiving a previous dose of DTP/DTaP
Tetanus, diphtheria (DT, Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • GBS within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine
***Haemophilus influenzae* type b (Hib)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Age younger than 6 weeks	• Moderate or severe acute illness with or without fever

http://www.immunize.org/handouts/view-all.asp

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Vaccine Management:
Recommendations for Handing & Storage of Selected Biologicals

Handouts for Patients & Staff | Clinic Resources | Vaccine Information Statements | Diseases & Vaccines | Talking about Vaccines | Topics

IAC Resources

- IAC Home
- Resources Home
- Handouts
- Clinic Resources
- Shop IAC
- VISs
- IAC Image Library
- IAC Publications
- Adult Vax Guide

Other Resources

- Apps
- Blogs
- Books and Periodicals
- Immunization Coalitions
- Continuing Education
- Email News Services
- Government Agencies
- Hotlines
- International Organizations
- Manufacturers
- Package Inserts
- Partners
- PowerPoint
- Resources by Disease/Vaccine
- Resources by Topic

CDC Resources

- CDC Materials

Package Inserts

Vaccine index

View all	HPV	Pneumococcal - PPSV	Td
Anthrax	Influenza	Polio - IPV	Tdap
Chickenpox (varicella)	Japanese encephalitis	Rabies	Typhoid
DTaP	Measles	Rotavirus	Yellow fever
Hib	Meningococcal	Rubella	
Hepatitis A	Mumps	Shingles (zoster)	
Hepatitis B	Pneumococcal - PCV	Smallpox	

Package Inserts - Anthrax

BioThrax Package Insert
Emergent BioSolutions

Package Inserts - Chickenpox (varicella)

ProQuad Package Insert
Combination vaccine: Varicella+MMR
Merck & Co., Inc.

Varivax Package Insert
Merck & Co., Inc.

Package Inserts - DTaP

DAPTACEL Package Insert
sanofi pasteur

Tripedia Package Insert [product discontinued]
sanofi pasteur

Infanrix Package Insert
GlaxoSmithKline

Pentacel Package Insert
Combination vaccine: DTaP+Hib+IPV
sanofi pasteur

KINRIX Package Insert

Pediarix Package Insert

http://www.immunize.org/packageinserts/

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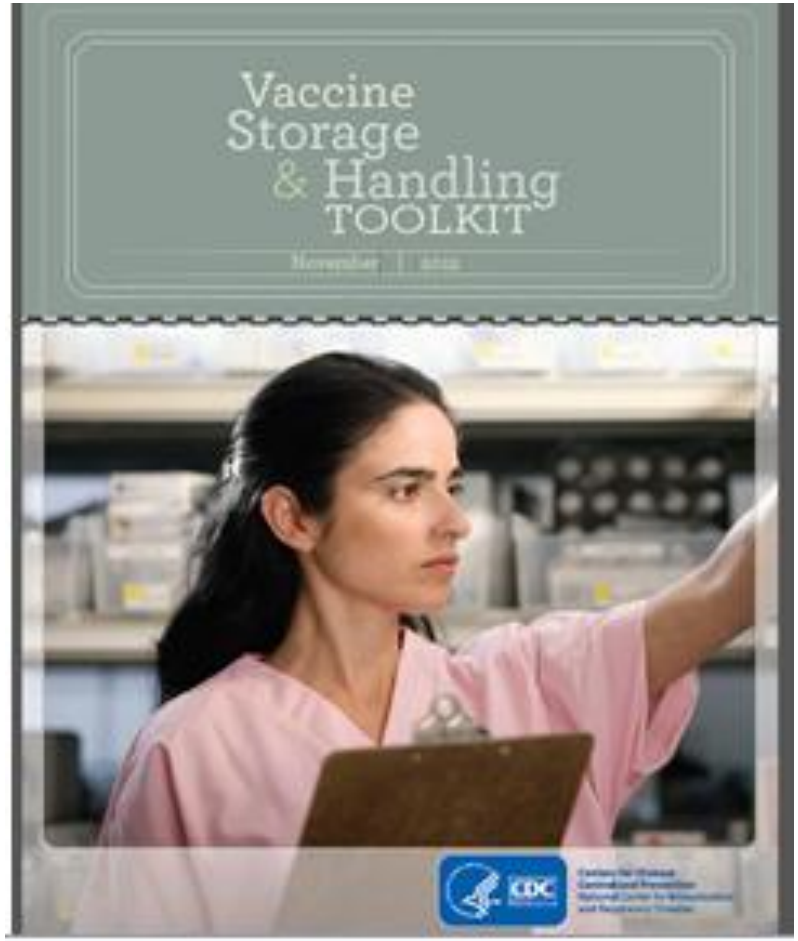
Vaccine Storage and Handling Toolkit



http://www.cdc.gov/vaccines/recs/storage/toolkit/

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Types of VFC Site Visits

- VFC Enrollment
- VFC Compliance Visits
- Unannounced Storage and Handling Visit
- VFC Vaccine Management Education

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Annual Immunization Training Requirements

Vaccines: Ed/You Call the Shots - Windows Internet Explorer

http://www.cdc.gov/vaccines/ed/youcalltheshots.htm

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Vaccines & Immunizations

Vaccines Home > Education & Training > Immunization Courses > You Call The Shots

Vaccine-Related Topics

- Immunization Schedules
- Recommendations and Guidelines
- Vaccines & Preventable Diseases
- Basics and Common Questions
- Vaccination Records
- Vaccine Safety and Adverse Events
- For Travelers
- For Specific Groups of People
- Campaign Materials

Additional Resources

- Publications
- News and Media Resources
- Calendars and Events
- Education and Training
  - Immunization Courses
  - NetConferences
  - On-Site Training
  - Podcasts
  - Patient Education
- Programs and Tools
- Statistics and Surveillance

Education & Training:

You Call The Shots

Web-based Training Course

At a glance:

This product was developed through the Project to Enhance Immunization Content in Nursing Education and Training, which is supported by funding from the National Center for Immunization and Respiratory Diseases(NCIRD) of the Centers for Disease Control and Prevention (CDC), through a Cooperative Agreement with the Association for Prevention Teaching and Research

Immunization You Call the Shots

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- Vaccine Storage and Handling FEB 2013
  Scroll to bottom of page and click "continue" to start program
- Vaccines For Children (VFC) FEB 2013
  Scroll to bottom of page and click "continue" to start program
- Understanding the Basics: General Recommendations on Immunization Oct 2012

Two required programs to meet VFC Provider educational requirement

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Education Roster

2013 PA VFC Education Roster

Site Name_____

Date	Time	Format/Presenter	Educational Topic	Attendee Signature
Example	*1p.m.– 3p.m.*	*On Line Training/CDC*	*You Call the Shots*	*Joe Smith, RN*

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Websites

http://www.cdc.gov/vaccines/schedules/hcp/childadolescent.html

http://www.immunize.org/handouts/view-all.asp

http://www.immunize.org/packageinserts

http://www.cdc.gov/vaccines/recs/storage/toolkit

http://www.immunize.org/

http://www.cdc.gov/vaccines/default.htm

http://www.cdc.gov/vaccines/ed/youcalltheshots.htm

www.cdc.gov/vaccines/pubs/vis/vis-facts.htm

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Thank you for your attention and participation

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