

Vaccine Incident Report and Worksheet  
 Pennsylvania Department of Health  
 Vaccines for Children Program

Date	Pin #
<b>Demographics</b>	
Practice Name	
Address	Phone #
	County <span style="float: right;">District</span>
<b>Incident Criteria</b>	
Date /Time of Incident	
Type of Incident (Power failure, refrigerator/freezer failure, improperly stored, thermometer malfunction, shipping/transporting error etc.)	
Reported by	Reported to
<b>Temperature Data</b>	
<b>Refrigerator-</b> circle appropriately below	<b>Freezer-</b> circle appropriately below
Pharmaceutical   Commercial   Standalone   Combo	Pharmaceutical   Commercial   Standalone   Combo
Make/Model	Make/Model
Date/Time                      Temperature	Date/Time                      Temperature
Min                                      Max	Min                                      Max
Temperatures are reviewed and documented twice daily during operating hours? <b>YES NO</b>	
Water bottles are stored in both refrigerator and freezer? <b>YES NO</b>	
<b>Description of Incident</b> (Write a narrative giving details of incident; attach additional sheet of paper if needed.)	
<b>Incident Resolution</b> (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_____	
Notified your VFC Immunization nurse of storage repairs/replacements   Date_____	
Manufacturers contacted immediately   and completed incident report faxed within 5 days <b>YES NO</b>	
Other/Additional information:	
Must complete all four pages of worksheet and fax within 5 days to 717-214-7223	

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Temperature Log and Calibration Certificate

NIST-certified temperature monitoring device/buffered probes are in the center of each unit

Calibration certificate included with incident report is current \_\_\_\_\_ date

Temperature logs complete and copy included with the incident report

Action taken with OOR temperature noted on Step 3 of temperature log

Vaccine Waste

Was it necessary to waste vaccine because of the incident **YES NO**

Details of contact with manufacturers are documented on Vaccine Worksheet

Vaccine Return and Accountability Forms are completed for all wasted vaccine doses

Revaccination (only complete if revaccination is necessary.)

Were any compromised vaccines administered to patients requiring revaccination? **YES NO**

If revaccination is necessary, how many patients need revaccination? \_\_\_\_\_

Were patients notified of need for revaccination? **YES NO**

Interim/Final Status Report of Corrective Actions Following Cold Chain Failure completed? **YES NO**

Corrective Action Plan (Write a narrative giving details of actions taken; attach additional sheet of paper if needed.)



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**Vaccine Incident Report and Worksheet Instructions**

If temperatures are out of range **less than 30 minutes**

- Take immediate action to correct the problem
- Document corrective action on Step 3 of temperature log
- Recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable range.

If temperatures are out of range **more than 30 minutes**

- Mark vaccine "Do Not Use"
- Immediately contact Manufacturers

VACCINE	MANUFACTURER	TELEPHONE #
<b>DT, DTaP</b> (Tripedia), <b>DTaP</b> (Daptacel), <b>DTaP-IPV-Hib</b> (Pentacel) <b>EIPV</b> (Polio), <b>Flu</b> (Fluzone), <b>Hib</b> (ActHib), <b>Meningococcal</b> (MCV4), <b>Td</b> (Decavac), <b>Tdap</b> (Adacel )	sanofi pasteur <a href="http://www.us.aventipasteur.com">www.us.aventipasteur.com</a>	1-800-822-2463
<b>Flu</b> (Afluria), <b>Hep A</b> (Vaqta), <b>Hep B</b> (Recombivax), <b>HepB-Hib</b> (Comvax), <b>Hib</b> (PedvaxHib), <b>HPV</b> (Gardasil), <b>MMR, MMRV</b> (Proquad), <b>Pneumococcal PPV23</b> (Pneumovax), <b>Rotavirus</b> (RotaTeq), Varicella (Varivax)	Merck <a href="http://www.merck.com">www.merck.com</a>	1-800-672-6372
<b>DTaP</b> (Infanrix), <b>DTaPHIBIP</b> (Pediarix), <b>DTaP-IPV</b> (Kinrix), <b>Flu</b> (Fluarix), <b>Hep A</b> (Havrix), <b>Hep B PF</b> (Engerix), <b>Hep AB</b> (Twinrix), <b>HPV</b> (Cervarix), <b>Tdap</b> (Boostrix), <b>Rotavirus</b> (Rotarix), <b>Meningococcal</b> (Menveo) <b>Meningococcal B</b> (Bexsero)	GlaxoSmithKline <a href="http://www.gsk.com">www.gsk.com</a>	1-888-825-5249
<b>PNU13</b> (Prevnar PCV 13), <b>Meningococcal B</b> (Trumenba)	Pfizer <a href="http://www.pfizer.com">www.pfizer.com</a>	1-800-572-8221
<b>Flu Mist</b> (LAIV)	MedImmune <a href="http://www.medimmune.com">www.medimmune.com</a>	1-877-358-6478

- Vaccine Worksheet is completed to document manufacturer recommendation.
- Vaccine Return and Accountability Forms documents vaccine waste to be returned to distributor.
- Complete all four pages of the Vaccine Incident Report and Worksheet within five days.
- Fax completed paperwork and supporting documentation to 717-214-7223.
- All paperwork for the VFC program is to be retained for three years.