

Safe Storage and Handling

Indiana Immunization Conference 2008
ISDH Immunization Program

Objectives

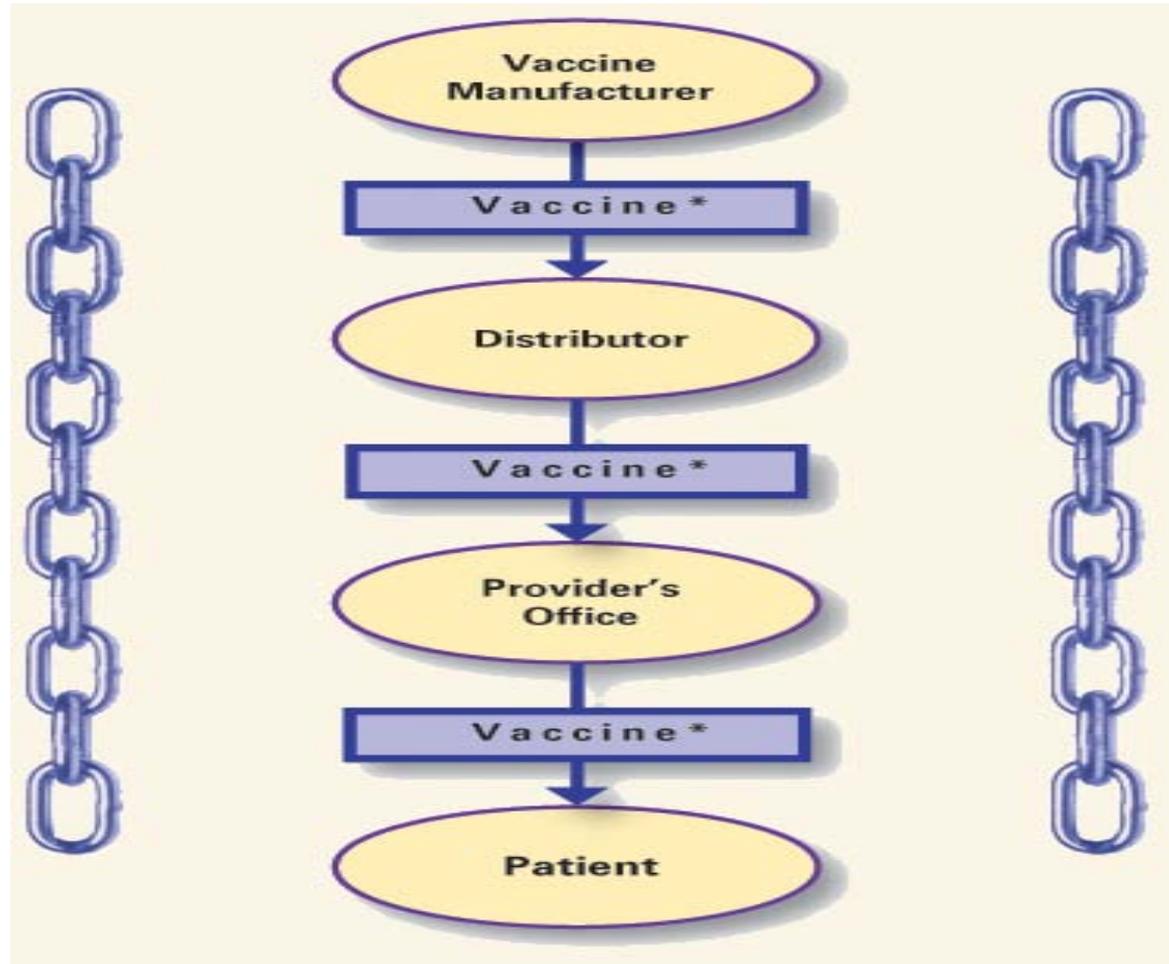
- List three best practices for storage of vaccines
- State what actions should be taken when vaccine integrity is compromised
- Identify which vaccines should be protected from light
- Identify three potential breaks in the cold chain

What is the Cold Chain?

Cold Chain - Three Main Components

1. Transport and Storage Equipment
2. Trained Personnel
3. Efficient Management Procedures

What is the Cold Chain?



Transport and Delivery of Vaccines

McKesson shipping



3M MonitorMark Time Temperature Indicator decision table:

Indicator Color	Vaccine Type	
	MMR	All Other Vaccines
0-1	Begin using vaccines	
2	Contact VFC Program	Begin using vaccines
3-5	Contact VFC Program	

Storage Equipment

- Refrigerator Policy #II-2

- Size requirements:

- *Refrigerator only*: minimum of 4.9 cu ft. with intact sealing door gaskets.
- *Freezer only*: minimum of 3.0 cu. ft. with intact sealing door gaskets.
- *Combination Unit*: minimum of 9.0 total Cubic Feet (cu ft.), with at least 6.6 cu ft. of refrigerator space and no less than 2.4 cu ft freezer compartment with separate doors and intact door seal gaskets.

Storage Equipment:

- Maintain required vaccine storage temperatures year-round
- Large enough to hold the year's largest inventory
- Certified calibrated thermometer inside each storage compartment
- Dedicated to the storage of vaccines
- Food and beverages should **not** be stored in a vaccine storage unit



Regular Household Refrigerator

Unit can hold approximately:

463 to 770 - 10 syringe boxes

Or

6,480 – 10,800 - 10 dose vials

Or

1,023 to 1,705 - 5 syringe boxes



2 DOORS

15 – 25 cubic feet of storage

Temperature Monitoring

Thermometer Requirement

- *Certified, calibrated thermometers are required for ISDH VFC program
- *Thermometer purchase must come with a certificate indicating traceability to standards provided by National Institute of Standards and Technology (NIST).
- *Calibrated Thermometers will need to be recalibrated periodically. The time frame between recalibration differs amongst manufacturers.



Fluid-filled biosafe liquid thermometer.

Recommendations for Monitoring Temperatures

The National Center for Immunization and Respiratory Diseases (NCIRD) Center recommends:

- Check/record temperatures first thing in the morning
- Check/record temperatures at the end of the clinic day

Recommended Temperature Range

Refrigerated vaccines:
35°-46°F (2-8°C)

Set the temperature mid-range to achieve an average of about 40°F (5°C). This temperature will provide the best safety margin.

NEVER FREEZE REFRIGERATED VACCINES!

Freezer vaccines:
5°F (-15°C) or colder

The freezer compartment should maintain an average temperature of 5°F (-15°C).

NO FREEZE/THAW CYCLES!



Temperature Logging

Temperatures must be checked twice daily!

Temperature Log for Vaccines (Fahrenheit) Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. Store the vaccine under proper conditions as quickly as possible. 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. 3. Call the immunization program at your local health department for further assistance: (_____) _____. 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
Exact Time															

Take immediate action if temperature is in the shaded section.

Refrigerator Temp.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
44°															
43°															
42°															
41°															
40°															
39°															
38°															
37°															
36°															
35°															
34°															
33°															
32°															
Take immediate action if temperature is in shaded section*															

Freezer Temp.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
8°															
7°															
6°															
5°															
4°															
3°															
Take immediate action if temperature is in shaded section*															

Adapted by the Immunization Action Coalition (a part of the Michigan Department of Community Health and the California Department of Health Services).
 *Initial actions outlined by the Center for Disease Control and Prevention, Jan. 2007. www.immunize.org/isg/ajp3029.pdf • Item #P3029 (1/07)
 Distributed by the Immunization Action Coalition • (811) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

Temperature logs must be kept for 3 years.

Required Record

► If temperatures are outside the acceptable range, your site **MUST** document steps taken to correct temperature.

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

Required

Primary Vaccine Coordinator

Each practice should designate one staff member to be the primary vaccine coordinator.

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine shipments
- Monitoring, at least twice daily, of refrigerator(s) and/or freezer(s)

F° Check Both Temperatures Twice A Day

Month: 3/07

Refrigerator

Days 1-15 (16-31 continued on other side)

Staff Initials	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15															
Time	am	pm																												
≥ 49°F																														
48°F																														

The refrigerator at the clinic repeatedly dropped below freezing over a 17-month period in 2005 and 2006

"We just didn't notice it" (Clinic administrator)

37°F																														
36°F																														
35°F																														
34°F																														
33°F																														
≤ 32°F	x	x	x	x					x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	

Both of these providers documented similar out of range temperatures for at least 6 months

Temp	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Fg	38	30	28	30	30					30	30	30	30	28			32	30	30	30	30			34	33	30	28	32				
Fr	-10	-8	-10	-8	-8					-8	-8	-10	-8	-10			-8	-10	-10	-10	-10			-8	-2	-10	-8	-10				

visit
↓

Burden of Cold Chain Failure

- An estimated 17% to 37% of providers expose vaccines to improper storage temperatures
- 15% of refrigeration units had temperatures of 34°F (1°C) or lower



**Out-of-range
temperatures require
immediate action!**

Myth #1

Refrigerators
keep the same
temperature
throughout



False

- Temperature varies with:
 - The position of the vaccine within the storage unit
 - The running of the compressor
 - The defrost cycle
 - The opening/closing of the door
 - The amount of vaccine in the storage unit

Important Things to Keep in Mind

- Adjusting the temperature is a total trial and error process
 - May take up to a week to regulate temperature in a new storage unit
- Temperature changes throughout the day
 - May be an indication that the storage unit is failing
- There are many things that can disrupt the refrigerator
 - Someone may leave the door open or ajar
 - The site is a victim of a natural disasters and/or temporary power outage

Myth #2

The refrigerator runs more efficiently if filled completely



False

- Packing any vaccine storage unit too tightly will affect the temperature:
 - Vaccine should be placed with space between the vaccine and the compartment wall
 - Storage of vaccine against refrigerator walls increases risk of freezing
 - Ensure space between each large box, block or tray of vaccine to allow for air circulation
 - Adequate air circulation between vaccine boxes is necessary to maintain a more constant ambient temperature

Myth #3

All
refrigerators
maintain
temperatures
the same

Dorm Style Refrigerator



False

- Dormitory-style or bar-style units should not be used for permanent storage of vaccines
- The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store MMRV, Varicella and zoster vaccines

Short Term Storage

Dorm style refrigerators are acceptable for short-term storage of vaccines under these conditions:

- Each unit must have a dedicated certified thermometer in place and temperatures must be monitored and documented twice daily
- The unit is never used for storing varicella-containing vaccines
- The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day
- The vaccine must be returned to the main storage unit at the end of each clinic day

Myth #4

Refrigerators cannot drop to temperatures at or below zero, only freezers can get this cold.

F° Check Both Temperatures Twice A Day Month: 3/07

Days 1-15 (16-31 continued on other side)

Refrigerator	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials	DD	DD	DD	DD	DD	DD	DD	DD	DD			DD	DD	DD	DD	
Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Time	8:55	8:55			9:55	8:55	8:55	6:55	5:55			5:55	8:55	8:55	5:55	
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Free High																
≥ 49°F																
48°F																
47°F																
46°F																
45°F																
44°F																
43°F																
42°F																
41°F																
Aim for																
40°F																
39°F																
38°F																
37°F																
36°F																
35°F																
Free Low																
34°F																
33°F																
≤ 32°F	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

False

A compressor blows cold air from the freezer to the refrigerator and air exiting the vents will be well below 32°F or 0°C.

The colder the freezer unit, the colder the refrigerator.

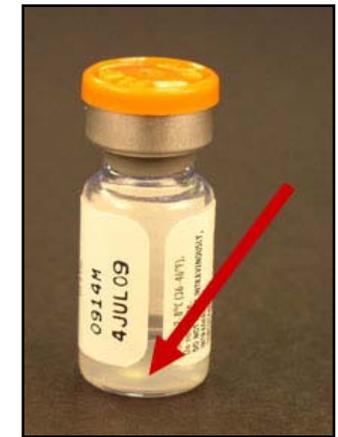


Myth #5

If a vaccine has been exposed to freezing temperatures, the vaccine will appear as a frozen or solid form (frozen \neq solid)



**Properly stored
vaccine
Full Potency**



**Improperly
stored vaccine
Diminished Potency**

False

Visual inspection of vaccines is an unreliable method of assuring potency

- Vaccine exposed to temperatures outside of the recommended range does not look any different
- Vaccine stored at or below 32°F (0°C) will not appear frozen
- Precipitate may not be visible to the eye but the vaccine will no longer be viable

Vaccine Stability

- Depends on the vaccine
- Length of time of exposure
- Environment during the exposure
- When in doubt- do not use

Vaccine Stability Monitors

The Ideal Vaccine Monitor:

- Instantly warns when the cold chain breaks
- Detects all cold chain problems, not just elevated temperatures
- Accurately reports vaccine stability
- Logs/records temperatures before and after the cold chain break
- Is easy to validate
- Is simple, quick and easy to implement

Myth #6

Vaccines should be within easy reach and stored out of the boxes in containers.

It is fine to stack as many boxes as possible in the storage unit.



False

- Keep vaccine in original cartons to protect from light
- Allow space between boxes for circulation of air and temperature stability
- Arrange vaccines so that like vaccines are not stored in same proximity
- Label VFC vaccine to differentiate from private stock

Fact #1

Thermometers should be placed in center of refrigerator and/or freezer compartments.

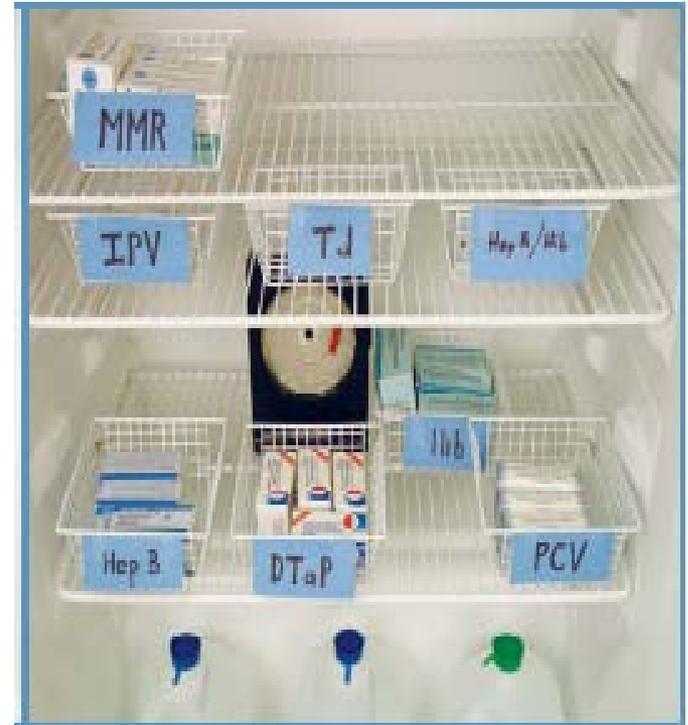
Acceptable temp ranges:

- Refrigerated vaccines:
35-46° F (2-8° C)

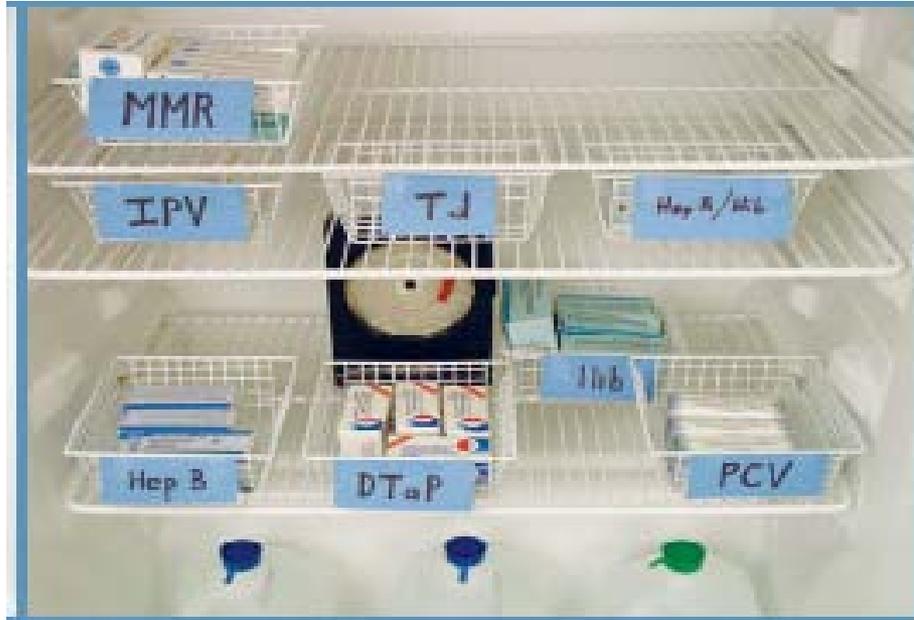
NEVER FREEZE!

- Freezer vaccines:
5° F (-15° C) or colder

**NO FREEZE/THAW
CYCLES!**



Fact #2



- Usable space is approximately 30% of volume
- Do not use top or bottom shelves
- Leave 3" on each side and back wall

Fact #3

Air vent
from freezer



Note
Diluents may be
stored in
refrigerator door.
Vaccines
should **not** be
stored in
refrigerator door.

In the refrigerator, vaccine should be stored in the middle of the compartment, away from the walls and coils and off the floor.

Reminder #1

- Keep people out of the storage unit except when accessing vaccine
- Do not store food in the refrigerator
- Do not store drinking water or other beverages in the refrigerator
- Post a sign on the refrigerator telling people to stay away
- Keep people away from the plug and the circuit breaker
- Check the refrigerator and door at least twice daily
- Consider using an alarm system



Reminder #2

- Providers should not move vaccine between locations without first notifying the Indiana State Department of Health at 1-800-701-0704
- Any movement of vaccine must be approved by the ISDH VFC Program
- We will advise you on the vaccine movement and ensure that your site has all the appropriate packing materials to safely transport or temporarily store vaccine

Necessary Materials for Vaccine Transport



Approved Insulated Containers



Refrigerated/Frozen Packs



Packing Materials

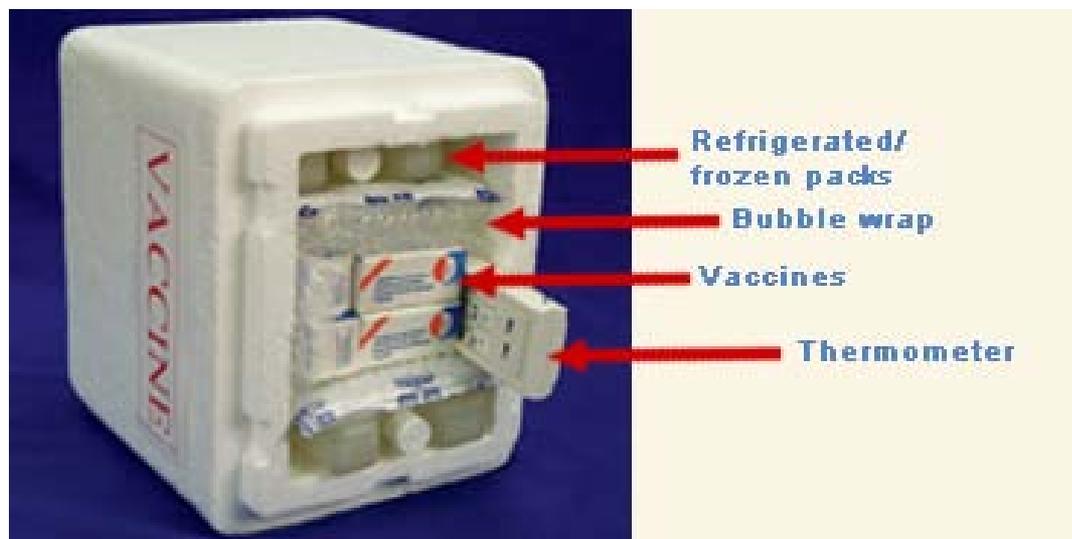


Thermometers

Call your VFC Representative

The contents of the container should be layered as follow:

- Refrigerated/frozen packs
- Barrier
- Vaccine
- Thermometer
- Barrier
- Refrigerated/frozen packs



An insulated barrier (e.g. bubble wrap, crumpled brown packing paper, styrofoam peanuts) must always be placed between the refrigerated/frozen packs and the vaccines to prevent accidental freezing

Questions?

Thank You!

How to contact the
Immunizations Division:
1-800-701-0704

Email: immunize@isdh.in.gov

<http://www.in.gov/isdh/17094.htm>