

You Did What With Your Vaccine?!

Vaccine Storage and Handling



January 2008

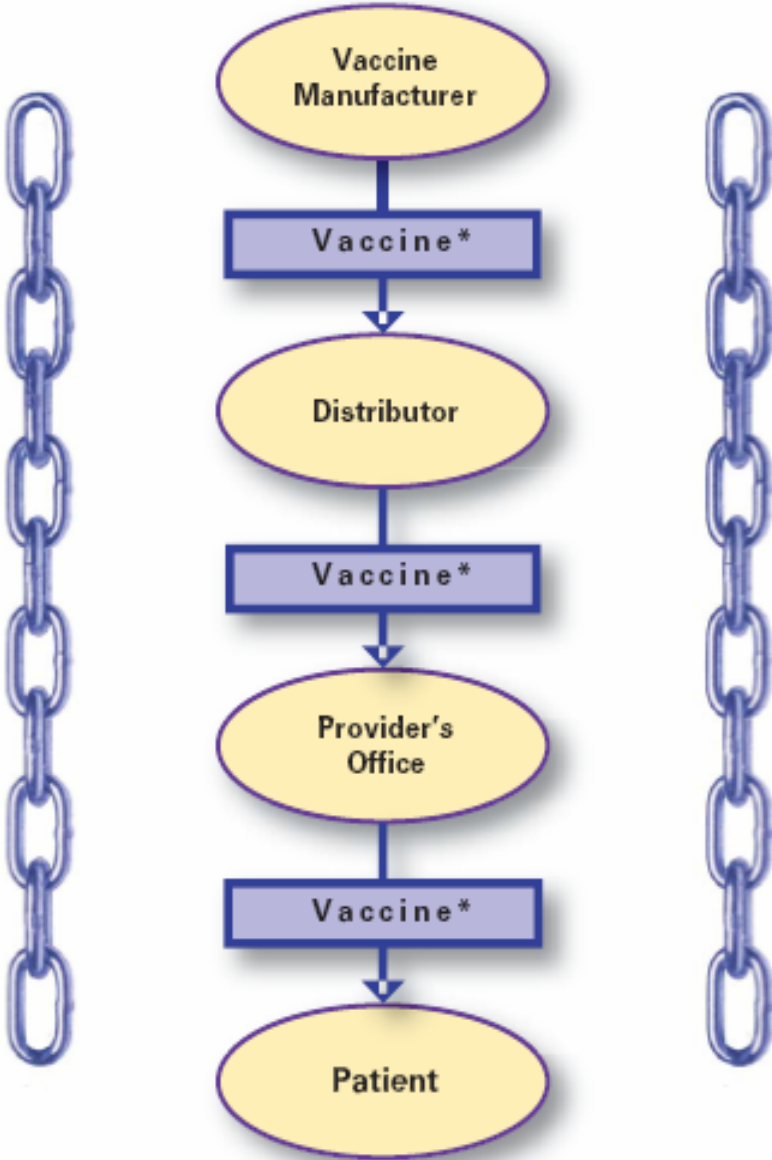
So much to talk about...

- The vaccine Cold Chain
- Appointing Vaccine Personnel
- Vaccine Storage Practices
- Temperature Monitoring
- Maintaining your inventory
- Organized information

The Cold Chain

- What is it?
 - A system used to keep and distribute viable vaccine.
- What does it look like?
 - Three main components
 - Transport and storage equipment
 - Trained personnel
 - Efficient management
- Why is it important?
 - Proper storage temperatures must be maintained at every link in the chain to ensure vaccine viability.

The Cold Chain



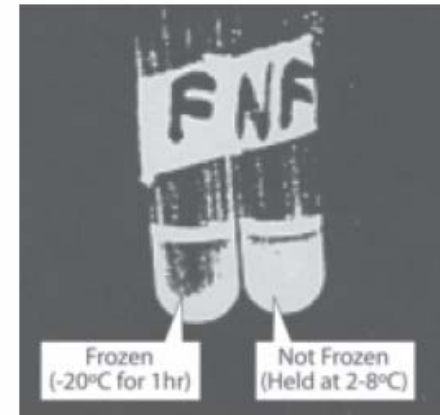
*Vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°- 46°F [2°- 8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck.

Why is the Cold Chain Important?

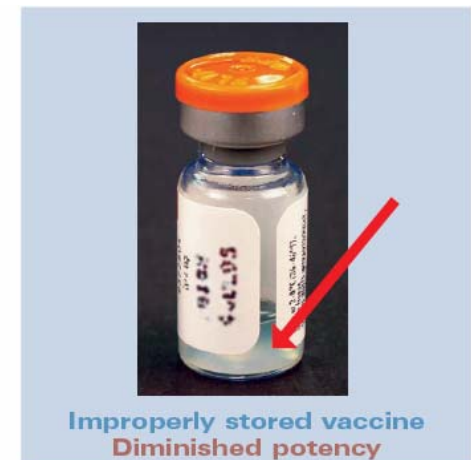
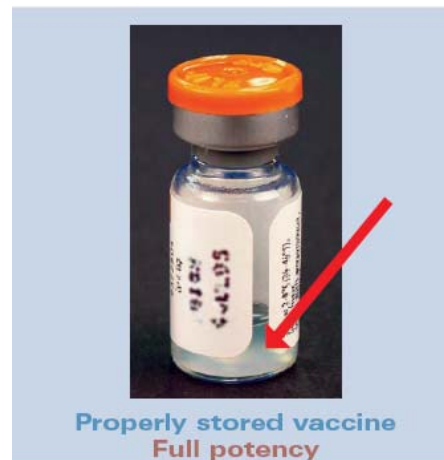
- Breaks in the cold chain can damage vaccine, resulting in a loss of potency.
- Once potency is lost, it cannot be restored.

Vaccine Appearance After Inappropriate Storage Conditions

- Some vaccines may show physical evidence of altered potency when exposed to adverse temperature conditions.



- Others may look perfectly normal.

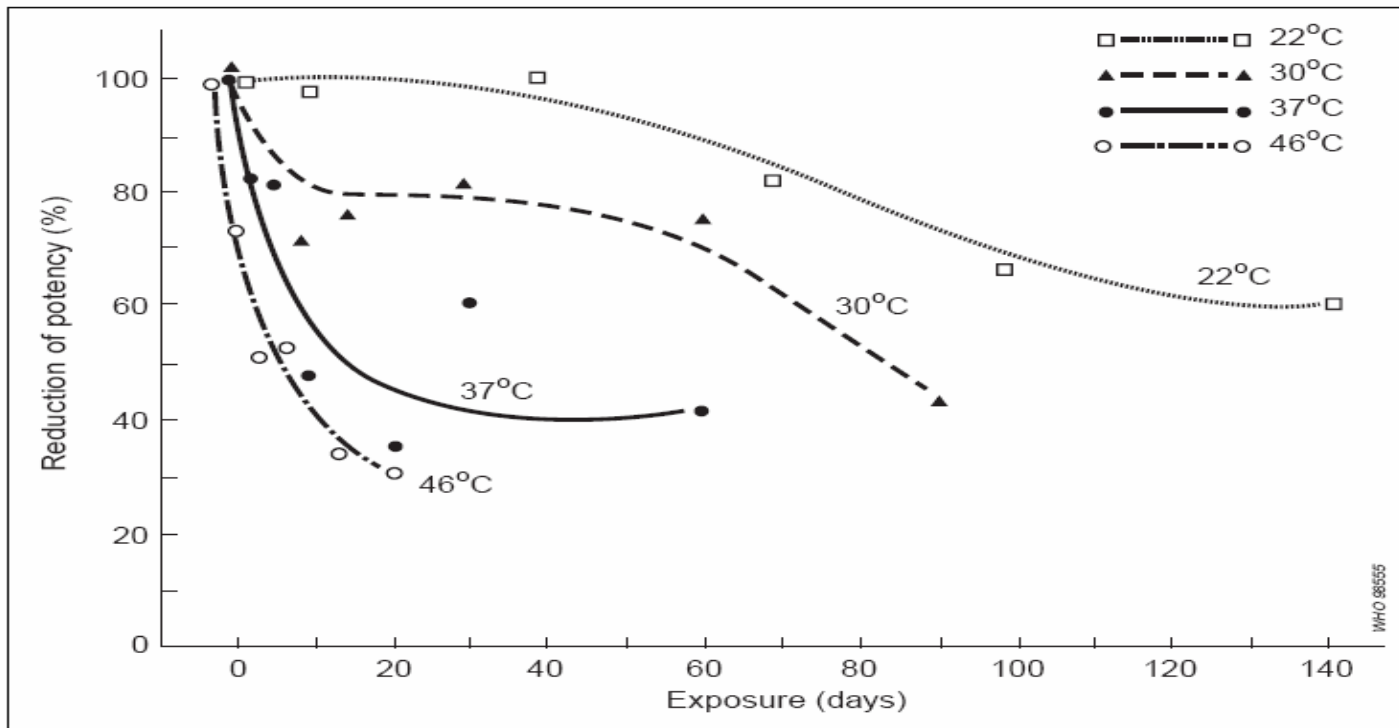


Storage and handling errors aren't that frequent...right?

- An estimated 17%-37% of providers expose their vaccine to improper storage temperatures.
- One study involving site visits showed that 15% of refrigeration units had temperatures 34°F (1°C) or colder.
 - Most clinics keep their refrigerators too cold rather than too warm.

So, what happens to my vaccine when it becomes too warm?

Figure 6: Loss in potency of pertussis component of DTP vaccine kept for various lengths of time at different temperatures



Source: World Health Organization (44)

Warm vaccine...

Table 3: Stability of five hepatitis B vaccines as indicated by immunogenicity tests on animals

Vaccine tested	Parameters used in testing vaccines	Storage temperature (°C)			
		2 - 8	20 - 26	36 - 40	45
A (plasma)	Longest storage without significant loss of potency	24 months	12 months	3 months	-
C (plasma)	Remaining potency (%) after specified time	100% after 24	70% after 24	70% after 24	-
D (plasma)	Longest storage with relative potency upper confidence interval >1	44 months	-	-	-
E (recombinant)	Longest storage with relative potency upper confidence interval >1	53 months	12 months	7 months	1 month
	Half life*	-	9 months	1 month	3 days
F (plasma)	Half life	>3 years	4 months	7 days	-

* Half life: time at which 50% loss of original potency occurs

Source: *Manufacturers' data.*

Vaccine Personnel

Appointing Vaccine Personnel

- Designate one staff member to be the primary vaccine coordinator.
- Responsibilities include;
 - ✓ Checking and recording temperatures at least twice a day;
 - ✓ Responding to outside the recommended range;
 - ✓ Maintenance records and storage and handling equipment;
 - ✓ Rotating stock;
 - ✓ Monitoring expiration dates;
 - ✓ Ordering
 - ✓ Receipt and storage of shipments;
 - ✓ Overseeing proper vaccine transport

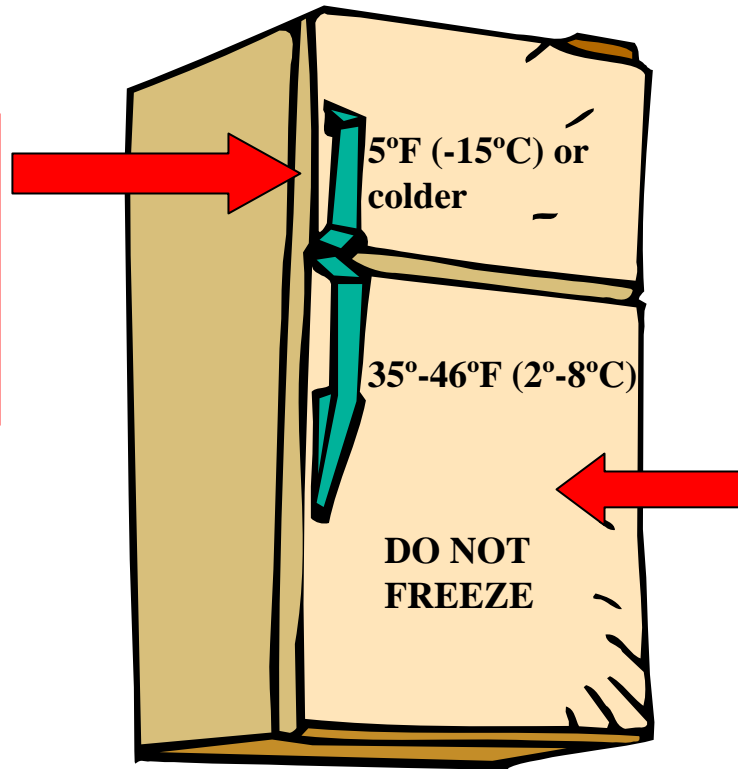
In addition...

- Designate a backup.
- Offer training to other staff members who handle or administer vaccines
- Make sure all new staff read and review vaccine storage and handling practices
 - Standard Operating Procedures

Vaccine Storage and Handling Practices

Where should you store your vaccine?

- Varicella
- MMR-V
- Zostavax®



- Hepatitis A
- Hepatitis B
- Hib
- IPV
- Pneumococcal (PCV & PPV)
- Inactivated Influenza
- FluMist (live influenza)
- Meningococcal (MCV4 & MPSV4)
- MMR
- Tdap and Td
- DTaP
- Rotavirus

Storing your vaccine properly...

Live vaccines

- Live vaccines are sensitive to heat.
- Varicella, MMRV and Zostavax® must be stored in a frozen state at 5°F (-15°C) or colder until administration.
- MMR, Varicella, and MMRV are also extremely sensitive to light.
 - All should be stored in their closed boxes until they are used.

Storing your vaccine properly...

Inactivated vaccines

- Inactivated vaccines are sensitive to both heat and freezing.
- Stored in a refrigerator at 35°-46°F (2°-8°C), with a desired average of 40°F or 5°C
- Temperatures outside of this range could adversely effect the potency of the vaccine.

Location, location, location

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.

Location, location, location

MMR is stored at the top since it's the least sensitive to colder temps



Attach labels directly to the shelves on which the vaccines are sitting or label trays or containers according to the vaccines they contain.

Temperature Monitoring

Monitoring temperature

- To ensure your refrigerator or freezer is maintaining the proper temperature, check and record the temperature at least twice a day.
 - Regardless of whether or not there is a temperature alarm, continuous recording, or digital data logging thermometer

What should you do when your temp chart looks like this?

- A. It's fine. Do nothing.
- B. Place vaccine in a "DO NOT use"-labeled container and place in another fridge/freezer.**
- C. Move the vaccine to a working unit.
- D. Call the Oregon state immunization program.

Temperature Log for Vaccines (Fahrenheit)

Month/Year: August 2004 Days 1-15

*Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 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: (404) 555-8212. and 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
Exact Time	3:25 AM	9:00 AM	8:10 AM	5:45 PM	7:00 PM										
F Temp															
Refrigerator temperature															
Freezer temp															
Room temp															
Staff initials	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW	AW

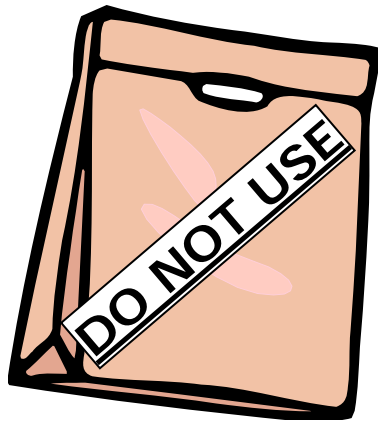
Note: The table shows 'X' marks in the 37-39°F range for refrigerator temperature on days 1, 2, 3, 4, and 5. A red circle highlights an 'X' at 37°F on day 5, with a red arrow pointing to it from the text 'Take immediate action if temperature is in shaded section'.

Never do nothing!

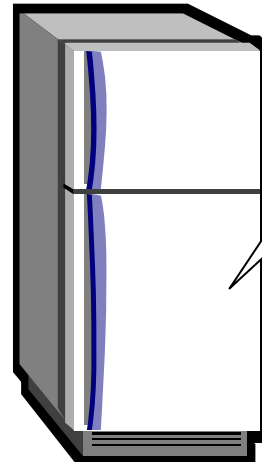
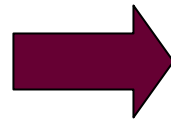
- B. Place vaccine in a “DO NOT use”-labeled container and place in another fridge/freezer
- C. Move the vaccine to a working unit.
- D. Call the Oregon state immunization program to help determine the next step AND if vaccines are still viable



If Temperature Is Out-of-Range:



Bag up all refrigerated vaccine and label "DO NOT USE"



Move vaccine to a working refrigerator

35°F - 46°F
Or
2° - 8°C



Call your Health Educator for directions on what to do next!

And remember!

- Recording is not enough. If temperature is outside the recommended range you must act immediately.

Tips for checking your temps

1. Post a temperature log on the vaccine storage unit door.
2. Read the thermometers in both the refrigerator and freezer at least twice a day: once in the morning when the refrigerator or freezer is opened for the first time, and again at night just before the door is closed for the last time.
3. Record the times the thermometers are read, and make sure to initial the temp log.
4. If a reading is missing, leave it blank.

Maintaining your temp logs

- Logs should be kept for three years.
- As your fridge or freezer ages, you can track recurring problems or identify how long problems have existed.
- If a continuous recording thermometer is used, the graphs should be kept with the logs for a minimum of three years.

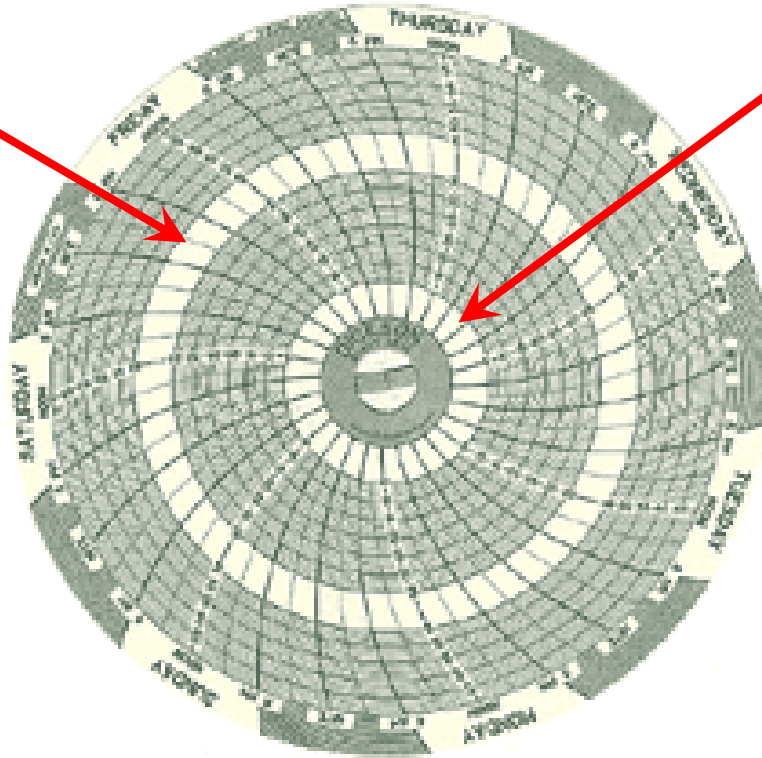
Continuous Tracking Thermometers

- They're great...if you know how to use them.
- Must be re-calibrated to maintain accuracy.
- Provides specific temperature information.



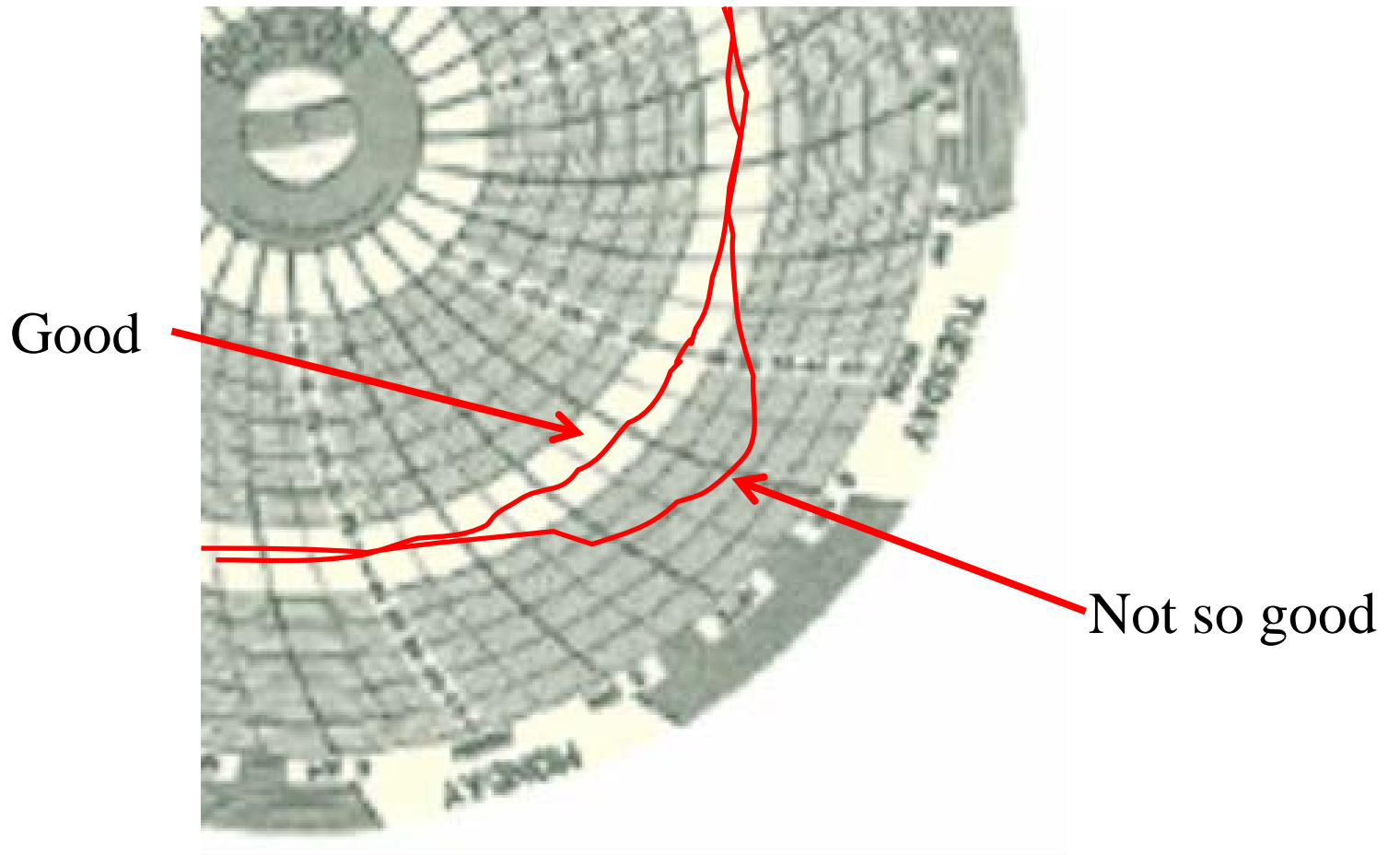
The Dickson Wheel...

- Identifies “within range” temps for your fridge.



- Identifies “within range” temps for your freezer.

The Dickson Wheel



Maintaining Your Vaccine Inventory

Labeling

- Date and time reconstituted.
- Mark with the date it was first opened.
- This is important for two reasons;
 - Some vaccines expire within a certain time after opening or after reconstitution. This may not be the same as the expiration date.
 - Dating opened or reconstituted vials helps manage vaccine inventory by identifying which vials should be used first.

How long is my reconstituted vaccine good for?

Vaccine Name	Must be used within	Protect from light?
Varicella	30 minutes	YES!
TriHIBit	30 minutes	No
meningococcal polysaccharide (single dose)	30 minutes	No
MMR	8 hours	YES!
ActHIB	24 hours	No
meningococcal polysaccharide (multidose)	35 days	No
LAIV (Flumist)	60 hours*	No
MMRV	30 minutes	YES!

*If not used immediately after thawing by hand or if not used within 60 hours of thawing at refrigerator temperatures, must be discarded.

Determining the Expiration of Different Vaccine Products

- Multi-dose premixed vaccine (IPV and some flu)
 - Contain bacteriostatic agents that prevent the growth of bacteria.
 - Vaccines can be used until the date of expiration, unless they become contaminated.
- Single dose vials are meant for one time use only
 - Once the protective cap has been removed, it may not be possible to determine if the rubber seals have been punctured

Time to Test Your Storage and
Handling Knowledge

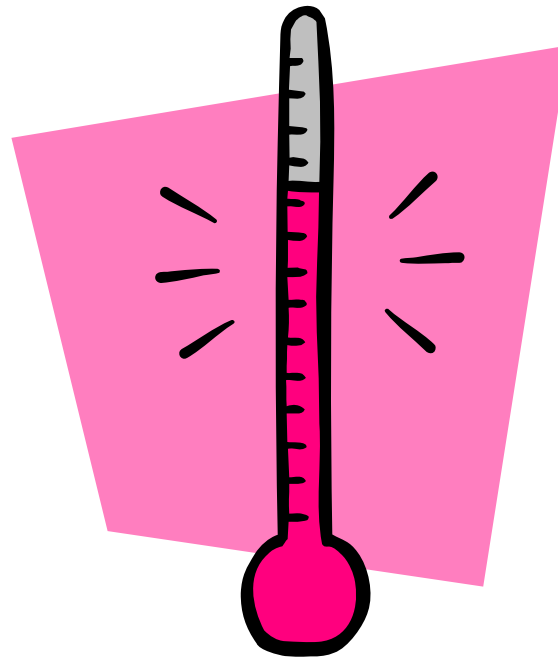
What is the proper temperature range for your refrigerated vaccine? frozen vaccines?

Refrigerator

35° to 46°F

OR

2° to 8°C



Freezer

5°F or colder

OR

-15°C or colder

You have some vaccine that you're not going to use before its expiration date. How many days notice does your Health Educator need for you to not be billed?

A. 100 days

B. 90 days

C. 75 days

D. 60 days

E. 30 days



Why 90 days?

Alerting your health educator 90 days before a vaccine's expiration date allows enough time to find a new home for your vaccine. It also ensures that the recipient will have enough time to use all of the vaccine.

Packing Your Vaccine



1-2 inches



You should never store vaccine in which of the following places?

- A. In the fridge door
- B. In the crisper bin
- C. Near the outlet valve (usually near the top shelf)
- D. In closed plastic storing trays
- E. All of above

What is the minimum amount of time you should retain your temp logs?

A. Six months

B. One year

C. Three years

D. Seven years

If you have wasted or expired state supplied vaccine, will you be billed for those doses?

YES

- If you have wasted state supplied vaccine, you may be billed for those doses.
- If you do not give your Health Educator ≥ 90 days advance notice of expiring vaccine, you may be billed.

It can happen to anybody...

You get to work on Monday morning after a tough weekend. You're glad to be back at work.

But then...

It can happen to you...



- You notice the fridge door is open slightly.
- Thankfully, you've got a continuous tracking thermometer running in your fridge.
- You check the temperature and it's currently 59°F. What do you do next?

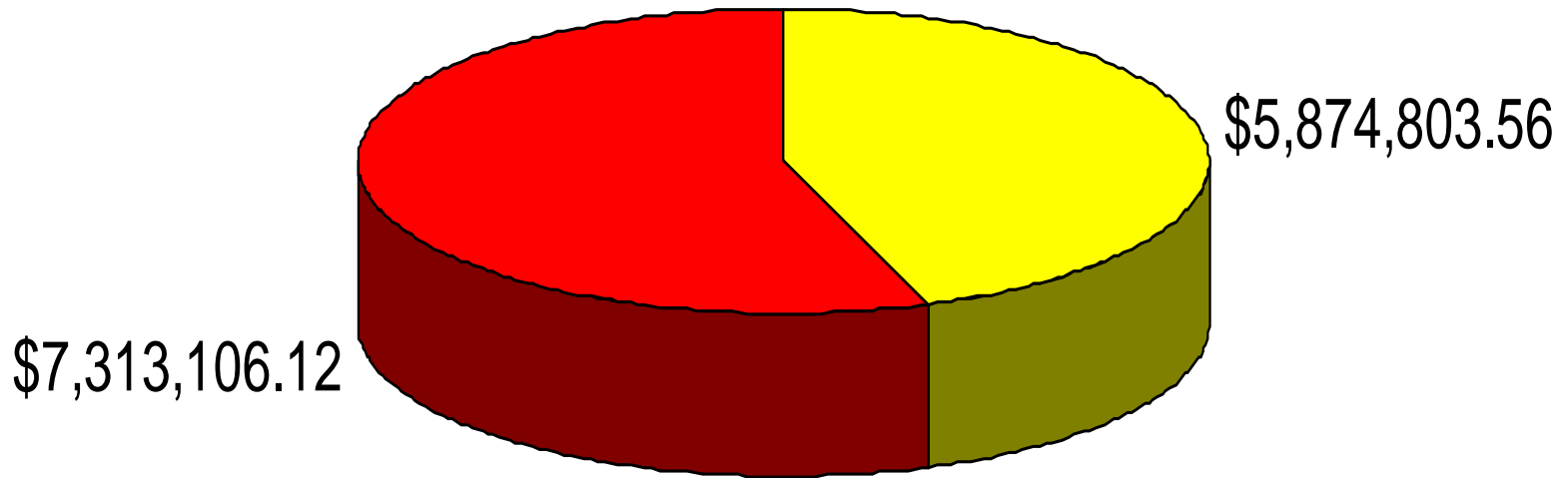
Your options...

- A. ~~Do nothing.~~ **NEVER DO NOTHING!**
- B. ~~Immediately throw the vaccine away because it can't be used.~~
- C. Label the vaccine “Do Not Use Until Further Notice” and move it to a functioning refrigerator.
- D. Call your Immunization Health Educator.
- E. ~~Call the vaccine manufacturers.~~

Oregonized Information

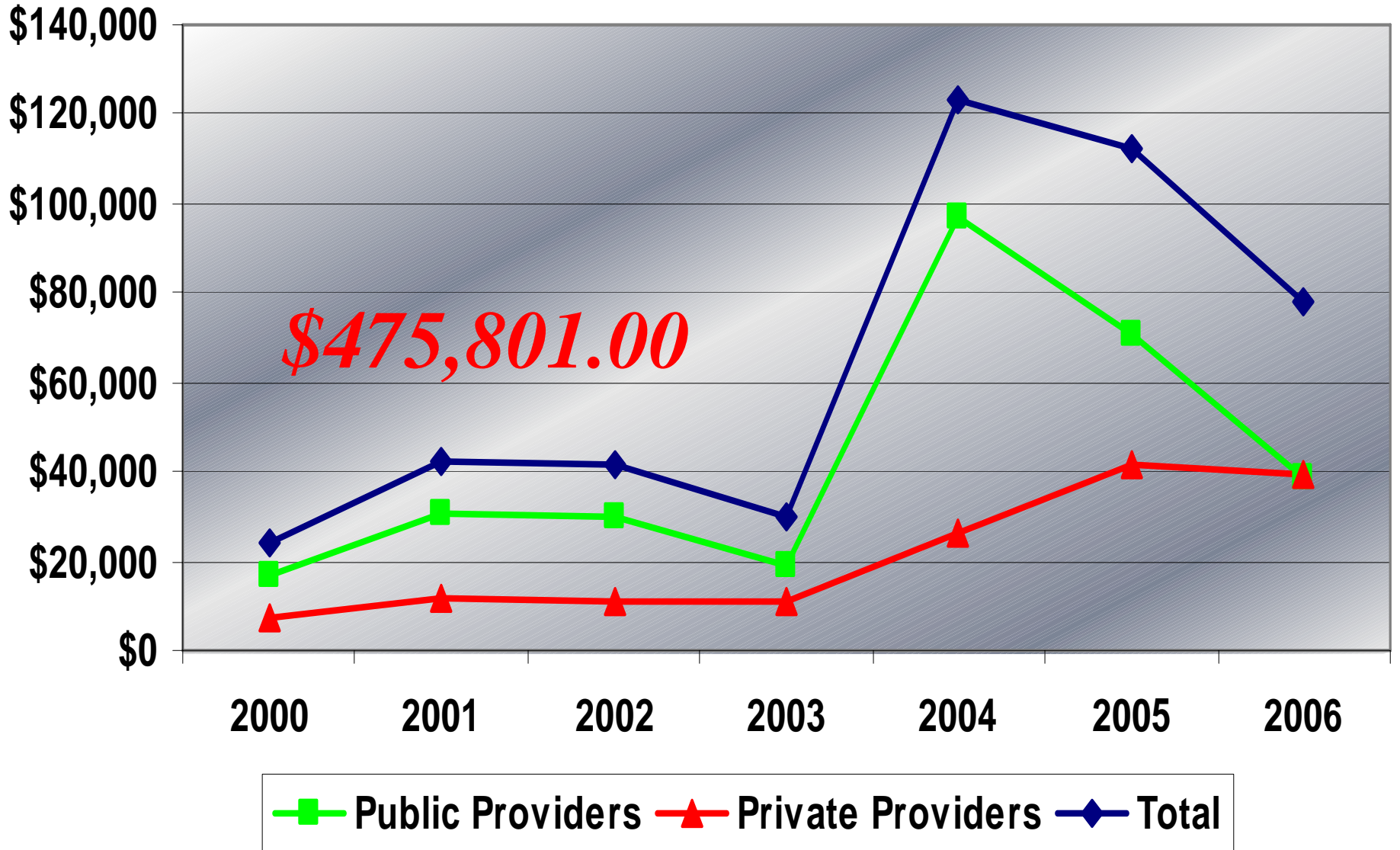
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2005 State Supplied Vaccine Distribution

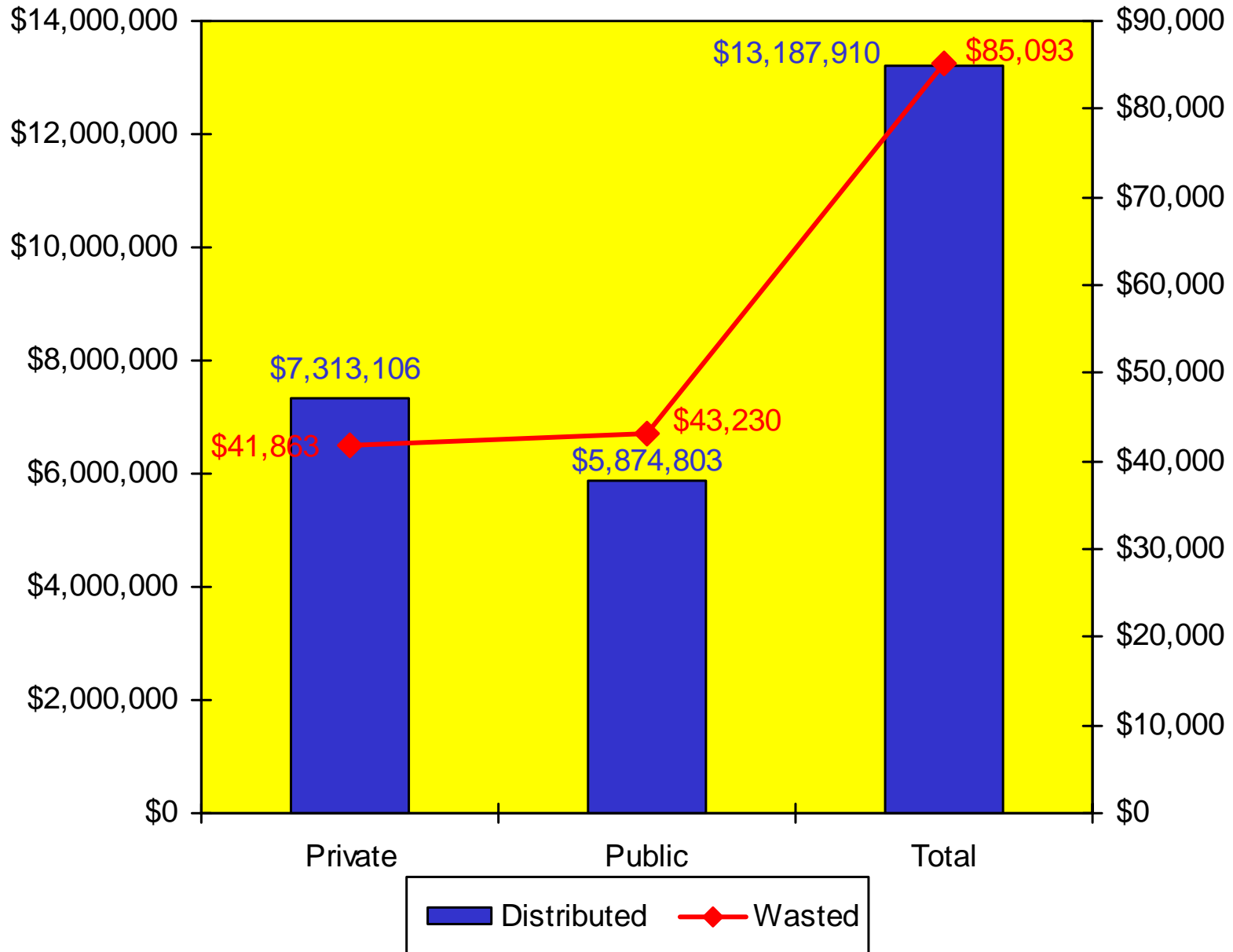


Public Private

TRENDS IN WASTED VACCINE



State Supplied Vaccine Distributed vs. Vaccine Wasted



Questions?

