How easy is it to freeze vaccine during transport? Very easy!

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BACKGROUND

As H1N1 vaccine was being shipped throughout California in fall 2009, providers were requesting guidance from the Immunization Branch about how to transport the vaccine from one site to another. In-house and internet resources were researched in an attempt to find an easy-to-use procedure for a job aid that providers could use to transport refrigerated vaccine, which would maintain recommended temperatures (35º to 46ºF) and prevent freezing. Although many references were found, the suggested methods and materials varied widely. It became necessary to conduct some validation of materials and methods to develop reasonable and reliable recommendations.

The most common cause of exposure to freezing temperatures is the failure to correctly condition ice packs prior to transport. The practice of immediately placing deep-frozen ice packs, which can reach temperatures as low as -20ºC (-4 ºF), in well-insulated cold boxes places freeze-sensitive vaccines at the greatest risk. World Health Organization (WHO)

GOAL

To develop a method and procedure for transporting and storing refrigerated vaccine for up to 12 hours that would not freeze (recorded temperature 32ºF or below) the vaccine and would maintain vaccine temperatures between 35ºF and 46ºF.

METHODS

A series of 55 tests were conducted with expired flu vaccine using three insulated coolers/containers of varying size and thickness of insulation, and a variety of combinations of refrigerated water bottles, cold packs, and insulating material. Most tests were conducted in ambient indoor temperatures ranging from 55ºF to 75ºF. Temperatures were monitored with calibrated MIN/MAX vaccine thermometers with digital displays and gel probes. An additional four tests were conducted without vaccine to monitor the temperatures of frozen and conditioned cold packs over time.

PACKING METHODS THAT CAN HARM VACCINE

Test #	Contents (in order packed bottom to top)	Elapsed time since packing	Temp	Container
#5	• 3 frozen cold packs • 1 box of vaccine • No insulation • 2 frozen packs • No insulation	16 min	32 ºF	Small hard sided plastic Coleman cooler
		1 hr 2 min	17 ºF	
#14	• 5 frozen cold packs • 2 sheets bubble wrap • 3 layers boxes of vaccine • 2 sheets bubble wrap • 5 frozen cold packs	28 min	29 ºF	Large Styrofoam container from vaccine distributor
		1 hr 21 min	23 ºF	
#18	• 6 frozen cold packs • 1 inch bubble wrap • 3 layers boxes of vaccine • 1 inch bubble wrap • 6 frozen cold packs	1 hr 20 min	30 ºF	Large hard sided plastic Igloo cooler
#34	• 10 conditioned cold packs • 2 inches bubble wrap • 3 layers boxes of vaccine • 9 conditioned cold packs • 2 inches bubble wrap	20 hr	33 ºF	Large Styrofoam container from vaccine distributor
#32	• 10 conditioned cold packs • 2 inches bubble wrap • 3 layers boxes of vaccine • 2 inches bubble wrap • 9 conditioned cold packs • Bubble wrap to fill to top	21 hrs	34 ºF	Large Styrofoam container from vaccine distributor

LOCATION, LOCATION, LOCATION!

Cold air sinks. Since air does not circulate in a cooler, cold air collects at the bottom. The bottom layer of vaccine can be much colder than the top layer of vaccine. (See the examples below.) The best and easiest way to know if the cooler is maintaining recommended temperatures is to use a digital MIN/MAX thermometer. Place the probe of the MIN/MAX under the bottom layer of vaccine. Place the display on top of the cooler's contents. That way, the temperature at the lowest layer of vaccine can be easily read by briefly lifting the lid of the cooler to view the thermometer display.

Below are examples of temperatures at the top and bottom layers of vaccine from a few of the 55 tests conducted to develop the *Transporting Refrigerated Vaccine* job aid. The difference between the top and bottom layers ranged as much as 24 degrees!

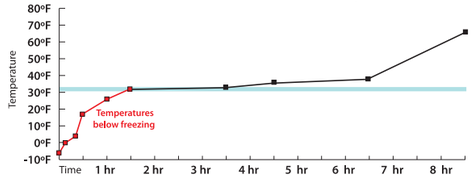
Test #	#16	#18	#22	#16	#15	#37	#46	#31	#31
Temp at Top layer	39ºF	37ºF	43ºF	44 ºF	46ºF	51ºF	57ºF	64ºF	69ºF
Temp at Bottom layer	32ºF	31ºF	35ºF	33ºF	34ºF	29ºF	35ºF	40ºF	49ºF

HOW COLD IS COLD?

The difference in temperature between frozen and conditioned cold packs can be as much as **36 degrees** (from -4ºF to 32ºF)!

"The difference between using frozen cold packs instead of conditioned cold packs is like the difference between putting the vaccine in the freezer instead of the refrigerator." Natalie Nakahara

Cold Packs From Freezer to Room Temperature



Notes: The first temperature reading was taken in the freezer.
All other readings were done in ambient air (71ºF.)
Temperature gun was used.

SURPRISING FINDINGS

- Temperatures in coolers with refrigerated water bottles exceeded recommended temperatures in as little as 18 minutes and continued to rise.
- Temperatures in coolers with frozen cold packs and little or no bubble wrap reached temperatures as low as 32ºF in 16 minutes and continued to drop.
- Vaccine packed with the right combination of conditioned cold packs and thickness of bubble wrap in hard-sided containers maintained temperatures within the recommended range, but the thickness of bubble wrap needed depended on the size of the cooler.

DID YOU KNOW . . . ?

- Temperatures in "conditioned" cold packs remain at 32/33ºF until the cold packs are completely defrosted. That's why insulation must still be used between conditioned cold packs and vaccine.
- Conditioned cold packs are sometimes referred to as "sweating packs" even though cold packs don't always sweat when they are conditioned.

THIS METHOD WORKS!

This job aid was developed by CDPH based on the results of the tests described in this poster.

HERE'S THE PROOF!

Here is an example of temperatures monitored during a 16-hour period for vaccine packed for transport in a large hard-sided cooler according to the procedure in the job aid above.

Clock time	Total elapsed time	Current temp	MIN temp	MAX temp
12/29/09 3:35 pm	N/A	46	N/A	N/A
3:49 pm	14 min	47*	47*	47*
4:20 pm	45 min	46	46	47*
4:35 pm	1 hr	45	45	46
5:00 pm	1hr 25min	45	45	45
6:05 pm	2hr 30min	45	45	45
7:21 pm	3h 46min	43	43	44
9:33 pm	5hr 58min	41	41	43
11:13 pm	7hr 38min	40	40	41
12/30/09 7:30 am	15hr 55min	39**	39**	40**

* Temperatures often temporarily exceed recommended storage temperatures by a few degrees for the first hour after vaccine is packed. This is not a problem and will not compromise the efficacy of the vaccine.
** When this test was stopped after almost 16 hours, temperatures were still dropping.

CONCLUSION

It is very easy to freeze vaccine. And it is very difficult to find the right combination of cold packs, insulation, and cooler that will prevent vaccine from freezing and still maintain vaccine temperatures within the narrow recommended temperature range (35ºF to 46 ºF) during vaccine transport and storage for up to 12 hours.

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Download the *Transporting Refrigerated Vaccine* job aid and other valuable resources at eziz.org