Preventing Accidental Freezing in the Cold Chain

An introduction to cold chain freezing and some options for reducing it.

Topics Presented

- Freezing damages certain vaccines.
- Accidental freezing is frequent in most cold chains.
- Freezing during transport can be avoided.
- Freezing during storage can be avoided.
- Monitoring temperature is important.

Freezing Damages Vaccines

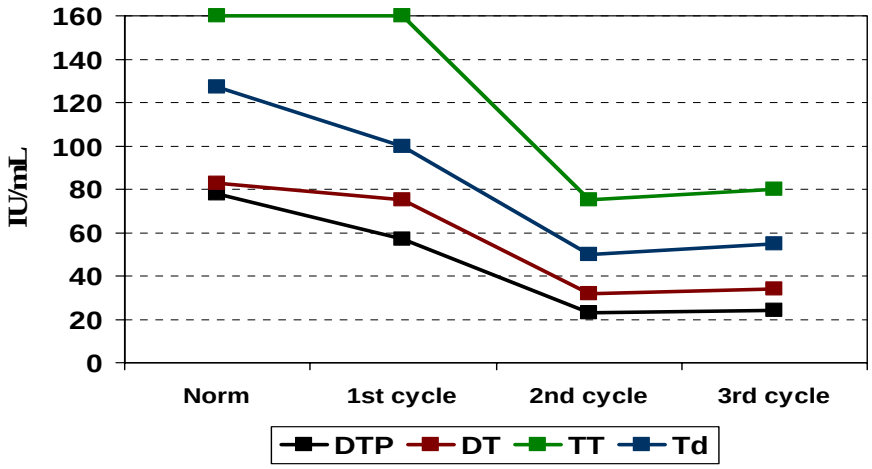
- DTP, TT, DT, DPT combinations, and liquid Hib.
- Hepatitis B vaccine and any Hep B combos.

DTP,TT,DT

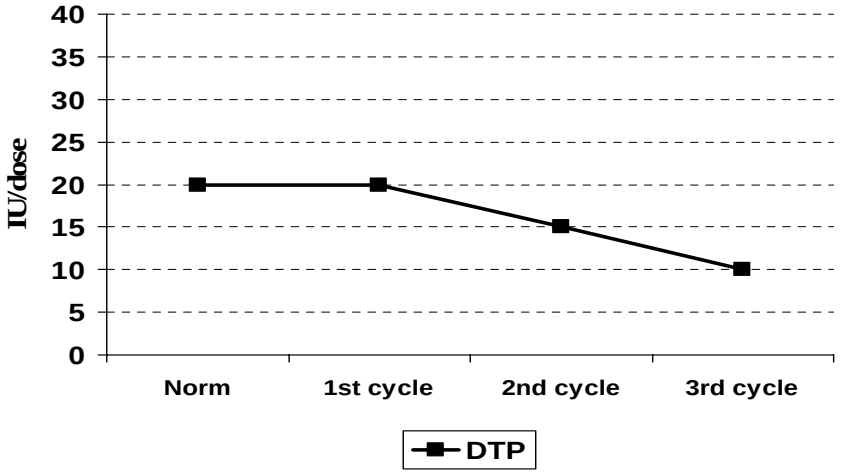
Tests for WHO
at the Serum Institute
of India confirm that:

Freezing
irreversibly
reduces vaccine
potency.

Tetanus vaccine (in DPT, DT, TT, Td)



Pertussis vaccine (in DTP)



Hepatitis B Vaccine

- The HBsAg antigen **MUST** remain bonded to the alum adjuvant to confer protection against hepatitis B. This bond is broken by freezing, therefore…
- "…Hepatitis B vaccine completely loses its immunological potency upon freezing or freeze-drying."*

*Diminsky, D.; Moav, N.; Gorecki, M.; Barenholz, Y. Physical, chemical and immunological stability of CHO-derived hepatitis B surface antigen (HBsAg) particles. Vaccine18 (2000).

Literature Review Available

Effects of Freezing on Vaccine Potency
with a summary data table

Accidental Freezing is Frequent in Most Cold Chains

Where Does Cold Chain Freezing Occur?

Tropical Regions

- **Malaysia:** 232 out of 234 Freeze Watch™ * indicators broke during storage of HB vaccine at state stores.
- **N. Australia:** 48% of HB vaccine exposed to <-3ºC, mostly during clinic storage.
- **N. Australia:** 4 times more freezing than heat exposure (transport and storage).
- **India:** 12 ILRs: 62% of days <-3ºC
  - Only 0.2% of days >10ºC

* Freeze Watch™ is a trademark of 3M.

Where Does Cold Chain Freezing Occur?

Industrialized Countries

- **Australia:** 12 of 32 clinics <2ºC for more than 20% of the time.
- **New Zealand:** Suggested vaccine failure in pertussis and measles epidemics in '91.
- **U.K.:** Only 16 of 40 clinics knew proper vaccine storage temps. Freezing in 3 of 8 practices.
- **U.S.:** 63% of 27 physicians' offices <2ºC.

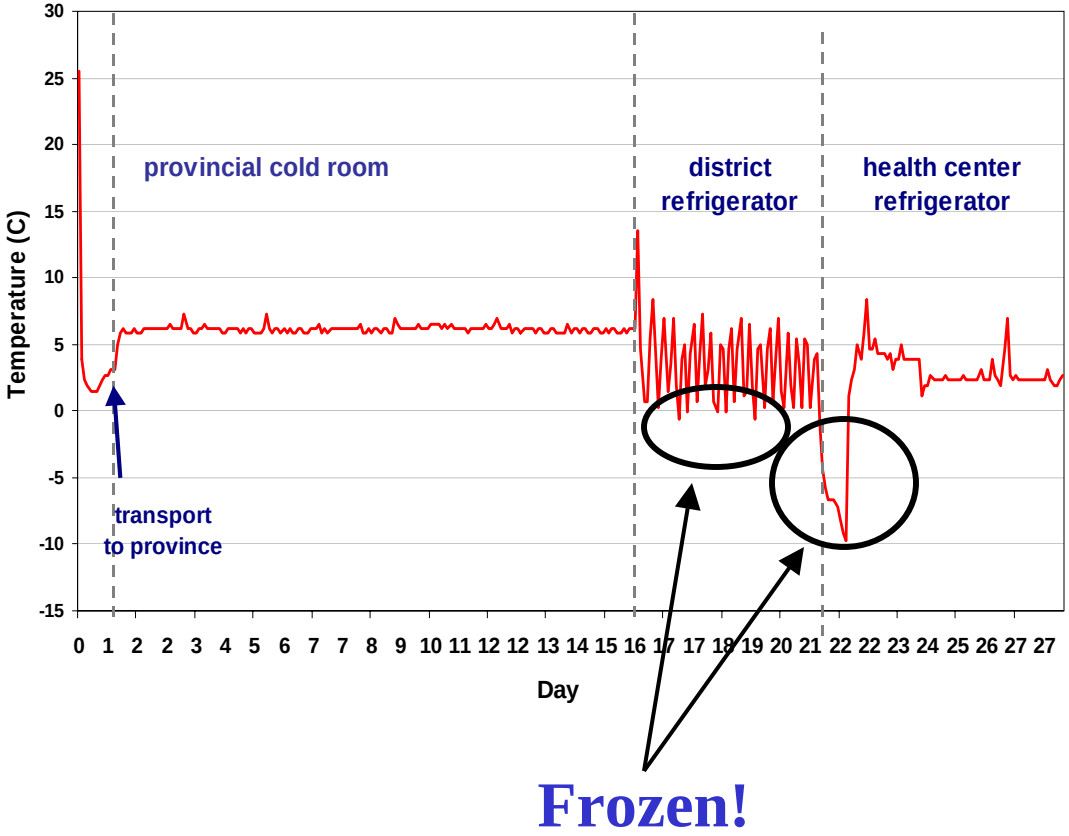
Literature Review Available

Evidence of Vaccine Freezing in the Cold Chain

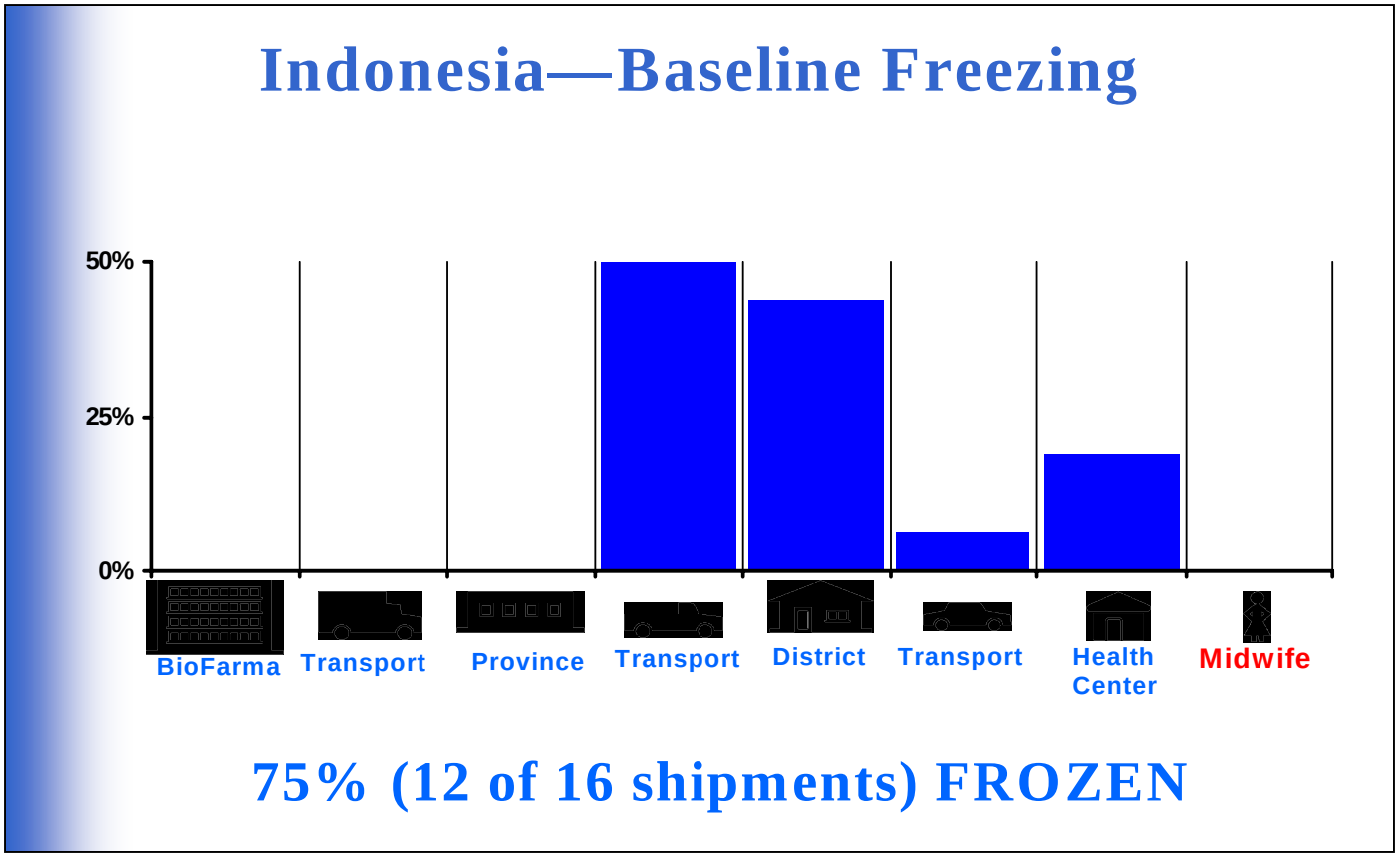
Freeze Study in Indonesia

- Vaccine shipments monitored through normal cold chain distribution.
- Data loggers recorded temperature every 2 hours.
- 2 provinces, 4 districts, 8 health centers were monitored.

Refrigerator temperatures—Indonesia

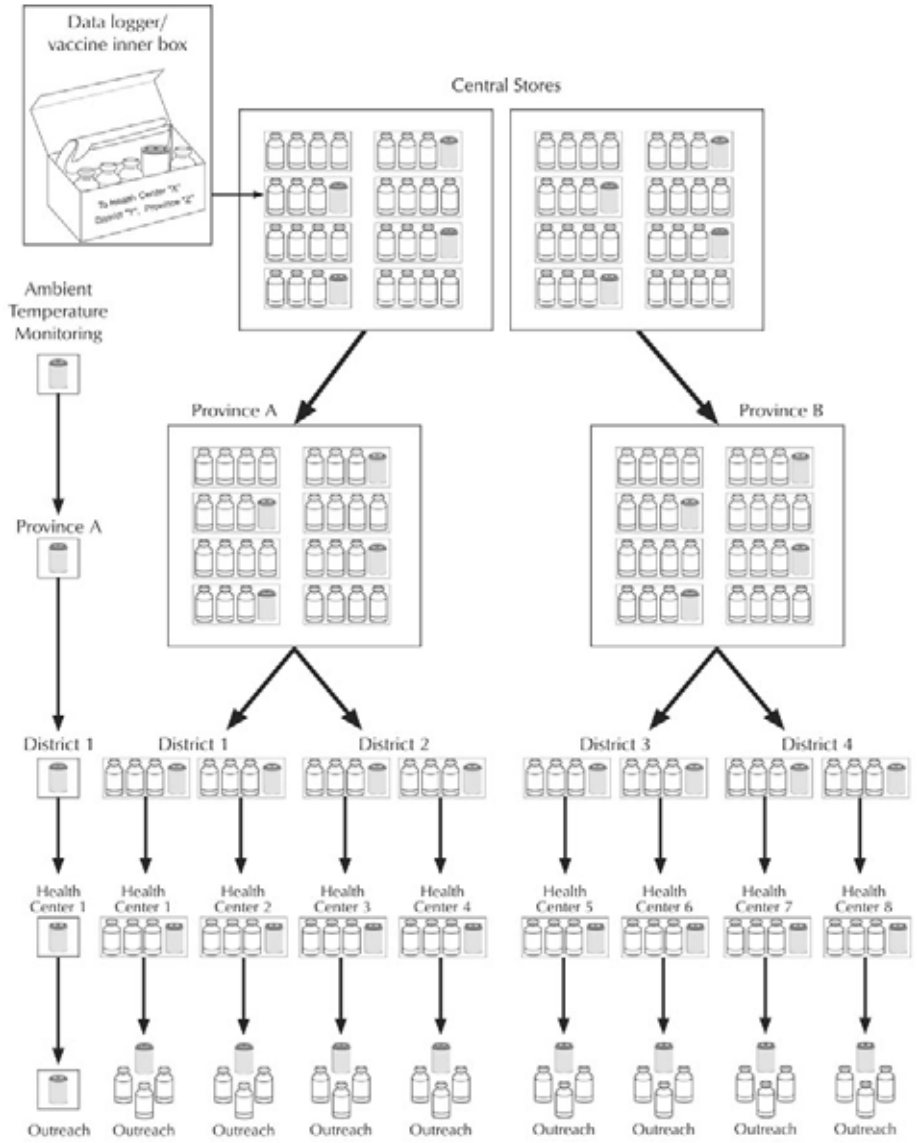


Results: Freeze Study in Indonesia



Evaluate Your Cold Chain:

Freeze Study Protocol Available



Freezing During During Transport can be Avoided

Options

- Short term

  Ensure that frozen icepacks are **conditioned:**

  - Until you can hear water when shaken
    (15 to 45 minutes, depending on room temperature)

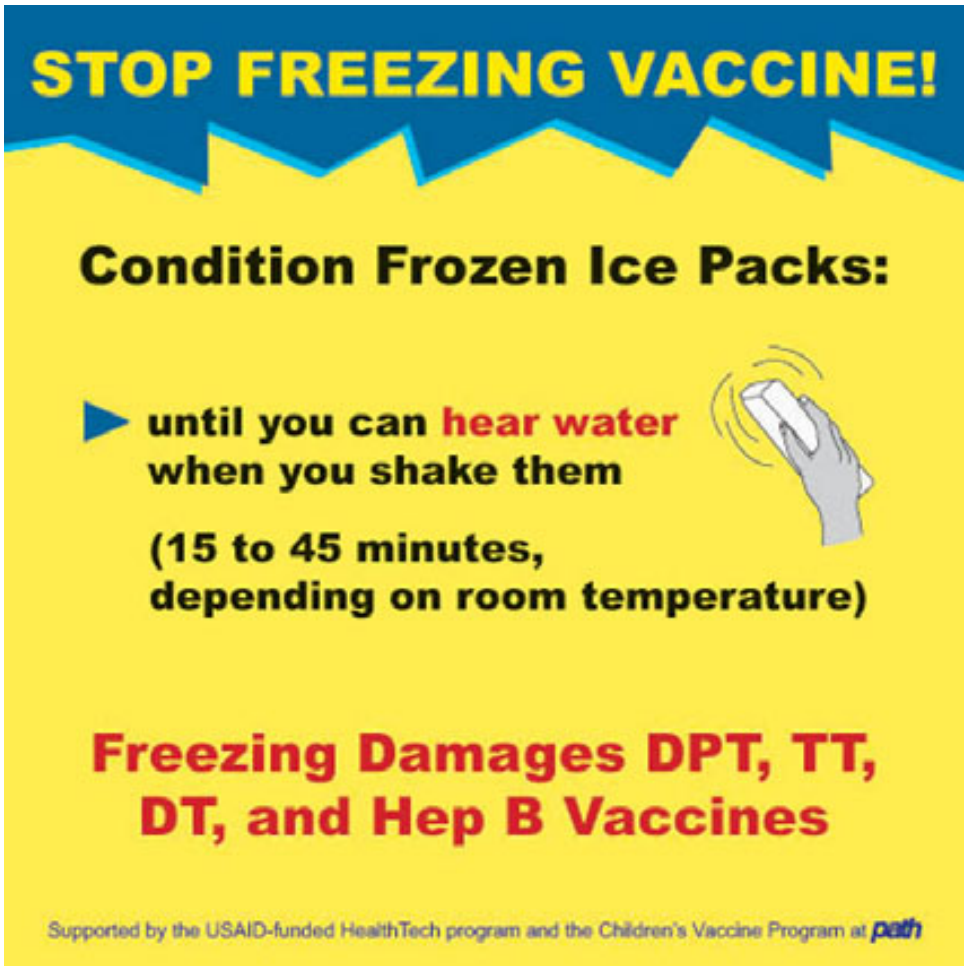
- Medium term *(currently being adopted by WHO):*

  Create a **"two temperature"** cold chain

  - Freeze-sensitive vaccines transported with chilled water packs and/or at ambient temperature (without ice or icepacks)
  - Heat-sensitive vaccines (OPV, measles, BCG) transported with frozen icepacks
    (No need to condition them!)

Vaccine Carrier Sticker:

A reminder that it is important to condition frozen icepacks.



Freezing During Storage can be Avoided

Avoiding Freezing During Storage

- **In cold rooms:**
  - Use the temperature recorders properly.
  - Make sure the alarm system is *always* working.
  - Store freeze-sensitive vaccines away from evaporator.

Avoiding Freezing During Storage

- **In ice-lined refrigerators (ILRs):**
  - Turn off the ice-lining switch (if there is a switch).
  - Keep freeze-sensitive vaccine >20cm from base.
  - Adjust the thermostat
    - Set the thermostat to the MEDIUM power setting.
    - If after 3 days the temperature is less than +2°C at any time, reduce thermostat to MINIMUM power setting.
    - Most ILRs made before 2000 work best at MINIMUM
  - Do not adjust the thermostat after power cuts or if the temp occasionally rises above 8 °C

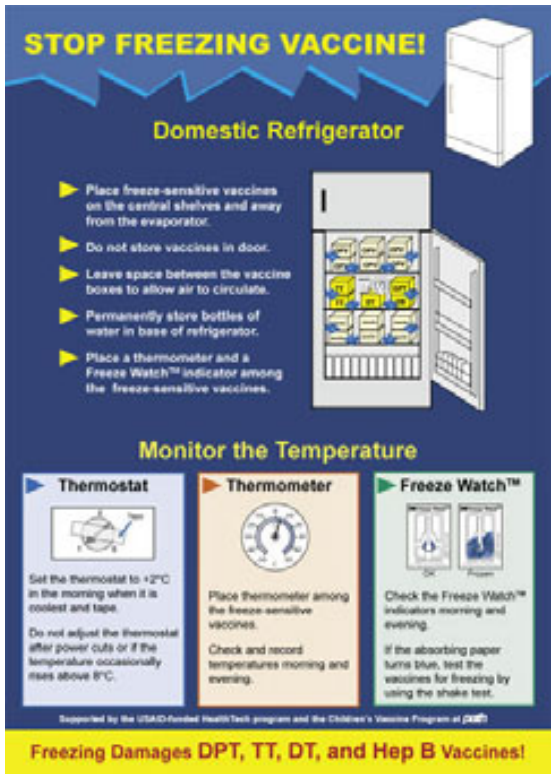
Avoiding Freezing During Storage

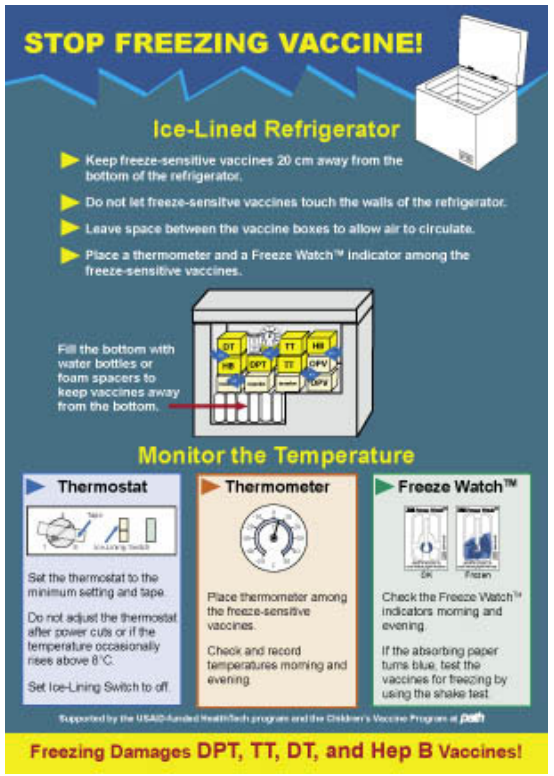
- **In ordinary refrigerators:**

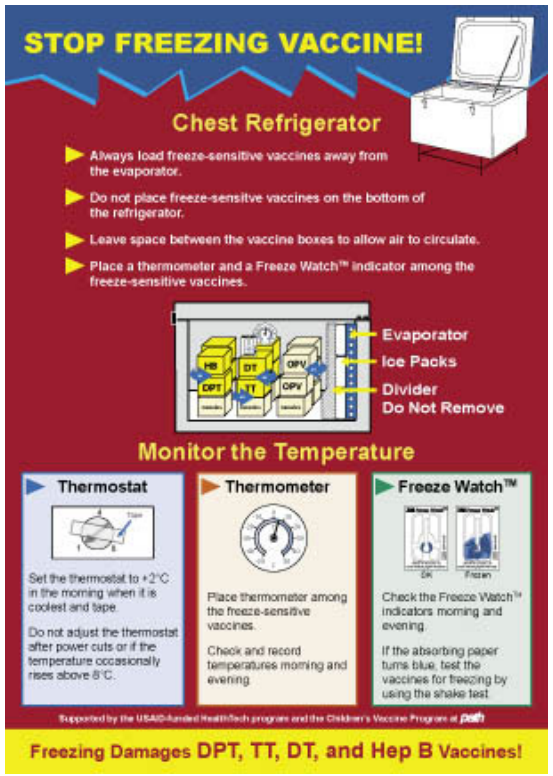
  - Set the thermostat to give +2°C in the early morning when it is coolest. Tape in place
  - Do not adjust the thermostat after power cuts or if the temp occasionally rises above 8 °C
  - Place the thermometer with the freeze-sensitive vaccines and check it twice a day!
  - Load freeze-sensitive vaccines away from evaporator
  - Leave space for air circulation

Vaccine Refrigerator Posters:

Promoting Correct Vaccine Storage and Equipment Use



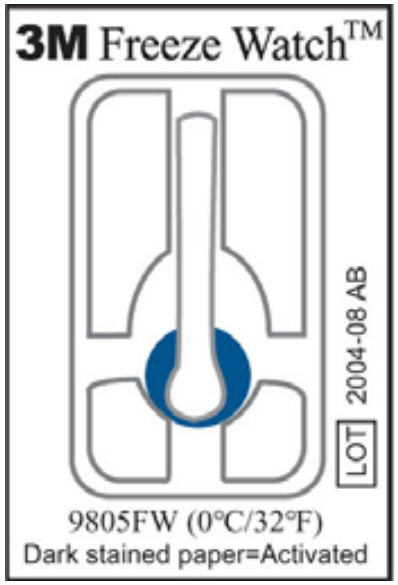




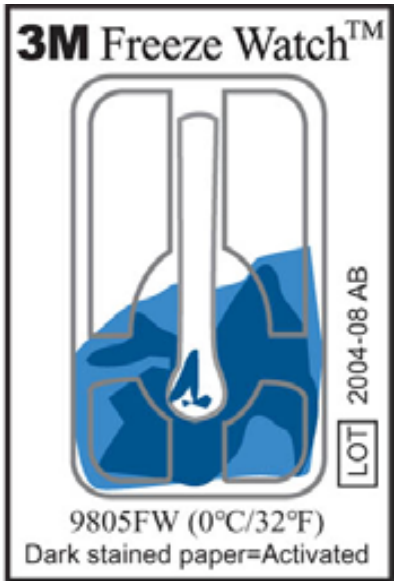
Monitoring
Temperature is Important

Monitoring: Use FreezeWatch

- Place a Freeze Watch indicator in every refrigerator with freeze-senstitive vaccines.
- Use the Freeze Watch to warn of exposure to freezing temperatures, **NOT** to decide whether to discard vaccine.



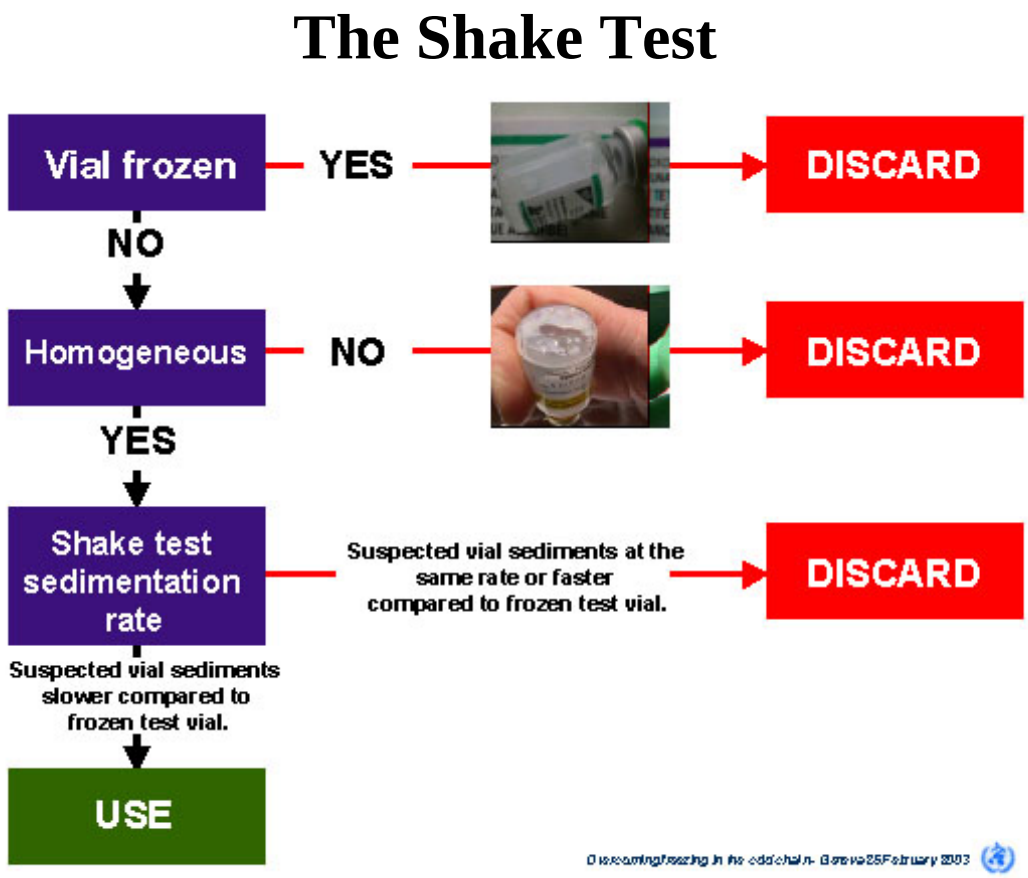
No Freezing



Freezing!

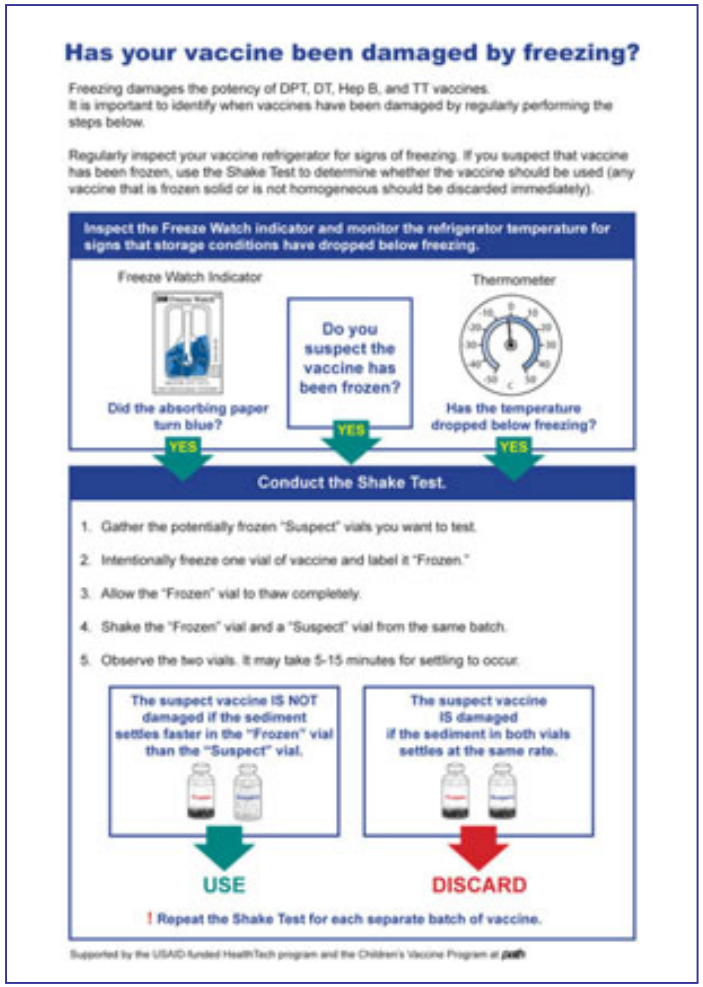
Monitoring: Shake Test to Decide Whether to Discard Vaccines

- Use the **correct** Shake Test procedure to decide whether to use or discard each vial!
- **Freeze a vial** first, then watch how it sediments compared to suspect vials *(same batch, same vaccine, same manufacturer)*!



Shake Test:

The correct way to perform this test for freeze damage



Has your vaccine been damaged by freezing?

Freezing damages the potency of DPT, DT, Hep B, and TT vaccines.
It is important to identify when vaccines have been damaged by regularly performing the steps below.

Regularly inspect your vaccine refrigerator for signs of freezing. If you suspect that vaccine has been frozen, use the Shake Test to determine whether the vaccine should be used (any vaccine that is frozen solid or is not homogeneous should be discarded immediately).

Inspect the Freeze Watch indicator and monitor the refrigerator temperature for signs that storage conditions have dropped below freezing.

Freeze Watch Indicator

Did the absorbing paper turn blue?

YES

Do you suspect the vaccine has been frozen?

YES

Thermometer

Has the temperature dropped below freezing?

YES

Conduct the Shake Test.

1. Gather the potentially frozen "Suspect" vials you want to test.
2. Intentionally freeze one vial of vaccine and label it "Frozen."
3. Allow the "Frozen" vial to thaw completely.
4. Shake the "Frozen" vial and a "Suspect" vial from the same batch.
5. Observe the two vials. It may take 5-15 minutes for settling to occur.

The suspect vaccine IS NOT damaged if the sediment settles faster in the "Frozen" vial than the "Suspect" vial.

USE

The suspect vaccine IS damaged if the sediment in both vials settles at the same rate.

DISCARD

! Repeat the Shake Test for each separate batch of vaccine.

Supported by the USAID-funded HealthTech program and the Children's Vaccine Program at path

Implementing Changes

- Create awareness of problem
  - Explain global evidence and dangers of freezing certain vaccines.
  - Conduct a local cold chain freezing study.
- Push policy change
  - Establish new guidelines and procedures for preventing accidental freezing in the cold chain.
- Implement
  - Retrain, supervise, and provide materials such as the posters, shake test, and sticker
  - **Make freeze prevention a priority!**