Cold Chain Management

Pan American Health Organization

Regional Office of the World Health Organization

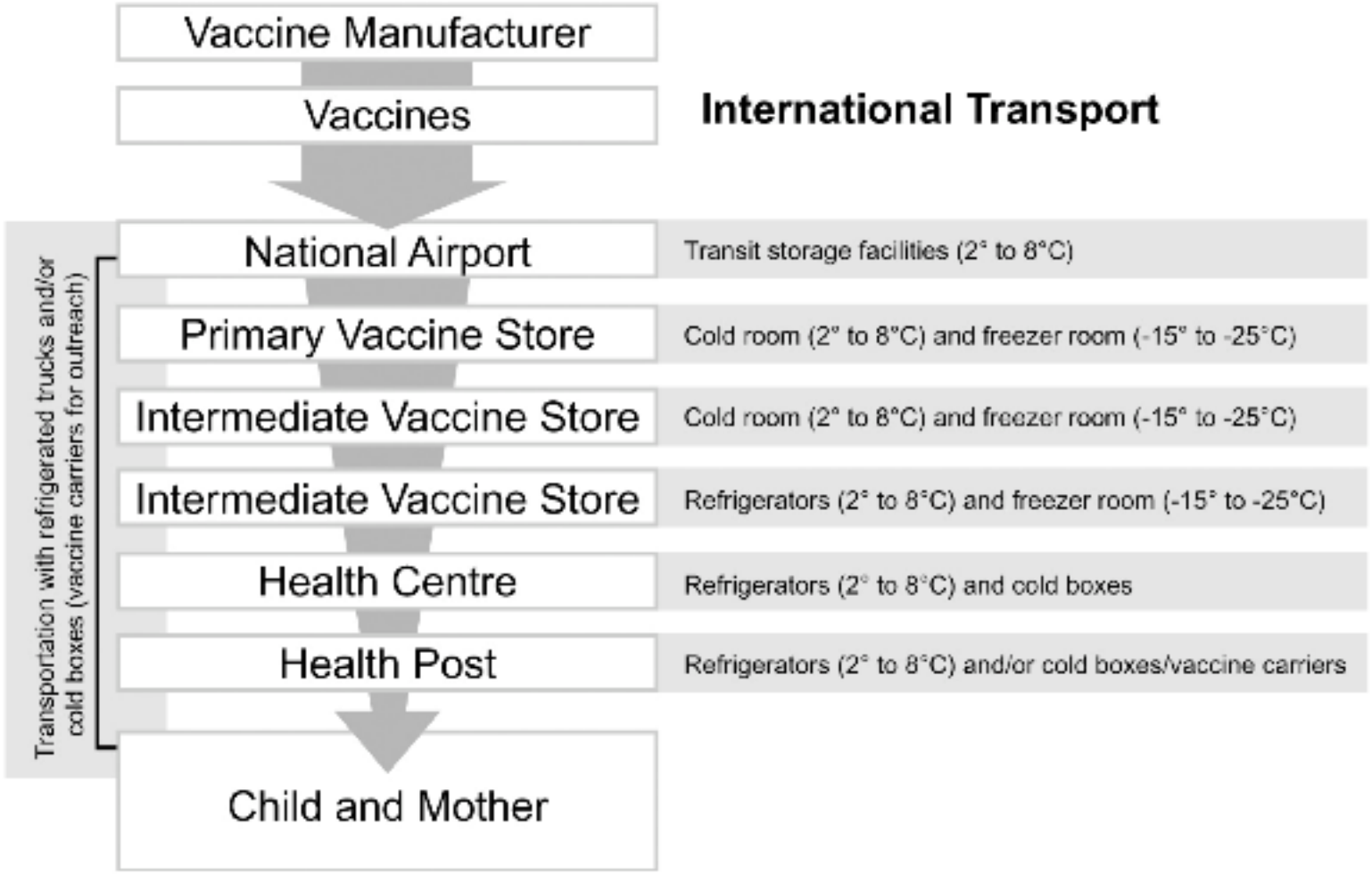
Introduction

- The cold chain
  - Definition
  - Cold chain equipment
  - Monitoring a cold chain
  - How to freeze icepacks
  - Maintenance of the cold chain

The cold chain

- The cold chain is the system used for keeping and distributing vaccines and other Biologicalsin good conditions.
- It consists of a series of storage and transport links, all designed to keep vaccines within an acceptable range until it reaches the user.
- Vaccines are sensitive to heat and freezing and must be kept at the correct temperature from the time they are manufactured until they are used.

The cold chain (cont)



The cold chain equipment

Different levels within the health care system need different equipment for transporting and storing vaccines and diluents at the correct temperature

- **Primary vaccine stores: need cold or freezers rooms, freezers, refrigerators, cold boxes and sometimes refrigerator trucks for transportation**
- **Intermediate vaccine stores: depending on their size and capacity need cold and freezer rooms, and/or freezers , refrigerators and cold boxes**

The cold chain equipment (cont)

- **Health facilities:** need refrigerators with freezing compartments, cold boxes and vaccine carriers

Selecting a refrigerator and / or a Freezer

- **Compression Models:**
  - Powered by electricity
  - Cooling capacities 4 times better than absorption modes
  - Most reliable
  - Safest and easiest to maintain
  - If electricity available = best choice

Cold chain equipment (cont)

- Where electricity or fuel supply is not reliable, ice-lined refrigerators can maintain appropriate temperature for 16 hours without power if they operate with power continuously for at least 8 hours a day

- **Absorption models**
  - Working on gas or kerosene
  - Less performing
  - Need constant attention, more maintenance is needed
  - If available, prefer the gas model

Cold Chain equipment (cont)

- **Solar models:**
  - **Batteries maintenance**
  - **Less performing**
  - **Small capacities**
  - **Not ideal for campaigns**
  - **But: New technologies under development**

Refrigerators-Freezers- capacities

Brand	Model	Negative Volume (liters)	Positive Volume (liters)
Sibir	V110		17
Sibir	V170	36	55
Vestfrost	MF114	72	
Vestfrost	MF214	192	
Vestfrost	MF304	172	
Vestfrost	MF314	264	
Vestfrost	MK074		20
Vestfrost	MK144		45
Vestfrost	MK204		63
Vestfrost	MK304		100
Electrolux	TFW791	50	
Electrolux	TFW800	144	

Cold Boxes

- Isotherm container which is lined with frozen icepacks to keep large quantities of vaccines between 2° C -8° C for several days
- The most common is ELECTROLUX RCW25
  - Vaccine storage capacity: 20.7 liters (=7000 doses of measles vaccine)
  - Cold life without opening at 43° C: 129 hours
- Can be used for vaccine storage at peripheral level when no refrigerator on the condition of renewing regularly the icepacks

Vaccine carriers

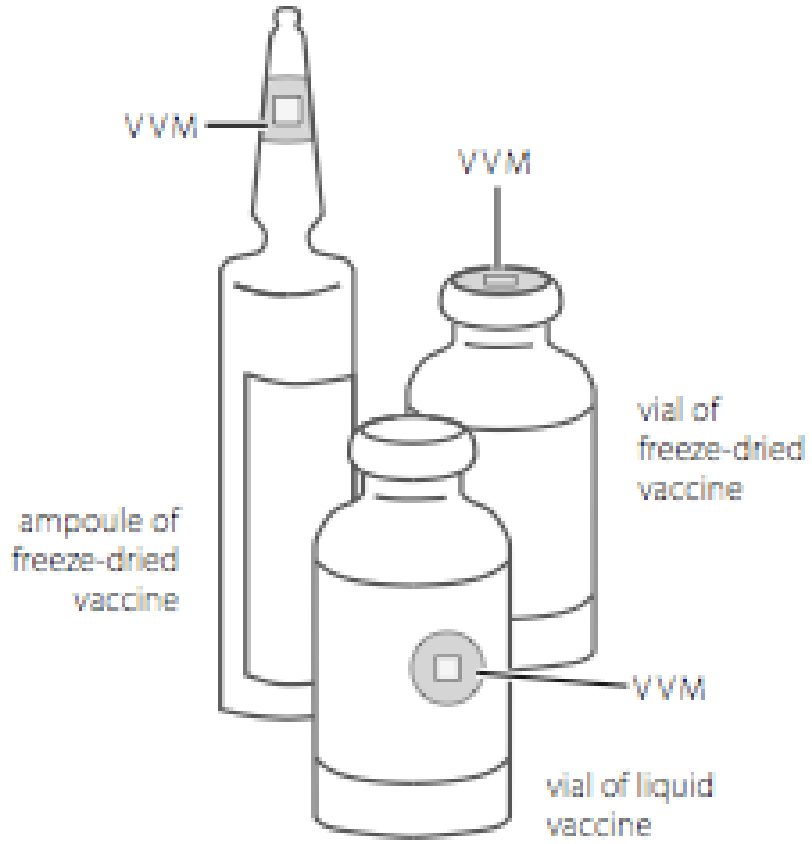
- Isotherm container which is lined with frozen icepacks to keep small quantities of vaccines between 2° C-8° C for 24 to 72 hours
- Used for vaccination sessions and short journeys
- Cold life without opening at 43° C external temperature varies from 24 to 32 hours depending the model

Cold chain monitoring equipment

- The purpose of cold chain monitoring equipment is to keep track of the temperature to which vaccines and diluents are exposed during transportation and storage
- The different monitors are:
  - Vaccine vial monitors
  - Vaccine cold chain monitor card
  - Thermometers
  - Freeze indicators

Vaccine Vials Monitors (VVM)

- **VVM on vial label or cap**



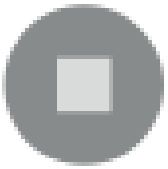
VVM (cont)

- Use only vials with inner squares that are lighter in color than the outside circle
- Vials with VVMs in which the inner square has begun to darken but is still lighter than the outer circle should be used before the vials with a lighter inner square

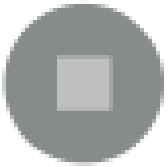
!!! VVM do not measure exposure to freezing temperatures (for freeze sensitive vaccines)

VVM (cont)

- **How to read a vaccine vial monitor (VVM)**

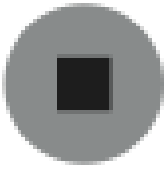


Inner square lighter than outer circle.
If the expiry date has not been passed, USE the vaccine.



At a later time, inner square still lighter than outer circle. *If the expiry date has not been passed, USE the vaccine.*

Discard point:
Inner square matches colour of outer circle.
DO NOT use the vaccine.
Inform your supervisor.

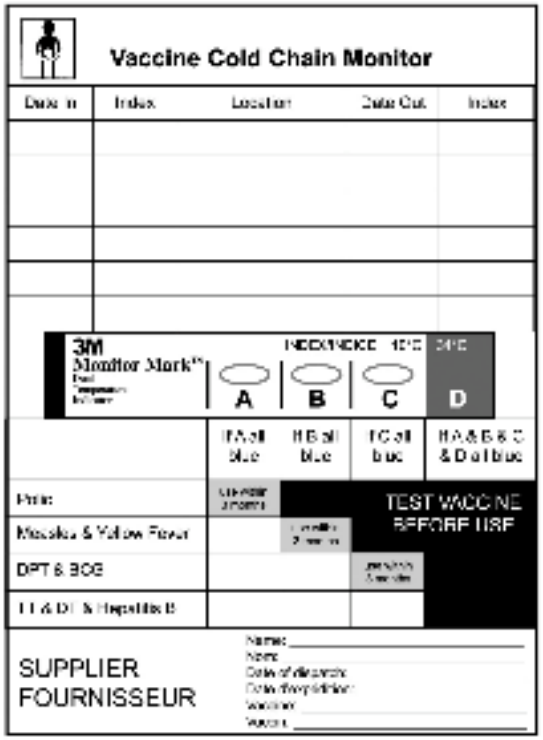


Beyond the discard point:
Inner square darker than outer circle.
DO NOT use the vaccine.
Inform your supervisor.

Vaccine Cold Chain Monitor Card

- A vaccine cold chain monitor is a card with an indicator strip that changes color when the vaccines are exposed to temperatures too high.
- The vaccine cold chain card is used to estimate the length of time that vaccine has been exposed to high temperatures
- Manufacturers pack these monitors with vaccines supplied by WHO and UNICEF
- Usually used for large shipments of vaccines
- Same card should remain with same batch
- Change of color is cumulative

Monitor card (cont)



Vaccine Cold Chain Monitor

Date in	Index	Location	Date Out	Index

3M Monitor Mark™

	A	B	C	D
	If A all blue	If B all blue	If C all blue	If A, B & C & D all blue
Polio		TEST VACCINE BEFORE USE		
Measles & Yellow Fever				
DPT & BCG				
TT & DT & Hepatitis B				

SUPPLIER
FOURNISSEUR

Name:
Date of dispatch:
Date of expiration:
Vaccine:
Batch:

Keep the Cold Chain Monitor with your vaccine.

When the Monitor arrives.....
complete the top part of the card
- fill in the date
- fill in the index (-, A, B, C, and/or D)
- fill in the location

When the Monitor leaves.....
complete the top part of the card
- fill in the date
- fill in the index (-, A, B, C, and/or D)

If window A, B, C and/or D are all white the vaccine is normally

If windows A to C are completely blue but window D is still white, it means that the vaccine has been exposed to temperatures above 10°C but below 34°C for the following number of days:

	Index		
	A	AB	ABC
At a temperature of 10°C	8 days	4 days	14 days
At a temperature of 34°C	2 days	1 days	4 days

If window D is blue it means there has been a break in the cold chain of a temperature higher than 34°C for a period of at least two hours. Check the cold chain.

The instruction 'use within three months' should not be followed if either the expiry date or any local cold chain policy requires a shorter period before use and disposal of the vaccine.

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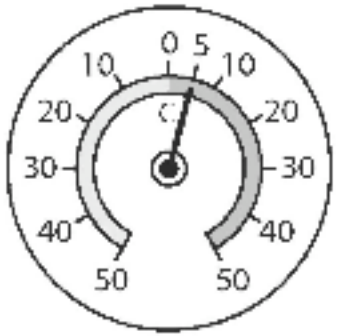
Thermometers

- Used to monitor temperatures of refrigerators and /or cold boxes
- Dial thermometers tend to loose their accuracy over time. They can be re calibrated
- (facility screw to be adjusted)

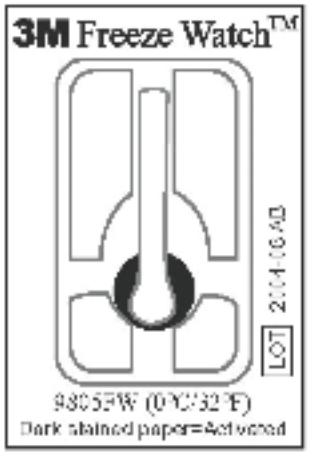
Dial thermometer



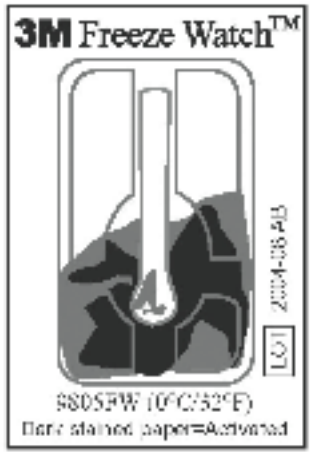
Stem thermometer

Freeze indicators

- **Freeze watch**



Activated: Vaccines OK



Not activated: Do the shake test for freeze-sensitive vaccines

- **Irreversible temperature indicator which shows if a product, such as vaccine, has been exposed to freezing temperatures . If exposed to temperatures below 0° C for more than 1 hour the vial releases the colored liquid**

Freeze indicators (cont)

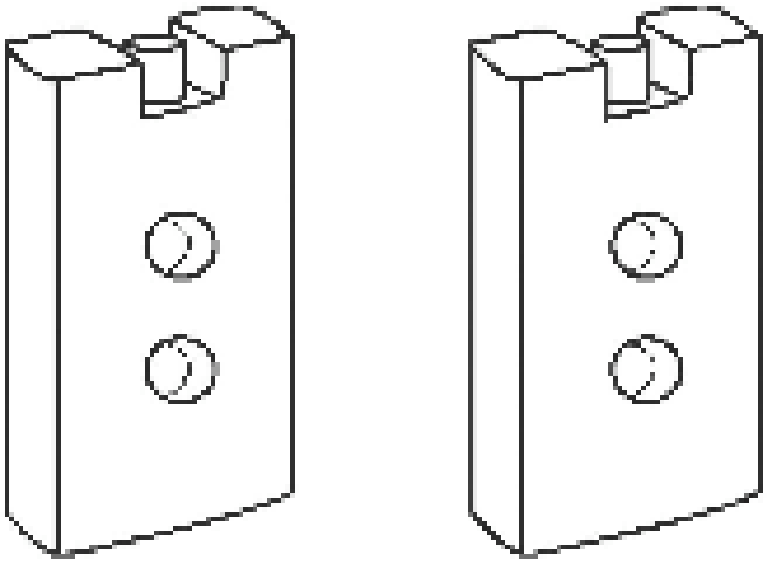
- Freeze Tag : electronic temperature measuring circuit with LCD display. If indicator exposed to temperatures below 0° C for more than 1 hour the display changes to “alarm”

Vaccines OK Do shake test

- See the shake test below

How to freeze Ice Packs

- Ice-packs are flat, square plastic bottles that are filled with water and frozen.
- They are used to keep vaccines cool inside the vaccine carrier or cold box.



How to freeze Ice-Packs (cont)

- The proper freezing and use of ice-packs is essential for good quality of the vaccines
- Make sure that the size and number of ice-packs correspond to the cold boxes and vaccines carriers
- To freeze an Ice-Pack
  - Fill with water leaving a little air space at the top
  - Hold each ice-pack upside down and squeeze it to make sure it does not leak
  - Put Ice-packs upright on their sides in the freezer
  - Let the air circulate in between the ice-packs

Freezing Ice-packs

- It take time (24 hours) to freeze an Ice-pack
- Gas refrigerators or ice-lined refrigerators with a freezing compartment can freeze up to 6 large (0,6 liter) or 12small ice-packs per day. More packs will take longer to freeze
- TIP: good to keep unfrozen icepacks in the bottom of the refrigerator compartment, it will keep this section cold in case of power failure and when you put them in the freezer they will freeze more quickly as the water inside is cold

Freezing ice-packs (cont)

Brand	Model	Freezing capacity	Number small ice-packs (0,3 liter)	Storage capacity (in liters)
Vestfrost	MF114	17,5 kg/24H	58	72
Vestfrost	MF214	22,3 kg/24H	74	192
Vestfrost	MF314	32,4 kg/24H	108	246
Sibir	V170	1,2 kg/24H	3	36

Freezing Ice-packs

- Never fill a Freezer completely with unfrozen Ice-Packs at one time, it will take too long to freeze and the compressor will suffer.
- The best option is to put one row every 24 hours and to leave some space in order to keep a good ventilation
- Start freezing ice-packs as soon as possible

How to maintain cold chain equipment

- **Vaccine refrigerators:**
  - **A refrigerator works well only if it is properly installed, cleaned and defrosted regularly.**
  - **Thick ice in the freezer compartment does not keep the refrigerator cool, it makes the refrigerator work harder and use more power, gas or kerosene.**
  - **You should DEFROST the refrigerator when the ice becomes more than 0,5 cm thick or once a month.**

How to defrost and clean a refrigerator

- Take out all the most heat sensitive vaccines (OPV, measles, BCG, yellow fever) and transfer them to a cold box lined with frozen ice-packs
- Take out all the freeze sensitive vaccines (DTP, DT, Td, hepatitis B,) and diluents, and transfer them to a cold box lined with conditioned ice-packs
- Turn off the power supply to the refrigerator
- Leave de door open and wait for the ice to melt
- Clean the inside and the door seal with a clean wet cloth and turn the refrigerator on again.

How to defrost and clean a refrigerator

- When the inside temperature in the main section falls to 2° C- 8° C return the vaccines, diluents and ice packs in appropriate places.
- TIP: If you need to defrost your refrigerator more than once a month, it could be because:
  - Opening it too much (more 3 x/day)
  - The door not closing properly
  - the seal of the door needs to be replaced
  - If breakdown of refrigerator: THINK TO PROTECT VACCINES FIRST !!!

Maintaining cold boxes and vac. carriers

- Must be dried after their use
- If left wet with closed lids, they become moldy and the seal will be affected
- Store them with the lid open when not used, if possible
- Don’t store them outside under the sunlight, it can cause cracks and reduce the efficiency of the cold box

The Shake test

- Used to know if freeze sensitive vaccines have been subjected to freezing temperatures that have damaged them.
- After freezing, the vaccine no longer appearance of HOMOGENOUS cloudy liquid but tend to form flakes which settle at the bottom of the vial after shaking
- Sedimentation is faster in a vial which has been frozen than in a vial (from same manufactured) which has not been frozen.

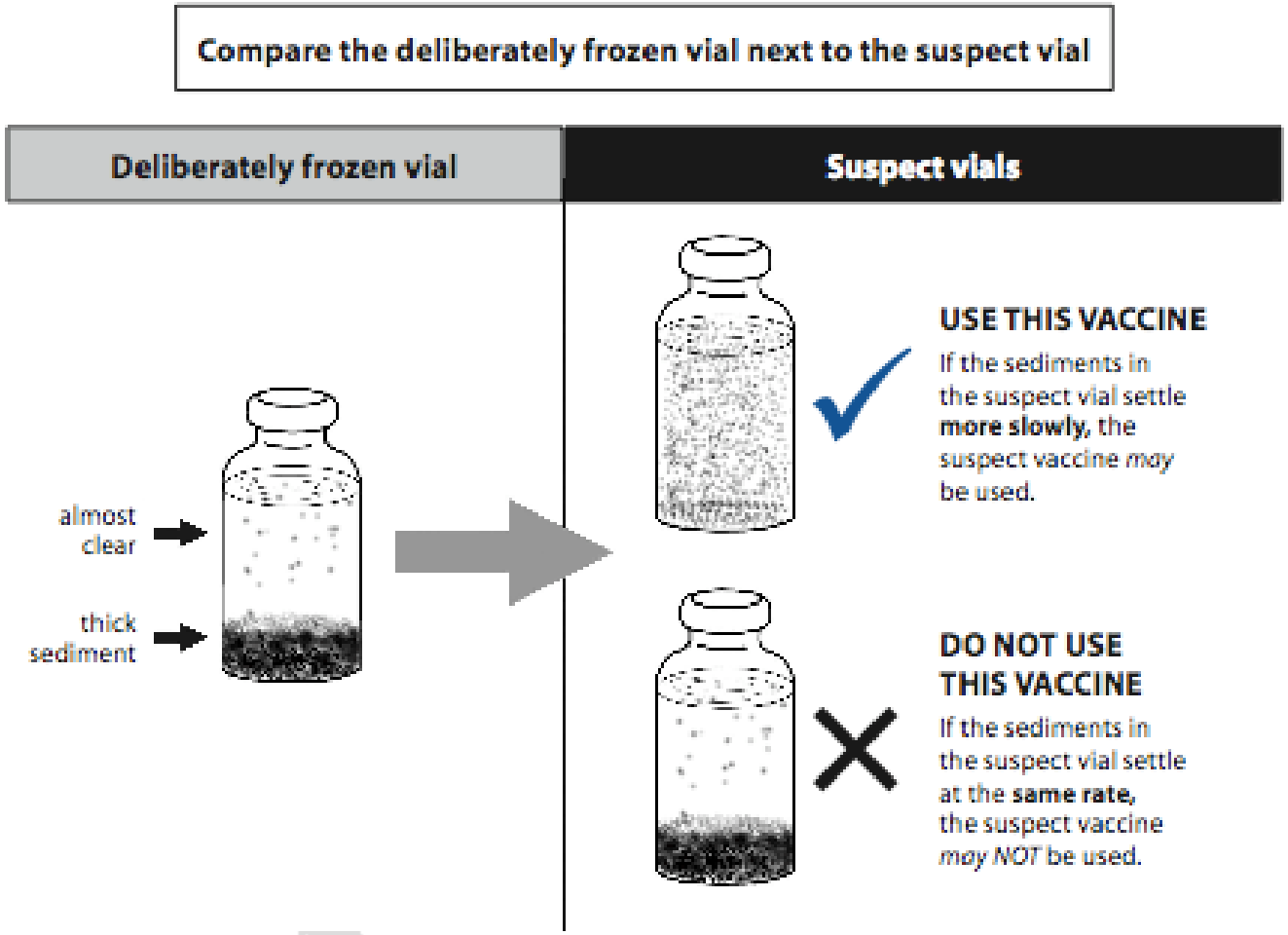
The Shake test

- How to do the SHAKE test:
  - 1. Prepare a frozen control sample
    - Take sample same batch same manufacturer
    - Make it freeze, min 10 hours at -10° C
    - Then let it thaw
    - This will be the CONTROL SAMPLE
    - Mark the vial clearly
  - 2. Choose a test sample
    - Take a vial from the batch you suspect has been frozen this will be the TEST SAMPLE

The Shake test

- 3. Shake the CONTROL and TEST samples
  - Shake them in the same hand for 10-15 seconds
- 4. Allow to rest
- 5. Compare the vials
  - View both vials against the light to compare the SEDIMENTATION rate
    - If test sample shows MUCH LESS sedimentation than the control then it has not been frozen and OK
    - If same sedimentation NOT TO BE USED, then all the vials need to be tested

The Shake test



Heat sensitivity

Range	Vaccine
most sensitive	OPV
	Measles, MR, MMR
	DTP, DTP-HepB, DTP-Hib, DTP-HepB+Hib, YF
	BCG
	Hib, DT
least sensitive	Td, TT, HepB, JE

Freeze sensitivity

Range	Vaccine
most sensitive	HepB
	Hib (liquid)
	DTP, DTP-HepB, DTP-Hib, DTP-HepB+Hib, YF
	DT
	Td
least sensitive	TT, Hib lyophilised

Light sensitivity

- Some vaccines are very sensitive to strong light and their exposure to ultraviolet light causes loss of potency.
- These vaccines need ALWAYS to be protected from sunlight
  - BCG, measles, MR, MMR and rubella

IT IS VERY IMPORTANT:

Measles efficiency of the vaccines = 85%

This is why you need >95% coverage to stop the spread. If coverage 75%, children protected only 63%. If efficiency only 65 % and coverage 95%, children protected 61 %, not enough

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