Cold Chain Management
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 Biologicals in 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)

- Vaccine Manufacturer
- Vaccines
- National Airport
  - Transit storage facilities (2°C to 8°C)
- Primary Vaccine Store
  - Cold room (2°C to 8°C) and freezer room (-15°C to -25°C)
- Intermediate Vaccine Store
  - Cold room (2°C to 8°C) and freezer room (-15°C to -25°C)
- Intermediate Vaccine Store
  - Refrigerators (2°C to 8°C) and freezer room (-15°C to -25°C)
- Health Centre
  - Refrigerators (2°C to 8°C) and cold boxes
- Health Post
  - Refrigerators (2°C to 8°C) and/or cold boxes/vaccine carriers
- Child and Mother
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 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

<table>
<thead>
<tr>
<th>Brand</th>
<th>Model</th>
<th>Negative Volume (liters)</th>
<th>Positive Volume (liters)</th>
</tr>
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<tbody>
<tr>
<td>Sibir</td>
<td>V110</td>
<td>17</td>
<td></td>
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<tr>
<td>Sibir</td>
<td>V170</td>
<td>36</td>
<td>55</td>
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<tr>
<td>Vestfrost</td>
<td>MF114</td>
<td>72</td>
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<td>MF214</td>
<td>192</td>
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<td>MF304</td>
<td>172</td>
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<td>Vestfrost</td>
<td>MF314</td>
<td>264</td>
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<td>MK074</td>
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<td>45</td>
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<tr>
<td>Vestfrost</td>
<td>MK204</td>
<td>63</td>
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<tr>
<td>Vestfrost</td>
<td>MK304</td>
<td>100</td>
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<tr>
<td>Electrolux</td>
<td>TFW791</td>
<td>50</td>
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<tr>
<td>Electrolux</td>
<td>TFW800</td>
<td>144</td>
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</tbody>
</table>
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)
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)
Thermometers

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

- Freeze watch

- 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”

- 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 12 small 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)

<table>
<thead>
<tr>
<th>Brand</th>
<th>Model</th>
<th>Freezing capacity</th>
<th>Number small ice-packs (0.3 liter)</th>
<th>Storage capacity (in liters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vestfrost</td>
<td>MF114</td>
<td>17.5 kg/24H</td>
<td>58</td>
<td>72</td>
</tr>
<tr>
<td>Vestfrost</td>
<td>MF214</td>
<td>22.3 kg/24H</td>
<td>74</td>
<td>192</td>
</tr>
<tr>
<td>Vestfrost</td>
<td>MF314</td>
<td>32.4 kg/24H</td>
<td>108</td>
<td>246</td>
</tr>
<tr>
<td>Sibir</td>
<td>V170</td>
<td>1.2 kg/24H</td>
<td>3</td>
<td>36</td>
</tr>
</tbody>
</table>
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 the 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 appears 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

Compare the deliberately frozen vial next to the suspect vial

**Deliberately frozen vial**
- almost clear
- thick sediment

**Suspect vials**
- USE THIS VACCINE
  - If the sediments in the suspect vial settle more slowly, the suspect vaccine may be used.
- DO NOT USE THIS VACCINE
  - If the sediments in the suspect vial settle at the same rate, the suspect vaccine may NOT be used.
### Heat sensitivity

<table>
<thead>
<tr>
<th>Range</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>most sensitive</strong></td>
<td>OPV</td>
</tr>
<tr>
<td></td>
<td>Measles, MR, MMR</td>
</tr>
<tr>
<td></td>
<td>DTP, DTP-HepB, DTP-Hib,</td>
</tr>
<tr>
<td></td>
<td>DTP-HepB+Hib, YF</td>
</tr>
<tr>
<td></td>
<td>BCG</td>
</tr>
<tr>
<td></td>
<td>Hib, DT</td>
</tr>
<tr>
<td></td>
<td>Td, TT, HepB, JE</td>
</tr>
<tr>
<td><strong>least sensitive</strong></td>
<td></td>
</tr>
</tbody>
</table>
**Freeze sensitivity**

<table>
<thead>
<tr>
<th>Range</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>most sensitive</strong></td>
<td>HepB, Hib (liquid)</td>
</tr>
<tr>
<td></td>
<td>DTP, DTP-HepB, DTP-Hib, DTP-HepB+Hib, YF</td>
</tr>
<tr>
<td></td>
<td>DT</td>
</tr>
<tr>
<td></td>
<td>Td</td>
</tr>
<tr>
<td><strong>least sensitive</strong></td>
<td>TT, Hib lyophilised</td>
</tr>
</tbody>
</table>
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
THANK YOU