ISSUES IN COLD CHAIN MANAGEMENT

S.K. Saxena, Consultant Cold Chain, Uncef, New Delhi
Hep-B Vaccine at bottom of ILR
Full ILR
Overfilling of Deep Freezer
You often see this in field
Do you still see this in field?
Exposure to heat more than $8^0$ C

- All vaccines lose potency
- More heat – quicker the loss
- Damage is irreversible
Vaccines vulnerable to heat

- BCG (after reconstitution)
- OPV
- Measles
- HepB
- DPT
- DT
- BCG (before reconstitution)
- TT
## Stability of vaccines at various temperatures

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Storage temperature in °C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-8</td>
</tr>
<tr>
<td><strong>DT</strong></td>
<td>3-7 yrs</td>
</tr>
<tr>
<td><strong>DPT</strong></td>
<td>18 to 24 months</td>
</tr>
<tr>
<td><strong>BCG (FD)</strong></td>
<td>1 year</td>
</tr>
<tr>
<td><strong>Measles (FD)</strong></td>
<td>2 years</td>
</tr>
</tbody>
</table>
## Holdover time of Cold chain equipment

<table>
<thead>
<tr>
<th>EQUIPMENT</th>
<th>At 32°C</th>
<th>At 43°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF -140 ltrs</td>
<td>22 hrs</td>
<td>18 hrs</td>
</tr>
<tr>
<td>DF – 300 LTRS</td>
<td>26 hrs</td>
<td>18 hrs</td>
</tr>
<tr>
<td>ILR</td>
<td>78 hrs</td>
<td>62 Hrs</td>
</tr>
<tr>
<td>Vaccine Carriers</td>
<td>34 hrs</td>
<td>5 hrs</td>
</tr>
<tr>
<td>Day Carrier</td>
<td>6 hrs</td>
<td></td>
</tr>
</tbody>
</table>
## Types of VVMs (VVM registers cumulative exposure)

<table>
<thead>
<tr>
<th>Type of VVM</th>
<th># of days to reach End point at 37° C</th>
<th>On which vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>VVM 2</td>
<td>2 days</td>
<td>OPV</td>
</tr>
<tr>
<td>VVM 7</td>
<td>7 days</td>
<td>Measles</td>
</tr>
<tr>
<td>VVM 14</td>
<td>14 days</td>
<td>DPT</td>
</tr>
<tr>
<td>VVM 30</td>
<td>30 days</td>
<td>Hep-B, DT, BCG (FD)</td>
</tr>
</tbody>
</table>
Some vaccines are vulnerable to Freezing

- JE (Mouse brain) $0^\circ$C
- Hep- B; - 0.5
- DPT; - 3
- DT; -3
- TT; -3
To prevent Freezing -

Preparing icepacks for use: Conditioning

- On the session day, take the frozen ice-packs you need from the freezer and place on a table.
- Allow ice-packs to sweat at room temperature for 15 minutes.
- Shake the ice pack to listen to melted for water.

A Conditioned an ice-pack
Preventing Accidental Freezing in the Cold Chain

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

Program for Appropriate Technology in Health (PATH)
Freezing Damages Vaccines

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

---

Countries That Have Found Cold Chain Freezing

- Canada
- UK
- USA
- Bolivia
- S. Africa
- Iraq
- Hungary
- Moldova
- Romania
- Ukraine
- Indonesia
- Vietnam
- Malaysia
- Mozambique
- Australia
- New Zealand
- India
Steps for Eliminating Freezing

- Awareness of problem
  - Monitoring study to document freezing
  - Priority for policymakers and health workers

- Guidelines and procedures
  - Loading
  - Transport

- Retraining health workers and supervisors

- Monitoring
Typical Causes of Freezing

- Ice-lined refrigerators
- Transport with frozen ice packs
- Belief that colder is better
- Low awareness and understanding
- Incorrect thermostat adjustments
## Studies Using PATH/UNICEF/WHO Protocol

<table>
<thead>
<tr>
<th>Country</th>
<th>Transport Freezing</th>
<th>Refrigerator Freezing</th>
<th>Overall Freezing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>50%</td>
<td>50%</td>
<td>75%</td>
</tr>
<tr>
<td>India different protocol</td>
<td>Not measured</td>
<td>60%</td>
<td>Not measured</td>
</tr>
<tr>
<td>Vietnam</td>
<td>63%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Bolivia</td>
<td>100%</td>
<td>60%</td>
<td>100%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>75%</td>
<td>80%</td>
<td>100%</td>
</tr>
</tbody>
</table>
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

Frozen!
Results: Freeze Study in Indonesia

Indonesia—Baseline Freezing

75% (12 of 16 shipments) FROZEN
Bolivia cold chain monitoring study; March–May 2005

Nelson, C; Froes, P; Dyck, AMV; Chavarria, J; Boda, E; Coca, A; Crespo, G & Lima, H 2006
‘Monitoring temperatures in the vaccine cold chain in Bolivia’, Vaccine, Volume 25, Issue 20, 16 May 2007, Pages 3980-3986
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!)
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 +4°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
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!
Performing the Shake Test

- Freezing damages the potency of DPT, DT, Hep B, and TT vaccines.
- Look for signs that storage conditions have dropped below freezing.
- If you suspect that vaccine has been frozen.

Do a shake test to determine whether the vaccine should be used.
Shake Test

- Take a vaccine vial you suspect may have been frozen – This is “test” sample.
- Take a vaccine vial of the
  - same type, same manufacturer, same batch number
  as the suspect vaccine vial you want to test.
Shake the control and test samples

- Hold the Control and the Test sample together in hand and vigorously shake the samples.
- Place both vials to rest on a flat surface, side-by-side observe them for 30 minutes.
- Compare for rate of sedimentation.
Shake Test: Summary

1. Vial frozen
   - YES: DISCARD
   - NO: Homogeneous
2. Homogeneous
   - NO: DISCARD
   - YES: Shake test sedimentation rate
3. Shake test sedimentation rate
   - Suspected vial sediments at the same rate or faster compared to frozen test vial: DISCARD
   - Suspected vial sediments slower compared to frozen test vial: USE
Right way of keeping vaccines in ILR

- Keep all vaccines in baskets
- Avoid placing vaccines at bottom of ILR. (never diluents, freeze sensitive)
- Leave space between the vaccine boxes
- Place a thermometer in the center of the ILR.
- Same vaccines in same area.
- Diluent / freeze sensitive/ Closer expiry date vaccines on top
- Heat sensitive / Further expiry date vaccines in the bottom of basket
Measles vaccines to be placed on ice-packs during sessions
ICE PACK FREEZING

- Ice Packs to be frozen ROCK solid.
- Freezing is faster & uniform if gap is left between ice packs.
- Ice packs are best frozen in Deep freezers.
- Large DF freezes 42 packs / 24 hours.
- Small DF freezes 20 – 25 packs / 24 hours
Common observations – Equipment

- Door not closing properly
- Equipment not leveled
- Placed very nearer to the wall
- No Basket into ILR
- No plug connection
- No Stabilizer
Common Observations – Vaccine Store

- Vaccine not properly placed and in large quantity.
- Storage beyond time limit
- Frozen T series
- OPV in Stage III & IV
- Expired vaccine
- Partly shortage of vaccine
- Vaccine without label
Common Observations – Operational Fault

- **False recording of temperature**
- Ice packed not stacked properly
- Temperature not in proper range
- Sitting on Cold Box or Vaccine carrier
- No Thermometer
- No proper recording of stock of vaccines.
- Issuing vaccine without target
- Issue of Diluents in less qty.
- No proper wrapping of T series vaccine in Paper.
- Half Filled or Over filled Ice-packs
Cont.

- No Foam or Paper packing in cold box/Vaccine Carrier.
- No Polyethylene bag.
- Any Eatable items in ILR/D/F
- Drinking Bottle in ILR/D/F
- Day Carrier in use
- Frosting into D/F
- **Water into ILR**
- Issuing Two Ice packs in Vaccine Carrier.
- Not sweating of Ice packs before putting in to cold box/Vaccine Carrier.
- Leaking of Ice Packs.
Thank You