ENSURING THE VACCINE SUPPLY CHAIN

The role of Immunization Devices in ensuring the safe transport, storage, distribution and administration of vaccines
COLD CHAIN CHALLENGES

• INCREASE IN VACCINE VOLUME PER Fully Immunised Child
  — Increased number of vaccines
  — Extension of immunization targets
  — Increased supplementary immunization activities (SIAs)
  — Growth of single dose presentations
  — Integration of vaccine with device
  — Incorporation of the diluent

• THIS CAN BE OFFSET IN FUTURE BY
  — Thermostable vaccines
  — Intradermal administration (requires less dose for same immune response)
# Vaccine-related equipment (PQS) categories: progress overview

<table>
<thead>
<tr>
<th>PQS Categories</th>
<th>Description</th>
<th># Products PQ 2009</th>
<th># Products PQ 2010</th>
<th># Products PQ 2011</th>
<th># Products PQ 2012</th>
<th># Products PQ 2013</th>
<th># Products PQ 2014</th>
<th># Products PQ 2015</th>
<th># Products PQ 2016</th>
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</thead>
<tbody>
<tr>
<td>E001</td>
<td>Cold rooms and related equipment</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
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<td>4</td>
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<tr>
<td>E002</td>
<td>Refrigerated trucks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Still under development</td>
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<tr>
<td>E003</td>
<td>Refrigerators and freezers.</td>
<td>7</td>
<td>16</td>
<td>28</td>
<td>33</td>
<td>36</td>
<td>44</td>
<td>51</td>
<td>63</td>
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<tr>
<td>E004</td>
<td>Cold boxes and vaccine carriers.</td>
<td>1</td>
<td>32</td>
<td>32</td>
<td>34</td>
<td>37</td>
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<td>41</td>
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<tr>
<td>E005</td>
<td>Coolant packs - water-packs</td>
<td>0</td>
<td>16</td>
<td>16</td>
<td>18</td>
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<td>E006</td>
<td>Temperature monitoring devices.</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>17</td>
<td>22</td>
<td>24</td>
<td>31</td>
<td>32</td>
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<tr>
<td>E008</td>
<td>AD syringes</td>
<td>30</td>
<td>28</td>
<td>26</td>
<td>29</td>
<td>33</td>
<td>36</td>
<td>39</td>
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<tr>
<td>E010</td>
<td>Waste management: Safety boxes</td>
<td>9</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>12</td>
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<tr>
<td>E013</td>
<td>Therapeutic injection devices</td>
<td>37</td>
<td>48</td>
<td>61</td>
<td>72</td>
<td>80</td>
<td>84</td>
<td>89</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td>93</td>
<td>162</td>
<td>187</td>
<td>216</td>
<td>238</td>
<td>258</td>
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</table>
The ‘Guidelines for International Shipment of Vaccines’ published in 2005 is the main guidance document for packaging and shipment of vaccines.

Currently under revision with publication of the revised version scheduled for Q4 2017.

Purpose of the revision is to incorporate changes in technology and policies over the last 10 years since the first version was published.
Guidelines contain a section on insulated packaging standards for OPV, Freeze dried vaccines (BCG, Measles, MR, MMR, Meningococcal A&C, yellow fever) and freeze sensitive vaccines (DTP, DTP Hep-B, IPV, TT etc)

Also contains sections on temperature monitoring devices, storage volume standards, labelling and packaging and shipping arrival procedures
International Shipments of Vaccines – Monitoring Devices

- Electronic shipping indicators -
  - single use pre-programmed electronic time-temperature loggers which accompany vaccines from the manufacturers warehouse to the receiving country’s primary store.
  - They display the shipment’s time-temperature exposure without the need for download onto a PC

- Cold Chain Monitors (CCMs) –
  - provide a warning when excessive heat exposure occurs during transport.
  - They are used primarily to monitor the international shipment of freeze-dried vaccine consignments where dry ice is used as the cooling medium.
# International Shipments of Vaccines –
Current types of vaccine packaging and alarm settings

<table>
<thead>
<tr>
<th>Class</th>
<th>Type of vaccine</th>
<th>Ambient temperature</th>
<th>Minimum temperature allowed</th>
<th>Maximum temperature allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>OPV</td>
<td>+43°C</td>
<td>no limit</td>
<td>+8°C</td>
</tr>
<tr>
<td></td>
<td>BCG, Hib (freeze-dried), measles, MR, MMR, meningococcal A&amp;C, yellow fever</td>
<td>+43°C</td>
<td>no limit</td>
<td>+30°C</td>
</tr>
<tr>
<td>B</td>
<td>DTP, DTP–HepB, DTP–Hib (liquid), DT, IPV, HepB, Hib (liquid), Td, TT</td>
<td>+43°C</td>
<td>+2°C</td>
<td>+30°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-5°C</td>
<td>+2°C</td>
<td>+30°C</td>
</tr>
</tbody>
</table>
International Shipments of Vaccines – Prequalified devices
## Vaccine Storage and Transport – Recommended Temperature Monitoring Devices for Storage and Transport of Vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>International transport</th>
<th>Primary vaccine store</th>
<th>Transport</th>
<th>Intermediate vaccine store</th>
<th>Transport</th>
<th>Service level</th>
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</thead>
<tbody>
<tr>
<td>Electronic shipping indicators</td>
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<tr>
<td>Vaccine cold chain monitor</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Vaccine vial monitor</td>
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<tr>
<td>Irreversible freeze indicator</td>
<td></td>
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<tr>
<td>Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options</td>
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<tr>
<td>Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers</td>
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<tr>
<td>Wall-mounted pen recording thermometer</td>
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<tr>
<td>User programmable temperature data loggers</td>
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<tr>
<td>30-day electronic refrigerator temperature logger</td>
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</tbody>
</table>
Vaccine Storage and Transport – Freeze Prevention in Vaccine Fridges

- **Freezing risk classification in vaccine refrigerators**
  - **Grade A, user-independent freeze protection (UIFP):** No intervention required by the user to ensure that the vaccines will not be exposed to freezing temperatures as defined earlier, whatever the position of the vaccine in the vaccine compartment.
  - **Grade B, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items to avoid vaccine freezing constitute one level of intervention by the user).
  - **Grade C, user-dependent freeze protection (UDFP):** Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring several levels of intervention (e.g., an absorption refrigerator not only requires the use of baskets, but also the adjustment of the wick).
Vaccine Injection devices – ISO Standards

• **Standards**
  
  – ISO 7864:1993
    Sterile hypodermic needles for single use
  
  – ISO 7886-1:1993
    Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
  
    Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps
  
  – ISO 7886-3:2005
    Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization
  
  – ISO 7886-4:2006
    Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature
Vaccine Injection devices – Risks of unsafe injections

- Injection safety issues are similar therapeutic/immunization
- People's confidence is critical for the success of immunization as well as therapeutic treatments that can be easily jeopardized
  - Especially for medical intervention on children
  - Fear of AEFI and increased demand for safety
- Large number of injections during campaigns require special attention
Vaccine Injection devices – Proposed solutions

- Improper use of equipment
  - Reuse
  - Recapping needles
  - Needle stick injuries
  - Use of AD syringes & RUP syringes
  - Use of AD/RUP/SIP syringes

- Unsafe collection of used equipment
  - Use of inadequate containers
  - Use of single use safety box

- Unsafe disposal (improper procedures)
  - Treatment of waste (disinfection)
  - Incineration or burying
  - Recycling of plastic
  - No "magic bullet"
  - In accordance with national policy
  - Proper incineration preferred
Vaccine Administration – AD syringes

- Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)
  - A feature that automatically activates upon administration of the intended fixed dose to prevent subsequent re-use of the syringe and needle
  - Activate and remains effective when injection is commenced
  - Activate and remains effective when 50% of the intended fixed dose has been delivered
  - Activated on completion of the delivery of the intended fixed dose
Vaccine Administration – AD syringes

Fixed needle

- Reduced dead space
- Scale with two marks only

AD mechanism

ISO definition of AD feature

- Automatically activated at start, middle or end of injection
- No additional action required
- No possibility to reuse syringe and needle after injection

Volumes: 0.05ml, 0.1ml, 0.25ml, 0.5ml
THANK YOU