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

PQS Categories	Description	# Products PQ 2009	# Products PQ 2010	# Products PQ 2011	# Products PQ 2012	# Products PQ 2013	# Products PQ 2014	# Products PQ 2015	# Products PQ 2016
E001	Cold rooms and related equipment	0	2	3	3	3	3	4	4
E002	Refrigerated trucks	Still under development							
E003	Refrigerators and freezers.	7	16	28	33	36	44	51	63
E004	Cold boxes and vaccine carriers.	1	32	32	34	37	39	41	42
E005	Coolant packs - water-packs	0	16	16	18	17	17	17	17
E006	Temperature monitoring devices.	9	10	11	17	22	24	31	32
E008	AD syringes	30	28	26	29	33	36	39	39
E010	Waste management: Safety boxes	9	10	10	10	10	11	12	12
E013	Therapeutic injection devices	37	48	61	72	80	84	89	89
	Total	93	162	187	216	238	258	284	298

International Shipments of Vaccines – Guidance 1

- 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

International Shipments of Vaccines – Guidance 2

- 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

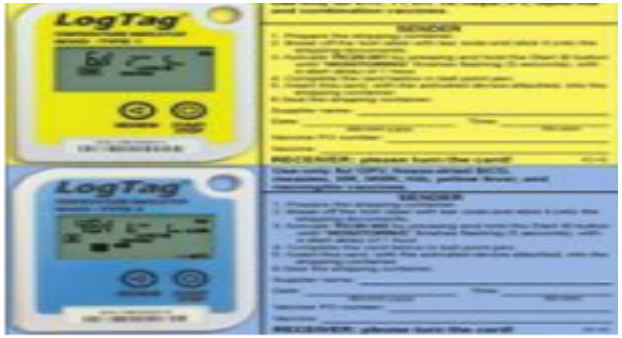
- Electronic shipping indicators-
  - single use pre-programmed electronic time-temperature loggers which accompany vaccines from the manufacturers warehouse to the receiving country's primary store.
  - They display the shipment's time-temperature exposure without the need for download onto a PC
- Cold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

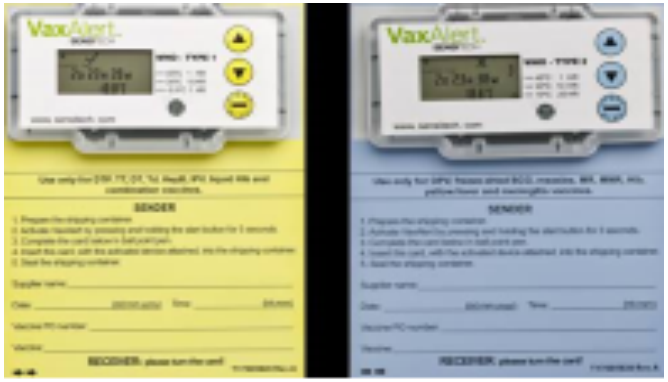
International Shipments of Vaccines –

Current types of vaccine packaging and alarm settings

Class	Type of vaccine	Ambient temperature	Minimum temperature allowed	Maximum temperature allowed
A	OPV	+43°C	no limit	+8°C
B	BCG Hib (freeze-dried) measles MR MMR meningococcal A&C yellow fever	+43°C	no limit	+30°C
C	DTP DTP–HepB DTP–Hib (liquid) DT	+43°C	+2°C	+30°C
	IPV HepB Hib (liquid) Td TT	-5°C	+2°C	+30°C

International Shipments of Vaccines – Prequalified devices





Vaccine Storage and Transport – Recommended Temperature Monitoring Devices for Storage and Transport of Vaccines

Description	International transport	Primary vaccine store	Transport	Intermediate vaccine store	Transport	Service level
Electronic shipping indicators						
Vaccine cold chain monitor						
Vaccine vial monitor						
Irreversible freeze indicator						
Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options						
Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers						
Wall-mounted pen recording thermometer						
User programmable temperature data loggers						
30-day electronic refrigerator temperature logger						

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
  - ISO 7886-2:1996
    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