Module 2
The vaccine cold chain
2.1 The Cold Chain

- The system used for storing vaccines in good condition.
- It is sometimes referred to as the vaccine supply chain, or the immunization supply chain.
- The cold chain consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration.
In order to maintain a reliable vaccine cold chain, the following key procedures must be observed:

- store vaccines and diluents within the required temperature range at all sites
- pack and transport vaccines to and from outreach sites according to recommended procedures
- keep vaccines and diluents within recommended cold chain conditions during immunization sessions
Temperature Requirements for Vaccines

- **Vaccine potency**: its ability to adequately protect the vaccinated patient, can diminish when the vaccine is exposed to inappropriate temperatures.
- Once lost, vaccine potency cannot be regained.
- To maintain quality, vaccines must be protected from temperature extremes.
- Vaccine quality is maintained using a cold chain that meets specific temperature requirements.
Vaccines According to Heat Sensitivity

More sensitive
- OPV
- MCV
- DTP
- BCG
- Hib
- DT
- TT
- Hep B

Less sensitive
Vaccines According to Freezing Sensitivity

More sensitive

- HepB
- Hib (liquid)
- D T P
- T d
- T T

Less sensitive
Vaccines According to Light Sensitivity

More sensitive

BCG

MCV

Rubella

Less sensitive
2.2. The cold chain at health centre

☐ Keep vaccines in appropriate vaccine refrigeration equipment.

☐ Use a temperature monitoring device to ensure temperatures remain between +2 °C and +8 °C.

☐ Transport vaccines to immunization sessions in a vaccine carrier, correctly packed, using coolant packs that have been properly prepared.

☐ During immunization sessions, fit a foam pad (if available) at the top of the vaccine carrier.
At the health facility, one person must have overall responsibility for managing the vaccine cold chain. A second person can fill in when the primary person is absent. Their responsibilities should include:

- checking and recording vaccine temperatures twice daily; typically in the morning and at the end of the session or day
- properly storing vaccines, diluents and water packs
- handling preventative maintenance of the cold chain equipment.

*All health workers in a facility should know how to monitor the cold chain and what to do if temperatures are out of range*
Refrigerators

A health facility refrigerator must never be packed solid - always leave plenty of space around the vaccines and diluents to allow air to circulate freely, and to make vaccine handling easier.
Figure 2.5 Three commonly used refrigerator types

Top opening:
- ice-lined mains electric, solar-battery
- or solar direct-drive

Vaccine storage compartment
(most models have baskets which MUST be used)

Freezer compartment
(on some models)
Front opening:
gas, kerosene or domestic mains
electric model
Cold boxes

A cold box is an insulated container that can be lined with water packs to keep vaccines and diluents in the required temperature range during transport or short-term storage.

Figure 2.6 Vaccine cold box
Vaccine carriers

- Vaccine carriers are smaller than cold boxes and easier to carry

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Water packs

☐ Water packs are flat, leak-proof plastic containers that can be filled with tap water. They are used to line the inside of the cold box or vaccine carrier.
Water packs can be used in any of the following ways:

- **frozen ice packs**, taken directly from a freezer at temperatures between −10 °C and −25 °C

- **conditioned ice packs** containing a mixture of water and ice at an initial temperature of about 0 °C

- **cool water packs**, containing liquid water at an initial temperature of +5 °C or less

- **warm water packs**, containing liquid water, initially at room temperature, between +18 °C and +24 °C.
Foam pads

A foam pad is a piece of soft spongelike material that fits precisely on top of the water packs inside a vaccine carrier while still permitting the lid of the vaccine carrier to fully close.
2.3 Temperature Monitoring Devices

❑ Vaccine vial monitors (VVMs) are the only temperature monitoring devices that routinely accompany vaccines throughout the entire supply chain.

❑ A VVM is a chemical indicator label attached to the vaccine container (vial, ampoule or dropper) by the vaccine manufacturer.

❑ As the container moves through the supply chain, the VVM records its cumulative heat exposure through a gradual change in colour.
**Figure 2.10** VVM showing colour change sequence and interpretation

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**Cumulative heat exposure**

- **VVM start colour**
  - The VVM start colour of the inner square is never pure-white, it is always slightly purple and begins lighter in colour than the outer circle. From this point forward, the inner square starts to darken in colour, until the temperature and/or duration of heat reaches a level which degrades the vaccine, at which time the VVM's discard point will be evident.

- **Discard point**
  - Beyond discard point. Square colour is darker than the outer circle.

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**USE THIS VACCINE**

**DO NOT USE THIS VACCINE INFORM YOUR SUPERVISOR**
How VVMs work

- Vaccine Vial Monitors (VVMs) are heat-sensitive chemicals applied to the vial label or the cap.
- VVMs show whether the vial has been exposed to excessive heat since leaving the manufacturing site.
- The VVM for vaccines with preservative (can be used for subsequent sessions) is on the label while the VVM for vaccines without preservative must be usually on the cap.
Figure 2.11 Location of VVMs on ampoules and vials
2.3 Temperature monitoring devices

Figure 2.12  30-day electronic temperature loggers

FridgeTag2™ with USB

LogTag® temperature recorder
Electronic freeze indicators

Figure 2.13 Electronic freeze indicators
Integrated digital thermometers

Figure 2.14 Integrated digital thermometer

Source: Dulas Solar
Stem thermometers

- Figure 2.15 Stem thermometer
- Figure 2.16 Dial thermometers – not recommended by WHO anymore
2.4 Monitoring cold chain temperatures

Figure 2.17 Vaccine refrigerator temperature monitoring chart (filled example)

Temperature monitoring chart for temperature logger devices

Cold room/refrigerator number: ILR # 1
Equipment model: MFR 123
Start date: 03 Oct 2015
Location: Erewan RC

Key: FI = freeze indicator (status OK or X)

| Raw | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|     | +8 | +7 | +6 | +5 | +4 | +3 | +2 | +1 | +0 | -1 | -2 | -3 | -4 | -5 | -6 | -7 | -8 | -9 | -10 | -11 | -12 | -13 | -14 | -15 | -16 | -17 | -18 | -19 | -20 | -21 | -22 | -23 | -24 |
| Raw | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

Fl (x or OK)

<+8 °C alarm
Once every 24 hours, enter high alarm status and maximum temperature recorded by the continuous temperature monitoring device.

Maximum °C
+7.5 | +6.5 | +6.3 | +6.1 | +5.9 | +5.7 | +5.5 | +5.3 | +5.1 | +4.9 | +4.7 | +4.5 | +4.3 | +4.1 | +3.9 | +3.7 | +3.5 | +3.3 | +3.1 | +2.9 | +2.7 | +2.5 | +2.3 | +2.1 | +1.9 | +1.7 | +1.5 | +1.3 | +1.1 | +0.9 | +0.7 |

B <+5 °C alarm
Once every 24 hours, enter low alarm status and maximum temperature recorded by the continuous temperature monitoring device.

Alarm or OK
OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK | OK |

Revised

Province: Jazir
District: District 9
Health centre: Erewan

Month: October
Year: 2015
Supervisor: AG

Remarks: Thermostat incorrectly adjusted by temporary health worker. Corrected on 12 Oct

Immunization in Practice: A practical guide for health staff – 2015 update (WHO)
Maintaining the correct temperature in cold boxes and vaccine carriers

- Place the correct number and type of properly conditioned ice packs or cool water packs in the cold box or vaccine carrier.
- If you are using conditioned ice packs you should put a thermometer in each cold box or vaccine carrier containing freeze-sensitive vaccines.
- Keep the cold box or vaccine carrier in the shade.
- Keep the lid tightly closed.
Maintaining the correct temperature in cold boxes and vaccine carriers

- Use the foam pad to hold opened vials at the top of the vaccine carrier during an immunization session; keep the hard carrier lid closed whenever possible.

- During the immunization session, vaccines must be kept at the recommended temperatures after opening. In particular, it is important to keep opened multi-dose vaccine vials that do not contain preservative - whether lyophilized or liquid - cooled at temperatures between +2 °C and +8 °C.
Maintaining the correct temperature in cold boxes and vaccine carriers

At the end of the immunization session, health workers should follow national policy in handling remaining vials. In general, this means:

- discarding all opened vials of vaccines that do not contain preservative; this includes all reconstituted vaccines and some liquid multidose vaccines

- checking the VVMs of all unopened vials and returning the unopened vials with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible
Maintaining the correct temperature in cold boxes and vaccine carriers

- where multi-dose vial policy is applied, check the VVMs of all opened vials that contain preservative and return those with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible. Use these vaccines first for the next immunization session.
2.5 Arranging vaccines inside cold chain equipment

- If vaccines or diluents are supplied in their original cartons, arrange the boxes so that there is at least a 2-centimetre space between stacks.

- Mark the cartons clearly and make sure the markings are visible when the door or lid is opened.
2.5 Arranging vaccines inside cold chain equipment

- If vaccines or diluents are supplied as individual containers (vials, ampoules or tubes), use a plastic tray, plastic box or other arrangement to store the vaccines in an orderly fashion.
2.5 Arranging vaccines inside cold chain equipment
2.5 Arranging vaccines inside cold chain equipment

- Wherever possible, store vaccines and diluents in a refrigerator that is reserved for this purpose only.

- If other heat-sensitive supplies, such as drugs, ointments, sera and samples, have to be stored in the refrigerator, label them clearly and keep them completely separate from the vaccines and diluents.

- Always arrange vaccines and diluents so that air can circulate freely; this also makes it easier to handle the vaccines.
Water Packs

OPV and MCV

BCG, Penta, Hepa B, Hib
DPT, TT, Diluents

Water packs

Open vials should be put in a box labelled "use first."
2.5 Arranging vaccines inside cold chain equipment

- Place vaccines with VVMs that show the most heat exposure (darker squares) in a separate container in the refrigerator, clearly marked “Heat-exposed vials - use first”.

- If there are other vaccines of the same type in the refrigerator, the vaccines with the darkest squares should always be used first even if the expiry date is later than the vaccines with the lighter squares.
2.5 Arranging vaccines inside cold chain equipment

DO arrange the vaccines in the health facility refrigerator like this:

Figure 2.18 Purpose-made tray for vials and ampoules

Source: Anthony Battersby
2.5 Arranging vaccines inside cold chain equipment

Never store food or drink in a vaccine refrigerator.

Do not open the door or lid unless it is essential to do so. Frequent opening raises the temperature inside the refrigerator.

If there is a freezer compartment, do not use it to store vaccines and diluents.
2.5 Arranging vaccines inside cold chain equipment

- Do not keep expired vaccines in the refrigerator.
- Do not keep vaccines with VVMs that have reached, or are beyond, their discard point.
2.5 Arranging vaccines inside cold chain equipment

☐ Do not keep reconstituted vaccines for more than six hours, or after the end of an immunization session.

☐ Discard all these items immediately according to your national guidelines.

☐ Refer any questions to your supervisor.
Specific rules for using top-opening refrigerators with baskets

The following rules apply to these refrigerators:

- Always store vaccines and diluents in the baskets provided. Never store them outside the baskets.

- If there is an internal lid on the freezer compartment and/or the refrigerator compartment, always replace it before closing the main lid.
Specific rules for using top-opening refrigerators with baskets

- Use the bottom baskets to store measles, MR, MMR, BCG, OPV, yellow fever, Japanese encephalitis and/or any other vaccines not damaged by freezing.
Specific rules for using top-opening refrigerators with baskets

- Use the top baskets to store products for immediate use and to store diluents, DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, HPV, rotavirus and/or any other freeze-sensitive vaccines.

- Never put freeze-sensitive vaccines in the bottom baskets. In some models there is a risk of freezing in these areas.
Specific rules for using top-opening refrigerators with baskets

☐ Store the diluents close to the freeze-dried vaccine with which they were supplied.

☐ If this is not possible, make sure the diluents are clearly labelled so they can be easily identified to their matching vaccine.
Water Packs

For Freezing

Water Packs
Figure 2.22 Vaccine and diluent arrangement in a top-opening refrigerator with baskets

- **FREEZER COMPARTMENT** (some models): KEEP LID CLOSED
- **ICE-BANK COMPARTMENT** (some solar direct-drive models): DO NOT remove ice packs

**DO NOT** store vaccines outside the baskets provided

- **TOP BASKETS**: Store freeze-sensitive vaccines and diluents and USE FIRST items
- **BOTTOM BASKETS**: Store OPV and freeze-dried vaccines (BCG, measles, MMR, JE, YF, meningococcal A and any vaccines not freeze-sensitive)

**USE FIRST**: Box containing vaccines with darker VVMs

**USE FIRST**: Box containing opened vials

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Specific rules for using top-opening refrigerators with baskets

- In baskets with thermometer - vaccine safe
- No baskets, no thermometer - vaccine at risk
Preparing ice packs and cool water packs

Filling and checking water packs

☐ New water packs are supplied empty and must be filled before use. All water packs should be checked for leaks. Proceed as follows:

1. New empty water packs: Fill each pack with clean water, up to the fill line. Do not over-fill; leave a little air space at the top. Fix the cap on tightly.
Preparing ice packs and cool water packs

2. Used water packs: It is not necessary to empty and refill water packs unless they have leaked. If there is a leak, top up the water and make sure the cap is fixed securely.

3. Before use: Hold each pack upside down and squeeze it to make sure it does not leak. If the pack has been damaged, discard it.
Freezing ice packs

- Depending on a range of factors, it can take 24 hours or more to fully freeze a batch of ice packs.

- Always follow the manufacturer’s instructions and never overload the freezing compartment. Put packs in the freezer, arranged upright or on their sides so that the surface is touching the evaporator plate. If there is a door or lid to the compartment, make sure it is properly closed.
Conditioning frozen ice packs

1. Remove the required number of frozen ice packs from the freezer compartment. The number and type of pack required is shown on the inside of the lid of the cold box or vaccine carrier.

2. Lay the frozen ice packs on a work surface in a single layer leaving gaps of about 5 cm between packs.

3. Wait until all packs are properly conditioned – there must be liquid water inside every pack and the ice-cores should move inside the packs when shaken (see Figure 2.23). This will take at least 30–45 minutes in hot weather and much longer in cooler conditions – from 90 to 120 minutes at +20 °C.

Figure 2.23 Checking that an ice pack is properly conditioned
Conditioning frozen ice packs

Note: If a cool water pack strategy has been adopted for outreach operations, one or more frozen ice packs must be brought to the session to ensure that opened multi-dose vaccine vials are kept at recommended temperatures. It is particularly important that vaccines that do not contain preservative – whether lyophilized or liquid – are kept at temperatures between +2 °C and +8 °C during the session.
Packing vaccines in cold boxes and vaccine carriers

Figure 2.24 Arranging a vaccine carrier

1. Prepare ice packs for freezing
   - Fill the ice pack with water to mark. Check water level before every use. Do NOT add salt to this water.
   - Fit the stopper and screw on the cap tightly.
   - Make sure the ice pack does not leak.
   - Wipe the ice pack dry and place in the deep freezer.
Packing vaccines in cold boxes and vaccine carriers

2. Condition frozen ice packs

- Place frozen ice packs in the open till they “sweat” (some condensation or droplets of water).
- Check if an ice pack has been conditioned by shaking it and listening for water.

*Unconditioned ice packs may damage freeze sensitive vaccines.*
Packing vaccines in cold boxes and vaccine carriers

3 Pack the vaccine carrier

- Place four conditioned ice packs against the sides of the carrier.
- Place the plastic bag containing all vaccines and diluents in the centre of the carrier.
Packing vaccines in cold boxes and vaccine carriers

4 Remember

- Collect vaccines in the carrier on the session day (note that vaccine carriers may not store vaccines effectively beyond 12 hours).
- Do not drop or sit on the vaccine carrier.
- Do not leave in sunlight. Keep in shade.
- Do not leave the lid open once packed.
2.6 Basic maintenance of cold chain equipment

Defrosting vaccine refrigerators

☐ Remove all the vaccines and transfer them to another refrigerator or to a cold box or vaccine carrier lined with conditioned ice packs.

☐ Switch off the electrical supply for a mains or solar-battery refrigerator. Turn off the gas supply for a gas refrigerator. Extinguish the flame for a kerosene refrigerator.
2.6 Basic maintenance of cold chain equipment

☐ Leave the door open and wait for the ice to melt. Never try to remove the ice with a knife or ice pick; this can permanently damage the refrigerator.

☐ A pan of boiling water can be placed inside and the door closed.

☐ Clean the inside of the refrigerator and door seal with a clean damp cloth.
2.6 Basic maintenance of cold chain equipment

- Re-start the refrigerator. Do not adjust the thermostat.
- When the temperature in the main section falls to +8 °C or lower (but not less than +2 °C), arrange the vaccines, diluents and water packs in their appropriate places.
2.6 Basic maintenance of cold chain equipment

If a refrigerator needs to be defrosted more than once a month, check for these common problems:

- Staff are opening the door too often (more than three times daily).
- The door is not closing properly.
- The door seal needs to be replaced.
Managing vaccine refrigerator breakdowns

Protecting the vaccines

Move the vaccines to other cold chain equipment until the refrigerator is repaired. For a problem that can be solved quickly, a cold box or vaccine carrier lined with conditioned ice packs can be used for temporary storage. For a problem that might take longer to solve, another refrigerator is needed. Always keep a freezer indicator with the freeze-sensitive vaccines.
Maintaining cold boxes and vaccine carriers

- Vaccine carriers and cold boxes must be dried well after use, with their lids propped open. If they are left wet with their lids closed, they will become mouldy. Mould and damp can affect the seal of the cold boxes and vaccine carriers and may contaminate the vaccines.
- If possible, store cold boxes and vaccine carriers with the lids open.
Maintaining cold boxes and vaccine carriers

❑ Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. This exposes the insulation and increases the risk of heat exposure to the vaccines inside.

❑ If a cold box or vaccine carrier wall has a small crack, use adhesive tape to cover it until an undamaged container becomes available.
THANK YOU!!!