

Cold Chain

Introduction

Cold chain management includes all of the means used to ensure a constant temperature (between +2°C and +8°C) for a product that is not heat stable (such as vaccines, serums, tests, etc.), from the time it is manufactured until the time it is used.

It involves the equipment and people needed to keep vaccines at the correct temperature (between +2°C to +8°C) during transport and storage from the time they are manufactured up until they are administered.

The cold chain must never be broken. Vaccines are sensitive to heat and extreme cold and must be kept at the correct temperature at all times.

Health workers at all levels are often responsible for maintaining the cold chain while vaccines are stored in the vaccine stores at the province and county levels, or while they are being transported to township and villages, and while they are being used during immunization sessions or rounds. More and more often it is becoming the logistician's responsibility to manage the cold chain as a part of the supply chain.

The Logistics staff must be trained to both use and manage these materials. They must acquire knowledge about the cold chain, must develop thorough work techniques, specifically with respect to maintenance, and must be stable in order to ensure better follow-up. This includes having appropriate efficient logistics mechanisms to manage shipping, fuel, spare parts etc. Without training, the program will be seriously compromised and put at risk.

Definition

Cold Chain: a network of refrigerators, cold stores, freezers and cold boxes organized and maintained so that vaccines are kept at the right temperature to remain potent during vaccine transportation, storage and distribution from factory to the point of use.

(Taken from Mid Level Management Course for EPI Managers, Module 8: Cold Chain Management, World Health Organization, 2004)

Evaluation of Existing Means

The system for guaranteeing vaccines quality is generally referred to as "cold chain". Cold chain management has two categories: managing equipment and managing people.

Evaluations of existing means revealed that some countries needed to improve their systems of vaccines management. Although there were many positive aspects to the functioning of the cold chain, the following weaknesses were observed:

- frequent breakdowns in cold chain (sometimes for a long time) because of the lack of fuel, spare parts and back-up energy source;
- lack of planning for maintenance and cold chain rehabilitation;
- incorrect use of the Vaccines Vial Monitor (VVM) as a management tool; and
- Lack of planning for emergencies resulting in organizations not having effective cold chain systems during responses.

These problems slow down improvement in routine vaccination services and hinder efforts to eliminate and eradicate disease. To solve these problems, it is necessary to:

- identify problems in the cold chain and their causes;
- undertake specific actions to remove these causes; and
- Strengthen management systems to prevent recurrence of the same or similar problems.

(Taken from Mid Level Management Course for EPI Managers, Module 8: Cold Chain Management, World Health Organization, 2004)

Active Cold Chain (Materials for producing cold)

These include active thermal systems that do not use any phase change materials (PCM) such as water/ice or dry ice. These systems use mechanical or electric systems powered by an energy source, combined by thermostatic control to maintain proper product temperatures.

The equipment used in active cold chain is split into two categories as follows:

- compression refrigerators/freezers;
- Absorption refrigerators/freezers.

Adapted from Rushton, A. et.al.: "Handbook of Logistics & Distribution Management", 1998, Kogan Page Limited, London.

Compression Equipment

These are the models most commonly used. They run solely on electricity (220V / 110V or on a battery). These models use little energy, require little maintenance, produce significant amounts of cold quickly and are easy to repair. They are equipped with a thermostat for setting the desired temperature. Some models require only eight hours of energy per day ("ice lined refrigerators").

Solar models are of the compression type (source of energy: solar panels, battery). They are expensive and maintaining them requires specialized knowledge.

Note: These models may only be equipped with an HFC 134a coolant which is not harmful for the environment (the ozone layer). This is valid only for compression models since absorption models function with a water/ammonia/helium (or hydrogen*) mixture.

(*) Cannot be purchased locally given the risk that the hydrogen will explode.

Absorption models

The energy sources are: kerosene, gas, electricity (heating resistor). They use more energy and require more maintenance. They produce less cold and are slower. However, they are suitable for situations where electricity is not available or reliable.

Since the cooling circuit is closed, it is not possible to fill it with gas or repair it if there is a leak. However, these models are very reliable.

Models used to store vaccines are particularly well insulated and equipped with a temperature stabilizing device, except for the kerosene model which does not have a thermostat (the best known manufacturers are Sibir and Electrolux). They are used extensively for the Extended Vaccinations Programs (EVP).

Domestic absorption models are generally insulated less well and it is occasionally difficult to maintain a low temperature for storing vaccines, particularly when the external temperature is high (higher than 32°C).

The efficiency of the models that run on oil depends on the quality of the fuel. Decanting and filtering are often required. A kit is available to modify certain burners, in order to improve operating efficiency, despite oil of inferior quality.

Passive Cold Chain (Shipping/storage materials)

These include passive thermal systems that commonly use phase change materials (PCM) such as water/ice or dry ice. These shipping systems are the most basic and cost effective. Some of the basic systems in use are as follows:

- freezers for province, county and sometimes at the township level;
- Refrigerators and, in some areas, the new water-jacket refrigerators for province, county and township levels.

Some villages do not have access to a refrigerator for vaccine storage and therefore use:

- cold/cool Boxes at all levels for transporting vaccines;
- vaccine carriers to store vaccines during the immunization session or round;
- isothermal packaging/control materials like paper to wrap the vaccines up when using a vaccine carrier;
- ice packs or ice, as a last resort, to keep the vaccines at a temperature between +2°C and 8°C;
- a thermometer to measure the temperature inside the vaccine refrigerator and cold boxes; and
- A chart to record the day and time of the temperature of the vaccine refrigerator. The chart should be used to record the temperature two times a day (morning and night).

See Equipments for visuals.

Logistics

A rapid logistics evaluation can determine the status of materials and vaccines management at field level, along with the status of the vaccine distribution strategy. Based on this information, and taking into account the geography of the country, Expanded Program on Immunization (EPI) managers can decide which option to use.

Whatever the chosen immunization strategies, the cold chain structure is based on two options: fast cold chain (see active cold chain) and slow cold chain (see passive cold chain).

(Taken from Mid Level Management Course for EPI Managers, Module 8: Cold Chain Management, World Health Organization, 2004.)

Example: See Logistics requirements for a vaccination site.

(Source: Médecins Sans Frontières)

Some of the logistics activities related to cold chain management are:

- shipping/customs clearance/storage;
- vaccine management;
- insulated shipping containers;
- Shipping/storage material (see passive cold chain paragraph).

Shipping, Customs Clearance and Storage

Customs

Regarding the customs clearance of the vaccines, the same procedures as described in the Customs topic apply, but with additional specific requirements linked to vaccine management. Note that requirements vary from country to country.

The first step in the customs clearance process, is contacting the following entities to obtain or verify the import procedures:

- National regulatory authorities (NRA) or head of customs in the destination country. To be cleared, the vaccines must have received marketing authorization and a release certificate from the national regulatory authority;
- WHO office: vaccines must meet WHO recommended norms and standards (pre-qualification process); and
- Local Ministry of Health (MOH): depending on country specific requirements, the MOH may issue a letter approving the shipment.

As reference, usually the general steps are:

- submission of vaccine shipping documents (as soon as they are received) with a request to customs authority for the provisional clearance of shipment to the nominated C&F agent;
- C&F agent immediately processes the shipping documents as per established rules and regulations of government and contacts customs and airlines to coordinate the arrival, transport, checking and safe storage of the vaccines;
- continuous contact is maintained well in advance with the concerned airlines to get accurate and updated information of the flight arrivals of the shipments;
- once the flight arrives, immediate action is taken to release and take delivery of the vaccine shipment and to safely transport the vaccines to the cold storage locations;
- C&F agent checks the cold-chain monitor(s) and other mechanism (if necessary) to identify and reconfirm that the vaccines arrived in good condition before removing the shipment from the airport;
- irrespective of the condition of the vaccines at the time of clearance, the C&F agent clears the vaccines and delivers as per regular procedures;
- the C&F agent informs the concerned official(s) in a timely manner and arranges for the cold room and the required staff to be ready and available to receive/store the vaccines;

- there should be a system in place to arrange to open the cold room and liaise/contact with the store keeper/cold room staff at any time (24-hours/day, including weekends and holidays);
- in the event of emergencies or unplanned shipments, if the cold room is inaccessible, the C&F agent is expected to arrange safe and appropriate storage of vaccines at the airport cold room or alternative location, ensuring proper temperature for storage;
- under no circumstances can any vaccine be left unattended, or outside of the cold room in an open space;
- unannounced shipments are cleared in time, like all other shipments;
- a reliable transport system including a refrigerated/insulated van should be made available at all times for effective transportation and delivery of the vaccines; and
- In emergencies, the use of charter flights is very common. There are separate rules, regulations, systems and procedures for clearance of charter flights with vaccines including obtaining special permission for landing, fly over etc. and various No objection certificates (NOCs) from Ministry of Civil Aviation, etc (Reference “UNICEF”).

Shipping

This involves:

- Cool Box – Vaccine Carrier
- Isothermal Packaging
- Control Materials
- Monitoring Means

All shipping documents for vaccine shipments should be sent in advance of arrival of shipment. The number of days will be determined by the destination country rules. This requirement has been established to facilitate the pre-customs formalities for clearance of vaccines to ensure prompt clearance of the heat or cold sensitive items upon arrival. Some countries have an exceptional early release procedure pending document processing during emergencies.

Documents that accompany shipments

The following original documents must accompany the consignment when it is shipped, and a copy of these must also be placed in the box numbered “one”:

- airway bill;
- supplier’s invoice;
- packing list;
- lot release certificate issued by the national regulatory authority of the country of manufacture for each lot of vaccine supplied; and
- Any other documents, certificates or instructions specified in the individual contract.

The shipping carton containing the documents should be clearly labeled with the words “Containing vaccine shipping documentation”.

Due to the sensitive nature of vaccines, shipments are handled with utmost diligence and special care. Vaccines are mostly transported by air.

The following information shall be stated on the airway bill:

- consignee’s name, address and telephone number;
- purchase order reference;
- consignee’s requisition reference;
- type of vaccine and quantity;
- instructions to: “Telephone consignee upon arrival (repeat telephone number)”; and
- Handling information: “Medicines – Vaccine – For human use – Highly perishable – Not to be delayed.”

For all vaccines other than oral polio vaccine (OPV), the following instruction should be stated in the AWB: “Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2°C to +8°C (i.e., +35°F to +50°F)”. For OPV, the following instruction should be stated in the AWB: “Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15°C to -25°C (i.e., +5°F to -13°F).”

Airlines web online tracking is checked before the arrival of every vaccines shipment to see if there is any change in schedule. Constant touch with airlines and customs and forwarding agents is maintained.

Storage

After arrival vaccines are cleared and immediately offloaded from the aircraft and directly loaded onto trucks for further transportation to the cold storage facility. Delivery of vaccines at the cold storage is strictly monitored to ensure maintenance of the cold chain in an appropriate manner. Some countries have special requirements for vaccines. There is therefore no standard clearing process but generally the following will apply.

Vaccine management

- The vaccines must be kept at the correct temperature when being transported.

Insulated shipping containers

Insulated shipping containers are a type of packaging used to ship temperature sensitive products such as foods, pharmaceuticals, and chemicals. They are used as part of a cold chain to help maintain product quality or condition.

An insulated shipping container might be constructed of:

- a vacuum flask similar to a "thermos" bottle;
- fabricated thermal blankets or liners;
- molded expanded polystyrene foam, similar to a cooler;
- other molded foams such as polyurethane, etc;
- sheets of foamed plastics;
- reflective materials;
- bubble wrap or other gas filled panels; and
- Other packaging materials and structures.

Some are designed for single use while others are returnable for reuse. Some empty containers are sent to the shipper disassembled or “knocked down”, assembled and used, then knocked down again for easier return shipment.

Insulated shipping containers are part of a comprehensive cold chain which controls and documents the temperature of a product through its entire distribution cycle. The containers may be used with a refrigerant or coolant such as:

- dry ice
- gel packs (often formulated for specific temperature ranges)

Some products (such as frozen meat) have sufficient thermal mass to contribute to the temperature control; etc

A temperature data logger is often enclosed to monitor the temperature inside the container for its entire shipment.

Labels and appropriate documentation (internal and external) are usually required.

Personnel throughout the cold chain need to be aware of the special handling and documentation required for some controlled shipments. With some regulated products, complete documentation is required.

Installation, Care and Maintenance

Installation – Points to note

Respecting certain parameters concerning position helps the refrigerator function well:

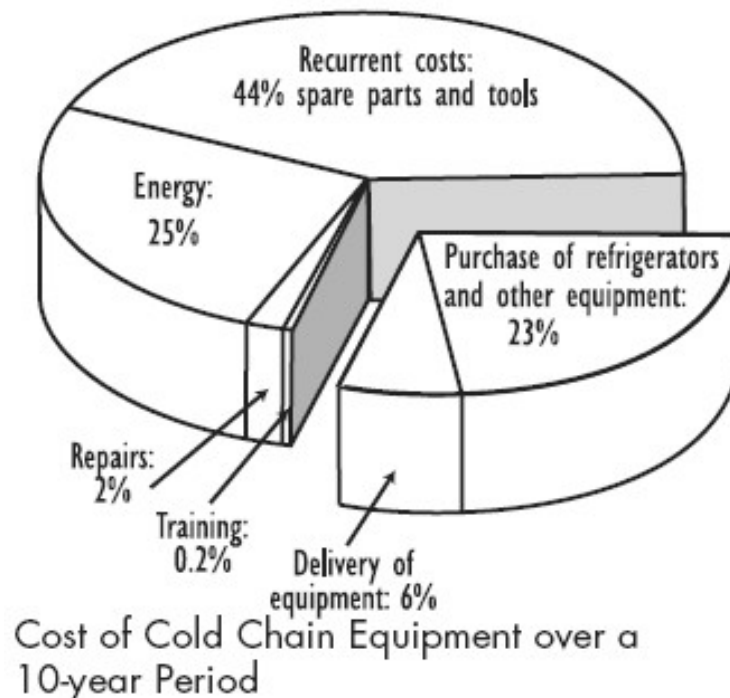
- out of the sun and away from any source of heat;

- in a well aerated area, cool if possible, but not ventilated (risk that the flame will be blown out in the case of a model running on oil or gas);
- with a space of 30 to 40 cm around the equipment in order to allow air to circulate and facilitate maintenance;
- placed on wedges for protection against humidity; and
- Installed horizontally (absorption models) to ensure good circulation of the cooling gas. Use a plumb line or an air bubble level.

Care/Maintenance – Points to note

- Maintenance is essential for ensuring that the equipment runs well, but having trained, conscientious and stable staff is the best guarantee of this.
- A minimum amount of spare parts (glass, wicks, etc.) must be available. In the case of maintenance and small repairs, the staff must be specially trained; in the case of major repairs, a refrigeration technician is required.
- Storage: specific rules apply depending on the type of equipment (chest or front opening) and the products to be stored in it.

To simplify maintenance and repair, cold chain equipment managers and donors are advised to procure the same types and models of equipment. The costs of spare parts, tools, repairs, and fuel to run the equipment must not be overlooked during budget preparation. As the pie chart shows, these costs are much more significant over a ten-year period than the initial cost to purchase cold chain equipment.



Distribution

From a logistics point of view, the same principles of distribution apply as in general logistics distribution. These principles are covered in the Distribution topic with the exception of the use of specialized carriers and containers as discussed in this topic. The distribution of cold chain should be built into the organizational distribution plan to maximize on the limited transport facilities available during emergencies.

The logistician must pay attention to the following in relation to cold chain:

Vaccine Arrival

Every international shipment of vaccines from a manufacturer should include a blank vaccine arrival report (VAR) form, as shown on the following page. When the shipment arrives, the individual responsible for monitoring vaccine arrivals and storage fills in the VAR and gives a copy to the local office of the procuring agency. The report documents the condition of the shipment and the quantities received, and it confirms that all other necessary documentation is included. If problems occur, the VAR can be the basis for initiating corrective action or making claims.

Vaccine Arrival Report (WHO/UNICEF)

The logistics function must avoid:

- shipment of vaccines by way of airports that lack cold rooms;
- consignments to the wrong party;
- shipment of the wrong vial sizes;
- shipment of the wrong quantity of vaccines and diluents;
- shipment of vaccines that are due to expire soon;
- arrival of vaccines on weekends or holidays;
- shipment of vaccines without:
 - advance notification
 - sufficient icepacks
 - cold chain monitors
 - documentation needed for customs clearance

(Taken from Immunization Essentials – A Practical Field Guide, USAID, 2003)

The organization of supply within a country is an integral part of the overall cold chain system, and should be properly planned and executed. There are two types of supply procedures:

- vaccines and other supplies to be collected by lower level institutions; and
- Supplies to be delivered to the lower level institutions.

See Organization of Vaccine supply for details.

Temperature Control

Some vaccines are very resistant to heat and are shipped from the manufacturer without insulation. They are, however, damaged by temperatures above +48°C. A special device is therefore used to monitor temperatures during shipment. One indicator is included with each shipment of minimum doses. The shipping indicator should be kept with vaccines if they have to be stored outside the cold chain.

In cold climates, vaccines should be protected from freezing during transport. They should therefore be packed with a cold-chain monitor and Freeze Watch TM, according to the procedures. To avoid damage to the vaccines the staff must know how temperatures are monitored and understand how to interpret temperature readings (indexes).

See some Tools for Monitoring Temperature.

Example: Table 2: Recommended temperature ranges

Vaccines	Stages of the cold chain	Maximum temperatures	Minimum temperatures
OPV, BCG, measles, yellow fever	All	+ 8°C	-20°C
Hepatitis B, DTP	All	+ 8°C	+ 2°C
DT, TT	Transport	+ 40°C	+ 2°C
DT, TT	Storage	+ 8°C	+ 2°C
Diluents	Transport	Ambient	+ 2°C
Diluents	Storage	Ambient	+ 2°C
Diluents	Point of Use	+ 8°C	+ 2°C

To retain maximum potency a vaccine should be kept in its safe temperature range.

Conclusion

Trained and experienced logisticians are critical to the effective management of cold chain. Because of the perishable nature of the product, good knowledge of cold chain, close monitoring, timely movement and appropriate storage is highly recommended to minimize risk exposure, avoid wastage and therefore be cost effective and reach the aim of properly vaccine the target population.