

Cold room temperature mapping studies

A cold room temperature mapping study establishes the temperature distribution in cold rooms – the largest vaccine storage equipment within a country's cold chain, generally used at central or subnational levels to store large quantities of vaccines. As stated in the WHO Vaccine Management Handbook, in "How to monitor temperatures in the vaccine supply chain" [1], countries should not accept a new cold room or freezer room from an installer until it has been fully mapped as part of the commissioning procedure. Furthermore, vaccines should not be stored in the room until the temperature mapping exercise has been completed and the results have been analysed to identify and address performance gaps. Cold room mapping is also valuable for existing cold rooms after a major repair, or for compliance control.

Data collected in a temperature mapping study can provide evidence of whether vaccines can be stored safely in the equipment according to the WHO recommended range of temperatures; the mapping study can also provide valuable information to guide the setup of sensors for a routine temperature monitoring system (e.g. the number and locations of sensors in the cold room)

This evidence brief provides supply chain managers in low- and middle-income countries with examples of results of temperature mapping studies conducted in an existing cold room to control compliance, and in two newly-installed cold rooms where performance gaps were identified and addressed before vaccine was stored.



Cold rooms at central level where large quantities of costly vaccines are stored
Credit: Adama Sawadogo

The need for a temperature mapping study of cold rooms

Ensuring that all areas of a cold room are maintaining optimal temperatures for vaccine storage is critical to prevent exposure of vaccines to temperatures outside the recommended range.

The WHO technical supplement on temperature mapping of storage areas [2] establishes requirements for mapping the storage and transport of time- and temperature-sensitive pharmaceutical products (TTSPPs), including vaccines. These requirements include:

- + All new temperature-controlled storage areas must be temperature-mapped as part of a fully documented verification process, before the installation is commissioned and handed over by the installer. Until this has been done, it is not safe to store TTSPPs in such storage areas.
- + Subsequent mapping exercises must also be carried out on a periodic basis – for example, every three years – in order to demonstrate continuing compliance. Mapping should also be carried out whenever significant modifications are made to the

storage facility. Examples include changes in the pattern of use that may increase loading or affect air circulation, or changes to the refrigeration equipment, such as an alteration to the set point. It may be necessary to do a remapping exercise whenever an analysis of temperature or humidity monitoring records shows unexplained variability outside the normal operating limits.

- + All mapping exercises should be fully documented to demonstrate compliance to management, clients and the regulatory authorities.

Implementation of the mapping study

The WHO technical supplement on temperature mapping of storage areas [2] outlines guidance for conducting a temperature mapping study in a storage area. In the field, implementing cold room mapping is a relatively new activity in immunization programmes in low- and middle-income countries. Effective Vaccine Management assessments completed in 87 countries across all six WHO regions from 2010 to 2015 [3] show that only 31% of countries completed a temperature mapping study at the central level and 19% at subnational levels.

Different tools are available to implement a temperature mapping study in the cold-chain equipment; however, many are expensive and require experienced staff for their use. The WHO-UNICEF Immunization Supply Chain and Logistics Hub (WHO-UNICEF Hub) has undertaken the development of a step-by-step temperature mapping guide and software to provide countries with a tool to perform mapping studies of their cold-chain equipment [4]. The tool has been piloted, adjusted and fine-tuned, based on field tests and feedback.

The four major steps in this mapping tool [4] involve:

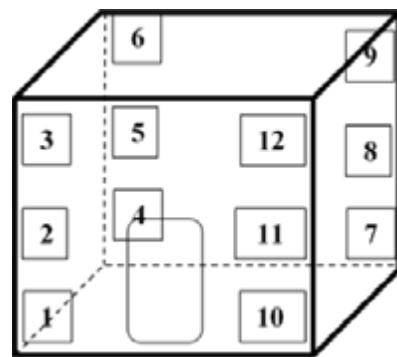
1. Deciding when to perform temperature mapping.
2. Placing an appropriate number of sensors in different areas – particularly areas that may go above or below the specified safe temperature ranges – and record the temperatures, on a specified interval, continuously for a period of at least 48 hours.

The tool guidance document [3] recommends placing:

- + 12 sensors (numbered 1 to 12) in fixed positions (in four corners and at three levels as illustrated in the cold room sketch below)
- + up to eight optional sensors (numbered 13 to 20) can be placed on the shelves and are generally placed wherever there may be some risk zones inside the equipment to be temperature mapped;

FIGURE 1.

Sketch of fixed sensors set up in a cold room



- + a further sensor (numbered 21) should be placed immediately outside the equipment at a mid-height of the equipment to measure ambient temperature.
- 3. Reading and transferring recorded temperatures (minimum, maximum and mean kinetic¹) to a three-dimensional sketch of the storage equipment to be temperature mapped, and identifying areas where vaccines and thermosensitive pharmaceutical products should not be stored.
- 4. Taking action to reduce the volume and areas where vaccines or pharmaceuticals may be at risk.

¹ Mean kinetic temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods. MKT is widely used in the pharmaceutical industry.

Temperature mapping studies offer solutions

Data collected in a temperature mapping study provide essential evidence on whether temperatures in the cold room are within the recommended temperature ranges to store the vaccines; they can also help to:

- + determine the best arrangement of the vaccines in a cold room;
- + identify performance gaps of the cold room to be addressed; and
- + inform the setup of sensors for routine monitoring in the cold room.

Below are presented results from three case studies of temperature mapping in the cold rooms of a country. Case study 1 presents results of the study in an existing cold room for compliance control; case studies 2 and 3 present results of studies in two newly-installed cold rooms, before the vaccine is stored.

Case study 1: Temperature mapping study in an existing cold room

Figure 2 shows an example of the profile of the temperature readings measured by two of the 20 individual sensors (1 and 8) placed in the cold room.

The temperature readings remain within the recommended ranges for vaccines storage (+2°C to +8°C) for the period of the study (~55 hours).

Profile of temperatures measured by sensors 1 and 8 in the cold room

FIGURE 2.

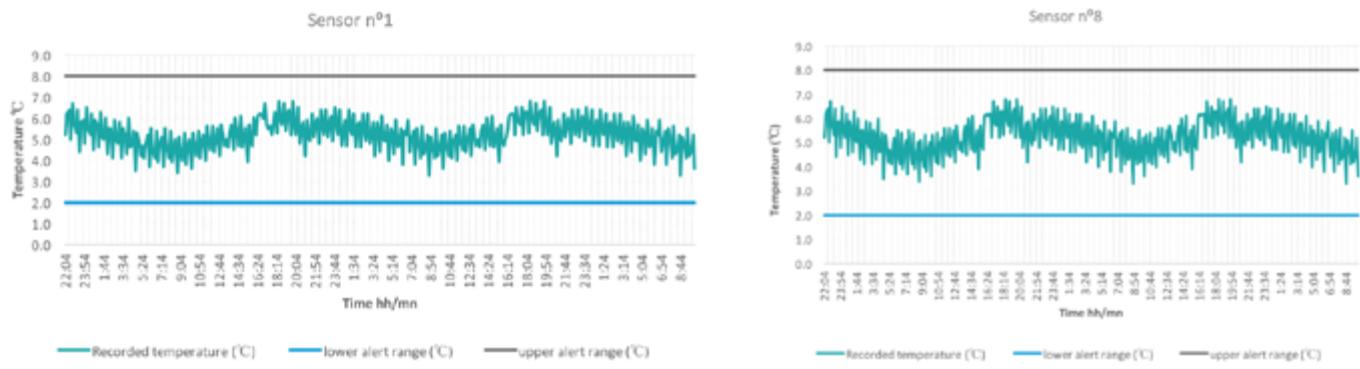
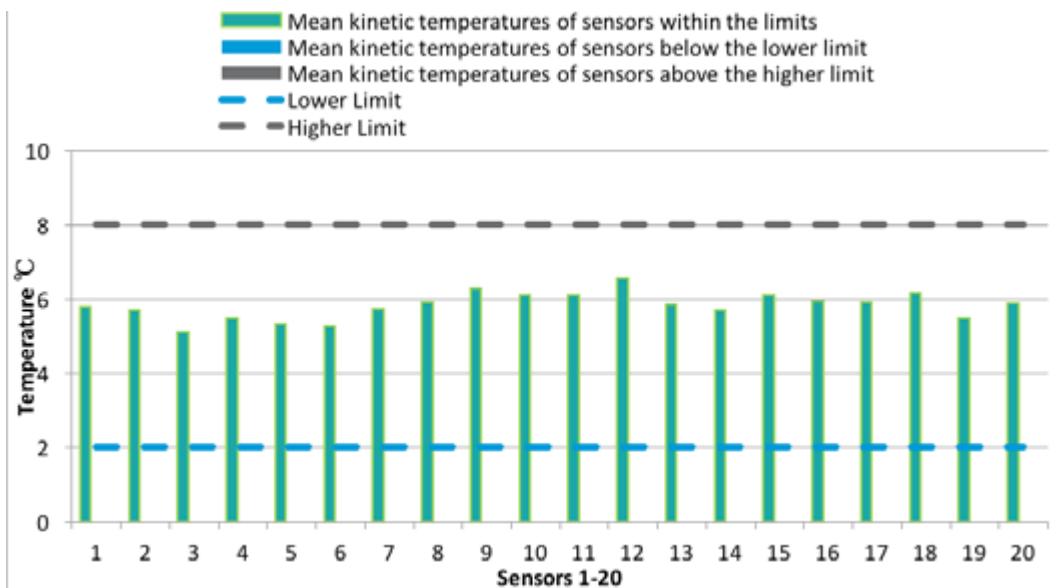


Figure 3 shows the mean kinetic temperature (MKT) profile for all 20 sensors in the cold room.

FIGURE 3.

Mean kinetic temperatures for all 20 sensors in the cold room



The MKTs for all locations remain within the recommended ranges to store the vaccines (+2°C to +8°C).

The results of the temperature mapping study in this cold room show evidence of compliance with the recommended range of temperatures (+2°C to +8°C) acceptable to safely store the EPI vaccines.

Case study 2: Temperature mapping study in a cold room newly installed

Figure 4 shows examples of the profiles of temperature readings measured by two of the 20 individual sensors (3 and 11) placed in the cold room for the period of the study (~67 hours). When compared with the

recommended range for the vaccine storage (+2°C to +8°C) the temperatures measured show a shifted trend, as illustrated in the examples below for sensors numbers 3 and 11.

FIGURE 4

Profiles of temperatures measured by sensors 3 and 11 in the cold room during outreach sessions

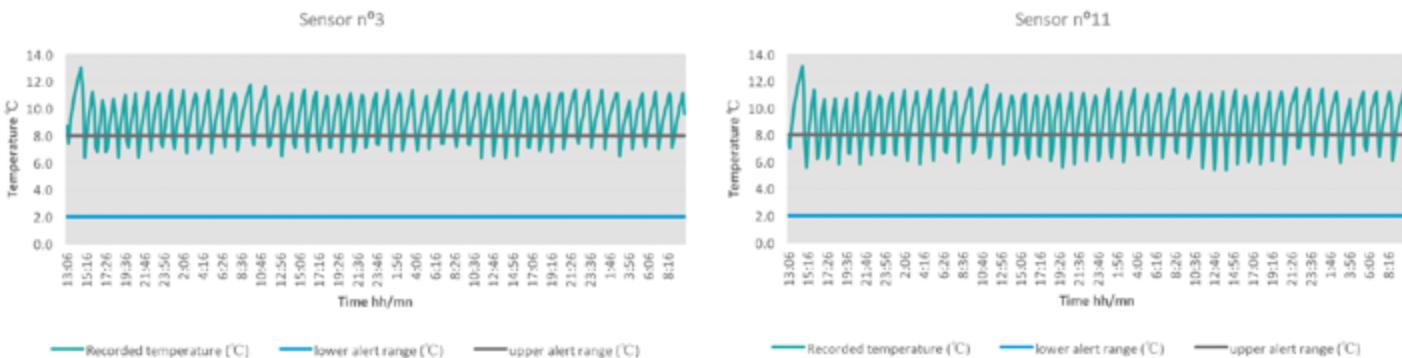


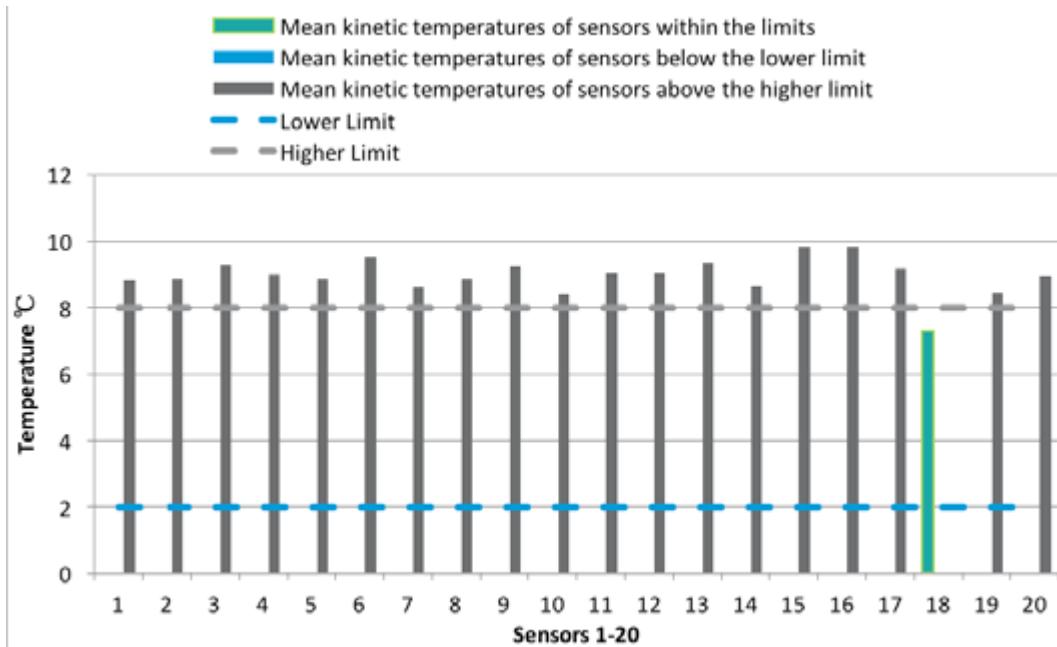
Figure 5 below shows the MKTs for all 20 sensors in the cold room.

The graph shows that only the MKT of sensor number 18 was between +2°C and +8°C; in the setup of the sensors in the cold room, sensor number 18 was one located

directly facing the operating cooling unit. The MKT for all the other sensors in the cold room was found higher than 8°C; such a temperature distribution in the cold room is not acceptable for storing the vaccines. There was thus a performance gap that needed to be addressed.

FIGURE 5.

Mean kinetic temperatures for all 20 sensors in the cold room



Actions to address the performance gap

The analysis of the results led to the adjustment of the refrigeration unit controller settings as follows: the controller was set to +2°C with a differential of 5°C, which meant the compressor was programmed to stop when the temperature in the cold room was +2°C and to restart when the temperature reached +7°C. The photo to the right shows the refrigeration unit and the technician reading the guide to adjust the controller settings.

The temperature mapping was conducted again in the cold room after the adjustment of the controller settings.

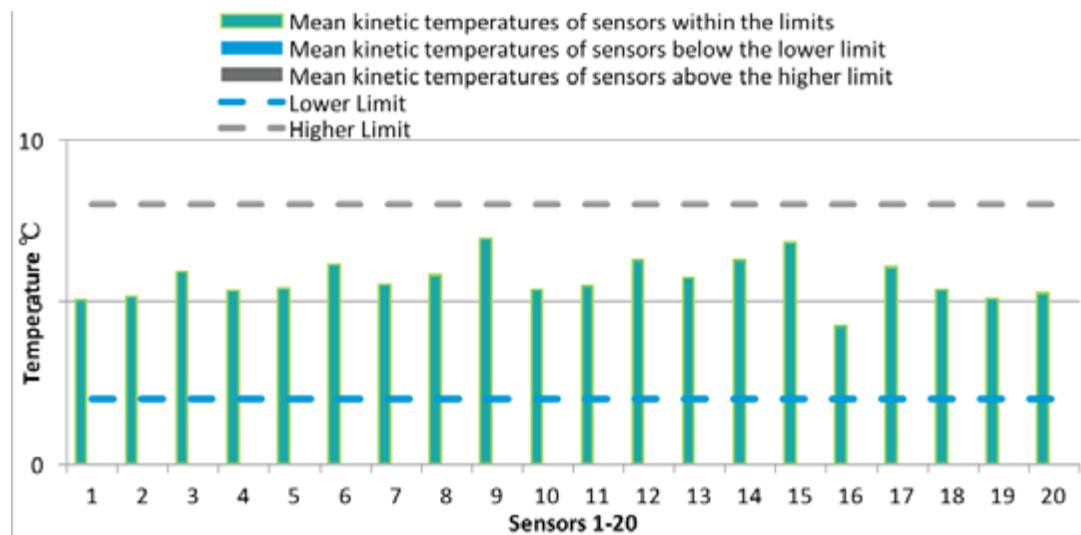
Figure 6 below shows the results of the temperature mapping study reconducted in the same cold room operating under the new controller settings.



Adjustment of the refrigeration unit controller settings
Credit: Adama Sawadogo

Mean kinetic temperatures for all 20 sensors in the cold room with the new settings

FIGURE 6.



The results of the temperature mapping conducted after the adjustment of the controller settings show evidence that the temperature distribution (MKT for all 20 sensors

in the cold room) remained within the recommended range (+2°C to +8°C) acceptable for the storage of vaccines.

Case study 3: Temperature mapping study in another cold room newly installed

Figure 7 shows an example of the profile of the temperature readings measured in the newly-installed cold room for the period of the study (~48 hours).

For almost 48 hours, the temperatures measured by the 20 sensors in the cold room did not go below 14°C,

which was entirely outside the recommended ranges for the vaccines storage (+2°C to +8°C) and was not acceptable to store vaccines. There was a performance gap that needed to be addressed.

Examples of temperature trends measured by 4 sensors in the cold room

FIGURE 7.



Actions to address the performance gap

The analysis of the study results led to the verification of the working status of the refrigeration units and it appeared that due to a loose screw in the cooling circuit, the refrigerant leaked and the refrigeration unit was no longer cooling the cold room.

The refrigerant was properly refilled and the cooling circuit was checked. Figure 8 below shows the defaulting unit and the refill of the refrigerant by the technicians.

The defaulting unit and the refill of refrigerant

FIGURE 8.



Credit: Adama Sawadogo (UNICEF)



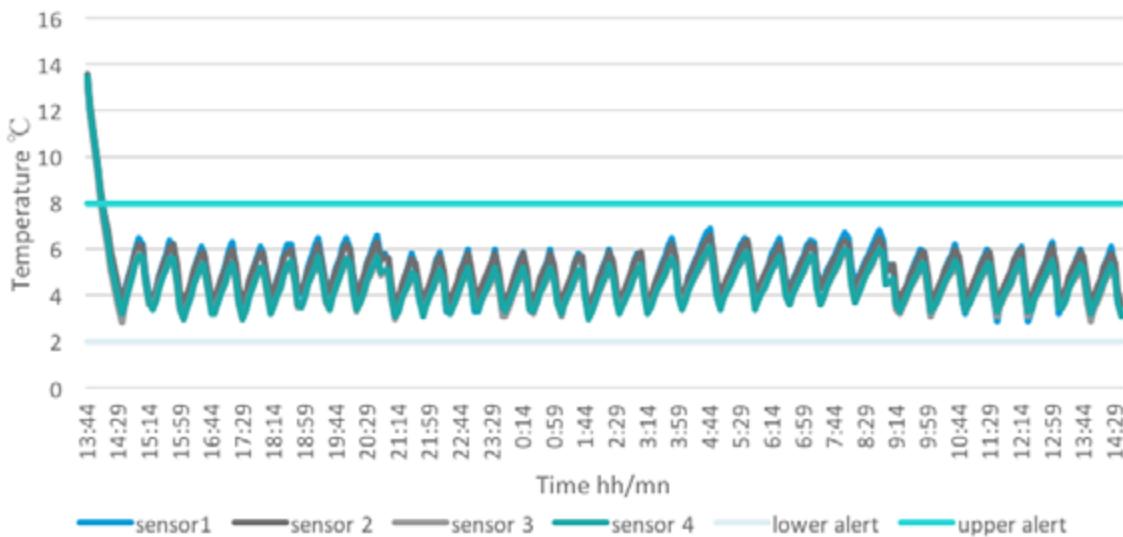
Credit: Adama Sawadogo (UNICEF)

The temperature mapping was conducted again in the cold room after the refilling of the refrigerant

Figure 9 shows the new temperature reading profile of sensors 1–4 in the cold room. Figure 10 shows the MKT profile after the refilling of the refrigerant.

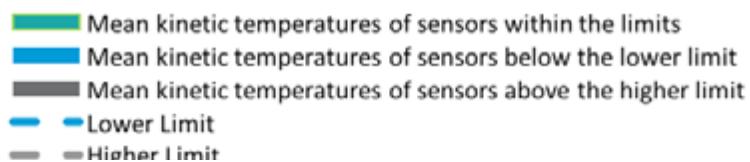
Temperature trends for sensors 1–4 after the refilling of the refrigerant

FIGURE 9.



Mean kinetic temperatures for all 20 sensors after the refilling of the refrigerant

FIGURE 10.



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