Effective Vaccine Management

EVM Good Practice

E2 Temperature management

E7 Distribution of vaccines and dry goods

C2 Equipment

C4 Human Resources

How to temperature map cold chain equipment and storage areas

Second edition

World Health Organization

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Abbreviations

2D	two-dimensional
3D	three-dimensional
EPI	Expanded Programme on Immunization
EVM	effective vaccine management
LED	light-emitting diodes
MKT	mean kinetic temperature
MS	Microsoft
PAHO	Pan American Health Organization
PDF	portable document format
PQS	performance, quality and safety
SD	standard deviation
TM	temperature mapping
UNICEF	United Nations Children's Fund
ULT	ultra-low temperature
USB	universal serial bus
WHO	World Health Organization

1. Background

The central-level cold room of any country may hold millions of dollars' worth of vaccines.[1] In highly populated countries this may also be the case for provincial- and even district-level cold rooms. The WHO effective vaccine management (EVM) initiative sets standards for safe vaccine handling and storage to ensure that heat and freezing temperatures do not damage vaccines.[2]

The standards require all vaccine cold and freezer rooms to be temperature mapped routinely every 2 years. This document provides guidance for undertaking the process. The first temperature mapping should take place at the time of the storage unit's commissioning, and then should be performed when the cold and freezer rooms, as well as associated storage units (refrigerators and freezers), undergo any modifications or major repairs. Annex 1 provides further information on conducting temperature mapping after modifications or major repairs.

Temperature mapping is not limited to vaccine cold and freezer rooms. Temperatures in refrigerators, freezers and dry stores – where diluents, injection equipment and other pharmaceuticals are kept – should also be temperature mapped.

1.1 The problem

The high cost of vaccines justifies the routine temperature mapping of all vaccine cold and freezer rooms and vaccine storage units. That said, EVM assessments completed to date by national immunization programmes have not shown thorough documentation of effective temperature distribution within cold rooms. There are several reasons for this, including:

» lack of trained immunization programme managers and store managers, and the lack of a simple tool to facilitate carrying out a temperature mapping exercise;
» cost of hiring external consultants to carry out these studies; and
» cost of compliance with the technical requirements and standards for temperature mapping. For example, temperature mapping requires at least 48 hours of continuous temperature recording with an appropriate number of temperature sensors (pre-qualified by WHO) placed accurately within empty and fully stocked storage units.

1.2 The solution

One practical solution is to empower and equip field-level Expanded Programme on Immunization (EPI) programme staff, especially store managers, to conduct temperature mapping. This can be achieved through several simple, well-defined, clearly explained and step-by-step actions, assisted by an open-access, user-friendly, computer-based application.

In response to this need, WHO has developed the Temperature Mapping tool which aids the process of mapping temperatures in various types of cold chain equipment and dry stores. The Temperature Mapping tool is a computer-based application in Microsoft (MS) Excel® available in official United Nations languages. The tool and this guidance are downloadable from the WHO Vaccine Management and Logistic Support website.

[1] A 40 m^3 cold room may house approximately US$ 2.5 million worth of vaccines when fully loaded.

[2] WHO (2016). WHO/UNICEF Joint Statement. *Achieving immunization targets with the comprehensive effective vaccine management (EVM) framework*. 10 March 2016. WHO Reference WHO/IVB/16.09 (http://apps.who.int/iris/bitstream/10665/254717/1/WHO-IVB-16.09-eng.pdf?ua=1, accessed 5 March 2021).

1.3 The importance of temperature mapping

Temperature mapping is the process of recording and mapping temperatures within three-dimensional (3D) spaces, such as cold and freezer rooms, dry storage areas, and refrigerator and freezer units. Temperatures will not be the same everywhere within the storage area. Whether in a small refrigerator, a well-designed cold or freezer room, or, particularly, in a large warehouse, temperatures can vary by as much as 10 °C from one location to another within the same unit. Temperatures in the corners will most likely be different from those measured in the centre or close to cooling units. In dry stores, the temperatures close to the ceiling tend to be higher than those close to the floor. There are also specific areas within the cold rooms where the temperature will differ. For example, temperature will be coldest next to the cooling fans and likely to be warmest close to the doors.

Temperature mapping and temperature monitoring are integral to the appropriate storage conditions for pharmaceuticals. Good manufacturing practice for pharmaceutical products recommends regular temperature mapping in all types of warehouses.[1]