

# Temperature monitoring study: a fully documented process to detect weaknesses in the supply chain

*Immunization is one of the most powerful and cost-effective of all health interventions. It prevents debilitating illness and disability, and saves millions of lives every year; temperature excursions significantly impact the potency of the vaccine. Studies in both industrialized and developing countries have revealed that vaccines are commonly exposed to damaging temperatures, especially exposure to sub-zero temperatures [1]. As stated in the WHO Vaccine Management Handbook, in "How to monitor temperatures in the vaccine supply chain" [2], the simplest way to identify these risks is to conduct a systematic temperature monitoring study of the entire vaccine supply chain.*

*The goal of a temperature monitoring study is to gather temperature data for vaccines throughout the supply chain in order to identify risks and prevent temperature excursions that may damage vaccines. A well-functioning supply chain is a cornerstone of any successful immunization programme.*

*This evidence brief provides supply chain managers in low- and middle-income countries with examples of results from temperature monitoring studies that show evidence of the potential risks to vaccines in the supply chain.*



*Reaching the last mile with potent vaccines is a challenge  
Credit: Dereje Haile*

## The need for temperature monitoring studies

When vaccines are exposed to temperatures outside the recommended ranges, they may lose their potency and become inactive; this can lead to children not being properly protected against preventable diseases, outbreaks of illness, and monetary loss.

Conducting a temperature monitoring study can help supply chain managers understand related risks in each cold-chain segment of the supply chain when the vaccines move from the primary store to service delivery.

The supply chain, from primary stores to service delivery points in low- and middle-income countries, faces many challenges including difficult terrain (rivers to cross, poor

roads, erratic and unstable electricity supplies); poor warehousing and stocks management capacity; ancient and inefficient equipment; and poor maintenance.

The Effective Vaccine Management initiative [3] which sets standards for safe vaccine handling in the supply chain and the *WHO Vaccine Management Handbook*, in "How to monitor temperatures in the vaccine supply chain" [2] recommend that a temperature monitoring study should be conducted at least once every five years to document the risk of exposure of vaccines outside the adequate temperature ranges in the supply chain, and identify specific areas where corrective actions are required.

## The vaccine journey in the country supply chain



## Implementation of a temperature monitoring study

The WHO protocol “Study protocol for temperature monitoring in the vaccine cold chain” [4] provides guidance on how to implement a temperature monitoring study, including the methodology. UNICEF developed a temperature monitoring study handbook [5] that provides best practices and tips to conduct a successful study and analyse the results for action. This handbook should be used as a supplement to the WHO protocol; both are designed to guide the following:

- + **The preplanning of the study** (engaging stakeholders, ordering study material)
- + **The study design** (selection of distribution routes and sites, selection of the study vaccine, outlining the timeline, preparing the tracking forms, defining roles and responsibilities, training the sites’ health workers)

- + **The study implementation** (preparation of study packets, monitoring the study progress, collection of study packets, interviewing of site personnel)
- + **The data analysis**
- + **The presentation of the results** (dissemination of the results)
- + **The identification of specific problem areas and corrective measures**

As seen in the global analysis of Effective Vaccine Management assessments [6] conducted in 87 countries from 2010 to 2015, only 22% of countries assessed completed a temperature monitoring study.

## Temperature monitoring studies offer evidence of vaccine vulnerabilities in the supply chain

The WHO-UNICEF Immunization Supply Chain and Logistics Hub (WHO/UNICEF Hub) strongly supports the implementation of temperature monitoring studies as a fully documented process to detect weaknesses in the supply chain and develop greater awareness and understanding among health workers about the vulnerabilities of vaccines during storage and transport.

Below are two examples of study results showing exposure to four temperature zones throughout the journey of the vaccines in two distribution routes.

The four temperature zones considered are:

- + Exposure to temperatures **+2°C to +8°C**
- + Exposure to temperatures **< -0.5°C**
- + Exposure to temperatures **-0.5°C to +2°C**
- + Exposure to temperatures **> +8°C**

## Example 1

Figure 2 below presents the proportion of time the shipment spent in the four temperature zones at the different segments of the supply chain (from the primary store to the service delivery at peripheral level).

With the exception of storage at regional level and district level - where the shipment was kept within the recommended range of temperatures (+2°C to +8°C) for most of the time (99%) - the shipment experienced

exposure to overheating or freezing conditions for at least 50% of the time at the other segments of its journey in the supply chain, and actually experienced conditions for both freezing alarms and heat alarms.

During its journey in the supply chain from central store to health facility, the total time the vaccine shipment spent in storage was 2356 hours; the total time spent in transit/transport was 174 hours.

**Proportion of time shipment spent in the four temperature zones in each segment of the supply chain**

**FIGURE 2.**

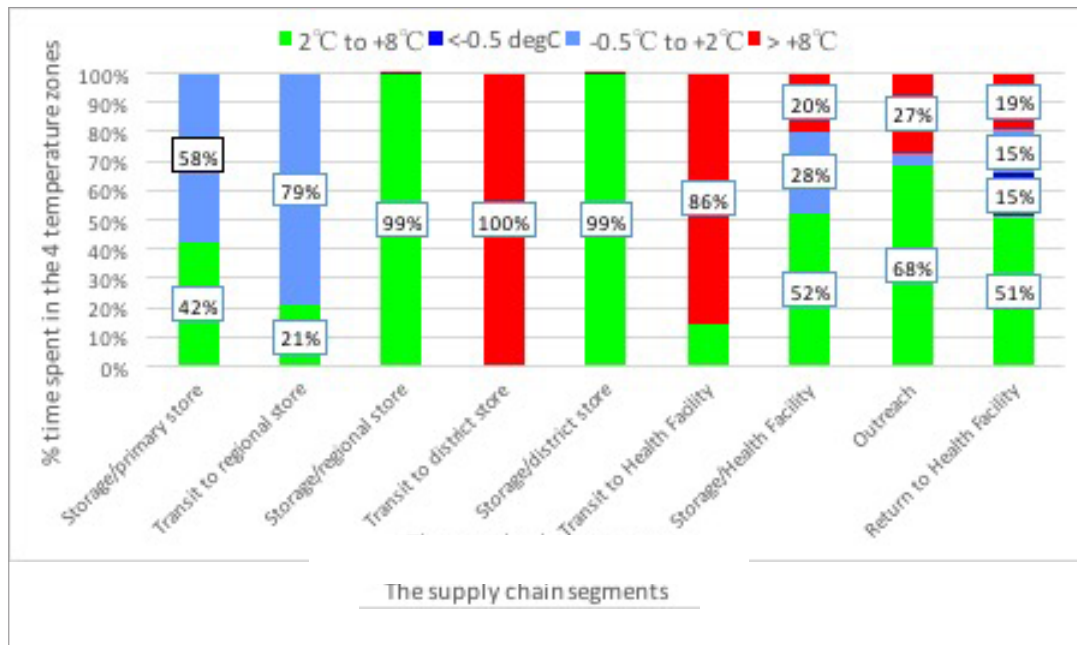
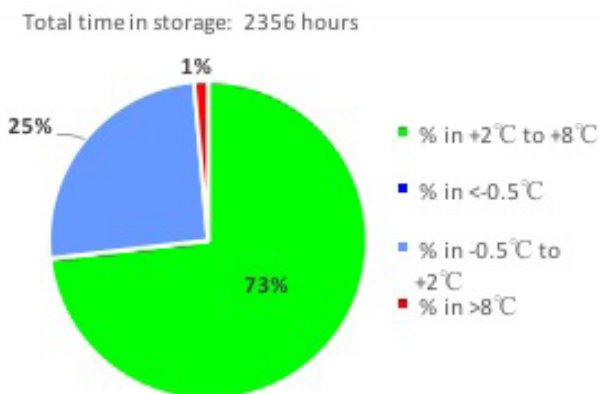


Figure 3 shows the proportion of time the shipment spent in each of the four temperature zones during storage.

**FIGURE 3.**

**Proportion of time shipment spent in the four temperature zones during storage**

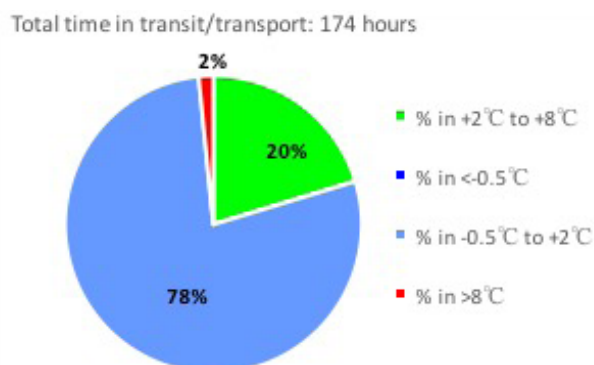


During the time in storage, the shipment was out of the recommended range of temperature for 26% of the time; it was stored mainly in the range -0.5°C to +2°C (25% of the time).

Figure 4 below displays the proportion of time the shipment spent in each of the four temperature zones during transit/transport.

**FIGURE 4.**

**Proportion of time the shipment spent in the four temperature zones during transit/transport**



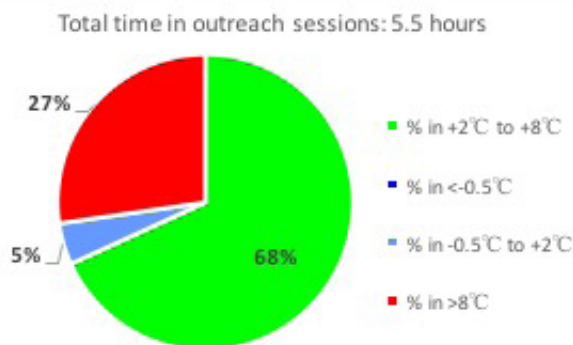
During the time spent in transit/transport, the shipment was out of the recommended range of temperature for 80% of the time; it was stored mainly in the zone -0.5°C to +2°C (78% of the time).

At service delivery level, the vaccines moved from the health facility to outreach sessions then returned to the health facility. During this study period the total time the vaccines spent in outreach sessions was 5.5 hours; the total time vaccines spent at the health facility when returned from outreach sessions, was 362 hours. Figure 5 and 6 show how the handling of the vaccines at peripheral level exposed the vaccine to overheating or freezing.

Figure 5 below presents the proportion of time the shipment spent in each of the four temperature zones during the outreach sessions.

**FIGURE 5.**

**Proportion of time shipment spent in the four temperature zones during outreach sessions**

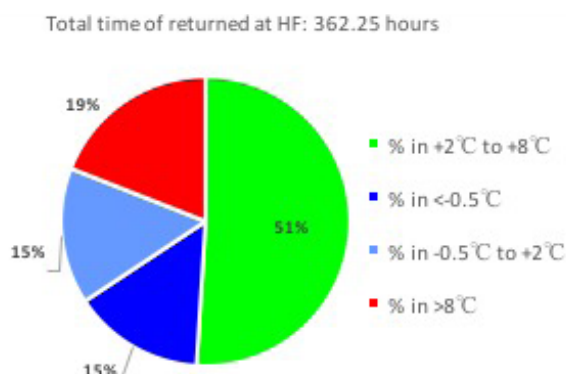


During outreach sessions, the shipment was out of the recommended range of temperature for 32% of the time, mainly in the temperature zone >8°C (27% of the time).

Figure 6 below shows the proportion of time the shipment, returned from outreach, spent in each of the four temperature zones at the health facility.

**FIGURE 6.**

**Proportion of time shipment spent in the four temperature zones at the health facility (HF) when returned from outreach sessions**



The returned shipment was in the recommended range of temperature (+2°C to +8°C) for 51% of the time, but was exposed to temperatures out of the recommended

range for almost 50% of the time (above 8°C for 19% of the time; between -0.5°C and +2°C for 15% of the time; and below -0.5°C for 15% of the time).

## Example 2

In this example, Figure 7 below presents the proportion of time the shipment spent in the four temperature zones at the different segments of the supply chain (from the primary store to the service delivery at peripheral level).

With the exception of transit from the primary store to the regional store and from the district store to the health facility - where the shipment was kept within the recommended range of temperatures (+2°C to +8°C) all the time (100%) - elsewhere in its journey in the supply

chain it experienced exposures to overheating or freezing conditions. The shipment experienced conditions for freezing alarms both during storage at the health facility and when returned to the health facility after outreach sessions.

During its journey in the supply chain from the central store to the health facility, the total time the shipment spent in storage was 2072 hours; the total time it spent in transit/transport was 175 hours.

**Proportion of time shipment spent in the four temperature zones in each segment of the supply chain**

**FIGURE 7.**

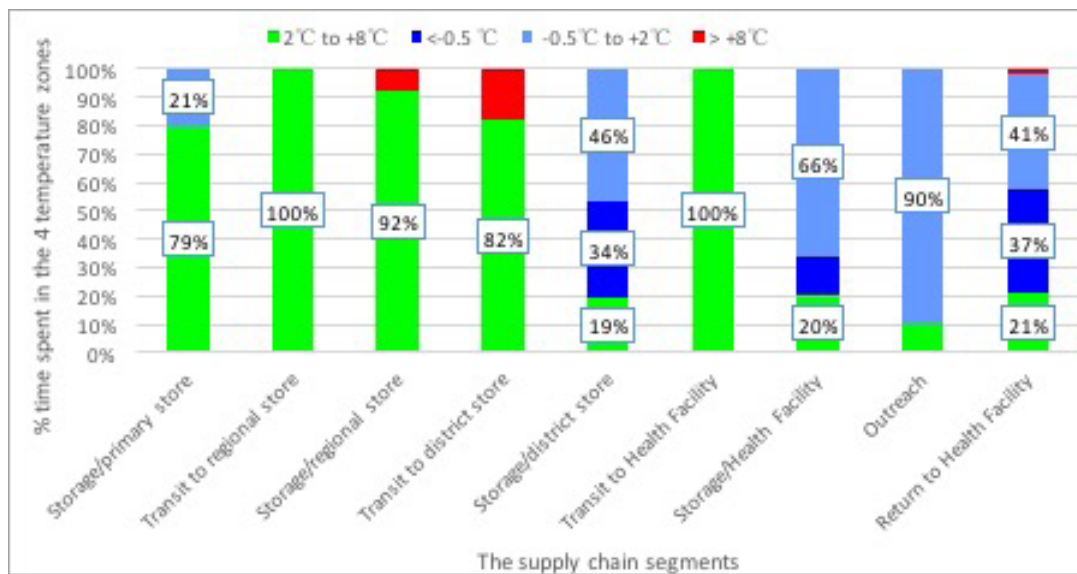
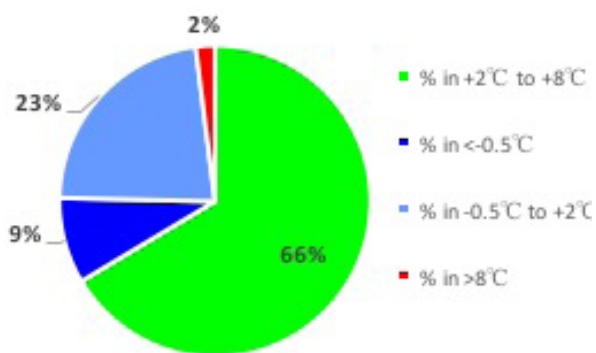


Figure 8 shows the proportion of time the shipment spent in each of the four temperature zones during storage.

**FIGURE 8.**

**Proportion of time shipment spent in the four temperature zones during storage**



During the time in storage, the shipment was in the recommended range of temperature (+2°C to +8°C) for 66% of the total time, but was exposed to temperatures out of the recommended range for 34% of the time (above 8°C for 2% of the time; below -0.5°C for 9% of the time; and between -0.5°C and +2°C for 23% of the time).

Figure 9 below illustrates the proportion of time the shipment spent in each of the four temperature zones during transit/transport.

**FIGURE 9.**

**Proportion of time shipment spent in the four temperature zones during transit/transport**

Total time in transit/transport: 175.25 hours



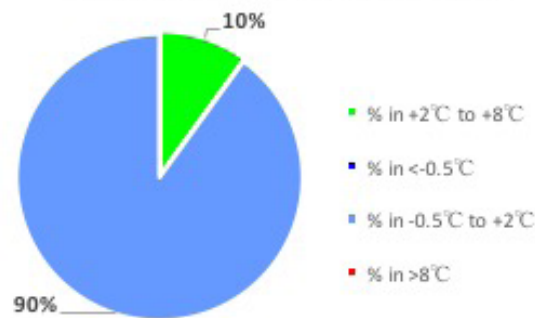
During the time in transit/transport, the shipment was kept within the recommended range of temperature 100% of the time.

Figure 10 below illustrates the proportion of time the shipment spent in each of the four temperature zones during the outreach sessions.

**FIGURE 10.**

**Proportion of time shipment spent in the four temperature zones during outreach sessions**

Total time in outreach sessions: 2.5 hours

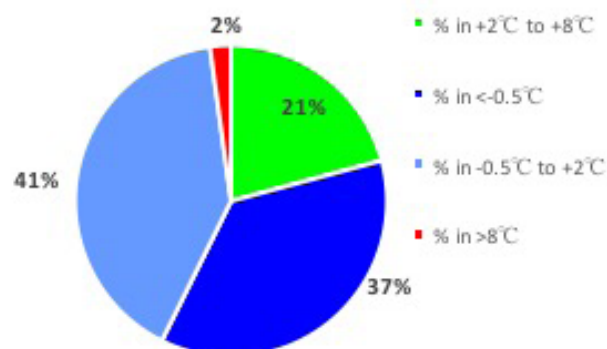


During outreach sessions the shipment was mainly stored in the temperature zone -0.5°C to 2°C (90% of the time).

Figure 11 below shows the proportion of time the shipment, returned from outreach sessions, spent in each of the four temperature zones at the health facility.

**FIGURE 11.**

**Proportion of time shipment spent in the four temperature zones at the health facility (HF) when returned from outreach sessions**



The returned shipment was in the recommended range of temperature (+2°C to +8°C) for 21% of the total time, but was exposed to temperatures out of the recommended range for almost 80% of the time (above 8°C for 2% of the time; between 0.5°C and +2°C for 41% of the time and temperature below -0.5°C for 37% of the time).

## Lessons learned

Results from temperature monitoring studies conducted in many countries generally do not show the frequent occurrences of freezing or overheating that require vaccines to be discarded; however, evidence of frequent temperature excursions on these study samples of routes remains a significant concern. Awareness of this should be raised, as the sample of distribution routes in the studies represents less than 1% of the total distribution routes of vaccines in countries.

The studies show that excursions occur during both storage and distribution, and as vaccines move down the supply chain, temperature control deteriorates.

Whereas for the past decade, awareness of the potential dangers for vaccines has focused on exposure to high temperatures, exposure to freezing temperatures is now the major concern in the supply chain, not only in low- and middle-income countries, but also in industrialized countries. This was confirmed in a recent review published in the journal *Vaccine* [1].

## Ways for improvement

Where temperature monitoring studies have been conducted, results were generally disseminated at a workshop, where health workers and managers highlighted the main reasons for temperature excursions and defined appropriate actions for correcting the issues. Examples of these actions include strengthening training activities for health workers to improve the way they handle vaccines, and a review or revision of current

handling practices and procedures, policies on storage and transportation of vaccines, and procurement of more efficient equipment.

More broadly, at global level, steps are being taken to create better storage and distribution conditions for the vaccines (e.g. promotion of remote monitoring in cold-chain equipment; availability of grade A PQS<sup>1</sup> cold-chain equipment).

## Conclusion

This evidence brief highlights the importance of temperature monitoring studies as part of routine monitoring in EPI<sup>2</sup> programmes. Large investments are made to acquire vaccines, and it is therefore critical to invest in strengthening the supply chain to maintain vaccine potency. A temperature monitoring study provides a snapshot of the potential risk areas and can

pave the way for further investigation of the key issues required to correct them.

## References

1. Is Freezing in the Vaccine Cold Chain an Ongoing Issue? A Systematic Literature Review, Celina M. Hanson, Anupa M. George, Adama Sawadogo, Benjamin Schreiber, *Vaccine* 35 (17), 2017
2. World Health Organization (WHO). WHO vaccine management handbook. Module VMH-E2-0.11. How to monitor temperatures in the vaccine supply chain. Geneva: WHO; 2015. ([http://apps.who.int/iris/bitstream/10665/183583/1/WHO\\_IVB\\_15.04\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/183583/1/WHO_IVB_15.04_eng.pdf))
3. World Health Organization (WHO). EVM Model SOP. User guide for the Effective Vaccine Management Model Standard Operating Procedures. Version 1. Geneva: WHO; 2011. ([www.who.int/immunization/programmes\\_systems/supply\\_chain/evm/en/index2.html](http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html))
4. World Health Organization (WHO). Study protocol for temperature monitoring in the vaccine cold chain. WHO/IVB/05.01 REV.1. Geneva: WHO; 2011. ([http://apps.who.int/iris/bitstream/10665/70752/1/WHO\\_IVB\\_05.01\\_REV.1\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/70752/1/WHO_IVB_05.01_REV.1_eng.pdf))
5. UNICEF. Temperature monitoring study handbook. Supplement to the WHO protocol for temperature monitoring in the vaccine cold chain. WHO\_IVB\_05.01. 2015. TechNet-21 [www.technet-21.org/en/resources](http://www.technet-21.org/en/resources)
6. World Health Organization (WHO) and UNICEF. Effective Vaccine Management (EVM) global data analysis 2010–2015. ([www.who.int/immunization/programmes\\_systems/supply\\_chain/EVM-Global-Data-Analysis-2009-2015.pdf?ua=1](http://www.who.int/immunization/programmes_systems/supply_chain/EVM-Global-Data-Analysis-2009-2015.pdf?ua=1))

<sup>1</sup> The WHO Performance, Quality and Safety process.

<sup>2</sup> The Expanded Programme on Immunization.

## Finding more information

The following resources may be useful when investigating temperature monitoring:

### RESOURCE 1

#### Cold Chain Temperature Monitoring in Vietnam – Path

Improving temperature monitoring in the vaccine cold chain at the periphery

+ [https://www.path.org/publications/files/TS\\_opt\\_vn\\_hpv.pdf](https://www.path.org/publications/files/TS_opt_vn_hpv.pdf)

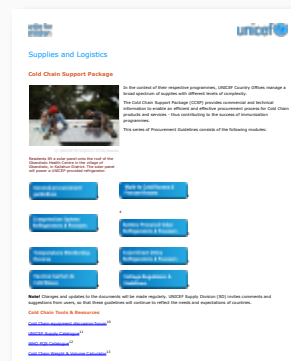


### RESOURCE 2

#### Cold Chain Country Support Package, UNICEF Supply Division

A website to support UNICEF country offices and procurement service partners in strengthening immunization supply chains through the procurement of cold chain equipment and services. The website provides information on important technical and commercial considerations in the planning and procurement phases of cold chain implementation projects.

+ [www.unicef.org/supply/index\\_68367.html](http://www.unicef.org/supply/index_68367.html)



### RESOURCE 3

#### PQS Catalogue, WHO

A list of WHO-prequalified equipment, including solar-powered vaccine refrigerators and freezers, is available in the PQS Devices Catalogue, available on the WHO website.

+ [http://apps.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_catalogue](http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue)





## Temperature monitoring – technical resources

This area of the TechNet-21 website is intended to support countries with technical resources to adequately design and implement/upgrade systematic and effective temperature monitoring in their cold chain. It covers 30-Day Temperature Recorders (30DTR) and Remote Temperature Monitoring (RTM) devices.

+ [www.technet-21.org/en/resources](http://www.technet-21.org/en/resources)



## Acknowledgements

The authors would like to express their thanks to the following individuals and organizations who contributed to these documents.

### UNICEF

Ousmane Dia  
Serge Ganivet  
Dereje Haile  
Celina Hanson  
Shaikh Humayun Kabir  
Hailu Kenea  
Joseph Mabirizi  
Adama Sawadogo  
Benjamin Schreiber

### WHO

Dan Brigden  
Isaac Gobina  
Souleymane Kone

### Independent consultants

Ibnou Diaw  
Claire Frijs-Madsen  
Anupa George

### Edition

Pamela Knight  
Angela Newill



**EVM**  
Setting a standard for the  
vaccine supply chain

© World Health Organization 2017. Some rights reserved.  
This work is available under the [CC BY-NC-SA 3.0 IGO licence](https://creativecommons.org/licenses/by-nc-sa/3.0/).  
WHO/IVB/18.04