Temperature Monitoring Study Handbook

Supplement to the WHO protocol for Temperature Monitoring Studies (WHO_IVB_05.01.rev1)

Electronic versions of this document and the appendices (templates, tools) are available on Technet-21, Topic: “Temperature Monitoring”, Page “Risk to Vaccines”, from the table at the bottom of the page.

unicef

Acknowledgments

Adama Sawadogo

Ahmet Afsar

Anupa Mariam George

Benjamin Schreiber

Claire Frijs-Madsen

David Brown

Diana Chang-Blanc

Debra Kristensen

Denis Maire

Joe Little

Maria Muniz

Markku Toryalai Hart

Mike Brison

Ranjit Dhiman

Serge Ganivet

Shobhana Chitrakar-Rijal

Sophie Newland

Contents

Abbreviations

CCE	cold chain equipment
EPI	Expanded Programme on Immunization (WHO)
GPRS	general packet radio signal
GSM	global system for mobile communications
NIP	national immunization program
RTMD	remote temperature monitoring device
SP	service point
TOR	terms of reference
UNICEF	United Nations Children's Fund
USB	universal serial bus
VVM	vaccine vial monitor
WHO	World Health Organization
WICR	walk-in cold room

1. How to use this handbook

This handbook is a supplement to the World Health Organization (WHO) protocol for Temperature Monitoring Studies (http://www.who.int/immunization/documents/WHO_IVB_05.01/en/). Please read the WHO protocol before reading this handbook. The handbook will facilitate the implementation of the WHO protocol by introducing practical tips, a generic work plan, data collection templates, and an Excel-based temperature data analysis tool. These documents and tools were developed and refined during many early temperature monitoring studies. Accessing and adapting these tools and templates can make it much easier to implement temperature monitoring studies.

As outlined in the WHO protocol, temperature monitoring studies record temperatures continuously as vaccine shipments travel through the cold chain, from primary stores, to intermediate stores, to health centers, and finally, to the outreach delivery sites. The WHO protocol can be tailored to meet the individual resources of any program: either a simple, low-cost study can be conducted—without sophisticated monitoring tools—or a more comprehensive approach can be taken to provide a program with more details.

The objectives of a temperature monitoring study are to:

- Document temperatures throughout the vaccine cold chain, with a special emphasis on freezing temperatures.
- Identify where corrective actions are needed.
- Justify any needed investments or corrective actions to address identified risks.
- Reinforce staff awareness of vaccine transport and storage temperature requirements.
- Assist policy makers in updating policies and standard procedures when needed to address cold chain performance gaps.

The target audiences for the WHO temperature monitoring study protocol and this handbook are national immunization program (NIP) managers, cold chain managers, and logisticians as well as in-country United Nations Children's Fund (UNICEF), WHO, and other partner organization staff supporting these NIP leaders. Each country team implementing a temperature monitoring study will need to review and adapt the protocol and implementation tools introduced in this handbook.

The checklist in Appendix 1 summarizes the important and sequential steps of implementing a temperature monitoring study. This handbook is organized in the same sequence as this checklist. Electronic versions of the tools and templates introduced in this handbook can be downloaded from the temperature monitoring section of the Technet-21 website.[1]

2. Pre-planning

Pre-planning steps will focus on assembling the human, technical, and financial resources needed to implement the temperature monitoring study. The NIP and its study implementation partners should start these steps three to four months before the study starts.

[1] Electronic versions of the tools and templates introduced in this handbook are available at: https://www.technet-21.org/en/topics/temperature-monitoring/scoping/identify-challenges-and-risks.

2.A Engage key cold chain stakeholders

- Start discussions early to engage cold chain partners that can help the NIP and contribute technical, financial, or logistical support to the implementation, analysis, and reporting phases of this study.
- When possible, the National Logistics Working Group should oversee the study. NIP partners should be kept informed throughout the study and be prepared to help NIP address any cold chain gaps identified during this study.

2.B Identify a study coordinator and contract technical assistance

- Clarify who will act as the study coordinator. Ideally it should be an NIP staff member.
- If the NIP and its cold chain partners need to hire additional technical experts, please see Appendix 2 for a terms of reference (TOR) template for an external consultant. The template can be adapted according to the NIP needs and advertised for contracting. This process may take well over a month.

One consultant could potentially be contracted to provide technical assistance to multiple countries in the same region.

2.C Determine the number of study routes and supply parameters

A temperature monitoring study will often cover less than one percent of the vaccine distribution and service delivery sites in the national immunization supply chain. The WHO protocol recommends that at least eight shipment routes be monitored. However, a larger number of routes should be considered to ensure the sample size is representative of a diverse set of NIP vaccine distribution scenarios.

As many as 16 to 40 routes may be needed to effectively represent the complexity of the immunization supply chain, but the exact number will depend on each country and factors such as complexity, budget, and time.

- Design a temperature monitoring study that represents the diversity of the vaccine supply chain.
- To minimize potential bias and capture temperature data from a variety of supply chain routes, discuss how many study routes are needed and how these routes will be distributed.
- This discussion must occur early to determine the number of data loggers to order. The details of these routes can be finalized during study planning.
- Each route typically starts at the national vaccine store, passes through each segment of the country's cold chain: subnational vaccine store, lowest distribution store before the vaccine is delivered at a service point (SP) during an immunization session at a health facility or during an outreach session.
- A minimum of four subnational (for example, regional) vaccine stores and eight lowest distribution (for example, district) stores should be monitored during this study.
- The study should be designed to capture data that help identify important differences in cold chain performance, for example differences between:
    - Performance, Quality and Safety prequalified cold chain equipment (CCE) and domestic refrigerators.
    - CCE types (for example, solar, AC-powered, or absorption types) or equipment models.
    - Transport using conditioned ice packs, chilled water packs, or refrigerated vehicles.
    - Facilities using refrigerators or those using passive storage containers.
    - Routing through regional store versus direct distribution to district/facility.
    - SP located in urban, rural, or hard to reach locations.
    - Facility types, such as hospitals, health centers, and health posts.

- Appendix 3 shows an example of routes.

2.D Purchase temperature data loggers

There are several electronic temperature data loggers that can considered when planning a temperature monitoring study. The WHO protocol recommends the LogTag TRIX-8 device (USD 22 to 32),[2] which has been proven to be accurate, reliable, and easy to use. However, a similar model, TRIX-16, has twice as many data points for little extra cost (USD 37)[3] provides more time flexibility for countries where the distribution to the SP takes more than 83 days. A third option to consider is the UTRIX-16 (USD 27 to 39), which is similar to the TRIX-16 and uses the same software for configuration and analysis, but the UTRIX-16 is manufactured with a USB connector and does not require ordering a USB interface cradle (USD 55) to interface with a computer.

- For a comparative list, please see Appendix 4.
- Additional costs to consider include taxes, shipping, and customs costs.
- For the LogTag TRIX-8 or TRIX-16, remember to order two cradles.

While there is increasing interest in using remote temperature monitoring devices (RTMDs) for temperature monitoring studies, the current market options are not well designed for this purpose. The use of RTMDs would significantly increase study costs and have little benefit. It would also introduce the risk of data errors/loss from GSM (global system for mobile communications)/GPRS (general packet radio signal) or web-based software interface issues.

- RTMDs are not recommended at this time.

The WHO protocol recommends using a second temperature data logger for each study route to measure ambient temperatures. However, experience from previous temperature monitoring studies suggests that adding an ambient temperature logger for each study route increases the workload of the NIP staff handling the data loggers. If necessary, a representative ambient temperature measurement can be obtained from meteorological databases.

- This handbook does not recommend monitoring the ambient temperatures when the ambient temperature conditions are expected to be between +10°C and +43°C.[4]

2.E Set the date and organize the workshop

- As early as possible, the NIP schedules a workshop to discuss the study objectives and modify the generic protocol.
- It is recommended that NIP staff from all sites involved in the study participate in the workshop for direct training on how to handle the study packets.
- The workshop may be 1 to 3 days depending on the country. An example of a workshop agenda is shown in Appendix 5.
- A template for a presentation of the overview of the temperature monitoring study is shown in Appendix 6.

---

2. Pricing information is available at: https://www.loggershop.co.uk and https://www.microdaq.com/data-loggers/temperature.php.

3. Loggers can be ordered from UNICEF Supply Division, directly from LogTag Temperature Recorders, or distributers such as MicroDAQ. Five packs of UTRIX-8 and UTRIX-16 can be ordered from Amazon.

4. The Performance, Quality and Safety performance specifications (E003 for ice-lined refrigerators) for the minimum rated temperatures in moderate climates is +10°C and the maximum temperature set for Performance, Quality and Safety equipment prequalification in hot climates is +43°C.

2.F Order study materials

In addition to data loggers, some additional supplies may need to be ordered. Two types of clear plastic bags will need to be needed to assemble the study packets, as described in the Study implementation section below.

3. Study planning

Study planning finalizes the operational details for the study implementation. Many of these steps can be addressed during a planning workshop, the date of which was set in Step 2E above.

3.A Clarify roles and responsibilities

3A.1 Study coordinator

The study coordinator's responsibilities may include:

- Preparing the packets including programming loggers.
- Overseeing the flow of packets through the distribution chain.
- Ensuring timely shipment departures and arrivals at every site.
- Ensuring adherence to the instructions sent.
- Conducting interviews of site personnel.
- Organizing the return and collection of the study packets.
- Conducting and shake tests at the end of the study.
- Assisting with data analysis and report writing.

3A.2 Technical consultant

The consultant(s) can support the study coordinator and NIP leadership and partners as needed.

- The development of the TOR during the pre-planning phase is an opportunity to ensure necessary pre-planning, planning, implementation, and analysis support.

3A.3 Vaccine vial monitor readings

Decide who will read and record vaccine vial monitor (VVM) data.

- At minimum, VVMs should be read at the final immunization or outreach session.
- The **monitoring form** described in Section 3D.2 has space for recording the VVM stage of the vaccine vials in each study packet before their return.

3A.4 Shake test

Decide who will perform the shake tests and when and where they will be performed.

- This handbook recommends that experienced NIP staff performs the shake test upon return of the packets at the national store.

3A.5 Expanded Programme on Immunization staff feedback

Decide who will collect feedback from cold chain personnel on vaccine handling attitudes and practices.

- Appendix 7 shows sample questions.
- If an NIP staff member is conducting these interviews, supportive supervision can be provided at the end of the interview, as needed.

3A.6 Data analysis and report writing

Clarify which agencies, staff, or consultants will analyze the collected temperature monitoring data, VVM and shake-test results, and feedback to develop the draft report.

- Develop a process and timeline for providing feedback and finalizing and sharing the report.
- One or more staff should be able to use the UNICEF Excel-based temperature data analysis tool introduced in Section 5B below.

3A.7 Decide how to collect and return study packets at the end of the study

At the end of the study, the study packets will need to be returned to the central level.

- The return of the study packet to the central office must be done **outside of the cold chain** (without any refrigeration) to ensure that the shake-test results only captures damage to vaccines caused during the distribution to the SP.

3.B Conduct the workshop: train participating staff

The purpose of the workshop is two-fold: 1) to explain the purpose of the study and to train participating staff, 2) to adapt the study methodology to the country context.

At each level of the study route, an NIP focal point is responsible for handling the study packets and recording information on the **monitoring form.** Participants need to be trained on:

- The objectives of the temperature monitoring study.
- The contents and handling procedures for study packets.
- The importance of maintaining routine handling procedures.
- How to use the **instruction sheet** as a job aid.
- How and when to fill in the **monitoring form.**
- How to handle situations when a facility has more than one piece of equipment.
- How to handle situations when there is an equipment breakdown (details should be made in the Comments section of the **monitoring form**).
- How and when to contact the study coordinator (for example, notification of the arrival and departure of study packets or with questions or concerns).

Training strategies to consider include:

- Field visits to each site.
- Trainings organized at different administrative levels or by region.
- Training at central level (most common and practical).

3.C Adapt the study protocol to the country context

The WHO study protocol should be adapted to ensure that study findings will reflect the realities of the national cold chain. Final decisions can be made after discussions during the workshop.

- A generic study protocol template is provided in Appendix 8.

3C.1 Study routes

- Study routes are defined by the distribution (journey) of the vaccines all the way from the primary store to the final SPs.
- The sites monitored during this study should be both representative and also be sufficient in number to support useful conclusions.

3C.2 Study vaccine

The NIP should decide which vaccine antigen and presentation to monitor. The protocol is designed to monitor the cold chain conditions experienced by a multi-dose, freeze-sensitive vaccine product that uses an aluminum adjuvant.

- Multi-dose vaccine presentations of pentavalent (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenza* type B) or pneumococcal conjugate vaccine are examples of potential study vaccine presentations.
- The study vaccine vials must have VVMs at stage 1 and be recently received from the vaccine manufacturer.
- Two vials will be used for each study packet; one vial will be intentionally frozen as a shake test positive control when the study packet returns to the central vaccine store, and the other will be used as the shake 'test' vial that will be assessed for freeze damage.

3C.3 Study timeline

It is important to follow normal vaccine distribution schedules as much as possible. However, the distribution schedule may require slight modifications, particularly when using data loggers with limited capacity (for example, TRIX-8).

- When vaccine shipments from primary vaccines stores to subnational stores are infrequent, the NIP may need to organize a special vaccine shipment to launch the study from the primary vaccine store.
- Often vaccines are stored at subnational stores for several months. It may be useful to accelerate the movement of vaccine supplies at subnational vaccine stores for the purposes of this study.
- It may be valuable to increase the time study packets are stored at some cold chain levels. For example, when vaccines are distributed to SPs as soon as they arrive at the lowest distribution point, you may want to require that there is a minimum storage time at the lowest distribution point (for example, district vaccine store for one to two weeks). By lengthening the storage time at this level, the temperature data recorded at these sites are more likely to detect equipment temperature performance issues.
- Even if the distribution schedule is modified, standard handling processes should continue to be used.
- Make sure to take into account the logger capacity when planning the study start and end time and when deciding on the logging intervals. Plan for at least an additional two to three weeks in case of delays.

3C.4 Authorization to discard study vaccines

At the end of the study, the NIP may need to formally authorize the use and discarding of the study vials of vaccines included in the study packets. All study vials will be transported back to the central level at the end of the monitoring period.

3C.5 Data-sharing agreement

When a temperature monitoring study is funded by WHO, UNICEF, the Clinton Health Access Initiative, PATH, or other partners, this agreement will need to be formalized to help ensure transparent communication between the different partners and to ascertain that the intended use of the study data is agreed upon by all parties. A data-sharing agreement template is shown in Appendix 9.

3.D Adapt the forms and the study packet

A **master tracking form** is created to have an overview of the routes and the staff responsible for the study packets at all participating sites. The study packets will include a **monitoring form**, an **instruction sheet,** two vials of the study vaccines, and a temperature data logger.

3D.1 Master tracking form

A **master tracking form** template is shown in Appendix 10. This form is designed to support the study coordinator to track the study packets and is not included in the study packets. The **master tracking form** shows the following information for each route:

- Origin at primary vaccine store, all subnational vaccine stores, lowest distribution stores, and final SP of each route.
- Temperature logger serial number or the unique ID assigned during configuration.
- Approximate schedule of movements from each storage or SP, according to the decisions made above.
- Contact information for personnel at each site in each route so that follow-up calls can be made. This information can be obtained during the workshop.

3D.2 Monitoring form

The **monitoring form** template is shown in Appendix 11. This form is included in the study packet so that health workers can record the times and dates when the study packet is removed or placed in a refrigerator or cold room.

- DO NOT record the date and times when the study packet is removed or placed in a cold box, carrier, or refrigerated truck for transit.
- Any exceptions to routine conditions or other key information should be recorded in the comments section of the **monitoring form.**
- Staff should be trained to correctly complete this form at each point in the vaccine supply chain, or the data analysis is highly challenging.

3D.3 Instruction sheet

The **instruction sheet** contains instructions for study packet handlers at each site and will be included in the study packet.

Instructions should describe the reporting and handling procedures needed at each cold chain level. For example, staff at a regional vaccine store will need different guidance than staff at a health post collecting a single study packet from a district vaccine store.

- Appendix 12 provides an **instruction sheet** template.

3D.4 Adhesive packing slip

An **adhesive packing slip** should be prepared that is small and ideally laminated to avoid moisture damage. This packing slip should show route details and provide contact information for the study coordinator. This slip is affixed to the outer bag of each study packet, described in the Prepare study packet section below.

- See Appendix 13 for an **adhesive packing slip** template.

3.E Confirm temperature data logger functionality

It is important to test each temperature data logger prior to study implementation.

This step verifies the functionality of each device and can help the study coordinator become more comfortable with programming and downloading of data. Once the temperature loggers are delivered, the study coordinator or consultant can program these devices to collect data for a few days. Download the data from each data loggers to confirm functionality. See Section 4A for more details about programming the loggers.[5]

4. Study implementation

At least a week before the study packets are placed into a walk-in cold room in the primary vaccine store, the following steps should be taken.

4.A Program data loggers

It is essential to verify that the loggers have sufficient data storage capacity to record the longest study route, inclusive of an additional two- to four-week buffer for unexpected events.

Recommended programming parameters include:

- Logging intervals of 15 minutes or less.
- An identical start time for all data loggers—at 16.00 (24-hour clock) or 4:00 PM (12-hour clock), the loggers are placed in the national vaccine store.
- Being programmed to stop data logging when the data storage capacity is full (no overwriting data). This is often the default setting of the loggers.
- A unique logger ID entered when programming each device—ID includes an administrative code of the destination.
    - Write the destination ID on the logger with a permanent marker or small adhesive label.
    - Write the logger serial number or unique ID on the **master tracking form.**

4.B Prepare study packets

Each study packet will use the two plastic bags as described below. Each study packet should be clearly labeled with the destination SP.

As shown below in Figure 1, the smaller inner-plastic bag includes the data logger and two study vaccine vials. This bag will not be opened until the end of the study when the data are downloaded, and the shake test is performed. It must be transparent to allow for VVM readings at the end of the study.

[5] When using LogTag devices, additional support is available at: https://www.logtag-recorders.com/en/support/.

Figure 1: Inner bag with logger and two study vaccine vials

As shown below in Figure 2, the outer bag plastic contains the small plastic bag and the **monitoring form** and **instruction sheet** described above. This outer bag should have the packing slip affixed on its front.

Figure 2: Outer bag with smaller plastic bag: Left) monitoring form; Right) instruction sheet

The **monitoring form** and **instruction form** can be stapled together and must follow the study packet.

- The study packets should be handled and transported alongside routine vaccine supplies.
- At the subnational and district level, the study packets can be inserted into secondary vaccine cartons.
- If a study site has several walk-in cold rooms (WICR) or refrigerators and receives multiple study packets, the cold chain focal point may store the study packets in different equipment if compliant with good vaccine handling practices. For example, all study packets going to province A could be placed in WICR 1, and all study packets going to province B can be placed in WICR 2.

4.C Monitor study progress

When the pre-planning and planning steps of a temperature monitoring study are performed properly, the study packets will move without much effort through the designated routes. Even in the best planned studies, the study coordinator must communicate at least weekly with the study sites to confirm the scheduled departure and arrival of the study packets.

- The study participants at each site should be trained to contact the study coordinator(s) when study packets arrive and depart, and if there are problems.

- The study coordinator should use the **master tracking form** to monitor the movements of the study packets.

4.D Collect feedback

The study coordinator should conduct interviews of study site personnel to help capture knowledge, attitudes, and practices regarding vaccine handling. Appendix 7 shows sample questions.

4.E Return study packets

The monitoring phase of the study ends either when the vaccine vials (traveling with the study packets) are delivered to patients, either at a static or outreach service session, or after they are returned to the facility and the packets are taken out for the return.

Before the SP staff are asked to send the study packets back to the central NIP office, the study coordinator may consider calling each SP focal point to ensure the:

- **Monitoring form** is filled in and returned with the study packet. In the event of missing or incomplete forms, the coordinator will need to contact the sites to reconstruct the timeline.
- VVM readings are recorded on the **monitoring form.**
- Study packets will be returned outside the cold chain and will not be opened until they reach central NIP level.

4.F Conduct shake tests

The people who were assigned this role will conduct the shake test on all study packet vaccines at the central level.[6] One of the two vials in the study packet should be frozen overnight. This vial will act as the positive control, as shown in the job aid. The non-frozen study vial from each packet will be compared with the positive control from the same packet.

- If possible, two people should independently conduct the shake test and compare their interpretations.
- Take photographs before, during, and after the shake test.
- Results for each study packet should be recorded.

5. Data analysis

Once all the study packets are returned to the central level, the monitoring forms are checked for completeness and errors, the shake-test results are recorded, and data analysis begins.

The analysis will take approximately two weeks and can be done by the NIP with partner or consultant support, as needed. The analysis steps are outlined below.

5.A Preparing data

5A.1 Logger data

- Data must be downloaded from each of the loggers as .csv files or another Excel friendly format. These files will be imported or pasted into the UNICEF Excel-based data analysis tool.[7]
- If LogTag data loggers are used, the LogTag Analyzer software available online should be used to download the .csv files.

---

6. More information on how to conduct the shake test is available at: http://www.paho.org/immunization/toolkit/resources/paho-publication/job-aids/How-to-perform-the-Shake-Test.pdf?ua=1

7. https://www.technet-21.org/en/library/main/5008-tms-data-analysis-tool

- Online support materials are also available.[8]
- It is important that the date and time settings on the computer used for the programming of the loggers are correct.

5A.2 Monitoring forms

The **monitoring form** is rarely completed perfectly—particularly when it comes to the entry/exit time of study packets into CCE at a storage facility.

- When reviewing the data, it may be necessary to revise the record. For example, if the data show rapid freeze exposure one hour before the exit time, it is almost certainly the result of exposure to unconditioned ice packs, but the time on the form may have been entered when the packet left the facility (and not when it left the storage CCE). Make a comment and adjust the record accordingly.
- Check for any discrepancies or issues on the **monitoring form;** study focal points at study sites can be contacted for follow-up. Common issues include:
  - Time and date information are incomplete or missing.
  - Transit times are extremely long/short or require travel time.

- In most cases, one of the start or end times is incorrect. Review similar shipments from that site to see whether the error is obvious. If unclear, contact the study site.
- It is important to review and validate both the data from the data loggers and from the monitoring forms before starting the data entry process into the Excel-based data analysis tool otherwise, data entry can be delayed by checks with the relevant EPI staff at different locations.

5A.3 Feedback questionnaires

Feedback from NIP staff should be incorporated during data analysis and report writing.

5.B Use data analysis tool

For data analysis, the Microsoft Excel-based tool created by UNICEF headquarters can be used. The UNICEF TMS data analysis tool can be downloaded at the Technet-21 website.[9] The guide for the tool is provided in Appendix 14.

5A.4 'Overall Input' tab

On this tab, the temperature alarm conditions will be set. By default, the WHO heat and freeze time and temperature alarm conditions are configured. Based on this input, the tool will analyze heat and freeze excursion frequency and durations for each facility.

Inputs also include the number of static storage levels in the vaccine supply chain and the number of routes that were used during this study.

- This step takes time, and it is very important to correctly enter these inputs before proceeding to the next step.

5A.5 'Equipment and Time Input' tab

On this tab, the date and time data recorded on the **monitoring form** are entered into the Excel tool after conducting a quality check of the data. The SP that sent study packets to outreach sessions will be identified, along with any deviations noted on the monitoring forms.

---

8. Software and quick start guides are available at: https://www.logtag-recorders.com/en/support/.
9. https://www.technet-21.org/en/library/main/5008-tms-data-analysis-tool

5A.6 'LogTag Data Input' tab

After the date/time data are entered for a study route, the data logger is downloaded. The LogTag download automatically creates a file with extension .ltd, but each file should also be saved as .csv file. This file can then be opened in Excel before being copied and pasted into the UNICEF tool.

5A.7 'Route Output' tab

During this review step, some problems will be discovered. Carefully go through the temperature profiles and determine if there needs to be adjustments to the 'From' and 'To' dates/times on the 'Equipment and Time Input' page.

- The study coordinator or consultant conducting this analysis should work with NIP leadership and call the study site focal points to better understand how to resolve any identified issues.
- If corrections are made to the dates/time on the 'Equipment and Time Input' page, click the 'Recalculate' button on this tab to see the updated results.
- Graphs and charts can be formatted to conform scale or improve labeling by exporting these outputs.

5A.8 'Summary' data tables and charts

Once the tables, charts, and graphs are produced on the 'Route Output' page for all the routes, go to the 'Summary' page. Click 'Create Summaries' at the top of the page.

- Yellow cells should be filled out (shake-test results, VVM readings, and shake test/VVM reading dates).
- Appendix 14 provides detailed instructions on how to use the tool.

6. Presenting analysis and recommendations

6.A Presentation

A PowerPoint deck or other visual presentation should be developed to disseminate the results. This presentation can be distributed by email or shared during meetings. It should communicate any identified cold chain temperature risks and recommendations to reduce these risks. It should include

- Objectives
- Background/Methodology
- Key Findings & Recommendations
- Map of country w/ Sites Identified
- Study Profile
- Study Results
- Summaries by Levels
- Summary of Transit, Outreach, etc.
- Key Findings and Possible Causes
- Analysis of Each Route: Temperature profile plus any relevant details for each segment
- Conclusions
- Recommendations/Corrective Actions

Appendix 15 provides a presentation template.

Graphs will effectively illustrate temperature excursions. Rather than showing all the collected data, it might be more effective to select meaningful examples. To ensure graphs can have a targeted impact, consider the following:

- Choose a few clear examples.

- Use both graphs and summary tables.
- Relate the outcome to the cause.
- Ask for input from the audience as to the probable causes of the results instead of stating them; ask what would be needed to address these issues.
- Make graphs easily comparable: use a standardized x-axis—such as hours or days—to make graphs easier to interpret and compare.

When delivering the PowerPoint deck, make the presentation more dynamic by involving the audience; for example, show a highlighted issue on one slide, asking for feedback as to the possible interpretations of the results and possible causes, before showing the likely scenario on the next slide.

The presentation is a good forum for raising awareness of vaccine thermostability and handling requirements while discussing the findings and suggested remedies to highlighted issues. This presentation can provide an opportunity for constructive dialog among different levels of the cold chain stakeholders.

6.B Report

A comprehensive written report should summarize the methodology and findings of the study. A report template is provided as Appendix 16. The following report elements are included:

- Objectives.
- Study design, implementation, data collection, and analysis process.
- Summary of key findings.
- Recommendations to address points of risk.

The country-specific protocol developed during the planning phase can provide some of the content for this report. When summarizing the study findings, tables and summaries generated by the Excel-based analysis tool should be used.

When preparing this report, focus on communicating the most important and actionable findings. Answer the following questions:

- What types of temperature risk are vaccines being exposed to and why?
- Where in the cold chain are these risks prevalent?
- How common is this risk at those levels?

If ambient temperature loggers were not used, an indicative ambient temperature range for the study period should be noted in this report to provide context to readers.

- It may be important to highlight the fact that a single alarm at one of the higher levels will be counted in the analysis tool as one alarm for each route that traverses that storage location. This will inflate the number of alarms experienced at this level during the study. A note on this point can be added to the report template.

When possible, during analysis and reporting look at important factors that may contribute to temperature excursions, such as whether or not Performance, Quality and Safety prequalified CCE is used to store vaccines, differences in CCE types or models, whether vaccines are transported using conditioned frozen ice packs, chilled water packs, or refrigerated vehicles.

The main objective of this study is to identify risks to vaccines from inadequate cold chain temperatures and based on evidence to help the NIP develop an actionable, evidence driven plan to

address these gaps. If some of the collected data has no significant implications, it may not need to appear in the main body of the report.

This report will need to be reviewed by the EPI and national logistics working group or others prior to finalization. A version of this report should be provided to WHO, UNICEF or to the funding agency, as agreed upon in the data-sharing agreement. An anonymized version of this report (without names of staff, administrative areas, or health facilities) can be shared more widely to help partners identify opportunities where they may be able to support recommendations.

7. Knowledge management

It is important that good document management and archiving practices are practiced during this study. An agreed upon naming convention may help ensure that contributions from different partners are included in the final document.

Documentation should be managed by the NIP coordinator and emailed to the identified study coordinator for archiving on a local computer and/or uploaded to a storage cloud to be shared with the appropriate staff. The documents should include:

- Country-specific protocol.
- Signed data-sharing agreement.
- Other relevant workshop materials (agenda, presentations).
- Master tracking form.
- Continuous time series data (from temperature loggers).
- Filled out monitoring forms.
- Filled out interview recording sheets.
- Photos, including those of the study packets and shake tests.
- Data analysis tool with the analyzed data.
- Study report.
- A presentation of the study results.

8. Appendixes

Appendix 1: Study checklist

		Steps/actions	Handbook section	Timeline
Pre-planning				
□	**1**	Engage key cold chain stakeholders	2A	At least 4 months before the study starts
□	**2**	Identify a study coordinator and contract technical assistants	2B	
□	**3**	Determine the number of study routes and supply parameters	2C	
□	**4**	Purchase temperature data logger	2D	
□	**5**	Set the date and organize the workshop	2E	
□	**6**	Order study materials	2F	
Study planning				
Clarify roles and responsibilities				Starting at least 2 weeks before the study start date
□	**7**	Confirm the study coordinator	3A.1	
□	**8**	Initiate technical assistance	3A.2	
□	**9**	Decide who will record VVM readings	3A.3	
□	**10**	Decide who will perform the shake tests	3A.4	
□	**11**	Decide who will collect feedback from site personnel	3A.5	
□	**12**	Decide who will conduct the data analysis and write the report	3A.6	
□	**13**	Decide how to collect/send study packets at end of study	3A.7	
Conduct the workshop and finalize the country-specific protocol and documentation				
□	**14**	Train participating NIP staff	3B	
□	**15**	Decide on study routes	3C.1	
□	**16**	Decide on study vaccine	3C.2	
□	**17**	Determine study timeline	3C.3	
□	**18**	Get authorization to discard study vaccines	3C.4	
□	**19**	Data-sharing agreement	3C.5	
□	**20**	Prepare the **master tracking form**	3D.1	
□	**21**	Update the **monitoring form**	3D.2	
□	**22**	Update **instruction sheet**	3D.3	
□	**23**	Prepare **adhesive packing slips**	3D.4	
□	**24**	Confirm data logger functionality	3E	
Study implementation				
□	**25**	Program data loggers	4A	During the study
□	**26**	Prepare study packets	4B	
□	**27**	Monitor study progress	4C	

		Steps/actions	Handbook section	Timeline
□	**28**	Collect feedback from NIP staff	4D	
□	**20**	Return study packets to the central office	4E	
□	**30**	Conduct shake tests	4F	
Data analysis				
Prepare data				1 to 2 weeks after the study
□	**31**	Download data loggers	5A.1	
□	**32**	Check monitoring forms	5A.2	
□	**33**	Collect feedback questionnaires	5A.3	
Configure and run data analysis tool				
□	**34**	Enter data into 'Overall Input' tab	5B.1	
□	**35**	Enter data into 'Equipment and Time Input' tab	5B.2	
□	**36**	Paste logger data into 'LogTag Data Input' tab	5B.3	
□	**37**	Review data quality on 'Route Output' tab	5B.4	
□	**38**	Analyze 'Summary' data tables and charts for key findings	5B.5	
Presenting analysis and results				
□	**39**	Prepare a presentation to debrief partners on findings	6A	2 to 3 weeks after the study
□	**40**	Complete study report	6B	
Knowledge management				
□	**40**	Retain electronic copies of monitoring forms, data logger files, final Excel analysis tool, reports, and presentation	7	During and after the study

Terms of Reference

Consultancy: Temperature Monitoring Studies

Highlighted texts in yellow (and maybe other details) need to be adapted accordingly…

1. Background

Vaccines are biological products and there have been two general types: live viral and bacterial vaccines and non-replicating vaccines. The former type is more sensitive to elevated temperatures and can potentially lose potency during storage and distribution. The latter type often requires adjuvants to enhance the immune response. Unfortunately, these adjuvants are sensitive to freezing as they tend to aggregate and this can also result in efficacy and potency losses. Due to this fact that vaccines are heat and/or freeze sensitive, it is imperative to store and transport them at the recommended temperatures at all times.

With this ultimate aim in mind, UNICEF supports countries in achieving national immunization goals with an increased focus on the vaccine cold chain and logistics (CCL) systems. The goal for CCL systems is to 'optimize' their performance based on three key parameters: availability, quality and cost; the aim is to achieve adequate supply for every immunization session without temperature damage and at the lowest possible cost per fully immunized child. As immunization programs add new vaccines to their schedules, the demand on CCL systems increases as these vaccines tend to be more expensive, bulkier, and less thermo-stable than traditional vaccines. To identify temperature deviations affecting storage areas such as cold rooms or freezers, it is recommended that countries conduct temperature mapping studies at least once every three years. With this mapping study, the temperature distribution within different storage areas is established and documented. In addition, to ensure good storage and transportation practices, temperature monitoring studies are conducted according to WHO protocol (WHO/IVB/05.01 Rev[10]) at least once every five years. Their principle is based on continuous temperature recording throughout the whole storage and distribution system from vaccine arrival to the point of use. The data from these studies from different countries may be shared appropriately for global analysis and research to provide further insight into cold chain and vaccine management issues.

2. Purpose and Activities

The purpose of this consultancy is to provide, in close collaboration with UNICEF country/regional offices, ministries of health, and immunization partners, technical support to countries in the effective implementation of temperature monitoring and mapping studies, development/adaptation of study guidelines, and the development of institutional capacity to enable sustainability of national systems. In particular:

[10] http://www.who.int/immunization/documents/WHO_IVB_05.01/en/

1. **Implementation of Temperature Monitoring Studies**
    i. Phase 1:
        1. Ensure selection and procurement of temperature loggers have been completed
        2. Ensure an adequate number and diverse selection of study sites (routes)
        3. Organize a workshop with national study director and Immunization Program staff to:
            a. Explain and adapt protocol template to create a country specific methodology
            b. Select study vaccines
            c. Have authorization to discard study vaccines (some or all study vaccines will be damaged)
            d. Review selected sites and ensure appropriateness in terms of number and selection
            e. Ensure completion of the data sharing agreement
            f. Practice shake tests
            g. Prepare data collection forms (monitoring form, instructions, packing slip, etc.) using the existing templates
        4. Organize a training for the site focal points
            a. Explain the objectives and ensure understanding of the protocol
            b. Train on how to fill out monitoring form
            c. Practice shake tests, if needed.
        5. Ensure preparation of study packets including programming data loggers
        6. Prepare schedule for shipping (master tracking form) and send reminders to shipping focal point
        7. Remote support for site focal points if needed.

    ii. Phase 2:
        1. Collect or coordinate collection of data loggers, study forms, study packets, etc.
        2. Interview field staff in study sites as described in the protocol
            a. Field visits to the different sites/facilities will be ideal, but because of time/budget constraints, not all sites may be visited. In general, preference is to utilize the opportunity to train personnel and spread awareness about temperature monitoring procedures/issues and thus, build capacity.
        3. Ensure proper completion, otherwise repetition, of “shake tests”.
        4. Analyze data utilizing the existing data analysis tool
        5. Prepare debriefing notes on the result of the study, including recommendations (collaborating with MOH and other partners) as well as a formal presentation for the presentation of the study results during the dissemination workshop.
        6. Prepare a technical report based on methods, results, and recommendations (collaborating with MOH and other partners). Prepare an anonymised version of the report, without the country name and site names.

2. **Capacity Development**

    UNICEF and partners are interested in developing sustainable local capacity to implement these studies, take remedial actions based on results, and in general, improve vaccine storage and management.

i. During field visits and focal point trainings, familiarize the health workers with the purpose of the study and why good vaccine management is important.
ii. Identify local resources that can potentially carry on the work once the consultant leaves and train them.
iii. Develop comprehensive implementation guidance notes based on the existing protocols. Report both country specific lessons learned and generic implementation lessons.

3. Duration Start date: May 1, 2018 End date: December 31, 2018

4. Duty station: The consultant will be based in his/her home country, but will need to travel to (names of countries) for part of the work that needs to be conducted in-country. Some work (planning, data analysis, report writing, etc.) can be done remotely.

5. Timeframe: Up to **29** working days, as requested by the Immunization Team

Note: the # of days listed below is a rough estimate for one country. It should be adjusted depending on how many countries and how the different work can be balanced (if combining with temperature mapping studies, etc.)

Deliverables	Due Date	(Maximum # of Days)
Plan temperature monitoring study in ___ countries (names of countries), including trainings. Prepare country specific protocol and complete phase 1.	??	10
Develop a country-specific protocol for adapted implementation in each country for temperature monitoring studies and adapt the forms to each country. Document the process and report both country specific lessons learned and generic implementation recommendations.	??	5
Data analysis discussed with national EPI for a formal presentation of the study results	??	7
Temperature monitoring study report (complete phase 2) including methodology, data analysis results, and recommendations adapted for general publication for ___ countries (names of countries). Anonymized version without the sites names in the text and the graphs should be provided, adapted for publication.	??	7
Provide trip reports after each trip.	??	--
Follow current and appropriate data/knowledge management and data sharing protocol.	??	--
Total		29 Days

*Can include weekends/holidays, but only with supervisor's written approval

*Payment will be based on the deliverables accomplished and on the actual number of days worked.

6. Key competencies, technical background, and experience required:

Competencies

- Strong analytical, oral, & written communication skills
- Effective facilitator with proven ability to engage and train a group of individuals
- Demonstrated ability to work in a multi-cultural environment
- Effective presenter including ability to adapt the message and visual aids for multiple audiences is an advantage

Technical skills and knowledge

- Educational background in mechanical engineering or related field (university degree *preferred*; advanced training may be considered in combination with relevant work experience).
- Proficiency in the use of the Microsoft Office applications including Excel, Word and PowerPoint
- Proficiency in the development of technical SOPs/protocols and reports
- Experience with hardware and software integrations
- Proficiency in WHO PQS-listed temperature devices
- Familiarity with WHO-recommended vaccine management practices *an advantage*

Work experience

- At least 5 years of experience in cold chain hardware and software installation & maintenance or at least 2 years of experience conducting temperature monitoring and/or temperature mapping studies
- Proficiency in data collection and data analysis
- Experience in the use of the TMS tool *an advantage*
- Experience interfacing with national ministries of health, UN agencies, or other NGOs *an advantage*

Languages

- Written and spoken fluency in English
- Proficiency in French is required (for French-speaking countries)

Authorized by:

Signature_____ Date:_____

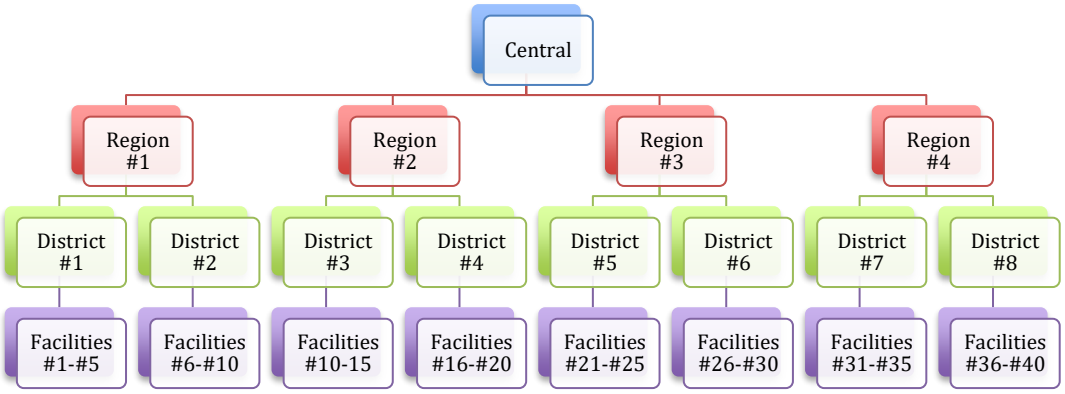
Consultant Name:

Signature_____ Date:_____

----------End of consultant terms of reference template----------

Appendix 3: Routes examples

Example of routes for a four-level supply chain



Appendix 4: Temperature data loggers

	Device	PQS**	Indicative Cost ($)	Memory	Output format	Extra Equipment	Configuration software needed ?	Analysis software needed?	Comments	Link
1	LogTag Trix-8	E006/006	22-32	8000	pdf, Excel	Cradle ($55)	Yes, free software		Recommended choice for cold chain up to 3 segments	https://logtagrecorders.com/products/trix-8/
2	Libero Ti1	E006/024	150	16000	pdf	None	Preset configuration but can reconfigure using 'LiberoConfig' software	Software not needed to get pdf summary	Will need a pdf converter to analyse data using Excel	https://shop.elpro.com/EL30/ArticleContentPageServlet?action=show&key=ARTIKELNR&value=800004
3	TT4	E006/028	37,5	16000	pdf, Excel	None	Yes		Can accidentally be stopped	http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/LinkPDF.aspx?UniqueID=ef0b21db-198c-4bca-88e0-ff9d7c01632e&TipoDoc=DataSheet&ID=0
4	Q-tag CLm doc LR	E006/032	69,2	38000	pdf, ASCII→Excel	None	Preset configuration but can reconfigure using 'Easygo' software	Not needed, but can utilize 'Smartview' software	Can accidentally be stopped	https://www.berlinger.com/fileadmin/user_upload/temperature-monitoring/training_and_support/brochures/q-tag_clm_doc_family/Brochure_Q-tag_CLm_doc_family_EN.pdf
5	LogTag Trix-16	No	37	16000	pdf, Excel	Cradle ($55)	Yes, free software		Recommended choice for cold chain with 4+ segments	https://logtagrecorders.com/products/trix-16/
6	UTRIX-16	No	27-39	16000	pdf, Excel	None	Yes, free software for more detailed analysis		Adequate choice	https://logtagrecorders.com/products/utrix-16/
7	Tinytag Talk 2	No	75	16000	Excel, word friendly format available	CAB-0005-USB:Tinytag transit/Talk USB download cable	Yes (paid)		Recommended in earlier versions of protocol	https://www.geminidataloggers.com/data-loggers/tinytag-talk-2/tk-4014
8	Tinytag Plus 2	No	110	32000	Excel, word friendly format available	CAB-0007-USB:Tinytag transit/Talk USB download cable	Yes (paid)			https://www.geminidataloggers.com/data-loggers/tinytag-plus-2

*All these are programmable, multi-use temperature data loggers; all software listed are free except inytag
** Based on PQS Catalogue version

Temperature Monitoring Study Implementation Workshop

City, Country – Dates

Highlighted texts in yellow (and maybe other details) need to be adapted accordingly…

BACKGROUND

Vaccines are biological products and there have been two general types: live viral and bacterial vaccines and non-replicating vaccines. The former type is more sensitive to elevated temperatures and can potentially lose potency during storage and distribution. The latter type often requires adjuvants to enhance the immune response. Unfortunately, these adjuvants are sensitive to freezing as they tend to aggregate and this can also result in efficacy and potency losses. Due to this fact that vaccines are heat and/or freeze sensitive, it is imperative to store and transport them at the recommended temperatures at all times.

As immunization programs add new vaccines to their schedules, the demand on supply chain management systems increases as these vaccines tend to be more expensive, bulkier, and less thermo-stable than traditional vaccines. To ensure proper storage and transportation practices, temperature monitoring studies are conducted at least once in every five years. Their principle is based on continuous temperature recording of a shipment throughout the entire distribution system from vaccine arrival to the point of use.

The primary purpose of this workshop is to plan the implementation of a temperature monitoring study in Country according to the WHO protocol (WHO/IVB/05.01.rev1:

http://www.who.int/immunization/documents/WHO_IVB_05.01/en/).

OBJECTIVES

- Common understanding of the Country immunization supply chain system and status
- Adapting the WHO protocol and produce a Country specific study protocol
- Training of personnel involved to ensure appropriate implementation of the adapted protocol
- Prepare forms and planning schedule to help the implementation process

---

AGENDA

DAY 1

9:00-9:15	Opening – welcome and introduction
9:15-10:00	Overview of the Immunization + cold chain system in country
10:00-10:30	Objectives of the workshop/what we expect by end of the workshop
10.30-11.00	Coffee/Tea Break
11:00-11:30	Overview of the WHO temperature monitoring study protocol
11:30-11:45	Overview and display of the LogTag temperature logger
11:45-13:00	Adapt protocol for country context

- Status of cold chain
- Overview of selected sites/agree on routes
- Choose an appropriate study vaccine and determine # of vials needed
- Determine how study materials will be shipped (packet/box, etc.)
- And clearly identify/introduce the study coordinator(s)

13:00-14:00 Lunch

14:00-15:30 Adaptation of protocol continued

- Duration at each cold chain level
- Timeline for the completion of study

15:30-16:00 Coffee/Tea Break

16:00-17:00 Adaptation of protocol continued

- Decision on how and when the shake tests will be conducted (centrally or health facility level)
- Decision on how and when VVM readings will be completed
- Decision on how to collect packets at the end of study
- Decision on who can conduct "interviews" of health workers involved

DAY 2

9:00-9:30 Recap of day 1

9:30-10:30 Authorization to use vaccine vials for the study and to discard at the end

Data sharing agreement and outlining responsibilities for different personnel/agencies

- Study coordinator responsibilities
- Other participating personnel responsibilities
- Decision on how to train/inform the health workers
- Decision on who will conduct data analysis, report writing, and debrief

10.30-11.00 Coffee/Tea Break

11:00-13:00 Adaptation of forms

- Monitoring form
- Instruction sheet
- Master tracking form (prepare schedule for study packets/organize contact information for all facility personnel)

13:00-14:00 Lunch

14:00-15:00 Practice in groups filling the monitoring form

15:00 – 15:30 Finalization of the country specific protocol

15:30-16:00 Coffee/Tea Break

16:00-17:00 Practice shake tests

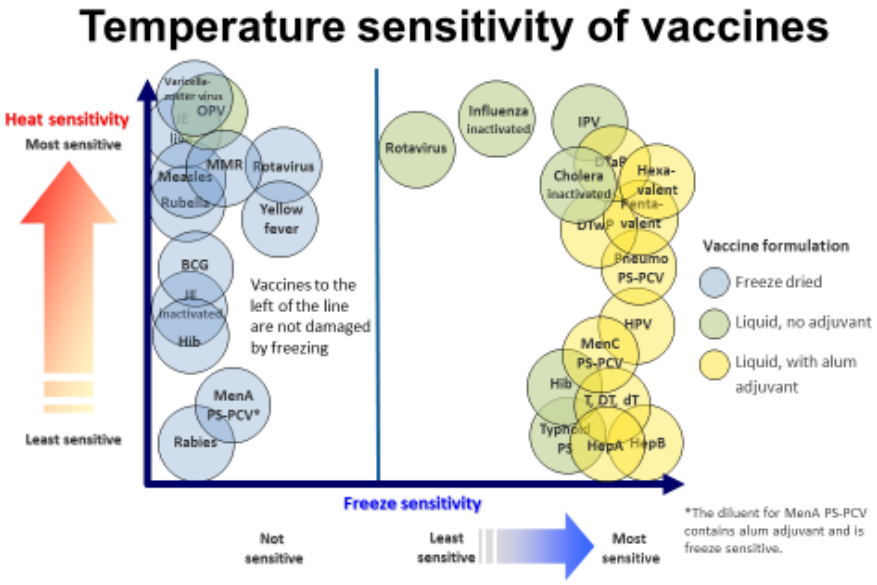
----------**End of Implementation workshop template**----------

Appendix 6: Workshop overview presentation template

Temperature Monitoring Studies (TMS)

Country, Year

Texts in red (and maybe other details) need to be adapted accordingly…



Temperature Excursions

•Live vaccines → heat sensitive
  – VVM detects heat damage to a certain extent (and if read correctly)

•Non replicating vaccines with aluminum adjuvant → freeze sensitive
  – Harder to detect freeze damage
  – Shake tests can help to a certain extent

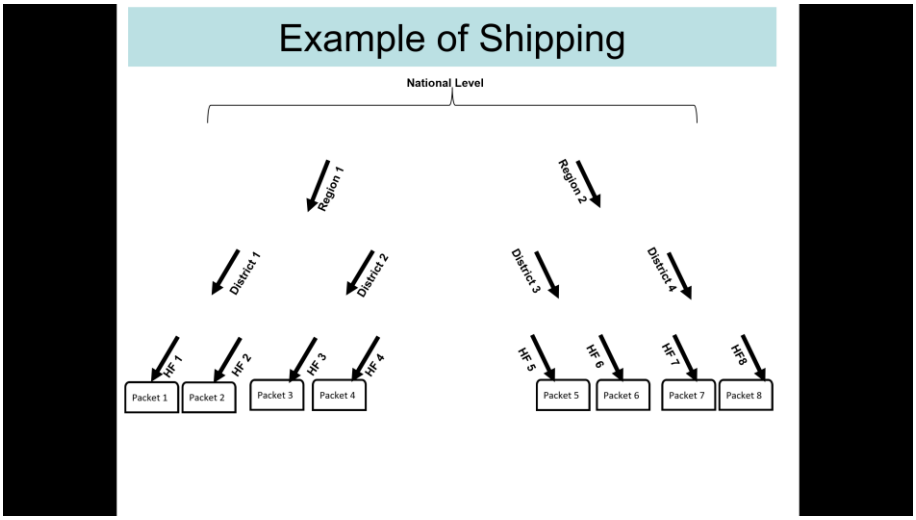
•Damage

- If undetected: potentially damaged vaccines
- If detected: potential stockouts, wastage

Continuous temperature monitoring: detects excursions and can help avoid future excursions

Temperature Monitoring Study (TMS): Overview

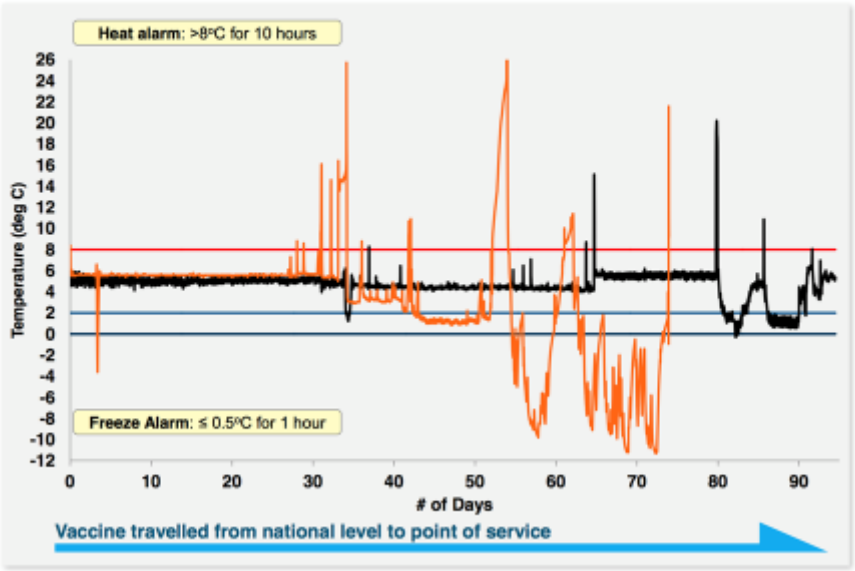
- Continuous temperature monitoring throughout the cold chain from national level to immunization session/outreach
  - At least 8 health facilities selected (8 routes)
  - Study packets prepared for each route with a temperature recorder and vaccine vials
    - A monitoring form follows the routes – record date/time in and out of cold chain equipment at each storage facility
  - 2 to 6 weeks at each level of the cold chain
  - VVMs read and shake tests conducted at the end
  - Results give a perspective on the level of risk in relation to storage temperatures/transportation, and under what circumstances
- Although a study and hard to eliminate bias, normal procedures should be followed, if possible



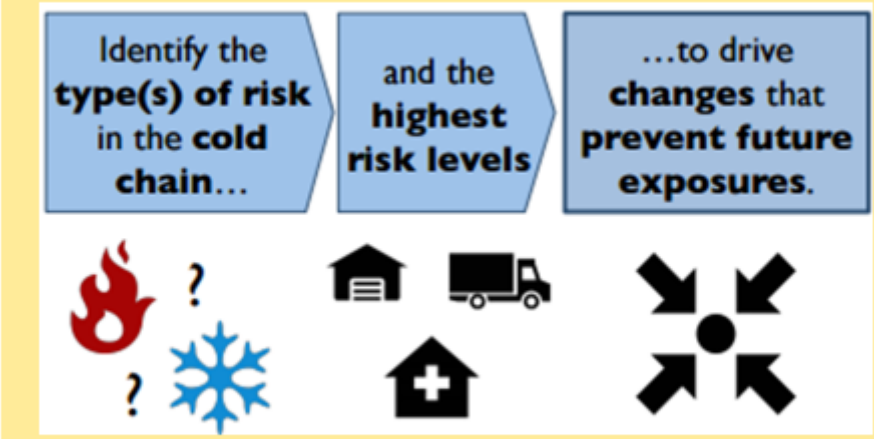
Example of Results

Example from another study

Examples of Temperature Profiles



TMS: Objectives



This evidence can build substantial political and institutional will for adopting targeted solutions to reducing temperature risk in the cold chain

TMS: Best Practices

- More sites/routes improve data quality/reliability
  - At least 8 routes, more routes the better (increase to the number of loggers available)
- Include sufficient # of sites for each level
  - At least 2 regions, 4 districts, and so on…
- Diverse routes/sites – based on geography, accessibility, equipment/process variations, performance, etc.
- Create a schedule for routes, but leave buffer time in case of delays
  - Study coordinator follows up with sites
- Ideally, transport segments should be at least 1-2 hours so we have sufficient data points
- Include an immunization session or outreach for each route

Temperature Logger: _____

- _____ data points
- Temperature must be recorded at least every 15 min
  - ➢ Decrease interval to increase data quality (also based on timeline/duration of the study)

Discussion Points

1. Site selection: ensure an adequate number of routes have been selected and that selected sites/routes are appropriate/diverse
2. Study Coordinators are chosen and understand their responsibilities
3. Choose an appropriate study vaccine and determine # of vials needed (at least 2)
4. Determine how study materials will be shipped
5. Timing:
    a) Duration at each cold chain level
    b) Timeline for the completion of study
    c) How/when to prepare packets, start study, and end study
6. Decision on who will conduct shake tests and how (ideally centrally)
7. Decision on how and when VVM readings will be completed
8. Decision on how to collect packets at the end of study
9. Decision on who can conduct "interviews" of health workers involved
10. Authorization to discard vaccines at the end of the study
11. Data sharing agreement signature
12. Adaptation of forms (monitoring form, instruction sheet, master tracking form)
13. Responsibilities for different personnel/agencies
    a) Study coordinator
    b) Decision on who will conduct data analysis, report writing, etc.
    c) Decision on how to train/inform the health workers at different sites (workshop, field visits, etc.)

----------End of workshop presentation template----------

Appendix 7: Interview recording sheet

Cold Chain Temperature Monitoring Study, *Country, Year*

Interview Recording Sheet

To gather additional information on the behavior and practices of health personnel with respect to the sensitivity of the vaccines to temperature, health personnel involved in the study at the national, regional, district, and health facility levels will be interviewed.

The interviews will be the responsibility of the study coordinator.

Date of the interview: _____

Method: _____ (in person, telephone, etc.)

Ask the below questions clearly WITHOUT mentioning the choices/suggested answers listed. If the answer(s) is among the choices listed, circle it. Otherwise, circle 'Other' and write under 'Comments'.

1. How can you tell if a vaccine was:

Frozen?	Exposed to heat?
a. Temperature reading b. Freeze indicator (FreezeTag, for example) c. Visibly frozen d. Other (complete 'Comments' below)	a. Temperature reading b. VVM reading c. Other (complete 'Comments' below)
Comments:	Comments:

2. What do you do if you know that a vaccine was:

Frozen?	Exposed to heat?
a. I discard the vaccine vial b. I conduct a shake test c. I inform my supervisor and await instructions d. Other (complete 'Comments' below)	a. I discard the vaccine vial b. I inform my supervisor and await instructions c. Other (complete 'Comments' below)
Comments:	Comments:

3. At your level (during storage and/or transport), do you think there is a risk of:

freezing?	*Exposure to heat?*
a. Yes b. No	a. Yes b. No
What could be the cause?	What could be the cause?

Once the interview is completed, training can be provided (including the correct answers to the interview questions); this should be used as an opportunity to build capacity as well.

----------End of interview recording sheet template----------

Country Year Temperature Monitoring Study: Protocol

Highlighted texts in yellow (and maybe other details) need to be adapted accordingly…

RATIONALE

Vaccines are biological products and there have been two general types: live viral and bacterial vaccines and non-replicating vaccines. The former type is more sensitive to elevated temperatures and can potentially lose potency during storage and distribution. The latter type often requires adjuvants to enhance the immune response. Unfortunately, these adjuvants are sensitive to freezing as they tend to aggregate and this can also result in efficacy and potency losses. Due to this fact that vaccines are heat and/or freeze sensitive, it is imperative to store and transport them at the recommended temperatures at all times.

As immunization programs add new vaccines to their schedules, the demand on supply chain management systems increases, as these vaccines tend to be more expensive, bulkier, and less thermo-stable than traditional vaccines. To ensure proper storage and transportation practices, temperature monitoring studies are conducted at least once in every five years. Their principle is based on continuous temperature recording of a shipment throughout the entire distribution system from vaccine arrival to the point of use. The data from these studies from different countries may be shared appropriately for global analysis and research to provide further insight into cold chain and vaccine management issues across different countries and regions.

Cold chain context for the country: how is the temperature monitored now, how can the study help the current situation, etc.

STUDY

The study will build upon the WHO protocol "WHO/IVB/05.01.rev.1: *Study protocol for temperature monitoring in the vaccine cold chain*," (http://www.who.int/immunization/documents/WHO_IVB_05.01/en/) as called for in the EVM recommendations. In this protocol, "temperatures are monitored continuously as vaccine shipments travel through the cold chain, from primary stores, to intermediate stores, to health centers and, finally, to the outreach delivery site/s." The study will be planned by adapting/utilizing the tools and templates provided in the Temperature Monitoring Study Handbook.

OBJECTIVES

1. To ascertain the extent to which temperature excursions are occurring throughout the supply chain, and under what conditions.
2. To quantitatively establish a basis for prioritization of technical and infrastructural assistance for cold chain strengthening.
3. To develop in health workers a greater awareness and understanding of vaccine thermo-stability and vulnerabilities during transport and storage

4. To review the current practices and procedures and if needed, change the National EPI policy for storage and transportation of vaccines

METHODOLOGY

Study Team

The National Center for Immunization and CHAI, PATH, UNICEF, WHO, etc. will conduct the study jointly. A study coordinator(s) will oversee the execution of the study with guidance/technical assistance from _____.

Study coordinator responsibilities include:

1. Overseeing the preparation of the packets including programming loggers
2. Overseeing the flow of packets through the distribution chain
3. Ensuring timely shipment departures and arrivals at every site
4. Ensuring adherence to the instructions sent
5. Conducting "interviews" of site personnel
6. Conducting and reporting on shake tests centrally at the end of the study
7. Assist with data analysis and report writing

Site Selection

The facility profile for country includes 1 Central Store, ____ Regional Stores, ___ District Stores, ___ health centers. ____ study routes were chosen (as randomly as possible) that reflect broad areas of the country in terms of geographic distribution, accessibility, equipment and process variations, performance, etc. Some of the key parameters that were considered at different sites are:

- PQS vs. non PQS or absorption equipment
- Frozen ice packs vs. chilled water packs vs. refrigerated vehicles
- Refrigerators vs. passive storage containers
- Intermediate depot vs. Regional store routing
- Urban vs. rural sites
- Hospital vs. clinic vs. health post

In addition, only sites that are staffed with responsible personnel who would be able to fulfil study requirements were considered.

Each of the ___ routes will start from the central store with varying regional, district, and health centers and will end at an immunization or outreach session. ___ regional, ____ provincial, and ____ district sites will be studied. The summary of the routes (with the names of the sites) is shown in Appendix 1.

Pre-shipment

1. **Vaccine selection:** _____ vaccine was chosen as it is a freeze sensitive vaccine with aluminum adjuvant. ___ (multi) dose vials at VVM stage 1 will be utilized. Two vials will be used for each route/study packet, 1 of which will be frozen upon return to the central store as a shake test control and the other will be the 'test' vial.

2. **Other study materials:**

a. Logger: ____ LogTag TRIX-8/Trix-16 temperature loggers are available to be used for this purpose. The maximum capacity is ____ data points.

b. Packing slip: will show the route and the contact information of the study coordinator in case of emergency/questions.

c. Study bag/box: a plastic Ziploc bag that contains the logger and two vaccine vials will be placed in a bigger Ziploc bag with the instruction sheet and monitoring form stapled together. The "normal" shipping/packaging procedures will be followed as much as possible, though this is a study. Please see Appendix 2 for the chosen bag/box.

3. **Master tracking form:** will be created with below details
   a. Route summary with all the site names and the temperature logger serial numbers/IDs.
   b. A schedule for the shipments to each level and facility. The normal distribution schedules for different facilities will be followed if possible and an appropriate storage duration at each level has been decided as outlined in the 'Timeline' section below.
   c. Contact information for each site in each route so that follow-up calls can be made.
4. **Monitoring Form:** each study packet must include the data collection form where the dates and times when the study packets entered and exited the cold chain equipment at the storage facility. This form must be properly filled out at all levels, or data analysis becomes highly challenging. Please see Appendix 3 for the adapted form.
5. **Instruction sheet:** Instructions for each route must be created and sent with each packet. Additional instructions for some levels (for example, a regional store that will receive 3 packets to be distributed to different districts) must also be conveyed to the appropriate personnel. Please see Appendix 4 for the adapted instructions.
6. Authorization to discard vials at the end of study: To ensure that the shake test results are recorded accurately, they will be conducted centrally, by trained EPI staff. This can help avoid validation issues at the facility level, and can increase confidence about results amongst EPI and partners. For this purpose, the study packets (with forms) at the end of the study will be returned without exposing them to potential freezing, i.e. transport them at room temperature and do NOT refrigerate them in any way. After the shake tests, the vaccine vials will be discarded. Authorization to use ___ vials of vaccines for this study was granted by _____ prior to the study start.
7. Data sharing agreement template (Appendix 5) will be completed by (official titles).

Shipment

The temperature data loggers must be programmed before shipment.

i. ____ min interval (maximum total study time will be ___ days)
ii. All loggers start at the same time (04:00 PM or 16:00, the day the loggers are placed in the National store)
iii. Set to stop recording values when full (no overwriting data)
iv. Give specific IDs based on final destination
v. Write final destination ID on the logger with a permanent marker

A logger to record ambient temperature will not be used for any routes, since such data are rarely utilized and this also simplifies the process for health workers. In addition, the loggers can be utilized for additional sites increasing the comparison volume and in turn, data quality.

Plastic zip lock bags that contain one configured temperature logger and 2 vaccine vials will be prepared and placed in a bigger bad containing a monitoring form (Appendix 3) and handling instructions (Appendix 4. The packet should be attached to or placed in a normal vaccine box with vials so that it is clear normal procedures should be followed for the packet as well. The date and time the packet enters and leaves a cold chain equipment should be accurately recorded on the monitoring form plus other details such as type of equipment, etc. These should go with the normal paper work for vaccine delivery/pick up. Each study packet should be clearly labeled with the destination facility and contact information for the study coordinator.

Training

Training for all participating facilities will be conducted. It will be in-person training, organized by levels conducted by _____. The objective is to have all the participants:

- Understand the objectives of and rationale behind the study
- Know how to identify and handle the packets, according to written instructions sent
- Know how to try to retain and follow standard/normal conditions and procedures in order to minimize bias
- Understand proper completion and handling of the monitoring form.
- Know how to inform/update study coordinator about arrival and departure of packets
- Know how to contact the study coordinator in the event of challenges or questions.

IMPLEMENTATION

Timeline

The approximate duration for each storage level is as below:

• Central	-	6 weeks
• Regional	-	6 weeks
• District	-	3 weeks
• Health Facility (including Immunization session or outreach)	-	3 weeks
Total	**-**	**18 weeks***

*In addition to 13 planned weeks in storage, transport between levels will take time as well. However, as the exact durations will depend on the route, it's not included here.

The LogTag Trix-16 loggers can hold a maximum of 16000 data points and at __ min interval data collection, they will reach full capacity around ___ days. Anticipating certain delays in the planned schedule, the study will be scheduled for 20 weeks (18 weeks of storage + ~1 week of transport + some buffer time). The study *implementation* should start on 19 July, 2018 and be scheduled to end on 22 December, 2018, so that the analysis and reporting can be completed in January 2019.

The estimated duration to complete the study is as follows:

• Planning	-	2 weeks
• Implementation	-	20 weeks (July - December, 2018)
• Analysis and reporting	-	3 weeks (January 2019)
Total	**-**	**25 weeks**

Timelines for specific facilities in each route should be mapped out and recorded in the master tracking form based on the specific distribution schedules, keeping the above duration recommendations in mind. The study coordinator should follow up with each facility regarding the packet arrival, completing the monitoring form, proper handling and storage, and packet departure.

Reactivity/Bias

The study may cause health-worker desire to alter their standard behavior due to the awareness they are being observed. The training will emphasize the need to follow the standard procedures. Reactivity and bias, to the extent it persists, is expected to have a positive programmatic effect nonetheless, particularly as monitoring is routinized.

Data Management/End of Study

- Collection of study packets (loggers, vials and monitoring forms): study coordinator will organize collection of materials from facilities to transport them to central level. The monitoring form must be collected as data analysis will be difficult without it.
    - VVMs should be read at the health facility level during immunization session or outreach. Ensure this was completed; otherwise, make a note and complete at this stage.
    - Packets should not be opened until they reach central level
    - Transport the sealed packets back at ambient temperature (do not cool or freeze)
- Interviews of vaccine handlers in study sites will be conducted by _____ to assess knowledge around heat and freeze sensitivity of vaccines, ice pack conditioning, etc. using the interview recording sheet in Appendix 6.
- Study coordinator should conduct shake tests centrally
    - Freeze one of the vials from each packet. Use this vial as the control
    - Conduct shake test for the 2nd vial from each packet by comparing to the control from the same packet
    - Take photographs before, during, and after the shake test

ANALYSIS

The data must be downloaded from each of the loggers as .csv files (or another Excel friendly format) so that they can be opened in Microsoft Excel. Data cleaning and analysis will also include relating forms and logger data, annotating the temperature-over-time curves, calculating frequency and duration of continuous freeze and heat exposures at each level, and processing the data to characterize the process inputs (user behavior, equipment) and temperature outputs. The outputs will illustrate the status of the current cold chain infrastructure.

For data analysis, the Microsoft Excel based tool created by UNICEF HQ can be utilized. The data from the monitoring sheets must be entered into the tool. Then, the data from the loggers can be copied and pasted. The tool will analyze heat and freeze excursion frequency and durations for each facility. It will also create summary tables comparing different levels, etc.

REPORTING

The National Center for Immunization, CHAI, PATH, UNICEF, and WHO will collaborate on a final report with actionable results. This report should include the methodology used, analyzed data and conclusions from the study, and recommendations for improvements to meet the objectives of the study.

APPENDICES

Appendix 1

Summary of routes

Appendix 2

Study bag/box

Appendix 3

Monitoring Form

Appendix 4

Instruction sheet

Appendix 5

Data sharing agreement

Appendix 6

Interview recording sheet

----------End of country specific protocol template----------

TEMPERATURE MONITORING STUDIES

Data Sharing

Narrative

The United Nations Convention on the Rights of the Child states that all children have the right to live and have equal access to ***quality healthcare***. UNICEF is the world's largest buyer of childhood vaccines, reaching over one third of the world's children. A critical component of the Global Vaccine Action Plan (GVAP) is improving the quality of vaccines.

One of the quality control parameters is vaccine temperature. Exposure to temperatures outside the recommended ranges may reduce the potency and safety of the vaccines. This can cause vaccine wastage leading to stock outs. These can ultimately result in loss of patient confidence. As immunization programs add new vaccines to their schedules, the demand on cold chain systems increases as these vaccines tend to be even less thermo-stable than traditional vaccines. Therefore, temperature monitoring studies are conducted to identify areas of improvement in the cold chain as vaccines travel from the national level to health facilities.

At a global level, aggregating data from different countries helps to inform policies and the work to improve vaccine temperature stability. Analysis of multi-country data from temperature monitoring studies is needed to understand where the underlying issues are in the cold chain and what common problems exist among multiple countries. This analysis is for research purposes only. **The research results will only be published in an anonymous and aggregated form without publicizing the name of the country and facilities.** This research may result in further investments for capacity building and equipment/technology improvement with the ultimate goal of strengthening supply chain systems and in turn, improving the health system as a whole.

Data Sharing Agreement

Purpose: Agreement on the data[11] collected from the temperature monitoring studies conducted in country from 1st of April, 2018 between Ministry of Health (MOH) and United Nations Children's Fund (UNICEF) Health Section.

1. MOH permits this data to be used for statistical and research purposes and global analysis by UNICEF.
2. MOH permits the aggregated and anonymized form of the data to be shared with research partners and to be published in reports, scientific journals, and/or presentations at conferences. Data sources will be acknowledged. Country name and names/details of facilities and local staff involved will be NOT be made public)
3. No attempt will be made by UNICEF to identify or investigate any individual person, family, business, or enterprise.
4. Reports based on the anonymized data may be published on Technet-21.org.
5. If there are any changes to the planned use of data, UNICEF will seek MOH's agreement to such changes through a revised data sharing agreement.
6. This agreement comes into force on the date approval is given for access to the data.
7.

Please check the box below and sign

☐ I hereby agree to release the temperature monitoring study data as per the agreement above.

Agreed By - Country MOH Representative

Name:

Title:

Department:

Email:

Signature: Date:

Agreed With - UNICEF Representative

Name:

Title:

Division/Section:

Email:

Signature: Date:

[11] Continuous time series data (from the temperature loggers), analyzed data, report, and other relevant documents detailing the study.

Appendix 10: Master tracking form template

Appendix 10a: Routes

Route Summary

Route	National		Regional		District		Health Facility	Vaccination: Immunization Session or Outreach Session or Mobile Strategy	Logger Serial #
1	PNA	→	Kaolack	→	Nioro	→	Keur Madiabel	Outreach Session	
2		→		→		→			
3		→		→		→			
4		→		→		→			
5		→		→		→			
6		→		→		→			
7		→		→		→			
8		→		→		→			
9		→		→		→			
10		→		→		→			
11		→		→		→			
12		→		→		→			
13		→		→		→			
14		→		→		→			
15		→		→		→			
16		→		→		→			

Appendix 10b: Dates and contacts

Master Tracking Form

Route		Duration			
		6 weeks	6 weeks	3 weeks	3 weeks
		National	*Regional*	*District*	*Health Facility*
1		PNA	Kaolack	Nioro	Keur Madiabel
	Dates (Exit)	Sep-15			
	Contacts	Name Phone #	Name Phone #	Name Phone #	Name Phone #
2	Dates (Exit)				
	Contacts				
3	Dates (Exit)				
	Contacts				
4	Dates (Exit)				
	Contacts				
5	Dates (Exit)				
	Contacts				
6	Dates (Exit)				
	Contacts				

Appendix 11: Monitoring form template

Cold Chain Temperature Monitoring Study: Monitoring Form

Study Packet # _____ **Logger Serial #** _____ **Vaccine Lot #** _____

QUESTIONS? Call
_____ at _____
_____ at _____

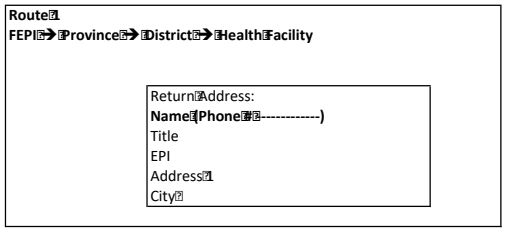
Route: PNA → Kaolack → Nioro → Keur Madiabel | Outreach Session

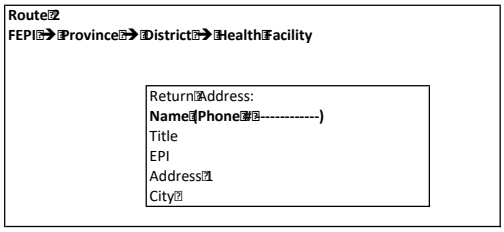
Level				Cold Chain Equipment				Last Name	First Name	Title	Telephone	Comments
				Type of Equipment	Make/Manufacturer	Model	Equipment ID #					
Central												
1		Entry	Date ___/___/___ Hour ____:____	☐ Cold Room ☐ Refrigerator								
		Exit	Date ___/___/___ Hour ____:____	☐ Refrigerated Truck ☐ Reused International Shipping Carton ☐ Cold Box *Type of ice-pack used:* ☐ Frozen ☐ Conditioned ☐ Cool pack								
Regional												
2	Regional Store: _____	Entry	Date ___/___/___ Hour ____:____	☐ Cold Room ☐ Refrigerator								
		Exit	Date ___/___/___ Hour ____:____	☐ Reused International Shipping Carton ☐ Cold Box *Type of ice-pack used:* ☐ Frozen ☐ Conditioned ☐ Cool pack								
District												
3	District Store: _____	Entry	Date ___/___/___ Hour ____:____	☐ Refrigerator								
		Exit	Date ___/___/___ Hour ____:____	☐ Cold Box ☐ Vaccine Carrier *Type of ice-pack used:* ☐ Frozen ☐ Conditioned ☐ Cool pack								
Health Facility												
4a	Health Facility: _____	Entry	Date ___/___/___ Hour ____:____	☐ Refrigerator								
4b	**Vaccination** ☐ Immunization Session ☐ Outreach Session • Village _____ • Distance one way (km) _____ • Time to village (hours) _____	Exit	Date ___/___/___ Hour ____:____	☐ Cold Box ☐ Vaccine Carrier *Type of ice-pack used:* ☐ Frozen ☐ Conditioned ☐ Cool pack								
		Entry	Date ___/___/___ Hour ____:____	☐ Refrigerator								
Collection												
5		Exit	Date ___/___/___ Hour ____:____	**VVM Readings:** ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Other: _____								
In case the packet was moved from one facility to another because of equipment/power failure, etc., please fill out this section.												
Deviations/Exceptional Circumstances: emergency transfer of vaccines												
•	☐ Regional ☐ District ☐ Health Facility Name of the facility: _____	Exit	Date ___/___/___ Hour ____:____	☐ Cold Box ☐ Vaccine Carrier *Type of ice-pack used:* ☐ Frozen ☐ Conditioned ☐ Cool pack								
		Entry	Date ___/___/___ Hour ____:____	☐ Refrigerator								

Appendix 12: Instruction sheet template

Instruction Sheet		
Contacts		_____ *at* _____
		_____ *at* _____
Materials		1 small sealed bag with Pentavalent vials and data logger
		(Do not open the small bag)
		1 bigger bag containing the small bag and
		1 Monitoring Form
Instructions:		1 Intruction Sheet
1	**For all**	Place the packet in the cold chain equipment (2-8°C) - please follow normal procedures
2		Fill in ENTRY line on the monitoring form FOR YOUR FACILITY ONLY. Date/time should be the time the packet was placed in the cold chain equipment. Cold chain equipment should be the type of storage used.Do NOT open packet and do NOT use any vials. Do not judge other vials based on the vials in this packet (VVM stage, etc.). This packet is for study purposes only. Leave the packet near the vials being used.
3		Keep the monitoring form + instruction sheet with the "packet".
4		Allow the packet to stay in the cold chain equipment for:
		If Central level: 42 days
		If Regional/Intermediate level: 42 days
		If District level: 21 days
		Health Facility level: 21 days
5		After the appropriate number of days, plan to transport the packet plus the monitoring form and intruction sheet to the next level with the next scheduled shipment
6		Fill in EXIT line on the monitoring form FOR YOUR FACILITY ONLY. Date/time should be the time the packet was taken out of the cold chain equipment. Cold chain equipment should be the type of transport used to send the packet to next level.
7		Call ---------- and report departure
8	**For Health Facilities**	After the immunization session or outreach, place the packet back in the cold chain equipment at the health facility. Fill in the ENTRY Line in Section 4b on the monitoring form. Date/time should be the time the packet was placed back in the cold chain equipment. Cold chain equipment should be the type of storage used. After or during the required days of storage, plan to send the packet to the next scheduled immunization session or outreach.
9		Fill in EXIT line on the monitoring sheet in the Collection section, check and record the VVM stage.

Appendix 13: Adhesive packing slip





Highlighted texts in yellow and routes (and maybe other details) need to be adapted accordingly…

Study Packet # 1

Step	Activity	Level
[1]	Storage	
[1]->[2]	Transport	↓
[2]	Storage	
[2]->[3]	Transport	↓
[3]	Storage	
[3]->[4]	Transport	↓
[4a]	Storage	
[4b]	Vaccination	**Immunization Session/Outreach/Mobile**

QUESTIONS?
Call _____ at _____

Study Packet # 2

Step	Activity	Level
[1]	Storage	
[1]->[2]	Transport	↓
[2]	Storage	
[2]->[3]	Transport	↓
[3]	Storage	
[3]->[4]	Transport	↓
[4a]	Storage	
[4b]	Vaccination	**Immunization Session/Outreach/Mobile**

QUESTIONS?
Call _____ at _____

Appendix 14: Data Analysis tool guide

Data Analysis Tool for Temperature Monitoring Studies

Download at:

https://www.technet-21.org/en/library/main/4941

Table of Contents

1. Software Requirements

Microsoft Excel on a PC is required to use this tool (with macros enabled). As this tool includes some ActiveX buttons, it does not work properly on a Mac.

2. How to use this guide

It is recommended that this guide should be utilized the first time a user is testing the temperature monitoring study tool. The tool is created to be user friendly; however, the guide is developed as a step-by-step instruction (especially for novice users). Once the user feels comfortable with the tool, he/she may not need to use it. However, if there is a specific question on a page on the tool, that particular section can be referred.

3. Tips

A. To get an idea of what the outputs of the tool are, it is recommended that you look through the Annex quickly.
B. Just like any new tool, it is recommended that the user familiarizes himself/herself with the tool and its capabilities (use old/dummy data) before using it for real analysis.
C. Please save your work frequently. Please note that there is no 'undo' after the codes run.
D. There is a 'Reset' button on the 'Overall Input' page. If you want to erase some of the steps you have completed or go back to a blank template, you can utilize this.
E. Some of the input steps are time consuming. Completing the route table on the 'Overall Input' page and time/dates for each route on 'Equipment and Time Input' page can take a bit of time. However, please ensure you complete them accurately and carefully. The rest of the calculations and analyses are fast, but are based on the input.
F. There are many error checks for the different inputs. This is to try to avoid human error as much as possible. If there is an error when you submit your input, a message will pop up asking to rectify something specific. You can change accordingly and submit again.
G. Some codes will take several seconds to run, especially after you submit data on 'LogTag Data Input'.

4. Using the Tool

The continuous time series data files (from the temperature loggers) must be downloaded in an excel-friendly format (.csv files) so that the data can be copied and pasted into the tool when prompted. The tool can be downloaded from:

https://www.technet-21.org/en/library/main/4941

When you open the tool, you'll see the 'Cover Page' where you should enter the country name and the date. Then you should move on to the 'Overall Input' page with four buttons.

A. 'Overall Input' Page

1. Please see Annex: Section A to get an idea of what this page will look like.
2. Click on the '1. Initial Menu' button

a. Fill out the details and press 'Ok'.
b. Wait for a few seconds. The information will appear in A1-B5.
c. The 'Temperature and Time Thresholds' screen is displayed.

3. 'Temperature and Time Thresholds': fill out the details.
   a. Temperature and time thresholds are pre filled based on the WHO heat and freeze alarms. Please do NOT change unless completely necessary.
   b. # of static storage levels: this number should NOT include any of the transportation segments or outreach. This should only include the sites where the vaccine was stored. For example, if the vaccines travelled from national → state → province → health facility, the # you input here should be 4. If the route was from central store → regional store → health facility → outreach, the # should be 3 (you should NOT count outreach).
   c. # of routes/terminal sites: this is the number of health facilities. For example, if one vaccine box went from national → state → province → health facility, this whole trip is considered one route. Normally, # of routes correspond to the # of vaccine boxes in the study.
   d. Press 'Ok'.
   e. Wait for a few seconds. The information will appear in A8-C16. Some other background work will be done as well.
   f. A message saying 'Now enter the level names in COLUMN F and steps for each route from COLUMN G. Then press the SUBMIT ROUTE TABLE button.' is displayed.
   g. Press 'Ok'.
4. Follow the suggestions from the message box. Please note that this may take some time to fill out, but make sure to do this properly. You will notice (lock cells here) the route table starting from E7.
   a. Fill in the level names starting from F8, then going down in column F. For example, national, province, district, etc.
   b. Fill in the specific names of sites for route 1 starting from G8, then going down in column G.
   c. You'll notice that the first level for the rest of the routes is automatically filled now. This is only to make this process easier as the first step is usually the same for all routes. If that is not the case, you can change this manually.
   d. Fill in the specific names for the other routes for all levels.
   e. If for some routes, one (or more) levels were skipped, leave that cell completely empty/blank.
   f. Once the route table is filled out, press the '3. Submit Route Table' button
   g. If there are any errors in the input, a message will pop up. If so, rectify the specific error and press '3. Submit…' button again.
   h. Wait for a few seconds. Some background work will be done. This will also take you to the 'Equipment and Time Input' page. The 'Outreach Component' screen is displayed.
5. 'Reset' Button: If you want to erase some of the steps you have completed or go back to a blank template, you can utilize this. When you click, there are four options to choose from. If you want to use some of the inputs to copy and paste later, you can create another sheet/workbook because when resetting, most of the data will be erased based on the option chosen.

B. 'Equipment and Time Input' Page

6. Please see Annex: Section B to get an idea of what this page should look like.

7. ‘Outreach’: if there is an outreach component or immunization session for any of the routes, choose ‘Yes’; otherwise ‘No’. Then press ‘OK’.
    a. If you prefer to add the outreach segments later, you have the option of using the ‘Outreach’ button at the top of the page (A1).
    b. If you pressed ‘No’, the ‘Deviations’ screen is displayed. Skip to step 8 below.
    c. If you pressed ‘Yes’, a screen showing all the routes is displayed. Check the routes with an outreach component or immunization session. Press ‘Proceed’.
    d. Choose one of the three options (Immunization Session, Outreach Session, or Mobile Strategy). Press ‘Proceed Further’.
    e. If the study packet was returned to a storage facility after the immunization session or outreach component, check the boxes for the appropriate routes. Ensure you scroll down to the bottom and check off all the routes. Press ‘Ok’.
    f. You’ll see rows added for the appropriate routes. The ‘Deviations’ screen is displayed.
8. ‘Deviations’: if there was a deviation in any of the routes, choose ‘Yes’; otherwise ‘No’. Deviations mean that the vaccine box with the logger was moved from one facility to another deviating from the original route plan (normally because of equipment or power failure).
    a. If you would prefer to add the deviations at a later stage, you have the option of using the ‘Deviations’ button at the top of the page (A1).
    b. If you pressed ‘No’, a message saying ‘If you want to add more outreach or deviations later, please click on the 'Outreach' or 'Deviations' button at the top of the page.’ Press ‘Ok’. Another message saying ‘Now, fill out the details and press the 'Go to Logger Data Input Page' button. You can fill out details for one route at a time.’ is displayed. Press ‘Ok’. Skip to step 9 below.
    c. If you pressed ‘Yes’, a screen is displayed where you can pick the route and level where the deviation happened. For level, you choose the level at which deviation happened. For example, if the vaccine box was moved from level 3-district to level 2-province, choose level 3 since that is where the deviation occurred. Press ‘Ok’.
    d. Another screen is displayed. If you have more deviations, you can press ‘Yes’ and repeat the process. Otherwise, press ‘No’. A message saying ‘If you want to add more outreach or deviations later, please click on the 'Outreach' or 'Deviations' button at the top of the page.’ Press ‘Ok’. Another message saying ‘Now, fill out the details and press the 'Go to Logger Data Input Page' button. You can fill out details for one route at a time.’ is displayed. Press ‘Ok’.
    e. For all the deviations, rows are added appropriately. Please fill out the Site/Transit Description. Level # will automatically be filled in as the level at which deviation occurred. If needed, change this at this time. For example, if the vaccine box was moved from level 3-district to level 2-province, change level # to 2 at this time.
9. ‘Delete Rows’: If needed, you can delete rows (button displayed at the top of the page D1). You can choose the appropriate route and press ‘Proceed’. The site descriptions of that specific route will be listed. Check the sites or outreach sessions you want to delete and press ‘Ok’. Please note that the transit to the site chosen will also be deleted and return component will be deleted if outreach is chosen.

    Fill out the details for each route one at a time. All fields in yellow are required. The cold chain equipment type and make/manufacturer information are mandatory and need to be selected from the drop-down list.

    a. ‘From’ and ‘To’ columns must have dates/times in date-month-year-time-AM/PM format (e.g., 30/Jan/18 9:30:00 PM). All ‘From’ and ‘To’ dates/times must be in between the first and last dates/times obtained from the dataset

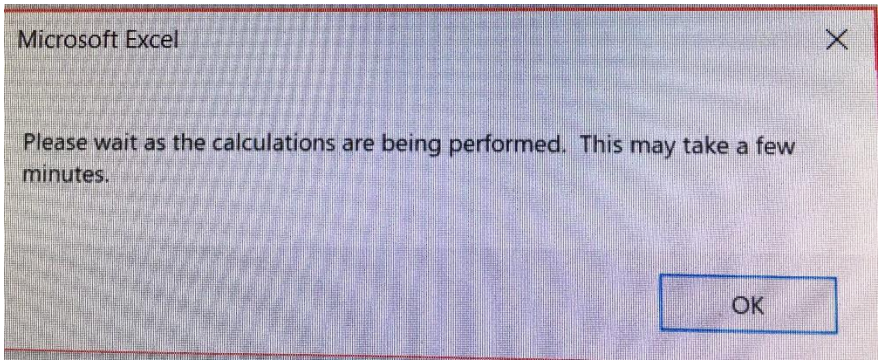
(loggers' data). Any date/time attempted to enter as 'From' and 'To' date/time which is a date/time before or after the dates/times in the dataset is not a valid 'From' and 'To' date/time.

b. For all transit, please fill in the conditioning of icepacks in column 'H'.

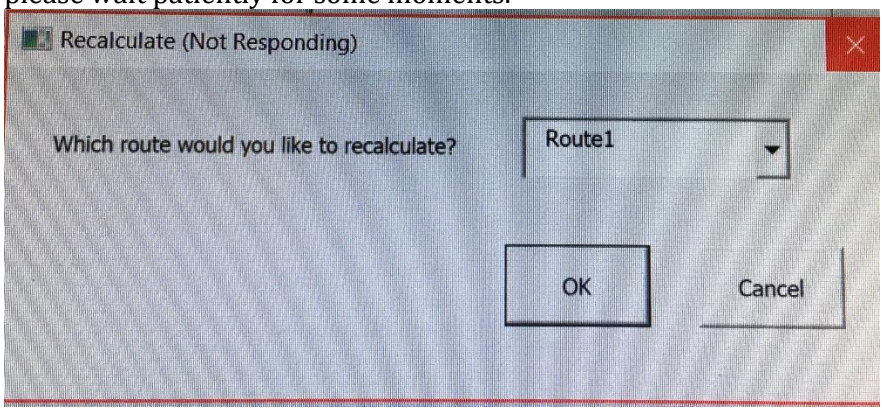
10. Once details for one route is filled out, click the 'Go to Logger Data Input Page' button at the top of the page.
11. If a route information is not completed or data from loggers used in a route is not available due to any reason (damage, missing loggers etc), fill out the levels of that route up to which information is available and do not select that route when running the logtag data input macros. If a route was devoid of an entire level in between the higher and lower storage levels (e.g., a district level was not used between a primary/provincial and health center levels), that level may be removed from the respective section of the 'Equipment and Time Input' tab by using the 'Delete rows' command button. Similarly, if a route has a level with which is to be out of study, that level can be deleted/removed in the same way. In case the entire route logger's data is not available, skip that route.
12. In some computers, the text size pertaining to the command buttons (e.g., 'Initial Menu', 'Submit Route Table', 'Outreach', 'Deviation' etc.) in different tabs of the tool may change with repeated clicking. Such behavior has no impact on the data inputs and analysis functions of the tool. All these changes revert when 'Reset' is done on 'Overall input' tab.

C. 'LogTag Data Input' Page

13. Please see Annex: Section C to get an idea of what this page should look like.
14. 'Data Input Columns': This screen tells you where to paste the data from LogTag.
    a. Vaccine date, time, and temperature data should be pasted in Columns A, B, & C. Column A must be in date-month-year format.
    b. Ambient date, time, and temperature data should be pasted in Columns D, E, & F. If you don't have ambient data, you can leave these columns blank.
    c. If the data set is not in the LogTag format (i.e. date, time, and temperature), click the 'Change date/time' button.
        i. If your date and time are together, you can click on the first option. On the 'Format Conversion 1' page, you can paste the data in Columns A & B and then click 'Convert'. You can copy the converted data in Columns D, E, & F and paste into the appropriate 'LogTag Data Input' page columns.
        ii. If your dates come combined with days, you can click on the second option. On the 'Format Conversion 2' page, you can paste the data in Columns A, B, & C and then click 'Convert'. You can copy the converted data in Columns E, F, & G and paste into the appropriate 'LogTag Data Input' page columns.
    d. Click the 'Submit Data' button at the top of the page (A1).
        i. Choose the appropriate route at this time and press 'Ok'.
        ii. If there are errors in your input on the 'Equipment and Time Input' page for the specified route, a message will pop up. You can fix the error and press 'Submit' again.
        iii. The calculations may take a minute. Another pop up window with message "Please wait as the calculations are being performed. This may take a few minutes" may appear (see screen shot below). Please click "OK" and wait until it is completed and the summary table for the specified route is shown on the 'Route Output' page.



The screen may also say 'not responding' (see screen shot below), but please wait patiently for some moments.



e. Please note that the data submitted are copied and saved on this page itself. Scroll to the right of column H to view.
f. Please also note that the 'Calculations' page will be displayed showing some explanations and some of the calculations.

D. 'Route Output' Page

15. Please see Annex: Section D1 and Annex: Section D2 to get an idea of what this page should look like.
16. Summary Table: A summary table with relevant information about the specific route will be displayed.
17. Graphs: A time summary chart and a temperature profile chart for the entire route will be displayed to the right of the summary table. Temperature profiles for each of the transit segments will also be displayed separately.
18. Carefully go through the temperature profiles and determine if there needs to be adjustments to the 'From' and 'To' dates/times on the 'Equipment and Time Input' page.
19. 'Recalculate' button in cell R1 of the 'Route Output' page: if you need to change the dates/time on the 'Equipment and Time Input' page, please do so. Then, click the 'Recalculate' button to see the updated results.
20. Repeat steps 10-18 for each valid route and results for each route will be displayed on the 'Route Output' page.
21. If you would like to move the data labels for the charts/graphs, you will need to copy the chart to another sheet (unprotected), change/move labels, and copy and paste back to its original position (to keep it organized). It is an Excel glitch that cannot be fixed at this time, so this is the workaround.
22. Some of the tables need to be better formatted, i.e. summary table needs the borders and in some graphs, the x-axis labels are not fully visible, this can also be fixed by copying the graphs to another Excel spreadsheet.

E. 'Summary' Page

23. 'Create Summaries' button: Once the tables, charts, and graphs are produced on the 'Route Output' page for all the routes, go to the 'Summary' page. Click 'Create Summaries' at the top of the page (A1). Wait for a few seconds.
    a. A variety of tables are displayed.
    b. Yellow cells should be filled out (Shake test results, VVM readings and shake test/VVM reading dates) at the bottom of column P.
24. Please see Annex: Section E1 and Annex: Section E2 to get an idea of what this page should look like.

5. Annex

A. Example of 'Overall Input' Page Data Entry

Date	1/Aug/15	
Country	Anonymous	
Study Start Year	2015	
Study ID	Unidentified	
Data Analyst and Affiliation	Anupa	
Affiliation	UNICEF	
Thresholds/Limits	Temperature (deg C)	Time (hours)
Lowest	-0.5	1
Lower	2	
High	8	10
# of static storage levels (not including outreach or transit)	4	
# of routes/terminal sites	3	

Contacts: Benjamin Schreiber at bschreiber@unicef.o
at angeorge@unicef.org

1. Initial Menu | 2. Thresholds, Levels, Routes | 3. Submit Route Table

Level #	Level Name	Route1	Route2	Route3
1	National	N	N	N
2	Province	P1	P2	P3
3	District	D1	D2	D3
4	Health Center	HC1	HC2	HC3

B. Example of 'Equipment and Time Input' Page Data Entry

Outreach	Deviations		Delete Rows	Route 1	Go to Logger Data Input Page (You can fill out details for one route at a time)		
End Point/Route ID		1		Vaccine Logger ID	1	Ambient Logger ID	
Level #	**Site/Transit Description**	**From**	**To (Not Including)**	**Comments**	**Cold Chain Equipment Used**	**Make/Manufacturer**	**Icepack Conditioning, Power Source, CCE Model**
1	DMT	03/Nov/15 1.51 PM	16/Jan/16 10.40 AM		Walk-in Cold Room	Other	Euromon
	Transit to Abeche	16/Jan/16 10.40 AM	16/Jan/16 10.00 PM		Refrigerated Truck Crates	Other	NA
2	Abeche	16/Jan/16 10.00 PM	23/Jan/16 11.00 AM		Walk-in Cold Room	Other	Euromon
	Transit to Guereda	23/Jan/16 11.00 AM	23/Jan/16 5.00 PM		Reused International Shipping Carton	Other	NA
3	Guereda	23/Jan/16 5.00 PM	02/Feb/16 7.15 AM		Two mode: Refrigerator mode	Other	NA
	Transit to Willikore	02/Feb/16 7.15 AM	02/Feb/16 10.40 AM		Cold Box	Other	NA
4	Willikore	02/Feb/16 10.40 AM	14/Feb/16 9.53 AM		Two mode: Refrigerator mode	Other	Sibir
Outreach	1	14/Feb/16 9.53 AM	14/Feb/16 4.05 PM		Vaccine Carrier	Other	NA
Return	1Returned to a facility CCE	14/Feb/16 4.05 PM	14/Feb/16 4.15 PM		Two mode: Refrigerator mode	Other	Sibir

C. Example of 'LogTag Data Input' Page Data Entry

Submit Data: Vaccine & Ambient

(After pasting the data below, press this button. You can indicate which route at that time.)
If you have to change the format for your data before you paste below, press the button to the side.

Change date/time format

Date (2-Mar-14 for example)	Time	Vac T (oC)	Date (2-Mar-14 for example)	Time	Amb T (oC)
1/Dec/14	9:00 AM	6.3			
1/Dec/14	9:30 AM	6.3			
1/Dec/14	10:00 AM	6.2			
1/Dec/14	10:30 AM	6.7			
1/Dec/14	11:00 AM	6.1			
1/Dec/14	11:30 AM	6.9			
1/Dec/14	12:00 PM	6.2			
1/Dec/14	12:30 PM	6.9			
1/Dec/14	1:00 PM	6.2			
1/Dec/14	1:30 PM	6.4			
1/Dec/14	2:00 PM	5.9			

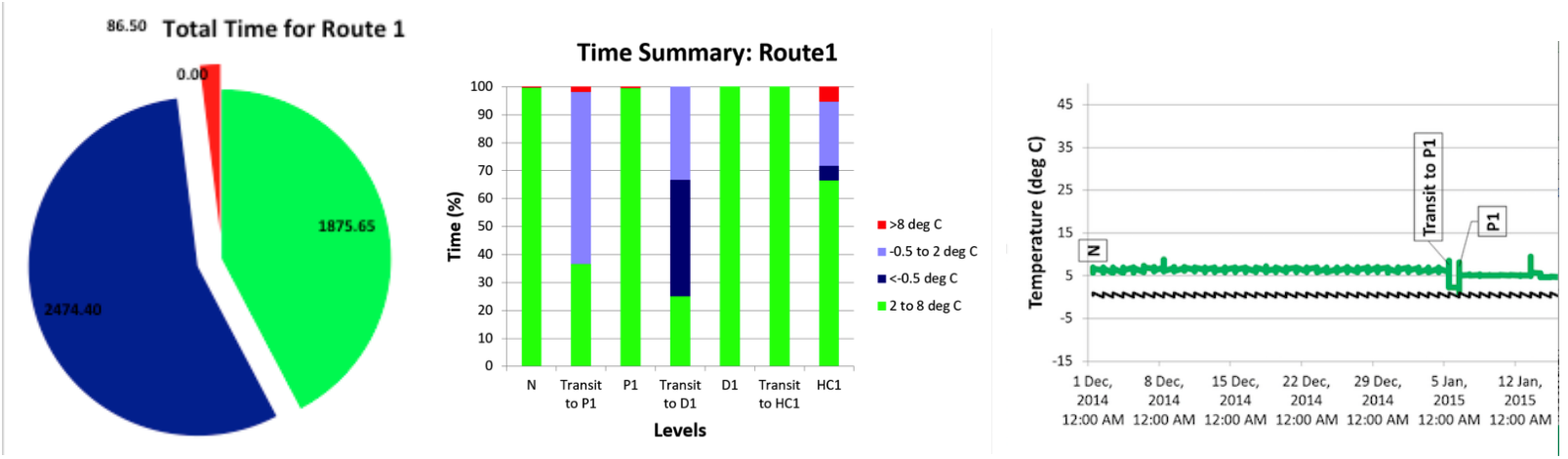
D. Example of 'Route Output' Page Results

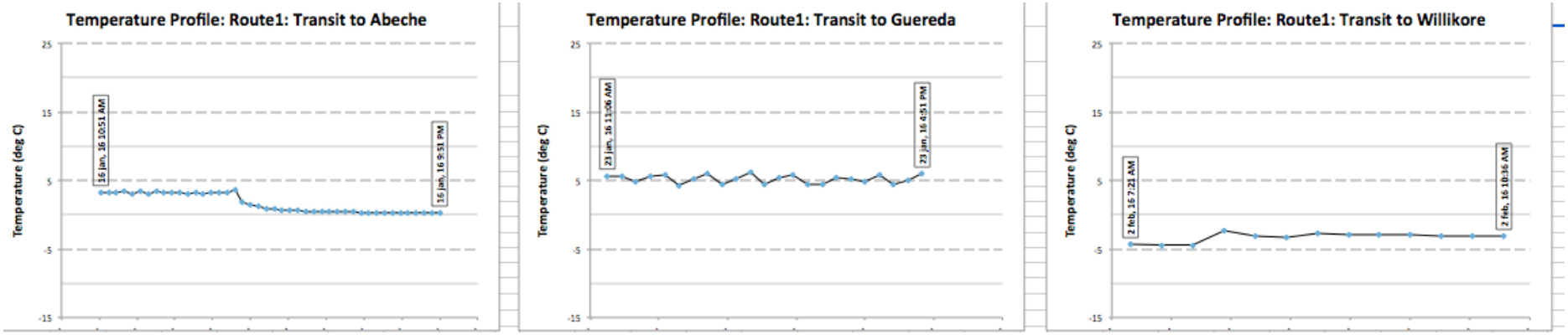
i. Table

Summary Table: Route 1

Level #	Site/Transit Description	Ambient Temperature (°C)		Vaccine Temperature (°C)				Time (h)					Continuous Freezing < -0,5 deg C for >1h		Continuous Heat > 8 deg C for >10h	
		Min (°C)	Max (°C)	Min (°C)	Max (°C)	Avg (°C)	St. Dev. (°C)	Total time (h)	2 to 8 deg C	< -0,5 deg C	-0,5 to 2 deg C	> 8 deg C	Time (h)	# of Deviations	Time (h)	# of Deviations
1	DMT	N/A	N/A	2,0	32,7	4,1	2,1	3545,50	1686,50	1772,75	0,00	86,25	1772,75	1	14,00	1
	Transit to Abeche	N/A	N/A	0,3	3,7	1,6	1,4	15,75	4,50	11,25	0,00	0,00	11,25	1	0,00	0
2	Abeche	N/A	N/A	0,2	6,3	4,2	2,0	280,00	123,00	157,00	0,00	0,00	157,00	1	0,00	0
	Transit to Guereda	N/A	N/A	4,3	6,2	5,2	0,6	12,00	6,00	6,00	0,00	0,00	6,00	1	0,00	0
3	Guereda	N/A	N/A	-6,3	7,2	-2,2	3,3	257,25	27,00	230,25	0,00	0,00	230,25	1	0,00	0
	Transit to Willikore	N/A	N/A	-4,4	-2,3	-3,3	0,6	3,50	0,00	3,50	0,00	0,00	3,50	1	0,00	0
4	Willikore	N/A	N/A	-3,5	8,9	-0,1	1,7	315,00	27,50	287,25	0,00	0,25	287,25	1	0,00	0
Outreach	1	N/A	N/A	0,3	2,3	1,6	0,5	6,75	0,75	6,00	0,00	0,00	6,00	1	0,00	0
Return	1Returned to a facility CCE	N/A	N/A	2,1	2,2	2,2	0,1	0,80	0,40	0,40	0,00	0,00	0,00	0	0,00	0
	Storage subtotal	0,0	0,0	-6,3	32,7	3,0	3,1	4397,75	1864,00	2447,25	0,00	86,50	2447,25	4	14,00	1
	Transit subtotal	0,0	0,0	-4,4	6,2	1,8	3,0	31,25	10,50	20,75	0,00	0,00	20,75	3	0,00	0
	Outreach subtotal	0,0	0,0	0,3	2,3			6,75	0,75	6,00	0,00	0,00	6,00	1	0,00	0
	Return subtotal	0,0	0,0	2,1	2,2	2,2	0,1	0,80	0,40	0,40	0,00	0,00	0,00	0	0,00	0
	Route Totals	0,0	0,0	-6,3	32,7	3,0	3,1	4436,55	1875,65	2474,40	0,00	86,50	2474,00	8	14,00	1

ii. Charts/Graphs





E. Example of 'Summary' Page Results

i. Study Results

Study Results			
Level Name	**Route1**	**Route2**	Route3
National	N	N	N
Province	P1	P2	P3
District	D1	**D2**	D3
Health Center	**HC1**	HC2	HC3
Outreach			
Return from Outreach		**Return from Outreach**	
Transit	**Transit**	**Transit**	
% of routes with freeze exposure = 67			
% of routes with heat exposure = 67			
Vaccine Temperature (deg C)			
Minimum	-3.2	-0.7	-0.3
Maximum	16.6	15.6	14.9
Total Time in Hours (Exposure to Low Temperatures)			
< -0.5 deg C	121	2	0
-0.5 to 2 deg C	538	87	1153
< -0.5 deg C for >1h	111	1.5	0
{# of deviations}	{12}	{1}	{0}
Total Time in Hours (Exposure to High Temperatures)			
> 8 deg C	124.5	48	14
> 8 deg C for >10h	60.5	28.5	0
{# of deviations}	{2}	{2}	{0}
Shake Test Results			
Passed/Failed?			
VVM Results			
Any at stage 3 or later?			
Study Dates			
Start	1-Dec-14	1-Dec-14	30-Oct-14
End	17-May-15	17-May-15	15-Apr-15
Shake Test VVM Reading			

ii. Study Profiles and Summaries for each level, etc.

Create Summaries

Study Profile

Level #	Level Name	Total Study Time (h)	Vaccine Temperature		Time (h)				Continous Freezing < -0.5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0.5 deg C	-0.5 to 2 deg C	> 8 deg C	Time (h)	# of Deviations	Time (h)	# of Deviations
1	National	3311	5.7	9.7	3305	0	0	6	0	0	0	0
2	Province	2392.5	-0.3	9.5	1393.5	0	993	6	0	0	0	0
3	District	1377.5	0.5	11.5	1298.5	0	61	18	0	0	17.5	1
4	Health Center	2971.5	-3.2	16.6	2056	118.5	668.5	128.5	109	11	60.5	2
--	Outreach	3.5	3.2	3.5	3.5	0	0	0	0	0	0	0
--	Return from Outreach	1855	1.5	15.6	1818.5	0	11	25.5	0	0	11	1
--	Transit	87.5	-1.1	12.1	36	4.5	44.5	2.5	3.5	2	0	0
	Totals	11998.5	-3.2	16.6	9911	123	1778	186.5	112.5	13	89	4

Summaries with %

Study Profile

Level #	Level Name	Total Study Time (%)	Vaccine Temperature		% of Time at Level				Continous Freezing < -0.5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0.5 deg C	-0.5 to 2 deg C	> 8 deg C	% of Time at Level	% of Total Deviations at All	% of Time at Level	% of Total Deviations at All
1	National	27.6	5.7	9.7	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
2	Province	19.9	-0.3	9.5	58.2	0.0	41.5	0.3	0.0	0.0	0.0	0.0
3	District	11.5	0.5	11.5	94.3	0.0	4.4	1.3	0.0	0.0	1.3	25.0
4	Health Center	24.8	-3.2	16.6	69.2	4.0	22.5	4.3	3.7	84.6	2.0	50.0
--	Outreach	0.0	3.2	3.5	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--	Return from Outreach	15.5	1.5	15.6	98.0	0.0	0.6	1.4	0.0	0.0	0.6	25.0
--	Transit	0.7	-1.1	12.1	41.1	5.1	50.9	2.9	4.0	15.4	0.0	0.0
	Totals	11998.5 h	-3.2	16.6	82.6	1.0	14.8	1.6	0.9	100.0	0.7	100.0

Summary: National Level

Route #	Site Name	Total Study Time (h)	Vaccine Temperature		% of Time at Site				Continous Freezing < -0.5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0.5 deg C	-0.5 to 2 deg C	> 8 deg C	% of Time at Site	% of Total Deviations at Level	% of Time at Site	% of Total Deviations at Level
1	N	846.5	5.7	8.8	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
2	N	846.0	5.9	8.5	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
3	N	1618.5	5.7	9.7	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
	Totals	3311.0	5.7	9.7	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
% of shipments w/ freeze exposure =					0.0		% of shipments w/ heat exposure =				0.0	

Summary: Transit

Route #	Site Name	Total Study Time (h)	Vaccine Temperature		% of Time at Site				Continous Freezing < -0.5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0.5 deg C	-0.5 to 2 deg C	> 8 deg C	% of Time at Site	% of Total Deviations at Level	% of Time at Site	% of Total Deviations at Level
1	Transit to P1	26.0	1.1	8.1	36.5	0.0	61.5	1.9	0.0	0.0	0.0	0.0
1	Transit to D1	6.0	-1.1	5.0	25.0	41.7	33.3	0.0	33.3	50.0	0.0	0.0
1	Transit to HC1	1.5	4.0	5.2	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2	Transit to P2	26.5	0.7	8.0	24.5	0.0	75.5	0.0	0.0	0.0	0.0	0.0
2	Transit to D2	6.0	-0.7	5.3	33.3	33.3	33.3	0.0	25.0	50.0	0.0	0.0
2	Transit to HC2	2.0	2.2	2.8	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
3	Transit to P3	14.5	1.8	5.0	69.0	0.0	31.0	0.0	0.0	0.0	0.0	0.0
3	Transit to D3	2.5	3.0	12.1	40.0	0.0	0.0	60.0	0.0	0.0	0.0	0.0
3	Transit to HC3	2.5	3.7	11.5	80.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0
	Totals	87.5	-1.1	12.1	41.1	5.1	50.9	2.9	4.0	100.0	0.0	0.0
% of shipments w/ freeze exposure =					22.2		% of shipments w/ heat exposure =				0.0	

Appendix 15: Results presentation template

Objectives of the Temperature Monitoring Study

1. To ascertain the extent to which temperature excursions are occurring throughout the supply chain, and under what conditions.
2. To quantitatively establish a basis for prioritization of technical and infrastructural assistance for cold chain strengthening.
3. To develop in health workers a greater awareness and understanding of vaccine thermo-stability and vulnerabilities during transport and storage.
4. To review the current practices and procedures and if needed, change the National EPI policy for storage and transportation of vaccines.

What is a Temperature monitoring Study?

Based on: WHO protocol WHO_IVB_05.01
and UNICEF supplement: the temperature monitoring study handbook

- A temperature monitoring device is packed together with the vaccines and "follows" the vaccines all the way on their journey from the central store to the health facility or outreach activity.
- The device performs continuous measurement of the temperatures to which the vaccines are exposed all the way.
- Data from the device is downloaded and analyzed and used to take corrective measures if necessary.

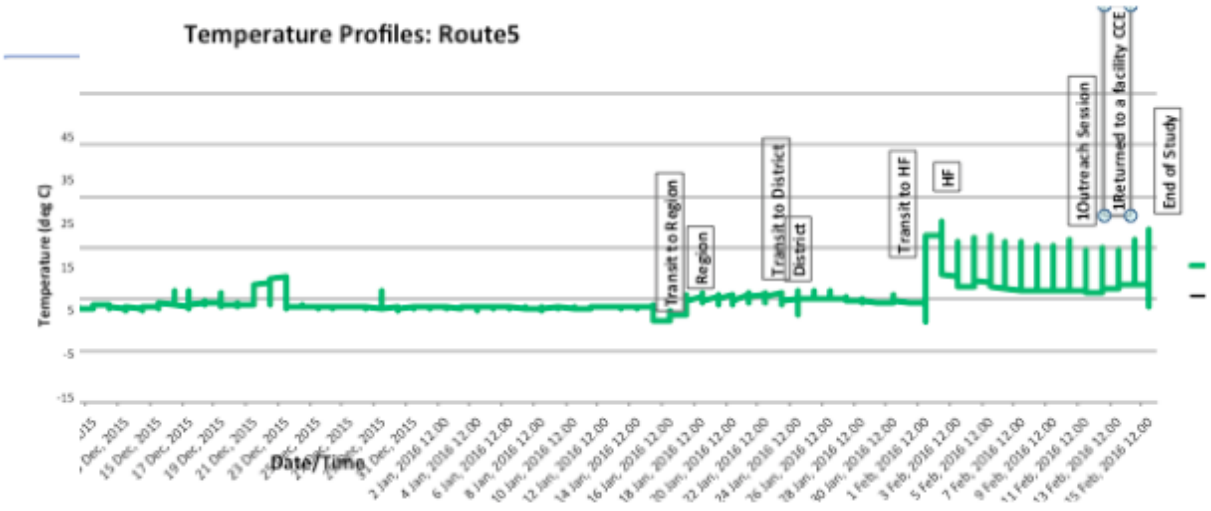
Study Profile and Methodology

(Map of country with routes and summary of the process)

	Major steps
	Measurements started on date while all loggers were at the central store
	Data loggers from all sites (XX) were recollected on date along with study vials
	X routes, X provinces X districts, X Health facilities
	Data retrieved and reviewed using analysis software
	VVM of all the vials checked locally at end of study
	Shake tests performed on all the vials
	Analysis done using dates and times of vaccine storage, transportation and outreach at all level

Key findings

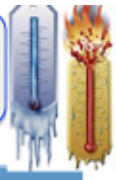
Example of temperature profile graph



Key Findings

Heat alarm: >10 hours over 8 °C

Freeze alarm: >1 hour below -0,5 °C



Cold Chain Level	Results
National EPI	No issue
Transit 1 Central EPI to Province	Major challenges ➔One big issue with the refrigerated truck going to Province A that shows freeze alarms. It impacts 20% of the population
Provincial level	Province A had excellent results but Freezing in Province B for 5 hours
Transit 2 Provinces to Districts	Alarms in transits to 4 districts: 3 were freeze alarms and 1 heat alarm
Districts	Good results: only 3 out of 8 districts had deviations/issues
Transit 3 District to HF	…
HF	…
Outreach	…
Return to HF after outreach	…

Study profile in total numbers

Study Profile

Level #	Level Name	Total Study Time (h)	Vaccine Temperature		Time (h)				Continous Freezing < -0,5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0,5 deg C	-0,5 to 2 deg C	> 8 deg C	Time (h)	# of Deviations	Time (h)	# of Deviations
1	Central EPI	31.608	2,7	15,4	31.584	0	0	24	0	0	0	0
2	Province	30.976	-8,2	18,2	30.856	34	3	83	30	12	0	0
3	District	24.876	-10	17,2	20.940	781	2.662	493	753	86	344	18
4	Health Facility	12.785	-13,9	26,5	10.132	230	2.103	320	208	46	163	3
---	Outreach	126	-14,2	13,1	76	6	30	14	5	2	0	0
---	Return from Outreach	6.312	-16,6	33,9	4.688	271	944	409	256	33	154	9
---	Transit	878	-12,4	18,4	177	182	119	400	174	19	353	20
Totals		107.561	-16,6	33,9	98.452	1.503	5.862	1.744	1.427	198	1013	50

Total hours of the study for all destinations

Total number of Freeze alarms

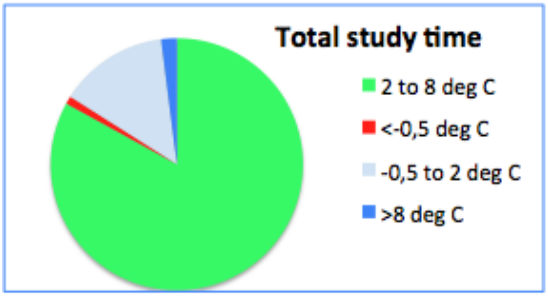
Total number of heat alarms

XXXXXX temperature measurements

Study profile in percentage

Study Profile

Level #	Level Name	Total Study Time (%)	Vaccine Temperature		% of Time at Level				Continous Freezing < -0.5 deg C for >1h		Continous Heat > 8 deg C for >10h	
			Min (°C)	Max (°C)	2 to 8 deg C	< -0.5 deg C	-0.5 to 2 deg C	> 8 deg C	% of Time at Level	% of Total Deviations at All Levels	% of Time at Level	% of Total Deviations at All Levels
1	National	27.6	5.7	9.7	99.8	0.0	0.0	0.2	0.0	0.0	0.0	0.0
2	Province	19.9	-0.3	9.5	58.2	0.0	41.5	0.3	0.0	0.0	0.0	0.0
3	District	11.5	0.5	11.5	94.3	0.0	4.4	1.3	0.0	0.0	1.3	25.0
4	Health Center	24.8	-3.2	16.6	69.2	4.0	22.5	4.3	3.7	84.6	2.0	50.0
--	Outreach	0.0	3.2	3.5	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--	Return from Outreach	15.5	1.5	15.6	98.0	0.0	0.6	1.4	0.0	0.0	0.6	25.0
--	Transit	0.7	-1.1	12.1	41.1	5.1	50.9	2.9	4.0	15.4	0.0	0.0
	Totals	11998.5 h	-3.2	16.6	82.6	1.0	14.8	1.6	0.9	100.0	0.7	100.0

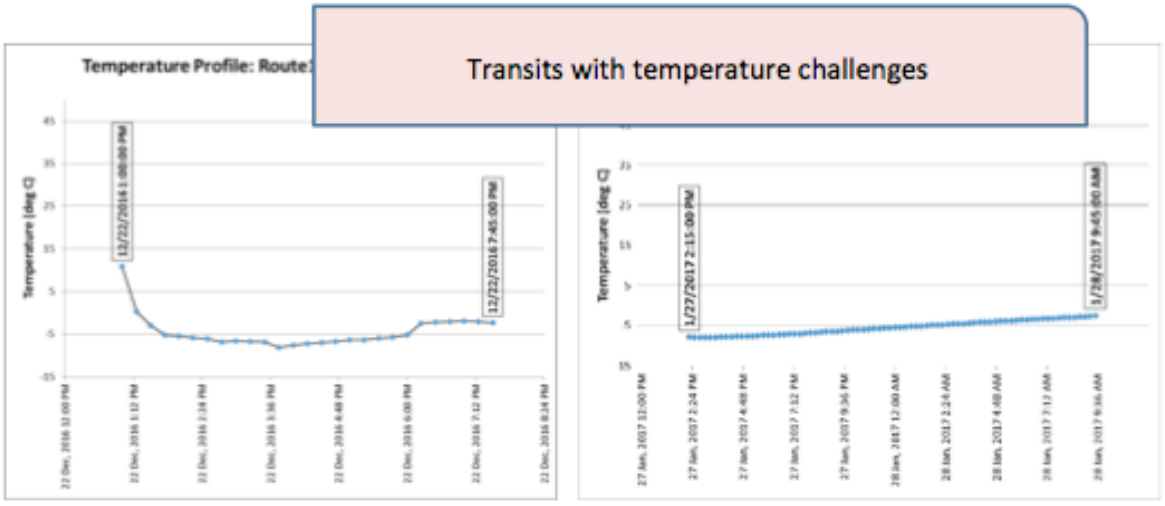


84% of all freeze alarms are at HF level

50% of all heat alarms are at HF level

Summaries by Level: Districts

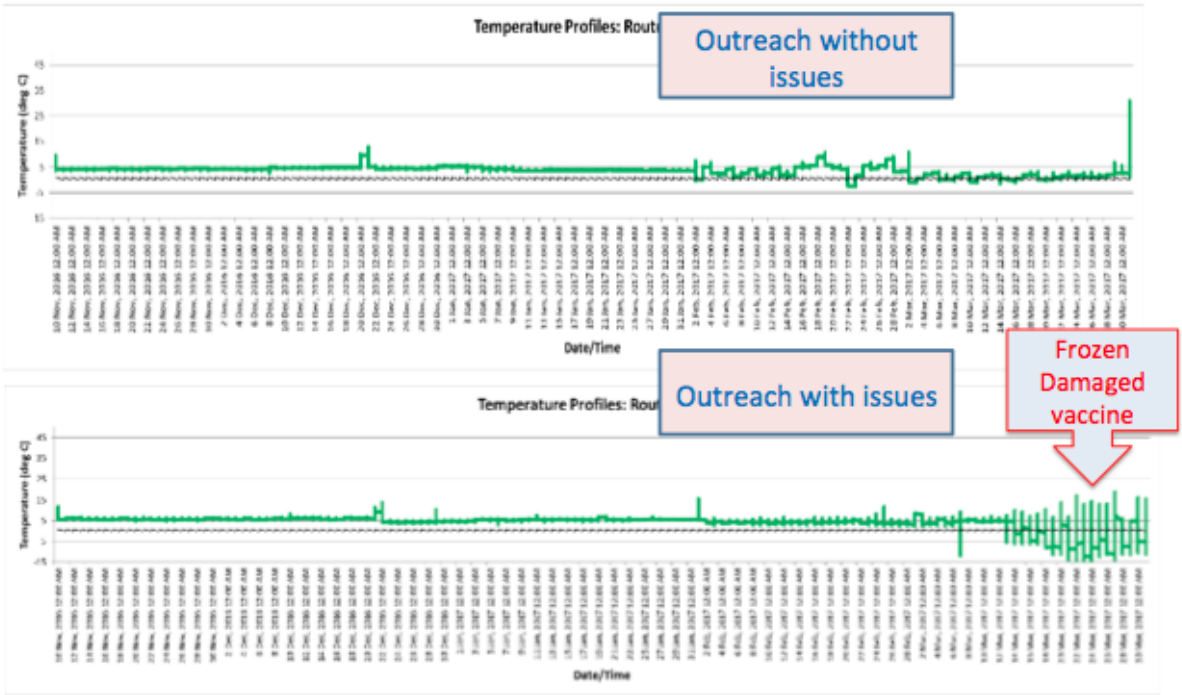
Summary by Level: Transits



Refrigerated truck (with 100 icepacks)

Reused shipping carton with icepacks

Summary by Level: Outreach



Conclusions

Temperature studies enable **risk identification**, i.e. what can go wrong and where.
They usually only cover <1% of sites in the cold chain, so they are not statistically significant. They only provide a snapshot that helps detect problems.

It must be followed by **Risk analysis and risk evaluation:**
Assessing how it went wrong to review and control these risks.

Next step is to put in control measures that would reduce the risks (if it cannot be entirely eliminated).

Temperature Monitoring Study in Country

Start Year

Highlighted texts in yellow (and maybe other details) need to be adapted accordingly…

Conducted by:

National Expanded Program on Immunization, Country, CHAI, PATH, UNICEF, and WHO

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

Short summary of routes and results including recommendations.

2. BACKGROUND

Some background information about temperature monitoring study and how it will help the country (include country cold chain context).

The 'Rationale' section from the country specific study protocol that the country developed by adapting Appendix 4 can be utilized here.

3. OBJECTIVES

a. To ascertain the extent to which temperature excursions are occurring throughout the supply chain, and under what conditions.
b. To quantitatively establish a basis for prioritization of technical and infrastructural assistance for cold chain strengthening.
c. To develop in health workers a greater awareness and understanding of vaccine thermo-stability and vulnerabilities during transport and storage
d. To review the current practices and procedures and if needed, change the National EPI policy for storage and transportation of vaccines

4. METHODOLOGY

Summarize the methods used to design and implement the study. Also, include the methods used for data collection and data analysis.

The 'Methodology', 'Implementation', and 'Analysis' sections from the country specific study protocol that the country developed by adapting Appendix 4 can be utilized here.

Some of the suggested sub-headings are:

4.1 Study Team

4.2 Study Sites (include summary of routes chosen and explain the selection process)

4.3 Training

4.4 Study packet shipments (include temperature logger details)

4.5 Timeline

4.6 Data collection (include forms used, methods of VVM readings/shake tests, interviews of site personnel, and collection of study packets at the end of the study)

4.7 Timeline

4.8 Study definitions

- **Recommended range of storage temperatures** for _____ vaccines is 2-8°C (WHO recommendations).

- **Freezing** was defined as a recorded temperature of -0.5°C or lower for more than 60 minutes, i.e. the vaccine was considered to have been exposed to freezing temperatures if the data logger recorded a value of -0.5°C or lower for more than 60 minutes. Temperature/time considerations are important, so vaccines exposed to temperatures at or below -0.5°C may not necessarily be frozen. However the potential for freezing exists in such circumstances, so this definition was used for the purposes of this study.

- **Heat exposure** was defined as a recorded temperature of 8°C or higher for more than 10 hours.

5. RESULTS

Show findings from the data analysis. Provide sufficient details (include graphs, charts, and photos in Appendices). Ensure to include:

- Summary of each route (graphs and tables from the data analysis tool can be utilized)
- An analysis on the storage and transport equipment types used (information from the monitoring forms/'Equipment and Time Input' page on the data analysis tool)
- VVM reading and shake test results' analysis
- Analysis of the "Interviews" of the site personnel

It is critical to focus on the most actionable and relevant findings. To do this, orient analysis towards answering the following questions:

- What types of temperature risk are vaccines being exposed to and why?
- Where in the cold chain are these risks prevalent?
- How common is this risk at those levels?

Following this approach will help identify the key break-points in the cold chain and create actionable, evidence driven plans to further investigate and address the situation. Since the purpose is to call out areas of concern and develop recommendations against them, if a piece of data has no significant implications, it may not need to appear in the main body of the report. But can be included in the Appendix.

Then, summarize the key findings. Remember to summarize (very concisely) what key processes and procedures should be continued as is.

Some examples are provided below:

In summary

- No freezing episodes occurred during **transport of vaccines between central store and the two provinces,** which was in a cold box with ice packs.

- **Vaccines were transported between the provinces and districts** in cold boxes with ice packs and it took 1.5 - 6.5 hours. Five of eight shipments were frozen with temperatures as low as –4.4°C
- Vaccines were stored at **district level** for an average of 5.5 days in chest refrigerators and freezing temperatures were experienced in two districts, reaching temperatures of – 4.0°C and affecting 50% of all shipments.
- During **transport to outreach and during outreach sessions,** with vaccine in vaccine carriers with cool packs, no problems with freezing occurred.

6. DISCUSSION

Explain the findings and discuss the possible causes.

7. CONCLUSIONS

Summarize the overall conclusions of the study in terms of the overall status of the cold chain in the country.

8. RECOMMENDATIONS

List the recommendations (specific, actionable items). Some examples are provided below:

a. Immediate measures need to be taken to improve awareness of the problem of vaccines being exposed to freezing temperatures. This should include alerting EPI staff at all levels to the issue, using methods such as written communications, meetings, training and development of IEC materials. This includes reinforcing:
    i. Temperature sensitivity information for each type of vaccine (i.e. whether each is sensitive to freezing or heating, which vaccines are most heat stable)
    ii. Maintenance of appropriate temperatures of refrigerators (not below 2°C), careful monitoring of temperatures and appropriate loading of refrigerators (i.e. freeze sensitive vaccines stored away from freezer coils, etc.)
    iii. The correct method of packing cold boxes and vaccine carriers (with insulating material between ice/ice packs and vaccine) as described by WHO
    iv. The importance of properly conditioning ice packs prior to use for transport
    v. Shake test practice: all staff at province and district levels responsible for management of vaccines must know how to conduct and interpret the shake test and understand that it must be performed if there is a suspicion that vaccine shipments have been exposed to sub-zero temperatures.
b. Install RTMDs (Remote temperature monitoring devices) at national and province level with at least 4 sensors for cold rooms and one sensor each for refrigerator.
c. Implement the new temperature monitoring sheet for 30 DTRs (30 Day Temperature Recorders) for recording alarms at district and health facility levels.
    i. Include temperature monitoring review in supportive supervision checklist including random sampling of transportation boxes
    ii. Share the temperature data of at least one month from 30 DTR with national and provincial technicians and cold chain manager to take action at relevant sites

d. The national policy should be changed so that chilled water packs are used at the last mile. But this should be supported using controlled introduction with temperature monitoring using data loggers.
e. After action to address the problems identified in this study has been taken, the study should be repeated in other locations to determine if further measures are required.

9. REFERENCES

Cite the references used.

10. APPENDICES