# RTM Implementation guide

21 April 2016

# Abbreviations and Acronyms

| | |
|---|---|
| 30DTR | 30-Day Temperature Recorder |
| CC | Cold Chain |
| CCE | Cold Chain Equipment |
| CHAI | Clinton Health Access Initiative |
| cMYP | Comprehensive Multi-Year Strategic Plan |
| DIVO | District Immunization and Vaccination Officer |
| DTP | Tetanus, Diphtheria and Pertussis |
| EPI | Extended Immunization Programme |
| EVM | Effective Vaccine Management |
| HF | Health Facility |
| HR | Human Resources |
| HSS | Health System Strengthening |
| LTA | Long Term Arrangement |
| MOH | Ministry of Health |
| OPV | Oral Polio Vaccine |
| PC | Personal Computer |
| PCV | Pneumococcal Conjugate Vaccine |
| PQS | WHO Performance, Quality and Safety |
| RIVO | Regional Immunization and Vaccination Officer |
| RTM | Remote Temperature Monitoring |
| RTMD | Remote Temperature Monitoring Devices |
| SD | UNICEF Supply Division |
| SIM | Subscriber Identification Module |
| SMS | Short Messaging System |
| SOP | Standard Operating Procedure |
| TM | Temperature Monitoring |
| TMS | Temperature Monitoring System |
| UNICEF | United Nations Children's Fund |
| VVM | Vaccine Vial Monitor |
| WHO | World Health Organization |
| WICR | Walk-in Cold Room |
| WIFR | Walk-in Freezer Room |


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# Executive Summary

Effective monitoring of cold chain equipment (CCE) performance is essential to ensuring that vaccines are stored safely at each stage of the cold chain, and reach the child in a potent state. Remote Temperature Monitoring (RTM) systems may offer benefits over previous systems because, through their use of cellular network, they provide continuous real-time temperature monitoring and real-time alarms that alert health workers and supervisors to dangerous temperature excursions. Leveraging the use of web portals, RTM systems allow supervisors to see summaries of temperature excursions across multiple pieces of CCE, without requiring additional effort by health workers to record, submit and process data.

When considering the implementation of RTM, it is important to evaluate the chosen segments of the cold chain for implementation, and the associated feasibility, effectiveness and affordability. This last point is particularly important. While all TM systems involve both upfront (e.g. procurement) and recurrent costs (e.g. training, supportive supervision, maintenance visits), RTM carries additional costs over traditional monitoring systems (e.g. 30DTRs). All RTM systems currently on the WHO PQS incur monthly fees (E.g. web portal access).

As of today, RTM systems have been installed in many countries at central and regional levels (e.g. Walk-in Cold Room sites), and RTM is now recommended as best practice by WHO for high-level stores[1]. However, while a number of countries have piloted RTM at lower levels of the cold chain[2] (e.g. district, facility level), scaled implementation is rare. As such, the decision to implement RTM must factor in the ability of countries to fund routine portal access and device maintenance fees for a given segment, with lower levels incurring greater cost due to the larger volume of CCE to monitor.

Once the appropriate segment has been identified, the implementation of RTM requires careful planning and system design to achieve maximum value. While RTM data is most directly used at the sites where it is installed and sends alarms, the primary value of an RTM system is how it can facilitate visibility into CCE performance across multiple levels of the cold chain. In this way, RTM shifts responsibility for cold chain management from the health worker to the managerial levels of the immunization system. This leads to accelerated and more effective response, as managers are usually better equipped to coordinate and support corrective action. The use of web-based portals also assists with this, as built-in analytics can automatize the reporting process, as well as create an audit trail for accountability.

However installing RTM does not in itself safeguard the potency of the vaccines. Like with all TM solutions, RTM must be implemented alongside complementary systems. Resolution of CCE issues requires the responsible personnel to have the right training, resources and guidance to interpret the data and most importantly to react to the information by taking the appropriate steps to remedy the temperature issues highlighted by the RTMD alarm. Given this, introducing RTM requires thorough planning and the adaptation of the cold chain (CC) system in order to generate impact. Its success depends on the establishment of a well-structured ***system of communication, interaction and responsibility***.

**Device + Process + Responsibility = Success**

## Intended target audience

This document presents a few pragmatic step-by-step guidelines for partners intending to implement RTM solutions. It aims to reassess the fact that even the most appropriate technology depends on effective management. The installation of the devices is the tip of the iceberg. What requires time and attention is the preparation, processes review, training and allocation of accountability. The device itself cannot protect the vaccines without a strong commitment to take appropriate action in response to the information collected and shared through the system.

[1] *SOP-EVM-E2-01 Monitoring vaccine storage temperatures at fixed storage locations, 07 Oct 2011.*
[2] OPTIMIZE in Albania tested FoneAstra and in Senegal used Beyond Wireless

# I. Why RTMD?

As with all temperature monitoring solutions, the purpose of RTM systems is to keep CCE in optimal working order, to ensure vaccines are stored safely and kept potent.

## A. Expected objectives

The goals when introducing RTM can be summarized into three main categories:

- Enabling rapid response to temperature excursions through continuous surveillance of the equipment with immediate alarming triggering faster reaction by health workers to prevent damage to the vaccines;
- Allow for systematic and routine review of CCE at a given level of the cold chain (through analysis of available data from the RTMD), and to increase accountability for corrective follow-up actions (e.g. maintenance and repairs of equipment);
- Collection of data enabling high-level review to inform relevant decisions (e.g. procurement of equipment, maintenance planning).

**Additional benefits may include:**

- Improved understanding of the CC data as main alarm triggers are exposed through RTM, helping to reduce/eliminate these common causes (door being open too often, inadequate cold storage loading, over loading, equipment or generator out of kerosene, lack of weekend gas management protocol, mechanical failures of the equipment, bad state of the door seal, thermostat needing adjustments, solar panels not cleaned, solar battery needing replacement, etc.).
- EPI managers having direct access to the data are better aware of the cold chain issues it reveals. Since they also control resources (including maintenance budget) this can reduce the burden of regional or district logisticians having to make their case for equipment replacement.
- Increased procedural compliance by health workers due to increased transparency of temperature excursions.
- Reduced replacement costs due to improved maintenance of equipment.
- Reduced fuel and per diem costs for CC technicians, as diagnosis on equipment failure can be remotely performed, so the technician only travels for serious issues that could not be resolved by staff on-site.
- Reduced closed-vial waste due to CC failure and possibly leading to stockout.

The ultimate goal is to design a structure that can record temperature, notify the relevant individuals and **trigger** follow up actions on critical issues to achieve increased equipment uptime (e.g. for refrigerators, within the temperature range recommended by WHO of 2-8 d$^{o}$ Celsius), increased transparency and vaccine management efficacy, to make sure that no child is inoculated with vaccines of substandard quality.

## B. Needs Case and Business Case: when is RTMD worth the investment?

Thanks to developments in new vaccine antigens and funding opportunities (e.g. GAVI), countries continue to introduce new and more expensive vaccines. This increases the value of vaccine stocks stored at all levels of the cold chain, and thus the need to invest in their protection. Temperature protection is particularly critical, as a large proportion of vaccines (79% - 86%) are now sensitive to damage from freezing and/or heat. To manage this risk, countries must implement a temperature monitoring strategy that is appropriate to the needs of each level of the cold chain.

A tentative segmentation of the TM products was made by WHO and can be found both in the WHO Vaccine Management Handbook[3] and in EVM-SOP-E2-01[4] to help determine the TM device/solution most appropriate for each segment of the CC but new products are being introduced that were not included in this segmentation. A review of the WHO PQS can provide the most up-to-date list of options.

[3] *WHO and UNICEF, How to monitor temperatures in the vaccine supply chain, Vaccine Management Handbook Module VMH-E2-01.1, July 2015*
[4] *EVM-SOP-E2-01 Monitoring vaccine storage temperatures at fixed storage locations, 07 Oct 2011.*

When choosing which device to use at a given segment, there are three factors to consider:

- Functionality
- Effectiveness
- Sustainability/Affordability

**Functionality**

The first requirement of any TM system is that it can function at a given site. While traditional monitoring tools (e.g. 30DTR) are designed to work in off-grid sites, RTM has additional requirements.

All RTM devices require access to cellular data services. In areas with weak or intermittent signal, data cannot be transmitted, which means that the device will not be able to upload data or send alarms. *Note: Most RTMD alarms are sent by the central server, and not by the device itself. Therefore, if a device does not transmit the alarm status to the server, no alarm will be sent to health workers.*

In addition, some RTMs run on rechargeable batteries. These require consistent access to mains or to another power supply; otherwise the device will go offline. Others run on long-life internal batteries, but these will require regular replacement.

When considering an RTM approach, ensure the above criteria are met. Otherwise, there is significant risk of device failure, and they will not be able to support the necessary processes.

**Effectiveness**

It is also important to choose a device that best serves the needs and capabilities of a given site, at an appropriate cost. In the case of RTM, decision makers should evaluate a) which features users will be able to take full advantage of, and b) whether that justifies the cost.

At high level stores, the value of RTM has been validated across multiple countries, and represents a strong investment in vaccine protection. However, effectiveness at the lower levels (e.g. district, facility) is less established.

For example, consider excursion alarms. At urban, high-level sites, it is likely that a cold chain officer is able to safely travel to the site at any time of day or night. However, at a rural health facility, a health worker may not be able to respond to an alarm that comes at night, as travel may not be possible or safe. In such a situation, the alarm functionality does not deliver more added value than the existing 30DTR twice-daily checks.

When discussing the effectiveness of a TM system, the following aspects are important to consider, while keeping in mind functionality and cost):

- Alarm response – How does the system enable health workers to detect and address temperature alarms?
- Reporting CCE status – How does the system enable reporting on CCE status, and review by managers?
- Creating accountability – How does the system keep managers responsible for following up on alarms, and ensuring sites have functional CCE?

***Callout Box: Evidence on Effectiveness at Lower Levels of the Cold Chain***

To date, most lower-level pilots have been small and of relatively short duration. Thus, there is limited statistical evidence to answer whether RTMD at District or HF level represents a justified investment in long-term vaccine protection. However, some of these studies have indicated possible future uses of RTM, over and above the core use cases of alarming and routine CCE performance review:

- District supervisors better able to track equipment failure as a permanent record on the performance of equipment is maintained centrally and improving the process for damaged equipment repairs and replacements.
- District supervisors better able to track slow response or lack of response to alarms.
- Savings in transport and per diem costs as the technicians can perform remote diagnosis of equipment and guide health facilities staff (through phones) to perform basic corrective actions and only travel to health facilities for more complicated issues.

**Cost**

The choice of a model/solution very much depends on the cost of the device, compared against the nominal value of the vaccines at the site and the strategic risk to the EPI programme. For example, at a remote location that cannot get regular resupply, the consequences of temperature excursions might result not only in a waste of vaccines but might also jeopardize the program if replenishment of the site is delayed. Similarly, large volume sites present a strong investment case in maximizing the efficacy of temperature monitoring, as even a single event could have serious consequences. However, if a site only stores a small volume of vaccines and has good access to a district store (e.g. urban or peri-urban locations), the risk is significantly less, and investment may not be justified.

When considering the investment case for a temperature monitoring system – and especially RTM – two types of costs should be considered:

- **Up-front costs:**
  - These cover the initial hardware procurement, installation and training, as well as any further investment required in infrastructure (e.g. PC), development of documentation and dissemination of various relevant materials (e.g. SOPs).
- **Recurring costs:**
  - These cover costs associated with the ongoing management of the TM system. All effective TM systems require a certain amount of funding for routine data review, supportive supervision and refresher trainings.
  - However, RTM carries additional costs associated with the transmission of data, computer infrastructure, and supplier fees. Depending on the system, the EPI program may have to pay for cellular fees (SMS), and maintenance and technical support, over and above the standard service fee.

Whichever type of system is chosen, it is important that a budget line at the level of the EPI program be established for the recurring costs. Moreover, it is particularly necessary for RTM deployments, as failure to pay regular service fees will lead to the disconnection of the RTMs, and the loss of monitoring for the vaccines.

A tool providing estimates of these costs of different products was developed as a follow-up of the Zanzibar Temperature Monitoring workshop[5]. It can help make the business case for multi sensors RTM, one-sensor RTM versus 30DTR data loggers, or 30DTR + SMS. It summarizes the total cost of devices, ancillary costs (transport etc.), installation and training costs as well as cost of ownership.

[5] *Temperature monitoring Cost and Benefit Evaluation Tool (CHAI/PATH), Tara Banani from CHAI and Mercy Mvundura from* PATH <http://www.technet-21.org/en/resources/technet-resource-library/2470-temperature-monitoring-cost-and-benefit-evaluation-tool>

| Functionality | 30DTR | 30DTR + SMS | RTM 1-sensor | Central or Local Temperature Monitoring | RTM + extended data visualization |
|---|---|---|---|---|---|
| Read temperature | √ | √ | √ | √ | √ |
| Historic recording | √ | √ | √ | √ | √ |
| linking with other Health info systems | (√) | (√) | √ | (√) | √ |
| Real-time recording | √ | √ | √ | √ | √ |
| Continuous monitoring | √ | √ | √ | √ | √ |
| Immediate alarming about Temp excursions | (√) | (√) | √ | √ | √ |
| Ability to direct alarms to accountable parties | X | (√) | √ | √ | √ |
| Provides a data visualization and reporting system | (√) | (√) | √ | (√) | √ |

| √ | (√) | X |
|---|---|---|
| Function available | Function partially available | Function not available |

*Fig.1 Functionality of the different products*

Other factors have emerged in RTM pilots conducted at various levels of the cold chain, which are important to consider.

- When the RTM system covers a large number of sites, managers have faced issues with the overload and/or error data, preventing effective decision making (e.g. in Haiti[6]);
- Given the proprietary nature of many RTM platforms, there has been a challenge in ensuring data integration with other health metric systems (e.g. HMIS);
- Missing budget line or delays in budget release for recurring costs (SIM cards), leading to device deactivation;
- Issues with SMS alarms successfully reaching the target recipient;
    - Heavy training requirements to manage the program;

**Conclusion**

The preceding criteria will help EPI decision makers debate and discuss the appropriate TM for a given level of the cold chain, and whether RTM is indicated. In the following sections, a step-by-step process is provided to walk through how to effectively implement that decision.

# II. Preparation: Pre-implementation and Planning

## A. Pre-implementation

The starting point of an RTMD project would often be highlighted issues from EVM assessments, TM studies and cMYP. The first approach could be to organize a workshop with the stakeholders to present problem statements,

[6] In Haiti a RTM system using a mobile phone directly connected to a temperature sensor in the cold room was installed and sent SMS messages by mobile phone to several people at the facility. The messages were sent daily with temperature information even when the temperature was within acceptable ranges; additional messages were sent when it was outside range. There were so many messages that the SIM cards ran out of credit in the middle of the month. Additionally the messages were in English, which is not very user-friendly for a French-creole-speaking population and since there was no correlation between most of the messages and required action, nobody paid any attention.

root cause analysis and possible solutions, but first a number of pre-requisite must be in place or achievable for the project to be feasible, both in terms of budget and HR.

## 1. Pre-requisites

**Pre-requisites at program level**

- EPI/MOH has given approval, as this is part of the national priorities;
- Acceptance from EPI/MOH to transfer data hosting rights, when data is to be hosted in a server outside the country;
- Funding is available for capital investment and recurring costs;
- The project has a core advocate within the MOH;
- Sufficient infrastructure: connectivity and power (grid/solar)/generators/voltage stabilizer availability;
- Sufficient maintenance services and trained personnel.

**Pre-requisites at storage facility level**

- Cell data coverage and cellphones must be available to site staff that will receive SMS alerts;
- Availability of post paid SIM card for sending SMS. For ease of payment and management of all the lines, one person/one payment plan ensures reliable data upload and manages all the SIMS and monthly recharge in a province/district;
- Internet or network coverage for uploading data;
- Ability to take care of the device (locks at night);
- One trained staff responsible for basic technical overview and for answering basic questions regarding the device.

## 2. Device selection

RTM devices query the connected temperature sensors at regular intervals and send alarm notifications in case of temperature excursions. Furthermore, RTMDs provide detailed temperature logs to a central server via SMS, mail or GSM/GPRS. All the data received on the server including alarm notifications and temperature reports sent at programmable intervals are stored in a database with audit trails and can be easily viewed using a standard web browser or a client- software installed on a PC.

The WHO PQS website and corresponding catalogue[7] provides a detailed overview of pre-qualified products and devices. The pre-qualified products must fulfill set conditions including a minimum of 2 sensors, an external display, and calibration certification and only few products are currently pre-qualified.
UNICEF Supply Division (SD) currently supplies the pre-qualified RTM solutions and can also procure other products in special circumstances. For more information on procurement, cost, availability, and installation of the devices through SD, please refer to the SD Cold Chain Support Package[8] and Supply Catalogue[9].

When choosing the appropriate devices, some factors should be considered in order to define the product best suited for specific needs.

- Wired/wireless device;
- Device to be used in Cold/Freezer Rooms in one location /site with several locations;
- Language of the software (most software is in English only);
- User-friendliness of the software/cloud-based user interface for data analysis;
- Portal subscriptions included in the contract/not included and for how long? Generally 3 years;
- Installation and some maintenance included in the contract/not included;
- Degree of software compatibility with other health metrics software used in the country (LMIS...);
- Possibility to remotely program and change some settings, including adding new recipients phone number for the SMS alerts;

Some products classified as **Local Temperature Monitoring System** or **Central Temperature Monitoring System** provide most of the functionality of RTMDs and do not require portal subscription for data administration, which significantly reduces the recurrent costs since they are not web-based. However they are linked to a local always-on

[7] *WHO PQS devices catalogue: pre-qualified equipment for Expanded Programme on Immunization (EPI) at < http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/ >, Login and password required.*
[8] *The UNICEF Cold Chain Support Package can be found at <http://www.unicef.org/supply/index_74631.html>*
[9] *The UNICEF Supply Catalogue can be found at < https://supply.unicef.org/unicef_b2c/app/displayApp/(layout=7.0-12_1_66_67_115&carea=%24ROOT)/.do?rf=y>*

PC and the risk is that the whole system depends on one local PC that could accidentally be switched off or broken which would jeopardize the whole TM system.

Actionable alerts include local audible and visual alerts on wireless sensors as well as remote alerts sent by email, SMS, and phone calls. Most products use local mobile phone networks to document temperature readings and generate alerts if the storage temperature exceeds defined thresholds. The system is remotely accessible and configurable from any internet- connected mobile device or computer. Some products include a reporting tool that enables the tracking of incidents and corrective actions, as well as automated reports for compliance and quality control.

The pre-qualification criteria have been extended to include smaller Remote TM products with sensor/s linked to a central temperature-recording unit with alarm systems and detailed reports. These smaller, less robust, devices are not WHO recommended for larger storage units (Regional, state or national level) but have been piloted at district level and in single refrigerator storage sites in Haiti, Mozambique, Kenya, Albania, Nigeria and India. Some of them are hand-held while others are mounted externally. They provide SMS alerts for temperature excursions, and simple data reports on a real-time dashboard.

The market is constantly evolving and new products are being introduced. A new generation of 30DTR devices has been released integrating a remote temperature monitoring system, based on GSM/GPRS connectivity that can send data to a web-based system and parameters can be modified through a mobile phone. The back-end SAP/Logistimo system (similar to LMIS inventory system) can read/accept its SMS/mails. It runs on power but uses a battery as backup.
A new version of the one-sensor device, which has been piloted in several countries at HF level, now includes better data visualization and device calibration traceability. Installation of such devices is very simple and could theoretically be performed by nurses at HF.

PQS in the context of Solar Energy Harvesting will in the near future prequalify devices with the possibility to charge RTMDs batteries.

## 3. Definition of implementation strategy and implementation team

The way RTM can be deployed depends on previous experience with TM in the country, available HR capacity at all levels and the scope of the RTM project. It is advisable to start with the introduction of RTM in a limited segment and to use iterative methodology for scaling up. For deployment of RTM at small district or HF level, small scale piloting is recommended as the introduction of RTM requires a high level of attention, training, technical resources, which could be too intensive and disruptive to the programme if directly implemented on a larger scale.

Being able to gather the right team is an important factor and this team would at the minimum comprise:

a. A core advocate/focal point within the MOH management;
b. A project manager;
c. At least one CC technician;
d. One or two software & data management proficient persons available at MOH for the monitoring of collected data;
e. Site-level respondent/logistician.

## 4. Presentation workshop and coordination meetings

Common to all good projects is the recognition of the need for improved CC monitoring. Greater buy-in for the project can be achieved through the organization of an advocacy/ presentation workshop to introduce the project to all stakeholders, agencies involved in the CC and logistics and in the programme delivery: Chief Medical Officer, District Health Officer, Health Record Officer, Head nurses, MOH Maintenance Officer, Regional Immunization and vaccination Officer (RIVO) and DIVO. This meeting must also include site-level respondents, Logisticians, CC Managers and higher-level manager who understand the current processes and responsibilities in order to introduce the impacts to the current system.

These meetings should make sure that all are on-board and that they understand:

- The core-functionality of the system: sensors and unit, alarms and escalation, the portal and reporting and more in-depth what can be achieved through the system and how it can help them perform better in their job;
- The roles and responsibilities of all stakeholders;

- The roll out procedure: description of all the stages to get their buy-in for a slow iterative introduction of the features.

In order to avoid resistance to data transparency and accountability, care should be taken to position the tool as an opportunity to provide transparency and evidence on system and equipment performance leading to improvements that can benefit all parties in the program including health personnel. Better functioning equipment can relieve stressed health personnel of some of the cumbersome tasks of managing chronically underperforming equipment.

## B. Planning

### 1. SOP Breakdown

SOPs should include the following processes and examples can be found in the EVM SOP manual[10].

- Resource deployment plan
- Alarm calibration/configuration
- Temperature mapping for the cold /freezer rooms (WHO model)
- Roles & Responsibilities table (users & management).
- Escalation tree (best practice for elevation of alarms for example, how much time should the first person warned be given to fix the alarm)
- Documentation and archiving
- Training guidance for staff at site level and for the supervisor
- Installation
- "Soft transitional start" (phase of progressive activation with quality control & validation of equipment & software)
- Technical data review, trouble shooting
- Reporting (by level)
- Active support phase and transition
- Contingency Plan in case equipment failure cannot be addressed (should be rehearsed)
- Contingency Plan in case of TM system failure (back-up devices and increased monitoring by personnel)

SOPs should not only describe "**what"** needs to be done. In order to be efficient, they should further explain **"why"** these actions should be performed and "**how**". An identified **good practice** is to use draft SOPs as a working tool during training, installation and implementation in order to validate them. High-level SOPs should be supplemented by one-pagers for daily use. Example of these can be found in annex 3.

### 2. Role mapping and definition of HR needs

The HR needs to be considered, include technical skills, data management skills but also managerial skills.

"Roles and Responsibilities tables" or escalation trees should be designed at this stage either as a table or as a flow chart (best practice for elevation of alarms for example, how much time should the first person warned be allocated to fix the alarm before it is elevated). An example of a Roles and Responsibility table is provided in Annex 5. The definition of the different roles has a huge impact on the success of the project and depends on the local context; how fast can the site manager reach the site on weekends, how reliable is the back-up equipment etc.

**The first respondent** (probably the site Manager) must be a person who is on site many hours and who has the possibility of reaching the site quickly outside of working hours. This person must be very reliable in responding to alarms, must be trained in the correct responsive actions and must inform the system administrator and supervisor of longer periods of unavailability so that the critical function can then be switched to somebody else. This person is responsible for escalating if the problem is beyond his normal scope of action.

**The second respondent** (could be the EPI logistician) has the overall responsibility of managing the appropriate response of the first respondent but also must make sure that the site is covered at all times and that in the case of holiday, disease or travel of the first respondent, the function is covered by the back-up person. This person will be responsible for taking follow up action in case of escalation and when follow-up action and repair or maintenance is necessary and for escalating to higher level if applicable, in case of major breakdown or critical issues. The same

[10] *The EVM SOP manual can be found at < http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html>*

back-up system must be organized for holidays and absence, with the system administrator implementing the changes in the system and continuously updating it.

**The third respondent** (could be the EPI manager) has the overall responsibility for managing the first and second level respondents. He must ensure that they get the necessary support to perform their tasks in terms of budget and authorizations, if the vaccines need to be moved out or a generator must be rented or borrowed, depending on the contingency plan. The back-up system in case of absence applies for the third respondent as well.

It is important to note that the third respondent, in a higher position should only receive alarms when they become critical, i.e. should not be overwhelmed with notifications of temperature increases by a few degrees, e.g. due to power cuts. On the other hand he must receive alarms when fluctuations become critical.

Since freeze alarms are much more time-critical than heat alarms, the threshold for involving the second and third respondent would probably be different for freeze and heat alarms. Even though the immediate corrective action in case of freeze problem can be easy: to open the door whereas heat alarms can be more technically complicated to resolve.

All job descriptions should be reviewed to define what job profiles are needed, to check if current resources are adequate and if extra training or recruitment is necessary.

## 3. Resource & time-planning: (Gantt)

The budget must include funds necessary for the purchase of the devices, installation, training needs and a budget for technical post-installation visits that will most probably be required. The payment logistics should be organized in good time and must include the purchase of the SIM cards and monthly payment of the transmission fees to the cellular service provider, which could be higher than expected during the transitional start period. This is a very crucial point and any failure to perform this on time would compromise the system. Pre-paid SIM cards should be avoided due to the fact that, when they run out, renewal is harder to manage.

The installation time and process varies significantly, depending on the physical environment, the number of cold/freezer rooms and how they are located in the different buildings, how far apart they are and how complicated the cabling connections will be. Complex installations can take 3-4 days per RTMD.

For simple, single sensor devices, it is estimated that each installation team of 1-2 people can perform a minimum of 2-3 installations a day. This is contingent on the pre-requisites and local parameters, like distance from one clinic to the next, good pre-installation documents produced, and good communication with the local staff for their involvement. If some of the more time-intensive tasks are completed at central level beforehand, i.e. before the units go out to the field for installation and when the installation team becomes experienced, it could be reduced to 30 min for the hardware and a total of 3 hours for installation and validation. 16-20 clinics can be installed in one week for the smaller RTM devices.

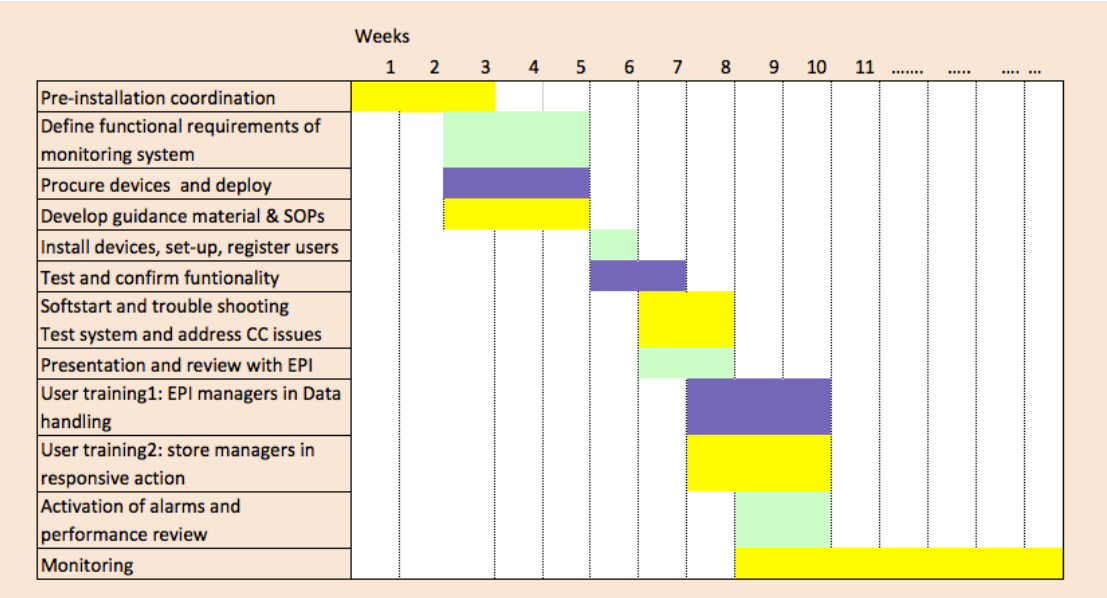


*Fig 2. Gantt chart*

It is important at this stage to be aware of potential risks to the project. Prior experience of implementation has shown that in spite of good planning, some projects have been jeopardized by unexpected factors. Due to the inter-dependency of the phases, some contingency should be built into the planning. The timing element for the procurement and installation can be tricky, in particular if the installation of a new RTM is done in connection with the construction and installation of new cold /freezer rooms in a new building. As all the phases linked with the project depend on multiple actors, delays in one part will affect the other phases. For example, the walk-through and decommissioning of the building ought to be fully completed before the WICR can be installed and the WICR must be installed and decommissioned before the temperature monitoring system can be installed. A potential damage in one of the shipments of equipment or a short delivery will have repercussions on the contract with the technician responsible for the RTM installation. The timing of the downstream tasks should be flexible enough to account for possible delays without having to renegotiate or start from scratch. If it is a requirement that the installation engineers should be able to speak the local language for a better training and transfer of competencies, it should be kept in mind that these engineers/consultants can have tight calendars and need to be booked a long time in advance.
Another risk factor is inappropriate storage of the upstream equipment while waiting for the other parts/phases of the project. This can result in theft or damages to these parts requiring a new procurement process to replace them, further delaying the whole project.

## 4. Documentation and communication plan

What to do with all these data feeds received from the system? How to select which data feeds are beneficial, how they translate into actions and how they can be used to improve the system? Value comes from knowing how to create optimized use of the data and how to manage data coming from multiple cold rooms and fridges.
A specific SOP on documentation can provide the overview on the necessary documents: installation /configuration documentation, calibration documentation, temperature reports, who should have access to them, how they should be archived and how long they should be kept.

It was identified as **good practice** to record in the inventory which vaccines are normally stored in which equipment in case of temperature excursion/ malfunction, given that corrective action will depend to some degree on the vaccine and its heat-freeze sensitivity as per WHO table in annex 4.

**Notification flow and frequency equilibrium**
Design of communication- and information flow is a very important exercise. If mismanaged, communications concerning the program can be counter-productive. Not everybody needs to be informed daily of temperature excursions and equipment performance. The EPI manager does not need to know that the fridge door was left open for 5 minutes at a health facility. He is more interested in aggregate information for analysis, e.g. to determine faulty equipment that needs to be replaced or poor management practices that can be corrected. Stakeholders should receive only the information necessary to fulfill their function and to empower them to resolve more issues at their level but not more. For example, no one needs to receive a message saying that temperature is in the acceptable

range (this would furthermore increase the cost of SIM card use). What they need to know is when it is not. The recipient of the information must be able to understand it (language) and to take action upon it. Information overload can damage attention given to, and confidence in the system as well as user buy-in. Monthly PDF reports emailed to national, provincial and district levels are sufficient for high-level decision making on the functionality of the equipment and reliability of the CC.

Data integration must be included in the documentation and communication plan.

| Staff | Alarm reason | | | | | |
|---|---|---|---|---|---|---|
| | Channel | Temperature alarm | Door open alarm | Power failure alarm | Data transmission interrupt alarm | Comments |
| Supervisor | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Logisticians How many? Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Technical staff How many? Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Others How many? Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |

*Fig.3 Communication table from the Berlinger pre-installation questionnaire that can be found in Annex 5*

Evidence from some TM studies[11] shows that even though the EPI staff has access to the data 24/7, they still prefer receiving a monthly report by email; possibly because it acts as a reminder for them to check the data at regular intervals.

## 5. Up-front training on how to manage the system

Training includes a procedure for the responsible store managers or nurses at the health facility[12] to seek out the cause of the alarms, address the issues when possible or escalate, i.e. it should incorporate the decision making process. Training on how District Managers and supervisors can monitor the system through the portal, and how they can maintain the lists of contacts phone numbers, access the reports and use them, should also be organized. Another important training is for the technicians and/or CC managers to learn to recognize patterns of graphs, in order to be able to diagnose equipment issues based on the temperature graphs. Periodic retraining is necessary in particular in case of high staff turnover and should be part of the budget allocations.

SOPs should be developed for District Managers/District technicians receiving an escalated alert and for EPI staff handling the monthly reports of alarms, cases, solutions and long-term impacts. Using SOPs for training purpose has been clearly identified as **good practice.**

## 6. Procurement & installation plan

The procurement and distribution plan needs to be prepared at the early planning stage well ahead of the start of the project. Even though manufacturers' lead-time might be in principle as low as 1-4 weeks (as shown in part II below on Procurement & Installation), experience shows that the whole process can take up to 6 months. The contract for the installation can also take time and depend on the availability of the person doing the installation, in particular if the person is required to know the local language.

[11] *Report Cold Trace Year one: Feedback from the Field, November 2015, MOH Mozambique, VillageReach, Nexleaf Analytics*
[12] *Poster of the corrective actions SOP for nurses in Kenya, Nexleaf/VillageReach, see annex 2*

**Peripherals configuration (incl. sensors, SIM cards)**[13]
The number of sensors per cold storage unit should be decided upon.
For cold rooms and freezer rooms, two sensors are the very minimum, one situated in the coldest area, normally in front of the evaporator and one in the warmest area, normally in the middle shelf in front of the door but a thorough mapping of the room should be performed as per the WHO mapping protocol, to obtain detailed information on the temperature in all areas when the room is empty, half full and full. A dedicated sensor is recommended for the door opening.

At HF level, ideally, each fridge should have two sensors – one for the upper (heat-risk) area, and another for the lower (freeze-risk) area. If only one sensor is feasible to install, it should be placed in the lower middle area as recommended by WHO. The measures are to ensure detection of most freeze risk events. Vaccines should be placed in baskets as baskets help to avoid wall-contact freeze risk.

Some suppliers have designed a facility questionnaire to be filled in prior to the installation in order to make sure the technicians performing the installation have all necessary parameters in advance. This provides information about the building and material elements, number and type of temperature controlled units, available power outlets and the planned communication flows. It is especially important if the facility has separate buildings, as an increased quantity of cables would be necessary. It is recommended that the following questions be addressed in advance: Does the installations allow for a back-up SIM cards or does it have SIM cards picking up the strongest network? Is a gateway required in order to protect sensitive data? Is a central alarm unit required and where should it be placed (for visual and audio alarms). A copy of the questionnaire is provided in annex.6.
The upfront provision of detailed site information, maps and information about on-site resources (as highlighted in paragraph II.D on installation) has been identified as **good practice**.

### 7. High level Roadmap and Deployment plan

A project roadmap is a good way to plan and to present the project to all the stakeholders. It highlights the important milestones and explains what to expect and when. It defines the budget allocations and their timing and it clarifies the different high-level activities of the project. Finally it identifies the risks areas (and dependencies) and areas where non-completion will delay the project.

# III. Procurement & Installation

## A. Ordering process

UNICEF Supply Division (SD) Cold Chain Support Package[14] provides procurement guidance and technical support for procurement of CC equipment and services. UNICEF SD can assist countries in their procurement through Procurement Services[15] benefiting from bulk prices for products that are on LTA. SD can review procurement plans and assess if the order is consistent with the country specific CC available information. The temperature monitoring devices for which UNICEF SD currently has an LTA with the supplier can be found in the Supply Catalogue [16].

Countries can also manage their own procurement directly with suppliers. UNICEF SD procurement guidelines[17] provide reference to the public procurement process. Processing time for the bidding, procurement process and transport should be added to the supplier lead-times of 1-4 weeks for temperature monitoring devices.

For complex products to be deployed at national or regional storage facilities, it is recommended to include installation and "on-boarding" support in the contract for the procurement of equipment. Some suppliers provide the installation support from their own certified technicians but this technician might not be able to speak the local language. This situation represents a missed opportunity as it limits the possibility for the technical installation specialist to train the local technicians who will eventually be in charge of maintaining the system. When a third-party technician is hired to install the equipment, it is important to ensure that the supplier can provide immediate and continuous support to cover all time zones (24/7), in case of challenges due to glitches in the installation of the product.

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[13] *Remote Temperature Monitoring Device Rollout Guide [CHAI Internal Document, Public Version Pending]; Brison M. Nadadur G. Banani T. 2015*
[14] *The UNICEF Cold Chain Support Package can be found at <http://www.unicef.org/supply/index_74631.html>*
[15] *UNICEF Procurement Services can be found at < http://www.unicef.org/supply/index_26072.html>*
[16] *The Supply Catalogue can be found at < https://supply.unicef.org/unicef_b2c/app/displayApp/(layout=7.0-12_1_66_67_115&carea=%24ROOT)/.do?rf=y>*
[17] *Procurement guidelines can be found at < http://www.unicef.org/supply/files/General_Procurement_Guideline_Oct_28_2014.pdf>*

**Generator**
For countries where power supply is unreliable, available on-site generator power must be sufficient to also cover power-based RTMD even though the power requirements are minimal. RTM units should be connected to the same source as the refrigeration unit as the RTM normally sends power-off alerts, it thus provides information for both units.
**Voltage stabilizer**
Furthermore, voltage stabilizers should be available, either using the unit available for the WICR or a dedicated one for the RTMD. If not, a voltage stabilizer should be ordered when procuring the RTMD.

## B. Shipping & receiving (customs clearance, quality check)

All shipments must be thoroughly inspected upon arrival to check that all devices/parts are received and that the shipping boxes/packaging are in good condition. Shortly after arrival all equipment must be inspected/tested to ensure working status (electronics can be damaged by heat and humidity). In case of failure, it is very important that the supplier or procurement agent (in particular if it is UNICEF SD) is notified as early as possible and that the devices are returned to the supplier. Insufficient packaging and physical damage in transit are not uncommon.

It is **good practice** to record the device in the cold chain inventory.

## C. Installation

### 1. Installation of the devices

Even though RTM has been used for many years in cold rooms, its use in refrigerators is still limited and it is thus hard to identify 'best practice' for the installation of remote sensors in refrigerators. However, the following points should be kept in mind:

- **Priority vaccines**: If available resources do not provide sufficient RTMDs for all sites, at district level for example, the focus should be on monitoring storage entities with freeze- (PCV, Penta/DTP) and heat-sensitive (OPV, Measles, Rota) vaccines.

- **Placement of RTM sensors***:* There should not be any need to modify the layout of the room. RTMDs should be located somewhere that is visible and easy to interact with, likely mounted on a wall close to the CC equipment. In some circumstances, the devices may need to be secured with a metal cage to avoid theft or being tampering with.

  It is now known that some ILRs tend to show colder temperature in the middle and upper areas compared to the lower areas. Therefore, sensor placement should be based on model and type to ensure accurate monitoring. Incorrect sensor placement can lead to too many alarms. In case of doubt, advice should be sought from appliances manufacturers for coldest point inside the ILR.

  For the smaller single sensor devices, if a door-alarm sensor is used, one of the 2 magnetic bars should be attached to the refrigerator and the other one to the door. Some fixing methods[18] are to use screws. If it is considered too invasive, the device can also be affixed to the adjacent wall. Industrial-strength double-sided mounting tape has been used in Haiti but it is not as robust as screwing. The need for robustness of the installation (i.e. screws versus tape) depends of the purpose of the installation: for analysis purposes (for a study) or for a longer-term monitoring of the fridge. In any case, manufacturers' guidelines and recommendations should be followed.

- **Labeling:** If the fridges or some fridges are not already labeled, this must be done in connection with the installation with a unique identifier for each sensor, for each equipment and for each facility, as it is necessary in order to connect alerts to specific equipment and specific sensors in the equipment. A protocol needs to be defined if no system is in place. A template is suggested in annex 1. Labeling standards should be consistent with existing inventory management systems in order to facilitate RTM data integration with existing systems in country.

- **Wire routing:** For refrigerators, this can be challenging. It can be done in many ways; it can be run directly out of the door. This used to pose a risk of gaping in the door's rubber seal but with the new thin ribbon-like wires this should no longer be an issue. Alternatively, it can be performed by drilling a hole in the wall of the refrigerator (which can be

[18] Like the ones used by Beyond Wireless FridgeFone

risky) or by running the wires along the ventilation system. This was the chosen method in Haiti. They used a small hole in the interior back hole through which condensation is collected to be drained through a tube that empties externally. This would depend on the model of refrigerator and requires careful attention. It is also important to avoid placing the rubber-coated wires too close to the hot heat exchanger on the exterior back wall of the fridge. For multiple cold/freezer room installation using electric cables, the wires connecting the main device to the different sensors in the different rooms must be clearly labeled.

- An outlined **good practice** is to request responsible staff on site to provide in advance the necessary information regarding the site configuration: buildings, materials, cold chain equipment, and available power outlets, as it helps the installation team make sure they have all the necessary material and equipment and a good understanding of the site prior to the installation. This saves time during the installation.

- For installation at HF level, another outlined **good practice** is to identify a **pre-defined installation kit**, in particular if several technicians are doing the installation to make sure that the installation person or team has all the necessary equipment. Even standard tools as screwdrivers might not be available on-site.
  Example of installation kit from a pilot project in Kenya[19] contained:

  - ✓ Laminated SOP for the nurses on routine maintenance of the fridge and corrective actions in case of heat/freeze alert
  - ✓ Installation box with phone and adapter
  - ✓ Cage and locks for installation on the wall
  - ✓ Trouble-shooting booklet for the nurse on possible issues with the device
  - ✓ Registered SIM card for each clinic (possibly additional back-up SIM card)
  - ✓ Clips to secure sensor cable in the fridge

  We would also suggest:
  - ✓ Trouble-shooting booklet
  - ✓ Tools (appropriate screwdrivers, duct tape)
  - ✓ Templates like the "RTMD on-boarding tool" see next paragraph on software.
  - ✓ Sensor map.

### 2. Complete RTMD site on-boarding tool

It is critical for an effective use of RTMD to have a clear understanding of where data is coming from. Therefore, during the installation, the install team must record the details of the CCE being monitored, and how devices and sensors have been located. The "RTMD on-boarding tool" or rollout tool produced by CHAI[20] provides this functionality. It contains the necessary information to provide and maintain a clear overview for all parties. A copy of the tool with all the information pertaining to each site should be saved with the name of the site in a specific central on-line folder for easy access and record keeping. Since the tool contains not only technical installation information (Sensors and SIM cards installed in different equipment) but also organizational information, like the names and phone numbers of the respondents to the alarms, it must be maintained regularly and the task of maintaining the records within the tool must be included in a SOP. Some of the RTM products contain bespoke software incorporating this record keeping feature[21] but it is also advisable to keep it in a simple Excel file as per the template suggested.

**Good practice:** sites should also be provided with a sensor map that describes how devices and CC equipment are connected. A version is available as annex 1 of this document. The main suppliers of Central RTM devices provide a template for this documentation.

### 3. Verification of technical functionality (quality control+ validation+ calibration)

A number of parameters must be defined and validated when setting up the installation:

- It must be decided and programmed how often the system should query the sensors, as there is no established standard. Some of the current installations are set to sample temperature every 2-10 minutes, which is considered appropriate. Proper signaling by all sensors should be verified.

[19] Installation kit from ColdTrace/PATH pilot in Kenya (2014-March 2015)
[20] The RTM on-boarding tool or rollout produced by Mike Brison from CHAI based on his extensive experience of RTMD installation and deployment.
[21] E.g. Smartview from Berlinger

- Rules for the alarms need to be set up using WHO recommendations as guidelines. The standard from 30DTR alarms (i.e. the criteria for low alarm is set to -0,5°C or lower for 60 minutes and the high alarm is set to +8° C or higher for 10 hours.) can be used but the threshold can be slightly adjusted. How long the fridge/WICR should be outside the recommended temperature range before an SMS is sent depends on local geographic and organizational factors (e.g. whether there is staff on site able to do the first basic checks on the equipment and take basic corrective action outside of working hours and whether this staff has access to a mobile phone to escalate if necessary. One should bear in mind that the cost of SMS communication increases with the number of SMS alarms. Alerts are customizable so that countries can configure their systems based on these and other factors and can modify them if needed after evaluation.
- User accounts and escalation trees must be checked one last time and programmed, i.e. who needs to receive alarms and when and who needs to access the portal. This includes both primary respondents at the site, and the supervisors/managers who provide higher-level support and oversight. This should also be documented in the on-boarding tool.
- An identified **good practice** from Tanzania was a back-up SIM card provided for central locations or location storing high quantity of vaccines.
- A thorough **temperature mapping exercise** should be performed to define the most suitable position of the sensors if it was not recently performed as part of the installation of the cold rooms or freezer rooms

# IV. Active Support Phase – "Soft transitional Start"

CHAI has been piloting RTMDs in Ethiopia, Nigeria, Tanzania and Mozambique. In their lessons learned from early roll outs, they highlighted the importance of a "Soft Start". This is a period where the system is in place but not fully activated, a period of observation and fine-tuning before all the features of the system are introduced to the users. This strategy has sometimes been pushed back due to the extra time it takes, i.e. increased cost, but it enables the users to have a much better understanding and ownership of the system and drastically improves sustainability. The extra cost should be assessed in the perspective of the lifespan of the system. Soft transitional start can greatly help with the review and eventually revision of SOPs, thereby rendering them more **effective**.

## A. Technical data review and fine-tuning

After installation and activation of the devices, the technical installation staff progressively introduces the system to the technical team of implementers, reviewing the data and the potential reactions of the system when the alarms are activated to prepare them for what is to come. The installer must verify that all devices are signaling properly and sorting all remaining technical issues.
The core users are walked through the initial range of data for "familiarization" with the data, identification of problems and resolution of issues.

RTM will bring visibility into the system, uncovering previously hidden issues that will need to be dealt with before moving forward and handing over. It is recommended to engage only a small group of users in the beginning together with the implementation team for the resolution of these newly identified issues. This serves to highlight the power of the reporting system. If these issues are not resolved before full activation of the alarms and hand-over, the health workers and EPI staff might be overwhelmed with the large number of alarms. Failing to do so risks creating a long-lasting bad first impression of the system and rejection or at least skepticism.

In this phase, it is recommended to focus on the system and not only on the devices, as it is important for the users to understand that RTM in itself is not sufficient to protect the vaccine if alarms are not followed by corrective action. Even though the data gathering and reporting is automatized, RTM should not give users a false sense of security. The vaccines are not protected if alarms do not trigger appropriate action and these actions cannot be automatized. RTM places a high level of responsibility on health workers to respond to alerts and prevent vaccine wastage, but also on EPI managers, since they have access to all the data.

## B. Feed-back to the EPI and training on charts/graphs (National logisticians or technicians)

EPI staff must be introduced to the system, in particular the GUI (Graphical User Interface) of the visualization tool. They should be walked through the possible graph patterns and how to interpret the findings. Learning the main patterns of graphs can enable technicians or logisticians to make a remote diagnosis of the equipment issues, e.g. the thermostat is too low or the solar battery needs replacement but this needs to be trained. TM studies can

provide examples of the graphs and can be used to help staff recognize the patterns[22]. It is crucial to verify that the users are able to understand and use the data and to familiarize them with the scale and range of data RTM introduces. Remote diagnosis of the equipment can save time and resources, with technicians only physically travelling to the sites for cases, where the graph data does not give an obvious picture of the issue.

### C. User training and "Support Centers"

Long-term sustainability and efficacy is determined by a good understanding of the system by users and access to supportive resources.

- Creation of training material
- Training on SOPs/use-based training
- Hardware training
- Software and graph patterns training
- Management training, training in risk management approach to help managers prioritize preventive, detective and mitigation measures and make data-supported pro-active rather than reactive decisions
- Maintenance training

Pre-qualification criteria are looking at including long-term support by RTM providers through service support centers for devices and data systems issues.

### D. Country specific hand-over documentation (language)

For non-English-speaking countries, a translation of the hand-over and documentation manual might be necessary. For the time being, most suppliers do not provide installation manual, hand-over documentation in other languages than English. Furthermore, it could be more user friendly to create customized, possibly simplified hand-over material to adapt to the cultural context and the education level of the staff it is ultimately intended for. In many environments, illustrated instructions can efficiently replace written instructions.

## V. Long-term strategy and sustainability

After one month, a review meeting should be organized in order to review the alarm setting (too little/too much) and verify that the SOPs are in line with the practice.

### A. Transfer of support

Transfer of ownership from implementation team or service provider to owner and users of the project must focus on the long-term sustainability.

Here are some examples of **Good practice** identified from the RTM pilot in Mozambique:

- Having a full-time technology officer providing on-line support (hotline) in the local language and when needed on-site technical support. This function should be transferred to the MOH, as soon a person with adequate capacity is available.
- Regular EPI staff meetings on the issue of the temperature monitoring findings in order to build a more robust and sustainable system. Many questions should be raised before the transfer of ownership and should be addressed in the transition SOP (including but not limited to):
    - Defining who is responsible for the system?
    - Who is the backup?
    - What happens if someone quits?
    - What happens when equipment is replaced?

[22] *MOH Mozambique, Nexleaf Analytics and VillageReach: "Why fridges fail part 2: RTM data for maintenance, January 2016 Mongolia EPI Monitoring Study, May 2011, STC WHO Ranjit Dhiman*

## B. Performance review with users – Monitoring

The measure of an effective RTM system can be summarized through the following criteria:

- Increase of equipment uptime (reduction of time where equipment are out of range)
- Reduction of delays for repairs through the creation of a pro-active, evidence-based maintenance strategy
- Increased visibility into CC system performance
- Improved decision-making around procurement of new CCE and spare parts
- Reduction in the vaccine closed vial wastage resulting from exposure to damaging temperatures

Sustained monitoring of the system and the users is mandatory, i.e. that responses to temperature excursions are rapid and become faster, delays for repairs are decreasing and to make sure that the system drives the expected change.

## C. Data protection and archiving

All data is owned by the MOH and will be stored in a central database. The cloud-based solutions often host the data in servers situated outside of the country and must get from the MOH data hosting rights. Most RTM systems provide very secure user-specific data segregation via login-in for user authentication. Users get access to specifically defined data within the database. There is no hardware on the client site but the solutions are web-based. Furthermore backup data is regularly sent to an alternate server to ensure uninterrupted secure data access in the event of primary database failure, thereby ensuring zero downtime to the users. The data is encrypted as per international ISO standards (ISO/IEC 27001). However, a clear definition of who is responsible for managing the server during implementation and after is required. Clear guidelines should define in the SOPs the data to be archived, the staff responsible for the archiving, the timeliness of the reports and rules for archiving structure and backing up and who owns the data after the first 3 years of the duration of the contract where it is generally hosted by the supplier of the RTM solutions. The longer term should be considered, even though the most crucial data is the data for the last 6 months.

RTMD providers may be involved in not only integration but also in ongoing dashboard data usability. Providers working in cooperation with MOH IT managers can help secure data hosting and provide software updates with useful visualization tools as an ongoing partner with countries in RTMD management and upkeep.

Proper archiving of data is an EVM standard and this will also apply for temperature data. Some RTMDs provide a software feature for archiving, whereby all data is stored on the cloud-based server with a direct access by the authorized administrator for up to 7 years. The data can then be available on request for up to 15 years. If this is not included in the product package, an archiving convention must be defined and recorded in an SOP and should be consistent with archiving standards in the country.

# Conclusion

Before deciding an RTM small pilot study can help pinpoint where the main issues are and this can impact the focus of the corrective actions. There can be many disparities from country to country. For example some studies performed in India and Mozambique showed that in India, 90 % of heat excursions were due to power outages whereas in Mozambique, it was only 38%[23]. A TM study in Albania[24] showed that 31 % of alarms happened during weekends and even with an efficient 30DTR monitoring system almost 2 days might pass between the alarm occurring and its detection, let alone any corrective action taken. Whereas 30DTR technology relies on manual spot readings from health workers and retroactive data for weekends, RTM being automatized provides **continuous** real-time data.

RTMDs for lower storage levels can be considered on the basis of the use cases that the country finds most aligned with its priorities and resources. For example, some countries might opt for RTM for a limited period of time in conjunction with new CCE to ensure proper installation, maintenance, and longer-term functionality of the equipment. Others might decide on RTM on existing CCE to re-shape and inform the priorities of a new national maintenance strategy.

[23] *From the PATH/Nexleaf report: Why do refrigerators fail, quantifying the Problem and Preliminary Evidence on the Causes, Dec. 2014*
[24] *Assessment of a remote alarm system for vaccine storage in Albania, June 2011, PATH/WHO/OPTIMIZE*

The industry is still looking to improve RTM products and it has been recommended that PQS could include in the pre-qualification requirements: mandatory technical remote support for the duration of the contract in addition to a mandatory installation manual, a service manual (maintenance) and training material in 3 languages. The functionality of RTMD can still be improved upon: for example with the possibility of programming differentiation of alarms between weekdays and weekends. The legitimation and segmentation of smaller one-sensor devices is being looked into with the development of new PQS specifications, for devices that are in-between 30DTR and RTM systems, both in terms of price range and functionality. It represents an important step since, for many countries, the choice of a solution is greatly influenced or even determined by the approval of a device by WHO through the PQS. More temperature studies are needed to bring more evidence into the business case of using RTM for long-term continuous monitoring of single refrigerators. One of the largest RTM projects in terms of numbers of units starts in India who just ordered 15.000 units and this will bring new evidence on large-scale deployments.

Sometimes the most effective solutions are not the most expensive. While effective temperature monitoring solutions are critical, investment in them must be proportionate with the risk and the right solution must be evaluated with respect to their opportunity costs in alternative uses of EPI programme funds (e.g. CC equipment replacement). In any respect and as for other TM interventions (like 30DTR or 30DTR+ SMS) the efficacy of RTMD is not device-driven but is depending on a system of user training, clear accountabilities and supportive management.

# Annexes

| | |
|---|---|
| Annex 1 | Sensor maps and labeling samples (Multilog) |
| Annex 2 | One-pager SOP |
| Annex 3 | Vaccines heat-freeze sensitivity table |
| Annex 4 | Pre-installation facility questionnaire from Berlinger |
| Annex 5 | Roles and Responsibilities table |

Annex 1 - Sensor map, Multilog

MULTiLOG Hardware Installation

***Sensor location plan***

Site: _____ Today's date: _____

Comments: _____

| Sensor number | Sensor location description | Temperature Maximum | Temperature Minimum | Time delay (mins) |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| 15 | | | | |
| 16 | | | | |

Take care when installing sensors not to pull the cable or snag it on sharp surfaces

Installer: (name) _____

Annex 2 – One-pager SOP

# When The Temperature in Your Fridge is TOO COLD: Below 2° C

**When you receive an ALERT from ColdTrace that the temperature in your fridge is too cold, go through the following checklist**

**If you act immediately, you can help keep vaccines safe!**

**1. Make sure ColdTrace probe is not touching the ice, the metal wall or the bottom of the fridge. The probe should be secured on the wall with the clips.**

**2. Defrost the fridge if necessary.**
- Check your defrost log: if you have not defrosted the fridge this month, please defrost
- If the ice thickness if more than 3 mm, then you need to defrost your fridge. Follow the guides on the PPM SOP for steps on how to defrost the fridge properly.

**3. Do the shake test on one vial for every type of vaccine in the fridge. If the shake test fails for any vaccine:**

- Perform the shake test on more vaccines and if they fail the test then remove all vaccines of that type.
- Record the failure in a vaccine wastage log. This step is important for showing the malfunction of your fridge.
- Set all failed vaccines aside for returning to the MOH. You call ----------for guidelines on how to proceed.

**4. If Alert is not cleared (and you continue to get additional SMS alerts), then:**
**Move thermostat down 1 or 2 steps.**
- For example if the knob is at 4, you will place it on 2.
- If the knob is at the lowest setting, then your fridge has a problem and you need to report this issue.
- After adjusting the knob, monitor the temperature inside of the fridge until it is between 2-8 ° C .
- Make sure the door is securely closed.
- If you tried all these steps and it did not solve the problem then follow the next step for moving vaccines.

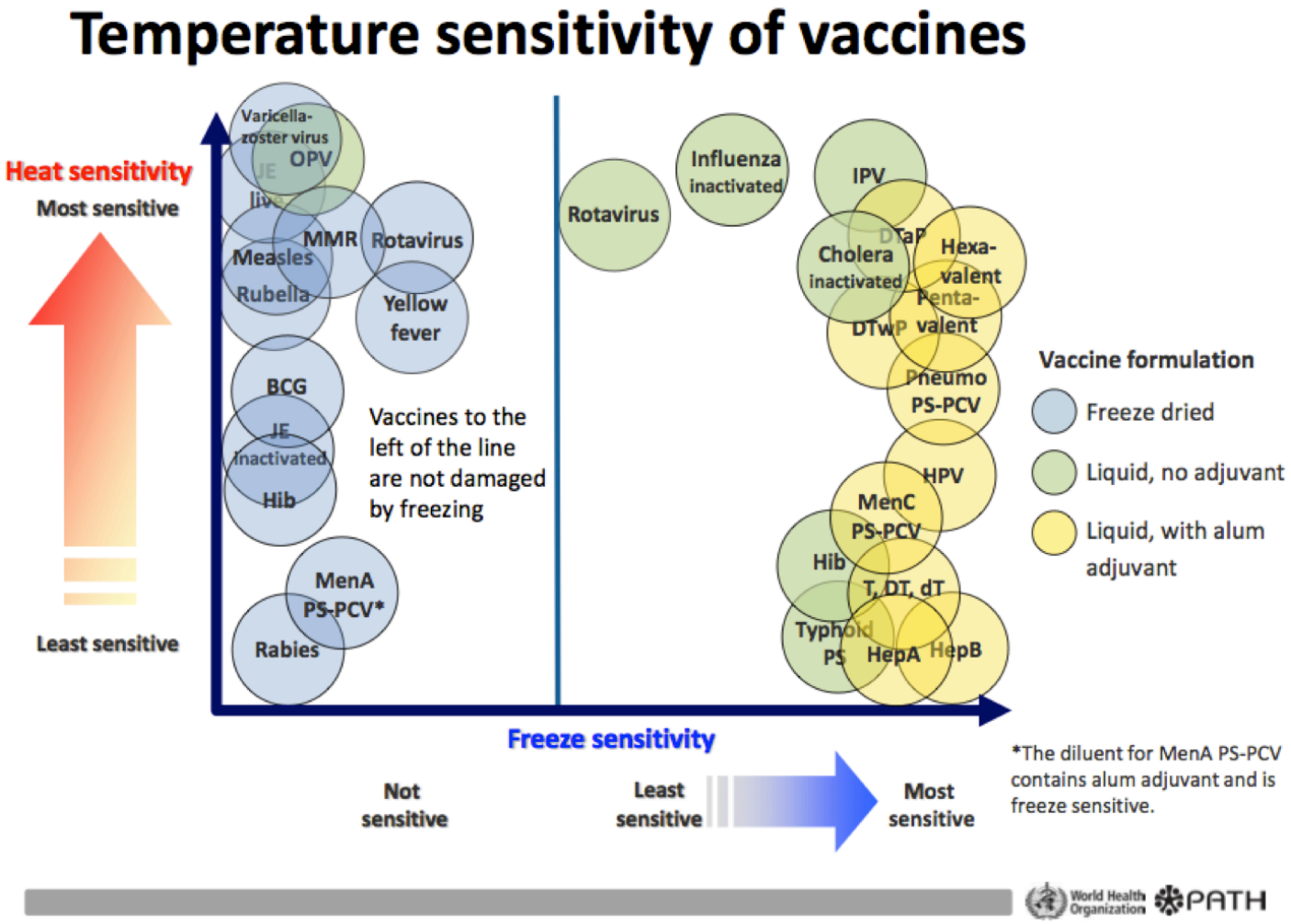
**5. If the vaccines are OK, and if the fridge problem continues, move the vaccines to a safe place. Choose one of the following options:**

Option #1)
- Move the vaccine to back-up storage unit, if available OR store the vaccines in a pre-cooler insulted container with cold packs and a thermometer. Continue to monitor the temperature inside the container until the normal vaccine refrigerator is ready for use again.

Option #2)
- Call _____to coordinate moving the vaccines to a clinic in close proximity with a working fridge.
- For transferring the vaccines, have a cold box with enough cold packs to keep the temp between 2-8 ° C
- Check the temperature of the box with a thermometer before placing and transferring the vaccines.

Contact Information to report problems with your fridge:
_____, Phone Number: _____

Annex 3 - Vaccines heat-freeze sensitivity table

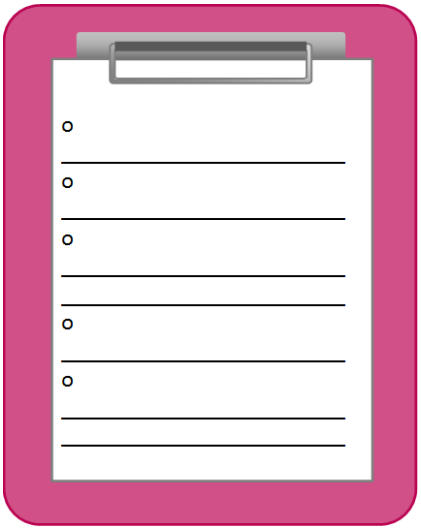



Annex 4 – Pre-installation questionnaire from Berlinger

BERLINGER/42-Berlinger_Storage_Facility_Questionnaire

## Smartview Central Monitoring System

# STORAGE FACILITY QUESTIONNAIRE



berlinger
feel safe

berlinger
feel safe

# Facility questionnaire

## Storage Facility Questionnaire for smartview CMS

The Central Monitoring Solution smartview CMS consists of a wireless sensor network which measures temperature, power supply status, and whether the cold room doors are correctly closed. It sends the collected measurements to a central data base which alerts responsible staff when there is a deviation from pre-set limits in the supervised storage facilities.

The wireless sensor network must be correctly designed for reliable operation. This questionnaire collects information about layout, dimensions and construction of the temperature controlled storage facilities. The information needs to be filled in as accurate and detailed as possible by responsible staff.

**Berlinger CMS Quick Ref Guide System** document provides additional information on how to fill in the questionnaire.

**Please provide the following information individually for every facility (site)**

## GENERAL

- Where is the cold storage facility located in the building (please mark as appropriate)?
  - ☐ Independent building (dedicated only to cold storage)
  - ☐ In a shared building (please indicate at which level the cold store is located)

- Provide a map of the facility (indicating any internal walls, obstacles etc.). The plan does not need to be to scale, but the dimensions and distances must be indicated.

- What are the main construction materials of the facility (Please tick appropriate cells)?

| | Material/Element | | | | |
|---|---|---|---|---|---|
| | Concrete / iron girders | Metal construction | Bricks | Wood / plastics | Other, please state |
| **Walls** | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| **Ceiling** | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| **Roof** | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| **Obstacles between cold rooms** | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| **Obstacles between cold rooms and the cold store staff office** | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |

- Please indicate name, dimensions and story (e.g. basement, or 1st floor) of all buildings in which temperature monitoring will be installed (length x width x height). Add rows as needed.

| Building name | Dimensions | | | Story (which floor?) |
|---|---|---|---|---|
| | Length | Width | Height | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

## MONITORING

- How many temperature controlled rooms does the facility have? Click here to enter text.

- Please indicate the dimensions of all cold rooms to be monitored and their temperature range (length x width x height). Indicate the location of these cold rooms in the facility plan. Add rows as needed.

| Room name | Dimensions | | | Temperature range |
|---|---|---|---|---|
| | Length | Width | Height | |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

## ICT & POWER

- Indicate in the plan where power outlets are currently available in the facility. They may be needed to supply wireless sensor network components. In the course of network deployment it may become necessary to place additional power outlets if the existing are out of reach.

- The Gateway transmits the data to the central data base. It shall be placed in the center of the network (cold rooms) and if possible in a protected area like an office. Please indicate possible position in the facility plan (indicate all possible locations).

  State below if protection of the Gateway is necessary.

☐ To be located in the staff office, no special protection is needed

☐ To be located elsewhere in the building, special protection is needed

☐ To be located outside the building, unsheltered, special protection is needed

☐ To be located outside the building, sheltered, special protection is needed

Additional comments

Click here to enter text.

▶ Do you need a Central Alarm Unit (visual and audio alarm) on site?

☐ YES ☐ NO

Comments Click here to enter text.

▶ Which type of connection is available to connect the sensor network with the Internet?

☐ LAN ☐ WiFi ☐ GPRS mobile network

Comments Click here to enter text.

▶ In case of LAN or WiFi: is a firewall blocking outgoing communication?

☐ YES ☐ NO

Indicate fixed IP address Click here to enter text.

Comments Click here to enter text.

## ALARMS

Please provide information about who, when and how has to be alerted under different alarm scenarios. Number of staff (and therefore e-mail addresses and/or phone numbers) have direct impact to the data transmission costs:

| Staff | Alarm reason | | | | | |
|---|---|---|---|---|---|---|
| | Channel | Temperature alarm | Door open alarm | Power failure alarm | Data transmission interrupt alarm | Comments |
| Supervisor | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Logisticians<br>How many?<br>Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Technical staff<br>How many?<br>Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| Others<br>How many?<br>Click here to enter text. | email | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |
| | SMS | ☐ | ☐ | ☐ | ☐ | Click here to enter text. |

Do you have any other comments relevant for the system implementation?

Click here to enter text.

Annex 5 – Roles and responsibilities table

**Example of roles and responsibilities mapping for temperature surveillance with RTM at regional store**

| No | Process | Frequency | Expected action | Responsible | Supervisor |
|---|---|---|---|---|---|
| 1 | Daily reading and recording of temperature (30DTR) | Daily, workdays | Each working day, spot reading of 30DTR temperature mornings and evenings, reading and recording of alarms. After weekends, reading of alarms from previous days | Site manager | Regional EPI manager |
| 2 | Weekly and monthly maintenance and cleaning | Weekly and monthly | Perform the weekly and monthly routine maintenance and cleaning tasks as per SOP | Site manager | Regional EPI manager |
| 3 | Automatic SMS alarm when temperature is out of range | When alarm occurs | Send automatic SMS alarm when temperature reading shows that temperature is out of range for a set time interval, repeated if temperature still out of range | RTM system | |
| 4 | Response to temperature alarm (SMS) | When alarm occurs | Respond to alarm on-site and take corrective actions as applicable (according to SOP) within set response time (KPI) if not able to solve the problem, contact EPI manager | Site manager | Regional EPI manager |
| 5 | Response to temperature alarm (SMS) | When site manager has not resolved the issue | Contact technician and plan technical visit or other corrective action | Regional EPI manager | |
| 6 | Response to temperature alarm (SMS) | When informed of an alarm | Assess the causes of alarms; initiate repairs and maintenance as required; document problem and solution in a log; preventive maintenance training to health workers as needed, if cannot solve problem escalate to national technical staff within set response time | Regional technician | Regional EPI manager |
| 7 | Automatic monthly submission of temperature reports (via SMS) | Monthly | Monthly submission of temperature reports by 1st day of the new month | RTM System | |
| 8 | Response to identified CC equipment problem (SMS) | When informed of major equipment issues | Provision of major repairs or replacement to reduce downtime of CC equipment within set response time (KPI) and update of inventory | National equipment management technical staffs | Director - equipment management authority |