Training resource

WHO PQS Post-market monitoring (PMM)

How-to guide to Sentinel Surveillance

June 2024

World Health Organization

Purpose of this training deck

This training deck is intended to support the transmission of “how to” and best practices for post-market monitoring sentinel surveillance programmes for health centre staff and other equipment monitoring personnel.

It covers:

The objectives and outputs of sentinel surveillance

How to set-up and maintain a sentinel surveillance programme

Links to supplementary tools for rapid and effective implementation

Contacts and further support

Complete guide to PMM Sentinel Surveillance

A complete **"How-to" guide to PMM Sentinel Surveillance** is available on the IMD-PQS Website and should be read in conjunction to this training deck:

https://extranet.who.int/prequal/immunization-devices/pmm-toolkit-sentinel-surveillance

This current training deck provides an introduction.

All references to « Sections » described in this training deck refer to the main How-to Guide.

Navigation

INTRODUCTION

Post Market Monitoring (PMM) :

Is the collection and analysis of equipment performance data from health and storage facilities to enable corrective and preventive action leading to improved CCE performance.

Sentinel surveillance :

Was identified by a PMM-strengthening Working Group[1] as a key way to collect standardised performance data at the country level and address an existing gap in quality feedback on equipment performance.

The approach was piloted in four countries, DRC, Haiti, Pakistan and Bangladesh in 2020-2021.

1 The working group, chaired by WHO Product, Quality and Safety (PQS), currently has representatives from WHO (PQS and EPI teams), UNICEF (Programme and Supply Divisions), the Bill and Melinda Gates Foundation, the Gavi Secretariat, PATH, the Clinton Health Access Initiative, as well as independent experts

GLOSSARY

CCE	Cold Chain Equipment
CCIS	Cold Chain Information System, an online data collection tool
EPI	Essential Programme on Immunization
Failure analysis	Procedure to identify the causes(s) of cold chain equipment failure
Fridge Tag	A high precision temperature data logger for the continuous monitoring of sensitive vaccines a
Immunization coverage	% of individuals in a target group who have received all the recommended vaccines for their age.
MoH	Ministry of Health
MoU	Memorandum of Understanding
NIP	National Immunisation Programme
Non-functional equipment	Equipment is considered non-functioning if certain thresholds are crossed in the monthly reported data
PMVM	Post-market monitoring
PMVM indicators	A set of 10 key indicators to be reported on monthly for each of the CCE included in the surveillance.
Routine reporting	Monthly reporting of indicators from health facilities
Sentinel surveillance	Methodology used primarily in infectious disease data collection.
WhatsApp	Online instant messaging application
Zero reporting	Reporting of not only the **presence** but also the **absence** of cases
WHO PQS	Product, Quality and Safety Team at WHO headquarters

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Introducing Sentinel Surveillance

INTRODUCING SENTINEL SURVEILLANCE

The sentinel surveillance approach has been selected for PMM as it is a tried and tested data collection method.

It is both **rapid** and **cost effective** and when well implemented can yield **high quality results**.

The relatively small investment in time and resources, coupled with a low reliance on technology at the country level, means that the approach is more likely to be sustainable in the long term.

DATA OWNERSHIP & SHARING

Performance data collected through sentinel surveillance programmes serves a dual purpose:

- provides the WHO Product, Quality and Safety (PQS) Team with data so that member states and UN purchasing agencies are assured of equipment suitability for use in immunization programs, and important insight into the reasons for equipment failure. The information can inform equipment specifications and verification
- provides valuable performance data, at the country level that can be used to improve countries' vaccine management systems.

METHODOLOGY OVERVIEW

1. A list of sentinel surveillance sites is selected for routine monitoring of cold chain performance.
2. The surveillance consists of monthly zero reporting from the sites (Section 2.4), based on a standard set of indicators (Section 4.3).
3. The routine reporting (Section 2.7) is coupled with regular site visits, accompanied whenever possible by NIP CCE technicians, to verify data and follow up on findings.

METHODOLOGY OVERVIEW

In addition:

A key component of the approach is failure analysis* (Section 2.9), which is carried out if the routine reporting indicates non-functioning equipment.

** The failure analysis aims to conclude whether the reported non-functionality is due to a equipment performance issue (i.e. design fault) or other causes (i.e. power fluctuations or human error).*

KEY TOOLS FOR SET-UP & MANAGEMENT

TOOL	Use in PMM	Timing
Site selection criteria	Guidance on how to select the sentinel surveillance sites – **Annex 1**	During the **Set-up Phase**
PMM indicators	A set of 10 key indicators to be reported on monthly for each of the CCE included in the surveillance. If certain thresholds are met the equipment is deemed non-functional until failure analysis can determine the cause - **Annex 2**	Training during the **Set-up Phase**, active use during **Implementation Phase**
PMM Taxonomy	Recommended terms and definitions to describe CCE parts and failures – **Annex 3**	Throughout PMM work
Follow-up and failure analysis questionnaire	A set of questions to guide the follow-up and failure analysis when CCE has been identified as non-functional – **Annex 4**	Training during the **Set-up Phase**, active use during **Implementation Phase**
CCIS Data collection application	Application for managing cold chain equipment, including inventory and maintenance. The application includes a data collection function for the PMM indicators and the follow-up and failure analysis - **Annex 10 (access, set-up and use)**	Training during the **Set-up Phase**, active use during **Implementation Phase**

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Implementing Sentinel Surveillance

Overview Phase 1, Set-Up

Phase One

Phase 1 objective: Prepare for successful PMM sentinel surveillance		
	**Who should be involved?**	• Senior Ministry of Health (MoH) staff • Senior implementing organisation staff (if other than MoH) • PMM Surveillance Officer (once hired) • Local IMP staff (officials, health centre, technicians)
	**Duration**	Approximately 3 months
 	**Outputs**	• Signed MoUs or agreements (as necessary) • Budget and workplan • Site visit plan • Final list of sentinel surveillance sites with up to date inventory • CDR II set up for data collection • Health centre staff trained on data collection and reporting • Technicians at central and local level trained and sensitized • Local IMP authorities sensitized
	Tools and resources (see section 4 of this guide)	• Site selection criteria • PMM Sentinel Surveillance Scope of Work • Sentinel Surveillance Officer ToRs • PMM indicators • CDR application and guidance

Human resources

- The hiring of a PMM Surveillance Officer is a key first step.
  - *The Surveillance Officer's profile and required experience is described in **Section 4.5**.*

- The Officer should be a **proven project manager, experienced in cold chain, vaccine management and temperature monitoring procedures**, with a good understanding of the national immunisation system. Experience of cold chain equipment maintenance is a plus.

Human resources

- PMM is a full-time role, but it combines both project management and technical skills. **It may be better shared by two officers**; one responsible for management and coordination, the other responsible for the technical aspects.
- Sentinel Surveillance programmes also requires:
  - **Input from NIP staff,** especially local technicians and staff at the participating health facilities (see ***section 2.6***, roles & responsibilities). Contracts or MoUs may be needed to ensure full participation.
  - **Leadership and involvement from senior MoH staff** to ensure that there is full buy-in for all the elements of the planned Sentinel Surveillance.

Selecting surveillance sites

Section 3.2 describes the criteria for selecting surveillance sites:

- Sites selected should include equipment from a range of manufacturers and a mix of easy and hard to reach areas, as well as well performing and low performing areas and health system levels.
- When selecting sites, the willingness and ability of local staff to participate should be considered.
- Sites should be selected in close collaboration with national and regional NIP programme staff using existing inventory, deployment and installation data. In some cases a sign off on the final list of sites from the MoH may be needed.

Selecting surveillance sites

Box 1: Cold chain inventory as a data source

Lessons from pilot countries show that the available inventory of cold chain equipment is often incorrect or not fully up to date and cannot be used on its own as a source of information for the selection of sites. During the **Set-up Phase** it is important to visit all the sites initially selected, update the inventory and, if needed, revisit and revise the list of sites to better reflect the reality on the ground.

Developing a budget work plan

The pilots have demonstrated that the key budget lines for PMM are:

1. **human resources,**
2. **training for surveillance set-up and**
3. **transportation to and from site visits.**

Depending on the country context, the cost of NIP technicians accompanying the Surveillance Officer on site visits for failure analysis will *need to be fully budgeted* to ensure their participation.

In some cases, a small stipend may be necessary to ensure timely and quality reporting from health centre staff.

Developing a budget work plan

The budget and workplan should plan for routine site visits with at least two planned visits per year to each site, ensuring participation of NIP technicians/staff whenever possible.

The plan should also include funds for ad-hoc site visits when failures have been detected. Depending on the number of sites being monitored these could be up to 1-2 visits a month.

Setting up zero reporting from surveillance sites

Lessons from pilot countries show that a successful set-up ideally involves **an initial visit to each of the sites** to review and update the available inventory in the CCIS data management tool and check the availability and functioning of FridgeTags (see **Box 2 and *Section 3.11***).

Box 2: FridgeTag as the source of reported temperature data

To ensure comparability of the data collected it is recommended that the monthly temperature data reported through PMM is read from a FridgeTag. An essential step in the set-up of the Surveillance System is therefore to ensure that all the monitored CCE have a functioning FridgeTag device and health centre staff are trained on their correct use. Detailed guidance on the use of FridgeTags is available in ***Section 3.11***.

Selection, set up and training on the data collection tools

- The **Cold Chain Information Systems (CCIS) application is the recommended data collection tool** for PMM but depending on the local context it might be more appropriate for some or all sites to report using WhatsApp or a simple excel sheet (**see Section 3.7**).
- In cases where the reporting sites are not using CCIS it is still recommended that all data be inputted into CCIS at the central level.
- Irrespective of which tool is used, there is a **need to also collect monthly FridgeTag PDF read outs** to allow for verification of the reported temperature data.

Selection, set up and training on the data collection tools

CCIS set up and training : CCIS is a comprehensive tool for the management of inventories and cold chain equipment. The application, that can be uploaded on to any Android smartphone, also includes the PMM indicators for routine monthly reporting as well as questionnaires for failure analysis follow up.

Detailed guidance on how to set up CCIS as well as training materials is available in ***Section 3.6****.*

Selection, set up and training on the data collection tools

Other tools: Where the use of smartphones for reporting is not appropriate, a simple paper-based word or excel template can be used for reporting. One of the pilot countries used WhatsApp successfully to collect photos of paper-based reports filled in at the health facilities.

*Examples of templates can be found in **Section 3.7.***

Roles & responsibilities

Roles and responsibilities of all stakeholders from the health facility through to the national programme, as well as relevant development partners, **should be clearly defined at the start**.

See next slide for specific roles & responsibilities

If PMM is implemented by an entity outside of the MoH there is a need to **establish an agreement or** MoU with the national authorities for the setting up of the sentinel surveillance sites and monitoring system. The MoU should include agreement on the sites selected, indicators to be monitored, workplan for surveillance activities and roles and responsibilities of designated government focal points.

Roles & responsibilities

Stakeholder	Recommended role in PMM
Ministry of Health	Data ownership, analysis and use to improve national vaccine management systems.
NIP Manager	Oversight of the PMM work at the country level, followup when failures are identified.
Sentinel Surveillance Officer	Day to day management of PMM: routine data collection, site visits, follow up, failure analysis, reporting to MoH and the regional immunisation programme.
NIP Technicians	Analysis of the causes of failure and maintenance.
Regional EPI	Oversight of PMM work at the regional level, follow up when failures are identified.
Health Centre Staff	Monthly reporting of the PMM indicators.
Partner Organisation(s)	Support to MoH. If implementer of PMM, oversight of PMM work.
WHO HQ Geneva	Custodian of global level data and analysis, improvements of equipment specifications and feedback to manufacturers.

Overview Phase 2, Management

Phase Two

Phase 2 objective: Ensuring successful routine surveillance and follow up		
	**Who should be involved?**	• PHM Surveillance Officer • Local immunisation programme staff (officials, health centre, technicians) • National Immunisation Programme Manager • Partner Organisation(s) (as relevant) • WHO HQ Geneva
	**Outputs**	• Complete monthly reports from all surveillance sites • Failure analysis reports (as required) • Aggregated quarterly reports (as required)
	**Tools and resources (see section 4 of this guide)**	• COIS application and guidance • Excel version of monthly questionnaire and failure analysis questionnaires (Follow up and Failure analysis templates) • Quarterly reporting slide deck template

Monthly reporting from sentinel sites

- The Surveillance Officer should compile data on the **10 PMM indicators** from sentinel sites **each month**.
- Reporting formats depend on the capacity at each site i.e. CCIS, email, paper, WhatsApp or whichever is most appropriate.
- The Officer will also collect FridgeTag PDF read outs to allow for verification of the reported temperature data. If the data is reported in another format the Officer will then input the data into the CCIS application.

Routine site visits

- The Surveillance Officer should carry out routine surveillance visits **each month to selected sites** based on the workplan.
- Each site should be visited **at least twice a year**.
- The purpose of the routine visits is to **improve the completeness of reporting** and provide supportive supervision and feedback.

Follow up and failure analysis

Monthly reporting will indicate if there is non-functioning equipment at any of the sentinel sites.

Equipment is **considered non-functioning** if any of the following thresholds are met in the reported temperature data:

- 5 or more heat alarms in a month
- 1 or more freeze alarms in a month
- 1 or more heat alarms with duration of 48h or more in a month

Follow up and failure analysis

When non-functioning equipment is reported, a two-step process is recommended to identify the cause of the failure.

The Surveillance Officer starts by carrying out the **'Follow up'** procedure, which is then followed by the full **'Failure Analysis'** procedure, if needed.

Follow up procedure

The **follow-up procedure** is a short questionnaire that can be conducted remotely over the phone with health facility staff and does not require any technical knowledge or tools. The responses can be recorded in an Excel sheet (see **Section 3.4** for the template) or recorded directly into CCJS.

The purpose of the Follow up procedure is to determine if a technician visit is needed or if immediate cause(s) of failure can be identified and address by health facility staff or the Surveillance Officer without a technician.

If the failure cause is known after completing the Follow up procedure, the component that failed and the failure cause(s) should be recorded in the Failure Reporting section of the data collection tool.

Failure analysis procedure

The failure analysis is a detailed questionnaire that can only by conducted on site by a trained cold chain technician with a set of tools. The responses can be recorded in an Excel sheet (see **Annex 4** for the template) or recorded directly into CCIS.

The purpose of the failure analysis procedure is to identify the causes(s) of failure which could not be identified or resolved during the Surveillance Officer's initial follow-up.

Once identified, the component that failed and the failure cause(s) should be recorded in the Failure Reporting section of the data collection tool.

Failure analysis *continued*

Note: Even when the Surveillance Officer has the technical background to carry out a full failure analysis alone, lessons from the pilot countries point to the importance of always involving the relevant local technical staff both for their expertise and ability to follow up on identified failures.

Note: Lessons from the pilot countries highlight the importance of swiftly repairing equipment and resolving problems following reporting and failure analysis. This is not only good practice in vaccine management, but also helps to ensure continued regular reporting from health facility staff who see immediate actions resulting from their participation in PMM.

Follow up and failure analysis

Box 2: Three causes of failure

- Performance Issues (i.e. faulty thermostat)
- Programmatic Issues (i.e. fridge door left open) and
- External Issues (i.e. power fluctuations).

Failures due to Programmatic or External factors can usually be identified using only the Follow up procedure, to fully investigate Performance Issues the Failure Analysis procedure is needed.

Reporting to national authorities and WHO

PMM data is owned by the country and the raw data set should be accessible to MoH at all times. If PMM is implemented by an entity outside of the MoH, basic analysis and key finding should be made available to MoH for review on a monthly basis.

With country approval, the WHO PQS team takes on the role of custodian of data and its analysis at the global level. Each month, participating countries share the raw PMM data, FridgeTag PDF files and failure analysis findings with the PQS team.

Quarterly in-country review of findings

Surveillance Officer convenes key technical national and/or regional cold chain staff and other relevant stakeholders on a quarterly basis to review the data and CCE performance issues identified, and to discuss necessary mitigation actions.

Lessons from pilot countries show that regular review meetings with key stakeholders are especially important when PMM is being implemented by development partner organisations.

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Tools & resources

TOOLS & RESOURCES

Annex 1. Site selection criteria
What: Criteria for selecting PMM site
Who: PMM implementer
When: during the set-up phase

Annex 2. PMM Indicators
What: A set of 10 key indicators to be reported monthly for each of the CCE included in the surveillance. If certain thresholds are met the equipment is deemed non-functional.
Who: Sentinel Surveillance Officer/reporting health facility staff
When: during monthly reporting

Annex 3. PMM Taxonomy (English and French)
What: Recommended terms and definitions to describe CCE parts and failures.
Who: Sentinel Surveillance Officer/technicians
When: During failure analysis

TOOLS & RESOURCES

Annex 4. Follow up and Failure Analysis Questionnaire/Methodology **What:** A set of questions to guide the follow up and failure analysis **Who:** Sentinel Surveillance Officer/technicians **When:** When CCE has been identified as non-functional
Annex 5. PMM Sentinel Surveillance Pilot-Lessons Learned from implementing countries **What:** Summary of key lessons from the three PMM pilot countries **Who:** PMM implementer **When:** during set up phase training and sensitisation
Annex 6. Excel template for PMM indicator reporting from health facilities **What:** Excel version of the indicator reporting template **Who:** Sentinel Surveillance Officer/ reporting health facility staff **When:** during monthly reporting

TOOLS & RESOURCES

Annex 7. Sentinel Surveillance Scope of Work and Sentinel Surveillance Officer ToR **What:** Scope of work and terms of reference **Who:** PMM implementer **When:** during the set-up phase hiring of Sentinel Surveillance Officer
Annex 8. FridgeTag Guidance (English and French) **What:** Guidance on the use of FridgeTags **Who:** Sentinel Surveillance Officer/health facility staff **When:** during set up phase and initial health facility visit and training

TOOLS & RESOURCES

Annex 9. PMM Sentinel Surveillance training slide deck
What: Slides outlining the PMM Sentinel Surveillance Guidance
Who: PMM implementer
When: during set up phase training and sensitisation

Annex 10. CCIS Guidelines: *PENDING*
What: Guidelines on how to set up and use the CCIS X application
Who: Sentinel Surveillance Officer/ reporting health facility staff/technicians
When: during monthly reporting and failure analysis

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Contacts & further support

CONTACTS & FURTHER SUPPORT

WHO PQS Post-market monitoring
pqspmm@who.int

ODK -X Helpdesk – coming soon