



Training resource

WHO PQS Post-market monitoring (PMM)
How-to guide to Sentinel Surveillance

June 2024



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 IMB-PQS Website and should be read in conjunction to this training deck:

<https://www.who.int/countryinfo/immunisation-devices/pmm-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



1 Introducing Sentinel Surveillance

Slide 7



2 Implementing Sentinel Surveillance

Slide 13



3 Tools & resources for implementation

Slide 38



4 Contacts & further support

Slide 45

GLOSSARY

Health equity

Health for all

Health

Well-being

Health care

Quality of care and access to health services

Technology used primarily to improve health care delivery. It covers conditions like a range of oral health topics that are important for achieving the 4 pillars of the Sustainable Development Goals. It also covers health topics such as oral cancer, dental disease and topics of importance to oral health programs.

Oral health program activities

Impact of an oral health program is the difference of oral health status that participants have achieved compared to non-

participants. Health and safety topics that are addressed are:

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1

Introducing Sentinel Surveillance

INTRODUCING SENTINEL SURVEILLANCE

The sentinel surveillance approach has been selected for PMVM 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.
1. The surveillance consists of monthly zero reporting from the sites (Section 2.4), based on a standard set of indicators (Section 4.3).
1. The routine reporting (Section 2.7) is coupled with regular site visits, accompanied whenever possible by NIP CDE 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 entire surveillance site – Annex 1	During the Set-up Phase
PMM indicators	List of energy indicators to monitor on a daily basis for each of the OEE 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 OEE parts and failures – Annex 3	Throughout PMM work
Follow-up and failure analysis questionnaire	List of questions to guide the follow-up and failure analysis when OEE has been identified as non-functional – Annex 4	Training during the Set-up Phase , active use during Implementation Phase
OEE X Data collection application	Application for managing tobacco equipment, including inventory and maintenance. The application includes a data collection function for the PMM indicators and the follow-up and failure analysis – Annex 5 (access, set-up and use)	Training during the Set-up Phase , active use during Implementation Phase



2

Implementing Sentinel Surveillance

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 **MIH** staff, especially local technicians and staff at the participating health facilities (see **section 3.6**, roles & responsibilities). Contracts or **MOUs** may be needed to ensure full participation.
 - Leadership and involvement from senior **MIH** 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 **MP** 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 [DHIS2](#) 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 PHMIS 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 [ODDS-X](#) application is the recommended data collection tool for [ESAM](#) 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 [ODDS-X](#) it is still recommended that all data be inputted into [ODDS-X](#) at the central level.
- Irrespective of which tool is used, there is a need to also collect monthly [EriqsTag](#) PDF read outs to allow for verification of the reported temperature data.

Selection, set up and training on the data collection tools

ODK-X set up and training : [Open Data Kit-X](#) 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 [PMMI indicators](#) for routine monthly reporting as well as questionnaires for [failure analysis](#) follow up.

El Detailed guidance on how to set up ODK-X 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 **FMM** 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

Role	Responsibilities
Chairman of the Board	Overall responsibility for the success of the company and for the long-term interests of the company and its stakeholders.
CEO	Responsible for the overall management of the company and for the implementation of the strategy.
Executive Director	Responsible for the overall management of the company and for the implementation of the strategy.
Non-Executive Director	Responsible for the overall management of the company and for the implementation of the strategy.
Director	Responsible for the overall management of the company and for the implementation of the strategy.
Senior Executive Director	Responsible for the overall management of the company and for the implementation of the strategy.
Executive Director	Responsible for the overall management of the company and for the implementation of the strategy.
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Overview

Phase 2, Management

Phase Two

Activity	Deliverables	Key Performance Indicators (KPIs)
1. Project Management	Project Charter, Work Breakdown Structure (WBS), Project Schedule, Risk Register	Project Completion Rate, Budget Adherence, Risk Mitigation Effectiveness
2. Resource Management	Resource Allocation Plan, Staffing Levels, Training Programs	Resource Utilization Rate, Staff Turnover, Training Completion Rate
3. Financial Management	Budget, Financial Statements, Cost Control Measures	Budget Variance, Cost Savings, Financial Stability

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. **ODK-X**, email, paper, **WhatsApp** or whichever is most appropriate.
- The Officer will also collect **FridaeTag** 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 **ODK-X** 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 [DHIS-2](#).

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 be 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 [iDCC-2](#).

The purpose of the [failure analysis](#) procedure is to identify the cause(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 findings 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, **FridayTag** 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 **LCE** 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.



3

Tools & resources

TOOLS & RESOURCES

<p>1. Finding a suitable model to use in the classroom</p> <p>Goal: Find a model to use in the classroom</p> <p>Resources:</p> <ul style="list-style-type: none">• Model to use in the classroom• Model to use in the classroom• Model to use in the classroom	
<p>2. Finding a suitable model to use in the classroom</p> <p>Goal: Find a model to use in the classroom</p> <p>Resources:</p> <ul style="list-style-type: none">• Model to use in the classroom• Model to use in the classroom• Model to use in the classroom	
<p>3. Finding a suitable model to use in the classroom</p> <p>Goal: Find a model to use in the classroom</p> <p>Resources:</p> <ul style="list-style-type: none">• Model to use in the classroom• Model to use in the classroom• Model to use in the classroom	

TOOLS & RESOURCES

<p>1. Tools developed by WHO and other agencies for health facilities:</p> <ul style="list-style-type: none">FormWHO Health Worker Skills Indicators Reporting TemplateWHO Health Worker Skills Indicators Reporting Health FacilityFormForm	
<p>2. WHO resources for reporting the Health Worker Skills:</p> <ul style="list-style-type: none">WHO resources to support implementation of monitoringFormForm	
<p>3. WHO Resource for health facility survey data tool:</p> <ul style="list-style-type: none">FormFormForm	



4

Contacts & further support

CONTACTS & FURTHER SUPPORT



WHO PQS Post-market monitoring

pqs@who.int

DDK -X Helpdesk – coming soon