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TECHNET WEBINAR SERIES ON TEMPERATURE MONITORING:
KEEPING A COLD CHAIN COLD

Equipment Monitoring Systems (EMS): The future of interactive cold chain performance monitoring

15:00 CET, 2 December 2021

Isaac Gobina, WHO PQS | Denise Habimana, WHO PQS | Karuna Luthra, Gavi | Brian Pal, New Horizons | Omileye Toyobo, CHAI

Session agenda

- Welcome *(Karuna Luthra, Gavi)*
- Introduction of WHO PQS *(Isaac Gobina, WHO PQS)*
- Overview of EMS *(Brian Pal, New Horizons)*
- Use of data *(Omileye Toyobo, CHAI)*
- EMS on the market (*Isaac Gobina)*
- EMS and Gavi CCEOP *(Karuna Luthra)*
- Menti survey questions throughout *(Denise Habimana, WHO PQS)*
- Q&A / Discussion

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INTRODUCTION OF SESSION

Menti Survey Questions

This presentation will feature interactive Menti survey questions

Please go to https://www.menti.com/

Enter code: **3517 8029**

Which country/countries do you work in?

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What is your title or job function?

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- Program officer
- QA Consultant
- Data Scientist
- CEO
- Project Manager
- Supply chain analyst
- Consultant
- Kiribati
- Engineer

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What is your title or job function?

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- Marketplace Project manager
- Innovation manager C CE
- Global Logistics Delegate, Africa (Danish Red Cross)
- Director, Global Business - SCS
- Chief Operations Officer
- ISC Consultant
- R&D electronic engineer
- junior supply chain analyst
- Technical specialist cold chain

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What is your title or job function?

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Project and Data Manager, Cold Chain

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What does PQS stand for?

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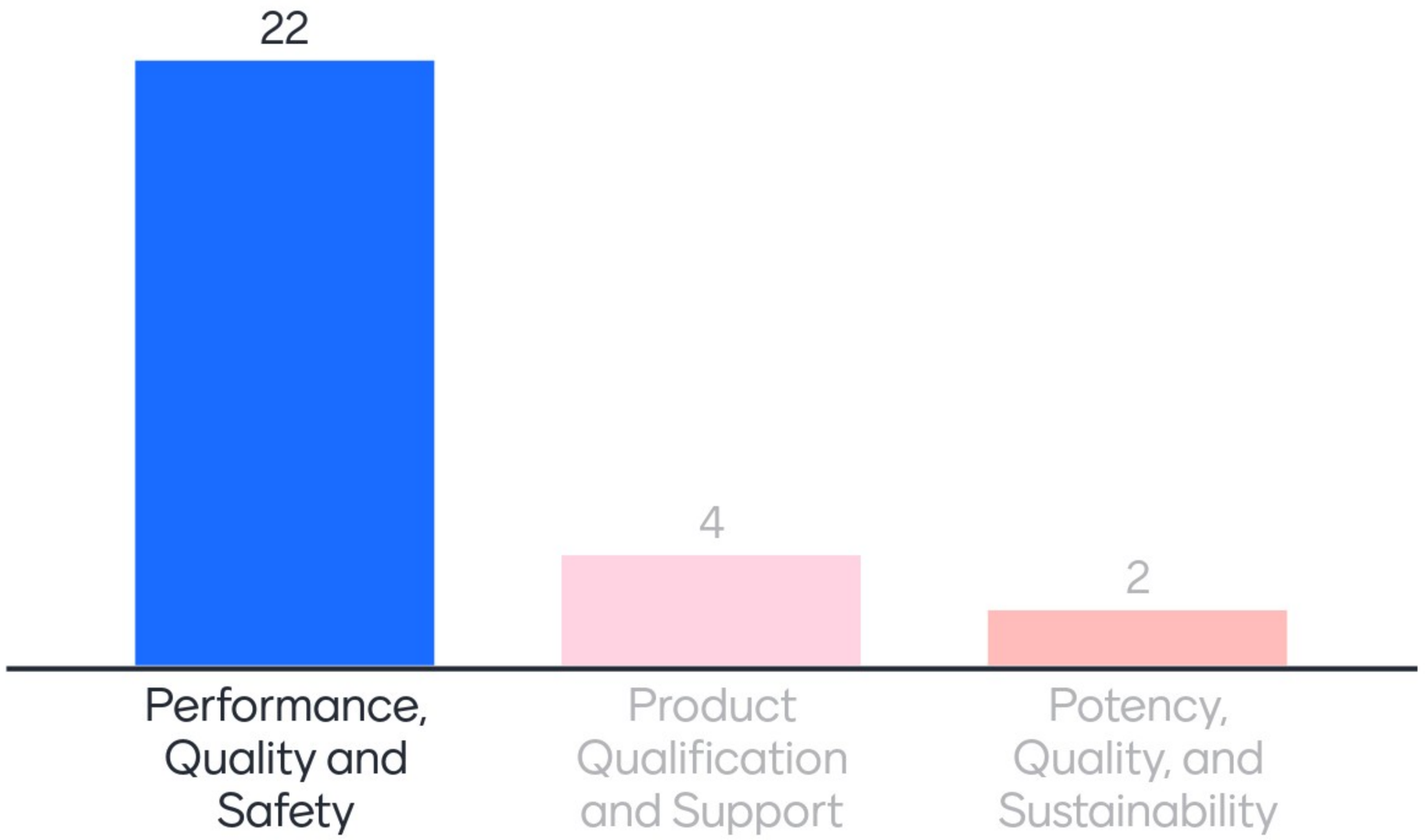

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INTRODUCTION OF WHO PQS

What do you think PQS does?

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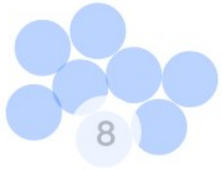
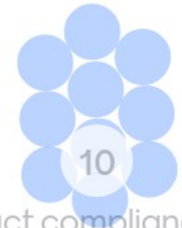
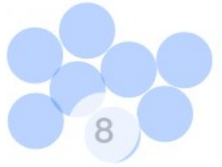


Set norms and standards



Verify product compliance with WHO standards



Evaluate products for prequalification

Stimulate product innovation

Assess product testing laboratories

Gather equipment field performance and user feedback

All of the above

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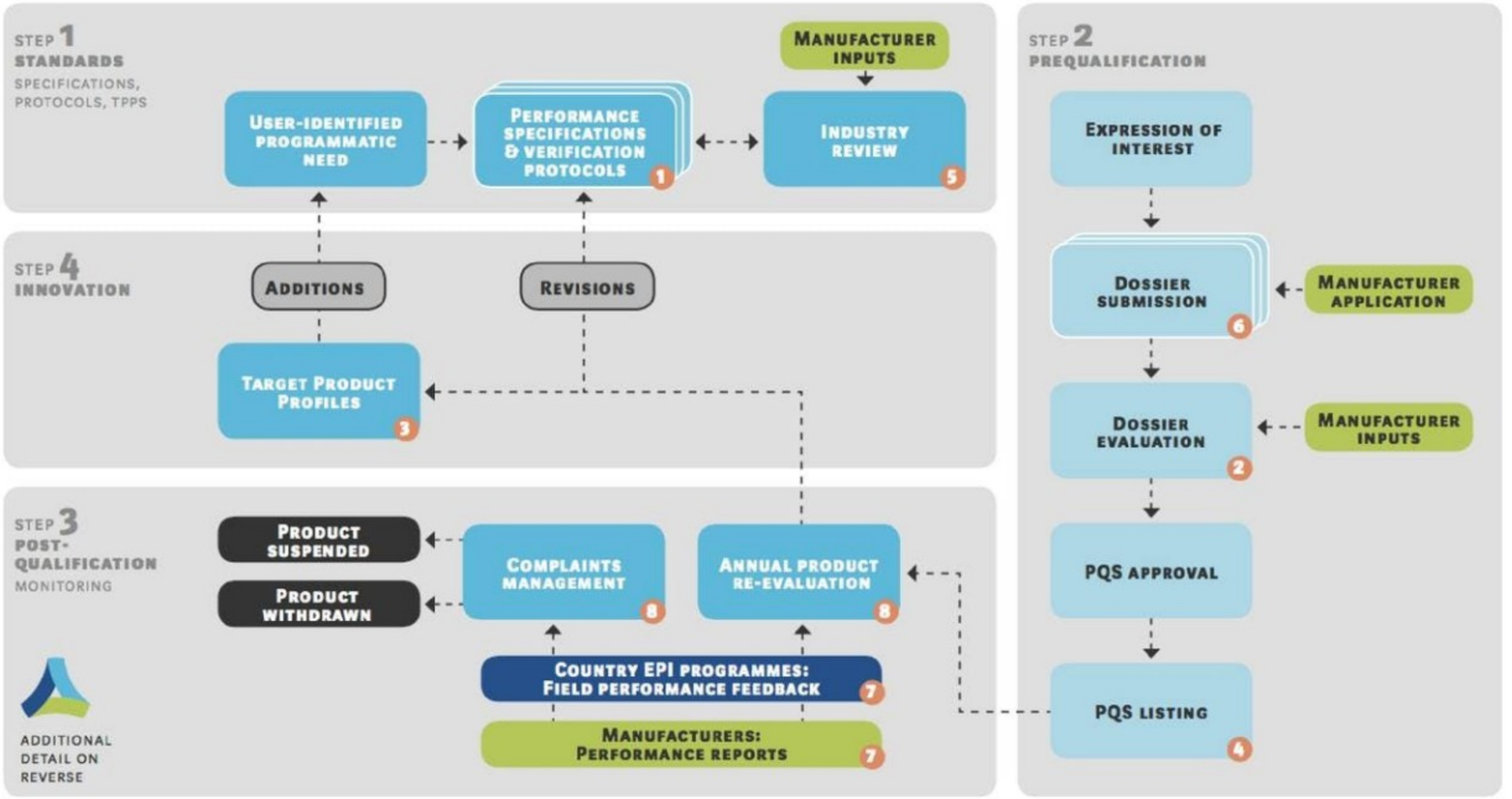
Immunization Devices Categories

- Link: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

  - E001: Cold rooms, freezer rooms, and related equipment
  - E002: Refrigerated vehicles
  - E003: Refrigerators and freezers
  - E004: Cold boxes and vaccine carriers
  - E005: Coolant-packs
  - E006: Temperature monitoring devices
  - E007: Cold chain accessories
  - E008: Injection devices for immunization
  - E010: Waste management equipment
  - E013: Injection devices for therapeutic purposes

How does the PQS process work?



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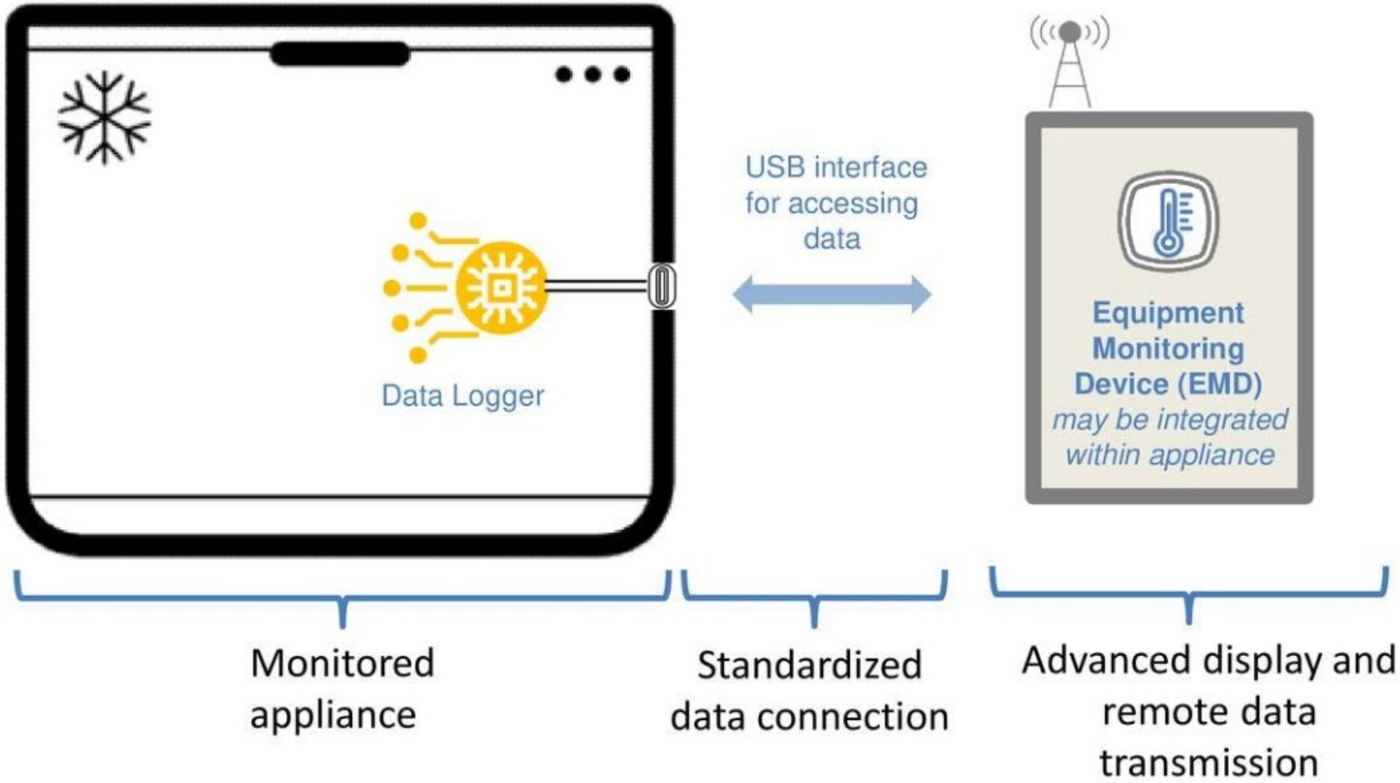
OVERVIEW OF EMS

EMS system introduction and overview

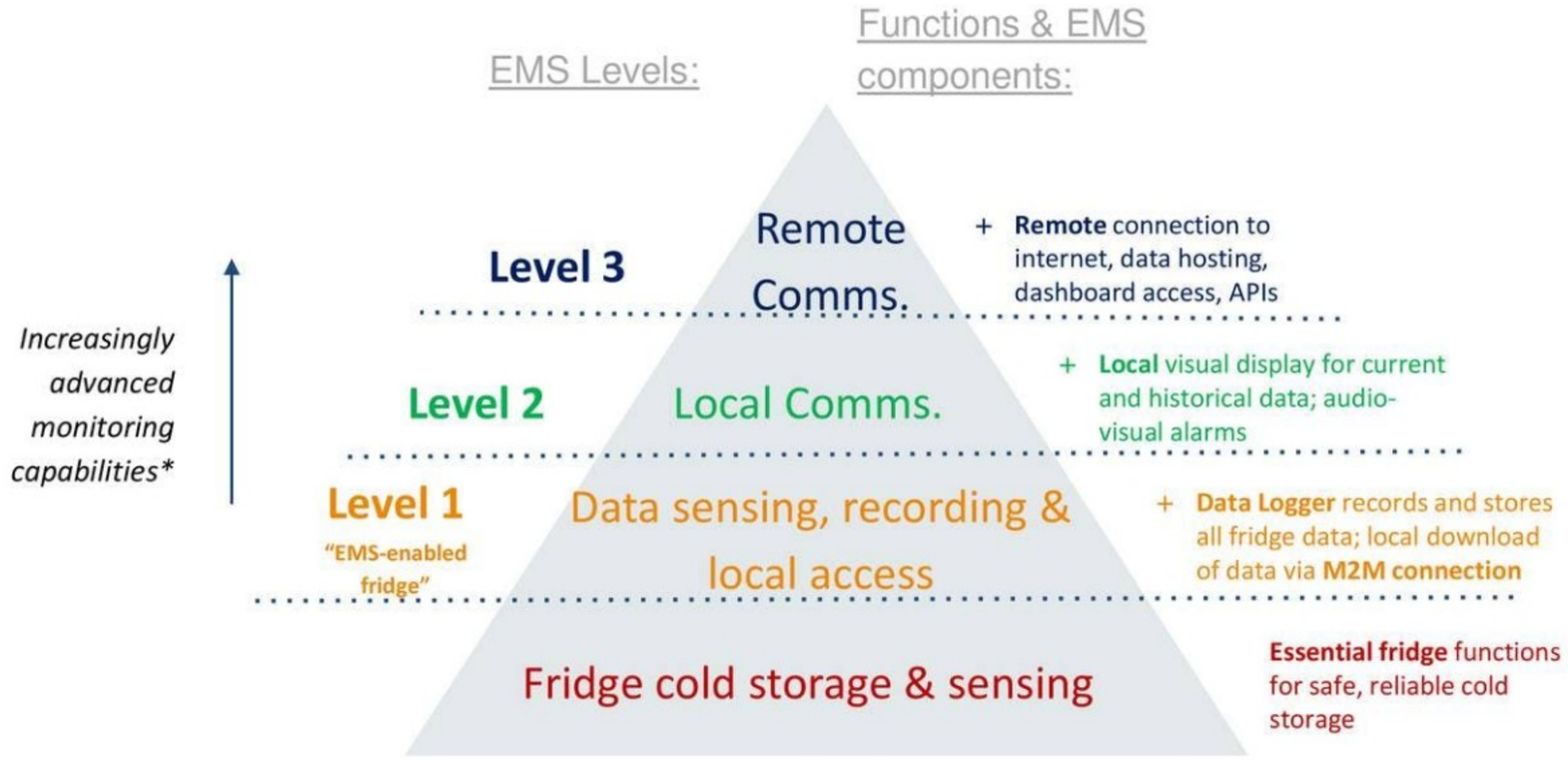
The Equipment Monitoring System (EMS) specifications define future cold chain equipment monitoring functionality, to achieve:

- Integrated logging of data and admin information to improve diagnostics and reporting
- Modular interface for local data access and plug-and-play upgradeability
- Data standardization for interoperability



EPI programs may choose what level of EMS functionality is most appropriate for their country's immunization system

Hierarchy of EMS levels, functions and considerations:



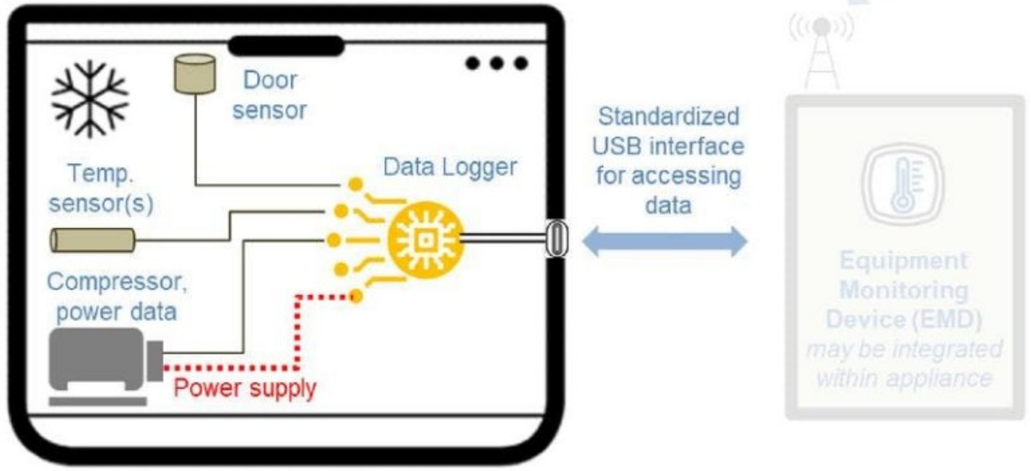
*Each level includes the functions of the lower levels e.g. Level 3 must also contain Level 1 and Level 2 functionality

Standardized EMS functions improve CCE “data flow” from recording to access and communication

EMS Level 1 - Integrated sensing and local data access:

On-site users may download and review files that include:

- 1 year of historical performance data:
  - Admin info (serial #s)
  - Fridge performance (temp.)
  - Environmental (power avail.)
  - Use (door opening)
- 60-day summary reports, including default alarms



All EMS Levels – Standardized CCE data

Standardized data and JSON format enables ease of integration within and across informations systems

EMS Level 3 – Remote Communication and KPIs

Remote user communications for:

- Data delivery to dashboards and eLMIS-like systems
- Management-level review of data, reports, alarms, CC inventory
- KPI summaries (KPIs also available locally)
- Advanced analytics for various program planning and maint. purposes

EMS level 2 - Local Communication

On-site user communications for:

- Review of data, reports, alarms via visual display
- Audio-visual alarms for temperature, door opening, power availability

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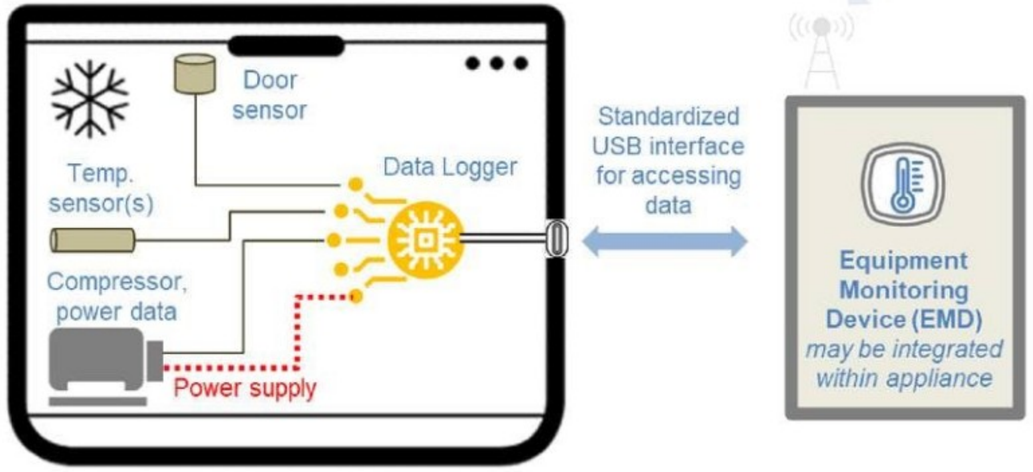

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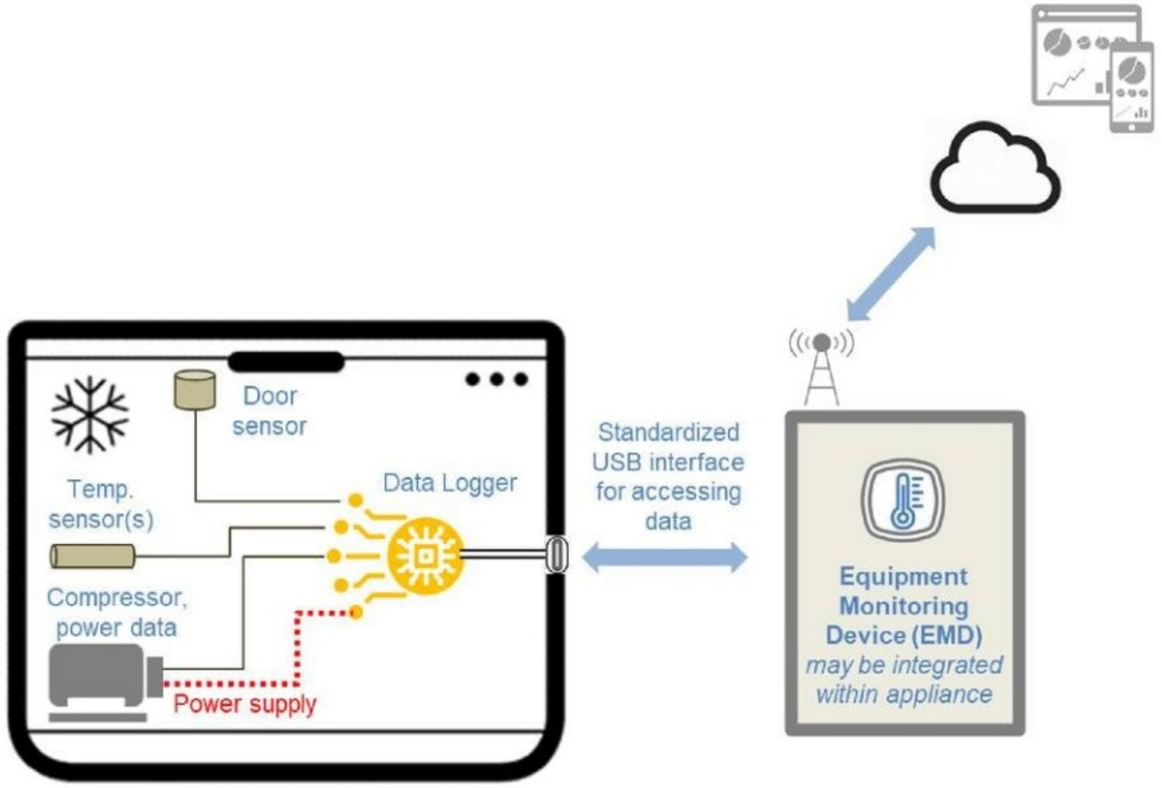

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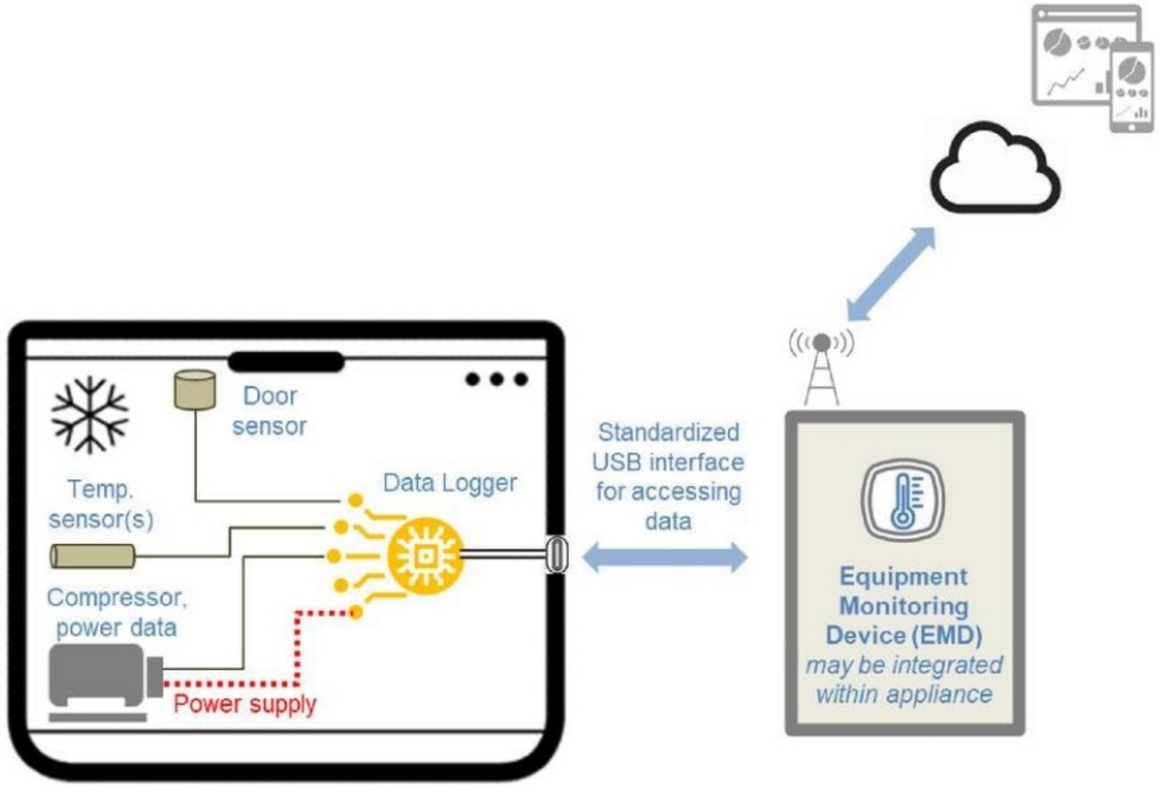

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On-site user communications for:

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*Standardized USB data interface means Level 2 and 3 functionality can be easily added or upgraded at any time, even after CCE commissioning

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Factors that may affect what level of EMS functionality is most appropriate for a country's immunization system

Hierarchy of EMS levels, functions and considerations:

EMS Levels and functions:		Use cases:	Procurement implications:
Level 3	Remote Communications	In addition to Level 1 and 2 use cases: • Remote users can see performance via web portal and/or country eLMIS system with low latency • Remote users can be automatically alerted to alarms, and can coordinate interventions	• Similar hardware cost to level 2, but with monthly fee for data transmission • **May be best fit for:** EPI programs where data reporting and remote response protocols are robust
Level 2	Local Comms.	In addition to Level 1 use cases: • Local users are visually/audibly alerted to alarms and can intervene or call for help	• Higher hardware cost than Level 1, but no monthly fee for data transmission • **May be best fit for:** EPI programs where remote response and coordination of interventions are unlikely, and where empowering local users to transmit data using mobile device is a priority
Level 1 "EMS-enabled fridge"	Data sensing, recording & local access	• Technicians can see diagnostic data and error codes using smartphone or laptop • Users can routinely download and transmit reports to EPI managers and eLMIS systems using apps such as Varo • CCE can be plug-and-play upgraded to more advanced Levels 2 & 3	• Lowest cost, while maintaining full diagnostic data availability and upgradeability to Levels 2 and 3. • **May be best fit for:** EPI programs that are most cost-sensitive, or where visualizing and transmitting data/alarms using smartphone satisfies key use cases.

***Note: As suppliers are planning their product roadmaps, it would be useful to provide them with country feedback about which Level(s) are most desirable.**

Which EMS level is most needed to strengthen cold chain equipment performance monitoring?

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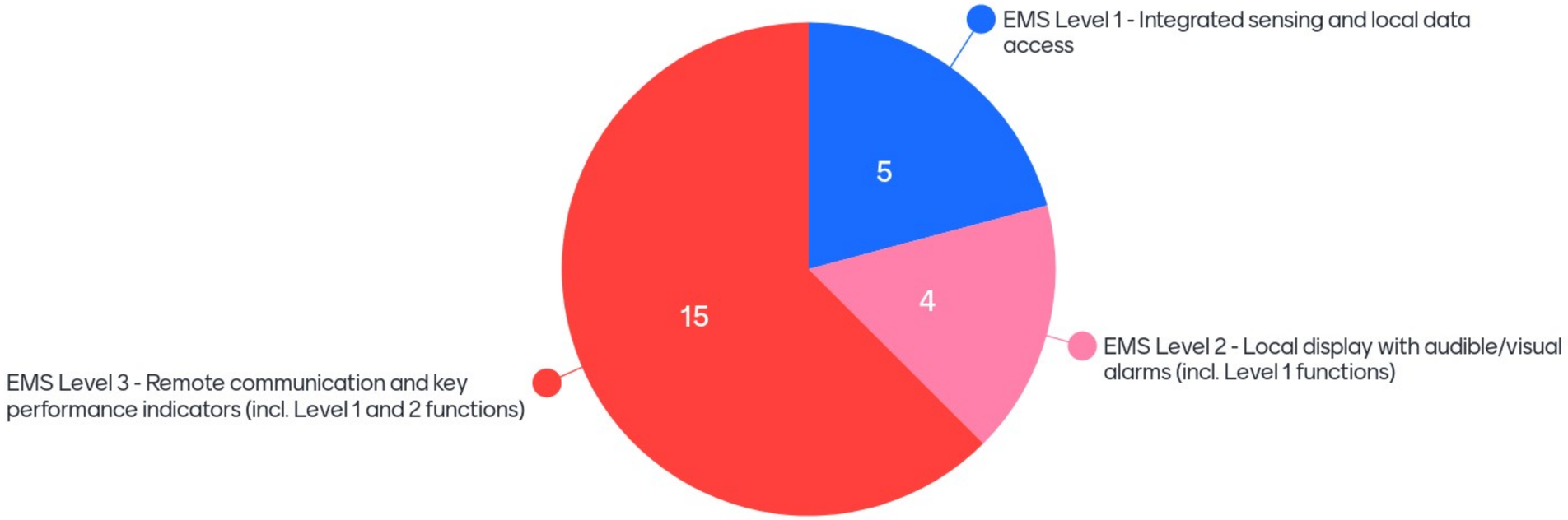

EMS-enabled fridges will have integrated sensors to record admin, environment, performance, safety and use data

Data elements recorded on every EMS-compliant fridge, to inform failure diagnostics and downstream analytics :

Admin Data Objects

Monitored Data Objects
(***bold italics:*** key differences mains vs. solar)

Mains-powered Appliances (ILR)

Admin:
1. Appliance manufacturer
2. Appliance model
3. Appliance manufacturer serial number
4. Appliance date of production
5. Appliance PQS code
6. Compressor Electronic Unit Manufacturer
7. Compressor Electronic Unit Product Code
8. Compressor Electronic Unit Software version
9. Compressor Electronic Unit production date

Environment:
1. Ambient temperature
2. ***AC supply voltage availability (ON/OFF)***

Performance:
1. Compressor runtime
2. Vaccine Compartment Temperature (coldest)

Use:
1. Door/lid opening

Solar-powered Appliances (SDD)

Admin:
1. Appliance manufacturer
2. Appliance model
3. Appliance manufacturer serial number
4. Appliance date of production
5. Appliance PQS code
6. Compressor Electronic Unit Manufacturer
7. Compressor Electronic Unit Product Code
8. Compressor Electronic Unit Software version
9. Compressor Electronic Unit production date

Environment:
1. Ambient temperature
2. ***DC supply voltage to appliance***

Performance:
1. Compressor runtime
2. ***DC current drawn by compressor***
3. Vaccine Compartment Temperature (coldest

Use:
1. Door/lid opening

EMS specifications focus on satisfying minimum needs of programs while also affording flexibility for innovation

Summary of EMS key features & functions:

Standardized fridge monitoring and local user data access: EMS-enabled fridges to come standard with built-in sensors, a data logging device, and a USB-C data access port for local download and use of data, including standardized raw data and summary reports

More complete and accessible data in every fridge: Monitored data available from the fridge will include administrative information about the fridge, environmental conditions, performance, and use data. Data and a 60-day summary report may be directly downloaded from the fridge via an integrated USB port to cellphones, laptops, other external devices.

Program flexibility in choosing preferred level of functionality: To turn the fridge's data into user action, levels of EMS functions include options for more advanced local display of data, and remote transmission of data.

Essential local communications with remote option: local and remote EMDs will have on-site displays and essential alarms that include: heat/freeze alarm conditions, extended door openings, extended loss of power availability for mains and solar. Devices capable of remotely communicating with internet-based software systems will be supported but not required given varying program preferences.

Future-ready and flexible: with common connections for external devices, programs are afforded flexibility to upgrade local and remote communication EMDs as monitoring technology evolves over time. Fridges may last for 10 years, but monitoring devices may be added or upgraded as innovation continues and programs desire new capabilities.

Information system integration-ready: Remote software systems and CCE data will be fully standardized to simplify integrations with program management information systems e.g. eLMIS. Data delivery from EMS data service providers to program software systems will be required in addition to the sharing of service provider APIs.

Which EMS features would benefit immunization programs the most? Select all that apply.

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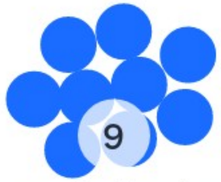
Standardized fridge monitoring and local user data access

Data and a 60-day summary report directly downloadable from the fridge via an integrated USB port

Program flexibility in choosing preferred level of EMS functions

Essential alarms and on-site displays on both local and remote electronic monitoring devices



Option to upgrade monitoring devices as technology evolves over time

Simplified integration with program management information systems

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USE OF DATA

How to use the data from EMS and benefits to programme

The true value of EMS will be created by effectively **generating, recording, communicating,** and **turning** CCE performance data into **actionable insights** for end-users and immunization programs to ensure vaccine safety and cold chain network performance. **Two functional areas** where EMS data can provide significant benefits include:

1

Cold Chain Network Monitoring and System Management

2

Maintenance Planning and Troubleshooting

1. Cold chain network monitoring and system management

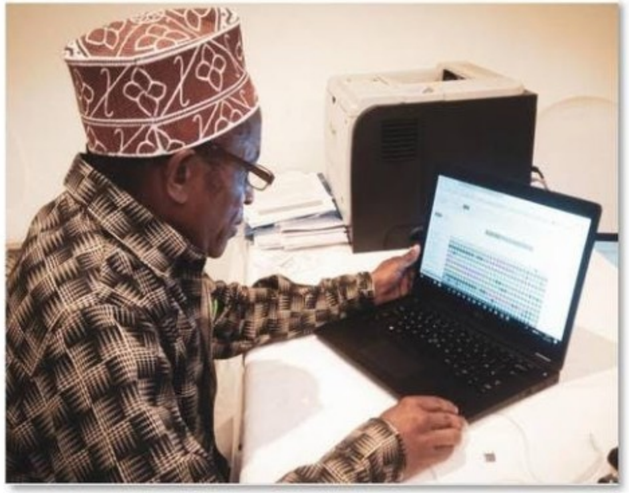
Benefits to the immunization program

- ❑ In-depth understanding of CCE network functionality and asset tracking
- ❑ Visibility into staff use of appliance, informing supportive supervision
- ❑ Visibility into safe and unsafe vaccine storage temperatures, better managing vaccine quality and wastage to ensure vaccine potency

Examples of how EMS provides this value:

- ❑ Local display and remote visibility via an online dashboard can provide real-time access into the functional status of CCE for optimal management
  - *Conveniently update country cold chain inventories more routinely*
  - *Verify the proper installation and commissioning of new CCE or conduct to determine if it is safe for vaccine storage.*

- ❑ Remote data visibility from EMS fridges can also facilitate routine KPI reporting at regular management-level EPI review meetings.
  - *Managers can track indicators, such as % CCE functionality, % of CCE with temperature excursions to assess if CCE is performing as desired.*
  - *Where gaps exist, decision-makers can prioritize corrective actions to close these gaps and check that progress towards more optimal targets.*



2. Maintenance planning and troubleshooting

Benefits to the immunization program

- ❑ Planned preventive maintenance notifications
- ❑ Visibility into non-functional equipment requiring urgent attention
- ❑ Predictive maintenance alerts to preempt potential CCE failures and facilitate proactive stocking and management of replacement spare parts
- ❑ Empowers countries with real-time data to troubleshoot faulty CCE, provide product feedback to manufacturers to enforce warranty and to WHO PQS to help improve future equipment specifications and design

Examples of how EMS provides this value:

- ❑ Through regular planned preventive maintenance (PPM) reminder alerts, healthcare workers (HCWs) can be notified to conduct regular appliance checks and cleaning
  - *Solar panel cleaning, defrosting, dust removal from condenser*

- ❑ Local access via USB download and remote communication that transmits performance data to a central servers can help technicians with maintenance troubleshooting
  - *Identify and replace faulty compressors, defective thermostats or damaged voltage stabilizers*

Which functional area would benefit EPI the most from the use of EMS data?

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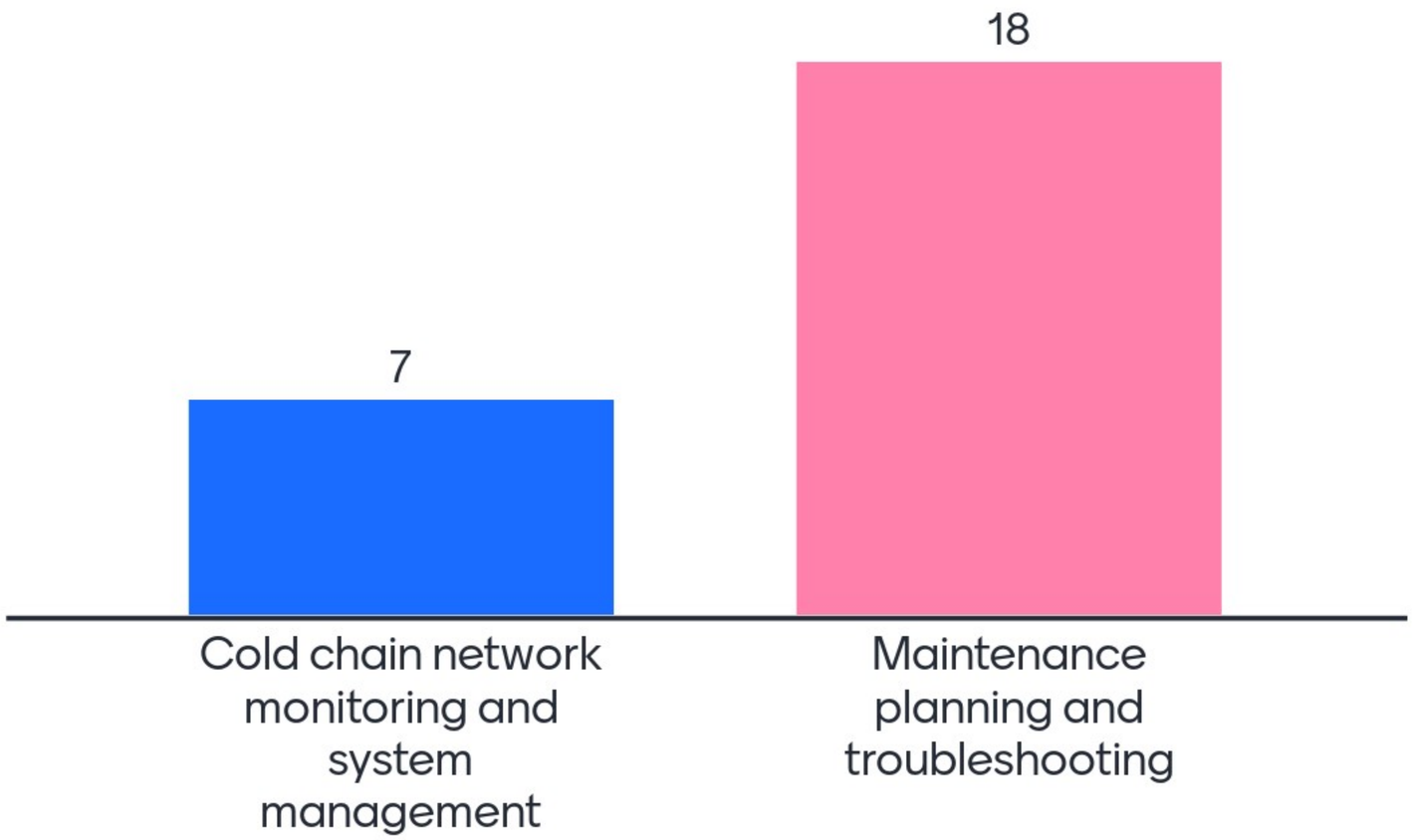

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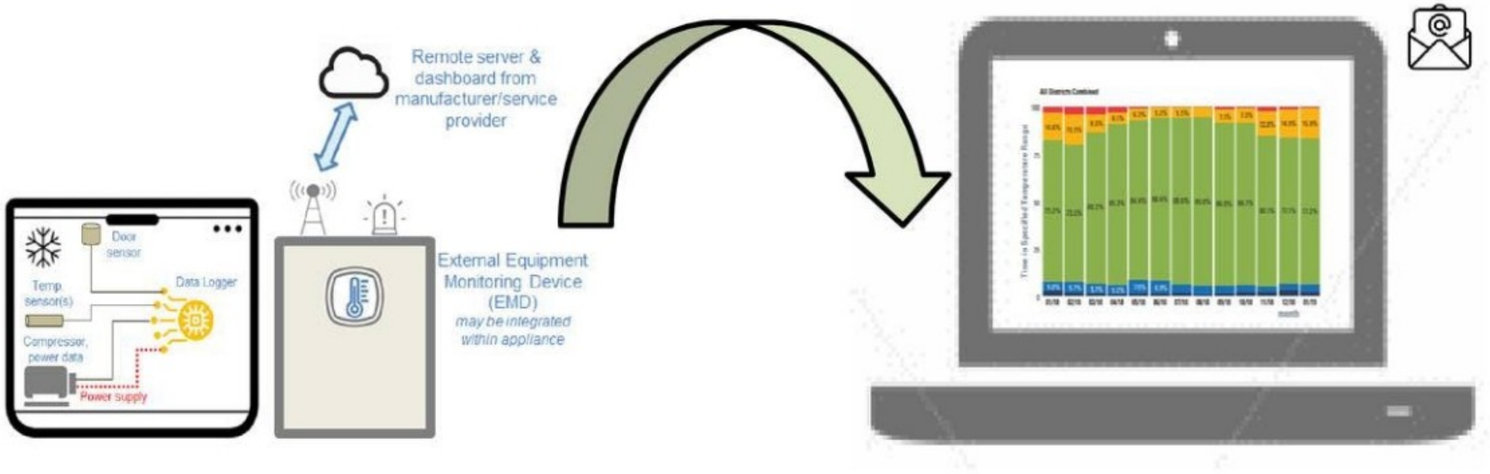
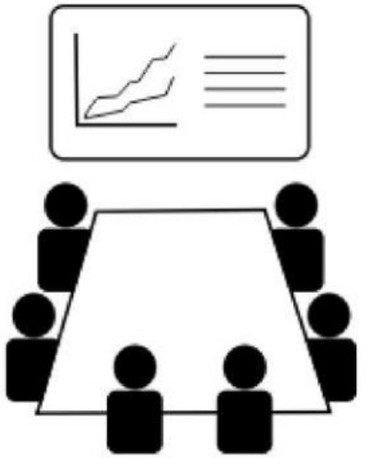
Additional platforms where EMS data can be used:
Electronic Logistics Management Information Systems

EMS data and software will be fully compatible with country program management information systems (e-LMIS). CCE data could be delivered to dashboards and can be interoperable with eLMIS-like systems provided APIs are available.





1. Data Generation and Transmission

- ❑ Performance data from EMS-equipped CCE can be transmitted remotely to any MOH approved e-LMIS dashboard at either the district, regional and national level.

2. Data Management, Analysis and Review

- ❑ e-LMIS classifies data by temperature profile (heat and freeze alarms) to determine % CCE uptime
- ❑ e-LMIS can also generate dashboard reports to spotlight CCE in need of maintenance and repairs

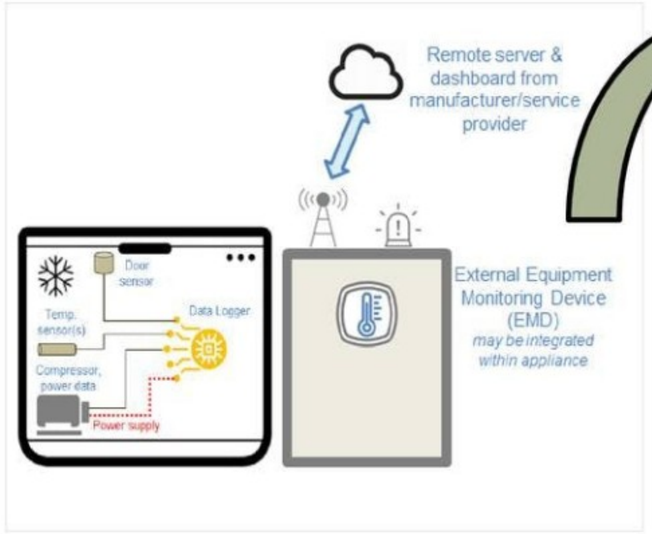
3. Data-driven Decision Making

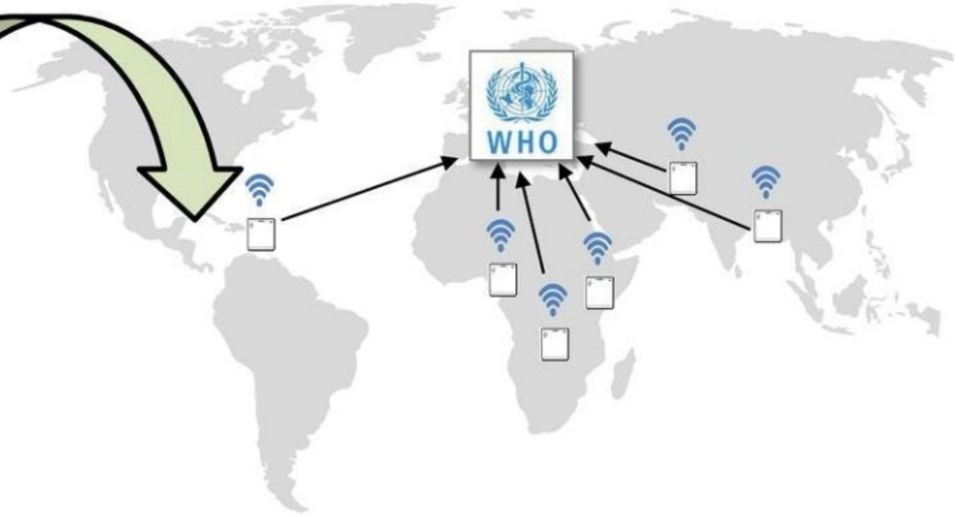
- ❑ Understanding data patterns will enable EPI programs improve CCE management. (i.e., provide maintenance, organize spare parts and plan for long term CCE replacement)

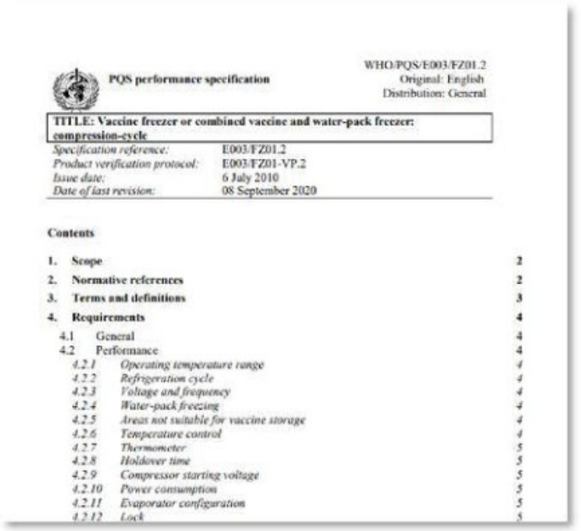
Additional platforms where EMS data can be used:

Post Market Monitoring (PMM)

PMM utilizes CCE data obtained through well-designed country sentinel surveillance systems to signal performance trends, identify breakdowns and, through follow-up, ascertain the root causes and components that caused these failures.







PQS performance specification

WHO/PQS/E003/FZ01.2
Original: English
Distribution: General

TITLE: Vaccine freezer or combined vaccine and water-pack freezer: compression-cycle

Specification reference:	E003/FZ01.2
Product verification protocol:	E003/FZ01-VP.2
Issue date:	6 July 2010
Date of last revision:	08 September 2020

Contents

1. Data Generation and Transmission

- ❑ Performance data from EMS-equipped CCE can be transmitted remotely or accessed locally by sentinel surveillance teams.
- ❑ Routine PMM data flow into the WHO-PQS' CCE performance database

2. Data Management, Analysis and Review

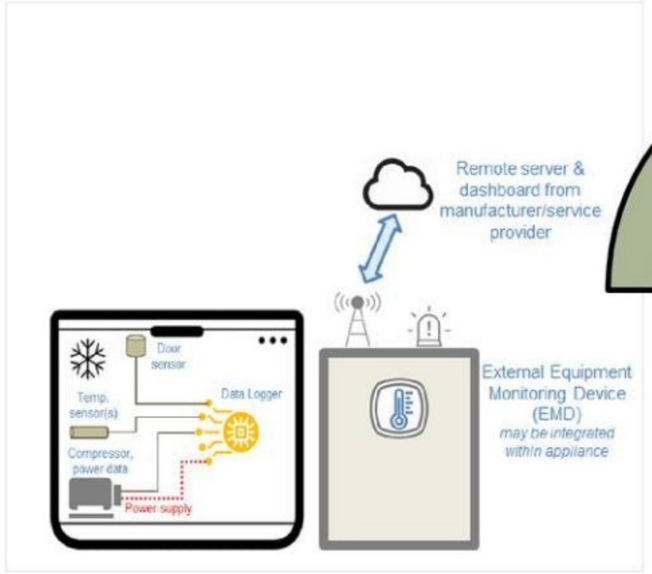
- ❑ KPI thresholds are used to detect faulty equipment
- ❑ Triggers site visits to conduct RCFA to identify the reasons for equipment failure modes.
- ❑ Monthly PMM data review at national level by NLWG
- ❑ Equipment Quality improvement review at global level

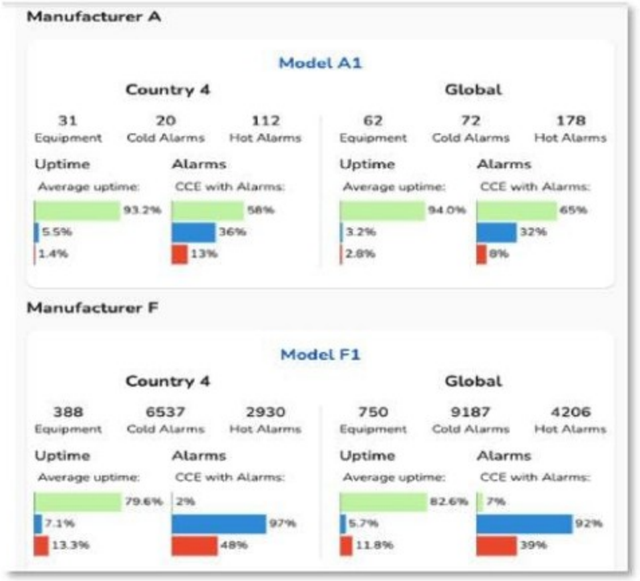
3. Data-driven Decision Making

- ❑ EPI programs can use product feedback data to take preventive and corrective actions.
- ❑ WHO-PQS can use verified data to modify equipment specifications, and incentivize manufacturers to upgrade their equipment

Additional platforms where EMS data can be used: Intelligent Maintenance and Planning Tool (IMPT)

IMPT is a tool that can be used to access the performance of CCE, differentiate equipment flaws from other user-related issues, hold manufacturers accountable for warranties and Inform smart investments in the best possible CCE.





1. Data Generation and Transmission

- ❑ Performance data from EMS-equipped fridges can be transmitted remotely and directly into a countries IMPT platform

2. Data Management, Analysis and Review

- ❑ IMPT aggregates CCE data across manufacturers
- ❑ IMPT generates analytics for each country
- ❑ Countries can review the results and use it to inform maintenance and procurement decisions

3. Data-driven Decision Making

- ❑ Which CCE models does Country 4 need to prioritize maintenance resources against?
- ❑ Which CCE models should Country 4 invest in to expand its CCE for COVID vaccines?

In what other way(s) could EMS data benefit immunization programs?

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Vaccine Wastage Reduction

Planning

Assurance of vaccine efficacy

It will support budget with planning exercices

predictive maintance

increase the visibility for allocation of resources

Support development of maintenance budgets

To which geographical area you can use which model of CCE

Advocacy tool for resource mobilisation

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In what other way(s) could EMS data benefit immunization programs?

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EPI strategic planning

Imputing accurate information to the system, to guide the program

Yes, for sure

For proper cold chain system management

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EMS ON THE MARKET

Timelines for EMS

- January 2022– Finalization and publication of E003 TPPs and EMS specifications
- January 2024 – EMS becomes a requirement for prequalification of new E003 products
- January 2026 – EMS becomes a requirements for all prequalified E003

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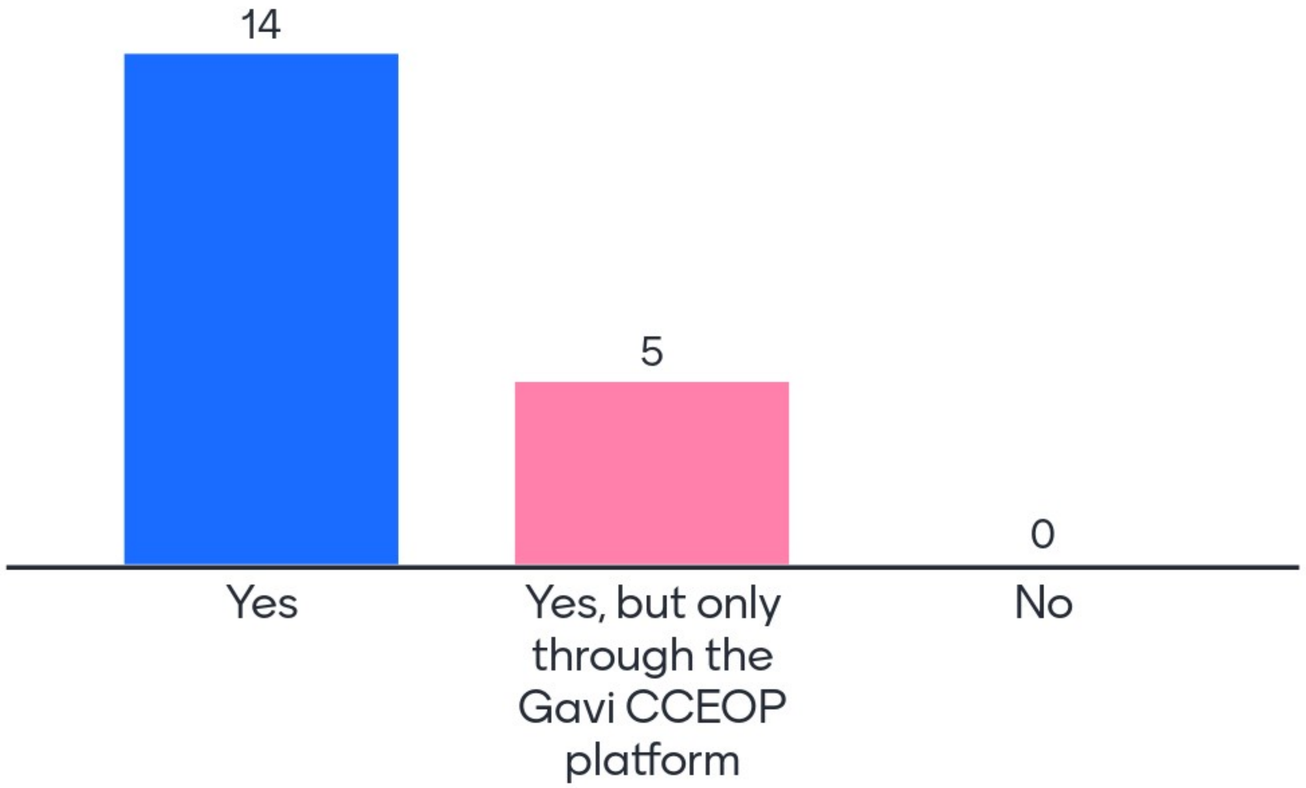
EMS AND GAVI CCEOP

EMS will be CCEOP platform eligible and supported by Gavi

- EMS will be CCEOP-platform eligible once there are WHO PQS prequalified products and UNICEF SD is able to procure these
- Gavi is considering the following:
  - If EMS should become a requirement for CCEOP-supported fridges *ahead* of the January 2026 timeline
  - If EMS functionality at Level 2 (local data access) or Level 3 (local and remote data access / transmission) would be the CCEOP requirement
- As with any Gavi-funded CCE and monitoring device, Gavi will require country ownership of the EMS data

Would immunization programs in your country, or the countries you work in, be interested in procuring cold chain equipment with EMS functionalities?



Which determining factor(s) would influence immunization programs' decision to procure cold chain equipment with EMS functionalities?

Mentimeter

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Mentimeter

TechNet-21

Q&A