World Health Organization

WHO PERFORMANCE, QUALITY & SAFETY

WHO PQS
Immunization Cold Chain
Manufacturer Consultation

- 2022 –

November 14th
In-person
Seattle, WA

Performance, Quality and Safety (PQS)
Vaccines Assessment Team (VAX)
Prequalification unit (PQ)
Regulation and Prequalification (RPQ)
World Health Organization

Published : 22 December 2022

Executive summary

On Monday 14th November 2022, the WHO Immunization Devices (IMD), Performance, Quality and Safety (PQS) team conducted its annual technical consultation with manufacturers of PQS-prequalified immunization products and devices from the E001 (Cold rooms and freezer rooms), E003 (Refrigerators and freezers) and E006 (Temperature Monitoring Devices) equipment categories. The meeting took place in-person at the Bill & Melinda Gates Foundation, Seattle, Washington. Links to previous reports are available here:

- 2021 consultation https://www.technet-21.org/en/knowledge-hub/main/16554
- 2020 consultation https://www.technet-21.org/en/library/main/7523
- 2019 consultation https://www.technet-21.org/en/library/main/6730
- 2018 consultation https://www.technet-21.org/en/library/main/4926

53 participants joined the consultation, with over 80% present in-person, and the remaining joining by video conference. Of the 53 participants this included industry representatives alongside non-industry members and partners of the WHO PQS Working Group (*Annex 1*).

The purpose of the 2022 consultation was to present general PQS progress updates plus next steps on the following prevailing themes discussed during the 2021 PQS consultation (teleconference) and relative to the current PQS workplan:

1. PQS E006 Re-categorisation
2. Equipment Monitoring Systems (EMS) Refresher & documents
3. Environmental Standards
4. Humidity
5. Corrosion
6. Post-market Monitoring & Post-PQS Commitments
7. UNICEF Partner Update
8. Gavi Partner Update
9. Closing remarks: Innovation & Access

The *2022 WHO PQS Manufacturer Consultation* continued the trend of building efficiently on the highly successful first collaboration of 2018. It was the first time since 2018 that the consultation has been able to take place in-person, due to Covid-19 restrictions during 2020-2021. It remains a core element of the PQS Annual Workplan for ensuring manufacturers remain up to date and integral to the PQS standards development processes.

Background to WHO PQS manufacturer engagement

The WHO PQS mission is to lead the setting of performance, quality and safety standards for immunization equipment and devices, such that country programmes, procurement agents and product end users can be assured of the programmatic suitability and performance characteristics of WHO prequalified products. Central to this mission is the development and improvement of product specifications, product verification protocols and description of future desired product features (target product profiles, TPPs). Prior to 2018 manufacturers expressed a desire to have earlier and more substantive involvement in the PQS standard-setting process[1], The 2018 consultation served as an initial forum to improve engagement with manufacturers, gather inputs on PQS standards and to signal new directions for TPPs. This (fifth) consultation was another important step in the ongoing work to drive greater engagement between WHO PQS and manufacturers.

[1] This insight was collected via a summer-2017 McKinsey Management Review of the WHO PQS initiative and during the October 2017 TechNet-21 conference.

Consultation sessions

The general progress update and the topical sessions were each composed of a presenter-led introduction to the issues provided by a member of the WHO PQS Working Group or a WHO PQS Partner, along with a description of relevant action points, progress and key updates. In most cases, direct questions related to the topic were put to manufacturers via MentiMeter[2] in order to gather their input and/or feedback on future action items. Participants were also invited to submit any additional questions or comments via MentiMeter (facilitating the anonymous participation of manufacturers amongst industry peers if required) or in the Teams chat.

Annexes to this document include:

List of participating manufacturers – *Annex 1*

List of WHO PQS and partner organization participants – *Annex 2*

Link to the conference presentations (.pdf) – *Annex 3*

A graphic presentation of manufacturers' responses to MentiMeter questions – *Annex 4*

[2] A software programme accessible to participants via their laptop or smartphone that allows anonymous questions or suggestions to be submitted to the session presenter in real time. It also enables voting/polling of participants on specific questions posed by the presenters.

I. PQS Updates

In this session Dr. Isaac Gobina and Mr. Paul Mallins, WHO PQS WHO Technical Officers, provided a review of action points and key updates on WHO IMD-PQS impact, current workstreams and priorities:

- *WHO IMD-PQS is an indispensable component in the success of global immunization which delivers 2 billion doses annually, has saved 4 million lives between 2000-2020 and supplies now 70 countries.*
- *WHO IMD-PQS has now prequalified 425 products, has developed over 100 standards and lists prequalified products from 66 manufacturers, amongst other achievements.*
- *Dr. Gobina described how WHO IMD-PQS is a World Health Organization agency, and that as such, as does the WHO generally, sets standards and norms, articulates ethical standards and provides leadership on health matters.*
- *Dr. Gobina situated IMD-PQS within the WHO organigram and described the complete process and workflow with the aid of an IMD-PQS flowchart.*
- *Dr. Gobina concluded the introduction by providing key statistics and learnings from the 2022 Annual Review of Prequalified Products.*
- *Mr. Mallins then described how aligning IMD-PQS with WHO's environmental and climate change goals is a priority moving forward; while acknowledging it is a very complex issue. He also referenced the anticipated impact of climate change on the acceleration of vaccine-avoidable diseases such as malaria.*

Discussion

- Mr. Mallins additionally reminded the consultation participants that WHO IMD-PQS equipment specifications are minimum performance standards, and that the prequalification processes are entirely confidential between PQS and individual manufacturers.
- Mr. McCarney, WHO Consultant and Technical Expert commented that new technologies require a field evaluation in order to obtain PQS prequalification.

Menti question responses

1. What are some of the things that you (manufacturer participants) are hoping to learn in during today's consultation?
    - Any movement on lowering the storage temperature back to 0C from 2C?
    - Better understanding about the PQS processes
    - Clarifications on humidity and EMS implementation
    - Clear understanding of the pipeline of future PQS requirements
    - EMS cost and price assumptions
    - EMS details
    - EMS rollout
    - Market forecast
    - EMS updates
    - Environmental targets
    - Impact and expectations on humidity control
    - Future directions & timeframes for new standards
    - Any forecasts on fridge and RTM for EMS
    - Latest technology and its application

- More about monitoring
- New categorization plans
- Timelines for PQS prequalification for new categories (E003 - TS 01.1)
- Upcoming PQS requirements for E006

Action points from this session:

- *WHO IMD-PQS recognises that environmental considerations and standards need to be developed, and this will be done collaboratively with manufacturers. PQS will be reaching out to external experts and manufacturers in the near future to begin this process.*

II. E006 Recategorisation

In this session Dr. Umit Kartoglu, Technical Expert and WHO consultant, provided an overview of the recent work to re-organise the categorization of the IMD-PQS category E006 - Temperature Monitoring Devices. Dr. Gobina provided an introduction to the need for recategorization, and Dr. Kartoglu went on to describe his methodology and his findings. Dr. Kartoglu noted that there are several sub-categories that are empty ("dormant"), some device technologies that are redundant (functions that are now integrated into other devices), some that are expected but as yet empty (e.g. solar powered devices), and some that are overlapping or duplicate, such as irreversible freeze indicators, chemical freeze indicators and threshold indicators. Dr. Kartoglu then talked over a flow chart that depicts the proposed reorganization solution. Lastly he reiterated that the objective of the project is to make it easier for countries to identify the appropriate products to procure for their country's specific circumstances and needs.

Discussion

- Ms. Robertson of PATH expressed a concern that electrical requirements may be a reference requirement; for example, if a manufacturer of a solar device needs to meet that specification in addition, we need to make sure we don't lose that from E006 categorization.
- Mr. Yemamu of UNICEF noted that solar systems to power RTMDs are not necessarily required – unless there are MFCs who want to offer it – because SDD fridges with USB ports are already a standard offering.
- Mr. Harbers of Berlinger enquired about the overall purpose of the recategorisation and its prioritization.
    - Dr. Gobina replied that the intention is to facilitate procurement by making the catalogue easier to navigate. He also noted that no decision will be made without including all concerned manufacturers.
    - Mr. Mallins noted that PQS has received feedback from countries that this category is difficult to navigate.
    - Dr. Kartoglu noted also that it is not currently possible, for example, to download or identify directly real-time temperature monitoring devices (TMDs).
- Mr. Ten Houten of Berlinger requested that definitions of key terms be provided as part of the project.

- Mr. McCarney commented that the low-power solar specifications also could be used for procuring quality power system for health facility loads (lights, etc.). Solar power components and systems are not tested and prequalified, unlike appliances, cold rooms and E006 devices.
- Mr. Diesberg suggested that it will be useful for PQS to consider the naming in detail of the new groupings. If a certain name is used ubiquitously by EPI and country-level staff, changing to another term that may be technically better, may also lead to more confusion (examples like VVM and 30DTR, if they are still correct in the new groupings, IMD-PQS might consider not attempting to rename them).
    - Mr. Toyobo replied in agreement. He stated this will require a process of sensitization, and if terms and groupings were to be changed on the IMD-PQS website and catalogue, we may need to consider consistency with regards to the UNICEF catalogue and Gavi technology guide.

Menti question responses

1. Should we remove all dormant subcategories? (Scale NO 1 – YES 3)
   2.8 /3

Action points from this session:

- *WHO PQS to reach out to all concerned manufacturers for their direct feedback on the proposed solution(s) and their potential impact.*
- *Dr. Kartoglu to develop and include a section with definitions / a glossary.*

III. Equipment Monitoring Systems refresher & document overview

This session was comprised of three separate sections. Firstly, Mr. Morio of PATH presented a report from the Ugandan Ministry of Health on using "CCE Temperature Data In Decision Making" and which reported data on the number of days that temperature was above 8˚C, the number of days temperature was below 2˚C, the number of high alarms and number of low alarms. This data was collected in order to facilitate decision and action on CCE faults, procurement analysis and mentorship of health centre staff. A second section of the presentation was delivered by Mr. Pal of New Horizons, with the aim of providing CCE suppliers and stakeholders with a framework for navigating the PQS Equipment Monitoring System (EMS) standards suite. The presentation covered: background/purpose of the EMS specification package, EMS functionality overview and range of EMS-compliant systems, EMS specification document overview – which documents are relevant for which EMS implementations, and frequently asked questions. Dr. Gobina also explained the rationale for EMS, along with outlining that it enables: standardized and interoperable data collection, local data access and collection of performance and diagnostics parameters, and machine to machine (M2M) data port for plug and play upgradability. A final section was delivered by Ms. Luthra of Gavi, who provided an overview of the evolving Gavi position on EMS.

Discussion

Uganda case

- Mr. Kiluva, WHO Consultant and Technical Expert noted that low temperature is more dangerous for vaccine storage.
- Mr. Kiluva requested to know the specific models of the equipment that was monitored.
- Mr. Yemamu asked if root cause analyses have been done?
    - Mr. Morio replied that root cause analyses are underway and are anticipated to be completed for the TechNet-21 conference in 2023.

EMS presentation

- Mr. Richardson of Beyond Wireless noted that the requirements may be daunting for health workers. In addition, the specification is complex and timing is challenging with regards to data gathering requirements. He asked if it is practical and achievable to enforce it with the current timeline.
    - Mr. Pal replied that the base level requirements are not a significant extension beyond what has been done in the past. He noted that New Horizons are happy to engage on how manufacturers plan to prototype it in cost effective ways. He suggested that implementation timelines are feasible but ambitious from the PQS side.
    - Dr. Gobina noted that with regards to implementation timelines, based on EMS Working Group feedback, complexity was not a major concern for most manufacturers. Flexibility will depend on how PQS receives reactions from refrigerator manufactures.

→ See below for the list of questions submitted anonymously by manufacturers, and their responses from Mr. Pal and Dr. Gobina.

Gavi EMS

- Ms. Hamblin of the Bill & Melinda Gates Foundation referenced an earlier question on whether other donor procurements request EMS as well?
    - Ms. Luthra replied that based on anecdotal information other donors might do so. Also, it is noteworthy that CCEOP has had various requirements, which differ from other donors, while CCEOP requirements have also been adopted by others too. In addition, as countries have adjusted to standards of equipment or approaches, (e.g. RTMDs or service bundles) that are only Gavi requirements, in some cases countries have requested UNICEF to implement these requirements even when they are not requirements of the relevant donor in that case. We have also seen a big interest from the World Bank, and other donors have started to play a big role in this space during pandemic. It is currently unknown if it will continue. In Gavi 5.0 or 6.0, Gavi may be a smaller share of UNICEF procurement, so it may no longer have the same influence.
- Mr. Harbers of Berlinger queried how, on one hand, PQS asks for EMS to be enabled by January 2024, but it will not be a Gavi requirement before end of 2025 – how does that correlate? The investments will not pay off if they are not requirements of CCEOP; countries buy the cheapest solutions and these EMS will be much more expensive – e.g. who will finance Level 3 remote?
    - Ms. Luthra replied that PQS requirements become by default a Gavi requirement. 2024 refers to new equipment, 2026 is all equipment. The greatest part of the portfolio is existing equipment, so the working hypothesis is that the 2026 deadline is the biggest impact on CCEOP procurement. Also, what is on LTA with UNICEF is what countries can procure.
- Mr. Harbers of Berlinger also drew attention to the delays on parts availability and procurement in the post-pandemic context, noting that his company are currently procuring parts for 2024. There are many delays currently.
- Mr. Mallins reaffirmed that "access" to equipment is a priority for PQS, meaning that product availability and manufacturer diversity and number is key. He noted that PQS does not want EMS to be a reason for access to decrease (i.e. manufacturers dropping out) and so every effort will be made to ensure that the process is reasonable and successful for manufacturers of prequalified products as it was in the multi-year transparent collaborative iterative process that created EMS .

Menti question responses

1. After today's presentation, do you have a better understanding of the EMS documents and how to implement?
    YES 22
    NO 2

2. Do you intend to bring an EMS product to market?
    YES – EMS enabled fridge 3 votes
    YES - EMS enabled fridge with integrated Level 2 or 3 compatibility 3 votes
    YES – standalone EMD device (level 2 or 3) 6 votes

NO – not relevant for my product category	1 vote
UNSURE	5 votes

3. For E003 manufacturers: What is your initial thought on phasing EMS functionality into your models?

Update entire product line as soon as EMS system is available	8 votes
Phase in as new models are developed/prequalified in 2024	1 vote
Phase in only as PQS grandfathering timelines elapse	3 votes
Unsure at current time	2 votes

4. Would you be interested in providing EMS systems for other (non-immunization CCE) global health equipment types in the future?

YES expanding into monitoring other equipment is interesting	14 votes
NO we are focused only on immunization CCE	4 votes
Unsure at the current time	1 vote

5. What are the biggest challenges you anticipate in fulfilling the EMS specification? (Ranked)

1st place	Unclear demand or Gavi/UNICEF requirements
2nd place	Financial investment required
3rd place	Unclear what level EMS countries want
4th place	Technical / engineering challenges
5th place	Timeline to meet specifications
6th place	Other

6. What additional market shaping information would be helpful to you as you plan your approach to EMS? (Ranked)

1st place	Demand forecast (units) on fridges with EMS (by level) and/or EMDs
2nd place	Programme information (policy and eligibility requirements)
3rd place	Market shaping strategy information
4th place	Country funding
5th place	Other

7. Would you prefer: (Ranked)

1st place	Providing options for either Level 2 or Level 3 modules inclusion
2nd place	Sell Level 3 hardware with all fridges (or in all EMDs), but with the option for remote data services to not be activated at time of installation.

8. What is your anticipated timeline to have EMS available (minimum level 1) in existing products and ready for PQS evaluation?

2023	6 votes
2024	5 votes
2025	0 votes
2026 (PQS deadline)	3 votes
Unsure	3 votes

9. What is your anticipated timeline to have EMDs with level 2 or level 3 functionality (standalone or integrated) and ready for PQS evaluation?

2023	4 votes
2024	5 votes

2025	2 votes
2026 (PQS deadline)	7 votes
Unsure	0 votes

10. Would you plan to implement EMS in additional CCE (e.g., ULT or WICRS)?

YES	7 votes
NO	3 votes
UNSURE	5 votes

11. Do you foresee any challenges or limitations in implementing EMS in ULT or other types of CCE?
    - Environmental differences inform components
    - Power availability in portable refrigerators
    - Mounting/installation of sensors in WICRS
    - Cost
    - Countries making use of the data/systems in effective ways
    - Sharing of data
    - Remote technical support
    - There are multiple valid temperatures for a WICR

Anonymous questions posed by manufactures after the EMS presentation session:

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- How will sensor failures be addressed?
    - This comes down to how EMS is implemented in the refrigerator by the supplier. The target is for sensors to be replaceable within the refrigerator where possible. During implementation, it will be important to consider what the likelihood of failure for different sensing components is, and how can those be as serviceable as possible. It is the responsibility of suppliers to define that.

- Is there any consideration given to wireless M2M interface, such as Bluetooth, WiFi?
    - We discussed during the industry consultation whether there was value in also having a BLE or Bluetooth interface. It was decided against because of the complexity of defining that interface. A really nice thing about the EMS USB interface is when you plug into the fridge, the USB host (i.e. the laptop or the phone) provides power. This means that if that monitoring module's battery has died, you can still wake up that module and get data from it. Whereas if it was a wireless data interface, you would be counting on that module to have some functional power supply. As Mr. Mallins mentioned earlier, PQS sets the base level requirements. There's nothing in the EMS specification that prevents suppliers from also including a Bluetooth or Wi-Fi connection to the appliance as well.

- What is the role of temperature monitoring within EMS?
    - Temperature is certainly one of the key data elements within EMS, and alarm definitions based on temperature are a key element, if not the most important one.

- Are testing laboratories ready for testing to these specifications?
    - I don't know that we've talked about any specific coordination that is necessary with the test labs, but that might be something that we can take within the IMD-PQS group to think through what else might be required there.

- Will EMS become a CCEOP requirement as of 1st Jan 2024?
    - Please refer to the Gavi presentation that follows this one.

- Is there a process to request a new data element be added to the standard?
    - Suppliers can create new data elements using a naming convention in the specification. If there is a data element that is not defined, but which would be useful across suppliers, certainly reach out to IMD-PQS and it can be considered in the next specification revision.

- Will there be a standard sensor?
    - This was a topic raised with the industry working group very early on; whether there was any value in creating some kind of standard sensor interface specification within the refrigerator, to provide a simpler way for multiple suppliers to integrate. This was not seen as a priority by manufacturers in the working group, so PQS likely does not have a role in defining such a standard interface. If there are suggestions, feel free to reach out with them.

- Any consideration to covering transportation use cases with EMS?
    - Two possible use cases here would be either refrigerated vehicles or transportable powered vaccine storage devices, essentially portable refrigerators. The EMS specifications were written to be relevant for these and other IMD-PQS categories. Currently there is not a timeline for required implementation of EMS in other categories, but suppliers could choose to implement for commonality across their products.

- If an integrated EMD is provided with the fridge, is an externally-accessible USB port for M2M interface with other devices still needed?
    - Yes, suppliers must still satisfy the DL 01.1 specification, which is the USB downloadable data and the power output. One of the reasons is that monitoring technologies are still developing. In the last 10 years we've seen quite a bit happen in the remote monitoring space and the next 10 years there will be more progress. The M2M interface provides the ability for monitoring modules to be added on to the fridge in the future regardless of what was built in there from the outset, so that customers aren't limited by whatever technologies and assumptions were made upon procurement.

- How are the data standards going to be tested? Someone looking to output? What about with remote EMDs, how will the data standard/interfaces be evaluated by laboratories/IMD-PQS?
    - The objective would be that as long as suppliers are meeting the data standard and the JSON schema requirements that would ensure that they are specification compliant. There is also a basic process within the verification protocol for the test laboratory to do an assessment of compliance with the specified data interface. I'm sure there will be a little bit of collaboration and back and forth

required here as we get into the actual rollout of this, but the intent is that the specification documents have provided a high level of specificity.

- Will other donor procurements request EMS as well?
    - Please refer to the Gavi presentation.

- Will current field fitted temperature loggers be disqualified in the future or are they grandfathered in?
    - Data logger functionality is required for newly prequalified fridges in 2024, and for all prequalified fridges in 2026. This means that newly purchased equipment would include EMS functionality. Field-fitted temperature loggers aren't germane to the EMS requirements.

- How do we ensure forward and backward compatibility?
    - The EMS M2M data interface and file naming/contents specification was designed to be forwards and backwards compatible. Any proposed changes to the M2M interface will be evaluated for impact to backwards compatibility.

- If a PQS-approved EMS is integrated into an appliance, would it still be needed to supply the fridge/freezer with a "standard" PQS data logger as well?
    - If Level 2 or higher EMS is incorporated into the refrigerator, a 30DTR will not be required to meet IMD-PQS requirements as Level 2 and 3 EMS provides all functions of a 30DTR. Exact procurement policy will depend on customer/procurer specifications.

Action points from this session:

- *Uganda case study: Mr. Morio to feedback to manufacturers about what the "blank" labelled percentage reading on the high/low temperature events charts refers to.*
- *Uganda case study: Mr. Morio to feedback on whether the equipment that was tested is PQS prequalified, and what types (categories) of equipment it is.*
- *Mr. Pal & PQS to develop and share an "explainer" for the portfolio of EMS standards. Due early 2023.*

IV.Environmental standards

In this session, Mr. Paul Mallins, WHO Technical Officer, and Mr. Steve McCarney of Sunny Day LLC and WHO consultant, described the ongoing IMD-PQS work to develop and align with WHO standards for environmental sustainability. Dr Gobina described IMD-PQS plans as concerning evolving PQS standards in 2023-2028, refrigerant transition in 2022, energy consumption index, foams used for insulation and decommissioning guidelines. Thereafter Mr. McCarney went on to describe the outcomes of his investigation, relating to Partners' and World Bank greenhouse gas (GHG) emission reductions goals. He went on to describe the sources of indirect and direct emissions, the link of indirect emissions to energy consumption, the relevance of energy sources, and concluded with an evaluation of the work to be done on the PQS catalogue on climate-friendly guidance.

Discussion

- Mr. Toyobo of CHAI noted that there has been some discussion about using some form of product climate labelling or green stickers. He asked if that would be something that would be a viable option for PQS.
- Mr. Ries of B-Medical Systems asked for clarification on the date of phase-out for the R134A.
    - Dr. Gobina confirmed the phase-out date to be end of 2022.
- Mr. Copois of UNICEF noted that for cold rooms, a new LTA will be based on R134 for 2022 but R290 with GWP3 for 2023.
- Mr. Tansley of Surechill noted that the company has worked with E4A on greenhouse gas emissions, and that only about ½ of emission are energy consumption from the device itself; the rest of the emissions are the raw materials. Therefore there is a massive variation on energy consumption based on the raw materials (coal, solar etc.) across the whole life cycle.
    - Mr. Toyobo asked what is the cost of having to re-engineer technology to be greener. He noted that the market is not fully ripe for all of these spare parts; what are the lifetime costs of having to go green.
- Mr. Bechter of Berlinger described how the company has recently developed their first fully climate-neutral product. This entailed a full analysis across the supply chain, and still 80% of the emission comes from the raw materials. So it is very pertinent to ask how many times can the raw materials be re-used.
- Mr. McCarney suggested adding "planetary cost" to the Total Cost of Ownership (TCO) tool.
    - Mr. Toyobo noted that costs will be either passed-on or subsidized to customers.
- Mr. Ten Houten of Berlinger commented that Berlinger had conducted 15 years of research on this topic.
- Dr. Gobina asked whether it is possible to extract energy consumption data from cold rooms?
    - Mr. Ortmann of Viessman stated that it depends on user-behaviour. Energy consumption is related to door-opening and entering. It could be collected empirically.

Menti question responses

None.

Action points from this session:

- *IMD-PQS to roll out further consultative work with experts and manufactures of PQS-prequalified products during the process to identify upgrades to standards and identify potential environmental processes. Note: WHO IMD recognizes that introducing environmental requirements into PQS standards is a very complex issue that requires expertise beyond the current expertise of IMD or its expert working groups. PQS-IMD will explore getting expert input from global specialists to guide the process in collaboration with countries, manufacturers and partners.*

V. Humidity

Dr. Gobina, WHO PQS Technical Officer, provided an update to the PQS progress on humidity standards. He explained how humidity-related issues worsened with Grade A freeze protection. WHO IMD-PQS, with support from partners at PATH, has developed a humidity specification that is available now. Dr. Gobina described how manufacturer (internal) testing has taken place, to verify level of compliance with the specification using the draft Verification Protocol, and additional test results are required from those manufacturers who have not yet submitted their test data. Results of the test will be used to finalise the Verification Protocol. The implementation date for compliance with the humidity specification is postponed until January 2024.

Discussion

- Dr. Gobina encouraged manufacturers to submit humidity reports and feedback to enable PQS to verify the specification and develop the testing protocol.
- Dr. Gobina confirmed that some amount of equipment redesign may be required to meet the specification.
- Dr. Gobina also confirmed that the humidity threshold set in the specification is not final, and may change depending on the remaining feedback that will be received.
- Mr. Ries of B-Medical commented that condensation control of the vaccine secondary packaging is more important that measuring the actual humidity.

Menti question responses

1. How prepared are you towards meeting the humidity requirements by January 2024?

>75% prepared	3 votes
51%-75% prepared	1 vote
<30% prepared	8 votes

Action points from this session:.

- *The implementation date for compliance with the humidity specification is postponed until January 2024. The implementation will not be postponed again.*

VI. E001 Cold Rooms

Dr. Gobina, WHO PQS Technical Officer, and Mr. McCarney, Technical Expert from Sunny Day LLC and WHO Consultant, provided a brief update on solar direct-drive (SDD) cold rooms. They noted that the success of SDD technology in EPI is undisputed and that it has revolutionized the vaccine cold chain. It provides more storage capacity at the local level and is cost-effective. They announced that the solar cold room PQS specification has been published and that the protocol for the field evaluation requirement is being finalized. Technologies are already being developed by several manufacturers.

Menti question responses
None.

Action points from this session:

- *SDD manufacturers will be invited by PQS to submit their SDD CRs to a field study that will begin in 2023*.

VII. Corrosion

Mr. David Lehmann, Technical Expert and WHO Consultant provided an update on the ongoing investigation into refrigerator corrosion. The session began with an introduction from Dr. Gobina, WHO Technical Officer, who stated the importance of resolving this issue, and described a recent corrosion survey that had been shared with the consultation participants on potential incidences of corrosion on their devices. Mr. Lehmann then described key findings of the broader investigation, including that condensers, evaporators and connecting tubing are components commonly found to be linked to most corrosion-related failures. He discussed potential solutions, including component-specific standards, sharing best manufacturing practices and improving feedback, as well as technical solutions such as protective coatings.

Discussion

- Mr. Watson of Aucma commented that energy efficiency will be very important to consider for SDD cold rooms. He described how Solar PV is getting cheaper but it will be good to take the opportunity to ensure cold rooms are as efficient as possible (and not just increase PV size).
- Mr. Ries of B-Medical Systems noted that the industry has seen examples of corrosion that were not apparent in laboratory testing, nor on the salt-spray climate chamber parts exams but, when the fully-assembled refrigerator is in a humid environment the problems appear. He suggested that a solution is to test fully-assembled working devices in a working environment. Also, a corrosion-resistant coating would be useful, but attention must be paid to the risk that a parts-supplier might change the coatings.
    - Mr. Lehmann replied that it would be very useful for PQS to receive feedback from manufacturers when such corrosion events are detected.

- Mr. Elliot of Dulas requested that PQS-IMD share (anonymized) data on corrosion events with manufacturers when possible, to support them in remedying or avoiding similar issues with their devices.
- Mr. Toyobo of CHAI asked whether the end-user has any role to play in corrosion protection; are there any best practices in this regard, or is it solely related to the device manufacturing.
    - Mr. Lehmann replies by describing an experience when working in the field, with one particular charter company, whereby each time they would clean the fridge with a bleach solution, any small scratch on the aluminum permitted humidity to penetrate. He asserted that end-user guidelines would be very helpful. Lots of failures are related to user actions, and not the manufacturer responsibility. For example, oxygen together with moisture and acids that will cause corrosion. It is a solution simply to remove one of these three elements. Revising manufacturing methods can indeed therefore help avoid problems that could occur later due to user error.
    - Mr. Toyobo added that many CCE devices are installed close to open windows that lets in moisture (from rain fall) and oxidization tends to happen faster on the back surfaces of the devices.
- Mr. Cording of Vestfrost requested that the presenter(s) elaborate on the PMM activities that were undertaken related to corrosion. In particular, was it undertaken on equipment that had been in service since a long time or more recently-deployed equipment? He noted that at Vestfrost they have not been aware of a big issue with corrosion in recent times. They would like to know the risks, for example, associated with installation next to windows etc.
    - Mr. Mallins replied that PQS undertook a PMM pilot; if a manufacturer did not hear from PQS it means there was no corrosion identified by the PMM pilot in those refrigerators. He noted that the detailed, actionable feedback from countries is imperative but rather weak/infrequent. He described how the pilot was small, and intended to test the methodology via EPI programmes, with a view to establishing that the system is sustainable and could be eventually handed over to EPI programmes to integrate. He described how PQS specifically requires actionable PMM CCE performance data to evaluate if the issue could be solved by revising a PQS specification in the first instance. Secondly if the PMM feedback is quality related, PQS can go directly to the manufacturer to collaborate, to solve the issue in a timely manner, all of which maintains equipment/device access for countries, which is a priority for IMD-PQS. Mr. Mallins noted that the root cause of performance issues related to sensors identified in the PMM pilot was not identified.

Menti question responses

1. With better testing and the use of more corrosion resistance components, we can achieve the zero failure in ten years? (Scale: Strongly disagree (1) – Strongly agree (5))
    2.8 /5 Moderately agree

2. Under ISO 9001 manufacturers should provide documentation from component vendors that components meet or exceed the minimum requirements? (Scale: Strongly disagree (1) – Strongly agree (5))
    3 /5 Moderately agree

3. The minimum corrosion standards for each component been identified and is there an issue with applying these standards? (Scale: Strongly disagree (1) – Strongly agree (5))
   2.4 /5 Moderately agree

4. Because the manufacturing process can have a link to corrosion, should there be a guideline or requirement of do and don'ts? (Scale: Strongly disagree (1) – Strongly agree (5))
   3.9 /5 Agree

5. Do you have an inhouse expert on corrosion testing and standards? (Scale: Strongly disagree (1) – Strongly agree (5))
   3.1 /5 Moderately agree

6. You apply any special coating to the condenser (or any other component) to help prevent formicary corrosion?
   3.8 /5 Agree

Action points from this session:

- *IMD-PQS to proceed with further survey activities on the theme of corrosion.*
- *IMD-PQS to engage all E003 & E006 manufacturers in next steps to define new standards, requirements and best practices for corrosion-protection.*

VIII. Post-market Monitoring & commitments

Mr. Mallins, WHO PQS Technical Officer, opened the session with the question 'what is the 3-fold increase in PQS applications over the past 2 years due to?'. Audience feedback is provided below in the section 'Menti question responses'. Thereafter Mr. Mallins explained why post-market monitoring is crucial for PQS, namely to help strengthen specifications, enable PQS to address performance issues and empower PQS to foster product improvements and innovations. Mr. Mallins then reminded manufacturer participants that the PQS Terms & Conditions oblige manufacturers of prequalified products to report equipment performance complaints in real time, and why it is so crucial for manufacturers to provide this information to PQS. Ms. Huckerby, Consultant to PQS-IMD explained the additional reporting obligations that are part of the Annual Review of prequalified products. Mr. Mallins then provided an overview of the PMM Taxonomy, which manufacturers must use to report CCE complaints or failures. Lastly as an example of how PQS analyses Prequalified Annual Review data , Mr. Mallins provided, as examples, breakdown of failure reporting statistics over 2020-2022, as well as the current PQS CAPA (corrective action, preventative action) quality management system. He noted that 7% of manufacturers of PQS prequalified products reported recurring failures in combination with an earlier completed CAPA.

Discussion
None.

Menti question responses

1. In your view, the 3-fold increase in PQS applications over the past 2 years has been due to:

Increased demand of cold chain equipment from countries	5 votes
Increased awareness of PQS work	2 votes
Increased profile due to Covid	5 votes
Other	2 votes

2. Is the time provided to prepare for the annual review adequate?

YES	66%
NO	20%
UNSURE	13%

Action points from this session:
- *None.*

IX. GAVI updates

Ms Karuna Luthra of Gavi presented an update to the cold chain equipment optimization platform (CCEOP). Ms. Luthra provided a reminder of the six different funding streams for CCEOP, along with the original objectives and goals of the CCEOP. She described the ongoing steady scale-up of the CCEOP since 2017, and its success despite pandemic-related delays. Ms. Luthra provided a view on the initial demand forecasts for the CCEOP under Gavi 5.0, followed by an overview of elements of CCEOP that have been redesigned. She touched on the prioritisation according to the 5.0 healthy-markets framework, on COVAX-related support and ultra-cold chain (UCC). In a second segment of the presentation Ms. Luthra discussed the Gavi IMPT (Intelligent Maintenance and Planning Tool) and its imminent deployment. A third and final section discussed Gavi CCE Market Shaping Efforts in non-ILR/SDD product categories.

Discussion

- Mr. Bechter of Berlinger notes that, in terms of supply planning, it is important to bear in mind that following the Covid-19 pandemic, lead times for some components is currently greater than one year. He suggested that some form of risk sharing might be appropriate in this context. He commented also that constant supply is more important than stockouts.
- Mr. Harbers of Berlinger suggested that we need to decide if the relationship is as partners or transactional suppliers.

Menti question responses

1. What information from Gavi would be helpful? (Ranked)
    - 1st Demand forecast
    - 2nd Programme requirements
    - 3rd Country funding available
    - 4th Market shaping strategy information
    - 5th Procurement updates
    - 6th Market notes
    - 7th Programme updates
    - 8th Other

2. Which market do you primarily target for new products?

WHO IMD-PQS	9 votes
UNICEF	3 votes
Commercial	2 votes
Other	1 vote

3. What are the biggest challenges you face in bringing new (a) product(s) to market (for UNICEF/Gavi markets)?

Financial investment required	4 votes
Unclear demand (volume)	13 votes
Unclear what product/features countries want	10 votes
Technical / engineering challenges	4 votes
Other	2 votes

Action points from this session:

- *Manufacturers may reach out to Ms. Luthra in case of questions.*

X. UNICEF updates

Mr. Komrska provided an update for UNICEF Supply Division (SD) which detailed the unprecedented demand for cold chain equipment that has happened in response to the Covid pandemic, which has been met thanks to the solid CCE foundation that UNICEF has provided with the support of the Gavi cold chain equipment optimization platform (CCEOP). He outlined the need for more storage volume at central levels of the cold chain. Mr. Kormska described the success in terms of the speed of mobilization to roll out ultra-cold chain (UCC) devices as an emergency response on top of CCEOP and the COVAX CCE roll-out. He commented on the solid supplier performance despite world supply chain turmoil, and provided results from the post-installation inspections (PII). He concluded with the future outlook for UNICEF SD's operations.

Discussion

- Mr. Kormska additionally underlined the pressing need for additional human resources to manage remote temperature monitoring devices (RTMDs) and cold room installations.
    - Mr. Mallins articulated PQS' alignment with this position; the need to support staff in learning for equipment installation and management.
    - Mr. Kormska noted that the challenge arose with COVAX as all refrigerators at local and regional level required the installation of RTMDs; all manufacturer's responded to the challenge. Overall it was a challenge that was underestimated in advance.
- Mr. Ries of B Medical asked Mr. Kormska to provide further information on tendering on blood banks.
    - Mr. Kormska commented that besides vaccine refrigerators, we are asked to provide for laboratory services and also blood banks. There is not a huge demand, but it requires lot of technical discussions (for example, how do we want to be involved and what type of equipment we can include in our portfolio?). He noted that UNICEF are reaching out to suppliers to find out what have in their portfolio.
- Mr. Tansley of Surechill asked for more information about health facility solarization projects.
    - Mr Kormska replied that 200 health facilities would like to solarize. With the CCEOP-identified solar potential we saw opportunity to offer them full solarization. UNICEF is currently at the stage of identifying funding and our team are now tendering. A dedicated team have identified the power of different components, and different options that countries could pick based on health facility level, energy needs and what this type of equipment this energy can then power.

- Mr. Harbers Berlinger asked whether tendering for RTMD for Q4 planned?
    - Mr Kormska replied that UNICEF see the value of these devices but need to reconcile with the human resources in the field to operate and manage them. With respect to 30-day temperature recorders (DTRs) in a normal clinical trial, when there is the need to document temperature storage it is more rigorous than in the vaccines sector, to ensure proper use and recording to enable decision making etc.
- Mr. McCarney asked whether, with regards to health facility solarization, there is a choice to put in batteries off which to run ILRs or other devices, and to use SDD alongside of a solar battery system.
    - Mr Kormska replied that there is not yet a firm decision on this, but there is serious discussion. Solarization will require batteries, and going backwards when we have a good product would not be optimal. There is also still a cost discussion.

Menti question responses

1. Do you have products in the pipeline for the following categories?

Temperature monitoring (RTMD/EMS/30DTR)	YES 12 votes
Passives	YES 3 votes
Last mile innovation	YES 8 votes
Other	YES 3 votes

Action points from this session:

- *None.*

XI. Closing remarks

Dr. Gobina, WHO Technical Officer, provided an overview of the ongoing and future IMD-PQS innovations, namely: Equipment Monitoring Systems (EMS), humidity control, SDD cold rooms and corrosion prevention. He provided detail on the EMS specification timelines for publication and compliance, and SDD cold rooms looking forwards.

Discussion

- Dr. Gobina also reminded the participants that:
    - The EMS specifications have been published.
    - The deadline for the implementation of the IMD-PQS humidity specification has been postponed until January 2024.
    - SDD cold rooms specification are now published.
    - The corrosion investigation is ongoing and IMD-PQS will share the outcome of the survey with manufacturers.

Menti question responses
None.

Action points from this session:

- *IMD-PQS to share an "explainer" for the portfolio of EMS standards. Due early 2023.*
- *Manufacturers to respond to the humidity enquiry with additional reports to complement the current draft as soon as possible. The deadline for implementation of the humidity specification requirements is January 2024.*
- *IMD-PQS to share the outcomes of the corrosion survey with the E003 & E006 manufacturers.*

ANNEXES

Annex 1: List of manufacturers that participated in the event

Manufacturers that participated in the meeting, in alphabetical order:

Aucma Co.
Blackfrog Technologies
B Medical Systems
Berlinger Group
Beyond Wireless Technology
Coolfinity
Deltatrak Inc.
Dulas
Haier Biomedical
Ikhaya Automation Systems
mSupply Foundation
Nexleaf Analytics
Parsyl
Solar 23
SunDanzer
Sure Chill
Vestfrost Solutions
Viessmann Group

Annex 2: List WHO PQS and partner organization participants

Representatives of the WHO PQS Working Group & other non-industry attendees were, in alphabetical order:

Brian Pal – New Horizons
David Lehmann – Independent Expert
Eugene Adu Afari – Gavi, the Vaccine Alliance
Gemma Huckerby – Consultant to WHO PQS
Greg Kiluva – Independent Expert
Isaac Gobina – WHO PQS Technical Officer
Jacobus Schoevers - UNICEF Supply Division
Jan Komrska – UNICEF
Jean-Baptiste Certain - SELF
Jenny Hu – New Horizons
Joanie Robertson – PATH
Karuna Luthra – Gavi, the Vaccine Alliance
Kelly Hamblin - The Gates Foundation
Lauren Goodman – WHO PQS Project Manager
Matt Morio – PATH
Omileye Toyobo – Clinton Health Access Initiative (CHAI)
Pat Lennon – PATH
Paul Mallins – WHO PQS Technical Officer
Rob Rallo – Solar System Services
Rod Hinman – New Horizons
Simon Leach – White Box Thinking
Steve McCarney – Sunny Day, LLC
Steven Diesberg – PATH
Teshome Yemamu – UNICEF Supply Division
Thierry Copois – UNICEF Supply Division

Annex 3: Meeting presentations

The consolidated presentations for the PQS progress update and the technical themes can be accessed here:

https://drive.google.com/drive/folders/16k_qw5y7w9uElOQrISKtdinSYlZv5Ur7

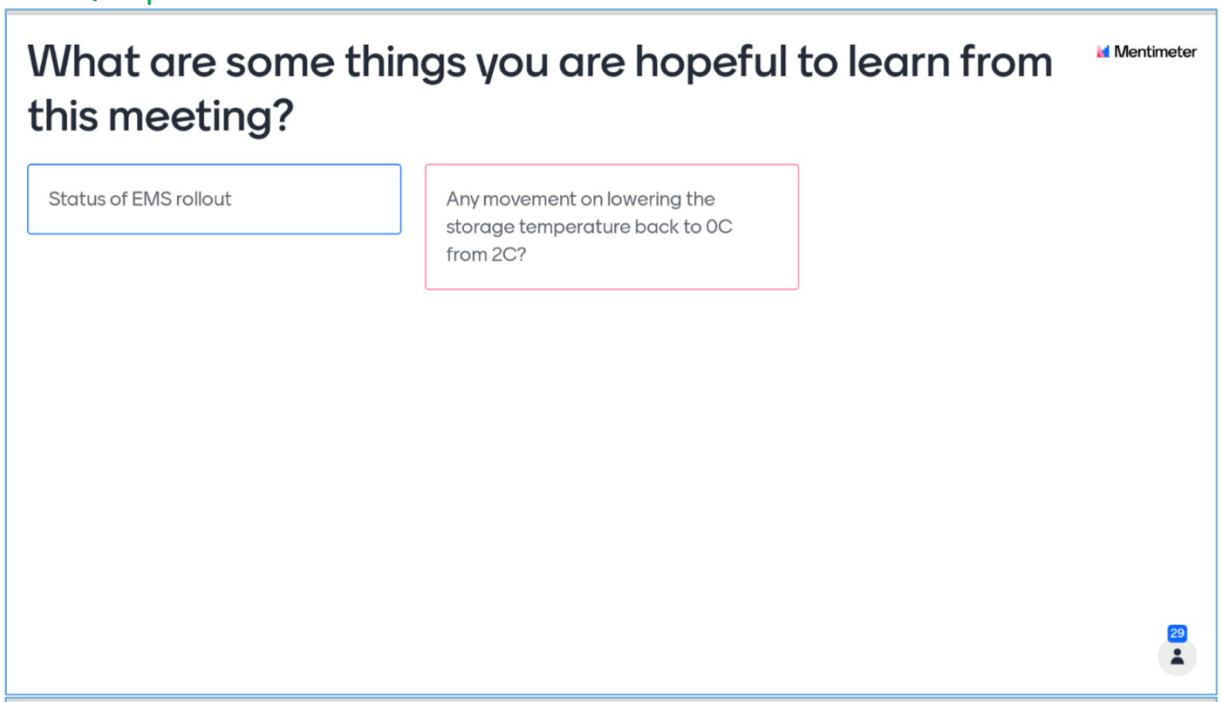
Annex 4: MentiMeter manufacturer responses to PQS (closed) questions

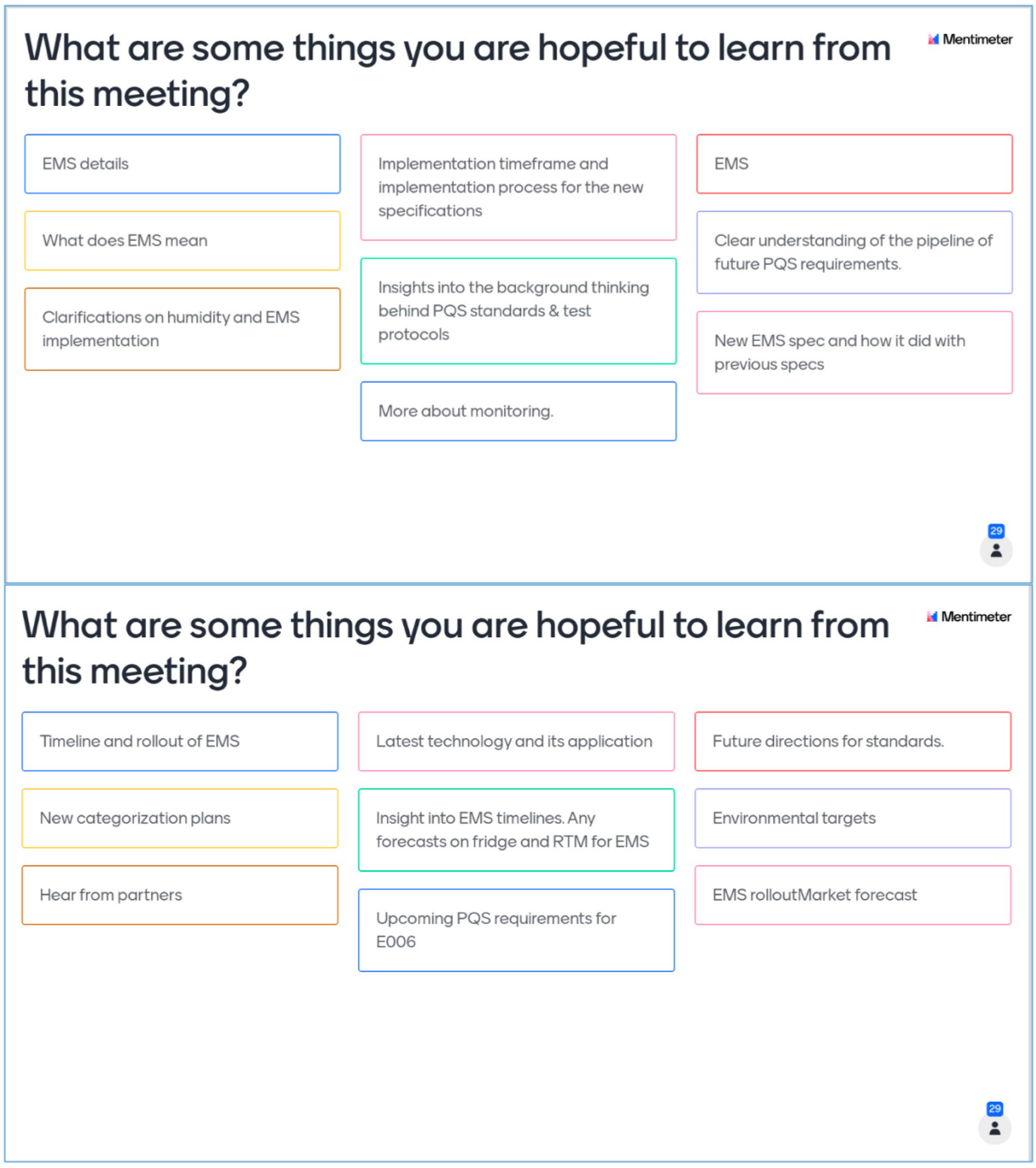
Note: PQS presenters' responses to questions posed by participants are discussed in the respective sections of the main body of this report, as are participants feedback on open-ended questions.

I. WHO PQS Introduction

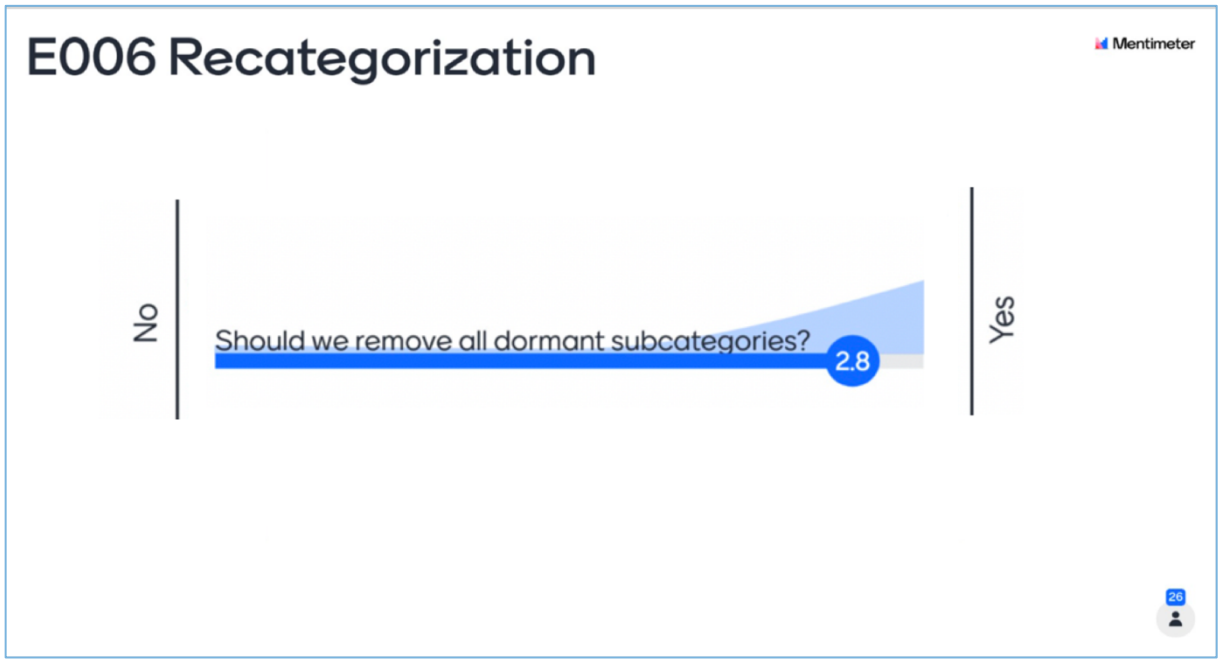
None.

II. PQS Update

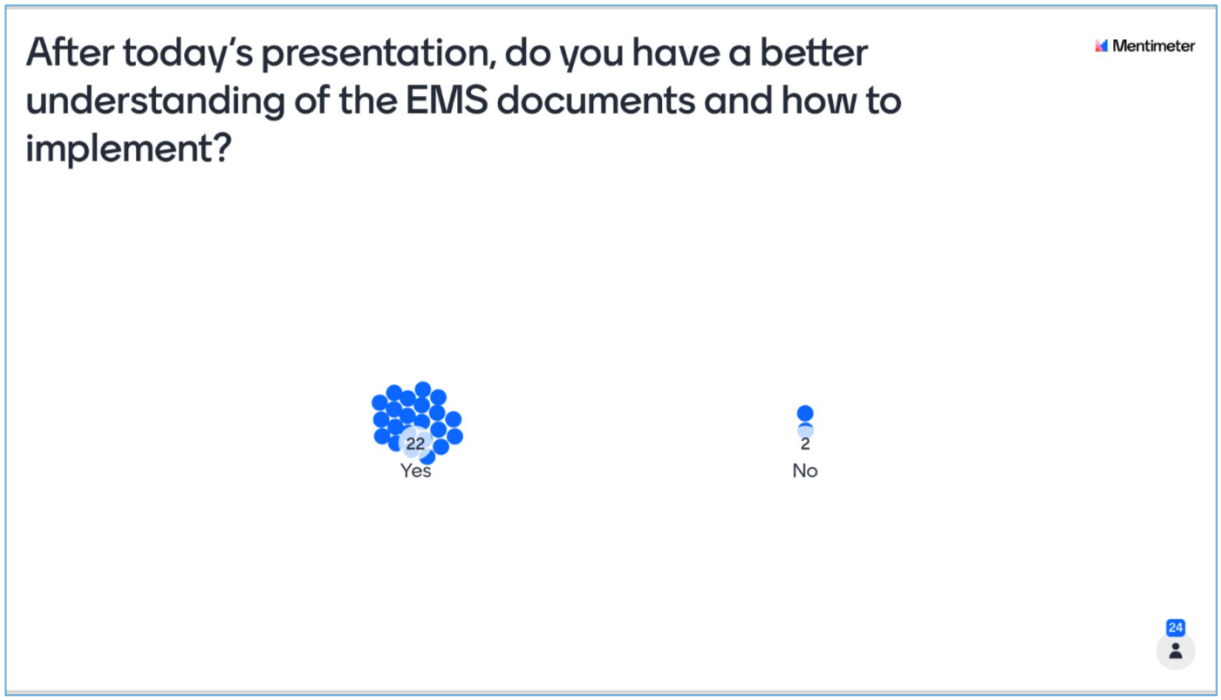



What are some things you are hopeful to learn from this meeting?
Mentimeter
EMS details
What does EMS mean
Clarifications on humidity and EMS implementation
Implementation timeframe and implementation process for the new specifications
Insights into the background thinking behind PQS standards & test protocols
More about monitoring.
EMS
Clear understanding of the pipeline of future PQS requirements.
New EMS spec and how it did with previous specs
29
What are some things you are hopeful to learn from this meeting?
Mentimeter
Timeline and rollout of EMS
New categorization plans
Hear from partners
Latest technology and its application
Insight into EMS timelines. Any forecasts on fridge and RTM for EMS
Upcoming PQS requirements for E006
Future directions for standards.
Environmental targets
EMS rolloutMarket forecast
29

III. E006 Recategorisation

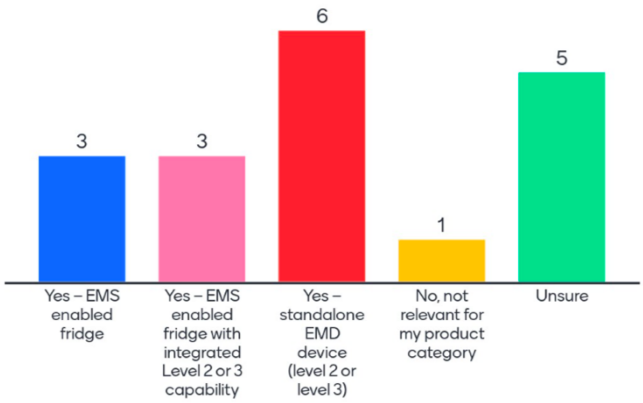


IV. EMS Refresher



Do you intend to bring an EMS product to market?

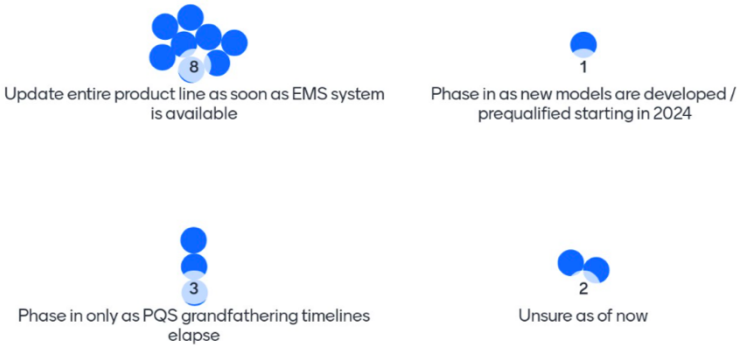
Mentimeter



18

For E003 manufacturers: What is your initial thought on phasing EMS functionality into your models?

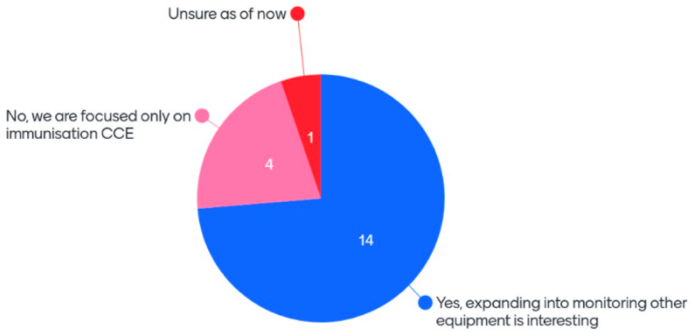
Mentimeter



14

Would you be interested in providing EMS systems for other (non-immunisation CCE) global health equipment types in the future?

Mentimeter



19

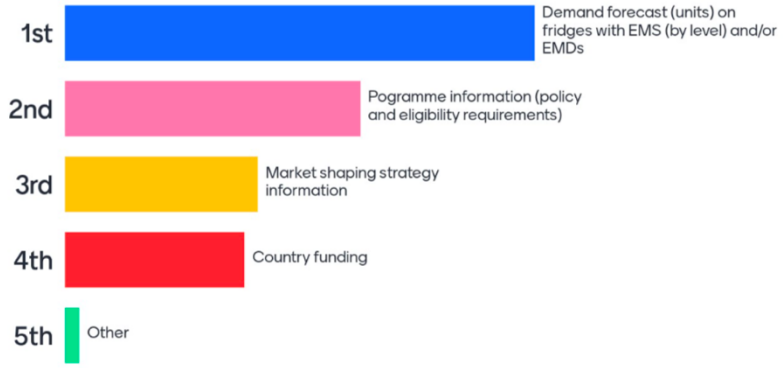
What are the biggest challenges you anticipate in fulfilling the EMS specification?

Mentimeter

23

What additional market shaping information would be helpful to you as you plan your approach to EMS?

Mentimeter



23

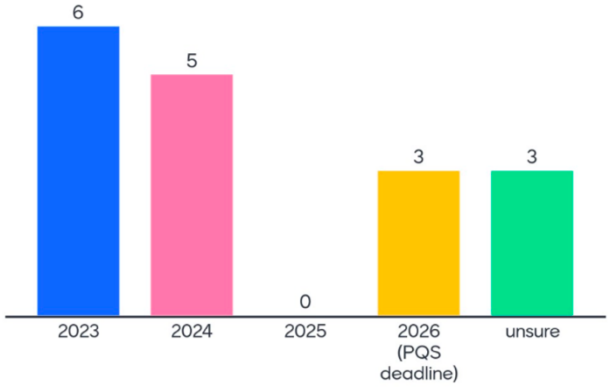
Would you prefer:

Mentimeter

20

What is your anticipated timeline to have EMS available (minimum level 1) in existing products and ready for PQS evaluation?

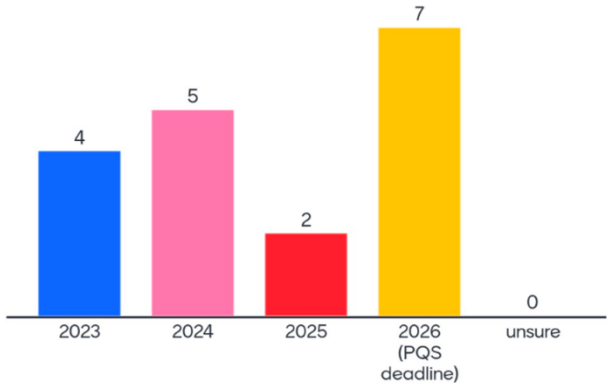
Mentimeter



17

What is your anticipated timeline to have EMDs with level 2 or level 3 functionality (standalone or integrated) and ready for PQS evaluation?

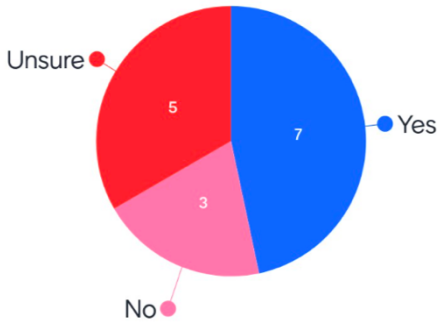
Mentimeter



18

Would you plan to implement EMS in additional CCE (e.g., ULT or WICRS)?

Mentimeter



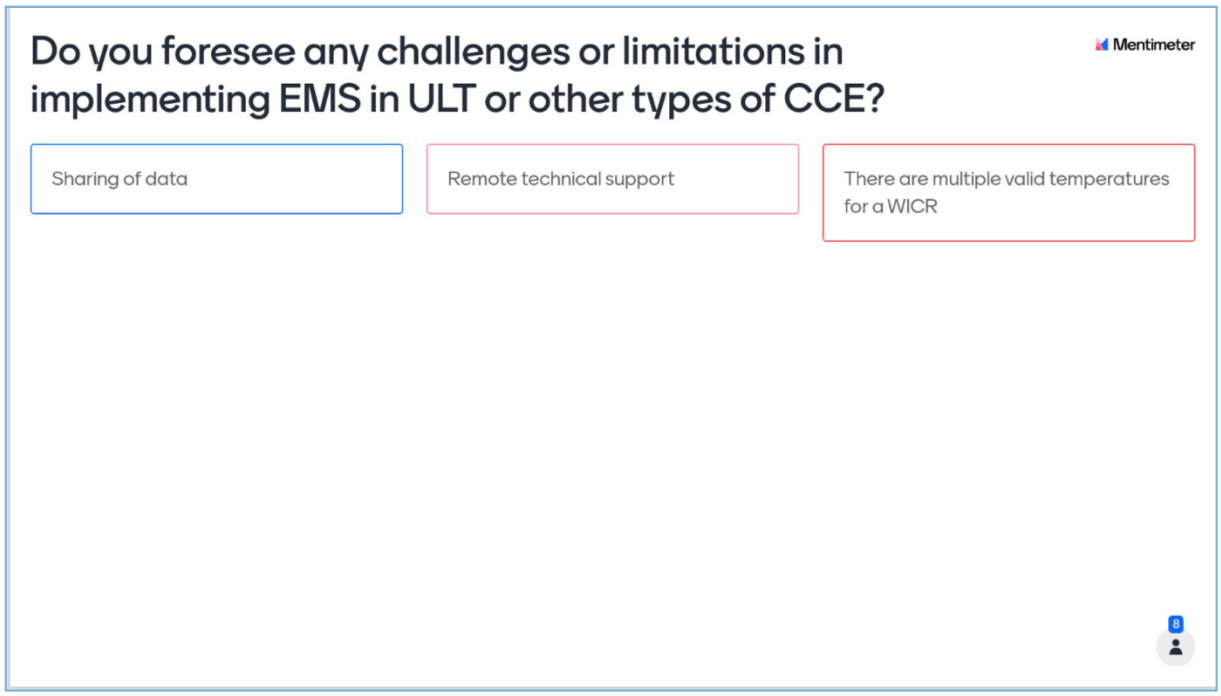
15

Do you foresee any challenges or limitations in implementing EMS in ULT or other types of CCE?

Mentimeter

No	Environmental differences inform components	Not really
Power availability in portable refrigerators?	No	Mounting/installation of sensors in WICRS
cost	Countries making use of the data/systems in effective ways	cost

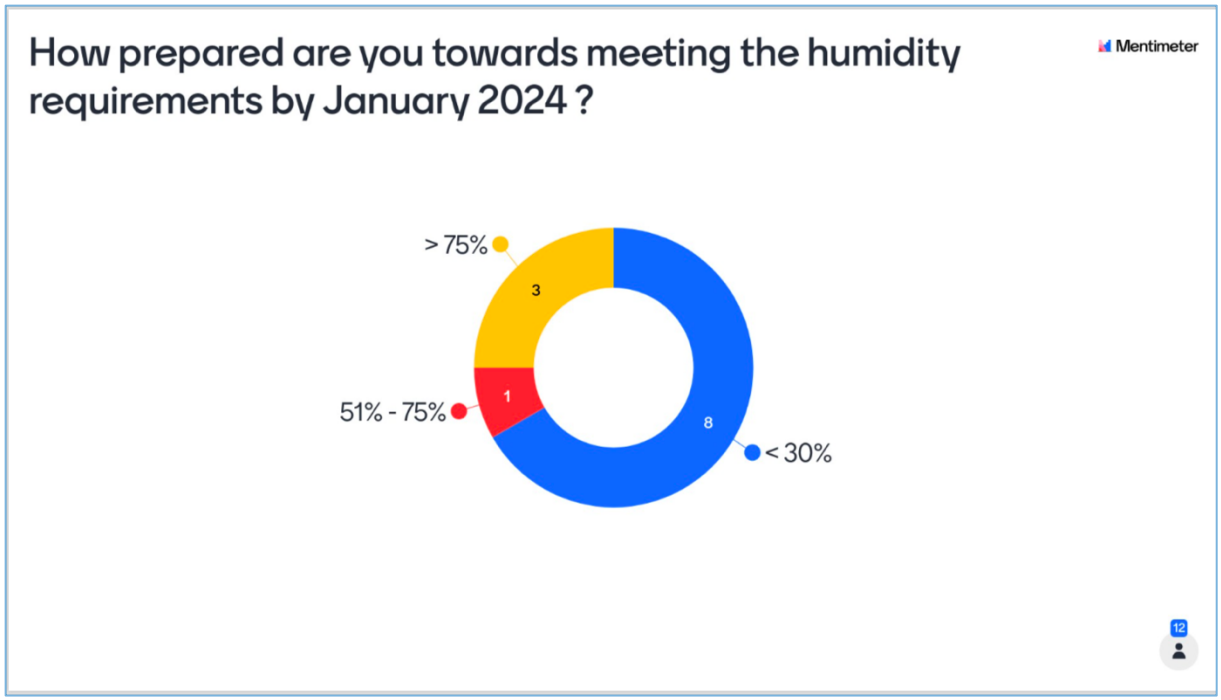
8



V. Environmental standards

None.

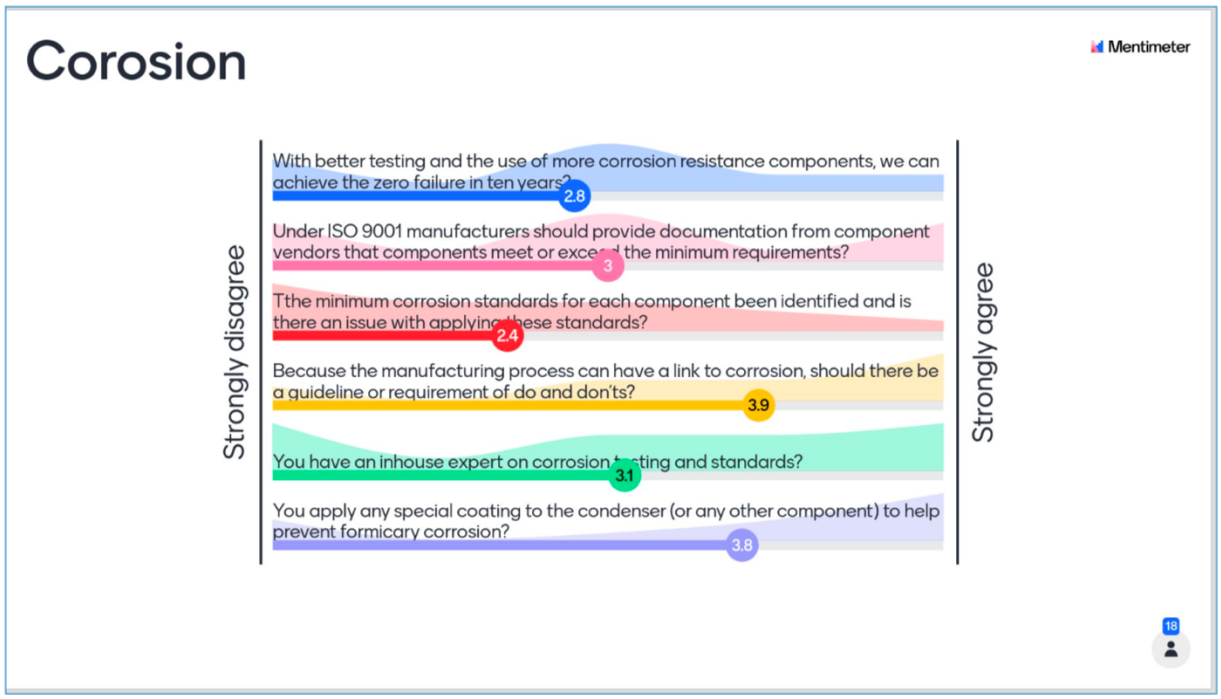
VI. Humidity



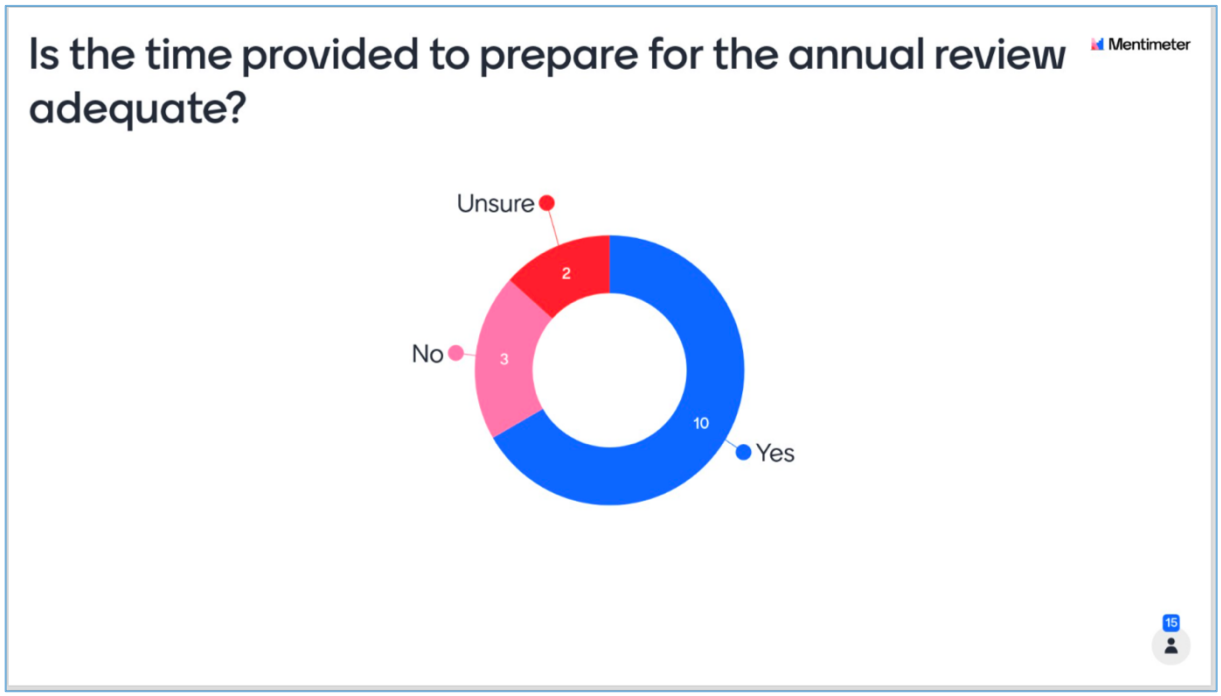
VII. E001 Cold Rooms

None.

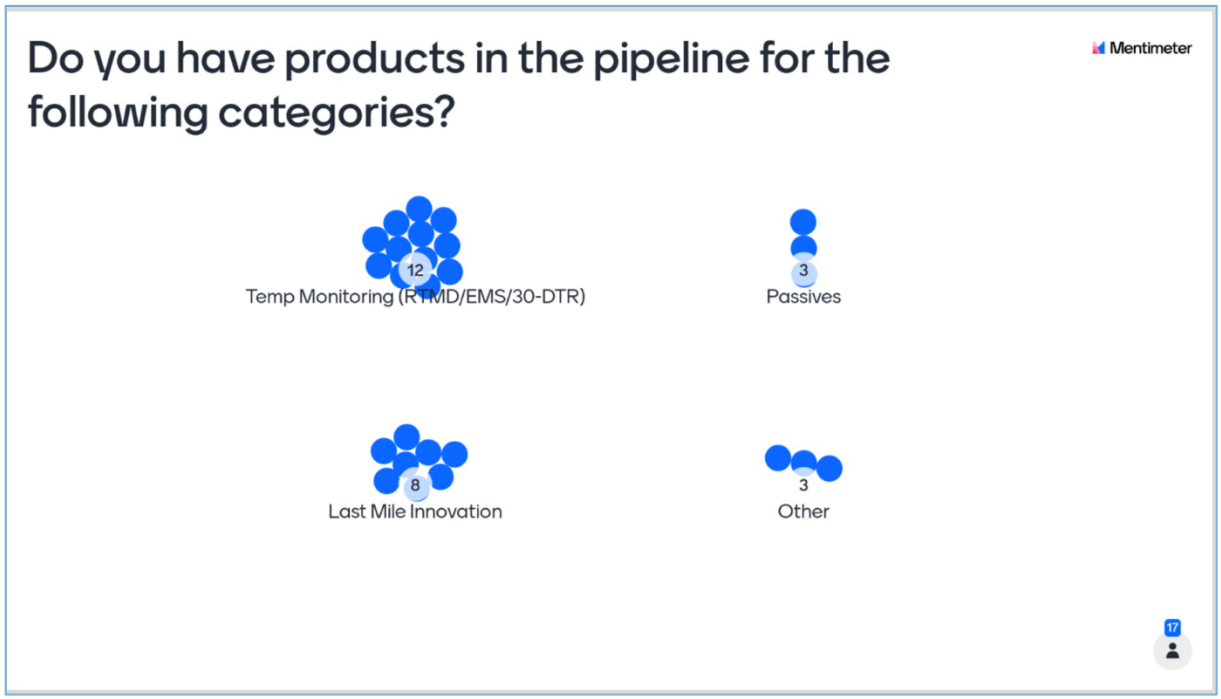
VIII. Corrosion

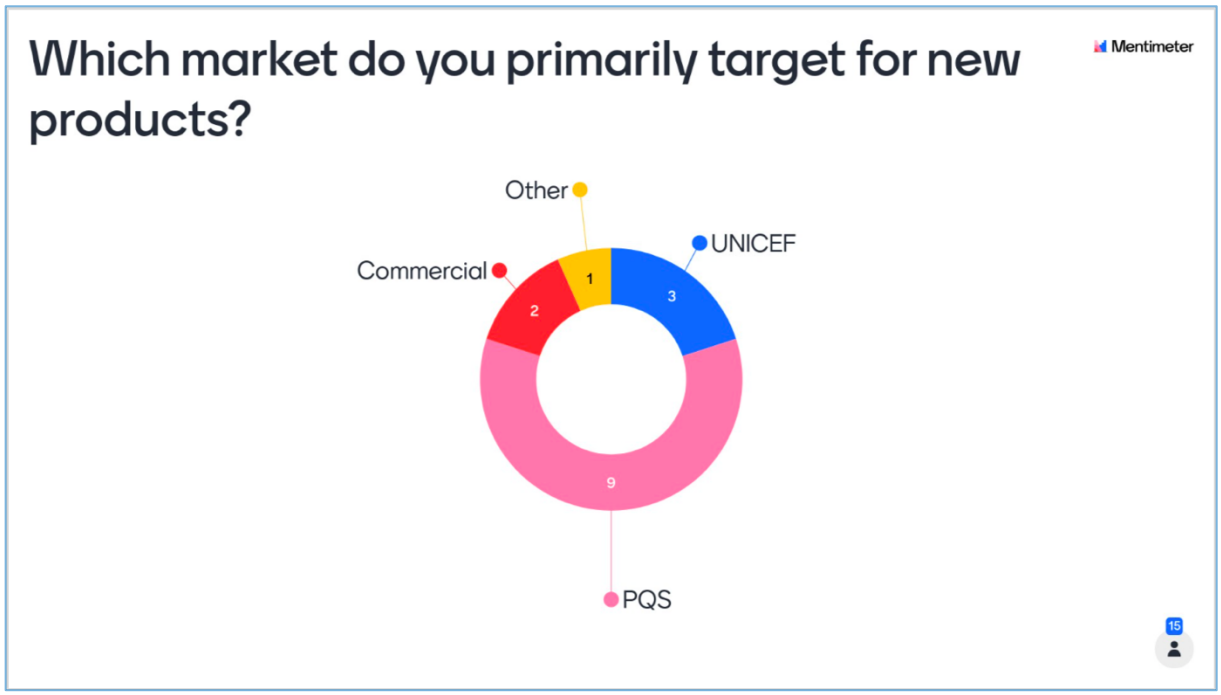


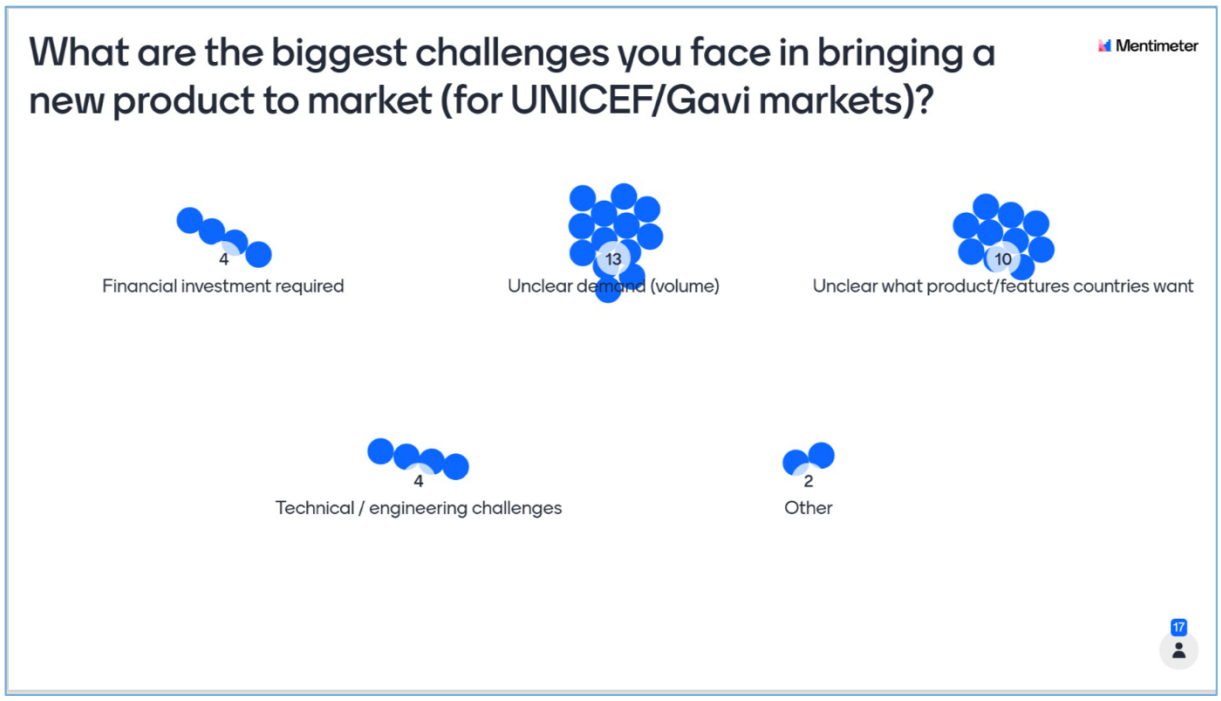
IX. Post-market monitoring



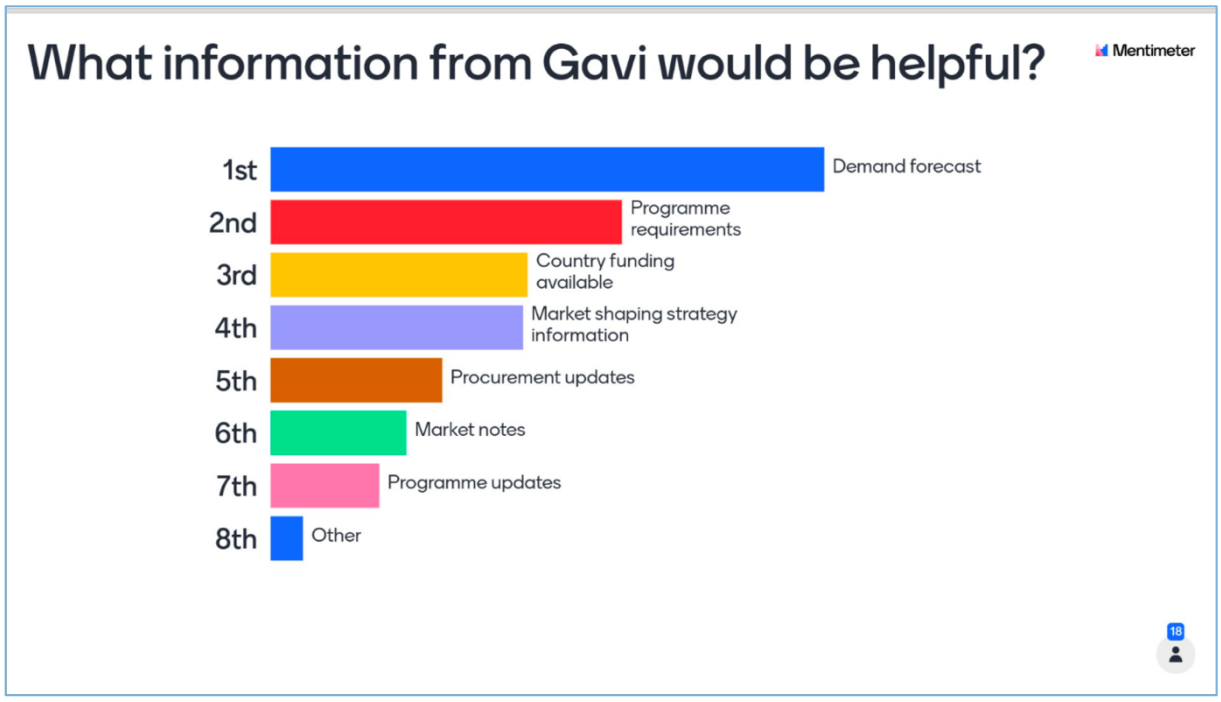
X. Unicef update



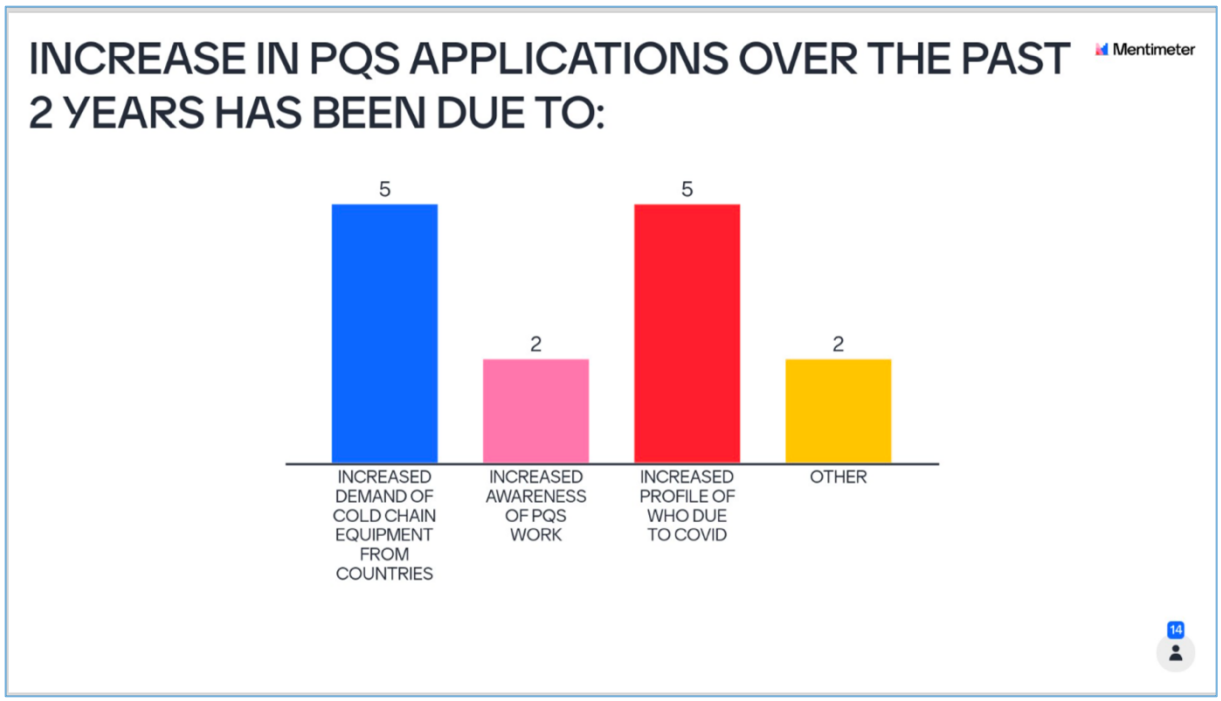




XI. Gavi update



XII. Closing remarks


INCREASE IN PQS APPLICATIONS OVER THE PAST 2 YEARS HAS BEEN DUE TO:
Mentimeter
5
2
5
2
INCREASED DEMAND OF COLD CHAIN EQUIPMENT FROM COUNTRIES
INCREASED AWARENESS OF PQS WORK
INCREASED PROFILE OF WHO DUE TO COVID
OTHER
14