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WHO PERFORMANCE,  
QUALITY & SAFETY

# WHO PQS Immunization Cold Chain Manufacturer Consultation

- 2021 –

December 9  
*Virtual teleconference*

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World Health  
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## Executive summary

On Thursday 9th December 2021, the WHO Performance, Quality and Safety (PQS) Team conducted its annual technical consultation with manufacturers of PQS-prequalified immunization products and devices from the E003 (Refrigerators and freezers) and E006 (Temperature Monitoring Devices) equipment categories. The meeting took place virtually by teleconference in lieu of a face-to-face meeting due to the ongoing Covid-19 pandemic. A link to previous consultation reports can be found here:

- 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>

75 participants joined the teleconference (an increase of more than 15% compared to 2020), including industry representatives alongside non-industry members and partners of the WHO PQS Working Group (see *Annex 1*).

The purpose of the 2021 consultation was to present general PQS progress updates plus next steps on the following prevailing themes discussed during the 2020 PQS consultation and relative to the PQS 2021 workplan:

1. Environmental issues, refrigerants and energy efficiency
2. WHO PQS post-market monitoring, corrosion issues
3. WHO PQS electronic monitoring system (EMS) specifications
4. WHO PQS specifications updates:
  - Solar direct drive cold rooms
  - Voltage stabilizer PQS specification
5. UNICEF supply division updates
6. Gavi cold chain equipment optimization platform updates

**The 2021 WHO PQS Manufacturer Teleconference continued the trend of building efficiently on the highly successful first collaboration of 2018 via remote conferencing. It was once again a core element 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 and 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 adequate and appropriate 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). Manufacturers have previously expressed a desire to have earlier and more substantive involvement in the PQS standard-setting process<sup>1</sup>, and the 2018 consultation served as a forum to improve engagement with manufacturers, gather inputs on PQS standards and to signal new directions for TPPs. This (fourth) consultation was another important step in the ongoing work to drive greater engagement between WHO PQS and manufacturers.

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<sup>1</sup> 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, along with a description of relevant action points, progress and key updates. In many cases, (a) direct question(s) related to the topic was put to manufacturers via MentiMeter<sup>2</sup> 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 anonymously participation of manufacturers amongst their industry peers if required) or in the Teams chat.

Annexes to this document include:

List of invited manufacturers – [Annex 1](#)

List of WHO PQS and partner organization participants – [Annex 2](#)

Link to the conference presentations (pdf) – [Annex 3](#)

A list of manufacturers' responses to MentiMeter questions – [Annex 4](#)

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<sup>2</sup> 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. WHO PQS Introduction & updates

### 1. WHO PQS 2021 Workplan

In this session Mr. Isaac Gobina, WHO PQS Technical Expert, provided a review of action points and key updates on the following current workstreams:

- *Connected cold chain specifications and testing protocols (E006) – actions are on track. The specifications have been reviewed by E006 manufacturers; final inputs will be integrated and the specifications will be published in January 2022.*
- *Humidity control E003 specifications & verification protocol revisions – actions on track. Humidity specification is already published. Feedback remains open to manufacturer on potential testing methods before it becomes a requirement in January 2023.*
- *Portable fridge testing protocol – actions also on track. The testing protocol has been published contributing to this new category.*
- *ULT monitoring devices specification and verification protocol - actions are on track. Publication Q1 2022.*
- *ULT shipping guidelines - actions are on track. Publication Q1 2022.*
- *External evaluation of PMM sentinel surveillance plan – delayed (cancelled) due to Covid restrictions. Final report & tools will be published in Q1.*
- *Implementation of four manufacturer inspections (quality inspections) – delayed due to Covid priorities. Quality management systems (QMS) inspections are expected to resume in Q3 2022 if possible, whereafter the QMS inspections SOP can be published.*
- *Scheduling of regional/in-country PQS WG meeting – delayed. Due to ongoing Covid pandemic, the F2F will take place once restrictions are lifted.*
- *3-phase voltage stabilizer specifications – delayed. Due to issues related to the need to include voltage stabilizers in the cold rooms specifications, the voltage stabilizer specifications will be delayed on into 2022.*

#### Discussion

None.

#### Menti question responses

None.

#### Decision points from this session:

None.

#### Action points from this session:

- *Connected cold chain standards will be published in January 2022.*
- *Humidity control E003 specifications will become requirements in January 2023.*
- *ULT monitoring devices specification Q1 2022.*
- *ULT shipping guidelines Q1 2022.*
- *PMM sentinel surveillance pilots evaluation cancelled, report will be published in Q1 2022*
- *QMS inspections: scheduled to resume in 2023 Q3 if possible.*
- *Regional / in-country meeting to resume when Covid restrictions are lifted.*
- *3-phase voltage stabilizer specifications to be published in 2022.*

## 2. WHO PQS Website updates

*Mr. Isaac Gobina provided a brief introduction to the new PQS website, scheduled now for go-live in January 2022.*

*Mr Gobina described that the new website has new features, functions and navigability to improve user experience. The website URL and a brief introduction will be communicated to PQS manufacturers at launch.*

### Discussion

None.

### Menti question responses

None.

#### Decision points from this session:

None.

#### Action points from this session:

- *New PQS website to go-live in January 2022.*
- *An introduction for PQS manufactures and other stakeholders will be provided at the time of launch.*

## 3. WHO PQS E003 Target Product Profiles

*Mr Isaac Gobina provided a brief update to the status of the PQS E003 Target Product Profiles development. Mr Gobina noted that incorporation of the TPPs into the E003 specifications has begun. He also reminded manufacturers that the grandfather period has been set at two to three years (depending on the clause). Lastly, Mr Gobina noted that the humidity TPPs have already been incorporated to the E003 specifications (although they are not yet a requirement – see grandfathering period).*

### Discussion

- Mr Gobina encouraged manufacturers to provide any further inputs or comments in the time remaining before the coming into force in 2023.

### Menti question responses

None.

#### Decision points from this session:

None.

#### Action points from this session:

- *TPPs will be incorporated into E003 specifications during the course of 2022.*
- *There is a grandfathering period of two to three years (before compliance is required).*

## II. Environmental issues & refrigerants

*In this session Mr. Philipp Denzinger, of GIZ (the German society for international cooperation), a service provider in international cooperation for sustainable development, presented on how to establish a sustainable and climate resilient vaccine cold chain. Mr Denzinger began by introducing the 'Proklima' initiative, which was established via the Montreal Protocol and later extended via the Kigali Amendment to implement technical projects for ozone and climate protection. Mr Denzinger traced the history of climate protection obligations across Montreal and Kyoto Protocols, the Paris Agreement and the Kigali Amendment. He concluded the introduction with an overview of the Ozone Depletion (ODP) and Global Warming Potential (GWP) of refrigerants and blowing agents and related best practices. The bulk of the presentation focused on conventional and climate friendly technologies, including monoblocks with ultra-low GWP, climate friendly laboratory refrigerator/freezer units and freezer units, SDD vaccine freezers and climate friendly ultra-low temperature (ULT) vaccine freezers. The final topics of discussion were standards, trainings and certification, and management, recycling or destruction of obsolete vaccine cold chain equipment.*

### Discussion

- Mr Denzinger urged manufacturers to consider the design and production of climate friendly and energy efficient equipment, reminding participants of the urgency of establishing smart, sustainable, green and climate friendly equipment system.
- Mr Denzinger concluded with a summary of the GWP, insulation material, energy efficiency ratio (EER) and back-up power parameters and best practices (see *presentation*).
- Mr Viessmann (of Viessmann) enquired about the current timing of this request to upgrade GWP/ODP. He also noted that the market tends to react only once refrigerators are phased out.
  - Mr Gobina, of WHO PQS, replied that historically WHO PQS has focused on performance, and is now extending the focus to environmental parameters.
  - Mr Denzinger noted that energy consumption is now more present on the PQS product sheets, and PQS is working to extend this.
  - Mr Gobina noted that an "energy efficiency index" is being developed" (see *following presentation*), and industry input will be sought.
  - It was also noted that the <2500 GWP transition happened in 2020.
- Mr Viessmann noted that currently no eco-efficiency design guidelines or labels exist, but expressed his company's willingness to implement them once available.
  - Mr Denzinger also noted that it will help the consumer and procurement agent if PQS can state the energy use of devices (in the PQS Catalogue).
  - Mr Denzinger also subsequently suggested that it would be pertinent to include equipment under MEPS and national labelling schemes.
- Mr Mallikarjun Kadambari, of UNICEF SD, asked whether UNICEF should use the work excursion proof on the recovery pumps. Mr Kadambari also asked if Mr Denzinger could recommend a recovery kit for small machines.
  - Mr Denzinger replied that If the lower flammability level is in use, chances are very low as cold rooms are hermetically sealed. In addition, monoblocks, don't need to worry about destruction as it is sufficient to ensure release to the atmosphere. But for FCs / HFCs there are more options; and they run until the

unit no longer works. If the unit is broken, one should try to recover the refrigerant. Given SD procurement is mainly global, there would need to be a national supply chain focus; perhaps an offer to reappropriate the old equip and deliver it to a national collection centre. Foam is much more complicated: at the very least it is necessary to recover the refrigerant and the oil. The remaining job thereafter is tricky and expensive. Hydrocarbons can just be released outside (they are not flammable if sealed).

- Mr Viessmann asked whether it is a myth that R190 monoblocks are hermetically sealed. We are collaborating with Rivacold, and they don't guarantee that. This means you also have to think of safety concepts.
  - Mr Denzinger replied that generally monoblocks are hermetically sealed. Very low leakages might occur from time to time but are normally negligible and do not cause any safety risks. Monoblocks for cold rooms contain usually around 150g of R290 which is very little and leakages occur usually slowly and therefore there is no safety risks. Frequent maintenance is recommended.
- Mr Kadambari commented that “blow foaming agent” can be rephrased to insulation agent or material. To the best of my knowledge the insulation material is not always blown it can be injected to get desired densities.
  - Mr Denzinger replied that the term “blowing agents” is used generally and this was also confirmed by other participants.

### Menti question responses

1. Have you switched already, or are you planning to switch in the near future to ultra-low GWP refrigerants and blowing agents?
 

YES	19
NO	0
NOT SURE	10
  
2. Is your equipment under national MEPS and labeling schemes?
 

YES	1
NO	2
NOT SURE	15
  
3. How are you ensuring training of technicians regarding service and repair?
  - a. Yes we train locally
  - b. Blended learning methods: combination of video, online and presence training
  - c. Outsource
  
4. What is your current practice regarding recycling and recovering of refrigerants of obsolete equipment?
  - a. We take them back to ensure proper recycling
  - b. Contractors

**Decision points from this session:**

WHO PQS will continue to work together with GIZ to extend the energy consumption information in product sheets, and evaluate the climate protection requirements of PQS standards.

*Action points from this session:*

- *WHO PQS to extend energy consumption and energy efficiency information on the product sheets.*
- *Guidelines and labels to be developed for eco-efficiency.*
- *Manufacturers to be consulted in depth on the new PQS-energy consumption tool.*



### III. Energy efficiency suggestions

*In this session Mr Steve McCarney of Sunny Day LLC presented a work-in-progress Energy Efficiency Consumption Comparison tool, which would apply to refrigerators, freezers or combined refrigerator/freezers. He described the advantages of the tool (notably the absence of need for additional testing, the readiness of data and the flexibility of use across partner organizations among others) and its' disadvantages (notably its limitations related to predictions for operating cost and annual consumption among others). Lastly Mr McCarney provided several examples of the calculation for vaccine refrigerators.*

#### Discussion

- Mr McCarney noted that the PQS Catalogue should include short “guidance” instructions on how to use the tool (or how not to).
- Mr Kadambari noted that energy consumption data must specify the load such as half load, full load, and door opening sequences etc.
  - Mr McCarney commented that the load is defined in PQS VP's and does not included door openings. Since the intent of the tool is to compare electricity consumption between models and not to predict consumption an index such as described would fulfill that goal (but the proposed approach will not be directly useful to estimate annual energy consumption/cost).
- Mr Kadambari noted that the kWh value could be taken from the day-night test. The ambient temperature might be considered to be more realistic. He also notes that door opening during an energy test can create several problems.
  - Mr McCarney commented that while day/night test is more realistic the difficulty of gathering the data would need to be considered and then funding needed to review the historical status of the test conditions and then consolidate the test results. If the goal is to estimate annual energy and costs then this test would be preferable to Stable Running test (at +43C continuous). However, it may then also be necessary to establish the accuracy of the results if users were to apply the tool to cost estimations.

#### Menti question responses

1. Is this a fair and useful tool?

YES	12
NO	1
NOT SURE	12
2. If not what suggestions would improve it?
  - a. More dynamic temperature measurement
  - b. High wireless remote temperature monitoring
  - c. Better coatings of exposed components

**Decision points from this session:**

None.

*Action points from this session:*

- *WHO PQS & Mr McCarney will continue to develop the tool, including further round of input and feedback from manufacturers.*

## IV. Post-market monitoring: corrosion

*In this session, Mr Paul Mallins of WHO PQS and Mr David Lehmann, Independent Expert, provided an update to the WHO PQS post market monitoring pilot study, including a key finding of equipment failure: corrosion. Mr Mallins provided a brief background to the project (notably it is active since 2018, the pilot study remains in roll-out, and pilots launched in 4 countries in 2019/2020, including a surveillance officer engaged for 15 months, all supported by the Gates foundation, in collaboration with PATH, IRD and SELF, and in close collaboration with national EPI program & local partners). Mr Mallins also described the Sentinel Surveillance pilots which aim to help strengthen PQS and manufacturers' ability to identify and address performance issues and complaints. Mr Mallins introduced the corrosion theme, noting that 3% of devices were found non-functional. Mr Lehmann continued the presentation by describing how refrigerant leaks have proven to be one of the major areas of failure, occurring for three reasons: corrosion (which may occur due to factors in the environment, cleaning products, chemicals in manufacture or galvanic action), or due to connections or fatigue. He outlined that there are potential ways forward by using other materials or preparations.*

### Discussion

- Mr Mallins encouraged manufacturers to (continue to) provide feedback to PQS when they receive information about equipment performance issues, or other equipment complaints.
- Mr Viessmann, of Viessmann, asked whether there is any information about climatic circumstances of the corrosion cases?
  - Mr Lehmann responded that the only information is that the locations are next to the ocean.
- Mr Viessmann also asked whether Mr Lehmann recommends to not use dissimilar materials for joints, such as steel to copper or copper to aluminum joints?
  - Mr Lehmann responded that copper to aluminum can cause issues due to electrolysis of the dissimilar metals. Moisture and environment can expedite failure. Lifespan seems to vary, but he has seen copper aluminum fail in two to three years, and certainly in 10 years. An all-copper system is ideal. He also noted that it is important to address materials' issues in order to not create new corrosion issues (Formicary corrosion) with chemicals used in the manufacturing process.
- Mr Teshome Yamamu, of UNICEF SD, asked which one of the three reasons for refrigerant leak is the most critical: environmental, connection or fatigue?
  - Mr Lehmann replies that fatigue should be fairly rare if the equipment is properly secured. Environmental would be the most concerning.
- Mr McCarney asked, once there has been fan failure, what are the ramifications to the components of the fridges.
  - Mr Lehmann replied that the tube and fin design is the most efficient, it depends on air movement across the coil. Refrigeration capacity can be reduced by 50 to 75%, resulting in the refrigeration system unable to maintain safe temperatures. For systems that use thermal storage, an alarm could give enough time to make repairs before the refrigerator compartment gets too warm. Lint buildup on the condenser coils happens over many months, during this time the higher head pressure of the refrigeration system will gradually rise. At some point the system will not be able to maintain proper temperatures. During this time, many components (compressor,

motor controller, compressor oil) are being stressed, and can lead to early failure. Mr Lehmann notes that there are lots of advantages for installing an alarm.

- Mr Kadambari asked what kind of protection Mr Lehmann recommend for an immersed evaporator coil ? In water or PCM ? He also asked whether Mr Lehmann recommends ultrasound self-cleaning technique for the condenser unit?
  - Mr Lehmann replied that isolating PCM materials from the evaporator coil, to reduce corrosion, would be a recommendation. He noted that many methods are possible, designs of coils etc. These evaporator designs may be directly inserted into the PCM solution or directly connected so there is no contact with the evaporator. In the opinion of Mr Lehmann, the isolated evaporator and PCM will be the most reliable.

## Menti question responses

1. Is corrosion reported to you or observed in the field?

YES	15
NO	6
NOT SURE	2

2. What are your recommendations for addressing the corrosion issue?

- a. Look for well protected refrigeration circuit in PQS test – visual inspection
- b. Clarify climatic conditions in the tender phase of the projects
- c. In-country training of end users in basic preventative maintenance
- d. Cleaning guidelines for the materials
- e. Prescribe materials vs. performance specification (if a test could realistically determine in-situ corrosion resistance)

3. If the tube and fin style of condenser is chosen, should there be requirements for fin spacing?

YES	2
NO	1
NOT SURE	10

4. Should a temperature alarm be used to monitor a plugged coil or fan failure?

YES	8
NO	2
NOT SURE	2

5. Should easy access for cleaning of the coil be required?

YES	11
NO	2
NOT SURE	1

**Decision points from this session:**

None.

**Action points from this session:**

- *Manufacturers requested to continue to provide feedback and information to PQS related to performance issues or complaints.*
- *WHO PQS will continue to work together with Mr Lehmann and the PQS Corrosion Working Group to study these causes of failure and their solutions. Further conclusions and recommendations, and their implications for PQS standards, will be communicated to manufacturers in Q2 2022.*

## V. Electronic monitoring suggestions

*Mr Isaac Gobina of WHO PQS, Mr Brian Pal, of New Horizons, and Ms Karuna Luthra of Gavi provided an update to the development of the electric monitoring system specifications and requirements development process. This update followed the conclusion of the primary manufacturers consultation process which ran from April to October of 2021, and in which many of the participants present actively participated. Mr Gobina provided an introduction and background to the EMS project, including to note that there has been an increased need from EPI programmes for more reliable temperature monitoring and long-term fridge specific performance data, and that the refrigerators will serve as the repository for temperature data. He also underscored that data alone is not the solution; rather that in parallel country systems' use of data is also being strengthened by WHO programmes. Mr Pal continued with the technical overview, including its purpose to achieve integrated logging of data and admin information to improve diagnostics and reporting, modular interface for local data and plug-and-play upgradability, and data standardization for interoperability. He thereafter provided an overview of the technical components, and the industry working group feedback, inputs and outputs. Lastly he covered the pertinent changes incorporated since the completion of the industry working group, and put several questions to the group to evaluate their perspective on the working group process. The technical presentation concluded with an overview of the timelines for the phase-in and applicability (see action steps below) and a review of the EMS requirements applicability to other PQS categories (and upcoming changes to the relevant standards). Ms Luthra concluded the session with an update on how the Gavi Cold Chain Equipment Optimization Platform will support EMS, including Platform-eligibility and other potential support measures for PQS prequalified products.*

### Discussion

- Ms Melita Marks of Sensitech asked about the relevance of EMS for annual calibration.
  - Mr Pal replied that one condition of EMS is for recalibration to not be a requirement, as calibration in the field after shipping is not realistic.
- Mr Kadambari asked whether humidity data capability has been removed at this stage.
  - Mr Pal replied that yes, absolutely it will be an optional functionality for data to be transmitted, but it will not be a requirement at this stage.
- Ms Marks asked whether there is any mention of real-time notifications from the EMD discussed.

- Mr Pal replied that yes, there is an expectation of 15 mins alarm communication.
- Mr Dion Rachelson of Beyond Wireless asked what are the timelines for the move from current PQS accredited devices to those that need to conform to new EMS specifications.
  - Mr Pal referred the group to the slide covering this topic later in the presentation.
- An anonymous question was also posed via the Menti-tool: will field testing / pilot testing be required prior to launch?
  - Mr Pal replied that EMS systems will be field tested as with any new technology to the PQS system, and PQS will collaborate with suppliers to define efficient field test protocols and to minimize the cost and burden of the field testing as much as possible.

### Menti question responses

1. Did you find the Industry Working Group process useful for increasing industry visibility and input into the EMS specifications development?

VERY USEFUL	11
SOMEWHAT USEFUL	12
NOT USEFUL	0

2. Would you participate in another industry working group facilitated by PQS for other specifications?

YES	21
NO	0
MAYBE	3

3. What improvements would you suggest to the industry working group process?

- a. Simplify the process and make meetings shorter
- b. More suitable meeting time
- c. Quicken the process
- d. A better method to collaborate online
- e. More focused, shorter sessions on more individual single targeted topics
- f. Simpler online collaboration with more clear focus and fewer topics
- g. Focus specialist topics to experts in that field
- h. Format is fine. Transparency on considerations to make certain decisions (to incorporate or dismiss suggestions)
- i. Establish a timeline for completion
- j. Hardware and software compatibility with the existing analog circuits may be a challenge

4. What would be most helpful to accelerate adoption of EMS functionality into your products?

- a. If off-the-shelf products / modules were available
- b. Availability of final standard and assurance the technical specifications will not change for the next five years
- c. EMS combine with temperature controller available

- d. More transparency on market demand published
- e. One standard for all countries and clients
- f. Stability of specifications
- g. Procurement fund support
- h. Need to understand financial impact compared to current RTMDs
- i. Changes should be forward and backward compatible

**Decision points from this session:**

None.

*Action points from this session:*

- *Final EMS specification will be published in January 2022*
- *EMS will become a requirement for prequalification of **new** E003 ILR and SDD fridges and combine fridge/freezers in January 2024*
- *EMS will become a requirement for **all** prequalified E003 ILR and SDD fridges and combine fridge/freezers in January 2026*

## VI. WHO PQS Specifications updates

### 1. Solar direct drive cold rooms: PQS specification & field study

*Mr Steve McCarney, Independent Expert of Sunny Day LLC, provided an update on the contents and progress of the new solar direct drive cold room specification and accompanying field evaluation requirement. Mr McCarney noted that the specification and its accompanying verification protocol have passed through one round of industry feedback and publication is foreseen for early to mid 2022. He described how the specification is based on existing standards for walk-in cold rooms and freezer rooms, solar and SDD standards and the new energy harvest control specification. In addition it includes key performance aspects of SDD appliances, such as battery-free, energy harvest options, and that there will be limited testing to establish cool down, autonomy, minimum rated ambient temperature. Lastly, field evaluations will be required for this new category. Mr McCarney concluded with an overview of the key technical requirements (see presentation).*

### Discussion

- Mr Viessmann of Viessmann asked for clarification whether Mr McCarney was expressing a preference for the cold rooms to be standing outside of the building rather than inside.
  - Mr McCarney replied that either traditional room with in a room or standalone room now proposed. This is the first time a standalone WICR-FR building would be allowed.
- Mr Leach, independent expert, enquired about what technical challenges there may be.
  - Mr McCarney replied that autonomy, battery free cooling operation and development of new technology are a few challenges. A participant asked about funding: WHO / Gavi may consider this.
- Mr Kadambari of UNICEF SD noted that DC voltages exceeding 48V requires operating personnel protections. He also asked whether Mr McCarney considers additional training and protective gear?
  - Mr McCarney replied that yes, added safety in instructions would be included (and protective gear where needed).

### Menti question responses

1. Could your company meet these specification or test requirements in 2022?

YES	2
NO	4
NOT SURE	4
2. In not, what would prevent your company from meeting the specification or testing?
  - a. This is very new so some grant funding is needed
  - b. Out of our current product range
  - c. In general it is interesting, but a new technology. So we need an attractive quantity. So we need to analyze if there is more demand for this kind of application.



**Decision points from this session:**

None.

**Action points from this session:**

- Publication of the protocol in early to mid 2022
- Additional round(s) of manufacturer feedback will be required before publication.

## 2. Voltage stabilizers Cameroon field study

*Mr Mallik Kadambari of UNICEF & Mr Omileye Toyobo of CHAI provided an update on the voltage stabilizers (VS) Cameroon field study (supporting the PQS VS specification currently in development). Mr Toyobo began by reminding the group of the major benefits of VS, and yet that high failure rates for these devices have been noted. This situation has prompted PQS to develop a revised specification to push for more reliable VS. Mr Toyobo went on to sharing a brief recap and update on the proposed goals/research questions of the field evaluation, including that Cameroon was chosen due to the particularly high VS failure rates in this context. He noted that the study so far validates the clear difference in performance between PQS pre-qualified and non-prequalified devices. The presenters went on to discuss the scope, methodology and equipment to be used during the field evaluation (including guide to VS allocation, site selection, questions for health workers etc.). The presentation concluded with a lively discussion with several questions posed by participants.*

### Discussion

- Mr Gobina, of WHO PQS asked what is the redundancy planning in case a voltage stabilizer breaks?
  - Mr Toyobe replied that CHAI will procure extra voltage loggers and keep one spare stabilizer in standby per PHC as a backup.
- Mr McCarney prompted Mr Toyobe to ask local participants to recall power outage frequency and durations (early in the evaluation) and then compare to their measured findings (since we so often do not have monitored data and thus rely on participant's memory and anecdotal reporting)?
  - Mr Toyobe replied that yes, this will be in the study: monthly cycle for this data, including to look for the impact of climatic conditions on this.
- Mr Gobina asked whether the voltage logger will also have this information.
  - Mr Toyobe replied that yes there will be a GPS feature and the creation of a metadata stream (data installation; season etc.) and that it is possible to build a back-end system for additional system. However, they are looking for ways to keep it simple and can also obtain data using a qualitative questionnaire.
- Mr Gobina noted that PQS would like to come up with an estimate of the number of voltage stabilizers that are failing.

- Mr Toyobe replied that, the project team currently has a statistician that can do this on the team. This capacity can also be moved to 20 different locations to extend the study. Infrastructure will be in place, so it is repeatable.
- Mr Kadambari of UNICEF SD asked whether it is possible for the datalogger supplier to develop a 3-phase logger also?
  - Mr Toyobe replied that at the moment this is out of scope for our study. The voltage loggers was developed specifically for single-phase AVS units.

## Menti question responses

1. What additional field data / information (quantitative and qualitative) will be important to get out of the voltage stabilizers evaluation in Cameroon?
  - a. Historical failure data (not necessarily highly controlled) and associated root cause analysis
    - Response from Mr Toyobe: Data will be collected by leveraging local technicians to conduct RCFA on failed units and share with EPI, manufacturers, and PQS in the final report.
  - b. Momentary peak duration of outage or high/low events
    - Response from Mr Toyobe: Multiple indicators will be collected using the logger (ranging from voltage spikes, voltage sags, power outage and frequency fluctuations).
  - c. Whether proper lightning protection system are installed
    - Response from Mr Toyobe: CHAI will try to obtain this data during set-up and installation, but it may depend on the institutional knowledge of the health teams and district technicians.
  - d. Visibility on the power outage and voltages experienced.
    - Response from Mr Toyobe: This data will be collected qualitatively and quantitatively.
  - e. Any failures of other equipment on each site
    - Response from Mr Toyobe: We will consider this feedback during monthly calls to the health facilities to check if there are any voltage related medical equipment failures besides from the stabilizer and if there is any correlation that can be made.
  - f. How many PQS-prequalified stabilizers are currently failing in the field?
    - Response from Mr Toyobe: We do not know how many have failed this year, but as of 2020 we had reported 5% of CCEOP-deployed stabilizers failing.
  - g. Power consumption; to ensure stabilizer is not overloaded by additional loads (e.g. vacuum cleaners)
    - Response from Mr Toyobe: We encourage only one cold chain device per AVS unit. If we record any sudden spike in power consumption, we will proceed to investigate the cause.
  - h. Whether electrical systems of the sites are inspected and tested at any point?
    - Response from Mr Toyobe: No, this is out of the study scope and should ideally have been done during pre-site installation to determine if the site was suitable to receive an ILR.

**Decision points from this session:**

None.

*Action points from this session:*

- *The study will be concluded in Q3 to Q4 2022.*
- *VS specifications will be published in 2022*

## VII. UNICEF updates

Mr Teshome Yemamu, Mr Jan Komrska and Mr Hailu Kenea of UNICEF SD provided a range of updates on the SD cold chain equipment procurement strategy. They noted the major shifts in CCE equipment demand (32% includes in overall), in large part related to Covid, as well as the changes in the type of equipment demanded. A list of major changes faced in 2021 was also discussed, followed by an update on the LTA tender evaluations of 2021. Lastly, they discussed the participation of 16 countries in CCEOP post-installation inspections (PIIs) and reported on the results pertaining to the quality of the installation service, including where installation services could be improved.

### Discussion

- Mr Yemamu additionally provided the link to the TechNet webinar series on temperature performance monitoring: <https://www.technet-21.org/en/topics/temperature-webinars>
- Mr Toyobe asked whether there was a reason why only extended range AVS will be preferred for ILRs?
  - Mr Yemamu replied that extended type AVS has wide input voltage regulation range (it performs better in areas where the input voltage varies significantly), while standard type supply power to the equipment within narrow input voltage range.

### Menti question responses

No menti questions.

#### Decision points from this session:

None.

#### Action points from this session:

- Concerning energy consumption of mains powered refrigerators and freezers: UNICEF SD will provide the information about energy consumption of every model of mains powered refrigerator/freezer in UNICEF's catalogue. In addition it will be shared with countries for decision before placing order.
- Concerning the latest environmental requirements: PQS shall revise/update the specifications of the foaming agent used as thermal insulation to align the specs with latest global environmental requirements.

## VIII. GAVI updates

*Ms Karuna Luthra of Gavi presented an update to the cold chain equipment optimization platform (CCEOP). She described the CCEOPs steady scale-up since 2017 and progress despite pandemic delays. She noted that there have been significant improvements in country capacity and reach of immunization programmes, contributing to the Gavi 4.0 strategy. Ms Luthra went on to describe how under the new Gavi 5.0 strategy some aspects of the CCEOP have been redesigned, carrying implications for stakeholders. Ms Luthra explained of how the new application and procurement approach will shift to a 3-preferences approach, and concluded with a description of the CCEOP priorities under 5.0.*

### Discussion

- Ms Luthra additionally provided the links to:
  - The CCEOP Technology guide:  
<https://www.gavi.org/sites/default/files/publications/Cold-chain-equipment-technology-guide.pdf>
  - The Gavi CCEOP requirements (noting updates also coming in the next few weeks): <https://www.gavi.org/our-support/guidelines>
  - And the Alliance ILR/SDD Market Shaping Roadmap public summary:  
<https://www.gavi.org/sites/default/files/document/ice-lined-and-solar-direct-drive-refrigerators-freezers-public-summary.pdf>
- One anonymous question was received via the Menti application: will freeze-free passives receive more focused?
  - Ms Luthra replied that freeze-free passives continue to be CCEOP-platform eligible and we have seen significant uptake of these in 2021 in the pandemic context outside of the CCEOP. In 2022 Gavi is conducting analyses to look at which of several product CCE categories may benefit from market shaping support, which will include consideration of freeze-free passives, however no decisions are yet made.

### Menti question responses

1. What CCEOP market shaping or programme information/updates from Gavi would you find helpful in 2022?
  - a. Clarity on the scope of product support – RTMDs +?
  - b. A list of acronyms would be helpful
  - c. Do you reduce the number of spare parts that are not required and encourage the countries to invest that money in the procuring of new equipment?

#### **Decision points from this session:**

None.

#### *Action points from this session:*

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

## ANNEXES

### Annex 1: List of manufacturers invited to the meeting (not participants)

#### **Manufacturers that were invited to the meeting, in alphabetical order:**

B-Medical Systems	New Horizons
B Prolabs	Nexleaf
Berlinger & Co AG	Parsyl
Beyond Wireless	Remonsys
BluLog	Rueger
Budenberg	Runngren
Carrier	Sensitech
Coolfinity	Solar System Services
Deltratrak	Sundanner
Dulas	Surechill
Eiffage	Switrace
Elpro	TempAlert
Foster-Gamko	TempSen
Godrej	TempTime
Honeywell	Vestfrost Solutions
Hurre	Viessmann
Haier Biomedical	Zebra
Ikas	Zero Appliances
LogTag Recorders	Zhendre
Modum	

### Annex 2: List WHO PQS and partner organization participants

#### **Representatives of the WHO PQS Working Group & other non-industry invitees were:**

Isaac Gobina – WHO PQS  
Paul Mallins – WHO PQS  
Maricel Castro – WHO EPI  
Pat Lennon – PATH  
Denise Habimana – PATH  
Steven Diesberg – PATH  
Teshome Yemamu – UNICEF Supply Division  
Thierry Copois – UNICEF Supply Division  
Jacobus Schoevers - UNICEF Supply Division  
Omileye Toyobo – Clinton Health Access Initiative (CHAI)  
Karuna Luthra – Gavi, the Vaccine Alliance  
Jenny Hu – New Horizons  
Steve McCarney – Sunny Day, LLC  
Simon Leach – White Box Thinking  
Rob Rallo – Solar System Services  
Greg Kiluva – Independent Expert

David Lehmann – Independent Expert  
Gemma Huckerby – Consultant to WHO PQS

### **Annex 3: Meeting presentations**

The presentation given for each of the five technical themes and the progress update can be accessed here:

[https://drive.google.com/drive/folders/1pHR\\_sh8tWFAkRqdzuFBjtY4ZrHVI5rLG](https://drive.google.com/drive/folders/1pHR_sh8tWFAkRqdzuFBjtY4ZrHVI5rLG)

## 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.

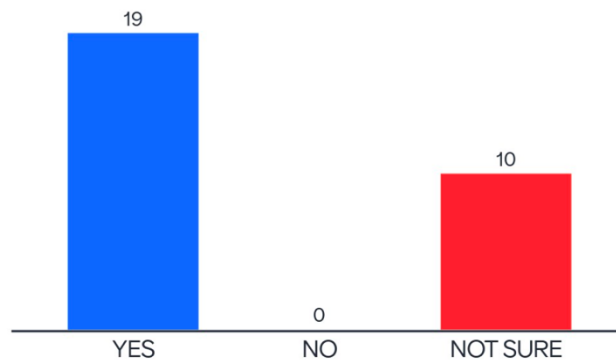
### I. WHO PQS Introduction

None.

### II. Environmental issues & refrigerants

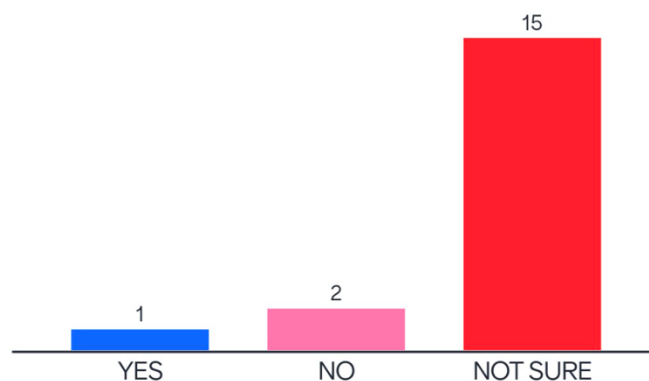
Have you switched already or are you planning to switch in the near future to ultra-low GWP refrigerants and blowing agents?

Mentimeter



Is your equipment under national MEPS and labeling schemes?

Mentimeter





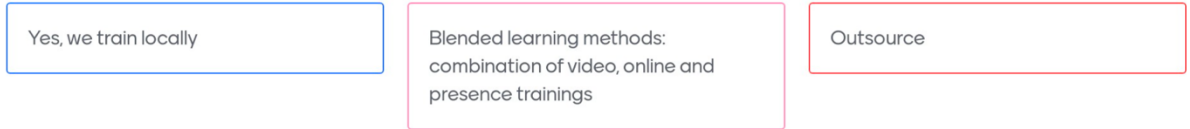
# What is your current practice regarding recycling and recovering of refrigerants of obsolete equipment?

Mentimeter



# How are you ensuring training of technicians regarding service and repair?

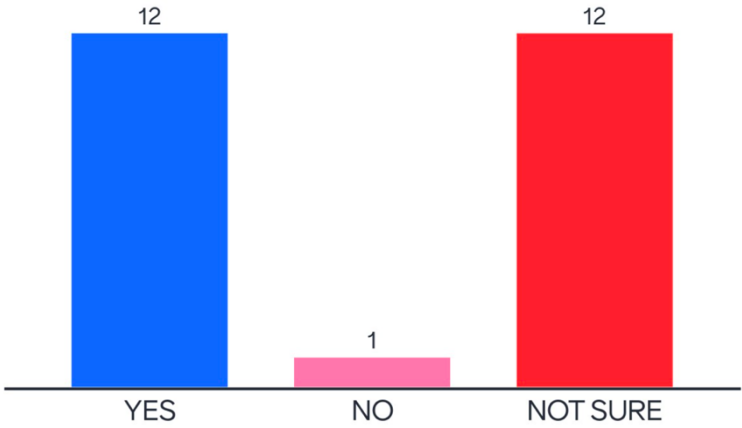
Mentimeter



## II.b Energy efficiency solutions

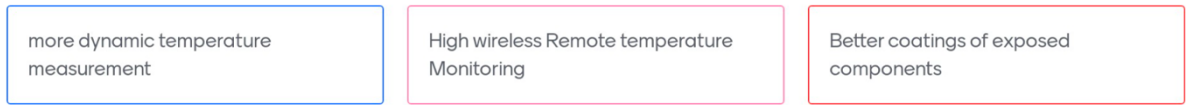
# Is this a fair and useful tool?

Mentimeter



## If not, what suggestion(s) would improve it?

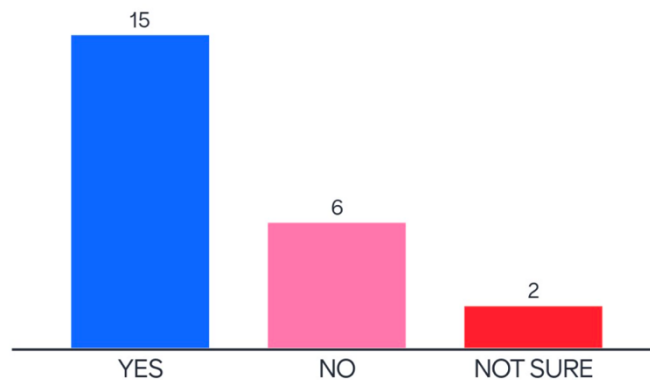
Mentimeter



### III. WHO PQS post market monitoring: corrosion

## Is corrosion reported to you or observed in the field?

Mentimeter



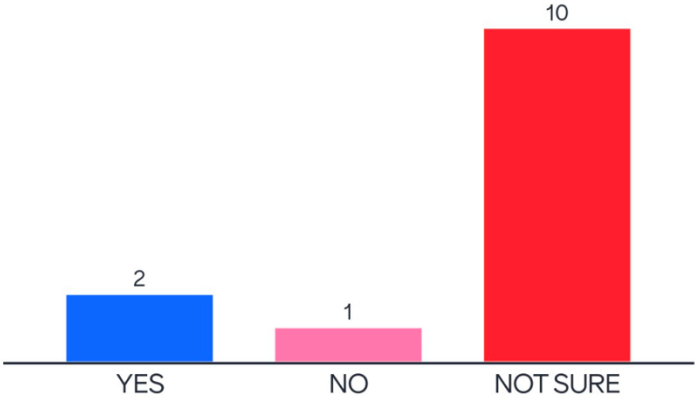
# What are your recommendations for addressing the corrosion issue?

Mentimeter

look for well protected refrigeration circuit in PQS test - Visual inspection	Is the presenter, recommends Blue-fin(Epoxy) or Gold-fin coating for condenser	we will need to look into that
Clarify climatic conditions in the tender phase of the projects	Cleaning Guidelines for the materials	Prescribe materials versus performance specification ( if a test could realistically determine in situ corrosion resistance ).
In country training of end users in basic preventive maintenance.	No, that would limit innovation, define outcome	

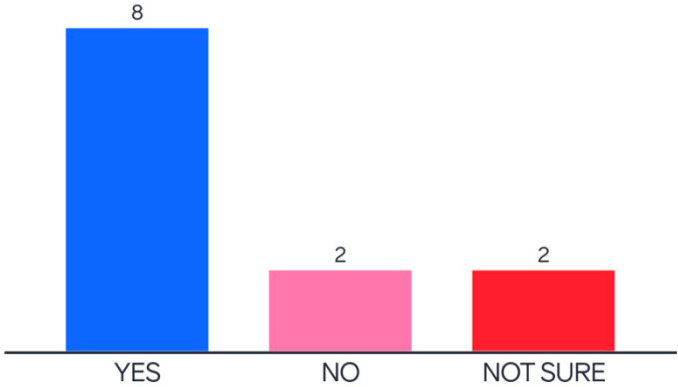
# The tube and fin style of condenser is chosen, should there be requirements for fin spacing?

Mentimeter



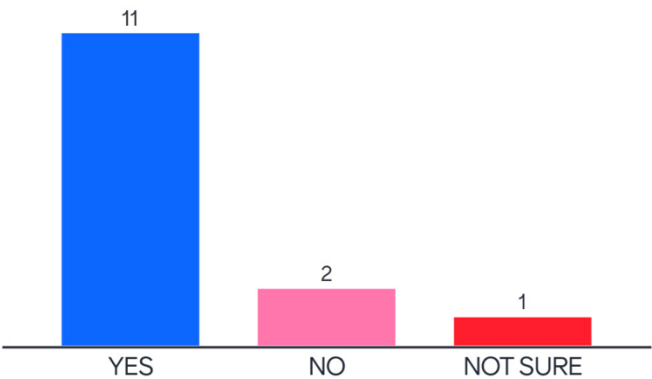
# Should a temperature alarm be used to monitor a plugged coil or fan failure?

Mentimeter



Should easy access for cleaning of the coil be required?

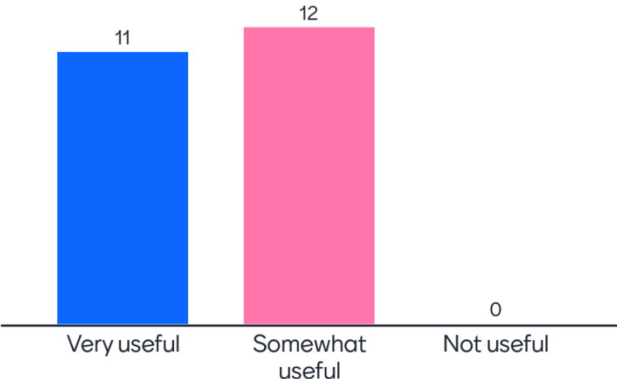
Mentimeter



IV. WHO PQS EMS specifications

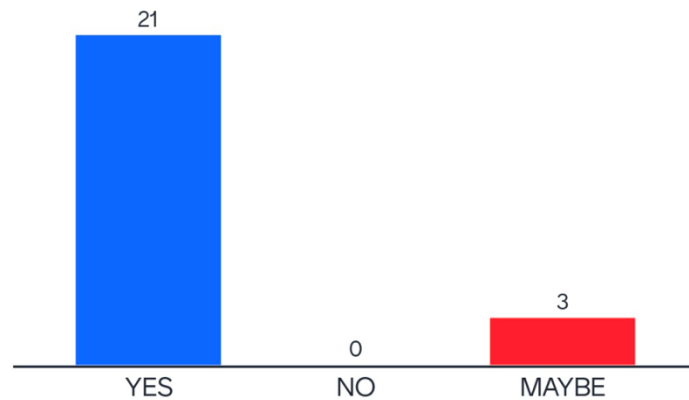
Did you find the Industry Working Group process useful for increasing Industry visibility and input into the EMS spec development?

Mentimeter



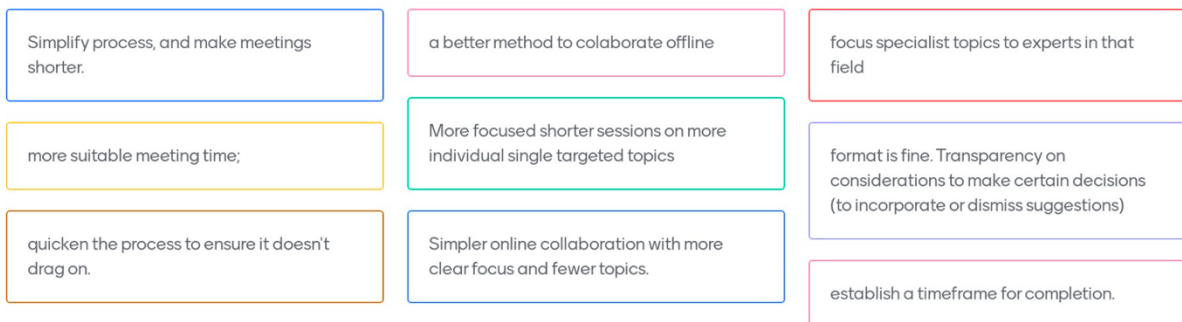
## Would you participate in another Industry Working Group facilitated by PQS for other specifications?

Mentimeter



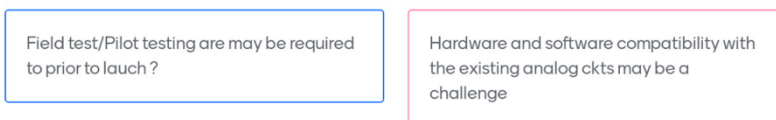
## What improvements would you suggest to the Industry Working Group process?

Mentimeter



## What improvements would you suggest to the Industry Working Group process?

Mentimeter



# What would be most helpful to accelerate adoption of EMS functionality into your products?

Mentimeter

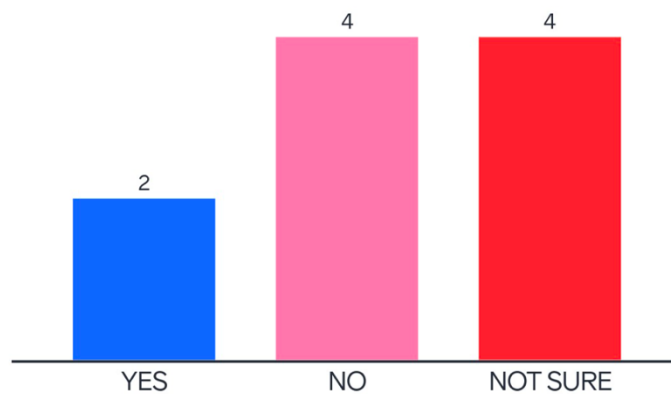
If off-the-shelf products/modules were available	More transparency on market demand published	Procurement fund Support
Availability of final Standard, and assurance the tech specs will not change for next 5 years	one standard for all countries and clients	Need to understand financial impact compared to current RTMD's
EMS combine with temperature controller available.	@Brian + Isaac: indeed stability of specs.	changes should be forward and backward compatible

## V. WHO PQS Specifications updates

### a. Solar direct drive cold rooms specification & field study

# Could your company meet these specification or test requirements in 2022?

Mentimeter



## If no, what would prevent your company from meeting the specification or testing?

Mentimeter

This is very new so some grant funding is needed

Out of our current product range.

IN general it is interesting, but a new technology. So we need an attractive quantity. So we need to analyse if there is more demand for this kind of application

### b. Voltage stabilizers PQS specification

## What additional field data/information (Quantitative and Qualitative) will be important to get out of the voltage stabilizer evaluation in Cameroon?

Mentimeter

Historical failure data (not necessarily highly controlled) and associated root cause analysis

It'd be great to see the power outage and voltages experienced

power consumption will also be good to ensure stabiliser is not overloaded by additional Loads (vaccum cleaner etc)

momentary peaksduration of outage or high/low events

Good to log any failures of other equipment on each site.

Are the electrical systems of the sites inspected and tested at any point?

can each site flagged whether proper lightning protection system is installed or not?

Do we already know how many of these PQS stabilisers are currently failing in the field?

## VI. UNICEF updates

None.

# VII. Gavi Cold Chain Equipment Optimization Platform Update

What CCEOP market shaping or program information/updates from Gavi would you find helpful in 2022?



clarity on the scope of product support - RTMD's +?

Will Freeze free passives be focused on more?

A list of acronyms would be helpful!

Do you reduce the number spare parts that are not required and encourage the countries to invest that money in the procuring of new equipment.