

Landscape Analysis

Cool Chain Technologies

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Batiment Avant Centre
13 Chemin du Levant
01210 Ferney Voltaire
France

Phone: 33.450.28.00.49
Fax: 33.450.28.04.07
www.path.org
www.who.int

OPTIMIZE

Immunization systems and technologies for tomorrow



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Table of contents

Background	1
Objectives and activities	2
Major findings.....	3
Impact of expanding vaccine storage requirements.....	3
Impact on reception and primary storage	4
Impact on intermediate storage and distribution	6
Impact on peripheral storage and outreach.....	8
Impact of changing energy preferences	9
Opportunity to upgrade information technology	11
Cool chain MIS applications	11
Temperature monitoring oversight.....	12
Product identification and counting	13
Use of PDAs.....	14
Need to streamline WHO’s PQS process	15
Conclusions and next steps from the Optimize Cool Chain Technologies meeting	15
Primary storage.....	15
Transport.....	16
Health center.....	16
Outreach	16
Information technologies.....	17
PQS system.....	17

Background

Technologies related to the temperature control of vaccines during the distribution process are essential to the cool chain today, and until all vaccines and drugs are entirely thermo-stable, will be essential in the future. Typically, the quality of domestic and commercial cooling equipment is regulated in the country of manufacture. To ensure the appropriateness of this equipment for use with vaccines in the developing world, the World Health Organization (WHO) Department of Immunization, Vaccines, and Biologicals developed the Performance, Quality, and Safety (PQS) system of norms and laboratory-verified prequalification. Included are the following categories and subcategories of equipment:

- Refrigeration (E01, E03, and E07).
- Passive cooling (E04, E05, and E11).
- Temperature monitoring (E06).

The PQS system requires manufacturers to submit product dossiers demonstrating compliance with a set of performance criteria. Once prequalified, the equipment is catalogued on a WHO website and available for countries and their external partners to browse. Equipment that is not listed in the PQS catalogue is not recommended for purchase or use in immunization settings.

From the viewpoint of the Optimize project, there are three issues affecting the near and distant future that need to be addressed by this landscaping activity:

- Most of the equipment now listed in the PQS catalogue is in a period of transition from WHO's previous Product Information Sheet (PIS) specifications to the new requirements of PQS. Unless manufacturers supply the necessary prequalification dossiers by deadlines already set by WHO, their equipment will be removed from the list. Today, only the equipment that has met PQS norms is ensured continued recommendation; the rest is not yet known.
- A handful of European manufacturers dominate the 49 refrigerators and/or freezers and the 47 cold boxes/vaccine carrier models currently listed in the PIS. Although one-third of these models are powered by solar photovoltaics, they represent only a very small percentage of sales. It is clear that more effort is needed to expand the selection of PQS-qualified manufactures and to make solar photovoltaic technology a more important part of cool chain equipment procurement.
- The design and capacity of the cool chain is changing fast to accommodate new vaccines, single-dose presentation options, and new delivery systems. Preferences are also changing as energy costs soar, environmental issues evolve, and vaccine handling policies switch focus. Finally, rapid evolution of information technologies has opened opportunities to improve the management and monitoring of the cool chain.
- The PQS system includes mechanisms to establish new performance specifications and conduct field tests of equipment to assess their adherence to these qualifications. However, few human or financial resources have been devoted to the proactive identification of evolving cool chain equipment needs or to advocacy in the equipment manufacturing industry. To date, the modification of products to meet the needs of immunization settings and the creation of new product profiles has been left largely to the countries themselves and their external partners.

Objectives and activities

The goal of this landscape analysis is to inform the Optimize project on the current availability of cool chain technologies, the expected availability within five years, and the projected availability by 2025. Specific objectives of the activity are:

- To anticipate the characteristics of cool chain equipment that will be needed in 2012 and 2025 and to assess, in broad terms, the need for modified or new performance specifications.
- To forecast the availability of cool chain products that are likely to meet PQS requirements at or soon after the WHO deadlines for submission of dossiers by category and by climatic zone.¹
- To seek equipment not yet PQS-qualified that appears to potentially meet the needs of the cool chain.
- To assess evidence of the comparative whole-life cost and performance of different models of equipment to identify “best-buys” in relation to current and future needs.²
- To review, in broad terms, the strengths and weaknesses of the current PQS performance specifications by category and anticipate probable demands for cool chain equipment in the future.

In order to meet the above-mentioned goals, the following activities were undertaken:

- Assessed the trends affecting the future design and equipping of the cool chain.
- Arrayed all equipment products existing in the PIS (WHO website) and prioritized manufacturers based on the number of products they currently have listed.
- Visited the top-priority companies to assess their intention to meet the PQS deadline, evaluated their product pipeline to determine if new technologies of interest are on the horizon, and determined any evident trends from manufacturer activities.^{3,4}
- Evaluated cost and performance of different models of existing equipment based on energy consumption and capacity.
- Analyzed the available models of existing equipment against projections of vaccine volumes accounting for the rollout of new vaccines into the Expanded Programme on Immunization (EPI) programs. Assessed the gaps that might exist between future needs and existing equipment choices.
- Conducted a cool chain technologies summit meeting to bring together various experts and stakeholders; presented findings from manufacturer visits and existing product analysis; and engaged in group analysis of future preferences for cool chain equipment and system performance including considerations of energy, capacity, and the environment.

¹ Subcategories: E01, E03, E04, E05, E06, E07, E11.

² “Cool Chain Futures,” presentation to Cool Chain Technologies meeting 10-11 June 2008.

³ Top-ranked companies according to the number of equipment models that they offer in the current PIS system: Vestfrost in Denmark, Dometic in Luxembourg, Huurre in Finland, Sibir in Sweden, Bright Light Solar and Dulas in the United Kingdom, and Zero in South Africa. Additionally, two US solar manufacturers were contacted for phone interviews: SeaFreeze (manufacturer for Kyocera) and SunFrost.

⁴ Refrigerator/Freezer Manufacturers Interviews Project, OPTIMIZE PATH Consultant, Steve McCarney, 4 June 2008.

These landscaping activities are being used to develop a plan of action for the Optimize project in conjunction with other WHO and PATH initiatives to prepare for a successful future of distributing and managing vaccines.

Major findings

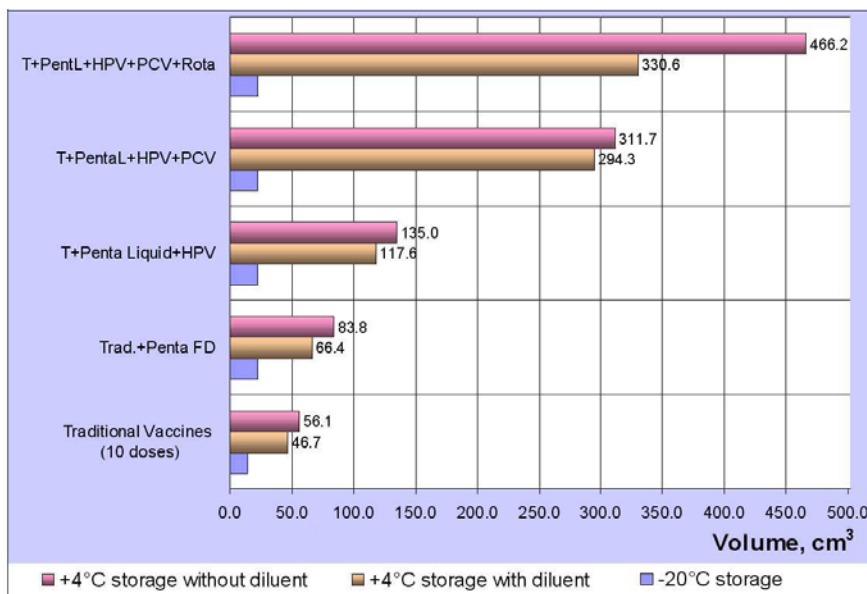
Through this landscape analysis, four major findings have been identified:

- Impact of expanding vaccine storage requirements.
- Impact of changing energy preferences.
- Opportunity to upgrade information technology.
- Need to streamline WHO’s PQS process.

Impact of expanding vaccine storage requirements

In the next few years the volume of vaccines that need to be managed in the EPI cool chain is expected to expand dramatically. Figure 1 illustrates the packed vaccine volume requirements of five scenarios of immunization schedules from the traditional vaccines in scenario 1, to schedules containing up to four additional new vaccines as shown in scenario 5. The volumes are expressed per fully immunized child using the WHO vaccine calculator.

Figure 1. Vaccine (packed) volumes per fully immunized child (FIC)



As demonstrated in Figure 1, there is an expansion of refrigerated vaccine volumes of eight to ten times as one progresses from scenario 1 to 5. This estimate is conservative, taking into account only vaccines emerging from the development pipeline in the next few years and not considering vaccines with only regional coverage such as Japanese encephalitis, meningitis, and yellow fever.

The estimated impact of this increase in storage volumes on the cool chain can be seen at three stages of the distribution system: reception and primary storage, intermediate storage and transport, and peripheral storage and outreach.

Impact on reception and primary storage

The volume of vaccines needing to be refrigerated at the primary storage level will increase almost eight-fold and will require an increase in quantity and/or size of cold rooms. The existing cold room equipment in national stores and, typically, the province/regional stores will need to be expanded, and cold rooms will be chosen over refrigerators at a larger number of lower-level intermediate stores. This new requirement raises the following issues:

- Vaccines may no longer be stored in their insulated packaging (as is the practice in some national stores today), which raises the issue that secondary packing may be too small for convenient handling. Shrink-wrap bundling, as already done for pharmaceuticals, may now be necessary.
- When vaccines are unpacked, secondary packaging may need to be placed on pallet and handled with vehicles such as forklifts in larger cold rooms.
- Shelving systems (today 47 cm deep, not suitable for pallets) will need to be installed throughout the cold room, not just against the walls as is the practice today.
- Today's maximum standard (PQS) cold room is only 40 m³, requiring two rooms for a six-month supply of vaccines for 10 million people. Larger countries will require larger cold rooms, necessitating a new PQS specification for rooms over 40 m³ (see Figure 2).
- Above 40 m³, cooling systems are split (evaporator, condenser, and compressor set) instead of being in one unit: this raises the cost and the maintenance burden.
- Cold rooms are less likely to be "squeezed" into existing ministry of health buildings as they may require warehouses with ceiling suspension support for larger cold rooms.
- Power requirements and sufficient standby generation capacity will be greater than today—a higher investment and a higher running cost.
- Installation services and long-term maintenance contracts will become mandatory to ensure reliability. While manufacturers currently are only involved occasionally, they will need to become more involved in every installation and its required servicing.
- Existing freezer rooms that are no longer needed after changes in requirements can be kept at 4°C by adjusting the condenser/compressor settings.

Figure 2. Impact on cold room size



The volume of single-dose vaccines, particularly when integrated with a delivery device (e.g. the Uniject™ device), may challenge current practices of shipping insulated packages by air freight due to high volume. This problem has been addressed by the commercial sector with a particular focus on important air shipment routes by a container system with specific carriers (Emirates), as shown in Figure 3. The system uses high-performance vacuum panels as insulation for a container that maintains 2°C–8°C for up to nine days.

Figure 3. Air shipment of large volumes at chilled temperatures



Impact on intermediate storage and distribution

The pressure on intermediate stores may be addressed in two ways—expansion of quantity or size of refrigerators, or through more frequent deliveries from primary stores:

- Step-in cold rooms (approx. 1.2 m³ net) may be a better choice than refrigerators in stores where there is 16–24 hours of electricity and where there are standby supplies.
- New models of ice-lined refrigerators (ILRs) will be introduced to meet the PQS by March 2009. These models will not freeze vaccines in any storage area and will be fitted with fixed thermostats not adjustable by the user. The current ILR models will be used in a large number of smaller stores in more voluminous vaccine scenarios.
- New models of ILRs were discussed with manufacturers based on larger gross capacities of 400 liters. Larger capacities will enable ILRs to be used in stores where a cold room would otherwise be necessary.
- Vaccines may be distributed more frequently and more successfully through distribution systems rather than collection systems. In the distribution system, it is the upper-level store that is responsible for delivering the vaccines. Under these circumstances, there is the potential for delivery trips to be combined with supervision and monitoring visits.

Vaccines are now typically distributed in cold boxes of around 20–25 liter capacity—with 15 liters occupied by icepacks—using non-refrigerated vehicles. Only countries with large regional populations currently use refrigerated transport, which has a high maintenance burden particularly where the road infrastructure is poor. The volume of vaccines envisaged for distribution in scenario 5 is so vast that cold boxes, in many circumstances, will no longer be appropriate. One problem with current cold box design is that due to extensive insulation, their external volume is up to six times the net volume of packed vaccine. Instead, it may become more practical and economically efficient to pack vaccines in a refrigerated vehicle or “reefer” (refrigerated container), or in large volume (1.2 m³) containers. These containers (Figure 4) are already manufactured and used for distribution of chilled food in supermarket chains in Europe, either by active refrigeration onboard or through passive cooling by eutectic-filled pre-frozen panels that are inserted with the produce.

Figure 4. Examples of passive container systems



These containers (on rolling wheels) may either be loaded onto trucks several at a time using tail elevators, or bolted into the back of pick-up and double-cab vehicles. The wider use of such container systems raises the following issues:

- In areas where roads are bad, active refrigeration on insulated trucks is unreliable and has a high maintenance burden for the system. Passive containers have a lower maintenance burden and should be evaluated for use in the cool chain.
- For smaller vaccine requirements, such as outreach services in very remote areas, reciprocating compressor refrigeration systems specifically developed for vehicles are offered by one manufacturer and should be evaluated.

Lessons can be taken from countries that have already begun to expand their vaccination schedule, including several countries in the Americas region that have started to introduce rotavirus and pentavalent vaccines and also deliver regional vaccines in addition to standard global childhood vaccines.

Impact on peripheral storage and outreach

Table 1. Impact of expansion on peripheral storage

Cooled vaccine storage volume per FIC and by population size (with diluent)

Vaccine schedule	Packed vol/FIC	5K pop/ 5 weeks	15K pop/ 5 weeks	50K pop/ 5 weeks
	Cms ³	Liters	Liters	Liters
Traditional: OPV, BCG, TT DTP, MEA	56.1	0.9	2.8	9.4
Traditional, with Pentavalent FD	83.8	1.4	4.2	14.1
Traditional, Pentavalent Liquid, HPV	135.0	2.3	6.8	22.7
Traditional, Pentavalent Liquid, HPV, PCV	311.7	5.2	15.7	52.4
Traditional, Pentavalent Liquid, HPV, PCV, and Rotavirus	466.2	7.8	23.5	78.4

Key: FIC=Fully immunized child, K pop=population in thousands

Table 1 shows that in the smallest health facilities—those serving a population of 5,000 or under—small refrigerators with less than 10 liters of vaccine capacity will be sufficient, even in scenario 5. The storage requirement for an average-sized health center will be much greater (approx 30–60 liters), and fortunately the trend among manufacturers has been to develop larger-capacity refrigerators that tend to meet the new requirements for storage space. Several factors may moderate the demand for health center refrigeration in the future:

- “Out of the cool chain” policies may permit certain vaccines to be stored in a controlled ambient temperature for limited periods instead of in a refrigerator at the health center.
- High-performance insulated containers with a replaceable or rechargeable cooling device may be used instead of refrigerators to provide passive cooling for vaccines.
- Intermittent active cooling devices—such as the Zeolite system illustrated in Figure 5—may provide cooling on demand, either in the health center or during outreach.

Figure 5. Prototype “Zeolite” intermittent cooler for passive containers



As vaccine volumes rise, so does the demand for icepacks or chilled water packs to cool vaccine in conventional carriers during outreach immunization. Table 2 suggests that the weight of vaccine carriers with sufficient vaccine capacity for scenario 5 may be too high to conduct outreach without porters or vehicles. For this reason, more human resources may be required for outreach, or refrigerators may be installed on vehicles or animals for long-range outreach services in order to carry the weight of ice or water packs with the vaccines.

Table 2. Weight of ice/chilled water packs for outreach services

Vaccine carrier products	Capacity Liters	Vol/FIC Sc. 5 Cm ³	Number of FIC served	Population (4 wk supply)	Cold life hours at 43°C	Weight Kgs
Blow Kings E4/83M	1.7	466.2	4	1250	36	4.5
Dometic E4/85M	5.3	466.2	11	3898	49	13.8

Key: FIC SC.5=Fully immunized child (FIC), scenario 5

Impact of changing energy preferences

Wherever there is sufficient grid electricity (more than 8 hours per day), the most energy-efficient solution remains the ILR. Vertical, front opening ILR products are now in development for those countries that prefer to manage their vaccine storage on shelves rather than in baskets. ILRs provide the best security for vaccine storage, and the cost of running them is minimal. A cost study in Indonesia showed that ILRs have the lowest whole life costs of all alternatives tested.⁵ Table 3 illustrates the low annual running cost per unit storage volume of ILRs in contrast to absorption type refrigerators when powered by electricity. Where there is some electricity (grid or generated), there may be potential for creating hybrid ILR installations using the available hours of electricity in tandem with solar energy.

⁵ Widjaya A, Santoso W, Moniaga V, et al. *Report on Evaluation of Alternative Refrigerator Models for Primary Health Facilities*. Seattle: PATH; 2006.

Table 3. Annual energy costs for different types of refrigerator

Type/Model/PIS code			Vaccine storage capacity at +4°C	Energy consumption/24hrs		Cost/24hrs	Cost/year	Cost/year /liter vaccine stored
			Liters	Value	Units	\$US	\$US	\$US
1	Ice-lined refrigerator/icepack freezer	TCW2000 (E3111M)	76	0.55	kWh/24h	0.15	54.20	0.71
2	Ice-lined refrigerator	MK204	63	0.6	kWh/24h	0.16	59.13	0.94
3	Absorption refrigerator/icepack freezer	V170GE (E3/84M)	55	0.6	kg/24h	0.51	186.15	3.38
4	Ice-lined refrigerator	MK144	40	1.41	kWh/24h	0.38	138.96	3.47
5	Absorption refrigerator/icepack freezer	RCW50EG/CF (E3/88M)	24	0.43	kg/24h	0.37	133.41	5.56
6	Ice-lined refrigerator/icepack freezer	MK074	20	1.62	kWh/24h	0.44	159.65	7.98
7	Absorption refrigerator/icepack freezer	RCW50EG/CF (E3/88M)	24	2.5	kWh/24h	0.68	246.38	10.27
8	Absorption refrigerator/icepack freezer	V170GE (E3/84M)	55	6.3	kWh/24h	1.70	620.87	11.29
9	Absorption refrigerator/icepack freezer	RCW42EG/CF (E3/21M)	10	1.6	kWh/24h	0.43	157.68	15.77
10	Absorption refrigerator/icepack freezer	RCW42EG/CF (E3/21M)	10	0.7	kg/24h	0.60	217.18	21.72

ILRs are superior to domestic refrigerators in performance and security of vaccines, and they also provide a superior level of security at a lower price than pharmaceutical refrigerators in conditions of intermittent electricity. ILR models now exist with steel cabinets and foamed-in evaporators at a low price and with rotation-molded cabinets and removable or renewable evaporators at a higher price. The trade-off in lifetime and repair costs against price has not yet been evaluated.

In situations where there is no electricity, preferences are likely to change. Absorption type refrigerators and freezers that are powered by bottled gas, kerosene, or electricity must now meet the same performance standards as compression electric systems under the new PQS requirements. Manufacturers of absorption equipment have stated that their kerosene-powered models will not meet the new requirements in a number of respects including holdover time, day-night testing, and user control of the thermostat to compensate for changing ambient temperatures. Kerosene-powered models are now very rarely purchased for use in the cool chain, and their performance shortcomings are widely known. Recently, during the Optimize Cool Chain Technologies meeting, it was recommended that they be banned from use for vaccine storage.

Gas-powered models are also affected, though to a lesser extent, and it is possible that with changes to the test procedures these models may meet the PQS for temperate and moderate zones. The strategic implications of this are:

- Solar photovoltaic (PV) is the only alternative to kerosene where no access to electricity or gas is available. Kerosene models may be discontinued beginning in March 2009 under the PQS if there is consensus that solar PV systems are an acceptable alternative.

- Gas is still widely used, although gas prices and pilfering make gas-powered refrigeration the most expensive option over a 10-year period—more than grid electricity and battery-free solar options. Cost data to support this statement exist but needs to be updated and more widely collected.
- PV systems, particularly battery-free ones, have the potential to be supplied by hybrid solar power and grid electricity (via an inverter) in areas where some electricity (less than 8 hours) exists and where solar radiation is lower than the autonomy of a PV system. This needs further evaluation in the field.
- PV systems that use batteries require, in many countries, special arrangements to ensure the batteries can be imported and replaced. All PV systems, both with and without batteries, require electrical maintenance services to remain in use. Experience with both of these issues has been problematic.

Opportunity to upgrade information technology

Modern information systems and technology are critical to the high-efficiency logistics systems that now exist in industrialized countries. The cool chain for vaccines in developing countries has been managed with little use of information technology (IT) hardware and software in the past, and poor communications have hindered the transfer of information to various levels within the system. Today, the symptoms of management with insufficient information are seen in the weak performance reported in Optimize landscape analyses from country evaluations. IT remains a necessary but not sufficient criterion for a successful management system.

Information systems and technology are needed in the following managerial processes of the vaccine cool chain:

- **Vaccine and supplies management.**
 - Transactions: order-tracking, forecasting, scheduling.
 - Temperature control: recording, alarms, monitoring.
 - Product recognition, auto-stock counting.
- **Equipment inventory management.**
 - Survey, forecasting, tracking changes, repairs monitoring, operating costs.
 - Product recognition.
- **Transport management.**
 - Scheduling trips, maintenance.
 - Monitoring utilization, consumption, cost, repairs.

The following four types of hardware and software have been discussed during manufacturer visits, during other Optimize landscape analysis debates, and during the Optimize Cool Chain Technologies meeting:

Cool chain MIS applications

There has been broad agreement that software applications are needed to help manage vaccines and supplies, cooling equipment, and transport in all developing countries. A recent review of existing software applications being used for immunization logistics has revealed that all but three applications were Excel-based. The review also revealed that all were stand-alone applications with limited networking capability. They lacked the ability to transfer data to cellular telephones and handheld computer personal digital assistants (PDA) or reading

devices.⁶ The WHO review also showed that few applications are released with accompanying user-friendly instruction manuals.

The advantage claimed for open-source applications of this kind has been that IT support in country has the ability to modify, maintain, and sustain the software in use. Experience seems to suggest, however, that local IT resources are scarce, data corruption is frequent, and as local versions diverge from the original, external international support becomes impractical.

Two important conclusions were reached during discussions at the Cool Chain Technologies meeting:

- Further investigation is needed of the software packages now available on the market that may meet some or all the needs of the cool chain. It was noted, however, that these are typically proprietary to third-party logistics (3PL) companies and large retailers and, if publicly available, they are expensive and sophisticated.
- As an alternative to the current strategy of developing and promoting open-source applications using Microsoft Access, a more modern online platform (MySQL/PDP/Ajax) might be adopted, offering a standard set of vaccine supply chain functions on a nationally or internationally maintained database. Such a system would provide for cellular telephone or computer updating, and would integrate product recognition tools and temperature monitoring.

Temperature monitoring oversight

Continuous temperature monitoring with alarm systems is already required by PQS in cold rooms used to store vaccines. However, the requirement is usually implemented separately, appliance by appliance, and is often simply a paper chart recorder with local or telephone alarm functions. In contrast, three of the refrigeration manufacturers that were visited offered proprietary systems for centralized temperature logging systems for all appliances at a single site, in addition to a centralized system for all appliances at multiple sites.

The use of a facility to monitor multiple primary stores, including the central store and all stores at the next level, offers the following advantages over the current systems in use:

- Monitoring of multiple temperature points in each appliance (usually 2–4) to detect low- and high-temperature areas. Reports would be available and possibly integrated with stock reports.
- Telephone alarm systems would be centralized and the alarm messages would refer to specific appliances and give explicit problem modes.
- Central monitoring of appliances at multiple sites would provide oversight to the local monitoring process, making it more secure and ensuring better compliance.

Continuous temperature recording is recommended but not required by the PQS at levels below the primary stores. At this level, only thermometers are required on each appliance. A low-cost electronic recorder (FridgeTag by Berlinger, Switzerland) is available in the PQS

⁶ Consultation on Effective Vaccine Stock Management & Cool Chain for New Vaccine Introduction, WHO, Leysin, Switzerland, 16–18 June 2008.

for monitoring temperatures over a month and provides alarm threshold recording and display. More research needs to be done to determine if it would be technically possible to install multi-site “oversight” for health facility refrigerators using automatically generated short message service (SMS) messages from a cellular telephone linked to such a recording device.

Centralized temperature monitoring for multiple health facilities or primary stores may help to improve the weak manual monitoring systems that are currently in place and provide better historical information to assess failures after they have taken place. However, the question remains whether remote monitoring would, in practice, trigger appropriate and effective response at the time of the failure.

Product identification and counting

Vaccines, supplies, and cooling equipment need to be identified and counted in order to be effectively managed. Vaccines are already identified at the level of primary and secondary packaging by proprietary printed labels, though format and languages vary. The following issues with the current system need to be addressed:

- Secondary packing has been sized for multi-dose vaccines. As new vaccines in single-dose presentations are more widely introduced, secondary packs will need to grow, or tertiary packaging of these secondary packs will be needed inside the outer insulated packaging.
- The current secondary packs typically hold 10–25 doses, a quantity that will usually reach the health center without breaking down. Such packaging would be suitable for an international bar code, standardizing all the essential information for the vaccine manager and permitting a readout in the local language.
- Physical stock-counting of vaccines is universally poor, according to the latest landscape analyses of cool chain practice in developing countries. If the secondary packing was labeled with a radio frequency identification (RFID) tag instead of or in addition to a bar code, the vaccine stock could be monitored by scanning the store with a portable wireless reader or by use of a reading station upon entry and exit to the store.
- RFID tags (see Figure 6) are also capable of temperature recording, allowing for a history of each secondary package to be maintained in stock records alongside the stock data. The cost-benefit of this extension of the use of RFID tags would need to be further investigated before a decision is made to test it.

Figure 6. Example of an RFID label and handheld scanner



Cooling equipment, including refrigerators and freezers, also needs to be identified so that a complete inventory of equipment can be maintained. An accurate inventory is essential for forward planning of equipment needs and for monitoring equipment movement and repair. Visits made to refrigeration manufacturers confirmed their unanimous use of bar code systems to identify refrigerator products. Some manufacturers also repeat these bar codes on the outside of the packing so they can be read without opening the package on arrival.

An internationally standardized bar code system would greatly assist in registering new equipment on arrival, updating equipment inventories, tracking new purchases, and identifying the need for new equipment in the field. The current bar codes in use conform to the general European standard but vary in the content of the code.

Use of PDAs

Experience with the use of PDAs for survey work or data collection for research in developing countries has been generally very encouraging. Experience in routine applications has been less successful, but is improving as devices become more suited to tough environmental conditions and as the user interface facilitates a lower training burden.

PDAs have application in the following procedures within the vaccine cool chain:

- Product identification (in association with bar code readers and RFID scanners).
- Inventory transactions (equipment arrival, movement, repairs, withdrawal).
- Selection of vaccine supplies, physical stock count in warehouses.
- Distribution and transport tracking (in association with a global positioning system), vaccine/supplies issues.
- Registration of births and immunizations.

Need to streamline WHO's PQS process

During the visits to manufacturers, a number of concerns were voiced about the current PQS system. Among them were the following:

- Unless manufacturers have equipment that is defined in PQS specifications, there is not a well-documented path for their products. This is a barrier for potentially useful new technologies to reach developing-country cool chains.
- There are currently not sufficient WHO accredited labs to manage the testing load for PQS submissions. Manufacturers with high-performing internal labs would like to be able to test onsite, perhaps with a third-party observer.
- At least one manufacturer of absorption equipment noted that the PQS for that category seems restrictive and that vaccine vial monitors (VVMs) may allow for a less-restrictive cool chain. Manufacturers of absorption equipment agree that kerosene-powered equipment will not pass the current PQS specifications.
- Feedback from buyers is seldom received, though manufacturers are eager for information from customers.
- One manufacturer who had submitted a request for review was discouraged by the lack of communication from PQS over many months. He bemoaned the lack of a customer service person at PQS that he could call and readily ask questions and discuss strategies.
- Some manufacturers consider the PQS process to be prohibitively intimidating, and because they do not attempt to receive qualification their technologies are not available to developing-country markets.

Many of the frustrations voiced by manufacturers are shared by staff administering the PQS system. Unfortunately, this function within WHO is under-financed and thus under-staffed.

Conclusions and next steps from the Optimize Cool Chain Technologies meeting

Due to the addition of new vaccines, a dramatic increase in storage capacity requirements is unavoidable. While the landscape analysis has identified possible solutions and new processes to mitigate the demands that will be put on the cool chain, much still needs to be learned before we can begin demonstrating these solutions in countries. Following are next steps to evaluate solutions at each level of the cool chain.

Primary storage

- Evaluate the feasibility and desirability of wrapping and using bar codes on secondary packing for palletted central storage.
- Prepare a planning/design guide for larger primary stores and explore the advantages and disadvantages of larger primary stores (e.g., 200 m³) versus multiple smaller stores (e.g., 40 m³).
- If larger stores are more cost-effective, consider multi-level storage (smaller plot of land needed, less heavy equipment).

- Explore the possibility of outsourcing primary storage and/or primary distribution to 3PL companies via a private-sector tender. Examine the potential for regional repacking and distribution “hubs” for groups of countries (similar to Suva, Fiji).
- Select country collaborators for demonstration projects that are planning to or have made the decision to introduce new vaccines.

Transport

Considering the increased cost of air freight and large volumes:

- Explore the feasibility of active and passive refrigerated containers for international transport of vaccine by air, boat, or rail.
- Explore passive cooling containers with eutectic plates (e.g., Dometic/Intermarché types).
- Prepare specifications and circulate broadly; explore what already exists.
- Demonstrate systems of in-country distribution integrated with supervision and monitoring rather than collection.
- Explore the potential for outsourcing and opportunities for back-transporting other products to recoup some of the costs of the return trip.
- Analyze the advantages and disadvantages of active and passive refrigerated vehicles.
- Develop interactive modeling to optimize the vaccine distribution system design.
- Determine appropriate standards and qualifications of outsourcing distribution systems.

Health center

Explore solar PV battery-free refrigerators and hybrid battery free systems:

- Develop detailed performance specifications for battery-free systems.
- Collect the public information and documentation on SolarChill research.
- Design a program to provide an incentive for companies to develop new solar refrigerator products to meet the PQS specifications, with possible use of funding from HealthTech, Health Innovation Portfolio, or/and other projects.
- Circulate the information above broadly to refrigeration manufacturers, including a target list of manufacturers with known interest.
- “Ban” the use of kerosene absorption refrigerators for vaccine storage.
- Explore US (and other) large refrigeration companies that have not been in the market for vaccine cooling technology to date.
- Explore whether there are sites where passive cooling or simple heat protection containers make sense at health care level these new vaccines could:
 - Augment refrigerator volume for more stable vaccines.
 - Protect from heat where out of cool chain (OCC) is used.

Outreach

- Gather data on outreach sessions—sizes, distances, and needs—to better understand the storage volume requirements evolution:
 - Review existing PATH studies on outreach sessions.

- Collect data from countries that have introduced rotavirus vaccine, for example among the PAHO countries. Is it causing decrease in outreach activities?
- Do diluents need to be cooled before reconstitution?
 - For all vaccines? For multi-dose vs. single-dose vaccines?
 - Check PATH archives for existing reports on outreach studies about chilled water packs.
- Develop specifications for research and development (R&D) for active cooling devices for reconstituted vaccines operating without batteries.
- Develop specifications for R&D for controlled ambient temperature carriers for heat protection without batteries.
- Include out-of-cold-chain exploration in demonstration projects.

Information technologies

- Explore central and remote temperature monitoring and reporting.
- Identify technologies available for vaccine stock management or examine the whole system and identify specific improvements to demonstrate.
- Further investigate the feasibility of using RFID/bar code:
 - Demonstrate bar code for stock management.
 - Gather more data on RFID and determine feasibility of demonstration.
 - Determine what manufacturers other health programs are using.
- Further investigate software for immunization MIS:
 - Encourage continued work on Cool Chain Equipment Maintenance (CCEM), vaccination supply stock management (VSSM), SMT, other tools.
 - Explore long-term sustainability.
 - Determine which functional improvements (internet connectivity, for example) are necessary.
 - Seek recommended business models for introduction and ongoing support.

PQS system

- Support the establishment of mechanisms to allow PQS to evolve over time:
 - Develop new specifications to recognize emerging technologies, including portable active cooling devices, to achieve controlled ambient vaccine storage in the field.
 - Develop new specifications to meet evolving needs including cooling chilled water packs, transportable passive-cooled container systems, and portable refrigeration systems.
 - Improve the mechanism to obtain feedback from the field on the performance of equipment; explore equipment for remote monitoring of equipment in the field.
 - Explore human resource aspects of the maintenance of the PQS system.
 - Explore systems/mechanisms to get information back to manufacturers; TechNet may be one option.
 - Link applications such as CCEM with the PQS database so that WHO prequalified specifications can be updated automatically.
 - Make prequalification to the PQS system easier for manufacturers in order to encourage participation including faster feedback on submissions, better

resources for getting immediate information during the process, and more qualified labs.

- Further discuss outstanding issues:
 - How do we move toward more restrictive standards while not losing needed equipment options (e.g., gas-absorption refrigerators)?
 - Where within the cool chain would a more flexible approach e.g., OCC be useful and acceptable.
 - Should WHO continue using qualified laboratories only or can manufacturers self-test under independent supervision?