Understanding the root causes of cold chain equipment failure

Results from a pilot study in Uganda

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Background

Many vaccines are temperature sensitive and need to be kept in a cold chain to remain potent. However, challenges including intermittent and fluctuating power supplies, extreme ambient temperatures, inconsistent preventive maintenance, and inadequate parts for repair prevent some cold chain equipment (CCE) from fully protecting vaccines. Given these challenging conditions, it is crucial that CCE remain fully functional and operate within required specifications.

In some settings, countries have successfully used temperature monitoring to notify cold chain personnel and health workers when equipment begins to operate outside specifications, resulting in improved maintenance practices and better health care worker compliance to operating procedures (PATH, unpublished report, 2014).[1] However, providing a sustainable solution to continued temperature excursions for specific CCE requires an understanding of the root causes of its failure.

The World Health Organization (WHO) Performance, Quality and Safety (PQS) working group sets the specifications for CCE and uses independent validation to confirm that the equipment meets the required PQS specifications before field introduction. The United Nations Children's Fund (UNICEF) Supply Division recommends equipment based on WHO PQS standards and procures this equipment on behalf of many countries. The UNICEF Supply Division also works with manufacturers to resolve specific equipment problems when reported by countries. Information about the field performance of equipment is not systematically collected, analyzed, nor publicly reported, though valuable to manufacturers and countries alike. This pilot study is a first attempt to publicly and systematically collect, analyze, and report the root causes of CCE failure, using data collected in Uganda.

Uganda's vaccine cold chain

The Uganda National Expanded Programme on Immunization (UNEPI) is a part of the Uganda Ministry of Health (MOH). UNEPI is responsible for ensuring effective immunization service delivery across the country including provision of supportive supervision, cold chain maintenance, and capacity-building. UNEPI works in collaboration with the national medical stores (NMS), which in 2012 took over the procurement, storage, and distribution of vaccines and related supplies up to the district level. In 2014, UNEPI and NMS reached more than 78 percent of the target population with the third dose of pentavalent vaccine and more than 82 percent of the target population with measles containing vaccine.[2] Uganda's cold chain is a tiered system (each tier is called a level) consisting of the national level, district level, and health center level. There are ten walk-in cold rooms and one walk-in freezer room at the national-level store, 112 district vaccine stores with vaccine refrigerators and freezers, and 5,229 health facilities, 3,218

[1] Lloyd J, Lydon P, Ouhichi R, Zaffran M. Reducing the loss of vaccines from accidental freezing in the cold chain: the experience of continuous temperature monitoring in Tunisia. *Vaccine*. 2015;33(7):902−907.

[2] World Health Organization (WHO). WHO and UNICEF estimates of national immunization coverage [brief]. Geneva: WHO; 2015. Available at: http://www.who.int/immunization/monitoring_surveillance/data/uga.pdf.

of which offer immunization services. About 87 percent of those facilities offering immunization services have vaccine storage refrigerators, and 92 percent of those refrigerators are WHO PQS prequalified. The latest CCE inventory (October 2014) shows 3,423 working refrigerators among the district vaccine stores and health centers. The MOH employs approximately 19,600 health care workers that work in the immunization program, 5 national cold chain technicians, and 31 district cold chain technicians. NMS employs 5 staff in the vaccine section; 1 vaccine stores management officer, 1 supervisor, 2 support staff and 1 national cold chain technician.

Study objective and hypothesis

This pilot used data collected in Uganda to report on the root causes of CCE failure. The resulting information may be used to inform global policy, equipment design, and country-level cold chain improvements. We hypothesized, based on the Pareto principle,[3] that relatively few failure mechanisms were causing the majority of equipment failures. If true, the performance of CCE could be significantly improved with the adoption of relatively few equipment improvements.

Methods

PATH assembled a team consisting of a CCE maintenance expert, a staff member from the MOH's Expanded Programme on Immunization, and a PATH project manager to diagnose equipment failures over a three-week period. The team reviewed maintenance records and consulted MOH staff to locate equipment that was nonfunctional or operating outside WHO temperature specifications.

The study was designed to target equipment with an age of eight years or less. However the available inventory data on installed equipment at the national level was incomplete, and only a few devices could be identified through those records, so we had to restrict our population of failed fridges to those that we could verify were procured within eight years. Over the past eight years, UNEPI has received approximately 600 Dometic model RCW 42 EG absorption refrigerators and 240 Dulas Solar VC-65F refrigerators through a donation from the Japanese International Cooperation Agency. Unfortunately the exact installation dates could not be determined due to incomplete equipment record keeping.

We selected and visited sites with failed equipment to collect data on a sufficient number of equipment in the short time allocated for this pilot. Our maintenance expert assessed a total of 59 failed refrigerators or freezers. The data collection tool for each CCE included the manufacturer name, model, approximate date of installation, and suspected root cause(s) of failure. In addition, the team also inspected passive CCE (cold boxes) to determine the common failures. Information about these failures is summarized below.

[3] The Pareto principle states that 20 percent of the inputs in a system are often responsible for 80 percent of the outputs.

Our study was a small pilot with a small sample size, and it used a purposive sampling process; therefore, the overall rates of CCE failure cannot be inferred from the resulting data.

Summary of key findings

This section summarizes our key findings for refrigerators and freezers, voltage regulators, and cold boxes.

Refrigerators and freezers

The table below shows the refrigerators and freezers we examined by cause of failure.

Failure cause	Manufacturer and model (count) and device type					
	Dometic RCW 42 EG[a] (n = 44)	Dulas VC-65[b] (n = 11)	Vestfrost MF 314[c] (n = 1)	Sibir V 170 GE[b] (n = 2)	Vestfrost MK 304[d] (n = 1)	Total (n = 59)
	Absorption	Solar compression	Freezer, AC compression	Absorption	AC compression	
Cooling-unit fault	44					44
Refrigerant leak		5			1	6
Control unit fault		2	1			3
Thermostat fault		2				2
Stolen solar panel		2				2
Blocked gas tube				2		2

Note: a, refrigerator; b, refrigerator and freezer; c, freezer; d. ice-lined refrigerator.

AC, alternating current.

The failure modes listed in the table are described below:

- Cooling unit fault: A failure in the sealed cooling unit of an absorption refrigerator. The exact problem is difficult to diagnose and repair requires replacing the entire cooling unit.
- Refrigerant leak: A leak in the evaporator or elsewhere in the cabinet.
- Control unit fault: A failure of the electronic control unit that turns the compressor on and off using a signal from the thermostat.
- Thermostat fault: A failure of the thermostat that opens or closes the compressor on/off circuit depending on the set point and internal temperature.
- Stolen solar panel: Solar panels removed and thus no longer provide power to the refrigerator.
- Blocked gas tube: The tube that goes from the liquid petroleum gas canister to the refrigerator is blocked.

In addition to the equipment we examined, UNEPI records showed a high rate of failure on the hinges of the Dulas VC-65, and 70 percent of the 240 units procured over the last eight years have had their hinges replaced. Dulas indicated an improved hinge design was released in 2011 and replacements were sent for prior installations.

Voltage regulators

During the root cause analysis, we determined that voltage regulators could protect all mains-powered refrigerator control units from the power fluctuations that are prevalent in Uganda. After discussions with the MOH, this recommendation resulted in the addition of voltage regulators for an incoming shipment of 700 refrigerators funded by Gavi, the Vaccine Alliance. In addition, the MOH subsequently changed national policy to require voltage regulators for all mains-powered CCE.

Cold boxes

During the evaluation, cold boxes were inspected at the district vaccine stores in Mukono, Kahyunga, Ibanda, Kabale, and Kiruhura. Numerous cold boxes were found to be faulty. We documented cold boxes with broken cases, poor hinge alignment, hinge screws missing, and seals falling off or missing. However, because detailed information on failed passive equipment (manufacturer, model, age, performance) was not available, it is difficult to draw conclusions based on these findings. More detailed information and photos can be found below in the Analysis section.

Analysis of the findings and discussion

This section analyzes and discusses refrigerators and freezers, voltage regulators, and cold boxes.

Absorption refrigerators

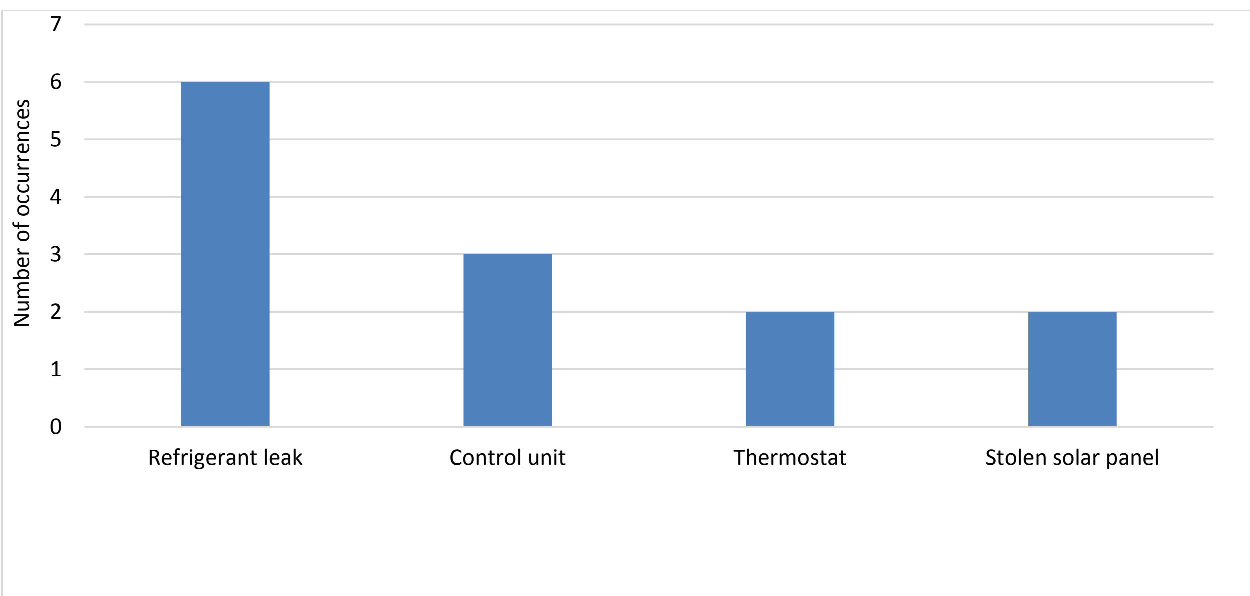
Absorption electric/gas refrigerators had two common failures—either the cooling unit was faulty or the liquid petroleum gas tube was blocked. The majority of failures from our sample (44 of 46) were due to cooling-unit issues from one make and model (see Figure 1). Repair could not be managed locally, and international technicians would be required to do the repairs, but UNEPI estimated the cost of organizing the repair by international technicians to be more than the replacement cost of new refrigerators. The reliability of the underlying technology is well known with a long history in many countries, so the cooling-unit failure is uncommon for this type of refrigerator as useful life is usually in excess of ten years. Therefore, the high incidence of failure indicates a manufacturing defect. Manufacturers can limit this type of issue to a small number of production runs if they detect the problem and correct it quickly. In addition, the PQS prequalified equipment comes with a warrant so quick identification and communication about product defects may result in supplier supported repair or replacement.

Figure 1. The national medical store's "equipment graveyard" in Entebbe is reported to contain more than 40 absorption refrigerators that failed because of faulty cooling units.

Compression refrigerators and freezers

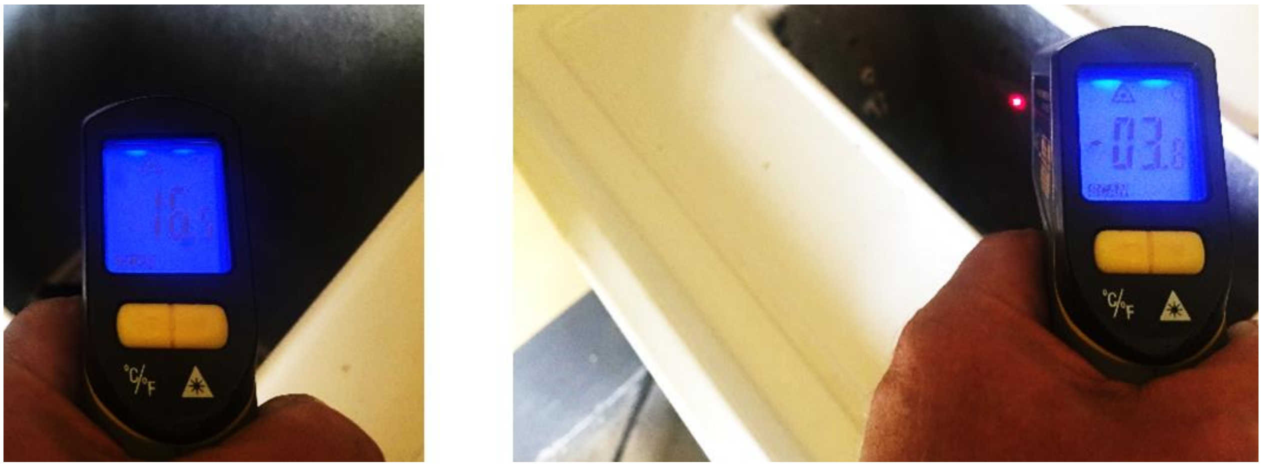
Due to the relatively small sample size for the compression refrigerators and freezers, this section combines AC- and solar-powered models. Figure 2 shows the distribution of root-cause failures.

Figure 2. Distribution of root-cause failures in compression refrigerators and freezers.



The most common cause of failure for compressor-based refrigerators was a refrigerant leak internal to the cooling system. Through examining in-country records, we observed this failure in other devices of this type in Uganda and in other countries, including Sierra Leone and Kiribati. These leaks can be caused by inappropriate material choice or poor soldering. Figure 3 below shows temperature probe readings in a refrigerator/freezer with this fault.

Figure 3. Temperature readings from a solar refrigerator/freezer with an internal refrigerant leak in Nyarukika health center. The readings show that the refrigerator compartment is not cooling adequately (16.5°C, left side) while the freezer compartment is still operational (-3.8°C, right side).



The second most common failure for the compression equipment was the control unit. Controllers tend to fail over time—national EPIs should plan to replace a percentage of these control units over time.

Other compression equipment failures included faulty thermostats and stolen solar panels. The panels that were stolen were pole-mounted, while roof-mounted panels were not missing.

In addition, Figure 4 below shows a charge regulator that has been bypassed by an electrical bridge presumably because there was no spare unit to replace the failed one. Unfortunately this results in a charge that is not regulated, possibly resulting in premature battery failure due to overcharging.

Figure 4. A faulty charge regulator in Rubaya health center has been bridged (see arrow).

Improving the reliability of the cooling circuit and the control unit would address 9 of the 13 documented failures or approximately 70 percent of the failures in our sample. (Note: given the small sample size, this statement cannot be generalized.) Having spare parts available for components that are likely to fail, for example thermostats and control units, is also important to the long-term performance of CCE.

The results of the pilot were shared with the manufacturers Dulas and Dometic (now B Medical Systems). Both manufacturers are working to resolve and further understand these failures and were helpful in providing input on how to improve information collection in future studies.

Cold boxes

Figure 5a, b, and c shows examples of damaged cold boxes documented during the evaluation. Since these products are WHO PQS prequalified, the severe damage is surprising, but without knowing the age of the cold boxes, it is difficult to ascertain the degree of the problem. Over many years, our team's cold chain expert has witnessed a variation in the quality of devices coming from some cold box manufacturers. Validating the quality of cold boxes upon their arrival in country could be an important step for ministries of health.

Figure 5. Examples of damaged cold boxes by type: a) cracked lid, b) misaligned hinge, and c) missing screw.

a b c

Recommendations

Based on our analysis, this section makes recommendations to four key stakeholders: manufacturers, equipment donors, the MOH, and future study implementers.

Manufacturers:

- Perform small-scale field validation to uncover any unexpected problems that could be resolved prior to large-scale order fulfillment when new equipment is introduced or old equipment undergoes significant manufacturing or design changes.
- Suggest voltage regulators when preparing a bid for a procurement from countries with unreliable electricity. In addition, manufacturers could consider integrating voltage regulators into their mains-powered equipment to reduce costs and improve usage compliance.

Equipment donors:

- Make voltage regulators mandatory with all CCE that is powered by fluctuating grid electricity.
- Implement a random quality-check program for passive equipment that validates that production devices are meeting the same quality criteria as the devices that were tested for PQS prequalification.
- Determine a way to share information about CCE performance with manufacturers and other buyers, without sacrificing procurement principles and required confidentiality.
- Support further studies to inform spare part inventory requirements.

MOH:

- Choose rooftop rather than pole-top mounting for solar panels wherever possible. When pole-top mounting is the only option, efforts should be made to increase the security of the installation, such as filling the lower portion of the pole with cement to make it harder to cut down, or securing the solar panel with a second pole attached horizontally to a building.

- Keep equipment information current and use it for tracking equipment performance and managing maintenance and replacement plans.
- Track performance of refrigerators to identify and rectify problems as they occur.
- Send a description of the failure and the serial number of the failed equipment to the manufacturer in a timely manner especially when under warranty.
- Validate the quality of cold boxes upon their arrival in country to be sure they meet specifications.

Future study implementers:

- Create and use a standard failure definition list.
- Follow a standard method for determining root cause of failure (e.g., 5 Why's).[4]
- Collect and report serial numbers for each piece of failed equipment.
- Try to determine if the failure is a result of poor maintenance or user error.

[4] For more information on the 5 Why's, please visit: https://en.wikipedia.org/wiki/5_Whys.