Domestic Refrigerators for Vaccine Storage in Tunisia

Conclusion and recommendations

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OPTIMIZE Immunization systems and technologies for tomorrow

PATH World Health Organization

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Acronyms

CETIME	Centre Technique des Industries Mécaniques et Electriques
DSSB	Direction des Soins de Santé de Base
EPI	Expanded Programme on Immunization
PATH	Program for Appropriate Technology in Health
PQS	Performance, Quality and Safety
WHO	World Health Organization

Executive summary

Today, the Tunisian government does not classify refrigerators from the domestic market that are procured and used to store vaccines as medical equipment, and their performance is not controlled. This document summarizes a laboratory report on performance testing of four models of domestic refrigerators that are available on the Tunisian market to assess their suitability for storage of vaccines. Project Optimize contracted the tests to demonstrate to the government the importance of prequalification of models according to World Health Organization (WHO)/Quality, Safety and Standards norms for the storage of vaccines and to provide appropriate recommendations.

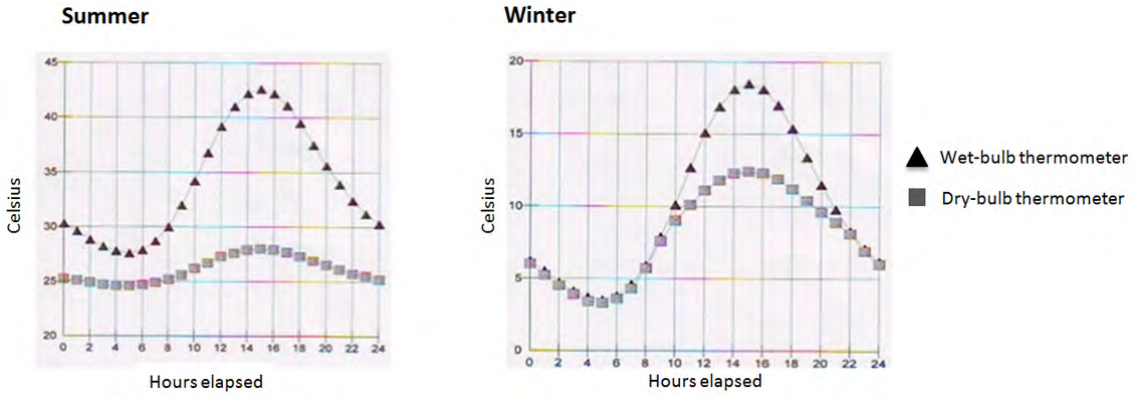
The testing revealed a number of weaknesses in the performance of all models in ambient test temperatures of 32°C and 43°C, which call for close monitoring of temperatures in the field. The refrigerator model BOSCH KDN36X03/04 performed the best of the four models tested and is therefore closest to meeting WHO requirements. To minimize the risk of using refrigerators from the domestic market, project Optimize recommends the following policies and practices:

- Reclassify refrigerators intended for vaccine storage as medical equipment that should meet international or national norms of performance.
- Require that models be prequalified in an independent laboratory according to these norms before countries and partners procure them.
- Require that health workers use a wall of water-filled packs to surround the vaccines within the refrigerators to protect them from temperature fluctuations.
- Require that health workers follow the standard refrigerator operating procedures.
- Require that health workers use 30-day temperature recorders that meet WHO norms (E006/TR06.3) to monitor the temperatures in all refrigerators used to store vaccines and that sufficient training is provided for this purpose.

Background

Refrigerators that are used to store vaccines are required by the World Health Organization (WHO) to meet certain performance standards so that the conditions of storage are maintained even in the extremes of ambient temperature in areas where they are used. In many areas of Tunisia, including the region of Kasserine, the ambient temperature in summer can reach 43°C (see Figure 1), and the temperatures in winter can drop toward 0°C, even within store buildings. Therefore, it is important that vaccines are protected against high temperatures and freezing temperatures, and that storage temperatures are maintained during power cuts.

Figure 1. Annual range of ambient temperatures in the region of Kasserine.



The Tunisian government does not verify the performance of refrigerators used for vaccine storage because they are not classified as medical equipment. Instead, domestic refrigerators designed to store food in temperate climates are used in the majority of district stores and health centers to store vaccines. In early 2010, the project team logged temperatures in ten refrigerators over 82 days. The results revealed problems including both freezing temperatures and high temperatures placing vaccine at risk.

The Tunisian Ministry of Health is aware of these problems and in recent years has tried to interest local suppliers of refrigerators to adapt a model to meet the needs of vaccine storage. This initiative has been blocked to date by the small scale of the vaccine cold chain market in Tunisia (approximately100 units per year) and the unwillingness of parent international corporations to license deviations from the standard domestic models.

The refrigerator testing reviewed in this report is part of a broader demonstration of improvements to the vaccine supply chain in Tunisia by project Optimize. Project Optimize and the Tunisian Ministry of Public Health are collaborating to explore new logistics and supply chain solutions that can optimize the vaccine supply chain. The project aims to establish a high-efficiency cold chain from Tunis to the point of vaccine administration. The effectiveness of the vaccine cold chain depends on refrigerators functioning correctly so that they can maintain a constant 2°C to 8°C, the required temperature range for vaccines.

Objectives of testing

Considering the risks of using domestic refrigerators for vaccine storage, the project Optimize team decided to safeguard the quality of the Tunisian cold chain from Tunis, through Sousse, to the region of Kasserine. In order to accomplish this, the project:

- Established a system of 30-day recording of temperatures in every refrigerator and a system of monthly supervision supported by temperature compliance reports of all refrigerators by area.
- Conducted performance testing in the laboratory on a selection of preferred models of refrigerators for this purpose available in the Tunisian market.

In this way the project sought to identify and replace dysfunctional refrigerators with new refrigerators whose performance had been verified by laboratory tests to WHO Performance, Quality and Safety (PQS) norms.

Selection of refrigerator models

The Ministry (DSSB) selected four models (see Table 1) for testing from those available in the Tunisian market. The models were selected on the basis of the following criteria:

- Purchase cost between 700 and 1000 dinars.
- Capacity usable for vaccines.
- Energy rating (class 1, 2, or 3).

Table 1. Refrigerator models selected for testing against WHO norms.

Manufacturer	Model	Energy rating (kWh/year)	Volume of refrigerator (liters)	Volume of freezer (liters)	Cost (Dinars)	Remarks
LG	GN392	3 (468)	260	61	900	Thermometer, auto-defrost
Bosch	NKD 36 X 03	2 (383)	257	78	1000	
Samsung	RT45MASW	3 (408)	266	78	949	Auto-defrost
Electrolux	ERD24001W	2 (363)	186	44	900	

kWh = kilowatt hour.

Test program at CETIME, Tunis

Testing was conducted at the Laboratories of the Centre Technique des Industries Mécaniques et Electriques (CETIME), the Tunisian state refrigeration testing facility in Tunis. This was done according to selected test procedures of WHO/PQS (see Table 2) in two phases:

1. Testing at 27°C and 32°C ambient temperature.

2. Testing at 43°C ambient temperature.

Table 2. Test phases by PQS and ambient temperature.

	PQS test number	Ambient temperature	Test descriptions
1	WHO/PQS/ RFO1-VP.2[i]	27°C and 32°C	Tests included cool-down, stable running, ice pack freeze capacity, holdover time, and day/night cycle tests.
2	WHO/PQS/ RFO1-VP.2[ii]	43°C	Tests included stable running, holdover time, and day/night cycle tests.

Phase 1 testing

Of the models tested, none of the models **passed** all the tests, and all models **failed** the holdover test. One model, BOSCH KDN36X03/04, **passed** all of the tests at 32°C except the holdover test. Based on the results at 27°C and 32°C ambient temperatures, the project team decided that only two models, BOSCH KDN36X03/04 and ELECTROLUX ERD24001W, would be tested at 43°C in Phase 2.

Table 3. Comparative performance at 27°C and 32°C against test pass criteria.

Models	Tests	Results at **27**°C	Results at **32**°C	Pass criteria
BOSCH KDN36X03/04	Cool-down test empty	Between 2.2°C and 8.3°C	Between 3.3°C and 7.3°C	Between 2°C and 8°C
	Stable running test	Between 3.3°C and 10.5°C	Between 3°C and 7.3°C	Between 2°C and 8°C
	Ice-pack freezing rate	16.675 kg	16.675 kg	2.4 kg/24 hours
	Holdover test	43 minutes	50 minutes	Greater than 4 hours at less than 10°C within the vaccine load
	Day/night test: 32°C/15°C and 27°C/10°C	Between 2.8°C and 10.8°C	Between 3°C and 7.3°C	Between 2°C and 8°C
ELECTROLUX ERD24001W	Cool-down test empty	Between 2.3°C and 7.4°C	Between 3°C and 9.1°C	Between 2°C and 8°C
	Stable running test	Between 2.8°C and 7.9°C	Between 4.2°C and 9.4°C	Between 2°C and 8°C
	Ice-pack freezing rate	13 kg	13 kg	2.4 kg/24 hours

[i] "Essais de performances des réfrigérateurs congélateurs combinés selon le protocole d'essai de type indépendent – PQS à 32C"; Rapport IAT 103/2012 Project A3031202.

[ii] "Essais de performances des réfrigérateurs congélateurs combinés selon le protocole d'essai de type indépendent – PQS à 32C"; Rapport: IAT 456-b /2010 Project A30310137.

Models	Tests	Results at 27°C	Results at 32°C	Pass criteria
	Holdover test	34 minutes	44 minutes	Greater than 4 hours at less than 10°C within the vaccine load
	Day/night test: 32°C/15°C and 27°C/10°C	Between 1.85°C and 7.88°C	Between 4.4°C and 9.3°C	Between 2°C and 8°C
LG GN392	Cool-down test empty	-3.5°C	-1.6°C	Between 2°C and 8°C
	Stable running test	-3.5°C	-1.2°C	Between 2°C and 8°C
	Ice-pack freezing rate	17.4 kg	17.4 kg	2.4 kg/24 hours
	Holdover test	99 minutes	80 minutes	Greater than 4 hours at less than 10°C within the vaccine load
	Day/night test: 32°C/15°C and 27°C/10°C	-3.9°C	-1°C	Between 2°C and 8°C
SAMSUNG RT45MASW	Cool-down test empty	Between 0.9°C and 7.4°C	Between 4.13°C and 9.4°C	Between 2°C and 8°C
	Stable running test	Between 3.1°C and 7.7°C	Between 2.8°C and 9.1°C	Between 2°C and 8°C
	Ice-pack freezing rate	17.4 kg	17.4 kg	2.4 kg/24 hours
	Holdover test	64 minutes	64 minutes	Greater than 4 hours at less than 10°C within the vaccine load
	Day/night test: 32°C/15°C and 27°C/10°C	Between 2°C and 7.5°C	Between 2.5°C and 8.9°C	Between 2°C and 8°C
	Pass			
	Fail			

Phase 2 testing

The project team modified the test procedures for Phase 2 to conduct the tests two times to evaluate the stabilizing effect of adding mass surrounding the vaccine load. The team reasoned that considering the performance results at 32°C, the extra stability would be important at 43°C.

Therefore, the laboratory conducted two test cycles:

1. With a dummy vaccine load **only**, as specified in WHO procedure.
2. With a dummy vaccine load and with a wall of water-filled packs surrounding the vaccine, or with a wall of water-filled packs surrounding the vaccine.

Neither model passed all criteria for 43°C testing. Test data showed marginal improvements in performance in cycle 2 of the testing compared to cycle 1. The performance of the two models was similar, but the Bosch passed the day/night test and only marginally failed the stable running test (1.1°C above the limit) in cycle 2.

Table 4. Comparative performance at 43°C ambient against test pass criteria.

Models	Tests	Results	Pass criteria
BOSCH KDN36X03/04	Holdover test with water-filled packs	3 hours	Greater than 4 hours at less than 10°C within the vaccine load
	Holdover test with vaccine only	42 minutes	
	43°C/25°C day/night test with water-filled packs	2.4°C/9.1°C min/max	Between 2°C and 8°C
	43°C/25°C day/night test with vaccine only	Between 3.7°C and 12.7°C	
	Stable running with water-filled packs	Between 2.4°C and 9.1°C	Between 2°C and 8°C
	Stable running with vaccine only	Between 3.7°C and 12.7°C	
ELECTROLUX ERD24001W	Holdover test with water-filled packs	13 minutes	Greater than 4 hours at less than 10°C
	Holdover test with vaccine only	0 minutes	
	43°C/25°C day/night test with water-filled packs	Between -5.5°C and 9°C	Between 2°C and 8°C
	43°C/25°C day/night test with vaccine only	Between -8.5°C and 8.3°C	
	Stable running with water-filled packs	Between 5.8°C and 11.1°C	Between 2°C and 8°C
	Stable running with vaccine only	Between 4.3°C and 8.8°C	
Note:	43°C/25°C—The "/" indicates the day/night temperature profile of this test.		
	Fail		
	Pass		

Conclusion on laboratory testing

Although all four models failed one or more tests at the two test temperatures, the performance of two models in Phase 2 was improved by adding a wall of water-filled packs surrounding the vaccine load (see Figure 2).

Figure 2. Arrangement of water-filled packs in refrigerator.

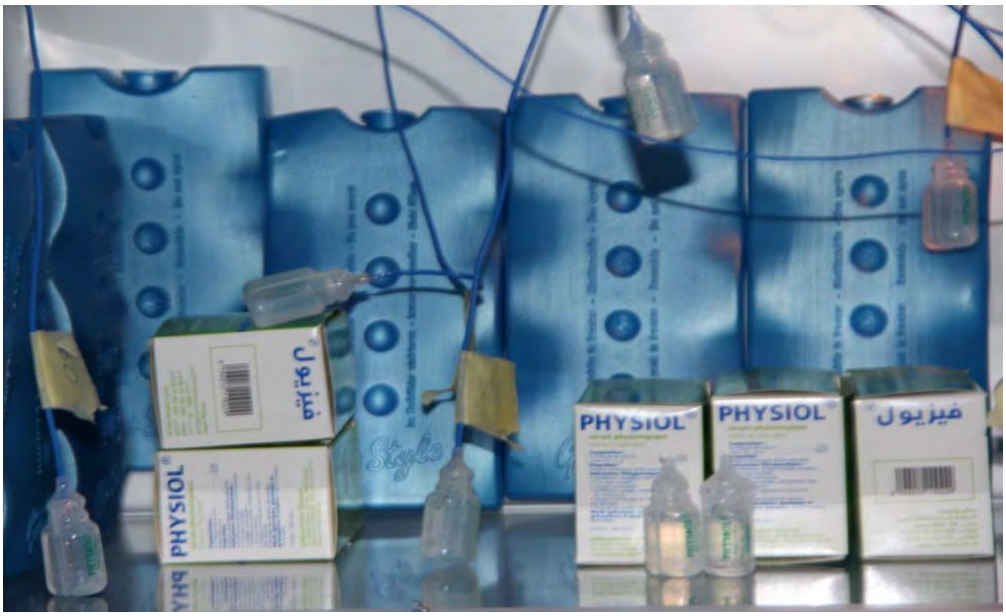


Photo: WHO/Dr. Ramzi Ouhichi, Tunisia 2012

Although neither refrigerator succeeded in passing the holdover test, there was a marked performance improvement associated with packs filled with water. The team recommends that, of the two options, the water-filled packs will protect best against accidental freezing of vaccine that has occurred frequently in the project facilities following a power cut.

Overall, one model, BOSCH KDN36X03/04, performed best in the Phase 1 and 2 testing and came closest to meeting WHO norms.

Field monitoring in the Kasserine Region

Temperature records on vaccine storage are now available from all facilities included in the in the Kasserine Region studied by project Optimize for the first six months of 2012. They show that pharmaceutical refrigerators designed for the storage of biologicals in the Kasserine Regional store (Electrolux) maintain correct temperatures. However, 79 percent of domestic refrigerators (n = 34) used in district and health center facilities have demonstrated one or more of the following failure modes:

- Temperature excursions above 8°C without alarm.
- Temperature excursions below 2°C without alarm.
- High-alarm incidents(s): above 8°C for more than 10 consecutive hours.
- Low-alarm incidents(s): below -0.5°C for more than 60 consecutive minutes.

The causes of these failures have not yet been fully investigated but they include:

- Thermostat failure.
- Inadequate insulation.
- Door left open.
- Thermostat incorrectly adjusted.
- Prolonged power cut.

The responses to the failures include:

- Planned for replacement of refrigerator.
- Training provided by supervisor on refrigerator management.

Discussion and recommendations

Domestic refrigerators often pose higher risks for vaccines than pharmaceutical refrigerators that meet WHO norms. The risks associated with the use of domestic refrigerators for vaccine storage are evident in these results and they are well known in the literature[iii,iv] from other countries. The problems include:

- Refrigerator warm-up during a power failure is too rapid due to inadequate insulation or door seals.
- Thermostat allows too wide a fluctuation of temperatures and has a short life.
- Danger of freezing vaccines when ambient temperature fluctuates or following a power cut when ice packs have been inserted to maintain cooling.

Domestic refrigerators are not classified or prequalified as medical products in Tunisia and are available at competitive prices. On the other hand, pharmaceutical refrigerators meeting WHO norms are more costly and are not available locally. Although domestic refrigerators on the Tunisian market are now subject to energy testing to national norms that ensure a higher standard of insulation and performance, they still fail to meet the WHO norms for vaccine storage.

If pharmaceutical refrigerators meeting WHO norms cannot be imported for vaccine storage purposes, Optimize recommends that the Tunisian Ministry of Health should:

- Reclassify refrigerators intended for vaccine storage as medical equipment that should meet international or national norms of performance.
- Require that models be prequalified in an independent laboratory according to these norms before countries and partners procure them.
- Require that health workers use a wall of water-filled packs to surround the vaccines within the refrigerators to protect them from temperature fluctuations.
- Require that health workers follow a national standard refrigerator operating procedure.
- Require that health workers use 30-day temperature recorders that meet WHO norms (E006/TR06.3) to monitor the temperatures in all refrigerators used to store vaccines and that sufficient training is provided for this purpose.

[iii] McColloster PJ. US vaccine refrigeration guidelines: loose links in the cold chain. *Human Vaccines*. 2011;7(5):574–575.

[iv] McColloster P, Vallbona C. Graphic-output temperature data loggers for monitoring vaccine refrigeration: implications for pertussis. *American Journal of Public Health.* 2011;101(1):46–47.