OPTIMIZE

Immunization systems and technologies for tomorrow





EVIDENCE BRIEF SERIES

Innovative passive cooling options for vaccines

This document reports results from field demonstrations of some new vaccine cold boxes that could soon be available as World Health Organization (WHO)-prequalified devices for vaccine storage and/or transport. They are innovative both in their use of new materials and in the way they enable us to think about storing and transporting vaccines in different ways than is currently the norm. They also focus on freeze prevention, as freezing temperatures in vaccine cold boxes and carriers have been widely documented. This information is intended for national Expanded Programme on Immunization managers and logisticians who are interested in learning about new technologies in the pipeline for use in countries

THE NEED FOR NEW COOLING TECHNOLOGIES

For four decades now, immunization programs have been using insulated containers with frozen water packs to transport vaccines. As of 2013, there are 16 vaccine carriers prequalified by WHO with capacities ranging from 0.80 L to 3.61 L. These carriers are generally used for "last-mile" transport of vaccines. They can be carried by humans walking, on bicycles, or on motorbikes.

For longer-distance transport, WHO has prequalified 21 cold boxes with vaccine capacities ranging from 6.3 L to 24.4 L. These cold boxes are used for transporting larger quantities of vaccine and generally need to be loaded on trucks for the journey.

Both cold boxes and vaccine carriers require conditioned ice packs or cold-water packs to keep vaccines cool. However, if ice packs are not sufficiently conditioned (allowed to reach a stable temperature of 0°C, which is achieved when ice packs contain a mixture of water and ice) prior to being loaded, they pose a freezing risk to vaccines. Because many vaccines are freeze sensitive, including diphtheria-tetanus-pertussis, all diphtheria-tetanus-pertussis-containing multivalent vaccines, tetanus toxoid, diphtheria tetanus, hepatitis B, pneumococcal conjugate, rotavirus, human papillomavirus, typhoid, cholera, and inactivated polio vaccines, the risk of freezing has emerged as a serious issue.

Between 1990 and 2010, a large number of temperature studies were conducted to examine vaccine supply chains in many different countries. A review article published in *Vac*-



Motorbikes are commonly used for last-mile transport of vaccines. Photo: PATH



Cold boxes are generally used for transporting vaccines in trucks and other vehicles. Photo: PATH

cine found that among 35 of those studies, 34 found freezing temperatures in the cold chain, and 14 of those found more than 50 percent occurrence of freezing among recorded temperatures (Matthias, 2007).

TECHNOLOGIES THAT MINIMIZE THE RISK OF FREEZING

As awareness of freezing occurrences in vaccine supply chains has increased, there has been a greater demand for insulated vaccine carriers that can prevent freezing. Technical design and special materials can be employed to create carriers and cold boxes that prevent freezing even when fully frozen ice packs are used, which can result in long cold life and easier operations for the health workers that load the containers.

in the near future.

Development of the first highperformance vaccine cold box at the National Bacteriological Laboratories, Stockholm, Sweden, and 1974 to 1977 field tests in Ghana feasibility on Immunization.

CARRIERS AND COLD BOXES WITH LARGER VACCINE VOLUME CAPACITY

In addition to freeze prevention, there is a need for technologies that can transport larger volumes of vaccines and make more efficient use of transport volume.² In recent years, a number of cold boxes have come on the market that have a larger carrying capacity than traditional cold boxes. These have generally been produced for industrialized-country applications. Since they are bigger than traditional cold boxes, they often incorporate either a pallet-handling structure or are designed with wheels in the base. They offer the possibility of simpler, freeze-safe transport for large quantities of vaccine within countries, from the national to provincial level, as well as intraprovince transportation in large countries.

POINT-OF-USE, SMALL-VOLUME VACCINE STORAGE

As countries face the challenge of expanding the physical capacity of the cold chain, some have explored the possibility of increasing storage capacity at the point of use, in small health centers. Refrigerators are often a poor technology choice at this level because the volume of vaccines stored can be very minimal and because it is very expensive to equip every small health center with vaccine refrigerators that need to be powered with electricity or gas and to be regularly maintained. However, highly insulated containers that can go for a week, two weeks, or even up to a month between ice changes could be a game-changing technology for vaccine storage at the health center level. If there is a convenient method for making or purchasing ice when needed, then vaccines can safely be stored at every health center at the proper temperature without reliance on electricity or refrigeration maintenance services. This can increase availability of vaccines at small health centers, which is especially important for the vaccines that are given immediately after birth, such as the hepatitis B vaccine to prevent mother-to-child transmission of hepatitis B and the tetatus toxoid vaccine to prevent neonatal tetanus.

NEW TECHNOLOGIES OFFER A SOLUTION

Several manufacturers have responded to the technology needs of vaccine programs in developing countries and have come up with new designs for cold boxes and vaccine carriers. To determine how these newly emerging technologies would perform in developing-country immunization logistics systems, project Optimize, a collaboration between PATH and WHO, evaluated several of them in demonstration projects with country partners. Table 1 below lists each technology and the country in which it was evaluated.

² Large-capacity containers typically require 37% less space to transport a given volume of vaccine (160 L) than the smaller, traditional cold boxes.

Table 1.

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New-generation cold boxes			
and vaccine carriers.	Description	Strengths	Challenges
Savsu Nano-Q™	 Stationary passive cooling for storage. Six to eight day cold life depending on the ambient temperature. Vaccine storage capacity: 6 L. Evaluated in Vietnam. 	Excellent temperature performance.	Difficult to procure ice locally in winter months.
Dometic RCW 27 cold box	 Short duration cold life for transport.	Good temperature performance.	Users reported the device was too heavy. A dedicated refrigerator was required to cool ice packs.
Dometic RCW25 vaccine carrier	 Long duration cold life for transport. Uses PCM packs to prevent freezing. Vaccine storage capacity: 4 L. Evaluated in Senegal. 	Good temperature performance.	 Users commented that the capacity was too small. To increase capacity, users initially did not load all PCM packs.
Aircontainer Package System Bigbox-container	 Large-volume container with PCM packs to prevent freezing. Vaccine storage capacity: 170 L. Evaluated in Senegal. 	Good temperature performance. Users appreciated large capacity.	Hinges were fragile. Protocol to condition the PCM packs was cumbersome.



Savsu Technologies Nano-QTM stationary passive cooler. Photo: PATH/Nguyen Phu Cuong

VIETNAM: SAVSU NANO-Q™ PASSIVE COOLER FOR LONG-TERM STORAGE

Project Optimize, in collaboration with the Vietnam National Expanded Programme on Immunization, evaluated the Nano-QTM, a new device from United States-based Savsu Technologies that uses state-of-the-art insulation materials and a unique configuration designed to maintain appropriate temperatures for vaccine storage without electricity. In Vietnam, we wanted to demonstrate the use of these devices for long-term storage in small health centers that are not normally equipped with vaccine refrigerators.

Optimize chose Nano-QTM because it can provide up to seven days of cooling at an outside temperature of 32°C before the ice needs replacing, and it uses normal ice available for purchase close to the health centers. A total of 12 devices were evaluated in different commune health centers for periods

ranging from four to eight months. Researchers monitored the temperature of all the devices and interviewed users about their experience with the equipment.

Results show that the device maintained adequate storage temperatures and that users were compliant with monitoring the temperature and replacing the ice when the temperature began to rise. No freezing temperatures were observed over more than 65 months of cumulative data for the 12 devices.

Users appreciated having vaccine storage that was independent of the electric grid, as electricity cuts are common. They also like the ease of monitoring the temperature and the availability of vaccine whenever they needed it without having to travel to the district center. The main drawback mentioned by users was the difficulty of locating ice for sale in the winter months in the central and northern

regions of Vietnam.

TUNISIA: DOMETIC RCW 27 WITH FREEZE PREVENTION FOR VACCINE TRANSPORT

In Tunisia, in collaboration with the Ministry of Public Health, Optimize evaluated several approaches to prevent freezing during vaccine transport in their demonstration in the Kasserine region of the country. One of these was the incorporation of the RCW 27 cold box from Luxembourg-based Dometic. The RCW 27 is based on the WHO performance, quality and safety (PQS)-prequalified RCW 25 cold box, but is larger (27 L versus 19 L) and is cooled using non-water PCM. PCMs are engineered to freeze at a temperature above 0°C (in this case 5°C), which prevents them from freezing the contents of the cold box (in this case, vaccines). PCM packs are cooled in a refrigerator rather than a freezer. The RCW 27 was designed to maintain temperatures below 10°C for more than 24 hours at 43°C ambient temperature.



Dometic RCW 27 cold box. Photo: WHO/Ramzi Ouhichi

In Tunisia, enough PCM packs were supplied to cool two RCW 27 cold boxes for vaccine transport from the Kasserine regional store to the districts and three RCW 27 cold boxes for vaccine transport from each of the three project districts to the health centers that they serve monthly. The supplying stores took responsibility for preparing the PCM packs and packing and transporting the vaccine to the designated stores during each delivery trip.

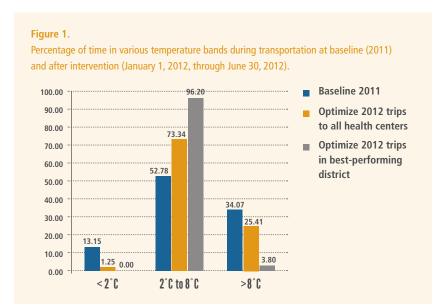


Figure 1 provides a summary of temperatures recorded during vaccine transport before and after the intervention.

As noted in Figure 1, the percentage of time when vaccines were exposed to temperatures below 2°C fell from 13.2 percent to 1.3 percent between the baseline and the intervention period when the RCW 27 cold boxes were being used. These small excursions were associated with incorrect procedures at some stores early in the demonstration period and a faulty setting on one of the refrigerators used to freeze the PCMs, which caused them to reach -20°C until the problem was discovered. When these issues were resolved, the occurrence of

freezing temperatures dropped to zero. Heat exposures were also recorded, but they were minor (under 20°C) and for short durations.

In the district with the best performance, the percentage of transport time at 2°C to 8°C reached 96.2 percent, demonstrating the level of performance that can be achieved.

Users reported liking the RCW 27 due to the significant reduction in the risk of freezing vaccines compared to the conventional cold box lined with frozen ice packs. They also reported liking the more streamlined loading of the cold box, as they can immediately pack the cold box without the need for the WHO-recommended process of conditioning frozen ice packs.

Despite their apparent success in maintaining safe temperatures during transport, the RCW 27 containers with PCM packs posed two challenges. First, because PCM packs are designed to freeze at 5°C, they must be stored in a refrigerator instead of in a freezer. However, reaching 5°C overnight required setting the temperature in

the refrigerator to 2°C. Since the immunization officials and storekeepers considered this setting too low for vaccine storage, an additional refrigerator dedicated to freezing PCM packs was provided in each store. Second, users commented that the RCW 27 cold boxes were too heavy.

SENEGAL: DOMETIC RCW25 VACCINE CARRIER WITH PCM PACKS FOR VACCINE TRANSPORT AND AIRCONTAINER PACKAGE SYSTEM BIGBOX-CONTAINER WITH PCM PACKS

In late 2010, the Government of Senegal launched a new project to demonstrate the impact of vaccine supply chain improvements, including the use of "moving warehouses" in the Saint Louis region to deliver vaccines to the peripheral levels of the



Dometic RCW25 vaccine carrier. Photo: Fatou Kandé

health system. A moving warehouse is a truck that travels in a circuit from the regional pharmaceutical store in Saint Louis to health centers on a set monthly schedule to deliver vaccines and consumables. The moving



Aircontainer Package System Bigbox-container. Photo: Fatou Kandé

warehouse includes a delivery and supervision team who checks stock levels and replenishes stock as needed, provides supportive supervision to health care workers, and ensures that cold chain equipment is operating correctly.

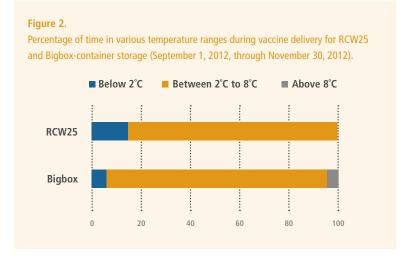
To keep vaccines cool in the moving warehouse for multi-day trips, two innovative cooling technologies were deployed and tested: the 170 L Aircontainer Package System Bigbox-container and the Dometic RCW25 vaccine carrier. Both containers use PCM packs to help prevent freezing. The larger Bigbox-container, with a cold life of about 2.5 days, was used for the shorter circuits from the regional pharmaceutical store to health centers in the Saint Louis, Richard Toll, and Dagana districts. The RCW25, with a cold life of about 4.5 days, was used during transport to the more remote districts of Podor and Pété (325 km from the regional pharmaceutical store). The moving

warehouses were equipped with continuous temperature monitors to record vaccine temperatures. Figure 2 shows three months of temperature data from the Bigbox-container and the RCW25 vaccine carriers. Both containers maintained safe temperatures for 84 to 89 percent of the time during this period.

Temperatures below 2°C were found in both containers; however, these were associated with user error at the beginning of the intervention. When the RCW25 was initially used (prior to the temperature readings above), health workers did not load PCM packs on the lid/top of the box to increase the capacity, and as a result the initial temperature readings were inconsistent. Retraining addressed this issue, and in the end users reported that the

Dometic RCW25 is a very sturdy carrier and is well adapted to the type of environment in northern Senegal. However, many users also commented that the 4-L capacity is too small.

The Bigbox-container also faced some challenges early in the pilot. Because the PCM material in the Bigbox-container could not be refrigerated in Senegal, the protocol required 36 hours of freezing and 24 hours of conditioning prior to use.



Coordinating this lengthy protocol with departure dates led to temperature excursions early in the project. These excursions led to the Department of Prevention's decision to suspend use of the container and temporarily transport vaccines in a refrigerated truck. However, once the protocol was consistently followed and more consistent temperature data were available for the Bigbox-container, vaccines were again transported in the Bigbox-container. At the end of the project, users reported liking the size of the Bigbox-container, but suggested it could benefit from upgrades to the hinges and locks, as well as the inner insulation, which was fragile. This feedback was provided to the manufacturer.

SURE CHILL® LONG COLD LIFE ICELINED REFRIGERATOR BY SURE CHILL COMPANY LTD.

EVIDENCE BRIEF

In Senegal's Saint Louis region, another innovative solution for vaccine storage was demonstrated—a more reliable and energy-efficient ice-lined refrigerator with a long holdover time, Sure Chill®, by Sure Chill Company Ltd. (formerly True Energy). This refrigerator can provide stable temperatures for long periods in intermittent power conditions. In fact, the use of Sure Chill® technology can eliminate the need for backup generators for refrigeration if grid electricity provides an average of at least four hours of power per day. The holdover time of the Sure Chill® is an impressive ten days and 9 hours in 43°C ambient conditions. This means that once properly cooled,



The Sure Chill® icelined refrigerator is PQS prequalified bv WHO. Photo: PATH

the Sure Chill® can withstand a complete absence of electricity for ten days while still maintaining temperatures in the vaccine compartment below 10°C.

In total, 12 Sure Chill® ice-lined refrigerators were installed at the regional pharmaceutical store in Saint Louis. Continuous temperature monitoring records show that the refrigerators kept vaccine storage temperatures within the range between

2°C and 8°C 93 percent of the time.

NEXT STEPS FOR THESE TECHNOLOGIES

All of the passive devices evaluated in Senegal, Tunisia, and Vietnam are available for purchase, but as of July 2013, none have been pregualified by WHO. New specifications for these devices were published by WHO in December 2012, which suggests that several devices may be prequalified soon.

As the need for longer-life, larger-capacity cooling technologies becomes evident, more manufacturers are starting to respond. At the time of printing, there are at least two new passive devices under development by different manufacturers that may allow for a cold life of more than 30 days.

In all cases, manufacturers appreciated having the opportunity to field test their technologies in real-life settings. Each country provided a unique set of challenges to overcome and useful user feedback that can be incorporated into product design and training.

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FINDING MORE INFORMATION

PQS devices catalogue

http://apps.who.int/immunization_standards/vaccine_quality/ pqs_catalogue/

Project Optimize country reports from Albania, Senegal, Tunisia, and Vietnam

www.path.org/publications/series.php?i=40

A moving warehouse delivers vaccines and essential health supplies in Senegal

http://www.path.org/publications/detail.php?i=2307

PATH http://sites.path.org/vpsse/optimize

World Health Organization

http://www.who.int/immunization_delivery/optimize/en/index.html