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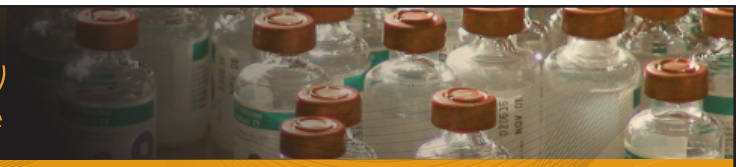

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Oral polio delivered safely without ice packs in recent study

by Ariane Halm, EPIET (European Programme for Intervention Epidemiology Training); and Olivier Ronveaux, WHO

Optimize recently completed a study with the World Health Organization (WHO) Country Office and the Ministry of Health in Mali to determine the feasibility of using oral polio vaccine (OPV) out of the traditional cold chain temperatures during a National Immunization Day campaign. In four health areas, 39 vaccination teams successively transported OPV in the vaccine carrier with ice packs (keeping the vaccine at cold chain temperatures) and without ice packs in order to evaluate the outcome of transporting the vaccines without ensuring a continuous cold chain. The practice at ambient temperature was limited to a maximum of one outreach day.

The study concluded successfully with no major problems or deviations to the methodology. A total of 14,913 children were vaccinated in the study areas. About half of the vials (54%) were transported in vaccine carriers without ice packs, and all of these vials were still usable as indicated by the vaccine vial monitors at the time of the last administered dose despite ambient temperatures ranging from 25° to 40°C (mean of 27°C). Wastage rates were lower for the vials traveling without ice packs because they did not have the problems usually caused by melting ice and ice packs (e.g., moisture on the label making it unreadable, vials contaminated with water, etc.). Health workers also reported that the ambient temperature transport facilitated preparation and implementation activities, reduced the weight they needed to carry, and required less time (possibly resulting in more kids immunized). Direct costs for the ambient temperature transport were lower, primarily because ice packs did not need to be resupplied.

The study suggests that ambient temperature transport of OPV may provide a safe alternative in geographically challenging settings or where cold chain material cannot be made available. However, vaccines transported in ambient temperature must come with vaccine vial monitors and staff must be adequately trained to interpret them.

This study adds evidence to the possibility that ambient temperature supply chains may be one of the solutions to address constraints in cold chain space that are likely to occur with new vaccine introduction.

A paper on this experience is being submitted for publication in a scientific journal.

Generic preferred product profile for vaccines

by Osman David Mansoor, UNICEF; and Souleymane Kone, WHO

In June, the Vaccine Presentation and Packaging Advisory Group (VPPAG) completed a draft generic preferred product profile (gPPP) for vaccines. The VPPAG developed the document to be a reference for vaccines in the early stages of development providing recommendations on formulation, presentation, labeling, and packaging to vaccine producers. In cases where evidence is insufficient to make a recommendation, the VPPAG outlines the work required to gather the evidence. The latest version of the gPPP is available on the VPPAG's website. The document is currently being reviewed by the Technologies and Logistics Advisory Committee (TLAC) to the WHO for further review and consultation with industry and national and regional immunization officials.

The need for a gPPP stems in part from the rich vaccine research and development pipeline and increasing availability of and financing for new vaccines that may result in a variety of products that could be administered via novel routes and delivery devices. The value of these future novel products will need to be weighed against the added complexity that they pose for national immunization programs. Many of the new vaccines now supported by the Global Alliance for Vaccines and Immunization were not developed specifically for developing-country markets and come in new containers that have much higher packed volumes than the previous generation of vaccines—putting pressure on an already strained logistics and supply chain system and stretching the capacity of health workers who often receive little training, insufficient supervision, and unreliable compensation. In such an environment, products that are well labeled, have inherent safety features, and are intuitive and easy to prepare and administer are far likelier to reach target populations.

The gPPP is meant to be a starting point for discussion between industry and public health agencies in early phases of product development. As such, the generic profile does not replace preferred product profiles for specific vaccines. The VPPAG is also available as a resource for development of specific product profiles—to help weigh the trade-offs between product features taking into account the immunization program context and manufacturing constraints.

Tunisia explores new supply chain solutions for health

by Patrick Lydon, WHO

After several preliminary discussions, WHO and PATH will collaborate on a project with the Ministry of Health in Tunisia to demonstrate and validate: (a) approaches that address anticipated challenges in the supply chain system for vaccines and other health products; and (b) new solar technologies as a means of using renewable energy for the cold chain in selected field sites and health centers.

Specifically, Tunisia is interested in optimizing their health commodities supply chain by integrating the procurement, warehousing, distribution and relevant information systems for vaccines and drugs. Currently, vaccines and drugs follow separate supply chains. The idea is to pilot how the supply chain for vaccines and other temperature-sensitive health products could be streamlined and how the configuration

of the current supply chain could be changed in order to improve vaccine availability, efficiency in distribution, and quality of storage.

In addition, Tunisia is keen on reducing its dependence on fossil fuels for energy and reducing its carbon footprint. Combined with the fact that remote health centers do not have access to reliable sources of energy, the collaboration will test new solar technologies that could be widely used in Tunisia to optimally run the vaccine cold chain system and respond to the needs of health centers.

By the end of the project, Optimize and the Tunisian Ministry of Health will have information that can guide decision-making when it comes to developing an optimal vaccine supply chain for the future.

Is that a Toyota Prius in your refrigerator?

by Steve McCarney, PATH

Solar refrigeration has been a promising technology for rural health outposts in developing countries for two decades, but it has one fatal flaw, the batteries tend to die long before the rest of the system is ready to give up. Solar modules themselves have a tremendous life span of 20 to 25 years, and refrigerators can last 10 years or more. But batteries tend to die within 5 to 8 years. In small rural health posts where cotton swabs and soap are in scant supply, replacement batteries are next to impossible to find, fund, and deliver.

To overcome this challenge, Optimize has been working on two fronts. One is to develop a battery-free solar refrigerator that uses an ice bank to cool the system through nights and cloudy days. The other is to build a better battery—perhaps even one that lasts a lifetime.

Battery technology has come a long way in the last 20 years, and the new nickel metal hydride (NiMH) battery has made a mark in products like the Toyota Prius while the lithium ion family of batteries is safely propelling the Segway personal transporter. Working with two battery manufacturers, PATH will introduce versions of these long-life, maintenance-free batteries into solar-powered vaccine refrigerators. In Vietnam we are introducing both lithium-ion and NiMH batteries into two identical solar-powered refrigerators. These batteries are to be installed in two nearly identical health centers which will have nearly identical, challenging remote locations. Early field testing will help determine how close these products are to entering the market and, hopefully, solving the battery problem. Time will tell the rest of the story, but prospects are promising as battery makers compete fiercely to lower price in a bid to win the race to supply next-generation hybrid and electric vehicles. A positive side effect is the expected benefit to solar technologies.

Vietnam to assess and evaluate opportunities to Optimize

by Joanie Robertson, Huong Vu, and James Cheyne, PATH

Optimize is drafting a memorandum of understanding with the Ministry of Health, National Institute of Hygiene and Epidemiology (NIHE), in Vietnam to possibly implement two phases of work. The first, an assessment phase, will evaluate opportunities for supply chain system improvement and identify cold chain technology requirements required to optimize supply systems. The second, a demonstration phase,

will implement technologies and system interventions that can improve the vaccine supply chain and establish a long-term vision for the evolution of immunization services and support systems.

During the assessment phase, NIHE, PATH, and WHO staff will conduct an effective vaccine management study which will help highlight areas needing improvement in the vaccine supply chain. The team will also discuss future vaccine introduction plans and review and document potential approaches for information systems strengthening as well as potential areas of collaboration with fee-based immunization services. Based on the assessment results, the team will craft a vision for an optimal supply chain that can be compared to the existing public-sector supply chain.

In phase two, Vietnam and partners will begin to demonstrate new approaches and technologies on a pilot scale in three provinces. Those approaches and technologies that prove successful can then be scaled-up nationwide, potentially serving as a model to other countries wishing to implement similar interventions.

Temperature monitoring study to commence in Vietnam and Uganda

by Joanie Robertson and James Cheyne, PATH

While some vaccines will lose their potency if they are stored at temperatures above or below the standard 2° to 8°C, many vaccines are quite heat stable and can tolerate temperatures up to 40°C for months without spoiling (see figure 1). Allowing these relatively heat-stable vaccines to spend time outside of refrigeration for controlled periods of time could facilitate some outreach strategies and might free up valuable space in the vaccine cold chain.

Figure 1. Vaccines licensed for storage at 2° to 8°C...despite stability.[1]

Storage at up to 40°C	Vaccine	Formulation
1-2 months	Japanese encephalitis (inactivated) Rotavirus Bacillus Calmette-Guérin Cholera (WC/rCTB)* *Haemophilus influenzae* type b Yellow Fever	Current, liquid Spray dried Spray dried Liquid Current, liquid Lyophilized
2-6 months	Influenza Diphtheria HPV Meningitis A conjugate Rabies Tetanus	Spray dried Current, liquid Current, liquid Spray dried Lyophilized Current, liquid
≥6 months	Hepatitis A Hepatitis B Typhoid (live)	Current, liquid Spray dried Vacuum dried

* WC/rCTB= recombinant cholera toxin, b-subunit.

1. Table extracted from Robertson J, Levin C, Zaffran M. Optimizing Vaccine Supply Chains. Seattle: PATH, WHO; 2009.

To better understand the parameters of a future supply chain for vaccines that do not require full-time refrigeration, Optimize is supporting two studies, one in Vietnam and another in Uganda, to gather ambient temperature data in multiple geographic settings and seasons as part of ongoing Human Papillomavirus (HPV) vaccine delivery demonstration projects. When compiled, these data will provide a set of real temperatures during real vaccine sessions that would serve as examples of the type of conditions that vaccines might be exposed to if they were out of the cold chain. Ultimately this will add to the discussion on future supply chain policies that dictate how vaccines are stored and transported within a country.

In the study, small temperature recording devices will be attached at the district-level Expanded Programme on Immunization (EPI) offices to the interior and exterior of vaccine cold boxes when vaccine is picked up for transport by commune-level health staff for delivery in schools and community health facilities. The temperature recorders will be kept with the vaccines at all times until the cold boxes are returned to the district level. The person in charge of these vaccines will document the date, time, and location of each place that the vaccine is stored and delivered. When the vaccination sessions are over, the recorders will be removed and returned to the PATH office for download and analysis in collaboration with the local ministries of health.

Senegal to explore integrated supply chains and new delivery models

by Modibo Dicko, WHO; Dr. Aboubakry Fall, Ministry of Public Health, Senegal; and Dr. Ndiouga Diallo, PATH

Optimize is discussing an agreement with the Ministry of Health in Senegal to explore several new approaches to supply chain and logistics management. The project will begin with an assessment of the existing supply chain using the newly completed Effective Vaccine Management tool, as well as a cold chain and transport inventory. Based on these assessments, the team will study the feasibility of a moving warehouse distribution system adapted from a model developed by VillageReach in Mozambique and also identify areas where the vaccine supply chain can be integrated with storage and distribution systems for heat-sensitive pharmaceuticals run by the National Procurement Pharmacy.

Initial discussions with VillageReach suggest that a moving warehouse might be an excellent fit for Senegal where health workers are often required to travel to provincial or district warehouses for supplies. In the moving warehouse distribution system, rural clinics would receive monthly deliveries from the district with necessary vaccines and supplies. Delivery staff would also receive necessary training and equipment in order to ensure refrigerator maintenance and collect data on consumptions and vaccinations at each clinic. If the model works in Senegal, Optimize will work with the ministry to develop a plan for nationwide scale-up at the end of the project.

Optimize would follow a similar plan for scale-up of an integrated cold chain should the pilot prove successful. An integrated cold chain is one that integrates a portion or all the storage, transport, delivery, and record keeping of two or more vertical supply chain. At present, there are completely separate supply chains for the immunization program and other public health interventions in Senegal. Both carry heat-sensitive health products (vaccines, drugs, reagents, etc.) to the same general areas within a similar time frame. They face the same logistical difficulties of storage and transportation, but they maintain

completely separate warehouses, vehicles, and management structures. By working together, both programs may reduce cost and eliminate redundancies, improve efficiencies, and learn from each other.

Finally, Optimize plans to explore the impact and efficiency of outsourcing equipment maintenance to the private sector for public health interventions in Senegal. Two objectives are being pursued: (1) alleviate the public-sector maintenance workload in all areas where the private sector can be profitable, thus enabling the public sector to put their limited resources toward difficult areas of the country, and (2) provide alternative employment options for recently graduated maintenance technicians.

How accurate weather data can strengthen logistics

by Steve McCarney, PATH

Chihuahua, Mexico, just south of the US border, is so predictably sunny, one hardly needs to consult a newspaper to predict the weather. Chances are it will be sunny and dry. A few hours south, in Mexico City, the weather is more temperate, and cloud cover is more frequent during the year. Until now, if both cities followed WHO Performance, Quality, and Safety (PQS) standards procedure they would need a solar refrigerator capable of lasting five days without sunshine. In fact, lacking data to support a different policy, WHO has reluctantly maintained a global policy stating that all solar refrigerators, anywhere in the world, must be capable of providing five days of solar autonomy. As a result, a health center in Chihuahua would have more battery space than it needs, and a health center in Mexico City would never have enough.

To remedy the situation, PATH's HealthTech program, funded by the United States Agency for International Development, has developed a tool to estimate the days of solar autonomy required in a specific location using local, historical weather data. PATH did this by selecting locations with 5 to 30 years of daily solar radiation data and charting the data to see periods of bad weather. Considering data over a 20- to 30-year period reveals how well a location supports solar energy collection. This in turn determines the size of the battery needed to maintain power at that location during periods of low sunlight. In areas with no solar radiation data, the tool provides a best guess based on regional data and local data.

Optimize is working with PATH and WHO to incorporate this battery requirement estimation tool into the WHO PQS standards for solar power systems. Accompanied by new standards for solar-powered, ice-lined fridges with no battery and refrigerators with longer-lasting batteries, this tool can not only predict accurate solar needs but also identify a product to meet those needs.

New resources

A heat-stable hepatitis B vaccine formulation

A collaborative effort between PATH and Arecor has resulted in a new formulation for recombinant hepatitis B vaccine that demonstrates improved stability at elevated temperatures.

[read more]*

**Published in Human Vaccines. Subscription or purchase required for full article.*

Characterization of a thermostable hepatitis B vaccine

A new hepatitis B vaccine formulation developed and tested by PATH scientists and partners at Arecor and University of Colorado has proven stable against repeated freezing at -20°C. In addition, it has proven stable for 12 months at 37°C.

[read more]*

**Published in Vaccine. Subscription or purchase required for full article.*

Vaccine presentation assessment tool

The vaccine presentation assessment tool (VPAT) is designed to model the logistical and financial impact of adding a new vaccine to an immunization schedule.

[read more]*

**Published by the PATH Malaria Vaccine Initiative.*

Logistics of health care waste management information and approaches for developing-country settings

This document considers the reality of health care waste management practices in resource-limited settings. Solutions offered within this text are based on actual experience in developing countries.

[read more]*

**Published by USAID/Deliver.*

New request for proposals

Optimize recently issued a new request for proposals (RFP) for vaccine storage containers and carriers with high thermal efficiency. RFP is now closed.

Optimize
Batiment Avant Centre, 13 chemin du Levant
Ferney Voltaire 01210 FRANCE
+33.450.28.43.75 | technet21.org
who.int/immunization_delivery | path.org/vaccine-delivery.php

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