

# OP • TI • MIZE *(transitive v.)*

To make as effective or functional as possible

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## Why Optimize?

*by Daisy Mafubelu, Assistant Director General, WHO Family and Community Health Cluster; and Chris Elias, President and CEO, PATH*

In 2007, the [World Health Organization \(WHO\)](#) and [PATH](#) jointly launched [Optimize](#), a five-year effort to help countries anticipate and manage the growing complexity of the logistics of immunization programs. The project draws strength from [WHO's](#) expertise in setting norms and standards, establishing policies, and developing guidelines and from [PATH's](#) 20 years of experience in improving vaccine transport and storage and advancing appropriate technologies to deployment in developing-country immunization systems. The collaboration, funded by the [Bill & Melinda Gates Foundation](#), is not exclusive: national governments, the [United Nations Children's Fund \(UNICEF\)](#), donors (including the [GAVI Alliance](#)), industry, and many others have critical roles to play in shaping logistics systems of the future.

In contrast to supply chains that simply react to ongoing logistical problems, Optimize and its partners envision supply chains that actively predict, propose, and meet the needs of rapidly changing immunization programs, so that as vaccination products, schedules, and policies evolve, so do the logistics systems that bring those services to people in need.

There are three dimensions to this effort. One is to create an enabling environment for innovation. This means creating preferred product profiles for new vaccine, device, transport, and refrigeration technologies so that the needs of developing countries are considered in the earliest stages of research and development. It also means creating an enabling policy environment—one that ensures that new technologies, systems, and processes are safely assimilated into country programs within a reasonable time frame. For example, a policy that allows relatively heat-stable vaccines to be used in a controlled environment, but not necessarily in the “cold chain,” could free up limited space in refrigerators and cold rooms that make up the vaccine supply chain. When coupled



*PATH/Julie Jacobson*

with a policy that requires vaccine vial monitors on these vaccines, health personnel can ensure that each individual vaccine vial has not been ruined by exposure to heat.

A second dimension of the project is to demonstrate the utility of new management processes and technologies that may improve the efficiency, flexibility, and cost-effectiveness of the supply chain. For example, the integration of the storage and distribution of vaccines with other heat-sensitive products can reduce redundancies in storage and transport equipment. Similarly, the introduction of computerized monitoring and tracking systems can help countries move beyond paper-based systems and make vaccine management and ordering more accurate and efficient.

A third dimension to the project is to share our findings and observations in real time, allowing the global community to participate in and influence discussions on future supply chain designs.

The result we seek is a globally accepted supply chain model that meets the ever changing needs of populations in low- and middle-income countries.

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## The role of handheld devices in immunization

by Olivier Ronveaux, Technical Officer EPI, WHO

For 30 years, paper and pencil have been the dominant form of record keeping in immunization programs throughout the world. After all, paper is inexpensive and ubiquitous, functional in case of power-outage, and easy to use. But when it comes to searching for data, crunching numbers, and creating reports, paper systems are almost useless. For many years, immunization programs have considered the merits of moving beyond a paper-based tracking system but have been stymied by a dizzying array of ever evolving hardware, software, and networking options—none of which were developed with the unique needs and constraints of low- to middle-income countries in mind. Recognizing that these problems are unlikely to disappear, Optimize is approaching information technology with a “systems view,” exploring handheld devices, such as PDAs, cell phones, Smart phones and other technologies, as part of a much broader information technology platform that brings together application, data, devices, and users.

There are a variety of potential applications for handheld devices within immunization, including:

- Supervision.
- Survey delivery and assessments such as effective vaccines management (EVM) and data quality surveys.
- Equipment management and specifically the [cold chain equipment management \(CCEM\)](#) tool.
- Supply chain management.
- Monitoring and reporting.
- Birth registration.

Over the next several years, Optimize will be working with collaborating country partners to explore the ways in which handheld devices can be applied in these areas to streamline the flow of data within a larger information technology platform.

## Public sector and industry: working together to better meet developing-country needs

by Debra D. Kristensen, Senior Technical Officer and Policy Advisor, PATH; and Christopher B. Nelson, Senior Director, Medical Affairs and Policy, Merck & Co, Inc.

Originally established in 2007 by the [GAVI Alliance](#) to provide presentation and packaging guidance for rotavirus and pneumococcal vaccines, the [Vaccine Presentation and Packaging Advisory Group \(VPPAG\)](#) now hosted by [WHO](#) and chaired by [UNICEF](#) has a broader mandate to discuss preferred product profiles for vaccines currently under development.

The revitalized VPPAG has begun the task of developing a generic preferred product profile for new vaccines that are destined for use in public-sector immunization programs in low-resource settings. The group is also advancing a specific preferred product profile for second-generation human papillomavirus (HPV) vaccines.

Ideally, the product profile documents will facilitate the provision of vaccines in packaging and presentations that are appropriate for use in low-resource, public-sector programs. Issues to consider include: type of container, doses per container, packaging and container packed volumes, recommended storage temperatures, and labeling. Until recently, the public sector has not routinely defined the preferred profiles of future vaccine products in a timely way.

The group aims to influence the process as early as possible in a vaccine's development lifecycle as it is costly to make substantial changes in vaccine packaging and presentation once the product is beyond preclinical development. For example, including additives to improve the thermostability or to serve as a preservative for multidose formats of a vaccine currently commercialized or in late-stage development would require repeating clinical trials, licensure, and [WHO](#) prequalification steps, all of which are time consuming and can be extremely costly.

The VPPAG is the only forum where vaccine industry and immunization program stakeholders interact to discuss details regarding vaccine product characteristics and their impact on immunization programs. The group's new Terms of Reference, draft HPV vaccine profile, and a profile previously completed for pneumococcal vaccine are available for download on the [VPPAG web site](#).

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## The battery-free solar refrigerator challenge

by Joanie Robertson, Technical Officer, PATH

In March 2009, six companies submitted designs to [PATH](#) in response to its Battery-Free Solar Refrigerator Challenge. Product designs that meet desired specifications will receive financial assistance to cover the cost of third-party testing required for consideration under [WHO's Product Quality and Service \(PQS\) process](#).

The purpose of the Battery-Free Solar Refrigerator Challenge is to encourage the development of new products in the solar refrigeration category for use in developing-country immunization programs. Solar-powered refrigerators are an attractive alternative to gas- and kerosene-powered absorption devices: they are environmentally sound, provide an alternative to grid electricity where it is unreliable, and can

be produced affordably. However, most existing solar refrigerator products are inadequately designed to meet the needs of developing-country immunization programs. The main issues relate to the lack of or inappropriate replacements for exhausted batteries, inappropriate system sizing, and poor installation work. The Battery-Free Solar Refrigerator Challenge is designed to help address the first of those issues.

By providing clear specifications to known solar refrigerator manufacturers and helping facilitate the PQS testing and submission process, Optimize hopes to reduce some of the market barriers and spur innovation and growth in this important refrigeration category.

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## **A new, comprehensive, effective vaccine management tool**

*by Osman David Mansoor, Senior Advisor EPI, UNICEF; Hailu Kenea, Technical Officer EPI, WHO; and Andrew Garnett, PATH Consultant*

Following a consultative meeting held at WHO in Geneva March 9–10, 2009, WHO and UNICEF recently completed field testing for a new effective vaccine management (EVM) tool that addresses current and anticipated challenges in vaccine management.

The latest challenges in vaccine management arise from the planned introduction of several newer vaccines into immunization programs in low- and middle-income countries. Although future presentations of pneumococcal and rotavirus vaccines should ease the problem, vaccine supply chains will need more physical space to accommodate these and other vaccines that are likely to be introduced in the coming years. At the same time, as the cost of vaccines rises, programs are under considerable pressure to avoid stock-outs, minimize wastage, and improve safe and efficient vaccine management.

Although Effective Vaccine Stores Management (EVSM) and vaccine management assessment (VMA) tools are also used to meet these challenges, experience with these tools has demonstrated that neither provides a complete assessment of the vaccine supply chain. The EVSM tool focuses on the primary store where errors can result in catastrophic loss of vaccine, whereas the VMA tool focuses more on lower levels of the supply chain where errors can result in delivery delays or in children being vaccinated with vaccine that is no longer potent.

The new EVM tool combines the best of the EVSM and VMA tools and eliminates the redundancies and incompatibility of results between the two tools. This new tool is not only an assessment tool, but it also provides the framework for management, monitoring, supervision, and improvement of the immunization supply chain system.

The EVM tool has been field-tested in Microsoft Excel format and will be field-tested again using a web-based platform. When the EVM tool is ready for widespread implementation, it will be available for download. The web-based platform offers several advantages: it will allow countries to download the latest version of the assessment tool at any time as well as electronically linked guidance materials in pdf format. Once an assessment is complete, the data can be uploaded to a central archive for analysis and safekeeping until the next assessment. The system will also have multi-language capability.

The new EVM web-based tool and the training materials will be available for download by the end of November 2009.

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## Are vertical supply chains still necessary?

by Modibo Dicko, Coordinator, Project Optimize, WHO

For the past 30 years, immunization—like many other health programs—has been managed as a vertical program with its own management team, reporting requirements, personnel, and supply chain. Attempts to link with other health programs to improve both efficiency and effectiveness have been limited to service delivery. Experience with integrating complex supply chains in low-resource settings is still rare.

However, because carefully managed “cold-chains” are no longer a privilege of vaccines only, many immunization programs are now making integration of supply chains a priority. There are many heat-sensitive drugs and other health products distributed throughout the public and private health sectors that need to be kept at 2° to 8°C during storage and transport, including insulin, reagents for HIV test kits, oxytocin, some ophthalmology drugs, and others. Like vaccines, these products are currently stored, transported, monitored, and delivered in separate supply chains, each with its own cold rooms, vehicle fleets, tracking systems, and personnel. In the future, we expect that some less-heat-sensitive vaccines will be licensed for storing and transporting at temperatures higher than 8°C, which could allow them to be integrated into the supply chains of non-heat-sensitive drugs.

By integrating one or all of the storage, delivery, or information system functions of immunization programs with other health care initiatives, countries may be able to create a more efficient and less costly supply chain system. Possible benefits to the immunization program include a reduction in average delivery time, reduction in cost per dose delivered, lower maintenance and running costs of vehicles, increased volume capacity, and improved expertise of delivery and logistics personnel. The same potential benefits will accrue to other health interventions as well.

Across countries, managers of vertical programs are becoming more sensitized to the advantages of supply chain integration. Despite the complexities of integrating some of these vertical supply chains, many governments are now eager to give it a try. Optimize has outlined the possible benefits and challenges to integration as well as the system changes and political ramifications when adopting this approach. At least two collaborating country partners (Senegal and Tunisia) are considering integration and will help us gain new insights into the merits of this approach.

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## Demonstration projects to evaluate innovative system changes

by Carol Levin, Senior Health Economist, PATH

Starting in 2009, Optimize will begin large-scale demonstration projects with four collaborating countries and conduct operational research with several others to build an evidence base for the effectiveness and appropriateness of new interventions relating to vaccine supply chain and logistics.

These new—and some not so new—interventions came out of an exhaustive search for new ideas and innovations in various sectors within and outside of the immunization sector, including some from sectors outside of health. In total, Optimize conducted ten landscape analyses on the following topics:

- Analysis of effective vaccine stores management (EVSM) indicators.
- Cool chain technologies.
- Trends in vaccine availability and novel vaccine delivery technologies.
- Analysis of vaccine management assessment tool (VMAT) indicators.

- Handheld digital devices.
- Health information systems solutions, technologies, and management practices in immunization.
- Outsourcing and innovative financing in the health sector.
- Policy process in immunization systems.
- Supply chain and logistics for immunization: main findings from the landscape analyses.
- Supply chain and logistics for health: main findings from the landscape analyses.

The most promising designs—in the form of products, system changes, and processes—from these analyses will be evaluated in demonstration projects. The purpose of the demonstration project work, while focused primarily on evaluating new ideas, is multifaceted. Specifically, we aim to (1) develop and/or refine a design, and (2) demonstrate how the system will work and test its feasibility. As part of the demonstration projects, we will also build capacity to implement proposed system changes.

Within the next several years, Optimize and its collaborating partners will be able to share our learning about how supply chain and logistics systems can evolve to better manage the changes in the vaccine field now and in the future.

# OPTIMIZE

Immunization systems and technologies for tomorrow

## Optimize

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