

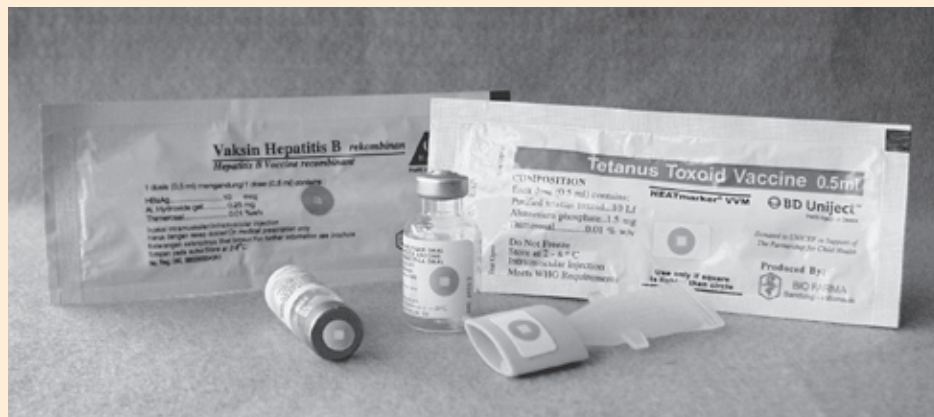
While the evolution of each health technology is unique, this case profile provides a glimpse into the activities that brought vaccine vial monitors (VVMs) to the global stage. Over the course of nearly 30 years, PATH has helped move VVMs from a concept to a product that is enhancing immunization programs around the world.



Philippe Blanc

PRODUCT INTRODUCTION CASE PROFILE

Vaccine Vial Monitors: Small Labels With an Immense Impact



PATH/Jennifer Fox

Imagine the challenge of getting the extremely heat-sensitive polio vaccine from a pharmaceutical company in Europe to a remote village in Ghana. The vaccine leaves by truck, is flown to Africa, and is carried by truck or bicycle to a refrigerator in a rural clinic, where power outages are commonplace. The journey may take days or weeks, during which the vaccine is constantly at risk of being spoiled. In the past, heat-damaged vaccines were sometimes unknowingly delivered to children, or good vaccine was thrown out because health workers feared it had gone bad.

To address this “cold chain” problem, PATH found a technology originally used by the food industry to label perishable products and worked with its owners to adapt it. The resulting product—the vaccine vial monitor, or VVM—is a small sticker that adheres to the vaccine vial and changes color as the vaccine is exposed to heat, letting the health workers know whether the vaccine can be safely used for immunization.

Identifying—and developing—a viable product

In the late 1970s—with funding from a number of partners, particularly the US Agency for International Development—PATH began working with the World Health Organization (WHO) to turn the idea of a VVM into reality.

PATH searched various industries to identify a chemical that could be used to monitor the exposure of heat-sensitive vaccines. After rigorously evaluating the first promising candidate—which PATH produced and refined—in more than 20 countries,

we discovered a superior technology manufactured by LifeLines Technology, Inc. (now known as the TEMPTIME Corporation) that applied to a broader range of vaccines, including the very heat-sensitive oral polio vaccine (OPV). In 1989, we began working with LifeLines to adapt and produce VVMs with their HEATmarker™ technology.

Design field trials and validation studies were essential to obtaining input directly from users. From 1990 through 1992, we conducted studies with HEATmarker prototypes in eight countries. We then worked with Zimbabwe’s Ministry of Health to analyze the impact of VVMs on the discard rates for measles vaccine. Based on positive results, PATH, WHO, and other partners continued to refine the VVM specifications and address the feasibility of integrating VVM labels into their products.

Once VVMs were validated, PATH worked to secure WHO’s official recommendation and policy development and encourage the inclusion of VVMs in UNICEF’s vaccine procurement specifications. This journey took nearly a decade.



PATH's product introduction framework



PATH developed training materials—manuals, instructional stickers, and posters—to help health professionals use VVMs correctly.



PATH also integrated VVM information into training programs for immunization managers, national logisticians, and health care workers.



1455 NW Leary Way
Seattle, WA 98107 USA

Tel: 206.285.3500

info@path.org

www.path.org

Introducing VVMs for widespread use

Because VVMs were to be adopted by UN agencies, PATH and its partners could quantify the annual supply needs. PATH and WHO began approaching potential VVM manufacturers, meeting with more than a half-dozen companies to create market competition. Ultimately, only one manufacturer—LifeLines—proved able to manufacture the product at a price that was sufficiently affordable for the developing world. Concerns about their ability to serve the entire vaccine market soon arose, however, and PATH helped LifeLines procure a low-interest loan to create back-up production lines. We also spoke with UN agencies about mechanisms to address supply issues in vaccine-procurement contracts.

In 1995, WHO and ministries of health in Tanzania and Vietnam began pilot introduction of VVMs for OPV. The following year, all OPV procured by UNICEF included VVMs. WHO completed VVM impact studies during national immunization days in four countries—Kenya, Nepal, Tanzania, and Turkey—and performed an in-depth study of the impact of VVMs in Bhutan. India imported OPV with VVMs for their national immunization days and later issued an official request for WHO assistance in supplying VVMs on locally produced OPV. Eventually, the Indian Government applied for and received funding from the UK Department for International Development and achieved this goal.

Targeted activities were essential to making VVMs available in these national or special programs. To make the information widely available, we created and published training documents at WHO's request, assisted with in-country vaccine management training, and provided information to policymakers, industry collaborators, and other immunization professionals.

PATH also assisted vaccine producers with VVM implementation. At first, they were reluctant to add the monitors because of the additional (although relatively minor) cost. But several years of persistence by public-sector advocates and stakeholders, including PATH, finally paid off, and manufacturers started to comply with the UNICEF requirements for VVMs on all UNICEF-procured vaccines. WHO support was essential to this effort, as was the GAVI Alliance's requirement that new vaccines funded by the Vaccine Fund be labeled with VVMs.

Integrating VVMs into health systems

Today, VVMs are available for all vaccines used in immunization programs in developing countries, and UNICEF requires them on all vaccines they purchase. Health workers can make informed decisions about whether vaccine vials need to be thrown away due to heat exposure and feel confident that vaccine they use has not been damaged by the heat. PATH and WHO have developed and tested training materials for health workers that help them learn how to handle vaccines and use VVMs effectively.

PATH estimates that over the next ten years, VVMs will allow health workers to recognize and replace more than 230 million doses of inactive vaccine and deliver 1.4 billion more doses in remote settings—actions that could save more than 140,000 lives and reduce morbidity for countless others. Thanks to the presence of VVMs, WHO was able to revise its policies to allow open vials of liquid vaccine to be used for more than a single day. That alone has saved immunization programs around the world millions of dollars. UNICEF and WHO have estimated that the use of VVMs, even if only on basic vaccines, could save the global health community \$5 million per year.

VVMs are also used to extend the reach of immunization programs by taking the vaccine beyond the cold chain. This has been especially useful for polio-eradication efforts in war-torn and inaccessible regions of the world, as well as for outreach efforts that deliver vaccines to newborns' and mothers' homes.

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