

A HealthTech Historical Profile

Vaccine Vial Monitors

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Acknowledgment

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HealthTech Historical Profile: Vaccine Vial Monitors

The Problem

A major problem in immunization programs throughout the world has been the challenge of monitoring and managing the temperature of vaccines as they “travel” through the distribution chain to the destinations where they are used. Vaccines require careful storage and transport to the point of use to avoid harmful heat exposure. In the past there was no way to detect whether individual vials had been exposed to heat, so national immunization programs adopted conservative guidelines for vaccine handling and disposal of vaccines when heat exposure was suspected. This often resulted in disposal of good vaccine—by programs where resources were already scarce.

When recognized by PATH

The initial concept for a heat exposure indicator that could be placed on individual vaccine vials was conceived by World Health Organization (WHO) officials in 1979. In response, with funding from non-USAID sources PATH developed first generation prototypes for measles vaccine using a chemical licensed from Allied Corporation. Once the HealthTech program was started in 1987, one of the initial subprojects was established to identify an appropriate heat exposure indicator technology for oral polio vaccine (OPV), as the chemical from Allied was not sufficiently responsive enough for the extremely heat sensitive OPV. Under HealthTech, a new core technology owned by LifeLines Technology, Inc.,* (New Jersey) using diacetylene polymers was discovered. Unlike the Allied chemical, the new technology was found to be applicable to all vaccines and easier to manufacture.



VVMs on various vials

PATH/HealthTech worked with LifeLines Technology, Inc., to successfully modify their proprietary technology for use with all vaccines used in developing-country immunization programs. The resulting products became generically known as vaccine vial monitors (VVMs). The LifeLines' brand is HEATmarker.^{TM†} HEATmarkers became commercially available in 1991 and are now a standard feature of all vaccines purchased through United Nations (UN) agencies.

* Now TEMPTIME Corporation.

† HEATmarker is a trademark of TEMPTIME Corporation.

Since 1987, USAID has carried the primary responsibility for VVM development and introduction through HealthTech for over 18 years.

When recognized by international agencies

The need for a heat exposure indicator for individual vaccine vials, as mentioned above, was originally recognized by WHO/EPI (Extended Programme on Immunization) staff. Success with use of cold chain monitors (heat exposure indicators used for shipment of cartons of vaccine) at higher levels of the cold chain prompted interest in a vial indicator to extend monitoring to the periphery where maintaining the cold chain was most difficult. As the original proponent of the VVM concept, WHO has worked closely with PATH/HealthTech on all aspects of VVMs.

United Nations Children’s Fund (UNICEF), the major vaccine supplier to developing countries, began to be involved in discussions on VVM introduction through the multiagency “Technology Introduction Panel” in 1990.

The Pan American Health Organization (PAHO) became involved in early dialogue regarding VVMs with WHO and PATH in 1985, and PAHO provided support and oversight to VVM studies conducted in PAHO countries.

Technology Solutions/Strategies

Design/Development

PTS Technology

As mentioned earlier, product development on a VVM for measles vaccine began at PATH in 1979 using a PTS (p-toluenesulfonate) chemical licensed with permission from Allied Corporation. The measles VVM prototypes were produced and refined by PATH, and design field trials were conducted in 1981 in Mexico and the Philippines.

Validation field testing of measles VVM prototypes were conducted collaboratively by PATH, WHO, and ministries of health (MOHs) between 1982 and 1985 in ten countries (Argentina, Brazil, Egypt, Kenya, Nepal, Pakistan, Peru, the Philippines, Yemen, and Zimbabwe). Introductory trials took place in five countries from 1987–1990 (Indonesia, Kenya, Sierra Leone, Thailand, and Zambia). Prototype production for these studies highlighted several constraints to the PTS technology, including a reaction rate too slow for use with oral polio vaccine, dermal toxicity issues, and printing difficulties.

HEATmarker Technology

Funding from HealthTech in 1987 allowed PATH to expand on the work performed to date and cast a wider net for a more appropriate technology. In 1988, PATH identified a new core technology for VVMs (using diacetylene polymers), owned by Lifelines Technology, Inc., that overcame the constraints of the PTS technology. In 1989, PATH began work with LifeLines to adapt and produce VVMs using their core technology.

As noted by the Chairman of LifeLines, *“In 1989, PATH provided a contract to LifeLines Technology to adapt its time-temperature technology for use on oral polio vaccine. The money to support this initiative came from USAID funding. After many months of experimentation without achieving technical success, LifeLines “gave up” on the program. Representatives from PATH traveled to LifeLines. The global significance of the humanitarian aspect of the contract was described deeply by PATH. It was at this meeting that the VVM program was given a second life. PATH convinced LifeLines to continue working to reach the technical goal, and to do so without additional funding.”* LifeLines rededicated itself to the project.

From 1990–1992, design field trials of the new HEATmarker VVMs were conducted in eight countries (Bangladesh, Bolivia, Cameroon, Indonesia, Kenya, Sierra Leone, Thailand, and the United States). In addition, a detailed study was conducted in Zimbabwe with the MOH that analyzed the impact of VVMs on measles vaccine discard rates due to heat exposure. During this time period, WHO and PATH representatives met with eight UN vaccine suppliers to discuss the feasibility of integrating VVM labels into their products. HEATmarker prototypes were subsequently sent to ten UN vaccine suppliers and PAHO to obtain further feedback. In 1993, LifeLines developed a capability to print VVMs directly onto vial labels. This helped to overcome vaccine manufacturer resistance to purchase labeling equipment for a separate VVM label.

In 1995, WHO released specifications for VVMs for OPV, and in 1999 they released specifications for VVMs for all vaccines used in developing-country immunization programs. Four VVM types (VVM2, VVM7, VVM14, and VVM30) were deemed to be sufficient to cover the thermal stability of all vaccines. The types are identified by the time to reach end point at 37 degrees C. For example, a VVM7 reaches end point after seven days at 37 degrees C. The specifications were updated and test procedures for validation were released by WHO in 2002.¹

Other Technologies

PATH and WHO worked diligently to encourage other companies to develop competitive VVM products. Technical assistance was provided to Albert Browne, Ltd. (UK), 3M (US), Rexam/Bowater (UK), CCL Label (US), and Sensitech (US). Unfortunately, none have been successful in developing a product that can meet the performance requirements of the UN agencies and successfully compete with HEATmarker prices.

Validation—own or third partyLaboratory Testing

1980	Connaught Laboratories (now Sanofi-Aventis), Canada	Testing of the early PTS prototypes.
1987–1991	PATH under HealthTech	Numerous physical tests on PTS and HEATmarker prototypes: durability, water resistance, integrity of adhesives, effect of light exposure, response rates.
1992	Strasburger and Siegel (US)	Independent laboratory evaluation of HEATmarker, supported by WHO.
1998–1999	Consumers' Association Research and Testing Centre [‡] (UK)	Second validation of VVM2 conducted under WHO contract.
1999	National Institute for Biological Standards and Control (UK)	Validation study commissioned by WHO to correlate OPV stability with VVM response. Good correlation between vaccine potency and VVM status was shown for vaccines produced by all four OPV suppliers to UN agencies.
1999–2001	Precision Measurements and Instruments Corporation (US)	Tested the conformity of HEATmarker VVM7, VVM14 and VVM30 to WHO specifications under contract from the WHO.
2001–2003	Consumers' Association Research and Testing Centre (UK)	Completed an additional real time validation test of the HEATmarker VVM7 at 8 degrees C under WHO contract.

[‡] Now the ITS Research and Testing Centre.

Validation by Vaccine Producers

Multiple years	Seventeen UN vaccine producers	Each of these producers has completed an internal validation process prior to procurement of VVMs. Many duplicated the complete WHO protocol to test conformity to WHO specifications. In addition, these producers regularly sample and test HEATmarker VVMs upon receipt and prior to labeling.
	PATH, CCL Label, and LifeLines worked with Serum Institute of India	To demonstrate the feasibility of labeling VVMs onto the caps of a freeze-dried vaccine (i.e., measles) under funding from the US Centers for Disease Control and Prevention (CDC).
2001	PATH assisted PT Bio Farma (Indonesia)	Identification, installation, and validation of equipment to label VVMs onto the packaging of Uniject™ prefill injection devices under funding from UNICEF and CVP.

Validation by Users

HEATmarker VVMs were extensively field tested in 14 countries.² In 1997, UNICEF sent a questionnaire to 50 countries to determine whether they had any difficulties with VVM introduction.

Technology Transfer or Licenses

The principal patents held by LifeLines, now called TEMPTIME, for the VVM technology have expired. However, production know-how is significant. PATH and TEMPTIME have discussed the possibility of technology transfer to other companies on a royalty basis; however, since TEMPTIME is able to easily supply sufficient quantities for global use, technology transfer of VVM production has not been pursued.

Policy Environment**Involvement of international agencies**

This technology had to become a requirement in UN tender specifications for vaccines in order to encourage adoption. WHO developed product specifications and testing requirements and encouraged UNICEF to include VVMs in all tenders for OPV. Later, WHO and UNICEF developed a joint policy statement recommending placement of VVMs on all vaccines, and UNICEF began integrating VVMs into vaccine procurement tenders. However, UNICEF did not enforce the specifications for many years—largely due to their lack of leverage in markets with limited suppliers.

Changes in policy needed and completed

The primary product availability route pursued by PATH under the HealthTech program was official recommendation and policy development by WHO (once the product was validated in both field and laboratory studies), followed by inclusion of VVMs in vaccine procurement specifications by UNICEF. Despite heroic efforts by WHO to make the technology available, the journey was an arduous one.

UN Requirement for VVMs on OPV (1991–1996)

VVMs were originally discussed at a Technology Introduction Panel meeting at UNICEF in New York in 1990. In 1991, another meeting was held in New York at which WHO requested that UNICEF include VVMs for OPV in the 1992–1994 vaccine tender. UNICEF included a clause in the tender notifying manufacturers that they would request labeling with VVMs prior to 1994. The tender for 1994–1995 (released in 1993) requested quotations for VVMs on both measles and oral polio vaccines, but only a few manufacturers provided such quotes.

WHO, UNICEF, and OPV manufacturers met in 1994 and agreed to include VVMs on all OPV beginning in January 1996. In 1995, WHO released final specifications for VVMs for OPV. By 1996, all five OPV suppliers to UNICEF (SmithKline Beecham, Biocine, Pasteur Merieux Connaught, Chiron Behring, and PT Bio Farma) were supplying VVMs on their products.

UN Requirement for VVMs on All Vaccines (1994–Present)

In 1994, the Technical Network for Logistics in Health (TechNet) consultation to WHO recommended that VVMs be included on all vaccines, beginning with OPV.

In 1996, the Strategic Advisory Group of Experts (SAGE) released a statement in support of VVM introduction.³

In 1998, TechNet again recommended that VVMs be introduced for all vaccines as soon as possible. In the same year, a meeting on the introduction of VVMs on all vaccines was held at WHO Geneva and attended by WHO, UNICEF, PATH, USAID, LifeLines, and 3M. As a follow-up to the meeting, WHO sent a letter to all UN prequalified vaccine producers requesting feedback on VVM specifications.

In 1999, WHO and UNICEF issued a joint policy statement⁴ advocating the use of VVMs on all vaccines. At a pre-tender meeting in Copenhagen, UNICEF announced that VVMs would be included on all vaccines in the 2000 tender with an expectation of full implementation by January 1, 2001. WHO then updated the VVM specifications to make them relevant for all vaccine types.

In 2000, UNICEF included VVMs among the “minimum requirements for vaccines to be procured by UNICEF” in the invitation to bid for 2001–2003. VVMs were also included among the minimum requirements for vaccines in the request for proposal for the Global Alliance for Vaccines and Immunization (GAVI) for under-used vaccines.

But by 2001, only three UNICEF vaccine suppliers (Japan BCG, Pasteur Dakar, and Chiron) fully complied with the VVM specification for vaccines other than OPV. UNICEF solicited

documentation from vaccine suppliers on all issues limiting their ability to provide VVMs on vaccines, and WHO provided UNICEF with a document addressing each technical concern raised. PATH provided technical assistance to WHO, GAVI, and UNICEF to support their negotiations with vaccine producers.

During 2002, a “Technical Session on Vaccine Vial Monitors” was held in Geneva in March and involved all UN vaccine suppliers, UNICEF, WHO, and PATH. The objective of the meeting was to finalize the WHO-UNICEF action plan on VVMs.

Since the meeting, implementation has slowly, but surely progressed. As of May 2005, seventeen of the twenty-two current UN vaccine suppliers include VVMs on their products. Of these, Sanofi-Pasteur (formerly Aventis Pasteur) is the only major supplier that refuses to label vaccines, other than OPV, with VVMs.

GAVI Policy

In 2002, the GAVI Board stipulated that from the beginning of 2004 all vaccines purchased through The Vaccine Fund must include VVMs—a target that will be met this year, with the exception of Yellow Fever vaccine.

Multi-dose Vial Policy

The availability of VVMs facilitated the implementation of the “multi-dose vial policy” by WHO in 1995, which allows opened, multi-dose containers of liquid vaccine (DTP, TT, DT, Td, hepatitis B, liquid formulations of Hib, and OPV) to be used for more than one day. With VVMs, the heat exposure of opened vials of vaccines is known and conservative policies to discard all liquid vaccine after it has been opened and possibly taken on outreach were no longer necessary. The result was a dramatic decrease in vaccine wastage. The policy was updated in March 2000.⁵

Flexible Cold Chain Policies

VVMs are making it possible to establish new policies for use of vaccines beyond the cold chain. In 2000, WHO created a new policy advocating the use of VVMs to extend the outreach of polio eradication efforts.⁶ As VVMs became available on additional vaccines, countries began studying the storage and transport of heat stable hepatitis B and tetanus toxoid vaccines outside of the cold chain. An added benefit of taking these vaccines outside of the cold chain is that they are freeze-sensitive and are most at risk of freezing while in the cold chain. In 2005, WHO convened a meeting of experts to develop flexible cold chain policies for all vaccines. Two policy papers have been drafted. The first outlines procedures for transporting all vaccines within country without ice in order to prevent freeze damage to the aluminium adjuvant-based vaccines. The second recommends methods to improve coverage by transporting vaccines beyond the cold chain. Both proposed WHO policies rely on the VVM to ensure that vaccines are not exposed to excessive heat exposure.

Introduction Phase

Product roll-out with oral polio vaccines

Pilot introduction of VVMs for OPV began in 1995 in Tanzania and Vietnam by WHO and ministries of health. By 1996, all OPV procured by UNICEF included VVMs. In 1997, VVM impact studies were completed by WHO during national immunization days (NIDs) in four countries (Kenya, Nepal, Tanzania, and Turkey). An in-depth study on the impact of use of VVMs and the multi-dose vial policy was completed in 1998 by WHO in Bhutan; technical assistance for the study was provided by HealthTech staff.



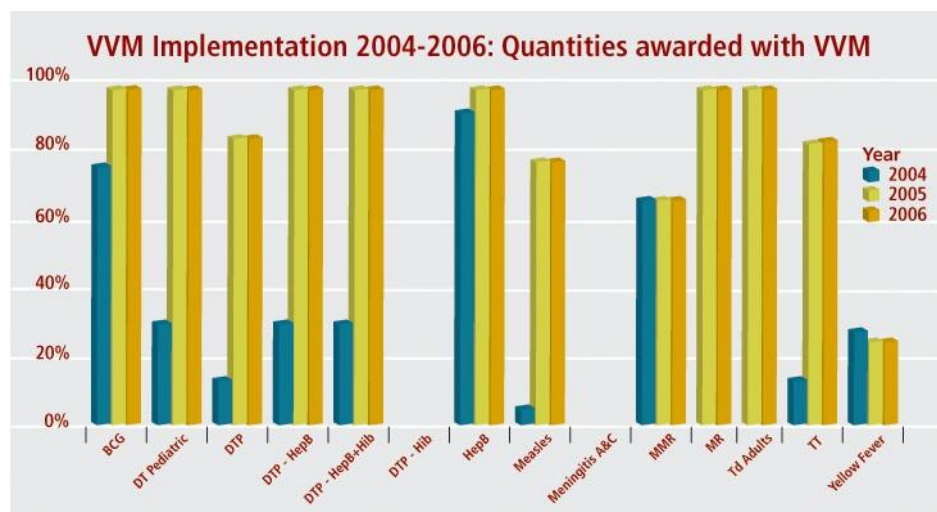
VVMs have been available on polio vaccine since 1995. Source: GAVI.

In 1996, India imported OPV with VVMs for national immunization days. After the experience, they issued an official request to WHO for assistance in supplying VVMs on locally produced OPV. The United Kingdom's Department for International Development (DFID) funded and managed activities that resulted in successful integration of VVM labeling onto OPV vials produced in India for government purchase and VVM training material development for national use.

Product roll-out with other vaccines

Between 2001 and the present, there has been a gradual increase in availability of VVMs on UNICEF-procured vaccines. Today, the majority of vaccines purchased by UNICEF are labeled with VVMs (see Figure 1) and over one billion VVMs have been used in immunization programs throughout the world.

Figure 1: VVMs on vaccines supplied through UNICEF 2004–2006. Source: UNICEF



Targeted efforts to make VVMs available in national or special programs have also been successful. National vaccine manufacturers in four developing countries are using VVMs.

Training

PATH, under HealthTech, has assisted WHO with all aspects of WHO training material development for VVMs⁷ and with VVM training for immunization program managers and/or national logisticians in more than 14 countries.

In addition, PATH directly created and published some training and policy documents at WHO's request and in order to make information available in a timely fashion. PATH developed the following documents and made them available on line and by CD-ROM for use by national immunization programs.

- A policy document was developed for WHO entitled “Adopting Global Vaccine Management Policies for National Use” to assist countries in implementing policy on VVMs and other vaccine-management issues under HealthTech funding.
- Vaccine Vial Monitor “training cards” in English, French, and Portuguese were printed and distributed in Africa for use by WHO/AFRO with funding from UNICEF.
- PATH produced a VVM fact sheet that was included in the UNICEF/GAVI “Vaccine and Immunization Products Guideline”—used in 50 GAVI country consultations.

Finally, PATH has also provided information about VVMs through presentations to policy makers at regional Expanded Programme on Immunization (EPI) meetings, presentations to collaborators, posting information on the PATH and TechNet websites, writing briefing documents for publications of GAVI, and training PATH program staff worldwide so that they can appropriately represent the issues.

Mainstreaming/General Acceptance

Since introduction in 1996, VVMs have helped to ensure that only potent vaccine is used to immunize children and in efforts to extend the reach of services, thus increasing coverage. The presence of VVMs made it possible for the Polio Eradication Campaign to safely carry oral polio vaccine into remote areas without refrigeration, thus contributing significantly to the success of the campaign. It also enabled WHO to implement the “multi-dose vial policy” that allows health workers to use opened vials of vaccine for more than one day. This has markedly reduced vaccine wastage, saving millions of dollars in immunization programs throughout the world. The VVM is considered a standard feature on vaccines used in developing countries. Acceptability is high (see “Evidence of Impact” section below).

Hurdles/Constraints

Obstacles affecting availability of VVMs

- Vaccine producers lack incentives to incorporate VVMs on their products because VVMs will not yield additional profit, may decrease quantities of vaccine purchased, and involve extra work. A market “pull” mechanism—using a large public-sector purchaser to create the demand for the product—was therefore essential.
- The VVM is a novel, paradigm-shifting technology that is currently only available from a single supplier. UNICEF Supply Division was not comfortable with the sole source issue,

the deviation from procurement of commodity products, and the strain that the extra requirement caused on relationships with suppliers. VVMs for OPV were commercially available and recommended by WHO in 1991; however, they were not required in UNICEF specifications until 1996. VVMs for other vaccines were commercially available in 1993, but not placed in UNICEF specifications until 2001, and are still not available on all vaccines procured by UNICEF. Strong support from WHO, USAID, GAVI, CDC, and others, has been necessary to continue to move the availability of VVMs forward.

- Although PAHO supported a number of field trials with early VVM prototypes, they have never required VVMs on products purchased through the PAHO revolving fund, citing lack of cold chain difficulties in their region and unwillingness to pay the slight price increases for products with VVMs. Vaccine suppliers complained that they had to supply vaccine with VVMs for UNICEF and without for PAHO, but eventually most complied with the UNICEF requirement.
- One repeated difficulty has been the inability of the UNICEF supply system to consistently send the same brands of vaccines to countries or to notify WHO with regard to which countries would receive vaccines with VVMs. WHO was therefore unable to target early training efforts to countries that would definitely receive the VVMs. For many years, countries received supplies of vaccines both with and without VVMs and therefore could not rely on their use as a routine management tool.
- While VVMs are increasingly supplied on vaccines purchased for the international market through UNICEF, they are not yet available on many of the vaccines produced in developing countries for domestic markets.
- Vaccine procurement for developing and emerging countries is becoming increasingly decentralized, meaning that a variety of purchasers must include VVMs in their tender specifications to ensure consistent availability to immunization programs. Continued work to strengthen procurement at the country level (e.g., through interagency coordinating committees) will be necessary to ensure vaccine quality and availability of vaccines with VVMs. PATH has edited the relevant section of the “WHO Procurement of Vaccines” reference manual to ensure that countries have the latest information on VVM specifications.

Expanding the source of VVM supply

- The fact that there is a single source of VVM supply creates some inherent risks and means that there is a lack of price competition. To mitigate the risk to vaccine suppliers, language has been added to UNICEF and other vaccine tenders to relieve vaccine producers from the VVM specification for a specific order if TEMPTIME does not meet specified delivery terms and conditions. TEMPTIME has also established multiple printing lines to ensure ongoing production capability should one line fail.
- The current VVM specifications are geared toward the polymer technology used in products from TEMPTIME. Other technologies may not be well suited to the limits of these specifications. Additionally, multiple VVM formats would create confusion for end users.

- While new VVM suppliers have been encouraged to enter the market over the years, the prognosis is not good due to the low profit margins on these products and the significant research and development investments required. In addition, a substantial private-sector market does not yet exist for time/temperature indicators for other perishable goods.

Evidence of Impact

Experience thus far has shown that health workers using VVMs can:

- Prevent delivery of heat-damaged vaccine to children.^{4,8,9,10,11}
- Reduce the discard of usable vaccine when heat-exposure occurs.^{8, 11,12,13}
- Facilitate implementation of the multi-dose vial policy, which allows opened containers of liquid vaccine to be used for more than one day, thus, markedly reducing vaccine wastage.^{6, 11,14,15}
- Allow vaccine to be safely transported beyond the cold chain without ice, minimizing logistics and increasing outreach capabilities.^{6, 14,16}
- Better manage vaccine stocks by determining which vials have experienced some heat-exposure (but are still good and should be used first).^{11,13,17}
- Improve the cold chain by using VVMs to identify weak links requiring correction.^{17,18,19,20}

VVMs provide health workers with a clear warning when vaccine should be discarded. At minimum, they allow health workers to prevent delivery of heat-damaged vaccine and reduce the discard of usable vaccine. There are also more sophisticated and revolutionary uses for VVMs.

Polio eradication NIDs have demonstrated that VVMs can be used to remove heat labile polio vaccine from the cold chain for significant periods without compromising the potency of the vaccine. The use of VVMs can therefore facilitate outreach beyond the cold chain and help to overcome the cold chain space constraints associated with the increasing move toward single-dose vaccine presentations.

VVMs are also a powerful management tool to enable immunization programs to make changes to their cold chain infrastructures to minimize costs and decrease the chances of damaging freeze-sensitive vaccines. The level of vaccine wastage indicated by the VVMs can become the basis on which a particular cold chain is managed. Investment will be needed where wastage is high, and flexibility may be permitted where wastage is low. In this way, the cold chain may be “tuned” to eliminate costly redundancies inherent in the system today.

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 to deliver 1.4 billion more doses in remote settings—actions that could save more than 140,000 lives and reduce morbidity for countless others. UNICEF and WHO have estimated that the use of VVMs, even if only on basic vaccines, could save the global health community US\$5 million per year.

Third Party Comments

“Used properly, this can be a miracle tool to reduce wastage and prevent the use of heat damaged stock,” says Dr. Umit Kartoglu of WHO’s department of Vaccines and Biologicals.

“VVMs are currently one of the best contributions that vaccine manufacturers can make to the lives of children,” says Dr. Mercy Ahun, formerly the manager of Ghana’s national immunization programme, and now with the GAVI Secretariat.

The following is from a WHO 1997 report on a polio sub national immunization day activities in Sudan: *“A supervisor of a number of vaccination teams is waiting for vaccine carriers and icepacks to start immunizing against polio in the region for which he is responsible. He received the vaccines, but to his astonishment, he hears over the radio that the vaccine carriers were delivered on the wrong spot, and that he is expected to manage by whatever means he can think of. The local population tells him about what they call, ‘the local fridges’: gourds with water and charcoal, that allow to keep the contents cool. The supervisor decides to ask the population for a number of gourds. First there is some resistance, because the people are afraid the gourds will break, but when the supervisor asks whether they prefer polio or broken gourds, the argument is settled. The supervisor puts a ‘kick polio out of Africa’ T-shirt on top of the water and charcoal and places the vaccines, wrapped in ‘kick polio out of Africa’ caps, on top of these. He then sets off for the cattle camp, where he starts immunizing after arrival. However, another team, with vaccine carriers and ice, had also decided to immunize in the same camp. The supervisor of this team accuses the gourds team of using non-potent vaccines, because of improper storage, and advises people to bring their children to his teams. The supervisor of the gourds team can of course not accept this insult to his professional pride and clearly expresses his opinion in front of the VC supervisor. This nearly develops into a fight, when the village elders decide to interfere. They ask the VC supervisor why he thinks his vaccine carriers are any better than their gourds. On his guard, and realising how delicate the question is, the VC supervisor challenges the gourd supervisor by accusing him of using non-potent vaccine. The latter takes 2 vials of OPV, one out of the gourd and one out of the vaccine carrier and says proudly: ‘Look my friend, your VVM is as good as mine’. The story above sounds like a commercial for VVM, but it is not. It is a true story, and only one of many, describing how health workers in South Sudan solved the numerous cold chain problems they had to cope with. They could only do this because they were instructed to find local solutions to cool vaccines in case they ran out of ice, and to trust the VVM as an indicator for heat exposure. In this example the VVM started changing colour after 4 days, well after the teams had immunized their target populations.”*

Hull HF, de Quadros C, Bilius J., et al. Perspectives from the Global Poliomyelitis Eradication Initiative, CDC MMWR, 1999, stated: *“Technological changes that simplify logistics and reduce costs produce the greatest advantages to the initiative. For smallpox, these were the jet injector and then the bifurcated needle. One important technological advance for the poliomyelitis eradication initiative is the individual vaccine vial monitor (VVM), a thermostable marker which changes colour when exposed to heat. VVMs allow a vaccinator with minimal training to tell at a glance if a vaccine vial has been exposed to excessive heat. They increase confidence that the vaccine is potent at the time of administration and permit OPV to be taken out of the cold chain.”*

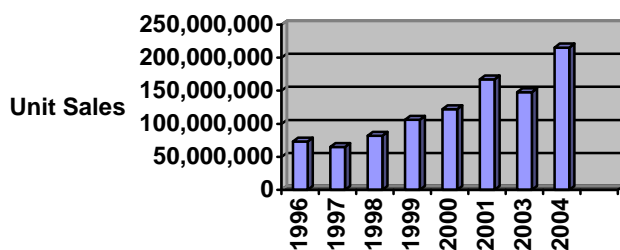
“We must act now because we have innovative new tools that will make easier to immunize all children, including the hardest to reach...For example, the vaccine vial monitor, which changes colour when a vaccine vial has been exposed to damaging heat, can markedly reduce the cost of refrigeration equipment, and allow vaccines to be used with confidence in remote locations.”— Carol Bellamy speech, entitled The GAVI Children’s Challenge, January 2000.

“Directly stated, without PATH’s involvement over the last years, the VVM would probably not exist”—2001 Letter from Dr. Jean-Paul Martin (Chairman, CEO and President), Bob Tetu (COO), and Thaddeus Prusik, PhD (Senior Vice President), LifeLines Technologies.

Sales Data

One proxy of impact is data on sales of the units worldwide. From this point of view, the product is an overwhelming success. As of the end of 2004, over 1.2 billion vaccine vial monitors have been sold to over 20 vaccine manufacturers.

VVM Sales by Year



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