



photo: R. Lord

The Radically Simple Uniject™ Device

In 2003—for the first time in history—every newborn in Indonesia will receive a life-saving first dose of hepatitis B vaccine. By 2005, the United Nations Children's Fund (UNICEF) anticipates that its global campaign will have eliminated maternal and neonatal tetanus; this year, UNICEF plans to immunize 500,000 women in Afghanistan alone.

These pivotal achievements were made possible, in part, by an extraordinary PATH invention: the Uniject™ device. The success of this easy-to-use, “all-in-one,” nonresuable injection device represents the culmination of PATH's 25-year product-development and introduction process, and it heralds a new chapter in our effort to deliver vaccines safely, efficiently, and effectively around the world.

The Early Years

In the early 1980s, PATH—then called PIACT—worked to develop new designs for syringes that would meet the needs of health systems in developing countries and provide protection from transmission of diseases by needle re-use. PATH's field experience suggested that a simple, pre-measured, pre-filled injection device would enable health workers and midwives to deliver immunizations safely, thus greatly expanding the reach of vaccine programs.

Uniject is a trademark of BD.

With support from the International Development Research Center, PATH began to refine its design for a nonreusable syringe—the “Ezeject”—that had been provided by the pharmaceutical manufacturer, Merck. In July 1987, PATH demonstrated the Uniject device (then called SafeTject) and other self-destructing injection devices to the Evaluation Panel for Injection Technologies (EPITECH), which had been assembled by the World Health Organization (WHO). This panel of experts identified Uniject as one of the most promising devices to support immunization programs.

Over time, the United States Agency for International Development (USAID) emerged as the major supporting agency for Uniject development, initially through the HealthLink Program and later through a series of USAID awards to PATH for the development of appropriate technologies. This support marked the beginning of PATH’s Technologies for Child Health Program—commonly known as HealthTech—which continues to thrive today.

While refining early Uniject designs, PATH also set out to identify a commercial partner with the capability and capacity for large-scale manufacturing and filling of Uniject. PATH soon realized

that it was an anomaly to most private- and public-sector companies; most had never seen an organization that developed and advanced health technologies without either the profit motivation of a private company or the sole-source public funding of a government research organization. Many also recognized that PATH’s approach would require significant changes for the vaccine industry.

In 1989, PATH licensed its design to Acacia Laboratories (subsequently named Horizon Medical, Inc.), a small company in California that was interested in the possibilities that Uniject presented. For several years, PATH and Horizon developed, analyzed, and redeveloped the manufacturing requirements and tools necessary for mass-production, while further refining the device itself.

Uniject Proves Promising

PATH also began to test Uniject’s effectiveness and acceptability in the field. In 1995, PATH led a study with the Pan American Health Organization (PAHO) and the Bolivian Ministry of Health in which traditional birth attendants used Uniject to administer tetanus toxoid vaccine to women. The results were encouraging and showed that community health workers—people who had never given

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PATH starts developing syringe designs.	Experts support Uniject™ concept at WHO’s EPITECH meeting. With funding from USAID, PATH launches the HealthTech program.	PATH licenses Uniject design to Horizon Medical, Inc.	More than 20 products have been tested in Uniject for storage stability and compatibility
Mid-1980s	1987	1989	1992



Uniject's Revolutionary Design and Function

The Uniject™ design uses a plastic bulb filled with the required dose for one injection. The device is quite easy to use: simply push in the cap to activate it, insert the needle into the patient, squeeze the bulb, remove, and dispose.

Developing such a radically simple design entailed a complex research and development process. As researchers recognized that re-use of needles was contributing to the spread of HIV and other blood borne agents, the public health community identified a need for syringes that would “auto-disable”—that is, they would include mechanisms that prevented them from being used more than once. To address this need, Uniject uses a one-way valve to expel the medicament and prevent uptake of other contents.

Another unique Uniject feature is that it is made of plastic, not glass. Glass is heavier, more expensive, and more fragile than plastic. To ensure that plastic matched or surpassed the benefits offered by glass, PATH conducted extensive evaluations of its stability, leakage, and toxicity. As a result of PATH's decision to use plastic, Uniject is a viable storage device as well as an effective delivery instrument.

Uniject is field-tested with vaccines in Bolivia and Indonesia.

1995 and 1996

PATH licenses Uniject to BD.

1996

The first automated filling and sealing line is launched at BioFarma, a vaccine manufacturer in Indonesia. The first commercial Uniject product (with hepatitis B vaccine) becomes available.

2000

Indonesia delivers hepatitis B vaccine in Uniject to approximately 5,000,000 newborns.

2003

UNICEF anticipates completion of global campaign to use Uniject to eliminate maternal and neonatal tetanus.

2005

injections before—could safely provide vaccinations with Uniject. This proved to be a significant milestone.

Soon after, PATH evaluated Uniject on a larger scale in Indonesia, where midwives used Uniject to administer tetanus toxoid to women and hepatitis B vaccine to infants at birth in rural areas. Again, the results were overwhelmingly positive. For the first time, midwives could access newborns at home and reach women in high-risk areas for maternal and neonatal tetanus. Midwives also reported a strong preference for Uniject over traditional needles and syringes. Uniject had arrived at an important milestone.

In 1996, PATH and Horizon licensed Uniject to BD (formerly Becton, Dickinson and Company), the world's largest manufacturer of syringes. BD is now working with pharmaceutical companies to distribute a wide range of vaccines, contraceptives, and other medicines via Uniject. This year, approximately 20 million Uniject units will be produced and distributed.

Uniject Goes Global

As Uniject production and use grow under BD's stewardship, PATH is implementing communication and training programs, and actively working to expand the types of medicaments that can be delivered through Uniject. We are also working with ministries of health in developing countries to study

or introduce Uniject as a safe injection tool. UNICEF is using Uniject to expand its maternal and neonatal tetanus elimination program in communities. Indonesia is moving toward delivering all of its hepatitis B vaccine in Uniject, simultaneously expanding immunization coverage and reducing the costs of vaccine wastage. Also, PATH continues to evaluate the cost-effectiveness of the product to provide evidence to countries considering use of Uniject in their immunization programs. USAID is considering using the device to deliver injectable contraceptives. Other manufacturers are testing it for use with oxytocin and gentamicin.

Uniject's development and ultimate success demonstrate the determination and commitment of PATH's staff and collaborators. The PATH team brings skills ranging from product design, engineering, and fabrication to business development, manufacturing, and vaccinology. During 20 years of Uniject development, these multi-faceted team members coalesced around an idea and a vision. As result, they produced a device—so revolutionary in its simplicity—that saves lives every day.

PATH's entrepreneurial spirit and determination continue to foster new technologies, like Uniject, that ensure we achieve the greatest impact on the health of people and communities in developing countries.