
Photo : C. Nelson

Nearly 170,000 infants were immunized at birth using Uniject™, resulting in a ten-fold increase in neonatal protection against hepatitis B.

Using Uniject™ to Increase the Safety and Effectiveness of Hepatitis B Immunization

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Rice terraces and coffee plantations, luxuriant in the rich volcanic soil, sped past as we raced to meet midwife Lestari before she left home that morning. We were anxious to hear her thoughts about a new task she had been given over the past 12 months—making sure that every baby she delivered at home received a birth dose of hepatitis B vaccine, and received it safely.

A new way to deliver vaccines

Lestari lives in Blitar district, East Java, one of the three provinces where the Indonesian Ministry of Health, with support from the Program for Appropriate Technology in Health (PATH's) Children's Vaccine Program, evaluated use of the Uniject™ injection device.[1] Uniject™ is a technology specifically designed for low-resource settings, including places where children are born at home rather than in a hospital and where it is unlikely that a vaccinator would be able to attend the birth (or visit within a few days). It was designed for use by people like Lestari.

[1] Uniject is a trademark of BD (Becton, Dickinson and Company). The Uniject™ device is filled with hepatitis B vaccine in Indonesia by PT Bio Farma. Uniject™ was developed by PATH under the HealthTech program, supported by the United States Agency for International Development, then licensed to BD in 1996.

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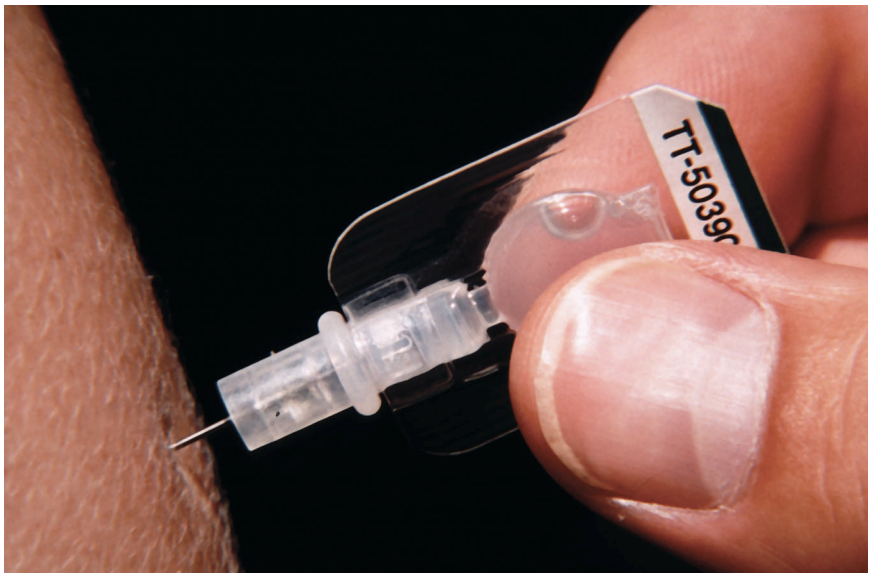
Since hepatitis B vaccine is relatively heat stable, midwives can store Unijects™ prefilled with the vaccine at home, ready to use when they attend a delivery.



The Uniject™ injection device is easy to use and improves injection safety.

Uniject™ is a small plastic bubble with a needle attached. It can be pre-filled with any injectable medication, in this case a pediatric dose of hepatitis B vaccine. Since the device can only be used once, it is appropriate for situations where sterilization of contaminated needles and syringes is difficult, if not impossible. And since hepatitis B vaccine is relatively heat stable—it maintains potency for months even at tropical temperatures—midwives can store the devices at home, ready to use. There is no need for them to make a detour to a health center to pick up bulky vaccine cold boxes and other immunization supplies. Lestari can simply slip a Uniject™ into her pocket and go.

Since the 1990's the government of Indonesia has offered hepatitis B vaccine to most infants using a standard syringe and ten-dose vaccine vials, with the first dose provided at about two months of age. The problem is that hepatitis B is hyper-endemic in Indonesia and the virus is frequently transmitted from mother to child during birth. Children infected early in life are likely to become chronic carriers of the virus. Chronic carriers can infect others throughout their lives and have an increased risk of developing liver disease, including liver cancer, as teenagers or adults. The sooner the infant is vaccinated, the better the chance of avoiding chronic infection. In a study on the island of Lombok, Indonesia where vaccinators visited newborn's homes within a week of birth, only 1.4 percent of children vaccinated within the first seven days of life were chronically infected, as opposed to 3.0 percent of children who received vaccination later.[2]

Awareness of the importance of neonatal immunization led the Indonesian Ministry of Health to search for a way to immunize earlier in life—and in a manner that was more sustainable than asking all vaccinators to make home visits or forcing midwives to pick up vaccination supplies on their way to a home delivery.

More early immunizations, and more questions

During the twelve months of the demonstration project, 168,517 newborns were immunized at birth using Uniject™. Approximately 90 percent of the births occurred at home, the rest in a hospital or other health facility. In the project areas the percentage of infants receiving their first dose of vaccine within seven days of birth jumped from less than 5 percent to 52 percent—a clear success, though not as high an increase as the government had hoped. Questions remained about why home rates are not higher, and about other impacts the new system might have on health workers and the immunization infrastructure, especially the cold chain. Hence our need to meet with Lestari, other midwives and health care providers, and their immunization program managers.

When we finally reached Lestari's home, she was happy to talk about her experiences. "Uniject™ is smaller and faster than a regular syringe—it is easy for me to carry and takes less time to use. Also, I know that it contains the correct dose. I find that my patients prefer it because they are confident it is sterile and cannot have been used before. They also like a sharp needle because it causes less pain." But what about the extra work? "I like giving the vaccine because I can offer a more complete service to my patients and it increases their trust in me."

[2] International Task Force on Hepatitis B Immunization. Internal report "Indonesia Model Immunization Program." 1988

"Uniject™ is smaller and faster than a regular syringe—it is easy for me to carry and takes less time to use. Also, I know that it contains the correct dose."

Lestari, a midwife from Blitar District

Other midwives had similar feelings. One said, "It is simple to use—just one practice injection into an orange and I felt confident." Another mentioned, "Since there is no complicated preparation, assembly, or dosing process, I don't worry about making mistakes—even with the entire family watching me! I tell them that it is a new syringe from the West and that it makes the injection safer and less painful. They all accept it."

A survey[3] of 319 health workers in the project areas showed that more than 94 percent of midwives felt that using Uniject™ resulted in higher hepatitis B vaccine coverage, 87.5 percent said that using Uniject™ caused families to give them more respect, and 100 percent of midwives preferred Uniject™ over a conventional syringe. Respondents often said that Uniject™ was extremely *praktis* (practical or appropriate) for their situation. Approximately nine percent of respondents reported having a slight problem "activating" Uniject™, indicating a need for further practice with the device prior to field use.

Immunization managers also were positive about Uniject™. Agus Suparnadi, head of Blitar district's immunization activities, described Uniject™ as a better method of immunization, both for neonatal home visits and for monthly immunization posts. He cited the simplicity—and the increased confidence midwives gain in using such a simple device—as a major factor in improving their performance. "Home visits are more successful now that we are using Uniject™. It is so small and quick, the family is not afraid of the injection. This is important in cases where they may be reluctant to allow their newborn to be vaccinated. Hepatitis B vaccine coverage would not be as high without Uniject™."

Suparnadi also felt that Uniject™ saved the district a considerable amount of money by reducing wastage of hepatitis B vaccine. "Before Uniject™, we used ten-dose vials for hepatitis B vaccine. Since we seldom used all ten doses before the vaccine had to be discarded, we wasted about 60 percent of the vaccine. With Uniject™ there is no wastage."

[3] Indonesian Ministry of Health/CDC. Presentation at the National Immunization Meeting July 2002 "Improving the Safety and Effectiveness of Hepatitis B Immunization in Indonesia through Uniject-HB Introduction in D.I. Yogyakarta, East Java, and West Nusa Tenggara Provinces August 2000 – July 2001."

A different experience in the northeast

We also visited Probolinggo, a rural district of about one million people on the northeast coast of Java. There we spoke with Siti Hidgir, the coordinator of family health activities for the district. Siti explained that hepatitis B immunization within the first seven days of life is still uncommon in the district. Immunization has not yet been integrated into family health activities and midwives are not as involved in immunization work. Siti also reported that midwife turnover is high—most serve their three year contracts and then move off to a more prosperous part of the island.

Although neonatal immunization may be taking longer to catch on in Probolinggo, the district health officers felt strongly that Uniject™ is the only way to accomplish it. As proof of their commitment to the technology, they are taking advantage of newly decentralized procurement authority to purchase Uniject™ for all hepatitis B vaccinations in the district. Solikin, head of the district's disease control activities, gave several reasons why the district made this decision. "Uniject™ provides one sterile syringe per person; it is extremely practical; families and midwives strongly prefer Uniject™; and it reduces our hepatitis B vaccine wastage from 30 percent to zero. Frankly, the decision was easy."

"Uniject™ ...is extremely practical; families and midwives strongly prefer Uniject™; and it reduces HB vaccine wastage to zero."

Solikin, supervisor from Probolinggo District.

Probolinggo district will use Uniject™ for all hepatitis B vaccinations and the governments of Indonesia and Vietnam plan to introduce it for birth doses nationwide.

Concerns about the cold chain and transport issues

Uniject™ is a dose of vaccine and an injection device packaged together, and ten Unijects™ require more storage space than a single, ten-dose vaccine vial. This might cause problems in refrigerators and during transport to districts. However, we found no difficulties with storage of Uniject™ in any level of the East Java health system. The provincial cold room—which supplies all the districts—had sufficient capacity to handle the additional volume. In Blitar, Suparnadi reported that most health centers are able to continue their usual practice of one vaccine pick-up per month, though some now pick up twice per month because of the increased volume. He noted that this really does not represent any additional effort since they typically come in for supplies several times per month anyway. Similarly, the three health centers we visited in Probolinggo reported no storage problems. One center now picks up vaccines twice per month while the other two continue their once per month schedule.

Because hepatitis B vaccine is relatively heat stable, Unijects™ containing the vaccine can be safely stored without refrigeration when partnered with another new technology—color-coded Vaccine Vial Monitor (VVM) labels. A VVM allows health workers to determine whether the vaccines have been exposed to too much heat—when the VVM color changes, the vaccine must be discarded. All the midwives we talked with understood how to read the VVM and said they always checked it prior to using Uniject™. But because they typically use their supply of vaccines within a couple of weeks, none had yet seen a Uniject™ with an expired VVM.

What about cost?

In another study,[4] researchers compared costs of providing hepatitis B vaccine in locally manufactured Uniject™ devices versus administration with reusable syringes or administration with other auto-disable (AD) syringes. They found that the programmatic costs using Uniject™ were about the same as the cost of using other AD syringes plus the cost of vaccine in multi-dose vials. And using Uniject™ at its current price was about 14 percent less expensive than using sterilizable syringes.

A second cost study[5] also found that hepatitis B vaccine in Uniject™ is cost saving at current immunization coverage levels. In fact, providing a birth dose of hepatitis B vaccine, using midwives to administer the injection within seven days of birth and during a home visit, saves money despite additional costs of labor and travel related to the midwife visit. Injection safety also increases, resulting in further public health savings.

Providing a birth dose of hepatitis B vaccine, using midwives to administer the injection during a home visit, saves money...Injection safety also increases, resulting in further public health savings.

Based on these findings, the Indonesian Ministry of Health plans to introduce Uniject™ for hepatitis B vaccination of all infants throughout the country—almost five million births per year. The government of Vietnam has also requested that the Global Alliance for Vaccines and Immunization (GAVI) provide hepatitis B in Uniject™ for national use by 2003.

For more information about Uniject™ or about hepatitis B immunization, contact PATH's Children's Vaccine Program (see back cover) or visit our website ***www.ChildrensVaccine.org.***

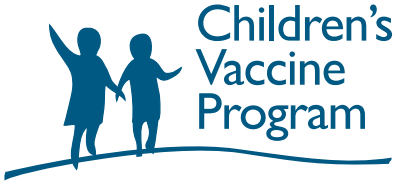
[4] Nadjib et al. "Comparative costs of alternative presentations of HepB-DTP vaccines in AD syringes and in Uniject devices to ensure safe injections in Indonesia." Abt Associates Inc.. Draft dated May 2002.

[5] Levin, C., Widjaya, A., and Moniaga, V. "Cost-Effectiveness Analysis of Hepatitis B Vaccine in the Uniject™ Device in Three Provinces in Indonesia." Program for Appropriate Technology in Health (PATH). Draft dated July 2002.

More Immunization Information from PATH's Children's Vaccine Program

Visit ***www.ChildrensVaccine.org*** to download any of these materials:

- *Proper Handling and Disposal of Auto-Disable Syringes and Safety Boxes—A Training Module*
- *Giving Safe Injections: Using Auto-Disable Syringes for Immunization*
- *Immunizing Children Against Hepatitis B—A Training Module*
- *Hepatitis B Vaccine Introduction—Lessons Learned In Advocacy, Communications, And Training*
- *GAVI Training for Stronger Immunization Programs*
- *Training Vaccinators in a Time of Change*
- *Immunization and Child Health Materials Development Guide*
- *The Case for Childhood Immunization*
- *Advocacy for Immunization—How to generate and maintain support for vaccination programs*
- *Realizing the Full Potential of Childhood Immunization—How Health Professionals Can Make a Difference*
- *Helping Young People Become Youth Advocates for Immunization*



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