



PATH's Children's Vaccine Program

Increasing immunization coverage
with improved financing, management,
advocacy and training

Improving immunization safety
through technology

Expanding protection
by introducing new, lifesaving vaccines

December 2004

PATH's Children's Vaccine Program Increasing coverage – Improving Safety – Expanding protection

PATH's Children's Vaccine Program (CVP) was launched in December 1998 through a US\$100 million grant from what was then known as the William H. Gates Foundation. This short paper highlights some of the key achievements of CVP on the occasion of its sixth anniversary.

CVP's continuing mission is to promote equal access to new and lifesaving vaccines worldwide. We accomplish this by creating new tools and procedures that result in safer, more effective immunization programs—programs that protect more children with more of the vaccines they need. Today a diverse array of activities—disease burden studies; testing better ways to manage and dispose of injection waste; and designing innovative, e-learning modules for immunization program managers; among others—are generating significant results.

PATH's CVP efforts are aligned closely with initiatives of the Global Alliance for Vaccines and Immunization (GAVI), The Vaccine Fund, the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), the World Bank, and other key partners in global health. CVP also collaborates with other PATH programs, such as the Japanese Encephalitis Project, the Rotavirus Vaccine Program, the Meningitis Vaccine Program, the Malaria Vaccine Initiative, and PATH's Technologies Solutions team.

Innovate, demonstrate, replicate

PATH does not run clinics or pay vaccinator salaries. Instead, we work with local colleagues to design and test innovative approaches to immunization delivery at the district level, then encourage partners to replicate them—whether by expanding to scale nationally or introducing the innovation in other countries and regions. For example, PATH has sponsored groundbreaking studies to determine how to best provide “birth doses” of hepatitis B vaccine to infants delivered by midwives in their homes.¹ Our initial, localized work resulted in rollout of the program across Indonesia. And a PATH site in remote, northern Senegal has become a showcase for West Africa, providing workshops and study tours for program managers from other countries in the region.

Achievements realized in our model programs in Andhra Pradesh, India; Cambodia; and Senegal are reported in-depth in three related

“CVP has been a valuable partner in revitalizing global and local attention to immunization. They are a key partner in GAVI and have been key advocates to support the introduction of new and needed vaccines in developing countries. We applaud their commitment to work in new and innovative ways.”

Carol Bellamy
Executive Director of UNICEF



Needle removers separate used needles from syringes, trapping them in a jar for safe disposal. CVP initiatives are helping local managers understand how best to integrate promising technologies—like this needle remover—into their programs.

¹ A CVP paper on the experience, “Using Uniject™ to Increase the Safety and Effectiveness of Hepatitis B Immunization,” is available from www.ChildrensVaccine.org

papers.² This document focuses on interventions tested in the world’s largest countries—China, India, and Indonesia—along with activities developed for application throughout the developing world.

Helping global partners reinvigorate their immunization efforts

PATH was one of the founding members of GAVI and The Vaccine Fund, along with the Bill & Melinda Gates Foundation, UNICEF, WHO, the World Bank, vaccine manufacturers, and others. PATH, together with the Bill & Melinda Gates Foundation, also helped conceive and administer The Vaccine Fund. PATH continues to actively collaborate on GAVI initiatives at the global and country levels, such as PATH’s extensive contributions to increase the financial sustainability of immunization programs.

“The Children’s Vaccine Program continues to make amazing contributions to GAVI. CVP has a keen ability to anticipate challenges and problems—when we need them they are there.”

Tore Godal
the GAVI Secretariat

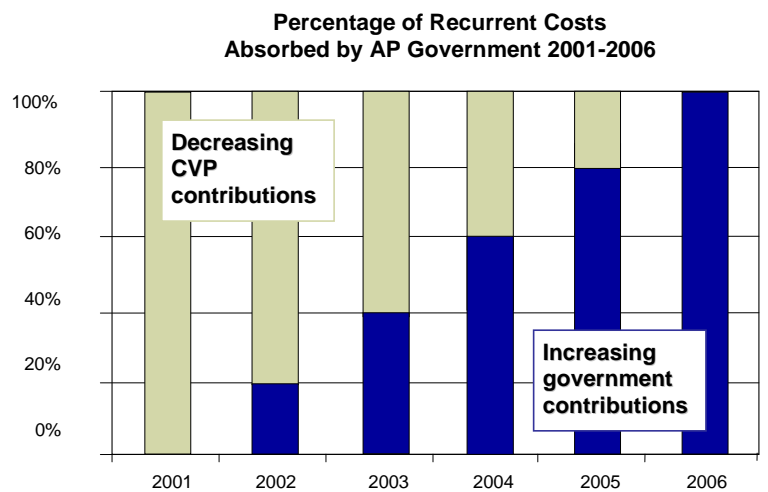
One of CVP’s earliest objectives was to help major international organizations refocus on routine immunization, so nearly 25 percent of the overall CVP grant was allocated to UNICEF, WHO, and the World Bank. This allowed the agencies to increase staff needed to move the GAVI process forward and to support country efforts to strengthen immunization programs.

Increasing immunization coverage: Improved financing, management, advocacy, and training

PATH understands that routine childhood immunization is part of a comprehensive package of health interventions offered to families and that a systems-perspective is necessary to achieve maximum benefit and impact. So PATH interventions support many aspects of health programs, not only immunization. Examples include improved financial planning, advocacy for increased support for health, better program management, communications for social change, micro-planning, data collection, injection safety, medical waste disposal, and staff training and supervision.

Planning for financial sustainability

Costs rise as immunization programs increase the number of vaccines they offer and as they improve service quality, increase demand, and adopt safer systems for medical waste disposal. Without attention to future financing, improvements made with GAVI and The Vaccine Fund resources will not be sustainable after the GAVI project period. Financial planning is key to building sustainable immunization programs and PATH has taken a lead role in many related GAVI activities, including support for financial sustainability plan (FSP) training. PATH also collaborated



Andhra Pradesh state government funds will cover all hepatitis B vaccine and AD syringe costs by 2006.

² “Andhra Pradesh—Building a Model Immunization System,” “Cambodia—Coverage Improvement Planning Pays Off” and “Senegal—Changing the Face of Immunization in West Africa” are available from www.ChildrensVaccine.org.

with other partners to create tools for forecasting future vaccine demand so that manufacturers can scale up production, which in turn stimulates vaccine price reductions. And PATH management and technology innovations have helped save money by exposing—and correcting—vaccine freeze problems, thereby reducing wastage and improving program efficiency and cost-effectiveness.

Better program management

PATH always is looking for innovative, effective strategies to increase access and utilization of high-quality immunization services. The process often begins by building a valid evidence base for immunization program performance—information sorely lacking in many countries. PATH was central to development of GAVI’s Data Quality Audits—processes designed to assess the quality of local coverage data. Once accurate baselines are established, detailed coverage improvement plans are designed to strategically address locale-specific challenges. For example, PATH assessments in Andhra Pradesh revealed that there was no system of supportive supervision to help frontline workers. So the AP government and PATH tried a new approach—outsourcing supervision to staff of local medical colleges. After only a few months of operation and two rounds of supervision visits, the new system improved the quality of immunization on several fronts: more effective session planning, better cold chain management, safer handling and disposal of sharps, and improved drop-out tracking. Another benefit: health workers reported higher levels of satisfaction because of the enhanced support.

Increased access to reliable information and more effective advocacy for immunization

Accurate disease burden and vaccine cost-effectiveness data, lessons learned, improved policies, and new tools and techniques are critical pieces of information for program managers. Without effective dissemination, that information can have no impact beyond the immediate study or project.

For this reason, PATH created the CVP website—www.ChildrensVaccine.org—a vast immunization library on the web. The site makes it easy to find and download the best immunization materials available worldwide, including original PATH publications. In 2003, users downloaded an average of 88,000 pages of information from the website each month. Usage increased a further 12 percent in 2004.



Fragile Lives—Immunization at Risk, an independent film commissioned by PATH, was seen by over 100 million BBC World viewers in 2004. It will be re-broadcast on national networks in several countries soon, and it is available for viewing on the CVP website.

CVP Website Evaluation and Usage Statistics			
	2002	2003	2004
Individual page requests	50,477 / month	56,030 / month (11% increase from 2002)	62,630 / month (12% inc. from 2003)
Immunization information downloaded	2.9 gigabytes/ month (~83,000 pages)	3.1 gigabytes / month (~88,000 pages; 7% inc.)	4.6 gigabytes / month (48% increase)
“Website was easy to use”	95%	n/a*	n/a*
“I found everything I needed” or “I found more than I needed”	73%	n/a*	n/a*
User visited website more than once	59%	n/a*	n/a*

* Evaluation responses to these questions were elicited through an online survey in 2002 only.

Working with the “Big Three” — China, India, and Indonesia

At GAVI’s request, CVP took on the challenge of working with three of the world’s most populous countries to design special programs for Vaccine Fund support:

China

- Assistance with China’s GAVI application and development of a Memorandum of Understanding between GAVI and the government.
- Introduction of hepatitis B vaccine for free in the poorest provinces and counties—with a 50 percent matching contribution from the Chinese government. Coverage increased from 36 percent to 100 percent in those areas.
- Introduction of auto-disable (AD) syringes and safety boxes throughout the project area.
- Initiation of an immunization financing study and policy review in support of FSPs.

India

- Building on successes in the state of Andhra Pradesh, development of a pilot hepatitis B vaccine and AD syringe project in 15 major urban areas and 33 rural districts, with the potential to reach 2.5 million infants per year. At the request of the government, CVP also took a lead role developing training curricula and managing the training effort.
- Development of a national FSP.
- Creation of the Indian Injection Safety Coalition—a partnership of key stakeholders—and establishment of “model injection safety centers.”
- Trials of needle removers to reduce the volume of hazardous medical waste.

Indonesia

- Assistance with three successful applications to GAVI (the Five-Year Strategic Plan for Immunization Services, the National Injection Safety Plan, and the Financial Sustainability Plan).
- Research on the impact of Uniject™, an innovative, prefilled injection device to deliver hepatitis B vaccine out of the cold chain, especially to infants delivered outside of hospital settings.
- Technical support for local production of a tetravalent, DTP-hep B vaccine. By 2006 the Indonesian manufacturer should be able to satisfy national demand.
- Groundbreaking research into the extent of damage done to freeze-sensitive vaccines as they travel through the cold chain, complemented by trials of new, freeze-avoidance technologies such as computer-monitoring systems in vaccine cold stores.
- Rollout of sharps waste training programs and development and testing of innovative waste management systems.

Improved training for vaccinators and managers

PATH recognizes that training is key for sustainable, high-quality immunization services in the developing world. PATH and WHO co-chair the Global Training Partnership which coordinates immunization training among diverse GAVI partners such as UNICEF, WHO, universities, and non-governmental organizations (NGOs).

In addition to applying cutting-edge adult learning techniques to country-level immunization training, PATH, in consultation with WHO, developed a new training approach for senior-level immunization managers: the *Advanced Immunization Management (AIM)* e-learning tool. AIM modules are designed to be relatively short (two to three hours) so that they can be used in a variety of settings—for example, as an add-on to a regularly scheduled meeting. Available on both the internet and CD-ROM, AIM was developed based on encouraging results from a six-month pilot study of e-learning as a development tool.



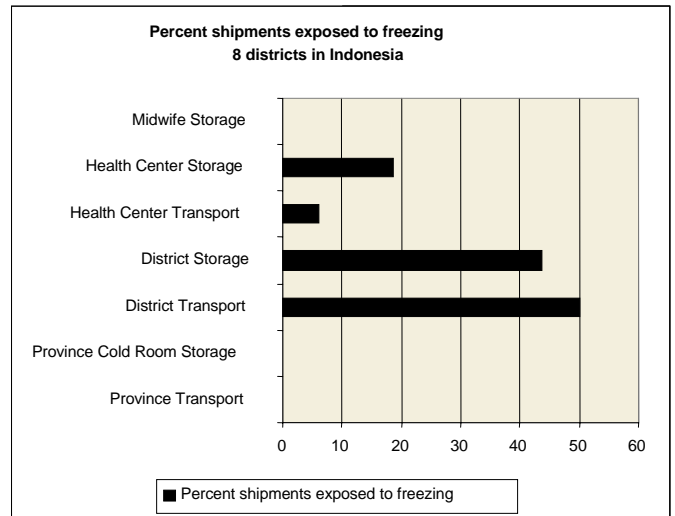
AIM distance-based e-learning, combined with face-to-face teaching, maximizes impact. Try AIM online at <http://aim-e-learning.stanford.edu>

Increasing immunization safety: improved technologies

PATH advances technologies with a special focus on two key areas: (1) improving immunization program efficiency and reducing vaccine wastage (especially reducing the danger of damaging freeze-sensitive vaccines like hepatitis B, Hib, tetanus toxoid, and DTP) and (2) reducing the danger of cross-infection due to reuse of non-sterile injection equipment and improper disposal of contaminated needles and syringes.

Vaccine freeze problems exposed

PATH research revealed that in some countries up to 70 percent of freeze-sensitive vaccines are at risk of freezing in one or more stages of the cold chain (see the chart at right). This is a serious concern since the vaccines can be rendered ineffective if frozen. When this happens, millions of children are at risk of receiving impotent vaccine and of not being protected against diphtheria, tetanus, pertussis, hepatitis B, and other diseases. To address the issue in Indonesia, PATH worked closely with the government to develop a unique, two-temperature cold-chain policy and introduce it nationwide. Freeze-sensitive vaccines are now distributed with cold water-filled packs instead of icepacks.



CVP studies documented where freeze-sensitive vaccines like DTP, hepatitis B, and Hib are at highest risk of freeze damage. This chart documents problems at districts and health centers. Data like these encouraged government staff to explore new solutions.

Because the risk of freezing is highest in ice-lined refrigerators (designed to function even when power is cut temporarily), PATH also worked with manufacturers to improve use of that technology. The resulting freeze prevention training materials now are available worldwide. And to address the freeze problem in large vaccine stores, PATH evaluated computer-based, automatic, continuous temperature recording. Soon after the system was installed in Java, its remote alarm alerted staff about a chronic, intermittent malfunction that was placing vast supplies of vaccine at risk of freezing. The defective units were replaced and now function correctly.

Improved management and disposal of contaminated needles and syringes

When GAVI and The Vaccine Fund began widespread distribution of AD syringes in 2001, most GAVI countries did not have robust policies for dealing with contaminated injection equipment and had little experience with safe disposal. PATH staff worked with colleagues at GAVI and in Cambodia, India, Indonesia, Nepal, and Senegal to develop and test innovative solutions to disposal challenges, including:

- **Solar melters:** PATH is assessing use of solar cooking technology to melt syringes in rural health facilities in Senegal. This on-site solution can be more economical and practical than transporting contaminated syringes long distances for incineration at the district center.
- **Needle removers:** PATH is evaluating needle removal devices to safely segregate sharps from syringe barrels, thereby preventing re-use and dramatically reducing the volume of sharps waste. CVP also is providing technical assistance to another PATH initiative to develop a safe, needle-free injector.
- **Sharps waste management workshops:** In India, Indonesia, and Senegal, PATH and partners organized national sharps waste-disposal planning workshops, installed protected needle pits, and demonstrated appropriate use of small scale incinerators. PATH also jointly sponsored and organized inter-country workshops with WHO, so that immunization managers and environmental officials could learn more about sharps waste-disposal policy and make plans for their own countries.
- **Changing social norms and behaviors:** Operations research in Nepal documented individual and community social change related to proper disposal of waste and safe injection procedures.³ Solutions developed through the project are now being adopted in towns and villages throughout the country.



Solar melters can compress a full safety box—including syringes and needles—into a cake the size of a compact disc.

³ “Practical, Local Solutions for Safely Managing Contaminated Syringes and Other Medical Waste,” a paper describing the Nepal project, is available from www.ChildrensVaccine.org

Expanding protection: introducing new vaccines

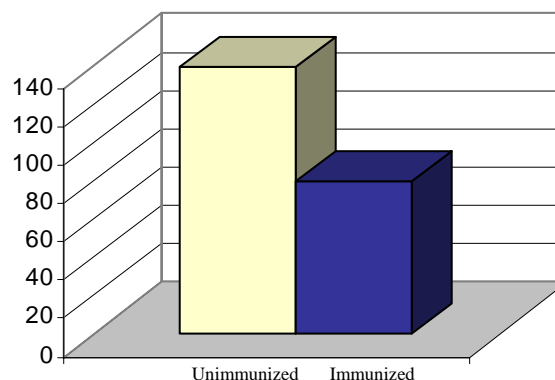
PATH has put considerable effort into helping make GAVI and Vaccine Fund-supported introduction of hepatitis B and Hib vaccines a success. Disease burden and cost-effectiveness data, policy updates, management assistance, and provision of user-friendly training materials⁴ are among our many contributions. Overall, the global experience suggests that adding new vaccines can invigorate stagnant immunization programs because they encourage managers to carefully examine and improve existing logistics, training, management, and supervision systems.

Underutilized vaccines—such as yellow fever and Japanese encephalitis—and vaccines on the horizon (rotavirus and meningococcal vaccines especially) require pre-introduction advocacy and strategizing. Decision-makers often are unaware of these diseases or are confused about the toll they take. By generating better data about the diseases now, PATH is helping ministry officials plan for the future.



This girl sustained significant brain damage as a result of JE. Some days she cannot recognize her own mother.

**Effect of Hib Vaccine on Bacterial Meningitis
Rate per 100K Children < 2 years old, Lombok, Indonesia**



Researchers thought there was little Hib meningitis in Asia, but significantly reduced levels of disease after vaccination suggest they were wrong. These new data were generated through CVP-funded research.

Over the past two years PATH has expanded its work on new vaccine development in three areas:

Japanese encephalitis (JE) project: JE is the leading viral cause of encephalitis and disability in Asia. The disease primarily infects children under the age of 15, leaving up to 70 percent of those who develop illness either dead or with a long-term neurological disability.

PATH's JE project, funded by the Bill & Melinda Gates Foundation, was designed to pave the way for control of clinical JE and to help halt the devastating death and disability JE causes. By the end of the project, a second-generation JE vaccine will be available for use throughout Asia, and increased awareness of JE will result in greater regional and national commitments to JE vaccine introduction. Please see www.JEproject.org for more information.

⁴ See the Training Materials and Clinical Information section of www.ChildrensVaccine.org.

Rotavirus Vaccine Program (RVP): RVP is a GAVI-supported effort to reduce child morbidity and mortality from diarrheal disease by accelerating the availability of rotavirus vaccines appropriate for use in developing countries. Please see www.rotavirusvaccine.org for more information.

Meningitis Vaccine Program (MVP): MVP, a partnership between PATH and the WHO, was created to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa. Please see www.meningvax.org for more information.

As we approach our seventh year, CVP is consolidating gains made in immunization coverage, quality, and financial sustainability in the country programs. And in 2005 we plan to publish a series of practical, “how to” papers on new vaccine and technology introduction, injection safety, and immunization training.

Over the longer term, PATH’s immunization solutions portfolio is evolving away from broad immunization initiatives and focusing instead on disease-specific efforts aimed at saving lives through the development and use of new, more effective vaccines.

For more information about PATH’s immunization programs:

Immunization Solutions

PATH

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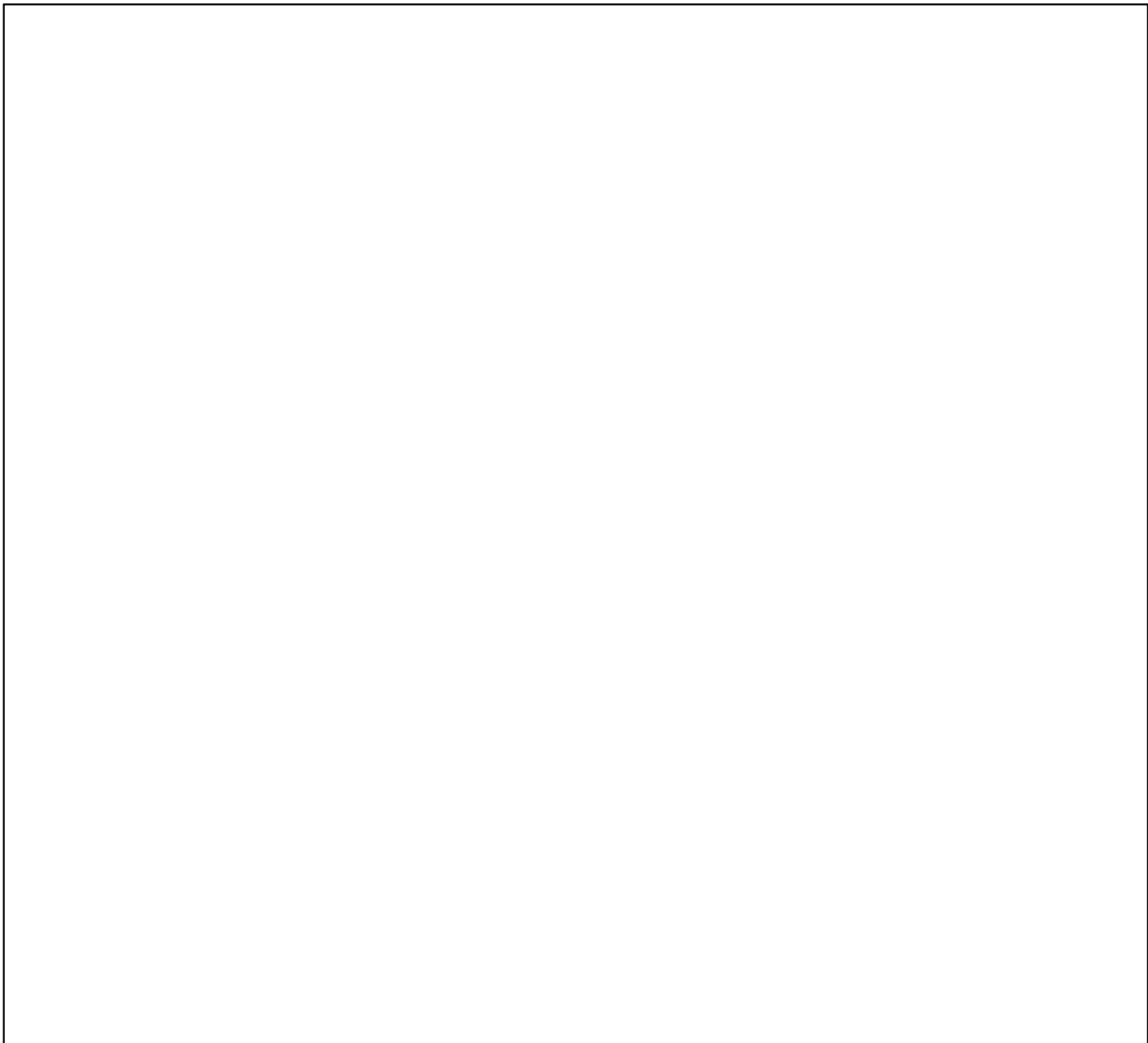
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Email info@childrensvaccine.org

Web www.ChildrensVaccine.org and www.path.org



PATH Immunization Publications

These documents are available from www.ChildrensVaccine.org

Most are available in both English and French; some are available in Spanish and Russian as well.

Use the site search engine to locate titles of interest

(or click on the titles below if you are reading an electronic version).

Advocacy for Immunization

- The Case for Childhood Immunization
- Fragile Lives—Immunization at Risk (film)
- Childhood Immunization: A Worthwhile Investment (PowerPoint show)
- Advocacy for Immunization
- Childhood Immunization: What You Need To Know (for parents)
- Hepatitis B Vaccine Introduction: Lessons Learned in Advocacy, Communication and Training
- Realizing the Full Potential of Childhood Immunization: How Health Professionals Can Make a Difference
- Helping Young People Become Youth Advocates for Immunization

Immunization Management and Training

- Immunizing Children Against Hepatitis B
- Immunizing Children Against *Haemophilus influenzae* type B
- Immunizing Children Against Japanese Encephalitis
- Immunization and Child Health Materials Development Guide
- Preventing Vaccine Freezing in the Cold Chain
- Guidelines for Supportive Supervision
- Training Vaccinators in a Time of Change
- Advanced Immunization Management (AIM) e-learning modules

Injection Safety

- Giving Safe Injections
- Proper Handling and Disposal of Auto-Disable Syringes and Safety Boxes
- Designing Safe Syringe Disposal Systems for Immunization Services
- Using Uniject™ to Increase the Safety and Effectiveness of Hepatitis B Immunization
- Unsafe Injections, Fatal Infections
- Practical, Local Solutions for Safely Managing Contaminated Syringes and Other Medical Waste
- Technologies for Vaccine Delivery in the 21st Century
- Perceptions About Injections and Private Sector Injection Practices in Central Nepal
- Immunization Injection Safety in Nepal

Other papers describing PATH's immunization solutions

- Andhra Pradesh—Building a Model Immunization System
- Cambodia—Coverage Improvement Planning Pays Off
- Senegal—Changing the Face of Immunization in West Africa
- Vietnam—Progress Beyond High Coverage
- PATH's Children's Vaccine Program—Increasing coverage, improving safety, expanding protection