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# An Overview of PATH's Injection Safety Work: 1999–2009

# **Background**

In the field of safe injection, PATH has served for over 20 years in a global leadership role, championing improved approaches to injection safety for the developing world. As one of the first organizations to advocate for specific classes of safe injection devices, PATH, in collaboration with multiple partners, has designed, developed, tested, patented, licensed, and/or facilitated the availability of multiple new, appropriate, and affordable technologies that address different issues related to injection safety. These have included Uniject® prefilled injection devices, autodisable syringes, disposable-syringe jet injector devices, and safety syringes (syringes with built-in reuse prevention and/or needlestick protection features). One device developed at PATH, the SoloShot<sup>TM</sup> autodisable syringe, is now supplied by the licensee BD, who had distributed over 5.4 billion devices by mid-2009.

PATH has also worked on developing and advancing medical waste technologies such as needle removers and syringe melters for disposal of used syringes and needles. PATH's work has included technology evaluation both in the laboratory and in health care settings, with the latter work focused on understanding the cost-effectiveness, usefulness, and acceptability of the technologies. Much of this work has been supported by the United States Agency for International Development (USAID) under the HealthTech program.

#### Advocacy

Working closely with international agencies and decision-makers, PATH has advocated for policy reform and participated actively in the founding and implementation of the Safe Injection Global Network (SIGN). As a founding member and chair of the Injection Safety Alliance in India—whose objectives and activities include reducing unnecessary injections—PATH has carried out nationwide studies of injection safety in association with the Government of India. PATH has also

published relevant training materials and tools and trained health care workers, primarily in Africa, India, and Indonesia, on appropriate safe injection techniques.

#### Waste management and procurement

PATH acted as chair of the Implementation Task Force on the disposal of sharps waste from 2002–2003 for the GAVI Alliance. During this time PATH initiated and jointly organized with the World Health Organization (WHO) five health care waste management workshops in Africa and Southeast Asia. At these sessions, attendees formulated short- and medium-term policies for waste disposal and determined their best options for disposal of immunization sharps waste. In these capacities, PATH works with communities to generate "innovative local solutions" to injection safety and sharps waste management problems.

This work continued under the Making Medical Injections Safer (MMIS) project funded by the President's Emergency Plan for AIDS Relief (PEPFAR) and managed by John Snow, Inc., with PATH as the partner responsible for sharps waste management activities. PATH has worked in 11 PEPFAR countries, assessing local waste management practices and providing technical assistance and training in appropriate procedures. In the area of international procurement, PATH has worked to train and build country capacity in procurement methodologies and procedures for safe injection equipment. In the MMIS project, PATH is responsible for the procurement of safe injection equipment for all the countries—with over 250 million safety syringes introduced for curative use.

#### **Technologies and product evaluations**

The following pages outline the technologies, evaluations, introduction efforts, and policy work that PATH has undertaken over the last ten years in an effort to improve the safety of injections around the world and support the efforts of SIGN.

# Policy and standards regarding injection safety

PATH has contributed to the development of key global policies for injection safety over the last ten years including:

- (1) WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services. WHO. 1999.
- (2) In 2009, UNICEF began to phase out the distribution of standard disposable syringes for vaccine reconstitution and replace them with reuse-prevention (RUP) syringes. A full transition is expected by the end of 2010.

PATH has provided technical advice on the development of a number of WHO Performance, Quality and Safety (PQS) specifications including those related to:

- (1) Safety boxes
- (2) Safety syringes
- (3) Lower-cost needle removers

Table 1. Availability of safe injection devices

Product	Status	Global distribution
SoloShot <sup>™</sup>	Commercially available	5.4 billion
Uniject <sup>®</sup>	Commercially available	73 million
Needle- remover devices	Commercially available	unknown
Disposable- syringe jet injectors	In clinical trials	

Table 2. Evaluations of safe injection technologies conducted by PATH

Technology evaluated	Location	Year
Uniject® (with oxytocin)	Angola, Guatemala, Indonesia, Mali, Vietnam	1999–2009
Uniject® (with Cyclofem®)	Mexico	1999–2000
Uniject® (with hepatitis A & B vaccines)	China, India, United States	2000–2003
Electric needle destroyers	United States	2000
Uniject® (with tetanus toxoid)	Afghanistan, Burkina Faso, Ghana, Mali, Somalia, Southern Sudan	2003
Needle removers	India, Senegal, Uganda, Vietnam	2001–2007
Sharps barrel and funnel	Senegal, United States	2004
Disposable cartridge jet injector	Brazil, China, India, South Africa, Tanzania	2004–2009
Multiuse nozzle jet injector	China, Senegal, United States	2002–2007
Syringe melters	India, Indonesia	2007–2008
Reuse-prevention feature reconstitution syringe	India, Indonesia	2007–2009
Retractable syringes	Peru, South Africa	2007–2008
Intradermal adapter	India	2009
Plastic spike reconstitution syringe	Oman	2009
Uniject® (with gentamicin)	Nepal	2009

At the country level, PATH's work to introduce new technologies and provide technical assistance for health care waste management under the MMIS project has led to significant policy shifts around the world including:

- Development of improved national standards/guidelines for injection safety in Ethiopia, Tanzania, and Kenya.
- (2) Development of national health care waste management plans in Nigeria, Mozambique, Kenya, and Tanzania.
- (3) The successful introduction of needle removers in India and national policy supporting their use in 2006.
- (4) The successful introduction of needle removers in Vietnam and national policy supporting their use in 2007.

# PATH reports and technical resources

#### Historical profiles

<u>HealthTech Historical Profile: Technologies for Injection</u> Safety. 2006.

<u>HealthTech Historical Profile: The Uniject® Device.</u> 2005.

#### Technology updates

<u>Technology Update: Disposable-Syringe Jet Injection.</u> 2009.

Technology Update: Gentamicin in Uniject®. 2009.

<u>Technology Update: Injectable Contraceptives in</u> Uniject®. 2009.

Technology Update: Oxytocin in Uniject®. 2009.

Technology Update: Safe Injection Manual. 2006.

Technology Update: SoloShot<sup>TM</sup>. 2009

<u>Technology Update: Technologies for Immunization</u>
<u>Safety. 2009.</u>

Technology Update: Vaccine Vial Monitors. 2009.

Technology Update: Vaccines in Uniject®. 2009.

#### Health care waste management

Health Care Waste Management Resources Page. Launched 2009.

Quantifying Infectious Waste Produced by HIV/AIDS, Malaria, and Tuberculosis Programs and the Needs for Injection Safety Equipment. 2009.

<u>Talking Points: Health Care Waste Management: A</u> PEPFAR Priority. 2009.

Framework for Conducting a Self-Assessment of National Progress in Injection Waste Management: Version 1. 2008.

Small-Scale Autoclaves to Manage Medical Waste: A Buyer's Guide to Selecting Autoclaves Manufactured in India. 2008.

Personal Protective Equipment and Segregation Supply Specifications for Health Care Waste Management. 2008.

Managing Sharps Waste in Andhra Pradesh: Introduction and Scale-Up of a Sharps Waste Management Program. 2007.

Medical Waste Management for Primary Health Centers in Indonesia. 2005.

<u>Treatment Alternatives for Medical Waste Disposal</u>. 2005.

# Immunization safety

Intradermal Delivery of Vaccines: A Review of the Literature and the Potential for Development for Use in Low- and Middle-Income Countries. 2009.

### **Technology evaluations**

Summary Report: Evaluation of Retractable Syringes in a Measles-Rubella Immunization Campaign in Peru. 2008.

<u>Final Report: Evaluation of Three Reuse-Prevention</u> <u>Feature Reconstitution Syringes in Three Districts of Indonesia. 2007.</u>

Evaluation of a Retractable Syringe in South Africa: Acceptability, Safety, and Cost Implications, KwaZulu Natal, South Africa. 2007. Evaluation of a Needle Remover Demonstration Project: A Study from Huong Khe District, Ha Tinh Province, Vietnam. 2007.

<u>Field Evaluation of the Acceptability and Feasibility of</u> Syringe Melters in Indonesia. 2007.

<u>Evaluation of a Disposable Needle-Removal Device in</u> Uganda: A HealthTech Report. 2005.

<u>Evaluation of a Needle-Remover Device and Sharps</u> Barrel in Health Posts in Senegal: Final Report. 2005.

#### **Training materials**

<u>Using Oxytocin in the Uniject® Device (10 IU in 1 ml).</u> 2009.

<u>Training Health Workers in the Management of Sharps</u> Waste. 2006.

<u>Giving Safe Injections: Using Auto-Disable Syringes for</u> Immunization. 2001.

#### Resources for introduction

Introducing Oxytocin in the Uniject® Device: An Overview for Decision-Makers. 2008.

<u>Introducing TT Uniject® in Maternal and Neonatal</u> Tetanus Elimination. 2003.

#### Journal articles

Fleming J, Hoekstra E, Moniaga V, et al. Reuse prevention syringes for reconstitution of lyophilized vaccines. *International Journal of Occupational Environmental Health*. 2009;15:9–13.

Kelly K, Loskutov A, Zehrung D. Preventing contamination between injections with multiple-use nozzle needle-free injectors: a safety trial. *Vaccine*. 2008;26(10):1344–1352.

Muller N, Steele M, Balaji K, et al. Evaluating the use and acceptability of a needle-remover device in India. *Tropical Doctor*. 2007;37:133–135.

Tsu VD, Sutanto A, Vaidya K, et al. Oxytocin in prefilled Uniject® injection devices for managing third-stage labor in Indonesia. *International Journal of Gynaecology and Obstetrics*. 2003;83(1):103–111.

Jackson L, Austin G, Robert C, et al. Safety and Immunogenicity of varying dosages of trivalent

inactivated influenza vaccine administered by needle-free jet injectors. *Vaccine*. 2001;19:4713–4709.

Otto B, Suarnawa M, Stewart T, et al. At-birth immunisation against hepatitis B using a novel prefilled immunisation device stored outside the cold chain. *Vaccine*. 2000;18:498–502.

Nelson C, Sutanto A, Suradana I. Use of Soloshot<sup>TM</sup> autodestruct syringes compared with autodisable syringes, in a national immunization campaign in Indonesia. *Bulletin of the World Health Organization*. 1999;(77)1:29–33.

Sutanto A, et al. Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device. *Bulletin of the World Health Organization*. 1999;77(2):119–126.

Catlin M, Muller N. The physician's role in improving injection safety. *Africa Health*. 1999;22(1):12.

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#### For more information

For more information on injection safety, please visit our vaccine resources webpage at <a href="https://www.path.org/vaccineresources/injection-safety.php">www.path.org/vaccineresources/injection-safety.php</a>. For more information on managing sharps and other infectious waste, please visit our health care waste management resources page at <a href="https://www.path.org/projects/health-care">www.path.org/projects/health-care</a> waste resources.php.

Or contact:

Nancy Muller PATH 1455 NW Leary Way Seattle, WA 98107 USA

nmuller@path.org Phone: 206.285.3500 Fax: 206.285.6619