

A HealthTech Historical Profile

Technologies for Injection Safety

January 2006

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Acknowledgment

This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the HealthTech program, cooperative agreement #GPH-A-00-01-0005-00. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the United States Government.

HealthTech Historical Profile: Technologies for Injection Safety

The Problem

Needles and syringes are the standard way of delivering most vaccines and therapies. In developed world health care settings, these devices are either carefully sterilized between uses, or immediately and properly disposed of. Yet, in the developing-world environment of scarcity, low-infrastructure, few resources, and limited training and oversight, needles and syringes are frequently reused. Up until the early 1990s, most primary health care programs were supplied with glass or plastic syringes designed to be washed and sterilized between uses. In earlier times, boiling was deemed to be an acceptable way to decontaminate these syringes, but evidence on the thermostability of resistant spores and hepatitis viruses prompted a change to steam sterilizers or pressure cookers, particularly in immunization programs. These decontamination procedures were highly dependent upon the availability of fuel for heating, regular maintenance of the sterilizers, availability of spare parts, well-trained health care workers, and good oversight. Lack of one or more of these essential conditions often resulted in the use of contaminated injection equipment. The introduction of disposable syringes and needles designed for single use tended to exacerbate the problem because the conditions and culture of scarcity still prevailed, the disposable products could be easily reused, and they were not designed to be cleaned and sterilized.

To add to the problem, many injections are unnecessary; patients come to expect an injection as a satisfactory outcome of their visit to a health facility. Also, there are many informal, untrained practitioners available to give injections often with very low standards of care.

When recognized by international agencies

Although there were many anecdotal accounts of unsafe injection, it was not until 1999 that the World Health Organization (WHO) published an estimate of transmission of disease due to the use of re-used, contaminated needles. Of more than 16 billion injections administered in the developing world, 50 percent of them were estimated to be unsafe.¹ More recently, health officials estimate that annually the reuse of injection equipment may cause 20 million infections with hepatitis B virus, 2 million infections with hepatitis C virus, and 250,000 infections with HIV worldwide.²

Technology Solutions/Strategies

Initial discovery/vision

In 1985, more than a decade before the international public health community mobilized around the problem, PATH began to assess the availability of suitable technologies to ensure safe injection in developing-world health care programs. One design was developed to proof-of-concept and filed as a patent in 1987. The start of the USAID-supported HealthTech program in 1987 enabled an aggressive development program to move forward, culminating in 1990 with the licensing to BD, one of the world's largest syringe manufacturers, of the technology that

would eventually be known as SoloShot™*, the first commercialized **auto-disable** (AD) syringe. Several other injection technologies with reuse-prevention features were also advanced during that time. One technology, the **Uniject™† device**, is the topic of a separate HealthTech historical profile.



Auto-disable syringes

In the mid to late 1990s, as the newly introduced auto-disable syringes with fixed (non-removable) needles were taken up by immunization programs, it became evident that the absence of waste collection infrastructure would lead to a growing problem of sharps waste disposal. Concern was growing that improper handling and disposal of sharps waste would increase the threat of disease transmission from the health system into the communities. Under HealthTech, PATH began to develop, adapt, and model appropriate solutions to manage sharps waste at the health center level. Based

upon this early investigation, PATH concluded that the contaminated needle constituted by far the largest risk and that the large bulk volume of waste represented by the plastic syringe itself compromised safe handling, storage, and disposal of used needles. PATH launched a program to introduce mechanized needle removal and encapsulation at the point-of-care as a standard practice in regions lacking adequate infrastructure for collection of infectious waste. Several underused commercial technologies were discovered including one product that had been included in WHO Extended Program on Immunization (EPI) Product Sheets for several years yet never taken up by immunization programs. Collaborations were initiated to adapt and test these devices in challenging settings. This approach using **needle removers** for safely removing and encapsulating needles from syringes immediately after use, dubbed “**defanging**,” also cut off the hub of the syringe, thus ensuring that even syringes without reuse prevention features would be incapacitated.

Jet injectors, which had been successfully used in the campaign to eradicate smallpox, offered another solution by eliminating needles altogether. However, traditional jet injectors were expensive, high maintenance, and complex, limiting their use to campaigns and mass injection scenarios. PATH set out in 1989 to miniaturize and simplify jet injectors. The Medivax jet injector, in collaboration with a Brazilian private-sector firm, was developed and granted a 510k license by USFDA in early 1990s. However, traditional jet injectors with reusable nozzles came under increased scrutiny around that time due to a documented incident of hepatitis B transfer in a California weight-loss clinic. PATH shifted focus to a Russian design featuring disposable protection caps and focusing upon campaign, pandemic, and other high-throughput needs for fixed-dose injection. This design, developed in collaboration with Felton International, has also received USFDA 501k clearance and is currently undergoing extended clinical testing in China.

* SoloShot is a trademark of BD.

† Uniject is a trademark of BD.

Anticipating further needs for needle-free methods of administering vaccines and drugs in health care centers and the need for dose-sparing to make expensive new or combination vaccines more affordable, PATH is also collaborating with Bioject on the development of low-cost jet injectors with disposable nozzles and intra-dermal injection capability. Intra-dermal delivery of vaccine holds promise for reduction in dose size which could lead to large savings in vaccine costs.

These developments over two decades represent a stepwise strategy to the development of safe injection technologies. Through experience with technology introduction, it is evident that new solutions must be phased in order to minimize disruption of existing health care practices and to ensure sustainability. In the same way as standard disposable syringes replaced reusable glass syringes, AD syringes have now replaced standard syringes for immunization for all programs supplied by UNICEF and the Global Alliance for Vaccines and Immunization (GAVI). Resources are now being applied to the introduction of AD syringes for curative applications as well as technologies for proper handling of medical waste. While these approaches will increase safety for patients and community, PATH is working on the introduction of injection devices such as retractable needle syringes that will protect health workers from needlestick injury and simplify sharps waste management. PATH's ultimate priority is to eliminate needles altogether for many vaccines or medicaments through needle-free administration. With each new technology building on its predecessor, operational changes at the service-delivery level can become evolutionary with minimum disruption.

Design/development of test applications

Safe injection technologies explored, designed, adapted, advanced and/or introduced by PATH under the HealthTech program with USAID funding, and their current status, include:

Auto-Disable and Other Syringes:

Auto-disable reconstitution syringe	Under development
Auto-disable syringes other than Soloshot	On the market
Soloshot (originally called Syringelock)	On the market
Nonresuable hypodermic needle	Shelved
Uniject Core Technology (Originally called SafeTject) (Note that the history of Uniject is available in a separate historical profile)	On the market
Uniject with injectable contraceptives	Under development
Uniject with hepatitis B vaccine	On the market
Uniject with tetanus toxoid	On the market
Uniject with prostaglandin	Shelved
Uniject with oxytocin	Under development
Uniject with gentamicin	Under development

Jet Injector Technologies

Bioject needle-free injector	Under development
Medivax jet injector	Shelved
Felton needle-free injector	USFDA-approved

Medical Waste Technologies

Needle destroyer	On the market
Needle disposal can	On the market
Needle remover—PATH design	Offered to companies
Needle removers—other	On the market

Validation—PATH's and third party

To achieve independent validation of SoloShot, the USAID-supported REACH project managed by John Snow Inc. carried out the first validation tests of the device in Pakistan, under the direct observation of WHO. Publication of the results in *The Bulletin of the World Health Organization* in 1989 quickly disseminated the findings of high acceptability and effective prevention of syringe reuse to global injection safety planners. These successful field trials led to scale-up, production, and introduction of the first commercial AD syringe for immunization of children. Later, in 1996, PATH conducted its own evaluation of AD syringes in Indonesia in collaboration with the ministry of health. The study, called “Comparison of SoloShot Autodestruct Syringe to a Disposable Syringe in a National Immunization Campaign in Indonesia,” demonstrated the acceptability and appropriateness as well as the technical feasibility of the device for use in immunization campaigns. Vaccinators preferred SoloShot, describing it as easier to use, faster, and more accurate than the disposable syringe.



Balcan needle remover

To validate the needle remover approach, PATH assessed local needs and practices, collected input from policymakers and safety experts, developed and evaluated prototype devices, and drafted specifications for the separation of the needle from the syringe at point-of-use. PATH carried out bench and field testing and provided critical feedback for design improvement. In India, a study of needle removers, where 125,000 needles were removed after use, has been completed and showed that needle removal is acceptable and desired. PATH has also developed two needle-remover devices; these as well as many other technologies from private-sector collaborators have been tested in the field.

Technology Transfer or Licenses

Technology transfer of the safe injection technologies that PATH itself has designed and developed and that have been licensed to manufacturers in both developing and developed countries include:

Technology	Date Entered HealthTech	Date of Hand Off	Year Product First Sold	Recipient	Country
Uniject core technology	1987	1989	-	Horizon Medical	US
Uniject advanced technology	1992	1996	2000	BD	Singapore
Uniject with hepatitis B vaccine	1996	1999 2004	2000 2005	P.T. Biofarma Shantha	Indonesia India
Uniject with tetanus toxoid	1995	1999	2000	P.T. Biofarma	Indonesia
Needle disposal can	2001	2002	2003	Medipham	Vietnam
Needle remover	2001	2003	2003	Balcan	India
SoloShot	1987	1988	1992	BD	US

Policy Environment

Involvement of international agencies

PATH tries to anticipate future needs in global health and identify technology solutions that can be developed and commercialized by the time the problems are broadly recognized and programs are ready to adopt solutions. Adjustments in policy, budgets and guidelines at international and national levels are invariably required to assure uptake and proper use of the technologies. PATH plays a facilitating role in initiating dialogue among global policymakers. PATH's expertise in technology development has gained respect among policymakers. By bringing next-generation technologies to the discussion table, PATH helps to ensure that practical yet progressive approaches drive policy development.

PATH was one of the founding members of WHO's TechNet Immunization Technology group, as well as a founding member of the Safe Injection Global Network (SIGN). These international groups have played a critical role in the advancement of safe injection technologies and practices. PATH developed initial content for the SIGN website, which has become a central point for policy development and dialogue for program managers around the world.

In the case of AD syringes, PATH presented field evaluations and rationale at TechNet and other WHO/UNICEF meetings. WHO accepted the field trial results, endorsed the technology, and, with UNICEF, issued a policy on the use of AD syringes in immunization services. The 1999 statement declared that AD syringes are the equipment of choice for administering vaccines and

urged all countries to use only AD syringes by 2003. As of 2001, UNICEF supplies only AD syringes for immunization programs.

To facilitate global policy support for use of needle removers, PATH is currently participating in WHO's Performance, Quality, and Safety (PQS) working group to develop specifications for needle removers. In 2004, WHO turned to PATH to assist with development of a protocol for a WHO-funded evaluation of a needle remover in a campaign setting in Madagascar. Preliminary results suggest that there is a reduction in the number of safety boxes required by facilities using needle removers. They also found no increased risk of needle-stick injury.

Similar policy dialogues are underway regarding jet injectors, retractable needle syringes, reconstitution safety syringes, and syringe disposal technologies.

Mainstreaming/General Acceptance

Alternative AD syringe designs became available in the last half of the 1990s; these were enabled, encouraged, and facilitated by PATH under the HealthTech program. These competitive forces and the growing scale of use around the world have reduced the price of AD syringes dramatically. The price of AD syringes is now within US\$0.01 of the price of disposable syringes. This has led to a general adoption of AD technologies by GAVI and many governments and agencies around the world. Syringes with reuse-prevention features are now improving the safety of routine immunizations, as well as injectable contraceptive administration and injections for a growing number of curative procedures.

Since commercial introduction in 1992, more than 2.5 billion SoloShot syringes have been supplied to public health programs in more than 40 countries in Africa, Asia, Eastern Europe, and Latin America. UNICEF—which has already distributed hundreds of millions of AD syringes to immunization programs—now provides only AD syringes to countries requesting disposable syringes, many of which are Soloshot. It is anticipated that the transmission of bloodborne diseases due to dirty needles will be reduced by 90 percent in programs using these products.

A major boost in the mainstream use of AD syringes occurred when the President's Emergency Plan for AIDS relief (PEPFAR) was announced in 2003, with injection safety as one of the top priorities. Although AD syringes were already widely used for immunization, they had not yet been widely introduced for curative injections, which represent 90 percent of all injections given worldwide. The PEPFAR program changed this dramatically when PATH partnered with John Snow Inc. to help USAID- and CDC-funded projects. The team has procured products and supplied 12 of the 15 PEPFAR countries in Africa and the Caribbean with over 60,000,000 syringes with reuse-prevention features or retractable needles for use in curative care. Introduction of safety syringes for curative care will be expanded each year through 2009.

Through PATH's development, evaluation, and introduction activities, needle removers are already being used in immunization and waste management programs in Africa and Asia. WHO has recently included needle removal as a safe disposal option in health care waste management plans for sub-Saharan Africa. PATH's procurement role in the PEPFAR project facilitated the

introduction of several thousand needle removers into health facilities in African and Caribbean countries where other waste handling solutions were not available.

In 2001, the government of Andhra Pradesh (AP) in India, in partnership with PATH, launched an accelerated program to strengthen the state's immunization system and to add hepatitis B vaccine to the state schedule of infant vaccines. To enhance the safety, quality, and management of the immunization services, the program is providing AD syringes for all immunization injections and over 14,000 needle removers for sharps waste handling. These activities have led to a national adoption of AD/safety syringes and needle-removal technology.

Hurdles/Constraints

Initially, AD syringes were priced at approximately three times the price of standard disposable syringes. These prices created skepticism about whether AD syringes would be affordable to developing-country programs. As demand slowly increased, prices began to fall and new manufacturers entered the market. Competition reduced prices further to the current levels where no significant price difference exists. In particular, the appearance of local manufacturers producing WHO-approved designs in a range of sizes suitable for curative procedures has greatly stimulated local awareness and acceptance, reduced production and delivery costs, helped to extend use of safety syringes from immunization into the curative applications, and is helping to build markets in all regions.

Skepticism about needle removers exists based on developed-country perspectives where US and European standards require that used syringes be placed immediately in a safety container. Initial concerns were raised—that the extra handling step of removing the needle may result in increased needlestick injuries. These issues have been dismissed as a result of WHO field studies that proved otherwise.

Challenges to identify appropriate disposal solutions for the plastic syringe, once the needle is removed from the syringes, remain. Ideally, these would not involve incineration. Research is underway on ways to disinfect and disable the syringe, rendering it safe for plastic recycling or disposal as general waste. Lower cost technologies for needle removal are also being evaluated.

Evidence of Impact

The use of AD syringes, especially for immunization, has clearly increased as evidenced by the reports of sales volumes by both manufacturers and by UNICEF as a main supplier. The effect their use is having on reduced transmission of disease has not been directly measured yet but can be estimated based upon WHO estimates of disease due to unsafe injections:

By the year 2015, estimated patient infections eliminated through use of AD syringes in immunization settings will be 2.3 million and for curative care, over 6.2 million. In terms of disability adjusted life years (DALYs) averted, the numbers by the year 2015 are 1.7 million and 1.9 million for immunization and curative care respectively.

PATH has a long history of advocating for changes in safe injection policy. PATH staff have published numerous papers on safe injection issues and developed a 98-page manual, entitled

“Giving Safe Injections: Using Auto-Disable Syringes for Immunization” intended for health workers who give injections in immunization programs in resource-poor settings. The manual, which has been translated into French, Spanish, and Vietnamese, discusses current policies and practices for the delivery of safe injections along with providing specific instructions for WHO-approved AD syringes. The document has been downloaded from PATH’s website almost 10,000 times in the past year. PATH and USAID also adapted components of the manual to develop training aids for introduction of AD syringes and sharps disposal containers with USAID-supplied depo medroxyprogesterone acetate (DMPA) for family planning programs. *Bulletin of the World Health Organization* has published articles on acceptability of PATH-developed AD syringes in Pakistan and reduction of vaccine waste when using AD syringes in Indonesia.

The greatest evidence of impact of AD syringes is seen in the global acceptance of these technologies for immunization programs. With UNICEF distributing only AD syringes, many developing-country manufacturers are beginning to produce a variety of syringes with features to prevent reuse and accidental sticks. Now with the availability of these syringes for curative injections, auto-disable or other safety syringes are becoming the world’s primary tool for improving injection safety practices.

While technologies cannot replace the need for good management, training, and supervision, well-designed and timely technologies can provide cost-effective solutions to unmet needs in developing countries, leading to a rapid and sustainable improvement in quality of care. USAID, and other funding partners through the HealthTech program, continues to advance and introduce such technologies. In due course, it is anticipated that needle-free systems for administering vaccines and medications will further reduce the risks and costs associated with needles in resource-limited settings.

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