DEPO-SUBQ IN UNIJECT:
PLANNING FOR INTRODUCTION

PATH

One in a series discussing PATH's activities, research findings, experiences, and recommendations to support decision-making and product introduction planning for the injectable contraceptive depo-subQ provera 104™ in the Uniject™ injection system.

BRIEFING SUMMARY FEBRUARY 2011

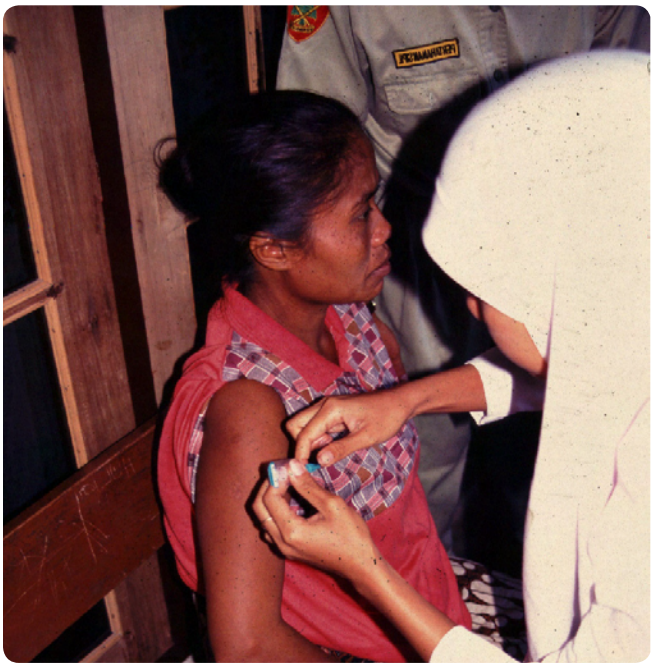
The Uniject injection system: Multi-country experience and evidence

OVERVIEW

More than two decades ago, through the USAID-funded HealthTech program, PATH began work to develop a prefilled, auto-disable injection device. The goal was to design a simple tool to meet persistent logistics, safety, and cost-effectiveness challenges posed by widespread distribution of vaccines and other injectable medications in low-resource settings.

The result of these efforts was the Uniject™ injection system, which has been used to administer more than 75 million doses of vaccines and other medicines worldwide. Because of its features, the Uniject device has the potential to greatly improve access to and delivery of contraceptives, vaccines, and maternal and child health medicines. In a more recent application of Uniject, PATH is preparing for the global introduction of depo-subQ provera 104™ in the Uniject™ injection system (depo-subQ in Uniject). The objective is to increase women's access to injectable contraceptives. Due to its ease of use, delivery of contraceptives in non-clinic settings may be expanded, including administration of depo-subQ in Uniject by community health workers and, potentially, by family members or by the client herself through self-injection.

PATH conducted a literature review to identify published and gray literature reporting international experiences with Uniject. The findings shed light on user acceptability of Uniject and highlight potential cost savings in terms of training time, waste management, and reduction in drug wastage when Uniject is used instead of a standard auto-disable syringe. This document synthesizes the experience and evidence on the use of Uniject worldwide with medicines such as the injectable contraceptive Cyclofem®, hepatitis B and tetanus toxoid vaccines, as well as the drug oxytocin, which is used to prevent postpartum hemorrhage.



PATH/Carib Nelson

The Uniject injection system has been used to administer more than 75 million doses of vaccines and other medicines worldwide.

FINDINGS

Easier than a standard syringe

Several studies indicate that midwives and other health providers find Uniject easier to use than a standard syringe. Providers said the device is safer, poses less risk of needlestick, and is more efficient because it is already prefilled with the right amount of medicine or vaccine:

- Midwives in Indonesia who used Uniject to deliver 10,000 hepatitis B vaccines during a ten-month period expressed a preference for the device over a standard syringe. All of the 33 midwives who were surveyed after using the device for several months reported its ease of activation and ease of injection to be acceptable. None reported any problems using the device. When asked what they liked or disliked about the device, 67 percent replied that it was more practical and efficient than a standard syringe, and 36 percent stated that it was easier to use and/or carry. None of the midwives mentioned anything they disliked about using Uniject.[1]
- Ninety-nine percent (139 out of 140) of providers in Mali who were surveyed said they preferred Uniject to a standard syringe for administering oxytocin. Eighty percent of the providers said Uniject is "easy to place in the injection safety box, easy to handle, and more practical." The providers also cited fewer needlestick injuries (14 percent), no need to load the syringe (9 percent), and efficiency and ease of use (8 percent) as reasons for preferring Uniject. A vast majority (80 percent) of providers indicated there were no disadvantages of Uniject when compared to standard syringes.[2]
- Almost all of the 128 midwives in Indonesia who responded to a questionnaire after delivering oxytocin in Uniject over a four-month period identified the device as being easier to use and more practical than either reusable (99 percent) or disposable (95 percent) syringes.[3]
- Among 20 providers in Brazil who administered 120 injections of Cyclofem, 90 percent reported that Uniject was easy to activate and inject, and all of them reported that it was easy to transport and store. Additionally, 80 percent reported that the device was easier to use than a traditional vial and syringe because it did not require disinfection or filling prior to administering the injection. The providers also believed their clients were reassured to know that the syringe and needle had not previously been used. Eighty percent of the providers reported that they would prefer Uniject to a traditional syringe in the future.[4]

Summary of Uniject research findings

Easier than a standard syringe: Health providers find Uniject easier to use than a standard syringe, reporting that it is safer, poses less risk of needlestick, and contains the correct dose.

Less painful and intimidating than a standard syringe: Health providers and clients prefer Uniject to a standard syringe as it caused less discomfort.

Training time is short: Health workers can learn to use Uniject in a short time through peer-led or self-guided trainings and materials.

Safe for self-injection: Health providers say women can safely and correctly give themselves injections with the device.

Generates less waste: Uniject generates less waste than a traditional needle and syringe.

Saves time: Use of Uniject requires less time and fewer physical motions by health providers.

- Midwives in Viet Nam who used Uniject to deliver oxytocin injections preferred the device to a standard syringe. Among 216 midwives surveyed, 39 percent indicated that standard syringes are difficult to fill and 29 percent said that filling the syringes is too time consuming. When asked what single characteristic they most preferred about the Uniject devices, the midwives most commonly cited convenience and ease of use. Almost all (97.6 percent) stated it was easy to activate and administer injections with the Uniject device.[5]

Less painful and intimidating than a standard syringe

Midwives and clients in two studies found Uniject preferable to a standard syringe. Pregnant women and new mothers noted the device was less painful than conventional injections:

- Mothers in Indonesia expressed a strong preference for Uniject when their infants were vaccinated by midwives trained to use the device. Ninety-four percent of 860 mothers surveyed following their children's injections said they experienced no anxiety before the injection, and 92 percent said they would agree to future injections with Uniject. Among the mothers who had also received injections with the device, 94 percent said they had experienced no anxiety, and

97 percent said they would agree to receive future injections with the device. More than half of the women (56 percent) said they felt less pain when injected with Uniject compared to an injection with a standard syringe.[1]

- Among 30 pregnant women in Bolivia who received injections of tetanus toxoid with Uniject, 50 percent said it was less painful than previous injections received via a conventional syringe, 10 percent reported the pain was comparable to a conventional syringe, and 7 percent said it was more painful. The remaining 33 percent were unable to compare. Eighty percent of the women said the appearance of Uniject did not cause them any anxiety, in part because of its small size.[6]

Training time is short

Health workers can learn to use Uniject in a short time through peer-led or self-guided trainings and materials:

- Among 140 providers in Mali who were trained to use Uniject to deliver oxytocin, 97 percent felt competent in using the device after completing training activities, which ranged from a formal two-hour training to training by colleagues, to reading printed instructions. Providers who read printed instructions (n=2) felt as confident as those who had been trained by colleagues (n=68) or trained by governmental and nongovernmental project personnel (n=64). Of the trained providers who delivered an oxytocin injection to a client, 92 percent felt confident after only one injection.[2]
- In Ghana, 94 percent of traditional birth attendants (TBAs) who received a three- to four-hour training felt it was sufficient to use Uniject properly. The vast majority stated that they felt comfortable with Uniject after using it five times. During the ensuing immunization campaign, TBAs used Uniject properly and safely.

Safe for self-injection

In addition to the ease of use providers cite with Uniject, health professionals say women can safely and correctly give themselves injections with the device:

- Nurses in Brazil said that more than 90 percent of 88 women trained to use the Uniject device could correctly self-administer Cyclofem, a monthly contraceptive injection, with the device. Among the 56 women who agreed to three self-injections over the course of three months, 57 percent reported they would prefer to self-administer using Uniject in the future.[7]

Generates less waste

Uniject generates less waste than a traditional needle and syringe, according to multiple studies:

- An analysis comparing depo-subQ in Uniject and the intramuscular formulation of Depo-Provera® (DMPA IM) administered in a syringe found that the Uniject packaging generates 39 percent less waste by volume. The comparison focused on a 1-ml dose of DMPA IM packaged in a glass vial and administered with a 1-ml SoloShot™ auto-disable syringe. Donor shipments of DMPA often also include one 5-L safety box for every 100 syringes.[8]
- The same study found that Uniject generates 70 percent less total waste volume than a SoloShot syringe and Depo-Provera vial. It also occupies less than half the volume of the syringe and vial in distribution.[8]
- Recent bench testing shows that because of the Uniject device's small size, 2.6 times as many depo-subQ in Uniject devices fit into a 5-L safety box as a standard auto-disable syringe (500 compared to 195, respectively).[8]

Saves time

Use of Uniject to administer injections requires less time and fewer physical motions by health providers.

- Project Optimize conducted a study comparing injection delivery time and technique across four products: single-dose vials, two-dose vials, ten-dose vials (all in combination with a retractable syringe) and the prefilled Uniject device. The study found that administration with Uniject was faster, averaging 18 seconds compared with 28.2 to 38.9 seconds for the other products. Results show that Uniject also required fewer steps to delivery—18 compared with 23 to 30 steps for the other products.[9]

CONCLUSION

Data collected from country experiences and studies indicate that health providers and patients support using Uniject for delivering injectable contraceptives, vaccines, and other injectable medications. Studies show that Uniject is generally acceptable, suitable for delivery of selected medicines in non-clinic settings, and presents potential cost savings in training and waste management.

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About depo-subQ in the Uniject device

A new formulation and presentation of the contraceptive depot medroxyprogesterone acetate (DMPA) for subcutaneous administration in a prefilled injection system, known as depo-subQ provera 104™ in Uniject™ injection system (depo-subQ in Uniject), will soon be available to women in developing countries. The contraceptive will be prepackaged with a single dose inside device, an autodisable syringe developed by PATH. Due to its ease of administration and likely high acceptability among women seeking contraception options, introduction of depo-subQ in the Uniject device provides opportunities to both strengthen clinic injection services and extend injectable contraceptive delivery safely and effectively beyond the clinic, such as through community-based distribution. The product is also expected to have advantages for supply chain management. The product will be marketed by Pfizer, and PATH is leading global planning for its introduction.

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For more information, please visit www.path.org.

MAILING ADDRESS
PO Box 900922
Seattle, WA 98109 USA

STREET ADDRESS
2201 Westlake Avenue, Suite 200
Seattle, WA 98121 USA

info@path.org
www.path.org

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