DEPO-SUBQ IN UNIJECT:PLANNING FOR INTRODUCTION





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

Logistics and waste management benefits of depo-subQ in Uniject

OVERVIEW

To understand how the current intramuscular version of depot medroxyprogesterone acetate (DMPA) injectable contraceptive compares with the new formulation packaged in the Uniject™, PATH conducted a comparative analysis of the two products. The analysis focused on the waste management implications, identifying key quantitative and qualitative differences between the two products. PATH also commissioned John Snow, Inc. (JSI) to conduct a similar comparative study to identify logistics costs and challenges of depo-subQ in Uniject and intramuscular DMPA (DMPA IM) bundled with separate needle and syringe.

This brief summarizes the results of these analyses. The results are intended to provide information for decision-makers, donors, and collaborators on logistics, supply chain, and waste management considerations related to the introduction of depo-subQ in Uniject, especially in developing-country settings.

ABOUT THE ANALYSES

At PATH's request, JSI conducted a quantitative and qualitative analysis comparing logistics costs and challenges of depo-subQ in Uniject and DMPA IM bundled with separate needle and syringe. The study emphasized data from Kenya, Malawi, Pakistan, Rwanda, and Senegal, five countries of particular interest to PATH for product introduction planning. JSI's analysis used a combination

of key informant interviews, review of country documents, supply chain costing studies, quantitative review of Reproductive Health Interchange (a web-based tool for reproductive supply orders), and a spreadsheet tool to enable countries to estimate potential savings.

PATH conducted a comparative analysis of depo-subQ in Uniject and DMPA IM with a focus on the waste management implications of each product. The objective of this comparative analysis was to identify quantitative and

At-a-glance: Benefits of depo-subQ in Uniject Logistics

- Integrates medicine, syringe, and needle in one package.
- Saves on costs for international freight, in-country distribution, and storage.
- Likely to enhance community-based distribution.

Waste management

- All-in-one product produces less waste, lowers disposal costs.
- Requires less than half the space in a safety box as SoloShot™ syringes.
- No glass disposal needed.
- Will not leach into water supplies.



Comparing a vial of DMPA IM and 1-ml auto-disable syringe with depo-subQ in the Uniject injection system.

qualitative differences in waste management between the two products with regard to:

- · Quantity and type of health care waste produced.
- Impact on safe containment options, including safety box requirements and the use of needle removers.
- Cost.

The waste management analysis compared the health care waste produced by depo-subQ in Uniject to DMPA IM administered with a SoloShot™ syringe. PATH conducted bench testing and analysis on the:

- · Weight and volume of syringes.
- Quantities of syringes that fit into a 5-L safety box and into a 2.5-L safety box.
- Feasibility of using needle removers with depo-subQ in Uniject.

The comparison focused on a 1-ml dose of DMPA IM packaged in a glass vial and administered with a 1-ml SoloShot IX auto-disable syringe. Similarly, PATH referenced several sources of both qualitative and quantitative information to identify programmatic and cost implications for the introduction of depo-subQ in Uniject on health care waste management systems.

FINDINGS

Logistics benefits

The results of JSI's logistical analysis indicate that depo-subQ in Uniject may improve injection safety and contraceptive security, would offer savings in international freight, and may contribute to reduced in-country distribution and storage costs. JSI's analysis also suggests that the product is likely to enhance community-based distribution (CBD).

Contraceptive security and injection safety: Because depo-subQ in Uniject integrates the medicine, syringe, and needle in one unit, the drug-device combination eliminates any possibility of a mismatch between the availability of product and a suitable syringe at the point of use. While family planning programs aim to provide a "bundled" supply of DMPA with an auto-disable syringe, the various methods of bundling these products do not uniformly meet the goal of ensuring that appropriate supplies are available together at the point of service. In many cases, product and syringes procured or supplied together become separated. This can mean that DMPA is not used on schedule or is administered with an unclean or inappropriate device, or that clients must provide their own syringes, all of which introduce unneeded risks for

clients. Depo-subQ in Uniject eliminates all potential problems caused by failures in bundling systems.

International freight savings: Depo-subQ in Uniject is estimated to be 62 percent lighter and 25 percent less voluminous than the equivalent DMPA vials packed with syringes and safety boxes. JSI estimated theoretical savings on international freight based on 2009 data for DMPA shipments in PATH's five focus countries. These savings are estimated to be greater for air shipments, which are usually based on weight, than for sea shipments, which are usually based on volume. It is assumed that most shipments are by sea. The analysis concludes that in 2009, Kenya would have saved 25 percent on freight—equivalent to US\$0.03 per unit—if the product shipped was depo-subQ in Uniject instead of DMPA. Likewise, Malawi would have saved 51 percent (US\$0.12 per unit), Pakistan would have saved 32 percent (US\$0.03 per unit), Rwanda would have saved 26 percent (US\$0.03 per unit), and Senegal would have saved 54 percent (US\$0.11 per unit). JSI developed an Excel spreadsheet tool to estimate potential savings in other countries based on different scenarios. It is important to note that these freight savings would accrue to the product's purchaser—in this case, the purchaser is USAID and the USAID Missions.

In-country distribution and storage savings: Quantifying in-country logistics costs and potential savings is more difficult due to a lack of consistent, reliable local data. Most countries do not quantify their supply chain costs and fees for handling or shipping are usually charged on a value basis and not on the actual economic cost of storing, handling, and distributing goods. Depo-subQ in Uniject is expected to allow for in-country logistics savings because it is lighter, smaller, and a single product. Data derived from a recent supply chain costing exercise in Zimbabwe provides a hypothetical indication of in-country distribution savings for transport of depo-subQ in Uniject, indicating that the country could save 25 percent on handling costs, or US\$10,000 on 1 million vials, by using deposubQ in Uniject instead of DMPA in a traditional syringe. Other supply chain benefits may include:

- Elimination of the need to manage a separate syringe procurement.
- · Savings on storage space.
- Savings for ordering, inventory management, and logistics management information systems in having only a single product to manage versus at least two.
- · Savings on fuel for transport.
- The possible use of lighter pallet racking.

Community-based distribution: Depo-subQ in Uniject is expected to have widespread utility for distribution in non-clinic settings. In situations where health providers have to carry products or manage a small number of items, depo-subQ in Uniject could offer substantial logistical benefits due to its smaller volume, lower weight, and elimination of need to manage both syringe and vials. Pilot CBD programs in a number of countries have experienced delays in administering DMPA due to shortages of syringes. The JSI analysis suggests that the new product could be advantageous in a handful of country settings where stockouts of syringes occur due to injectables being shipped without syringes, where they are separated in-country due to lack of bundling, or where adequate quantities of sterile, single-use syringes are not ensured.

Waste management benefits

The lower weight and smaller size of depo-subQ in Uniject mean it will generate less waste than DMPA IM, thereby reducing costs and simplifying overall waste handling, transport, treatment, and disposal. The primary waste management benefits of depo-subQ in Uniject are summarized below.

Less waste produced: The depo-subQ in Uniject drug and device combination eliminates the need for a glass vial, which would need to be properly handled and disposed. As a result, the total waste volume generated by depo-subQ in Uniject is 70 percent less than the total waste volume from the SoloShot and an empty DMPA vial.

Fewer safety boxes required: Uniject must be deposited into a safety box after use to prevent needlestick injuries, but the devices take up less space than SoloShot syringes. For example, a standard 5-liter safety box can hold 500 Uniject compared to 195 1-ml SoloShot syringes and a 2.5-liter safety box holds 180 Uniject compared to only 65 syringes.

Lower costs associated with disposal supplies: Based on 2009 global shipments of DMPA, countries would have saved an estimated US\$119,815 in safety box costs if DMPA IM had been replaced with depo-subQ in Uniject.

No challenge of glass disposal: Depo-subQ in Uniject eliminates the need for glass vials, disposal of which has become increasingly problematic in low-resource settings. Glass does not melt in small-scale incinerators or by burning and it can quickly fill waste pits. Vials that are not disposed of properly are often left exposed in garbage piles for potential reuse.

Reduced risk of environmental contamination: Potential risks of residual progesterone-based contraceptives

leaching into the water table have not been documented, though researchers have documented risks from the leaching of estrogen-containing contraceptives. Uniject's plastic reservoir can be incinerated, thereby eliminating the risk of the contraceptive leaching into the water table. It is unknown whether there is an environmental risk from the incineration of residual contraceptive.

CONCLUSION

Results of these analyses demonstrate that depo-subQ in Uniject may have logistics and waste management benefits when compared to DMPA IM. The integrated design of depo-subQ in Uniject ensures the availability of both the drug and the syringe at the point of use, eliminating the possibility of a mismatch of key delivery supplies. While difficult to quantify, anecdotal accounts suggest that supply mismatch has caused disruptions in delivery of DMPA IM and other injectable contraceptives to end-users in many countries. The drugdevice combination's lighter weight and smaller size also represent cost savings on international freight and in-country transportation and storage. Additionally, the handling, treatment, and disposal of any waste resulting

from use of depo-subQ in Uniject is anticipated to be less expensive than the associated costs with DMPA IM.

SELECTED REFERENCES

Hudgins T and Dowling P. Comparative Analysis of Supply Chain Characteristics of Sayana IS and Depo-Provera® IM. John Snow Inc., March 2010.

Introducing Auto-disable syringes and sharps-disposal containers with DMPA, PATH/HealthTech. July 2001.

PATH. Waste management analysis of depo-subQ in Uniject® compared to Depo-Provera® intramuscular injections. PATH, July 2010.

PATH. Planning for introduction of depo-subQ in Uniject: Waste management considerations. PATH July 2010.

Stanback J, Mbonye A, et al. Safety and Feasibility of Community-Based Distribution of Depo Provera in Nakasongola. Uganda, 2005.

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About depo-subQ in the Uniject injection system

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 (depo-subQ in Uniject), will soon be available to women in developing countries. The contraceptive will be prepackaged with a single dose inside Uniject, 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 Uniject 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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