

Sayana[®] Press: Pilot introduction and evaluation

RHSC 14th Annual Membership meeting

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7-11 October 2013



SAYANA PRESS:
PILOT INTRODUCTION

Product information and evidence

What is Uniject™?

Developed by PATH



Made by BD (Becton, Dickinson and Company)

Single dose
Prefilled and sterile
Non-reusable

Used with:

- Hepatitis B vaccine
- Oxytocin
- Tetanus toxoid
- Cyclofem

In these countries:

- Bolivia
- Brazil
- China
- Egypt
- Guatemala
- India
- Indonesia
- Vietnam

What is Sayana Press? How is it different from DMPA IM?

Current standard

DMPA IM 150



Depo-Provera®
Contraceptive Injection
medroxyprogesterone acetate injectable suspension

- 150 mg DMPA.
- Delivered every 3 months.
- Glass vial with syringe.
- Intramuscular injection.
- 1" needle.
- Site: deep muscle tissue.
- 99% contraceptive efficacy.
- Depo-Provera® brand: Pfizer, Inc.
- Generic equivalents made by various manufacturers.

DMPA IM 150

Sayana Press

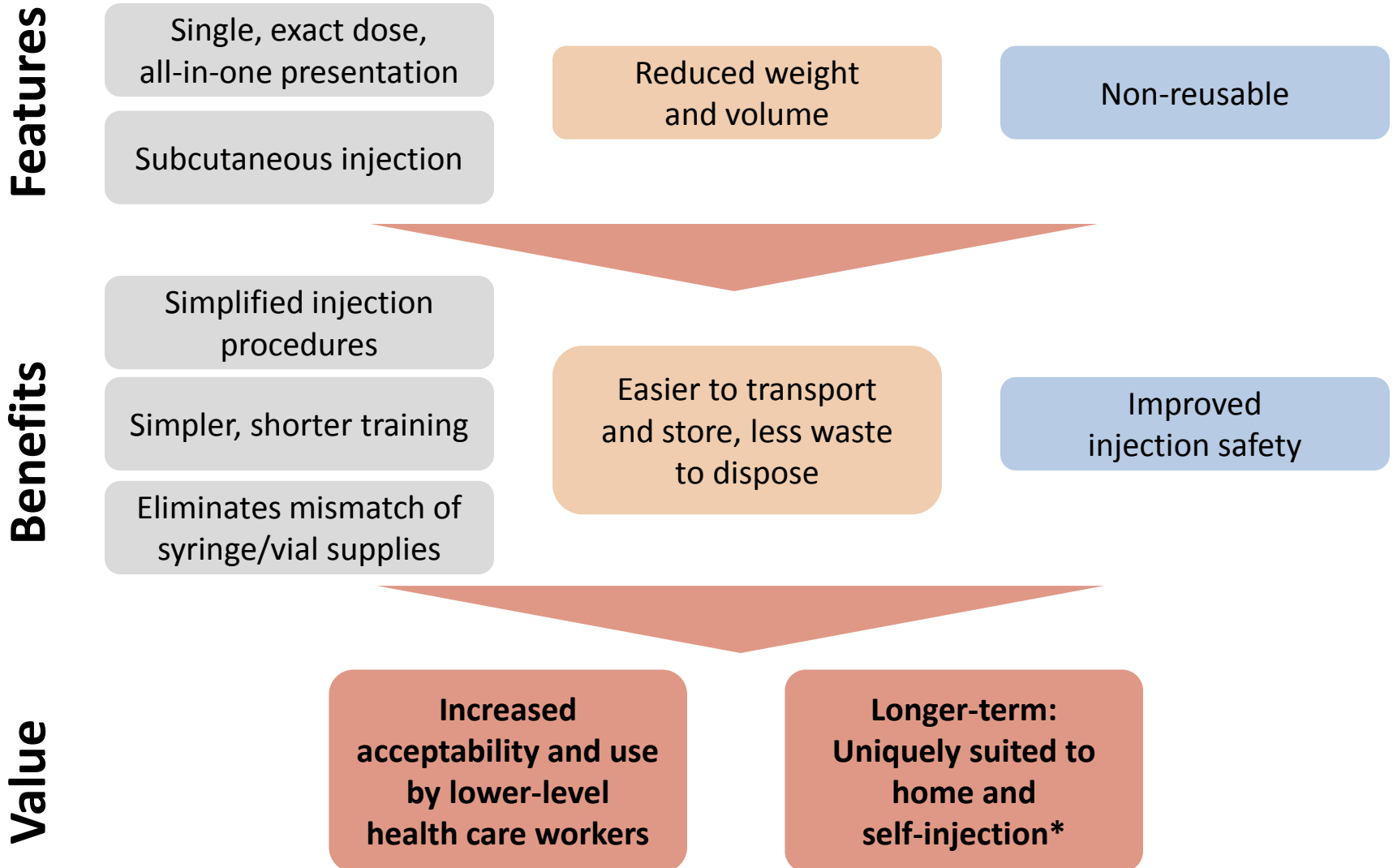


**depo-suba
provera 104™**
medroxyprogesterone acetate injectable suspension
(104 mg/0.65 mL for subcutaneous use)

- 104 mg DMPA.
- Delivered every 3 months.
- Prefilled in Uniject.
- Subcutaneous injection.
- 3/8" needle.
- Site: subcutaneous fat.
- Equivalent contraceptive efficacy, safety, and side effects.
- Pfizer product: Patent until 2020.

Sayana Press

What are Sayana Press' potential benefits?



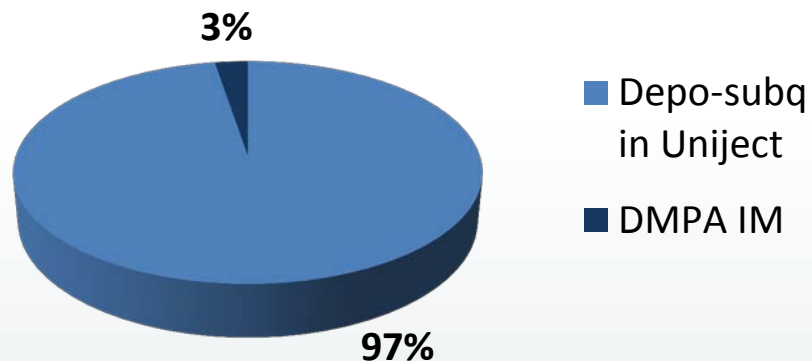
*Sayana Press is not labeled for self-injection and does not have regulatory approvals for self-injection.

Who might benefit from Sayana Press?

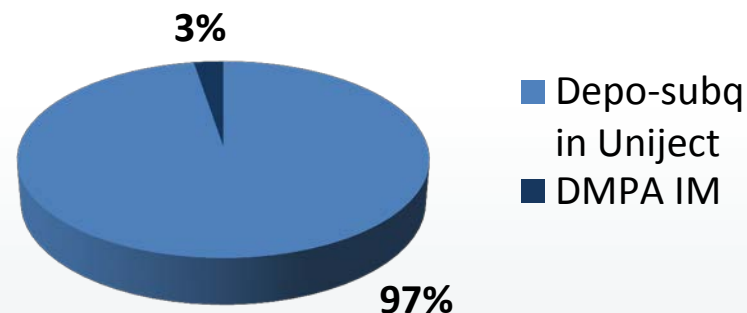


Comparison between Depo-subQ in Uniject and DMPA IM – Uganda (n = 38)

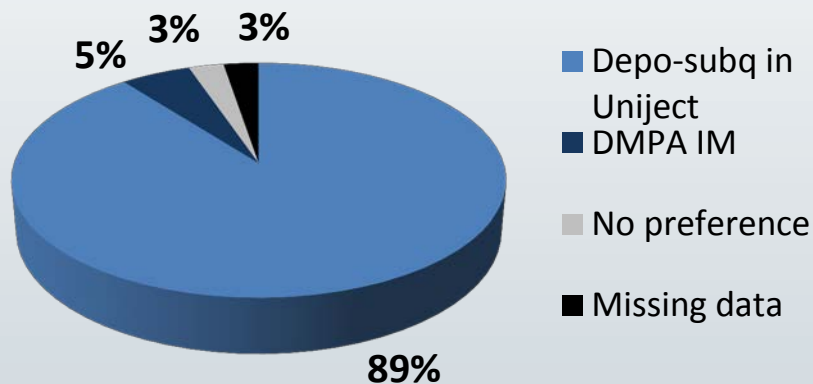
Easier to prepare



Easier to administer



Easier to dispose



Client acceptability of Depo-subQ in Uniject

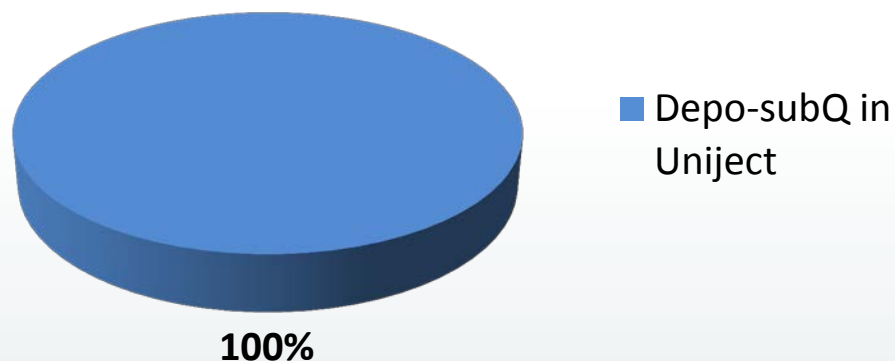
If given the choice, would select Uniject at next family planning appointment (versus DMPA IM, no preference, don't know)	Uganda (n = 120) n (%) 95% CI**	Senegal (n = 242) n (%) 95% CI**
Post-injection	100 (83%) 76%, 91%	170 (70%) 64%, 77%
3-month follow-up*	85 (85%) 76%, 94%	110 (77%) 67%, 87%

*Data collection still on-going; preliminary result only includes 83% of expected data from Uganda and 59% expected data from Senegal

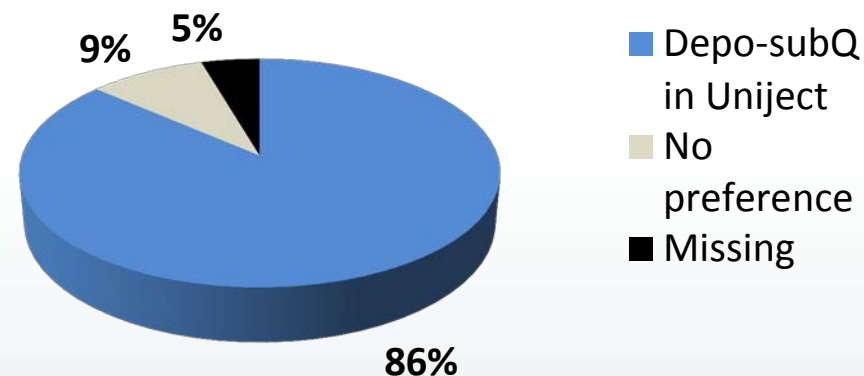
**Adjusted for clustering of clients within providers

Comparison between Depo-subQ in Uniject and DMPA IM – Senegal (n = 22)

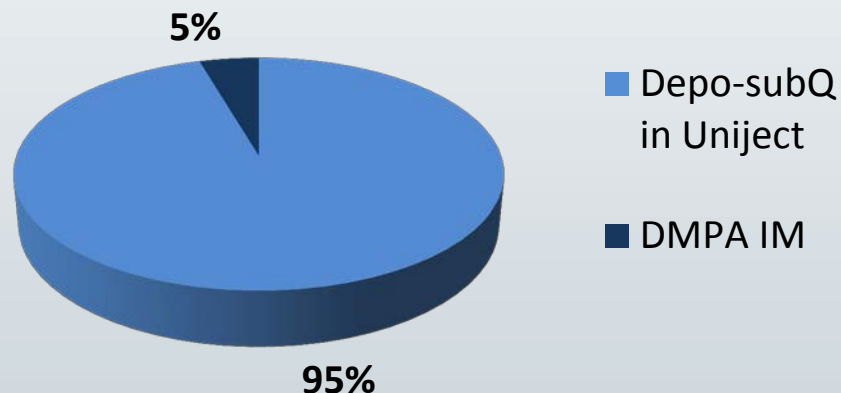
Easier to prepare



Easier to administer



Easier to dispose



What is the price of Sayana Press?

- Currently Sayana Press is more costly than DMPA IM.
- Future price is unknown.
 - New products are normally more costly than existing products.
 - Cost and price are influenced by demand and production volumes.
 - At current volumes, the price of Sayana Press is likely to be close to double the price for Depo Provera (\$0.78 to \$0.99 per unit).
 - Donors and partners are strategizing to support possible longer-term, affordable pricing for Sayana Press.

Overview of pilot introduction initiative

Pilot introduction of Sayana Press

Goals

- Support achievement of FP2020 goals by increasing injectable contraceptive use.
- Develop an evidence and experience base to inform global and country-level decisions concerning whether and how to include Sayana Press as a contraceptive option.

Objectives

- Deliver up to 12 million units of Sayana Press in four to six countries in Sub-Saharan Africa and South Asia, 2013–2016.
- Expand access to injectables for new users, improve continuation, and reduce delivery costs.
- Evaluate the value proposition of Sayana Press: Inform decision-making about whether to include Sayana Press in family planning programs in the future.

Pilot introduction of Sayana Press

Product registration process

- Sayana Press is approved by stringent regulatory authorities in Europe.
- The drug in Sayana Press is approved by European regulatory authorities and by the US Food and Drug Administration (USFDA).
- The product will be registered in country before pilot introduction begins.
- Pfizer is responsible for preparing and submitting country registration dossiers.



PATH/Eric Becker

Pilot introduction—country implementation

Introduction principles

- Country ownership and collaboration with donors and implementing partners.
- Include Sayana Press in regular family planning distribution and delivery systems.
- Involve MOH personnel—trainers, supervision systems, community health workers and other providers.
- Begin forward planning for possible future procurement.



Country contributions

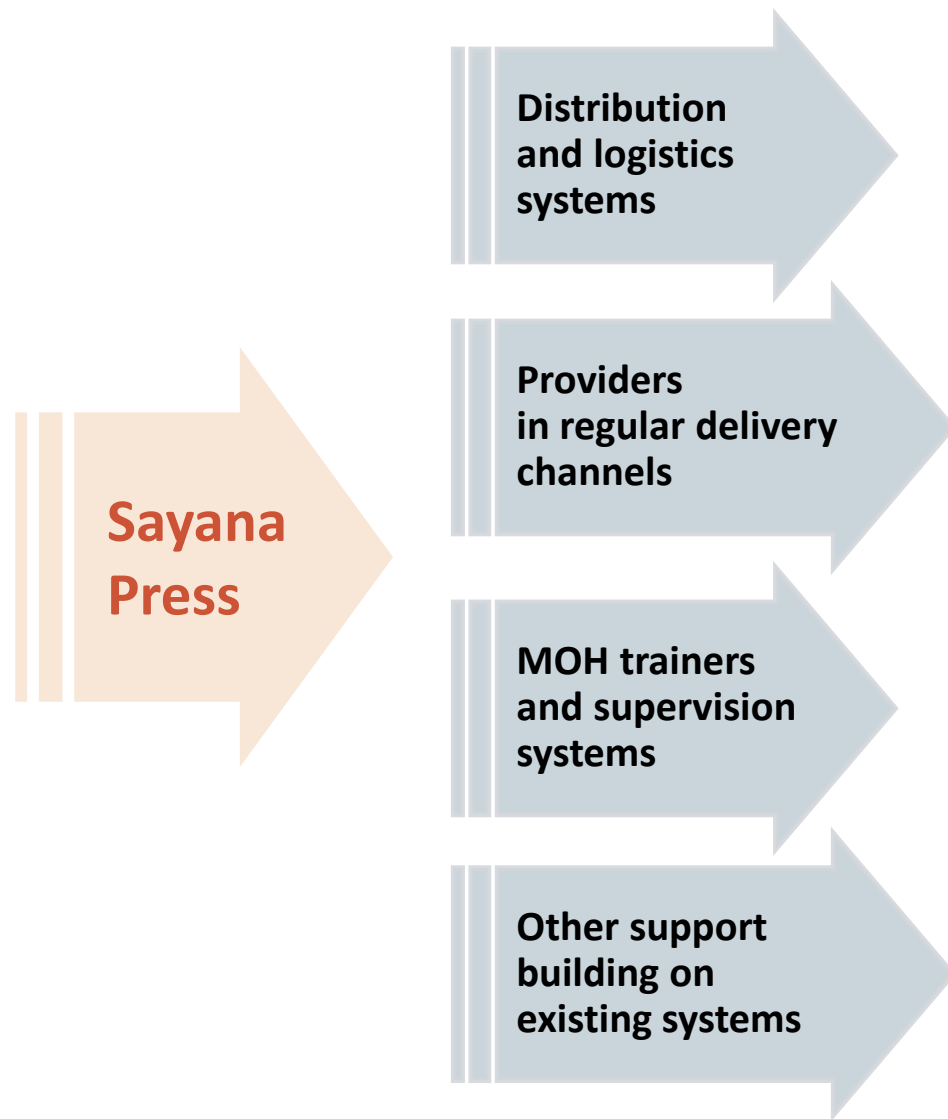


Photo: David Jacobs

Service delivery channels



Public sector

- Includes community-based distributors and community health workers.
- Shifting tasks to less specialized cadres.

NGO outreach

- Includes community-based programs.
- Extending number of outreach points.

Private sector networks

- Providing services through social marketing in places where people normally shop—pharmacies, drug shops, and commercial outlets.

Future decision-making about Sayana Press

Countries



Donors



Considerations

- Meeting women's reproductive intentions.
- Demand for family planning.
- Country goals.
- Costs and benefits.



**Sayana
Press?**



Evaluation framework

Evaluation framework

- The pilot introduction of Sayana Press evaluation component expects to assess the product's ability to:
 - Generate new users.
 - Improve contraceptive continuation.
 - Reduce service delivery costs.
- Information from the evaluation will be made available to donors and partners to inform decisions about use of Sayana Press.
- Evaluation Technical Advisory Group (E-TAG) will oversee evaluation design, implementation, and data review.



PATH/Monique Berlier

Challenges

- Price
- Registration time lines
- Complexity: multiple funding flows through multiple channels

Opportunities

- Lots of interest at global and country level
- Strong country partnerships
- Evidence for decision making
- Possibility of expanding provider base
- Possibility of self administration

Thank You

Jane Hutchings

Director, Reproductive Health Program

PATH



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