Sayana® Press: Pilot introduction and evaluation

RHSC 14th Annual Membership meeting
New Delhi, India
7-11 October 2013
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**
- 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.

**Sayana Press**
- 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.
What are Sayana Press’ potential benefits?

**Features**
- Single, exact dose, all-in-one presentation
- Subcutaneous injection

**Benefits**
- Reduced weight and volume
- Non-reusable
- Simplified injection procedures
- Easier to transport and store, less waste to dispose
- Improved injection safety
- Simpler, shorter training
- Eliminates mismatch of syringe/vial supplies

**Value**
- Increased acceptability and use by lower-level health care workers
- Longer-term: Uniquely suited to home and self-injection*

*Sayana Press is not labeled for self-injection and does not have regulatory approvals for self-injection.
Who might benefit from Sayana Press?

- Hard-to-reach and special populations
- Women without access to injectable contraceptives
- Women who prefer to obtain contraceptives through commercial outlets
Comparison between Depo-subQ in Uniject and DMPA IM – Uganda (n = 38)

**Easier to prepare**
- 97% for Depo-subq in Uniject
- 3% for DMPA IM

**Easier to administer**
- 97% for Depo-subq in Uniject
- 3% for DMPA IM

**Easier to dispose**
- 89% for Depo-subq in Uniject
- 3% for DMPA IM
- 3% No preference
- 5% Missing data
Client acceptability of Depo-subQ in Uniject

<table>
<thead>
<tr>
<th>If given the choice, would select Uniject at next family planning appointment (versus DMPA IM, no preference, don’t know)</th>
<th>Uganda (n = 120)</th>
<th>Senegal (n = 242)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>95% CI**</td>
</tr>
<tr>
<td>Post-injection</td>
<td>100 (83%)</td>
<td>76%, 91%</td>
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<tr>
<td>3-month follow-up*</td>
<td>85 (85%)</td>
<td>76%, 94%</td>
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*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**: 100% in favour of Depo-subQ in Uniject.
- **Easier to administer**:
  - 86% find Depo-subQ in Uniject easier to administer.
  - 9% have no preference.
  - 5% find DMPA IM easier to administer.
- **Easier to dispose**:
  - 95% find DeposubQ in Uniject easier to dispose.
  - 5% have no preference.
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.
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

- Distribution and logistics systems
- Providers in regular delivery channels
- MOH trainers and supervision systems
- Other support building on existing systems

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

Considerations
• Meeting women’s reproductive intentions.
• Demand for family planning.
• Country goals.
• Costs and benefits.
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.
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
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