The Promise of Contraceptive Self-Injection: Evidence From Uganda

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What is the promise of contraceptive self-injection for women and adolescent girls?

“I don't need to travel long distance. It is easy, safe, and gives me the freedom to manage it myself.”

– Research participant
Today’s speakers

Jennifer Drake
Today’s webinar moderator

Jane Cover
Access to DMPA-SC in Uniject and self-injection in Uganda

Allen Namagembe
PATH/Ministry of Health
self-injection feasibility study design and results
If you have questions...

- If you have questions for today’s presenters, please send them using the chat feature on your computer.
- We will be collecting questions and plan to address them during a Question and Answer session after the presentations.
### How is DMPA-SC different from traditional DMPA-IM?

<table>
<thead>
<tr>
<th>DMPA-IM 150</th>
<th>DMPA-SC in Uniject</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="DMPA-IM 150 Image" /></td>
<td><img src="image2.png" alt="DMPA-SC in Uniject Image" /></td>
</tr>
<tr>
<td><strong>• 150 mg DMPA</strong></td>
<td><strong>• 104 mg DMPA</strong></td>
</tr>
<tr>
<td><strong>• Delivered every 3 months</strong></td>
<td><strong>• Delivered every 3 months</strong></td>
</tr>
<tr>
<td><strong>• Glass vial with syringe</strong></td>
<td><strong>• Prefilled in the Uniject™ injection system</strong></td>
</tr>
<tr>
<td><strong>• Intramuscular injection</strong></td>
<td><strong>• Subcutaneous injection</strong></td>
</tr>
<tr>
<td><strong>• 1” needle</strong></td>
<td><strong>• 3/8” needle</strong></td>
</tr>
<tr>
<td><strong>• Site: deep muscle tissue</strong></td>
<td><strong>• Site: subcutaneous fat</strong></td>
</tr>
<tr>
<td><strong>• 99% contraceptive efficacy</strong></td>
<td><strong>• Equivalent contraceptive efficacy, safety, and side effects</strong></td>
</tr>
<tr>
<td><strong>• Depo-Provera® brand: Pfizer Inc.</strong></td>
<td><strong>• Sayana® Press brand: Pfizer Inc. under patent until 2020</strong></td>
</tr>
<tr>
<td><strong>• Generic equivalents made by various manufacturers</strong></td>
<td></td>
</tr>
</tbody>
</table>
DMPA-SC in Uniject (Sayana Press) increases access to contraceptive injections through multiple channels

**Features**
- Single, exact dose, all-in-one presentation
- Subcutaneous injection
- Reduced weight and volume
- Non-reusable

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

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

DMPA-SC in Uniject (Sayana Press) increases access to contraceptive injections through multiple channels.
Background: Nearly half a million doses administered in four countries

More than 490,300 doses of DMPA-SC in Uniject have been administered by lay health workers and other providers since 2014.
EXPANDING INJECTABLE ACCESS IN:

UGANDA


- **2,284** Number of providers trained in pilot
- **130,673** Doses administered during pilot
- **29%** Proportion of doses administered to new users
- **44%** Proportion of doses administered to users under 25

COUNTRY OVERVIEW
- Total population: 36 million
- Contraceptive prevalence rate (CPR), modern methods, all women: 21%
- Injectables as proportion of the method mix, married women: 56%
Self-injection research evidence to date

- Small, but positive findings from developed country settings:
  - Most women found self-injection easy and convenient
  - No evidence of any difference in continuation (but sample sizes are small)
  - No serious adverse events or pregnancies
  - Some study interventions are difficult to replicate (at scale) in lower-income countries
- No self-injection studies had been conducted in sub-Saharan Africa until 2015
- PATH and ministries of health in Uganda and Senegal are assessing the feasibility, acceptability, and potential impact of self-injection in the African context
- These results are from the first study, conducted in Uganda, and completed in 2015
Regulatory status of self-injection with Sayana Press (DMPA-SC)

- 2015: Sayana Press approved for self-injection in United Kingdom by lead regulatory authority, the Medicines & Healthcare products Regulatory Agency (MHRA)
- Pfizer is applying for the same label change in several additional countries
- In Uganda, there is conditional approval for self-injection
- Label change has been approved in Niger, Ghana, and Nigeria
2015: WHO recommends self-injection in specific circumstances

Table 21. Self-administration of injectable contraception*

<table>
<thead>
<tr>
<th>Self-administration of injectable contraceptives</th>
<th>Recommendation</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women (self-administration)</td>
<td>Recommended in specific circumstances</td>
<td>There is evidence from high-resource settings that continuation rates for self-administered injectable contraceptives are similar to injectable contraceptives being provided by clinic-based providers (low certainty). The option may result in time and financial savings for women. There is evidence that some women prefer self-injection and the option may increase choice and autonomy in contraceptive use within a rights-based framework.</td>
</tr>
</tbody>
</table>

Self-injection: Potential pathway in Uganda

- Positive evidence of feasibility and acceptability of self-injection
- Successful pilot introduction of Sayana Press given by CHWs
- NDA approval of self-injection, MOH authorization for pilot
- Self-injection roll-out in 3 districts, public and private sectors
- Additional offers of self-injection
- Evidence of best practices for scale-up
- Evidence that Sayana Press from CHWs and via self-injection is effective/cost effective
- MOH HPAC approves self-injection; operational policies in place

Scale
- Donor support
- Sustained national access to Sayana Press
PATH/MOH self-injection feasibility study design and results
Feasibility and acceptability of self-injection in Uganda

Primary outcomes:
- Percent of women who demonstrate injection competence at three months
- Percent of women who reinject on time, within one week (±/-) of their reinjection date

Secondary outcomes:
- Identify operational considerations for the design of a future self-injection program, including:
  - Challenges with injection steps that may need extra attention during training
  - Adequacy of training and use of the client instruction booklet
  - Reliance on lay caregivers or providers for assistance
  - Storage of Sayana Press
  - Disposal of used devices
- Assess the acceptability of self-injection and identify the characteristics of women for whom self-injection is appealing or not
Research approach

Study design:
• Prospective, observational study with women who try self-injection (n=380)
• Interviews with women who decline self-injection (refusers) (n=62)

Study procedures:
• Women were trained in self-injection and practiced injections on a model
• They self-injected under the supervision of a study nurse, who used an observation checklist to evaluate their injection technique
• Those judged competent were given one Sayana Press unit to take home
• Women who declined to try self-injection were interviewed to understand why
• Self-injectors were followed up 3+ months later at home, after their injection date
• They were asked to demonstrate the injection steps (on a model) and were interviewed again
What does training in self-injection entail?
Primary outcomes: Injection competence and timing

- **Injection competence**: Five critical steps demonstrated correctly
- **Injection timing**: Within one week (+/-) of planned reinjection date

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent posttraining (1\textsuperscript{st} injection)</td>
<td>372</td>
<td>380</td>
<td>97.9</td>
</tr>
<tr>
<td>Competent after 3 months (2\textsuperscript{nd} injection)*</td>
<td>324</td>
<td>368</td>
<td>88.0</td>
</tr>
<tr>
<td>On-time reinjection**</td>
<td>342</td>
<td>360</td>
<td>95.0</td>
</tr>
<tr>
<td>Both competent and on time</td>
<td>313</td>
<td>360</td>
<td>86.9</td>
</tr>
</tbody>
</table>

*8 women were judged not competent to continue after the 1\textsuperscript{st} injection, 5 women discontinued the injectable, and 7 were lost to follow-up

**All but 3 injections were given within the WHO-recommended reinjection window for DMPA
Primary outcomes: Profiles of women deemed competent vs. not competent

<table>
<thead>
<tr>
<th>Variable</th>
<th>Demonstrated competency (n=324)</th>
<th>Not competent (n=44)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age</td>
<td>25.9 (SD=6.0)</td>
<td>27.1 (SD=6.5)</td>
<td>0.10</td>
</tr>
<tr>
<td>Adolescents (&lt; 20 years old)</td>
<td>12.0%</td>
<td>13.6%</td>
<td>0.76</td>
</tr>
<tr>
<td>Average years of education</td>
<td>6.8 (SD=3.5)</td>
<td>5.6 (SD=4.2)</td>
<td>0.02</td>
</tr>
<tr>
<td>Never attended school</td>
<td>7.4%</td>
<td>20.5%</td>
<td>0.004</td>
</tr>
<tr>
<td>Primary or less education</td>
<td>64.8%</td>
<td>72.7%</td>
<td>0.30</td>
</tr>
<tr>
<td>New users of family planning</td>
<td>11.1%</td>
<td>6.8%</td>
<td>0.28</td>
</tr>
<tr>
<td>Experienced injectable user</td>
<td>79.0%</td>
<td>79.6%</td>
<td>0.93</td>
</tr>
<tr>
<td>Used Sayana Press previously</td>
<td>17.5%</td>
<td>13.8%</td>
<td>0.62</td>
</tr>
</tbody>
</table>
Secondary outcomes: Operational considerations

• Ease of injection and challenges with the injection steps:
  o 92% of women called self-injection ‘very easy’ after the second injection (61% after the first)
  o Women who found self-injection difficult identified ‘pressing the reservoir’ as the most challenging step

• Adequacy of training:
  o All but eight women felt adequately prepared to do self-injection independently after training
  o Women practiced injections 2.7 times before injecting themselves the first time

• Use of instruction booklet for self-injection:
  o Almost all women (95.6%) relied on the instruction booklet for reinjection

• Reliance on caregivers or providers for injection assistance:
  o All women, save one, reported that they gave themselves the injection
Secondary outcomes: Reinjection dates

• After self-injecting for the first time, women were asked how confident they were that they knew when to reinject and how to schedule the subsequent injection

<table>
<thead>
<tr>
<th></th>
<th>Know when to reinject</th>
<th>Know how to calculate reinjection date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Very confident</td>
<td>274</td>
<td>75.5</td>
</tr>
<tr>
<td>Pretty confident</td>
<td>88</td>
<td>24.2</td>
</tr>
<tr>
<td>A little confident</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>Not confident</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

• The vast majority of women who reinjected (95%) gave the shot within one week of the reinjection date
Secondary outcomes: Calculating reinjection dates

- At the follow-up visit, women were asked to provide the date for their next (3rd) injection, if known

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correctly calculated next injection date</td>
<td>332</td>
<td>92.5</td>
</tr>
<tr>
<td>Incorrectly calculated date</td>
<td>15</td>
<td>4.2</td>
</tr>
<tr>
<td>Did not know next injection date</td>
<td>12</td>
<td>3.3</td>
</tr>
<tr>
<td>Total</td>
<td>359</td>
<td>100</td>
</tr>
</tbody>
</table>
Secondary outcomes: Secure storage and safe disposal

- Storage: 97.5% of women reported that they were able to keep the Sayana Press unit secure (free from discovery by children or others).
- Disposal:
  - Most women reported that they disposed of the spent Uniject device in the pit latrine.
  - 71.5% of women reported that they placed the spent Uniject device immediately into a lidded container until they could dispose of it.

<table>
<thead>
<tr>
<th>Disposal method</th>
<th>Number*</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threw it in the latrine</td>
<td>333</td>
<td>93.8</td>
</tr>
<tr>
<td>Returned it to the clinic/study nurse</td>
<td>20</td>
<td>5.7</td>
</tr>
<tr>
<td>Put it in the household garbage</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Total</td>
<td>355</td>
<td>100.1</td>
</tr>
</tbody>
</table>

* Sample size is smaller by 5 women who gave the injection during the follow-up visit
Secondary outcomes: Who is interested in self-injection?

<table>
<thead>
<tr>
<th>Variable</th>
<th>Self-injectors (n=380)</th>
<th>Refusers (n=62)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued injectable previously</td>
<td>32.9%</td>
<td>19.4%</td>
<td>0.04</td>
</tr>
<tr>
<td>Number of methods ever used</td>
<td>2.0 (SD=1.2)</td>
<td>1.7 (SD=1.2)</td>
<td>0.04</td>
</tr>
<tr>
<td>Missed work for clinic visit</td>
<td>34.9%</td>
<td>24.2%</td>
<td>0.10</td>
</tr>
<tr>
<td>Paid for transport to reach the clinic</td>
<td>44.6%</td>
<td>26.7%</td>
<td>0.009</td>
</tr>
<tr>
<td>Mean cost to reach the clinic (US$)</td>
<td>0.38 (SD=.64)</td>
<td>0.13 (SD=.28)</td>
<td>0.002</td>
</tr>
<tr>
<td>Level of anxiety about needles</td>
<td>0.2 (SD=.47)</td>
<td>0.4 (SD=.62)</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Secondary outcomes: Acceptability of self-injection

- Among women followed up after three months, nearly all (97.8%) would like to continue with self-injection, if it were available
- All but four would recommend self-injection to others

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very likely to recommend self-injection</td>
<td>318</td>
<td>87.4</td>
</tr>
<tr>
<td>Somewhat likely</td>
<td>42</td>
<td>11.5</td>
</tr>
<tr>
<td>Somewhat unlikely</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>Unlikely</td>
<td>3</td>
<td>0.8</td>
</tr>
<tr>
<td>Total</td>
<td>364</td>
<td>100</td>
</tr>
</tbody>
</table>
In their own words: What women say about self-injection

Self-injectors:

• “It is secretive, it does not consume money, and it does not waste time.”

• “It saves time of waiting at the hospital for a provider. I overcome missing my dose due to stockout because with this, I keep my medicine with me.”

• “When on a journey, I move with my drug. Even if I stay there for long, my schedule is not missed.”

• “Saves me from movement every three months to the hospital; I will do my farm work without interference.”

• “I don’t need to travel long distance. It is easy, safe, and gives me the freedom to manage it myself.”
In their own words: What women say about self-injection

Refusers:
• “Within me, I feel shaky. Let me call it shaking internally. I am a coward when it comes to injections.”
• “Since I am not trained, I may make mistakes. I may give it wrongly. Even if I am trained, I may self-inject badly due to fear.”
• “If I see someone else using it who does not get problems, I will come with my husband for training; and if I am unable to inject myself, then my husband can do it.”
• “If I have learnt how to give myself injection, apart from fear of my husband, I can keep it with my neighbour. I run there and inject myself then come back to sit.”
• “The one today, you train me and still inject me. But the second one, I am trained again, then try; thereafter, I may be able to inject myself.”
Implications for self-injection program design: Uganda

Who can learn to self-inject?
• Women with only primary education are fully capable of self-injection
• Women who have never been to school may need extra support
• Younger women are equally competent as more mature women
• Women who have never used family planning, Sayana Press, or the injectable are equally competent

What are the implications for training?
• Careful review of the injection steps seems to help women self-inject independently, especially nonliterate women
• Practice on a model was helpful; on average, women practiced three times

What are the implications for support?
• Most women injected independently, without relying on lay caregivers; may ease anxiety for women who are reluctant
• Almost all women used booklet as a visual aid for independent self-injection
Implications for self-injection program design: Uganda

What reminders are needed?
• Writing future injection dates in the booklet may be sufficient
• While probably helpful, reminder systems (phone calls, texts) may not be feasible

Is storage problematic?
• Women who choose to self-inject are able to store Sayana Press securely at home

How should disposal be managed?
• Latrine disposal, while not ideal, removes the device from contact
• Extra focus during training is needed to encourage women to secure the device in an impermeable container prior to elimination
• Improved, creative solutions for disposal are needed
Conclusions

• Self-injection is feasible and highly acceptable among this group of relatively rural Ugandan women

• Convenience and cost savings seem to be a major motivator: Women who pay for transport to clinics, and whose transportation costs are higher, are more likely to try self-injection

• Based on these findings and MOH approval, self-injection was rolled out in late 2016 on a pilot basis in one district of Uganda, with plans to roll out in additional districts in 2017
Question and answer session
For more information on DMPA-SC in Uniject (Sayana Press):
sites.path.org/rh/?p=292
sayanapress@path.org
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