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?

**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

**DMPA-SC in Uniject**
- 104 mg DMPA
- Delivered every 3 months
- Prefilled in the Uniject™ injection system
- Subcutaneous injection
- 3/8” needle
- Site: subcutaneous fat
- Equivalent contraceptive efficacy, safety, and side effects
- Sayana® Press brand: Pfizer Inc. under patent until 2020

Depo-Provera and Sayana Press are registered trademarks of Pfizer Inc. Uniject is a trademark of BD.
DMPA-SC in Uniject (Sayana Press) increases access to contraceptive injections through multiple channels

**Features**
- Single, exact dose, all-in-one presentation
- Subcutaneous injection
- Simplified injection procedures
- Simpler, shorter training
- Eliminates mismatch of syringe/vial supplies

**Benefits**
- Reduced weight and volume
- Easier to transport and store, less waste to dispose of
- Improved injection safety
- Non-reusable

**Value**
- Increased acceptability and use by lower-level health care workers
- Uniquely suited to home and self-injection
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
  - NDA approval of self-injection, MOH authorization for pilot
  - Successful pilot introduction of Sayana Press given by CHWs
  - Additional offers of self-injection
  - Self-injection roll-out in 3 districts, public and private sectors

- 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
  - MOH HPAC approves self-injection; operational policies in place
  - Donor support
  - Sustained national access to Sayana Press

- Operational policies in place
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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:
  o Challenges with injection steps that may need extra attention during training
  o Adequacy of training and use of the client instruction booklet
  o Reliance on lay caregivers or providers for assistance
  o Storage of Sayana Press
  o 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>Outcome</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
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.

The vast majority of women who reinjected (95%) gave the shot within one week of the reinjection date.

<table>
<thead>
<tr>
<th></th>
<th>Know when to reinject</th>
<th>Know how to calculate reinjection date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Percent</td>
<td>Number</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>

Secondary outcomes: Reinjection dates
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

<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

- 71.5% of women reported that they placed the spent Uniject device immediately into a lidded container until they could dispose of it
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.
For more information on DMPA-SC in Uniject (Sayana Press):

sites.path.org/rh/?p=292

sayanapress@path.org
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