The Promise of Contraceptive Self-Injection: Evidence From Uganda

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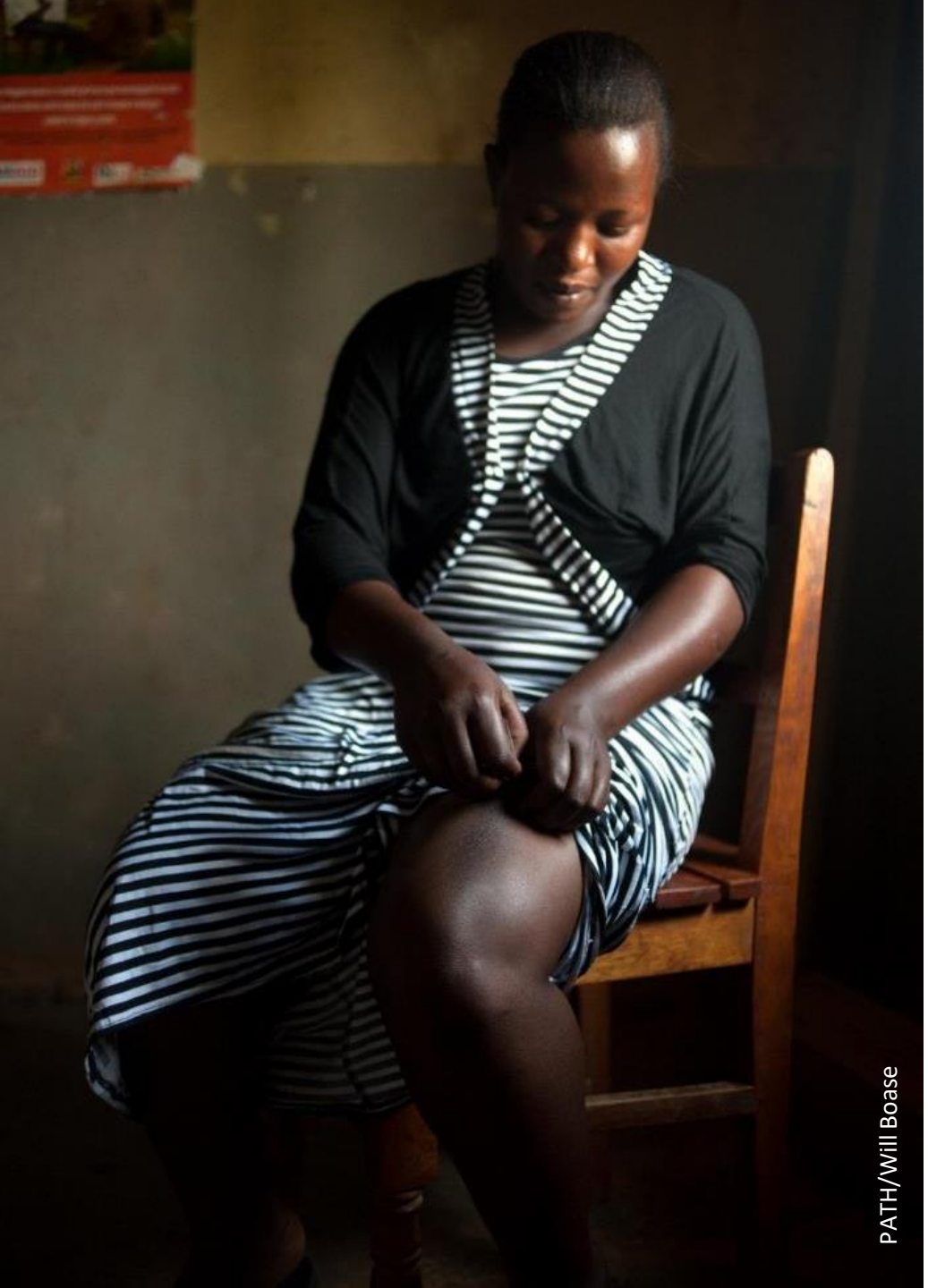
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What is the promise of contraceptive self-injection for women and adolescent girls?

“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

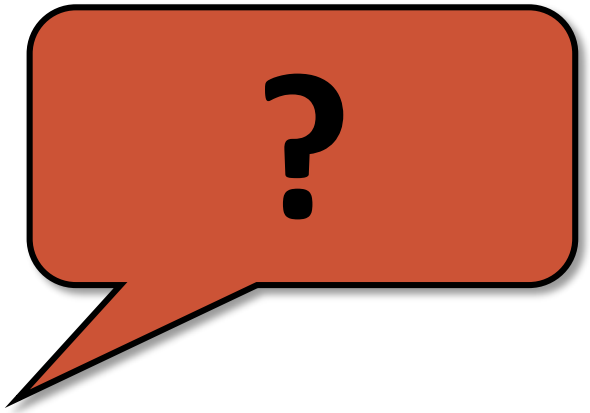
Jennifer Drake
Today's webinar moderator

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.



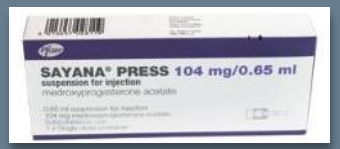
How is DMPA-SC different from traditional DMPA-IM?

DMPA-IM 150

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

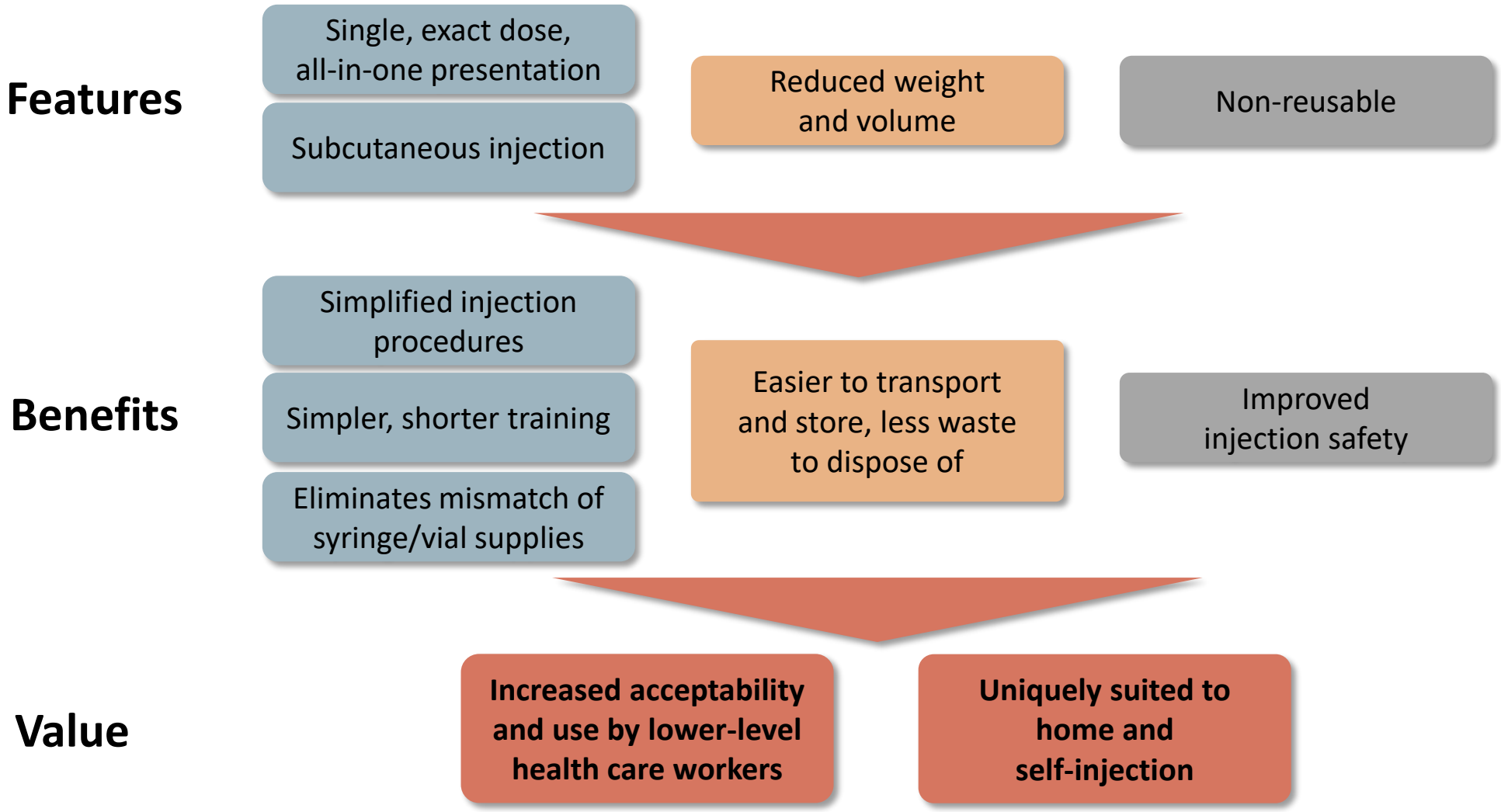
DMPA-SC in Uniject



- 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

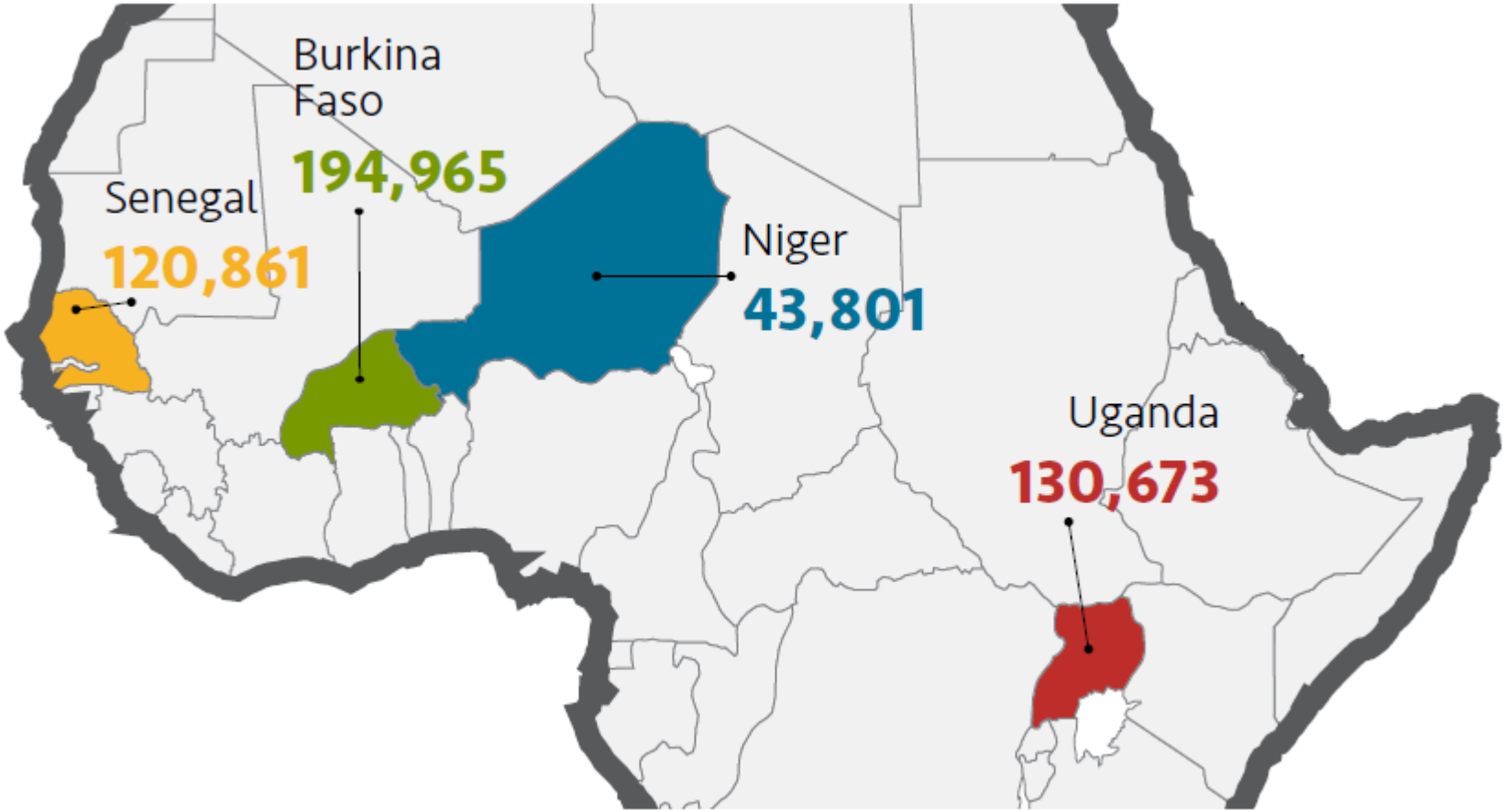
PATH

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

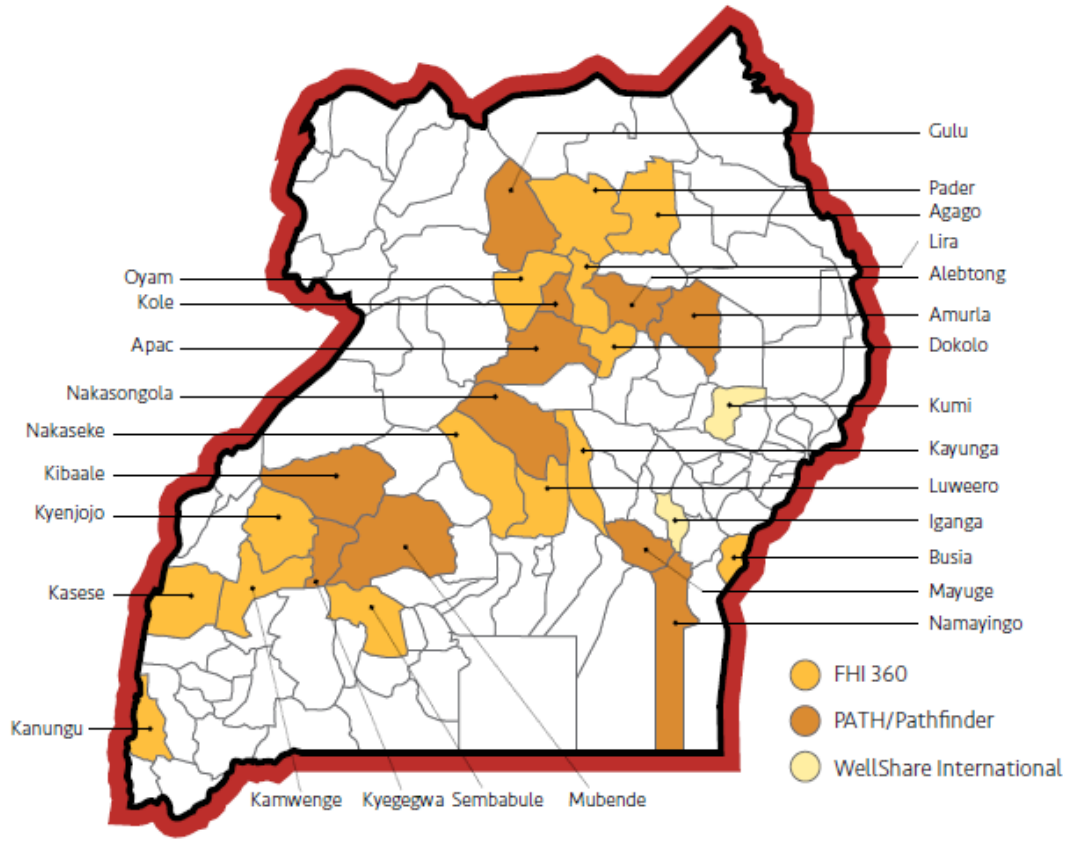
UGANDA PILOT INTRODUCTION BY THE NUMBERS: OCTOBER 2014–JUNE 2016

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

Pfizer's Sayana® Press Becomes First Injectable Contraceptive In The United Kingdom Available For Administration By Self-Injection

Builds on Current Momentum Towards Broadening Access to This Contraceptive Option for Women Across the Globe

Thursday, September 24, 2015 - 12:01am EDT

Pfizer Inc. announced today that the company's injectable contraceptive, Sayana®Press (medroxyprogesterone acetate), is now available to women in the United Kingdom (UK) for administration by self-injection. This follows the recent approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) of an update to the Sayana® Press label, adding the option for self-injection by women when considered appropriate by a healthcare professional (HCP).

"This is an exciting milestone for women in the United Kingdom, and, potentially, in countries around the world, who might prefer this method of contraception and mode of administration."

Sayana® Press is the first injectable contraceptive in the UK available for administration via self-injection[i,ii]. This new method of administration is also approved or pending local approval in additional European Union (EU) markets (Austria, Belgium, Hungary, Ireland, Netherlands). Pfizer will continue its efforts to help bring this updated label to more countries across the globe, with an initial focus on those in the developing world – such as in Burkina Faso, Senegal and Uganda – where data show unmet need[iii] and demand for injectable contraceptives[iv]. Sayana® Press is not yet approved for self- injection outside of the EU.

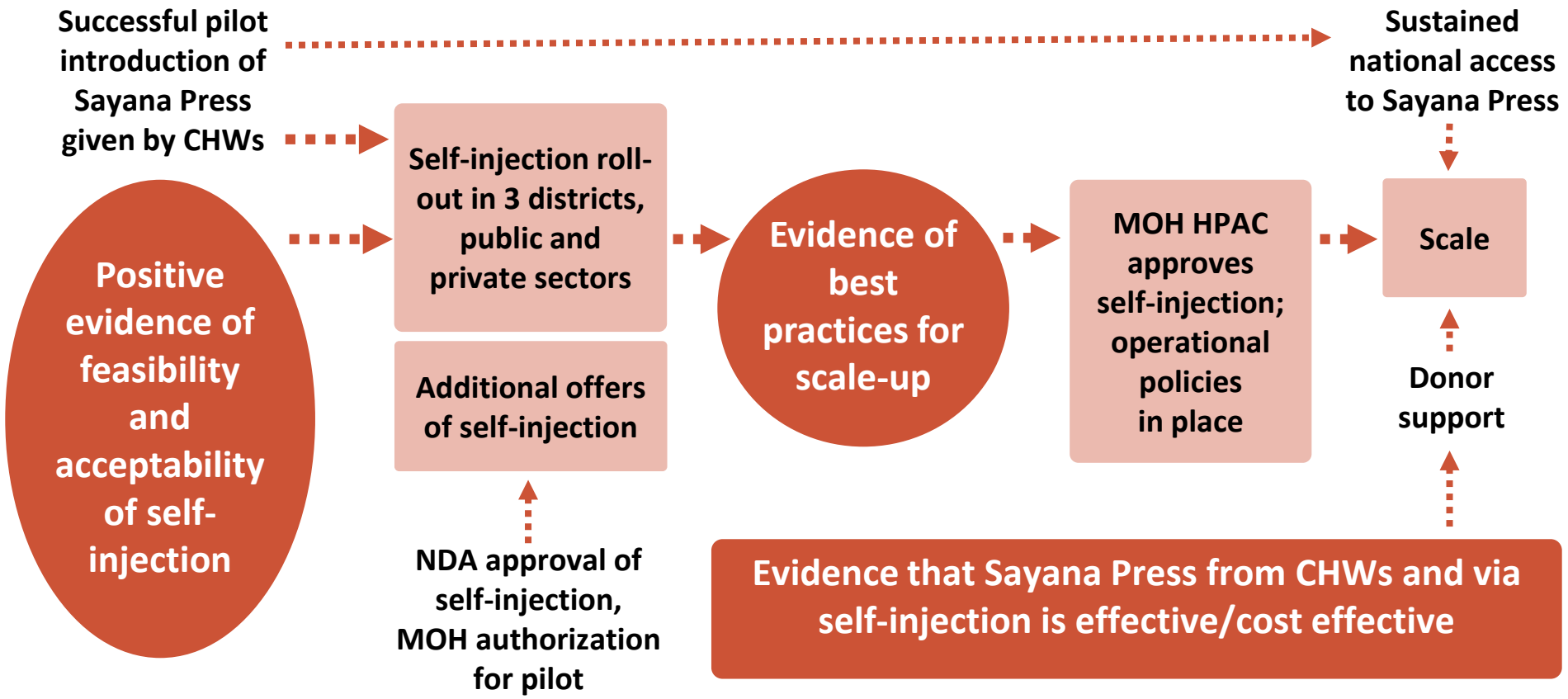
2015: WHO recommends self-injection in specific circumstances

Table 21. Self-administration of injectable contraception*

Self-administration of injectable contraceptives	Recommendation	Justification
Women (self-administration)	Recommended in specific circumstances  We recommend this option in contexts where mechanisms to provide the woman with appropriate information and training exist, referral linkages to a health-care provider are strong, and where monitoring and follow-up can be ensured.	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.

*Source: *Health worker roles in providing safe abortion and post abortion contraception.* Geneva:WHO;2015.

Self-injection: Potential pathway in Uganda



PATH/MOH self-injection feasibility study design and results

PATH/Gabe Bienczycki

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

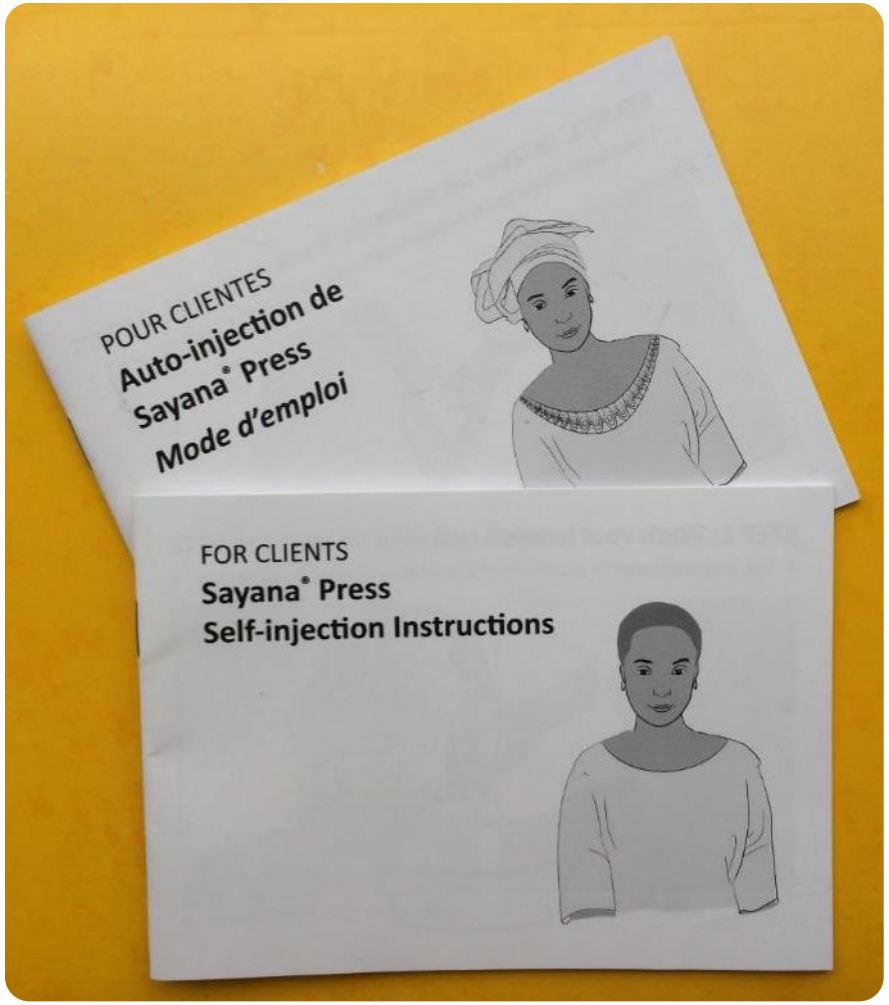
Study design:

- 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

	Number	Total	Percent
Competent posttraining (1st injection)	372	380	97.9
Competent after 3 months (2nd injection)*	324	368	88.0
On-time reinjection**	342	360	95.0
Both competent and on time	313	360	86.9

*8 women were judged not competent to continue after the 1st 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

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

Secondary outcomes: Operational considerations

- Ease of injection and challenges with the injection steps:
  - 92% of women called self-injection ‘very easy’ after the second injection (61% after the first)
  - Women who found self-injection difficult identified ‘pressing the reservoir’ as the most challenging step
- Adequacy of training:
  - All but eight women felt adequately prepared to do self-injection independently after training
  - Women practiced injections 2.7 times before injecting themselves the first time
- Use of instruction booklet for self-injection:
  - Almost all women (95.6%) relied on the instruction booklet for reinjection
- Reliance on caregivers or providers for injection assistance:
  - 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

	Know when to reinject		Know how to calculate reinjection date	
	Number	Percent	Number	Percent
Very confident	274	75.5	249	69.9
Pretty confident	88	24.2	102	28.7
A little confident	1	0.3	3	1.0
Not confident	0	0	2	0.6

- 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

	Number	Percent
Correctly calculated next injection date	332	92.5
Incorrectly calculated date	15	4.2
Did not know next injection date	12	3.3
Total	359	100

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

Disposal method	Number*	Percent
Threw it in the latrine	333	93.8
Returned it to the clinic/study nurse	20	5.7
Put it in the household garbage	2	0.6
Total	355	100.1

* 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?

	Uganda		
Variable	Self-injectors (n=380)	Refusers (n=62)	P value
Discontinued injectable previously	**32.9%**	**19.4%**	**0.04**
Number of methods ever used	**2.0 (SD=1.2)**	**1.7 (SD=1.2)**	**0.04**
Missed work for clinic visit	34.9%	24.2%	0.10
Paid for transport to reach the clinic	**44.6%**	**26.7%**	**0.009**
Mean cost to reach the clinic (US$)	**0.38 (SD=.64)**	**0.13 (SD=.28)**	**0.002**
Level of anxiety about needles	**0.2 (SD=.47)**	**0.4 (SD=.62)**	**0.01**

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

	Number	Percent
Very likely to recommend self-injection	318	87.4
Somewhat likely	42	11.5
Somewhat unlikely	1	0.3
Unlikely	3	0.8
Total	364	100

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."*

PATH/Will Boase

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."*

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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

PATH/Will Boase

Question and answer session

PATH/Gabe Bienczycki

For more information on DMPA-SC in Uniject (Sayana Press):

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

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PATH/Will Boase

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PATH/Will Boase