# Stakeholder views on self-injection of DMPA-SC in Senegal and Uganda

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# **Acronyms**

CBD Community-based distribution

CHW Community health workers

CPR Contraceptive prevalence rate

DMPA-IM Depot medroxyprogesterone acetate – intramuscular

DMPA-SC Depot medroxyprogesterone acetate – subcutaneous

ICCM Integrated community case management

MHRA Medicines & Healthcare products Regulatory Agency

MOH Ministry of Health

NDA National Drug Authority

NGO Nongovernmental organization

VHT Village Health Team

WHO World Health Organization

# **Executive summary**

Injectable contraceptives are among the world's most popular methods for preventing pregnancy, offering women safe and effective protection, convenience, and privacy. Until recently, however, injectable contraception has not been widely available outside of clinic settings. Sayana® Press is a new, lower-dose, subcutaneous formulation and presentation of depot medroxyprogesterone acetate (DMPA) that can readily be given by health workers in communities, and by women themselves through self-injection.

In late 2014, PATH conducted interviews with 13 stakeholders in Senegal and 13 stakeholders in Uganda to assess general receptivity to self-injection as well as the evidence requirements and processes necessary to chart a strategic course for adoption and future introduction and scale-up of self-injection as a service-delivery practice for Sayana Press in the two countries. The specific objectives of the interviews were to:

- Understand perceived benefits to and specific concerns about self-injection.
- Understand what evidence is required to consider introduction and scale-up of self-injection.
- Identify sources of self-injection support and resistance.
- Understand steps that have historically contributed to policy change related to family planning practice.

These studies suggest that the environment for self-injection of Sayana Press is generally supportive among key stakeholders in both Senegal and Uganda. All of the stakeholders interviewed in Senegal and the majority of stakeholders interviewed in Uganda perceived benefits for women—including the potential ability to overcome obstacles to access associated with provider-administered contraceptive methods—and for the national family planning programs of both countries.

Potential benefits for individual women cited by respondents included savings in time and money, as well as greater autonomy and discretion (when contrasted with traveling to the nearest clinic to receive provider-administered injections). Potential benefits for national health care systems cited by respondents included cost savings for programs—e.g., through reductions in workloads for clinic providers.

While respondents agreed on several potential benefits of self-injection, they also cited potential challenges and concerns. Stakeholders in both countries expressed concern as to whether women could reliably inject themselves correctly; they cited a need for routine follow-up with self-injectors, which could compromise the potential benefits of autonomy and discretion. In Senegal, a government representative also noted that self-injection could lead to lost opportunities for women to interact with the health care system.

Respondents in both countries cited a need for additional evidence on self-injection in three areas: feasibility, potential impact, and acceptability. Feasibility—the ability of women to successfully

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self-administer Sayana Press—was the concern most frequently mentioned by stakeholders in both countries. Stakeholders in Senegal were particularly interested in compiling research data to determine the potential feasibility of self-injection with women at differing levels of literacy and occupying a range of geographic locations (e.g., rural areas as well as urban). Respondents in both countries demonstrated interest in gathering data to project the potential national impact of self-injection (e.g., the ability of self-injection to attract new users of contraception and/or to improve continuation rates for injectable contraceptives).

While respondents from both countries rejected the concept of placing restrictions on eligibility for women who wish to self-inject, they differed in their views on the populations most likely to be the first to adopt self-injection. Stakeholders in Senegal agreed that educated women would be most likely to opt to self-inject; those in Uganda also believed that educated women would find the option attractive, but added that self-injection would appeal to rural women (for whom transport to clinics can be challenging), current users of injectable contraceptives, and new users of contraception. Respondents from both countries felt that self-injection would be popular among younger women, including unmarried women and adolescents aged 15 to 19; they noted that the opportunity for greater discretion would be a driving factor for these clients (who often avoid health facilities due to stigmatization of contraceptive use by unmarried women in both countries) and that Sayana Press and self-injection could thereby increase contraceptive access among younger women.

Respondents from the two countries differed in their views on whether self-injection training should be provided by community-based health workers or facility-based providers. In both countries, community-based health workers are recognized as having close links to the populations that they serve, and stakeholders who supported their offering self-injection training cited advantages of this positioning. Those who felt that self-injection training was best limited to facility-based providers cited concerns including questions regarding the ability of community-based providers to adequately train women.

Stakeholders in both countries agreed that the integration of self-injection as a practice into the national family planning service delivery systems would require an evidence base of validated research data. The respondents differed on whether or not an official policy change would be necessary to authorize self-injection as a practice, but the majority of respondents agreed that the World Health Organization (WHO) guidelines would be influential if policy change was required.

Study results offered guidance for PATH's research studies and advocacy efforts, as well as for continuing efforts towards adoption and future introduction and scale-up of Sayana Press in Senegal and Uganda. Recommendations based on the interview results include:

Compile a solid body of validated research data on the feasibility, potential impact, and acceptability
of the practice of self-injection—focusing especially on women's ability to administer Sayana Press
correctly and on schedule, injection safety, and safe storage and disposal practices—to advance any
program design or policy process that would facilitate adoption and/or scale of this new servicedelivery practice.

- Include a diverse sample of women in the research (specifically including women from rural communities and unmarried younger and adolescent women) and explicitly assess the characteristics of women who choose to self-inject and those who do not, as well as explore reasons why some women decline self-injection.
- Work with country partners, including Ministry of Health representatives, to craft training curricula and materials that are readily accessible to women with differing levels of education and skill.
- Conduct research, present data, address regulatory issues, develop guidelines for implementation, and keep stakeholders informed along the way as part of a plan for policy change.

## Introduction

Women in sub-Saharan Africa use injectable contraception more than any other modern contraceptive method, primarily due to the method's discretion, convenience, and lack of interference with sexual activity.<sup>2</sup> Women who must travel long distances to receive their injections or attain permission from partners to leave their homes face obstacles to accessing injectable contraception from providers. Expanding service delivery options for injectable contraception may help reduce access barriers and increase women's autonomy and ability to manage their health. Training, equipping, and supporting community health workers (CHWs) to provide a wide range of family planning methods has been identified as a proven high-impact practice that can help increase women's access to family planning.<sup>3</sup> Community-based distribution (CBD) of injectable contraception, including the intramuscular formulation of depot medroxyprogesterone acetate (DMPA-IM), is safe and effective. 4 Several sources suggest that subcutaneous injections are simpler than intramuscular injections for health practitioners, including CHWs, to administer.<sup>5,6</sup> Subcutaneously administered depot medroxyprogesterone acetate (DMPA-SC) was added in 2015 as a new contraceptive injectable product to the World Health Organization Medical Eligibility Criteria (WHO MEC) guidance. <sup>7</sup> DMPA-SC packaged in the Uniject™ injection system, known as Sayana Press, received regulatory approval in Europe in 2012 and is now registered in a number of countries worldwide, including in sub-Saharan Africa.

Sayana Press was first introduced in Burkina Faso, Niger, and Uganda in 2014, and in Senegal in early 2015. Between June 2014 and December 2015, more than 300,000 doses of Sayana Press were administered by health providers or community health workers in those four countries. The highest number of doses over time (150,000+) have been administered in Burkina Faso, where health worker training began first and was implemented most rapidly and where the product is available at all levels of the health system in a relatively large proportion of the country. By contrast, Niger and Uganda have experienced higher proportions of doses administered to new users of family planning (44 percent and 34 percent, respectively), likely because distribution in those two countries has been through the most peripheral contraceptive delivery channels in the public sector. As of mid-2016, all four countries have plans in place for expansion and/or scale, and Sayana Press is in the process of being introduced in several other countries as well (e.g., Bangladesh, Democratic Republic of the Congo, Madagascar, Nigeria, Tanzania).

Due to its subcutaneous and prefilled, single-dose presentation, Sayana Press can readily be given by a wide range of providers, including community health workers—and through self-injection. Studies from higher-income settings, including Scotland and the United States, indicate that self-injection of DMPA-SC is both feasible and acceptable.<sup>8-11</sup> There were no pregnancies among women practicing self-injection in these studies, and the majority reported it to be convenient and easy. Prior to new self-injection studies in Uganda, Senegal, and Malawi which launched in 2015, no studies had involved home-based self-injection in low-resource settings. A qualitative study in Ethiopia found that family planning clients, providers, and other key stakeholders were supportive of the hypothetical concept of self-injection of Sayana Press.<sup>12</sup> In September 2015, the United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) approved an update to the Sayana Press label that adds the option

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for self-injection when considered appropriate by a health care professional. In August 2016, the Uganda National Drug Authority (NDA) issued a conditional approval of self-injection, and a similar update is under review for Senegal and several other countries.

Of course, self-injection represents one specific delivery mode for a specific type of contraceptive method (subcutaneous injectable contraception). The development of Sayana Press, its widespread registration, and interest and support from global donors and country governments in the new method represent a particular opportunity for one method to contribute to broadening family planning access. At the same time, introduction of this new technology and the self-injection delivery mode should be considered in the context of comprehensive approaches such as the WHO's Strategic Approach to Contraceptive Introduction and more recent Strategic Approach to Strengthening Reproductive Health Policies and Programs. <sup>13,14</sup> The WHO Strategic Approaches emphasize the importance of a participatory process that prioritizes country-led decisions and involves donors, multilateral organizations, and nongovernmental organizations to guide three stages of work: assessment of needs, research, and use of research for policy and planning.

Consistent with these approaches, the Sayana Press pilot introduction programs involved country-led planning processes that situated the method in the context of informed choice and national family planning priorities. For example, in Uganda, CHWs trained to offer Sayana Press actually received a comprehensive family planning training to build their knowledge of the full range of contraceptive methods available. Design and introduction of any new self-injection program should follow the same principles of engaging actively with the Ministry of Health (MOH) and promoting informed choice as a fundamental principle of quality of care in the provision of family planning services. As of late 2016, research studies in both Senegal and Uganda to assess the feasibility of self-injection and identify operational considerations for future program design were complete, and research studies to assess the potential impact of the practice compared with administration of DMPA-IM by providers were underway. To help inform the design of those studies, in 2014, PATH conducted a qualitative study of the perspectives of key family planning stakeholders regarding self-injection in Senegal and Uganda—a participatory approach to assessing needs and perspectives that was also designed to inform future policy and program planning in both countries. The study involved in-depth interviews with 26 stakeholders across the two countries to assess perceived benefits to and specific concerns about self-injection and the evidence requirements and processes for potential introduction of the practice.

## **Methods**

# Country contexts

Senegal and Uganda are both countries with historically low contraceptive prevalence rates (CPR) that have increased in recent years—for married women, from 10 percent modern method CPR in 2005 to 20 percent in 2014 in Senegal, and from 18 percent in 2006 to 30 percent in 2015 in Uganda. Injectable contraception is the most popular contraceptive method in both countries for married women and the second most popular contraceptive method for unmarried sexually active women (after male condoms; see Table 1). <sup>15,16</sup>

Table 1. Among married and unmarried women aged 15 to 49 in Senegal and Uganda, percentage using a contraceptive method.

	Senegal		Uganda	
	Currently	Unmarried,	Currently	Unmarried,
	married women	sexually active	married women	sexually active
		women (no data		women
		available from		
		2014		
		Demographic		
		and Health		
		Survey)		
Any modern contraception	20.3	26.6	31.8	44.9
Injectable contraception	8.4	8.3	16.3	17.0

Senegal and Uganda were chosen as settings for PATH's overall self-injection research portfolio based on the hypothesis that evidence gathering in those countries might more likely facilitate policy and program changes in support of self-injection in the near future. Senegal and Uganda are two of the first four sub-Saharan African countries where Sayana Press has been introduced in the health system, in early 2015 and late 2014, respectively. This provided a strong foundation of familiarity with the product. Senegal and Uganda explicitly permit CBD of injectable contraception by lay health workers. While CBD is not a prerequisite for self-injection, we expected that both countries would have relatively receptive environments for studies focused on the self-injection of Sayana Press, compared with environments where self-injection may represent a more dramatic shift in practice because injectable contraceptive delivery is restricted to a more skilled cadre of health care providers.

# Study design and analysis

This analysis draws on qualitative data collected through in-depth interviews with key family planning stakeholders. Participants were sampled purposively to capture a broad range of stakeholders from different types of organizations active in family planning. PATH included representatives from government bodies, donors, intergovernmental groups, family planning nongovernmental organizations (NGOs) including social marketing organizations, and professional associations, inviting the most senior representative from each organization to participate. All participants who were asked to participate did so. PATH conducted a total of 13 interviews in each country (a total of 26 interviews). Studies show that saturation is likely to be reached (i.e., no new themes emerge) within 12 interviews in a relatively homogeneous population discussing a focused topic (see Table 2).<sup>17</sup>

Table 2. Number of family planning stakeholders interviewed, by occupation and country.

Occupation	Senegal	Uganda
Donor representative	2	1
Government representative	2	4
Nongovernmental organization representative	7	4
Professional association representative	1	2
Intergovernmental organization representatives	1	2

PATH developed semi-structured interview guides in English to be consistent across the two settings and translated the interview guide for Senegal into French. During each interview, key stakeholders were given an overview of Sayana Press and reminded of PATH's activities coordinating Sayana Press introduction and conducting research on self-injection in each country. In cases where participants were unfamiliar with the product, interviewers demonstrated a Sayana Press injection. The instrument addressed the following themes: self-injection with other medicines; benefits and challenges of self-injection; data needs for future decision-making regarding self-injection; service delivery considerations; and policy environment for self-injection.

Interviews were conducted from July to September 2014 in Uganda and in November 2014 in Senegal by two PATH researchers experienced in in-depth interviewing. Interviews were conducted in English in Uganda and in French in Senegal, took place in private settings (the participant's office), and lasted 30 to 90 minutes. One interview in Uganda took place in the presence of the participant's colleagues, at her request, but only the participant's responses were analyzed. All but one of the interviews in Senegal and three in Uganda were audio-recorded, and the recordings of the interviews were transcribed verbatim; French transcriptions were then translated to English. A transcript was developed from the notes for the four interviews that were not recorded. All interviews were analyzed in English using qualitative software (MAXQDA) to identify key themes. Information and coding followed an inductive approach, with codes and themes evolving organically from the transcripts.

We did not undertake this activity as a research study in itself, but rather to assess the receptivity of country stakeholders to self-injection and to plan systematically for future research. Therefore, this project was evaluated by and received a Non Research Determination from the Research Determination Committee at PATH, as per the U.S. Government's definition of research, Regardless, we treated the interviewees as though they were study participants, informing them before the interviews that their responses would remain confidential, and that a report would summarize findings—but that comments would not be attributed to individuals by name, position title, or specific organizations or institutions. Their verbal consent to be interviewed and to record the interviews was also obtained.

## **Results**

## Perceived benefits or advantages of self-injection

When asked, all stakeholders in Senegal and nearly all stakeholders in Uganda perceived that self-injection of Sayana Press could have benefits for individual women and also for the family planning program.

#### Benefits for individual women

The most frequently identified benefits of self-injection for individual women included potential savings in time and money, as women would need to visit health facilities less frequently and spend less time and money on transport and/or waiting for services. Many respondents also observed that self-injection offers women greater autonomy and discretion compared with visiting a clinic to receive the injection from a health worker.

"[Sayana Press self-injection] is really revolutionary for family planning. Not being dependent on a system where it takes a lot of time to get services...the fact that [women] can manage it themselves can be an advantage. It can make them autonomous." (NGO representative, Senegal)

"In many areas, you will find long lines to see the health worker, and sometimes it ends up killing the whole day because they had to go the clinic." (Government representative, Uganda)

"As far as advantages, I would cite discretion for the patient. There is also the fact that the individual controls the product...there is the opportunity to manage one's reproductive health in complete confidentiality." (Government representative, Senegal)

"...If it's self-injected, it will be easier for them to use it...[She does not need to be] lying to the husband about where she is going. She is just going inside their bedroom—*choop*—and then discard everything." (Professional association representative, Uganda)

Two respondents in Uganda perceived that some women prefer to access their family planning (or injection services in general) through clinics and, therefore, that self-injection might not necessarily appeal to them.

"For some women, especially for the lower class women, they like to come out of home to a facility and get a chance to talk to others..." (Government representative, Uganda)

Similarly, a government representative in Senegal noted that self-injection might represent a lost opportunity for a woman to interact with the health system (quote not shown).

#### Benefits for the family planning program

Many stakeholders in Senegal perceived societal benefits of self-injection and suggested that, by expanding method choice and introducing a new delivery mechanism outside of facilities, self-injection

could increase contraceptive use. In both Senegal and Uganda, a few stakeholder responses also highlighted potential cost savings for the program due to self-injection—for example, by alleviating workload for health providers who already have limited time and heavy client loads in the facilities.

"It would actually be good, because it will really help increase contraceptive prevalence rates. We are trying to accelerate things, so it is important to try all possible means." (Donor representative, Senegal)

"The aim [of the program] is to increase coverage and, of course, [self-injection] helps increase coverage. The expansion of the mix, another way of obtaining and taking the product without having to go to a health facility, these all affect choice." (Government representative, Senegal)

"It will save money in the long run for the health program, but it saves money for the women mainly. It may help health workers to save time and reduce their workload." (Government representative, Uganda)

## Potential challenges or concerns about self-injection

Just as respondents perceived many benefits or advantages to self-injection of Sayana Press, all respondents in Senegal and most in Uganda described specific potential challenges or concerns. In both countries, a majority of stakeholders expressed concerns about whether women could inject themselves correctly, which meant different things to different respondents: for example, forgetting to inject on schedule or how to inject. In Senegal, many respondents noted the importance of following up with women who opt to self-inject—especially on issues like side effects management, injection safety, waste management and disposal of the device, and reinjection timing and reminders. Some stakeholders suggested approaches for addressing these challenges, such as routine follow-ups. The real or perceived need to follow up with women who self-inject may constitute a challenge for the practice in and of itself, as the value of self-injection lies in its potential to increase discretion and autonomy.

"There are chances of also forgetting that the time has come and you do it yourself. Because no one else will give her the appointment, she will have to know [when] to do it." (Government representative, Uganda)

"I can imagine that there would be those who either do not know how to use it properly, mistime the injection, or even do the wrong thing." (Intergovernmental organization representative, Uganda)

"It is still a product that can have side effects. So, the health care provider can direct her in order to solve her little problem. This is pretty important, instead of leaving her alone. Because the risk is that if she doesn't have a solution, she might abandon it." (Government representative, Senegal)

"You need to implement a system of occasional follow-ups, to make sure that everything is going well. You have to follow up with them periodically—once every six months, once a year—to verify that she is still using the product and is still injecting correctly." (Donor representative, Senegal)

These concerns about self-injection and the need for follow-up were not universal. At least two stakeholders in Uganda expressed few or no reservations about the safety of self-injection. A few

respondents in both countries noted that people living with diabetes safely inject insulin, a more complex or potentially dangerous process (although others pointed out that it might be easier to remember when and how to administer daily insulin injections than injections every three months). A few respondents in Senegal posited that too much follow-up undermines the autonomy and discretion that were named as key advantages.

"Insulin is injected by non-literate as well literate people... The prefilled syringe of Sayana Press is easier than that for diabetes." (Donor representative, Senegal)

"And one important thing is that insulin is more dangerous than these hormones—because if you give yourself a higher dose or a low dose, you could die." (NGO representative, Uganda)

"It's a very tiny needle. I think we have more unsafe products of other types than that device would be." (NGO representative, Uganda)

"Too close of follow-up can actually discourage women. We do not follow up [with] all women who buy their family planning through the private sector." (Donor representative, Senegal)

#### Research needs

Participants in both countries emphasized that more evidence was needed on self-injection in three areas: feasibility, potential impact, and acceptability to women. They often mentioned these issues in linked or overlapping statements. Stakeholders in both countries mentioned a desire to understand more about the "effectiveness" of self-injection, and they varied in how they defined effectiveness. For example, stakeholders mentioned effectiveness in terms of overall impact and potential increases in contraceptive prevalence to be achieved through self-injection—but some also mentioned evidence that an individual woman could administer an effective injection or that the expected benefits for women manifest.

"Key stakeholders would want to know whether this is feasible, whether it is safe, and whether it is effective." (Intergovernmental organization representative, Uganda)

"If self-injection is effective...how it went, what the results were at the end as far as impact and use, and even rates of correctly observing the treatment plan." (Intergovernmental organization representative, Senegal)

Feasibility—whether women could successfully administer Sayana Press themselves—was the most prominent theme mentioned by almost all stakeholders in both countries. In Senegal in particular, several participants underscored the importance of conducting research with a diverse sample of women to gather more information on the feasibility of self-injection among women from non-literate populations and rural areas.

"We need to understand whether our people who are going to inject themselves really can inject themselves successfully..." (Intergovernmental organization representative, Uganda)

"Show that it is feasible with the non-literate. Make a solid case." (Donor representative, Senegal)

"It's important to start far away, where there are no structures... Starting there to gauge acceptability, in the rural environment. Because if it's easy for them, I don't think anyone else will have any problems either." (NGO representative, Senegal)

A few respondents in both countries noted an interest in generating information about the potential impact of self-injection (e.g., in terms of improving continuation rates for injectable contraception and/or attracting new users, which could translate into increased contraceptive prevalence and reduced fertility, although this link was not made explicitly).

"We need to know that self-injection is acceptable and improves continuation rates." (Government representative, Uganda)

"Demonstrate that, by enlarging the range of methods [through self-injection], you can increase contraceptive prevalence and attract new users." (Donor representative, Senegal)

A number of stakeholders advocated for generating qualitative data that would give voice to women's perspectives on self-injection—gathering evidence of acceptability and, as noted above, evidence of benefits for women.

"Offer testimonials from women. A woman who says, 'With Sayana Press, I'm more independent; there is more confidentiality. I no longer have to go to the facility." (Government representative, Senegal)

"So you will also get the voices of those people, the voices of the young people. The voices of men and women..." (Government representative, Uganda)

# Early adopters of self-injection

Respondents discussed a variety of potential early adopter populations for self-injection. In Senegal, nearly all respondents felt that educated women would be the self-injection pioneers. In Uganda, respondents mentioned more educated women but also cited rural women for whom transport is a challenge, current injectable users, and new family planning users. In both countries, many respondents rejected restrictions on eligibility.

"The easiest population—and the one that would be more accepting and spontaneously so—are the literate, educated women." (Government representative, Senegal)

"For illiterate women—it can sometimes be difficult. They need more time to be convinced. But for the intellectuals, they adapt much better to change." (NGO representative, Senegal)

"[It will be] continuing users in the rural areas who have to walk long distances to access family planning services [who will take it up]." (Government representative, Uganda)

"We shouldn't think that those illiterate women can't—we shouldn't underestimate them." (NGO representative, Senegal)

"For continuous users, of course, it would be more beneficial because they already know the benefits, and then they would have easy access to Sayana [Press]... And for new users also... here is a method that you can do it yourself without waiting for any other person, without getting permission." (NGO representative, Uganda)

"It should be available to all users. Expose it to all because it will be beneficial to all." (Government representative, Uganda)

#### Young women

PATH specifically explored respondents' perspectives on self-injection among young women, including unmarried women and adolescents aged 15 to 19. Most respondents felt that young women would be eager to take up self-injection. Specifically, stakeholders in both countries emphasized that young women often avoid health facilities due to the stigmatization of contraceptive use among unmarried women and that self-injection would likely make it possible to increase access by enhancing discretion. In Senegal, some participants specifically noted young women's preference for pharmacies as a source of contraception—and the potential linkages with self-injection. In Uganda, a few stakeholders also emphasized that Sayana Press and self-injection could help reduce maternal deaths and prevent abortions among young women because of its novelty and appeal to youth, or because of the increased autonomy offered by self-injection.

"The adolescent is more comfortable with going to a pharmacy to get her self-injection than going to a healthcare facility, where she might see an uncle or an aunt, who will tell her to go back home. Because everyone is everyone's aunt." (Government representative, Senegal)

"...It's also an opportunity for these women to access family planning, because what we've noticed is young women—mostly unmarried—do not go to family planning services. And I think that initiatives of this kind would allow them to be included." (NGO representative, Senegal)

"The young people. There is no doubt about that, and that's part of my excitement about Sayana Press because it speaks to the young people. And we know that the majority of maternal deaths are attributed to teenagers. So if we can have it embraced, and I think it will—we'll save lives. A lot of lives." (NGO representative, Uganda)

"Since the majority of the population are young and since they are the ones who hate most our [public-sector] health services, they are also the ones that can't go to [Village Health Teams for family planning] because they don't want to be known." (Government representative, Uganda)

In addition to recognizing the likely benefit and appeal of self-injection for young women, stakeholders in both countries noted that it would be advisable to proceed cautiously in terms of framing self-injection as an intervention for adolescents. For example, stakeholders noted concerns about use of family planning and injectables overall among adolescents that are common in their contexts.

"If you target young people, it will trigger resistance. Unlike if you target the general population, which is made up of many young people." (Donor representative, Uganda)

"...The only problem is that when [an adolescent] would go talk to the midwife, the midwife will often tell her, 'Yes, but you don't yet have the experience of children, it's better not to take this'; this is a risk for all products being offered." (Government representative, Senegal)

## Service delivery

In both countries, participants expressed diverse perspectives on whether training women to self-inject should be led by facility-based providers or CHWs. Those who felt that community-based health workers were the appropriate channel emphasized the advantages of their close links with communities in rural areas and the fact that they could relate to the experiences of the women they would be training. In Uganda, some respondents felt reassured by other services provided by community health workers, called Village Health Team members (VHTs). In Senegal, a few respondents also noted that community-based providers, called matrons, are often highly skilled and well educated.

"But with a trusted partner in the community [VHT] next to me, whom I can run to and say... 'Can you do it for me this time so that I see?' ...[or] 'what did we say again, and how did I do it?'" (NGO representative, Uganda)

"I think in rural areas, matrons are better positioned—because they have the same mind frame and will encounter the same difficulties as the other women around them." (NGO representative, Senegal)

"I think that the VHTs can also do the trainings. If VHTs are training people on how to use malaria medicines—or even we've explored [using] them for HIV counseling and testing—those are pharmacomplex tasks, so I think a VHT could also train." (NGO representative, Uganda)

"And matrons, some of them, have very high education levels. I have supervised some of them—often they are women with a high school diploma who return to the village because they haven't found work... And I've seen matrons who are more skilled than some healthcare providers. Very skilled." (Government representative, Senegal)

A few respondents in Senegal and about half in Uganda expressed a preference for restricting self-injection training to facilities, questioning the ability of community-based health workers to convey accurate information and train women adequately. In Uganda, a few respondents questioned whether equipping VHTs to train women to self-administer provided any value beyond having VHTs simply providing injections (presumably, the assumption being that VHT services are relatively accessible and convenient for all women). In Senegal, one participant expressed concerns about overburdening matrons.

"We need structured training. VHTs will deliver these methods, but do they have the capacity to train users in a group?...If it is a group, then training by service providers to maintain standards and quality of care. If VHTs, we might stand a risk of disseminating myths and biases." (Donor representative, Uganda)

"For quality purposes, for me, I think that it would be best from provider to woman...A VHT, I think, should be administering, I don't think they should be training the women to self-administer. Because then there is no added value." (NGO representative, Uganda)

"It is important to remember that overburdening a matron, who does not get paid, is problematic. And there is very technical information that should normally be complemented by knowledge in physiology—and certain knowledge in this and that—that actually might not work with the matrons..." (Professional association representative, Senegal)

Respondents in both countries described a need for training that will meet the needs of diverse women with variable abilities and education levels. In Senegal, a few respondents also specified that self-injection training should be comprehensive regarding family planning issues (e.g., side effects management).

"I think they need to be a very simple, user-friendly method that everybody should think whoever wants to do that with a very simple training. I don't want it to be as a very technical, high-level training." (NGO representative, Uganda)

"I think you have to put it in pictures, the different steps and the injection sites—even the possible side effects. But also write it at the bottom in French for those who can read." (Professional association representative, Senegal)

"That is a question of contact and education, as well as good counseling that addresses the issues of undesirable effects, so that women are able to say 'That is an undesirable effect. I recognize it, and so I can tolerate it." (NGO representative, Senegal)

# **Enabling environment**

The interviews also explored the issue of whether a policy directive or regulation might be required to support introduction of self-injection into the health system in each country. In both countries, respondents emphasized that if there were compelling data and experience to support the practice, then policy revisions would not be a major barrier to integration of self-injection into the country's family planning service delivery system. Especially in Senegal, stakeholders felt that some type of authorization would be needed.

"If, after the pilot study, Senegal decides to adopt this as a method option, it must be included in the policy documents where they cite the reference to an offer of service. But before being able to integrate it, there needs to be completed and validated research." (Intergovernmental organization representative, Senegal)

"You need a governmental order for the authorization of self-injection. If the pilot goes well and you document well...the scaling up will be no problem." (Donor representative, Senegal)

"Self-injection, because it is nothing new in the medical field, should only require a policy influenced by evidence at the Ministry of Health level...and the necessary staff or health workers are trained on how they can counsel the people that are going to do the self-injection." (Intergovernmental organization representative, Uganda)

"As a policy for self-injection...first of all we need data; we can try data to justify that that is possible and need to really be sure that it is safe." (Government representative, Uganda)

A few respondents in both countries proposed that a policy change might not be required, either because self-injection was already covered by existing policies (e.g., allowing administration of injectable contraception at the community level) or because there was no explicit restriction of the practice.

"If we can do it in the health huts, we can do it anywhere else. The community level is not only in the health huts—it's also within the population." (NGO representative, Senegal)

"If there is no policy that prevents you from doing something, you can follow the guidelines, you execute, you roll out." (NGO representative, Uganda)

"Laws are made based on established practices. As long as there are no problems." (Government representative, Senegal)

Nearly all respondents, when asked, noted that World Health Organization (WHO) guidelines would be influential in influencing policy change (although not necessarily a substitute for local research or experience).

"Even if it's not in Senegal, if you can show that elsewhere there are positive effects—then the WHO's authorization will help facilitate the adoption of certain initiatives." (NGO representative, Senegal)

"If WHO can come up with advice about self-injection, our community would pick it up. They take seriously what the WHO is advising. If [the Ministry of Health] worked with WHO, that would be very effective." (Donor representative, Uganda)

#### Discussion

PATH's stakeholder interviews in Senegal and Uganda point to moderately receptive environments for self-injection—environments which could be significantly affected by gathering and disseminating information on the feasibility, acceptability, and potential impact of the practice. Key common themes and notable differences between these two countries may be instructive for family planning practitioners considering research or programs focused on self-injection of Sayana Press and any other subcutaneous injectable contraceptive products in the development pipeline—as well as similar innovations that share the common attributes of increased user autonomy and demedicalization.

Stakeholder feedback helped confirm that evidence of the benefits and safety of a new practice are precursors to considering formalizing that practice, including through policy change. This feedback helped drive development of a participatory research agenda in both countries, focused first on feasibility and acceptability and then on possessing potential impact (measured through continuation and ultimately cost-effectiveness). For example, feedback from the stakeholders helped inform a feasibility study design in Senegal and Uganda that placed a heavy emphasis on providers training women prior to self-injection, and that explored key questions about storage and disposal. In turn, it is anticipated that the results of those research studies will be applied through a participatory process in each country to design self-injection policy and program in the context of national family planning goals and priorities. This will require consideration of many programmatic issues, including which providers will be trained to offer self-injection; how ongoing support will be provided; how many units women will be given to take home for independent injection; and how women will be advised to dispose of used products.

This finding also aligns with previously documented experiences changing health policy and practice, including CBD of injectable contraception in Uganda. That important shift in service delivery took place without policy change, based on an evolving evidence base that helped to normalize the practice on an ongoing basis; the higher-level addendum to policy was signed approximately seven years after practices were initiated. Evidence and local research to shift key stakeholders' perspectives was also highlighted in an analysis of the policy change process for integrated community case management (ICCM) of childhood illnesses in six sub-Saharan African countries. In addition, linking new practice to broader health goals (i.e., the Millennium Development Goals), support or endorsement by trusted development partners (e.g., the United Nations, WHO), availability of funding, and strong MOH engagement were also highlighted in the ICCM analysis and reflected in these results. In other words, additional action beyond local evidence-generation can also contribute to changing policy and practice.

Stakeholder perspectives in Senegal and Uganda also helped to underscore that special attention will be needed throughout research and introduction to ensure that all women can benefit from self-injection, if and when it becomes available. The fact that stakeholders in Uganda identified more diverse groups of potential early adopters than stakeholders in Senegal may be attributable to the fact that injectable contraception use has penetrated hard-to-reach communities to a greater extent than has occurred in Senegal. Future research studies on self-injection can anticipate questions about whether women in rural, remote settings with limited education can self-inject and prioritize the inclusion of a diverse sample of women from different socioeconomic backgrounds. In terms of program design, any materials or approaches for training women to self-inject should be developed with low-literacy audiences in mind, as was emphasized by respondents in both countries.

The likely appeal of self-injection for young women, including adolescents and unmarried women, was nearly universally acknowledged by respondents, despite reservations about adolescent contraceptive and/or injectable use also acknowledged in both settings. Given the significant unmet need for family planning among women aged 15 to 19 in sub-Saharan Africa (67 percent for married adolescents and 42 percent for unmarried adolescents), self-injection may hold great promise for helping adolescents to overcome obstacles to accessing family planning. For example, adolescents face particular challenges obtaining family planning services through facilities outside of school or working hours, or finding time and money to travel to facilities in rural areas. In addition, stigma and negative provider attitudes

regarding sexual activity and related contraceptive services for unmarried youth and adolescents remain a persistent and well-documented barrier <sup>22,23</sup> and has been specifically noted in Uganda. <sup>24</sup>

Leveraging the potential for self-injection to increase access for hard-to-reach groups, including adolescents, will be more likely if the injectable commodity and any services for training and support are available through a variety of channels in the public and private sectors—including pharmacies and drug shops. <sup>25,26</sup> Mixed responses regarding the delivery of self-injection through clinic- and community-based services help to underscore that several types of providers will have a role to play in supporting self-injection. Research and program design approaches should consider the roles of government clinics, CHWs, and pharmacies and drug shops—among others—to increase access to self-injection, as well as tools to support women to self-inject relatively independently (e.g., written materials, video tutorials accessible through mobile phones). Whatever the specific access points in a given country, self-injection programs will need to strike a balance between providing sufficient support to women so that they can self-inject safely and effectively and yet not compromising autonomy, discretion, and confidentiality.

Finally, participant responses helped to emphasize the importance of offering self-injection of any DMPA-SC product in the context of high-quality contraceptive services, in alignment with WHO's emphasis on a philosophy of reproductive health and rights. <sup>13,14</sup> For example, respondents in Senegal made several references to the importance of resources to help self-injecting women understand and manage side effects. Discontinuation of injectable contraception is driven in large part by side effects and health concerns. <sup>27</sup> Self-injection programs will need to support women to manage side effects—for example, training providers, including those based in communities who might serve as resources for women, to recognize the importance of client concerns about side effects and to identify strategies for managing them. In addition, self-injection of Sayana Press should be offered in the context of a full range of contraceptive options, in part so that women who want to discontinue self-injection (due to side effects or any other reason) have alternatives available.

As one respondent stated, self-injection of Sayana Press represents a potentially "revolutionary" family planning innovation. Ongoing research studies in Senegal and Uganda implemented by PATH and the respective ministries of health are helping to answer key research questions regarding women's ability to inject themselves correctly and on schedule, as well as providing more information about program design considerations. In addition, the next phase of studies implemented in Senegal and Uganda, and an additional study by FHI 360 and the MOH in Malawi, will help to assess whether self-injection of Sayana Press improves continuation rates among injectable contraceptive users. The PATH studies will also assess the costs of self-injection relative to the cost of provider-administered DMPA-IM.

This study has a number of limitations. Because the sampling strategy was purposive and included a relatively small number of participants, the opinions of participants may not be representative. This article does not include the perspectives of individuals or groups who are opposed to family planning and might have dramatically different views on self-injection. In addition, it does not reflect the direct perspectives of health providers actively involved in service provision or of family planning clients at the community level. More generally, because Senegal and Uganda are both countries where community health workers

are authorized to give injections, the viewpoints of Ugandan and Senegalese stakeholders may not be very representative of stakeholders from more medically-restrictive contexts.

Many participants may have been aware that PATH and the MOH in the respective country planned to conduct feasibility and impact research on self-injection with Sayana Press, and that may have influenced the nature of their responses. For example, they may have been predisposed to emphasize the importance of evidence of feasibility of self-injection due to their knowledge of or support for the upcoming research. In addition, Sayana Press was still a new commodity at the time of these interviews, which probably magnified the desire for more information and evidence. It is important to interpret these results in that context and consider information needs in new environments strategically as the global evidence base on self-injection continues to evolve.

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