



**COMMUNICATIONS GUIDANCE FOR  
INTRODUCING SAYANA® PRESS**

For ministries of health and nongovernmental partners implementing  
the Sayana Press Pilot Introduction and Evaluation project

# Acknowledgments

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This guide contains information to help local experts develop communications plans and materials for pilot introduction of Sayana Press. It includes:

- Broad recommendations for communications strategy.
- A description of key audiences.
- Suggested messages for each audience.
- Channels that may be especially effective in pilot areas.
- Useful links to further information.



Sayana Press is currently being introduced in pilot programs in Burkina Faso, Niger, Senegal and Uganda.

## 1. Introduction

In 2014, a new injectable contraceptive product, Sayana® Press, will be introduced on a pilot basis in four African countries: Burkina Faso, Niger, Senegal, and Uganda.\* The pilots will provide information on how best to introduce and scale up use of this product to help increase contraceptive options for women and thereby reduce unmet need for family planning.

Targeted, effective communication is crucial to success. By encouraging women to access family planning and by building a social and cultural environment that encourages uptake, strong communication can help to increase the use of modern contraceptives (including Sayana Press) to delay and space births. Communication can also foster understanding and dialogue among pilot communities, improving trust and discouraging the spread of misinformation.

This guide was created to support ministries of health and nongovernmental implementing partners as they develop communications strategies and activities related to the introduction of Sayana® Press. It is based on a comprehensive review of the literature on communications and behavior change strategies to increase use of family planning methods, with emphasis on injectable contraceptives and the four pilot countries.

After providing background information on Sayana Press and the pilot introduction efforts, this document outlines communication strategies, audiences, and key messages recommended for successful introduction of the product. It also suggests specific communication channels based on previous experience.

PATH is an international health organization serving as the overall lead for pilot introduction across all four countries. At PATH, we understand that communications professionals in the pilot countries bring broad experience and talent to this project, along with deep knowledge of behavior change communication methods. Further, every country will need to set its own communications goals and objectives for product introduction and determine how best to achieve those goals.

\* Sayana Press is registered trademark of Pfizer, Inc.

# 1. INTRODUCTION



Pilot introduction partners include ministries of health, UNFPA, and non-profit groups such as the social marketing organization ANIMAS-Sutura in Niger.

This document is intended to complement local expertise. We hope that local partners will share feedback and experiences with others involved in Sayana Press introduction so we can all learn from one another. PATH recommends that communications partners convene country-specific workshops with relevant communications, social marketing, and training partners in early 2014 to discuss the guidance provided in this document and to integrate the most relevant strategies into their communications efforts. These workshops will also be a good time to discuss crisis communications plans. PATH staff will be available to attend these workshops and provide additional material or advice as needed.

PATH hopes the information in this document—when coupled with national-level knowledge of culture, language, and belief systems—will help our country partners develop actionable, strategic behavior change communications plans for Sayana Press introduction pilots that will leverage limited resources for maximum impact.

## 2. Sayana Press and pilot introduction efforts

Sayana Press provides a safe, effective, reversible, and discreet method to prevent pregnancy. It contains a single dose of depot medroxyprogesterone acetate (DMPA; commonly known by the brand name Depo-Provera®) that is formulated for subcutaneous administration with the Uniject™ injection system (a prefilled, autodisable device).\*

Introduction of Sayana Press will improve women’s access to injectable contraceptives by increasing the ease, safety, and reach of delivery through means such as community-based health workers or private clinics and pharmacies. Although Sayana Press is not currently labeled for self-injection, it may ultimately offer women more control over their use of contraception through self-injection at home.



While most injections are still given in health centers, community-based provision is becoming more common.

### Community-based provision of Sayana Press

In most pilot areas, Sayana Press will be available to women through community health workers (CHWs). By making injectable contraception more accessible at the community level, many programs have seen a sharp increase in new family planning users. For example, after expansion of community-based provision of injectables in Uganda in 2006, program managers found that the number of women initiating use of DMPA intramuscular (IM) injections with a CHW was 56 percent higher than the number of new DMPA IM acceptors served by clinics.<sup>1</sup> Similarly, in Madagascar, community provision of injectables resulted in 1,662 new DMPA IM clients within seven months, 41 percent of whom were first-time or resuming users.<sup>1</sup> In this same pilot, a large majority of clients reported that they intended to continue receiving DMPA IM from a CHW and that they would recommend the service to a friend.<sup>1</sup> Likewise, when injectables became available through community-based distribution in Malawi, the contraceptive prevalence rate rose from 33 percent in 2004 to 46 percent in 2010.<sup>2</sup> Injectables now account for 62 percent of the method mix in Malawi.<sup>2</sup>



Intramuscular formulations of Depo-Provera are currently socially marketed in some countries and sold through pharmacies and nonprofit organizations.

### Social marketing

In some Sayana Press pilot countries, the product will be over-branded and sold in private clinics or in clinics or pharmacies run by nongovernmental organizations (NGOs) under a social marketing approach. Communications

\* Depo-Provera is a registered trademark of Pfizer Inc. Uniject is a trademark of BD.

efforts from social marketing partners should complement distribution through the public sector, and social marketing partners should work closely with public-sector communications partners on messages and strategies for reaching all audiences with family planning messages.<sup>3</sup>

### Potential home and self-injection

Providing Sayana Press for self-injection is a near-term opportunity for pilot countries. Although Sayana Press is currently not labeled for self-injection, the World Health Organization (WHO) has recognized the potential for self-injection associated with DMPA in a prefilled device.<sup>4</sup> Health workers in Senegal and Uganda who used Sayana Press in recent acceptability studies commented on the ease with which the product could be used for self-injection.<sup>5</sup> Self-injection could increase timely access to injectables in places where community-based services are sporadic or unreliable.<sup>6,7</sup> Assessments of the self-injection of DMPA in Uniject suggest that the Sayana Press formulation is both feasible and acceptable.<sup>8</sup> A 1997 study of self-injection of Cyclofem<sup>®</sup> using Uniject found that, after receiving training in a clinic under the supervision of a provider, 90 percent of participants could self-administer their IM contraception injection safely and easily, and 57 percent said they would prefer to self-administer using Uniject in the future.<sup>9</sup> Another study of just ten women in the United States compared self-injection (IM) with clinic-based injection of a monthly contraceptive called Lunelle<sup>®</sup>. The study found that eight of ten women preferred self-injection to clinic administration.<sup>10</sup> A 2013 study of 55 adolescent women in the United States found that 35 percent opted for self-injection of subcutaneous DMPA.<sup>11</sup> Historical evidence of self-injection of other medications suggests that self-administration is acceptable and even routine for some users.<sup>6</sup>

Communications considerations for potential self-injection of Sayana Press include the need to bolster health worker training so clinicians can train women on proper storage and use, injection safety, waste management, and side-effects management while providing support and supervision for the initial injections. Previous experiences suggest that programs should set up a system such as a health worker visit or a local phone number for women to ask questions or receive support and counseling once training is complete.<sup>13-14</sup> A system for providing clients with reminder messages for their three-month reinjection date is also crucial.



© 2009 Rafael Avila, Courtesy of Photoshare  
Research shows that self-injection of Sayana Press is both feasible and acceptable to many women.

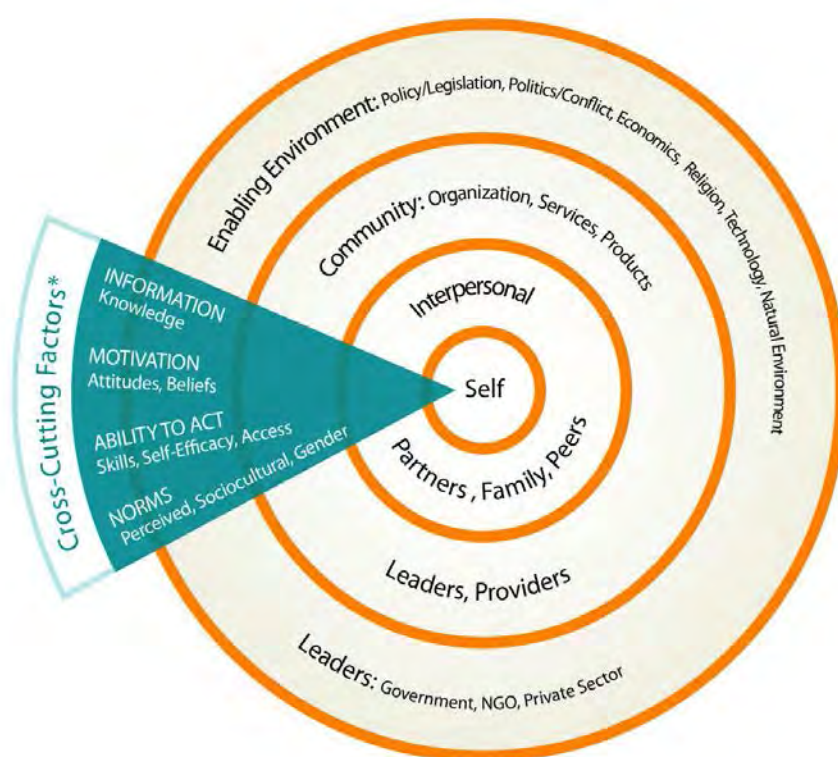
#### INSIGHTS FROM THE LITERATURE

Patients currently self-inject many medications, including enoxaparin, epinephrine, heparin, sumatriptan, erythropoietin, insulin, gonadotropins, and human recombinant parathyroid hormone. Reports demonstrate good clinical effectiveness, safety, and patient satisfaction with self-injection.<sup>12</sup>

## 3. Communications strategy for introduction of Sayana Press

The behavioral theory that guides the communications strategy outlined in this document is a socio-ecological model with the theory of planned behavior at its center. Figure 1 depicts the model, which was modified by Borwankar in 2012 and originally proposed by McKee, Manoncourt, Chin, and Carnegie.<sup>15,16</sup>

**Figure 1. Socio-ecological model for change**



\* These concepts apply to all levels (people, organizations, and situations). They were originally developed for the individual level.

Source: Adapted from McKee, Manoncourt, Chin, and Carnegie, eds. (2000)<sup>16</sup>

According to the theory of planned behavior, women are most likely to seek family planning services when they have a positive attitude toward them (attitude), when cultural norms appear to support them (norms), and when they feel empowered to seek them (self-efficacy). The socio-ecological component of the model recognizes that the larger social,



structural, and political context heavily influences a woman's behavior. In all project countries piloting Sayana Press, political support is relatively high and structural changes are taking place to improve reliable access to family planning as well as health worker knowledge and skills. The social, religious, and cultural environment, however, varies between and within the four countries and can present significant barriers to women wishing to access family planning.

The communications strategy therefore aims to increase awareness of Sayana Press as a contraceptive option, and increase use of Sayana Press and injectables in general. When most effective, behavior change communication activities have the potential to improve attitudes toward family planning among women and the many people who influence women and create positive cultural norms that support family planning.

## INSIGHTS FROM THE LITERATURE

Women's reproductive health decisions—including the choice to use contraception—are shaped by the norms and beliefs of the community and by the level of autonomy experienced by women.<sup>17-19</sup>



Most women seek family planning services at clinics. Introduction of Sayana Press is expanding options for community delivery in pilot settings.

## Overarching goals and objectives

Each country has its own specific behavior change communications goals and objectives, which are tied to its Sayana Press introduction plan. This communications guidance document was developed with a general set of goals in mind. For example, the goal of Sayana Press introduction may be to:

- Expand opportunities for community-level access to injectable contraception.
- Increase method choice.
- Increase the number of new users of contraceptives.
- Improve injectable continuation rates and/or method satisfaction.
- Contribute to an overall increase in contraceptive prevalence in pilot areas.

Organizations leading communication activities to support Sayana Press pilot introduction may develop specific behavior change goals such as the following illustrative examples:

- Increase the number of women seeking family planning services.
- Increase the number of women who know about injectables as a family planning option.
- Increase awareness of Sayana Press and service delivery points.

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- Increase the number of new users of injectable contraceptives.
- Improve the quality and availability of family planning information for both men and women.
- Increase the number of women who speak positively with other women about their family planning experiences.
- Publicly promote the benefits of birth spacing to both women and men.
- Increase convenience and improve trust of family planning services through community-based services.



Actors in a village theatre production demonstrate how a health provider will take a woman's blood pressure when she comes in for family planning consultation.

Although the end goals for communication campaigns may involve changing behavior to improve health status, evaluating these changes in a way that can be generalized can be methodologically challenging and costly. Therefore, organizations leading communication activities to support Sayana Press introduction may choose to measure activities conducted rather than results achieved. Some illustrative examples of activities to measure may include numbers of:

- Radio broadcasts on family planning topics by location and size of audience.
- Communication sessions on family planning conducted by location.
- Community theatre events on family planning and size of audience by location.
- Printed materials on family planning topics distributed by location.

## Recommended strategic approach

Although communications plans will differ across countries and regions where Sayana Press is introduced, some general strategies should be considered in every country because they are well supported by evidence and practice.

- Any product-specific communications and behavior change efforts should have a **narrow geographic focus** (matching pilot introduction areas). For example, if radio campaigns broadcast an advertisement for a new injectable contraceptive (Sayana Press) in areas where the product is not available, clients and providers may experience frustration or confusion. Where geographic access is irregular, more localized forms of interpersonal or small-group communication limited to areas where the product is in stock may more effectively reach prospective clients.

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PATH/Siri Wood



When given effective skills training, health workers can influence behavior as well as provide accurate information.

- **Prioritize audiences by highest likelihood of adopting family planning services rather than by highest need.** Because acceptance of family planning in sub-Saharan Africa has traditionally been low and cultural resistance high, this strategy leverages early adopters as possible peer influencers in social groups and contributes to normative changes in family planning acceptance and use.<sup>20-22</sup> Marginalized groups such as adolescents are still a priority and need service improvements to meet their special needs.
- **Aim to change behavior, not just provide information.** Because family planning choices are made in a broader context of social and gender norms, outreach to audiences requires more than just information, education, and communication. Strong evidence supports the use of social and behavior change communication in areas with high levels of unmet need.<sup>3</sup> Behavior change communication is a process that motivates people to adopt healthy behaviors or lifestyles.<sup>23</sup> Behavior change strategies for introduction of Sayana Press should focus on promoting a lifestyle involving modern family planning methods as the preferred alternative to traditional practices or nonuse of contraception.<sup>24</sup> See Annex A for a list of behavior change communication resources, including a tool from the Johns Hopkins Bloomberg School of Public Health’s Center for Communication Programs for behavior change communication program development.
- **Focus on increasing contraceptive prevalence generally, not one method specifically.** This means that Sayana Press communications strategies should be focused on promoting all family planning services, using new methods (Sayana Press) or outreach strategies (distribution through CHWs or pharmacies) as a possible means of attracting new users. As Simmons and colleagues have noted, “Attention should not be placed on a particular brand or method, but instead on quality of care, reproductive choice at all stages of a person’s lifecycle, and user perspectives and needs.”<sup>25</sup> This advice is aligned with the WHO’s “strategic approach to contraceptive introduction,” which recommends that new technologies are introduced within a quality-of-care and reproductive health framework that meets the needs of users, providers, managers, policymakers, and women’s health advocates.<sup>26</sup> In light of this advice, communications efforts for Sayana Press can and should be integrated into existing communications strategies for family planning services in general.

## Recommended tactical approach

This document outlines high-priority audiences for Sayana Press introduction and provides guidance on messages and tactics for reaching those audiences. It is up to partners to decide how to best incorporate this guidance into their own communications strategies. However, there are several tactical considerations that have been proven to work well when introducing a new family planning method, and these are summarized below. The purpose of this summary is to bring forward the most salient findings and help communications partners decide when and where to direct limited financial and human resources for this pilot.



A small group community sensitization session in northern Benin.

- **Training and community sensitization.** Before attempting to generate demand for family planning in Sayana Press introduction areas, partners should prioritize health worker training, modification of key materials and forms, and community sensitization. Most training and print materials for health workers will be prepared by training partners, but communications partners should be aware of these efforts and supportive wherever possible (e.g., by pretesting messages and aligning messages and strategies). Community sensitization includes efforts to reach out to tertiary audiences (e.g., the medical community, civil society, political leaders, and media; see section 4) with general information about the pilot and Sayana Press. It also includes efforts to reach out to local cultural and religious leaders who might have questions or concerns that need to be addressed before the product is widely promoted. This early outreach can mitigate the spread of rumors and ensure that key stakeholders feel that they are informed about the pilot activities. Given the number of partners involved in Sayana Press pilots, it may be useful to divide the list of tertiary audiences between partners and coordinate messages so more personal contacts can be maintained.
- **Interpersonal communications and radio.** After completing training, modifying print materials, and reaching out to community leaders, demand-generation efforts can begin in earnest. Evidence suggests that two channels are more important than others when generating demand for family planning services: (1) interpersonal communication between health workers and patients and (2) radio dramas and programs targeting men and women.<sup>27</sup> Putting these channels to work requires partners to develop appropriate materials that support clinic- and community-based health workers to counsel their clients on family planning methods and

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side effects and to develop radio programs (i.e., call-in programs or short public service announcements) that reach both men and women in a community or region with positive messages about family planning.

- **Community outreach, hotlines, and print materials.** Additional demand-generation strategies that merit an investment of time and resources include outreach to social and religious groups, development or modification of community theatre dramas, and the establishment of easy-to-access, confidential information sources such as toll-free hotlines and print materials that describe each method in detail, including side effects. Communications partners should assess their existing communications programs and decide which methods and channels are most effective in their context.



Tools such as flipchart books can be used in individual counseling or small-group educational sessions.

## 4. High-priority audiences

This section describes the most important audiences for communications efforts related to Sayana Press introduction. Information about how to meet their information needs and possible key messages to test are provided in the next section.

### Primary audience: Women with unmet need for family planning

#### Married women

Demographic and Health Surveys (DHS) from Burkina Faso, Niger, Senegal, and Uganda measure the number of women who wish to delay or limit future births but do not use any family planning method (Table 1). These are women with an unmet need for family planning. Because DHS surveys only include married women in their estimates of unmet need, the results are generally conservative, as they do not include sexually active unmarried women or girls who may also wish to delay childbirth.



Women with several children are often early adopters of injectable contraception.

**Table 1. Demographic and health data from Sayana Press introduction countries**

Variable	Niger <sup>28</sup>	Uganda <sup>29</sup>	Senegal <sup>30</sup>	Burkina Faso <sup>31</sup>
Percentage of married women with an unmet need for contraception	17%	34% (37% in rural areas)	29% (30.3% in rural areas)	24%
Total fertility rate	7.6 children per woman	6.2	5.0	6.0
Percentage of married women using any method of modern contraception	12% (27% in urban areas; 10% in rural areas)	26% (up from 14% in 2006)	16% (up from 5% in 1993)	15% (up from 9% in 2003)
Percent of women using injectable contraceptives	2%	14%	6%	6%
Political commitment to increase the contraceptive prevalence rate (CPR)	CPR = 25% by 2015; 50% by 2020 <sup>32</sup>	Reduce unmet need to 10% by 2020 <sup>33</sup>	CPR = 27% in 2015 <sup>34</sup>	CPR = 25% by 2015 <sup>35</sup>

Married women with an unmet need for family planning can be segmented into different types or groups for communications planning. To characterize two common types of married women found in the introduction countries, PATH has created fictional profiles for two women, named Fatima and Ebele, who are described below.

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Women with several children, basic education, favorable attitudes and spousal support are often interested to learn more about family planning.



Demand for contraception among some rural women is fragile and highly influenced by the level of social support for family planning.

## INSIGHTS FROM THE LITERATURE

For most women, barriers to meeting family planning needs include insufficient knowledge about contraceptive methods and how to use them, fear of social disapproval, fear of side effects and health concerns, and women's perceptions of their husbands' opposition.<sup>43</sup>

*Fatima is 25 years old and has three children. She has completed some postprimary education. Although she lives and works in a rural farming area, she has relatives in the city. She is interested in delaying her next pregnancy and knows that family planning is available at the clinic, but she has not had the time or money to go there. She has two friends who have started using contraception and speak positively about it.*

According to the literature, the most likely early adopters of injectable contraceptives in Africa are married women in their 20s who have already had multiple children and are breastfeeding.<sup>36,37</sup> They are relatively well educated and have a positive attitude toward one or more family planning methods, but they may have previously had limited access to services or method choices.<sup>38</sup> Women like Fatima may earn a small income as well.<sup>38,39</sup>

In the context of the Sayana Press introduction, women like Fatima have previously lacked access to convenient services and are attracted by the idea of a new family planning option. Leveraging one or both of these attributes can result in higher contraceptive prevalence.

Our second profile is for Ebele, who is 30 years old and has four children.

*Ebele has had only a few years of formal education. She lives in a relatively poor rural area in which high gender inequity is the norm. She does not know anyone personally who uses modern contraception, but she notices that some women in the village can space their pregnancies further apart. She would like to delay her next pregnancy and knows that family planning can help her do that, but she is uncertain about the safety and long-term effects of contraception. She is busy with farm work and child care and could not easily visit a clinic. She does not discuss sexual matters with her husband and believes that he would not approve of her learning about or using family planning.*

In many countries, women like Ebele make up the majority of married women reporting an unmet need for family planning.<sup>27</sup> Their demand for family planning services is fragile and highly influenced by perceived social expectations for fertility and commonly held beliefs regarding side effects.<sup>17,18</sup> Where physical access and availability are not limiting factors, four common barriers prevent women like Ebele from seeking contraception: lack of knowledge about contraception, perceived disapproval by spouse, fear of side effects (including long-term impact on fertility), and perceived disapproval by family, social, or religious groups.<sup>40-43</sup> In areas where social stigma and spousal disapproval are prevalent, women can often be discreet users of contraception (6 to 20 percent in one study).<sup>25,44</sup>

Existing family planning communications strategies should already be addressing the concerns of women like Ebele, but the introduction of a new method and/or outreach strategies can be leveraged to reinforce or reinvent some of these messages and communications campaigns.

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In Uganda, 67 percent of girls have their first sexual experience by the age of 18, and very low contraceptive use among this age group means high adolescent fertility.<sup>29,45</sup>



Whether married or unmarried, youth face many barriers to contraception, including communication within the couple about timing and spacing of pregnancy.

### Youth

Sexually active, unmarried adolescents are not represented in DHS calculations of unmet need for family planning. However, sexual activity among this age group is high and use of modern contraception is low.

Youth face many barriers to contraception. These include a lack of trust in providers who may judge or refuse to counsel them, the need for confidentiality even among other patients at the clinic, a lack of money to pay for contraception, strong social and familial disapproval of premarital sex, lack of knowledge of modern family planning methods, and fear of side effects, including potential loss of fertility.<sup>14,45</sup>

Meeting the needs of young women is difficult using communications strategies alone. Family planning programs in Africa have had most success reaching adolescents by providing youth-friendly services at existing clinics, creating specific teen-friendly service centers, or directing them to pharmacies or drug shops where contraception can be easily (and anonymously) purchased.<sup>22,46-48</sup> When services are available, communications efforts to reach girls and boys directly with information and counseling should include community sensitization, evidence-based sex education and life skills curricula, referral networks between schools and health centers, and community-wide efforts to delay the age of marriage.<sup>3</sup>

### Other audiences

Polygamous men and their spouses generally have high fertility rates. Research shows that polygamous families have fewer societal and economic incentives to limit family size. However, contraception for birth spacing is commonly supported in Islam to minimize health risks to mothers and children.<sup>49</sup> Thus, family planning messages that focus on spacing childbirth for the health of the mother and child may resonate with women in polygamous marriages. In those cases, those perceiving a need for family planning will fall under one of the two categories of married women characterized previously.

HIV-positive women are also important audiences for family planning. However, a recent literature review of seven studies in Africa indicates that a specialized behavioral intervention among this audience may be unnecessary.<sup>50</sup> Many HIV-positive women will fall under the primary audience categories listed previously. It is more important that health workers understand the special needs of HIV-positive women and address them individually during family planning counseling sessions. Couples who wish to prevent unintended pregnancy and who are at



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risk of transmitting or acquiring HIV should be counseled to use dual protection—condoms and another contraceptive method, such as hormonal contraceptives. This is advised by the WHO and included in PATH training materials available at <http://sites.path.org/rh/?p=436.51>

Women with disabilities or mental health problems have been mentioned in Uganda as an overlooked audience for family planning. Sayana Press information should be woven into appropriate communications and behavior change strategies so that women with disabilities or mental health issues have access to information about the method and can use the method itself if it is a good fit.

## Secondary audiences: Key influencers

Key influencers are people who are not necessarily users of family planning but who can heavily influence the experience and perceptions of potential users and the social and political environment in which they live. Although the overarching communications strategy for Sayana Press focuses on promoting family planning services in general, certain key influencers need specific information and support for Sayana Press introduction.

### Public health providers and community health workers in pilot areas

Public health providers and CHWs working in the pilot areas are women's most trusted and valued sources of technical information on family planning methods.<sup>27,52</sup> In Burkina Faso, Niger, and Senegal, public-sector health providers are also the most widely used sources of information on family planning. Between 67 percent (Niger) and 85 percent (Senegal) of women access family planning services from the public sector and almost all get injectables through the public sector.<sup>28-31</sup> Although clinic-based and community health workers will receive specific training on Sayana Press before the pilot begins, there is a lot of new information to digest, and they may have lingering questions or concerns that can affect their interactions with patients.

Providing health workers with supplemental information on Sayana Press, counseling tools (such as fact sheets, as well as flipbooks or wall charts if resources allow), and access to relevant resources (such as training materials, supervisors, and in-depth information) should be part of the communications strategy for product introduction. This will be particularly important in areas where contraceptive-use levels are historically low, as women may be taking greater social and personal risks to seek family planning services.<sup>44</sup>



Health providers play an essential role in educating women and couples by providing counseling on family planning methods.

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An intensive service program can compensate for weak or ambivalent motives regarding family planning and create demand for services, leading to contraceptive adoption where it might not otherwise occur.<sup>53</sup>

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Drug shops and pharmacies are important sources of contraceptive products and services.

## Private providers, drug shop owners, and pharmacists located in pilot areas

Private providers, drug shop owners, and pharmacists located in or near pilot areas can also be key influencers among women with an unmet need for contraception. Women will often consult with private-sector physicians, pharmacists, and drug shop owners to learn about or discuss family planning methods and side effects because these providers are considered by some to be a trusted and confidential source of information.<sup>54</sup> Also, in certain countries and regions, women may prefer to purchase contraception through private providers, pharmacies, or drug shops because these outlets can be less conspicuous than family planning clinics and more ubiquitous.<sup>22</sup> According to Wafula and Goodman, drug shops are often the most widely used source for health services, information, and products in sub-Saharan Africa.<sup>55</sup> This is certainly the case in Uganda, where 60 percent of women using injectables purchase them from private-sector sources.<sup>56</sup>

Unfortunately, the quality of services can be highly variable in both public and private sectors. Research among 157 drug shops in three districts of rural Uganda revealed that injection practices need to be formalized and made safer and that “contraceptive knowledge was low, and attitudes toward family planning reflected common traditional biases.”<sup>57</sup> To counteract misperceptions about family planning in general and injectables in particular, it is important to provide basic information on safety, effectiveness, side effects, and eligibility characteristics to providers and shop owners about newer contraceptives such as Sayana Press. Enlisting the help of social marketing partners already working with pharmacies and in private/NGO clinics may be a good way to reach nonparticipating clinics and drug shops.

## Men and spouses

Men’s anxieties about family planning can be very serious. In Zimbabwe, a study of men’s perceptions of contraception found that “men feel anxious and vulnerable for lack of control over women.”<sup>58</sup> In Navrongo, Ghana, men reported concern that “women [who use family planning] will refuse to fulfill their reproductive and sexual obligations, that they will seek sexual satisfaction outside of the marriage and possibly abandon their families, that contraceptive use creates conflict among multiple wives, or that a man will lose control of his household if he is not consulted.”<sup>59</sup>

For many years, men were neglected in family planning programs, and their absence was later identified as a major cause of poor performance.<sup>60,61</sup> A great number of studies have found contraceptive adoption positively associated with communication between spouses on reproduction and



Facilitated discussions for men’s groups can increase their understanding of family planning options and spousal support for contraceptive use.

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family planning.<sup>61-63</sup> Similarly, when couples discuss family planning and approve of it in general, most go on to use contraception in the future.<sup>36,64-67</sup>

Most family planning communications strategies already include men as a target audience, and the introduction of Sayana Press provides another reason to reach out to men with family planning messages. We recommend that efforts to reach men initially remain separate from efforts to reach women, and that the focus of the communication to men is on improving attitudes toward family planning, supporting birth spacing, and changing perceived social norms.<sup>68</sup> In areas where family planning is supported by the community and in areas where home and self-injection is a possible strategy for Sayana Press, the couple may also be considered as a unit for communications messages.<sup>7</sup>

## Family members

Family members can also be important influencers. A qualitative study in Malawi found that a husband's family members considered childbearing to be a primary obligation of a wife and that more children equated to family wealth. As one woman put it, "Relatives will never tell you to stop [bearing children] at a particular number; all they want are more children."<sup>15</sup> That is not to say that family members are never sympathetic to women wishing to limit or space childbirths. A qualitative study in Mali found "substantial collusion between sisters-in-law in assisting each other to gain and hide methods of family planning and to keep their use secret from their spouses and older marital relatives."<sup>68</sup> Other studies have been written about the significant influence that the husband's family has on family planning decisions, particularly the mother-in-law.<sup>69</sup> Influencing the advice given and norms suggested to women by their husband's families can be a good strategy for reducing barriers to family planning among women.



A women's use of family planning methods is often influenced by the opinions of her family members.



Friends and peers are influential sources of information and referral because people trust their social networks. Introduction of a new method such as Sayana Press can create a "buzz" that spreads through word of mouth.

## Women's social and peer networks

Social networks of friends and peers appear to have a strong influence on the amount and type of information women receive about family planning, their attitudes toward it, their likelihood of adopting some form of modern contraception, and even method choice.<sup>17,70-72</sup> These studies confirm the importance of social learning (e.g., discussion about specific contraceptive methods) versus social influence (e.g., social pressure to adhere to norms or traditions), which is an advantage for programs introducing new method choices, as it provides a new occasion to discuss family planning methods. Studies of interpersonal communications networks have found that the influence of peers is most profound in areas where family planning is relatively new to a community or individual. Later, as people adopt more modern family planning methods, men and women increasingly rely on health workers for their technical expertise.<sup>17,73</sup> Many family planning programs have had success reaching out to existing peer networks—

# 4. HIGH-PRIORITY AUDIENCES

such as men's groups, women's groups, mothers' groups, and health committees—to provide an opportunity to discuss family planning with an expert in a nonthreatening environment.<sup>67,74,75</sup>

The introduction of a new contraception option should not significantly affect existing communications strategies to reach women's social and peer networks, but it may provide partners an opportunity to refresh messages and refine strategies that are not working.

## Religious and cultural leaders

Another influential audience is religious and cultural leaders. Throughout sub-Saharan Africa, men and women maintain a very high level of trust in the teachings and opinions of religious and cultural leaders.<sup>76,77</sup> However, the opinions that religious and cultural leaders have toward family planning can vary by faith and by cultural norms.<sup>78,79</sup> Based on its work in Ghana, Kenya, Nigeria, and Uganda, the NGO Pathfinder International has found that many religious leaders are initially opposed to family planning or misunderstand it but eventually come to accept the need for modern contraception, even among unmarried adolescents.<sup>79</sup> A study in northern Nigeria found that non-Catholic Christian religious leaders were quite supportive of family planning, although they tended to use and promote less effective methods such as withdrawal and the Billing's method.

Many family planning programs have successfully involved religious and cultural leaders in the development and implementation of family planning communications strategies or requested their explicit support of family planning programs.<sup>41,80,81</sup> These efforts target the dominant religious faiths found in sub-Saharan Africa, including Christianity (which includes Catholicism) and Islam, and generally focus on providing information and making room for discussion to help religious leaders understand how family planning supports the underlying values of their faith. Once religious leaders understand that family planning can improve physical and spiritual well-being of their congregations, they begin to understand the value of family planning and, in some cases, can become strong advocates.

## Tertiary audiences: Family planning stakeholders

Tertiary audiences influence the overall policy and cultural environment in which family planning services are offered. They can be powerful allies or difficult foes. They include members of the medical community, civil society organizations, political leaders, and influential journalists. Early and clear communication to these groups can earn their support and respect, and we recommend keeping them informed and giving them a channel to communicate with you should questions or concerns arise.

PATH/Cabe Blenczycki



When religious leaders understand that family planning can improve the well-being of their communities, they become advocates.

### INSIGHTS FROM THE LITERATURE

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Because the church is an important means of social mobilization, the attitude of church leaders toward family planning could have significant effects on the practice of family planning by members.<sup>78</sup>

### INSIGHTS FROM THE LITERATURE

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After a series of seven Pathfinder seminars, most clergy came to support birth spacing and can now cite passages of scripture in support of it.<sup>79</sup>

# 4. HIGH-PRIORITY AUDIENCES

While communications partners may not always take the lead on reaching these tertiary audiences, local partners should agree upon which organizations will be responsible for keeping them informed. Ideally, communications partners will identify key stakeholders who could be “champions” for the Sayana Press pilot and offer their public support and guidance in a crisis or in situations where credible, external support is needed.

## Medical community

The medical community includes regional and district health offices along with medical and nursing associations and groups that may be a source of information or influence for health workers involved in the pilot.

## Civil society

Civil society includes influential NGOs or charitable organizations that may be involved in family planning or other women’s health services in the pilot regions. Bringing them up to speed on the pilot goals and strategies will help them answer questions about the new product and possibly become allies in the effort to support family planning services.

## Political leaders

Studies have shown that policy-level support for family planning, particularly at the highest levels, translates to successful family planning programs.<sup>82</sup> Although the Sayana Press pilot has been approved by certain political leaders in all project countries, it may not be well known to political leaders at all levels, particularly those at the regional and district levels who can have a powerful influence on the pilot’s success. All relevant political leaders should be regularly informed of the project’s progress and successes. Some family planning projects have created political allies by inviting leaders to rural areas for clinic observations and interviews with community members to help them understand and feel invested in the program.<sup>25</sup>

## Media

Members of the local media should be included in communications about the pilot and its goal of increasing access to family planning services in the area. Most partners will have existing relationships with certain news outlets, and those can be leveraged to have personal discussions or to organize briefing sessions on the pilot. Otherwise, a brief announcement about the pilot along with some key messages about the benefits of family planning can be sent to reporters in the form of a press release.



PATH/Evelyn Hockstein

Members of the medical community and civil society can be effective sources of information on family planning.

## 5. Key messages for each audience

Each type of audience will have a different set of attitudes toward family planning, experience different social and cultural norms, and feel a different level of self-efficacy toward seeking family planning services. Sometimes, a well-timed message from a trusted source can change or clarify a person's perceptions about family planning.

### INSIGHTS FROM THE LITERATURE

When seeking to change behavior, messages should explicitly promote or request a new behavior or action.<sup>83</sup>



An actor in a community theater production explains the range of contraceptive methods available in local health centers.

The suggested messages outlined below for various audiences were developed to address the most common needs cited in the literature and are not yet tailored to audiences in each pilot country. Communications partners in countries will therefore need to adapt messages to each country's specific linguistic and cultural characteristics and then pretest them before they are used (especially when used in mass media or publications). Although PATH found few studies on specific family planning messages in the literature, those that exist offer valuable reminders of the importance of audience testing. For example, audiences in Egypt preferred language that emphasized "family welfare" or "family health" over language that focused on "family planning." Family planning partners in Egypt also had more success positioning family planning as a health issue rather than as a population issue.<sup>79</sup> With this advice in mind, PATH recommends that all messages below be tailored to local audiences and pretested before use.

Messages for women should emphasize that a wide range of family planning methods are available that are safe and effective, reversible, convenient, easy-to-use, and under their control. For men, messages should more broadly emphasize the economic and health benefits of child spacing for both mother and child. All messages should include a specific call to action (e.g., visit your health center today or call toll-free for more information).

### Primary audience: Women with unmet need

#### Married women

In the previous section identifying high-priority audiences, we introduced a fictional woman named Fatima to represent a segment of the population of married women who are more highly educated and motivated to begin using family planning services. Many women like Fatima are limited primarily by a lack of access to these services. Once these services are available and health workers are trained, the most important message

# 5. KEY MESSAGES FOR EACH AUDIENCE

to convey is where and how to access those services. Other women like Fatima have access to services but just need a good reason to visit a family planning provider. The mere availability of new contraceptive choices has been shown to increase contraceptive prevalence in several areas.<sup>53,84</sup> Reminding women of the economic and health benefits of family planning and the control they have over their own bodies are other possible messages to this group.<sup>53,68</sup>

Suggestions for content of messages for women like Fatima are outlined below. It is also important to consider the source of these messages. For women like Fatima, these messages may be most effective coming from a technical authority, such as a nurse or physician.<sup>17,73</sup>

- Self-efficacy: Explain where and how to access services, and what to expect.
  - ◇ A new injectable contraceptive that temporarily prevents pregnancy for three months is now available at [location] (home, local clinic, pharmacy) at [date/time].
  - ◇ Family planning counseling usually takes less than an hour and there is no obligation.
  - ◇ Screening and counseling services are always discreet and confidential.
  - ◇ Make an appointment or visit your health center today.
- Attitude: Emphasize positive attributes and value of family planning.
  - ◇ New family planning methods are safe, convenient, reversible, and easy to use.
  - ◇ Contraception is affordable and free to those with limited means.
- Norms: Link acceptable social norms to family planning.
  - ◇ Injectable contraception is the most common choice of contraception for women across Africa.<sup>36</sup> DMPA is the most prevalent injectable contraceptive used globally.<sup>54,85</sup>
  - ◇ Modern women use family planning.
  - ◇ Childbearing is a personal matter and is something you can control.
  - ◇ Condoms provide protection against HIV and unwanted pregnancy.



Health workers are trained, trusted, and credible sources of family planning information.

# 5. KEY MESSAGES FOR EACH AUDIENCE

We also previously introduced a fictional character named Ebele to represent married women with less education who are more ambivalent about contraception. They are highly concerned about the side effects of different methods, have less information about the range of choices available, and perceive that their spouses oppose contraception. Secrecy and privacy are important to women in contexts where spouses are perceived to oppose contraception or where spouses disagree about the number and timing of pregnancies.<sup>36,44,53,86</sup> The concept of spacing births is well accepted throughout Africa and the literature clearly shows a preference for birth spacing over limiting the total number of childbirths.<sup>82,87,88</sup> Thus, while long-acting methods are promoted in some family planning programs, women like Ebele may prefer temporary family planning methods.

A qualitative study in the Gambia asked women who had given birth to two or more children and who had limited formal schooling to describe their decision-making process about contraception. Women listed several criteria, “including effectiveness, confidentiality, speed with which fecundity returns after the practice ends, and risk of long-term fertility impairment.”<sup>89</sup> While these criteria may be shared by women with more education, providers must pay particular attention to these criteria to make family planning acceptable to women with lower levels of schooling. Demand for family planning among women with limited education may be latent, and tends to be more fragile in the face of familial and social pressures.<sup>53</sup>

Messages to women like Ebele might be best delivered by peers or family members because these women do not always consider technical experts the most trusted source of information. A radio program that highlights the key message below, for example, might put them in the context of a friend speaking with a friend.

- Norms:
  - ◇ Do what’s best for your family: use family planning to space pregnancies by at least 24 months.
  - ◇ Children born more than two years apart are healthier and have longer life expectancies.
  - ◇ Islam supports family planning because birth spacing enables the mother to be more physically fit and the father to be more financially at ease. Family planning does not violate any prohibition in the Koran or in the Prophet’s tradition (Sunnah).<sup>90</sup>



Some women may be most comfortable discussing family planning information with peers.





A health worker uses counseling techniques to understand a woman's family planning needs.

- Attitudes:
  - ◇ Family planning services are nonjudgmental and confidential.
  - ◇ Contraception is safe and will not affect a woman's health or long-term fertility.
  - ◇ Family planning methods are convenient and affordable.
  - ◇ Modern family planning methods are effective and can be completely reversed.
  - ◇ Side effects may include an increase or complete absence of monthly bleeding. These changes are not dangerous and may change over time.
  - ◇ Birth spacing is a good decision for your health, and for the health and economic situation of your family.
- Self-efficacy:
  - ◇ Talk to a health worker today about which method is right for you.
  - ◇ A consultation is free and there is no obligation to try.
  - ◇ Many husbands support the idea of using family planning to space childbirths.

Method-specific messages are also appropriate for women like Ebele. Details on the method, side effects, and eligibility can be incorporated into written materials, radio programs, community theatre, and counseling materials used by health workers. Because fear of side effects is great among women and their spouses, all communications that elaborate on specific methods should emphasize the product's overall safety and explain how to manage side effects.

## INSIGHTS FROM THE LITERATURE

Women need method choice, including contraceptive options that are temporary, are under their control, can be used covertly, and do not need to be stored at home.<sup>22,53</sup>

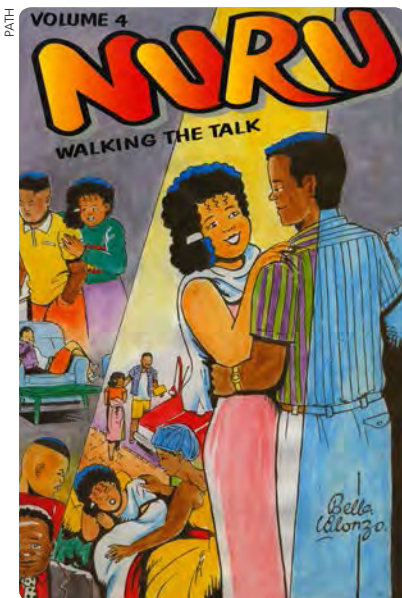
## Youth

Messages to youth may require explicit training of health workers as well as strong reinforcement from secondary audiences, and they may take longer to have an impact. Because this audience may not always trust older adults, the messages below can be rewritten to come from a peer or even a boyfriend who is concerned about the well-being of his partner.

- Address youth specifically:
  - ◇ For your and your baby's health, wait until you are at least 18 years old before trying to become pregnant.

# 5. KEY MESSAGES FOR EACH AUDIENCE

- ◇ Consider using a family planning method of your choice without interruption until you are 18 years old.
- ◇ Young women who control their fertility lead happier, healthier lives.
- Reduce barriers to seeking information:
  - ◇ Family planning services are nonjudgmental and confidential.
  - ◇ There is no obligation to use contraception when you visit a family planning specialist.
- Emphasize the benefits:
  - ◇ Contraception is safe, convenient, affordable, and easy.
  - ◇ Enjoy sex without fear of unwanted pregnancy.
  - ◇ Many contraceptive options are reversible and will not affect long-term fertility.
- Request immediate action:
  - ◇ Talk to a health worker today about which methods are available.



The Nuru comic book produced by PATH Kenya recounts the story of a young girl who faces choices about sexuality as she comes of age.

## CASE STUDY: ENGAGING YOUTH THROUGH COMIC BOOKS IN KENYA

The three-volume, Kiswahili-language comic book series, Nuru was designed to help young people in Kenya address the pressures and challenges of moving into adulthood. Developed by PATH for USAID's Implementing AIDS Prevention and Care (IMPACT) project, the topical stories focus on a teenage girl, Nuru, and her friends, who face numerous choices about friendships, dating, and sexuality. The sympathetic characters, bright colors, and youthful language attract young people, and the gripping accounts of the protagonists' problems and struggles encourage readers to consider issues such as quality relationships, sexual behaviors that can save their lives, and finding the courage to do what they know is right. The Nuru series provokes lively, informal discussion: Did Nuru do the right thing? Should Oscar emulate Leon's ways? Will Angel's relationship with the sugar daddy be her undoing?<sup>91</sup>

## Secondary audiences: Key influencers

### Health workers

Messages to health workers should complement and reinforce messages provided in training and should make it easier for health workers to relate to their clients and better understand and meet women's needs.

Training materials developed by PATH for countries introducing Sayana Press include important messages that can be reemphasized in communications materials for health workers. For example, when counseling clients on DMPA methods:

- Health workers should explain how DMPA works and possible side effects, such as irregular menstruation, heavy bleeding, spotting, and amenorrhea. See Annex C for a quick reference from the Johns Hopkins Bloomberg School of Public Health on how to counsel clients on methods that affect menstrual bleeding.
- Health workers should explain that menstrual changes will probably decrease over time, with the exception of amenorrhea. If they persist, or if the client would like to try a different method, a health worker can help the client choose a different method.
- Whatever method the client chooses, the health worker should take care to explain side effects and reassure the client that side effects can be managed.

Health workers should also be encouraged to initiate a conversation with clients about family planning as opportunities arise. Appropriate times may be after an abortion, during antenatal visits, after delivery, or when clients are seeking emergency contraception.

#### INSIGHTS FROM THE LITERATURE

Reductions in family size are associated with significant economic benefits for families and societies. When a family has fewer children, all of whom are likely to survive, it can invest in the children's nutrition, health, and education to an extent that is harder to achieve for families with nine or ten children. This investment then leads to higher incomes and better standards of living.<sup>3</sup>

#### Spouses/men

Messages to men should address their primary fears and concerns, counteract negative perceptions, and improve positive perceptions of family planning. In general, messages for men should more broadly emphasize the economic and health benefits of child spacing for both mother and child. A study in Malawi found that messages focused on the economic and health benefits of limiting births resonated most strongly with men.<sup>92</sup>

Similarly, efforts to introduce the idea of male sexual responsibility and to show how the Koran supports family planning have been effective.<sup>27,41,93</sup>

The following messages might be most effective when they come from community leaders or peers who can be credible and convincing advocates for family planning.

- Emphasize the economic benefits of family planning:
  - ◊ Family planning improves the financial health and well-being of your family.<sup>94</sup>

# 5. KEY MESSAGES FOR EACH AUDIENCE



Communication among couples about family well-being can enable spousal support for contraception.

- Portray men as supportive and caring:
  - ◇ Support your spouse by talking to her about family planning.
  - ◇ Men must take responsibility for the health and well-being of their children and support their wives to use family planning services for birth spacing.
- Address common misconceptions and fears:
  - ◇ There are a wide range of family planning choices, including short-acting, long-acting, and permanent. If you do not like one method, you can switch to another.
  - ◇ Modern family planning methods are safe and effective.
  - ◇ New contraceptive choices are available that can prevent pregnancy in the short term and have no long-term effect on fertility.
  - ◇ Side effects that change monthly bleeding are not dangerous, and their effects are reduced over time.
  - ◇ Islam encourages birth spacing by at least two years between pregnancies.
- Explicitly request the desired behavior:
  - ◇ Get the facts about family planning [explain how to gain access to family planning information in a way that resonates with men: e.g., pamphlets are available at (public place), a toll-free hotline, SMS text info, open house nights].
  - ◇ Discuss family planning with your wife and decide what's best for your family.
  - ◇ Encourage your wife to consult with a family planning provider today.

## Family members

Messages to family members are similar to messages to men. However, it can be useful to identify the intended audience in the message itself. This lets family members know that their perspective matters and that they have a responsibility to think about their attitudes toward family planning and children's well-being.

- Give your daughter-in-law some sage advice: properly spaced births can improve the health and well-being of her children.
- It is not the number of children that makes a family wealthy; it is the well-being of those children and their mothers.

# 5. KEY MESSAGES FOR EACH AUDIENCE



A mother attends a maternal health clinic to get information about birth spacing.

- Family planning is a safe and effective way of spacing childbirths.
- New methods are now available that temporarily prevent pregnancy until the family is ready for more children.
- There are millions of satisfied family planning users in [country] today.
- Get the facts about family planning from a health worker today.

## Social networks

Friends and other influential members of the community (e.g., community leaders, mentors, religious leaders) can provide support to women seeking family planning services. They can do this by talking to women about their needs, accompanying them to the clinic, and helping women prepare for counseling sessions with health workers. For example, in a study of family planning counseling in Indonesia, a patient educator coached women about the importance of asking questions and helped them prepare questions and practice asking them. Coached women asked more questions than uncoached women, and they expressed more concerns about contraceptive methods. As a result, providers gave the coached women more information specific to their situation.<sup>54</sup>

Messages to groups can focus on the important role that friends and mentors can play in supporting women as they decide how to handle family planning questions and how to address their family planning needs.

- Bring a friend to the clinic and learn about family planning services together.
- Help your friend get the facts about family planning.
- Talk to your friend about what she needs. Make sure she gets the facts from a health provider.

## Religious and cultural leaders

Messages to religious and cultural leaders are similar to those for other secondary audiences, but they should also reference passages in religious texts that support family planning and birth spacing.

- Islam encourages birth spacing by at least two years between pregnancies.
- Family size can limit parents' economic ability to feed, clothe, and provide medical care for their children.
- Birth spacing can keep families out of poverty and improve the health of mothers and children.



Social and community events such as women's group meetings provide an opportunity for education about family planning.

# 5. KEY MESSAGES FOR EACH AUDIENCE



2005 Richard Nyberg, Courtesy of Photoshare

A Muslim leader explains to members of a religious community that Islam supports women's health and a healthy family life.

## CASE STUDY: TRANSFORMING RELIGIOUS LEADERS INTO FAMILY PLANNING ADVOCATES

In Guinea, a program was developed to sensitize religious leaders to family planning through a series of workshops. The program also developed materials, such as a leaflet for men with a passage from the Koran 2:233 referring to the father's responsibility to clothe and feed his children properly and to the idea that no one should be charged beyond his means.<sup>80</sup> In Afghanistan, religious leaders (mullahs) were involved in developing packaging for an injectable contraceptive and included passages from the Koran on the packaging.<sup>41</sup> In Kenya, religious leader orientation sessions were organized by the Christian Health Association of Kenya "to introduce the community-based family planning services of church-based health facilities." During orientations, pastors developed plans for introducing family planning messages into sermons and Bible study discussions.<sup>79</sup>

## Tertiary audiences: Family planning stakeholders

Although the tertiary audiences such as medical community members and journalists may differ in their specific information needs, they will generally need an overview of the program and an invitation to participate. This can be accomplished through meetings or phone calls, letters, email, or other direct methods.

- Explain the pilot and the objective to increase the contraceptive prevalence rate through the introduction of a new hormonal contraceptive option.
- Emphasize the health and economic benefits of family planning:
  - ◇ Health benefits: "Meeting the unmet need for family planning yields multiple benefits, not least through preventing maternal deaths. It has been estimated that a full one-third of the total maternal deaths can be attributed to non-use or lack of availability of contraception—or 150,000 deaths per year. Family planning means that unwanted pregnancies and the resultant abortions can be largely avoided. Adolescent girls are particularly vulnerable to unintended pregnancy. Adolescents are twice as likely to die during pregnancy and delivery as women in their 20s."<sup>3</sup>
  - ◇ Economic benefits: Contraceptive use has been shown not only to have an impact on families' economic status, but to strengthen national economies as well. Women and couples who space births are better able to care for themselves or their families, support themselves financially, complete their education, and get or keep a job. These factors contribute to greater family savings and productivity, better

educational opportunities for children, and reduced pressure on natural resources. Analysis of public health and cost data shows that fulfilling unmet need for family planning and maternal health care would save women's lives, improve health, and alleviate system-wide costs related to morbidity and mortality, contributing to Millennium Development Goals 3, 4, and 5.<sup>95</sup>

- Provide information about Sayana Press and how it differs from DMPA IM.
- Explain the opportunity Sayana Press provides by allowing CHWs to provide DMPA directly to clients.
- Ask them how they can support the pilot.
- Provide contact information so they can communicate with you should they require more information or have ideas they would like to share.

## 6. Important communication channels

### INSIGHTS FROM THE LITERATURE

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Women who discuss family planning with a health care provider are twice as likely to use contraceptives as women who do not.<sup>52</sup>

### Provider-patient communication

One of the most effective ways to enhance provider-patient communication is to support the health worker. Communications partners in Sayana Press pilot areas can address some of the needs and concerns of health workers by providing tools and resources that reinforce new content and skills provided in training sessions.

- Materials such as pictorial flip charts, take-home pamphlets, wall charts, videos, and question-and-answer sheets about method choices and side effects of all products, including Sayana Press, can help health workers remember and more clearly communicate key messages and answer common questions. These materials may already be under development by training partners and should be informed by relevant sections of the training program. Communications partners should coordinate with training partners to make sure these materials are being developed, pretested, and distributed to health workers involved in the Sayana Press pilot.
- Health workers can also be encouraged and supported to develop their own outreach strategies, such as public bulletin boards where people can anonymously post questions that are then answered by a health worker.
- Mobile phones: Mobile teledensity is growing in all pilot countries. It is highest in Senegal, where mobile phones are used by 89 percent of the population and where market penetration is quickly approaching 100 percent. Mobile phone penetration is 64 percent in Burkina Faso (with a 30 percent growth rate in 2012) and 50 percent in Uganda.<sup>96</sup> No data were available on the growth of mobile phone use in Niger. In areas with high teledensity, health workers can use mobile phones to text clients with reminder notices for refills or reinjections. Mobile phones can be used to provide one-on-one phone support to clients who are having issues with side effects or who have questions that were not answered during their counseling sessions.



# 6. IMPORTANT COMMUNICATION CHANNELS



PATH/Eric Becker

Family planning programs are increasingly using mobile phone and text message services to support education, referral and reminders.

## CASE STUDY: USING TEXT MESSAGES TO COMMUNICATE FAMILY PLANNING INFORMATION

Mobile for Reproductive Health (m4RH) is an SMS text message system in Tanzania that provides automated information about eight different family planning methods. The service was promoted in a small number of family planning clinics through posters, fliers, and business-sized palm cards. Within the first nine months, 2,870 unique users queried the system, often more than once. Fifty-six percent of users were female. Adolescents and young adults were the heaviest users among those reporting their age.<sup>13</sup>

## Peer-to-peer and community-centered communication

Communications partners can encourage peer-to-peer communication in a variety of ways, depending on local resources and the willingness of community-level groups to participate in communications efforts.

- Once health workers are well supported, they can be encouraged to provide brief presentations at community meetings and encourage discussion of family planning in a nonthreatening, nonclinical atmosphere. These events can be organized by local champions, social groups, health committees, or religious associations and can be directed to different audiences: women, men, adolescents, grandmothers, etc. Community meetings are an interactive and public way to improve knowledge and answer questions about injectables and other methods. They also provide information for women who are unable to travel, and for men. For example, in the Social Marketing for Change (SOMARC) III project in Uganda “midwives set up one-hour community talks with women interested in family planning by working with local officials, religious groups, trade schools, and factories to set a date and identify attendees. In areas where meetings were held, sales of injectables more than doubled from the six months before the meetings to the six months after the meetings.”<sup>97</sup>
- Communications partners can offer education to individuals who are willing to act as peer educators (from women’s or mothers’ groups, lending groups, social clubs, men’s/fathers’ groups, religious groups, adolescent groups, etc.) and give them tools such as flip charts, pamphlets, wall charts, and other educational materials to help them answer questions and direct their group members to technical experts.
- Communications partners can also sensitize community leaders and religious leaders to family planning goals and services by providing orientation sessions, seminars, meetings, or workshops. For example, the



PATH/Eric Becker

Even family planning print communication materials that are designed to be read individually can spur conversation and communication.

## 6. IMPORTANT COMMUNICATION CHANNELS

Navrongo initiative in Ghana “encouraged support for family planning by enlisting the help of opinion leaders and using men’s and women’s social networks. Councils of elders formed health-care action committees, and village leaders and elders convened regular community gatherings to discuss health and family planning with the men. This approach involves constituting health-care action committees from existing councils of elders, mobilizing traditional peer networks, and implementing supervisory services with extant traditional village self-help schemes.”<sup>98</sup>

- Outreach to men in Navrongo used existing mechanisms for community gatherings, known as “durbars,” to serve as a forum for discussing family planning programs. In durbars, chiefs and elders led discussions on health and family planning themes that were openly discussed afterward.<sup>98</sup>
- Toll-free hotlines: Some programs have had great success reaching men and adolescents in particular by establishing a toll-free family planning hotline.<sup>13</sup> These hotlines are staffed by trained nurses and usually have set hours of operation.



2004 David Alexander, Courtesy of Photoshare

Family planning hotlines staffed by trained health workers have had success reaching men and adolescents.

### CASE STUDY: TELEPHONE SUPPORT FOR FAMILY PLANNING CLIENTS

The Ligne Verte hotline in the Democratic Republic of Congo was established in 2005 to provide confidential family planning information to callers and referrals to clinics and pharmacies. The hotline is available Monday through Friday from 8:00 a.m. to 4:30 p.m. and is staffed by trained, multilingual health educators working in four-hour shifts. The hotline was developed in partnership with a leading mobile phone service provider, Vodacom, and was only available to callers in the Vodacom network until it expanded in 2008. Within three years, the hotline received 80,000 calls, 80 percent of which were from men. Interestingly, many of the calls were made on behalf of partners who were experiencing side effects such as spotting and missed periods.<sup>13</sup>

- Websites and social media: Internet penetration in all pilot areas is still fairly limited (less than 20 percent of the total population in Senegal, less than 9 percent in Uganda, less than 3 percent in Burkina Faso, and less than 1 percent in Niger). Also, most people accessing the Internet use their mobile phones to do so.<sup>96</sup> A pilot project in Senegal to create a Facebook account for family planning questions and resources appears to have attracted few users. Until Internet penetration is higher, we recommend directing limited resources elsewhere.



Radio ownership in Africa is extremely high, at 80-90% on average in the pilot countries, making it the most common mass-medium.

## INSIGHTS FROM THE LITERATURE

Most clients interviewed about their contraceptive choices in Dakar, Senegal, reported the broadcast media to be the best source of family planning information.<sup>42</sup>

A cross-sectional survey on the effects of a family planning communications campaign in Burkina Faso showed that high campaign exposure was associated with an adjusted increase of 22 percentage points in the proportion of women using modern contraceptive methods, as well as increased knowledge about contraceptives and more favorable attitudes toward family planning.<sup>104</sup>

## Mass media communication

A large volume of literature has shown that mass media can have a positive impact on attitudes toward family planning and on contraceptive prevalence throughout Africa.<sup>42,72,99-102</sup> As most commercial marketing experts know, the more exposure a person has to a message from a variety of channels and sources, the better. An evaluation of a large-scale multimedia campaign in Tanzania found that current contraceptive use was higher among women who had been exposed to four or more media sources of family planning information than among women exposed to fewer sources. Contraceptive prevalence rose sharply as the number of sources grew. Nine percent of women exposed to one media source were using a modern method, compared with 15 percent for two media sources, 19 percent for three, and 45 percent among women exposed to six sources.<sup>103</sup>

Sayana Press partners will not have the budget or time to invest heavily in mass media. Further, given the limited geographic area of the pilots, mass media may not be the most appropriate communication choice. However, the introduction of Sayana Press presents an opportunity to insert new themes into existing local radio and community theatre dramas or talk shows as long as geographic coverage can be limited to pilot areas. The focus of these episodes can be on the introduction of a new method choice that can be delivered safely and conveniently by CHWs and provides effective contraception for three months. Again, messages about side effects and other health effects should be addressed directly in the programs along with a request for action.

Print media (fliers, wall charts, posters, flip charts, etc.) should be modified with the introduction of Sayana Press in pilot areas. As materials are modified, partners should take the opportunity to assess the effectiveness of the print material and refresh the headlines and images.

Popular types of mass media that could be considered for geographic areas introducing Sayana Press include:

- Community theatre.
- Radio public service announcement or interview (local stations reaching only pilot areas).
- Newspaper stories or advertisements (local newspapers reaching only pilot areas).
- Local newsletters.
- Announcements at sporting events.
- Posters, fliers, and wall charts.
- Advertisements on trucks or buildings.

## 7. Crisis communications

Each pilot country should have a plan for addressing the possibility that media, cultural leaders, or other stakeholders will raise doubts, misinterpret information, spread rumors, or propagate misinformation about Sayana Press (or any contraceptive method), especially as awareness of the method increases. PATH is developing crisis communications guidance and a series of useful discussion points on Sayana Press for interacting with the media. These materials are for all partners involved in the Sayana Press pilot introduction and evaluation project and will be circulated in 2014.

### INSIGHTS FROM THE LITERATURE

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Programs should be ready to respond to groups that publicly oppose injectables specifically or modern contraceptives in general. Maintaining good working relationships with the news media and making sure that reporters are well informed are important tasks for family planning programs.<sup>54</sup>

PATH



The PATH website has many resources to find out more about Sayana Press.

## 8. For more information

Additional information about Sayana Press is available through the PATH website at <http://sites.path.org/rh/?p=292>. Information includes:

- Sayana Press: Pilot Introduction and Evaluation project summary
- Sayana Press Clinical Brief
- Frequently Asked Questions About Sayana Press and Subcutaneous DMPA (see Annex B).

An excellent source of information about behavior change strategies for family planning is the [www.K4Health.org](http://www.K4Health.org) website. K4Health is funded by the US Agency for International Development and implemented by the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs in collaboration with FHI 360, Management Sciences for Health, and IntraHealth International.

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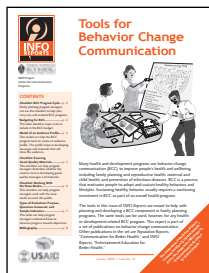
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# Annex A: Behavior change communication resources



O'Sullivan GA, Yonkler JA, Morgan W, Merritt AP. *A Field Guide to Designing a Health Communication Strategy*. Baltimore: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs; March 2003. Available at: [http://www.jhuccp.org/resource\\_center/publications/field\\_guides\\_tools/field-guide-designing-health-communication-strategy-](http://www.jhuccp.org/resource_center/publications/field_guides_tools/field-guide-designing-health-communication-strategy-)

*This practical and comprehensive guide provides guidance for program managers to design, implement, or support a strategic health communication effort. The 308-page document shares a set of steps and tools that can be used to plan, implement, and evaluate behavior change communication interventions. This resource also includes a review of behavior change theories and a series of international case studies.*



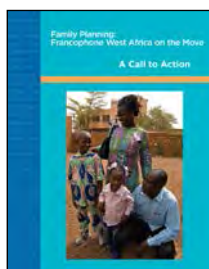
Johns Hopkins Bloomberg School of Public Health Center for Communication Programs. Tools for behavior change communication. *INFO Reports*. January 2008; 16. Available at: <http://www.k4health.org/sites/default/files/BCCTools.pdf>.

*This eight-page summary publication is organized as a practical checklist of key steps in a Behavior Change Communication Program Cycle that includes analysis, design, pretesting, budgeting, ensuring quality, working with the media, and evaluating.*



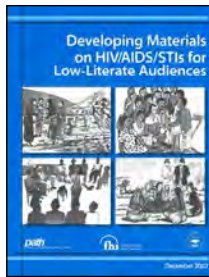
CORE Group. *Social and Behavior Change for Family Planning: How to Develop Behavior Change Strategies for Integrating Family Planning into Maternal and Child Health Programs*. Washington DC: CORE Group; June 2012. Available at: <http://www.coregroup.org/our-technical-work/working-groups/social-and-behavior-change/past-highlights/260-better-together>.

*This 166-page curriculum is designed for program staff working in maternal and child health programs who want to add family planning (counseling, referrals, or services) into their programs through social and behavior change. The document serves as a guide to run a 2.5-day training course that teaches the basics of "designing for behavior change."*



Ouagadougou Partnership. *Family Planning: Francophone West Africa on the Move: A Call to Action*. Ouagadougou Partnership; 2012. Available in English and French at: <http://www.k4health.org/toolkits/eonc/family-planning-francophone-west-africa-move-call-action>.

*This 28-page call to action identifies key investments in family planning that can be made to catalyze progress in West Africa.*



PATH. *Developing Materials on HIV/AIDS/STIs for Low-Literate Audiences*. Seattle: PATH; 2002. Available at: <http://www.path.org/publications/detail.php?i=688>. A prior version of this resource (PATH; 1996) is specific to family planning and is available here: <http://www.path.org/publications/detail.php?i=1968>

*Originally developed in 1989, PATH's guide to developing low-literate materials has become a classic in the field. The document details key steps in the process of developing culturally appropriate print communications materials, from conducting audience research to pretesting, production and evaluation. The 150-page resource includes sample pretesting techniques, focus group guides, illustrations from international health communications materials, and guidelines for comprehension and readability.*



Lande R, Richey C. Expanding services for injectables. *Population Reports*. 2006; Series K(6). Available at: <http://www.k4health.org/sites/default/files/k6.pdf>.

*More and more women are using injectable contraceptives today and very likely even more will use this method as it becomes increasingly available. Women choose injectables because they are effective, long-lasting, and private. For family planning programs, meeting increasing demand while maintaining good quality will be the key to success with injectables. Between 1995 and 2005, the number of women worldwide using injectable contraceptives more than doubled. About 12 million married women used injectables in 1995. In 2005, over 32 million were using injectables.*



de Fossard E, Lande R. Entertainment-education for better health. *INFO Reports*. January 2008; 17. Available at: <http://www.k4health.org/sites/default/files/EntertainmentEducation.pdf>.

*This report helps managers of family planning programs create and manage entertainment-education programs. This report accompanies "Communication for Better Health" in Population Reports and "Tools for Behavior Change Communication" in INFO Reports.*



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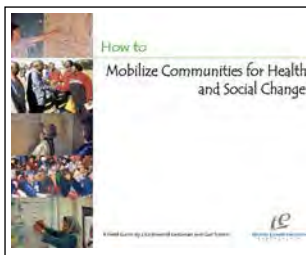
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*This 110-page document explains the use of Barrier Analysis, a tool that can be used to conduct rapid assessment to identify behavior determinants associated with a particular health behavior or topic. Barrier Analysis is particularly useful method that can be used to determine key messages and activities for intervention.*



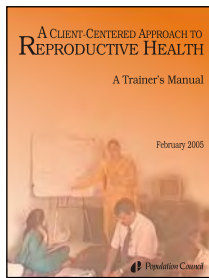
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*This guide is organized around the Community Action Cycle, a process of engaging with communities to build their ability to effectively lead social change related to health issues. The 264-page document includes many tools, checklists, case studies, and practical tips from around the world.*



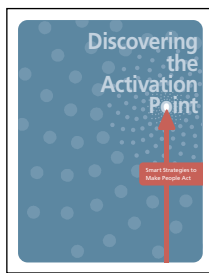
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*This curriculum was produced by PATH for the USAID-funded Program for Integrated Health in Borgou-Alibori (PROSAF) in Northern Benin. No English translation exists, however the curriculum includes many useful methods for implementing individual and social behavior change activities using songs, skits, home visits, theatre campaigns, and small group work. Content includes examples from the fields of malaria prevention, immunization, maternal health, HIV prevention and family planning.*



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*This comprehensive 268-page manual describes participatory training methodologies and materials to use during a six-day workshop covering gender, self-awareness, communication and communication tools, behavior, power, referral systems, team-building and evaluation. The manual's intended audience is health care providers working in reproductive health but the dozens of practical exercises and training sessions can be used with a variety of audiences.*



Spitfire Strategies. *The Activation Point: Smart Strategies to Make People Act*. Washington, DC: Spitfire Strategies; 2006. Available at: <http://www.activationpoint.org/>

*This document explores how to go beyond engaging an audience to build will for taking action or affecting social change. Spitfire Strategies developed this resource as a follow-up to a previous publication, *The Smart Chart*, which has been used by nonprofit organizations and funders to execute communications efforts that support social change. The *Activation Point* focuses on strategies for mobilizing people to supportive action by identifying and leveraging their activation points.*



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*This web-based toolkit offers dozens of family planning tools, resources, and publications available online. It addresses ten elements of family planning success, including supportive policies, evidence-based programming, leadership and management, effective communication, contraceptive security, trained staff, client-centered care, easy access, affordable services, and integrated services. The *All Resources* page offers links to dozens of resources in a searchable database.*



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*This 15-page journal article describes the current status of family planning around the world with a focus on countries that have the most to gain from investments in family planning.*

# Annex B: Frequently asked questions about Sayana® Press and subcutaneous DMPA

## Clinical information

### Is Sayana Press as effective as DMPA IM for contraceptive protection?

Studies indicate that Sayana® Press, manufactured and patented by Pfizer, Inc., provides efficacy, safety, and immediacy of contraceptive effect equivalent to the intramuscular (IM) presentation of depot medroxyprogesterone acetate (DMPA IM), registered by Pfizer as Depo-Provera®. Sayana Press is a single-dose presentation of the subcutaneous (SC) formulation of the drug, consisting of 104 mg/0.65 mL DMPA in the Uniject™ injection system. The drug is also available in a single-dose, prefilled glass syringe, licensed by Pfizer as Sayana®\*.

A number of clinical trials have been conducted for Sayana. In these trials, Sayana effectively suppressed ovulation for at least three months in all subjects regardless of ethnicity, race, and body mass index. In three multinational clinical studies conducted in North and South America, Europe, and Asia, no pregnancies were detected among 2,042 women using the injectable contraceptive for up to one year.<sup>1</sup> Sayana Press is expected to perform in the same manner as Sayana, because the only change in the product is delivery via a different injection device.<sup>2</sup>

#### LEXICON OF INJECTABLE DMPA PRODUCTS

MPA: medroxyprogesterone acetate, the active contraceptive agent.

DMPA: depot MPA. When injected intramuscularly or subcutaneously, MPA forms a reservoir or depot that releases the drug over time.

DMPA IM: generic name for the intramuscular form of DMPA.

DMPA SC: generic name for the subcutaneous form of DMPA.

Depo-Provera®: Pfizer, Inc., brand of DMPA IM, available in vials or prefilled syringe.

Depo-SubQ Provera 104®: Pfizer brand of DMPA SC in prefilled syringe.

Sayana®: Pfizer Limited (UK) brand of DMPA SC in prefilled syringe licensed in the UK and some other countries.

Sayana® Press: Pfizer Limited brand of DMPA SC in the Uniject.

### What is the advantage of Sayana Press over DMPA IM?

A key advantage of Sayana Press is its availability in the Uniject injection system, which provides ease of administration and the potential to benefit system-level logistics in terms of storage, transport, and distribution.<sup>3</sup> The Sayana Press formulation is expected to have at least comparable tolerability to the IM formulation, as it requires a 30-percent lower total dose and side effects are generally dose-dependent.<sup>4</sup>

\* Both Sayana and Sayana Press contain 104 mg/0.65 mL depot medroxyprogesterone acetate (DMPA), and are administered by subcutaneous injection; the dose is 0.65 mL. Depo-Provera® (DMPA IM) contains 150 mg/mL depot medroxyprogesterone acetate and is administered by intramuscular injection; the dose is 1 mL.

Sayana, Sayana Press, and Depo-Provera are registered trademarks of Pfizer, Inc. Uniject is a trademark of BD.



## What is the difference between intramuscular and subcutaneous injection? Does subcutaneous injection have advantages?

IM injections are given deep into skeletal muscles, whereas SC injections pierce only the epidermal and dermal layers of the skin and deliver the drug into the loose subcutaneous tissue. Following SC injection, the drug enters capillaries by diffusion or filtration.<sup>5</sup> Because of the distance between the surface of the skin and the muscle, IM administration requires a longer needle—typically one to two inches in length. SC injections typically use needles ranging from 3/8 inches to 5/8 inches in length.<sup>6</sup> Advantages of SC injections include:

- Improved safety profile—because larger blood vessels are located deeper, SC injections are less likely than IM injections to pierce a blood vessel.<sup>7</sup>
- Ease of administration—there is more surface area available for SC injections and they require fewer landmarks compared with IM injections; SC injections are administered with shorter needles.

## What is the difference between DMPA SC and Sayana Press?

DMPA SC was approved and licensed as Depo-SubQ Provera 104 by Pfizer in 2004. The drug is also available in a single-dose, prefilled glass syringe, licensed by Pfizer as Sayana. Sayana and Sayana Press are expected to perform in the same manner as DMPA SC, because the only change in the product is delivery via different injection devices; the dose of DMPA is the same.

## Has DMPA SC been shown to provide contraceptive efficacy in different racial/ethnic groups?

Yes. Multinational studies of DMPA SC conducted in North and South America, Europe, and Asia demonstrated equal contraceptive effectiveness across races and ethnicities.<sup>1,3,4,8,9</sup> Sayana and Sayana Press contain the same dose of DMPA SC used in these studies and are expected to perform identically.

## What are the most common side effects of Sayana Press?

Side effects for both the IM and SC formulations of DMPA include the following:

- Bleeding irregularities—including changes in menstrual bleeding patterns, such as amenorrhea, irregular spotting or bleeding, prolonged spotting or bleeding, and heavy bleeding. Irregular bleeding typically decreases over time, and amenorrhea then becomes more common.
- Headaches
- Increased weight
- Injection site reactions—typically mild injection site pain, granuloma or atrophy

## What is the risk of bone mineral density loss caused by use of DMPA SC?

Use of the IM and SC formulations of DMPA is associated with decreased bone mineral density (BMD). Most studies have found that women lose BMD while using DMPA but regain all or partial BMD after discontinuation. It is not known whether DMPA use among adolescents affects peak bone mass levels or whether adult women with long duration of DMPA use can regain BMD to baseline levels before menopause. The relationship between DMPA-associated changes in bone mineral density during the reproductive years and future fracture risk is unknown.<sup>10</sup>

## Does body mass index affect the efficacy of DMPA SC?

No. Clinical studies to date demonstrate that the contraceptive efficacy of the active ingredient in Sayana Press is not affected by body mass index (weight-to-height ratio).

## In which parts of the body can Sayana Press be administered?

Pfizer's current package insert for Sayana Press labels the product for injection in the abdomen or thigh. Recent research indicates that administration through injection in the back of the upper arm provides sufficient medroxyprogesterone acetate levels for contraceptive protection for three months (13 weeks) plus at least a two-week window for reinjection.<sup>11</sup>

## Can a woman switch between DMPA IM and SC?

Yes. Because the active ingredient in the IM and SC formulations is identical, it is safe to switch back and forth between these two formulations on a regular dosing schedule (i.e., every three months) with the same level of contraceptive protection. Sayana Press is expected to perform identically to other presentations of DMPA SC.

## Where have clinical trials been conducted?

Clinical trials of Sayana have been conducted in North and South America (Brazil, Canada, Chile, Mexico, Peru, and the United States); Europe (Bulgaria, Estonia, Latvia, Lithuania, Norway, Poland, Romania, Russia, and the United Kingdom); and Asia (Indonesia, Pakistan, and Russia).<sup>8</sup> Pharmacokinetics studies were conducted in Los Angeles, California (including Caucasian and African American participants), and Singapore (including a diverse group of Asian participants).<sup>4,9</sup>

## What will happen if Sayana Press is administered intramuscularly?

To ensure three months of contraceptive protection, Sayana Press must be administered subcutaneously. The short needle (3/8 inches) used with Sayana Press minimizes the likelihood of inadvertent intramuscular injection.

## Does DMPA use increase women's risk of contracting HIV?

Any type of hormonal contraception does not protect against HIV, therefore all individuals at risk of HIV should use condoms consistently and correctly. While some studies suggest that women using progestin-only injectable contraception may be at increased risk of HIV acquisition, other studies do not show this association. A WHO expert group reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current medical eligibility guidance, which states that women at risk of HIV may safely use progestin-only injectables. However, due to the inconclusive nature of existing evidence on possible increased risk of HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures.<sup>12,13</sup>

## Sayana Press and contraceptive implants both contain progestin. How are they different and what are the implications of the differences?

While Sayana Press is delivered via a subcutaneous injection every three months, contraceptive implants are small flexible rods or capsules that are placed under the skin of the upper arm through a minor surgical procedure. Like Sayana Press, implants are estrogen-free and contain a progestin hormone (like the natural

hormone progesterone) to thicken cervical mucus and disrupt the menstrual cycle. However, progestin is released from implants very slowly providing pregnancy protection for three to five years, depending on the type of implant. Implants are very effective, with less than 1 pregnancy per 100 women using implants over the first year. Potential implant side effects are similar to those associated with Sayana Press, including menstrual bleeding changes, headaches, abdominal pain, or breast tenderness.<sup>14</sup>

Some women may prefer the convenience of implants for longer-term protection, but implants must be inserted and removed by a trained provider—making it important for providers and facilities to be accessible to clients. Sayana Press is designed for use by health workers at lower levels in the health care system or, potentially, by women themselves.<sup>15</sup>

## The Uniject injection system

### What is Uniject?

Uniject is a prefilled, autodisable injection device that was developed to meet challenges of widespread distribution of vaccines and other medications in low-resource settings.

### What are the key benefits of Uniject for delivering Sayana Press?

- Easy to use: Can be used by health workers who do not normally give injections.
- Single dose: Minimizes wastage and facilitates outreach to individual patients.
- Prefilled: Ensures that the correct dose is given, is easy to inject, and simplifies procurement and logistics.
- All in one: Eliminates the need to bundle vials and syringes and prevents potential mismatches at the service delivery point.
- Nonreusable: Minimizes patient-to-patient transmission of bloodborne pathogens through needle reuse.
- Compact size: For easy transport, storage, and disposal.

### Where and how has Uniject been used in the past?

BD (Becton, Dickinson and Company) produces bulk, empty Uniject devices and provides these to vaccine and pharmaceutical producers. Since 2000, more than 88 million Uniject devices have been used to administer injectable medicines throughout Africa, Asia, and Latin America. For example, Uniject is used throughout Indonesia to deliver hepatitis B vaccine to newborns.

## Sayana Press registration, cost, and shelf life

### What is the registration status of Sayana Press?

Pfizer registered depo-subQ provera 104™, the same drug in Sayana Press, with the US Food and Drug Administration in 2004. Sayana and Sayana Press have been registered with the United Kingdom's Medicines

and Healthcare products Regulatory Agency (MHRA). Following regulatory approval via Decentralised Procedure in the European Union, Pfizer is preparing dossiers for registration of Sayana Press in a number of countries in other parts of the world.\*\*

### Will Pfizer seek WHO prequalification for Sayana Press?

Products that have attained approval from a globally recognized stringent regulatory authority (SRA) do not require WHO prequalification. Pfizer is unlikely to seek WHO prequalification because the drug contained in Sayana Press has been approved by the US Food and Drug Administration and regulatory authorities in Europe.

### What is the expected cost of Sayana Press?

There is not currently a published price for Sayana Press. Future pricing will depend upon multiple factors such as demand and volume.

### What is the stability and shelf life of Sayana Press?

The product has a three-year shelf life from the date of production when unopened. Once opened, the product should be used immediately or discarded.

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\*\* Sayana Press was approved in the European Union via procedure number UK/H/0960/002UK/H/0960/002. The UK was the Reference Member State. A Public Assessment Report is available at the Heads of Medicines Agency website and the MHRA webpage: <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con126147.pdf>

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## Annex C: Counseling guidance on changes in monthly bleeding

- Monthly bleeding changes with hormonal contraceptive methods and IUDs are a normal and rarely harmful side effect, but they are a common reason that women discontinue use.
- Family planning providers can help women anticipate and deal with bleeding changes through counseling and encouragement.
- When women know about bleeding changes in advance, they can choose a suitable method, be more satisfied with their choice, and continue to prevent unintended pregnancy effectively.

Bleeding changes are common among women using hormonal contraceptive methods and IUDs. These are among the most effective reversible family planning methods, and many women choose them for this reason. But the monthly bleeding changes they cause often lead to dissatisfaction and discontinuation. Many women who discontinue a contraceptive method do not immediately begin to use another one, or they switch to a less effective method, leaving them at risk of unintended pregnancy.

Combined hormonal methods—oral contraceptives (OCs), monthly injectables, the patch, and the vaginal ring—tend to make monthly bleeding shorter and more predictable. Progestin-only methods—long-acting injectables, implants, and progestin-only OCs (the “minipill”)—and the hormonal levonorgestrel-releasing IUD can cause changes that range from breakthrough bleeding and spotting to no monthly bleeding. Copper IUDs can cause somewhat heavier and longer bleeding. A method’s effects can differ among women, or differ over time for an individual.

### Research Findings: Counseling Improves Client Satisfaction and Continuation

Women who know beforehand about possible bleeding changes are more satisfied with their contraceptive method.<sup>1</sup> This finding may suggest both better-informed method choices and better-prepared users. Providers who offer information and counseling about potential bleeding changes in advance may help clients choose a method that suits them and also help them know what to expect from its use.

Several studies also suggest that new clients continue using their chosen method longer when providers have offered in-depth counseling about bleeding changes and encouraged them to return for help if they have problems.<sup>2</sup> Counseling and encouragement at follow-up visits also can help continuing clients manage bothersome bleeding changes and thus help them avoid discontinuation and the risk of unintended pregnancy.<sup>3</sup>

### What Family Planning Providers Can Do

To help clients choose and use methods that meet their needs, family planning providers can take the following steps:



## Help new clients decide whether to choose a family planning method that may change monthly bleeding:

- Describe the common bleeding changes in ways that clients understand, including how the changes may vary over time.
- Explain that the common bleeding changes are normal with these contraceptives. They are not harmful, and they are not signs of illness.
- Help each client consider how she would feel and what she would do if bleeding changes happened to her.
- Invite her to return any time that she has concerns.

## Help continuing clients manage bleeding changes caused by contraceptive use:

- In the first few months of use, explain that the changes probably will lessen with time.
- If the bleeding changes persist, or whenever a client asks, offer available treatments to relieve the bleeding.
- At any time a client finds bleeding changes unacceptable, help her choose a method that better suits her.

Additionally, providers can gain an understanding of cultural and social beliefs and behavior concerning menstruation. This knowledge can help providers be sensitive to their clients' attitudes towards contraceptive-related bleeding changes. To answer common questions that clients have about menstruation and the menstrual cycle, providers can refer to the INFO Reports issue, "Key Facts About the Menstrual Cycle." Full text of the report can be seen online at: <http://www.k4health.org/toolkits/info-publications/key-facts-about-menstrual-cycle>. This report presents information in a simple way, accompanied by illustrations that providers can use with clients.

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For more information: This brief is based on Population Reports, "When Contraceptives Change Monthly Bleeding: How Family Planning Providers and Programs Can Help Clients Choose and Use Suitable Methods," Series J, Number 54. Full text of the report can be seen online at: <http://www.k4health.org/toolkits/info-publications/when-contraceptives-change-monthly-bleeding-how-family-planning-provide-0>

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