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Implants: The Next Generation

How family planning programs and providers can prepare to provide new contraceptive implants

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Key Points

New contraceptive implants are becoming available to family planning programs around the world—the one-rod system *Implanon*®, the two-rod system *Jadelle*®, and in some countries *Sino-Implant (II)*®, also two rods. By 2008 *Norplant*®, the six-capsule implant system will no longer be available. Like *Norplant*, the new implants are highly effective at preventing pregnancy, and, like *Norplant*, they alter women's bleeding patterns. Their most important advantage over *Norplant* is easier and quicker insertion and removal.

- **Implants have advantages.** Implants are safe, highly effective, and quickly reversible long-term contraceptives that require little attention after insertion. Clients are satisfied with them because they are convenient to use, long-lasting, and highly effective. Continuation rates are high.
- **Programs should consider offering new implants.** The new implants offer the same benefits of the older system but are easier to provide. Programs may want to add the new implants to their method mix, and programs currently offering *Norplant* should plan for transition to a new implant.
- **Competency-based training works best.** It ensures that each provider gets enough training and supervised practice to insert and remove implants correctly. Training also covers counseling, which includes preparing clients to expect bleeding changes.
- **Demand appears high.** Evidence suggests that many more women would choose implants if they could.
- **Initial cost is high but is coming down.** Despite potential demand worldwide, use of implants is low, largely because the implants themselves are costly. Still, when implants are used for several years, they are relatively cost-effective compared with other methods. The prices that donors pay for implants have fallen recently. Strategies to address the high cost of implants must involve donor and government subsidies, expanding registration of a lower-priced implant, and sharing the cost with users.

See companion *INFO Reports*, "Implants: Tools for Providers"

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Injectables and Implants

USAID FROM THE AMERICAN PEOPLE

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Cover Photo: As part of a training of trainers in Madagascar, providers prepare to insert *Implanon* into a woman's arm. Insertion requires attention to infection prevention procedures, sterile conditions, correct placement of implants, and care to minimize tissue damage.

New Implants Can Expand Access

Family planning programs around the world are introducing the new one- or two-rod implant systems *Implanon*®, *Jadelle*®, and in some countries *Sino-Implant (II)*®. By 2008 *Norplant*®, the six-capsule implant system, first introduced in mid-1980s, will no longer be available. Like *Norplant*, the new implants are highly effective, and like *Norplant*, they alter bleeding patterns. Their most important improvement over *Norplant* is easier and quicker insertion and removal. *Sino-Implant (II)* may also cost much less than other implants.

The new implants are recommended for as much as three to five years of use, depending on the make. Thus they are particularly suitable for women who want to space births. Indeed, for many women implants are a convenient method. Once inserted into a woman's arm, the implants do not require any action by the user. Since implants do not contain estrogen, they do not decrease production of breast milk and thus are suitable for breastfeeding women. They are also a good choice for women who do not want more children but are not ready to opt for sterilization, which is permanent.

With new implants making the method easier to provide, more programs may want to begin offering implants. Programs currently offering *Norplant* will need to consider how to make the transition to the newer implants and to meet possibly greater demand.

What Is New About Implants?

The new contraceptive implants are small, thin, flexible plastic rods, each about the size of a matchstick, that release a progestin hormone, either levonorgestrel (*Jadelle*, *Sino-Implant (II)*) or etonogestrel (*Implanon*), into the body. The hormone prevents pregnancy by thickening the cervical mucus, which blocks sperm from meeting an egg, and by disrupting the menstrual cycle, including preventing ovulation—the release of an egg from an ovary. With *Implanon* the primary mechanism of action is the prevention of ovulation in most cycles. With *Jadelle* ovulation is prevented in about half of cycles. Implants do not interrupt an existing pregnancy (18, *19*, 31, 46, *47*, 55, 60, *69*, *124*).

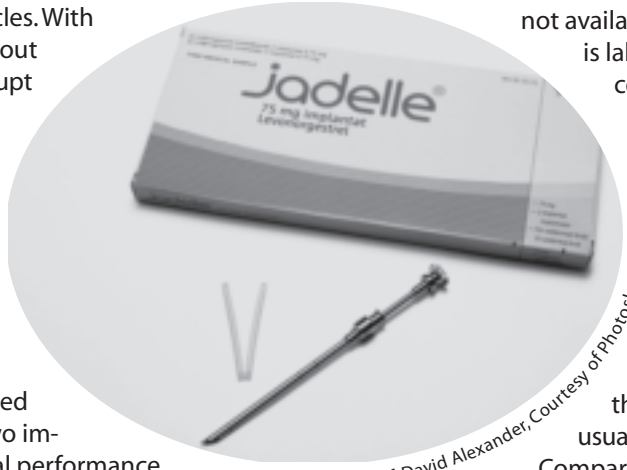
***Jadelle* and *Sino-Implant (II)* improve on *Norplant* for delivery of levonorgestrel.** *Jadelle*, developed by the Population Council and produced by Bayer Schering Pharma, shares many features with its predecessor *Norplant*. Randomized comparative trials show that the two implants are almost identical in clinical performance (*96*, *97*, *100*, *125*). *Jadelle* is a two-rod system, however, compared with *Norplant's* six capsules. Each rod contains 75 mg of levonorgestrel. *Jadelle* improves on *Norplant* by offering the same performance but also easier insertion and removal, and fewer complications associated with insertion and removal (94, *96*). Clients currently using *Norplant* can continue to use the method until it is time to get the capsules removed. *Norplant* is labeled for five years of use, but large studies have found that it is effective for seven years (*32*, *98*). *Jadelle* is labeled for up to five years of continuous use.

With new implants making the method easier to provide, more programs may want to begin offering implants.

The new implants can be inserted and removed very quickly —more quickly than *Norplant*—but the length of time needed depends on the skill of the provider as well as the number of rods (18, *19*, 31, 46, *47*, 55, 60). For experienced providers in comparative trials, inserting *Jadelle* took about an average of 2.5 minutes, compared with 4.8 minutes for *Norplant*. Removing *Jadelle* took 5 to 7.5 minutes, compared with 10 to 15 minutes for *Norplant* (*17*, *96*) (see Table 1, p. 5).

The World Health Organization's (WHO) Model List of Essential Medicines, as published in March 2007, includes a two-rod levonorgestrel-releasing implant (123). This inclusion is likely to create greater awareness of implants at the country level. Many countries base their national essential drugs list on WHO's Model List. (For more information, see http://www.who.int/medicines/publications/EML15.pdf.)

The Chinese two-rod implant system *Sino-Implant (II),* manufactured by Shanghai Dahua Pharmaceutical, has been available in China since the mid-1990s and has been registered for use in Indonesia since 2002. Like *Jadelle,* each rod contains 75 mg of levonorgestrel. Its clinical performance in terms of effectiveness and safety is comparable to that of *Norplant* (*25*, *57*). Insertion and removal times for *Sino-Implant (II)* are not available at this time. *Sino-Implant (II)* is labeled for up to four years of continuous use.



***Implanon* provides a one-rod option.** *Implanon*, a single-rod contraceptive implant developed by Organon, contains 68 mg of the progestin etonogestrel. Safety and effectiveness studies have demonstrated that *Implanon* is highly effective and that insertion and removal are usually fast and uncomplicated (*28*, 53). Compared with *Norplant*, *Implanon* was

How to Use This Report

This report can help family planning program managers to:

- Decide how to adopt new implants into their method mix.
- Prepare their staff to provide the new implants.
- Meet the demand for implants by assuring availability and good-quality services.

Providers can use the companion issue of *INFO Reports*, "Implants: Tools for Providers," to review the important elements of providing good-quality services to new and continuing users of implants. The issue of *INFO Reports* offers tools for counseling women and helping women use implants with satisfaction.

significantly quicker to insert and remove (*82*). Although complications are rare with both systems, fewer occurred with *Implanon* removals (67). Experienced providers inserted *Implanon* in an average of 1.5 minutes and removed the rod in about 2.7 minutes (see Table 1, p. 5). As the insertion procedure for *Implanon* is different from the other implants, training providers in proper insertion is essential (*69*).

Implanon is currently labeled for up to three years of continuous use. WHO is conducting a randomized clinical trial in seven countries to assess the clinical performance and contraceptive efficacy of *Jadelle* and *Implanon*. This will be the first large-scale study comparing the second generation of implants (75).

Implant Characteristics Important to Women

Contraceptive implants offer women many advantages that can suit their reproductive intentions and that make continued use easy (18, *19*, 31, 46, *47*, 55, 60, 113, *124*):

- **Highly-effective.** Implants are one of the most effective methods, comparable to intrauterine devices (IUDs), female sterilization, and vasectomy. Far fewer than one pregnancy per 100 users (five per 10,000) is expected during the first year of using levonorgestrel implants. A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using implants. Overall, in five years of *Jadelle* use, one pregnancy per 100 users can be expected. Similar rates have been found for *Sino-Implant (II)* (*25*). In three years of *Implanon* use, less than one pregnancy per 100 users can be expected (46, 113, *124*).
- **Convenient.** Once the implants are in place, no routine follow-up is required, and no action is required of the client until the implants need to be replaced (*122*, *124*).

Implants offer many advantages that can suit women and that make continued use easy.

- **Immediate return to fertility.** Once implants are removed, women can become pregnant as quickly as women who stop using nonhormonal methods.
- **Any side effects resolve immediately after removal.** In contrast with injectable contraceptives, the hormone does not remain in the body once the implants are removed. Therefore, any associated side effects will resolve shortly after removal.
- **Complications are few.** Few complications occur as a result of the insertion procedure. Rarely, infections occur at the insertion site. Most of these infections occur within the first two months after insertion. Expulsion of an implant is extremely rare. It most often occurs within the first four months after insertion and is often related either to infection or to incorrect insertion. Removal can sometimes be difficult, but this is rarely a problem if the implant was properly inserted and the provider is skilled at removal (*124*).
- **Suitable for nearly all women.** Nearly all women can use implants, including women who have or have not had children; are not married; are of any age, including adolescents; have just had an abortion, miscarriage, or ectopic pregnancy; are breastfeeding (starting as soon as six weeks after childbirth); have anemia; smoke cigarettes (regardless of age); or are infected with HIV or have AIDS, whether or not on antiretroviral (ARV) therapy. It is not certain whether ARV medications reduce the effectiveness of implants, but they are thought not to. Use of condoms would make up for any such reduction in the effectiveness of the implants. Usually, women who should not use implants include those who are breastfeeding and are less than six weeks since giving birth; have a current blood clot in deep veins of legs or lungs; have unexplained vaginal bleeding that requires evaluation; have breast cancer (currently or in the past); have severe liver disease, infection, or tumor; and currently use antiseizure drugs or rifampicin (*121*, *124*).

(For more information on the clinical characteristics of implants, see the companion *INFO Reports*, "Implants: Tools for Providers").

Continuation rates are high. Women who use implants tend to be satisfied, and continuation rates are high. A recent Cochrane Review found that the majority of women using contraceptive implants continued with the method long-term. Over 80% of women were still using their implant at two years (*82*). In clinical trials and observational studies in a number of countries, continuation rates for implants range between 78% and 96% at one year, and between 50% and about 86% at three years (*15*, *25*, *26*, *28*, 53, *57*, *95*, *96*) (see Table 2, p. 5). Continuation rates for *Norplant* and *Jadelle* are not significantly different (*82*). While there have been concerns that continuation may sometimes reflect difficulty finding removal services, the majority of implant users

Table 1. Comparing Implants

Common Trade Name	Formulation	Labeled Length of Use	Average Insertion Time[1]	Average Removal Time[1]	Registration	Bulk Public Sector Price[2]
Implanon®, manufactured by Organon	1 rod containing 68 mg etonogestrel	Up to 3 years	1.5 minutes (*69*)	2.7 minutes (*69*)	Registered in more than 40 countries.	US$19–$25
Norplant®, manufactured by Bayer Schering Pharma	6 capsules, each containing 36 mg levonorgestrel	Up to 5 years	4.8 minutes (*17*)	10 to 15 minutes (*17*, *96*)	Registered in more than 60 countries, but unavailable after 2008.	US$23
Jadelle®, manufactured by Bayer Schering Pharma	2 rods, each containing 75 mg levonorgestrel	Up to 5 years	2.5 minutes (*17*)	5 to 7.5 minutes (*17*, *96*)	Registered in more than 50 countries.	US$21–$27
Sino-Implant (II)®, manufactured by Shanghai Dahua Pharmaceutical	2 rods, each containing 75 mg levonorgestrel	Up to 4 years	Data not available	Data not available	Registered in China and Indonesia. Registration underway in Egypt and other African countries.	US$4.50–$7.50

[1]As measured in clinical trials [2]As of September 2007

Table 2. Continuation Rates for New Implants

Percentage of Women Keeping Their New Implants for One to Five Years, Selected Studies

Authors, Date (Reference Number)	Type of Study	Implant	Country	Number of Women Starting Implants	% Continuing to Use at… 1 Year	2 Years	3 Years	4 Years	5 Years
Kiriwat et al., 1998 (53)	Pilot project/ observational study	*Implanon*	Thailand	100		87	75	72	
Flores et al., 2005 (*28*)	Clinical trial	*Implanon*	Mexico	417	78	67	61		
Chaovisitsaree et al., 2005 (*15*)	Prospective observational study	*Implanon*	Thailand	92	92				
Sivin et al., 1997 & Sivin et al., 1998 (*96*, *100*)	Randomized clinical trial	*Jadelle*	6 countries	600	94	82	71	63	55
Sivin et al., 1998 (*95*)	Clinical trial	*Jadelle*	Dominican Republic & United States*	594	83	66	50	37	27
Liu et al., 1999 (*57*)	Prospective observational study	*Sino-Implant (II)*	China	315			80		
Fan et al., 2004 (*25*)	Randomized clinical trial	*Sino-Implant (II)*	China	1,000	96		86		68
Fang et al., 1998 (*26*)	Clinical trial	*Sino-Implant (II)*	China	9,934		90			

*Some women in this study may also be represented in the six-country *Jadelle* study in the row above *(96, 100)*

Table 3. Estimated Worldwide Use of Implants

Among Women Ages 15–49 (Married or In Union), 2005

Region	% Currently Using: Any Method	Any Modern Method	Implants
DEVELOPING AREAS	**58**	**52**	**0.4**
Sub-Saharan Africa	21	15	0.2
Near East & North Africa	52	40	0.1
Asia	63	59	0.5
Latin America & Caribbean	71	62	0.1
DEVELOPED AREAS	**68**	**56**	**0.2**
Europe	74	64	0.0
Eastern Europe & Central Asia	63	42	0.0
North America	75	71	0.9
Other Developed*	59	54	<0.1
WORLD	**59**	**53**	**0.3**

*Includes Australia, Israel, Japan, and New Zealand

Methodology and data sources: Country usage rates from United Nations, 2005 (115) are weighted by the size of the population of women ages 15–49, obtained from population projections for 2005 by the World Bank (120).

Which New Implant to Introduce?

The entry of new contraceptive implants and the exit of *Norplant* leaves family planning programs to decide whether to add one of the new implants to their method mix and if so, which one to introduce—*Jadelle*, *Implanon*, or *Sino-Implant (II).* Increasing or maintaining the range of methods offered is important because, when more methods are available, people are more likely to find a method that suits them (89). Where *Norplant* has been an important method, clients will expect an alternative implant to replace it. Such decisions are often made at the national level, by the ministry of health or national family planning program, or at the program level by program managers. If more than one implant is already in the country, local programs will probably want to decide on one implant to offer. Experience with injectable contraceptives finds that carrying multiple types of injectables complicates forecasting, distribution of supplies, training, and service delivery (44, 56, 85, 92).

Programs evaluate a variety of factors in deciding which implant to introduce. First comes regulatory approval. An implant already approved will be fastest to incorporate into programs. If another implant provides comparative advantages, however, starting the process to obtain regulatory approval can be appropriate. If none of the new implants has regulatory approval, programs consider the comparative ease of the approval process. Often *Jadelle* is easiest to approve because it is based on *Norplant,* which has already received approval in many countries. Currently, both *Jadelle* and *Sino-Implant (II)* meet the criteria for a two-rod levenorgestrel-releasing implant in the World Health Organization Model List of Essential Medicines (123). This, too, should help speed approval of these implants. At the same time, approval of *Implanon* may be just as straightforward. Many countries rely on U.S. or European regulatory approval as a guideline (119), and both *Jadelle* and *Implanon* have received regulatory approval in the United States and many European countries.

The second factor programs must consider is cost. Currently, *Sino-Implant (II)* is the cheapest implant available. At US $4.50-$7 per unit, several African countries are choosing to introduce this implant into their programs (see p. 18). Currently, *Implanon* is just slightly cheaper than *Jadelle* on a per-unit basis, but with large bulk orders, the total cost difference could be substantial. Programs must consider cost-effectiveness within the service delivery system as well. Does the longer, five-year active life of *Jadelle* make it more cost-effective than *Implanon*, which lasts three years? Any such comparison would need to incorporate the proportion of users who would actually keep the implants for longer than three years if it were an option.

Third, programs must consider service delivery issues, including training and support for providers. For programs that have substantial experience providing *Norplant*, it may be easiest to shift to *Jadelle*. Experience in the Dominican Republic (*12*) and Ghana (78) demonstrates that such a transition is smooth and easy, requiring only brief additional training of providers. Transition to *Implanon* can be easy, too. Organon, which produces *Implanon*, provides substantial support in countries introducing *Implanon*, including training of trainers programs (90). In Tanzania the Ministry of Health and Social Welfare, the ACQUIRE Project, and Organon are collaborating to train providers in *Implanon* insertion and removal. In 2006 and 2007 some 150 providers received training, and some 12,000 women had *Implanon* inserted (78).

Family planning programs will need to consider these factors and others in deciding which new implant to offer. A strategic approach to introducing a new method will improve the overall quality of family planning programs in addition to increasing users' contraceptive choices (*93*, *104*). For more information on introducing a new contraceptive method, see the World Health Organization's *Making Decisions About Contraceptive Introduction*, available at http://www.who.int/reproductive-health/publications/contraceptive_introduction/index.htm.

have had no problems getting their implants removed and acceptability studies find that women using the method over many years have been satisfied with the implants (*96*).

Use Could Increase if Barriers Overcome

Worldwide, the level of implant use is low (see Table 3, p. 5). In spite of over 25 years of development, refinement, and introduction in family planning programs around the world, contraceptive implants have failed to gain wide use. The largest barrier to implant use is the high cost of the method. As a result, few programs and clinics are able to offer the method and, among those who do, stock-outs are frequent (36, *42*, 60, *74*).

The costs of contraceptive implants, however, have fallen in the past few years and are likely to continue falling. Wholesale prices for bulk orders of *Jadelle, Implanon* and *Sino-Implant (II)* have been as low as US$21, US$19, and US$4.50 respectively. Continued support from donors and subsidized prices can make it easier for programs to provide implants. (For more information on cost issues, see p. 14.)

There is concern that overall costs of a family planning program will rise if it introduces implants. The cost of implants could be weighed against their potential to reduce unintended pregnancies, however (*47*). In a recent assessment using data from Kenya, researchers used a previously published simulation model to estimate the annual number of unintended pregnancies with implant use compared with the number of unintended pregnancies with oral contraceptive use. The simple exercise estimated that, if 100,000 users of oral contraceptives switched to implants, an estimated 26,000 unintended pregnancies would be prevented over a five-year period (*42*).

Providing implants requires planning. Because implants are a "provider-dependent" method, introducing or expanding implant services requires that programs have the capacity to deliver the method appropriately. This includes

having the equipment and facilities needed to provide implants, staff trained to perform insertions and removals and to counsel both new and continuing clients, as well as a well-functioning logistics system to maintain the supply of implants and other contraceptive methods (60) (see p. 8).

Because the new implants are easier to insert and remove than the six-capsule *Norplant* system, family planning programs that have provided *Norplant* should be able to switch quickly to providing the new implants. There may be a period of unavoidable overlap as a program continues offering *Norplant* while introducing newer implants. This overlap could complicate training and counseling. In addition, providing implants with different durations of action requires attention to appropriate counseling for each method and keeping careful records of which implant a woman has. Programs need to take these and other factors into account when deciding which implants they are going to offer and when (see box, p. 6). A clinic in the Dominican Republic serves as an example of switching successfully from *Norplant* to *Jadelle* (see Spotlight, below).

SPOTLIGHT

From *Norplant* to *Jadelle*: Smooth Transition in a Dominican Republic Clinic

PROFAMILIA, a private nonprofit clinic in Santo Domingo, Dominican Republic, had been routinely providing *Norplant* for 30 years when it successfully switched to *Jadelle* in 2002. The clinic was eager to start providing the new implant because *Jadelle* is quicker to insert and remove than *Norplant*, has fewer complications with removal, and is less visible in the arm.

During the transition researchers studied the acceptability of *Jadelle* to clients and providers. The clinic offered both *Norplant* and *Jadelle* to all clients at the same subsidized price of about US$30. The clinic's staff learned to provide *Jadelle* quickly and easily. Initially, some clients were hesitant to use an unfamiliar product. PROFAMILIA has now stopped offering *Norplant*, however, and its clients are satisfied with *Jadelle* as an alternative.

The study findings suggest that, especially where *Norplant* is well-known and liked, counseling clients about the comparative advantages of the new implants is necessary. This counseling led some women to choose *Jadelle.* Others, however, still preferred *Norplant,* while it was available. Once PROFAMILIA stopped offering *Norplant*, counseling was very effective in helping *Norplant*-seeking clients accept *Jadelle*.

Providers Adapted Quickly and Overwhelmingly Preferred *Jadelle*

Because the PROFAMILIA providers were familiar with *Norplant*, they needed little training to start offering *Jadelle*. The staff members attended a one-hour training followed by a question-and-answer session conducted by one of the researchers. The researcher discussed the two implants in terms of effectiveness, adverse events, continuation and termination rates, mechanism of action, and hormone levels in the blood. The researcher also explained insertion and removal procedures but did not perform either a live demonstration or use a model arm.

The majority of the providers were satisfied with this training. One-third would have liked an actual demonstration of insertion and removal as well. Still, none of the providers felt that the lack of a demonstration limited their ability to insert the new implants. A clinic supervisor reported that the staff became comfortable with *Jadelle* "immediately."

After providing the new implant for 18 months, the providers almost unanimously preferred *Jadelle* over *Norplant*. They favored *Jadelle* because fewer rods made insertion and removal easier.

Some Clients Hesitant to Choose an Unfamiliar Product

At the PROFAMILIA clinic some women were more comfortable with the method that was well-known and recommended by friends and family, even when an alternative was available. Since there had been little local promotion of *Jadelle*, most women were unfamiliar with it. Providers explained to clients that inserting and removing *Jadelle* is quicker, but that *Jadelle* needs to be replaced after five years, while studies have shown that *Norplant* is effective for seven years. After hearing this information as well as receiving it on a printed sheet, each client chose the implant that she preferred. Nearly half of the clients chose *Norplant*. The most common reason cited for this choice was that *Norplant* had been recommended by a friend, relative, or provider. More than 40% of the women who chose *Norplant* mentioned that it is better known. Another 15% mentioned that it is registered in the country. Less than 15% said they preferred *Norplant* because it lasts longer, which is in fact its only potential clinical advantage over *Jadelle*.

Slightly more than half of the clients chose *Jadelle*. Their most common reason was the fewer number of rods, followed by easier insertion and removal and less visibility in the arm.

Because almost half of the clients chose *Norplant*, the researchers initially concluded that providers should continue to offer it while making the transition to *Jadelle*. While this might ensure that women are comfortable with their contraceptive options, recent experience suggests that it may not be necessary. PROFAMILIA no longer offers *Norplant*. When clients request it, the provider explains the differences between *Jadelle* and *Norplant* and says that *Norplant* is no longer available. A clinic supervisor noted that virtually all clients accept *Jadelle* after receiving this counseling rather than choosing a different contraceptive method or declining contraception altogether.

Counseling alone will not persuade every client to choose an unfamiliar product, but it is important to give women complete and comparative information. Inadequate counseling may cause women to avoid a new product for the wrong reason. For example, nearly 9% of those who preferred *Norplant* chose it for the greater number of capsules, incorrectly reasoning that the additional capsules make it more effective. Thorough, clear counseling on the characteristics of new implants is essential to avoid such misperceptions and to help women make well-informed choices.

Sources: Brache, 2007 (11); Brache, 2006 (*12*)

Preparing to Offer New Implants

Good implant services require a competent and well-prepared staff that can perform insertion and removal procedures and can help clients make an informed choice about implants. Programs can prepare providers to insert and remove implants through competency-based training. Providers can help clients interested in implants by: counseling them about side effects with an emphasis on bleeding changes; screening clients using the World Health Organization (WHO) Medical Eligibility Criteria; describing and answering questions about insertion and removal; and determining whether the client can have implants inserted immediately. Programs should also make sure they can assure women's access to removal services.

Who Can Provide Implants?

Many different cadres of health care professionals can safely provide implants if they are thoroughly trained. These include nurses, nurse-midwives, nurse-practitioners, midwives, physicians, and, depending on educational and professional standards in each country, physician's assistants and associates (*16*, 60, *124*). Training a wide variety of health care professionals spreads awareness of implants and increases access to services (23, 30, 52, 79, 84, 103).

Good implant services require staff competent to insert and remove implants and to counsel clients.

Where only physicians can insert and remove implants, access to implants is unnecessarily limited. For example, when implant services were first introduced in Ghana, only doctors had been trained to provide implants. As a result, women seeking implants often encountered long waiting times or found that the doctor was unavailable. EngenderHealth and the Ghana Ministry of Health collaborated to train a large group of nurses in implant insertion and removal and in related counseling. This effort contributed to a tenfold increase in the number of women using implants in Ghana (see Spotlight, p. 9).

Competency-Based Training Helps Providers Learn By Doing

Competency-based training develops the skills, knowledge, and attitudes required to meet standards of competence. Training continues until each trainee is competent to provide implant services, and satisfactory completion of training is based on the achievement of all the specified competencies (108). Competence is defined as the point at which the trainee knows the steps in their sequence and can perform the required skill or activity (8). The approach focuses on the success of each trainee, recognizing that different providers need different amounts of practice to reach competence (*16*, 108). Although insertions and removals of implants are minor surgical procedures, experience in *Norplant* programs has shown that a formal competency-based training program, using model arms and supervised practice, leads to proficient and confident providers (9, 13, 38).

Many different cadres of health care professionals can safely provide implants if they are thoroughly trained.

Information and communication technology (ICT) tools can deliver some aspects of competency-based training. Computer-based training offers a new means of self-education (7). Computers enable participants to control the pace and flow of their learning. Organon, the maker of *Implanon*, has developed a number of computer-based ICT training tools. For example, a CD-ROM on insertion and removal techniques not only includes slides presenting relevant technical information, but also offers videos of actual insertions and removals (see box, p. 11).

Providers in Indonesia practice inserting Norplant *implants in a model arm. Providers later go on to perform actual insertions under supervision until they demonstrate competence.*

SPOTLIGHT

Training Nurses Increases Implant Use in Ghana

Between 1998 and 2003 more than 600 nurses in Ghana received training to provide *Norplant* implants (84, 103). Now more than 88,000 women have used or are using implants (*47*). Training nurses, as well as some doctors, was crucial to increasing access to implants and reducing waiting times for clients (23). The large number of providers trained to provide *Norplant* will make it easier for Ghana to start providing the new implants. The Ghana Health Service collaborated with EngenderHealth, a technical assistance organization, to carry out the training. The U.S. Agency for International Development (USAID) provided funding and supplies.

Ghana's previous policies implied that only doctors could insert implants. As a result, women seeking implants often encountered long waits or found that the doctor was unavailable. EngenderHealth staff documented these difficulties, and this helped to convince policy makers to clarify the guidelines in 1996. Ghana's national family planning guidelines now explicitly permit nurses to provide implants (23, 103).

The training was directed to nurses instead of doctors because more nurses were available, nurses were more likely to stay in their communities, and nurses were more motivated to learn insertion and removal procedures. By comparison, doctors tended to have too much to do and were less interested in learning implant procedures (79). Initially, only a few doctor/nurse teams received training each year, starting in 1994. Widespread training of nurses started in 1998, after Ghana clarified its policies (23).

By building training capacity within Ghana's health system, EngenderHealth and the Ghana Ministry of Health sought to assure that the training effort would be sustainable. EngenderHealth trained Ghana Health Service staff, who, in turn, trained providers to insert and remove *Norplant* (23).

In addition to teaching technical skills, the Ghana Health Service trained an even larger number—almost 2,800 nurses—in counseling and interpersonal communication skills for all family planning methods, including implants (23). As a result, a national survey found that providers encouraged new clients to ask questions or share concerns about methods during 71% of visits in 2002, compared with 31% of visits in 1993 (41).

The Ghana Health Service also promoted facilitative supervision, an approach that emphasizes mentoring, joint problem solving, and two-way communication between the supervisor and those being supervised. By playing a supportive, friendly role, supervisors helped providers improve various skills. For example, at first only 25% of providers said that their supervisors examined records and gave feedback, or observed them providing services. After the training this increased to 75% for both indicators (23). One supervisor summarized, "People are now happy to see me and no longer try to hide away…. We sit down and discuss issues. I make suggestions on how staff can solve their problems" (48).

Following the training, many more facilities offered implants, and 88,000 women had implants inserted (*47*). The number of facilities offering *Norplant* grew from 23 in 1994 to 168 by 2002 (23). The percentage of women of reproductive age using implants across the country increased from 0.1% in 1998 to 1.2% in 2006 (*47*).

Ongoing Challenges Include Staff Turnover and Stock-Outs

Training is an ongoing effort. In 2003 the trainers began to conduct refresher courses in *Norplant* removal (84). Depending on the caseload in a particular clinic, providers sometimes do not get enough practice performing removals to maintain their skills. Also, many providers leave the country or stop practicing, taking their new implant skills with them. Between 1996 and 2002 the number of doctors and nurses in Ghana decreased by 17% and 24%, respectively (23). As staff turnover occurs, trainers can educate the new staff, sometimes with on-the-job training, when courses are not possible (51).

Ensuring a constant supply of implants is another challenge. The Ministry of Health of Ghana recognized the importance of reliable supplies and earmarked a small amount of its budget for *Norplant*, beyond USAID's contributions (79). Still, problems with distribution and ordering have led to local shortages. In 1998 there were stock-outs of *Norplant* in almost every region (23). In 2002, while 17% of the facilities that provide family planning services in Ghana offered implants, almost one-third of these did not have implants available on the day that they were surveyed (30) (see p. 14).

Emerging challenges include funding and training for the transition to one or more of the new implants. *Norplant* will soon be discontinued, and USAID funding for Ghana's national family planning program ended in 2004, although some district-level funding continues (51, 79). In 2005 the Ghana Food and Drug Board approved *Jadelle* (84). The trainers received training in *Jadelle* in early 2007. In several regions trainers are now training providers to offer *Jadelle*. The Ghana Health Service is making plans for the transition to *Jadelle* in other regions (51). For the short term Ghana has secured funding from other donors to purchase *Jadelle*, but the need for support will continue (79).

Many African Women Will Choose Implants When Available

Attempts to introduce implants in Africa have often failed because trained providers, adequate supplies, and awareness of implants have been lacking (79). Levels of use remain low in most of Africa. In countries such as Ethiopia, Kenya, and Tanzania, however, implant use is increasing (14, *42*, 78). The experience of Ghana and other countries shows that many African women will choose implants when there are trained providers and implants available.

Training to insert *Jadelle, Sino-Implant (II)*, and *Implanon*. Training for insertion requires attention to infection prevention procedures under sterile conditions, correct placement of implants, and care to minimize tissue damage. The rods are inserted just under the skin of the inner side of the upper arm.

With *Jadelle*, the rods are loaded in a reusable hollow needle, called a trocar. Preloaded disposable inserters are available in a few countries. The clinician injects a local anesthetic into the woman's arm and makes a small incision—about 3 mm long—using a scalpel or the tip of the trocar. The rods are placed, one at a time, to form the shape of a V opening toward the shoulder. Alternatively, the trocar is used to puncture the skin and insert the rods, without the need for an incision. The procedure should take only a few minutes. Usually, the incision or puncture does not require stitches. A small adhesive bandage and protective gauze bandage are all that are necessary (*99*). *Sino-Implant (II)* is inserted in the same way as *Jadelle*.

Implanon comes packaged in a specially designed applicator. The provider identifies the location for insertion on the inner side of the upper arm. After injecting local anesthetic, the provider uses the pre-loaded applicator to puncture the skin and place the single implant under the skin (67, *69*) (see companion *INFO Reports*, "Implants: Tools for Providers," pp. 8–9). Gauze or a pressure bandage minimizes bruising.

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An Implanon *rod is inserted just below the skin of the upper arm. If implants are placed properly, removal usually is not difficult.*

Learning proper placement and removal requires practical, hands-on training. If an implant is not placed properly, removal may be difficult. Providers train for insertion on an artificial arm and later perform actual insertions under supervision until they can demonstrate competency (73). A study in Indonesia found that providers who were trained to practice on a model arm before performing supervised procedures with clients were more competent at insertions and removals than those who went directly from the classroom to performing actual insertions (10). Providers who are familiar with inserting and removing *Norplant* adapt quickly to the new implants (*12*). Providers who are new to providing implants need more training.

Training to remove *Jadelle, Sino-Implant (II),* and *Implanon*. Most removals are not difficult, but removal usually takes longer than insertion. Because the new implants have fewer rods, removing *Jadelle, Sino-Implant (II)*, or *Implanon* implants takes considerably less time than removing *Norplant*.

There are two most commonly used techniques for removing new implants. With the "pop-out" technique, the provider first feels the site to be sure she can locate the implant(s) underneath the skin. The provider then makes a small incision at the lower (distal) end of the implant, pushes the implant gently towards the incision until the tip is visible, and then removes it with forceps (54, *69*, *99*). The "U" technique (named after its developer Dr. Untung Praptohardjo) was developed for use when *Norplant* proved difficult to remove and also to make routine removals easier. The technique involves the use of an oval-ring-tipped forceps with an internal diameter of 2.2 mm to reach through a 4-mm incision to firmly grasp and remove each of the *Norplant* capsules. This technique is recommended for removing *Jadelle* as well (54, 58, 83).

Ongoing removal training is essential. Every user of implants should be able to have the implants removed whenever she wishes, including when the end of their recommended lifespan has been reached. To make this possible, there must be sufficient numbers and broad geographical distribution of providers trained in implant removal. As with training in insertion, training in removal starts with using the model arm, followed by closely supervised practice with actual clients. It can take time to gain clinical experience in removals, however. Early in a program, at least, many more women are having implants inserted than are asking to have them removed (84). Thus, over the years, ongoing training in removal, with refresher courses, is important. Providers can practice removals on anatomical models and watch videos of live removals. If it is not practical to keep up all providers' skills for implant removal, an alternative is training a core group of providers, giving them continued support and guidance, and referring clients to these providers for removals.

Helping Clients Make an Informed Choice

Counseling users of implants on what to expect can be as important to the client's satisfaction as proper insertion and removal techniques (*16*, *99*, 112). If the client is interested in implants, the provider should:

- Counsel the client about possible side effects, particularly bleeding changes,
- Screen the client, using the WHO Medical Eligibility Criteria,
- Describe and answer questions about the insertion and removal procedures (see box, p. 13), and
- Determine whether she can have the implants inserted immediately.

Counseling clients about side effects. Like some users of all other hormonal contraceptives, some users of implants report side effects such as weight gain, headaches, acne, and mood changes, but bleeding changes are the most common reason that women cite for discontinuing implants (*28*, 40, 53,

Information and Communication Technology Supports Implant Programs

Family planning programs with access to computers and Internet services can use information and communication technology (ICT) to help them introduce and manage contraceptive implants.

ICT Tools Can Help Train Providers in Implant Provision

A number of organizations have developed computer-based tools to help train providers in implant provision. These tools help providers develop competence with implant insertion and removal, improve their knowledge about the types of implants, and develop counseling techniques to help clients with continued use.

Organon. Where *Implanon* is available, Organon has held training programs to familiarize health care providers with all aspects of its use. Participants have the opportunity to practice insertion and removal techniques under professional guidance. In addition, Organon has developed numerous computer-based training materials in English, French, and Arabic. A CD-ROM with a PowerPoint presentation about *Implanon* gives a detailed scientific overview of the method. An accompanying clinician's manual and product monograph cover these topics in more detail. Another CD-ROM provides an animated display of the anatomy of the arm where the implant should be placed and insertion and removal demonstrations, including both correct and incorrect insertions. Videos show actual insertion and removal procedures and how to locate hard-to-find implants with ultrasound (67, *68*, *69*, 70, 71, 72, 73). For additional information, see http://www.implanon.md. For more information in French, see http://www.contraception.organon.fr.

Bayer Schering Pharma. Bayer Schering Pharma works locally with family planning programs around the world, offering support and technical expertise in providing *Jadelle*. The training programs use a CD-ROM showing both actual and animated insertion and removal procedures. A PowerPoint presentation on *Jadelle* for trainers and providers gives a detailed scientific overview of the method. All trainees receive a *Jadelle* Insertion Training Kit, which includes a card to help measure exactly where the rods should be placed in the arm, scalpel, trocar, forceps, and other supplies. A training manual and product monograph offers detailed information on the clinical profile of the method, bleeding characteristics, and insertion and removal techniques (4). To request materials, contact Bayer Schering Pharma Oy, PO Box 415, FI-20101 Turku, Finland.

JHPIEGO. JHPIEGO's Internet resource collection Reproline contains a section dedicated to *Norplant*. The *Norplant* Web site offers information about the method, service delivery guidelines, and a PowerPoint presentation that gives a thorough overview of the method. The site also offers a PowerPoint presentation on managing bleeding problems, checklists for providers, and materials for training courses. The *Norplant* materials on the Web site are ready-to-use resources for clinical trainers and resource managers. These resources can be used as visual aids or additional references for training, and they can be modified, adapted, and translated into local languages. The Web resources can be used in conjunction with a paper-based learning resource package that contains a reference manual and participant's and trainer's handbooks. As of August 2007 JHPIEGO is updating the Web site to reflect revised medical eligibility criteria as well as recent findings on effectiveness. These materials are also available on a CD-ROM (59). See http://www.reproline.jhu.edu/english/1fp/1methods/1ni/ni.htm.

Baylor College of Medicine. The Baylor College of Medicine provides a free online continuing medical education (CME) course on *Implanon*. The course covers the characteristics of the implant, common myths, and the benefits and side effects of the method. The course is presented in a PowerPoint format and is followed by a post-test (81). See http://www.contraceptiononline.org/slides/talk_cme_activity.cfm?tk=28&cmepage=cme_info.

Forecasting Tool Helps With Decision-Making

When countries and family planning programs consider adding contraceptive implants into their method mix, they should assess whether they have the capacity to deliver the method appropriately (60). The ACQUIRE Project has developed a planning package of evidence-based tools and approaches. The package includes Reality Check, a forecasting tool that helps national and district level staff to project family planning needs and plan realistically to meet them. Projecting contraceptive prevalence rates for each method is essential both to evaluate current efforts and to make plans for the future. This tool can be useful for considering the introduction of new implants. For example, Reality Check could forecast future levels of implant use, commodity needs, and costs of implants at the district and site level. This can help program managers assess whether they have the resources to meet the needs forecasted by Reality Check (1, *80*, 101, 110). For additional information contact the ACQUIRE Project at info-acquire@acquireproject.org.

Computer-Based Tools Help Manage Supply

To ensure a smooth introduction or transition to new implants, maintaining sufficient supplies is essential. Pipeline Monitoring and Procurement Planning System (PipeLine), a PC database application developed by USAID through the DELIVER Project at John Snow Inc., generates the information needed to ensure timely receipt of products and to maintain consistent stock levels at the national and program level (50).

Basic computer skills are all that are required to use PipeLine. For each product, PipeLine tracks rate of consumption, shipments of new products, inventory levels, and inventory changes. Graphic displays help managers to estimate supply requirements. The program can predict pipeline problems, including shortfalls, surpluses, or stockouts (50). This tool can be useful for planning implant procurements. The PipeLine software can be downloaded directly from the DELIVER Project Web site at http://www.deliver.jsi.com. To request a copy of the PipeLine CD-ROM, email deliver_pubs@jsi.com.

95, *96*, *99*, *100*, 102, *125*). A client who knows about possible side effects beforehand is more likely to keep using a method even if side effects occur (36, 118). In Indonesia users of *Norplant* implants who were more knowledgeable about the method and about potential bleeding changes were more satisfied with the method than those who had less knowledge. In the province with the greatest differences in levels of satisfaction, 98% of women with a high level of knowledge about the method were satisfied overall compared with 33% of women with a low level of knowledge (109). Similarly, in a *Norplant* study in Senegal, women who perceived their counseling to be "thorough"—that is, counseling included discussion of side effects and of other contraceptive options—were less likely than other women to discontinue use of implants when bleeding changes did occur (112).

Among the various side effects associated with implant use, bleeding changes can be particularly upsetting, especially if providers do not tell women about them and explain them in advance (111, 112). Providers should tell clients that, especially in the first year of using levonorgestrel implants, changes in bleeding patterns can include lighter bleeding and fewer days of bleeding, frequent irregular bleeding, prolonged bleeding or spotting that lasts more than eight days, infrequent bleeding, or no monthly bleeding. After about a year of use, bleeding changes typically include lighter bleeding and fewer days of bleeding, irregular bleeding, and infrequent bleeding. Users of etonogestrel implants are more likely than levonorgestrel users to experience infrequent or no monthly bleeding (*28*, 40, 53, *95*, *96*, *99*, *100*, 102, *124*, *125*).

In Madagascar a woman considers choosing Implanon *with the help of a family planning provider. Good counseling includes helping the client decide whether implants are right for her, discussing possible changes in menstrual bleeding, and describing the insertion and removal procedures.*

Providers can explain that bleeding changes are usually harmless and not likely to indicate a serious underlying condition. Usually, the bleeding changes gradually diminish. Every client should understand that she is welcome to come back to consult with the provider at any time. If the bleeding changes are not acceptable to the client, she should always have the option of switching to another, more appropriate method (*124*) (see companion *INFO Reports,* "Implants: Tools for Providers," p. 7).

Screening clients with the Medical Eligibility Criteria. Before a client can begin using implants, WHO recommends that a provider ask a client about medical conditions that could affect implant use (*121*). Using a checklist, a provider can ask a woman if she knows she has certain medical conditions—conditions that would make another method preferable (see companion *INFO Reports,* "Implants: Tools for Providers," p. 4). A pelvic exam, blood tests, breast examination, and cervical cancer screening are not needed to decide whether a woman can use implants, although they may be helpful for other reasons. They should never be required for implant use.

Can a client start implants immediately? A woman can start using implants any day of the menstrual cycle if it is reasonably certain that she is not pregnant. For example, a client who has regular menstrual cycles can begin implants within seven days after the start of her monthly bleeding (five days for *Implanon*). If it is more than seven days after the start of her monthly bleeding (more than five days for *Implanon*), she can have implants inserted if it is reasonably certain for other reasons that she is not pregnant—for example, if she has not had intercourse since her last monthly bleeding. She will need to abstain from sex or use a backup method for the first seven days after insertion. Also, if a woman is fully breastfeeding and her monthly bleeding has not returned, she can have levonorgestrel implants inserted any time between six weeks and six months after giving birth (*124*). Organon specifies that *Implanon* can be inserted 21 to 28 days after delivery without need for backup. If it is inserted later, a woman should use a backup method for the first seven days after insertion (*69*). (For more information on when to start implants and a checklist to help assess whether it is reasonably certain a woman is not pregnant, see *Family Planning: A Global Handbook for Providers* at http://www.fphandbook.org.)

Access to Removal Services Is Necessary to Good Quality of Care

Access to services for implant removal could strongly influence public perceptions of implants. Providers could be considered coercive if women cannot have implants removed when they want (43, 112). While the majority of *Norplant* users have had no problems getting their implants removed, some women have faced barriers. For example, clients have reported high prices charged for removal. One woman in Ghana who could not afford the cost said, "I have been here

What Clients Should Know About Insertion and Removal

A client who has chosen implants needs to know what will happen during the insertion and removal procedures. Explaining the following important steps in the procedures tells the client what to expect (67, *69,* 99, *124).*

Insertion:	Removal:
1 The woman receives an injection of local anesthetic under the skin of her arm to prevent pain while the implants are being inserted. This injection may sting. She stays fully awake throughout the procedure.	1 The woman receives an injection of local anesthetic under the skin of her arm to prevent pain while the implants are being removed. This injection may sting. She stays fully awake throughout the procedure.
2 For *Jadelle* and *Sino-Implant (II)*, the provider makes a small incision and inserts the implants just under the skin. Alternatively, the provider uses the trocar to puncture the skin and insert the implants, without the need for an incision. The woman may feel some pressure or tugging during insertion. With *Implanon*, there is no incision. The provider uses a special insertion applicator with a needle that punctures the skin and inserts the implant.	2 During removal the provider makes a small incision and uses an instrument (forceps or small tongs) to pull out each implant. The woman might feel some pressure or tugging and slight pain during the procedure and for a few days after.
3 After either procedure the provider closes the incision with an adhesive bandage. Stitches are not needed. The incision is covered with a dry cloth, and the arm is wrapped with gauze. Alternatively, two adhesive bandages can be used, one crossed over the other over the incision.	3 After removal the provider closes the incision with an adhesive bandage. Stitches are usually not needed. An elastic bandage may be placed over the adhesive bandage to apply gentle pressure for two or three days and keep down the swelling.
4 After implant insertion a provider tells the woman when she should return to have the implants replaced or else removed in favor of another method. She may be given a reminder card listing the type of implant she has, the date of insertion, the month and year when the implants will need to be removed or replaced, and where to go if she has problems or questions.	4 If a woman wants new implants immediately after her current implants are removed, they can be placed above or below the site of the previous implants or in the other arm. With *Implanon*, the incision that was made for removal can also be used to insert the new implant.
5 After insertion she should keep the insertion area dry. She can take off the elastic bandage or gauze after two days and the adhesive bandage after five days.	5 Return to fertility is immediate, so inform the client that if she does not get another implant or use another method, she could get pregnant immediately after removal.
6 After the anesthetic wears off, her arm may be sore for a few days. She also may have swelling and bruising at the insertion site. This is common and will go away without treatment.	
7 The contraceptive effect starts within 24 hours.	

three times, and the nurse told me to bring 50,000 Cedis" (about US$5.75) (30)—a fee that was over five times the minimum daily wage in Ghana in 2003 (116).

In an Indonesian study of 3,000 *Norplant* users in the 1990s, 8% still had their implants beyond their prescribed lifespan of five years. One-fourth of this 8% said that they never had the implants removed because the cost was too great. Among the women who had their implants removed, 9% reported having to make two or more requests (*27*). In Bangladesh 52% of *Norplant* users studied in the 1990s had to request removal two or more times. Some women were told that the doctor was too busy or that the implant could not be removed until at least five years of use. In a few cases clients removed the implants by themselves (*37*).

Every user of implants should be able to have the implants removed whenever she wishes.

Clinics that offer implants should develop and communicate a clear policy on removal that states the following:

- When a woman wants her implants removed, she should be able to have them removed promptly and free of charge, without undue waiting, regardless of where or when the implants were inserted.

- A woman should not feel pressured to keep her implants. They should be removed whatever her reason, whether it is personal or medical.

All staff must understand and agree that women must not be pressured or forced to continue using implants. Clinics that do not have staff trained to remove implants should arrange to refer women to convenient services elsewhere. Providers can explain the policies to clients during counseling before they decide on implants.

Reminders. Many clients need help to remember when their implants should be removed. In the study of *Norplant* removals in Indonesia, about 38% of women remembered on their own when the time came to have them removed. Some 13% were reminded by a family member or another user, and 49% were reminded by a family planning worker (*27*).

Clinics can develop systems for notifying users when to have their implants removed or replaced. Follow-up in many situations can be extremely difficult, but most programs give clients reminder cards to keep with other important documents. A notation on a client's records is important, too. Seeing the notation, a provider can remind the client of the date when she visits the clinic for other services (*62*, 88). If a woman realizes that she has missed the removal date and she is worried, but she has not become pregnant, a provider can reassure her that leaving the implants in place has caused no harm.

Meeting Demand for New Implants Requires Supply and Access

Throughout the world use of implants remains low, but demand exceeds supply. Many women want implants but are unable to obtain them. Women who want implants but cannot get them go on waiting lists or choose another method. Some experts contend that the true demand for implants is unknown because there are not enough supplies and services available to meet demand (*42*).

Currently, few clinics offer implants. For example, in Ghana, only 17% of clinics surveyed by the Demographic and Health Surveys in 2002 offered contraceptive implants, and only 12% had them available on the day of the survey (30). In both Egypt and Kenya 13% of surveyed clinics offered implants. In Egypt 6% of clinics surveyed in 2002 and in Kenya 4% in 2004 actually had them available on the day of the survey (63).

Programs that do offer implants often experience shortages. Shortages have been reported in Zambia (39) and Tanzania, and also in Madagascar, where clinics were reported to have run out of implants on the same day that the shipments arrived (*105*).

In Kenya demand for implants continually out-runs supply (20, *42*). Many women who want implants must choose other methods, while others prefer to wait—and risk unwanted pregnancy—until implants become available. Some Kenyan service providers keep lists of clients who are waiting for future shipments of implants (*42*). Word-of-mouth from satisfied users has created and sustained demand despite the recurrent stock-outs. A 2007 analysis of the implants market in Kenya concludes that, with an expansion of training in insertion, Kenya could make use of procurements of 200,000 implants per year. This would be an increase of more than fourfold, up from the 47,000 sets procured in 2005 (*42*).

Cost is the largest barrier to access to implants. Many of the reported shortages of implants are due to their cost. In terms of supply cost, after the levonorgestrel-IUD, implants are the most expensive supply method of family planning, currently up to US$27 per set. Equipment for insertion, program costs of training and retaining providers with insertion and removal skills, and the time involved in insertion and removal also contribute to the high costs of implants (60). By comparison, copper-bearing IUDs, which last for at least 10 years, are available to the public sector for about US$0.21 to US$0.27 apiece (114).

The relatively high initial per-unit cost of implants has prevented widespread provision of implants in resource-poor countries. Donors have limited their purchases because of the high price (*87*, *105*).

True demand for implants is unknown because not enough supplies and services are available.

Fortunately, manufacturing costs are declining, donors and governments are placing larger orders and negotiating lower prices, and a lower-priced implant has become available—priced as low as US$4.50 per set. With such efforts to reduce costs, programs are more likely to be able to meet the demand for implants and to offer them to clients at lower prices.

Programs Estimate Implants Needed

A smooth transition to offering new implants requires sufficient supplies on hand. National family planning programs estimate the number of implants needed based on forecasted consumer demand, on one hand, and, on the other, the capacity of the program to provide clients with implants (*87*). In practice, it is often challenging to estimate requirements for implants accurately when they are new to the program.

Accurate estimates of the need for implants enable programs to place timely orders to manufacturers, donors, or procure-

Manufacturing costs are declining, donors and governments are placing larger orders and negotiating lower prices, and a lower-priced implant has become available.

ment agents. The most accurate forecasts of consumer demand use several types of information. Usual information includes numbers of new and returning clients, recent trends in use and projected increases as implants become more available and changes in local population due to migration. The estimates of consumer demand, however, must be adjusted for program capacity, including the number of providers trained to offer implants (or any plans to train providers to offer them), the number of facilities that can provide implants, the availability of supplies required for insertion and removal (such as anesthetic, trocars, forceps), and in-country capacity to manage the distribution of implants, among other factors (*87*).

Because implants are relatively new to some programs, forecasting may require other ways to assess consumer demand. Clinics could keep track of requests for implants, for example. Also, the number of clients requesting long-term methods would suggest potential interest in implants. Logistics staff could periodically speak with providers about their perceptions of the demand. (Key resources for ensuring reliable implant supplies are listed in Table 4 p. 16.)

Once implants start to arrive, at the national level donors can meet periodically to review quantities of implants ordered and ensure that total quantities will meet the need without overstocking. At service sites logistics officers should review stock levels and trends in use each month and place orders as needed to maintain stock (24, *87*, 91). At the central warehouse many countries have computerized systems, such as Pipeline Monitoring and Procurement Planning System, to help with forecasting (45, 91) (see box, p. 11).

Warehouses must also keep track of supplies and ensure that the facilities are adequate to ensure quality. Storage requirements for implants are similar to those for other contraceptive supplies, such as oral contraceptives. Implants must be stored in a dry place at room temperature, about 15 to 30°C (59 to 86°F), and away from direct sunlight. Generally, implants are labeled for a shelf-life of five years.

Countries often purchase a portion of the implants required directly from the manufacturers (11, 64). For example, in late 2007 Ethiopia's Ministry of Health is in the process of placing an order for 160,000 sets of implants, and Tanzania's Ministry of Health is ordering 50,000 sets (106). Many thousands more are needed, however.

For the remaining quantities needed, countries submit requests to donor agencies. Donors base their purchases from the manufacturers on the total number of implant sets requested by all countries, taking budgetary considerations and current inventory into account. USAID usually can purchase and supply to countries only a portion of the estimated annual requirement of implants, plus some reserve for emergency orders (*87*).

Donor Commitment Essential for Ensuring Supplies

The availability of implants to users depends on affordability. The majority of women in low-resource settings would be unable to pay the full cost of implants and implant insertion. Some governments, such as the Dominican Republic's, do not purchase implants due to their high cost. They make implants available in governmental clinics only when they receive donations of supplies (11). Donor support and financial commitment from national ministries of health will be essential to meet the rising demand for implants.

Donors (and national family planning programs) must be able to purchase implants at the lowest possible price. The 2007 price for *Implanon* is about US$19 to US$25 (90) and for *Jadelle* is US$21 to US$27 (5). The Population Council developed *Jadelle*, largely with U.S. government funding, and then licensed it to Leiras Oy. Leiras Oy was taken over by Schering AG in 1996 and merged with Bayer in 2006. The resulting licensing company, Bayer Schering Pharma, is now making

Table 4: Key Resources for Program Managers and Providers of Implants

Resource	Availability
Preparing to Introduce Implants	
Title: *The WHO Strategic Approach to Strengthening Sexual and Reproductive Health Policies and Programmes* **Organization and Date:** World Health Organization (WHO) (2007) **Description:** An overview of the three stages of the WHO Strategic Approach: conducting strategic assessments, testing pilot interventions, and scaling-up. Includes guidance for programs looking to introduce new contraceptive methods, such as implants.	PDF available online at: http://www.who.int/reproductive-health/strategic_approach/index.htm For more information, contact: Peter Fajans, MD MPH, Scientist Department of Reproductive Health and Research World Health Organization 1211 Geneva 27, Switzerland Tel: +41-22-791-4137 Fax: +41-22-791-4171 E-mail: fajansp@who.int
Ensuring Reliable Supplies	
Title: *Pocket Guide to Managing Contraceptive Supplies* **Organization and Date:** U.S. Centers for Disease Control and Prevention (2000) **Description:** A quick reference guide for staff who manage contraceptive supplies and logistics for a variety of methods including implants. Includes logistics formulas and principles.	PDF available online at: http://www.cdc.gov/reproductivehealth/Products&Pubs/PocketGuide.htm To request print copies, contact: U.S. Centers for Disease Control and Prevention Division of Reproductive Health, MS K-22, 4770 Buford Hwy., NE Atlanta, GA 30341, USA E-mail: jtj2@cdc.gov
Title: *PipeLine Software Tool* **Organization:** John Snow, Inc. (JSI) **Description:** A computer-based tool to help program managers monitor stock and plan procurement through forecasting, maintaining consistent stock levels, and preventing stock-outs.	Tool available online at: http://www.infoforhealth.org/short_url/?PipeLine To request the PipeLine CD, contact: John Snow, Inc./DELIVER Project 1616 N. Fort Myer Drive, 11th Floor Arlington, VA 22209, USA E-mail: deliver_pubs@jsi.com Web site: www.jsi.com
Title: *UNFPA Procurement Services* **Organization:** United Nations Population Fund (UNFPA) **Description:** UNFPA is the largest public sector procurer of contraceptives. UNFPA accepts standard orders of US$6,000 or more, and also accepts emergency procurement orders.	For more information, contact: UNFPA Procurement Services Section Midtermolen 3, P.O. Box 2530 2100 Copenhagen, Denmark Web site: http://www.unfpa.org/procurement/index.htm
Developing Technical Guidelines	
Title: *Medical Eligibility Criteria for Contraceptive Use* **Organization and Date:** WHO (2004) **Description:** A guide for the safe use of 19 methods, including implants, for women and men with known medical conditions.	PDF available online at: http://www.who.int/reproductive-health/publications/mec/ To request print copies, contact: WHO/Department of Reproductive Health and Research 1211 Geneva 27, Switzerland E-mail: rhrpublications@who.int
Title: *Selected Practice Recommendations for Contraceptive Use* **Organization and Date:** WHO (2004) **Description:** Evidence-based guidelines answering important questions on the use of major contraceptive methods, including implants. A companion to WHO's *Medical Eligibility Criteria for Contraceptive Use.*	PDF available online at: http://www.who.int/reproductive-health/publications/spr/index.htm To request print copies, contact: WHO/Department of Reproductive Health and Research 1211 Geneva 27, Switzerland E-mail: rhrpublications@who.int
Helping Clients Make an Informed Choice	
Title: *Decision-Making Tool for Family Planning Clients and Providers* **Organization and Date:** WHO and the INFO Project, Johns Hopkins Bloomberg School of Public Health Center for Communication Programs (2005) **Description:** An evidence-based counseling resource for providers to help clients make informed choices about family planning. Incorporates WHO guidance from the Medical Eligibility Criteria and Selected Practice Recommendations. Includes counseling help for new and continuing users of implants.	PDF available online at: http://www.who.int/reproductive-health/family_planning/counselling.htm To request print copies, contact: Orders Center for Communication Programs Johns Hopkins Bloomberg School of Public Health 111 Market Place, Suite 310 Baltimore, MD 21202, USA E-mail: orders@jhuccp.org

Resource	Availability
Helping Clients Make an Informed Choice *(Continued)*	
Title: *Family Planning: A Global Handbook for Providers* **Organization and Date:** WHO and the INFO Project, Center for Communication Programs, Johns Hopkins Bloomberg School of Public Health (2005) **Description:** A technical guide for providing family planning methods, including implants.	Available online at: http://www.fphandbook.org To request print copies, contact: Orders Center for Communication Programs Johns Hopkins Bloomberg School of Public Health 111 Market Place, Suite 310 Baltimore, MD 21202, USA E-mail: orders@jhuccp.org
Training to Provide Implants	
Title: *Implanon Training Materials* **Organization:** Organon International **Description:** Tools for training providers from the makers of *Implanon*. These include: *Implanon* clinician's manual; *Implanon* product monograph; *Implanon* scientific information (CD-ROM); *Implanon* insertion, localization and removal techniques (CD-ROM); and *Implanon* guide de formation (CD-ROM in French).	To request materials, contact: Organon International Institutional Affairs and Family Planning Department Postbus 20 5340 BH Oss, The Netherlands Tel: +31-412-66-2068
Title: *Jadelle Training Materials* **Organization:** Bayer Schering Pharma **Description:** Tools for training providers from the makers of *Jadelle*. These include: *Jadelle* product monograph, *Jadelle* training manual, *Jadelle* insertion and removal video (CD-ROM). Also, a training kit for insertion and removal containing a model arm, instruments for insertion and removal, a leaflet for providers describing insertion and removal, and a reminder card for the client.	To request materials, contact: Bayer Schering Pharma PO Box 415 FI-20101 Turku Finland Tel: +358-0207-785-21
Title: *Norplant Implants Course for Nurse-Midwives: Trainers' Notebook* **Organization and Date:** Uganda Ministry of Health, United States Agency for International Development (USAID), Delivery of Improved Services for Health (DISH), Regional Centre for the Quality of Health Care of the Makerere University Medical School, JHPIEGO (2000) **Description:** This *Norplant* training manual includes a course guide and tips for trainers and a course guide for participants. Also, trainers' checklists for evaluating participants' counseling and clinical skills, including infection prevention practices and insertion and removal.	PDF available online at: http://www.ugandadish.org/norplanttrainer.pdf
Title: *Norplant® Implants Guidelines for Family Planning Service Programs: A Problem-Solving Reference Manual* **Organization:** JHPIEGO **Description:** This *Norplant* manual is a course guide for trainers. Also includes notebooks and handbooks for participants. Available in English and French.	To request print copies, contact: JHPIEGO 1615 Thames Street Baltimore, MD 21231-3492, USA Tel: +1-410-537-1800 Fax: +1-410-537-1473 E-mail: orders@jhpiego.net
Title: *Inserting and Removing Subdermal Contraceptive Implants: Training Guidance for Nurses* **Organization:** Royal College of Nursing (2007) **Description:** Information on how to acquire the clinical skills for inserting and removing implants. Includes forms to record training experience. Developed for use in the United Kingdom according to local guidelines, but could be adapted for use in other countries.	PDF available online at: http://www.rcn.org.uk/publications/pdf/InsertingRemovingContraceptiveImplants.pdf

Jadelle more widely available at a lower price than before. Bayer Schering Pharma submitted the winning competitive bid to supply USAID with *Jadelle* in 2007, at US$21 per unit.

USAID makes the implants that it buys available to a variety of sectors. In 2007 USAID donated 74% of its implants to ministries of health, 24% to non-governmental organizations, and 2% to contraceptive social marketing organizations. In 2006 and 2007 Ethiopia, Rwanda, and Haiti received the largest amounts of implants from USAID (*87*).

Other large donor organizations also make bulk purchases of implants at discounted prices. In 2006 the International Planned Parenthood Federation (IPPF), the United Nations Population Fund (UNFPA), and USAID combined purchased about 270,000 sets of implants, a mix of *Jadelle*, *Implanon*, and *Norplant*, at an average price of US$28 per unit (see Web Table 1). Average prices have come down for 2007 (*86*, *105*).

Cost-Effectiveness Studies Show Long-Term Returns

While the initial price of implants is high, they can be cost-effective when used for a number of years. For example, at the cost of US$27 for *Jadelle*, if a woman continues to use the implant for a full five years, the cost of the implants divided by the number of pill cycles needed for the same number of years would be US$0.42. This is within the range of the cost of a cycle of oral contraceptive pills for which UNFPA pays US$0.16–US$0.63 per cycle. Also, over the long term, making implants available may reduce workload on the health system, and thus costs, because implants have higher continuation rates and are more effective than most other methods (*47*).

Several detailed analyses have concluded that in the long run implants are relatively *less* expensive than shorter term methods such as pills and injectables, particularly when such factors as staff time, facility costs (such as consultation space), and equipment are taken into account (*21*, 66). A study in Mali found that, when implants are used for several years, they are comparable in cost to other methods. The study examined several actual costs including providers' time and costs of supplies and equipment. Researchers concluded that after four years of contraceptive use the cost of providing a couple with a year of contraceptive protection was similar for *Norplant*, oral contraceptives, IUDs, and injectables (*21*). Another study, done in a clinic in Turkey, compared the costs of *Norplant* with the costs of oral contraceptives, taking into account the costs of supplies and staff time spent in counseling and follow-up visits, and actual continuation rates. The analysis estimated the total costs for one month of *Norplant* use at US$1.04 and one month of oral contraceptives use at US$1.58 (76).

A modeling study in the United Kingdom (UK) comparing the levonorgestrel IUD, medroxyprogesterone acetate (DMPA), and *Implanon*, examined health care resources from the National Health Service's perspective. The study found that the levonorgestrel IUD was the most cost-effective long-term method in terms of unintended pregnancies prevented, but *Implanon* was more cost-effective than DMPA, primarily because of the additional pregnancies that implants avert (117). Another UK modeling study found that *Implanon* was the most cost-effective in terms of unintended pregnancies avoided (and avoiding the costs associated with birth, miscarriage, and abortion) when compared with *Norplant* and a levonorgestrel IUD, DMPA, and oral contraceptives. This model used perfect-use effectiveness rates (how well the method protects against pregnancy when used consistently and correctly) and national discontinuation rates for each method (77).

The cost-effectiveness of implants and other long-acting methods rises with length of use. Experience in both clinical trials and actual program use shows that most users of the new implants keep them for at least three years. Review of continuation data for *Implanon*, *Jadelle,* and *Sino-Implant (II)* from eight studies in a wide range of countries finds that 78% to 96% of users keep their implants for at least one year, and 50% to 86% keep their implants for at least three years (see Table 2, p. 5). (*Implanon* is intended for only three years of use.) In a multi-country study of *Jadelle*, over 55% of users continued using the implant up to the maximum five years (*96*).

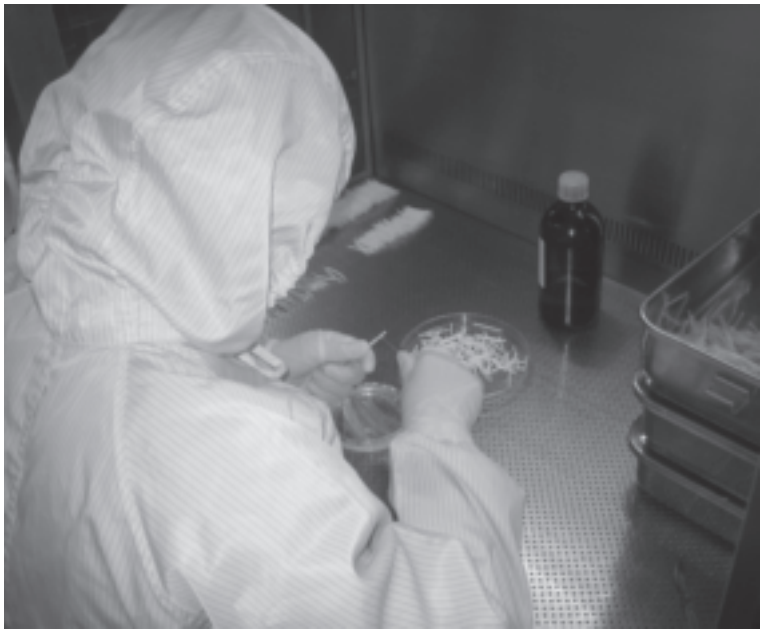
Implant services can be kept more cost-effective by avoiding routine follow-up visits, which provide no additional health benefits (61). No routine return visit is required until it is time to remove the implants (*122*). Of course, the client should be clearly invited to return any time she wishes, for any question or problem or any other reason (*124*).

Reducing Costs Will Improve Access

Why are implants so much more expensive than other contraceptive methods? First, both *Jadelle* and *Implanon* are owned by private pharmaceutical companies. The manufacturers try to recover expenditures for research and marketing as well as to make a profit before patents expire and they face potential price competition from other manufacturers. Second, the manufacturing technology is particularly costly and complex. The manufacturer must have skills in handling both polymers to make the rods and small quantities of steroids. Production processes must be carefully controlled to ensure the right release rate. Costs could probably come down with the development of better technology and further research into making the production process cheaper (34). Third, manufacturing costs per unit depend on volume. Compared with orders for other contraceptives, current orders for implants are small. Implants could become cheaper as orders increase (6).

***Strategies for providing lower-cost implants include registration of* Sino-Implant (II).**

Generic (nonexclusive) production of implants could reduce prices dramatically (*33*). *Sino-Implant (II)*, developed by an academic collaboration and purchased by a company in



A technician at the Dahua Pharmaceutical plant in Shanghai, China, assembles Sino-Implant (II) *rods. The company is manufacturing the implants in a new facility, which adheres to industry quality standards. By 2007 Dahua Pharmaceutical had distributed 5.3 million units of* Sino-Implant (II)*, mostly in China.*

China, is an example. The patent on *Jadelle* has expired, and therefore generic versions are legally possible. In the U.S. the patent on *Implanon* expires on September 29, 2009. There may be one or two other companies looking into producing generic implants. If experience with the production of other hormonal contraceptives is a guide, however, most companies would find it hard to meet acceptable quality assurance criteria (34, 35). Over the long term, manufacturers in the global south can be encouraged to raise their quality standards and consider making generic implants, as they commonly do other contraceptives (*33*). In the short term, implant prices already are falling as donors negotiate better prices for larger quantities. Manufacturers' prices generally decline over time in any case. The strategies for providing lower-cost implants in the near future include pursuing registration of *Sino-Implant (II)*, the cheapest implant available.

***Sino-Implant (II)* is cheaper.** Efforts are underway to increase the availability of *Sino-Implant (II)*, which now has a wholesale price of about US$4.50. Manufactured by Shanghai Dahua Pharmaceutical, this implant has been available in China since 1997. It has been exported to and used in Indonesia since 2002. To date, Shanghai Dahua Pharmaceutical has distributed 5.3 million units of *Sino-Implant (II)*. The company is manufacturing the implants in a new facility that adheres to industry quality standards (*107*). This implant is well-suited for widespread international registration because of its low price and because it is a "two-rod levonorgestrel-releasing implant," as listed in the March 2007 edition of the WHO Model List of Essential Medicines (123).

Family Health International (FHI) is working with local partners throughout Africa to ensure that *Sino-Implant (II)* meets regulatory standards for safety and quality—testing the rods as well as obtaining a second evaluation from an independent U.S.-based laboratory. FHI will help local partners register the implants with national drug regulatory authorities in Egypt and several other countries. As part of this initiative, FHI has negotiated price ceilings for the public and non-profit sectors once national drug regulatory authorities have approved the product (*107*).

Are clients willing to pay? While many women attending public clinics are accustomed to receiving family planning services free of charge, some women are willing to pay for good-quality family planning services, including a wider range of contraceptive choices that includes implants. Most private non-profit family planning clinics already recover at least some of the costs of services directly from consumers (2, *29*).

Some programs make services more affordable through cross-subsidy, charging more than the program's costs to provide less expensive services such as condoms or pills, to subsidize more expensive services such as implant insertion, and thus allow lower prices. Other strategies include sliding-scale fees—charging clients fees based on their ability to pay. Sliding-scale fees are more successful in middle-income countries, where some consumers can afford to pay higher prices, than in the poorest countries (3).

Private clinics in Kenya charge the equivalent of US$30 and in the Dominican Republic, US$54 for implant insertion. The charges cover the costs of the implants and operational costs of providing the implants, including staffing (11, *42*). In Nigeria, where the implants are subsidized by the government, clients pay the equivalent of about US$15 for *Implanon* (64). Still, the relatively high price of implants compared with other contraceptive methods is one of the main reasons for low use that were cited by program staff in Jos, Nigeria (*65*).

Studies that ask prospective and current contraceptive users how much they would be willing to pay for contraceptive methods (known as "willingness-to-pay studies") can be helpful in setting an initial consumer price for new implants (2, *29*). Once an initial price is decided, program managers might conduct brief, small-scale pricing trials in a few service delivery points to ensure that the price is reasonable.

In Guatemala USAID and the Population Council conducted a willingness-to-pay survey before introducing *Norplant* in clinics of the Asociación Pro-Bienestar de la Familia de Guatemala (APROFAM). Information from this survey was used to set the price of the product at 90 Quetzales, or almost US$12 (2).

Although some clients may be able to pay something, in reality most women will be unable to pay the full cost of implants and will require at least some subsidy. In Kenya

the insertion fee charged at many public facilities amounts to US$7, but less or nothing at all if a client cannot pay the usual fee. Efforts there to create a true private-sector market for implants, without donor support, have failed because the product has been too expensive to date (*42*).

Some programs have especially subsidized implants in an effort to encourage their use. When *Norplant* was introduced in Thailand in 1991, just over half of women received them at no charge. Because the national family planning program wanted to increase contraceptive use, the implants were highly subsidized, and the maximum price charged for *Norplant* amounted to US$8 (49). Because Egypt's ministry of health wanted to support the introduction of *Norplant*, it shifted from charging the equivalent of about US$3.50 to charging no fee at all. Demand for *Norplant* insertions at all ministry health facilities increased substantially (22). In the face of limited resources for reproductive health, increasing subsidies likely means cuts elsewhere. Programs will have to examine their priorities and decide how much to subsidize implants over other reproductive health services.

The new contraceptive implants hold substantial promise and are likely to broaden the appeal of the method. They are an important option in the range of long-acting methods. As family planning programs begin introducing the new implants or making the transition from *Norplant*, demand can be expected to rise. To meet the demand, programs will need to rely on donor and government subsidies, greater availability of lower-priced implants, and sharing the cost with users. Such strategies to improve access at lower cost will be key to the success of this contraceptive method.

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