

FAQs about Implants

1. Why should family planning programs consider providing implants?

Hormone-releasing subdermal implants are a highly safe, acceptable, effective, and reversible form of contraception. Implants prevent pregnancy for an extended period of time after a single administration; no regular action by the user and no routine clinical follow up are required (Isley & Edelman, 2007; Jacobstein & Pile, 2010; Power et al., 2007; Mavranouzouli, 2009; Salem et al., 2010). Implants have high continuation and client satisfaction rates (Mestad et al., 2009) and have become more affordable to countries in recent years (Hubacher et al., 2007).

2. What are contraceptive implants?

Contraceptive implants are small, thin, flexible plastic rods, each about the size of a matchstick, that are inserted under the skin of a woman's upper arm and release a progestin hormone into the body. The most common types include *Implanon* (one rod containing 68 mg of progestin etonogestrel); *Jadelle* (two rods, each containing 75 mg of levonorgestrel); and *Sino-implant (II)* (two rods, each containing 75 mg of levonorgestrel), which is currently marketed as *Zarin* in much of Africa. *Norplant* (a six capsule system) is no longer available as of 2008 (Isley & Edelman, 2007; Power et al., 2007; Ramchandran & Upadhyay, 2007).

3. How do implants work?

The progestin hormone released by the implants prevents pregnancy by thickening the cervical mucus, which blocks sperm from meeting an egg. Varying levels of ovulation suppression also occurs, depending on the type of implant used (Isley & Edleman, 2007).

4. Do implants interrupt a current pregnancy?

No. Implants do not interrupt an existing pregnancy, nor will they harm the fetus in the unlikely event that pregnancy occurs during use (Glasier, 2002).

5. How effective are contraceptive implants?

Implants are one of the most effective reversible methods ever developed, comparable to intrauterine devices (IUDs), as well as female and male sterilization. Overall, in three years of *Implanon* use, less than 1 pregnancy per 100 users can be expected. In five years of *Jadelle* use, 1.1 pregnancies per 100 users can be expected. In four years of use of *Sino-implant (II)*, the

cumulative pregnancy rate is 0.9-1.06%. (Coukell et al., 1998; Hohmann & Creinin, 2007; Isley & Edelman, 2007; Fischer, 2008; Steiner et al., 2010) In general, long-acting methods, including implants, are more effective in practice than shorter acting methods, including oral contraceptives and injectables, because compliance and continuation rates are higher with methods that do not require regular action by the user (Grimes, 2009)

6. How long can new implants be used?

Implanon, Jadelle, and Sino-implant (II) are currently approved by regulatory authorities for 3, 5, and 4 years of use, respectively (Ramchandran & Upadhyay, 2007).

7. How effective are implants if they are kept in place beyond the time period of labeled use?

Manufacturers decide on the duration of labeled use when they pursue product registration. However, clinical evidence suggests implants still remain effective beyond these time periods.

According to this evidence, when use is extended by at least an additional year, pregnancy rates for Implanon, Jadelle and Sino-Implant remain below 1-2%, depending on the type of implant. This compares favorably to pregnancy rates associated with common use of other reversible methods of contraception, such as COCs (8%), progestin-only injectables (3%) and condoms (15%).

For example:

- Eight randomized, controlled trials, involving 1578 women, with approximately half of them using Norplant and another half Implanon, reported no pregnancies over a 4-year period (Power et al., 2007).
- In a combined analysis of three clinical studies of Jadelle, the annual pregnancy rate was 0.8 per 100 users in year 5. It rose slightly above 1 per 100 in the sixth year of use, and above 2 per 100 in the seventh year (Sivin et al., 2001).
- Four randomized trials with a total of 15,943 women assigned to Sino-implant (II) had annual pregnancy rates well below 1% for the first 4 years of use. Three trials followed women through for five years; the five-year cumulative pregnancy rates were between 0.7% and 2.1% (Steiner et al., 2010).

Women should be counseled that replacing implants on time ensures maximum effectiveness. However, keeping implants another year likely means they are still relying on effective pregnancy prevention - more effective, in fact, than many other available methods of contraception. An understanding of the comparative effectiveness may help women in making an informed decision about implants (Steiner et al., 2006).

8. How do Implanon, Jadelle and Sino-implant (II) compare with Norplant?

Compared to *Norplant*, one- and two-rod implants are easier and quicker to insert and remove. Randomized comparative trials show that there is no difference in clinical performance between *Norplant* and the second generation implants, *Implanon*, *Jadelle* and *Sino-implant (II)*, in terms of

effectiveness and safety (Power et al., 2007; Fan et al., 2004; Qi et al. 2002).

9. Who can use contraceptive implants?

Implants can be used by women from menarche to menopause. Many women can safely use implants including lactating mothers, HIV-positive women, cigarette smokers of any age, postabortion women, diabetic women, women at risk for cardiovascular disease (including those with high blood pressure), and adolescents (Jacobstein & Pile, 2010). Studies have shown that use of the implant has no impact on breast-feeding or on the healthy development of breast-fed babies (WHO, 2009; Carson-DeWitt, 2007; Sivin, 2003; Diab & Zaki, 2000; Isley & Edelman, 2007). Implants can be initiated immediately after childbirth if a woman is not breast-feeding, and six weeks postpartum if a woman is partially or fully breast-feeding (WHO, 2004).

10. What are the other major advantages of contraceptive implants?

Implants offer women a number of advantages that can suit their reproductive intentions and that make continued use easy:

- Convenience
- Immediate return to fertility
- Any side effects resolve immediately after removal
- No known health risks
- Suitable for nearly all women

(Blumenthal et al., 2008; Hohmann & Creinin, 2007; Fischer, 2008; Isley & Edelman, 2007; Jacobstein & Pile, 2010; WHO, 2007; WHO, 2009)

Preparing to Offer Implants

11. What do good implant services include?

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 for conditions which may preclude safe use of implants; describing and answering questions about insertion and removal; and determining whether the client can have implants inserted immediately. Programs should also ensure women's access to removal services (Ramchandran & Upadhyay, 2007; WHO, 2007; WHO, 2009).

12. 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 physicians' assistants and associates; in some countries, community health workers are also being trained to insert implants (Chikamata, 2002; WHO, 2007).

13. How does competency-based training help implant providers?

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. Competence is defined as the point at which the trainee knows the steps in their sequence and can perform the required skill or activity. The approach focuses on the success of each trainee, recognizing that different providers need different amounts of practice to reach competence. 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, produces proficient and confident providers (Blumenthal et al., 1997).

14. How is *Implanon* inserted?

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 needle of the pre-loaded applicator to puncture the skin and places the single implant under the skin.

15. How are *Jadelle* and *Sino-implant (II)* inserted?

With *Jadelle* and *Sino-implant (II)*, the rods are loaded in a hollow needle, called a trocar. *Jadelle* is available with reusable and disposable trocars. *Sino-implant (II)* is distributed with a disposable trocar. After identifying the location for insertion on the inner side of the woman's upper arm, the clinician injects a local anesthetic and makes a small incision—about 3 mm long—using a scalpel or else just punctures the skin with the tip of the trocar. The rods are placed, one at a time, to form the shape of a V opening toward the shoulder.

16. What are the most commonly used techniques for removal of implants?

There are two commonly used techniques for removing new implants. With the “pop-out” technique, the provider first feels the site to ensure that the implant(s) can be located 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. The “U” technique 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 capsules (Rosenberg et al., 1997).

17. How important is ongoing removal training for providers?

Ongoing removal training is essential. It can take time to gain clinical experience in removals early in a program as many more women are having implants inserted than are asking to have them removed. 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.

18. How important is it to counsel clients considering implants about bleeding changes?

It is very important to counsel clients about bleeding changes, in easily understandable, appropriate language (and to ascertain that the client has understood what she is being told). Bleeding changes are the most common reason that women cite for discontinuing implants. For example, 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 (Ba et al., 1999). Providers can explain that bleeding changes are usually harmless and in most cases diminish over time. 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 acceptable method (WHO, 2007).

19. Why should clinics have a clear policy on removal?

Access to services for implant removal, or lack of access to removal, could strongly influence public perceptions of implants. Providers and family planning programs could be considered coercive if women cannot have implants removed whenever they want to have them removed. Clinics that offer implants should develop and communicate a clear policy on removal that states the following:

- Whenever a woman wants her implant(s) removed, she should be able to have them removed promptly free of charge or at an affordable price, without undue waiting, regardless of where or when the implants were inserted.
- A woman should not feel pressured to keep her implant(s). They should be removed whatever her reason, whether it is personal or medical.

Meeting Demand for New Implants Requires Supply and Access

20. Is there worldwide demand for contraceptive implants?

Throughout the world use of implants remains low, but demand exceeds supply. Many women want implants but are unable to obtain them. These women may 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. Widespread use of implants could significantly reduce the numbers of unintended pregnancies, abortions, and maternal deaths. However, worldwide use of implants is low; among married women between the ages of 15 and 49 around the globe, 53 percent use a modern method of contraception but only 0.3 percent use implants (Hubacher, et al., 2007).

21. What is the largest barrier to access to implants?

Historically, cost has been the largest barrier to access to implants. Many of the reported shortages of implants are due to their high commodity cost. Program costs related to 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. The relatively high initial per-unit cost of implants has prevented widespread provision of implants in resource-poor countries, and donors have limited their purchases because of the high price (Ramchandran & Upadhyay, 2007).

Although to date implants have been expensive, the commodity cost for *Sino Implant (II)* is between US\$7.50 and 8.50, which is at least 60 percent lower than the cost of other contraceptive implants procured by international donors and NGOs (RHSC, 2009). *Sino-implant (II)* is becoming available in a growing number of countries around the world through the registration efforts of Pharm Access Africa Limited, DKT, Marie Stopes International, Progyne and Women Care Global. As of April 2010, Sino-implant (II) is available in Malawi and Zambia (2010), Madagascar (2009), Kenya and Sierra Leone (2008), Indonesia (2002) and China (1994).

22. How can programs estimate the number of contraceptive implants needed?

National family planning programs estimate the number of implants needed based on forecasted consumer demand and the capacity of the program to provide clients with implants. Accurate estimates of the need for implants enable programs to place timely orders to manufacturers, donors, or procurement 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. The ACQUIRE Project has developed a planning package of evidence-based resources including RealityCheck, a forecasting tool that helps national and district level staff estimate supply needs. Additional resources are available, such as PipeLine Software Tool, from John Snow Inc., to help plan for procurement (The ACQUIRE Project, 2007; Ramchandran & Upadhyay, 2007).

23. How important is donor commitment in ensuring implant supplies?

Donor support and financial commitment from national ministries of health will be essential to meet the rising demand for implants. The availability of implants to users depends on affordability. The majority of women in low-resource settings are unable to pay the full cost of implants and implant insertion. Some governments do not purchase implants and only make implants available in governmental clinics only when they receive donations of supplies.

24. What are the commodity costs from the manufacturer for contraceptive implants?

The average price for implant commodities purchased in bulk in 2009 was US\$20-28 for *Implanon*, US\$21-23 for *Jadelle*, and US\$7.50 – 8.50 for *Sino-implant (II)* based on experiences in Kenya, Ethiopia and Sierra Leone (RHSC 2009).

25. Are implants cost-effective?

Evidence from developed countries including the US, the UK, Canada and Australia demonstrates that long-acting methods including implants are significantly more cost-effective over time than are short-acting hormonal contraceptives, barrier and behavioral methods (Mavranezouli, 2009; Trussell et al. 1995). Evidence from developing countries is much more limited, but recent analysis shows that with the introduction of *Sino-implant (II)*, implants are becoming much more affordable to programs. The cost of *Sino-implant (II)* per couple-years of protection (CYP), an indicator used by many programs, is lower than the cost per CYP for all reversible methods except for the copper IUD (Janowitz et al., 2009).

26. Does the cost-effectiveness of implants rise with length of use?

While the up-front cost of implants may be higher than that of other methods, this cost will be spread over the life of the implant, e.g., 3, 4, and 5 years, if clients do not discontinue early. The longer a woman keeps her implant in place, the less they cost per year. Experience in both clinical trials and actual program use shows that most users of the new *Jadelle* implants keep them for at least 3 - 3.5 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. (*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 (Ramchandran & Upadhyay, 2007).

27. How can the price of implants be reduced?

Production of generic or less expensive proprietary implants could reduce prices dramatically. *Sino-implant (II)*, a 2 rod system developed by Shanghai Dahua Pharmaceutical Company and marketed in China and Indonesia, is an example. Under a grant from the Bill and Melinda Gates Foundation, Family Health International is helping to register the product worldwide. As of April 2010, *Sino-implant (II)* is registered in 7 countries. As more products become available and competition increases, implants will be more competitive in their pricing. *Sino-implant (II)* is the least-expensive implant currently available at US\$7.50 – 8.50, compared to \$21-23 for *Jadelle* and \$20-28 for *Implanon* (RHSC 2009).

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