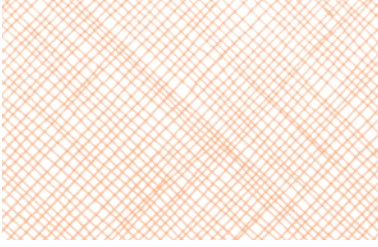
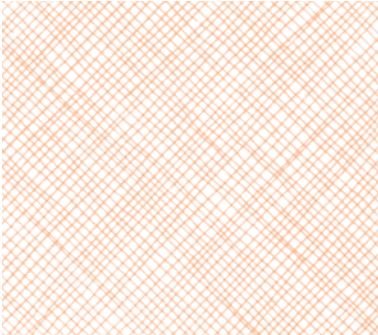


# Hormonal Implants

## *Service Delivery Considerations for an Improved and Increasingly Popular Method*



### OVERVIEW

Hormonal implants are a highly effective, very safe, and reversible form of progestin-only contraception that is quickly and easily provided by a trained provider in a few minutes via a minor surgical procedure. Nearly all women can use hormonal implants, at any stage in their reproductive life. Three implants are currently available: Jadelle<sup>®</sup>, Sino-implant (II)<sup>®</sup>, and Implanon<sup>®</sup>. The labeled duration of product use ranges from three to five years, depending on the implant. In service delivery, careful attention needs to be paid to client selection, counseling, proper placement of the implants, good side effects management, and reliable access to removal services. Lowered commodity costs and broadened categories of providers who are able to offer implants have increased the interest of family planning (FP) programs and donors in making implants more widely available.

### METHOD CHARACTERISTICS

**Composition and labeled duration of use:** Jadelle<sup>®</sup> and Sino-implant (II)<sup>®</sup> contain a total of 150 mg of levonorgestrel in two rods. Implanon<sup>®</sup> contains 68 mg of etonorgestrel in one rod. Jadelle<sup>®</sup> is labeled for five years of use, Sino-implant (II)<sup>®</sup> for four years, and Implanon<sup>®</sup> for three years. (A client does not need to use the implant for the full length of labeled use in order to receive it.)

**Mechanism of action:** The thin, flexible, matchstick-sized implant rods release small amounts of progestin hormone continuously into the blood, which prevents pregnancy by inhibiting ovulation and by increasing the thickness of cervical mucus (making sperm penetration difficult).

**Effectiveness:** The risk of failure (pregnancy) with implants is extremely low, 0.05% in the first year of use—that is, for every 2,000 women using implants, 1,999 do *not* become pregnant. In five years of Jadelle<sup>®</sup> use, there is one pregnancy per 100 users; Sino-implant (II)<sup>®</sup> and Implanon<sup>®</sup> have rates of effectiveness similar to Jadelle<sup>®</sup>'s.

**Safety:** Complications are uncommon, but may include infection at the insertion site (3–7% of insertions), expulsion (extremely rare), and difficult removal.

**Return to fertility:** There is no delay in return to fertility upon removal of implants. Use of implants has no negative impact upon a woman's ability to later become pregnant.

**Side effects:** Changes in bleeding patterns are likely; they may vary during use and usually diminish over time. Typical changes include lighter bleeding, fewer days of bleeding, irregular bleeding, and infrequent or no monthly bleeding. Other minor symptoms (in no more than 20–30% of clients) include headache, abdominal pain, acne, weight change, breast tenderness, dizziness, mood changes, and nausea.

**Protection against sexually transmitted infections (STIs) and HIV:** Implants, like all hormonal and most other methods of contraception, do not protect against HIV and other STIs.

## SERVICE PROGRAM CONSIDERATIONS

**Client eligibility:** Nearly all women can use implants, according to the World Health Organization (WHO), including women who wish to delay a first birth, space a next birth for two or more years, or limit further births. Women of any age, marital status, gravidity (number of pregnancies), or parity (number of children) can use an implant. Women who have just had an abortion or a miscarriage can receive an implant, as can women who have never been pregnant, are breastfeeding (starting six weeks after childbirth), have high blood pressure, smoke cigarettes, are HIV-infected, or have AIDS.

**Provider cadres able to provide implants:** Many cadres of health care providers, including nurses, auxiliary nurses, midwives, clinical officers, and physicians, can safely and effectively provide implants. In some countries (e.g., Ethiopia), health extension workers have been trained to insert and remove implants. What is important is that providers from any of these cadres have the necessary knowledge and skills, as well as adequate supplies, support, and supervision.

**Placement and convenience:** Implants are placed beneath the skin of the woman's upper arm. They can be inserted in two minutes or less and removed in five minutes or less. Pelvic examinations, routine blood and other laboratory tests, and routine follow-up visits are unnecessary. Implants may be inserted at any time during a woman's menstrual cycle, if it is reasonably certain that she is not pregnant, which can be determined by use of a pregnancy checklist.

**Service quality and access:** The fundamentals of care—informed choice, safety, and quality—must

be ensured in providing implant services to clients. Implants should be offered in programs as part of a range of contraceptive options available for clients to meet their reproductive intentions, throughout their life cycle. Age or parity restrictions, marriage requirements, or spousal or parental consent requirements are not medically justified and are a barrier to access.

**Counseling and choice:** Good counseling is critical to ensuring informed choice. In appropriate language, counseling needs to: 1) explain how implants work, and the approved duration of use; 2) inform the client of the likelihood of bleeding changes (although for any given client, the nature of these bleeding changes is unpredictable); 3) explore the significance of any possible bleeding changes in the context of the client's own life situation; 4) discuss practical management of side effects; 5) reassure the client that changes in bleeding patterns, as well as other minor side effects that may arise (e.g., headaches, abdominal pain, breast tenderness), are not only easily managed but also usually transient; 6) emphasize that the client can have the implant removed at any time, and not only when the approved duration of use has been reached; and 7) provide clients with a written date (month and year) when the implant must be removed or replaced.

**Return visits:** Routine follow-up of the client is not needed once implants are in place. Although a woman does not *need* to return for routine visits, she should be told that she can and should return at any time she wants, whether for advice, for reassurance, for treatment of minor side effects, or for removal of the implant.

**Continuation:** Continuation rates for implants are relatively high (78–96% for the first year of use in clinical trials and studies in a number of countries, and 50–86% at three years). However, women for whom menstrual disturbances are problematic are more likely to discontinue use. Proper client selection and good counseling and side effects management can enhance a client's continued use of implants (or the provider can help her switch to another effective method).

**Removal:** Removal of implants is usually easy; it depends upon proper—superficial, not deep—insertion. Removal of Jadelle<sup>®</sup>, Implanon<sup>®</sup>, and Sino-implant (II)<sup>®</sup> is even easier than it is for Norplant<sup>®</sup>, the previously available six-capsule implant. Access to removal

services must be ensured, with no program barriers to removal *whenever a client wishes to have her implant removed* (not just at the end of the duration of labeled use). A client does not need to use, or agree to use, an implant for the duration of its labeled use as a precondition to receiving it. Programs should keep adequate records and have a system of follow-up for removals.

**Service delivery models:** Implants can be provided at static health sites (clinics, health posts, outpatient departments of hospitals), as well as via mobile outreach to other sites. All service sites must be able to provide privacy, counseling, good surgical technique, and infection prevention. Implant services can be integrated with other health services, such as postpartum visits, postabortion care, and child immunization sessions. Strong referral links with community health programs and activities are an important component of any service delivery model.

**Policy considerations:** Appropriate, evidence-based standards, guidelines, and norms, based on WHO guidance, should be established and followed. Task-sharing and/or task-shifting should be encouraged; program policies should not prevent any cadre of worker shown to be able to safely provide implant services from doing so; this is particularly important in countries that face human resource constraints to wider provision of FP services, including implants. Programs also need to ensure that pricing policies do not inadvertently have a negative impact on clients' ability to access insertion and/or removal services.

**Training considerations:** A well-resourced and well-functioning training system is important to ensure ongoing capacity for provision of implants in FP programs. The clinical component of implant training should be "humanistic" (i.e., a trainee-provider should work with an arm model until demonstrating enough skill to warrant moving on to guided training with human clients). Caseloads during training must be adequate for the trainee to develop competency in both insertion and removal. Once trained, the trainee needs equipment, support, and supervision to become proficient in regularly providing good-quality insertion and removal services.

**Commodity security—instruments and supplies:** Programs need to ensure that their logistics system adequately forecasts program needs and regularly supplies and equips sites providing implant services. In

addition to the implant itself, trocars and other medical instruments and expendable supplies need to be made available. (Implanon® comes preloaded; Sino-implant (II)® and Jadelle® are provided with disposable trocars.) In some countries, implant kits have facilitated the availability of implant services. Programs should understand that "commodity security" alone does not equal, or ensure, "contraceptive security"; true contraceptive security for implants requires skilled, enabled providers, knowledgeable, empowered clients, and no cost or other access barriers that impede either provision or receipt of implant insertion and removal.

**Commodity cost:** The cost of the implant itself has been the main factor limiting the wider availability of implants in FP programs. Norplant®, the previously available six-capsule implant, cost around US\$24 per set. Implanon® and Jadelle® now cost US\$21–\$23 per set, and Sino-implant (II)® costs around US\$8 per set. This much lower price has generated optimism that once Sino-implant (II)® is registered in a country (see page 4), wider availability and use of implants may ensue. In 2009, more than 110,000 units of Sino-Implant (II)® were ordered by donors, at a cost saving of US\$1.6 million.

**Other cost and benefit considerations:** Clients as well as FP programs face costs and accrue health and economic benefits from implants use. A modeling study using data from Kenya estimates that if 100,000 users of oral contraceptives switched to implants, 26,000 unintended pregnancies would be prevented over five years, thus reducing program costs and workloads and health risks to women. Overall, if 20% of Sub-Saharan African women using oral contraceptives or injectables switched to implants, 1.8 million unintended pregnancies could be averted during the next five years. A Family Health International (FHI) study of 21 private-sector, public-sector, and nongovernmental clinics in Kenya found that clients pay a median price of US\$8 (range: US\$0.25–\$50) for implants, suggesting that Sino-implant (II)® might be provided sustainably in some settings. A related analysis found the service delivery cost per couple-year of protection (CYP) for Sino-implant (II)® to be about half the cost of providing a generic injectable contraceptive. To recoup or defray costs, programs should consider the feasibility of cost-recovery mechanisms, insurance schemes, social marketing, voucher subsidies, private-sector provision, and other ways to share and/or amortize costs.



**Availability/regulatory approval:** Jadelle® or Implanon®, or both, are approved for use in more than 80 countries worldwide. Sino-implant (II)® is approved for use in China, Indonesia, Kenya, Madagascar, Sierra Leone, and Zambia, and it is under active review by regulatory bodies in 10 additional countries. Jadelle® and Implanon® are both approved by the U.S. Food and Drug Administration (FDA), although only Implanon® is being made available by its manufacturer in the United States. WHO prequalification, which is necessary before some international donors may purchase implants, occurred in 2009 for Jadelle® and is anticipated in 2010 for Implanon® and Sino-implant (II)®.

**Use of implants in programs:** Because of their effectiveness and convenience, when implants have been made more widely available in FP programs, they have been popular, and demand for them appears high. After 600 nurses were trained in Ghana and commodities were made available, 88,000 women chose implants (Norplant®), and prevalence of implant use rose 10-fold, from 0.1% in 1998 to 1.0% in 2006. Among women in union who are using a modern FP method, one of seven in Burkina Faso, one of 17 in Senegal, one of 18 in Kenya, and one of 20 in Indonesia uses an implant. Overall, more than 1% of women in union currently use implants in Burkina Faso, Haiti, Indonesia, Kenya, Rwanda, and Zimbabwe and in the urban areas of Malawi, Nepal, Senegal, and Tanzania. To date, more than 7 million units of Sino-implant (II)® have been distributed in China, Indonesia, and elsewhere. Ethiopia has dramatically increased its levels of procurement of implants, from 31,000 units in 2005 and 60,000 units in 2006 to 430,000 units in 2008 and more than 830,000 units in 2009.

**Scale-up:** Plans for service expansion should be realistic in terms of: the commodities needed to provide implant

services on a regular basis without disruptive stock-outs; the numbers and types of skilled providers and supervisors needed; the anticipated demand for implants; and manageable caseloads. Forecasting tools (e.g., Fam Plan or Reality √) are useful in devising realistic scale-up plans and goals. In scale-up situations of increasing demand for and use of implants, projections of future need cannot rely on past trends. The adequacy of the complement of skilled providers available to provide implant insertions and removals is a major “rate-limiting step” to scaling up implant services. Programs need to ensure reliable access to both insertion and removal services, especially before embarking upon service expansion.

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