

Hormonal Implant Services

Delivering a Highly Effective Contraceptive Method Now Available at Reduced Cost

OVERVIEW

Hormonal implants are a convenient, highly effective, long-acting reversible form of progestin-only contraception. Nearly all women can use hormonal implants, at any stage of their reproductive life. Three implants are currently available: Implanon®, Jadelle®, and Sino-implant (II)®. The commodity cost of implants has recently been reduced by half, thanks to donor volume guarantees. Over 40 million implants are to be made available to low-resource countries between 2013 and 2018. These sizable price reductions and volume guarantees have generated much enthusiasm in the international family planning (FP) community. Lowered cost will not lead to wider access and use alone, however. Programs must also ensure: informed choice; careful client selection; an adequate, well-deployed complement of skilled and motivated providers; good counseling, especially about the likelihood and normalcy of menstrual bleeding changes; capable side effects management; adequate follow-up; and reliable availability of prompt removal services.

METHOD CHARACTERISTICS

Composition: Implanon® (and its newer versions, called Implanon NXT® or Nexplanon®) contains 68 mg of etonorgestrel in one rod. Jadelle® and Sino-implant (II)® contain 150 mg of levonorgestrel in two rods (75 mg in each rod). Implants are small and thin: 4.0–4.3 cm long and 2.0–2.5 mm in diameter.

Mechanism of action: The implant rods release ultra-low amounts of progestin continuously into the blood, which prevents pregnancy by inhibiting ovulation and thickening cervical mucus.

Effectiveness: Implants have unmatched effectiveness—only one pregnancy occurs among every 2,000 implant users in the first year of use (failure rate of 0.05%). This contrasts with the resupply methods of hormonal contraception, which depend on repeated human actions. Thus, in typical use, implants are 120 times more effective than injectables (6% failure rate) and 180 times more effective than the pill (9% failure rate).

Labeled duration of use: Jadelle® is labeled for five years of use, Sino-implant (II)® for four years, and Implanon® for three years, though a client need not plan or commit to use the implant for the full length of its labeled use to receive it. Implants likely remain effective for one or more years beyond their labeled duration of use.

Placement and timing of insertion and removal: Implants are inserted beneath the skin of the upper arm in 1–2 minutes, via a minor procedure performed under local anesthesia. Pelvic exams and laboratory tests are not required. Implants may be inserted at any time during a woman's menstrual cycle, if it is reasonably certain she is not pregnant, which can be determined by use of a pregnancy checklist (or a pregnancy test). Removal of implants is usually easy, taking 3–5 minutes.



Side effects: Menstrual bleeding changes are essentially universal, although the pattern in any individual woman cannot be predicted. Typical changes include lighter bleeding, fewer days of bleeding, irregular bleeding, and infrequent or no monthly bleeding. Other minor side effects (in less than 20–30% of clients) include headache, nausea, abdominal pain, and weight change.

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

Return to fertility: Implants are readily reversible upon removal. Return to fertility is not delayed or negatively affected. (Ovulation can resume as early as seven days after implant removal, so women who still want to avoid pregnancy need to be counseled to start using another contraceptive method or have another implant inserted.)

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

Service quality and access: The fundamentals of care—informed choice, safety, and quality—must be ensured in FP service provision. Implants should be offered in client-centered programs as part of a range of options that will enable clients to meet their reproductive intentions across their life cycle. Age or parity restrictions, marriage requirements, or spousal or parental consent requirements are not medically justified and are barriers to access.

Client eligibility: Implants are safe and suitable for nearly all women, including women who have never had children, have never been pregnant, have just had an abortion, are breastfeeding, or are living with HIV. Implants are suitable for any reproductive intention, whether to delay a first pregnancy, space a subsequent birth, or limit further childbearing. Women of any age and marital status, including adolescents and unmarried women, can use implants.

Recommendations regarding implant use by breastfeeding women during their first six weeks postpartum differ: World Health Organization (WHO) guidance states that the risks outweigh the benefits; the U.S. Centers for Disease Control and Prevention (CDC) advises that the benefits outweigh the risks (during the first four weeks postpartum, with no restrictions thereafter); and the UK's Royal College of Obstetricians and Gynecologists advises no restrictions at any time. Immediate postpar-

tum provision of implants would offer expanded program opportunities, as more births are occurring at facilities and more than 90% of postpartum women want to avoid a subsequent pregnancy for at least two years.

Counseling and informed choice: Thoughtful counseling is critical to ensuring informed choice. After (and if) implants have been chosen from a range of available methods, counseling—in appropriate language the client understands—needs to: 1) explain how implants work; 2) dispel any myths and misconceptions she may have; 3) discuss the labeled duration of use; and 4) emphasize that she can have the implant removed any time she wishes.

Client selection, changes in menstrual bleeding patterns, and side effects management: Careful client selection, anticipatory guidance, and reassuring management of side effects are often the difference between satisfaction and early discontinuation. Providers need to discuss the likelihood, unpredictability, and normalcy of changes in bleeding patterns (irregular, infrequent, or no bleeding), exploring their acceptability given the client's individual circumstances and sociocultural context. If such likely changes would be unacceptable to the client, another method should be offered.

Return visits and follow-up: Routine follow-up is not needed once implants are in place. However, the client should be told she can and should return (or call) at any time she wants, whether for advice, reassurance, treatment of minor side effects, or removal of the implant.

Continuation: Continuation rates for implants are 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. Menstrual irregularities are a chief reason why women discontinue implant use.

Removal services: Programs need to ensure routine, regular, and reliable removal services for clients, beginning by planning for removal at the outset of service expansion efforts. Programs should provide clients with a written date by which the implant needs to be removed or replaced; keep adequate records; and have a functional system of follow-up for removals.

Commodity costs and donor volume guarantees: Commodity cost has historically been a main factor limiting wider availability of implants. However, donor volume guarantees made to manufacturers in 2012 and 2013 enabled a marked reduction in the cost of Implanon® and Jadelle® (once as high as US \$23.80 per set) to US \$8.50 per set—comparable to the price of Sino-implant (II)®. More than 40 million implants are to be made available

to public-sector and noncommercial private-sector programs in low-resource countries between 2013 and 2018.

Commodity security and contraceptive security: Programs must ensure that their logistics system adequately forecasts program needs and regularly supplies and equips sites providing implant services. In addition to the implant, other medical instruments and expendable supplies are needed. (Implanon® comes preloaded; Sino-implant (II)® and Jadelle® are provided with disposable trocars.) Implant kits have facilitated provision of this method in some countries. Commodity security alone does not equate to or ensure contraceptive security: Full contraceptive security for implants requires skilled, enabled providers; knowledgeable, empowered clients; and no cost or other access barriers to insertion and removal.

Regulatory approval: Implants (of one type or another) are approved for use in around 100 countries worldwide. WHO prequalification is required before some international donors may purchase implants. WHO prequalified Jadelle® in 2009 and Implanon® in 2010. Prequalification is under way for Sino-implant (II)®. Jadelle® and Implanon® are both approved by the U.S. Food and Drug Administration (FDA), although only Implanon® (as Nexplanon®) is currently being made available by its manufacturer in the United States.

Provider factors: Implants are provider-dependent, and thus provider-level factors are key for programs to consider. Widespread, equitable access to implant services depends upon adequate availability and distribution of skilled, motivated, and enabled providers. Many provider cadres, including nurses, midwives, auxiliary nurses, clinical officers, and physicians, can safely and effectively provide implant insertion and removal. In some countries (e.g., Ethiopia), health extension workers have been trained to insert implants. It is important for providers from any of these cadres to have the necessary knowledge, skills, supplies, and facilitative supervision.

Training considerations: FP programs need well-resourced, well-functioning training systems, at both pre-service and in-service levels, to ensure ongoing capacity to provide implant services. The clinical component of implant training should be competency-based, with trainees using arm models until demonstrating enough skill to move on to guided training with clients. Caseloads during training need to be adequate for trainees to develop competency in both insertion and removal. Skills need to be retained subsequently through regular service provision and, where indicated, refresher training.

Service policy considerations: Appropriate, evidence-based standards, guidelines, and norms should be followed. Policies should enable task sharing and task shifting and should also ensure that no restrictions inappropriately impact clients' choices, including their ability to access implant insertion or removal services (e.g., limitations because of age, parity, or marital status; differential policies because of a client's HIV status; or pricing policies that impede removal).

Successful service delivery models and approaches:

Service programs need to take a holistic approach, paying attention to supply-side and demand-side elements as well as ensuring an enabling environment. Implants can be provided at static health sites (clinics, health posts, outpatient hospital departments), as well as via mobile outreach. All service sites must 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. A number of countries have successfully followed innovative models that entail use of "dedicated providers" and various types of public-private partnerships. These have also typically entailed task sharing among provider cadres and provision of services free of charge to clients.

Use and popularity of implants in programs: More than 9 million implants were provided to low-resource countries during 2009–2012, mostly to public-sector programs in Africa. Ethiopia alone increased its procurement from 90,000 implants in 2005–2006 to 2.4 million in 2009–2012. Knowledge of implants there increased from 20% in 2005 to 69% in 2011, and use rose 17-fold, to a contraceptive prevalence rate (CPR) of 3.4% among married women. In Burkina Faso, implant use also rose to 3.4%, accounting for 23% of overall modern method use among married women. In Rwanda, knowledge of implants became universal (97%) by 2010, and use rose accordingly, including among women of younger age, lower parity, rural residence, and no education. Rwanda's CPR for implants in 2010 was 6.3% among married women and 5.9% among sexually active unmarried women. These levels of use are the highest in Africa and among the highest in the world. Implants have become the second most popular method in Ethiopia and Burkina Faso and are third most popular in Rwanda. Other African countries with an implant CPR above 2% include Mali, Tanzania, Uganda, and Zimbabwe. In Zambia, 18 dedicated providers (retired nurse-midwives) at high-volume public-sector facilities inserted more than 22,000

implants in 14 months and served many younger and lower-parity women. In South Africa, implants became a program method in 2013, and at least 700,000 implants will be procured in 2013–2015.

Scale-up considerations: Successful scale-up of implant services requires: a strong policy commitment from the highest levels downward; supportive service policies that encourage task sharing; training to ensure widespread insertion and removal skills; substantial donor support for and government commitment to the purchase of commodities; and increases in individual and community knowledge of implants. Plans for service expansion should be realistic in terms of: commodities needed to provide implant services regularly, without disruptive stock-outs; numbers and types of skilled providers and supervisors needed; anticipated demand; and manageable caseloads. As demand increases, projections of future need cannot simply rely on past trends. The adequacy of the complement of skilled providers available to insert and remove implants is a “rate-limiting step” to scaling up implant services. Programs need to ensure reliable access to removal as well as insertion before expanding services.

Potential health benefits of greater access to implants: Over 220 million women in developing countries have an unmet need for modern contraception, mainly in South Asia and Sub-Saharan Africa. Access to highly effective clinical methods like implants is lower among poorer, younger, less-educated, and more rural women. Many women use resupply methods because more effective and convenient methods like implants are not easily accessed. If only one of every five Sub-Saharan African women now using the pill or injectables (i.e., other hormonal contraception) were to switch to an implant, more than 1.8 million unintended pregnancies would be averted in five years, resulting in almost 600,000 fewer abortions and

10,000 fewer maternal deaths. A Sub-Saharan African woman faces a one in 39 lifetime risk of maternal death, compared with a risk of one in 4,700 among women in industrialized countries. Risk of mortality as well as serious morbidity (e.g., obstetric fistula) is even higher among poorer women. Meeting the need for effective modern contraception is not only a family planning and health issue—it is an equity imperative. Greater access to implants can help meet this need.

REFERENCES

- EngenderHealth. 2011. *The SEED assessment guide for family planning programming*. New York.
- Hubacher, D., Mavranetzouli, I., and McGinn, E. 2008. Unintended pregnancy in sub-Saharan Africa: Magnitude of the problem and potential role of contraceptive implants to alleviate it. *Contraception* 78(1):73–78.
- Jacobstein, R., and Stanley, H. 2013. Contraceptive implants: Providing better choice to meet growing family planning demand. *Global Health: Science and Practice* 1(1):11–17. <http://dx.doi.org/10.9745/GHSP-D-12-00003>.
- Neukom, J., Chilambwe, J., Mkandawire, J., et al. 2011. Dedicated providers of long-acting reversible contraception: A new approach in Zambia. *Contraception* 83(5):447–452.
- Reproductive Health Supplies Coalition. RHInterchange. Summary of shipment reports for the world and sub-Saharan Africa. Accessed May 23, 2013, at <http://rhi.rhsupplies.org/rhi/shipmentssummary.doc>.
- The RESPOND Project. 2010. *Reality √: A planning and advocacy tool for strengthening family planning programs*. New York: EngenderHealth.
- Singh, S., and Darroch, J. E. 2012. *Adding it up: Costs and benefits of contraceptive services—estimates for 2012*. New York: Guttmacher Institute and United Nations Population Fund.
- World Health Organization Department of Reproductive Health and Research and Johns Hopkins Bloomberg School of Public Health Center for Communication Programs. 2011. *Family planning: A global handbook for providers (2011 update)*. Baltimore and Geneva.

Suggested citation:

The RESPOND Project. 2013. Hormonal implant services: Delivering a highly effective contraceptive method now available at reduced cost. *RESPOND Technical Brief No. 2*. September. New York: EngenderHealth (The RESPOND Project).



Managing Partner: EngenderHealth; **Associated Partners:** FHI 360; Futures Institute; Johns Hopkins Bloomberg School of Public Health Center for Communication Programs; Meridian Group International, Inc.; Population Council



USAID
FROM THE AMERICAN PEOPLE

This publication was made possible by the generous support of the American People through the U.S. Agency for International Development (USAID), under the terms of the cooperative agreement GPO-A-000-08-00007-00. The contents are the responsibility of the RESPOND Project/EngenderHealth and do not necessarily reflect the views of USAID or the United States Government.

© 2013 EngenderHealth/The RESPOND Project. This work is licensed under the Creative Commons Attribution-Noncommercial-Share Alike 3.0 Unported License. To view a copy of this license, visit <http://creativecommons.org/licenses/by-nc-sa/3.0/>.

Writer: Roy Jacobstein, MD, MPH, EngenderHealth (The RESPOND Project). Reviewers: Carmela Cordero, MD, EngenderHealth; Kelly Culwell, MD, MPH, EngenderHealth; and Maureen Clyde, EngenderHealth (The RESPOND Project). Editor: Michael Klitsch. Design/Layout: Elkin Konuk. Photo credits (top to bottom): A. Fiorente/EngenderHealth, Kenya Country Office/EngenderHealth, M. Smith/EngenderHealth

The RESPOND Project at EngenderHealth • 440 Ninth Avenue • New York, NY 10001 • 212-561-8000 • info@respond-project.org • www.respond-project.org