A provider in Ethiopia inserts a contraceptive implant. Implants are very popular where available.

Source: Cathy Solter/Pathfinder

A recent study estimates that if 20 percent of the women in sub-Saharan Africa who use oral contraceptives or injectables switched to implants, 1.8 million unintended pregnancies could be averted over the next five years.

– Hubacher, Mavranezouli, and McGinn, 2008

Sino-Implant (II) – A Dramatically Less-Expensive Implant Option

Contraceptive implants, introduced more than 25 years ago, are one of the most effective reversible family planning methods ever developed. But despite their acceptability to women and their potential to significantly reduce the number of unintended pregnancies, they are underutilized, primarily because of their high cost.

Introduction of a New, Lower-Cost Contraceptive Implant

Sino-implant (II) is a subdermal contraceptive implant manufactured in China by Shanghai Dahua Pharmaceutical Co., Ltd. It is available for at least 60 percent less cost than other contraceptive implants procured by international donors and NGOs. The implant is composed of two thin, flexible silicone rods, each containing 75 mg levonorgestrel (a synthetic progestin) and is currently labeled for four years of use.

The Population Council developed the first implantable hormone delivery system, Norplant, and its later version, Jadelle. Sino-implant (II) has the same amount of active ingredient and mechanism of action as Jadelle, and, like other implants, is one of the most highly effective contraceptive methods. Eleven published clinical trials, following a total of about 20,000 women for up to seven years, show that Sino-implant (II) is safe and highly effective with an annual pregnancy rate of less than 1 percent. Sino-implant (II) has been available in China since 1994 and has been used in Indonesia for the past seven years. To date, more than 7 million units of Sino-implant (II) have been distributed.
Sino-implant (II) was approved by drug regulatory authorities in Kenya and Sierra Leone in late 2008 under the trade name Zarin® and will be distributed by Pharm Access Africa Limited (PAAL). PAAL is seeking approval of Zarin® in nine African countries while Marie Stopes International (MSI), DKT International, Progyne, and Profamilia are moving forward with registrations in other countries (see box). Registration partners negotiate a long-term exclusive distribution agreement with the manufacturer, with technical assistance from Family Health International (FHI). In return, FHI ensures a public sector price, which will average US$8.

There are a number of requirements and restrictions affecting USAID procurement, including commodities such as Sino-implant (II). USAID does not procure Sino-implant (II) at this time.

### Cost Implications for Accessibility and Sustainability

The introduction of Sino-implant (II) and its availability at about 60 percent less cost than Jadelle or Implanon has sparked excitement in the many developing countries where demand for implants far exceeds supply. Substantial cost savings can be realized by programs switching to or incorporating Sino-implant (II). In the first four months of 2009, 90,600 units of Sino-implant (II) were ordered by donors, at an average price of US$8, representing a cost savings of US$1.4 million.

The provision of implants in some resource-constrained settings could recover enough costs to make it a sustainable commodity, according to a recent FHI study in Kenya. An evaluation of 21 clinics representing the private sector, NGOs, and the public sector revealed that clients pay a median price of US$8 for insertion of Jadelle. MSI Kenya charges up to US$30 per insertion, thus helping cover the cost of patients who are not able to pay. The current switch to the less costly Sino-implant (II) at MSI clinics will further aid the sustainable provision in such settings (Olawo and Steiner, 2009).

### Effect of Access to Implants on Unintended Pregnancies

An estimated 28 percent of unintended pregnancies in developing countries occur among women already using family planning, due to method failure or method discontinuation. In sub-Saharan Africa, short-acting oral contraceptives and injectables currently dominate the method mix. The provision of more effective and easier-to-use family planning methods such as implants could have significant benefits. A recent study estimates that if 20 percent of the women in sub-Saharan Africa who use oral contraceptives or injectables switched to implants, 1.8 million unintended pregnancies could be averted over the next five years (Hubacher, Mavranezouli, and McGinn, 2008). In Kenya alone, where demand for implants is high, 45 percent of all pregnancies are unintended. If one-quarter of oral contraceptive users chose implants instead, more than 26,000 unintended pregnancies could be averted over the next five years (Hubacher et al., 2007).

### Quality Assurance

FHI and its partners are closely monitoring the quality of Sino-implant (II). FHI has tested manufacturing lots according to approved testing standards, both at FHI and an independent laboratory. Moreover, FHI completed an extensive series of tests beyond those required for the release of product lots and concluded that Sino-implant (II) has been produced to meet international quality standards (e.g., ASTM, ISO, USP). FHI will continue to evaluate the quality
Sino-implant (II) has been registered successfully in Kenya under the trade name Zarin®. Photo credit: Aida Cancel/FHI

Programmatic Considerations for Introduction of New Contraceptive Methods

Introducing a new contraceptive implant (or any method for that matter) provides an opportunity to strengthen quality of care for all family planning services and methods and to give a country’s family planning efforts a boost. Adding a new option enables a program to reach new clients or to provide existing clients with a more effective or more appropriate option for individual women. To get the most out of this opportunity, it is important to consider the special program needs and issues requiring attention for quality implant services to be offered. Program considerations for Sino-implant (II) are similar to those for other implants, and its introduction and expansion will benefit from the many lessons learned from the introduction and expansion of Norplant, Jadelle, and Implanon. These are discussed briefly below:

Client Considerations
Implants should be offered as part of a range of contraceptive options and provided within a context of volunteerism and informed choice. Because of implants’ effectiveness and convenience, they are popular and in high demand when made available in family planning programs.

- Nearly all women can use implants, regardless of age, childbearing history, or marital status. Implants are suitable for women who wish to space, delay, or limit births, and can be provided to HIV+ women, women who have just had an abortion or miscarriage, and for breastfeeding women (starting six weeks after childbirth).

- Implant users discontinue use at much lower rates than do users of IUDs and injectables, and women who experience menstrual disturbances are more likely to discontinue use.

- Because of side effects related to contraceptive implants, programs must ensure that accurate information is available for clients, providers, and communities. Effective counseling should alert women to side effects and providers should be trained to manage them should they occur.

- Women need to have ready access to removal of implants, on demand and when the approved duration of use is reached (in the case of Sino-implant (II), after four years of use). Programs should have the capacity for client record-keeping and follow-up for removal services, coupled with counseling at the time of insertion to emphasize the timing for removal.

Provider and Service Considerations
Implants can be made widely available through a variety of providers and venues. A number of cadres of health professionals, including nurses, nurse-midwives, clinical officers, physicians, and well-trained community health workers, can safely provide implants. Services can be performed in any level of health facility where attention is paid to the fundamentals of care –
specifically informed choice, medical safety (including provider competence and infection prevention), and continuous quality assurance.

- Implants must be provided by well-trained and well-supervised providers with attention given to good surgical technique, asepsis and counseling.

- Programs may need to provide retraining in removal techniques as providers are often called upon to provide removals long after their initial training and require a skills refresher. Removal of Implanon (one-rod) as well as Jadelle and Sino-implant (II) (two-rod) implants is much easier than Norplant (six-rods).

- Mobile services provided by trained teams visiting health centers where services are not routinely available may provide a solution to human resource constraints and the lack of trained providers for implant services (particularly for removal).

**Program Policy and Financing Considerations**
Because the demand for implants seems to be high in many settings, the program strategy must ensure that service expansion efforts are well-planned, supervised, and monitored, both to maximize client satisfaction (and hence, increase continuation), and to ensure the ongoing availability of supply.

- Contraceptive security remains a critical issue for implants, given the up-front commodity costs (even at the lower cost for Sino-implant (II)). Programs should be able to predict the level of supplies needed over time without relying on past trends, since demand for implants tends to outpace supply where they have been offered.

- Policies and guidelines should support reliable access to both insertion and removal services, with no unjustified policy or practice barriers to provision (such as age and parity restrictions, marriage requirements, spousal or parental consent requirements, and/or provider bias), and no barriers to removal.

- Programs that involve and provide key stakeholders (Ministry of Health officials, program managers, service providers, community members, and health advocates) with accurate and clear information about the method help to reduce rumors and misconceptions that can adversely affect the method’s use and acceptability.

**Tools and Resources**

- **Sino-Implant (II) product brochure** [PDF, 354KB]

- **Checklist for Screening Clients Who Want to Initiate Contraceptive Implants**
  Family Health International (FHI) has developed a simple checklist to help health care providers screen clients who have been counseled about contraceptive options and who have made an informed decision to use implants. The checklist is based on recommendations included in the *Medical Eligibility Criteria for Contraceptive Use* (WHO, 2004; updated 2008). The checklist is available in English [PDF, 218KB], Spanish [PDF, 195KB], and French [PDF, 141KB].

- **Long-Acting and Permanent Methods: Addressing Unmet Need for Family Planning in Africa**
  This is a set of eight advocacy briefs on the benefits of LAPMs and the rationale for introducing or revitalizing them within national reproductive health and family planning programs. The briefs are available in English and French.

- **The Implants Toolkit**
  This toolkit is a comprehensive source of up-to-date, evidence-based information about implants. This online resource for program managers, policymakers, family planning
providers, and potential clients was developed by the Maximizing Access and Quality Initiative of USAID. It offers guidance on best practices and tools to help make implant services more accessible, acceptable, and effective.

NOTE: The Implants Toolkit is being modified and updated for release near the end of 2009.

- **Family Health Research: Long-Acting and Permanent Methods**
  This issue of the Family Health Research newsletter examines the unrealized potential of LAPMs to help family planning programs meet the needs of clients and improve public health.

- **Innovations in Family Planning Programs: An Interview with Jeff Spieler**
  Jeff Spieler, Senior Science Advisor, Population and Reproductive Health, USAID, talks about innovations in family planning programs including Sino-implant (II), community-based injections, technology, and communication.

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**We Want to Tell Your Repositioning Story**

Please contact Carmen Coles at ccoles@usaid.gov with your successes in family planning programming.

For more information on Repositioning Family Planning, please contact Alexandra Todd at atodd@usaid.gov or Carmen Coles at ccoles@usaid.gov.

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