



Contraceptive Security Brief

Hormonal Implants



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A client undergoes a surgical procedure for contraceptive implants.

Implants can be a cost-effective family planning method—they provide protection for up to five years, have lower total associated program costs, and are more effective when compared with other methods.

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Hormonal implants, although effective and acceptable to clients, are frequently an under-utilized family planning method. Implants could, potentially, reduce the unmet need for family planning. Due to the high upfront cost of implants, policymakers have previously been reluctant to support them, but this may be changing. Recently, the World Health Organization (WHO) added implants to their Model Essential Medicines List and the cost of implants is decreasing. The new product designs also have fewer rods and are easier to insert and remove—which increases client acceptability. In countries where implants are offered, their use is increasing—although, the increase started from a very low base. While their high upfront cost may make implants unattractive to policymakers, over the long term, they may be a cost-effective method because of their long duration of use, total associated program costs, and increased effectiveness compared with other methods.

Donors, however, may need to increase their financial commitments because of the procurement costs associated with implants. At the same time, the supply chain management of implants may require special attention—forecasts for implants are more difficult because of the unpredictable demand and because they are not a resupply method. In addition, their high unit cost may require special treatment, such as increased monitoring of stock levels, flexible procurements to reduce the possibility of overstocks or stockouts, and the ability to transfer stocks across the supply chain.

In this brief, the authors looked at trends in demand for implants in selected countries, the cost of implants compared with other methods, and issues that might arise for the supply chain management of implants. The brief concludes with recommendations to ensure their availability and accessibility in family planning programs.

Unmet Need for Long-Acting and Permanent Methods

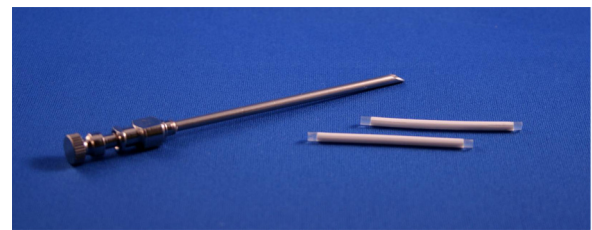
The unmet need for contraception—the percentage of married women who are not using a method of contraception but want to either delay

further childbearing for two or more years (spacing) or to stop further childbearing (limiting)—remains high in the developing world, particularly in sub-Saharan Africa. Data from Demographic and Health Surveys (DHS) from 2000 to 2005 for 15 countries in the region show total unmet need between 17 and 36 percent, with a significant share (about one-third) representing women who do not want any more children (Khan 2007). Despite significant decreases in unmet need during the 1980s, in many sub-Saharan African countries unmet need has stalled at high levels, or increased, since that time (Khan 2007).

Long-acting and permanent methods (LAPMs) can reduce the unmet need for limiting; long-acting methods can reduce unmet need for spacing. An analysis of four sub-Saharan African countries shows that the percentage of women using LAPMs is significantly lower than for short-term methods, and their use has declined or stalled during the past two decades (FHI 2007). In many countries in sub-Saharan Africa, fewer than 5 percent of users are using an LAPM (Janowitz 2006). Hormonal implants can play a critical role in reducing overall unmet need.

Product Characteristics

Hormonal implants, progestin-releasing, matchstick-sized rods, are inserted under the skin of the upper arm to prevent pregnancy. First introduced in the mid-1980s as Norplant, a six-capsule product, newer generations of products are smaller, require less time to insert and remove, and produce fewer bleeding disturbances for users.



An example of contraceptive implants.

Three main options are currently on the market:

- Jadelle, a two-rod product, contains levonorgestrel; it replaces Norplant and offers contraception for up to five years.
- Sino-Implant II, currently available in China and Indonesia—and has been registered in Kenya since 2008—is another two-rod system that contains levonorgestrel; it is effective for four years.
- Implanon, a single-rod system that contains etonogestrel, provides contraception for three years.

Implants provide several advantages for women that want long-acting pregnancy protection. They are extremely reliable and highly effective, comparable in effectiveness to intrauterine devices (IUDs); and they are more effective than short-term methods. Implants are registered in more than 60 countries and can be used by women of any age, whether they have previously given birth or not. Breastfeeding women can also use them, starting as early as six weeks after giving birth. The other major advantage of implants is that they are easily reversible—fertility returns immediately after the implants are removed (Carson-DeWitt 2007); any undesirable side effects also disappear as soon as the implants are removed. There are no restrictions on their use for HIV-positive women.

However, a few significant side effects may prevent the use of implants. For the users, the major complaint is the disruption of monthly bleeding. However, if the potential side effects are carefully explained and the user is told that these irregularities often stop after the first six to nine months, they are likely to accept the irregularities. Generally, continuation rates of implants are high—in several studies, after one year 78 percent to 96 percent continued with this method (Ramchandran 2007). The average duration of use for hormonal implants, across 15 different countries, is 3.6 years (Stover 2000), with a range of 2.8 to 4.5 years.

For service delivery, access is limited because trained professionals are required for both insertion and removal. However, after implants are inserted, no routine follow-up care or resupply is needed for three to five years (the effective period of the implants), unless there are side effects, or if the patient wants them removed. This reduces the patient burden on health care workers who can, in theory, provide a woman with long-acting contraception for up to

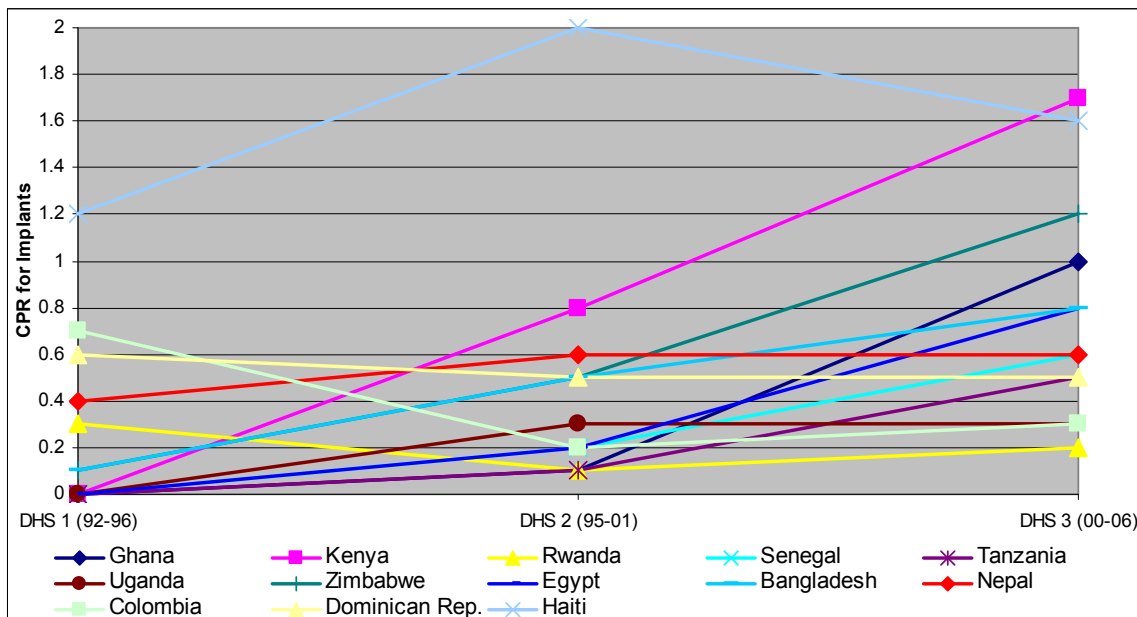
five years with only one visit, rather than several visits per year for additional injections, medications, supplies, or consultations. This also reduces the time burden for users.

Trends in Implant Use

The use of implants has increased slowly, but steadily, since Norplant was first introduced. Implants currently account for a small percentage of modern method family planning use, but this may have more to do with access than client acceptability. In many countries, implants are not available, either because programs do not offer them, or if they do, they are only available in a limited number of outlets. A USAID | DELIVER PROJECT stock assessment in Zambia found that only 30 percent of districts managed Jadelle and that 70 percent of service delivery points were stocked out of Jadelle on the day of visit (USAID | DELIVER PROJECT 2008). Figure 1 shows the trends in implant use—the percentage use of implants for countries with three separate Demographic and Health Surveys (DHS) that report implant use.

Implants could, potentially, reduce the unmet need for family planning.

Figure 1. Trend in Implant Use—Selected Countries Using Three DHS Surveys



Source: Measure DHS Stat Compiler—Demographic and Health Surveys Surveys at <http://www.measuredhs.com/>. Accessed August 12, 2008.

Note: All data are for married women, except for Egypt, Bangladesh, and Nepal where data are for all women.

While use is low, the trend is increasing in 10 out of 14 countries. Use remained essentially unchanged in two countries; while it declined only in Colombia and Indonesia.¹ The case in Indonesia is instructive. Implant use there is much higher than for any other country—it increased from 0.4 percent in 1987 to 6.0 percent in 1997, but then declined to 4.3 percent in 2002–2003. A recent report explained the decrease in use—

an apparent response to a decline in the availability of subsidized implants, as a combination of high procurement cost and budget constraints forced the family planning program to reduce the quantity of implants it could subsidize. (Mize 2006).

¹ Indonesia is not included in the graph because implant use in that country is much higher than for any other country.

Spotlight: Burkina Faso

Burkina Faso is one of many French-speaking West African countries that have very low contraceptive prevalence and very high unmet need. In 2003, the contraceptive prevalence rate (CPR) for modern methods was only 8.6 percent (women in union), while unmet need was 28.8 percent. Implants were a relatively popular method, with a CPR of 1.2 percent—the fourth most popular method after injections, pills, and male condoms. This was a six-fold increase from 1999, when overall CPR was 4.8 percent and implant use was only 0.2 percent. Representatives from the Family Health Division have reported a significant demand for implants where they are offered; word of mouth among women is responsible for much of the demand.

Shipments of implants to Burkina Faso show a generally significant upward trend, but with highs and lows (see figure 2). Quantities increased significantly from 2002 when just over 13,000 were shipped to nearly 39,000 in 2008 (2008 data includes both shipments and firm orders). When Jadelle was introduced in 2007, the popularity of implants was expected to increase.

Financing of implants is a significant contraceptive security challenge for Burkina Faso. The government recognizes contraceptive security as a national priority. The government funded almost \$500,000 worth of

contraceptives in 2005 and 2006—about 15 percent of the total required. Total funding requirements for contraceptive procurement for 2007–2009 is estimated at \$3.6 million. Almost half of that total is to fund implants. While recognizing the importance of implants in offering women more choices, policymakers in Burkina Faso consider them too expensive for national procurement. Data is not available for the lifetime costs of various methods; therefore, this judgment is based on their acquisition cost of \$20 to \$25 per unit. The government would like to continue to offer implants, but it must depend on donors to fund them, while the government concentrates its limited resources on other methods. So far, donors have stepped up—USAID, for example, contributed \$900,000 for implants in 2008. However, future donor commitments for contraceptives, in general, and implants, in particular, are far from certain.

Figure 2. Implant Shipments Burkina Faso, 2002–2008

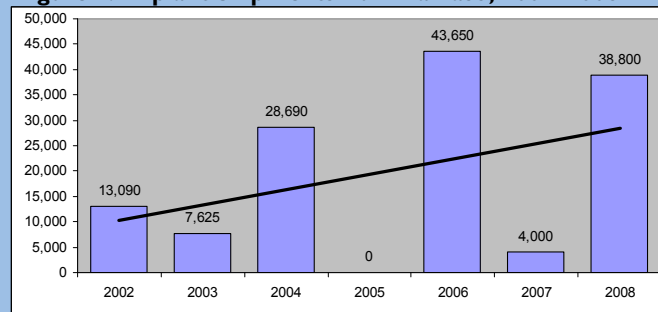


Figure 3 shows the volume and value of implants shipped worldwide by USAID, UNFPA², and IPPF, by year, from 2004 through July 8, 2008, as reported to the Reproductive Health Interchange (RHI). While not exhaustive because not all donors or government procurements are included, the data represent a significant share of the implants procured for public sector use in low- and middle-income countries, and it is interesting to note the trend for these donors. Shipments have increased almost four-fold in the past five years—from 2004, when just over 126,000 were shipped—to 2008 when almost 500,000 were either shipped or scheduled to be shipped.³ Similarly, the value of implants shipped has increased from \$3.4 million in 2004 to more than \$13.5 million in 2008.

Financing and Hormonal Implants

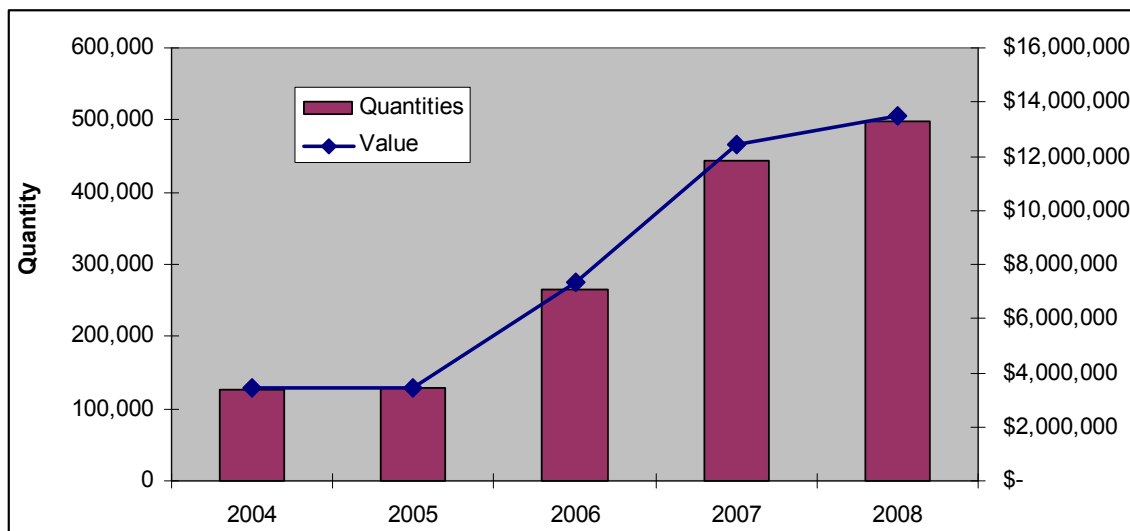
Donors and governments are often reluctant to procure implants because of their high per unit cost. However, unit costs are decreasing because of the improvements in manufacturing techniques and increased volume-based savings for donors that place large, pooled orders. Recent shipments of implants show that prices have been as low as \$21.00 per unit for Jadelle, \$19.00 for Implanon, and \$5.00–\$7.00 for Sino-Implant II. While these upfront costs are high compared with other methods of contraception, the cost is lower when the expense is amortized over the life of the product. For instance, if a woman uses an implant for 3.5 years at a cost of \$21.00, the \$6.00 annual commodity cost is comparable to short-term methods like pills and injectables, which have a per year commodity costs of approximately \$3.50 and \$4.00, respectively.⁴

² Also included are commodities financed by other entities, including the World Bank and the MOH, where UNFPA acts as a procurement agent.

³ The 2008 figure includes shipments up to July and the scheduled shipments for the remainder of 2008. While some scheduled shipments could be canceled, it is more likely that additional orders will be shipped and the total for 2008 will be higher than shown.

⁴ Based on USAID procurement cost for cycle of pills of U.S.\$0.231 × 15 = \$3.47 CYP cost; vial DPMA = \$1.00 × 4 = \$4.00 CYP cost.

Figure 3. Quantities and Value of Implants Shipped by USAID, UNFPA, and IPPF to All Countries (2004–2008)



Source: Reproductive Health Interchange. Provided by the Reproductive Health Supplies Coalition. Accessed July 7, 2008 at http://rhi.rhsupplies.org/rhi/index.do?locale=en_US.

Note: The 2008 data includes orders shipped and scheduled.

Because users make fewer facility visits when they have implants, if the costs associated with those visits were included—staff time, equipment costs, facility costs, and product distribution (resupply)—implants would be even more cost effective. Studies in Mali (Doucore 1995) and Turkey (Ortayli 2000) have shown that when provider costs are included in the analysis, the cost of implants was equal to or less than other forms of contraception. Studies in the UK found Implanon to be more cost-effective than Depo-Provera (Varney 2004), and both Depo-Provera and oral contraceptives (Phillips 2000).

In many countries in sub-Saharan Africa, fewer than 5 percent of users are using a long-acting and permanent method.

When the cost analysis includes the high rate of effectiveness of implants in preventing unintended pregnancies (i.e., the higher failure rate of other methods), the savings from implants is even greater. Simulations in Kenya on the number of unintended pregnancies averted when implants were used compared to the use of oral contraceptives, estimated that in more than five years, approximately 26,000 unintended pregnancies could be prevented if 100,000 users of oral contraceptives switched to implants (Hubacher 2007). Unintended pregnancies not only mean additional costs for families, but also for the health sector in antenatal care visits, on-going care, and supplies.

Therefore, while the initial procurement cost of implants may appear to be an unattractive option, an analysis of the total costs involved—the duration of use for a single implant, the reduced service costs associated with their use, and their greater effectiveness in avoiding unwanted pregnancies—may show that implants are actually more cost effective than other methods.

Supply Chain Considerations

To ensure success when introducing or scaling up access to implants in a family planning program, several important supply chain considerations should be considered.

Inclusion on National Essential Medicine List

The status of hormonal implants on the National Essential Medicines Lists (NEMLs) is an important consideration. Medicines listed on NEMLs receive priority and they should be available at all times. Usually, they are also included in Standard Treatment Guidelines and may be exempt from duties and taxes. Today, many countries do not include implants on their NEMLs. For example, only eight of 14 USAID | DELIVER PROJECT presence countries include implants, but every country includes combined oral contraceptive pills and DMPA injections. However, the 2007 WHO Model List of Essential Medicines added a two-rod levonorgestrel-releasing implant (each rod containing 75 mg of levonorgestrel) (WHO 2007). This may encourage individual countries to add implants to their NEMLs the next time they update their list.



A woman in a village near Shashemene, Ethiopia proudly shows off her arm where Norplant is implanted during a village gathering to discuss family planning.

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Brand Selection

Brand selection is an important decision for countries considering implants for their family planning programs. For supply management, having multiple brands complicates forecasting, procurement, and distribution; it should be avoided unless clinically warranted, for several reasons. If demand is uncertain or varies within a country, it will be important to be able to shift supplies to make the system as responsive as possible. If different regions or programs are using different brands, the supply becomes more complicated. Multiple brands, each requiring its own safety stock, lead to higher overall stock levels and more money tied up in inventory. Training of health care staff in the use of different brands is also an issue. Different brands may have very different insertion methods and equipment requirements, which necessitates additional training of staff and increases the burden on the health system.

Quality issues are also important to consider for brand selection. Of the three main implant brands available, both Jadelle and Implanon are approved by the United States FDA and other stringent regulatory authorities (SRA); Sino-Implant II has not applied for FDA or SRA approval. The most recent expression of interest from WHO for prequalification of reproductive health medicines includes a two-rod levonorgestrel-releasing implant, such as Sino-Implant II. The availability of less costly implants that meet international quality standards could greatly reduce some of the barriers to wider availability. Clearly, the prequalification of Sino-Implant II could be an important step for contraceptive security.

Donor contracts to procure particular brands are an additional consideration during brand selection. For example, USAID currently procures only Jadelle; in Tanzania, the public sector decided to distribute only Implanon. This excludes USAID as a financing source for implants in Tanzania.

Forecasting Demand

It is challenging to accurately forecast the demand for implants. A study of forecast accuracy for contraceptives found that implants had the highest levels of forecast errors of any method (USAID | DELIVER PROJECT 2007). Because hormonal implants may be a new method for a country, or one that previously had only limited availability, reliable consumption information may not yet be available; therefore, true demand would be difficult to estimate. Initial forecasts will probably rely heavily on demographic data, market research, or program goals.

As a longer-term method, recurring demand for implants is also more difficult to estimate. For resupply methods like pills and injectables, forecasts are typically based on current consumption, which is adjusted for likely future use, based on historical trends for new acceptors and discontinuing users. Implants are not a resupply method, because a

device can remain in place for up to five years. A forecast only needs to consider the needs of new users plus a percentage of current users that may need a new device (depending on how mature a program is). Another complication is that initial spikes in demand may occur after a new product is first offered because of a latent demand or effective promotion; over time, this will taper off. This does not mean that the prevalence rate for implants will decline, because prevalence includes both *existing and new users*. Program managers may be surprised to see forecasted consumption for commodities declining; but, they should understand that this does not necessarily indicate that prevalence is declining.

The quality of forecasts, as well as the maintenance of appropriate stock levels, are issues for all contraceptives. However, long-term and newer methods lacking significant historical consumption data have particular issues. These issues are especially important for implants because of their high initial procurement cost. One vital requirement is a nimble supply chain that can respond quickly to variations in demand. Managers should consider special treatment for implants, especially when a program is expanding and the demand is unpredictable. This could include flexible procurements so that shipments to the central warehouse can be advanced or delayed, supplies can be moved across levels to even out stocks, and stock levels can be monitored more frequently.

Collecting regular and reliable logistics data on the consumption and stock situation of implants can help improve forecast accuracy after implants are introduced into a program. In the beginning, logistics data can be compared with service statistics to confirm or adjust forecasts and distribution plans. Ideally, to capture unmet demand, programs could also collect data on the number of requests for implants that could not be fulfilled.

If program goals are to be used to quantify future demand, it is important that they are realistic and that they consider service capacity. In particular, implants require significant health worker capacity for the provision of insertion and removal services. Because programs may set optimistic goals for uptake, it may be advisable to separate the estimation of quantities to procure from the program targets. Decision makers should know what the financial implications will be when they make procurement decisions.

Associated Supplies

The insertion and removal of implants also require associated products, including trocars⁵, local anesthetic, gauze, protective gloves, scalpel, forceps, and sterile bandages. It is important to forecast for these ancillary supplies and to ensure adequate financing.

Service Delivery

Implants also require specific service delivery considerations. Training is the most important issue—health care workers need to be trained on the surgical procedures for inserting and removing implants; also, their skills must be updated as products change and new products are introduced. Some countries have specifically encouraged the use of implants and have made an effort to expand the capacity and numbers of health care workers who can provide this service. Ghana, for instance, increased the number of health care worker cadres that are formally accredited to insert



A nurse explains contraceptive options to a mother who wants to space her pregnancies further apart. Millions of women in Nigeria, Africa's most populous nation, would like to choose the timing of their pregnancies but lack access to family planning information and services.

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⁵ Jadelle comes with a separately packaged trocar for insertion (one per 10 implants); Implanon comes with its own specially designed, single-use applicator.

and remove implants; they also expanded the policy to include nurses, as well as doctors. After this change, Ghana implemented a program to train 600 more health service providers between 1998 and 2003. Between 1998 and 2006, there was a six-fold increase in the contraceptive prevalence of implants—from 0.2 percent to 1.2 percent—more than 88,000 women have elected to use them (Ramchandran 2007).

Regardless of what groups are authorized to insert implants, periodic refresher training will be needed to ensure that health care workers are always available to educate women about implants, to provide new implants, and to remove implants. Ongoing training will ensure that possible users are aware of implants as an available method of family planning. The training will also guarantee that insertion and removal services are consistently and readily available. It will also be vital that the health information systems can identify women who need to have their implants removed and replaced, if desired.



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A health worker counsels a client on family planning and contraceptive methods at a clinic in Indonesia.

Concluding Points

Hormonal implants can play an important role in ensuring contraceptive security for women around the globe, especially considering the few options for long-acting, reversible methods and the high levels of unmet need in developing countries. When deciding whether to expand access to implants, the following points should be considered:

- When making programming decisions, policymakers and program managers should consider the *total system costs* of implants versus other methods.
- To facilitate their financing and procurement, stakeholders should advocate for including implants on NEMs.
- To ensure the safe insertion and removal of implants, a sustainable cadre of trained health professionals should always be available.
- To ensure that clients can make an informed decision about using implants, health care workers should be trained to provide counseling and education to potential users.
- Because of the high upfront costs of implants, programs should take particular care in forecasting program requirements and making procurement plans. If procurement planning is based on program goals, those goals should be realistic.
- Implants may require special attention for supply chain management because of their higher costs. This could include flexible procurement plans, the ability to move supplies across levels in the supply chain, and increased monitoring of stock levels and consumption.
- To inform forecasting efforts when consumption data for implants is not available, programs should conduct an analysis of demographic data and research on potential interest in implants; the final quantification should reflect the capacity of the staff to insert and remove the implants.
- To refine and improve logistics data and service delivery statistics, both should be collected and compared with initial forecasts.
- Forecasts and budgets should include associated supplies and consumables needed for both insertion and removal.
- Stakeholders should continue to push for lower procurement costs. Product costs will likely decrease as volumes increase; the increased availability of cheaper alternatives like Sino-Implant II should also help. If WHO prequalifies products that are not already approved for use by a stringent regulatory authority, programs would have access to alternative and potentially cheaper implants.
- Because of their high upfront costs and the need for training health care workers, donor support will be necessary to initiate and sustain implant programs in countries that have fewer resources.

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