

Global Agenda Council on Sustainable Development (GAC-SD)

Using Financial Guarantees to Provide Women Access to the Modern Contraceptive Products They Want to Plan their Families

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The private sector has contributed substantially to increasing women's access to the modern contraceptive products they want to plan their families. In 2012, the London Summit on Family Planning made way for a bold new program, Family Planning 2020 (FP2020). FP2020 is a global partnership that supports the rights of women and girls to decide, freely, and for themselves, whether, when, and how many children they want to have. The organization set a goal of the goal of reaching 120 million additional women with modern contraceptive tools by the year 2020. The private sector is playing a critical role by expanding contraceptive access and options throughout the 69 FP2020 focus countries¹, mostly in Africa and Southeast Asia. The Implant Access Program (IAP) is a group of public and private organizations (including the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation, CHAI, and the governments of the United States, the United Kingdom, Norway, and Sweden) that came together to provide volume guarantees to make Bayer HealthCare's Jadelle® and Merck & Company's (MSD's) Implanon® and Implanon NXT® available to women in the world's poorest countries at price reductions of approximately 50 percent. Since the launch of this program in 2013, more than 25.6 million implants have been distributed. Annual procurement has more than doubled since 2012 and has led to more than \$240 million in savings for donors and developing country governments in the first three years of the program.

Background – the market for implants prior in 2012

In the summer of 2012, there was growing global support for family planning and growing demand for long-term, reversible methods of contraceptives, particularly implants. The historic Family Planning Summit in London brought together national governments, donors, civil society, the private sector, and the research and development community in support of increased access to family planning in low and middle income countries (LMICs). Family Planning 2020 (FP2020) was established following the Family Planning Summit as a global partnership to expand access to family planning information, services, and supplies to an additional 120 million women and girls in the world's 69 poorest countries by year 2020. The UN Commission on Life-Saving Commodities for Women and Children, formed in 2012, also prioritized implants as one of 13 focal commodities to save the lives of women and children.

¹ Family Planning 2020, "Countries," available at <http://www.familyplanning2020.org/countries/all-countries>.

In parallel, the Bill & Melinda Gates Foundation, with Melinda Gates taking on a leadership role in global family planning efforts, had begun assessing the need for interventions in the contraceptive implant market as a part of the organization's broader efforts.

In the summer of 2012, the Clinton Health Access Initiative (CHAI) and the Gates Foundation joined forces to explore the potential for the implant market to benefit from a global market-shaping intervention. As a first step in evaluating implant market opportunities, CHAI assessed the key barriers to access in the implant market by conferring with major suppliers, buyers, and implementing partners in LMICs. Interviews with suppliers suggested that low volumes and limited visibility into demand was a critical factor in the stagnation of implant pricing. In parallel, ministries of health (MOHs) and other purchasers reportedly constrained implant order volumes, perpetuating high prices. This pattern is indicative of a "high price/low volume trap."

Funding constraints on the part of these procurers coupled with the high upfront price of implants relative to other contraceptive methods limited purchasing of implants for the LMIC market. Furthermore, a lack of coordination on supply planning and forecasting at the global level undermined manufacturers' ability to optimally plan production and increased the risk of investing in production capacity. As a result, LMICs' procurement remained well below 3 million units per year from 2005 to 2011, and pricing only declined by 20 percent over that time.² At the time, two companies, Bayer and Merck & Co., produced implants that had received the stringent regulatory agency (SRA)³ approval. Also, there were only two major institutional buyers of contraceptives, the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID).⁴ This immediately focused the initial targets for the IAP partnership.

At this point, CHAI and partners had assembled sufficient data to confirm the market potential for implants. Partners working in the FP2020 focus countries forecasted implant demand through 2020 based on different contraceptive prevalence rate (CPR) and method mix⁵ scenarios within and across countries. Based on this data, the predicted global implant demand could reach approximately 9 million units per year by 2015, and could expand to over 11 million units by 2020 if countries met their FP2020 commitments.

After forecasting the potential demand, CHAI and the Bill & Melinda Gates Foundation both conducted studies to estimate the production cost of implants, including raw materials, labor, packing, overhead, etc. This allowed the partners to understand the key drivers (volumes, predictability, and standardization) that could help sustainably lower the cost of production and therefore translate into a lower price for LMICs.

Proposing a volume guarantee for implants

Demand aggregation through pooled procurement structures and volume guarantees are often useful in markets characterized by a high price/low volume trap. This type of agreement reduces risk to suppliers by allowing them to better plan production, and reduces the need to assign a risk premium to the market price; it also increases the value for money for donors and procurers.

In addition to the importance predictability, ordering patterns and overall volumes are also important determinants of production cost. A production facility is built to produce a certain number of units and has a significant amount of fixed costs which are present regardless of how busy the facility is. If a facility can run in a predictable way utilizing all or almost all of its capacity, its cost per unit is lower because the fixed costs are spread over more units. If it runs at only 50 percent of capacity, costs are much higher. Even worse, if a facility experiences unpredictable and low capacity utilization, it is extremely difficult to run efficiently with overtime and rush order costs added to high fixed costs per unit.

² RHInterchange, 2012.

³ For a complete definition of "stringent regulatory authority," please see WHO Technical Report Series 961, Annex 10, 45th report, 2011, <http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf>

⁴ Note a third supplier, Shanghai Dahua has applied for WHO pre-qualification and is currently undergoing clinical trials for Sino-Implant (II).

⁵ Contraceptive prevalence rate, or CPR, refers to the proportion of women of reproductive age who are using (or whose partner is using) a contraceptive method at a given point in time. Unmet need refers to the proportion of women who wish to space or limit births, but are not using a method of contraception at a given point in time. CPR can reflect both modern methods (such as implants) and traditional methods (including withdrawal), and is sometimes specified to refer solely to modern methods. Method mix describes the proportion of female contraceptive users who are using a particular method, and usually refers to modern method users only.

In the case of implantable contraceptives, both Bayer and Merck & Co. understood that if a guarantee could be structured properly, both their risk and cost of producing implants would be reduced. Therefore they could decrease prices per unit while still preserving overall profitability of their implants business line.

Negotiations with Bayer moved rapidly and culminated in an announcement in September 2012, in which Bayer agreed to reduce the price of their implant Jadelle from US \$18.00 to US \$8.50 in the FP2020 69 priority countries. In addition, Bayer extended the \$8.50 price to public sector purchases in other low and middle income countries. The agreement called for a steady procurement pattern so that the Bayer factory could operate at a high capacity utilization. In addition, the reliable offtake of annual production allowed Bayer to increase implant availability without capacity expansion because they were able to produce the guaranteed volume for certain months even in the absence of firm orders – product that was used in later months when the orders arrived and exceeded monthly production capacity.

The guarantors for this deal included a range of private and public sector funders, including the the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation, and the governments of the United States, Norway, and Sweden. The purchasing was funded by the governments of the United States, Norway, and the United Kingdom through UNFPA. Furthermore, the partners secured funding and provided programmatic support for capacity building activities in-country to support scale-up of implants to ensure that women had access to quality counseling and providers.

In early 2013, an agreement was also reached with Merck to reduce the price of Implanon and Implanon NXT by 50% in the 69 priority FP2020 countries. Merck's price reduction allowed women in the FP2020 countries to access their preferred implant method without a pricing consideration.

The Importance of Partnership

The particular mix of donors was especially important. The governments of the United States and the United Kingdom (through UNFPA) are the major funders for the purchase of implantable contraceptives, but neither are easily able to participate in long-term volume guarantees.

By contrast, the Swedish government, along with the Bill & Melinda Gates Foundation and the Children's Investment Fund Foundation, had the mechanisms in place to provide long term commitments but were not large funders of family planning commodities procurement.

The government of Norway, which was spearheading the creation of the UN Commission on Life-Saving Commodities for Women and Children, was interested in increasing access to implantable contraceptives as one of the Commission's 13 life-saving commodities, was able to provide a long term commitment in order to participate in the volume guarantee.

Bayer and Merck & Co. have very strong and high quality production and global support organizations and were able to respond effectively to different options as to how best to reduce costs and prices. As large, well-financed organizations they are able to take a long-term view and see the benefits for all sides in scaling up access to implantable contraceptives. Both companies have continued to invest in new capacity and automation improving the long term supply security for these products.

Results

Since 2012, more than 25.6 million implants have been distributed across the 69 FP2020 countries and South Africa. Annual procurement has more than doubled and has led to more than \$240 million in savings for donors and developing country governments. In late 2015, Merck and Bayer announced that they will extend their 50% price reduction for Implanon® NXT and Jadelle by an additional five years—through 2023. This extension *without* additional guarantee investment reflects the increased access and long-term sustained impact that can be achieved through improved demand visibility and scale procurement. It also underscores the incredible demand among women for long-acting contraceptive options, and the commitment of governments who have stepped up to give women more options so they are able to choose a method best suited to their needs. Our hope is that this success will continue to be sustainable, well beyond 2020, and will contribute to our ultimate vision of universal access to contraceptives.

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