Sino-implant (II) project

KEY POINTS

Sino-implant (II) is a low-cost, highly effective contraceptive implant.

Contraceptive implants can help reduce unmet need for family planning. Until recently, their high cost has limited their availability.

The Sino-implant (II) project has been at the forefront of helping reduce the cost of implants in resource-constrained settings.

FHI 360 provides technical assistance to support the introduction of Sino-implant (II) around the world.

With support from the Bill & Melinda Gates Foundation, FHI 360 provides technical assistance to facilitate the introduction of Sino-implant (II) — a low-cost, highly effective contraceptive implant — in resource-constrained countries. Under this initiative, FHI 360 (1) acts as an independent party to assess the quality of Sino-implant (II), (2) negotiates public-sector price-ceiling agreements with distributors, (3) works with distributors to secure national regulatory approvals of the product, (4) provides technical assistance to the product manufacturer to apply for World Health Organization (WHO) prequalification, (5) implements a new clinical study evaluating Sino-implant (II)’s safety, effectiveness and acceptability, (6) supports post-marketing studies, and (7) provides technical assistance for the introduction of Sino-implant (II) at the country level.

Highly effective, low-cost contraceptive method

Contraceptive implants are a highly effective, safe, long-acting and popular contraceptive method shown to be acceptable to women worldwide. They are also ideal for women with limited access to health care services because they do not require regular resupply from a provider. Although implants are popular in developing countries, their high cost has been a major barrier in many countries. The Sino-implant (II) project has been at the forefront of helping to reduce the cost of implants in resource-constrained settings.

Manufactured by Shanghai Dahua Pharmaceutical Co., Ltd. (Dahua), Sino-implant (II) is sold for approximately US$8 per unit and marketed in various countries as Zarin, Femplant, Trust, Simplant and other trade names. The product is composed of two thin rods, each containing 75 mg of levonorgestrel, the active ingredient. Sino-implant (II) is currently labeled for four years of use and is distributed with a disposable trocar with a CE mark (a mandatory conformity mark for the distribution of this medical device in European Union member states). A review of four randomized trials following more than 15,000 women showed that annual pregnancy rates were below 1 percent among users of Sino-implant (II).1

Quality testing

Quality evaluation efforts involve facilitating audits and inspections of the Dahua manufacturing plant, performing rigorous laboratory testing of the product, and leading clinical and post-marketing studies. The results from the first six years of the laboratory testing program (2008–2013) showed that Dahua demonstrates the ability to produce a contraceptive implant that meets international quality standards. For more information, see the “Quality Evaluation of Sino-implant (II)” fact sheet.

Product registration and regulatory approvals

As of January 2014, Sino-implant (II) was registered by more than 20 drug regulatory authorities. Under the Sino-implant (II) initiative, FHI 360 negotiates price-ceiling agreements with distributors to ensure that the product remains affordable in public and nonprofit sectors.

The Dahua manufacturing facility is deemed to be in compliance with WHO Good Manufacturing Practices (GMP). Registration and procurement of the product at the country level continues while the full WHO Prequalification review process for Sino-implant (II) is under way.

FHI 360 provides technical assistance to governments and service delivery groups that want to introduce Sino-implant (II). Information about training, clinical guidelines, logistics and other service delivery considerations can be found in the Knowledge for Health Implants Toolkit: http://k4health.org/toolkits/implants/.
About FHI 360: FHI 360 is a nonprofit human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. Our staff includes experts in health, education, nutrition, environment, economic development, civil society, gender equality, youth, research, technology, communication and social marketing — creating a unique mix of capabilities to address today’s interrelated development challenges. FHI 360 serves more than 70 countries and all U.S. states and territories.

**Ongoing research**

As part of the Gates-funded project and with funding from the U.S. Agency for International Development (USAID), prospective cohort studies have been completed in Bangladesh, Kenya, Madagascar and Pakistan, which followed more than 2,000 Sino-implant (II) users for 12 months. The results from these studies support existing evidence that indicates that Sino-implant (II) is a safe and highly effective method. In Bangladesh and Madagascar, no post-insertion pregnancies were reported, and in Kenya and Pakistan, the combined annual pregnancy rate was below 1 percent. In addition to these studies, a new clinical trial in the Dominican Republic will supplement existing clinical evidence regarding Sino-implant (II)’s effectiveness over four to five years of use.

**Impact of the Sino-implant (II) initiative**

More than one million units of Sino-implant (II) have been procured so far in countries included in the initiative. This translates into a commodity cost-savings of US$10.5 million for service delivery groups and donors. These savings can be reinvested into additional commodities, expanded training programs or other health services.

According to the Marie Stopes International impact calculator, the units of Sino-implant (II) procured to date can prevent more than 1.4 million unintended pregnancies, almost 3,000 maternal deaths and 175,000 abortions (http://www.mariestopes.org/Resources/Tools.aspx).

**Increased access for affordable implants**

The global landscape for implants is changing rapidly. In 2010, Jadelle, a two-rod implant manufactured by Bayer HealthCare, was available at an average price of US$22 for international procurement groups, and Implanon, a one-rod implant manufactured by Merck/MSD, was available for US$20, according to the RH Interchange. Bayer HealthCare lowered the price of Jadelle to US$8.50 per unit in low-income countries starting in January 2013 as part of an agreement brokered by a coalition of international partners. The agreement will guarantee funding for at least 27 million units through 2019. In addition, after reducing the price of Implanon to US$16.50 in 2012, Merck/MSD announced in 2013 another 50 percent price reduction to US$8.50 per unit in developing countries. These changes mean that both Jadelle and Implanon are now available at a price that is comparable to that of Sino-implant (II).

For more information about the Sino-implant (II) initiative, go to http://www.fhi360.org/en/Research/Projects/sinoimplant.htm or send an email to sino_implant@fhi360.org.

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5. MSD. MSD and partners announce agreement to increase access to innovative contraceptive implants Implanon® and Implanon NXT® in the poorest countries [press release]. 2013 May.