KEY POINTS

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

Contraceptive implants can help reduce unmet need for family planning. Although implants are popular in developing countries, 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 five years of the laboratory testing program (2008–2012) showed that Dahua demonstrates the ability to consistently 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 December 2012, Sino-implant (II) was registered by 24 drug regulatory authorities. Dossiers are under review in more than 10 additional countries. 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.

In 2010, Dahua submitted an application for Sino-implant (II) to the WHO Prequalification Programme. Registration and procurement of the product at the country level continues while the WHO 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, youth, research and technology — creating a unique mix of capabilities to address today’s interrelated development challenges. FHI 360 serves more than 60 countries, all 50 U.S. states and all U.S. 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 and Madagascar and are under way in Kenya and Pakistan. In the Bangladesh and Madagascar studies, no post-insertion pregnancies or product-related serious adverse events were reported in the more than 800 women who were followed over 12 months. The studies in Kenya and Pakistan have enrolled almost 700 additional women for 12-month follow-up, which will contribute to the evidence base on the effectiveness, safety and acceptability of the method in the first year of use. In addition, 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 870,000 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$10.4 million for service delivery groups and donors.5 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 1.2 million unintended pregnancies, almost 3,500 maternal deaths and 150,000 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. Under an agreement supported by the Reproductive Health Supplies Coalition, Merck/MSD announced in 2012 that it will reduce the price of Implanon to US$16.50, including a retroactive price reduction for units purchased since mid-2011.4 In addition, Bayer HealthCare announced that it will lower the price of Jadelle to under US$9 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 over the next six years5 and make Jadelle 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.

2 The study in Bangladesh was completed by EngenderHealth under the RESPOND project, which is funded by USAID. A final report is forthcoming; a summary of six-month findings is available at http://www.engenderhealth.org/. The studies in Kenya and Pakistan are funded by USAID under the PROGRESS project; final results are expected in early 2013.
3 Savings are based on a price of US$8 per unit for Sino-implant (II), assuming the alternative is to purchase Jadelle. The average price for Jadelle was US$24 in 2009, US$22 in 2010, US$19 in 2011 and US$18 in 2012 according to data from the RH Interchange available from: http://rhi.rhsupplies.org/rhi/index.do?locale=en_US.