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Report No. 8

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Acronyms and Abbreviations

CCSDP	Clinical Contraception Services Delivery Programme
DGFP	Directorate General of Family Planning
FWV	family welfare visitor
MCWC	Maternal and Child Welfare Center
MIS	management information system
mmHg	millimeter of mercury
MOHFW	Ministry of Health and Family Welfare
MSI	Marie Stopes International
NTC	National Technical Committee
UHC	Upazila Health Complex
USAID	United States Agency for International Development

Executive Summary

This report describes the results of a noncomparative prospective 12-month observational study that was conducted at 10 study sites in Bangladesh. The aim was to assess the acceptability and effectiveness of Sino-implant (II) among 595 women who had the device inserted in June and July 2011. The report presents data collected at baseline and at follow-up visits at three months, six months, and 12 months following insertion. Participants were interviewed using a standardized questionnaire, to evaluate insertion complications, method acceptability, pregnancy status, changes in menstruation, weight, or blood pressure, and any other side effects. Some data (e.g., weight and blood pressure) were gathered from participants' clinic records. Women who had the implant removed before 12 months were interviewed about the reasons for removal, their satisfaction with the removal, their health-seeking behavior and experiences, and any complications they experienced during or after removal.

Participant Satisfaction

At baseline

Women were satisfied with the implant insertion and were given clear counseling on what to do and where to go if they experienced any problems. Following insertion, all women (100%) reported that discomfort during insertion would not prevent them from getting another implant in the future. All stated that they were given clear instructions from the provider on what to do if they experienced any problems or side effects from the procedure and where to go if they wanted the device removed. More than 95% of women reported that they were satisfied or very satisfied with most aspects of their visit. Aspects that women rated below 95% included facility opening time (94%), privacy (91%), and waiting time (80%).

At follow-up

Most study participants remained satisfied with Sino-implant (II) over the 12-month period. The majority (95% at three months, 97% at six months, and 94% at 12 months) reported that their experience with the method was "very favorable" or "somewhat favorable." When asked what they did not like about the method, the most frequently mentioned aspect was a change in menstruation, although this percentage declined from 50% at three months to 33% at six months and 12 months each. The most frequently mentioned positive aspects were the device's four-year duration of use and its ease of use

Although bleeding patterns changed for the participants following insertion of Sino-implant (II), the majority of participants (70% at three months, and 68% at six months and 12 months each) found the changes acceptable. Despite the reported irregularities in menstrual patterns, just over half of participants at six months reported that their amount of menstrual blood loss was "about right." This percentage further increased to 60% at 12 months.

Safety and Efficacy

Serious adverse events and pregnancy

No serious adverse events or pregnancies were reported since the study began. The overall failure rate was zero during one year of use. Although three pregnancies were reported at the early stage of the study, these were due to misdiagnosis during participant assessment on the day of insertion.

Problems at the insertion site

The majority of women (91%) reported no problems at the insertion site. Of the participants who did report issues at 12 months, the major problems were pain at the insertion area (2.5%) and itching (2.9%). Thirty participants at three months, nine at six months, and eight at 12 months said that they had sought medical attention. Of this group, 70% at three months, 67% at six months, and 88% at 12 months found that getting medical assistance was very easy for them and that their problems were addressed.

Continuation/removal

At 12 months, out of 595 acceptors, 528 (89%) were continuing to use Sino-implant (II). Fifty-three (9%) had had the implant removed, and 14 (2%) were lost to follow-up. Among the women who had the device removed, the majority (64%, n=34) requested removal because of *side effects or health-related concerns*; some were side effects common to hormonal methods, such as lower abdominal pain and changes in bleeding patterns; others were clinically unrelated—such as weakness, weight loss, and typhoid—but were perceived by clients and/or providers to be linked to the method. A small proportion (15%, n=8) of removals were due to reported immediate or delayed *infections* to Sino-implant (II). In five of those eight cases, the participants reported that the entire rod or a portion of the rod had come out from the insertion site. Only in one case did symptoms of infection develop within one week of insertion. The other seven ranged in timing from two weeks to three months following insertion. *Other reasons* for removal were: spousal objection/physical separation/divorce (six), misdiagnosed pregnancy (three), and desire to become pregnant (two).

A small proportion (8%, n=4) of the 53 removals were *done by providers who were not physicians* and who charged the participants a fee for the service. In three of these cases, a "village doctor" removed the implants for fees ranging from 100 to 1000 Taka; in the fourth case, a pharmacist removed the implant for 200 taka.

Physical/mental health

More than half of the women (55% at three months, 63% at six months, and 67% at 12 months) reported no changes in physical or mental health that could be related to the implant use. Of the participants who reported issues, the major problems were headache, weakness, and body ache. The majority of complaints remained fairly constant, but a few changed over the course of the duration of use: Reports of headache decreased substantially (from 20% to 9% to 5%), while reports of vaginal discharge and back pain increased slightly at six months and then decreased by 12 months.

Weight and blood pressure

There were no substantial changes in weight or blood pressure from baseline. During the enrollment period, about 75% of the participants weighed between 40 kg and 59 kg. The participants' average weight at enrollment was 48 kg, and at three months, six months, and 12 months, this average was unchanged. At baseline, before implant insertion, nearly 80% of the participants had a

systolic blood pressure between 100 and 140 mmHg, with a mean of 105 mmHg. The mean dropped to 103 at three months, 102 mmHg at six months, and 100mmHg at 12 months. At baseline, before implant insertion, nearly 72% of participants had a diastolic blood pressure of between 60 and 79 mmHg, and the mean was 68 mmHg; this mean dropped to 67 mmHg at three months, 68 mmHg at 12 months, and 66 mmHg at 12 months.

Provider Perspectives

At follow-up

Overall, providers were very supportive of Sino-implant (II). At six months and 12 months, all but one of the 10 physicians and paramedics reported that insertion of Sino-implant (II) was easy. At six months and 12 months, all reported that removal was also easy. Although all providers stated that they themselves were satisfied with Sino-implant (II) as a family planning method at six months and 12 months, about half (nine of 20) at six months and one at 12 months thought that the participants were not satisfied with the method. The most frequent responses as to why this was so were irregular bleeding (56% at six months and 70% at 12 months). The most frequent provider response for the focus of scale-up was to improve counseling and follow-up.

Bangladesh Study Findings in Context

Sino-implant (II) has been commercially available since 1996 and has been approved in 24 countries; more than 7 million units have been distributed to date. Postmarketing studies in Kenya, Madagascar, and Pakistan are being coordinated by FHI 360, using a protocol similar to the one used in Bangladesh and using the same data collection processes. In Bangladesh, the insertions were performed as part of the ongoing service delivery system by experienced local physicians at seven governmental and three nongovernmental sites. In Kenya, the study was implemented at Ministry of Health sites, but the insertions were done by an FHI 360 doctor-nurse team, who performed the insertions for that study alone with equipment, supplies, and expendables supplied by FHI 360. In Madagascar and Pakistan, physicians employed by Marie Stopes International (MSI) also performed the insertions for those studies alone, with equipment, supplies, and expendables at private MSI-supported sites or through mobile clinics.

The Madagascar study (N=638) completed 12-month follow-up in February 2012, while the Kenya (N=603) and Pakistan studies (n=724) are currently completing a 12-month follow-up. Two very early postinsertion pregnancies, no product-related severe adverse events, and no removals due to infection have been reported among these 1,965 study participants, other than one case of removal due to infection in Madagascar reported at the three-month follow-up.

Recommendations

The findings from this study are intended to inform the Directorate General of Family Planning (DGFP) National Technical Committee's decision on whether to introduce Sino-implant (II) into the national family planning program. The below recommendations were developed for this purpose.

Sino-Implant (II) should be introduced into the national family planning program, as it is safe and effective and acceptable to Bangladeshi women. At 12 months, there were no serious adverse events or pregnancies due to contraceptive failure, and 89% of women were continuing to use Sino-implant (II), clearly indicating its acceptability. With a per-unit wholesale cost of approximately $8, Sino-implant (II) should prove a good option for the Bangladesh family planning program.

Implant training curricula and protocols should be reviewed and revised with a focus on insertion technique and infection prevention procedures. Although the 12-month discontinuation rate (9%) was very low and the number of removals (n=53) was compatible with the other countries, it is important to note that eight of the removals were due to participants' reports of immediate or delayed infections; in addition, five of the eight reported that the implant rods emerged from under the skin. Given the delayed timing and nature of most of the infections, it is possible that some of these infections were related to poor insertion technique, including incomplete insertion of the rods or partial removal of the rods upon withdrawal of the trocar, thereby creating a persistent open wound that over time could serve as a route of infection. Another explanation for the immediate postinsertion infection could be that there was a lapse in infection prevention protocols, specifically around management of autoclaved instruments and supplies. Therefore, the content of the implant training curriculum should be thoroughly reviewed, with a focus on proper provider insertion technique and infection prevention procedures; in the latter case, the focus should be on the relationship between the frequency of opening and closing the drum and the contamination of items inside it.

Counseling protocols for side effects management should be revised and conducted according to World Health Organization (WHO) guidelines. The majority of the 53 removals were due to side effects, particularly related to changes in vaginal bleeding. WHO suggests specific steps in treating the most common side effect, irregular vaginal bleeding. One is the use of nonhormonal methods, such as nonsteroidal anti-inflammatory drugs (NSAIDs). Another is hormonal treatments (if the woman is medically eligible), such as combined oral contraceptive pills or ethinyl estradiol. Removal of the implant is recommended if clients continue to find side effects bothersome. These steps are all included in the DGFP Family Planning Manual.

Our study found that providers did not always strictly adhere to the WHO counseling guidelines, and some participants endured some discomfort and side effects for extended periods of time. In addition, we found that providers on occasion removed the implant based on health complaints that were unrelated to the implant. It is possible that these women requested removal despite receiving adequate counseling from providers about the unlikely relationship between the implant and some of the reported side effects—in which case, removal would be appropriate, based on the client's wishes. However, it is important to stress that providers should be receiving refresher training on counseling based on WHO guidelines, with a focus on the management of side effects, information that the side effects may diminish over time, and a discussion about the potential impact of the side effects on clients' daily lives.

In addition counseling around implant removal should be strengthened. At baseline, all of the women stated that the provider gave them clear instructions on what to do if they

experienced any problems or side effects from the procedure and where to go if they wanted the device removed. Physicians are allowed to insert and remove implants, and this is done free of charge. Nevertheless, four participants went to pharmacists and "village doctors" to have the implants removed and were charged for the service. We therefore recommend that DGFP client protocols be strengthened, by placing a stronger emphasis on where to go to obtain advice and treatment for health concerns. In addition, pharmacists and village doctors should be educated about the importance of referring clients requesting implant removal to a trained provider.

Review pregnancy diagnostic tools and develop one integrated form. The physician and paramedics used a combination of the FHI 360 pregnancy checklists and the regular DGFP "implant client full history and informed consent form" to diagnose pregnancy prior to implant insertion. Because the study found three misdiagnoses of preexisting pregnancies, we recommend a review of the use of the pregnancy diagnostic tools and development and introduction into the national program of one synthesized form.

"Wound care kits" could be introduced to improve postinsertion wound care by the acceptors. In addition to the issues of insertion technique on the part of providers discussed above, participants' unhygienic wound care or poor wound healing due to unhealthy conditions may have contributed to the number of infections and removals. Providing clients at discharge with wound care kits containing alcohol, cotton, and waterproof bandages and counseling them on how to effectively care for the insertion site may help address this issue.

Background

The demand for long-acting family planning methods, in particular the hormonal implant, has increased in Bangladesh in recent years. Over the last five years, on average, 11,000 implants have been inserted each month. This number increased to 44,000 per month when the method was made fully available and accessible.[1] Following acceptability trials, the Directorate General of Family Planning (DGFP) of the Ministry of Health and Family Welfare (MOHFW) approved two types of implants (Implanon® and Jadelle®) for use in Bangladesh. (Only Implanon is currently available. Jadelle will become available following the completion of the Government of Bangladesh procurement process.) Both of these implants are relatively costly; the DGFP considers the high cost of implants a barrier to availability, and frequent stock-outs may continue to occur as a result. The DGFP seeks inexpensive, long-term options that are safe and effective. In this context, the RESPOND Project and the Mayer Hashi project[2] provided technical assistance to the DGFP to conduct an acceptability trial on Sino-implant (II), to determine if it could be introduced into the national family planning program.

Sino-implant (II) is a subdermal contraceptive implant made in China by Shanghai Dahua Pharmaceutical Company. Like Jadelle®, it is a two-rod subdermal implant containing 150 mg levonorgestrel, and it has an annual pregnancy risk less of than 1%. With a per-unit wholesale cost of approximately $8, these data suggest that Sino-implant (II) would be a good option for lower income women, in comparison with costlier implants.

Sino-implant (II)'s contraceptive effectiveness and safety have been well established, and the device has been approved by 20 drug regulatory authorities. However, there is no direct clinical experience with the device in Bangladesh. Therefore, the Mayer Hashi project provided technical assistance to the DGFP to conduct a noncomparative prospective observational study to assess the acceptability of Sino-implant (II) among Bangladeshi women over a 12-month period. The data from this trial are expected to be used by the DGFP National Technical Committee (NTC) to decide whether to introduce Sino-implant (II) into the national family planning program[3] and to provide lessons for scale-up.

FHI 360, a partner on the global RESPOND Project, works with licensees and local service delivery organizations to facilitate the registration of Sino-implant (II), with the financial support of the Bill & Melinda Gates Foundation. FHI 360 and Marie Stopes International (MSI) are conducting studies similar to this one in Kenya, Madagascar, and Pakistan. The

[1] Source: Management information system (MIS) data, Department of MIS, DGFP, MOHFW.

[2] The RESPOND Project (Responding to the Need for Family Planning through Expanded Contraceptive Choices and Program Services) is a five-year U.S. Agency for International Development (USAID) Leader with Associates Cooperative Agreement. RESPOND is led by EngenderHealth, in partnership with five other organizations: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs (JHU/CCP), the Futures Institute, the Population Council, FHI 360, and Meridian Group International, Inc. The Mayer Hashi project is a five-year Associate Award to the RESPOND Project that is being implemented in Bangladesh by EngenderHealth, in partnership with JHU/CCP and the Population Council.

[3] The Director of the Clinical Contraception Service Delivery Program (CCSDP) of the DGFP obtained a "No Objection Certificate" from the Drug Administration for this trial; this allowed women to use the product as part of the study only.

protocol for this study was adapted from a common protocol that was vetted and approved by the FHI 360 Institutional Review Board (the Protection of Human Subjects Committee) and by the Bangladesh Medical Research Council.

Objectives and Methodology

Objectives

The primary objective of this study was to assess the acceptability of Sino-implant (II) and user satisfaction among Bangladeshi women. The study also monitored the occurrence of complications during insertion and removal, the safety of the method, pregnancy rates, and service provider experiences during insertion, follow-up, and removal.

Methodology

Type of study and selection of study sites

The study was a noncomparative prospective observational study. Between June 14 and July 27, 2011, participants were enrolled at 10 clinics, seven from the governmental sector[4] and three from the nongovernmental sector.[5] Data were collected at the time of implant insertion and during three follow-up visits, at three months, six months, and 12 months following insertion. Sites were selected based on their monthly implant client flow and their geographic proximity, to ensure close monitoring and follow-up. Each clinic recruited between 30 and 90 study participants during the one-month enrollment period.

Sample size

Based on implant prevalence and continuation rates within and after 12 months of insertion, and at 95% confidence limit (with ±5 percentage-point error margin and 1.5 design effect), we estimated that a minimum sample size of 582 users was required. Therefore, we recruited 595 married women of reproductive age from the 10 study sites.

Data collector training

Ten research assistants, two supervisors, and one study coordinator were employed independently for this study alone.[6] All were thoroughly trained on the study objectives, data collection procedures, and ethical procedures for collecting and handling data during a three-day training session at baseline; they also received refresher trainings before each follow-up visit. The study coordinator, a physician, was trained on the protocols for defining and reporting serious adverse events to the technical advisory group, which included researchers, physicians, and obstetrician-gynecologists from the DGFP/MOH&FW, Mayer Hashi, the RESPOND Project, FHI 360, and Dahua Pharmaceuticals.

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[4] Mohammadpur Fertility Service and Training Center, Dhaka (90 women); Upazila Health Complex (UHC), Savar (90 women); UHC, Kaliakair (50 women); UHC, Akhura (30 women); Maternal and Child Welfare Center (MCWC), Cox's Bazar (85 women); MCWC, Manikgong (90 women); Union Health and Family Welfare Center, Mirzapur (50 women).

[5] Marie Stopes Bangladesh, Mohakhali (30 women); Smiling Sun Franchise Program, Tongi (30 women); Bangladesh Association for Voluntary Sterilization, Barisal (50 women).

[6] This is the first acceptability trial in Bangladesh that has used this method of employing data collectors solely for data collection, which may have reduced provider bias.

Clinical training

Mayer Hashi and the DGFP co-organized and conducted provider training on Sino-implant (II) on June 5–6, 2011, in Dhaka. A total of 27 providers were trained: 20 providers from the study sites (one physician and one paramedic/family welfare visitor [FWV][7] per site) and an additional seven physicians from the DGFP and the Mohammadpur Fertility Service and Training Center, who were to monitor the program activities. The training had both theoretical and practical components, with sessions on counseling, infection prevention, and collection of participant data.[8]

The physician trainees inserted 12 implants during the training (the 10 physicians from the 10 study sites each inserted at least one). All of the physician trainees were experienced, trained physicians, and all had been inserting Implanon and Norplant in Bangladesh for an average of five years prior to the training. Many also had been trained to insert Jadelle®, which was previously tested at many of the same sites. To assess post training competency, the training team used a skills checklist consisting of 12 critical steps to be followed in providing clinical contraception. All 10 physician trainees completed the 12 critical steps successfully and were certified as competent. A refresher training of the study site physicians and paramedics conducted three months after the first training enabled trainees to share experiences and refresh their skills on counseling, side effects management, and infection prevention.

Participant enrollment

The participants were enrolled during a routine family planning visit between June 14 and July 27, 2011. All participants were counseled about all available contraceptive methods. When a woman decided to use the implant as her primary contraceptive method and she was assessed for method suitability according to DGFP protocols, clinic staff offered her Sino-implant (II) as an option and invited her to participate in the prospective study. If she agreed, her informed consent was obtained and she was evaluated again for eligibility for method use by an FWV or paramedic, who took the client's history, counseled her, and performed medical examinations, as necessary. Once enrolled in the study, women were interviewed during the period between implant insertion and discharge from the facility, using a baseline data collection form, for details of the insertion procedure, quality of counseling, satisfaction, and complications (if any). All information was kept confidential and on file at Mayer Hashi. Only research staff had access to the data.

Follow-up interviews and interviews with removal cases

Women were instructed to return for follow-up at one, three, six, and 12 months to the site where the implant was inserted, and they were encouraged to return to the clinic at any time if they experienced medical or other problems related to Sino-implant (II), if they became (or suspected that they might be) pregnant, or if they wanted to have the implant removed. A

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[7] The paramedics/FWVs did not perform insertions because they are not allowed to insert implants under DGFP/MOH&FW protocols. Their role in the study was to administer informed consent after the client chose Sino-implant (II) as part of a routine family planning visit, counsel the clients again on all family planning methods, confirm participant choice and eligibility for the method, and take the participants' medical history.

[8] EngenderHealth has had a historical collaboration with the DGFP, initiated in 2001, to support the government's effort to improve couples' access to long-acting and permanent methods of contraception. This collaboration included the implementation of a similar study to assess the acceptability of Implanon, which is currently used in the National Family Planning Program.

participant was marked as "lost to follow-up" if three subsequent visits to her home and/or telephone inquiries were made unsuccessfully.

Data collectors administered a standard survey questionnaire at three months (September to October 2011), six months (December 2011 to January 2012), and 12 months (July to August 2012) to evaluate insertion complications, method acceptability, pregnancy status, changes in menstruation, weight, or blood pressure, and any other side effects. Some data (e.g., weight and blood pressure) were gathered from participants' clinic records. FWVs or paramedics performed urine pregnancy tests, as necessary. A few participants were interviewed through home visits or telephone, in cases where they could not come to the clinic (17 participants at three months, 26 at six months, and 11 at 12 months). Women who had the implant removed before 12 months were interviewed about the reasons for removal, their satisfaction with the removal, their health-seeking behavior and experiences, and any complications they experienced after removal.

Provider interviews

Twenty service providers (10 physicians who inserted Sino-implant (II) and the 10 FWVs and paramedics who provided counseling and follow-up) were interviewed at the six-month and 12-month follow-up, using a structured questionnaire to assess their level of satisfaction with Sino-implant (II), its ease of insertion, their management of side effects, and their experience with removals.

The data collected from the participants at enrollment, at three months, at six months, and at 12 months, as well as the information gathered from the providers at six months and at 12 months, were analyzed and are presented in this final report.

Results

Enrollment

In total, 595 women had Sino-Implant (II) inserted[9] at the 10 study sites. Ninety-six percent of interviews were conducted on the clinic premises, about 1% the at participant's home, and less than 1% over the telephone (Table 1).

Continuation and Removals

As of 12 months, 528 (89%) out of 595 participants were continuing users of Sino-implant (II). Fifty-three participants (9%) had discontinued the method, and another 12 participants (2%) were lost to follow-up (method status unknown) (Table 1).

Table 1. Outcomes of follow-up interviews with study participants

	Follow-up interview						Total at 12 months	
	3 months		6 months		12 months			
Outcomes of follow-up interview	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Participant was contacted and interviewed	582	97.8	567	97.9	557	97.5	na	na
Household could not be located	8	1.3	5	0.9	5	0.9	na	na
Client moved to another place	3	0.5	5	0.9	7	1.2	na	na
Client was not at home	2	0.3	2	0.3	2	0.4	na	na
Means/location of follow-up interview								
By phone	5	0.8	18	3.1	3	0.5	na	na
At clinic where Implant was inserted	565	95.0	541	93.4	546	95.6	na	na
At participant's home	12	2.0	8	1.4	8	1.4	na	na
Participant was not available	13	2.2	12	2.1	14	2.5	na	na
Status of Sino-implant (II) use								
Continued	566	95.1	559	96.5	528	92.5	528	88.7
Discontinued	16	2.7	8	1.4	29	5.1	53	8.9
Lost to follow-up	13	2.2	12	2.1	14	2.5	14	2.4
N	**595**	**100.0**	**579**	**100.0**	**571**	**100.0**	**595**	**100.0**

na=not applicable.

Among the 53 removals, 17 were reported by three months, another eight by six months, and the remaining 28 by 12 months. Women were asked at all three follow-up visits to provide reason(s) for removal. The study team then followed up on all removals by interviewing the women and the providers and by examining records, to produce a detailed history, which was recorded on a standard reporting form.

The majority (64%, n=34) of the 53 women requested removal because of *side effects* or *health-related concerns* (Table 2, page 8); some were typical side effects that are directly attributable to the use of hormonal methods, such as lower abdominal pain and changes in bleeding patterns;

[9] This includes the 12 participants who received Sino-implant (II) during the service provider training.

others were clinically unrelated—such as weakness, weight loss, and typhoid—but were perceived by clients and/or providers to be linked to the method. A small proportion (15%, n=8) of the 53 removals were due to reported immediate or delayed *infections*. In five of those eight cases, participants reported that the entire rod or a portion of the rod came out from the insertion site. Only in one case did the symptoms of infection develop within one week of insertion. The other seven ranged in timing from two weeks to three months following insertion.

A small proportion (8%, n=4) of the 53 removals were *done by providers who were not* physicians; these charged the participants a fee for service. In three cases, a "village doctor" removed the implants, for fees ranging from 100 to 1,000 Taka; in the fourth case, a pharmacist removed the implant for 200 taka. *Other reasons* for removal were: spousal objection/physical separation/divorce (six), misdiagnosed pregnancy (three), and desire to become pregnant (two). Almost one-quarter of participants (23%, n=12) reported that they were given oral contraceptive pills for the management of menstrual bleeding. Although most used these pills for several months to manage the bleeding, they reported that their problems either did not disappear or resumed when they discontinued taking the pills.

Table 2. Removals of Sino-implant (II), by major causes

	3 months		6 months		12 months		Total	
Reasons for removal	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Infection	6	35	1	13	1	4	8	15
Side effects/health concerns	7	41	6	75	21	75	34	64
Spousal objection/separation/ divorce	1	6	1	13	4	14	6	11
Misdiagnosed pregnancy	3	18	0	0	0	0	3	6
Desire to become pregnant	0	0	0	0	2	7	2	4
Total	**17**	**100**	**8**	**100**	**28**	**100**	**53**	**100**

In October 2011, in response to the initial six removals due to infection reported within the first three months of the study, Mayer Hashi assembled a global team of experts[10] to review the removal cases and to agree on action steps at the 10 study sites. The team concluded that none of the removals were serious adverse events, but, because of the infection cases, they recommended that Mayer Hashi and the DGFP organize refresher training for the providers at the 10 study sites, focusing on counseling, follow-up, side effects management, and other aspects of service quality. The team also recommended increasing the frequency of monitoring and supervision visits (from three to five visits per site during the study period) and having each visit include at least one Mayer Hashi clinician. This was done, and Mayer Hashi staff observed during their supervisory visits that physician trainees had improved their understanding of and management of and counseling about side effects. Data on removals were reviewed and analyzed at six months and 12 months.

[10] The team included Dr. Mahbubur Rahman, Line Director, CCSDP, DGFP/MOH&FW, who was the principal investigator for the study; Dr. Latifa Shamsuddin, a senior obstetrician-gynecologist and president-elect of the Obstetrics and Gynecological Society of Bangladesh, who was advising the study team in a consultant capacity; and physicians from Mayer Hashi. At the international level, feedback was received from the RESPOND Project, FHI 360, and Dahua Pharmaceuticals.

Participant Characteristics

About 94% of the enrolled participants were younger than 35 (Table 3). The mean age of the participants was 27. They had an average of 2.3 living children, and 66% of the participants had two or fewer children. The mean age of the last child was three years, seven months. About 43% of the participants had completed their primary education, and 6% had completed a secondary or tertiary education. About 94% of the participants were homemakers. About one-fifth had not been using any contraceptive method before starting Sino-implant (II), while the remainder were practicing some kind of contraception, predominately oral contraceptives (45%) and injectables (26%).

Table 3. Demographic characteristics of study participants

Age (in years)	**No.**	**%**
<20	15	2.5
20–24	182	30.6
25–29	180	30.3
30–34	107	18.0
35–39	86	14.5
>39	25	4.2
Mean		*27.5*
Median		*26.0*
Std. deviation		*5.8*
Number of living children		
1	137	23.0
2	259	43.5
3	126	21.2
4	49	8.2
>4	24	4.0
Mean		*2.3*
Median		*2.0*
Std. deviation		*1.1*
Contraceptive method used prior to Sino-implant (II)		
Pill	267	44.9
Condom	46	7.7
Injectable	152	25.5
IUD/Copper-T	2	0.3
Implant/Implanon	11	1.8
Withdrawal	6	1.0
Periodic abstinence	3	0.5
None	108	18.2
N/Total	**595**	**100.0**

Participants' Health and Experience with Side Effects

Weight and blood pressure

Users of Sino-implant (II) showed no substantial changes in weight or blood pressure from baseline. During the enrollment period and still at 12 months use of Sino-implant (II), about 75% of the participants weighed 40–59 kg. The participants' average weight was 48 kg, and this average did not change at three months, six months, or 12 months following insertion. At baseline, before Sino-implant (II) insertion, nearly 80% of the participants had a systolic blood pressure of between 100 and 140 mmHg, and the mean was 105 mmHg. The mean dropped to 103 mmHg at three months, 102 mmHg at six months, and 100 mmHg at 12 months. At baseline before implant insertion, nearly 72% of the participants had a diastolic blood pressure of between 60 and 79 mmHg, and their mean was 68 mmHg. This mean dropped to 67 mmHg at three months, 68 mmHg at six months, and 66 mmHg at 12 months (data not shown).

Menstruation and bleeding patterns

Bleeding patterns changed for the participants following insertion. While 88% of the participants had regular menstruation before insertion of Sino-implant (II), this percentage fell to 17% at three months and increased slightly to 20% at six months and 28% at 12 months. About 43% of the participants at three months and 51% at six months had developed amenorrhea due to use of Sino-implant (II). Encouragingly, amenorrhea due to use of Sino-implant (II) decreased significantly, to 31%, at the end of 12 months. Other menstrual bleeding problems that developed after insertion of Sino-implant (II) included irregular bleeding (30% at three months). However, irregular bleeding declined to 24% at three months and slightly increased to 30% at 12 months. About 10% of the participants developed spotting at three months of Sino-implant (II) use; this proportion declined slightly, to 8.5% and 8.8% at six months and 12 months, respectively (Table 4).

Table 4. Status of menstruation and breastfeeding among study participants

	At baseline	
Regular menstruation	**No.**	**%**
No	73	12.3
Yes	522	87.7
Breastfeeding status before insertion of Sino-implant (II)		
No	296	49.7
Yes	299	50.3
N	**595**	**100.0**

Status of menstruation since last clinic visit after insertion of Sino-implant (II)*	**Follow-up interview**					
	3 months (N=582)		**6 months (N=567)**		**12 months (N=557)**	
Status of menses	**No.**	**%**	**No.**	**%**	**No.**	**%**
Regular bleeding	97	16.7	111	19.6	158	28.4
Irregular bleeding	174	29.9	136	24.0	168	30.2
Frequent bleeding	32	5.5	20	3.5	26	4.7
Infrequent bleeding	41	7.0	25	4.4	36	6.5
Spotting	58	10.0	48	8.5	49	8.8
No bleeding/amenorrhea	250	43.0	287	50.6	175	31.4

*Multiple answers were possible.

Participants' perceptions of bleeding patterns

Just above half of the participants at three months and at six months reported that their menstrual blood loss was "about right"; this proportion increased to 60% at 12 months (Table 5). Additionally, 58% and 62% mentioned at three and six months that the duration of menstrual bleeding was "about right"; this percentage increased to 69% at 12 months. Despite some irregularities in menstrual bleeding patterns, about 70% of the participants at three months, 68% at six months, and 68% at 12 months said that their current pattern of menstruation was acceptable to them.

Women also were asked about acceptability of ceased menstruation. About 62% at three months and 67% at six months and 12 months mentioned that the current pattern of ceased menstruation was acceptable to them (Table 5).

Table 5. Participants' perceptions of menstruation and bleeding patterns

	Follow-up interview					
	3 months		6 months		12 months	
Volume of menstrual blood	**No.**	**%**	**No.**	**%**	**No.**	**%**
Too little	130	39.2	107	38.2	116	30.4
About right	175	52.7	152	54.3	230	60.2
Too much	27	8.1	21	7.5	36	9.4
Duration of menstrual bleeding episode						
Too short	84	25.3	52	18.6	55	14.4
About right	194	58.4	174	62.1	262	68.6
Too long	54	16.3	54	19.3	65	17.0
Acceptability of bleeding pattern (blood loss and bleeding episode)						
Acceptable	232	69.9	189	67.5	266	68.1
Not acceptable	100	30.1	91	32.5	122	31.9
N	**332**	**100.0**	**280**	**100.0**	**382**	**100.0**
Acceptability of ceased menstruation						
Acceptable	155	62.0	191	66.6	117	66.9
Not acceptable	95	38.0	96	33.4	58	33.1
N	**250**	**100.0**	**287**	**100.0**	**175**	**100.0**

Problems at insertion site/side effects

Most women had no complaint of local problems or side effects at the insertion site (85% at three months, 93% at six months, and 94% at 12 months). However, it is notable that 15% of participants experienced minor problems or side effects across all three periods. The most common were pain at the insertion site, itching, and numbness of the arm. Among the participants who had some local complaints, 58 (70%) at three months, 32 (78%) at six months and 25 (76%) at 12 months said they did not seek any treatment, due to the minor nature of the problem (data not shown). Of the participants who sought treatment; the majority—70% at three months, 67% at six months, and 88% at 12 months—said that getting medical assistance was very easy for them (Table 6, page 12).

Table 6. Participant-reported problems at insertion site and side effects,* and ease of receiving medical assistance

Problems/side effects faced*	Follow-up interview					
	3 months (N=582)		6 months (N=567)		12 months (N=557)	
	No.	%	No.	%	No.	%
None	494	84.9	526	92.8	524	94.1
Discharge/wetness at insertion site	1	0.2	1	0.2	0	0.0
Local redness/swelling	9	1.5	0	0.0	1	0.2
Infection	3	0.5	1	0.2	1	0.2
Pain in the insertion area	40	6.9	23	4.1	14	2.5
Numbness of arm	18	3.1	12	2.1	4	0.7
Pain in the inserted hand	5	0.9	5	0.9	0	0.0
Itching	26	4.5	6	1.1	16	2.9
Ease of receiving medical assistance for these problems/side effects						
Very easy	21	70.0	6	66.7	7	87.5
Fairly easy	5	16.7	1	11.1	0	0.0
Average	4	13.3	1	11.1	1	12.5
Fairly difficult	0	0.0	0	00.0	0	0.0
Very difficult	0	0.0	1	11.1	0	0.0

*Multiple answers were possible.

Physical and mental changes due to Sino-implant (II) use

At the first follow-up visit, more than half of the participants had no physical or mental complaints related to the use of Sino-implant (II); this percentage increased to 63% at six months and to 67% at 12 months (Table 7). Those who complained of some kind of physical or mental problems at three months mentioned headache (20%), weakness (12%), and body ache (10%). Less frequently reported problems included lower abdominal pain (4%), weight gain (3%), hair loss (3%), mood change (3%), back pain (2%), white discharge (2%), and weight loss (1%) (Table 7). At six months, headache complaints decreased substantially, from 20% to 9%; they decreased further, to 5%, at 12 months.

Table 7. Participant-reported physical/mental changes*

Physical and mental changes	Follow-up interview					
	3 months (N=582)		6 months (N=567)		12 months (N=557)	
	No.	%	No.	%	No.	%
None	321	55.2	355	62.6	396	66.9
Headaches	118	20.3	51	9.0	31	5.2
Weight gain	18	3.1	18	3.2	4	0.7
Hair loss	19	3.3	21	3.7	2	0.3
Acne	0	0.0	1	0.2	0	0.0
Mood change (depression, anxiety)	16	2.7	15	2.6	6	1.0
Weakness	72	12.4	73	12.9	90	15.2
Back pain/body ache	69	11.9	82	14.5	47	7.9
Lower abdominal pain	21	3.6	14	2.5	8	1.4
Whitish discharge	10	1.7	18	3.2	6	1.0
Weight loss	5	0.9	0	0.0	2	0.3
Breast secretion	0	0.0	1	0.2	0	0.0
Increased cholesterol	0	0.0	1	0.2	0	0.0

*Multiple answers were possible.

Other common complaints included weakness and body ache. The proportion reporting weakness increased slightly, from 12% at three months and 13% at six months to 15% at 12 months. While the proportion reporting body ache increased from 12% at three months to nearly 15% at six months, it decreased to 8% at 12 months. Some participants reported various atypical symptoms, such as acne, breast secretion, and increased cholesterol at six months, but these were not reported at the 12-month follow-up. While reporting of vaginal discharge increased from 2% at three months to 3% at six months, it decreased to 1% at 12 months (Table 7).

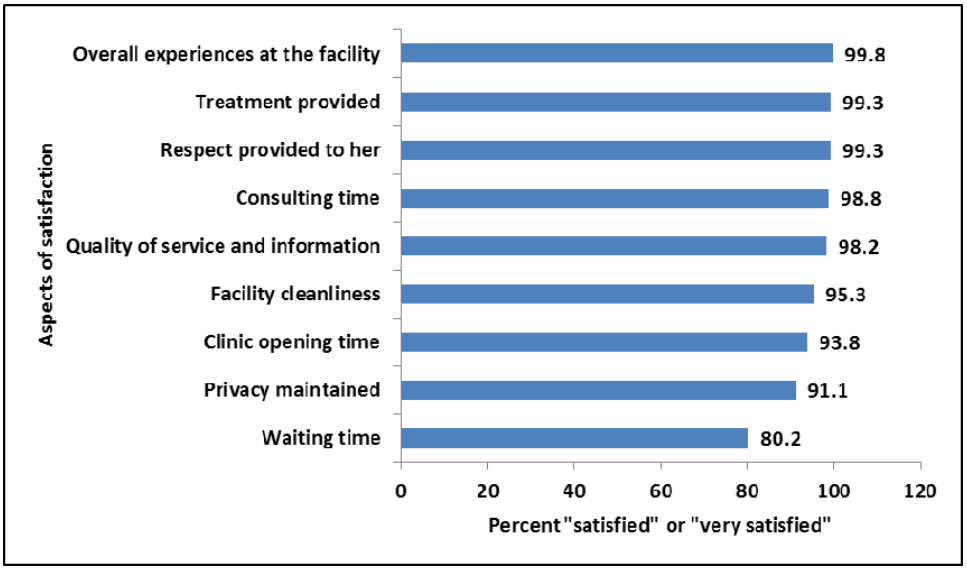
Participants' Perspectives

At baseline

Women were satisfied with the implant insertion and said they were given clear counseling on what to do and where to go if they experienced any problems. Following insertion, all women (100%) reported that discomfort during insertion would not prevent them from getting an implant in the future (data not shown). All stated that they were given clear instructions from the provider on what to do if they experienced any problems or side effects from the procedure and where to go if they wanted the implant removed. When asked where they would go and what they would do, all women stated that they would go to the clinic where Sino-implant (II) was inserted or any other governmental clinic. When asked how long they should wait before having the implant replaced, all said four years (data not shown).

Women also were asked about how satisfied they were with different aspects of their visit. More than 95% reported that they were satisfied or very satisfied with most aspects of their visit. Aspects rated below 95% included facility opening time (94%), privacy (91%) and waiting time (80%) (Figure 1).

Figure 1. Participants' satisfaction with different clinic activities



At follow-up

Almost all women at three months (99.1%), at six months (99.8%), and (100%) at 12 months reported that they were either "fairly satisfied" or "very satisfied" with the facility services provided to them (Table 8, page 14).

Table 8. Satisfaction level of participants at follow-up

	Follow-up interview					
	3 months		6 months		12 months	
Satisfaction with facility services	**No.**	**%**	**No.**	**%**	**No.**	**%**
Very dissatisfied	0	0.0	0	0.0	0	0.0
Fairly dissatisfied	5	0.9	1	0.2	0	0.0
Fairly satisfied	222	38.1	199	35.1	241	43.3
Very satisfied	355	61.0	367	64.7	316	56.7
N	**582**	**100.0**	**567**	**100.0**	**557**	**100.0**

The vast majority of the participants described their overall experience with Sino-implant (II) as "very favorable" or "somewhat favorable" at three months (95%), six months (97%), and 12 months (94.1%) (Table 9). When asked if they would recommend Sino-implant (II) to a friend, 98% of the participants at three months, 98% at six months and 97% at 12 months said "yes." When asked what they liked about the method, the most frequently mentioned aspects were four-year duration and ease of use (82% and 81% at three months, 86% and 87% at six months, and 79% and 84% at 12 months, respectively). The aspects most disliked about the method included changes in menstruation and other side effects (50% and 11% at three months, 33% and 13% at six months, and 33% and 15% at 12 months) (Table 9).

Table 9. Participant-reported experiences with Sino-implant (II)

	Follow-up interview					
	3 months		6 months		12 months	
Overall experience with method	**No.**	**%**	**No.**	**%**	**No.**	**%**
Very favorable	328	56.4	277	48.9	261	46.9
Somewhat favorable	226	38.8	275	48.5	263	47.2
Indifferent	4	0.7	1	0.2	1	0.2
Somewhat unfavorable	16	2.7	9	1.6	32	5.7
Very unfavorable	8	1.4	5	0.9	0	0.0
Would you recommend the method to a friend?						
Definitely not	2	0.3	4	0.7	0	0.0
Probably not	9	1.5	6	1.1	17	3.1
Probably yes	134	23.0	131	23.1	172	30.9
Definitely yes	437	75.1	426	75.1	368	66.1
N	**582**	**100.0**	**567**	**100.0**	**557**	**100.0**
Aspects liked*						
Lasts for four years	477	82.0	489	86.2	438	78.6
Easy to use	472	81.1	493	86.9	470	84.4
Low risk of pregnancy	199	34.2	209	36.9	221	39.7
Few side effects	223	38.3	281	49.6	224	40.2
Everything	7	1.2	5	0.9	18	3.2
N	**582**		**567**		**557**	
Aspects not liked*						
Changes in menstruation	291	50.0	184	32.5	182	32.7
Other side effects	64	11.0	71	12.5	83	14.9
Visibility	2	0.3	2	0.4	2	0.4
Feeling implant's presence	16	2.7	1	0.2	6	1.1
Insertion procedure	3	0.5	3	0.5	0	0.0
Do not dislike anything	249	42.8	327	57.7	336	60.3
Swelling and pain at insertion site	0	0.0	1	0.2	0	0.0
N	**566**		**559**		**557**	

*Multiple answers were possible.

Providers' Perspectives

Providers (10 physicians and 10 paramedics/FWVs) were interviewed at six months and 12 months. Eighteen out of the 20 physicians and paramedics at six months and 12 months reported that insertion of Sino-implant (II) was easy (Table 10, page 16). Two providers reported that insertion was not easy. When asked if they faced any problems while inserting or removing the implant, seven providers reported that the supplied trocar (surgical instrument) was not sharp enough to perform implant insertion. However, all of these providers reported no problem at six months. All reported that removal of Sino-implant (II) was easy at both six and 12 months.

All providers stated at six and 12 months that they were satisfied with Sino-implant (II) as a family planning method, but nine providers at six months and five providers at 12 months thought that participants were *not* satisfied with the method. (It is interesting to note the inconsistency of this view with the participants' perceptions of satisfaction.) The most frequent responses to why they thought this were irregular bleeding/spotting and cessation of menstruation at six months and irregular bleeding and weakness at 12 months.

When asked for suggestions for scale-up, nearly half (eight) at six months and six at 12 months suggested improvements to counseling and follow-up. Both at six months and at 12 months, five providers had no suggestions. Other responses at six months included increasing client fees (three), ensuring client follow-up every three months (one), ensuring follow-up up to two years (one), and providing nutritional supplements (two); at 12 months, providers suggested taking action to reduce side effects (five) and increasing trocar sharpness (one) (Table 10).

Table 10. Providers' experiences with Sino-implant (II)

Provider's perspectives	6 months		12 months	
Perception of ease of insertion	**No.**	**%**	**No.**	**%**
Easy	18	90.0	18	90.0
Difficult	1	5.0	1	5.0
Other	1	5.0	1	5.0
Perception of ease of removal				
Easy	20	100.0	20	100.0
Difficult	0	0.0	0	0.0
Other	0	0.0	0	0.0
Problem faced during insertion and removal				
No problem	20	100.0	13	65.0
Sharpness of the trocar is less	0	0.0	7	35.0
Overall evaluation of method				
Very good	3	15.0	9	45.0
Good	14	70.0	7	35.0
Satisfactory	3	15.0	4	20.0
Perception of users' satisfaction with method				
Satisfied	11	55.0	15	75.0
Not satisfied	9	45.0	1	5.0
Not sure	0	0.0	4	20.0
N	**20**	**100.0**	**20**	**100.0**
Participant problems/difficulties reported to providers				
Irregular bleeding	5	55.6	7	70.0
No bleeding	3	33.3	0	0.0
Spotting	1	11.1	0	0.0
Weakness	0	00.0	3	30,0
N	**9**	**100.0**	**10**	**100.0**
Suggestions for expanding services				
Improve counseling and follow-up	8	40.0	6	30.0
Ensure follow-up every three months	1	5.0	0	0.0
Ensure follow-up up to two years	1	5.0	0	0.0
Increase client fees	3	15.0	3	15.0
Provide nutritional supplement	2	10.0	0	0.0
No opinion	5	25.0	5	25.0
Need to reduce side effects	0	0.0	5	25.0
Trocar sharpness should be increased	0	0.0	1	5.0
N	**20**	**100.0**	**20**	**100.0**

Discussion

Sino-implant (II) has been commercially available since 1996 and has been approved in 24 countries; more than 7 million units have been distributed to date. Postmarketing studies in Kenya, Madagascar, and Pakistan are being coordinated by FHI 360, using a protocol similar to the one used in Bangladesh, using the same data collection processes.

The findings from this study are presented in this report specifically to inform the DGFP NTC in its decision on whether to introduce the Sino-implant (II) into Bangladesh's national family planning program. The study findings from the 12 months of use in Bangladesh indicate that Sino-implant (II) is a safe and highly effective family planning method, a finding supported in other studies (Steiner et al., 2010). The 12-month cumulative discontinuation rate was low (8.9%) and almost consistent with the national discontinuation rate (7.8%) (BDHS 2011). There have been neither serious adverse events nor reported cases of pregnancies due to contraceptive failure. Three cases of pregnancy were reported, but these were due to misdiagnosis at the time of insertion, likely related to a lack of sufficient or correct information with which to make a proper diagnosis. Several studies with progesterone-containing implants reported that such contraceptives have some effects on weight and blood pressure. However, our findings at 12 months showed no substantial changes in participants' weight and blood pressure due to use of Sino-implant (II).

Sino-implant (II) appears to be acceptable to Bangladeshi women, based on the continuation rate and on the participants' responses to satisfaction and acceptability questions during interviews at insertion and at follow-up, as well as on questions about complications (e.g., infections at removal sites, inability to remove the rods, broken rods) and experiences after removal at follow-up. Indeed, women were highly satisfied with the implant insertion and reported that they were given clear counseling on what to do and where to go if they experienced any problems at the time of insertion. This level of satisfaction with services did not vary much between the time of insertion and the follow-up visits.

Even though the overwhelming majority of women reported that they were satisfied with Sino-implant (II), a large proportion reported discontent about changes to menstrual bleeding patterns, and some reported cessation of menstruation. This finding has been reported elsewhere, in studies on Norplant® and Jadelle®, and in other countries for Sino-implant (II) (Hanitriniaina et al., 2011; Steiner et al., 2010). The effect is likely attributable to the progesterone agent in Sino-implant (II), which is common to other implants and progesterone-releasing contraceptive methods. It is encouraging to note that the participants' menstrual bleeding pattern became more regular as the year went on, at a rate of 1% per month.

Participants' discontent with irregular and increased bleeding patterns must be taken seriously, because in Bangladeshi culture, women's daily activities can be severely curtailed during menstruation. This point is also echoed by the service providers' concerns. Another important aspect of side effect management is the use of oral contraceptive pills. A number of women reported that they had taken such pills for the management of side effects for several months but that their problems either did not disappear or resumed when they discontinued taking the

the pills. This may indicate the need to reconsider the use of oral contraceptive pills for side effects management, as outlined in WHO protocols.

Interviews with service providers indicated that most liked the method and had no problems during insertion and removal. There were no reported incidents or complications during insertion, which is a proxy indicator that Sino-implant (II) can be easily inserted. It is interesting to note that service providers assumed that the participants were much less satisfied with the method than they actually reported, indicating a discrepancy in perceptions between the providers and participants.

Although few removals occurred, it is important to note that eight of the 53 removals were due to immediate or delayed infections. This proportion, coupled with the three cases where the implant spontaneously emerged in part, are surprising and inconsistent with the Kenya, Madagascar, and Pakistan postmarketing studies, where among 1,965 participants there was just one removal due to infection or irritation (in Madagascar). Moreover, the MSI program in Kenya has used approximately 14,000 Sino-implant (II) devices in its outreach program without reports of infection leading to removal.[11]

It should be underscored that the data collection occurred in different contexts. In Bangladesh, the insertions were performed as part of the ongoing service delivery system by experienced local physicians at seven governmental and three nongovernmental sites. In Kenya, the study was implemented at Ministry of Health sites, but the insertions were done by an FHI 360 doctor-nurse team, which performed the insertions for that study alone with equipment, supplies, and expendables supplied by FHI 360. In Madagascar and Pakistan, physicians employed by MSI also performed the insertions for those studies alone, with equipment, supplies, and expendables at private MSI-supported sites or through mobile clinics.

Only in one case did the symptoms of infection develop within one week of insertion. The other seven ranged in timing from two weeks to three months following insertion. The timing of the infections is puzzling. It is possible that some of these infections were related to poor insertion technique, including incomplete insertion of the rods or partial removal of the rods upon withdrawal of the trocar, therefore creating a persistent "open" wound that over time could have served as a tract for infection. It is also possible that the participants themselves contributed to the infections through itching at the insertion site.

Recommendations

The findings from this study are intended to inform the DGFP NTC's decision on whether to introduce Sino-implant (II) into the national family planning program. The below recommendations were developed for this purpose.

Sino-Implant (II) should be introduced in the national family planning program, as it is safe and effective and acceptable to Bangladeshi women. At 12 months, there were no serious adverse events or pregnancies due to contraceptive failure, and 89% of women were continuing to use Sino-implant (II), clearly indicating its acceptability. With a per-unit

[11] Personal communication with Markus Steiner, FHI 360.

wholesale cost of approximately $8, Sino-implant (II) should prove a good option for Bangladesh family planning program.

Implant training curricula and protocols should be reviewed and revised, with a focus on insertion technique and infection prevention procedures. Although the 12-month discontinuation rate (9%) was very low and the number of removals (n=53) was compatible with the other countries, it is important to note that eight of the removals were due to participants' reports of immediate or delayed infections; three of the eight reported that the implant rods emerged from under their skin. Given the delayed timing and nature of most of the infections, it is possible that some of these infections were related to poor insertion technique, including incomplete insertion of the rods or partial removal of the rods upon withdrawal of the trocar, thereby creating a persistent open wound that over time could serve as a route of infection. Another explanation for the immediate postinsertion infection could be that there was a lapse in infection prevention protocols, specifically around management of autoclaved instruments and supplies. Therefore, the content of the implant training curriculum should be thoroughly reviewed, with a focus on proper provider insertion technique and infection prevention procedures; in the latter case, the focus should be on the relationship between the frequency of opening and closing the drum and on contamination of items inside it.

Counseling protocols for side effects management should be revised and conducted according to WHO guidelines. The majority of the 53 removals were due to side effects, particularly related to changes in vaginal bleeding. WHO suggests specific steps in treating the most common side effect, irregular vaginal bleeding. One is the use of nonhormonal methods, such as NSAIDs. Another is hormonal treatments (if the woman is medically eligible), such as combined oral contraceptive pills or ethinyl estradiol. Removal of the implant is recommended if clients continue to find side effects bothersome. These steps are also included in the DGFP Family Planning Manual.

Our study found that the providers did not always strictly adhere to the WHO counseling guidelines, and some participants endured some discomfort and side effects for extended periods of time. In addition, we found that providers on occasion removed the implant based on health complaints that were unrelated to the implant. It is possible that these women requested removal despite receiving adequate counseling from providers about the unlikely relationship between the implant and some of the reported side effects—in which case, removal would be appropriate based on the client's wishes. However, it is important to stress that providers should receive refresher training on counseling based on WHO guidelines, with a focus on the management of side effects, information that the side effects may diminish over time, and a discussion about the potential impact of the side effects on clients' daily lives.

In addition, counseling around implant removal should be strengthened. At baseline, all of the women stated that the provider gave them clear instructions on what to do if they experienced any problems or side effects from the procedure and where to go if they wanted the device removed. Physicians are allowed to insert and remove implants, and this is done free of charge. Nevertheless, four participants went to pharmacists and "village doctors" to have the implants removed and were charged for the service. It is therefore recommended that DGFP client protocols be strengthened with a stronger emphasis placed about where to

go to obtain advice and treatment for health concerns. In addition, pharmacists and village doctors should be educated about the importance of referral to a trained provider for implant removal.

Review pregnancy diagnostic tools and develop one integrated form. The physicians and paramedics used a combination of the FHI 360 pregnancy checklists and the regular DGFP "implant client full history and informed consent form" to diagnose pregnancy prior to implant insertion. Because the study found three misdiagnoses of preexisting pregnancies, we recommend a review of the use of the pregnancy diagnostic tools and development and introduction into the national program of one synthesized form.

"Wound care kits" could be introduced to improve postinsertion wound care by the acceptors. In addition to the issues of insertion technique on the part of providers discussed above, participants' unhygienic wound care or poor wound healing due to unhealthy conditions may have contributed to the number of infections and removals. Providing clients at discharge with wound care kits containing alcohol, cotton, and waterproof bandages and counseling them on how to effectively care for the insertion site may help address this issue.

Conclusion

In summary, this 12-month trial demonstrates that Sino-implant (II) is a safe and highly effective family planning method and is acceptable to Bangladeshi women as well as providers. This method could be successfully introduced into Bangladesh's national family planning program. Prior to scale-up, the DGFP Implant Training Curricula and Protocols should be reviewed and revised with a focus on insertion technique, infection prevention procedures, and side effects management**.** Finally, the cost of Sino-implant (II) should be kept low—as close to US $8 as possible—to address the cost barrier to availability and frequent stock-outs that were the original impetus of the DGFP's request for this study.

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