

# Acceptability of Sino-Implant (II) in Bangladesh:

## *Six-Month Findings from a Prospective Study*

### CONTEXT

Interest in long-acting family planning methods (particularly in hormonal implants) among Bangladeshi women has risen in recent years. National service statistics indicate that over the past five years, an average of about 11,000 women adopted the implant per month; more recently, the monthly number of implant insertions jumped, to about 44,000.<sup>1</sup> This sudden increase suggests that latent demand for the implant is now being met because the device has become more widely available.

Currently, one type of implant (Implanon<sup>®</sup>) is available in Bangladesh. (Another brand of implant—Jadelle<sup>®</sup>—has been approved for use by Bangladesh's National Technical Committee, but it is not yet available.) Sino-implant (II), which is produced by Shanghai Dahua Pharmaceutical Company, is similar to Jadelle<sup>®</sup> but has not yet been introduced in the Bangladesh family planning program. Like Jadelle<sup>®</sup>, Sino-implant (II) is a two-rod subdermal implant containing 150 mg levonorgestrel; both have an annual unintended pregnancy risk of less than 1%. A major difference between the two, though, is that the per-unit wholesale cost of Sino-implant (II) (approximately US \$8) is less than half of that of Jadelle<sup>®</sup> (\$19) and Implanon (\$17).

Sino-implant (II)'s contraceptive effectiveness and safety have been well established, and the device has been approved by more than 20 drug regulatory authorities throughout the world.<sup>2</sup> Bangladesh's Directorate General of Family Planning (DGFP) of the Ministry of Health and Family Welfare (MOHFW), interested in adding Sino-implant (II) to the range of methods available there, asked the RESPOND Project and Mayer Hashi<sup>3</sup> (both led by EngenderHealth)<sup>4</sup> to conduct an acceptability trial of Sino-implant (II). The purposes of the trial were to inform the DGFP National Technical Committee's decision on whether to introduce Sino-implant (II) into the national family planning program and to provide lessons for scale-up. This brief includes main findings and observations at the midpoint of the one-year study.

### STUDY DESCRIPTION

Mayer Hashi and RESPOND conducted a prospective study to observe a cohort of 595 women from 10 clinics who in June 2011 chose Sino-implant (II) during a routine family planning visit. The participants were to return to the clinic at which they had the implant inserted at three, six, and 12 months, to be interviewed and evaluated for insertion complications, method acceptability, pregnancy, and adverse events, using a standard survey questionnaire. Women were encouraged to return to the clinic at any time if they experienced medical or other problems related to the implant, became (or suspected that they might be) pregnant, or wanted to have the implant removed. Those who had the implant removed before 12 months were interviewed about their reasons for removal, their satisfaction with the removal process, and any complications they experienced after removal.

Shanghai Dahua provided 600 units of Sino-implant (II) free of charge to the DGFP for the study.<sup>5</sup> FHI 360, which has worked with licensees and local service delivery organizations to facilitate the registration of Sino-implant (II), agreed to serve in an advisory capacity for the study and to provide Institutional Review Board oversight, in addition to the Bangladesh Medical Research Center (BMRC). FHI 360 and Marie Stopes International (MSI) are conducting similar studies in Kenya, Madagascar, and Pakistan. All four studies adapted the same FHI 360 research protocol.<sup>6</sup>

In June 2011, immediately before the start of the study, Mayer Hashi and the DGFP/MOHFW co-organized and conducted provider training on Sino-implant (II) in Dhaka. A total of 27 providers were trained: One physician and one paramedic/family welfare visitor<sup>7</sup> for each of the 10 sites, plus seven physicians from the DGFP/MOHFW and Mohammadpur Fertility Service and Training Center (MFSTC). All of the 17 physician trainees were experienced, trained physicians and had been inserting Norplant implants in Bangladesh for an average of five years prior to the training. Many of them also had been trained to insert Jadelle, which was previously tested at many of the same sites.

The training had theoretical and practical components, with sessions on counseling, infection prevention, and collection of participant data. The training team used a skills checklist to assess posttraining competency. All physician trainees completed the 12 critical steps successfully and were certified as competent.

About 94% of the enrolled participants were younger than 35. 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. Forty-three percent had completed their primary education, and 6% had completed a secondary or tertiary education. About 94% were homemakers. One-fifth had not been using any contraceptive method before starting Sino-implant (II), while the remainder had used some type of contraception, predominantly oral contraceptives (45%) and injectables (26%).

## MAIN FINDINGS AND DISCUSSION

Among the 595 women who had Sino-implant (II) inserted at the 10 study sites, 2% could not be contacted at three months or six months, either because their household could not be located or because the woman had moved to another place or was not at home. The findings that follow are based on the women for whom three- or six-month data were collected.

### *Serious adverse events and pregnancy*

No serious adverse events or pregnancies have been reported since the study began. Although three pregnancies occurred, these were due to misdiagnosis when the participants were assessed on the day of insertion.

### *Discontinuation*

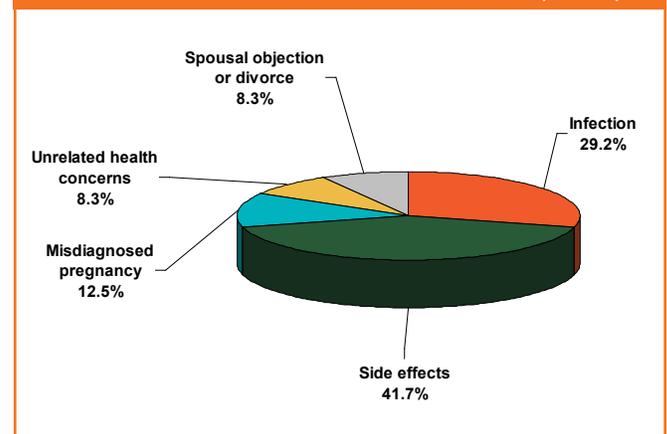
As of six months, 559 women (94% of the original group) were continuing users of Sino-implant (II). Twenty-four (4%) discontinued the method, and another 12 (2%) were lost to follow-up. Among the 24 removals, 16 had occurred by three months, and the remaining eight by six months.

The study team followed up on all removals by interviewing the women and the providers and by examining records, to produce a detailed history. Seven of the 24 removals were due to immediate or delayed infections. In three of these cases, the rod or a portion of the rod spontaneously erupted from the insertion site. The reported infections occurred anywhere from seven days to more than two months after insertion. Since the duration of time between insertion and removal for these cases ranged between one and eight weeks, it is difficult to tell what caused the infection—poor infection prevention practices among health care providers at insertion, or poor wound care among participants, or both.

Among the other 17 removals, 10 were requested because of side effects, such as lower abdominal pain, bleeding, nausea, and weakness. The other seven were because of misdiagnosed pregnancy (three), other unrelated health concerns (two), and spousal objection/dissolution of the marriage (two) (see Figure 1).

In October 2011, shortly after the three-month follow-up, Mayer Hashi assembled a global team of experts<sup>8</sup> to review the removal cases and to agree on action steps at the 10 study sites. The team concluded that none of the removal cases should be classified as a serious adverse event; however, because of the infections, they recommended that providers at the 10 study sites receive refresher training focusing on counseling, follow-up, side effects management, and other service quality aspects and that monitoring and supervision visits be made more frequently (from three times to five visits per site for the remainder of the study period), with at least one Mayer Hashi clinician on the team. These steps were carried out.

FIGURE 1. REASONS FOR REMOVAL (n=24)



### Menstruation and bleeding patterns

Many participants' bleeding patterns changed following insertion of Sino-implant (II). While 88% had regular menstruation before insertion, this percentage fell to 17% at three months and to 20% at six months (Table 1). About 43% of the participants at three months and 51% at six months had developed amenorrhea. Another menstrual change that developed after insertion of Sino-implant (II) was irregular bleeding (30% at three months). This, however, declined to 24% three months later, at the next follow-up visit.

Such findings have been reported elsewhere for Sino-implant (II) (Hanitriainaina et al., 2011; Steiner et al., 2010). The effect is likely attributable to the progestin agent in Sino-implant (II), which is common to other implants and progestin-releasing contraceptive methods. However, despite irregularities in menstrual bleeding patterns, about 70% of the participants at three months and 68% at six months said that their current pattern of menstruation was acceptable to them.

### Participants' perspectives

At the time of insertion, women generally were satisfied with the implant insertion procedure and said that they were given clear counseling on what to do and where to go if they experienced any problems. When asked where they would go and what they would do if there were complications, all stated that they would go to the clinic where Sino-implant (II) was inserted or to any other governmental clinic. When asked how long they should wait before having the implant replaced, all said four years. Women also were asked how satisfied they were with different aspects of their visit. More than 95% reported that they were satisfied or very satisfied with most aspects. Aspects rated below this threshold included: facility opening time (94%), privacy (91%), and waiting time (80%).

At both three months and six months of follow-up, almost all of the women reported that they were either "fairly satisfied" or "very satisfied" with the facility services. The vast majority described their overall experience with Sino-implant (II) as "very favorable" or "somewhat favorable" (95% at three months and 97% at six months). The aspects most liked by the majority of the participants included the method's four-year duration and its ease of use.

When asked what they did not like about the method, the most frequently mentioned aspect was a change in menstrual patterns (although this percentage declined from 50% at three months to 33% at six months). Such discontent with bleeding patterns must be taken seriously by providers, because in Bangladeshi culture, women's daily activities can be severely curtailed during menstruation (Alam, Bradley, & Shabnam, 2007).

The majority of women (85% at three months and 93% at six months) reported no problems at the insertion site. Of those with such issues, the major problems were pain

TABLE 1. STATUS OF MENSTRUATION SINCE LAST CLINIC VISIT AFTER INSERTION OF SINO-IMPLANT (II),\* THREE-MONTH AND SIX-MONTH FOLLOW-UPS

| Status                 | 3-month    |      | 6-month    |      |
|------------------------|------------|------|------------|------|
|                        | No.        | %    | No.        | %    |
| Regular bleeding       | 97         | 16.7 | 111        | 19.6 |
| Irregular bleeding     | 174        | 29.9 | 136        | 24.0 |
| Frequent bleeding      | 32         | 5.5  | 20         | 3.5  |
| Infrequent bleeding    | 41         | 7.0  | 25         | 4.4  |
| Spotting               | 58         | 10.0 | 48         | 8.5  |
| No bleeding/amenorrhea | 250        | 43.0 | 287        | 50.6 |
| <b>N</b>               | <b>582</b> |      | <b>567</b> |      |

\*Multiple answers were possible.

in the insertion area and temporary numbness of the arm. Thirty participants said that they sought medical attention. Of this group, 70% found that getting medical assistance was very easy for them.

Overall, at both the three-month follow-up and the six-month follow-up, 75% of the women said that they would definitely recommend Sino-implant (II) to a friend, and nearly all of the rest said that they would probably do so.

### Providers' perspectives

There were no reported incidents or complications during insertion, which is a proxy indicator that Sino-implant (II) can be easily inserted by a trained medical professional. All stated that they were satisfied with Sino-implant (II) as a family planning method, but more than half (11) thought that participants were *not* satisfied with the method. The most frequent responses to why they thought this were irregular bleeding/spotting and cessation of menstruation. This indicates a discrepancy in perceptions between the providers and participants, or, alternatively, is an example of courtesy bias on the part of the participants.

### PRELIMINARY OBSERVATIONS

Data have yet to be collected at 12 months. In the interim, several observations about the data may be made. More conclusive findings and recommendations will be issued in a final report in Fall 2012.

*Users of the Sino-implant (II) appear to have found it acceptable* after six months of use, based on continuation rates and on their responses to questions about satisfaction and acceptability during interviews at insertion and at follow-up, as well as to questions about complications and their experiences after device removal. Indeed, these 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 reported level of satisfaction with services was consistent between the time of insertion and the follow-up visits.

*Implant training curricula and protocols should be reviewed and revised, with a focus on insertion techniques and infection prevention.* Although the number of implant

removals (24) was comparable to the numbers seen in other countries, seven of them were due to immediate or delayed infection. Coupled with the three cases of spontaneous eruption of the implant, these observations signal an imperative to review the content of the implant training curriculum, with a focus on provider insertion techniques and infection prevention procedures. The physician trainees in Bangladesh were using FHI 360 pregnancy checklists to diagnosis pregnancy prior to insertion. A review of training protocols should also include an examination of the use of the pregnancy checklist within the Bangladeshi context, to ensure that service providers are successful in excluding preexisting pregnancy, before this tool is used in a national scale-up.

*Policies regarding medical monitoring should be reviewed, with a focus on evaluating the regularity of monitoring of infection prevention and insertion techniques among trainees.*

*A whole-site training approach should be implemented, with a focus on team training on client management and service delivery.* Providing optimal care to clients requires that all health providers at a site be well-trained, including nurses, paramedics, and support staff. Although the findings indicate that women were satisfied with implant insertion and that they were given clear counseling on what to do and where to go if they experienced any problems, 10 of the 24 women who requested removal did so because of side effects such as lower abdominal pain, bleeding, nausea, and weakness. It is therefore also critical to review the counseling component of the training curricula, with special attention to discussions regarding a) wound care of clients at home following insertion, and b) changes to bleeding patterns and the consequences of these changes for daily activities. Aspects of service delivery that the participants indicated needed more attention were facility opening and waiting times and privacy.

## REFERENCES

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## Endnotes

<sup>1</sup> Based on communication with Dr. Markus Steiner of FHI 360. FHI 360 facilitates the registration of Sino-implant (II), with the financial support of the Bill & Melinda Gates Foundation

<sup>2</sup> Source: Management information system (MIS) data, Department of MIS, DGFP, MOHFW.

<sup>3</sup> Mayer Hashi is a five-year associate award to The RESPOND Project; it is led by EngenderHealth, in partnership with Johns Hopkins Bloomberg School of Public Health Center for Communication Programs (JHU/CCP) and the Population Council.

<sup>4</sup> EngenderHealth has 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 (LA/PMs). This collaboration includes the implementation of a similar study to assess the acceptability of Implanon, which is currently used in the national family planning program.

<sup>5</sup> The Director of the DGFP's Clinical Contraception Service Delivery Program (CCSDP) obtained a "No Objection Certificate" from the Drug Administration for this trial; this allowed women to use Sino-implant (II) only as part of this study.

<sup>6</sup> The 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.

<sup>7</sup> The paramedics/family welfare visitors did not perform insertions because they are not allowed to insert implants under DGFP/MOH&FW protocols. Their role in the study is to provide counseling to clients to ensure informed choice prior to the implant insertion.

<sup>8</sup> The team included Dr. Mahbubur Rahman, Line Director, CCSDP, DGFP/MOH&FW who is the Principal Investigator of the study, and Dr. Latifa Shamsuddin, a Senior Ob-Gyn Specialist and President-Elect of the Obstetrics and Gynaecological Society of Bangladesh (OGSB), who is advising the study team in a consultant capacity, and physicians from Mayer Hashi, RESPOND, FHI 360, and Dahua.