Pathfinder
INTERNATIONAL
Population / Family Planning IV, Egypt.
USAID Funded Project

Milestone Report 1.3

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MILESTONE REPORT
CONTRACT NUMBER : 263-C-00-99-00017-00

To : Chris McDermott
COTR

CC : Donella Russell
Contract Officer

From Michael Jordàn
Chief of Party, Interim

Date : June 26, 2000

Task Number : *1*

Task Description : *Contraceptive Technologies and Services Expanded and More Widely Available*

Milestone No.: **1.3**

Milestone Description: **NORPLANT implementation strategy assessed and recommendations for expansion made**

Source of Verification: **Expansion plan document**

Planned End Date: **October 31, 1999**

Status : Completed

Comments: See 1.4

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MILESTONE REPORT

CONTRACT NUMBER : 263-C-00-99-00017-00

To : Chris McDermott
COTR

CC : Donella Russell
Contract Officer

From Michael Jordan
Chief of Party, Interim

Date : June 26, 2000

Task Number : *1*

Task Description : *Contraceptive Technologies and Services Expanded and More Widely Available*

Milestone No.: **1.4**

Milestone Description: **Expansion plan for NORPLANT developed with the MOHP**

Source of Verification: **Expansion plan document**

Planned End Date: **January 31, 2000**

Status : Completed

Comments: The two related milestones 1.3 & 1.4 have been delayed because MOHP postponed it's start. Being a sensitive issue for the MOHP; two top-notch STTA, namely Prof. Ezz El Idin Osman and Dr Douglas Huber worked on these miilestones. For the same reason the title did not mention "assessment" and was changed to the present title which is "Expanding Access and Improvement of Quality of Services for NORPLANT". Based on the attached reports the MOHP A I P for Norplant has been developed the milestone package include"
- Report of Dr. Ezz Eldin Osman "Expanding Access and Improvement of Services for NORPLANT"
- Appendices 1-16. Appendix 17 which is the flipchart is available in every center.
- Trip report of Dr. Douglas Huber
- MOHP gantt chart for the Norplant A I P

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The Futures Group International (TFGI)

Draft for review, 30 May, 2000--Not for Distribution

Trip Report, Egypt, 17-25 May, 2000

Douglas Huber, Pathfinder International

Purpose

- Exchange experience on Norplant implants expansion in public and private sectors
- Discuss the expansion and quality improvement plan document with Dr. Ezz Eldin Osman
- Give a presentation on implants and the experience of other countries

Findings

The draft plan for expanded access and quality of Norplant services in Egypt was based on the considerable experience in Egypt with Norplant in the early clinical trials and a review of the introductory stages of Norplant in training and service delivery programs.

DRAFT REPORT ON EXPANSION AND QUALITY OF NORPLANT SERVICES BY DR. EZZELDIN OSMAN HASSAN

This draft report was available just prior to my arrival; my visit was a good opportunity for it to be reviewed by me and Egyptian counterparts. It is an excellent overview of the past and current issues related to Norplant in Egypt—some of the highlights relevant to my visit are as follows:

The early large trial (1988-1994) conducted by EFCS have given a good foundation of experience on which to build the service delivery components. Women were satisfied with the method, and providers in the clinical trial were well trained. In addition the 1500+ removals at the end of the trial (1994) were used to train 2 or 3 staff in each of the five University Hospitals, in order to have a group of highly qualified trainers for future service programs. (All women in the trial had their Norplant removed, a significant effort even within the context of a well conducted clinical study.)

In addition, Egypt, through the EFCS was one of eight countries to participate in the large and important WHO Post-Marketing Surveillance Study from 1987-1997. Dr. Ezzeldin Hassan was one of the principal investigators.

A plan was developed for a phased Egyptian introduction of Norplant in 1994-1999 by the Norplant Task Force. This included an implementation plan. The intent was to extend services gradually through University hospitals, MOHP teaching hospitals and some general hospitals and insurance programs. This stepwise introduction was to ensure quality training, counseling and ready access to good insertions and removals.

However, it appears that the results from this introduction are not well documented, due in part to the MIS system working only partially for insertions and removals. Of the 40,000 sets of Norplant received from USAID from 1994-January 2000, 34,414 were distributed to teaching and university hospitals, the Regional training Center (RCT) and

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to MOHP (Min of Hlth and Pop) service units (5000+sets were sent to Colombia because the expiry date was approaching). Of the 34,414 sets, 13,865 were inserted, according the MIS system. This is apparently due to underreporting of insertions.

The MIS official MOHP records also show only 735 Norplant sets were removed (5.3% of the total inserted during this period—none were due for 5-year removal). Given the widely varying ratios of removals to insertions in the five University and teaching hospitals, from 53.5 removals/100 insertions during the perios to a low of 0.5 removals per 100 insertions, this raises the question about incomplete reporting of removals and/or the possiblility of a low level of access to removals at some institutions.

Galaa hospital, having the highest removal ratio 53.5, states that they remove Norplant inserted at other institutions. We do not know if this high ratio is because women choose to have them removed at Galaa, or whether other centers do not feel confident and competent, or are unwilling to do the removals.

The draft report correctly identifies the reporting problems in the first period and the need for more clear information about the adequacy of removals in various centers. This will require follow-up with the training centers about the access to removals and the completeness of removal training. Recommendations for improving the reporting system will also be needed.

One observation from the 13,400 Norplant insertion records processed centrally by the MOHP, is that the last contraceptive used was the IUD for 37%, injectables for 21%, COCs for 21%, and no method for 16%. Presumably, many Norplant acceptors were previously using the IUD or injectables. The implication is that those switching from a highly effective long-acting method like the TCu 380A IUD or injectables may not do much for improving program performance. However, given the large number of IUD users, it is not surprising that there are substantial numbers who may want to try a different method. This could be good for quality if the result is more highly satisfied clients who want highly effective contraception.

Dr. Hassan will redraft portions of the report to include a separation between the introduction period and the program after August 1999, based on suggestions from the MOHP during my visit.

OBSERVATIONS DURING VISIT

Several colleagues have pointed to the problem of untrained providers removing Norplant. Apparently private practitioners are not fully informed about Norplant, do not have access to providing it themselves, and are negative about Norplant as a family planning method. Therefore, when they see a woman with Norplant they urge her to have it removed by the original providers, or they attempt to remove it themselves. The number of such inappropriate removals is unknown, but has resulted in reports of large incorrect incisions made by those attempting to remove Norplant .

During our visit to Suiez, two of their six removals in the last 6 months were for women who still had capsules in place after attempted removals by untrained practitioners.

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Lack of training in removal apparently extends to many of the clinicians already trained through the RCT program. Lack of cases at the time of training courses resulted in having one or no supervised cases for the trainees to perform. We understand that lack of insertion cases during some courses may have resulted in no practical experience in insertion for some trainees. Both of these outcomes are understandable during the expansion of a new Norplant program with limited case loads. However, there is a broad consensus that new intensive efforts to train and retrain in Norplant removal (and insertion) are needed.

One would naturally suspect that providers not performing removals and with very little or no clinical training in insertion will not be inserting Norplant correctly. It is easier to insert Norplant deeper in the subcutaneous fat layer of the arm than subdermally and superficially just under the skin. Correct superficial insertions are very important for easy future removal.

NORPLANT SEMINAR AT PATHFINDER

Dr. Ezzeldin Ossman Hassan and I gave presentations on Norplant, both the Egyptian and international experiences at an informal three-hour seminar at the Pathfinder offices on 23 May (see overheads/handouts of my presentation, attached). Fifteen people attended, representing the MOHP, USAID, Schering/Leiras, CSI, EFCS, EPTC, MEDTEC, and Pathfinder International.

There was a general consensus that both new and refresher training were needed for Norplant removal, insertion, and counseling. In addition, women will need reminders to have Norplant removed at 5 years and will need to be advised to go to a clinician specially in removal. Some surgeons in the private sector encourage Norplant removal and attempt to do so without special training. Broad public information about the need for 5-year removals, as well as at the woman's request at any time before 5 years will help ensure that the MOHP policy and guidelines on removals is honored in the public and private sectors.

Norplant has be procured by USAID in the past and this will be turned over to the MOHP within the next 2-3 years. The MOHP purchased 10,000 sets of Norplant in the latter part of 1999, plus 10,000 additional sets due to be received within a few months. These were purchased at the public sector price of about $23, plus $2 for shipping.

There are no plans to introduce Norplant in the private sector. If this were to be done the public sector price would probably not apply. The Schering representative stated they would charge at least LE 700 (more than $200) for each set of Norplant, in order to cover costs of training private practitioners. There are no plans for such an introduction.

Some participants suggested that Implanon, a one rod implant, may be a suitable alternative to Norplant in the future, even though it is for 3 years. Implanon is currently being registered in Egypt, and its potential distribution is not currently known. Implanon comes with its own inserter and would be easier to insert and remove than six capsule Norplant.

Recommendations

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1. Support the MOHP position to discontinue inserting Norplant through mobile clinics. The plans are that mobile clinics now provide transportation only for potential Norplant clients to receive services at static sites.
2. Promote training in removal to serve women who request removal and those who will need a five-year removal in the relatively near future. Training in insertion should emphasize superficial subdermal placement. This training could be done through RCT supported training centers, possibly organizing removal clients at MOHP sites to have an adequate case load for clinical training. Refresher training will be needed for some clinicians and should include counseling as well as clinical skills in removal and insertion.
3. Encourage outside monitoring and supervision of the clinical training, since the RCT does not monitor clinical training at the designated training centers. The EFCS is has the most experience with Norplant and would be a logical choice.
4. Consider developing a special Norplant client card with her next visit appointment, and information reminding her that Norplant can be removed at any time she desires, and will need to be surgically removed after 5 years by a clinician trained in Norplant removal. The card could contain a few other key information items such as the frequency of bleeding side effects, as well as identifying conditions which would make continued use of Norplant inadvisable, such as if the woman became pregnant while using Norplant. A similar card may be very helpful for other modern methods, such as IUDs, injectables and COCs.
5. Incorporate simple informational messages--Norplant needs to be removed after 5 years by a trained clinician, and may be removed at any time before then that the woman requests--into ongoing radio and TV IEC materials on family planning. This can help reinforce the counseling information given to women about removal.
6. Use the information from the client assessment study by Laila Nawar, when it becomes available, to help craft informational messages on Norplant.
7. Provide information and training to strengthen management of common Norplant side effects, especially irregular or prolonged bleeding. The Arabic translation of The Essentials of Contraceptive Technology should be used to help meet these needs. The use of a short course of COCs (one cycle) or ibuprofen to control a bleeding episode, when counseling and reassurance are not adequate, is included in this book, and is not in the current standards of practice. These options for managing side effects are approved by WHO and USAID, and this endorsement should be used to expand the use of these materials.
8. Revise the standards to include the use of a second method of contraception for women who are not able to have Norplant removed at 5 years, while awaiting removal. This will protect against unwanted and ectopic pregnancies, which could occur if Norplant is not removed for an extended period beyond 5 years. The IUD, injectables, COCs or other methods may be used while awaiting Norplant removal.
9. Consider the advantages and disadvantages of a three year single rod implant, Implanon, as an easier implant to insert and remove than six capsule Norplant, for future programming.
10. Consider strengthening the current MIS reporting system for Norplant insertions and removals, rather than a new decentralized data collection system. Additional MIS training, availability of reporting forms, and feedback to the clinical sites about their performance, may be more useful in collecting accurate information than starting a new system that reports only insertions and removals to the MOHP.

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MOHP/PS/SDP Implementation Plan 2000/2001
Enhanced Supply / NORPLANT

Activity	Sub Activity	Persons Respond	SDP III Project Year 2											
			Q1			Q2			Q3			Q4		
			J	A	S	O	N	D	J	F	M	A	M	J
Committees	Review NORPLANT brochures and develop a modified one	NORPLANT Coordinator IEC Unit Director Pathfinder	X	X							X			X
	Test the new brochure	NORPLANT Coordinator			X	X								
	Print modified brochure and distribute	NORPLANT Coordinator					X	X	X					
	Develop inserts for mass media talks	IEC Unit Director Pathfinder			X	X								
	Organzie a schedule for broadcasting	IEC Unit Director SIS				X	X	X	X	X	X	X	X	X
	Include messages on NORPLANT removal with IEC Campaigns	IEC Unit Director, IEC Coordinators at governorates and districts	X	X	X	X	X	X	X	X	X	X	X	X
Training (Details with training)	Identify trainers from MOHP providers working in sites with high case load	Training Coordinators	X										X	
	Provide TOT course for trainers	Training Unit Director		X	X	X							X	X
	Identify training needs from Providers in units already providing NORPLANT service	NORPLANT Coordinator Training Unit Director FP Directors at governorates	X	X										
	Deliver training in the Universities coordinated by RCT				X	X	X	X	X	X	X	X	X	X
	Deliver training through apprenticeship at the selected sites	FP governorate directors, Training coordinators					X	X	X	X	X	X	X	X

MOHP/PS/SDP Implementation Plan 2000/2001
Enhanced Supply / NORPLANT

Activity	Sub Activity	Persons Responsible	SDP III Project Year 2											
			Q1			Q2			Q3			Q4		
			J	A	S	O	N	D	J	F	M	A	M	J
Committees	Review NORPLANT brochures and develop a modified one	NORPLANT Coordinator IEC Unit Director Pathfinder	X	X							X			X
	Test the new brochure	NORPLANT Coordinator			X	X								
	Print modified brochure and distribute	NORPLANT Coordinator					X	X	X					
	Develop inserts for mass media talks	IEC Unit Director Pathfinder			X	X								
	Organzie a schedule for broadcasting	IEC Unit Director SIS				X	X	X	X	X	X	X	X	X
	Include messages on NORPLANT removal with IEC Campaigns	IEC Unit Director, IEC Coordinators at governorates and districts	X	X	X	X	X	X	X	X	X	X	X	X
Training (Details with training)	Identify trainers from MOHP providers working in sites with high case load	Training Coordinators	X										X	
	Provide TOT course for trainers	Training Unit Director		X	X	X							X	X
	Identify training needs from Providers in units already providing NORPLANT service	NORPLANT Coordinator Training Unit Director FP Directors at governorates	X	X										
	Deliver training in the Universities coordinated by RCT				X	X	X	X	X	X	X	X	X	X
	Deliver training through apprenticeship at the selected sites	FP governorate directors, Training coordinators					X	X	X	X	X	X	X	X

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MOHP/PS/SDP Implementation Plan 2000/2001
Enhanced Supply

Activity	SubActivity	Persons Responsible	SDP II Project Year 2											
			Q1			Q2			Q3			Q4		
			J	A	S	O	N	D	J	F	M	A	M	J
Service Delivery	Identify legible women for removal through registration in units, RR & Community Leaders	FP Directors, Service Providers	X	X	X	X	X	X	X	X	X	X	X	X
	Provide proper counseling and referral to centers providing Norplant	Service Providers	X	X	X	X	X	X	X	X	X	X	X	X
Supervision	Develop a supervisory checklist for NORPLANT	NORPLANT Coordinator Pathfinder, TA			X	X								
	Develop the system for supervision	NORPLANT Coordinator Pathfinder, TA			X	X								
	Test the supervisory system	NORPLANT Coordinator					X	X						
	Train on supervision	NORPLANT Coordinator Training unit director						X	X					
	Institutionalize the system	NORPLANT Coordinator FP directors								X	X	X	X	X

Pre-Introductory Clinical Trial of Norplant Contraceptive Subdermal Implants in Egypt

Final Report

April 1995

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Edited by
Prof. Ezzeldin Osman Hassan

ACKNOWLEDGMENT

The Egyptian Fertility Care Society is grateful to all working staff in the departments of Obstetrics and Gynaecology of Ain Shams, Alexandria, Assiut, Mansoura and Al-Azhar Universities for their interest and valuable contribution to the study. Thanks are due to the USAID/Cairo and the National Population Council for sponsoring the project. The Society is grateful to the Family Health International for their technical assistance.

Finally, the EFCS wishes to acknowledge the contribution of the women who volunteered to participate in this study, without whose commitment and patience, completion of this research would have been impossible.

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EXECUTIVE SUMMARY

The Egyptian Fertility Care Society (EFCS) with support from the National Population Council (NPC) in Egypt, has implemented a Pre-introductory Clinical Trial on Norplant, sponsored by USAID Cairo, during the period 1988 - 1994. It was done through five University Centers; Ain Shams, Alexandria, Assiut, Mansoura and Al-Azhar, involving a total of 1536 cases.

Norplant is a long acting reversible hormonal contraceptive consisting of six flexible capsules inserted in the woman's arm. It steadily releases a synthetic hormone (Levonorgestrel) for 5 years.

This report is based on two main objectives fulfilled by the study:

1. Assessment of the efficacy of Norplant contraceptive implant.
2. Evaluation of the safety and acceptability of the method.

The advantages of Norplant implant use are that it is initiated by a single intervention, does not require the attention of the user, provides contraceptive protection for at least five years and its effect is rapidly reversed. The method is neither related to sexual intercourse nor genital manipulations.

The capsules are free from estrogen, thus no estrogen side effects are produced. The release rate of progestin is low and constant thereby avoiding the hormonal surge of oral contraceptives and the high initial dose of injectables.

Side effects of progestin-only contraception were found to occur with Norplant use, mainly some disruption of the normal menstrual function. More than 25% of cases complained of menstrual problems in the first year after insertion, and decreased thereafter. Intermenstrual spotting and bleeding occurred in 10.9% and 11.6% respectively during the first year and decreased gradually to 0.3% and 1.1% in the fifth year. Amenorrhea occurred in 17.3% of cases during the first year and decreased gradually to reach 1.7% in the fifth year. Other reported side effects included weight gain, headache, loss of appetite, nausea, dizziness, lower abdominal pain, psychological changes, local pain and redness at site of implants. Norplant use seems to have no significant effect on blood pressure.

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Results of this trial also confirmed that Norplant is an effective long term contraceptive method. It provides an extremely low cumulative pregnancy rate (2.86%) at five years. Method failure and the occurrence of pregnancy was reported in 2.1% of admitted cases. The cumulative 5-year discontinuation rates were 15.3% for menstrual problems and 13.4% for other medical reasons. This indicates good acceptability of the method.

Complications during insertion occurred only in 0.4% and during removal only in 0.8%. This is attributed to proper training of physicians that is considered to be vital for initial method acceptance and long term use.

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INTRODUCTION

Under the support of the National Population Council in Egypt, the Egyptian Fertility Care Society (EFCS) has implemented a pre-introductory clinical trial on Norplant contraceptive subdermal implants. This method provides long term contraception and can be an alternative to oral and injectable contraceptives for women choosing long acting steroidal contraception.

Norplant is an effective long acting reversible hormonal contraceptive. The implant system consists of six flexible capsules made of soft silicone and filled with synthetic hormone. The capsules are inserted in the woman's arm by a minor surgery. Each capsule is 34 mm long, 2.4 mm wide and contains 216 mg of crystallized levonorgestrel, a synthetic progestin. One third of the drug load is released in 5 years, the currently approved lifetime of the implant. Norplant implants are inserted sequentially beneath the dermal layer of the arm through a 2-3 mm incision after a local anaesthetic has been applied. A number 10 gauge trocar deposits the capsules in a superficial plane 5-6 mm above the incision. The recommended site of placement is in the inner aspect of the upper arm, contralateral to the handedness of the woman, well above the elbow fold. After insertion of the Norplant implants, levonorgestrel is slowly released through the polydimethylsiloxane tubing, at a rate of 85 micrograms per day during the first 12 months of use, which diminishes to 50 micrograms per day for the following 6 months before stabilizing at 25-30 microgram for the rest of the five years. The plasma level of hormone sufficient to prevent conception is reached within 8-24 hours after insertion and is maintained for five years (1).

Norplant implants achieve their contraceptive effect in a variety of ways: The drug renders cervical mucus impenetrable to spermatozoa. Ovulation is inhibited in many cycles. If ovulation occurs, low levels of progesterone render the women infertile. Under the influence of implants, cervical mucus is scanty, viscous and difficult to obtain. Controlled in-vitro and post-coital tests (Croxatto et al., 1987; Brache et al., 1985) have demonstrated the impenetrability of cervical mucus of implant users as compared with that of IUD and barrier method control subjects. In-vivo studies of women using Norplant implants have found only a few spermatozoa in the cervical canal, and these were characterized by poor motility. Microscopy reveals cervical mucus features consistent with poor sperm penetration (2).

The advantages of the Norplant contraceptive subdermal implant use are that it is initiated by a single intervention, does not require the attention of the user, provides contraceptive protection for at least five years and its effect is easily reversed. The method is neither related to sexual intercourse nor genital manipulations. The capsules are free from estrogen, thus no estrogen side effects are produced. The release rate of progestin is low and constant avoiding the hormonal surge of oral contraceptives and the high initial dose of injectables.

Progestin-only contraception is associated with some disruption of the normal menstrual function. The pattern of these changes varies markedly from one woman to the other and individual reactions vary as well. The side-effects most often reported with the use of the Norplant subdermal system are: frequent and longer bleeding episodes, spotting, reduction in total menstrual blood loss and sometimes amenorrhea. Failure of the method and the occurrence of pregnancy was reported in less than 2% of cases with the first generation "hard tubing", and 0.2% with the

second generation "soft tubing". Other side-effects as weight gain, headache, loss of appetite, nausea, acne, dizziness, lower abdominal pain, psychological changes, local pain and redness at site of implants were also reported.

This report is based on two main objectives fulfilled by the study: (1) assessment of the efficacy of Norplant contraceptive implant and (2) evaluation of the safety and acceptability of the method for which pregnancy and discontinuation rates due to menstrual, medical or personal reasons are used as indicators. The results include all data received by EFCS from 13.7.1988 to 31.01.1995.

The first part of the report, is a description of the study methodology and population. In the second part, the results of the study during the period 1988-95 are given. The last part of the report is a discussion of the results.

METHODS AND STUDY POPULATION

METHODS

The study was designed as a non-comparative longitudinal clinical trial. A study period of 5 years, starting from July 1988, was decided as the Norplant system was expected to be effective for at least 5 years. The recruited users were planned to be followed at periodic intervals from the date of insertion (one month, 3 months, 6 months, 12 months then annually till the end of the study). Follow-up of recruited users was completed at the end of the 5 years or until removal for accidental pregnancy, medical or personal reasons.

Recruitment of subjects was planned to be completed within 12 months but was extended to 16 months due to obligation to the selection criteria. A screening checklist for Norplant acceptors was completed for each woman considered in the study. Only women fulfilling the following inclusion criteria were enrolled:

- Healthy.
- Between 25-38 years.
- Sexually active.
- Have been previously pregnant.
- Have not received an injection for contraception in the 12 months before insertion.
- Be menstruating and within 5 days of the onset of her menses.
- Willing to rely exclusively on the implants as a method of contraception during the course of the study.
- Available for regular scheduled follow up visits.
- Give informed consent (volunteer agreement).

Women with any of the following conditions were excluded from the study:

- Pregnancy.
- Breast feeding.
- History or evidence of liver disease, jaundice, thromboembolic disease, hypertension, anemia, herpes genitalis, cancer, epilepsy, diabetes or pelvic inflammatory disease.
- Undiagnosed vaginal bleeding.
- Regular use of medications as antibiotics or barbiturates.

Potential Norplant acceptors received complete information about the purpose of the study, the risks and benefits associated with the use of Norplant contraceptive subdermal implants prior to enrollment. Informed consent was obtained from all study subjects. Women who accepted participating in the study were asked to sign a volunteer agreement at least one week prior to insertion. Norplant insertions were scheduled within 5 days from the onset of the following menstrual cycle.

Data collection was performed through five forms (Appendix I). An admission form was filled on the same day of insertion. Follow-up forms were filled for each scheduled follow-up visit. Unscheduled follow-up visits were also recorded and a special computer program was designed. A termination form was filled at the time of removal of the implants either after five years of use or earlier, when removal took place for any medical or personal reasons. A pregnancy confirmation form was filled in case of termination due to accidental pregnancy. Since bleeding irregularities, including amenorrhea, were likely to occur with Norplant use (1), a pregnancy test was performed in cases with amenorrhea lasting for more than six weeks to exclude pregnancy. Whenever the pregnancy was confirmed, the implants were removed immediately. If the pregnancy continues, the woman was monitored throughout pregnancy and the outcome was reported on a pregnancy outcome form.

STATISTICAL ANALYSIS

Data entry was done using the dbase III and analysis was performed using the SPSS computer packages. A Chi square test was used to calculate significant differences between proportions and for calculating significance in proportion

trends. This was done using the statcalc of Epi-Info computer software package.

WHO/HRP computer software package was used for life table analysis. Pregnancy rates and discontinuation rates for menstrual, medical and personal reasons were calculated as the ratio of the number of events on a given day divided by the number of women still in the trial on that day. The daily discontinuation rate was cumulated throughout the period of the study to derive the cumulative discontinuation rate. The continuous model (referred to as the Kaplan-Meier product limit estimate) was used to analyze the data. Accordingly it is assumed that on the given day, there are too many discontinuations that occur before any withdrawals. Thus the discontinuation rate was calculated as follows:

Discontinuation Rates=d'/n

Where d'= the number of events that day

n = the number of subjects still at risk on that day

DEFINITIONS OF TERMS

Amenorrhea was defined as any case with absence of vaginal bleeding for more than six weeks.

Hypertension was defined as any case with blood pressure exceeding 140/90 mmHg.

Adverse Experience was defined as any condition that the service provider considers as a serious or unexpected health problem or event that occurs during the follow-up period. These cases were classified as 'related' or 'possibly related' to Norplant use.

ABBREVIATIONS OF TERMS

F01: Follow-up visit one month from date of insertion

F03: Follow-up visit three months from date of insertion

F06: Follow-up visit six months from date of insertion

F12: Follow-up visit one year from date of insertion

F24: Follow-up visit two years from date of insertion

F36: Follow-up visit three years from date of insertion

F48: Follow-up visit four years from date of insertion

F60: Follow-up visit five years from date of insertion

STUDY POPULATION

A total of 1,536 women **(Table 1)** were enrolled in the Norplant Contraceptive Subdermal Implant study in five Egyptian University Centers (Ain Shams, Alexandria, Assiut, Mansoura and Al-Azhar University Centers) from July 1988 to October 1989. There were 350 cases (22.8% of total cases) recruited in Ain Shams University, 294 cases (19.1%) in Alexandria University, 242 cases (15.8%) in Assiut University, 350 cases (22.8%) in Mansoura University and 300 cases (19.5%) in Al- Azhar University.

The study population was divided into 3 groups as follows:

a. Intent to treat population: all women enrolled in the study. Analysis for this population are presented in the text for efficacy and safety parameters.

b. Efficacy population: all women who received the Norplant excluding women with major protocol violations. Women who got pregnant with estimated dates of conception on or before their dates of Norplant insertion were also excluded from the population.

c. Lost to follow-up population: all women in the intent to treat population who were not terminated from the study because they could not be traced. This happened mainly at Ain Shams center, as some women were displaced after the earthquake of October 1992.

Table 2 shows the frequency of protocol violations by center and at all centers. A total of 44 cases were inadvertently admitted with protocol violations: 17 cases were less than 25 years of age, and 2 were more than 38 years old; 8 cases had systolic blood pressure >140 mmHg, another 8 cases had intermenstrual spotting. One case had hepatosplenomegaly. One case had both age and systolic blood pressure violations while 6 women had history of both intermenstrual bleeding and spotting. One case had Norplant insertion on the 6th day of her menstrual cycle. These 44 cases were included in the data analysis to see whether Norplant can be safe for a wider range of women. Thus analysis is based on a total of 1536 women.

RESULTS

The results included all data received by the EFCS from 13.07.1988 to 31.01.1995.

ADMISSION

Voluntary recruitment of women was completed in sixteen months (from 13.07.1988 to 02.10.1989) and 1,536 women were enrolled in the study **(Figure 1)**.
The overall monthly proportion of recruitment showed an increase over time. A peak was reached during February 1989, then recruitment rates showed a decline thereafter ($P<0.001$). Two dips were encountered in October 1988 and May 1989. They were possibly related to the beginning of the academic year in October and the examinations at the end of this year in May. Recruitment may be considered as being completed in only 13 months as the main bulk of cases was recruited in that period, while the number of cases recruited in the last 3 months was almost negligible.

Table 3 shows the sociodemographic characteristics of Norplant users by center. Cases are distributed almost equally among the three age groups 25-29, 30-34 and 35-38 years. The mean age was (31.2 years). Except for Assiut and Mansoura, there is no great disparity in the age of women recruited at the 5 centers. A lower percentage of women in Assiut (25.6%) were above the age of 35 years in comparison to Mansoura (42%).

The distribution of Norplant users according to their weight on admission shows that

the greatest percentage (42.3%) weighed 70 kgs or more, 27.8% weighed 60-69 kgs, 22.9% were between 50-59 kgs and only 7% were less than 50 kgs. It should be noted that the percentage of women weighing 70 kgs or more was highest in Ain Shams (51.4%) and lowest in Assiut (17.8%).

More than half of participants (59%) had 4 to 6 living children (P <0.001), 32.2% have less than 4 children and 8.5% have more than 6 children. The overall mean number of living children is 4.3. Assiut has the highest percentage of living children as 20.7% of women have more than 6.

The majority of the women (82.6%) were illiterate (P<0.001) and only 1.6% had more than secondary education.

Table 4 shows that most of the participants (85.9%) had used a contraceptive method prior to Norplant use. Assiut was the only center to show high percentage of women (43%) with no previous contraceptive use. It is also shown that oral contraceptive pills were used by 53.1% of women, followed by IUDs (29.5%).

Table 5 shows the abnormal findings detected at the time of physical examination on admission to the study by center. Fifty one women (3.3%) had cervical infection and fifty six cases (3.6%) had vaginitis. Six cases (0.4%) had albuminuria, 5 cases (0.3%) had galactorrhea, 4 cases (0.3%) had abdominal scars due to previous laparotomies, 3 cases (0.2%) had cystocele and prolapse, and only one case (0.1%) had breast tenderness. These cases were not considered as protocol violations as the reported conditions were not specified in the study protocol as criteria for exclusion.

Table 6 shows that local complications had occurred in 6 cases (0.4% of admitted cases) during insertion of Norplant, five cases were in Al-Azhar and occurred during the first 3 months of the study. In four cases, there was slight bleeding at the insertion site and one case had a slightly larger incision. The sixth case, in Ain Shams university, complained from severe pain during insertion.

FOLLOW-UP VISITS

The total number of follow-up visits are reported for the intent-to-treat population. Women were asked to come for follow-up 1, 3, 6 and 12 months after insertion and every year afterwards. The follow-up windows were as follows:

Days 1-60 for the 1-month visit
Days 61-136 for the 3-month visit
Days 137-273 for the 6-month visit
Days 274-547 for the 12-month visit
Days 548-913 for the 24-month visit
Days 914-1278 for the 36-month visit
Days 1279-1643 for the 48-month visit
Day 1644+ for the 60-month visit

The overall follow-up attendance rates ranged between 81-94% in all 5 centers **(Table 7)**. The rate was highest in Mansoura and lowest in Assiut after F24. Efforts were done to increase the follow-up rates in Assiut. The Principal Investigator was contacted by the EFCS Executive Director and site visits were intensified. Social

workers were appointed and given the task of carrying out home visits to detect the cause of unattendance and persuade participants to present at the clinics for the scheduled follow-up visits. Follow-up rates improved drastically thereafter.

During the follow-up visits, the main subjective complaints were headache and menstrual problems **(Tables 8 and 9)**. This was the case in all the five centers. The complaint of headache tended to increase until the end of the second year and decreased thereafter ($P<0.05$). Menstrual problems showed a significant decline overtime ($P<0.001$). Complaints of nausea, vomiting, weight gain and insertion site pain and tenderness showed a significant improvement overtime ($P<0.01$). It is important to note that the perception of weight increase diminished by time in spite of a continuous steady increase in body weight. Other complaints such as breast discomfort, chest pain, dyspnea and abdominal distention showed a more or less constant percentages over the study period.

As menstrual problems are the most frequent side effects of Progestin-only contraceptives, these were analyzed separately **(Table 10)**. Amenorrhea was defined as cases that had no vaginal bleeding for more than 6 weeks. Thus the results of this subjective complaint recorded at the follow-up visit after the first month of insertion (F01) were disregarded. The percentage of participants reporting amenorrhea throughout Norplant use showed a significant decline overtime ($P<0.001$). Some Norplant users suffered from amenorrhea alternating with bleeding, these cases showed increasing percentages reaching its maximum after one year ($P<0.001$), then declined overtime.

The percentages of participants, who suffered from intermenstrual spotting and

bleeding **(Table 11)** showed a clear improvement over the study period (P<0.001). Spotting occurred among 10.1-18.2% of cases in the first year and diminished thereafter to reach 0.3% at 5 years. As well, bleeding occurred between 7.3-14.2% in the first 3 years and only among 1.1% of cases at 5 years.

Table 12 shows the percentage of cases reporting dysmenorrhea during the follow-up visits. It varied between 0.8-7.4% in different follow-up visits and the differences showed statistical significance (P <0.05). Fifty three cases reported having dysmenorrhea on admission. By the end of 5 years, almost all Norplant users (99.2%) were free from dysmenorrhea.

Table 13 shows that most cases complaining of dysmenorrhea were rendered free after Norplant use, while a small percentage developed dysmenorrhea after Norplant insertion.

Table 14 shows that on admission, the mean duration of the menstrual cycle was 29.1 days and the mean duration of the menstrual flow was 4.6 days. These two figures did not change significantly among women who menstruated regularly during Norplant use.

The majority (66-87%) of Norplant users reported moderate menstrual blood loss on admission and during the follow-up visits **(Table 15)**. The percentage of participants reporting scanty menses on admission was 6.4%. These reports increased to 31.1% during the first 3 months of use and diminished thereafter ranging between 11.2% and 21.2% at different follow-up intervals. The percentage of women reporting moderate blood loss showed a drop three months after Norplant insertion then

significantly increased thereafter (P<0.0001) mainly on the expense of diminution of the percentage of women who developed heavy bleeding. The percentage of women reporting heavy menstruation was 8.9% on admission, ranged between 14.3% and 10.5% during the first year then tended to decrease thereafter (P<0.0001), reaching 2.3% by the fifth year.

Table 16 shows that, on admission, the mean systolic blood pressure was 116.1 mmHg and the mean diastolic blood pressure was 75.7 mmHg. Both readings did not show statistically significant differences throughout the study period.

Table 17 shows that eight cases suffered from hypertension on admission. The differences in the percentage of cases reported as hypertensives on admission and during the different follow-up visits did not reach statistical significance.

Table 18 shows that women steadily gained weight with Norplant use. As well, there was a significant increase in the percentage of participants weighing 70 kgs and over throughout Norplant use (P<0.001). On admission, 42.3% of women weighed over 70 kgs. This percentage increased steadily to reach 61.1% five years after use. On the other hand, 6.8% weighed less than 50 kgs and 22.2% weighed 50-59 kgs in the first follow-up visit. These percentages diminished to 2.8% and 11.7% respectively at 5 years.

Table 19 shows that the percent increase in body weight for each body weight group has shown an increase overtime for all body weight groups. This increase was mainly marked among participants weighing < 50 kgs in the first follow-up visit. The percentage decreased among heavier participants and was least among those

weighing 70 Kgs or over in the first visit.

At each follow-up visit, some abnormal findings were detected on clinical examination **(Table 20)**. Vaginitis and cervical infections were the most commonly encountered findings. The percentage of both conditions grouped together showed a tendency to increase throughout Norplant use. Other abnormal findings were rarely encountered such as: local reactions at insertion site, breast tenderness, cardiovascular disorders, uterine or adnexal mass. These did not show a significant change over time.

Tables 21, 22 and **23** show the adverse experiences observed by the investigators among Norplant users at the different follow-up visits, classified according to body systems. The main adverse experiences encountered throughout Norplant use were vaginal bleeding, followed by irregular menses and headache. Eight cases developed diabetes while using the method. They were classified as possibly related to Norplant. However, filling an adverse experience form for any case was left up to the judgement of the physician. That was the reason for the wide variation seen in the number of adverse experiences reported by the different centers.

REMOVALS

Table 24 shows the numbers and percentages of cases that requested removal and those who never requested Norplant removal by center. Ain Shams center showed the highest percentage of cases that never requested but had the Norplant removed before completing 5 years for medical reasons (18.3%). Alexandria center showed

the highest percentage of women who never requested Norplant removal and completed 5 years with the method (64%). Assiut center had the highest percentage of women requesting Norplant removal and had the method removed before 5 years (40.3%).

Table 25 shows the reasons for termination of Norplant use. At the end of the five year period, a total of 1511 cases (99.4% of those admitted) discontinued Norplant use, of whom 209 (13.8% of users) terminated use because of menstrual problems; this represented the highest percentage of causes of removal. The non-menstrual medical problems constituted 173 cases of removals (11.3% of users), headache being the most common. The occurrence of pregnancy was the reason for removal in 32 cases, representing 2.1% of removals. Removal for personal reasons was done in 181 cases (11.8%). 913 cases (60.4%) had used the Norplant capsules for the recommended 5-year period.

During the study period, sudden collapse and immediate death occurred in one case in Assiut, most probably due to heart attack (the case was attended by a medical personnel and post mortem was not done); and one case in Mansoura died in an accident.

Figure 2 shows the percentages of removals for five year termination by center. Alexandria center had the highest percentage of cases who completed using the method for five years (65.4%), followed by Mansoura center (65%). Assiut center showed the least percentage of cases terminating Norplant after 5 years (50.4%).

Method failure (accidental pregnancy) was reported in 32 cases (2.1% of admitted cases) **(Table 26)**. Al-Azhar had the highest number (13 cases), followed by Ain Shams (8 cases). This shows statistical significance (P = 0.016). Only three cases of accidental pregnancy occurred in the first and second year, the majority occurring thereafter. Life table analysis **(Table 27)** showed a cumulative pregnancy rate of 2.86% after five years of Norplant use. The 5-year cumulative rates for the individual centers varied between 0.0 - 5.9%. In Assiut, no pregnancies occurred throughout Norplant use and it is important to remember that, in this center, the average weight was the least among all centers as 15.3% of the women weighed less than 50 kgs and only 17.8% weighed more than 70 kgs on admission). It had been noted that nearly all method failures had occurred in women over 70 kgs at the time of Norplant insertion, or in those who had gained weight and exceeded 70 kgs during Norplant use.

Table 28 shows the cumulative pregnancy rates by weight recorded at admission. The failure rates between different body weights are statistically significant, i.e., the risk for getting pregnant increases if body weight is 70 kgs or more at the time of Norplant insertion particularly after the second year.

The 5-year overall cumulative discontinuation rates **(Table 29)** reached 38.74%. The least discontinuation rates were detected in Alexandria (33.53%) while the highest rates were detected in Assiut (47.86%). The overall 5-year cumulative discontinuation rates were highest for menstrual problems (15.30%). However, in Ain Shams, the highest discontinuation rates were for non-menstrual problems (17.79%) and in Al-Azhar, the highest rate was for personal reasons (17.86%).

Table 30 shows the cumulative discontinuation rates by removal reasons and age on admission. Discontinuations for menstrual problems were statistically insignificant in the different age groups, while statistical significance was noted with the non-menstrual and personal problems. The non-menstrual medical problems were highest at the age group 30-34 years, while personal reasons for discontinuation were highest at the younger age group of 20-29 years.

Table 31 shows the removal experiences at the five centers. Difficulties during removal were reported in 3.9% of the cases. The figure was highest (9.6%) in Ain Shams, nearly equal in most centers: 2.6% in Mansoura, 2.9% in Assiut, 2.3% in Al-Azhar, and lowest (1.4%) in Alexandria. It should be noted that all removals were performed by the "classical" method described for removal.

Removal complications were encountered in 0.8% of the cases. It was highest in Assiut (1.7%) and lowest in Alexandria and Al-Azhar (0.3%). The main complications encountered during removal of Norplant were:

- Deeply embedded, scattered, broken or hard to retrieve capsules requiring repeated attempts for removal (21 cases).
- Larger than desired or multiple incisions (3 cases).
- Post-removal inflammation (one case).
- Severe pain during the removal procedure (one case).

Re-training sessions were conducted for the working staff in the five Egyptian University Centers at the end of the fourth year of the study to minimize removal difficulties and complications, and to increase the number of trained service

providers at each center to cope with the increasing demand for Norplant removals at the 5-year termination period.

36% of women who terminated the study intended not to use any contraceptive method after Norplant removal **(Table 32)**. 150 women (16.8%) expressed interest to use oral contraceptive pills, 239 (26.9%) intended to use Depo-provera injections, while 460 (51.7%) intended to insert an IUD. Only 15 cases (1.7%) were planning to use a barrier or a local method for contraception.

DISCUSSION

The idea of long-term contraception with the use of progestin-filled silastic Capsules was first proposed in 1967. In 1975, multinational trials were performed using the 6-capsules system of Norplant implants (3) and all indicate high effectiveness for at least 5 years.

Norplant research has started in Egypt since 1980. The study was sponsored by the Rockefeller foundation in four University Centers. The results of this research recommended a more elaborate pre-introduction trial.

This report includes the results of a pre-introductory clinical trial of Norplant contraceptive subdermal implants that had been performed in five Egyptian University Centers to determine the effectiveness and safety of Norplant Implants use among Egyptian Women. Pregnancy rates were taken as indicators of method

failure and hence ineffectiveness, while discontinuation rates were taken as one measure of the acceptability of the Norplant implants. The study started in July 1988 and intended to follow-up users for a period of 5 years.

Analysis of data is based on the total number of cases admitted to the study (1536), including 44 protocol violations.

The recruited women were all multiparae, their age ranged between 20-40 years old. Little variations in sociodemographic characteristics were seen between the centers. However, in Assiut participants tended to be younger, slimmer, with higher parity and showed a higher percentages of no previous contraceptive users. In Mansoura the participants tended to be of older age while in Ain Shams they showed a tendency to heavier body weight.

The results suggest that proper training of service providers is important for Norplant safety as during insertion complications occurred only in 0.4% of women. The follow-up rates were satisfactory in all centers except in Assiut where low rates were encountered and efforts were done to encourage follow-up attendance. Mansoura has shown a quite satisfactory rate throughout the study. The overall discontinuation rate at the end of 5 years was 38.74%, and this is comparable to the continuation rates mentioned in other International studies (4-6).

The main subjective complaints throughout the follow-up visits were headache and menstrual problems, a finding similar with other studies (7-9). Cases reporting headache on follow-up visits showed an increase up to the second year after Norplant insertion but improved thereafter. The percentage of cases reporting

menstrual problems showed a definite improvement after the third month of use and thereafter.

The length and duration of the menstrual cycles among women who continued to menstruate regularly after Norplant use did not show any change after Norplant insertion. Irregular menstrual patterns were reported by some users. The percentage of participants reporting amenorrhea showed an improvement overtime and reached 0.9% of cases at the end of the fifth year of the study. On the other hand, the percentage of participants reporting amenorrhea alternating with bleeding decreased from 9.1% at three months follow-up to 0.8% at the fifth year follow-up. Women need to be informed before use that amenorrhea during Norplant use is not a signal of pregnancy, in the absence of other signs. Instruction should also be given that oligomenorrhea or amenorrhea does not augur compromised future fertility, or the retention of "bad blood" or other harmful effects, as rumoured in various areas. The percentage of participants suffering from intermenstrual spotting and bleeding also showed a clear decline throughout Norplant use and a percentage of 0.3% and 1.1% were reported respectively at the end of the fifth year of follow-up. All cases reporting dysmenorrhea on admission were rendered free during Norplant use.

Norplant appears to have very little - if any - clinical effect on both systolic and diastolic blood pressure as both levels did not show significant changes during use. This finding is similar to other studies (6-7).

Body weight increased steadily after Norplant use with an increase of the percentage of women weighing 70 kgs or more. Expressed as a percentage from the

original body weight, weight increase is greater in the lower weight groups (< 50 kgs) compared to those in the higher weight groups (70 kgs or more).

At each follow-up visit, few abnormal findings were detected on clinical examination. The more pronounced abnormalities encountered were vaginitis and cervical infections and their percentage showed a tendency to increase throughout Norplant use.

Adverse experience throughout Norplant use was reported in 128 cases. The main conditions encountered that related to Norplant use were vaginal bleeding (40 cases), severe headache (10 cases), hypertension (6 cases) and weight gain (3 cases). Diabetes was reported in 8 cases and was classified as possibly related to Norplant use.

Norplant capsules showed good acceptability among users. The percent of cases who never requested removals and completed 5 years was 55.2

Norplant proved to be a very effective contraceptive. Only 32 pregnancies (2.1%) had occurred among Norplant users, all due to method failure: two occurred in the first year, two in the second year, eight in the third year, thirteen in the fourth year and eight in the fifth year of use.

All subjects in this clinical trial used capsules implants whose silicone rubber tubing ("hard" tubing) contained more inert silica filler than is contained in the currently manufactured and approved implants ("soft" tubing).

As in the original developmental studies of Norplant utilizing hard capsules, there was a positive correlation between body weight and pregnancy rates (8). Studies done by the Population Council showed that Norplant's efficacy rate is influenced by the women's weight. Among heavier women - those weighing more than 70 kgs - cumulative 5-year pregnancy rates were more than twice as high as for women weighing less than 70 kgs (9). 28 pregnancy cases (87.5%) were above 70 kgs on admission or reached 70 kgs at the time they had the accidental pregnancy. It should be noted that the trial had been undertaken using the "hard" capsules reported to have higher incidence of pregnancy among women > 70 kg (2).

Studies showed that differences in the pregnancy rates experienced by women using these two types of tubing proved to be statistically significant ($P < 0.05$). In clinical trials of the approved "soft" tubing implants, 5-year pregnancy rates have averaged 0.2 per 100 women per year, and there has been no discernible difference to date in pregnancy rates as categorized by weight.

Pregnancies may appear early in implant use either when fertilization occurred but went undetected in the cycle before placement, or when admission is more than one week after the onset of menses, and follicular development has proceeded to the point where implant placement cannot prevent ovulation and fertilization (2).

In this clinical trial, one such case was encountered, as Norplant was inserted on the 6th day of her menstrual cycle. One month later, she presented with amenorrhea and pregnancy test was positive. Gestational age was estimated as ± 5 weeks. This case was not considered as a method failure as estimated date of conception was prior to

Norplant insertion. It is therefore recommended that implants are inserted during menstruation (22).

A cumulative 5-year discontinuation rate of 37.38% was encountered and as with other trials, a good percentage was ascribed to menstrual problems (10-11). In our study a cumulative 5-year discontinuation rate of 14.73% was reached for menstrual problems, which compares with figures from other studies (12-19).

Proper insertion and removal of Norplant capsules by well trained staff could minimize difficulties and complications. In this study, 94.7% of removals were not associated with any difficulties or complications.

CONCLUSION

As no contraceptive method is 100% effective, these results confirm that Norplant subdermal implants is an effective long term contraceptive method. The method provides a low cumulative pregnancy rate (2.86%) at 5 years. Results found in other studies have shown five-year pregnancy rates of 0.0 to 2.0 per 100 women (20-21). Utilizing well trained staff, Norplant insertion and removal could be done safely without difficulties or complications. The cumulative discontinuation rate was 15.30% for menstrual problems and 13.41% for other medical reasons after 5 years. 60.4% of cases had completed using the method for 5 years. This indicates good acceptability of the method.

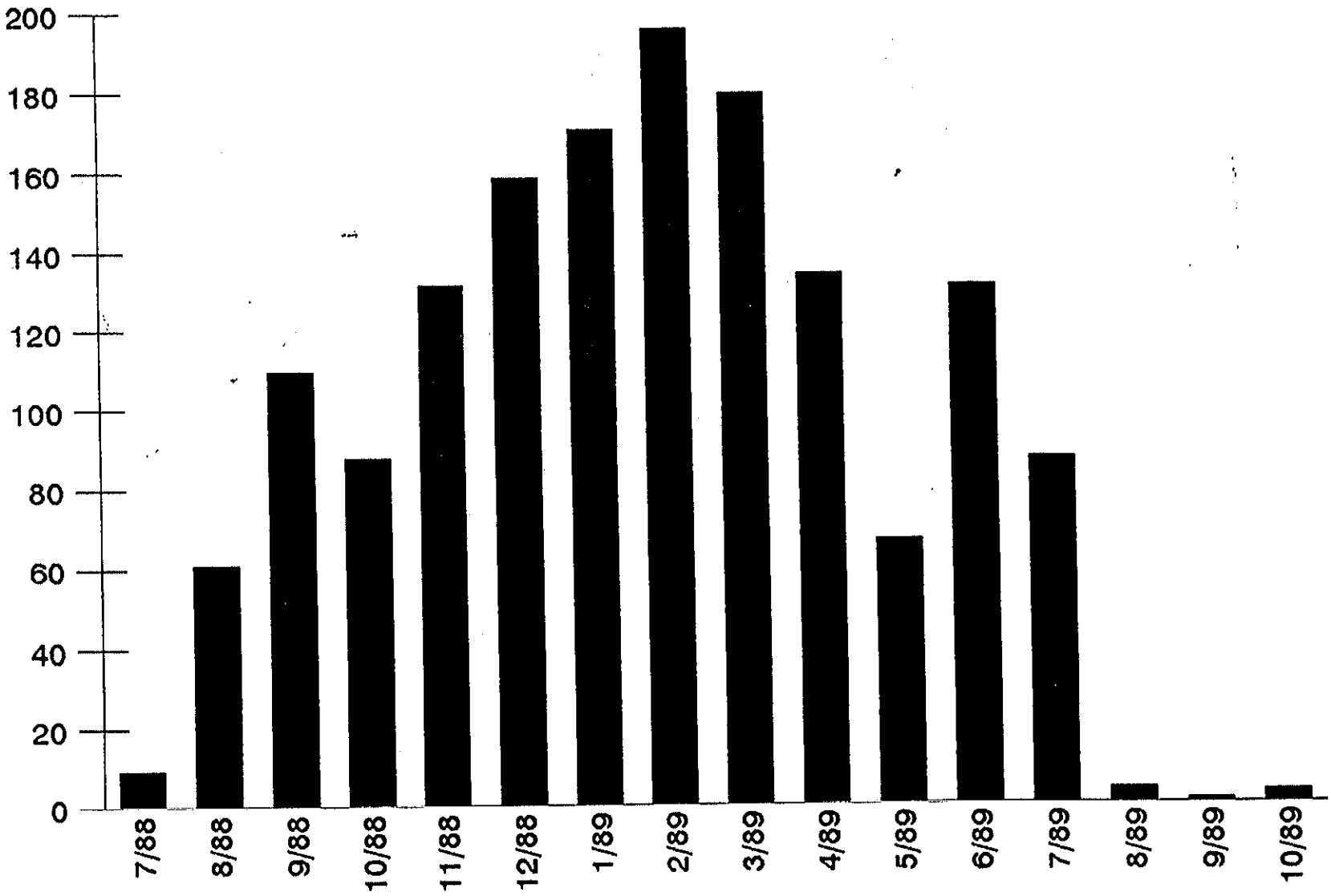

Fig 1:Number of monthly recruitment in the five Egyptian University Centers.

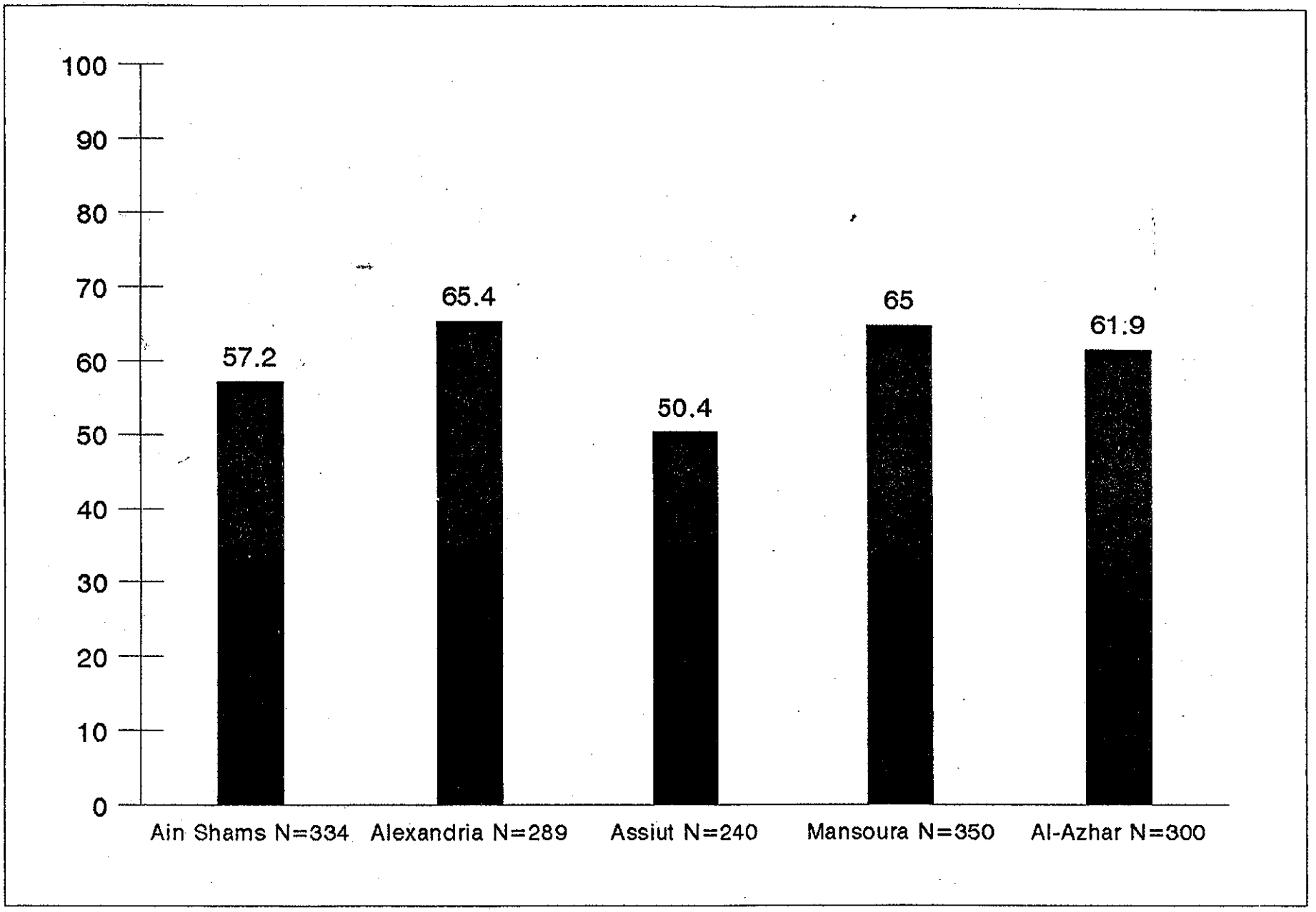

Fig 2:Percentages of Removals for Five Year Termination by Center

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TABLES

Table 1. Number and percentage of recruited participants in the five Egyptian University Centers

Item	Ain Shams	Alexandria	Assiut	Mansoura	Al-Azhar	Total
Intent to treat population						
No.	350	294	242	350	300	1536
%	22.8	19.1	15.8	22.8	19.5	100.0
Protocol Violation						
No.	1	9	22	1	10	43
%	2	20.9	51.2	2.3	23.3	100.0
Efficacy population						
No.	349	285	200	349	290	1493
%	23.4	19.1	14.7	23.4	19.4	100.0
Lost to follow-up population						
No.	16	5	2	0	0	23
%	1.0	0.3	0.1	0	0	1.4

N.B. Calculations in text are those of intent to treat population

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Table 2. Description of Protocol Violations by type and center in the five Egyptian University Centers

Type of violation	Ain Shams	Alex-andria	Assiut	Mansoura	Al Azhar	Total
Age < 25	1	0	11	0	4	16
Age > 38	0	2	0	0	0	2
Systolic B.P. > 140 mmHg	0	0	6	0	1*	7
Age <25y & Sys.B.P.>140mmHg	0	0	1	0	0	1
Intermenstrual bleeding	0	2	0	0	0	2
Intermenstrual spotting	0	4	4	0	0	8
Intermenstrual Spotting and Bleeding	0	1	0	0	5	6
Hepatomegaly	0	0	0	1	0	1
Pregnancy	0	1	0	0	0	1
Total	1	9	22	1	10	44

* Diastolic B.P. > 90 mmHg

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Table 3. Sociodemographic characteristics of participants on admission in each Egyptian University Center

Item	Ain Shams (N=350) No.	%	Alexandria (N=294) No.	%	Assuit (N=242) No.	%	Mansoura (N=350) No.	%	Al-Azhar (N=300) No.	%	Total (N=1536) No.	%
Age in years												
20-29	126	36.0	108	36.7	78	32.3	106	30.3	108	36.0	526	34.2
30-34	119	34.0	100	34.0	102	42.1	97	27.7	97	32.3	515	33.5
35-40	105	30.0	86	29.3	62	25.6	147	42.0	95	31.7	495	32.3
Weight in Kg												
<50	22	6.3	20	6.8	37	15.3	9	2.6	20	6.7	108	7.0
50-59 kg	69	19.7	57	19.4	82	33.9	78	22.3	66	22.0	352	22.9
60-69 kg	79	22.6	83	28.2	80	33.1	113	32.3	72	24.0	427	27.8
_70 kg	180	51.4	134	45.6	43	17.8	150	42.9	142	47.3	649	42.3
Mean weight	70.8		68.6		60.8		69.6		68.9		68.2	
Living children												
1-3	123	35.1	100	34.0	41	16.9	108	30.9	124	41.3	496	32.3
4-6	207	59.1	168	57.1	151	62.4	220	62.9	163	54.3	909	59.2
7 and more	20	5.7	26	8.8	50	20.7	22	6.3	13	4.3	131	8.5
Education												
Illiterate	273	78.0	240	81.6	218	90.1	293	83.7	245	81.7	1269	82.6
Primary	31	8.9	23	7.8	10	4.1	21	6.0	26	8.7	111	7.2
Prep.	17	4.9	13	4.4	3	1.2	6	1.7	13	4.3	52	3.4
Secondary	26	7.4	15	5.1	5	2.1	22	6.3	12	4.0	80	5.2
Higher	3	0.9	3	1.0	6	2.5	8	2.3	4	1.3	24	1.6

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Table 4. Number and percentage of participants by last contraceptive method used

Item	Ain Shams (N=350)	Alexandria (N=294)	Assiut (N=242)	Mansoura (N=350)	Al-Azhar (N=350)	Total (N=1536)
None						
No.	20	38	104	24	30	216
%	5.7	12.9	43.0	6.9	10.0	14.1
Pills						
No.	201	160	105	165	184	815
%	57.4	54.4	43.4	47.1	61.3	53.1
IUDs						
No.	116	86	27	146	78	453
%	33.1	29.3	11.2	41.7	26.0	29.5
Barriers						
No.	7	8	1	12	7	35
%	2.0	2.7	0.4	3.4	2.3	2.3
Others						
No.	6	2	5	3	1	17
%	1.7	0.7	2.1	0.3	0.3	1.1

Table 5. Number and percentage of abnormal findings detected at time of admission in each Egyptian University Center

Abnormal Findings	Ain Shams N=350		Alexandria N=294		Assiut N=242		Mansoura N=350		Al-Azhar N=300		Total N=1536	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Albuminuria	0	0.0	0	0.0	4	1.7	1	0.3	1	0.3	6	0.4
Galactorrhea	2	0.6	0	0.0	0	0.0	3	0.9	0	0.0	5	0.3
Breast tenderness	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	1	0.1
Cystocele & prolapse	1	0.3	0	0.0	0	0.0	2	0.6	0	0.0	3	0.2
Cervical infection	6	0.7	9	3.1	4	1.7	18	5.1	14	4.7	51	3.3
Vaginitis	9	2.6	28	9.5	3	1.2	6	1.7	10	3.3	56	3.6
Abdominal scar	1	0.3	1	0.3	1	0.4	1	0.3	0	0.0	4	0.3
Total with abnormal findings	19	5.4	38	12.9	12	5.0	31	8.9	26	8.7	126	8.2

Table 6. Local Complications during insertion in each Egyptian University Center

Complication	Ain Shams N=350	Alex-andria N=294	Assiut N=242	Mansoura N=350	Al Azhar N=350	Total N=1536
Slight bleeding at insertion site	0	0	0	0	4	4
Pain at insertion site	1	0	0	0	0	1
Slightly large incision	0	0	0	0	1	1
Total	1	0	0	0	5	6

FIGURES

Table 7. Follow-up attendance rates (per 100) in each Egyptian University Center

Follow-up	Ain Shams	Alexandria	Assiut	Mansoura	Al-Azhar	Total
F01 N	350	294	242	350	300	1536
Presented	317	262	210	348	269	1406
Rate	90.6	89.1	86.8	99.4	89.7	91.5
F03 N	345	293	237	347	298	1520
Presented	289	250	190	343	256	1328
Rate	83.8	85.3	80.2	98.8	85.9	87.4
F06 N	340	290	235	342	291	1498
Presented	291	245	196	339	231	1302
Rate	85.6	84.5	83.4	99.1	79.4	86.9
F12 N	335	284	228	330	285	1462
Presented	300	218	195	328	239	1280
Rate	89.6	76.8	85.5	99.4	83.9	87.6
F24 N	313	261	200	301	258	1333
Presented	247	220	155	291	192	1105
Rate	78.9	84.3	77.5	96.7	74.4	82.9
F36 N	279	233	171	277	236	1196
Presented	219	223	93	268	160	963
Rate	78.5	95.7	54.4	96.8	67.8	80.5
F48 N	242	221	148	257	209	1077
Presented	185	215	84	253	195	932
Rate	76.4	97.3	56.8	98.4	93.3	86.5
F60 N	216	216	133	231	195	975
Presented	200	200	122	230	185	915
Rate	92.6	92.6	91.7	99.6	94.9	93.8

N = expected number of cases to attend at each follow-up visit

Table 8. Number and percentage of subjective complaints reported at follow-up visits in the five Egyptian University Centers

Follow-up	Headache		Insertion site/pain tenderness		Weight gain perception		Nausea/ Vomiting	
	No.	%	No.	%	No.	%	No.	%
F01 (N=1406)	409	29.1	67	4.8	57	4.1	43	3.1
F03 (N=1328)	404	30.4	28	2.1	60	4.5	25	1.9
F06 (N=1302)	469	36.0	26	2.0	27	2.1	30	2.3
F12 (N=1280)	516	40.3	39	3.0	20	1.6	43	3.4
F24 (N=1106)	459	41.5	27	2.4	7	0.6	23	2.1
F36 (N=963)	327	34.0	12	1.2	3	0.3	10	1.0
F48 (N=933)	265	28.4	11	1.2	6	0.6	14	1.5
F60 (N=917)	149	16.2	7	0.8	5	0.5	2	0.2

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Table 9. Number and percentage of subjective complaints reported at follow-up visits in the five Egyptian University Centers (Cont.)

Follow-up	Menstrual Problems		Enlarged/ tender breast		Chest pain		Dyspnea		Abdominal distention	
	No.	%	No.	%	No.	%	No.	%	No.	%
F01 (N=1406)	356	25.3	8	0.6	8	0.6	24	1.7	16	1.1
F03 (N=1328)	415	31.3	8	0.6	7	0.5	14	1.1	21	1.6
F06 (N=1302)	357	27.4	11	0.8	11	0.8	18	1.4	32	2.5
F12 (N=1280)	343	26.8	11	0.9	19	1.5	27	2.1	36	2.8
F24 (N=1106)	247	22.3	8	0.7	15	1.4	26	2.4	25	2.3
F36 (N=963)	159	16.5	13	1.3	7	0.7	7	0.7	4	0.4
F48 (N=933)	114	12.2	8	0.9	2	0.2	7	0.8	14	1.5
F60 (N=917)	27	2.9	4	0.4	1	0.1	3	0.3	4	0.4

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Table 10. Number and percentage of cases reporting amenorrhea at follow-up visits in the five Egyptian University Centers

Follow-up	Amenorrhea Throughout Norplant use		Amenorrhea Alternating with bleeding		All cases that developed amenorrhea	
	No.	%	No.	%	No.	%
F03 (N*=1328)	183	13.8	121	9.1	304	22.9
F06 (N*=1302)	138	10.6	105	8.1	243	18.7
F12 (N*=1280)	92	7.2	129	10.1	221	17.3
F24 (N*=1106)	41	3.7	52	4.7	93	8.4
F36 (N*=963)	34	3.5	40	4.2	74	7.7
F48 (N*=933)	36	3.9	31	3.3	67	7.2
F60 (N*=917)	8	0.9	7	0.8	15	1.7

* N is calculated as the number of women at each follow-up visit with valid data

\+ Results after 1 month were excluded because amenorrhea has been defined in this study as the absence of menstruation for 45 days or more

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Table 11. Number and percentage of cases reporting intermenstrual spotting and intermenstrual bleeding at follow-up visits in the five Egyptian University Centers

Follow-up	Intermenstrual Spotting throughout Norplant use		Intermenstrual Bleeding	
	No.	%	No.	%
F01 (N*=1404)	142	10.1	103	7.3
F03 (N*1326)	241	18.2	188	14.2
F06 (N*=1302)	185	14.2	148	11.4
F12 (N*=1280)	139	10.9	148	11.6
F24 (N*=1106)	65	5.9	111	10.0
F36 (N*=963)	38	3.9	79	8.2
F48 (N*=933)	29	3.1	41	4.4
F60 (N*=917)	3	0.3	10	1.1

* N is calculated as the number of women at each follow-up visit

Table 12. Dysmenorrhea reported on admission and follow-up visits in the five Egyptian University Centers

Item	Total	Dysmenorrhea No.	%
Admission	1536	53	3.5
F01	1404	51	3.6
F03	1327	67	5.0
F06	1302	87	6.7
F12	1280	83	6.5
F24	1106	82	7.4
F36	963	33	3.4
F48	933	29	3.1
F60	917	7	0.8

($P < 0.05$)

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Table 13. Distribution of cases rendered free from dysmenorrhea and those who developed dysmenorrhea at follow-ups

Follow-up	Rendered free *		Developed **	
	No.	%	No.	%
F01 (N=1404)	45	84.9	43	3.2
F03 (N=1327)	45	90.0	62	4.9
F06 (N=1302)	38	84.4	80	6.4
F12 (N=1280)	42	89.4	78	6.3
F24 (N=1106)	40	90.9	78	7.3
F36 (N= 963)	33	94.3	31	3.3
F48 (N= 933)	35	97.2	28	3.1
F60 (N= 910)	30	100.0	7	0.8

* Cases who had dysmenorrhea on admission and improved after Norplant insertion
** Cases who developed dysmenorrhea after insertion

Table 14. Mean length of the menstrual cycle and duration of the menstrual blood flow by days as reported on admission and follow-up visits in the five Egyptian University Centers

Item	Length		Duration	
	Mean	SD	Mean	SD
Admission (N=1535)	29.1	1.7	4.6	1.3
F01 (N=818)	27.6	2.7	4.9	2.8
F03 (N=884)	29.1	2.4	5.4	2.8
F06 (N=931)	29.3	2.0	5.4	2.5
F12 (N=952)	29.3	1.9	5.3	2.3
F24 (N=904)	29.4	1.4	4.8	1.6
F36 (N=826)	29.3	1.5	4.8	1.5
F48 (N=830)	29.2	1.1	4.5	1.3
F60 (N=894)	29.2	1.0	4.3	1.2

N = Number of regularly menstruating women

Table 15. Amount of menstrual blood reported at admission and follow-up visits in the five Egyptian University Centers

Item	Scanty		Moderate		Heavy	
	No.	%	No.	%	No.	%
Admission (N=1535)	98	6.4	1301	84.8	136	8.9
F01 (N= 818)	305	37.2	543	66.3	86	10.5
F03 (N= 884)	275	31.1	683	77.3	126	14.2
F06 (N= 931)	197	21.2	778	83.6	118	12.7
F12 (N= 952)	133	14.0	804	84.4	136	14.3
F24 (N= 904)	150	16.6	789	87.3	88	9.7
F36 (N= 826)	137	16.6	702	85.0	68	8.2
F48 (N= 830)	157	18.9	671	80.8	48	5.8
F60 (N= 894)	100	11.2	777	86.9	21	2.3

N = Number of regularly menstruating women

Table 16. Mean blood pressure reported at admission and follow-up visits in the five Egyptian University Centers

Item	Systolic Mean	Systolic SD	Diastolic Mean	Diastolic SD
Admission (N=1536)	116.6	9.5	75.7	6.5
F01 (N=1406)	115.7	8.6	75.1	6.2
F03 (N=1328)	114.8	8.2	74.8	6.0
F06 (N=1302)	114.8	8.5	74.9	6.0
F12 (N=1280)	114.7	7.7	74.4	5.8
F24 (N=1106)	115.4	8.0	75.4	6.0
F36 (N= 963)	115.8	6.5	75.8	5.2
F48 (N= 933)	115.4	6.7	75.3	5.2
F60 (N= 917)	115.8	6.6	75.6	4.8

(P >0.05)

Table 17. Number and percentage of hypertensive cases reported at admission and follow-up visits

Item	Total	Hypertensive	
		No.	%
Admission	1536	8	0.5
F01	1399	7	0.5
F12	1280	2	0.2
F24	1106	7	0.6
F36	963	3	0.3
F48	933	3	0.3
F60	917	2	0.2

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Table 18. Number and percentage of cases in different body weight categories at admission and at follow-up visits in the five Egyptian University Centers

Item	<50 kg		50-59 kg		60-69 kg		_70 kg	
	No.	%	No.	%	No.	%	No.	%
Admission (N=1536)	108	7	352	22.9	427	27.8	649	42.3
F01 (N=1406)	95	6.8	312	22.2	395	28.1	604	43.0
F03 (N=1328)	76	5.7	284	21.4	365	27.5	603	45.4
F06 (N=1302)	88	6.8	265	20.4	345	26.5	604	46.4
F12 (N=1280)	74	5.8	253	19.8	334	26.1	619	48.4
F24 (N=1106)	46	4.2	211	19.1	304	27.5	545	49.3
F36 (N=963)	30	3.1	161	16.7	252	26.2	520	54.0
F48 (N=933)	27	2.9	141	15.1	248	26.6	517	55.4
F60 (N=917)	26	2.8	107	11.7	224	24.4	560	61.1

Table 19. Mean increase in body weight* at the follow-up visits in the five Egyptian University Centers

Follow-up	< 50 kg		50-59 kg		60-69 kg		_ 70 kg		All cases	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
F01 (N=1406)	3.5	14.3	1.1	4.5	0.5	4.8	0.2	5.0	0.7	6.0
F03 (N=1328)	5.0	16.3	2.6	7.4	1.5	6.3	1.1	6.2	1.8	7.5
F06 (N=1302)	5.1	15.3	3.3	8.7	2.2	7.5	1.5	6.4	2.4	8.2
F12 (N=1280)	6.9	17.5	4.6	8.2	3.3	7.5	2.5	6.5	3.5	8.5
F24 (N=1106)	9.4	19.2	6.1	9.6	4.6	8.0	2.9	7.1	4.6	9.4
F36 (N= 963)	13.3	22.7	7.2	10.0	6.2	8.6	3.9	7.2	5.8	10.1
F48 (N= 933)	16.9	23.6	9.0	9.6	7.1	9.8	4.3	8.1	6.9	11.0
F60 (N= 917)	14.6	14.3	12.5	12.0	10.5	11.1	6.7	9.7	9.5	11.3

* expressed as percentage from original body weight

Table 20. Number and percentage of abnormal findings detected at follow-up visits in the five Egyptian Centers

Follow-up	Insertion site (1)		Breast (2)		Cardiovasc. (3)		Vaginitis		Cervical infection		Uterine mass		Adnexal mass (4)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
F01 (N=1406)	21	1.5	0	0.0	1	0.1	78	5.5	13	0.9	1	0.1	0	0.0
F03 (N=1328)	9	0.7	3	0.2	0	0.0	56	4.2	13	1.0	4	0.3	0	0.0
F06 (N=1302)	4	0.3	5	0.4	1	0.1	57	4.4	14	1.1	2	0.2	0	0.0
F12 (N=1280)	5	0.4	4	0.3	1	0.1	63	4.9	19	1.5	3	0.2	2	0.2
F24 (N=1106)	6	0.5	8	0.7	3	0.3	134	12.1	22	2.0	3	0.3	1	0.1
F36 (N=963)	3	0.3	5	0.5	1	0.1	99	10.3	17	1.8	5	0.5	1	0.1
F48 (N=933)	3	0.3	7	0.8	0	0.0	71	7.6	14	1.5	10	1.1	0	0.0
F60 (N=917)	1	0.1	2	0.2	0	0.0	32	3.5	5	0.5	3	0.3	1	0.1

(1) Local reaction or infection
(2) Tenderness, discharge or galactorrhea
(3) Hypertension, extrasystole or functional murmur
(4) Ovarian cyst or unspecified

Table 21. Number of Women reported as having Adverse Experience related to Norplant among Norplant Users

Adverse Experience	<1m	1-3m	3-6m	6-12m	12-24m	24-36m	36-48m	48-60m	Total
I. Genito urinary system									
- Vaginal/Uterine bleeding (1)	10	4	4	8	5	3	3	3	40
- Irregular menses (2)	0	0	1	1	1	0	7	0	10
- Pelvic Inflammatory Disease	0	0	0	0	0	0	1	1	2
II. Circulatory system									
- Hypertension (3)	1	0	0	0	2	1	1	1	6
- Increased varicosities of lower limbs	0	0	0	1	0	0	0	0	1
III. Nervous system									
- Severe headache (4)	0	0	0	2	4	1	1	2	10
IV. Skin and subcutaneous tissue									
- Expulsion of one or more capsules after local Trauma	0	1	1	0	1	0	1	1	5
- Infection/pain at insertion site	2	1	0	1	0	0	2	0	6
- Local allergic reactions	1	0	0	0	0	0	0	0	1
- Herpes zoster	0	0	0	0	1	0	0	0	1
- Psoriasis	0	0	0	0	0	1	0	0	1
- Falling of hair	0	0	0	1	0	1	0	0	2
V. Blood									
- Anemia (5)	0	0	0	0	0	0	1	0	1
VI. Endocrine, nutritional, metabolic and immunity disorders									
- Weight gain (+10 kg)	0	2	1	-	-	-	1	1	5
- Weight loss	0	1	-	-	-	-	-	-	1
Total									92

(1) One of the cases with menorrhagia has also irregular uterine bleeding
(2) One of the cases with irregular bleeding, D & C showed endometrial atrophy
(3) One of the cases complaining of headache had amenorrhea for 6 months and abdominal distension
(4) The blood pressure was 150/95 mmHg
(5) Anemia = (Haemoglobin _ 9 gms)

Table 22. Number of Women reported as having Adverse Experience possibly related to Norplant among Norplant users

Adverse Experience	<1m	1-3m	3-6m	6-12m	12-24m	24-36m	36-48m	48-60m	Total
I. Genito urinary system									
- Leukoplakia Vulvae	1	0	0	0	1	0	0	0	2
- Vulvar dystrophy	0	0	1	0	0	0	0	0	1
- Pyelonephritis	0	0	0	1	0	0	1	0	2
II. Circulatory system									
- Transient syncopal attacks	0	1	0	0	0	0	1	1	3
III. Digestive system									
- Nausea and vomiting	1	0	0	0	0	0	0	0	1
- Infective Hepatitis	0	0	1	0	0	0	1	1	3
- Abdominal distension	0	0	0	0	0	0	0	1	1
- Calcular Cholecystitis	0	0	0	0	0	0	0	1	1
IV. Respiratory system									
- Psychic Aphonia	0	0	0	0	1	0	0	0	1
- Tuberculosis	0	0	0	1	0	0	0	1	2
- Bronchial Asthma	0	0	0	0	0	0	1	2	3
V. Nervous system									
- Myasthenia gravis	1	0	0	0	0	0	0	0	1
- Facial palsy	0	1	0	0	0	0	0	0	1
- Numbness and pain in left arm	1	0	0	0	0	0	0	0	1

Table 23. Number of Women reported as having Adverse Experience possibly related to Norplant among Norplant, users

Adverse Experience	<1m	1-3m	3-6m	6-12m	12-24m	24-36m	36-48m	48-60m	Total
VI. Musculoskeletal system and connective tissue									
- Rheumatoid arthritis	0	0	0	0	1	0	0	0	1
- Muscle twitches	1	0	0	0	0	0	0	0	1
- Disc prolapse/sciatica	0	0	0	0	1	0	1	0	2
- Chest pain	0	0	0	0	1	0	0	0	1
- Fatigue	1	0	0	0	0	0	0	0	1
VII. Endocrine, metabolic and immunity disorders									
- Generalized allergy	1	0	0	0	2	0	0	0	3
- Diabetes Mellitus	1	0	0	1	0	3	2	1	8
VIII. Tumors									
- Bilateral diffuse fibrodenosis of breast	0	0	0	0	1	0	0	0	1
- Breast cancer	0	0	0	0	1	0	0	0	1
Total									43

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Table 24. Number and percentage of cases who requested and never requested Norplant removal by center in the five Egyptian University Centers

Center	Never requested and completed 5 years		Never requested but removed for medical reasons < 5 years		Requested but reassured		Requested and removed < 5 years	
	No.	%	No.	%	No.	%	No.	%
Ain Shams (N=334)	134	40.1	61	18.3	57	17.1	82	24.6
Alexandria (N=289)	185	64.0	31	10.7	4	1.4	69	23.9
Assiut (N=238)	113	47.5	22	9.2	7	2.9	96	40.3
Mansoura (N=349)	221	63.3	56	16.0	6	1.7	66	18.9
Al-Azhar (N=299)	180	60.2	12	4.0	5	1.7	102	34.1
Total (N=1509)	833	55.2	182	12.1	79	5.2	415	27.5

Table 25. Number and percentage of reported reasons for Norplant discontinuation

Reason	Number of cases	% From study population N=1511+
1. Menstrual problems	209	13.8
2. Pregnancy	32	2.1
Non-menstrual medical problems	173	11.4
3. Headache & Dizziness	42	2.8
4. Hypertension	14	0.9
5. Other circulatory disorders	3	0.2
6. Infection at insertion site	3	0.2
7. Arm pain	19	1.3
8. Leg pain	4	0.3
9. Backache	1	0.1
10. Breast disorders	8	0.5
11. Diabetes	9	0.6
12. Allergic reactions	3	0.2
13. Weakness & nervousness	11	0.7
14. Other medical causes *	57	3.8
Personal reasons **	181	12.0
15. Desired pregnancy	61	4.0
16. Widow, separated or divorced	59	3.9
17. Other personal causes	61	4.0
18. Completion of 5 years without removal	913	60.4
Total discontinuation	1511	99.7

* Include: Transient syncopal attacks, myasthenia gravis, infective hepatitis, extrasystole, change to sterilization, bronchial asthma, loss of libido, tuberculosis, lymphadenitis,haematemesis, varicose veins, hepatic bilharziasis, urinary tract infection, increased weight and hepatomegaly

** Include: husband travel, husband request, death of daughter ..etc

\+ 23 cases (1.5%) were lost for follow-up

N.B. Sudden collapse and immediate death occurred in one case in Assiut, most probably due to heart attack (the case was not attended by a medical personnel and post mortem was not done); and one case in Mansoura died in an accident.

Table 26. Annual Number of pregnancies reported in each Egyptian University Center

Year	Ain Shams	Alexandria	Assiut	Mansoura	Al-Azhar	Total
First Year N = 1536	1	0	0	0	0	1
Second Year N = 1462	0	0	0	1	1	2
Third Year N = 1333	1	4	0	0	3	8
Fourth Year N = 1196	4	1	0	3	5	13
Fifth Year N = 1077	2	1	0	1	4	7
Total	8	6	0	5	13	32

Table 27. Life table cumulative pregnancy rates reported in each Egyptian University Center

Year	Ain Shams	Alexandria	Assiut	Mansoura	Al-Azhar	Total
First Year						
Rate	0.29	0.34	0.00	0.00	0.00	0.13
SE	0.29	0.34	0.00	0.00	0.00	0.09
Second Year						
Rate	0.29	0.34	0.00	0.32	0.38	0.28
SE	0.29	0.34	0.00	0.32	0.37	0.14
Third Year						
Rate	0.66	2.04	0.00	0.32	1.64	0.95
SE	0.46	0.90	0.00	0.32	0.81	0.27
Fourth Year						
Rate	2.39	2.48	0.00	1.49	3.94	2.16
SE	0.97	1.00	0.00	0.74	1.30	0.43
Fifth Year						
Rate	2.85	2.94	0.00	1.91	5.92	2.86
SE	1.07	1.00	0.00	0.85	1.60	0.50

(Assiut Center was excluded from the analysis)
(P = 0.0164)

Table 28. Life table cummulative pregnancy rates by weight on admission.

Year	50-59 kg	60-69 kg	70+ kg
First Year			
Rate	0.29	0.24	0.00
SE	0.29	0.24	0.00
Second Year			
Rate	0.29	0.76	0.00
SE	0.29	0.44	0.00
Third Year			
Rate	0.29	1.07	1.35
SE	0.29	0.53	0.51
Fourth Year			
Rate	0.29	2.10	3.47
SE	0.29	0.79	0.83
Fifth Year			
Rate	1.24	2.81	4.14
SE	0.72	0.93	0.91

(P = 0.075)

Table 29. Life table cumulative discontinuation rates for removal reasons reported in each Egyptian University Center

Item	(1)Menstrual Problems		(2) NonMenstrual Medical Reasons		(3)Personal Reasons		(4) All causes	
	Rate	SE	Rate	SE	Rate	SE	Rate	SE
Ain Shams								
First year	2.65	0.87	2.89	0.90	1.18	0.59	6.86	1.35
Second year	6.59	1.36	5.71	1.27	3.69	1.05	15.43	1.93
Third year	9.61	1.64	11.59	1.80	6.79	1.44	26.00	2.34
Fourth year	13.41	1.97	14.84	2.03	9.11	1.68	34.58	2.56
Fifth year	13.81	1.20	17.79	2.24	14.78	2.19	41.78	2.67
Alexandria								
First year	2.43	0.91	0.34	0.34	1.37	0.68	4.42	1.20
Second year	6.33	1.44	4.76	1.29	3.96	1.17	14.63	2.06
Third year	10.18	1.83	7.91	1.66	5.13	1.34	23.13	2.46
Fourth year	10.98	1.90	9.98	1.86	5.99	1.46	26.53	2.57
Fifth year	13.15	2.08	14.88	2.27	7.36	1.64	33.53	2.76
Assiut								
First year	5.13	1.44	3.40	1.18	0.87	0.61	9.15	1.86
Second year	13.01	2.26	7.17	1.73	7.14	1.78	25.01	2.80
Third year	18.00	2.62	9.85	2.05	9.32	2.05	32.97	3.04
Fourth year	23.87	2.97	12.75	2.36	11.69	2.31	41.35	3.18
Fifth year	26.81	3.14	14.08	2.50	17.09	2.85	47.86	3.25
Mansoura								
First year	2.65	0.87	1.79	0.72	3.18	0.94	7.43	1.40
Second year	9.97	1.65	3.38	1.00	5.12	1.21	17.73	2.04
Third year	12.53	1.83	4.09	1.11	8.47	1.57	23.46	2.27
Fourth year	13.90	1.93	5.56	1.32	11.61	1.83	29.19	2.43
Fifth year	15.35	2.03	9.06	1.71	13.82	1.99	34.35	2.54
Al-Azhar								
First year	2.05	0.83	1.37	0.68	3.42	1.06	6.69	1.44
Second year	6.36	1.45	3.99	1.18	7.39	1.55	17.06	2.17
Third year	7.17	1.55	6.77	1.54	11.60	1.93	24.75	2.49
Fourth year	9.77	1.83	8.47	1.73	15.25	2.20	32.78	2.71
Fifth year	10.24	1.88	10.84	1.99	17.86	2.38	38.16	2.81
All Centers								
First year	2.88	0.43	1.93	0.35	2.07	0.37	6.85	0.64
Second year	8.25	0.71	4.90	0.57	5.32	0.59	17.62	0.97
Third year	11.19	0.84	8.01	0.73	8.20	0.74	25.72	1.12
Fourth year	13.88	0.93	10.27	0.84	10.71	0.85	32.49	1.20
Fifth year	15.30	0.98	13.41	0.96	14.01	0.98	38.74	1.25

(1) Menstrual problems : P = < 0.001
(2) Non-Menstrual problems: P = 0.018
(3) Personal reasons : P = 0.017
(4) All reasons including pregnancy: P = 0.005

Table 30. Life table cumulative discontinuation rates by removal reasons and age on admission in the five Egyptian University Centers

Item	(1)Menstrual Problems Rate	SE	(2)Non-menstrual problems Rate	SE	(3)Personal reasons Rate	SE	(4)All causes* Rate	SE
20-29 years								
First year	3.31	0.79	0.98	0.44	2.53	0.69	6.85	1.10
Second year	8.02	1.22	3.10	0.79	7.94	1.22	18.10	1.68
Third year	10.92	1.42	5.68	1.09	11.92	1.48	26.69	1.93
Fourth year	14.33	1.63	7.73	1.28	15.76	1.70	34.61	2.08
Fifth year	16.73	1.77	11.29	1.59	21.36	1.98	43.86	2.18
30-34 years								
First year	2.41	0.69	3.16	0.78	1.60	0.56	7.20	1.14
Second year	8.28	1.25	7.45	1.20	4.02	0.90	18.87	1.73
Third year	11.95	1.50	11.13	1.46	6.69	1.18	27.84	1.98
Fourth year	14.20	1.64	14.08	1.64	8.78	1.37	34.69	2.10
Fifth year	15.57	1.72	16.49	1.78	11.36	1.58	39.49	2.16
35-40 years								
First year	2.91	0.77	1.65	0.58	2.06	0.64	6.48	1.11
Second year	8.47	1.28	4.11	0.92	3.84	0.89	15.79	1.64
Third year	10.73	1.44	7.18	1.23	5.74	1.10	22.47	1.88
Fourth year	13.14	1.59	8.94	1.37	7.26	1.24	27.97	2.02
Fifth year	16.65	1.62	12.42	1.62	8.89	1.39	32.55	2.11

(1) Menstrual problems : $P > 0.20$
(2) Non-menstrual problems: $P = 0.011$
(3) Personal reasons : $P < 0.001$
(4) All causes including pregnancy: $P = 0.006$
* Including pregnancy

Table 31. Number and percentage of cases reporting removal difficulties and complications in each Egyptian University Center

Center	Difficulties during removal*		Complications during removal	
	No.	%	No.	%
Ain Shams (N=334)	32	9.6	3	0.9
Alexandria (N=289)	4	1.4	1	0.3
Assiut (N=239)	7	2.9	4	1.7
Mansoura (N=350)	9	2.6	3	0.8
Al-Azhar (N=299)	7	2.3	1	0.3
Total (N=1511)	59	3.9	12	0.8

* These include:

- Embedded or hard to retrieve capsules requiring repeated attempts for removal
- Larger than designed incision
- Inflammation after removal
- Severe pain during procedure

Table 32. Number and percentage of cases intending to use contraceptive methods after Norplant termination in each Egyptian Center

Center	None No. %	Pills No. %	Injectables No. %	IUD No. %	Tubal liga-tion No. %	Barrier Methods+ No. %	Total methods No. %
Ain Shams (N=311)	69 22.2	14 5.8	176 72.7	35 14.5	15 6.2	2 0.8	242 77.8
Alexandria (N=268)	56 20.9	94 44.3	10 4.7	94 44.3	11 5.2	3 1.4	212 79.1
Assiut (N=235)	208 88.5	12 44.4	2 7.4	12 44.4	0 0	1 3.7	27 11.5
Mansoura (N=349)	60 17.2	19 6.6	51 17.6	214 74.0	0 0	5 1.7	289 82.8
Al-Azhar (N=227)	107 47.1	11 9.2	0 0	105 87.5	0 0	4 3.3	120 52.9
Total (N=1390)	500 36	150 16.8	239 26.9	460 51.7	26 2.9	15 1.7	890 64.0

+ include condoms and vaginal foam tablets

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APPENDIX I

PROTOCOL & STUDY FORMS

PROTOCOL

NON-COMPARATIVE CLINICAL TRIAL

OF THE

NORPLANT CONTRACEPTIVE IMPLANT SYSTEM IN EGYPT

March 1988

THE EGYPTIAN FERTILITY CARE SOCIETY
2(A) El-Mahrouky street,
Mohandeseen, Cairo
EGYPT

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THE EGYPTIAN FERTILITY CARE SOCIETY

Protocol Title : Non-Comparative Clinical Trial of NORPLANT Contraceptive Implant System in Egypt

Center Number :

Date approved by FHI PHSC : 13 June 1986

Date approved by EFCS Review Committee : 25 September 1986

Principal Investigator :

Site :

APPROVAL

I have reviewed this protocol and agree to conduct the study as described.

Principal Investigator	Signature	Date

I. INTRODUCTION

Contraceptive implant systems can provide an alternative to oral and injectable contraceptives for women who want steroidal contraception. Unlike oral contraceptives and to a lesser extent injectable methods, implants do not require daily or monthly motivation. Furthermore, the method is reversible since the implants can be removed at any time the woman wishes.

NORPLANT is the registered trade mark of the Population Council for contraceptive subdermal implants. The NORPLANT six-capsule system has received approval for marketing in Finland, where it is manufactured by Leiras Pharmaceuticals; it has also been approved in eight other countries in Europe, Asia, and Latin America. NORPLANT has also been approved for research use in the USA, and a US application for marketing approval is expected to be filed in 1988.

The NORPLANT system consists of six 3.4 cm. capsules, each of which contains approximately 36 mg. of levonorgestrel, a synthetic progestogen that is widely used in oral contraceptives. The total release rate of steroid into the bloodstream is about 50 mcg.per day during the first year of use and 30 mcg per day in subsequent years. The capsules are designed to be implanted subdermally in the upper arm but can be removed at any time the woman so desires. Both placement and removal are performed as a minor surgical procedure through a single 2mm. incision with a local anesthetic. The effective lifetime of the NORPLANT system

is at least five years.

The side-effects most often reported with the use of the NORPLANT subdermal system have been more frequent and longer bleeding episodes, increased spotting, a reduction in total menstrual blood loss and sometimes amenorrhea. Contraceptive effectiveness of NORPLANT capsules has been determined to be less than 0.5 pregnancies per 100 continuing users over the first three years of use. Since NORPLANT systems contain no estrogen, some of the major complications and side-effects that have been associated with the estrogen component of combined oral contraceptives would not be expected to occur with these implants.

In Egypt, a set of four coordinated trials was conducted in 1980-1983 at Al-Azhar, Assiut, Alexandria, and Zagazig Universities, involving 250 cases each. The results of these trials were presented at a symposium in Assiut on February 23-24, 1984.

II. OBJECTIVE OF STUDY

The primary objective of this clinical trial is to evaluate the safety, effectiveness and overall acceptability of the NORPLANT contraceptive implant system in different patient populations. Pregnancy rates, rates of removal for menstrual problems, side effects or other medical reasons, and continuation rates will be used to evaluate safety, efficacy and acceptability. Study sites under consideration for this trial include five research centers in Mansoura, Ain Shams, Al-Azhar, Assiut, and Alexandria Universities.

III. LENGTH OF STUDY

Women volunteering to participate in this clinical trial will be recruited over a maximum period of 12 months. Since the NORPLANT system is expected to be effective for at least five years, follow-up of the women will continue for five years or until the implants are removed, whichever comes first. If the woman continues use of the implants for the full five years, she <u>must</u> return to the same clinic for removal of the implants at the end of the five years.

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IV. NUMBER OF PATIENTS

The total caseload will depend on the number of interested investigators, in the different university hospitals, and on the number of cases that are acceptable to local regulatory agencies. Ideally, a total of 1500 women at 5 clinics will be recruited in this clinical trial. The exact number of investigators and number of cases per center will be determined individually for each center prior to initiation.

V. INSTITUTIONAL REVIEW

This study has received approval from the Protection of Human Subjects Committee of Family Health International (FHI), from the Egyptian Fertility Care Society (EFCS) Review Committee and from the Supreme Organization for Pharmaceuticals. Prior to shipment of any supplies, the Principal Investigator will provide EFCS with written documentation that the Study Protocol and Volunteer Agreement forms have been approved by the appropriate local institutional review committee.

The purpose of the study, as well as the benefits and risks of using NORPLANT contraceptive implants will be fully explained to each potential subject prior to entering the study. Women electing to participate in the study will read or will have read to them a copy of the Fact Sheet (Appendix A), which explains the reasons for the study, the way in which it will be conducted and potential side effects that they may encounter during the study. Each woman will be required to sign a Volunteer Agreement (Appendix B), acknowledging that the study has been explained to her and that she has been offered a copy of the Fact Sheet and Volunteer Agreement. The signed Volunteer Agreement will be retained by the Principal Investigator. The Volunteer Agreement Form should be signed at least one week prior to the insertion. Under no condition should the Volunteer Agreement be signed on the same day as the procedure.

Women will be screened for admission to the study according to the Screening Checklist for Norplant Users (Appendix C)

A. Inclusion Criteria

Each woman admitted to the study must:

1. Be in good physical health.
2. Be between the ages of 25 and 38 years old.
3. Be sexually active.
4. Have been previously pregnant.
5. Be menstruating and within 5 days of the onset of her menses.
6. Have not received an injection for contraception in the 12 months before insertion.
7. Be willing to rely exclusively on the implants for contraception during the course of the study.
8. Give informed consent (Volunteer Agreement).
9. Be willing to return for regularly scheduled follow-up visits.

B. Exclusion Criteria

Normal clinic criteria for contraindications to steroidal contraceptive use will be followed. In addition, women with any of the following conditions will be excluded from the study:

1. Pregnancy.
2. History or evidence of liver disease, jaundice,

gestationis, cancer or diabetes.

3. Pelvic inflamatory disease (PID).
4. Undiagnosed vaginal bleeding.
5. Breastfeeding.
6. The present use of internal medications, such as antibiotics and barbiturates, could reduce contraceptive effectiveness. In this case, the woman should be advised to use another contraceptive other than hormonal contraceptive

VIII. EXPERIMENTAL PROTOCOL

A. Study Design

The basic research design of this study is that of a non-comparative clinical trial. Women will be recruited into the study prospectively and followed up at periodic intervals. All women will be inserted with NORPLANT capsules by trained physicians. No comparison group will be enrolled.

Training in the proper placement and removal of the implants will be required of all investigators participating in this clinical trial. Each investigator will be required to observe the implant placement procedure and to perform a minimum of three placements and one removal under supervision of a trained physician. Training will be conducted in identified training centers according to the training program approved by the EFCS Research Committee.

B. Admission Procedures

A Screening Checklist for Norplant Users (Appendix C) will be completed for each woman considered for participation in this study. At this time, the purpose of the study and the risks and benefits associated with the use of this contraceptive method will be fully explained to each woman. Only women who meet all the patient selection criteria described in Section VII will be admitted to the study. Women elected to participate in the study must sign a Volunteer Agreemenrt Form (see Section VI) and an appointment will be scheduled for her to come within 5 days from the onset of the following menses for insertion of the implants.

A medical history will be taken and physical and pelvic examinations performed on each woman. Sociodemographic and medical data about the woman and information about the implant procedure will be collected for each subject admitted to the study and recorded on a NORPLANT Implant Study Admission Form (Appendix D). This form also records data about the woman's menstrual pattern and any complaints she may have had in the previous month. The Admission Form is printed on 2-ply paper with a confidential Patient Identification section at the top that should be separated with the duplicate copy and retained by the clinic. Only the original copy of the Admission Form, without the top portion, should be returned to EFCS. Each center will receive a NORPLANT Implant Study Instruction Manual, which explains the proper way of completing the data collection forms and reviews in detail each item included on the forms

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C. Follow-up Visit

All women will be required to return to the clinic for regularly scheduled follow-up visits at 1, 3, 6, and 12 months post-implementation and once a year thereafter, until removal of the implants or five years, whichever comes first. Every effort must be made to locate women who fail to return for their scheduled follow-up visits.

At each clinic follow-up visit, whether scheduled or unscheduled, a NORPLANT Implant Study Follow-up Form (Appendix E) will be completed for each woman. The woman will be queried about side effects or other complications or problems she has experienced since her last follow-up visit. A pelvic examination is recommended.

In addition to the standard Follow-Up Form completed at the woman's regularly scheduled 6-month follow-up visit, a User Satisfaction Questionnaire (Appendix J) should also be administered. This questionnaire provides more subjective information on acceptors' opinions and impressions about the method than the clinical data collected on the Follow-up Form. It should be administered only at the 6-month follow-up visit, regardless of whether the woman is continuing to use the implants or she has had them removed.

D. Termination of use

Women will be terminated from the study if they become pregnant or decide to discontinue use of the method for any reason. The implants can be removed at any time the woman so desires, but she should be told that she must return to the same

clinic for removal since physicians at other clinics may not be properly trained in removal technique and that improper removal could result in serious complications. If a woman has the implants removed but wants to continue contracepting she should be offered another method of contraception available at the clinic. Reason for discontinuation should be fully documented on a Termination Form (Appendix F).

If a woman expresses the wish to have implants removed, the physician should determine the reason why, and if appropriate provide information and counselling. If however, the woman genuinely desires to have the implants removed, the physician should do so immediately, regardless of the reason, without attempting to dissuade her. Reason for termination will be fully documented for each woman.

E. Pregnancy

A Pregnancy Confirmation Form (Appendix G) will be completed for all pregnancies that occur during the study. Since bleeding irregularities, including amenorrhea, are likely to occur with use of this method, careful attention should be given to women who are amenorrheic. If bleeding has not occurred within six weeks since the beginning of the previous bleeding episode, and there is reason to suspect that the woman may be pregnant, a pregnancy test should be performed. If the woman is confirmed to be pregnent, the implants should be removed immediately. If the woman chooses to continue the pregnancy, she should be monitored throughout the pregnancy, and the outcome should be reported to

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EFCS on a Pregnancy Outcome Form (Appendix H).

F. Adverse Experience

Each woman will be instructed to notify the clinic if she experiences any of the side effects listed on the Fact Sheet or she has any complications or adverse reactions not listed. The woman should be encouraged to return to the clinic for any problem she considers serious even if it is not a scheduled follow-up visit. Any serious or unanticipated adverse reactions, whether or not related to use of the implants, will be recorded on an Adverse Experience Form (Appendix I).

IX. STUDY SUPPLIES

All study supplies, including the NORPLANT sets, trocars, data collection forms and instructional materials will be provided by EFCS, after joint approval of this study by the Principal Investigator and the EFCS.

The Principal Investigator is responsible for proper storage conditions for the implants, avoiding its exposure to excessive heat or moisture. The Principal Investigator is also responsible for keeping an accurate inventory of the implants supplied by EFCS and the set supplied to each woman. All removed and unused sets of NORPLANT must be returned to EFCS.

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X. STUDY TERMINATION

The study as planned will continue until all women have used the implants for five years or had them removed prior to that time. EFCS will terminate the study in each participating center when it has determined that the data are complete from that center. However EFCS may terminate the trial at any time should sufficient evidence become available that shows the implant system to be associated with any major complications or discontinuation for medical reasons accidental pregnancy or other unanticipated or undesirable effects.

XI. INVESTIGATOR RESPONSIBILITIES

Each Principal Investigator will be responsible for carrying out the following tasks or for delegating them to appropriate clinic personnel and supervising their performance:

1. Informing each subject of the risks and benefits of her participation in the study and obtaining a properly executed, signed, and witnessed "Volunteer Agreement" for each study patient.
2. Performing all insertions and removals of the NORPLANT system following standard insertion and removal techniques.
3. Providing appropriate health care for the subject after her enrollment in the study if problems relating to the study products occur.

4. Completing data collection records as required at designated times.

5. Maintaining a master log of study participants and establish a filing system to alert clinic personnel to scheduled follow-up contacts; establishing procedures to follow those who miss scheduled appointments.

6. Providing the original copies of all completed Admission and Follow-up forms to EFCS on a monthly basis; maintaining clinic files, including "Volunteer Agreements" for this study for five years after the study is completed.

7. Responding to data queries initiated by EFCS project staff.

8. Making available for review patient clinic records which relate to this study for EFCS study monitors and authorized individuals.

9. Notifying EFCS immediately of any serious or unanticipated adverse experience by telephone or telegram and by submitting an Adverse Experience Form.

10. Signing all data collection forms.

11. Providing a curriculum vitae for all responsible study personnel to EFCS.

XII. DATA ANALYSIS

All completed data collection forms will be hand delivered to EFCS monthly for processing and analysis. On-site monitoring of each study, including a review of patient and clinic records, will be conducted throughout the course of the study by EFCS. All site visits will be arranged at the mutual convenience of the study investigator(s) and EFCS.

The primary analysis will consist of life table continuation rates and rates of discontinuation due to menstrual problems, side effects and other medical or personal reasons. The proportions of women reporting menstrual pattern changes and side effects not leading to discontinuation will also be evaluated. A final report will be sent to the Principal Investigator after completion of the study.

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Assiut University: The NORPLANT Subdermal Contraceptive System: Proceeding of the Symposium on Long-term Subdermal Contraceptive Implants, Assiut, Egypt, February 23 - 24, 1984. (Editor: Mamdouh Shaaban).

ثبت من استعمال " النوربلانت " انها وسيلة شبة موءكدة لمنع الحمل ولا تحدث اى مضاعفات او اثار جانبية خطيرة • والغرض من هذة الدراسة فى مصر هو التعرف على المزيد من المعلومات عن تقبل السيدة المصرية لهذة الوسيلة •

"النوربلانت " عبارة عن ست كبسولات توضع تحت جلد الذراع وتحتوى على مادة استعملت منذ سنوات طويلة كاحد مكونات اقراص منع الحمل • وتمنع هذة الكبسولات حدوث الحمل لمدة خمس سنوات متصلة تنزع بعدها الكبسولات • ويمكن نزعها فى اى وقت قبل مرور خمس سنوات ويعقب نزع الكبسولات مباشرة امكانية حدوث الحمل • لذلك فان النوربلانت يناسب السيدات اللاتى يرغبن فى وسيلة موءقتة لمنع الحمل لسنوات عديدة متصلة •

وتقدم عيادة تنظيم الاسرة هذة الوسيلة بالمجان وبدون اى مقابل • ويمكن لاى سيدة الا توافق على استعمال هذة الوسيلة • وفى هذة الحالة ستقدم لها عيادة تنظيم الاسرة المتاح من الوسائل الاخرى البديلة المناسبة •

ويتم وضع الكبسولات تحت جلد الذراع بعملية بسيطة للغاية بعد اعطاء بنج موضعى لضمان عدم الشعور باءى الم • وللنوربلانت مثل سائر وسائل منع الحمل – بعض الاعراض الجانبية التى يجب التعرف عليها تفصيليا لتجنب اى انزعاج عند حدوث اى منها : اهم هذة الاعراض هى بعض التغيرات فى الدورة الحيضية •

فيمكن ان تحدث الدورة مبكرة عن موعدها • وقد يحدث نزف متقطع خاصة عند بداية الاستعمال • وربما تقل كمية الدورة الشهرية او تزيد او تنقطع لفترة قد تقصر او تطول كما ان هناك بعض الاعراض الاخرى التى يمكن ان تحدث مثل زيادة الوزن والصداع وفقدان الشهية والغثيان وظهور حب الشباب او بعض التغيرات النفسية والعصبية •

وعند انقطاع الدورة الشهرية لا يعنى ذلك حدوث حمل • وبالرغم من ذلك سيقوم الطبيب بعمل اختبار للتاكد من عدم وجوده • واما اذا حدث الحمل فيجب ازالة الكبسولات فورا •

وهناك بعض الاعراض الجانبية التى تستوجب عند حدوثها مراجعة عيادة تنظيم الاسرة للكشف الطبى وهى :

١ – الاشتباة فى حدوث حمل

٢ – الاحساس بالام شديدة فى اسفل البطن

٣ – الاحساس بالم او احمرار فى مكان وضع الكبسولات

٤ – حدوث نزف رحمى شديد او متقطع

٥ – الشعور بصداع مستمر او متكرر او زغللة

[illegible]

الدراسات ان هذة الوسيلة تفشل فى منع حدوث الحمل فى حوالى ١٪ من الحالات سنويا وكما سبق ان ذكـــر فانه يتعين ازالة الكبسولات فور تشخيص حدوث الحمل لأن اثر النوربلانت على جنين غير معلوم على وجة التاكـيد حتى الان •

يجب مراجعة عيادة تنظيم الأسرة بعد شهر من وضع كبسولات النوربلانت ثم بعد ثلاثة اشهر وسته اشهر وسنة من تركيب الكبسولات • وبعد ذلك يجب زيارة العيادة سنويا حتى ازالة الكبسولات بعد خمس سنوات الا اذا نزعت قبل ذلك •

وعند الرغبة فى ازالة الكبسولات نرجو التقدم الى هذة العيادة بالذات حيث ان بها اطباء مدربين تدريبا عاليا علـــى هذة العملية •

وسوف تتسلمين بطاقة بها مواعيد المراجعة نرجو ان تحافظى عليها وتقدميها عند كل زيارة • كذلك نرجو ابلاغ عيادة تنظيم الاسرة باى تغيير فى عنوان السكن او عند التغيب لفترة طويلة •

موافقـــة اختياريـــة

أقر أنا السيدة ..... البالغة الرشيدة بأننى أوافق باختيارى على أن أشترك فى استعمال عقار النوربلانت المانع للحمل بعد موافقة زوجى تحت اشراف عيادة تنظيم الأسرة بمستشفى ..... كذلك فإننى قد أُعلمت بجميع الحقائق المتاحة عن هذا العقار وتسلمت نسخة مكتوبة منها .

وأيضاً فإننى أعرف تماماً أن من حقى طلب إزالة الكبسولات فى أى وقت وإنه فى هذه الحالة ستكون عيادة تنظيم الأسرة مستعدة لمساعدتى وذلك بتقديم الوسائل الأخرى لمنع الحمل المتاحة بالعيادة إلىَّ .

امضاء السيدة

التاريخ .....

أقر بأننى كنت حاضراً عند قراءة الحقائق عن النوربلانت على السيدة المذكورة أعلاه وعند امضائها على هذه الموافقة الاختيارية .

الاسم .....

التوقيع .....

التاريخ .....

بالنسبة للأُمِّيـــات :

أقر بأننى قرأت على السيدة المذكورة جميع الحقائق المتاحة عن النوربلانت وكذلك الموافقة الاختيارية . وقد أعلمتها بفوائد هذه الطريقة لمنع الحمل وكذلك أعراضها الجانبية وقد وافقت باختيارها على استعمالها .

الاسم .....

إمضاء .....

مشروع النوربلانت

قائمة معايير إختيار مستعملات النوربلانت

تملأ بمعرفة الممرضة أو الاخصائية

السيده _____

	نعم	لا
العمر من ٢٥ الى ٣٨ سنة		
سبق لها الأنجاب		
ليست حاملا الان		
لم تستعمل حقن منع الحمل خلال السنة الماضية		
لا ترضع من الثدى الان		
لاتريد حدوث حمل لمدة عام على الأقل		
توافق على الالتزام بالحضور للعيادة فى المواعيد التى تحدد لها		
لم يحدث لها حمل خارج الرحم من قبل		
لا تلاحظ افرازات من حلمة الثدى		
الدورة الشهرية منتظمة		
لم يسبق لها الاصابة بمرض الصفراء		
غير مصابة بمرض نفسى او صرع		
غير مصابة بمرض السكر		
لا تشكو من صداع مستمر		
لا تشكو من اى مرض بالقلب او الشرايين		
لا تشكو من ارتفاع فى ضغط الدم		
لا تتعاطى ادوية بصفة مستمرة		

× يتم استيفاء بيانات القائمة من السيدات الرغبات فى استعمال النوربلانت قبل العرض على الطبيب المختص لتوقيع الكشف الطبى اللازم وتكون الاجابة عن اى من الاسئلة الموجودة بالقائمة بنعم او لا وعلى مستوفى البيان ان يضع علامة ✓ فى العمود المناسب امام كل سؤال ومهمة الطبيب ان يدقق فى الاسئلة التى تكون اجاباتها بالنفى لمزيد من الفحص . وتحدد نتائج الاجابة على الاسئلة وكذا نتائج الكشف الطبى مدى مناسبة السيدة المتقدمة لاستخدام النوربلانت .

امضاء الممرضة او الاخصائية: _____ اعتماد الطبيب: _____

التاريخ: _____

THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY

ADMISSION FORM

تعريف السيدة : ١ – الرقم المسلسل للسيدة : ..... ٢ – التاريخ : .....
اليوم الشهر السنة

٣ – اسم السيدة : .....

٤ – عنوانها : .....

٥ – اسم قريب أو صديق السيدة : .....

٦ – العنوان : .... رقم التليفون : .....

7. Center number ..... ☐☐☐ 1-3

8. User order number ..... ☐☐☐☐ 4-7

9. Norplant set serial number ..... ☐☐☐☐☐ 8-12

USER CHARACTERISTICS

10. Age (years completed) ..... ☐☐ 13-14

11. Number of living children : total ..... ☐☐ 15-16
sons ..... ☐ 17
daughters ..... ☐ 18

12. Education ..... ☐ 19
0) none, 1) primary, 2) preparatory
3) secondary, 4) above secondary

13. Last contraceptive used ..... ☐ 20
0) none
1) pills
2) i u d
3) barriers
4) other (specify) .....
.....

14. Year last pregnancy ended ..... 19☐☐ 21-22

MENSTRUAL HISTORY (Past 3 cycles)

15. Date of onset of current menses ..... day month year ☐☐ ☐☐ ☐☐ 23-28

16. Average length of cycle (days) ..... ☐☐ 29-30
88 = irregular

17. Average duration of menses (days) ..... ☐☐ 31-32

18. Average amount ..... ☐ 33
1) scanty, 2) moderate, 3) heavy

19. Intermenstrual bleeding ..... ☐ 34
0) no, 1) yes

20. Intermenstrual spotting ..... ☐ 35
0) no, 1) yes

21. Dysmenorrhea ..... ☐ 36

MEDICAL EXAMINATION

22. Weight in Kg. ..... ☐☐☐ 37-39

23. Blood pressure : systolic ..... ☐☐☐ 40-42
diastolic ..... ☐☐☐ 43-45

24. Urine : albumin ..... ☐ 46
0) no. 1) yes
sugar ..... ☐ 47
0) no, 1) yes

25. Breast : ..... ☐ 48
0) normal
1) abnormal (specify) .....
.....

26. Abdomen : ..... ☐ 49
0) normal
1) abnormal (specify) .....
.....

PELVIC EXAMINATION
0) no, 1) yes

27. Vaginitis ..... ☐ 50

28. Cervical infection ..... ☐ 51

29. Uterine mass (specify) ..... ☐ 52
.....

30. Andexal mass (specify) ..... ☐ 53
.....

31. Other (specify) ..... ☐ 54
.....

INSERTION PROCEDURE

32. Date of insertion ..... day month year ☐☐ ☐☐ ☐☐ 55-60

33. Site of insertion ..... ☐ 61
1) right arm
2) left arm

34. Complication (s) of insertion ..... ☐ 62
0) none
1) present (specify) .....
.....

35. Investigator's name .....

36. Signature ..... Date .....

REMARKS .....
.....
.....

PLEASE DELIVER TO:
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(02) 3452018

THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY

FOLLOW-UP FORM

تعريف السيدة : ١ – الرقم المسلسل للسيدة : ..... ٢ – التاريخ : .....
اليوم الشهر السنة

٣ – اسم السيدة : .....

٤ – عنوانها (إذا تغير) : .....

رقم التليفون (إذا تغير) : .....

CONTACT DATA

5. Center number ..... ☐☐☐ 1-3
6. User order number ..... ☐☐☐☐ 4-7
7. Norplant set serial number ..... ☐☐☐☐☐ 8-12
8. Date of this visit ..... ☐☐ ☐☐ ☐☐ 13-18
   day month year

COMPLAINTS (AS PRESENTED BY PATIENT : DO NOT ASK LEADING QUESTIONS)

0) no, 1) yes

9. Headache ..... ☐ 19
10. Nausea/vomiting ..... ☐ 20
11. Enlarged/tender breast ..... ☐ 21
12. Chest pain ..... ☐ 22
13. Dyspnea ..... ☐ 23
14. Menstrual problems ..... ☐ 24
15. Abdominal distension ..... ☐ 25
16. Insertion site pain/tenderness ..... ☐ 26
17. Weight gain ..... ☐ 27
18. Other (specify) ..... ☐ 28
    .....
    .....

MENSTRUAL PATTERN

19. Amenorrhea ..... ☐ 29
    0) no, 1) present throughout,
    2) alternating with bleeding
20. Average length of cycle (days) ..... ☐☐ 30-31
    00) amenorrhea throughout
    88) irregular
21. Average duration of menses (days) ..... ☐☐ 32-33
    00) amenorrhea throughout
22. Average amount ..... ☐ 34
    0) none, 1) scanty, 2) moderate,
    3) heavy
23. Intermenstrual bleeding ..... ☐ 35
    0) no, 1) yes
24. Intermenstrual spotting ..... ☐ 36
    0) no, 1) yes
25. Dysmenorrhea ..... ☐ 37
    0) no, 1) yes

MEDICAL EXAMINATION

26. Weight in Kg. ..... ☐☐☐ 38-40
27. Blood Pressure : systolic ..... ☐☐☐ 41-43
    diastolic ..... ☐☐☐ 44-46
28. Insertion site : ..... ☐ 47
    0) normal
    1) complications (specify) .....
    .....
29. Breast : ..... ☐ 48
    0) normal
    1) abnormal (specify) .....
    .....
30. Cardiovascular : ..... ☐ 49
    0) normal
    1) abnormal (specify) .....
    .....

PELVIC EXAMINATION

0) no, 1) yes

31. Vaginitis ..... ☐ 50
32. Cervical infection ..... ☐ 51
33. Uterine mass (specify) ..... ☐ 52
    .....
34. Adnexal mass (specify) ..... ☐ 53
    .....
35. Other (specify) ..... ☐ 54
    .....
36. **REQUEST FOR REMOVAL** ☐ 55
    0) no
    1) yes, user reassured
    2) yes, removal scheduled
    3) yes, removed
    (IF REMOVED, COMPLETE TERMINATION FORM)
37. Investigator's name .....
38. Signature ..... Date .....

REMARKS .....
.....
.....

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THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY

ADVERSE EXPERIENCE FORM

تعريف السيدة : ١ – الرقم المسلسل للسيدة : ..... ٢ – التاريخ : .....
اليوم الشهر السنة
٣ – اسم السيدة : .....
٤ – عنوانها (إذا تغير) : .....
.....
رقم التليفون (إذا تغير) : .....

TO BE FILLED ONLY IN CASE OF SERIOUS MEDICAL PROBLEMS
OR DEATH RELATED OR NOT RELATED TO NORPLANT

CONTACT DATA

5. Center number ..... ☐☐☐ 1-3
6. User order number ..... ☐☐☐☐ 4-7
7. Norplant set serial number ..... ☐☐☐☐☐ 8-12
8. Date event reported ..... ☐☐ ☐☐ ☐☐ 13-18
   day month year

ADVERSE EXPERIENCE

9. Description of adverse experience : .....
   .....
   .....
10. Date started ..... ☐☐ ☐☐ ☐☐ 19-24
    day month year
11. Treatment given ..... ☐ 25
    0) none
    1) outpatient
    2) inpatient
12. Treatment outcome ..... ☐ 26
    0) no response
    1) improved
    2) recovered
    3) treatment ongoing
    4) died
    5) no treatment given
13. Relation to Norplant ..... ☐ 27
    0) not related
    1) possibly related
    2) related
14. Other possible causes ..... ☐ 28
    0) not related
    1) related to concomitant drug
    2) related to concomitant illness
    3) other (specify) .....
    .....
15. Current use of Norplant ..... ☐ 29
    1) Continuing
    2) stopped
    3) removal scheduled

DEATH NOTIFICATION

(FILL ONLY IN CASE OF DEATH)

16. Date of death ..... ☐☐ ☐☐ ☐☐ 30-35
    day month year
17. Cause of death (on death certificate) :
    .....
    .....
    .....
18. Investigator's name .....
19. Signature ..... Date .....

REMARKS .....
.....
.....

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THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY

PREGNANCY CONFIRMATION FORM

تعريف السيدة : ١ – الرقم المسلسل للسيدة : ..... ٢ – التاريخ : ..... اليوم الشهر السنة

٣ – اسم السيدة : .....

٤ – عنوانها (إذا تغير) : .....

رقم التليفون (إذا تغير) : .....

(COMPLETE THIS FORM ONLY IF PREGNANCY IS CONFIRMED)

CONTACT DATE

5. Center number 1-3
6. User order number 4-7
7. Norplant set serial number 8-12
8. Date of this visit ..... 13-18 (day month year)

PREGNANCY DIAGNOSIS

9. Date of onset of last menses ..... 19-24 (day month year)
10. Diagnostic method (s) 25
    1) pregnancy test
    2) pelvic examination
    3) 1 and 2
    4) other (specify) .....

PREGNANCY INFORMATION

11. Gestational age (in weeks) 26-27
12. Location of pregnancy 28
    1) uterine
    2) extrauterine
    3) undetermined
13. Pregnancy occured 29
    1) before Norplant insertion
    2) after Norplant insertion
    3) uncertain
14. Suspected cause (s) of method failure 30
    0) none
    1) incompatible drug administration
    2) scheduled removal overdue
    3) other (specify) .....
15. Investigator's name .....
16. Signature ..... Date .....

REMARKS .....

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THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY

PREGNANCY OUTCOME FORM

تعريف السيدة : ١ - الرقم المسلسل للسيدة : ..... ٢ - التاريخ : ..... اليوم الشهر السنة

٣ - اسم السيدة : .....

٤ - عنوانها (إذا تغير) : .....

رقم التليفون (إذا تغير) : .....

CONTACT DATA

5. Center number ..... ☐☐☐ 1-3

6. User order number ..... ☐☐☐☐ 4-7

7. Norplant set serial number ..... ☐☐☐☐☐ 8-12

8. Date of this visit ..... ☐☐ ☐☐ ☐☐ 13-18
day month year

PREGNANCY OUTCOME

9. Date of pregnancy termination ..... ☐☐ ☐☐ ☐☐ 19-24
day month year

10. Gestational age (in weeks) ..... ☐☐ 25-26

11. Pregnancy outcome ..... ☐ 27
1) live birth
2) still birth
3) induced abortion
4) spontaneous abortion
5) other (specify) .....

12. Congenital malformation .....
0) none ☐ 28
1) present (specify) .....

13. Intended contraceptive use ..... ☐ 29
0) none
1) norplant
2) pills
3) i u d
4) other (specify) .....

14. Investigator's name .....

15. Signature ..... Date .....

REMARKS .....

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THE EGYPTIAN FERTILITY CARE SOCIETY
NORPLANT IMPLANT STUDY
TERMINATION FORM

تعريف السيدة : ١ – الرقم المسلسل للسيدة : ..... ٢ – التاريخ : .....

اليوم الشهر السنة

٣ – اسم السيدة : .....

٤ – عنوانها (إذا تغير) : .....

رقم التليفون (إذا تغير) : .....

5. Center number ..... ☐☐☐ 1-3

6. User order number ..... ☐☐☐☐ 4-7

7. Norplant set serial number ..... ☐☐☐☐☐ 8-12

8. Date of removal ..... ☐☐ ☐☐ ☐☐ 13-18
day month year

9. Primary reason (s) for removal ..... ☐☐ 19-20

01) Menstrual problems
02) Pregnancy
03) Headache/dizziness
04) Hypertension
05) Other circulatory (specify) .....
06) Infection at insertion site
07) Pain in arm
08) Pain in leg
09) Backache
10) Breast disorders
11) Diabetes
12) Allergic reaction
13) Weakness/nervousness
14) Other medical (specify) .....
15) Desired pregnancy
16) Widowed/separated/divorced
17) Other personal (specify) .....
18) End of recommended use period

10. Difficulties during removal ..... ☐ 21
0) no
1) yes (specify) .....

11. Complications of removal ..... ☐ 22
0) no
1) yes (specify) .....

12. Reinsertion after removal ..... ☐ 23
0) no
1) yes (same arm)
2) yes (other arm)

13. Intended contraceptive use ..... ☐ 24
0) none
1) norplant
3) pills
4) other (specify) .....

14. Investigator's name .....

15. Signature ..... Date .....

REMARKS .....

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(02) 3473246
(02) 3452018

الجمعية المصرية لرعاية الخصوبة
نموذج تسجيل مستعملات النوربلانت

١ – اسم الوحدة _____ رقم الوحدة :..... ☐☐☐ ١ – ٣

٢ – اسم السيدة _____ الرقم المسلسل :..... ☐☐☐☐ ٤ – ٧

٣ – السن ..... ☐☐ ٨ – ٩

٤ – عدد الأطفال الأحياء ..... ☐☐ ١٠ – ١١

٥ – التعليم ..... ☐ ١٢

(١) أمية (٢) ابتدائى (٣) اعدادى
(٤) ثانوى (٥) فوق الثانوى

٦ – عنوان السيدة :

رقم المنزل _____ اسم الشارع _____ متفرع من شارع _____
اسم الحى _____ اسم المدينة /القرية _____ اسم المحافظة _____
رقم تليفون السيدة أو أقرب تليفون لها _____ .

٧ – اسم الزوج _____

٨ – أسماء أشخاص على صلة وثيقة بالسيدة ويمكن الرجوع إليهم عند الضرورة للاستدلال عليها وذلك من غير المقيمين معها فى نفس العنوان الموضح عاليه :

(أ) الشخص الأول :

الاسم _____ رقم التليفون _____
العنوان :
رقم المنزل _____ اسم الشارع _____ متفرع من شارع _____
اسم الحى _____ اسم المدينة /القرية _____ اسم المحافظة _____

(ب) الشخص الثانى :

الاسم _____ رقم التليفون _____
العنوان :
رقم المنزل _____ اسم الشارع _____ متفرع من شارع _____
اسم الحى _____ اسم المدينة /القرية _____ اسم المحافظة _____

هذا الجزء يجب أن يملأ بمعرفة الطبيب :

٩ – الرقم المسلسل للكبسولات التى وضعت :..... ☐☐☐☐☐ ١٣ – ١٧

١٠ – تاريخ التركيب : اليوم ☐☐ الشهر ☐☐ السنة ☐☐ ١٨ – ٢٣

١١ – اسم الطبيب القائم بالتركيب _____

١٢ – توقيع الطبيب _____

١٣ – التاريخ _____

يرسل النموذج بعد استيفائه إلى :
الجمعية المصرية لرعاية الخصوبة
٢ (أ) شارع الدكتور المحروق – المهندسين – القاهرة .
ص.ب ١٢٦ أورمان جيزة .
ت : ٣٤٧٠٦٧٤ (٠٢) – ٣٤٧٣٢٤٦ (٠٢) – ٣٤٥٢٠١٨ (٠٢)

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الجمعية المصرية لرعاية الخصوبة

مشـــروع النوربلانـــت

كارت مستعملة النوربلانت

اسم السيدة : _____

عنوانها : _____

_____ تليفون : _____

الرقم المسلسل للسيدة : ☐☐☐☐

الرقم المسلسل للنوربلانت : ☐☐☐☐☐

تاريخ وضع النوربلانت : _____

مواعيد زيارات المتابعة :

الزيارة رقم ١ : _____ (بعد شهر من وضع النوربلانت) .

الزيارة رقم ٢ : _____ (بعد ٣ شهور من وضع النوربلانت) .

الزيارة رقم ٣ : _____ (بعد ٦ شهور من وضع النوربلانت) .

الزيارة رقم ٤ : _____ (بعد سنة من وضع النوربلانت) .

الزيارة رقم ٥ : _____ (بعد سنتين من وضع النوربلانت) .

الزيارة رقم ٦ : _____ (بعد ثلاثة سنوات من وضع النوربلانت) .

الزيارة رقم ٧ : _____ (بعد أربع سنوات من وضع النوربلانت) .

الزيارة رقم ٨ : _____ (بعد خمس سنوات من وضع النوربلانت) .

كارت متابعة مستعملة النوربلانت

وحدة تنظيم الأسرة بمستشفى : .....

اسم السيدة : .....

الرقم المسلسل للسيدة : ☐☐☐☐

تاريخ وضع النوربلانت : .....

الرقم المسلسل للنوربلانت : ☐☐☐☐☐

رقم المتابعة	التاريـــخ	رقم المتابعة	التاريـــخ
(١)		(٥)	
(٢)		(٦)	
(٣)		(٧)	
(٤)		(٨)	

يرجا منك أن تقومى بزيارة الوحدة فى المواعيد المبينة أعلاه كذلك يمكنك أن تترددى على المركز فى أى وقت غير المواعيد المبينة على الكارت لأى سبب ترى ضرورة المشورة بشأنه .

رقم المتابعة :

١) بعد شهر من بدء الاستعمال
٢) بعد ثلاثة شهور من بدء الاستعمال
٣) بعد ستة شهور من بدء الاستعمال
٤) بعد سنة من بدء الاستعمال
٥) ، ٦) ، ٧) ، ٨) كل سنة بعد ذلك .

الجمعية المصرية لرعاية الخصوبة
نموذج تغيير عنوان مستعملات النوربلانت

١ – اسم الوحدة _____ رقم الوحدة : ☐☐☐ ١ – ٣

٢ – اسم السيدة _____ الرقم المسلسل : ☐☐☐☐ ٤ – ٧

٣ – العنوان الجديد :

رقم المنزل _____ اسم الشارع _____ متفرع من شارع _____

اسم الحى _____ اسم المدينة /القرية _____ اسم المحافظة _____

٤ – رقم التليفون الجديد _____

٥ – توقيع الطبيب _____

٦ – التاريخ _____

يرسل النموذج بعد استيفائه إلى :

الجمعية المصرية لرعاية الخصوبة

٢ (أ) شارع الدكتور المحروق – المهندسين – القاهرة .

ص.ب ١٢٦ أورمان جيزة

ت : ٣٤٧٠٦٧٤ (٠٢) – ٣٤٧٣٢٤٦ (٠٢) – ٣٤٥٢٠١٨ (٠٢)

مشـــروع النوربلانـــت

نموذج استطلاع رأى مستعملات النوربلانت

١ – اسم الوحدة _____ رقم الوحدة : ☐☐☐ ١ – ٣

٢ – الرقم المسلسل للسيدة ..... ☐☐☐☐ ٤ – ٧

٣ – التاريخ ..... اليوم الشهر السنة ☐☐☐☐☐☐ ٨ – ١٣

٤ – فى رأيك ما هى أهم مميزات النوربلانت ..... ☐ ١٤ ☐ ١٥

(٠) لا شىء

(١) نسبة احتمال الحمل أقل

(٢) سهولة الاستعمال

(٣) لا يحتاج منى أن أتذكر شيئا مثل بلع الأقراص ... الخ

(٤) أعراضه الجانبية أقل من غيره

(٥) يمكنى استعماله لمدة خمس سنوات

(٦) يمكن ازالته فى أى وقت

(٧) يمكن حدوث حمل فور ازالته

(٨) مميزات أخرى (رجاء توضيحها تفصيلياً) _____

٥ – فى رأيك ما هى أهم عيوب النوربلانت ؟ ..... ☐ ١٦ ☐ ١٧

(٠) ليست له أى عيوب

(١) تغيرات فى الدورة الشهرية

(٢) صـــداع

(٣) زيادة فى الوزن

(٤) آلام وثقل بالثدى

(٥) عملية وضع النوربلانت

(٦) عملية إزالة النوربلانت (إذا كانت قد ازالت فعلا)

(٧) شكل النوربلانت فى ذراعى

(٨) عيوب أخرى (رجاء توضيحها تفصيلياً) _____

٦ – هل لاحظ أحد وجود النوربلانت فى ذراعك ؟ ..... ☐ ١٨

(إذا كانت الإجابة بالنفى رجاء حذف السؤال رقم ٧)

(١) نعم

(٢) لا

٧ – ما أثر هذه الملاحظة عليك ؟ ..... ☐ ١٩

(١) أثر حسن

(٢) أثر سيىء

(٣) لم أبالى

٨ – ما رأيك فى عملية وضع النوربلانت ؟ ..... ☐ ٢٠

(١) تضايقت

(٢) لم أتضايق

(٣) شعرت بألم

(٤) شعرت بخوف

(٥) ملاحظات أخرى (رجاء توضيحها تفصيليا) _____

٩ – من واقع تجربتك هل ستنصحين أقل لك وصديقاتك باستعمال النوربلانت؟ ☐ ٢١

(١) نعم

(٢) لا « لماذا »

(٣) لست متأكدة « لماذا » _____

١٠ – هل قام المسئولين بعيادة تنظيم الأسرة بإيضاح وشرح الأعراض الجانبية للنوربلانت لك قبل وضعه ؟ ..... ☐ ٢٢

(١) نعم

(٢) لا

١١ – هل اطلعت أو قرأ عليك ورقة حقائق النوربلانت قبل وضعه ؟ ☐ ٢٣

(١) نعم

(٢) لا

١٢ – هل لكى أى ملاحظات أو تعليقات أخرى عن النوربلانت ؟ ☐ ٢٤

(١) نعم (رجاء توضيحها تفصيليا) _____

(٢) لا

هذا السؤال يوجه فقط لمن أزالت النوربلانت ..

١٣ – ما رأيك فى إزالة النوربلانت ؟ ..... ☐ ٢٥

(١) ضايقتنى

(٢) لم تضايقنى

(٣) شعرت بألم

(٤) شعرت بخوف

(٥) ملاحظات أخرى (رجاء توضيحها تفصيليا) _____

ملاحظات الباحث : _____

يرسل هذا النموذج بعد استيفائه إلى :

الجمعية المصرية لرعاية الخصوبة

٢ (أ) ش الدكتور المحروق – المهندسين – القاهرة

ص.ب ١٢٦ أورمان – الجيزة

تليفون : ٣٤٧٠٦٧٤ (٠٢)

٣٤٧٣٢٤٦ (٠٢)

٣٤٥٢٠١٨ (٠٢)

APPENDIX II

PREGNANCY REPORTS

AIN SHAMS CENTER

1)	Center name	: Ain Shams
	Center number	: 001
	User order number	: 18
	Norplant set serial number	: 00533

A 27 years old woman was admitted to the study on 10.09.1988. She was illiterate, para 3, used contraceptive pills before and her last menstrual period was on 06.09.88. She used to have regular menses 3/30 scanty in amount. Her weight was 79 kgs; blood pressure was 100/70 mmHg. There were no abnormalities detected on general or pelvic examination and Norplant capsules were inserted in the left arm without any complications.

After one month, she gained 2 kgs.

On 10.12.88, her weight reached 84 kgs, and on 11.03.89 she weighed 87 kgs.

On 11.09.90, she had symptoms of urinary tract infection, and vaginitis was detected on pelvic examination.

On 12.10.92 she complained of low back pain. She did not present for follow-up until she came back on 22.12.93 and was lactating. A history of pregnancy and normal delivery was given. She had a healthy baby. The capsules were removed on that day.

2) Center name : Ain Shams

Center number : 001

User order number : 128

Norplant set serial number : 1132

This case was a para 2 and used an IUD for 2 years before Norplant. On 18.12.1988, (third day of the menstrual cycle), the IUD was removed and Norplant was inserted and no complications occurred. At that time, she was clinically free, weighed 56 kgs and her B.P was 110/70.

On 18.1.1989, she presented for her scheduled one month visit. She was amenorrheic since insertion, and pelvic examination showed a normal size uterus. On 23.2.1989, she came for an unscheduled visit because of amenorrhea. A history of ampicillin intake was obtained. The last menses (that was at the time of insertion), was since 10 weeks. Pregnancy test proved positive. Pelvic examination revealed that the size of the uterus corresponded to eight weeks gestation confirmed by ultrasound. Ovulation most probably occurred around 29.12.1988; i.e. the pregnancy was a true method failure. Norplant use was terminated on the same day because of the diagnosed pregnancy.

On 28.2.1989, she reported that she had an induced abortion performed outside the hospital. She was seen once again on 8.3.1989, one week after the induced abortion.

3) Center name : Ain Shams
Center number : 001
User order number : 138
Norplant set serial number : 1206

This case was admitted on 25.12.1988. She was 27 years old, illiterate, para 2, her weight was 93 kg, her last pregnancy was 6 years prior to admission, and the last contraceptive method used before Norplant insertion was the IUD. Her menstrual pattern was 5/28 and of moderate amount, and she had no history of intermenstrual spotting or bleeding. Norplant insertion was done on the 3rd day of her menses. She weighed 93 kgs and her B.P. was 120/80 mmHg on admission.

At the one month follow-up visit, her weight was still 93 kgs, and she complained of amenorrhea throughout. Pelvic examination revealed vaginitis. At the 3rd month follow-up visit she had resumed menstruation and her menses was 10/30 and scanty in amount. Her weight decreased to 91 kgs. The case missed her scheduled 6 months follow-up visit.

At one year after insertion, her menstrual pattern was 5/30, of moderate amount and her weight was 91 kgs. At the two year follow-up visit, her menstrual pattern was 8/29, of moderate amount, and her weight had decreased to 90 kgs.

On 3107.1991, (31 months after Norplant insertion), she attended the clinic, complaining of a missed period; her last menstrual period was 3.6.1991. Pregnancy was confirmed, both by a pregnancy test and ultrasonography that estimated the gestational age to be eight weeks. The Norplant capsules were removed immediately. On 5.8.1991, the case developed vaginal bleeding and was admitted to Ain Shams Hospital. Ultrasonography revealed a living fetus and was diagnosed as threatened abortion. The case developed 2 more attacks of vaginal bleeding on

18.8.1991 and on 29.8.1991. On 3.9.1991, the bleeding increased in severity, and abortion was completed by surgical evacuation. The case intended to use an IUD thereafter.

4) Center Name : Ain Shams
Center No. : 001
User Order No. : 211
Norplant set serial number : 01273

A 25 years old woman was admitted on 21.2.1989. She was illiterate, para 3, with no past history of previous use of contraceptive methods, her last pregnancy was in 1987. She used to have regular menses 3/30 with moderate amount. She weighed 65 kg; her B.P. was 110/80 mmHg. There was no abnormality detected on general or pelvic examination and Norplant capsules were inserted without any complication.

She came for regular follow-up visits with no complaints. Her weight showed gradual increase to 81 kgs. Her menstrual pattern was regular except on her 6-month visit when she had amenorrhea alternating with bleeding.

On 31.3.1993 she attended the outpatient clinic complaining of nausea and vomiting, tender enlarged breasts and amenorrhea. She was not sure about her last menstruation, but recalled spotting on 9.3.1993. Pelvic examination revealed a soft cervix, and the uterus was enlarged (about 8 weeks) and soft.

Pregnancy test was positive. There was a history of antibiotic and vitamins intake.

Removal of the capsules was done on 7.4.1993 without complications; and she was followed up for antenatal care.

On 05.11.1994, pregnancy ended with a live birth (gestational age 39 weeks). Congenital biliary atresia was diagnosed after birth. Late neonatal obstructive jaundice was detected. The new born was incubated for 2 weeks but died the next day.

5) Center Name : Ain Shams

Center No. : 001

User Order No. : 223

Norplant set serial number : 01124

This case was admitted on 28.2.1989. She was 25 years old, illiterate, para 2, her last delivery was in 1984. She had used the contraceptive pills before. Her menstrual pattern was 4/28, moderate in amount, she weighed 74 kgs; B.P. 110/80 and no abnormality was detected on general, abdominal or pelvic examination.

She presented for follow-up visits through the years 1989, 1990, 1991 without any complaints.

On 18.10.1992 she attended the outpatient clinic complaining of amenorrhea for 6 months with perception of fetal movements, pregnancy was confirmed by abdominal and pelvic examination. Pelvic sonography confirmed pregnancy (26 weeks gestation). Norplant capsules were removed on 18.10.1992 (the same day) without any complications.

She gave a history of antibiotic therapy taken by her on April 1992 for common cold.

On 10.02.1993, the pregnancy ended with a live birth (39 weeks), with no congenital malformation. Depo provera will be used for contraception.

6) Center Name : Ain Shams

Center No. : 001

User Order No. : 271

Norplant set serial number : 01594

This case was admitted on 11.4.1989. She was 30 years old, illiterate, para 4, her last pregnancy was in 1983 and her last contraceptive method used before Norplant insertion was the pills. On admission she weighed 74 kgs, her B.P. was 100/80 mmHg. Her menstrual pattern was 3/30 moderate amount. General, abdominal and pelvic examination revealed no abnormality. She came for regular follow-up visits.

On 17.8.92 she came complaining of headache. On 3.4.1993 she attended the outpatient clinic complaining of nausea and vomiting with breast heaviness and tenderness although there was no missed period. The case has had menstrual-like flow during March. Pelvic examination revealed that the uterus was enlarged (about 10 weeks in size). Pelvic sonography revealed intrauterine pregnancy (gestational age = 11 weeks). Norplant capsules were removed on 3.4.1993 without any complication.

On 16.12.1993, the pregnancy ended with a live birth (41 weeks) with no congenital malformation. She intends to use an IUD.

7) Center name : Ain Shams
Center number : 001
User order number : 282
Norplant set serial number : 1585

This case was admitted to the study on 14.05.1989. She was 28 years old, illiterate and para 4. Her weight was 69 kgs and blood pressure was 120/80 mmHg.

She had no complaints, so she did not attend her follow-ups regularly. On 09.10.1990 her body weight was 72 kgs.

On 04.06.1991, she complained of amenorrhea and her weight reached 81 kgs.

On 12.07.1992 her menstrual problem was still persisting. On the follow-up dated 10.03.1993, her menstrual pattern was normal again and her weight reached 82 kgs. On 24.04.1993 she complained of amenorrhea, abdominal distension, nausea, vomiting and quickening. On medical examination her weight was 85 kgs, breasts were enlarged and the uterus was enlarged. Pregnancy test was positive and ultrasound showed ± 12 weeks pregnancy. Capsules were removed in the same setting.

On 26.10.1993 the pregnancy ended (39 weeks) giving a live birth with no congenital malformation. IUD was inserted for contraception.

8) Center Name : Ain Shams
Center No. : 001
User Order No. : 350
Norplant set serial number : 01958

This case was admitted on 2.10.1989. She was 37 years old, para 5, with secondary school education. The last pregnancy was in 1986. She was using Cu T 380 A IUD for contraception during the last 3 years before Norplant insertion.. Her menstrual pattern was 6/30 with moderate amount. Her weight was 78 kgs, B.P. 110/70 mmHg with no abnormalities detected on general, abdominal or pelvic examination. She presented for regular follow-up visits.

On 20.1.1993 the case attended the emergency outpatient clinic complaining of severe lower abdominal pain. Her vital signs were stable, yet abdominal examination showed tenderness, rigidity, and rebound tenderness in the suprapubic region. Pelvic examination revealed that the cervix is soft with severe pain induced on its movement. Pregnancy test was positive and pelvic sonography confirmed the presence of a disturbed tubal extrauterine pregnancy. Laparotomy was immediately performed, tubal abortion was found and right salpingectomy was done. The case had a smooth postoperative course.

Removal of the Norplant capsules was done on 17.2.1993 and one of the capsules was broken.

On removal she weighed 83 kg, her B.P. was 120/70 mmHg.

ALEXANDRIA CENTER

9)	Center name	: Alexandria
	Center number	: 002
	User number	: 0141
	Norplant set serial number	: 1005 (old)
		1007 (new)

The case was admitted on 27.12.1988. She was 35 years old, para 3, illiterate, her last contraceptive method was the pill, and her last pregnancy ended in 1982.

Her menstrual pattern was 3/30, and moderate in amount. She weighed 84 kgs and her blood pressure was 120/80. On insertion, one of the capsules fell on the ground, and another set was opened (serial No. 1007) for replacement. The case came for regular visits; she once complained of dizziness but on examination there was nothing abnormal. She showed a gradual weight gain as on the last visit before pregnancy she was 86 kg. On 18.4.1992 she presented complaining of amenorrhea, her last menstruation was on 10.3.1992. She weighed 94 kgs, her blood pressure was 120/80. Pregnancy was confirmed by a pregnancy test. The capsules were removed on the same day.

Abortion was induced 4 days after removal of the capsules. The general condition of the case was good and she is now using an IUD for contraception.

10) Center name : Alexandria
Center number : 002
User order number : 145
Norplant set serial number : 1078

This case joined the study on 13.01.1989. She was 38 years old, illiterate, para 6 and used and IUD before Norplant insertion. Her last pregnancy was in 1988. She weighed 71 kgs and her blood pressure was 110/70 mmHg. Irregular menstruation with intermenstrual spotting was present, and still existed on her third month follow-up, 18.04.1989, together with dysmenorrhea.

On her second year follow-up at 06.04.1991, she recalled that because of having amenorrhea for 1 month, a vaginal examination was done outside the center - by a private physician - and a pregnancy test turned out to be positive. Spontaneous abortion happened 2 weeks before date of Norplant removal which was on 06.04.1991.

11) Center name : Alexandria
Center number : 002
User order number : 253
Norplant set serial number : 01645

The case was admitted to the study on 14.6.1989. She was 30 years old, para 7, weight 74 kgs, B.P. 120/80, illiterate, the last contraceptive method used was the pills and her last pregnancy ended in 1987. Her menstrual pattern was 6/30 and moderate in amount.

On her follow-up visit dated 2.11.1989, she complained of nausea/vomiting and abdominal distention. Examination revealed no abnormality, her menstrual pattern was 3/30 with moderate amount.

On her follow-up visit dated 10.7.1989, she complained of amenorrhea that disappeared on her subsequent visit dated 20.6.1990, and her menstrual pattern became 3/28, of moderate amount. On 25.11.1991, she attended the clinic complaining of nausea/vomiting, enlarged tender breast and amenorrhea for 2 months. On examination the uterus was found to be 8 weeks in size, soft and the pregnancy test was positive. The Norplant capsules were removed immediately.

The pregnancy ended in a spontaneous abortion at 12 weeks gestation in Dar Ismail Hospital. Her husband is using the condom for contraception.

12)	Center name	: Alexandria
	Center number	: 002
	User order number	: 269
	Norplant set serial number	: 2052

The client was recruited on 01.07.1989. Her body weight at the time of insertion was 66 kgs. She had regular cycles.

After Norplant insertion, she complained of heavy menstrual bleeding which returned back to normal without treatment.

Her last menstrual period was on 25.05.1993. On 26.07.1993 the client suspected pregnancy by the development of amenorrhea and pregnancy symptoms. Pregnancy test was done on the same day and turned out to be positive.

On the following day, 27.07.1993, a pelvic examination was done and showed uterus size about 6-8 weeks. A second pregnancy test was done and confirmed the same positive result. Her weight was 76 kgs at that visit.

The Norplant capsules were removed on the same day. The client is willing to continue the pregnancy and her follow-up was conducted by the center.

On 02.03.1994, the pregnancy ended (40 weeks) with a live birth with no congenital malformation. IUD will be used for contraception.

13) Center name : Alexandria
Center number : 002
User order number : 276
Norplant set serial number : 01646

The case was admitted on 19.7.1989. She was 28 years old, para 4, illiterate. The last contraceptive method used was the IUD, and the last pregnancy ended on 1985. Her menstrual pattern was 5/30. On admission she weighed 62 kg and her blood pressure was 120/70.

She presented on two consecutive follow-up visits complaining of headache, and on examination she was found to be normal. On her visit dated 14.4.1992, she was complaining of amenorrhea and her last menstruation was on 20.2.1992. Her weight reached 66 kgs.

Pregnancy was confirmed by pelvic examination and pregnancy test. She was found to be 8 weeks pregnant. Norplant capsules were removed on the same day.

Abortion was induced 2 weeks after removal of the Norplant capsules. She is now using an IUD for contraception.

14)	Center name	: Alexandria
	Center number	: 002
	User order number	: 283
	Norplant set serial number	: 1650

The case was admitted on 22.7.1989. She was 25 years old, para 2, with preparatory education, her last contraceptive method used was pills, and her last pregnancy ended on 1987. Her menstrual history was 4/30. She weighed 72 kgs and her blood pressure was 110/80.

She came regularly for follow-up visits, complaining occasionally of headache and irregular menses, moderate in amount. On 11.7.1992, she presented complaining of amenorrhea and her last menstruation was on 18.5.1992. She was found to be 8 weeks pregnant by pelvic examination and pregnancy test was positive. The Norplant capsules were removed on the same day.

The pregnancy ended by normal vaginal delivery on 3.3.1993. She delivered a single living female baby, with no congenital anomalies.

MANSOURA CENTER

15)	Center name	: Mansoura
	Center number	: 004
	User order No.	: 8
	Norplant set serial number	: 00893

The case was admitted to the study on 30.7.1988, she was 38 years old, para 5 with primary education. Her last contraceptive method used was the pills and the last pregnancy ended on 1987.

On admission, she weighed 92 Kgs, her blood pressure was 120/80 mmHg and her menstrual pattern was 6/28. Her weight increased to 99 kgs on her last follow-up visit before pregnancy dated 20.7.1991. During her follow-up visits, she used to complain of headaches.

On 18.4.1992, she came complaining of amenorrhea, nausea, and vomiting. She was not sure about the date of her last menstruation. Pregnancy was diagnosed by clinical examination, pregnancy test and sonography, that confirmed a 6 weeks intrauterine pregnancy. The capsules were removed immediately.

She delivered on 4.12.1992, the gestational age was 40 weeks. The pregnancy outcome was a live birth with no congenital malformations.

16) Center name : Mansoura
Center number : 004
User order number : 54
Norplant set serial number : 827

This case was recruited on 15.10.1988. She was 35 years old, illiterate, para 5 and her last pregnancy ended 4 years prior to admission. The last contraceptive method used before Norplant was oral pills. Her weight was 65 kgs, B.P. 120/80 and no other medical problems were noted. Her menstrual history was 5/30 and of moderate amount. Norplant insertion was done on the 3rd day of her menses.

At the one month follow-up visit, her weight increased to 67 kgs, and no other significant clinical changes were noticed. At the 3rd month follow-up after insertion, she complained of headache, and her weight increased to 69 kgs. At the 6th month follow-up after insertion, she had no complaints and her menses was regular, but her weight increased again to 70 kgs.

The case presented on 26.12.1989 for an unscheduled visit, and was complaining of nausea/vomiting and secondary amenorrhea. She was not sure about the date of her last menstruation but recalled it at the end of October. Her weight was 70 kgs, and on pelvic examination the uterus was found enlarged, size of 8 weeks gestation and soft. The Norplant capsules were removed immediately and the case decided to continue her pregnancy.

She was followed-up regularly during the pregnancy that was uneventful and she was delivered at full term by C.S. done because of a breech presentation.

17) Center name : Mansoura

Center number : 004

User order number : 64

Norplant set serial number : 833

The case was admitted to the study on 01.11.1988. She was 28 years old, illiterate, para 4. Her body weight was 106 kgs.

During her follow-up visits, no abnormalities were detected except an increase in body weight reaching 115 kgs.

On 03.07.1993, the client complained of amenorrhea, with nausea and vomiting. Breasts were enlarged and hot. Pelvic examination revealed an enlarged uterus ± 8 weeks. Date of onset of last menses was 04.05.1993. Pregnancy test was done and proved positive. Norplant capsules were removed.

On 10.02.1994 the pregnancy ended (40 weeks) with a live birth with no congenital malformation. IUD is intended to be inserted for contraception.

18)	Center name	: Mansoura
	Center number	: 004
	User Order Number	: 136
	Norplant Set Serial Number	: 01186

The case was admitted to the study on 7.1.1989. She was 32 years old, para 4, illiterate, last contraceptive method used was IUD. Her menstrual pattern was 5/30. She weighed 77 kgs and her B.P. was 120/80 mmHg.

During the first 3 years after insertion of Norplant, no abnormalities were detected apart from pruritis vulva in her 6th month follow-up. However, during the follow-up visit dated 21.12.1992, she complained of amenorrhea, nausea and enlarged breasts. Her last menstruation was on 1.10.1992. Examination revealed an enlarged uterus ± 10 w and the pregnancy test was positive. There was no history of drug intake except for vitamins. The Norplant capsules were removed.

On 16.07.1993, the pregnancy ended (40 weeks) with a live birth with no congenital malformation. IUD is intended to be used for contraception.

19) Center name : Mansoura

Center number : 004

User order number : 318

Norplant set serial number : 1883

The case was admitted to the study on 09.04.1989. She was 30 years old and para 4. Her body weight was 83 kgs, blood pressure was 100/70 mmHg.

On her first and second follow-up visit, there were no complaints. After 6 months, she complained of headache and scanty menses.

On 28.09.1992, the client came to the center with symptoms suggestive of pregnancy; amenorrhea, nausea, vomiting and enlarged breasts. Date of onset of last menses was 30.07.1992. Examination revealed enlarged, hot breasts and an enlarged uterus of ± 8 weeks. Pregnancy test was done and proved positive. Norplant capsules were removed immediately.

Normal delivery took place on 18.12.1993 (gestational age 39 weeks), a live birth with no congenital malformations. No other contraceptive method was intended to be used.

AL-AZHAR CENTER

20)	Center name	: Al-Azhar
	Center number	: 005
	User order number	: 49
	Norplant set serial number	: 00969

This case was admitted to the study on 10.12.1988. She was 25 years old, illiterate, para 3, and her last pregnancy ended 3 years ago. The last contraceptive method used before Norplant insertion was the pill. Her weight was 84 kgs, B.P. was 110/70 mmHg, her menstrual pattern was 3/28 and of normal amount.

Her weight showed a steady increase to 100 kgs in the subsequent follow-up visits.

On her last visit before pregnancy (25.9.91), her menstrual pattern was 3/30 with no intermenstrual bleeding, her weight was 93 kgs. On 17.3.92, she attended the clinic and complained of headache, nausea, vomiting and amenorrhea since 19.10.91. Abdominal examination revealed a pelviabdominal swelling (20 weeks) confirmed by pelvic examination as a uterine mass. Sonography revealed a single, viable fetus, biparietal diameter = 53 mm = 21.2 wks. gestation. There was no history of concomitant use of medications. Norplant capsules were removed immediately.

On 15.12.1992, pregnancy ended (39 weeks) with a live birth with no congenital anomalies. IUD will be used for contraception.

21) Center name : Al-Azhar
Center number : 005
User order number : 54
Norplant set serial number : 966

This case was admitted to the study on 10.12.1988. She was 25 years old, with a preparatory education and para 3. She weighed 50 kgs and her blood pressure was 120/80 mmHg. Slight bleeding was encountered at the site of insertion, considered as a complication of insertion.

On 12.01.89, she had irregular menstruation, moderate in amount with intermenstrual bleeding.

On 20.03.89, she had irregular cycles, average duration 10 days and heavy in amount.

On 28.10.89, menstruation problems were still present. On 11.12.90, menstruation was heavy in amount with intermenstrual bleeding and spotting. Dysmenorrhea was also present.

On 14.12.91, her menstruation pattern was 8/28 and heavy in amount.

On 05.01.93, menstruation was regular. On 16.10.93, she was amenorrheic and stated that she was aborted since 20 days in a private clinic after 3 months pregnancy. Her weight was 59 kgs, and normal blood pressure. The capsules were then removed.

22) Center name : Al-Azhar
Center number : 005
User order number : 94
Norplant set serial number : 01420

The case was admitted to the study on 14.1.1989, she was 33 years old, with preparatory education, para 3, her last pregnancy was 6 years before insertion and the last contraceptive method used before Norplant was the IUD. Her weight was 72 kgs, her B.P. was 110/80 mmHg. Her menstrual pattern was 5/28 and of moderate amount. Norplant insertion was done on the 5th day of her menses.

At the one month follow-up visit, her weight dropped to 70 kgs. She complained of amenorrhea but the size of the uterus was normal and the pregnancy test was negative. At the 3rd and 6th months follow-up after insertion, her weight increased to 72 kgs and her menses was reported to be regular. Her last scheduled visit before pregnancy was on 11.2.1990; her menstrual pattern was regular 4/28, her weight increased to 73 kgs.

On 25.1.1992 (3 years after Norplant insertion), she attended the clinic, complaining of amenorrhea since 1.12.1991, enlarged tender breast, nausea and vomiting. On pelvic examination, the uterus was enlarged, 8 weeks in size and soft. Pregnancy test was done on 25.1.1992 and was found positive. Her body weight was 70 kgs, and she had no history of any medical treatment during Norplant use. The Norplant capsules were removed immediately.

On 5.9.1992 the pregnancy ended with a live birth (40 weeks gestational age), with no congenital malformation. No other contraceptive method was intended to be used.

23) Center Name : Al-Azhar

Center number : 005

User Order number : 106

Norplant set serial number : 01418

This case was admitted on 24.01.1989. She was 36 years old, illiterate, para 5, and her last pregnancy was 6 years ago. The last contraceptive method used before Norplant insertion was the pills. Her weight was 64 kgs, her B.P. was 130/80 mmHg. Her menstrual pattern was 5/30 and of moderate amount. Norplant insertion was done on the 4th day of her menses.

At the one year follow-up after insertion, her weight increased to 66 kgs, and her menses was regular.

On 10.08.1991 she came for an unscheduled visit, her weight increased to 67 kgs, her menses was regular and her B.P. was 110/70 mmHg.

At the 3rd year follow-up, her weight was 67 kgs, her B.P. was 110/70 mmHg, and her menses was regular.

On 5.9.1992, an unscheduled visit, her weight increased to 70 kgs, her B.P. 120/80 mmHg, and she complained of amenorrhea, headache, nausea, vomiting and enlarged tender breasts. Her last menstruation was on 23.06.1992. On pelvic examination the size of the uterus was ± 10 weeks, pelvic ultrasonography was done and revealed intrauterine pregnancy (gestational age = ± 10 weeks).

The Norplant capsules were removed immediately. There is no history of receiving any medical treatment through 1992. On 25.03.93, she delivered a female live birth with no congenital malformations.

24) Center Name : Al-Azhar
Center number : 005
User order : 147
Norplant set serial number : 01370

The case was admitted to the study on 20.2.1989. She was 33 years old, illiterate, para 6, her last pregnancy ended in 1987, and no method of contraception was used before Norplant insertion. Her weight was 88 kgs, her B.P. was 120/80 mmHg. Her menstrual pattern was 5/30 and of moderate amount. Norplant insertion was done on the 4th day of her menses.

At the one month follow-up, her weight was 87 kgs, her B.P. was 120/80 mmHg and her menses was regular.

At the 3rd month follow-up, her weight was 83 kgs, her B.P. was 120/80 mmHg, and her menses was regular.

At the 6th month follow-up, her weight has increased to 86 kgs, her B.P. was 120/80 mmHg, and her menses was regular but heavy.

At one year follow-up, her weight had increased to 92 kgs, her B.P. was 120/80 mmHg, her menses was regular and heavy. She complained of insertion site pain.

At the 2nd year follow-up, her weight was 92 kgs, her B.P. was unchanged, her menses was regular and of moderate amount, and she was complaining of headache.

On 6.5.1991, she presented for an unscheduled visit, her weight was 90 kgs, her B.P. was 120/80 mmHg, and she complained of menorrhagia. She was reassured and received homeostatic drugs.

At the 3rd year follow-up, her weight was 90 kgs, her B.P. was 120/80

mmHg, her menses was regular and of moderate amount.

On 19.12.1992, she presented for an unscheduled visit. She weighed 100 kgs, her B.P. was 120/80 mmHg, and complained of amenorrhea. Her last menstruation was on 10.10.1992. She also complained of headache, nausea, and vomiting. On pelvic examination the uterus was enlarged (size ± 10 weeks) and soft. Pelvic ultrasonography revealed intrauterine pregnancy (± 9 weeks). The capsules were removed immediately. The case had received antidepressant drugs (Tofranil and Tryptizol) for one year before pregnancy. On 10.07.93, she gave birth to a male live birth with no congenital anomalies.

25) Center name : Al-Azhar

Center number : 005

User order number : 0161

Norplant set serial number : 01407

This case was admitted to the study on 4.3.89. She was 34 years old, illiterate, para 4 and her last pregnancy ended in 1984. The last contraceptive method used before Norplant was a barrier method. Her weight was 93 kgs, her B.P was 130/80 mmHg. Her menstrual pattern was 5/28 and of moderate amount. Norplant insertion was done on the 3rd day of her menses.

At the one month follow-up visit, her weight dropped to 90 kgs and her menses was reported to be regular and heavy in amount. At the 3rd month follow-up, she complained of headache and heavy menstruation; her weight increased to 94 kgs. At the 6th month follow-up, she complained of headache while her weight was still 94 kgs.

Her last scheduled visit before pregnancy was on 9.3.1991 and her menstrual pattern was 4/30, of moderate amount, with no intermenstrual spotting or bleeding and she weighed 89 kgs.

On 25.5.1991, she attended the clinic with a missed period since 9.3.1991. On examination, the uterus was found enlarged, soft, and 10 weeks size. Pregnancy test was positive. There was no history of concomitant use of medications, and the Norplant capsules were removed on 25.5.1991.

Her pregnancy ended on 15.9.1991 with a single live birth (40 weeks gestational age). No congenital malformations were observed. The case intended to use the IUD for contraception.

26) Center name : Al-Azhar
Center number : 005
User Order number : 171
Norplant set serial number : 01425

This case was admitted to the study on 7.3.1989. She was 34 years old, illiterate, para 2, her last pregnancy ended in 1986 and the last contraceptive method used before Norplant insertion was the pills. Her weight was 66 kgs, her B.P. was 120/70 mmHg. Her menstrual pattern was 6/30 and of moderate amount. Norplant insertion was done on the 3rd day of her menses. At one month follow-up, her weight was 60 kgs, her B.P. was 120/80 mmHg and with regular menstrual cycle. At the 3rd month follow-up, her weight was 60 kgs, her B.P. was 120/80 mmHg and with regular cycle. At the 6th month follow-up, her weight increased to 65 kgs, her B.P. was 120/80 kgs, and her menstrual cycle was regular but heavy in amount. At one year follow-up, she complained of headache, her weight was 66 kgs, her B.P. was 120/80 mmHg and with regular cycle.

At the 2nd year follow-up, her weight increased to 67 kgs, her B.P. was 120/80 mmHg, her menstrual cycle was regular.

At the 3rd year follow-up, she weighed 68 kgs, her B.P. was 120/80 mmHg, and her menstrual cycle was regular.

The case made an unscheduled visit on 28.12.1992. She complained of nausea, vomiting and amenorrhea since 25.10.1992. Her weight has increased to 73 kgs, her B.P. was 120/80 mmHg. On clinical examination, the uterus was enlarged (± 8 weeks) and soft. Ultrasonography was done on 29.12.1992 and revealed intrauterine pregnancy, single viable fetus ±8.4 weeks gestational age. Norplant capsules were removed on 9.1.1993. The case delivered on 24.07.93 a male live birth with no congenital anomalies.

27) Center name : Al-Azhar

Center number : 005

User order number : 181

Norplant set serial number : 907

The case joined the study on 16.03.1989. She was 27 years old, illiterate, para 4. Her last pregnancy was 4 years ago, and the last contraceptive method used before Norplant insertion was an IUD. Her weight was 70 kgs, blood pressure 120/80 mmHg. Menstrual pattern was 5/30 and of moderate amount.

Norplant capsules were inserted on the second day of her menses.

At the first one month follow-up, her weight was unchanged, blood pressure 110/80 mmHg and menses was regular.

At the three month follow-up, her weight was still the same, blood pressure 120/80 mmHg, with regular menses, scanty in amount.

At the one year follow-up, her weight was 71 kgs, blood pressure 120/80 mmHg, and some intermenstrual bleeding was encountered.

In the second year follow-up, her weight increased to 73 kgs, her blood pressure was 110/80 mmHg, and her menses was again regular.

At the third year follow-up, her weight reached 74 kgs, blood pressure was 110/80 kgs and menses was regular.

At the fourth year follow-up, the weight was 72 kgs, blood pressure 110/80, regular menses, and complaint of pain at the insertion site.

The client came on 24.04.1992, for an unscheduled visit, with amenorrhea since 10.01.1993, complaining of headache, nausea and vomiting. Her weight was 74 kgs. Pelvic examination showed enlarged uterus ± 14 weeks. Pregnancy was confirmed by ultra-sonography. The capsules were removed immediately.

On 20.10.1993 the pregnancy ended (40 weeks) with a live birth with no congenital malformation. IUD will be used for contraception.

28) Center name : Al-Azhar
Center number : 005
User order number : 0200
Norplant set serial number : 01379

This case was admitted to the study on 4.4.1989, she was 35 years old, with primary education, para 4 and her last pregnancy ended in 1988. The last contraceptive method used before Norplant insertion was the pill. Her weight was 82 kgs; her B.P was 130/90 mmHg. Her menstrual pattern was 4/30 and of moderate amount. Norplant insertion was done on the 2nd day of her menses.

At the one month follow-up, her weight dropped to 80 kgs, and her menses was reported to be regular and heavy in amount. At the 3rd month follow-up, her cycle was regular with intermenstrual bleeding and her weight was still 80 kgs. At the 6th month follow-up, she complained of headache and her weight was 80 kgs.

Her scheduled visit before the pregnancy was on 28.10.1990, during which, her menstrual pattern was 5/30 with no intermenstrual spotting or bleeding and her weight was 80 kgs.

On 9.12.1991, she attended the clinic with a missed period. Her last menstruation was on 14.10.1991. A pregnancy test was done on 1.12.1991 and was found positive. There was no history of concomitant drug use before the missed period. Pelvic ultrasonography was done on 13.12.1991, and it showed a single, viable, intrauterine pregnancy CRL = 13.5 cm = 7.4 weeks. Removal of the Norplant capsules was difficult as 2 capsules were deeply embedded. Four capsules were removed on 9.12.1991, the case received ampicillin capsules 500 mg/8 hrs. and Haemoclar cream for one week. The remaining two capsules were removed on 22.12.1991 and the case was advised to return for antenatal care.

EFCS

On 15.7.1992, her pregnancy ended with a normal, single, live birth (38 weeks gestational age). No congenital malformations were observed. The IUD was her choice for future contraception.

29) Center name : Al-Azhar
Center number : 005
User order number : 0212
Norplant set serial number : 01842

This case was admitted to the study on 30.4.1989. She was 30 years old, illiterate, para 5, and her last pregnancy ended in 1984. The last contraceptive method used before Norplant was the pill. Her weight was 69 kg, her B.P. was 120/80 mmHg. Her menstrual pattern was 3/28 and of moderate amount. Norplant insertion was done on the 2nd day of her menses.

At the one month follow-up visit, there was no change in her weight; her menses was reported to be regular, yet she complained of pain at the insertion site. At the 3rd month follow-up, there were no complaints, only her weight increased to 70 kgs. At the 6th month follow-up visit, no complaints were made and she weighed 68 kgs.

Her last scheduled visit before pregnancy was on 4.6.1990 and her menstrual pattern was 4/28 with no intermenstrual spotting or bleeding and her weight was 70 kgs.

On 24.7.1990, she attended the clinic, her last menstrual period was on 25.5.1990. On examination, the uterus appeared to be enlarged, soft and about 10 weeks size. Ultrasonic scan performed on 24.7.1990 showed a single, viable, 8.6 weeks fetus. The Norplant capsules were removed on 1.8.1990. The pregnancy ended by induced abortion. There was no history of concomitant use of medications before the missed period.

30) Center name : Al-Azhar

Center number : 005

User order number : 0230

Norplant set serial number : 01800

This case was admitted to the study on 22.5.1989. She was 32 years old, with preparatory education, had five children, and her last pregnancy ended in 1989. The pill was the last contraceptive method used before Norplant insertion. Her weight was 89 kgs, her B.P was 120/70 mmHg. Her menstrual pattern was 3/25 and scanty in amount. Norplant insertion was done on the 2nd day of her menses. At the one month follow-up, her weight was 93 kgs, and her menses was reported to be regular. At the 6th month follow-up, she complained of increased body weight that reached 100 kgs.

Her last scheduled visit before the pregnancy was on 25.8.1991. Her menstrual pattern was 5/28, moderate in amount, with no intermenstrual spotting or bleeding and her weight was 98 kgs.

On 30.9.1991, she attended the clinic. Her last menstruation was on 25.7.1991. On examination, the uterus was found to be enlarged, 8 weeks gestational size and soft. On 30.9.1991, ultrasound revealed a single, viable 8 weeks fetus. There was no history of concomitant use of medications before the missed period. Five capsules were removed on 30.9.1991 and one capsule was deeply implanted. Three subsequent trials failed to remove that capsule.

A 4th trial for removal of the remaining capsule was done on 1.2.1992 with the assistance of a surgeon; under local anaesthesia, a longitudinal incision (3 cm) was done, dissecting a dense layer of fibrous tissue. The capsule was extracted and three sutures were taken.

Pregnancy continued to term and the case delivered on 25.4.1992 a normal, single live birth (40 weeks gestational age). No congenital malformation was noted. The IUD was the contraceptive method of her choice.

31) Center name : Al-Azhar

Center number : 005

User order number : 240

Norplant set serial number : 1759

On date of admission to the study, 30.06.1989, she was 35 years old, illiterate, para 7. Her last pregnancy was 2 years ago, and the last contraceptive method used before Norplant insertion was IUD. Her weight was 59 kgs and blood pressure was 130/80 mmHg. Her menstrual pattern was 2/30 and of scanty amount. Norplant insertion was done on the third day of her menses. At one and three month follow-up she complained of headache, her blood pressure, weight and menses were unchanged. At the sixth month follow-up, she complained of headache, nausea and vomiting and her weight became 60 kgs, then increased to 62 kgs at the one year follow-up. Still the weight increased to 65 kgs at the third year follow-up and she complained of scanty menses yet regular.

On 21.08.1993, she attended the clinic complaining of headache, nausea, vomiting, enlarged tender breasts and amenorrhea since 15.06.1993. Her weight was 65 kgs, blood pressure 120/80 mmHg. On physical examination the uterus was enlarged, pregnancy test was positive and ultrasonography confirmed a single intrauterine pregnancy of ± 9 weeks. Norplant capsules were immediately removed.

On 07.03.1994, pregnancy ended (38 weeks) with a live birth with no congenital malformation. IUD will be used for contraception.

32) Center name : Al-Azhar
Center number : 005
User order number : 268
Norplant set serial number : 1837

This case joined the study on 19.06.1989. She was 33 years old, illiterate and para 5. Her last pregnancy was 5 years ago and the last contraceptive method used was oral pills. The body weight was 90 kgs, blood pressure was 130/80 mmHg. Her menstrual pattern was 4/30 and of average amount. Norplant insertion was done on the second day of her menses. At the one month follow-up, her weight decreased to 88 kgs. At the sixth month follow-up, she complained of headache. Vaginitis was detected at the one year follow-up. At the second and third year follow-up, no complaints were given. Then at the fourth year follow-up, she complained of headache and amenorrhea since 13.05.1993, her weight decreased to 85 kgs. Through physical examination the uterus was found enlarged ± 8 weeks and ultrasound was done on 17.07.1993 to reveal intrauterine pregnancy ± 9 weeks. The Norplant capsules were removed immediately. It is worth mentioning that the client received antirheumatic treatment for three weeks before the last menstrual period.

On 05.02.1994, pregnancy ended (39 weeks) with a live birth with no congenital malformation. IUD will be used for contraception.

APPENDIX III

List of Research Team in the Five University Centers

List of Research Team
at the Five University Centers

Co-investigators and Investigators

Dr. Ihab Abdel Fattah	Ain Shams
Dr. Khaled Swidan	Ain Shams
Dr. Diaa Rizk	Ain Shams
Dr. Hesham Fathy	Ain Shams
Dr. Nasser Ahmed	Ain Shams
Dr. Osama El Ashkar	Alexandria
Dr. Aly Kholeif	Alexandria
Dr. Yakoub Abdalla	Assiut
Dr. Safwat Abdel Rady	Assiut
Dr. Alaa Abdel Hamil	Assiut
Dr. Essam El Din Abdalla	Assiut
Dr. Ahmad Makhlouf	Assiut
Dr. Momen Mohammed Kamel	Assiut
Dr. Ahmad Fayek	Assiut
Dr. Sabry Mahmoud	Assiut
Dr. Abdel Fattah Haroun	Mansoura
Dr. Mostafa Tewfik	Mansoura
Dr. Abdel Nasser Aly	Al-Azhar
Dr. Assem Anwar	Al-Azhar
Dr. Mostafa El Amly	Al-Azhar

Social workers and Nurses

Ms. Mounira Ibrahim	Ain Shams
Ms. Rawya Shehata	Ain Shams
Ms. Manal Hosny	Ain Shams
Ms. Zeinab Osman	Alexandria
Ms. Sabah Mohammed	Alexandria
Ms. Fatma Mahmoud	Alexandria
Ms. Fadya Abdel Meguid	Assiut
Ms. Fawzeya Galal	Assiut
Ms. Soad Mahmoud	Assiut
Ms. Farida Youssef	Mansoura
Ms. Samar Aly	Mansoura
Ms. Inas Kamal	Mansoura
Ms. Soha Bahnasy	Al-Azhar
Ms. Nahed Negm	Al-Azhar
Ms. Iman Mahmoud	Al-Azhar

الدورة الشهرية خلال السنة الأولى من إستخدام النوربلانت ثم تراجعت هذه النسبة بعد السنة الأولى من الإستخدام. وحدث تقطر دموى أو نزف متقطع بين الدورات الشهرية فى ٩ر١٠ ٪ و ٦ر١١٪ من الحالات على التوالى خلال السنة الأولى من الإستخدام ، ثم إنخفضت النسبة بعد ذلك. وحدث إنقطاع الدورة الشهرية فى ٣ر١٧٪ من الحالات خلال السنة الأولى ثم إنخفضت النسبة حتى وصلت الى ٧ر١٪ فى السنة الخامسة. ومن الأعراض الجانبية الأخرى : زيادة الوزن ، صداع ، فقدان الشهية ، غثيان ، دوخه ، ألم أسفل الظهر ، بعض التغيرات النفسية ، ألم واحمرار موضعى فى مكان تركيب الكبسولات. وقد تبين أن كبسولات النوربلانت ليس لها تأثير يذكر على ضغط الدم .

وقد أظهرت نتائج هذه الدراسة أن كبسولات النوربلانت وسيلة ذات فاعلية عالية فى منع حدوث الحمل وأن نسبة فشل الوسيلة كانت ١ر٢٪ خلال خمس سنوات هى مدة الدراسة وفى خلال نفس الفترة تم إزالة الكبسولات فى ٣ر١٥٪ من الحالات لأسباب متعلقة باضطرابات الدورة الشهرية وفى ٤ر١٣٪ لأسباب طبية أخرى. وهذه النسب تدل على تقبل جيد لكبسولات النوربلانت كوسيلة لمنع الحمل.

وقد حدثت مضاعفات بعد التركيب أو بعد الإزالة فى ٤ر٠٪ و ٨ر٠٪ من عدد الحالات. وهذه النسبة الضئيلة ترجع الى التدريب الجيد للأطباء والمتابعة المستمرة والذى كان له تأثيرا حيويا على مدى تقبل الوسيلة والاستمرار فى إستخدامها لمدة طويلة.

الملخص

قامت الجمعية المصرية لرعاية الخصوبة بتنفيذ تجربة إكلينيكية لكبسولات النوربلانت بتمويل من هيئة المعونة الأمريكية وبمساندة المجلس القومى للسكان وذلك فى خلال الفترة من عام ١٩٨٨ الى عام ١٩٩٤. وتم تنفيذ التجربة الإكلينيكية من خلال خمس مراكز جامعية فى عين شمس ، والأسكندرية ، وأسيوط ، والمنصورة، والأزهر. وشملت الدراسة ١٥٣٦ سيدة.

ومن المعروف أن كبسولات النوربلانت هى وسيلة هرمونية لمنع الحمل مكونة من ست كبسولات مرنه يتم تركيبها فى ذراع السيدة التى ترغب فى منع أو تأجيل حدوث الحمل. وعلى مدار خمس سنوات يتسرب من الكبسولات هرمون صناعى يسمى "ليفونورجسترل" ينتج عنه منع الحمل. وتستعيد السيدة خصوبتها مرة أخرى بعد إزالة الكبسولات مباشرة

ويوضح هذا التقرير هدفان رئيسيان تحققا من خلال الدراسة وهما:

١- تقدير مدى فاعلية كبسولات النوربلانت كوسيلة لمنع الحمل.
٢- دراسة مدى تقبل السيدات للنوربلانت كوسيلة مأمونة لمنع الحمل

ومن مميزات كبسولات النوربلانت أنها طويلة المفعول فمدة صلاحيتها خمس سنوات ، ولا تعتمد على إلتزام السيدة بالإستخدام الصحيح حيث أنها تزرع تحت الجلد.فتمنع الحمل طوال فترة الإستخدام وتستعيد السيدة خصوبتها بعد إزالة الكبسولات, كما أن الوسيلة غير مرتبطة بالمعاشرة الزوجية وبعيدة عن الجهاز التناسلى للسيدة.

وبما أن كبسولات النوربلانت خالية من هرمون "الاستروجين" فإنها لا تسبب الأعراض الجانبية لهذا الهرمون. ويتسرب هرمون "البروجستين" من الكبسولات بصورة بطيئة ومنتظمة بطريقة أفضل من الأقراص والحقن.

أما عن الأعراض الجانبية التى يسببها هرمون "البروجستين" ، والتى يحتمل حدوثهاعند إستخدام كبسولات النوربلانت ، فهى : إضطراب الدورة الشهرية. فإكثر من ٢٥٪ من عدد الحالات حدث لديهن تغيير فى

الجمعية المصرية لرعاية الخصوبة

التجربة الإكلينيكية لكبسولات النوربلانت فى مصر

التقرير النهائى

إبريل ١٩٩٥

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The acceptability of Norplant in Egypt

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Abstract

Currently, the pill and IUD account for 83% of contraceptive use in Egypt; Norplant* will be an important complement to those methods of family planning. In Egypt where childbearing begins early, and closely spaced pregnancies are the norm, the long duration of Norplant's effectiveness and its relative ease of use should be appealing. The Egyptian Fertility Care Society (EFCS) initiated a study in 1988 on the acceptability of Norplant in Egypt to study the clientele of the EFCS clinical trial in the five university teaching hospitals.

The clinical trial participants were women in their thirties who had an average of four children. Most had used a method of family planning before Norplant, and were anxious to maintain contraceptive protection as most wanted no more children. Satisfaction with Norplant among users was high. In the survey, 93% of the women expressed satisfaction with the method. More than half (67%) of the women said they would consider using Norplant again in the future, and another 22% were undecided. Eighty-seven percent of the women who had not discontinued were planning to continue with their current Norplant set for the full five years.

Egyptian women like Norplant because of its long duration of effectiveness, the site of insertion, its ease of use, and its relative lack of perceived side-effects compared to the pill and IUD. In Egypt where a reliable, long-term, but not permanent method of contraception is badly needed, Norplant should become a popular method of family planning.

* The Norplant system is a long-acting, low-dose, progestin-only contraceptive method for women. The drug, levonorgestrel, is delivered by means of six silastic capsules implanted subdermally in the arm by a minor surgical technique. Effectiveness is achieved by the steady release of the progestin from the interior of the capsules through the silastic into the blood. A level of levonorgestrel sufficient to prevent conception is reached 24 hours after placement and is maintained for more than five years [1].

Introduction

When approved for general use, the five-year subdermal contraceptive implant, Norplant, is likely to play a significant role in the family planning program in Egypt. Currently, the IUD and the pill account for 83% of contraceptive use in Egypt [2]. Norplant will be an important complement to those methods of family planning. In a country where childbearing generally begins when women are young, and closely spaced pregnancies are the norm, Norplant's long-term effectiveness and its relative ease of use could be appealing. Women may face several years at the end of their reproductive lives when they have completed their families, and yet they still need a reliable, yet reversible form of family planning.

Worldwide, over 55 000 women have participated in clinical or pre-introduction trials of Norplant in 44 countries [3]. Norplant has been found to be a highly effective and safe method of contraception. For a new contraceptive method to be widely used, however, safety and efficacy must be accompanied by acceptability. Norplant requires minor surgery for insertion and removal, which could give some women the feeling of having less control of this method than of other methods such as the pill or even the IUD, which can be more easily removed. Social or religious reactions to the menstrual disturbances caused by Norplant could discourage its use in some cultures. The long duration of use could be perceived as a constraint to its use for women who want to space their next birth, but not by five years. On the other hand, the long duration of use could make Norplant highly acceptable, as could the insertion site in the arm.

Women, and their partners where they have been asked, have generally been satisfied with Norplant [4–17]. Most information on the acceptability of Norplant has been derived from clinical trial data on discontinuation and complaints about side-effects, with user-satisfaction questionnaires administered after six months [5–7]. Some studies have specifically included acceptability components [8,11].

While Norplant has been found to be a highly acceptable method in a number of cultural settings, no work has been conducted previously on the acceptability of Norplant in an Islamic country in the Near East. The importance of religious observances and their link to menstruation could affect the acceptability of Norplant in Egypt, since the major side-effect of Norplant to date has been menstrual disturbances.

The Egypt Norplant clinical trials

Norplant has undergone two sets of pre-introductory clinical trials in Egypt. The first was supported by the Rockefeller Foundation and the Population Council in Assuit, Alexandria, Zagazig and Al Azhar in the early 1980s [18]. The second study was conducted in five university teaching hospitals in Assuit, Alexandria, Cairo (Ain Shams and Al Azhar), and Mansoura. Under the sponsorship of the Egyptian National Population Council, it was coordinated by the Egyptian Fertility Care Society (EFCS), with support from the United States Agency for International Development (USAID) and technical assistance from Family Health International.

As an integral component of the Norplant project initiated by the EFCS in 1988, research was included on the acceptability of Norplant in Egypt, to complement the clinical data on the safety and efficacy of this new method. The acceptability study focused on the clients in the clinical trial in the five university teaching hospitals. This paper discusses the acceptability of Norplant in Egypt, client satisfaction with Norplant services, access to removal, intention to use Norplant in the future, and the recommendation of Norplant to others.

Methodology

The study used both focus group discussions (FGD) and a survey to measure the acceptability of Norplant. The survey was used to quantify behavior and attitudes towards Norplant while the FGDs were used to explore opinions about and reactions to Norplant in more depth. The results of the FGDs cannot be generalized, but they provide a rich complement to the survey data. Table 1 shows the methods used for the study.

Table 1 Norplant acceptability study design, Egypt, 1989

Method	*Group*	*Number*
Focus group discussions	Users, initial	10 FGD; 3–11 participants
	Late, continuers <1 year	5 FGD; 10–13 participants
	>1 year	5 FGD; 8–10 participants
	Late, discontinuers	5 FGD; 4–5 participants
Field survey	Users, continuers and discontiners	1351

The acceptability study followed the experience of the EFCS clinical trial participants. It included two series of focus group discussions with users at the beginning of the five-center Norplant clinical trial and one year later, after some users had more than one year of experience with Norplant. Finally, all clients in the clinical trial participated in a field survey.

Table 2 Characteristics of participants in initial FGD on Norplant in five Norplant clinical trial centers, Egypt, 1989

	Center				
Characteristic	*Ain Shams*	*Alexandria*	*Assuit*	*Mansoura*	*Al Azhar*
Age (years)	26	30	31	33	31
Range	22–35	25–38	NA	28–38	24–38
Children ever born	4	4	5	4	5
Range	2–6	2–6	NA	2–10	4–6
Education (%)					
Illiterate	95	100	82	67	NA
Literate	5	0	18	33	
Does user work outside home (%)					
Yes	5	0	NA	NA	0
No	95	100			100
Residence					
Urban	100	48	39	60	100
Rural	0	52	61	40	0
No. of participants in FGD	22	25	18	15	NA

Note: These characteristics represent those of two FGD at each center. For Ain Shams and Al Azhar, both groups were from urban areas. For Alexandria, Assuit and Mansura, one group at each center was urban and the other group rural

Results

The EFCS Norplant clinical trial was initiated in 1988 at the five university teaching hospitals (Alexandria, Assuit, Ain Shams, Mansoura, and Al Azhar). Special care was taken to provide training to the health care providers in both technical and counseling aspects of Norplant. Enrollment of the 1537 women ended in September 1989. The acceptability study started in late 1988 with the initial reaction FGD.

Initial FGD with new users

FGD were held with users in each of the five centers in order to study clients' early reactions to Norplant. These participants had used Norplant for between one to six months at the time of the FGD. In three centers clients were divided into urban and rural groups; in two centers clients were homogeneous (all from semi-urban areas) so no division among clients was made [19,20].

The user reactions in this early stage are likely to be very important, as common side-effects frequently occur soon after insertion, when the woman may be anxious and uncertain, and when experience with Norplant is new. Clients may have many questions and the need for strong client–provider relations is greatest at this time. Clients may have complaints about the service delivery sytem.

Characteristics of the new users

The ages of the users ranged from 22 to 38 years, as shown in Table 2. They had between 2 and 10 children, with an average of 4. Most of the participants were illiterate women who did not work outside of the home. Virtually none of them wanted more children.

Knowledge of Norplant

Previous and present Norplant users play an important role in spreading information about the method, and in convincing relatives and neighbors to use it. FGD participants reported that their main initial sources of information about Norplant were users, relatives, neighbors, friends, and family planning clinic staff.

Advantages of Norplant

Almost all of the women had used another method of family planning before trying Norplant – generally the pill or IUD, and switched to Norplant due to the side-effects they had experienced with the previous method. Most were happy that Norplant had relatively fewer side-effects. The women considered the advantages of Norplant to be its long duration of effectiveness, its relative lack of side-effects, its ease of use (it cannot be forgotten like the pill), and its insertion site (unlike the IUD).

Problems encountered with Norplant

After two to six months of experience, the women had few complaints about Norplant. The most common side-effect experienced, as in other studies, was menstrual irregularity, but the women who had experienced amenorrhea generally said that it went away after two months or so. Other side-effects experienced were headaches, dizziness, weight gain or loss, and initial pain at the site of insertion.

Satisfaction with Norplant and services

Most of the women were satisfied with Norplant; only a few women had considered

removal, and they had been dissuaded from doing so. Women who had experienced side-effects said that these were a small price to pay compared to getting pregnant again. The users said they were generally satisfied with the services they had received, although many did complain that the waiting time (sometimes up to two hours) to see the doctor was too long. They were satisfied with the insertion procedures, although many said that the procedure was not fully explained to them. A few of the women mentioned the Norplant booklet they had received. EFCS developed, in collaboration with PATH/PIACT, three information booklets/leaflets for use during counselling, one of which was a user information leaflet in Arabic. The booklet for users was mostly pictorial, geared to illiterate clients [21,22]. Women who experienced side-effects said that they wished the drugs prescribed to alleviate the effects were free of charge since many of them said they could not afford to buy the treatments. Most of the participants mentioned that they would (or already had) recommend Norplant to others.

Follow-up FGD

One year after the initial discussion with users, three sets of FGD were again held in each of the five centers, this time with users of less than one year, users of more than one year, and with discontinuers. The purpose of these FGDs was to get users' opinions after a longer duration of use, and to talk more specifically to discontinuers.

Characteristics of the users

The characteristics of the three groups of users are shown in Tables 3–5. The women were, on average, between 29 and 33, had an average of three to six children, were mostly illiterate (60–100%), lived in either mostly rural or mostly urban areas, depending on the location of the center (Assuit was 90% rural, while Al Azhar in Cairo was 100% urban). Between 80–100% of the women worked at home. The discontinuers had similar characteristics to the users, although they tended to be slightly older, slightly more educated and to have up to one fewer children than the continuers. Most of the users and discontinuers had used a method of family planning prior to trying Norplant.

Satisfaction with Norplant

Reactions to Norplant were similar to those articulated during the initial FGD. Major advantages were Norplant's long duration, its ease of use, that it produced less side-effects than the pill or IUD, that insertion was in the arm rather than in the genital area, and its effectiveness in preventing pregnancy. Women again reported having first heard about Norplant mostly from other users, neighbors, relatives or friends.

Table 3 Characteristics of participants who had used Norplant for less than one year in five Norplant clinical trial centers, Egypt, 1989

	Center				
Characteristic	*Ain Shams*	*Alexandria*	*Assuit*	*Mansoura*	*Al Azhar*
Age (years)	29	30	29	35	29
Range	22–35	20–35	22–36	25–38	24–34
Children ever born	4	4	6	5	4
Range	2–6	2–6	3–10	3–7	1–6
Education (%)					
Illiterate	80	91	91	91	NA
Literate	20	9	9	9	
Does user work outside home (%)					
Yes	0	0	0	9	0
No	100	100	100	91	100
Residence					
Urban	90	45	36	18	100
Rural	10	55	64	82	0
No. of participants in FGD	10	11	11	11	10

All of the continuers and most of the discontinuers said they were satisfied with Norplant, with the exception of discontinuers at one center, where the 5 discontinuers in the FGD were not happy with the side-effects from Norplant. Some discontinuers at other centers understood that the problems leading to removal might have been associated with factors not related to the method (e.g. social or cultural). Others said that Norplant was not suited to some women. The majority of users said they had recommended Norplant to others as a good method; some of their relatives, friends and neighbors were already using it, due to their recommendation.

The women in these later FGDs also thought that they were treated well by the family planning clinics. Most women found the insertion to be painless, although they had been worried beforehand. Follow-up care and counselling were considered satisfactory, although going for follow-up was considered onerous, as was waiting if one had to see the doctor. The counselling, both pre- and post-insertion, which had been noted for its deficiencies during the initial FGDs, had definitely improved over the intervening year of the study. Women generally said that the insertion procedure was explained to them and that they understood how to care for the insertion site after insertion.

clinical trial centers, Egypt, 1989

Characteristic	Center: Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar
Age (years)	30	32	30	33	30
Range	25–37	26–40	28–35	25–38	22–33
Children ever born	4	5	5	5	3
Range	2–6	3–6	4–8	2–8	2–4
Education (%)					
Illiterate	77	100	100	89	NA
Literate	23	0	0	11	
Does user work outside home (%)					
Yes	8	0	0	0	0
No	92	100	100	100	100
Residence					
Urban	92	50	33	56	100
Rural	8	50	67	44	0
No. of participants in FGD	13	8	9	9	10

Problems associated with Norplant

The women complained mostly about menstrual irregularities, both excessive bleeding and amenorrhea (for continuers of more than one year and discontinuers). Other complaints continued to be headache, weight gain and loss, weakness, laziness, and hand and leg pain. Social problems were mentioned by some women: one woman thought she could not pray while she was bleeding; another woman's mother-in-law wanted her to have another child but she and her husband did not want one; and one woman complained about the curiosity of her neighbors.

Rumors

It appeared that worries and doubts about Norplant increased between the initial and later FGD, mainly due to the rumors that had been circulating regarding Norplant. Rumors included that Norplant causes cancer; it is under experimentation; it is not effective; it eats bones and skin; it causes diabetes, infertility, paralysis, and heart problems and that it moves around in the body. Interestingly, the main sources of rumors were reported to be doctors outside of the clinics, neighbors, and relatives. Most women discounted the rumors, but they were still worrisome.

Table 5 Characteristics of participants who had discontinued use of Norplant in five Norplant clinical trial centers, Egypt, 1989

Characteristic	Center: Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar
Age (years)	33	33	33	31	33
Range	29–36	25–40	29–36	25–38	30–40
Children ever born	3	5	5	4	4
Range	2–5	3–9	2–7	2–4	4–6
Education (%)					
Illiterate	60	83	100	80	NA
Literate	40	17	0	20	
Does user work outside home (%)					
Yes	20	0	0	20	0
No	80	100	100	80	100
Residence					
Urban	100	50	75	20	100
Rural	0	50	25	80	0
No. of participants in FGD	5	6	4	5	5

Discontinuation

Most of the women who had discontinued did so mainly due to menstrual irregularities and headaches. Social reasons included the desire for another child, husband's travel, and divorce. In one case a husband threatened to divorce his wife if she did not remove the implants. Discontinuers were generally satisfied with the removal procedure and counselling, although one woman was angry that the nurse had berated her for having Norplant removed.

It appears that one area of counselling did not improve over the year: post-removal contraceptive use. Most of the discontinuers did not have a contraceptive plan following Norplant; one woman was already pregnant and wished she had not had the implants removed.

Future use

Perhaps the best litmus test for satisfaction of a method is whether a woman would use it again in the future. Most users said they would. Many discontinuers commented that were it not for the side-effects, they would also consider using Norplant again.

Table 6 Selected characteristics of Norplant users in five Norplant clinical trial centers, Egypt, 1989

Characteristic	Center					
	Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar	All centers
Age (years)	32	32	32	33	32	32
Age at marriage (years)	18	18	16	17	18	17
Education (%)						
None	68	77	84	80	64	74
Read/write	16	7	8	8	19	12
Other	16	16	8	12	17	14
Does user work outside home? (%)						
Yes	8	6	9	20	8	11
No	92	94	91	80	92	89
Husband's education (%)						
None	29	42	62	36	42	41
Read/write	38	31	14	37	28	31
Other	33	27	24	27	30	18
Does husband work outside home? (%)						
Yes	98	94	97	98	100	98
No	2	6	3	2	0	2
Living children	4.1	4.3	5.2	4.3	3.9	4.3
Boys	2.2	2.4	3.0	2.3	2.1	2.4
Girls	1.9	1.9	2.2	2.0	1.9	1.9
Desire for more children (%)						
Yes	7	9	16	5	6	8
No	93	91	84	95	94	92

Survey of users and discontinuers

As a final step in the Norplant acceptability research, a survey of all the clients in the EFCS clinical trial was conducted to supplement and complement the FGD. Users' and discontinuers' reactions to Norplant on a range of topics were quantified, including past contraceptive use, knowledge of Norplant, counselling, problems encountered, removal, and Norplant continuation. A total of 1351 women (88%) were interviewed out of 1537 women in the clinical trial. The survey was conducted in November/December 1989. The average duration of use was 433 days, with a range of use of 9 to 688 days.

Table 7 Contraceptive history among women in five Norplant clinical trial centers, and reasons for discontinuation, Egypt, 1989

Method and reason for discontinuation	Center					
	Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar	All centers
Method(s) used prior to current Norplant*						
Never used	4	9	22	6	4	8
Pill	74	75	70	74	68	72
IUD	50	55	27	59	58	51
Injectables	5	7	9	15	3	8
Condom	1	4	7	2	3	3
Norplant	0	3	8	0	0	2
Other	1	7	9	3	3	4
Main reason stopped using last method						
Wanted pregnancy	0	2	2	0	1	1
Menstrual problem	26	26	24	27	17	24
Other side-effects	42	39	39	32	11	32
Method failure	12	6	12	6	7	8
To use Norplant	15	16	3	27	31	20
Other	4	12	21	9	33	15

*Totals do not sum to 100 since women could have used more than one method of contraception

The characteristics of the women in the survey mirrored those of the women in the focus groups, indicating that the FGD of users and discontinuers were reasonably representative of those enrolled in the clinical trial. Table 6 shows the characteristics of the women surveyed.

Characteristics of the women in Assuit showed the most variation compared to the other centers. The age of the women in each of the five centers ranged between 22 and 33, and their average age of marriage ranged from 16 to 18. Most (74%) of the women had no education; the husbands tended to be more educated than their wives. In only one center (Mansoura) did more than 20% of the women work outside of the home, whereas virtually all of the husbands (98%) had jobs.

Women in Assuit had the most living children, 5.2, compared to 3.9 in Al Azhar and just over 4 children in the three other centers. Eighty-four percent of the women in Assuit said they did not want more children, compared to over 90% of the women in the other centers.

Table 8 Main reasons for selecting Norplant over other methods of contraception, for women in five Norplant clinical trial centers, Egypt, 1989

Reason	Center					
	Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar	All centers
Norplant lasts longer	61	11	10	16	46	30
Not satisfied with other method	11	31	22	22	11	19
Ease of use	6	9	1	4	8	6
Cannot forget	8	7	11	11	15	11
Advice of neighbors, friends or relatives	4	25	31	17	8	16
Fewer side-effects	4	7	4	21	2	8
Advice of doctor	4	8	6	9	6	7
Other	5	9	19	21	6	12

Previous use of family planning

In Egypt it appears that Norplant, at least initially when it is introduced, may be a method of choice for women who have tried other methods of family planning and have experienced difficulty in using them. Over 90% of the women in centers other than Assuit had used another method of contraception before trying Norplant (Table 7).

Most women stopped using the method they were using prior to Norplant due to menstrual problems and other side-effects, although one-fifth of the women stopped specifically to try Norplant.

Information about Norplant

In all centers, the initial sources of information about Norplant were neighbors, friends, relatives, and doctors. Nearly three-quarters (72%) of the women had known someone who was using Norplant.

Women varied in their main reason for choosing Norplant (Table 8). Reasons include that Norplant lasts longer (30%), that they were not satisfied with their previous method (19%), that they had been advised to do so by neighbors, relatives or friends (16%), and that Norplant is easy to use (11%).

Women seemed to feel they received sufficient information about Norplant from the family planning clinics. With the exception of Assuit, over 85% of the women said that someone at the clinic had explained Norplant to them. Virtually all (96%) of the women knew that Norplant works to inhibit fertility for five years.

Table 9 Main problem caused by Norplant, for women in five Norplant clinical trial centers, Egypt, 1989

Reason	Center					
	Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar	All centers
Did Norplant cause a main problem?						
Yes	67	76	50	49	46	57
No	33	23	50	51	54	43
If yes, what was the main problem encountered?						
Menstrual	67	62	52	57	66	62
Other medical	32	37	48	42	31	37
Other non-medical	1	1	0	1	3	1

Problems encountered with Norplant

More than half of the women in the clinical trial experienced problems with Norplant (Table 9), including menstrual irregularities (62%), and other medical problems (37%). Only 1% said that the main problem they encountered was non-medical.

Discontinuation of Norplant

At the time of the acceptability survey, 13% of the respondents had requested removal and 7% of the women had actually had the implants removed (see Table 10). The others were generally reassured that the side-effects they experienced were not serious, or would diminish with time.

Women requested removal generally because of menstrual or other medical problems (44% and 37%, respectively). Four percent each wanted to get pregnant or cited other social problems as their reasons for discontinuation. Although a higher percentage of women from Assuit said they wanted more children (Table 6), the highest percentage of women who actually discontinued due to a desire for more children were from Al Azhar. Otherwise, personal or social problems were a small factor in discontinuation.

Table 10 Removal experience of Norplant, for women in five Norplant clinical trial centers, Egypt, 1989 (%)

Item	Center					
	Ain Shams	Alexandria	Assuit*	Mansoura	Al Azhar	All centers
Removal request						
Yes	10	18	15	16	15	13
Number	280	236	218	322	295	1351
Main reason for wanting removal						
Menstrual disturbance	32	49	46	43	53	44
Other medical	43	35	41	40	13	37
Desired pregnancy	7	5	3	0	13	4
Other personal	4	2	3	6	0	4
Other	14	9	8	10	20	11
Number	28	43	37	48	15	172
Were capsules removed at first request?						
Yes	36	16	11	10	67	21
Number	28	43	38	48	15	173
Why not removed at first request?						
Encouraged to continue	39	16	27	25	20	25
Doctor not in	39	33	6	7	20	18
Told to come back if symptoms not improved	22	19	15	33	60	24
Took medicine for side-effects	0	11	35	23	0	19
Other	0	19	18	12	0	13
Number	18	36	34	43	5	136
Did you feel pressure to keep it?						
Yes	22	11	24	12	20	16
Number	18	36	34	43	5	136
Who decided on removal?						
Self	76	50	57	59	86	64
Husband	18	14	0	5	7	8
Both	0	18	10	14	0	9
Doctor	6	14	24	9	0	11
Other	0	4	10	14	7	7
Number	17	22	29	22	15	97

Items may not sum to 100 due to rounding

*In Assuit, there were seven discontinuers who did not request removal; they were advised by the doctor to discontinue for medical reasons. These seven cases are included in the 'other' category for removal request, and are included in the remainder of Table 10

Most women themselves made the decision to discontinue, although husbands and doctors tended to be involved in decisions regarding discontinuation. While most of the women had to wait after their initial request for the removal to be done, the majority of women at all centers reported that they were not pressured to keep the Norplant against their wishes.

Satisfaction with Norplant

With the exception of Assuit, over 90% of the women surveyed in each of the centers said they were satisfied with Norplant (Table 11). In Assuit, 87% of the women expressed satisfaction with Norplant. Again, with the exception of Assuit, over 90% of the women were satisfied with the service they had received. In Assuit, 85% of the women were satisfied with the service. Most women (79%) reported going to the clinics on their scheduled dates for follow-up; of those who do not go on time, most said that it takes too long to get to the clinic and wait to receive service.

Continuation and future use of Norplant

When asked if they would consider using Norplant in the future, an average of 67% said they would, and an additional 22% said they were not sure. Most of the women (89%) mentioned that they would advise others to use Norplant.

Discussion

Norplant appears to be as acceptable in Egypt as it is in other countries, at least among the group of women under study. The participants in this study were women mostly in their thirties who had an average of four children. Most of them had used a method of family planning before Norplant, and were eager to maintain contraceptive protection as most wanted no more children. These women were motivated family planning users, who had already decided before enrolling in the study that they wanted to practice family planning.

It could be that the acceptability of Norplant will not be as high among the general population once the method has spread into the national population program, but results from these acceptability studies suggest an important role for this long-term method. Centers in the EFCS study reported that women still came asking for Norplant insertion one year after enrollment in the clinical trial was completed. Some women in the FGD recommend that Norplant be made available in rural areas as soon as possible. Nearly three-quarters (72%) of the women said they would be willing to pay for Norplant, with suggested prices ranging from 0–400 LE, and a median price of 5 LE ($1 = 3.3 LE).

Item	Center					
	Ain Shams	Alexandria	Assuit	Mansoura	Al Azhar	All centers
General satisfaction with use of Norplant	94	91	87	93	99	93
Overall satisfaction with the services provided by the clinic	90	89	85	98	99	93

The FGD and surveys found similar results: satisfaction with Norplant among users was high. In the survey, 93% of the women expressed satisfaction with the method. More than half (67%) of the women said they would consider using Norplant again in the future, and another 22% were undecided. Eighty-seven percent of the women who had not discontinued were planning to continue with their current Norplant set for the full five years.

Norplant is liked by the women in the clinical trial because of its long duration, the site of insertion, its ease of use, and its relative lack of side-effects compared to the pill and IUD. Egypt is a country where a reliable, long-term, but not permanent method of contraception is needed, as is a method that has less perceived side-effects than the IUD and is easier to use correctly than the pill. Norplant has both of these characteristics; as such it should become a popular method of family planning in Egypt.

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Resumé

Actuellement, la pillule et le dispositif intra-utérien représentent 83% des moyens contraceptifs utilisés en Egypte (EDHS, 1989). Norplant apportera un complément important à ces méthodes de planning familial. En Egypte, où les femmes sont très jeunes en âge de procréer et où les grossesses se succèdent généralement à intervalles très rapprochés, la longue durée et l'efficacité de Norplant ainsi que la facilité relative de son utilisation devraient être attrayantes. L'association égyptienne qui s'occupe des questions de fécondité (EFCS) a entrepris en 1988 une étude sur l'aaceptabilité de Norplant en Egypte. Cette étude porte sur des patientes qui se sont soumises à un essai clinique parrainé par l'EFCS dans cinq hôpitaux universitaires.

Les femmes participant à l'essai clinique étaient toutes âgées de 30 à 40 ans et avaient en moyenne quatre enfants. La plupart avaient fait appel à une méthode de planning familial avant d'utiliser les implants et souhaitaient continuer à bénéficier d'une protection contraceptive car elles voulaient, pour la

plupart, ne plus avoir d'enfants. Les utilisatrices de Norplant ont témoigné d'une très grande satisfaction. Au cours de l'enquête, 93% des femmes se sont dites satisfaites de la méthode. Plus de la moitié (67%) ont précisé qu'elles envisageraient d'utiliser Norplant dans l'avenir, alors que 22% n'en étaient pas absolument certaines. De celles qui n'avaient pas abandonné la méthode, 87% prévoyaient de continuer à utiliser leur série courante de Norplant pour la période complète de cinq années.

Les femmes égyptiennes aiment Norplant en raison de la longue durée d'efficacité, du site d'insertion, de la facilité d'utilisation et de l'absence relative d'effets secondaires perçus, par comparaison avec la pillule et les DIU. En Egypte, où il est absolument nécessaire de pouvoir compter sur une méthode de contraception fiable, à long terme mais non permanente, Norplant devrait devenir une méthode populaire de planning familial.

Resumen

La píldora y el DIU representan actualmente el 83 por ciento de la utilización de anticonceptivos en Egipto (EDHS, 1989); el Norplant será un complemento importante de los métodos de planificación familiar utilizados. En Egipto, donde se comienza a tener hijos a edad temprana y los embarazos con poco intervalo entre sí son lo habitual, la duración prolongada de la eficacia del Norplant y su relativa facilidad de uso habrán de ser características atractivas. La Asociación de Atención de la Fecundidad en Egipto (EFCS) inició en 1988 un estudio sobre la aceptabilidad del Norplant en Egipto a fin de examinar la clientela del ensayo clínico de la EFCS en los cinco hospitales escuela universitarios.

Las participantes del ensayo clínico eran mujeres de edad comprendida entre los treinta y cuarenta años que tenían en promedio cuatro hijos. La mayoría había utilizado un método de planificación familar antes del Norplant y tenía gran interés en mantener la protección anticonceptiva ya que no deseaba tener más hijos. Las mujeres manifestaron un alto nivel de satisfacción con el Norplant. En el estudio, el 93 por ciento de las mujeres se mostraron satisfechas con el método. Más de la mitad (67 por ciento) de las mujeres dijeron que considerarían volver a utilizar el Norplant en el futuro y el 22 por ciento de las mujeres se mostraron indecisas. El 87 por ciento de las mujeres que no habían interrumpido el uso proyectaban continuarlo con su actual Norplant durante el período completo de cinco años.

A las mujeres egipcias les agrada el Norplant por su prolongada duración de eficacia, el lugar de inserción, su facilidad de uso y su relativa falta de efectos secundarios advertidos en comparación con los de la píldora y el DIU. En Egipto, donde se necesita en gran medida un método anticonceptivo fiable, de larga duración pero no permanente, el Norplant podría llegar a ser un método popular de planificación familiar.

normanlea revised 30 April 1999

POST-MARKETING SURVEILLANCE OF NORPLANT® CONTRACEPTIVE IMPLANTS: I. CONTRACEPTIVE EFFICACY AND REPRODUCTIVE HEALTH

International Post-Marketing Surveillance of Norplant

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ABSTRACT

Norplant contraceptive implants have been studied extensively in clinical trials. To further examine the safety of Norplant in developing countries a cohort study of 5 year duration was undertaken of 7,977 women initiating Norplant use, and age matched initiators of IUDs (6,625) or surgical sterilization (1,419) in 32 clinics in 8 developing countries (Bangladesh, Chile, China, Colombia, Egypt, Indonesia, Sri Lanka and Thailand) from 1987 to 1997. Here is reported on contraceptive efficacy, continuation rates and reproductive health events.

At admission, women had a physical examination and their medical histories, demographic and socio-economic characteristics were recorded. Follow-up visits were scheduled 2 weeks after admission and every 6 months thereafter for 5 years irrespective of change of contraceptive method. At all visits, information about the woman's health was obtained; details of all hospitalizations or out-patient care were ascertained by extracts from hospital and clinic case records. The study evaluated efficacy of the methods, health events, surgical procedures, medications and pregnancy outcomes. Rates of major health events, adjusted for clinic or clinic and age were compared between groups.

The study accumulated 78,323 woman-years of observation, of which 39,337 were in the Norplant group, 31,915 in the IUD groups and 7,071 among sterilized women with mean age of 28,5, 28,5 and 29,6, respectively. Of the 16,021 women enrolled, 306 (1.9%) women were released by the end of 6 months because they had changed the initial method or became pregnant in the interval, and 553 (3.5%) women discontinued follow-up. By the end of 5 years, the mean duration of first segment use per initiator was 4.16 years for Norplant®, 4.10 years for the IUD and 4.96 years for sterilization. Overall Pearl pregnancy rates for Norplant implants, Copper IUDs and female sterilization, 0.27, 0.88, and 0.12 per 100 woman years, respectively. Users of Norplant® implants, Copper IUDs and sterilization had rates of ectopic pregnancy of 0.25, 0.65 and 0.11 per 1,000 woman years, respectively, this rate was 2.66 per 1,000 woman years for non-contracepting women.

Major health events related to the reproductive system were rare. The incidence of breast and cervical cancer was below 1 per thousand women-years in the three groups. Rates of acute

PID were significantly lower among Norplant users than in the IUD group ($p = 0.004$). The rates of ovarian enlargement was higher in Norplant users ($p<0.001$), but not hospitalization for this condition. Two deaths related to the reproductive system occurred (0.26 per 10,000 women-years). Rates of other reproductive health events were not significantly different between the groups.

This prospective, longer term post-marketing surveillance project in developing countries confirmed that the contraceptive methods studied were highly effective and safe, and were associated with few major reproductive health problems.

INTRODUCTION

Norplant subdermal contraceptive implants continuously release the synthetic progestogen levonorgestrel at a low concentration which is sufficient to provide effective contraception for five years. Long term users of Norplant implants are under the influence of uninterrupted exogenous steroid during several years of their reproductive life. Regulatory approval of Norplant implants was based on large-scale, well-designed clinical trials, which indicated that Norplant provides effective contraception, with a safety profile similar to that of other steroidal contraceptives, although its use is associated with prevalent bleeding irregularities (1-4). Pre-marketing clinical trials, however, are seldom large enough to evaluate the occurrence of rare adverse events that may have public health significance (5). Moreover, clinical trials are conducted under strict supervision, in circumstances that differ from the usual clinic management, and they involve selected participants who are usually released from follow-up after discontinuation of the method being investigated. Hence the safety of the method should be evaluated during use in the usual service conditions.

In 1985-86, three agencies concerned with reproductive health (Family Health International, FHI; the Population Council; and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, HRP) agreed to evaluate the safety of Norplant implants by means of a controlled cohort study. The international post-marketing surveillance of Norplant was initiated in 1987 in developing countries where this contraceptive had been approved by the national regulatory bodies. The objective was to evaluate, in the short and medium term, the occurrence of health events of public health importance which may have not been detected in the previous clinical trials.

This is to our knowledge, the first large-scale, prospective, multi-country, long-term drug surveillance project in developing countries. The five year follow-up study involved women initiating use of Norplant implants or intrauterine devices (IUDs) and women undergoing surgical sterilization. This report describes the methodology of the study and focuses on reproductive health events during and after use of these fertility regulation methods, the contraceptive efficacy of the methods, and the extent of continuing use of them. Health effects on other body systems are described in an accompanying paper (6).

METHODS

Study design: A concurrent cohort study of five-years duration in women initiating use of Norplant implants (index subjects), IUDs or sterilization (controls), the study was designed to have sufficient statistical power (80 %) to detect a doubling of event rates among implant users from a baseline incidence rate of 1 per 1,000 woman-years (5% significance, 2-sided test). This required observation of 30,000 woman-years in each of the index and control groups. Enrolment of 8,000 index subjects and the same number of controls was planned, given anticipated method discontinuation rates and losses to follow-up.

The protocol instruments and logistics of the study were reviewed, discussed and modified in meetings held before launching the study with potential country co-ordinators and principal investigators. The protocol, guidelines for investigators, forms and logistics were tested in a pilot phase in 1987-1988, engaging a total of 800 women in three centres in Chile, Sri Lanka, and Thailand. After revision of the study instruments, the main phase of the study was conducted in 32 family planning clinics in 8 developing countries (Bangladesh, 2 clinics; Chile, 2 clinics; China, 10 clinics; Colombia, 3 clinics; Egypt 5 clinics; Indonesia, 5 clinics; Sri Lanka, 1 clinic; and Thailand, 4 clinics). Enrolment into the main phase started in January 1989 and was completed in December 1991. Participants in the pilot study were included in the main study. Follow-up was completed in 1997. The study was monitored through frequent visits to the clinics by project co-ordinators from the three agencies involved and by the review of all study forms at the co-ordinating centre at WHO in Geneva. Problems and achievements were reviewed in several investigators' meetings.

Contraceptive methods: Norplant implants consist of 6 Silastic capsules which are placed subdermally (1-4). Each capsule contains 36 mg levonorgestrel. A set of six capsules delivers approximately 30 ug of levonorgestrel per day and provides mean plasma levels that range from 0.35 ng/ml in the first year to 0.29 ng/ml in the fifth year of use (7). Implants used in this study were manufactured with the so called "hard tubing" Silastic (2,3). Removal of implants was scheduled at the end of five years, if they had not been removed earlier. Locally available Copper IUDs were provided at all clinics while non-Copper IUDs were also used in some

countries, notably China and Indonesia. The sterilization procedures as preferred by the clinics were applied in the study. Other contraceptive methods were available for women who discontinued their initial method during the course of the study.

Admission requirements: Women attending family planning clinics who wanted to initiate use of Norplant implants, an IUD or sterilization, were eligible if they were: aged 18-40 years; living in the catchment area of the clinic; willing to participate and to attend the clinic semi-annually for 5 years; and if they satisfied medical criteria for the use of all three contraceptive methods involved. For each woman choosing Norplant implants, a control subject in the same five year age band (e.g. 20-24, 25-29 years, etc.) was enrolled.

Medical exclusion criteria were: current clinical evidence of pregnancy, hypertension, jaundice or active liver disease or anaemia, as defined according to local standards; history of hypertension, diabetes mellitus, mental illness, epilepsy, severe or frequent headaches, persistent abnormal genital bleeding, ectopic pregnancy, cancer, stroke, thrombophlebitis, thromboembolism, severe cardiovascular problems, or jaundice either during pregnancy or in the preceding year. Breast-feeding women were eligible six weeks post-partum.

Admission procedures: Contraceptive methods available in the clinics and their known side effects, were explained to clients. Women who selected Norplant implants, an intrauterine device, or sterilization were informed of the purpose of the study, the importance of recording all health events and of attending the clinic for semi-annual visits during 5 years. Women were also informed of their right to change contraceptive method at any time, if they wished. Although the counselling placed emphasis on the follow-up procedures, women were assured of their freedom to withdraw from the study.

At admission, women provided information on their demographic and socio-economic characteristics, on their medical, reproductive, and contraceptive history and on life-style variables such as alcohol and cigarette consumption. Physical examinations were performed, including breast and pelvic examination, cervical cytology, blood pressure and haemoglobin measurements.

Problems related to method initiation were recorded. Women were provided with a card, with subject number and clinic identification, the study name, and information that the study was co-ordinated by WHO. This card was used to record health events when the clients visited health care providers, clinics or hospitals, other than those involved in the study.

Follow up: Women were scheduled for follow-up visits in the first 6 weeks after admission and every 6 months thereafter for 5 years, irrespective of change of contraceptive method, except as noted in the following paragraph. Women were encouraged to visit the clinic if they had any problems related to their health or contraceptive method. After a change of contraceptive method, additional visits were scheduled according to local practices, but were mandatory for women when selecting Norplant, an IUD, or sterilization. Women who still used their original Norplant implants at the end of five years, had the implants removed and were followed-up with a visit at 6 weeks after removal. All other women were released from the study at five years.

Since the study was designed to investigate effects associated with longer term use of the three study contraceptives, women who discontinued their contraceptive method within the first six months were released from follow-up, after removal, as were women who became pregnant in the same interval.

At all visits, information about the health of the women was obtained through interviews. The interview, at semi-annual visits, included open-ended questions about general well-being and health complaints, as well as structured questions on current contraceptive method, smoking, last menstrual period (LMP), occurrence of pregnancy, health problems, out- and in-patient medical care including name and address of care provider(s), clinics and hospitals, surgery and medications. Physical examinations, cervical cytology, blood pressure and haemoglobin measurements were performed whenever women changed contraceptive method or when medically indicated. Pregnancy was confirmed by pelvic examination, urinary pregnancy tests and, in some centres, by ultrasound examination. Other laboratory tests or procedures were performed only when medically indicated.

Problems related to implant or IUD insertion, to the sterilization procedure or to implant removal were recorded as well as reasons for discontinuing the initial and subsequent methods.

To facilitate follow-up, women provided, in addition to their addresses and telephone numbers, those of husband's or partner's workplace, and of two friends or relatives not in the core family. Permission was sought to contact these persons in case of missed visits. At scheduled follow-up visits, inquiries determined whether the subject had moved or planned to move and women were asked about changes in the partner's workplace. Clinics established their own means to trace women who were overdue for scheduled visits. These included phone calls, letters, home visits and/or contacting the partner, relatives or friends, according to procedures agreed upon at admission.

Ethical aspects: All women had freely selected one of the study methods, and they gave informed consent to participate in the study after hearing and reading explanations of the study's purpose, and of the procedures and examinations involved. The study was approved by the ethical review committee of each participating institution and by the Scientific and Ethical Review Group of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction.

Country research teams: Providers in charge of admission and follow up were physicians, nurses or midwives trained in contraceptive counselling, insertion and removal of Norplant and IUDs and other clinical procedures. They were trained in the study protocol and procedures, including interviews and record keeping. All were aware of the importance of quality of care to ensure long term follow up. Each of the 32 clinics participating in the study had a responsible investigator who reviewed the completeness of forms and checked the coding of diagnoses. All countries had a country co-ordinator (two in China) who reviewed the forms of all subjects with health problems.

Data management: All complaints and symptoms, and diagnoses reported by the women were coded by the interviewer according to the International Classification of Primary Care, ICPC (8) and the International Classification of Diseases 9th Revision, ICD9 (9), respectively. The provider also assessed whether the interview or examination had uncovered any health problem or pregnancy. When needed, information about hospitalizations was supplemented by extract from hospital case records including duration of hospitalization, medication, and laboratory, x-

ray, surgery and histopathological reports and discharge diagnosis. Similar additional information was obtained from clinics visited for out-patient care when needed.

When pregnancy or health events were recorded, the case form and supplementary information were reviewed by the local principal investigator who coded diagnoses according to ICD9 and surgical procedures and medications according to International Classification of Procedures in Medicine, ICPM (10). The country coordinators subsequently reviewed the case forms and classified each event as a major or other event as defined below. Forms were despatched to WHO, Geneva, where they were checked for completeness and errors before data entry (SB). All study forms and extracts of supplementary information of subjects who experienced a major health event were reviewed by the overall project co-ordinator (OM), who checked the coding and assessed the validity of the diagnosis. Whenever a diagnosis of a major health event was uncertain, additional information was requested from the clinic before the final diagnosis was given. After data entry, detailed validity and consistency checks were applied. All problems identified were reviewed and resolved by correspondence with and/or visits to the centres. The diagnostic codes of other health problems, as defined below, were given at the clinics and reviewed by the country the co-ordinators. When OHPs were analysed at the ICD9 3 digit level for reasons described elsewhere (6), the forms and validity of the diagnoses were in several instances reviewed by the project co-ordinator. Thus the OHP 3 digit diagnoses were reviewed for myoma uteri (ICD9 218), benign tumours of the breast (ICD9 217) and diseases of the breast (ICD9 610-611), inflammatory disease of ovary, fallopian tube, pelvic cellular tissues and peritoneum, and uterus (ICD9 614-615), and symptoms and signs at site of Norplant insertion and removal.

Definitions: To achieve uniform review, validation and coding of health events at centre and country levels, and at the overall study level, health events were categorized as "major health event"(MHE) or "other health problem" (OHP). MHEs included deaths and morbid or traumatic events which are potentially life-threatening, required hospitalization or convalescence for a period of at least one month, had physical or mental sequela, or lead to long term medication (three months or more). OHPs were defined as events or conditions deviating from normal mental and physical health status, except common colds and minor injuries.

Pregnancies were considered major health events. The date of conception of pregnancies was estimated as 14 days after the onset of the last menstrual period (LMP), and adjusted by ultrasound diagnosis or duration of pregnancy as estimated at delivery. The post-partum period was defined as 42 days after a delivery.

Diagnosis of acute pelvic inflammatory disease (PID) (ICD9 614.0) required oral temperature of at least 38°C, and lower abdominal tenderness with guarding, and a pelvic examination revealing either tenderness on cervical motion, adnexal tenderness, or palpable adnexal mass. Women given an outpatient care diagnosis of acute PID but not fulfilling such criteria, were classified as "unspecified" PID (ICD9 614.9). Women hospitalized for repeated episodes of lower abdominal pain and given a diagnosis of PID but not fulfilling the criteria for acute PID, or who had laparoscopy or laparotomy revealing old pelvic adhesions, were classified as "chronic PID", hospitalized (ICD9 614.6-7), while outpatient diagnosis of PID among women with repeat episodes or prolonged pelvic pain not fulfilling the study criteria of acute PID, were classified as "other chronic PID", outpatient (ICDP 614.6-7).

Increased or irregular vaginal bleeding or both (ICD9 626.2; 626.4; 626.6; 626.8-9) was categorized as severe if it lead to hospitalization, dilatation and curettage, or both. A diagnosis of anaemia required a haemoglobin value of less than 10 g/dL. Diagnoses of myoma uteri (ICD9 218) were stratified by whether the myoma(s) were discovered incidentally by systemic screening or by symptoms compatible with myoma followed by clinical examination including ultrasound. A diagnosis of a neoplastic lesion of the breast (ICD9 174, 217) required biopsy or other surgery (except one case with metastatic breast cancer). Benign lesions of the requiring surgical biopsy were considered a major health event (ICD9 217).

Data Analysis: This report includes reproductive health events in Norplant users and control subjects from initiation to the last study visit, provided this occurred within 63 months of admission to study. Data from continuing users of IUDs and sterilized women were censored at that point while Norplant implants generally were removed around the 5 year point. Women who discontinued their contraceptive method within the first six study months contributed to events rates during any remaining study participation. When women moved out of the area,

were lost to follow up, refused to continue in the study or died, their data were censored as of the time of their last visit or the time of death.

Data have been analysed both by method in current use and by initial study method. Incidence rates for reproductive health events are given according to current method, unless otherwise stated. Observations during the second or subsequent segments of Norplant or IUD use and observations recorded in women who had switched from Norplant to an IUD or vice versa, contribute to event rates according to the method currently used at the time of the event.

When the data were analysed by method initiated at admission, all events recorded were considered, regardless of changes in contraceptive method that occurred during the study.

Statistical analysis: Life-table methods were used to summarise the cumulative and annual rates of pregnancy according to contraceptive method, of other reasons given for discontinuation, and of all reasons combined, treating all other reasons for discontinuation as censored. The cumulative rates reported here are indistinguishable from the cumulative net rates of Chiang or the gross cumulative rates computed using the Tietze-Potter method (11,12,13). Women determined to have been pregnant when stopping their contraceptive method for another expressed reason were classified as pregnant at the approximate date of conception, in preference to the originally stated reason and date. The incidence of pregnancies by current contraceptive method was expressed as a Pearl rate (pregnancies per 100 or per 1,000 woman-years) and confidence intervals computed from the Poisson distribution (14).

Incidence rates were expressed per 1,000 woman-years according to the initial method chosen or the method currently used at the time of the event. Only the incidence of first events of a specific type, or within a class of diseases, were considered and thus experience observed in the study after the first occurrence of an event was disregarded (censored) in the calculations for that endpoint. Crude disease incidence rates were computed according to the initial method chosen or the method used at the time of the event. Comparisons between incidence rates (rate ratios) were adjusted for differences between clinics by Poisson regression using STATA (11b). In addition, rate ratios comparing users of different contraceptive methods were adjusted for age of the woman at the start of the study.

RESULTS

Participants and contraceptive methods: Altogether 16,021 women were enrolled of whom 7,977 were Norplant users, 6,625 were IUD users, and 1,419 were women undergoing sterilization. Clinics in China recruited 38% of participants; Egypt, Indonesia, and Thailand each enrolled between 11% and 13%, Bangladesh, Chile, Colombia, and Sri Lanka each contributed between 5% and 8% of the participants (Annex 1). Some clinics (one each in Bangladesh and in China) recruited only sterilized women as controls while others (all 5 in Egypt, 6 clinics in China, and one each in Bangladesh, Chile, Indonesia, and Thailand) recruited only IUD users as controls. At admission locally available Copper IUDs (TCu 220C, TCu 380A, Multiload 250 and 375, Shanghai V) were provided to 5,996 women in all clinics, while 629 women in China and Indonesia, received non-Copper IUDs (Lippes Loop, Stainless Steel ring, Mahua ring, Plastic flower, UCD-indomethacin, Uterine cavity shape ring). The sterilization procedures at admission were minilaparotomy (1,073 subjects, 76 %), laparoscopy (307 subjects, 22%) and transcervical chemical sterilization with phenol atabrine (18 subjects, 1%) or quinacrine (2 subjects). Other contraceptive methods were available for women who discontinued their initial method during the course of the study.

When all countries were taken together, study and control groups differed moderately in terms of age, age at first union and at first full term pregnancy, parity, outcome of last pregnancy, educational level, tobacco consumption, and had similar alcohol consumption (Table 1). Although small, most of these differences were statistically significant given the large study size ($p < 0.001$). Mean age at last birthday before admission was 28.5 years for both Norplant and IUD users while sterilized women were on average 1.1 years older. About 1% of participants were as single or separated at admission. IUD users were oldest at the age of first union and of first full term pregnancy while sterilization subjects were the youngest. IUD users had the lowest parity and sterilized women the highest. Overall, 91.6% of sterilized women had a full term pregnancy as their last pregnancy outcome, in contrast with 71.5% of Norplant® users and 71,1% of IUD users, and induced abortion accounted for nearly all the remaining outcomes. Educational attainment was highest among IUD acceptors while sterilized women

had the least schooling. Less than seven percent of Norplant and IUD users and 10.6% of sterilized women had ever smoked, less than five percent of participants had ever drunk alcohol and still fewer women currently smoked or drank alcohol regularly (not shown). Mean weight ranged between 51.7 kg and 55.6 kg, women choosing sterilization being the lightest and those choosing IUD the heaviest. Few women reported previous diseases related to the reproductive organs: an ovarian cyst had been experienced by 0.8 %, 0.7% and 0.5% of women in the Norplant, IUD and sterilization groups, respectively, while a history of PID was reported by 1.5%, 0.9% and 1.8% of women in the three groups, respectively (not shown).

A higher proportion ($p < 0.001$) of Norplant users had previously used contraception before entering the study than were women in the control groups (Table 2). Overall, IUDs, oral contraceptives, barrier methods, and injectables, in descending order, were the methods that had been most frequently used; only 2.5 percent of the participants had previously used implants.

Follow-up and years of observation: Of the 16,021 women admitted to the study, 15,161 (94.6%) were followed through 5 years (Table 3). A total of 303 users of Norplant or IUDs were released from the study within the first six months because they had discontinued the method chosen at enrolment or became pregnant in this interval. Three women in the sterilization group were also released in the first six months because they were pregnant at or soon after admission; another woman in this group was released after 12 months because her admission cervical cytology had shown a carcinoma in situ. Thus, 1.9% of the initial acceptors were released in the early course of the study. Of the remaining 15,714 women, 15,161 women (96.5%) completed the 5 years follow-up, with similar follow-up rates for the three groups. The study encompassed 78,321 years of observation: 39,336 years (50.2%) in women initiating Norplant; 31,915 years (40.8%) in IUD initiators and 7,070 years (9.0%) in women undergoing surgical sterilization.

The mean duration of follow up per woman was 4.9 years in Norplant initiators, 4.8 years in IUD initiators and 5.0 years among sterilized women (Table 4). The mean number of scheduled follow up visits was 9.3 per woman with small, although significant differences between groups ($p < 0.001$) in the number of scheduled, unscheduled and total visits and in the

mean number of physical examinations, pelvic examinations and haemoglobin measurements. Sterilized women had the fewest physical exams and haemoglobin measurements.

Removals of the initial method (life table rates): First segment continuation and termination rates for the three methods are shown in Table 5. For most women, the scheduled removal of Norplant took place shortly after 5 years from insertion, while for 818 women it occurred shortly before they completed 5 years. Two clinics had policies requiring IUD removals in the fourth year. Of 701 such removals, 302 women had another IUD inserted during the same visit and are considered, in this analysis, to have continued the first segment. Life table rates were calculated by considering terminations for end of effective life of IUDs and implants as censored observations.

The first segment cumulative life table removal rates for all causes at the end of 5 years were 33.2%, 30.5% and 27.0% among women initiating Norplant, Copper IUDs and non-Copper IUDs respectively ($p < 0.001$). Norplant subjects stayed with their initial method an average of 4.17 (Standard error (se) 0.02) years while IUD users continued on average 4.10 years (se 0.02). First segment use of non-copper IUDs, principally in China, was on average 4.23 years (se 0.07) compared with 4.09 years (se 0.02) for Copper IUDs.

The removal rate for pregnancy in Norplant users included a total of 88 pregnancies, 77 clearly due to method failures (2 in the first year, 6 in the second, 20 in the third, 19 in the fourth and 30 in the fifth year), and 11 where it was not known whether conception took place before or after insertion (n=6) or removal (n=5), 1 in the first year and 2 each in the third and fourth year). In the IUD groups, no pregnancies were reported to have occurred around the time of insertion.

Bleeding problems were the most frequent medical reason for discontinuation in the Norplant group, leading to a cumulative discontinuation rate of 13.7% at the end of 5 years, significantly higher ($p < 0.001$) than in the Copper and non-Copper IUD groups, which were 6.4% and 4.7%, respectively. Other medical reasons for discontinuation included a large variety of complaints and health events. Among Norplant users, conditions associated with the use of hormonal contraceptives constituted the majority of reasons for discontinuations, being

headache, weight change, skin changes, mood changes and breast symptoms or diseases the most frequent. On the contrary, among IUD users, symptoms and diseases of the reproductive tract constituted, the majority of medical reasons for removal, pelvic pain and infection being the most frequent.

Annual first segment life table pregnancy rates and 5 year cumulative life table pregnancy rates (Table 6) were significantly lower ($p < 0.005$) among Norplant users and sterilized women than among IUD users in the first four years. Sterilized women had lower pregnancy rates than did Norplant users from the third year through fifth years ($p < 0.01$). Norplant pregnancy rates increased with duration of use from around 0.1 per 100 women in the first two years to 0.6 per 100 women in the fifth year of use ($p <0.001$). In contrast, annual pregnancy rates among IUD users declined with longer duration of use ($p < 0.001$). Copper IUDs were six-fold more effective than non-Copper IUDs in the first year ($p <0.001$) and two-fold more effective in the next four years.

Contraceptive dynamics: Women discontinued or changed their initial contraceptive method during the course of the study as indicated in Table 7. As a result the observations include more than 1,000 woman years of use for each of condom, combined oral contraceptives (COCs) and no method, and shorter accumulations of use with other methods. This permitted an assessment of contraceptive efficacy and ectopic pregnancy rates with study methods and other methods. Women who were pregnant or in the puerperium accounted for a further 966 woman-years of observation (not shown).

For methods with more than 1,000 woman-years of use and based on all segments of use, Pearl pregnancy rates (intra- and extra-uterine pregnancies considered together) were lowest for Norplant implants and female sterilization, 0.27 and 0.17 per 100 woman-years, respectively (Table 8). The pregnancy rate for Copper IUDs and COCs was less than 1 per 100 woman-years, while it was about three times higher among users of non-Copper IUDs. The pregnancy rate among users of condoms was substantially higher, 7.4 per 100 woman-years. Of the total 1,737 pregnancies recorded in the study, the great majority (1,134, 65.3%) were among non-contracepting women, in whom the pregnancy rate on average was 45.1 per 100 woman-years, the rate was 172 among those stopping contracepting for want of another child and 17.6 among

those who stopped for other reasons.

Seven pregnancies among non-contracepting women were ectopic (rate 2.7 per 1,000 woman-years). For women who conceived while using Norplant, Copper-IUDs or sterilization, the ectopic pregnancy rates were 0.30, 0.68 and 0.13 per 1,000 woman years, respectively, compared with 1.30 for those using non-Copper IUDs. The proportion of ectopic to total pregnancies was higher for users of Norplant, Copper IUDs and non-Copper IUDs, than for non-contracepting women

Outcome of pregnancies: The outcome of pregnancy was known for 1,720 of the 1,737 pregnancies recorded, 603 of which occurred while women were using contraception (Table 9). A total of 1,119 pregnancies were carried to delivery, and 10 of these were multiple. Among singleton live births, the mean birth weight of the infants of non-contracepting women and women using Norplant at the time of conception were similar. The birth weight of the infants of women with an IUD in uteri at conception appeared to be lower than the mean birth weight of the infants of non-contracepting women, but this difference was attributable to birth weight differences among clinics (stratified p-value 0.13). Of the 47 women giving birth to an infant conceived with an IUD in utero, 42 (89%) of them had the IUD removed before 13 completed weeks of pregnancy.

No malformations at birth were recorded among infants of women who used Norplant, IUDs or who were sterilized at time of conception. Three infants (0.3 %) of non-contracepting women had malformations recorded (including one infant with transposition of the great vessels). Most of the 603 contraceptive failures ended with an induced abortion. The percentages of such pregnancies ending in induced or spontaneous abortion varied for the different contraceptive methods. Two molar pregnancies occurred, in one Norplant user and in one condom user.

Problems at method initiation and discontinuation: Problems during or soon after the 8,146 recorded Norplant insertion were reported in 89 (1,1%) cases, including haematomas (n=42), inflammatory reactions (n=36), and complaints of pain, itching or other effects (n= 11). Problems recorded during or soon after the 8,876 IUD insertions were perforation (n= 1), fainting or dizziness (n=2) and severe pain (n=4); 43 expulsions were detected within the first

12 weeks. Problems during and after sterilization procedures were one case of bleeding in the mesosalpinx during laparotomy; excess damage of one tube at cauterization by laparoscopy; eight wound infections after laparotomy; and two episodes of fever after transcervical chemical sterilization with phenol atabrine paste.

At the end of the study, a total of 7,850 Norplant removals, including second segment removals, had been reported. Of these, 79 (1%) were considered difficult, including 36 cases of broken capsules.

Reproductive health events: Cancer of the breast was diagnosed in 4 initial acceptors of Norplant, two of whom were using other contraceptives at the time of detection, and one in a woman initiating IUD use who also used the IUD at detection of the cancer (Table 10). Four of these women lived in China, all of whom had the histopathological diagnosis confirmed by an independent referee pathologist. One women lived in Bangladesh and had a clinical diagnosis of advanced breast cancer. The overall incidence rate of breast cancer for Norplant initiators was 0.10 per 1,000 woman-years and 0.03 for IUD initiators ($p=0.21$).

In China one Norplant initiator had in-situ cancer of breast and another had a non-invasive phyllodes tumour according to the referee pathologist. Benign tumours of the breast requiring biopsy , had similar rates in women initiating Norplant or IUD, the rate ratio for Norplant vs. controls was 0.86 and not statistically different from unity. Analysis according to current use of Norplant, IUD or sterilization gave similar results.

Invasive cancer of the genital tract was diagnosed only once, in a sterilized woman in Chile who developed cervical cancer (Table 10). The incidence of carcinoma in situ of the cervix and cervical dysplasia was similar in all groups of contraceptive users whether analysed by initial or current contraceptive method. No invasive cancers were reported for the corpus uteri including the endometrium, or of the ovary. One sterilized woman in Chile had a choriocarcinoma diagnosed two months after the sterilization surgery. The incidence rates of myoma of the uterus, whether incidentally detected or symptomatic, were similar in the Norplant, IUD and sterilization groups.

Among women currently using Norplant the incidence of ovarian enlargement managed on an out-patient basis was approximately three times that among women currently using IUD or sterilization (Table 11). Further analysis of ovarian enlargements by functional cysts (ICD9 620,0 and 620,1) and other unspecified ovarian cysts (ICD9 620.2, 620.9) showed a similar pattern (not shown). The incidence of ovarian enlargements requiring hospitalization was similar among current users of Norplant and IUD or sterilization combined. Of the hospitalized women, 8 Norplant users, 5 IUD users and 1 sterilized woman had abdominal surgery.

Incidence rates of acute pelvic inflammatory disease (PID), as defined in the methods section, is shown in Table 11 according to current use of Norplant, IUD or sterilization. Acute PID was more frequent in current IUD users than in users of Norplant or sterilization. The incidence of acute PID was 0.18, 0.61 and 0.26 per 1,000 woman-years among current user of Norplant, IUDs, and sterilization, respectively ($p < 0.01$ for the comparison between Norplant and IUD users). Unspecified PID, a less specific diagnosis, also was less frequent in Norplant users than in current IUD users ($p < 0.001$). There was no evidence of a change in incidence of acute or other PID according to the time since insertion of the IUD. The frequency of repeated lower abdominal pain (chronic PID), whether requiring hospitalization or not, was similar among current users of Norplant and IUDs , it occurred at rates in the order of 1 per 1,000 woman-years or less. For all four types of PID the crude incidence rates among sterilised women were substantially higher than in Norplant users (1.4-fold for acute PID, 1.7-fold for unspecified PID, 2.9-fold for hospitalised chronic PID and 1.3-fold for outpatient chronic PID). However, the incidence rate ratio after adjustment for clinics were substantially attenuated (reduced to 0.8, 1.0, 1.4 and 0.5, for the four endpoints, respectively). This was due to the influence of Colombia which had the highest incidence rate of these endpoints, and which contributed a greater proportion of the total sterilisation experience (16%) than current Norplant exposure (5%) to the study. A similar pattern occurred with the ratio of incidence rates of PID in current IUD users compared with Norplant users, where the adjustment had the effect of slightly increasing the incidence rate ratios. Colombia contributed 4% of current IUD exposure in the study.

The most common diagnosis in this study was related to frequent or excessive vaginal bleeding (Table 11). Bleeding disorders characterized as excessive, irregular, or both, occurred at the

rate of 64 per 1,000 woman-years among current users of Norplant, more than twice that found among current IUD users (25 per 1,000 woman-years) (P <0.001 and an order of magnitude larger than reported by sterilized women (7 per 1,000 woman-years) (P <0.001). Altogether 1919 (23,6 %) Norplant users and 698 IUD users (9.5%) had excessive and/or frequent vaginal bleeding at least once during the course of the study. Despite the frequency of the diagnosis, few women (0.10 % of current Norplant users and 0.08% of current IUD users) were hospitalized for bleeding problems. The incidence of anaemia with haemoglobin <10 g/dl was low (1.4 per 1,000 woman-years in current users of Norplant and 2.2 per 1,000 in users of IUD) and not statistically different.

Amenorrhea, including scanty bleeding, was recorded at least once in 6.0 % of current Norplant users, and in 1.3 % and 0.9 % of current IUD users and sterilized women, respectively. The incidence of amenorrhea among Norplant users (15.5 per 1,000) was about four times the rate among IUD users.

Recovery of fertility: During the study, 436 Norplant users and 559 IUD users discontinued the method during the first segment of use, stating that they desired a child, pregnancy was diagnosed within one year in 214 and 291 of them, respectively. Table 12 shows the recovery of fertility and resumption of contraceptive use for these women during the first year after stopping Norplant or IUD. The median interval between removal of the device and the estimated conception date was 9.4 months (se 1.1) in the Norplant group and 6.0 months (se 0.3) in the IUD group. Of the women who discontinued Norplant or IUD stating that they planned pregnancy, 27 (12.6 per 100) and 41 (14.1 per 100) women, respectively, had reinitiated use of a contraceptive method within one year. For 222 former Norplant and 376 IUD users with parity 0-1 the lifetable rate for pregnancy at 12 months were 64.5 $\pm$ 3.5 and 66.3 $\pm$2.9, respectively. For women of higher parities the rates were lower, and lower among former users of Norplant than of IUDs. Among women aged <30 years the probabilities of conception at 1 year were 59.4 $\pm$3.2 and 67.5 $\pm$2.9 per 100 for former Norplant and IUD users, respectively; for women $\geq$30 years they were 48.8 $\pm$4.4 and 57.5 $\pm$4.0 per 100 for former Norplant and IUD users, respectively.

Deaths related to the reproductive system: Two out of 34 deaths recorded (described in the accompanying paper), were related to the reproductive system. One Norplant user from Sri Lanka, who had the device removed after two years, used no contraceptive method thereafter, and died one year later of gas gangrene following incomplete septic abortion. The second death occurred in the woman from Bangladesh with a clinical diagnosis of metastatic breast cancer.

DISCUSSION

This five year cohort study including 16,021 women from developing countries confirms the safety with respect to reproductive health and the high contraceptive efficacy of Norplant implants, Copper IUDs or female sterilization. Incidence rates of adverse reproductive health events were low among women in the study. The adherence of women to the study and the performance of the clinics ensured high follow-up rates in the study and high method continuation rates. The intended 30,000 woman-years of observation during use of Norplant and of non hormonal methods was exceeded.

Contraceptive efficacy is a component of contraceptive safety, particularly in countries where abortion is unsafe. Contraceptive failure rates were similar with Norplant implants and female sterilization and lower than failure rates with other reversible methods, with the exception of injectable contraceptives. The contraceptive efficacy of Copper IUDs was significantly higher than that of non-Copper IUDs. The pregnancy rate for Norplant implants was in the lower range of previously reported rates, most likely because of the low body weight of the women in this study. Pregnancy rates for IUDs, interval salpingectomy and other methods were similar to those reported elsewhere (2-4,16-20).

Rates of ectopic pregnancy varied among current users of contraceptive methods, but all were lower than the rate observed in women using no contraception. Ectopic pregnancy rates in Norplant and Copper IUD users were a tenth and a quarter, respectively, of the rate among non-users. In users of all other reversible contraceptive methods taken together, the rate of ectopic pregancy was 0.52 per 1,000 woman-years or about a fifth of the rate among non-

contraceping women. The proportion of ectopic pregancies to total pregnancies among Norplant and Copper IUD users was 0.11 and 0.08 per 1,000 woman-years, respectively, higher than that reported from other studies (2,3,21-23). This may result from the higher average age of women in this study compared to the previous studies.

Birth outcomes after Norplant method failures were similar to those of women not using contraception at the time of conception. This finding confirms a previous report on the outcome of childbirth among women conceiving while using Norplant (24). Although infants born following IUD failure appeared more likely to be below 2,500 g at birth, and their mean birth weight was about 200 g less than that of infants of non-contracepting women, this difference arose from birth weight variability among the clinics rather than from contraceptive method. The IUD was removed during the first trimester of the pregnancy in 40 (89%) of the 45 singleton birth conceptions while using an IUD, in compliance with established practice (21).

The study found low rates of adverse reproductive health events among users of all methods. Few significant differences were detected between women using Norplant and non-hormonal methods. There were five invasive breast cancers, an overall incidence of 0.07 per 1,000 woman-years, albeit that the study was not designed to have the statistical power to examine events as rare as reproductive cancers in the age range included in this study. Based on reported age-specific incidence rates of breast cancer (25) and the age-distribution of the women in this study, an estimated 8.6 breast cancers would have been expected during the five year follow-up. Four of the five breast cancers reported in the study were diagnosed in China where an estimated 2.8 breast cancers would have been expected (25).

The diagnoses of *myoma uteri* occurred at similar rates in users of Norplant and of non-hormonal methods. The apparent protective effect on *myoma uteri* from current and recent past use of other hormonal contraceptive methods, such as combined oral contraceptives and depot-medroxyprogestrone acetate reported previously (26,27), was not observed in this study. The incidence of invasive cervical cancer was low (one case, 0.01 per 1,000 woman-years) compared with the expected 9.5 cases based on age-specific incidence rates of invasive cervical cancer (25). The low incidence of cervical cancer may be because the women who enrolled to this study five-year follow-up study came from relatively stable social segments of the

the most likely reason for implant removal but nevertheless, removal rates for this reason were as low as 2.1 per 100 in the first year of use and only 13.7 per 100 at the end of 5 years. This low discontinuation rate of Norplant for bleeding problems may be related to the counselling and the quality of the services provided. In this study situation, some women possibly chose to keep the method because they were encouraged to tolerate the inconvenience associated with bleeding problems.

Among women who wished another child and stopped using Norplant or IUD for that reason, the lifetable pregnancy rates at the end of the first year after stopping, were 55.6 and 63,9 per 100, respectively. Women less than 30 years old and women of low parity had as expected, higher rates than women 30 years or older and women of higher parity. The pattern of slightly or moderately higher rates pregnancy rates among former IUD users compared to former Norplant users was seen among women of younger and older age, and among women with higher parity but the rates were similar among former Norplant and IUD users with low parity. These rates for recovery of fertility in the first year after stopping use of Norplant or IUDs are lower than that reported from most other studies (2, 38, 39, for IUDs see review 16), one recent study from Indonesia of women stopping use of Norplant or Implanon® reported pregnancy rates similar to those reported here (40). This study was not specifically designed to evaluate recovery of fertility after stopping contraception, the apparent low rates observed during the first year in this study should be further evaluated.

Of the 34 deaths recorded in this study, only two were related to reproductive health conditions. One woman who was using no contraception at the time of conception, died after a septic abortion. One woman, a former user of Norplant and COCs, died from a clinically diagnosed invasive breast cancer.

The study has similarities to other large contraceptive follow-up studies undertaken in developed countries such as the Oxford Family Planning Association study (41), the Royal College of General Practitioners Oral Contraception Study in the UK (42), and the Walnut Creek study in California, USA (43). The women were followed-up irrespective of change of contraceptive method. They had admission criteria which resulted in recruitment of married women with children, from stable, middle to low middle socio-economic segments of the

communities. The studies largely relied on passive follow-up as enrolled women regularly or spontaneously visited their medical practitioners for health care, although the Oxford studyalso used postal and telephone interviews and traced women lost to follow-up (38). The practitioners also routinely received the reports of hospitalizations, including discharge diagnosis and they reported the findings from the health care visits and the hospital stays to the study co-ordinators. In one important aspect, the Post-marketing Surveillance of Norplant study was different. This study applied active follow-up procedures, including tracing of women overdue for their scheduled 6 monthly visits and of hospital and outpatient clinics records. This active follow-up was deemed necessary because in most participating countries, the infrastructure of the health care services included no pre-existing systems for exchange of information between hospitals or outpatient clinics and the family planning clinics providing Norplant, IUDs and other contraceptives, and there was no previous experience in sustainable follow-up through 5 years. The final outcome of the study depended on ensuring client adherence to the return visits.

As in other observational studies some bias in reporting and recording health events according to contraceptive use may have occurred. Unlike IUDs and sterilization, Norplant subdermal implants were a new contraceptive method in most of the communities and clinics involved. Women starting use of Norplant had few relatives or friends with experience of and knowledge about Norplant with whom they could discuss concerns or fears. This may have prompted more frequent visits, and consequently more reports to health care providers by Norplant users than by users of IUD or sterilization of symptoms and conditions. Indeed there were more unscheduled visits to the study clinics by women using Norplant than by users of other contraceptive methods. Surveillance bias also may have occurred, as more care may have been taken by study providers to elicit responses about complaints and symptoms from women in the index group. Both these biases would lead to higher incidence rates of medical diagnoses among users of Norplant than among users of IUD or sterilization. Moreover, preferential attention may have been paid to symptoms known to be associated with the contraceptive method such as bleeding problems in Norplant users or PID among IUD users. If this latter bias has occurred, it would have magnified differences between groups in the known side effects of the methods studied. However, the definition of MHEs was such that these events seem unlikely to be affected by this type of bias.

The diagnoses of OHPs which were assigned at the clinics and reviewed by the country co-ordinators, do not have the same consistency across countries as the diagnosis of MHEs. Individual clinics within countries applied different patterns of use of the codes within the ICD9 sub-chapters, and within 3 digit codes the 4 digit (decimal) codes were applied differently. Therefore OHPs were generally analysed at the level of ICD9 sub-chapter. Only when indicated for reasons described elsewhere (6), were the OHPs analysed at the ICD9 3 digit level and the distribution of the 4 digit (decimal) ICD9 codes were reviewed at the project co-ordinating centre.

Another feature of the reporting of OHPs was that the frequency of reporting of them varied between countries and within countries between clinics. This pattern can be attributed to differences between countries and between regions within countries in the incidence of the conditions, to the importance the women assigned to the conditions and symptoms from them, the interest of the nurses and physicians to probe presence of symptoms and signs of the conditions, and also to the threshold at which complaints and symptoms resulted in assigning a medical diagnosis. With the information available to us it is not possible to separate the reasons for differential frequency of reporting OHPs by countries and clinics. For comparison of incidence rates of MHEs and OHPs, all incidence rate ratios were adjusted for differences between clinics, and selected additional factors when relevant, consistent with the design of the study whereby women undergoing IUD insertion or sterilisation, age-matched to the Norplant initiators, were enrolled as a comparison group within each clinic. This was in anticipation of the substantially different social conditions and health care environment in the participating countries and clinics. The design was also robust against the different levels of reporting between the participating clinics, particularly of Other Health Problems. It was impossible to apply uniform criteria for reporting all health problems, but the high sensitivity of the systems established in the study ensured that MHEs were not missed.

Some differences in socio-demographic and biomedical characteristics of women between contraceptive groups at admission were anticipated since the women had freely chosen their method of contraception. However, additional adjustment for these characteristics (such as

educational level) had little impact on the estimated incidence rate ratios.

Some clinical service aspects merit comments. The low incidence of problems at Norplant insertion and removals was probably because providers were well trained and had experience provision of Norplant. This low incidence appears to confirm the importance of adequate training of providers, both in insertions and removals (4). Similarly, the rates of expulsion and perforation of Copper and non-Copper IUDs in this study are at the lower end of the range of reported expulsion rates at one year for Copper IUDs (21). Virtually all women initiating use of IUD in the study were parous and they had a mean age of 28.5 years, characteristics which also contribute to the low IUD expulsion rate.

The high follow-up rates in this study and the high continuation rates for Norplant and IUDs throughout 5 years, could be explained by several factors. Women understood the purpose of the study and the importance it had for developing countries. They complied in a remarkable way with the visit schedule, responding positively to the interest shown by the providers about their concerns, health and symptoms experienced during use of the contraceptive methods. Because they wanted long-term contraception, the participants were probably interested in a long-term care program and selected themselves as recruits to the study. The participating clinics had experience in research and in the management of the methods provided and offered good quality services. In addition, the clinics made a great effort to ensure follow-up, through tracing women overdue for scheduled visits. Alternative contraceptive methods were available for women who were dissatisfied with their initial choice, and many chose to change. Nevertheless, the results of the study strongly indicate that the quality of the services affects in a favourable way the performance and continuation rates of provider dependent methods, although some women may have continued with their initially chosen method longer longer as a result of loyalty to and encouragement by the providers.

This prospective post-marketing surveillance study has shown that large scale follow-up studies are feasible in selected sites in developing countries and that they provide significant information on women's reproductive health, beyond the specific aspects that are relevant to the method under surveillance. The follow-up of women during five years, irrespective of change of method, also permitted the study of contraceptive dynamics in the cohort. Since this

study applied uniform recording and coding, it is possible to perform further analyses comparing health, method performance and other outcomes between countries and also in relation to the demographic and social background information collected at admission. We can conclude that, in settings similar to the clinics participating in the study, Norplant implants are a safe, well tolerated and highly effective contraceptive method.

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Table 1. Characteristics of women at admission

	Study group			
	Norplant	IUD	Sterilization	p values
No. of subjects	7977	6625	1419	
Age (%)				
<25 years	18.6	19.3	13.3	
25-29 years	39.9	40.4	36.6	
30-34 years	29.9	27.5	36.4	
>35 years	11.6	12.9	13.7	
Age (years)[a]	28.5 ± 4.5	28.5 ± 4.7	29.6 ± 4.1	<0.001
In union (%)	99.1	98.9	99.3	
Age at first union (years)[a]	21.1 ± 3.9	22.0 ± 3.8	19.9 ± 3.8	<0.001
Age at first delivery (years)[a]	22.4 ± 3.9	23.2 ± 3.8	21.2 ± 3.6	<0.001
Parity (%)				
0	0.6	0.7	0.1	
1	47.1	57.2	1.3	
2	25.6	20.2	48.6	
>2	26.8	22.0	50.0	
Parity[a]	2.1 ± 1.6	1.9 ± 1.5	2.9 ± 1.3	<0.001
Outcome of last pregnancy (%)				<0.001*
delivery	71.5	71.1	91.6	
abortion	28.1	28.5	8.4	
ectopic/molar	0.1	0.1	0.0	
never pregnant	0.3	0.4	0.0	
Education level (%)				0.000
< elementary	21.4	13.9	23.8	
elementary	22.2	18.2	47.5	
secondary	42.1	48.1	24.2	
higher[b]	14.3	19.8	4.5	
Ever smoked (%)	6.9	5.6	10.6	
Ever drank alcohol (%)	5.0	4.2	4.2	
Body weight (kg)[a]	53.7 ± 10.5	55.6 ± 11.0	51.7 ± 9.8	<0.001

[a] mean ± sd

[b] includes technical and university education

* comparing delivery with other outcomes

Table 2. Percentage of women with prior contraceptive use and use of specific methods

Methods used	Contraceptive group			p values
	Norplant	IUD	Sterilization	
No. of subjects	7977	6625	1419	
Any	85.4	75.9	74.8	< 0.001
Oral contraceptives	37.8	28.3	27.6	< 0.001
Injectables	19.2	11.2	15.2	< 0.001
Implants	3.5	1.5	0.9	< 0.001
IUD	37.6	33.9	48.2	< 0.001
Barriers	30.2	30.1	11.8	< 0.001
Spermicides	6.3	5.4	5.8	0.07
Other	9.5	9.3	7.2	0.02

Table 3. **Number of women admitted, released and followed-up by contraceptive method chosen at admission**

	Contraceptive group			
	Norplant	IUD	Sterilization	All subjects
Admitted	7,977	6,625	1,419	16,021
Released in first 6 months	95	208	4 [a]	307
Moved	29	4	0	33
Lost to follow-up	202	238	40	480
Refused to continue	25	10	5	40
Completed follow-up	7,626 (95.6%)	6,165 (93.1%)	1,370 (96.5%)	15,161 (94.6%)
Woman-years	39337	31915	7071	78323

[a] includes one woman with cervical cancer at admission, released at month 12

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Table 4. Follow-up experience by initial method

	Initial method			All subjects
	Norplant	IUD	Sterilization	
Number of women	7977	6625	1419	16021
Length of follow-up per subject (years)	4.9 ± 0.7	4.8 ± 1.0	5.0 ± 0.6	4.9 ± 0.8
Number of post-admission visits per subject:				
Scheduled follow-up				
Year 1	1.5 ± 0.6	1.4 ± 0.6	1.3 ± 0.5	1.4 ± 0.6
Year 2	1.9 ± 0.7	1.9 ± 0.7	2.0 ± 0.6	1.9 ± 0.7
Year 3	1.8 ± 0.7	1.8 ± 0.7	1.6 ± 0.7	1.8 ± 0.7
Year 4	1.9 ± 0.7	1.8 ± 0.7	1.8 ± 0.7	1.8 ± 0.7
Year 5	1.8 ± 0.7	1.7 ± 0.8	1.6 ± 0.7	1.7 ± 0.7
Year 6	0.7 ± 0.5	0.7 ± 0.5	0.8 ± 0.4	0.7 ± 0.5
Total	9.4 ± 1.7	9.2 ± 2.1	9.2 ± 1.7	9.3 ± 1.9
Unscheduled visit	0.7 ± 1.3	0.5 ± 1.0	0.3 ± 0.6	0.6 ± 1.2
Clinical follow-up	1.0 ± 0.5	1.1 ± 0.6	1.1 ± 0.5	1.1 ± 0.5
Procedures				
Physical examination	2.6 ± 2.3	2.5 ± 2.3	2.2 ± 1.8	2.6 ± 2.2
Pelvic examination	2.6 ± 2.3	2.5 ± 2.2	2.2 ± 1.8	2.5 ± 2.2
Haemoglobin measurement	1.5 ± 1.7	1.6 ± 1.7	1.0 ± 1.0	1.5 ± 1.6

Values are mean ± SD

or IUDs, cumulative net life table discontinuation rates and standard error per 100[a])

	Year 1		Year 3		Year 5	
	rate	SE	rate	SE	rate	SE
Norplant®						
Pregnancy[b]	0.1	0.04	0.5	0.09	1.5	0.16
Excessive bleeding	2.1	0.2	9.4	0.3	13.7	0.4
Other medical	1.4	0.1	5.5	0.3	9.1	0.4
Device complications	0.01	0.01	0.04	0.02	0.04	0.02
Planning pregnancy	0.3	0.1	3.3	0.2	6.8	0.3
Other personal	0.7	0.1	3.9	0.2	7.3	0.3
Method continuation rate	95.4	0.2	79.1	0.5	66.8	0.5
Copper IUDs						
Pregnancy	1.0	0.1	3.0	0.2	4.2	0.3
Excessive bleeding	1.9	0.2	4.7	0.3	6.4	0.3
Other medical	1.0	0.1	4.0	0.3	5.4	0.3
Expulsions	1.7	0.2	3.0	0.2	3.6	0.3
Other device complications	0.05	0.03	0.09	0.04	0.14	0.05
Planning pregnancy	0.9	0.1	5.5	0.3	9.8	0.4
Other personal	0.9	0.1	3.0	0.2	5.3	0.3
Method continuation rate	92.8	0.3	78.8	0.5	69.5	0.6
Non-Copper IUDs						
Pregnancy	6.3	1.0	10.6	1.3	13.0	1.4
Excessive bleeding	0.8	0.4	2.3	0.6	4.7	0.9
Other medical	0.2	0.2	1.1	0.4	1.1	0.4
Expulsions	2.7	0.7	3.9	0.8	4.3	0.8
Planning pregnancy	0.5	0.3	2.0	0.6	5.5	1.0
Other personal	0.2	0.2	0.5	0.3	1.6	0.6
Method continuation rate	89.7	1.2	80.9	1.6	73.0	1.8

[a] Cumulative life table discontinuations rates in percent (standard error) at 365, 1110 and 1826 days since insertion

[b] Pregnancy rate in Norplant® users includes pregnancies where it was questionable if conception had occurred before or after admission (n=6) or around the time of removal (n=5)

Table 6. First segment annual and cumulative (at the end of 5 years) pregnancy rates per 100 women

	Method			
	Norplant	Copper IUD	Non-Copper IUD	Sterilization
Year 1				
Woman years[a]	7827	5767	593	1409
Events	9	59	39	3
Rate (SE)	0.12 (0.04)	1.02 (0.13)	6.34 (0.98)	0.21 (0.12)
Year 2				
Woman years[a]	7232	5273	540	1395
Events	6	66	17	3
Rate (SE)	0.08 (0.03)	1.24 (0.15)	3.08 (0.73)	0.22 (0.12)
Year 3				
Woman years[a]	6558	4816	516	1380
Events	22	38	8	1
Rate (SE)	0.33 (0.07)	0.78 (0.13)	1.54 (0.56)	0.07 (0.07)
Year 4				
Woman years[a]	5957	4370	496	1368
Events	21	36	8	2
Rate (SE)	0.35 (0.08)	0.81 (0.14)	1.60 (0.54)	0.15 (0.10)
Year 5				
Woman years[a]	5403	4064	474	1353
Events	30	16	5	1
Rate (SE)	0.59 (0.11)	0.41 (0.10)	1.08 (0.51)	0.08 (0.08)
Cumulative rate at 5 years				
Woman years[a]	32977	24289	2619	6905
Events	88	215	77	10
Rate (SE)	1.46 (0.16)	4.19 (0.28)	13.00 (1.39)	0.72 (0.23)

[a] year intervals of 365 days

ɔle 7. **Contraceptive use dynamics during the study, according to contraceptive method chosen at admission**

	Initial method									
	Norplant		Copper IUD		Non-Copper IUD		Sterilization		All initiators	
rent method	N	Wyrs	N	Wyrs	N	Wyrs	N	Wyrs	N	Wyrs
orplant										
rst segment	7977	33206							7977	33206
ıbsequent segments	80	65	80	169	8	22	1	2	169	258
per IUDs										
rst segment			5996	24517					5996	24517
Subsequent segments	506	891	714	821	31	60	1	2	1252	1774
..-Copper IUDs										
First segment					629	2660			629	2660
ubsequent segments	121	249	52	109	23	44	3	6	199	408
rilization	238	435	133	236	3	7	1419	7041	1793	7719
ɡectables	155	183	166	207	12	18	0	-	333	408
Cs	503	758	378	506	14	25	2	2	897	1291
Ps	64	86	64	86	0	-	1	0	129	172
ondoms	812	1208	529	671	85	120	2	0	1428	1999
ermicides	30	43	21	17	2	1	0	-	53	61
ıer methods	91	129	74	103	7	10	2	7	174	249
methods		37253		27442		2967		7060		74722
lo method		1614		987		27		5		2633

N = number of women using method at least once during the study

Table 8. Intra- and extrauterine Pearl pregnancy rates by current contraceptive method: crude rates

Contraceptive method	Exposure (years)	Total pregnancies			Intrauterine			Ectopic			Ratio of ectopic to total pregnancy rate	
		N	Rate[a]	0.95 CI	N	Rate[a]	0.95 CI	N	Rate[b]	0.95 CI		0.95 CI
Norplant	33465	89	0.27	(0.21, 0.33)	79	0.24	(0.19, 0.29)	10	0.30	(0.14, 0.55)	0.112	(0.06, 0.2
Copper IUDs	26292	232	0.88	(0.77, 1.00)	214	0.81	(0.71, 0.93)	18	0.68	(0.41, 1.08)	0.078	(0.05, 0.1
Non-Copper IUDs	3067	85	2.77	(2.21, 3.43)	81	2.64	(2.10, 3.28)	4	1.30	(0.36, 3.34)	0.047	(0.01, 0.1
Sterilization	7720	13	0.17	(0.09, 0.29)	12	0.16	(0.08, 0.27)	1	0.13	(0.00, 0.72)	0.077	(0.00, 0.3
COCs	1292	11	0.85	(0.43, 1.52)	10	0.77	(0.37, 1.42)	1	0.77	(0.02, 4.31)	0.091	(0.00, 0.4
POPs	173	2	1.16	(0.14, 4.18)	2	1.16	(0.14, 4.18)	0	0.00	(0.00, 21.3)	0	(0.00, 0.8
Injectables	408	1	0.25	(0.01, 1.37)	1	0.25	(0.01, 1.37)	0	0.00	(0.00, 9.04)	0	(0.00, 0.9
Condoms	1999	148	7.40	(6.26, 8.70)	146	7.30	(6.17, 8.59)	2	1.00	(0.12, 3.61)	0.014	(0.00, 0.0
Spermicide	61	9	14.75	(6.75, 28.0)	9	14.75	(6.75, 28.0)	0	0.00	(0.00, 60.5)	0	(0.00, 0.3
Other methods	249	13	5.22	(2.78, 8.93)	13	5.22	(2.78, 8.93)	0	0.00	(0.00, 14.8)	0	(0.00, 0.2
No method[c]	2633	1134	43.07	(40.6, 45.7)	1127	42.80	(40.4, 45.4)	7	2.66	(1.07, 5.48)	0.006	(0.00, 0.0
Planning pregnancy	433	744	171.82	(159.8, 184.7)	740	170.90	(158.9, 183.8)	4	9.24	(2.52, 23.7)	0.005	(0.00, 0.0
Not planning pregnancy	2200	390	17.73	(16.0, 19.6)	387	17.59	(15.9, 19.4)	3	1.36	(0.28, 3.99)	0.008	(0.00, 0.0

per 100 woman-years

per 1000 woman-years

includes women not exposed to the risk of pregnancy while not using contraception, but excludes 984 w/years during pregnancy and post-partum period

or 11 (ten intrauterine and one ectopic) of the 89 pregnancies that occurred among Norplant® users, it is estionable if they are method failures or not since conception took place close to the time of Norplant® sertion (n=6) or removal (n=5). In the sterilization group, one pregnancy that may have occurred in the onth after or before surgery is included (*LMP 6 days before sterilization*).

Table 9. Outcome of pregnancies due to contraceptive failure and among women using no contraceptive method at time of conception

	Norplant	IUD	Sterilization	Inject./OCs	Condoms	Sperm./other	No meth
Total number of pregnancies	89	317	13	14	148	22	1134
Livebirths							
Multiple[a]	0 (0.0)	1 (0.3)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	8 (0.
Singleton	41 (46.1)	45 (14.2)	3 (23.1)	6 (42.9)	22 (14.9)	9 (40.9)	983 (86
Weight (g)							
unknown	1	1	1	1	1	0	44
< 2500	2 *(5.0)*	5 *(11.4)*	0 *(0.0)*	0 *(0.0)*	0 *(0.0)*	0 *(0.0)*	39 *(4.*
≥ 2500	38 *(95.0)*	39 *(88.6)*	2 *(100.0)*	5 *(100.0)*	21 *(100.0)*	9 *(100.0)*	900 *(95*
mean + SD	3386 ± 447	3119 ± 461	3475 ± 672	3420 ± 437	3275 ± 381	3141 ± 371	3246 ± 4
Crown-heel length (cm), mean +SD	50.2 ± 2.4	49.3 ± 2.1	51.5 ± 0.7	48.4 ± 4.8	50.1 ± 1.8	49.9 ± 1.7	49.6 ± 2
Sex ratio M/F	1.28	1.37	2.00	1.00	1.44	0.80	1.33
Malformations at birth	0	0	0	0	0	0	3
Stillbirths	2 (2.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (1.1
Spontaneous abortions	12 (13.5)	22 (6.9)	2 (15.4)	2 (14.3)	5 (3.4)	2 (9.1)	85 (7.5
Induced abortions	22 (24.7)	224 (70.7)	7 (53.8)	3 (21.4)	118 (79.7)	11 (50.0)	25 (2.2
Ectopic pregnancies	10 (11.2)	22 (6.9)	1 (7.7)	1 (7.1)	2 (1.4)	0 (0.0)	7 (0.(
Molar pregnancies	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.(
Unknown	1 (1.1)	2 (0.6)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	13 (1.1

[a] One triplet pregnancy conceived while using no method resulted in two livebirths and one stillbirth; the remaining multiple pregnancies all resulted in livebirths.

( ) numbers in parentheses are percentages

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Tman1mar.xls Table 9

Table 10B - Neoplastic diseases of female reproductive organs by Norplant, IUD, or sterilization initiators
Number, crude incidence rate per 1000 woman-years and rate ratio adjusted for clinic

Events	Severity[a]	ICD9 code[a]	Norplant		IUD		Sterilization		Rate ratio (controls/Norplant) adjusted for clinic		
			No.	Rate	No.	Rate	No.	Rate	RR	95% CI	P-value
Breast											
Invasive cancer	Major health event	174	4	0.102	1	0.031	0		0.25	(0.03, 2.20)	0.209
In situ cancer	Major health event	233.0	2	0.051	0		0		0.00		
Benign neoplasms, biopsy	Major health event	217	21	0.534	18	0.565	0		0.86	(0.46, 1.62)	0.650
Uterus											
Myoma uteri, with symptoms	Major health event	218	21	0.535	12	0.376	4	0.566	0.77	(0.40, 1.47)	0.429
incidental	Other event	218	26	0.662	13	0.408	7	0.991	0.77	(0.43, 1.38)	0.384
Cervix											
Invasive cancer	Major health event	180	0		0		1	0.141	∞		
In situ carcinoma	Major health event	233.1	6	0.153	4	0.125	3	0.425	1.18	(0.40, 3.51)	0.768

[a] These columns will not be included in the final version.

Events / Severity[a] / ICD9 code[a]		No.	Crude rate	Rate ratio adjusted for clinic: RR	95% CI	P-value	Rate ratio adjusted for clinic and age: RR	95% CI	P-value
Ovary									
Enlargement, hospitalized									
Major health event	Norplant	8	0.239	1.00 (reference)					
620	IUD	6	0.204	0.96	(0.33, 2.79)	0.945	0.98	(0.34, 2.83)	0.964
	Sterilization	1	0.130	0.29	(0.04, 2.34)	0.244	0.27	(0.03, 2.18)	0.217
Enlargement, not hospitalized									
Other event	Norplant	106	3.186	1.00 (reference)					
620	IUD	27	0.922	0.30	(0.19, 0.45)	0.000	0.29	(0.19, 0.45)	0.000
	Sterilization	7	0.911	0.19	(0.09, 0.42)	0.000	0.20	(0.09, 0.44)	0.000
Pelvic inflammatory disease (PID)									
Acute PID									
Major health event	Norplant	6	0.179	1.00 (reference)					
614.0,615.9	IUD	18	0.613	4.06	(1.58, 10.41)	0.004	4.05	(1.58, 10.39)	0.004
	Sterilization	2	0.259	0.75	(0.14, 3.96)	0.733	0.76	(0.14, 4.07)	0.748
Unspecified acute PID									
Other event	Norplant	55	1.650	1.00 (reference)					
614.9	IUD	100	3.434	2.28	(1.64, 3.18)	0.000	2.28	(1.63, 3.18)	0.000
	Sterilization	22	2.878	1.00	(0.60, 1.67)	0.989	0.99	(0.59, 1.66)	0.960
Chronic PID, hospitalized									
Major health event	Norplant	3	0.090	1.00 (reference)					
614.1-614.8	IUD	2	0.068	0.80	(0.13, 4.86)	0.807	0.84	(0.14, 5.14)	0.851
	Sterilization	2	0.259	1.44	(0.21, 9.78)	0.707	1.17	(0.17, 8.18)	0.876
Chronic PID, outpatient									
Other event	Norplant	23	0.688	1.00 (reference)					
614.1-614.8	IUD	18	0.614	1.06	(0.57, 1.96)	0.860	1.02	(0.55, 1.91)	0.938
	Sterilization	7	0.912	0.53	(0.23, 1.25)	0.148	0.59	(0.25, 1.39)	0.227
Bleeding disturbances									
Excessive/irregular, hospitalized									
Major health event	Norplant	8	0.239	1.00 (reference)					
626.2-.4-.6-.8-.9	IUD	6	0.204	0.85	(0.29, 2.46)	0.760	0.86	(0.29, 2.50)	0.782
	Sterilization	1	0.130	0.51	(0.06, 4.29)	0.535	0.45	(0.05, 3.85)	0.469
Excessive/irregular									
Other event	Norplant	1911	64.137	1.00 (reference)					
626.2-.4-.6-.8-.9	IUD	692	25.296	0.37	(0.34, 0.41)	0.000	0.37	(0.34, 0.40)	0.000
	Sterilization	48	6.481	0.09	(0.06, 0.12)	0.000	0.09	(0.07, 0.12)	0.000
Amenorrhoea									
Other event	Norplant	489	15.462	1.00 (reference)					
626.0-626.1	IUD	104	3.605	0.21	(0.17, 0.26)	0.000	0.21	(0.17, 0.26)	0.000
	Sterilization	17	2.246	0.15	(0.09, 0.24)	0.000	0.15	(0.09, 0.25)	0.000
Anaemia									
Haemoglobin <10 g/dl									
Major health event	Norplant	48	1.437	1.00 (reference)					
280,285	IUD	64	2.189	1.32	(0.90, 1.92)	0.154	1.32	(0.90, 1.92)	0.152
	Sterilization	5	0.650	0.98	(0.36, 2.70)	0.970	0.92	(0.33, 2.52)	0.869

[a] These data will not be included in the final version.

Annex I - Number of subjects admitted by study group

	Norplant	IUD	Sterilization	Total
BANGLADESH				
Dhaka	254	257		511
Khulna	250		252	502
CHILE				
Santiago ICMER	226	224		450
Santiago HCSBA	400	281	117	798
CHINA				
Beijing	320	324		644
Changsha	322	325		647
Chongqing	316	319	14	649
Guiyang	316	337		653
Jinan	317	224	98	639
Shanghai SIPPR	168	171		339
Shanghai SMU	319	333		652
Shenyang	315		315	630
Tianjin	315	315		630
Zhengzhou	315	217	99	631
COLOMBIA				
Bogota	200	111	89	400
Cali	150	80	70	300
Medellin	150	101	49	300
EGYPT				
Ain Shams	199	201		400
Al Azhar	199	201		400
Alexandria	197	203		400
Assiut	196	204		400
Mansoura	201	199		400
INDONESIA				
Bandung	230	186	38	454
Jakarta	300	300		600
Padang	128	119	1	248
Semarang	225	200	25	450
Ujung Pandang	119	146	3	268
SRI LANKA				
Colombo	415	225	157	797
THAILAND				
Bangkok Rajvithi	211	204	7	422
Bangkok Siriraj	350	350		700
Chiang Mai	101	98	1	200
Khon Kaen	253	170	84	507
Total	7977	6625	1419	16021

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Norplant® Consensus Statement and Background Review†

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Introduction

The purpose of this document is to review the worldwide application of the long-acting implant contraceptive preparation Norplant®, the first truly innovative contraceptive method for more than two decades, and to assess critically its efficacy and safety.

Controversy

Although on clinical and scientific grounds, it is generally agreed that Norplant has an important position in the range of contraceptive choices, at both the community and consumer levels, there is current controversy, particularly in the United States and the United Kingdom. These problems arise partly from the potential for coercive or inappropriate use of Norplant, partly from some cases of difficult or delayed removal of the implants, and partly from a litigious climate in which bleeding patterns, headaches, mood changes, and weight gain or loss also become the basis for legal action.

At the time of its initial marketing Norplant was a thoroughly investigated and tested novel method of contraception. Subsequent experience has confirmed its safety and value when used appropriately.

History and Development[1–4]

Norplant is the Population Council's trademark for the subdermal implants that can provide long-term contraception in women by release of levonorgestrel at a virtually constant rate over 5 years. The development of this contraceptive implant was based on the principle that steroids can diffuse into the tissues through biocompatible silicone elastomers and that effective contraception can be achieved by daily oral administration of a progestogen-only pill. Capsules providing a continuous release of different progestogens, when implanted subdermally, were first tested by the Population Council in 1966. A further 20 years of clinical research were concerned with selecting the most suitable progestogen, determining the appropriate dose, assessing metabolic and pharmacologic effects, evaluating efficacy, side effects, and acceptability, and elucidating the mechanism of action.

Worldwide Experience

Clinical studies have involved over 55,000 women. Some 400 articles on Norplant have appeared in peer-reviewed scientific journals. Norplant has been registered in 60 countries and the method has been used by some 6 million women worldwide.

Pharmacology[2,3,5]

Norplant, as currently marketed, consists of six small (34 mm long and 2.4 mm in diameter) Silastic® capsules, each containing 36 mg levonorgestrel, that is, a total of 216 mg levonorgestrel. The capsules are inserted under the skin of the upper inner aspect of the nondominant arm under local anesthesia through a trocar. Release of levonorgestrel into the circulation by physicochemical diffusion starts immediately after insertion of the capsules. Levonorgestrel is detectable in blood within 2 h, reaching mean concentrations of around 1300 pg/mL in the first day. Blood levels fall within a month to a mean of about 400 pg/mL and gradually decline thereafter to reach a mean of around 200 pg/mL at 5 years. Individual differences in blood levels are relatively large, higher mean concentrations being found in women with low body weight. Levonorgestrel release from the implants is initially at a rate of around 85 μg/day, falling to about 50 μ/day by 9 months and to about 35 μg/day by 18 months, after which release steadies to about 30 μg/day. A release rate of 35 μg/day levonorgestrel is <25% of the dose provided by a low-dose combination contraceptive containing levonorgestrel. The initial studies used "hard" tubing but the current system uses "soft" tubing, which results in a greater daily release of levonorgestrel into the circulation and is associated with lower pregnancy rates than the hard

*The Organizing Committee members and institutions are listed in Appendix 2.
†The Consensus Statement follows the end of Appendix 2.

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tubing, which produces lower circulating levonorgestrel levels.

Clinical Features

The contraceptive efficacy of Norplant is comparable with that of the most effective female methods, including sterilization. The cumulative pregnancy rate at the end of 5 years is approximately one per 100 women. Ectopic pregnancy rates are correspondingly low—0.3 per 1000 woman-years. The capsules can be removed through a small skin incision, thereby terminating contraception. After removal of the implant, levonorgestrel disappears from the circulation within a week. Fertility is restored promptly.

The major advantage of this method is its long-term effectiveness after one clinic visit. Its most frequent side effect is disturbance of menstrual cyclicity. The comparative paucity of major side effects combined with high efficacy and reversibility has made Norplant highly acceptable. It is often the method of first choice in women seeking the convenience of long-term protection against pregnancy.

Clinical and Biologic Effects of Norplant

The cumulative 5-year pregnancy rate with Norplant, 1.1%, is one of the lowest failure rates of currently available methods of reversible contraception.[5,6] The high efficacy results from the fact that levonorgestrel prevents pregnancy by at least three effects; 1) inhibition of ovulation, 2) prevention of normal sperm transport through the female genital tract, particularly through the cervix; and 3) inadequate development of secretory endometrium.

Levonorgestrel diffuses into the surrounding tissue at a relatively constant rate as soon as the capsules have been implanted. The circulating level of levonorgestrel is not, however, high enough to suppress gonadotropin release completely. Hence, ovarian follicular development occurs irregularly, associated with intermittent peaks in circulating estradiol.[5] Because the concentration of circulating levonorgestrel in the first 2 years after insertion of the implants is usually sufficient to inhibit the positive feedback effect of these estradiol peaks on LH release, peak LH levels are suppressed in the long term, even in Norplant users with regular cycles.[7] Ovulation is infrequent, especially during the first 2 years' use.[8,9]

If a serum progesterone concentration >9 nmol/L is used as a criterion of luteal activity, around one-third of the cycles in later years of Norplant use could perhaps be considered ovulatory. On this basis, the incidence of luteal activity increases after 2 years.[8,9] But because both mean peak progesterone levels and the duration of elevated progesterone are lower in Norplant users than in controls, the total amount of progesterone in the luteal phase is significantly smaller in Norplant users. The (presumed) ovulatory cycles in women who have received an implant are associated with a high incidence of luteal deficiency or unruptured luteinized follicles.[10]

Daily ultrasonographic scanning of the ovaries of Norplant users with regular cycles and elevated luteal phase progesterone levels has shown that in only about one-third of these cycles were there morphologic changes in the ovary characteristic of a normal ovulatory pattern.[11] Inhibition of ovulation and impairment of luteal function would, therefore, be important mechanisms by which Norplant provides contraceptive protection.

The presence of consistently elevated circulating levels of levonorgestrel also prevents the normal thinning of the cervical mucus at mid cycle. In vivo and in vitro studies have shown that cervical mucus remains scanty and viscid in Norplant treated women, and that normal sperm penetration does not take place.[10,12] The progestogen also interferes with normal endometrial development and only a small percentage of Norplant users form normal secretory endometrium.[13] On the rare occasions when fertilization may have occurred, the inadequate endometrial development will prevent implantation and hence normal embryonic development.

Mean estradiol levels in Norplant users are very similar to those in women with regular ovulatory cycles or with an IUD in situ irrespective of whether the cycles are ovulatory or anovulatory.[14] Three patterns of estradiol changes during the cycle have been observed: periodic irregular peaks of estradiol within the range normally found during the cycle, ie, up to 400 pg/mL (found in about 60% of women); fluctuating estradiol levels, with high broad peaks, above 500 pg/mL in 30%; and consistently low estradiol levels, less than 75 pg/mL in about 10%.[8] When estradiol levels fall, endometrial sloughing and uterine bleeding or spotting usually occur. Because the peaks and troughs of estradiol levels in women using Norplant occur at irregular intervals, uterine bleeding also occurs irregularly in the majority.

Changes in Menstrual Pattern

The major side effect is an irregular pattern of uterine bleeding. Changes in duration of bleeding and volume of flow are common but, overall, the loss is scanty. In general, the flow is light; heavy bleeding in women using Norplant is very uncommon. About half the women bleed fairly regularly at intervals of between 21 and 35 days; about 40% have irregular menses with intervals outside this range and about 10% are "amenorrheic," defined as no bleeding for at least 3

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months.[15] Irregularity of bleeding and prolonged bleeding tend to be more pronounced in the first years of use, after which some women will experience a more regular pattern. During the first year of Norplant use, about a quarter of the cycles are regular, two-thirds irregular, and 7% of women have no bleeding. However, by the fifth year, about two-thirds of the cycles are regular, one-third irregular, and amenorrhea is very uncommon. Overall, the mean duration of bleeding declines steadily with time—from 54 days in the first year to 44 days in the fifth year.[15] Mean total blood loss is about 25 mL per month, which is slightly less than the average blood loss of control women with regular cycles.[16] The mean hemoglobin concentration during the first 3 years of Norplant use tends to rise slightly. An increase in mean hemoglobin was also found in women who ceased using the implants because of bleeding problems.[17] In the rare case of a pregnancy occurring in a Norplant user, it is almost always in a woman with a recent history of regular cycles, ie, she was probably ovulating normally.[15] Hence, women who are amenorrheic or who have infrequent episodes of vaginal bleeding after insertion of Norplant, do not need monitoring for pregnancy with periodic HCG assays.

Ovarian enlargement due to persistent unruptured follicles has been noted in some 20% of Norplant users. The enlarged follicles, which may become as large as 5–7 cm in diameter usually regress spontaneously without therapy in 1 to 2 months.[18] Sometimes, abdominal discomfort or breast tenderness may accompany them.

Metabolic and Other Effects

Numerous metabolic studies have been performed in different populations. Measurement of routine biochemistry, liver function, blood cortisol, thyroid function, and investigation of carbohydrate metabolism have revealed only minimal and inconsistent changes.[19,20] Lipoproteins have been measured in several studies before and after insertion of Norplant. Most of these studies show a lowering of triglycerides, total cholesterol, and LDL concentrations whereas HDL cholesterol was only slightly diminished or even increased.[21] There was little change in the total cholesterol/high density lipoprotein cholesterol ratio, which might imply that Norplant should not aggravate risk factors for atherosclerosis. Coagulation parameters have also been measured in a few studies; no clinically significant changes were found.[22,23] Epidemiologic data have shown no increased risk of venous thrombosis or embolism.

About 30% of Norplant users have noted changes in body weight—either weight gain or weight loss, the former being more frequent.[6,24] Many of the women who reported weight gain also noted an increase in appetite after insertion of the implants. Headache and mood changes are common symptoms, but often transient and mild. Headache is the commonest medical reason, second only to bleeding problems, for which women request removal of the implants.[25] The mood changes reported include anxiety, nervousness and depression. Acne is the most common reported skin problem. Less than 1% of women request removal of the implants because of skin problems. Longitudinal studies of bone mineral density in adolescents[26] and women aged 20–45[27] have shown an increase in bone mineral density of the lumbar spine and distal forearm at 1–2 years after insertion of Norplant.

Discontinuation or Removal of Implants

At the end of 5 years, about a quarter of Norplant users will have requested removal of the implants because of a bleeding problem.[6] Another 15% discontinue because of medical problems, such as headache and weight gain. About a quarter of all implant removals occur because the woman wishes to become pregnant. Thorough counseling before insertion, in particular regarding the cause and nature of adverse effects such as bleeding disturbances to be expected with Norplant should reduce discontinuation of this method.

Experience With Norplant in Family Planning Services

Service Quality

Norplant is the only implant currently in large scale production and distribution in family planning clinics worldwide. The quality of the service provided is a major determinant of the successful use of this method and of the subsequent degree of satisfaction among users. It is essential that potential Norplant users are given adequate information at the outset about the various methods available. The quality of follow-up care, access to removal, and the skills and attitude of providers are also critical.

Informed Choice

Women should receive information about available contraceptives in order to be able to make an informed choice. Hence, they should be told about the effective life of the method, how the method will be inserted and removed, and when removal is due, which are the common side effects and how to deal with them, the biologic effects and mechanism of

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action, prevention of infection at the insertion site, when to return for a follow-up visit, and which problems should prompt an unscheduled visit to the clinic (eg, abdominal pain, excessive bleeding, or severe headaches).

The World Health Organization Medical Eligibility Criteria for Contraceptive Use should be applied if the woman has any preexisting health condition.[28]

The life style and reproductive intentions of the woman or the couple also must be taken into consideration. Norplant is not an ideal method for short-term contraception. A woman may use Norplant if she wants a long-term reversible method that does not entail taking contraceptive action daily or before intercourse, or if she has completed her family but does not want a permanent method, or if she is a smoker who desires a hormonal method. Women who are breastfeeding may use Norplant, starting 6 weeks postpartum, if nonhormonal methods are not acceptable or available to them. Norplant should not be inserted if pregnancy is suspected.

Counseling

Counseling of the woman is essential when prescribing Norplant. A critical aspect of counseling is that the most common side effect of Norplant is a change in menstrual bleeding pattern. This problem is no different and indeed very similar to that which occurs with progestogen-only pills. The first approach should, therefore, be counseling and reassurance. The woman should be told in advance and at the time of insertion that in the absence of other causes such as an infection, which can be checked, this type of bleeding is not harmful even if prolonged for a few weeks. If, however, the woman is not satisfied even after reassurance, she may be helped to continue using the implants by having a short course of one to three cycles of a combined oral contraceptive (containing 30–35 μg ethinyl estradiol, once daily for 21 days).

Counseling should also include other reproductive health issues, such as precautions against sexually transmitted diseases and HIV infection, as Norplant offers no protection against them. Counseling should also be given regarding prevention of infection at the site of insertion.

Counseling improves client satisfaction with Norplant. Allowing a woman time to think about the decision to use Norplant, provides her with the opportunity to ask questions that may arise only after reflection and which may be important to her subsequent satisfaction if she chooses Norplant. The continued availability of counseling after the initiation of use is also an essential factor in continued client satisfaction.

Problems with removal have caused much of the controversy surrounding Norplant. Such problems rarely occur if the capsules are placed correctly at insertion. Quality programs employ clinicians trained in the correct procedures for both insertion and removal. Even experienced providers may, however, need access to expert resources when faced with a difficult removal; an easily accessible system for advice and referral may help to address this need.

Follow-Up Care

Counseling of Norplant users should be a continuous process reinforced during followup, until the woman understands the biologic effects of the method, feels familiar with it, and accepts the symptoms or changes that may occur. Follow-up is also important for the management of bleeding problems, side effects, and medical problems.

Easy Access to Removal Services

Easy access to removal services should be provided. Women should be informed that Norplant implants are effective for 5 years and should, therefore, be removed by the end of the fifth year. If desired, a second set of implants can be inserted immediately after removal, informing women that the initial bleeding problems will not usually be repeated. It is also important to explain that the implants can, and should, be removed any time the woman wants, and how and where this can be arranged.

Training and Skill of Providers

Providers need training on the technical aspects, such as insertion and removal, and in the management of the side effects and medical problems. They also need to know the biologic aspects of the method (including mechanism of action, changes in the physiology of women that translate into symptoms and signs, and bleeding pattern), so that they may transfer this information to women when counseling them. Providers require training in counseling and communication procedures so as to understand the desires and reproductive intentions of clients, to offer women an informed free contraceptive choice, to assist her decision-making process regarding a long-term method, to understand her fears and concerns before and during Norplant use, to offer support during its use, and to ensure freedom to change her method according to altered needs.

The personal attitudes of providers are important factors. Respect for a woman's decision at the time of

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selecting the method and during use should be highlighted and supported by the clinic authorities and program managers to ensure that she fulfils her own reproductive goals and rights.

Providers need adequate supplies, good clinic equipment, and appropriate sterilization facilities to be able to perform correct and sterile insertion and removal.

Practical Experience in Family Planning Programs

Because paramedical personnel as well as physicians can insert and remove Norplant, provided they are properly trained, it is essential as discussed above that adequate training is given to the provider personnel, both medical and paramedical. Experience over the past 10 years in Indonesia, with a competency based training (CBT) method has been particularly helpful. The method involves breaking down particular clinical skills to be taught into their essential component steps. Each step is then analyzed to determine the most efficient and effective way to perform and learn the technique. This has led to widespread use of the U-technique as the preferred method for removal of the implants. Videos and anatomic models are very helpful for this purpose. Interaction between the provider and participants is vital. Using competency based training techniques results in fewer providers being required than after conventional teaching methods.

The experience of Chinese and Indonesian family planning workers in large scale introductory studies has shown:[29]

1) Insertion and removal of implants can be simple and safe. The low rate of insertion complications results from the care taken in supervised, "hands on" training in both insertion and removal. Aseptic techniques must be used and the woman must learn about them so as to prevent infection at the local site. The quality of insertion is crucial, ie, whether all implants are placed in the same superficial plane, will determine the ease of removal.
2) The Chinese experience emphasizes the importance of menstrual irregularity as the main factor in discontinuation of Norplant. Furthermore, the variation in termination rates because of menstrual problems at different centers in different phases, eg, between early and late acceptors at the same centers, seems to be attributable more to the growing experience of staff and to a consequent difference in counseling than to any inherent population differences (even in a culture such as China where menstrual disturbances are not generally well tolerated).

Although prolonged or irregular bleeding is the main reason why women stop using Norplant, hemoglobin levels were higher after Norplant use, even in women who had discontinued because of prolonged bleeding.

New Data on Long-Term Performance: Preliminary Results of International Collaborative Surveillance of Norplant

Methodology

The Post-Marketing Surveillance study of Norplant is the first large scale longer term prospective drug surveillance project in developing countries.[30] This 5 year follow-up study was conducted in 32 family planning clinics in eight countres (Bangladesh, Chile, China, Colombia, Egypt, Indonesia, Sri Lanka, and Thailand) from 1987 through 1997. Women were 20–40 years old when initiating use of Norplant, an intrauterine device, or sterilization for contraceptive purposes and willing to participate in the study and attend the clinic for a follow-up period of 5 years. At admission, information was obtained on the women's socioeconomic, medical, reproductive, and contraceptive history. Women were scheduled for follow-up visits every 6 months for 5 years irrespective of change of contraceptive method. They were encouraged to visit the clinic if they had any problems related to their health or contraceptive method. Information about hospitalizations was supplemented by extracts from hospital case records. All study forms and extracts of supplementary information about women with serious conditions were reviewed and coded by the study coordinator at the World Health Organization, Geneva.

Altogether 7977 women starting Norplant, 6625 starting with an IUD, and 1419 having sterilization were admitted to the study. The largest percentage of participating women were in China (38.2%), whereas Egypt, Indonesia, and Thailand each had a share of between 11.4% and 12.6%, and Bangladesh, Chile, Colombia, and Sri Lanka each contributed between 5% and 7.8%. A total of 306 women discontinued their method in the first 6 months of the study (Norplant 95 women, IUD 208, and three sterilized women because of contraceptive failure).

Summary of Results

Of the 16,021 women enrolled in the study, only 584 (3.6%) were lost to follow-up. Because the follow-up continued regardless of change of contraceptive method (including no method), information was obtained on pregnancy rates for a range of methods. The intrauterine pregnancy rates for Norplant and female

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sterilization were low and similar, 0.23 and 0.15 per 100 woman-years, respectively. Rates per 100 woman-years for ectopic pregnancy for users of Norplant were 0.03 per 100 woman-years, for sterilized women 0.01, and for users of copper-IUD 0.07. The 5 year continuation rates for Norplant and IUD were 67.3% and 65.4%, respectively. The incidence of difficult Norplant removals was 10.1 per 1000 removals.

No significant excess of malignant neoplastic disease or cardiovascular events, such as stroke, myocardial infarction, or venous thromboembolism, was observed in women using Norplant compared with that in women using nonhormonal methods or the expected number estimated from population based incidence rates. One Norplant and two IUD users were diagnosed as suffering from diffuse connective tissue disease; the rates of diagnosis of rheumatoid arthritis and polyarthropathies were low and not significantly different. Complaints of headache or migraine, mood disturbances, anxiety, and depression among Norplant users were similar to those reported by women who used combined oral contraceptives, and higher than recorded by women using IUD.

This large prospective study confirms the very high efficacy of Norplant in general (0.26 per 100 woman-years), which is similar to that of female sterilization (0.16). Current users of Norplant have a very low rate of ectopic pregnancy (0.03 per 100 woman-years). In the light of the Post-Marketing Surveillance of Norplant, the method appears to be safe, well tolerated, and a highly effective method for contraception.

Other Studies

The overall experience of the Chinese and Indonesian providers over seven years' of use of Norplant is that in women over the age of 30 years at admission and with a body weight of <65 kg, the overall pregnancy rate in the sixth and seventh year was only 0.32 per 100 woman-years. This suggests the possibility that the method may be used beyond 5 years. The incidence of ectopic pregnancy was not increased in the sixth or seventh year.

Recent Population Council studies in the United States, and in other developed as well as developing countries, initiated in 1990, all attest to the safety of Norplant implants. These studies embrace more than 9000 woman-years of observation. Mortality rates were 1.1 per 10,000 years of observation, approximately one-sixth of the mortality rate expected in the general population of similar age. Only low rates of serious health conditions, as measured by death or hospitalization, were observed. In the United States, women in these studies experienced hospitalization at a rate of only 25% of that of the general population of American women of reproductive age. Approximately half of all these hospitalizations to American women in the general population aged 15–44 are attributable to pregnancy and pregnancy related conditions. Use of Norplant implants reduced pregnancy associated hospitalizations toward the vanishing point, especially in the first 3 years following placement. Hospitalization rates of implant users did not exceed those of the general American women of reproductive age with respect to cardiovascular and blood diseases, connective tissue disease, and neoplastic and other conditions. These findings are not unexpected insofar as women entering such studies tend to be somewhat healthier than the general public and, in studies of hormonal contraceptives, must not have had specific preexisting cardiovascular and neoplastic diseases.

Table 1. The 20 most frequently encountered medical conditions and complaints during use of Norplant® implants*

Condition/Complaint	Average Annual Event Rate per 100 Woman-Years
Headache	12.8
Leukorrhea	12.6
Pelvic pain	7.3
Weight increase	5.4
Genital pruritus	5.1
Nervousness	4.3
Dizziness	4.1
Cervicitis	4.0
Breast pain	3.9
Yeast/fungus infection	3.3
Benign breast neoplasm	2.8
Cervical lesion	2.7
Acne	2.7
Nausea	2.6
Asthenia	2.4
Pain at implant site	2.2
Reaction at implant site	2.1
Alopecia	1.9
Fatigue	1.8
Dysuria	1.7

*Data from Sivin et al., 1997.[31]

A recent summary of the most frequent medical conditions and complaints during use of Norplant implants is presented in Table 1.[31]

Summary

This review has highlighted the attributes of a very important new method of contraception. The signatories to this document agree that, with the provision of appropriate information and instruction for the user, Norplant is a good contraceptive choice to be made available worldwide in family

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planning programs that have the resources for appropriate training and counseling. The signatories to this document are acting in their own personal capacity and not as representatives of any particular organization.

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Appendix 1

As a follow-up to Norplant, several second generation contraceptive implants are being developed, some of which are approaching marketing (Table 2). It is probable that they will face some of the same problems as occurred with Norplant. Several major organizations (Table 3) have undertaken recent detailed reviews of the very extensive data available about Norplant and have recommended its widespread availability as a safe and effective contraceptive.

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Table 2. Second generation contraceptive implants currently under development

Progestogen	Developer	Tradename	Duration of Action	Number of Implants	Stage of Development
Levonorgestrel	Population Council		3 yr	2 rods	Approved by FDA
	Leiras	Jadelle®			Approved in Finland
3-Keto-desogestrel	Organon	Implanon	2 yr	1 rod	Near marketing
Nomegestrol	South-to-South	Uniplant	1 yr	1 rod	Phase II
Nestorone	Population Council		2 yr	1 rod	Phase II

Table 3. Organizations that have recently undertaken detailed reviews of the efficacy, safety, and overall performance data of Norplant as a contraceptive

The Population Council
UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
The International Planned Parenthood Federation
Family Health International
The Contraceptive Special Interest Group of the American Society for Reproductive Medicine
Johns Hopkins Population Information Program
Program for Appropriate Technology in Health
The American College of Obstetricians and Gynecologists
The British Family Planning Association

Appendix 2: The Organizing Committee

Chairman: Ian S. Fraser, Department of Obstetrics and Gynaecology, University of Sydney, Sydney, Australia; Secretary: Aila Tiitinen, Department of Gynaecology, Helsinki University Hospital, Helsinki, Finland; Biran Affandi, Indonesian Society of Obstetrics and Gynaecology, Department of Obstetrics and Gynaecology, University of Jakarta, Jakarta, Indonesia; Vivian Brache, Profamilia, Santo Domingo, Dominican Republic; Horacio Croxatto, Instituto Chileno de Medicina Reproductiva, Santiago, Chile; Soledad Diaz, Instituto Chileno de Medicina Reproductiva, Santiago, Chile; Jean Ginsburg, Department of Medicine, Royal Free Hospital, London, U.K.; Sujuan Gu, Beijing Municipal Research Institute for Family Planning, Beijing, People's Republic of China; Pentti Holma, Department of Obstetrics and Gynaecology, Keski-Suomen Keskussairaala, Jyvaskyla, Finland; Elof Johansson, Center for Biomedical Research, The Population Council, New York; Olav Meirik, Special Program of Research, Development, and Research Training in Human Reproduction, World Health Organisation, Geneva, Switzerland; Daniel R. Mishell, Jr., Department of Obstetrics & Gynecology, University of Southern California, Los Angeles, California; Harold Nash, Center for Biomedical Research, The Population Council, New York; Bo von Schoultz, Department of Obstetrics and Gynaecology, Karolinska Institute Stockholm, Sweden; Irving Sivin, Center for Biomedical Research, The Population Council, New York.

Norplant® Consensus Statement

The purpose of this document is to review the worldwide application of the long-acting contraceptive implant Norplant®, and assess its efficacy and safety. Clinical studies have involved >55,000 women worldwide. Some 400 articles on Norplant have appeared in peer reviewed scientific journals. Norplant has been registered in 60 countries and has been used by some 6 million women worldwide. Although on clinical and scientific grounds it is generally agreed that Norplant has an important position in the range of contraceptive choices, there is currently controversy at both the community and consumer levels regarding its use.

Norplant is the Population Council's trademark for subdermal silicone implants releasing levonorgestrel at a virtually constant rate over 5 years. It consists of six small (34 mm long and 2.4 mm in diameter) Silastic® capsules, each containing 36 mg levonorgestrel, (ie, a total of 216 mg levonorgestrel). The capsules are inserted under the skin of the upper inner aspect of the nondominant arm through a trocar under local anesthesia. In the steady state, the release rate of 35 μg/day levonorgestrel is <25% of the dose provided by a low-dose combined oral contraceptive containing levonorgestrel.

The contraceptive efficacy of Norplant is comparable to that of the most effective female methods, including sterilization. The cumulative pregnancy rate at the end of 5 years is approximately one pregnancy per 100 women. Ectopic pregnancy rates are also low—0.3 per 1000 woman-years. The implants are effective for 5 years, and should be removed by the end of the fifth year, or earlier if the woman so wishes. If desired, new implants may be inserted immediately after removal of the 5-year-old implants. The high rate of contraceptive effectiveness results from at least three effects of levonorgestrel: 1) inhibition of ovulation; 2) prevention of normal sperm transport through the female genital tract; and 3) inadequate development of normal secretory endometrium. The capsules are removed through a small skin incision and fertility is

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raception
3;57:1–9

ored promptly after removal. The major advantage his method is its long-term effectiveness after one iic visit. Its most frequent side effect is disturbance menstrual cyclicity.

The major side effect—irregular vaginal bleed-;—is associated with altered duration and amount flow, but overall the amount of menstrual blood s is scanty; menorrhagia is rare. The mean duration bleeding declines steadily with time, whereas ean hemoglobin concentration tends to rise slightly iring the first 3 years. Metabolic studies have re-aled only minimal and inconsistent changes. About)% of Norplant users report changes in body eight—either weight gain or weight loss (more equently the former). Headache and mood changes ay be noted but are often transient or mild. Acne is e most commonly reported skin problem. Longitu-inal studies have shown an increase in bone mineral ensity. At the end of 5 years, about 25% of women ill have requested removal of the implants because bleeding problems and a similar number because he woman wishes to become pregnant. Another 15% scontinue because of other medical problems, such headaches and weight gain. Thorough counseling before insertion (in particular regarding the cause and ature of side effects such as the bleeding distur-ances to be expected with Norplant) and subsequent reinforcement, should minimize discontinuation.

- Experience in family planning services has shown iat Norplant implants are a suitable method for the ajority of women and particularly for those request-ing a long-term reversible method without the need take daily action. Breast feeding or smoking are not ontraindications. Norplant is not recommended for short-term contraception.
- Counseling is essential to ensure that women (and referably couples) make a contraceptive choice based on appropriate information and that the women learn to use the method safely and effectively. Pretreat-ent and continued counseling should emphasize the ost common side effect, namely, a change in men-strual bleeding pattern. Adequate training must be iven both in insertion and removal techniques and in ounseling and follow-up procedures to all medical and paramedical personnel involved. Availability of ppropriate family planning service infrastructure is nportant to optimize use of the method.

The International Collaborative Post-Marketing Surveillance of Norplant involving >16,000 women Norplant: 7977; intrauterine device (IUD): 6625; and terilization: 1419) is the first large-scale, prospective, long-term drug surveillance project in developing ountries. The intrauterine pregnancy rates for Nor-lant and female sterilization were similar (0.23 and 0.15 per 100 woman-years, respectively) and the rate for users of copper IUD was 0.80. Rates of ectopic pregnancy per 100 woman-years were 0.03 for Norplant users, 0.01 for sterilized women, and 0.07 for users of a copper IUD. The 5 year continuation rates for Norplant and the IUD were 67.3% and 65.4%, respectively. The incidence of difficult removals was 10.1 per 1000 removals. No significant excess of malignant neoplastic disease or of cardiovascular events such as stroke, myocardial infarction, or venous thromboembolism was observed in Norplant users. Recent Population Council studies initiated in 1990 in the United States and in other developed and developing countries also attest to the safety of Norplant implants. These studies embrace more than 9000 woman-years of observation. Mortality rates were 1.1 per 10,000 years of observation, approximately one-sixth of the mortality rate expected in the general population of similar age.

The signatories to this document agree that, with the provision of appropriate information and instruction for the woman and availability of adequate service facilities and training for the providers, Norplant is a good contraceptive choice in family planning programs that have these resources for training and counseling. The signatories to this document are acting in their own personal capacity and not as representatives of any particular organization.

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NORPLANT® INTRODUCTORY PROGRAM IN EGYPT

Implementation Plan

January 30, 1994

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NORPLANT® INTRODUCTORY PROGRAM IN EGYPT
THE IMPLEMENTATION PLAN

1.0 BACKGROUND

NORPLANT®, a subdermal contraceptive implant containing the synthetic progestin levonorgestrel, will be introduced in Egypt over 5 years starting April 1994. The introduction of NORPLANT® follows successful clinical trials conducted in Egypt.

There have been two sets of pre-introductory, or clinical trials of NORPLANT® implants in Egypt. The first was supported by the Rockefeller Foundation and the Population Council in the early 1980s. The second clinical trial began in 1988 under the coordination of the Egyptian Fertility Care Society (EFCS), with support by the United States Agency for International Development and technical assistance from Family Health International. Physicians from five University Hospitals in Egypt (Alexandria, Assuit, Ain Shams, Mansoura, and Al Azhar) have provided NORPLANT® implants to 1,537 women during 1988 - 1990. There have not been any new insertions since the closing of the clinical trials enrollment in 1990. Follow-up of NORPLANT® clients and removal of the implants upon the request of the client or their expiration is on-going in each of the five clinical trial sites.

The Egyptian Clinical Trials have gone very well by all accounts. An acceptability study (Hassan, et.al, 1992) indicated that 93 percent of the NORPLANT® clients surveyed were satisfied with the method. "The major advantages were NORPLANT®'s long duration, its ease of use, that it produced less side-effects than the pill or IUD, that insertion was in the arm rather than in the genital area, and its effectiveness in preventing pregnancy." (Hassan, et.al., 1992). Continuation rates of the 1988 Clinical Trial are comparable to other, international trials: after three years approximately 66 percent of the NORPLANT®'s clients were still using the method.

The clinical trials demonstrated the acceptability and safety of NORPLANT® to the satisfaction of the Government of Egypt (GOE). NORPLANT® was registered with the GOE and given regulatory approval in February 1993.

Preliminary results of the 1992 Demographic and Health Survey for Egypt show the contraceptive prevalence rate to be 47.1%, of which oral contraceptives and IUDs contribute over 80%. Introduction of NORPLANT®, which will expand the method mix and increase contraceptive choice will help the Government of Egypt achieve its CPR objective of 53% in 1997. [3] At the level of service projected by this strategy and implementation plan, NORPLANT® may account for approximately 2.6% of total CPR by 1999.

Based on the positive experience gained through the clinical trials and DHS indicators, the Ministry Of Health in Egypt developed the Strategy and Regulations for the Use of Subcutaneous Implanted Capsules (NORPLANT®). Furthermore, a NORPLANT® Task Force was formed to develop the Implementation Plan based on MOH strategy paper.

This document, NORPLANT® INTRODUCTORY PROGRAM IN EGYPT: The Implementation Plan, is the result of the NORPLANT® Task Force work and it provides the broad guidelines for expanding the use of NORPLANT® beyond the University Hospital environment of the 1988 Clinical Trials.

The health system in Egypt has over 250 hospitals and many health care centers managed by the public sector and parastatal organizations. PVOs and private practitioners also own and operate numerous clinics. Introduction of NORPLANT® will be primarily hospital-based and will spread vertically to three categories of health facilities as training and service delivery systems are strengthened.

(5) **Category 1** facilities are university hospitals, teaching hospitals and the Curative Health Organization (CHO) hospitals in Cairo and Alexandria. There are approximately 32 hospitals in this category which are concentrated in Cairo and Alexandria. The five university hospitals from the clinical trials are included in this category of service delivery points.

Category 2 facilities are Health Insurance Organization (HIO) hospitals, additional CHO sites and general hospitals and the major centers of the Clinical Services Improvement (CSI) program. This category is comprised mainly of networks of facilities and includes over 170 sites nationally that have a wide variation in the quality of the infrastructure as well as the range of services offered.

Category 3 facilities are District hospitals, Urban Health Centers, MCH Centers and some of the polyclinics of HIO. There are over 350 of these facilities located throughout the country.

Criteria will be established for selection of sites from the pool of available service delivery points of each category.

Implementation Plan describes the parameters of the NORPLANT® Introductory Program's overall design and principle activities as determined by the NORPLANT® Task Force. Working Groups will be formed during the pre-implementation phase of the Introductory Program to work on the principle activities described herein.

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2.0 *PROGRAM GOAL AND OBJECTIVES*

2.1 Program Goal

To increase contraceptive prevalence by expanding the choice of available contraceptive methods through the provision of NORPLANT® implants as part of the Egyptian family planning program

2.2 Program Objectives

At the end of the five year Introductory Program the following objectives will have been met:

a) To provide substantial programmatic experience with the provision of NORPLANT® implants in a variety of service delivery systems within two governorates;

b) To examine the effect on contraceptive use dynamics by adding NORPLANT® to the already existing method mix of the Egyptian family planning program;

c) To ensure availability of NORPLANT® implants in an adequate number of sites in each governorate in Egypt.

3.0 *PROGRAM DESIGN*

The Egyptian NORPLANT® Introductory Program is not a method specific introductory program. The program's design reflects a concern of identifying the most appropriate manner of adding this new contraceptive technology into the existing service delivery system so that the Egyptian family planning client may have her choice of available methods expanded.

The NORPLANT® Introductory Program is a transition between the Clinical Trials and the integration of NORPLANT® within the standard method mix of the Egyptian Family Planning Program. The five year period is an opportunity to develop the management capacity for ensuring the smooth operations of the clinical and programmatic sub-systems that support the provision of this new contraceptive, and to study the effect of adding NORPLANT® to the family planning program.

The Introductory Program will take into account the expansion of the injectable contraceptive into the public sector. Although this is not specifically highlighted in this Implementation Plan it is an important underlying consideration to the development of the NORPLANT® Introductory Program's activities (which are described in the following sections of this document).

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The expansion of NORPLANT® services into the private sector will be made after the mid-program evaluation in phase III.

The following three principles guided the development of the NORPLANT® Introductory Program Implementation Plan.

1. Ensuring high quality NORPLANT® services while broadly introducing the new contraceptive method through Horizontal Introduction. Kalyobeya & Fayoum

2. Examining the impact of introducing NORPLANT® on the service delivery systems through Vertical Introduction into a specific geographic area.

3. Understanding use dynamics of NORPLANT® through systematic monitoring and evaluation.

3.1 Ensuring High Quality (Horizontal Introduction)

The NORPLANT® Horizontal Introduction is a design strategy to ensure high quality NORPLANT® services in a broadly based introduction program.

The NORPLANT® Introductory Program will begin with an expansion into the Category 1 facilities[1] that meet the selection criteria. The horizontal introduction of NORPLANT® provides a broad geographic coverage in approximately 12 governorates ? in category 1 facilities then it will expand, based on the experience gained, into other governorates in category 2 facilities and so on. This approach will provide highly qualified OB/GYN specialists in leading institutions throughout Egypt with an experience in providing the new contraceptive. The vertical expansion from one category of health services to another will provide the Technical Steering Committee the opportunity to monitor and ensure the quality of NORPLANT® services.

On the other hand, the horizontal introduction will provide a relatively restricted environment for developing and fine tuning the function of the clinical sub-systems involved with NORPLANT®, (e.g., training, logistics, information systems, IEC and follow-up). The broad geographic introduction into a few Category 1 facilities in each ? governorate will not sufficiently penetrate the family planning service delivery system to provide an adequate programmatic experience with managing NORPLANT® implants in a wide variety of service delivery contexts, however, nor will it provide a large enough case load to adequately evaluate its contribution to the national family planning program. The Egyptian NORPLANT® Introductory Program will therefore complement the broad geographic expansion into a few sites with a restricted vertical expansion into many different sites within a limited geographic area.

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[1] The list of facilities that correspond to Category 1, 2 and 3 is presented in the Background section of the Implementation Plan.

3.2 Examining the Impact (Vertical Introduction)

The NORPLANT® Vertical Introduction is a design strategy to examine the impact of introducing NORPLANT® on the service delivery systems.

Two governorates, Kalioubia and Fayoum, are selected for vertical introduction of NORPLANT®. In these two governorates, NORPLANT® will be introduced into a variety of service delivery points, including Category 1, 2 and 3 facilities. Each of the facilities will be carefully selected for participation in the NORPLANT® Introductory Program.

The vertical introduction within a governorate will give the NORPLANT® Introductory Program an in-depth experience in a variety of Category 1, 2 and 3 service delivery points. The focus on a confined geographic area will enhance control of the Introductory program, (including selection and follow-up of clients, aseptic procedures, and removal of the NORPLANT® implants).

3.3 Understanding Use Dynamics

Program monitoring and evaluation is an important element to develop a sound understanding of the NORPLANT® use dynamics.

The Introductory Program is intended to be a transition period between the Clinical Trials and the widespread use of NORPLANT®. Fundamental questions regarding the method's contribution to the overall contraceptive prevalence and changes in the method mix of the Egyptian family planning program will be examined by the Introductory Program. The programmatic implications of different levels of NORPLANT® prevalence in Egypt are profound, (an illustration of the commodity requirements based on a one percent national prevalence rate is included in the Appendices as an example of the critical nature of this issue). The long term sustainability of providing NORPLANT® will be significantly enhanced by devoting adequate resources to the study of these issues during the next few years.

The use dynamics of adding NORPLANT® to the existing method mix will be studied in a comprehensive evaluation plan, described in the Monitoring and Evaluation section of this Implementation Plan. A capsule summary is presented here to orient the reader to the baseline studies that will be used in formulating the content of the ntroductory Program's activities.

A Situation Analysis of the service delivery points in the two vertical introduction governorates will provide baseline information on the quality of care provided in the NORPLANT® Introductory Sites, and will assist in developing the clinical sub-systems o an acceptable level of quality. A baseline contraceptive prevalence study will also

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be conducted in the same governorates prior to the NORPLANT® Introduction. A baseline Situation Analysis study will also be conducted in one district in each of the two governorates targeted for the Quality Improvement Project. This district will serve as a comparison group for assessing changes in the quality of care that are attributable to the NORPLANT® Introductory Program.

The results from the baseline Situation Analysis (in the vertical introduction governorate and the Quality Improvement Project's district) and contraceptive prevalence study will be compared to a post test study. The analysis of these pre-test / post-test studies will provide reliable data on changes in the quality of care and use dynamics. This information will help policy makers and program managers in Egypt design family planning services to deliver NORPLANT® effectively well beyond the catchment areas of the vertical introduction governorate.

A mid-project evaluation will be conducted. The composition of the mid-project evaluation team, and the evaluation indicators, will be developed by the Technical Steering Committee, described below, that focus on the management capacity and the quality of care provided by the NORPLANT® services. Based upon the results of the mid-project evaluation the Ministry of Health may decide to accelerate the introduction of the NORPLANT® Introductory Program to include a limited vertical introduction into other governorate(s).

4.0 PROGRAM COORDINATION

As the major source of financial and technical assistance for population and family planning activities in Egypt, the Ministry of Health (MOH) plans to support most of the activities related to NORPLANT® introduction through subprojects of the USAID/Cairo bilateral project, Population/Family Planning III (POP/FP III). Management of NORPLANT® introduction is the responsibility of the Executive Director of the Systems Development Project (SDP), a subproject of POP/FP III under supervision of the Undersecretary for Family Planning. The Executive Director will work with the Technical Steering Committee, the National NORPLANT® Coordinator and other POP/FP III subproject directors to coordinate activities and resources needed for NORPLANT® introduction.

4.1 NORPLANT® Technical Steering Committee

A NORPLANT® Technical Steering Committee will be responsible for supervising the implementation of the Implementation plan of NORPLANT® Introductory Strategy and for providing technical guidance to critical aspects of the NORPLANT® Introductory Program. The Undersecretary for Family Planning will chair this committee.

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The NORPLANT® Technical Steering Committee will provide an opportunity for bringing together key decision makers from each of the principle agencies involved in the NORPLANT® Introductory Program. The coordination role of this committee is therefore critical to smooth operations of the Egyptian NORPLANT® Introductory Program.

The composition of the NORPLANT® Technical Steering Committee should reflect the diversity of the agencies involved with the implementation of the NORPLANT® Introductory Program. In addition to the Ministry of Health technical and managerial staff, the NORPLANT® Technical Steering Committee could also include the following members:

- ✓ Undersecretary for Family Planning, Chairperson —— ?
- ✓ Minister Of Population and Family Welfare —— ?
- ✓ Dr. Ezz El-Din Osman
- ✓ Mrs. Sawsan El-Bakly, State Information Services (IEC Activities) Dr. Sondin
- ✓ Egyptian Pharmaceutical Trading Company, CIIS (Commodities)
- ✓ Dr. Roushdi Amar, Director, Regional Center for Training
- ✓ USAID Representative
- ✓ Population Council

The NORPLANT® Technical Steering Committee will oversee the Working Groups (e.g., Training, IEC, Standards of Practice, Standards of Health Facilities, Monitoring and Evaluation). Once the Introductory Program begins, the Technical Steering Committee will meet periodically to review progress made with the Introductory Program. The Technical Steering Committee will oversee the mid-project evaluation.

An important function of the Technical Steering Committee is the coordination of the technical assistance agencies that will provide support to the NORPLANT® program.

4.2 NORPLANT® Coordinator

The Ministry of Health will assign a staff member to be the NORPLANT® Coordinator, (seated within the Family Planning System's Development Project Office). The NORPLANT® Coordinator will manage the day to day activities of the NORPLANT® Introductory Program, including the following key personnel decisions:

- ✓ Selection and supervision of the NORPLANT® Introductory Program Working Groups within SDP units
- ✓ Designation of staff to provide local supervision and coordination for the program at the central and governorate levels
- ✓ Creation of a registry of trained physicians in each governorate
- ✓ Development of criteria for the selection of NORPLANT® providers, and selection of candidates for training

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5.0 INSTITUTIONAL FRAMEWORK

The Ministry Of Health will be the body responsible for the NORPLANT® Introductory Program. There will be other organizations involved in the implementation such as the Teaching Hospital Organization (THO), the Health Insurance Organization (HIO) hospitals and polyclinics, the Clinical Services Improvement (CSI) clinics, the Regional Center for Training (RCT) in Family Planning and cooperating Universities, the State Information Service (SIS), the U.S. Agency for International Development, the Population Council, and other institutions.

The Egyptian NORPLANT® Introductory Program will be conducted under the auspices of the Ministry of Health through its Systems Development Project (SDP) which is a subproject of the Population/Family Planning III project supported by USAID. Most of the service delivery points of NORPLANT® will be in the MOH hospitals and health facilities.

The THO hospitals will be service delivery points and three of their training sites will provide training on NORPLANT® to THO and MOH service providers. These activities will be mainly funded through the THO/FP subproject under POP/FP III supported by USAID.

The Health Insurance Organization (HIO) hospitals and polyclinics and the Clinical Services Improvement (CSI) clinics will participate as service delivery points of NORPLANT®.

The Regional Center for Training (RCT) in Family Planning at Ain Shams University will be the main training institution. The training curricula will be approved by ~~teh~~ The Technical Steering Committee. For its limited capacity to train all service providers in the country, RCT will have subagreements with the five Universities that conducted the clinical trial to conduct training as well. All NORPLANT® training activities in RCT and cooperating Universities will be funded through RCT subproject under POP/FP III supported by USAID.

The State Information Service (SIS) will be responsible for developing IE&C materials to promote the use of NORPLANT® based on the approval of the Technical Steering Committee. IE&C activities conducted by SIS will be funded through SIS subproject under POP/FP III supported by USAID.

USAID will support major activities in the NORPLANT® Introductory Program through its POP/FP III project and provide long and short term T.A., as appropriate, through I/G&S contract.

mplement. Goods & Services

The Population Council will contribute in the situation analysis study, the contraceptive prevalence studies, and other operations research studies.

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6.0 PROGRAM ACTIVITIES

There are five general categories of activities associated with the NORPLANT® Introductory program. The parameters of each activity are identified in this section. A Working Group will be composed for each category during the pre-implementation phase of the Introductory Program. The Working Groups will be charged with developing detailed implementation plans and substantive guidelines for each activity. Each Working Group will make clear distinctions between clinical service activities and program management issues in their implementation plans.

6.1 Standards of Practice

The *National Standards of Practice for Family Planning Clinical Services Delivery* (March 1993) produced by the Ministry of Health, (including the *Family Planning Clinical Procedures Manual for Physicians* and the *Family Planning Clinical Procedure Manual for Nurses*, and the *Standards of Service for Quality Improvement Program Monitoring System*) will be supplemented by a full and complete reference to NORPLANT® implants.

The following are the sections and some of the issues that need to be addressed in the revised Standards of Practice:

6.1.1 Counseling and IE&C

Informed choice is an essential part of quality services. Counseling must provide information about all family planning methods to prospective clients and help them make an informed choice of a method based on their medical histories, reproductive objectives and individual preferences. A client's ability to return regularly to the clinic for check-ups and for methods which require resupply, i.e., vaginal tablets, pills, condoms and injections, must also be taken into account during counseling. All of these considerations reinforce a family planning services orientation rather than a method-specific approach.

Because NORPLANT® is provider-dependent, client satisfaction depends to a large extent on counseling. Clients who select NORPLANT® will receive thorough pre-insertion counseling to inform them about the potential side-effects, especially menstrual irregularities. Insertion and removal procedures, physical exams and laboratory analyses which may be required will be explained to the client. The counselor will also explain the follow-up schedule and necessity of removal after five years.

Post-insertion counseling includes instructions for caring for the insertion site and warning signs of complications which require prompt return to the clinic. Post-insertion counseling also reinforces information about follow-up visits and eventual removal. The client will be assured that she can return to the clinic at any time if she has questions or concerns. Procedures and conditions for ensuring follow-up and removal of NORPLANT® implants, clarifying that "removal upon demand" is a priority of the Introductory Program, need to be developed.

Materials about NORPLANT® were found to be helpful by the clients in the clinical trials. Additional prints of the client booklet which was developed during the clinical trials will be done and other materials will be adapted or developed to provide clients with the information they need.

6.1.2 Clinical Services

Only physicians who have been trained will be allowed to insert/remove NORPLANT®. Insertions must be done carefully and according to proper procedures to prevent infection and expulsion. Guidelines for accrediting physicians for NORPLANT® insertion and removal need to be established. Selection criteria for NORPLANT® clients will be developed as part of the development of service standards and guidelines.

Although clients will be encouraged to keep the NORPLANT® implant for at least three years, access to removal upon request at any time will be assured. Women requesting early removal will be seen by a counselor to determine whether the client has questions and concerns about side-effects which can be addressed by counseling, whether she is generally dissatisfied with the method or whether she has decided to remove the implant because she wants to become pregnant. Whatever the reason, if after counseling the client still wants to have the implant removed, arrangements will be made for the procedure. Prior to leaving the clinic, clients who remove NORPLANT® because of concern or dissatisfaction will be counseled about other available contraceptives and encouraged to choose another method. Guidelines relating to method switching and the appropriateness of a "transitional period" between contraceptive methods, particularly between two hormonal contraceptive methods such as an injectable contraceptive and NORPLANT® implants need to be documented.

6.1.3 Technical support and supervision

Dynamic and supportive supervision is a demanding responsibility since staff and material resources in family planning clinics are often limited. Because NORPLANT® is a provider-dependent method and requires particular attention to asepsis and counseling, good supervision is critical to integration of NORPLANT® and quality service.

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6.1.4 Record Keeping

Client records and clinic registries will include information about NORPLANT® users. A suggested list of information which will be required includes:

- ✓ Name and location of clinic where NORPLANT® insertion occurred
- ✓ Date of the insertion
- ✓ Clear and complete client name and address / residence identifiers
- ✓ Expected date of removal
- ✓ Actual date of removal, including reference to the principle reason
- ✓ Complications, expulsions, etc..
- ✓ Information on FP use e.g. reinsertions, previous methods, etc..
- ✓ Name and address of a reference person not residing with the client.

6.1.5 Follow-up

A schedule of routine follow-up visits for NORPLANT® clients will be included in the service standards and guidelines.

Follow-up of clients five years after insertion is necessary to insure proper removal of NORPLANT®. Effective mechanisms for follow-up will be developed and tested during the course of the introduction period.

6.2 Standards of Health Facilities

A Working Group will be formed from existing SDP staff during the pre-implementation phase to develop the guidelines and establish the selection criteria of sites for the NORPLANT® Introductory Program. These guidelines for the accreditation of a clinic to provide NORPLANT® may include the minimum number of trained staff, equipment and facilities, aseptic procedures, information system capabilities. This Working Group will conduct site visits and assist in reviewing the pool of available service delivery points for each of the Introductory Program's phases. The Technical Steering Committee, or a sub-group of this committee, will be charged with the final selection of the sites. The results from the baseline Situation Analysis in the 'fast track' governorates, Kalioubia and Fayoum, can be applied to the determination of the final selection of sites.

6.3 Training

A training management plan will be produced by a Training Working Group from existing SDP staff that emphasizes the introduction of NORPLANT® into the existing family planning services. This orientation will hence provide for refresher training (where appropriate) in the technical management of other contraceptive methods,

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particularly hormonal methods, and improving providers's counseling skills for all types of clients.

The training management plan will elaborate upon several key issues, including:

- The number and category of providers to be trained in each site, including training of replacement providers due to transfers of certified staff;
- The minimum number of insertions and removals for each provider required prior to certification;
- Technical support and follow-up of providers during the post-training phase, with special reference given to removal procedures, counseling and ensuring aseptic procedures;
- Increasing awareness of and referrals for NORPLANT® Implants among service providers in family planning service delivery points that currently do not offer NORPLANT® Implants.

Initially NORPLANT® training will be conducted at the five University Hospitals that participated in the clinical trials. Priority will be given to establishing a governorate level training facility/program for the two vertical introduction governorates. The training management plan will work towards the creation of a cadre of master trainers in NORPLANT® that will branch out from the University Hospitals to form NORPLANT® training centers in other existing facilities such as THO Training Centers. More details regarding a number issues related to training, including cost and capacity estimates, are found in the Appendix to the Implementation Plan.

6.4 Information, Education and Communication

An IEC strategy and work plan will be developed by a Working Group on IEC in collaboration with the State Information Service (SIS). The strategy will identify target audiences and define the communication media for reaching each of them. The following are the objectives of the IEC program:

- Increase awareness of the new method among women matching the selection criteria
- Dispel rumors about NORPLANT® in the general public
- Expanding upon teaching materials for service providers developed during the Clinical Trials

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Since the NORPLANT® Introductory Program will not be national in scale (except in a few limited services) and will focus largely on two governorates, the communication strategy aimed to increasing awareness among potential users will have to rely on developing local communication events for increasing awareness and motivating new clients. Activities aimed at dispelling rumors, however, should be national in scale and target specific audiences (cited below).

Among the target audiences and communication channels that will be exploited are the following:

- Information dissemination to Non-Governmental Organizations, women's health advocates and the media to dispel myths and misconceptions about NORPLANT® (see Population Council, 1993 for a reference on the type of information available that targets these groups);
- Women that match the NORPLANT® selection criteria to increase their awareness of the new contraceptive method, including graphic arts, mass media and clinic pamphlets;
- Clinic based teaching aides to be used by service providers when explaining the mechanisms of NORPLANT®.

6.5 Logistics

A fifth Working Group will be composed to address issues related to the logistics required for the NORPLANT® Introductory program. This Working Group will mainly look into the work on forecasting demand, estimating needs, developing plans for receiving, storing, and distributing NORPLANT® sets.

6.5.1 NORPLANT® Procurement

The estimate for the initial quantity of implants requested is based on the consumer demand and client satisfaction expressed during the NORPLANT® clinical trials and on the volume of services expected during the first year of the introduction. Many of the sites to be targeted for NORPLANT® introduction during the first year of implementation are Category 1 facilities, which includes the five clinical trial sites. Service delivery capacity of these sites and the volume of consumer demand are expected to be similar to that of the clinical trials. Assuming that 20 sites (of the 32 in that category) begin NORPLANT® services within the first year and that supply is deliberately restricted to approximately 40 clients per month:

20 sites x 40 insertions/month x 12 months = 9,600 insertions

The request for 10,000 implants will cover new acceptors and some of the clients from the clinical trials who will be due for 5-year removal but who may wish to continue with the method.

USAID/Cairo will start procuring NORPLANT® sets during the pre-implementation phase of the Introductory Program. The MOH will submit commodities forecasts and procurement requests to USAID in June of each year of the introduction period, starting in 1995. An initial request of 10,000 NORPLANT® sets was submitted to USAID to cover the first year of service delivery and it will be activated pending submission of required documentation to USAID.

The volume of services and the projected commodity requirements for the two vertical introduction governorates will be determined. The results from the baseline Situation Analysis study of vertical introduction governorate's sites will be useful in developing precise equipment and supplies lists for support of the NORPLANT® Introductory Program.

The volume of services will be carefully monitored to provide accurate estimates of commodity requirements for subsequent years of the introduction to prevent under- or over-supply.

In addition to the NORPLANT® implants, USAID is requested to procure the trocars required for insertion. The trocars and commodities are usually packaged at a ratio of 1 trocar per to 50 sets. Trocars in the ratio of 1 to 20 will be requested.

Adequate quantities of sterilized linens and instruments for NORPLANT® insertions and removals must always be available. Site visits conducted prior to start-up of activities at new introduction sites will determine the need for redistribution or procurement of autoclaves for the family planning clinics to improve infection prevention practice. Procurement of this equipment will be discussed with USAID, UNFPA and other donor agencies.

6.5.2 NORPLANT® Storage and Distribution

Storage and distribution of NORPLANT® will be handled in the same manner as other contraceptives for public sector activities. This had been carried out by the Egyptian Pharmaceutical Trading Company (EPTC). Whether EPTC or another company will be responsible for distribution of USAID-donated commodities under POP/FP III will be determined by the MOH and USAID.

In addition to the NORPLANT® implants, insertion and removal requires expendable, medical supplies. Systems of distribution of the regular supplies to the family planning clinics will be provided through the same distributive systems of MOH and public sector, additional supplies specific to NORPLANT® will be verified by the MOH prior to the initiation of services.

6.6 Management Information Systems (MIS)

The scope of NORPLANT® related information to be recorded on the client medical record, and the most appropriate mechanism for ensuring its recording will be established by the Working Group on MIS. The purpose of the MIS is to upgrade the existing system to incorporate adequate information to enable the tracking of the NORPLANT® clients.

Guidelines for creating and maintaining governorate and central level registries of NORPLANT® clients will be specified prior to beginning the NORPLANT® Introductory Program.

Routine surveillance of the NORPLANT® information will be conducted and included into the existing the service statistics of the MOH. This information will prepared quarterly to track client characteristics, the volume of new clients per site, removal rate and categories of reasons for removal. These data will facilitate program monitoring and operations research.

6.7 Monitoring and Evaluation

This element is critical to the successful introduction of NORPLANT®. As specified under *Program Design* section (above) the NORPLANT® Introductory Program is organized to collect information relative to the use dynamics of expanding the contraceptive choice. In addition to the baseline and post - test data collection activities there will be a number of other, related operations research studies and routinely collected data for monitoring the implementation of the NORPLANT® program. This section of the Implementation Plan briefly describes the parameters of the types of operations research and monitoring activities that will be conducted during the Introductory Program. A Monitoring and Evaluation Working Committee will develop these topics into full research proposals.

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6.7.1 Situation Analysis Study

The Situation Analysis methodology focuses on the 'supply side' characteristics of the family planning program, i.e., those factors which are more or less under the control of a program manager. The Situation Analysis methodology was originally developed as a rapid and cost effective approach for diagnosing the quality of family planning services that a program provides its clients, (Miller, et.al., 1991).

The Situation Analysis study is usually (although not necessarily) conducted in a representative sample of service delivery points within a geographical area. Data is collected by teams of interviewers that utilize the following three research methods:

- Direct interview techniques with service providers and clients
- Structured observation of family planning consultations
- Inventory of the facilities' equipment and materials (including service statistics)

Clinic Sub - Systems Analyzed by a Situation Analysis Study

- ✓ Logistics / Supplies
- ✓ Facilities
- ✓ Staffing
- ✓ Training
- ✓ Supervision
- ✓ IEC
- ✓ Record Keeping

Indicators from each of these sub-systems are measured that will assist program managers and administrators to answer to the following basic questions:

1. Is each sub-system in place, (i.e., is it potentially ready to provide services)?

2. If in place, is each sub-system functioning, (i.e., is it providing some level of services to clients)?

3. If functioning, is each sub-system providing quality services in terms of the following elements (Bruce, 1990):

   - Choice of Contraceptive Methods
   - Provider - Client Information Exchange
     - Understanding Clients
     - Information to Clients
   - Provider Competence
     - Qualifications
     - Technical Skills and Knowledge
   - Client - Provider Relations
   - Mechanisms to Encourage Continuity
   - Appropriate Constellation of Services

A baseline and post-test Situation Analysis study will be conducted of the service delivery points of the governorate selected for the vertical introduction of NORPLANT®, and a comparison district where NORPLANT® will not be introduced but the Quality Improvement Program will enhance the quality of services provided. The baseline Situation Analysis study will provide useful baseline information for developing the Training, IEC and Resource Management elements of the NORPLANT® Introductory program. The comparison of the baseline and post test measures will be useful in understanding changes that the NORPLANT® Introductory Program made in the quality of the family planning service delivery system.

6.7.2 Contraceptive Prevalence Study

A study will be conducted to assess changes in method mix and contraceptive prevalence that are attributable to the NORPLANT® Introductory Program. The long term implications of the relative contribution of NORPLANT® to Egypt's contraceptive prevalence rate is a fundamental issue that the Introductory Program will address.

In addition to examining the impact of the NORPLANT® Introductory program on contraceptive prevalence, the use dynamics of adding a new method to the Egyptian family planning program are equally important for the national program to understand. For example, the extent to which the new method will make it possible for non users (never users and past users) to start practicing contraception, as opposed to simply having users of other contraceptives switch to NORPLANT®, is a critical dimension of the Introductory Program's objective of expanding contraceptive choice. The pre-test / post-test contraceptive prevalence studies will provide information on how well the Introductory Program met this objective.

6.7.3 Operations Research Studies

The NORPLANT® Introductory Program will conduct a number of highly focused operations research studies. These studies will be useful for fine tuning the implementation of key activities as well as building upon past client acceptability studies conducted during the Clinical Trials. Although the exact number and content of the NORPLANT® Introductory Program's operations research activities will be determined by the Monitoring and Evaluation Working Group, the following topics are indicated as a starting point for the deliberations:

- Client Acceptability Study
- Testing of Different Strategies for Ensuring NORPLANT® Removal
- Impact of Counseling Training on Providers and Clients' Behaviors
- Cost Elasticity Study and the Effect of Cost on Sustained Use
- Client Follow - Up Study (NORPLANT® users compared to users of other contraceptive methods)

7.0 *PROGRAM WORK PLAN*

7.1 Pre-implementation Phase: 9 months (4/1/94 - 12/31/94)

The duration of this phase extends for 9 months from April 1 through December 31, 1994. The major activities during this phase will include the following:

- Establish the NORPLANT® Technical Steering Committee
- Appoint the NORPLANT® Coordinator
- Compose the different Working Groups and develop plans
- Complete standards of practice of NORPLANT® services
- Procure, receive and distribute NORPLANT® devices
- Select health facilities for NORPLANT® service delivery based on standardized selection criteria
- Develop the MIS records/registry
- Conduct the baseline research in 2 vertical introduction governorates

7.2 Phase I: 15 months (10/1/94 - 12/31/95)

The duration of this phase extends for 15 months from October 1, 1994 through December 31, 1995. In this phase, both the horizontal and vertical introduction programs will be launched:

- Provide NORPLANT® services in Category 1 health facilities
- Train service providers in Category 1, Category 2 and in the health facilities selected for vertical introduction

7.3 Phase II: 24 months (7/1/95 - 6/30/97)

The duration of this phase extends for 24 months from July 1, 1995 through June 30, 1997. In this phase, the following activities are planned:

- Expand NORPLANT® services provision in Category 1 and 2 health facilities to ensure geographic coverage
- Train service providers in Category 2 and 3 health facilities
- Complete installation of services in all appropriate Category 2 and 3 facilities in the two governorates
- Conclude operations research studies

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7.4 Phase III: 24 months (1/1/97 - 12/31/98)

The duration of this phase extends for 24 months from January 1, 1997 through December 31, 1998. In this phase, a number of activities are planned including:

- Review Program Performance to fine tune program operations
- Expand number of sites in the horizontal introduction governorates if indicated by mid-program evaluation
- Conduct post-test research (situation analysis and contraceptive prevalence survey)
- Establish the regulations that govern the provision of NORPLANT® services in the private sector

7.5 Phase IV: 12 months (7/1/98 - 6/30/99)

This phase extends for 12 months from July 1, 1998 through June 30, 1999. There will be 2 major activities:

- Conclude post-test research
- Evaluate the NORPLANT® Introductory Program
- Develop post-introductory plan for NORPLANT® services

NORPLANT INTRODUCTORY PROGRAM IN EGYPT
FIVE YEAR WORK PLAN

April 1, 1994 - June 30, 1999

Calendar Year	94			95				96				97				98				
Quarters	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q
POP/FP III Project Year		YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5		
1.0 Preimplementation Phase	X	X	X																	
2.0 Phase I			X	X	X	X	X													
3.0 Phase II						X	X	X	X	X	X	X	X							
4.0 Phase III												X	X	X	X	X	X	X	X	
5.0 Phase IV																		X	X	X

8.0 PROGRAM SUSTAINABILITY

The long term sustainability of the NORPLANT® depends upon the extent to which the program is able to make an significant contribution to the Egypt's contraceptive use rate, the diversification of funding sources for the public sector program, and the expansion into the private sector.

Achievement of the GOE's demographic objectives and CPR of 53% requires increased use of effective contraceptive methods and decreased discontinuation rates. Introduction of NORPLANT® in the National Family Planning Program can significantly contribute to these objectives.

Despite the high up-front cost of NORPLANT®, the MOH considers it to be an important method for provision through the public sector. In addition to improved method effectiveness and continuation, NORPLANT® introduction will expand the method mix and improve choice.

IUDs and oral contraceptives currently account for over 80% of contraceptive use in Egypt. Subsidized prices for these commodities, available through both the public and private sectors, has been kept very low which may have contributed to their popularity. The cost of an IUD which can be used for 8 years is currently less than $1.00. A 5-year supply of pills at current prices would average $17.00. Pressure from international donors and commercial distributors to allow sales and distribution of contraceptive commodities at more realistic prices is likely to result in price increases for IUDs, pills, condoms, etc. The 5-year cost of injectables is approximately $21, almost equivalent to the cost of NORPLANT®.

The price of NORPLANT® device has been set at LE 50 ($15). This price is intended to contribute to partial cost recovery, to encourage long-term use and discourage early removals and to moderate demand which could otherwise overwhelm the capacity of the service delivery system.

The price of LE 50 was based on the responses of clients surveyed during the clinical trials about their willingness to pay for NORPLANT® and other anecdotal evidence. The current price of injectables was also taken into consideration. Market surveys and cost studies to be conducted during the introduction period will provide data to better understand the elasticity of demand for NORPLANT® and other contraceptive services and will provide the basis for establishing realistic a fee structure in the future. As the NORPLANT®, initially, will be donated by USAID, the revenues from the provision of NORPLANT® services will be governed by an agreement among the MOH, EPTC and USAID.

Introduction of this method through the vast network of public sector hospitals and clinics using donated product will create a service delivery base from which training and systems support can expand to the private sector.

Currently the private/commercial sector plays the major role in the provision of family planning commodities and services. The private sector is expected to provide an increasingly greater share of NORPLANT® services within 5-7 years. This method, once available from private practitioners, will probably have wide appeal to middle and upper class clients who can better afford to pay market rates for products and services.

To make more methods available to all potential acceptors of contraceptives in Egypt, NORPLANT® must be available through the public sector at subsidized prices. Financial sustainability, however, is likely only in the private sector.

During the 5-year introduction period, the MOH will discuss NORPLANT® commodities procurement and cost-sharing with other donors such as UNFPA and the World Bank.

APPENDIX 1.

Illustrative Example: Projected Commodity Requirements and Cost Estimates for One Percent Prevalence of NORPLANT® Users in Egypt within Ten Years

Egypt
Annual Acceptors, Users, and Cost Required to Have
One Percent of MWRA Using Norplant Within 10 Years
(and to Maintain One Percent Use Thereafter)

Year	MWRA	Prevalence End of Year	Acceptors During Year	# Users End of Year	Cost
1994	9,195,000	0.01	750	623	$23,760
1995	9,420,000	0.03	2,766	2,834	87,634
1996	9,655,500	0.05	3,270	5,155	103,594
1997	9,891,000	0.08	3,791	7,586	120,114
1998	10,126,500	0.10	4,331	10,127	137,217
1999	10,362,000	0.28	24,793	29,014	785,454
2000	10,608,000	0.46	29,992	48,797	950,150
2001	10,843,500	0.64	34,533	69,398	1,094,020
2002	11,079,000	0.82	39,256	90,848	1,243,618
2003	11,314,500	1.00	44,129	113,145	1,398,008
2004	11,550,000	1.00	33,523	115,500	1,062,004
2005	11,826,000	1.00	36,861	118,260	1,167,766
2006	11,944,260	1.00	37,570	119,443	1,190,218
2007	12,063,703	1.00	40,013	120,637	1,267,621
2008	12,184,340	1.00	42,530	121,843	1,347,343
2009	12,306,183	1.00	37,737	123,062	1,195,501
Total			415,847		$13,174,024

Note: Assumes continuation rate of ar-rt; with a=.9 and r=.15

(Source: P. Mauldin, Population Council 1993)

APPENDIX 2.

Training Load and Cost Estimates

2.1 *Costs of the Training Course*

The Regional Center for Training on Family Planning has developed a training course on NORPLANT for Ob/Gyn specialist. The course length is 6 days. The average number of participants will be 10, 3 from Cairo and 7 from outside Cairo. The direct costs of the course are:

Meals and M&I:		
7 part. x 6 days x L.E. 100	=	*L.E.4,200*
Transportation:		
7 part. x L.E. 40	=	*L.E. 280*
Training Materials:		
10 part. x L.E. 50	=	*L.E. 500*
TOTAL	=	*L.E.5,980*

L.E.6,000 will be used to simplify the computation of the cost.

NOTES:

1. *Since the training will start at 5 training sites almost at the same time, it is fair to assume that those who come from outside Cairo (or the vicinity of the training center) will be less than 7 participants. Therefore an estimate of 5 participants from Cairo or the vicinity of the training center may be reasonable which will lower the costs of the course.*

2. *The above per diem (lodging, meals, miscellaneous and incidental costs) and transportation rates are those used by RCT under USAID funding, these rates differ from the MOH rates. However, NORPLANT training in the introduction strategy will be mostly conducted by USAID funded training centers. It is therefore safe to use the above rates provided that all USAID funded projects use the same per diem rates for participants.*

3. *These are the direct costs, however, there are the indirect costs which include costs of developing, printing, and binding the materials; photocopying; clinical training supplies; trainers; and administrative support. These costs will be born by RCT and the other USAID funded training centers during the introduction strategy.*

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4. *A course for nurses and/or social workers may take as well 7 days, therefore the same figure of L.E. 6,000 will be used for training courses on infection control and counseling on NORPLANT.*

2.2 *Training Capacity*

1. Training is limited by the number of training centers available, the number of service delivery sites, and the number of providers that need to be trained.

2. In phase I there will be 5 training centers, in phase II there are an additional 13 centers (4 THO and 9 University Hospitals) while in phase III there are 5 more centers in HIO hospitals based on selection criteria established by the Technical Steering Committee.

3. Given the nature of "rotation on duty" in the hospitals, the reasonable number of service providers that need to be trained to ensure adequate coverage and quality of service would be 4 Ob/Gyn specialists, 2 nurses and 2 social workers/counselors. A 25% turnover per year needs to be considered.

4. In the first phase, there will be 38 hospitals involved, 5 University hospitals will be available as training centers and 33 hospitals will be visited for selection of potential sites for NORPLANT service delivery. It is estimated that at least 2 and a maximum of 4 Ob/Gyn specialists will be trained in each site. The maximum number of participants is therefore 132 specialists (33 sites by 4 specialists) since the specialists in the 5 Universities were already trained during the clinical trial. These 132 specialists may be trained in 13 courses, each course will cost around L.E.6,000. The subtotal costs of training Ob/Gyn specialists in the first phase will be then L.E.78,000. The training of nurses will require 6 courses (2 nurses per site, total 66 nurses divided on 6 courses) and the same of number of courses for social workers (2 per site). The subtotal cost of training nurses and social workers will then be L.E.72,000. The total training costs will then be L.E.150,000.

5. In the second phase, there will be an additional 170 sites introduced. If only 132 sites are selected in this phase for service delivery, this will constitute 4 times the capacity in the first phase. That means we need to conduct 52 courses for Ob/Gyn specialists and 48 courses for nurses and social workers in 18 training centers (4 THO and 14 University Hospitals). Therefore the estimated budget for training service providers on NORPLANT in phase II will be L.E.600,000

6. In phase III, it is projected that the estimated number of selected sites will be 396 sites, therefore the estimated budget for training will be L.E.1,800,000.

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7. A major constraint in accomplishing this training plan is the client flow in the training centers which will permit the participants to be adequately trained. Even with adequate clients coming for implanting the capsules, it seems that removals will be problematic. An entire training course may be conducted without a single case coming for removal. Therefore, flexibility may be allowed to conduct training courses with less than ten participants particularly in the first year.

8. It is important to note that a minimum number of clients should be served and flowing in any particular site before certifying this site for training. If the potential trainers did not serve an adequate number of clients and became skillful they will not be able to provide training on this skill. The implication is that the potential number of training sites may become less than what was assumed.

APPENDIX 3.

Estimated NORPLANT® Insertions during the Introductory Period

1) 20 sites x 40 clients/mo x 48 months of service = 38,400

2) 15 sites x 30 clients/mo x 36 months of service = 16,200

3) 35 sites x 30 clients/mo x 30 months of service = 31,500

4) 35 sites x 20 clients/mo x 24 months of service = 16,800

5) 85 sites x 15 clients/mo x 24 months of service = 30,600

6). 85 sites x 10 clients/mo x 12 months of service = 10,200

TOTAL = 143,700

Lines 1 and 2 represent the category 1 facilities targeted for NORPLANT® introduction and the number of years that services might be available.

Lines 3 and 4 represent approximately 50% of the category 2 facilities and reflect the number of years that services are expected to be available.

Lines 5 and 6 represent approximately 50% of category 3 facilities and reflect the number of years that services are expected to be available.

Assuming this level of service, NORPLANT® could account for approximately 2.6% of total contraceptive prevalence in 1999 through the public sector alone.

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IPPF *Medical Bulletin*

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Progestagen implants

Horacio B Croxatto

Norplant, introduced in the 1980s, was the first contraceptive implant that became available to family planning programmes.

Despite the menstrual bleeding disturbances intrinsic to all progestagen-only methods, it proved highly acceptable to many women. Progestagen implants for female contraception are currently growing into a family of options. So far, four different progestagens and two polymers have been used to design six different implants. These are listed in table 1 and a description of each of them follows: box 1 shows their availability.

Devices

Levonorgestrel releasing implants

The two levonorgestrel (LNG) releasing implants, Norplant and Jadelle, both developed by the Population Council, share many features and are almost identical in clinical performance;[1] therefore I describe them together. Norplant consists of six Silastic capsules whereas Jadelle consists of two Silastic rods. The implants do not exceed 4 cm in length and 2 mm in diameter and all are inserted subdermally under local anaesthesia by means of a trocar. The preferred site is the inner aspect of the non-dominant arm, but other locations such as the abdomen or the gluteal region have been used. Immediately after insertion they begin to release LNG continuously, at a rate that drops slowly and progressively over the months and years. In the case of Norplant, release rates at the first, ninth, and sixtieth months of use are 85, 50, and 30 µg/day. At sixty months, which is the recommended duration of use, 69% of the original steroid load remains in the capsules and this provides a safety margin for women who do not return promptly to renovate their contraceptive method. All progestagen implants have this safety feature. In the case of Norplant, contraceptive serum levels of LNG are sustained for eight years with the same set of capsules.

TABLE 1: PROGESTAGEN IMPLANTS

Progestagen	Trade name	Unit	Duration of action
Levonorgestrel	Norplant	Six capsules	5 yr
Levonorgestrel	Jadelle	Two rods	5 yr
Etonogestrel	Implanon	Single rod	3 yr
Nestorone	Elcometrine	Single capsule	6 mo
Nestorone	—	Single rod	2 yr
Nomegestrol acetate	Uniplant or Surplant	Single rod	1 yr

BOX 1: CURRENT AND NEAR FUTURE AVAILABILITY OF PROGESTAGEN IMPLANTS

Norplant
Registered in 60 countries
Used by some 6 million women

Jadelle
Ongoing registration in Europe

Implanon
Registered in Australia, Indonesia, and 11 European countries
Introduced in The Netherlands and UK, September 1999

Elcometrine
Registered in Brazil

Jadelle was designed to achieve the same performance as Norplant with a smaller number of units so that insertion and removal would be easier. In three years of use, LNG serum levels with the two systems were almost identical.[2] Apart from ease of insertion and removal, Jadelle and Norplant differ very little in performance.

Table 2 shows cumulative termination rates for the two systems during the third year of use. The mean pregnancy rate of Norplant at five years, in over 5000 woman-years of exposure, was 1.14 (standard error 0.37). The same level of contraceptive effectiveness is expected for Jadelle. Table 3 compares typical first-year pregnancy and continuation rates for Norplant with those of other contraceptive methods. The excellent performance of Norplant in these terms, characteristic of progestagen implants, is due primarily to its ability to prevent fertilization. Levonorgestrel's strong anti-oestrogenic effect makes cervical mucus impenetrable to spermatozoa.[4,5] In addition, it disrupts the ovulatory process causing dysfunctions that range from anovulation to inadequate luteal phase.[4,6-9] The endometrial cycle is also disrupted.

TABLE 2: GROSS CUMULATIVE TERMINATION AND CONTINUATION RATES PER 100 DURING THE THIRD YEAR OF USE OF LEVONORGESTREL RELEASING IMPLANTS (DATA FROM REF 1)

Item	Two-rod system	Norplant
Pregnancy	0.0	0.0
Menstrual problems	11.3	12.3
Medical reasons	9.6	7.6
Planning pregnancy	7.7	7.9
Other personal	4.1	3.3
Continuations	70.6	71.1
% Lost to follow-up	2.7	2.7
No started year	484	493
No completed year	410	411

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The most prevalent adverse event associated with all progestagen implants, and the main reason for discontinuation of these methods, is alteration of normal menstrual function. This is most frequent and severe in the early phase of method use and tends to decrease with time. The reported changes range from amenorrhoea to frequent, irregular, heavy, or prolonged bleeding. The bleeding patterns reported for different progestagen implants vary, but not greatly; and the same is true of women's tolerance of the methods. The most troublesome changes are long episodes of bleeding and frequent irregular episodes of bleeding. Although many progestagen implant users report an increase in the total number of days of bleeding and spotting, their total blood loss is actually lower than their normal basal menstrual blood loss.[10] Consquently there is no increased risk of anaemia – indeed, with Norplant, rises in haemoglobin have been reported.[11] Symptoms such as headache, weight changes, acne, and nervousness ('medical reasons'), are the second most frequent reason for discontinuation.

BOX 2: MAIN ADVANTAGES AND DISADVANTAGES OF PROGESTAGEN IMPLANTS

Advantages	*Disadvantages*
Long-term unattended use	Dependence on trained health care personnel to initiate and end use
Independence of efficacy from compliance	Require minor surgical procedure for insertion and removal
High efficacy and reversibility	High prevalence of endometrial bleeding disturbances during use
Lower progestagen dose than pills and injectables	High cost of the method in early discontinuations
Stability of progestagen blood levels	
Decreased total blood loss compared with spontaneous menses	
Lack of exogenous oestrogen	

By and large, the adverse events recorded during use of progestagen implants do not put women's health at risk. The Norplant post-marketing surveillance study coordinated by the World Health Organization enrolled nearly eight thousand Norplant beginners in eight countries. The comparison groups were similar numbers of women who had an intrauterine device inserted or were sterilised. In nearly 40 000 woman-years of exposure (mean duration 4.16 years) Norplant proved to be highly effective and safe (S Díaz, personal communication).

Implanon

This single implant system was developed by NV Organon, Oss, The Netherlands. It comes preloaded in a disposable applicator and is easy to insert and remove. Mean serum concentrations of etonogestrel provided by this implant start at about 450 pg/mL and decrease steadily to 200 pg/mL at the end of three years.[12] Implanon works by inhibiting ovulation – an effect seen in nearly 100% of cycles.[13] Its contraceptive effectiveness is outstanding in that not a single pregnancy has been observed in over 5000 woman-years of exposure.

TABLE 3: TYPICAL FIRST YEAR PREGNANCY AND CONTINUATION RATES FOR VARIOUS METHODS (DATA FROM REF 3)

Method	Accidental pregnancy %	Continuation %
Condom	12.0	63
Pill	3.0	72
Copper T380	0.8	78
Norplant	<0.1	85
Female sterilisation	0.4	99

Nestorone implant systems

The progestagen Nestorone, previously known as ST1435, is 16-methylene-17-alpha-acetoxy-19-norprogesterone. Dose-finding studies have been conducted with implants releasing 45-50 µg/day[14] and further studies are being conducted with implants releasing up to 150 µg/day. Serum levels of Nestorone for the implant releasing 150 µg/d start at 160 pmol/L and decrease steadily to reach 80 pmol/L at 24 months. Studies have been done in breastfeeding and non-breastfeeding women.

Nearly 4000 woman-months of exposure have been accumulated in non-breastfeeding women, during which only one pregnancy occurred (in a woman receiving one of the lower doses). The data suggest that a single implant releasing 150 µg/day of Nestorone will provide high contraceptive efficacy for two years with a margin of safety of half a year. A Nestorone implant has great potential for fertility regulation in breastfeeding women since this steroid is inactive by the oral route; thus, any of it transferred into breast milk should not affect the baby.

A single Silastic capsule containing Nestorone with an active life of six months has been introduced in Brazil under the trade name Elcometrine for the treatment of endometriosis.[15]

Uniplant

Uniplant, delivering nomegestrol acetate, was developed as a single one-year contraceptive implant but the company holding the progestagen patent has deferred plans to make it available.

Counselling

Counselling, a key element of quality care in family planning, is of paramount importance for progestagen implants[16] because starting and stopping are not under the user's control, requring minor surgical procedures; also, early removal is undesirable because of the high initial cost. Preinsertion counselling should address all advantages and disadvantages of the method, including the adverse events to be expected, with particular emphasis on bleeding disturbances. Before reaching a decision, the client should consider the relative merits of implants and other contraceptive choices available, in relation to lifestyle and health issues.

Postinsertion counselling may also be necessary. Women often need to be reassured about adverse events, and support is also needed when bleeding or other disturbances approach the limit of tolerability. The training of health providers should not stop at competent insertion and removal; development of their communication and counselling skills will greatly improve the self-selection of users who will be satisfied with progestagen implants.

Box 2 summarises the main advantages and disadvantages of progestagen implants for female contraception.

The future

The world-wide decline in family size will increase the demand for long-term contraceptive methods in the next millenium, since a couple aiming to have only two children will need long periods of fertility regulation. The main challenge in relation to progestagen implants is to find a transient adjunct therapy that alleviates bleeding disturbances when they reach the limit of tolerability. Since the most bothersome changes take place initially and are transitory, many users would be saved from discontinuing the method if, in addition to counselling, effective medical help could be offered. Other challenges include the application of implant technology to long-term male contraception, hormone replacement therapy, and treatment of gynaecological ailments including cancer.

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Owing to difficulties of space, we are unable to publish the list of references referring to this article. However, any reader interested in receiving the list should either write to the IPPF Medical Bulletin, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, UK, or send an e-mail to rmcglone@ippf.org

Highlights of IMAP meeting, December 1999

Below are highlights of selected discussion topics at the International Medical Advisory Panel (IMAP) meeting, 5–7 December 1999

The non-latex condom

Male condoms made from synthetic materials offer an alternative to latex condoms. Potential advantages are that they maintain structural integrity longer under a broad range of storage conditions. They can be used with various types of lubricants and may be an option for individuals who have allergies or sensitivities to latex. IMAP reviewed the results of a number of studies on the safety, functionality, and acceptability of condoms made of polyurethane in order to determine whether they should be included on the IPPF commodities list. The studies showed no clear advantages in terms of efficacy, and breakage and slippage rates were similar to or higher than those of the latex condom. The polyurethane condom is claimed to offer greater sensitivity, but overall acceptability and client satisfaction require further studies. After discussing the studies and taking into account the high cost of the non-latex condom, the Panel decided that for the time being it should not be included on the IPPF commodities list.

Male circumcision

IMAP had, at its previous meeting, made comments and recommendations on male circumcision in response to a referral by the South Asia Region. At that time the Panel were aware of, and had considered, the possibility of a relationship between HIV transmission rates and male circumcision when making their response. Since then, an article published in the Viewpoint section of the *Lancet* (*Lancet* 1999; 354: 1813–15) discussing this relationship had been published and was presented for comments to the Panel by an FPA from the South Asia Region. The article highlighted the results of studies from 8 countries that found a significant association between the lack of male circumcision and HIV infection. The authors argued that the dramatic discrepancies in regional HIV infection rates can be explained partly by differences in the prevalence of circumcision. IMAP reviewed the article and noted that some conflicting data on the issue had not been included. They agreed to liaise with UNAIDS and WHO in reviewing all the existing research on the links between transmission of HIV and male circumcision and to report back to the FPAs. At present IMAP maintains its view that routine circumcision is not medically justified.

Evaluation of IPPF medical and technical function

Sponsored by IPPF and the US Agency for International Development (USAID), the Centre for Population Studies at the London School of Hygiene and Tropical Medicine has evaluated the role and work of the Medical and Technical Unit in Central Office and IMAP. The assessment included: (a) the needs of FPAs with regard to medical and technical expertise, guidance, information, and training; (b) the contributions of IPPF in meeting these needs; and (c) the contribution of IPPF to the work of other international and national organisations.

The results of the evaluation highlighted that IMAP is a valued institution within and beyond IPPF. Its contribution to sexual and reproductive health advocacy at international and national levels is strong and valuable. The Panel represents an independent opinion and produces recommendations based on scientific evidence. The work of the Medical and Technical Unit is also highly valued and expert reviewers commented that the technical content of the various medical publications of IPPF were of high quality and internationally respected.

IMAP reviewed and commented on the conclusions and recommendations of the evaluation. The Medical and Technical Unit is developing a plan of action based on the recommendations.

International Medical Advisory Panel

The International Medical Advisory Panel (IMAP) is a body of medical scientists and technical experts with a mandate to formulate and disseminate recommendations to IPPF and other interested parties regarding best practices in sexual and reproductive health care and family planning. These recommendations address relevant programmatic, training, and service delivery issues.

The expertise of IMAP members includes contraceptive technology, obstetrics and gynaecology, endocrinology, public health, epidemiology, and family planning programme management. Many are clinical practitioners and distinguished academics; some bring invaluable experience from international research and development agencies. Members are drawn from all parts of the world, and a system of rotational membership ensures regular infusions of varied experience and expertise. Panel experts have access to the latest research findings on contraceptive safety and efficacy, both published and unpublished, so that the Panel's advice is based on the best possible evidence.

The Medical and Technical Unit of the IPPF acts as secretariat to IMAP, which usually meets twice a year. In

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SDP,POP&FP Sector

Norplant Program

Transaction Report Revels Movement of Product Norplant From 94 - Jan2000

YEAR	Beginning Stock	Receipt	Loss \ Adju.	Transfer (—)	Distributed				BALANCE ON HAND
					THO	UNIV.	RCT	MOHP	
1994	0	2500	10	0	0	0	0	0	2490
1995	2490	4200	30	0	150	1500	0	0	5010
1996	5010	2500	6	5010	1050	700	600	0	144
1997	144	6500	20	0	2105	3450	0	520	549
1998	549	15300	30	0	1295	3699	0	1950	8875
1999	8875	9000	20	0	1500	2500	0	11855	2000
Jan-00	2000	0	0	0	0	100	0	1440	460
TOTAL	0	40000	116	5010	6100	11949	600	15765	460

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المحافظة	عدد مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الوادى الجديد	٢	٩	٩	٦	١٠
بنى سويف	٩	١٢	١٣	٥	١٥
القاهرة	١٠	٢٦	٤	١٢	١
القليوبية	٧	١٥	٢٥	٨	٣٠
السويس	٦	٧	٨	٧	١٠
قنا	١١	١٩	٩	٧	١٦
كفر الشيخ	٢٠	١٤	١٠	٨	١٣
الجيزة	١٠	١٢	٢	٨	٢
سوهاج	١٥	١٩	٤٥	٩	٤٩
الشرقية	١٧	١٦	١٨	١٠	٢٠
البحيرة	٢٠	٢٢	٦	١٥	٩
دمياط	٩	١٥	١٧	٥	١٠
المنوفية	١٠	١١	٢١	٧	١٩
الغربية	٩	١٥	٤	١٥	٤
الاقصر	١١	٤		٤	
المنيا	٦	١١	١٣	١٢	١٤
اسيوط	١٥	٢٦	١٨	٢١	٢٧
جنوب سيناء	٤	٧	٥	٥	٦
الدقهلية	١٦	١٩	٢	١٤	٤
بور سعيد	٢٣	٣٠	٣١	٢٣	٢٦
الاسكندرية	١٨	١٦	١٧	٧	٢٣
الاسماعيلية	٩	٩	٦	٢	٨
البحر الاحمر	٥	٨	٠	٥	٠
مطروح	١١	٦	٢٨	٢	٣٠
المجموع	٢٧٣	٣٤٨	٣١١	٢١٣	٣٤٦

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمه النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
القاهرة	منطقة مصر الجديدة الـ	مستشفى البكرى العام	٥		١	
	منطقة السيدة الطبية	مشتشفى المنيرة العام	١	٢	١	
	منطقة حلوان الطبية	مستشفى حلوان العام	٣		١	
	منطقة المطرية الطبية	مركز طبى المطرية	١	١	١	١
	منطقة شبرا الطبية	مستشفى شبرى العام	٤		٢	
	منطقة السلام الطبية	العيادة المتنقة	٦		٢	
	منطقة المرج الطبية	العيادة المتنقة	١	١	٢	
	منطقة الزاوية	مستشفى الزاوية العام	٢		١	
	منطقة مضر القديمة	مستشفى دار السلام العام	١			
	منطقة الخليفة	مستشفى الخليفة الطبية	٢		١	
المجوع			٢٦	٤	١٢	١

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الدقهلية	المنصورة	م المنصورة العام	٢		١	
	لجا	م اجا المركزى	١		١	
	ميت غمر	م ميت غمر	١		١	
	السنبلاوين	م السنبلاوين	١		١	
	تماى الامديد	م تماى الامديد	١		١	
	ديكرنس	م ديكرنس	٢		١	
	بنى عبيد	م بنى عبيد	١	١		٢
	منى النصر	م منى النصر	١		١	
	المنزلة	م المنزلة المركزى	١		١	
	الجمالية	م الجمالية	١		١	
	سلسيل	م سلسيل	٢	١		٢
	المطرية	م المطرية	١		١	
	شربين	م شربين	١		١	
	بلقاس	م بلقاس	١		١	
	طلخا	م طلخا	١		١	
	نبروة	م نبروة	١		١	
المجوع			١٩	٢	١٤	٤

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
بور سعيد	بورسعيد	م النصر العام	٩		٢	١
	بورسعيد	م بور سعيد العام	٥		٢	١
	بورسعيد	م بورفؤاد العام	٣	١	٢	١
	بورسعيد	م الحميات	١	١		٢
	بورسعيد	م الرمد		١		٢
	بورسعيد	م المتوطنمة		١		٢
	بورسعيد	رعاية طفل بور فؤاد	١	٢	٢	
	بورسعيد	رعاية طفل العرب	١	٢	١	١
	بورسعيد	رعاية طفل المناج	١	٢	٣	
	بورسعيد	مركز طبى الكويت	٢	٢	٢	١
	بورسعيد	مركز طبى القباطى	٢	٢	٢	١
	بورسعيد	مركز طبى العرب		١	١	١
	بورسعيد	مركز طبى عمر بن الخطا	١	١	١	١
	بورسعيد	مركز طبى الزهور	٢		٢	١
	بورسعيد	مكتب صحة اول	١	١		٢
	بورسعيد	مكتب صحة رابع				٢
	بورسعيد	مكتب صحة بور فؤاد	١	٢		٢
	بورسعيد	عيادة متنقلة١		٢		١
	بورسعيد	عيادة متنقلة٢		٢	٣	
	بورسعيد	عيادة متنقلة٣		٢		١
	بورسعيد	عيادة متنقلة٤		٢		١
	بورسعيد	عيادة متنقلة٥		٢		١
	بورسعيد	عيادة متنقلة٦		٢		١
المجوع			٣٠	٣١	٢٣	٢٦

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الاسكندرية	المنتزهة	ابو قير البحرى	١	١		٢
	الجمرك	مكتب صحة الجمرك	١		١	
	شرق	رعاية الطفل		٢		٢
	شرق	مركز دنا		٢		٢
	شرق	مركز طبى سموحة	٢			٢
	شرق	مركزى طبى باكوس	٢	١		٢
	شرق	م اطفال الرمل	١	٢		٢
	شرق	مكتب صحة النواتير	١	٢		٢
	العامرية	رعاية طفل العامرية	٢		٢	
	العامرية	الدخيلة	٢		٢	
	العامرية	الانوقيل		٢		٣
	وسط	رعاية طفل محرم بك		٣		٣
	وسط	رعاية طفل الحضرة		١	١	١
	برج العرب	م برج العرب	١			
	الاسكندرية	م الشاطبى	١			
	الاسكندرية		١			
	الاسكندرية		١			
	وسط	مكتب صحة انبروزو		١	١	٢
المجوع			١٦	١٧	٧	٢٣

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الاسماعيلية	الاسماعيلية	م العام	١	٣		١
	الاسماعيلية	العيادة المتنقلة		١		١
	التل الكبير	م القصاصين	١		١	١
	التل الكبير	م التل الكبير	٢			١
	التل الكبير	عيادة متنقلة		١		
	فايد	م فايد	١			١
	فايد	ابو سلطان	١			١
	القنطرة غرب	م القنطرة غرب	٣		١	١
	القنطرة غرب	عيادة متنقلة		١		١
المجوع			٩	٦	٢	٨

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
مطروح	مطروح	م النساء والوليد			١	
		م العام	١	٢	١	
		المركز الطبي الحضرى		٤		٤
		رعاية الطفل	١	٢	١	٣
	الضبعة	م الضبعة	١	٢		٣
	برانى	م برانى	١	٢		٤
	الحمام	م الحمام		٢		٢
		م البنجر	١	٢		٢
	سيوه	م سيوة		٢		٢
	النجيلة	م التكامل		٤		٤
	العلمين	صحة المراة بعبد الرحمن		٢		٢
المجوع			٥	٢٤	٣	٢٦

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
البحر الاحمر		م الغردقة	٣		١	
		م سفاجة	٢		١	
		م راس غارب	١		١	
		م القصر	١		١	
		رعاية الغردقة	١		١	
المجوع			٨	٠	٥	٠

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
جنوب سيناء	الطور الصحية	م الطور العام	٣	١	٢	٢
	راس سدر	العيادة المتنقلة	١	٢	١	٢
	مرم الشيخ	العيادة المتنقلة بدهب	٢	٢	٢	٢
	جنوب سيناء		١			
المجوع			٧	٥	٥	٦

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
اسيوط	اسيوط غرب	م اسيوط العام	١	٣	٢	٢
	اسيوط غرب	م النساء والتوليط	٤		٣	١
	اسيوط غرب	م الايمان العام	٢	١	٢	٢
	ديروط	م ديروط المركزى	٢	٣	٤	
	القوسية	م القوصية المركزى	٣	١	١	٢
	منفلوط	م منفلوط المركزى	١	١	١	٢
	ابو تيج	م ابو تيج المركزى	٣		١	٢
	صدفة	م صدفة المركزى	٢	١		٢
	ابنوب	م ابنوب المركزى	٢		٢	٢
	البدارى	م البدارى المركزى	٣		٣	١
	الغنايم	م الغنايم المركزى	١	٢		٢
	ساحل سليم	م ساحل سليم المركزى		٢	١	١
		العيادات المتنقلة		٤		٨
		م التكامل	١			
		العيادة المتنقلة	١		١	
المجوع			٢٦	١٨	٢١	٢٧

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
المنيا	العدو	م المركزى	٢		٢	١
	غاغة	م المركزى	١	١	٢	
	بنى مزار	م المركزى	١	١	١	١
	مطاى	م المركزى	١	١	١	١
	سملوط	م المركزى		٢		٢
	ابو قرقاص	م المركزى		٢		٢
	ملوى	م المركزى	٢		٢	
	ديرمواس	م المركزى		٢		٢
	المنيا	م العام	٤	٢	٢	٣
	المنيا	مركز سوزان مبارك		١	١	١
	المنيا	المركز الطبى الشرقى		١	١	١
المجوع			١١	١٣	١٢	١٤

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الاقصر	الاقصر	الشيخ ~~مرسى موسى~~	١		١	
	الاقصر	م الاقصر العام	٢		٣	
	البياضية	م البياطية	١			
	البياضية	م الضبعة				
	البياضية	م العدسيات				
	~~الإجمالي~~		~~٤~~		~~٤~~	
المجموع			٤	٠	٤	٠

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الغربية	طنطا	م المنشاوى العام	٥		٤	
	طنطا	مركز طبى سيجر	١	١	١	١
	المحلة الكبرى	م المحلة العام	١		٢	
	السنطة	م السنطة المركزى	٢		٢	
	كفر الزيات	م كفر الزيات	٢		٢	
	بسيون	م بسيون المركزى	١	١	١	١
	زفى	م رفى العام	١	١	٢	١
	سمنود	م سمنود	٢		١	
	قطور	م قطور		١		١
المجوع			١٥	٤	١٥	٤

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
المنوفية	شبين الكوم	مركز صحى	٣	٢	١	٢
	قميسنا	م المركزى	٢	٢	١	١
	بركة السبع	م المركزى	١	٢	١	٢
	تلا	م المركزى	١	٢	١	٢
	اشمون	م المركزى	١	٣	١	٣
	منوف	م المركزى	١	٢	٢	١
	السادات	م المركزى	١	٢		٢
	الباجور	م المركزى	١	٢		٢
	الشهداء	م المركزى		٢		٢
	سرس الليان	م المركزى		٢		٢
المجوع			١١	٢١	٧	١٩

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
دمياط	دمياط	حى اول	٤	١	٣	٢
	دمياط	حي ثالث	١	١		٢
	دمياط	المنتزه	١			١
	دمياط	م التكامل بالسنانية		٢		١
	دمياط	م التكامل بالخياطية	١	٢		٢
	دمياط	المركز الحضرى بدمياط		٣		١
	دمياط	م دمياط العام	٦	٨	٢	١
		الزرقا	١			
		فارسكول	١			
المجوع			١٥	١٧	٥	١٠

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
البحيرة	دمنهور	رعاية الهلال	١		٢	
	دمنهور	دنشال التكامل	١		١	
	ايتاى البارودى	م المركزى	٢		١	
	كفر الدوار	العيادة الشاملة	١		١	
	كفر الدوار	م كفر الدوار	١		١	
	المحمودية	م المحمودية	١		١	
	المحمودية	رعاية المحمودية	١		١	
	الرحمانية	م الرحمانية	١	١	١	
	الدلنجات	م الدلنجات	٢		١	
	ابو المطامير	م ابو المطامير	١	١	١	
	حوش على	م حوش عيس	١		١	
	كوم حمادة	م كوم حمادة	٢			١
	التحرير	م التحرير	٢			١
	شراخيت	م شراخيت	١		١	
	ابو حمص	م ابو حمص	١			١
	وادى النطروان	م وادى النطرون	١		١	١
	رشيد	م رشيد	١		١	
	ادكو	م ادكو	١			١
	المحمودية	العيادة المتنقلة		٢		٢
	المديرية	العيادة المتنقلة		٢		٢
المجوع			٢٢	٦	١٥	٩

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الشرقية	الزقازيق	المستشفى العام			١	٢
	الزقازيق	عيادة حى الاشارة	١	١		١
	الزقازيق	مشستشفى بردين	١	١		
	الزقازيق	مستشفى القنايات		١	١	١
	منيا القمح	مستشفى ميناالفتح	١	١		١
	ابوحماد	مستشفى ابوحماد	٢	١	١	١
	كفر صقر	مركز طبى كفر صقر	٢	١		٢
	ابوكبير	مستشفى ابو كبير	٢	١	١	١
	فاقوس	رعاية الطفل	١	١	١	
	فاقوس	مسبشفى فاقوس	١	١		٢
	بلبيس	مستشفى بلبيس	١	١	١	١
	بلبيس	مركز طبى بلبيس		١	١	
	بلبيس	رعاية طفل	١			١
	ههيا		١	١	١	١
	مشتول السوق	مستشفى مشتول	١	١	١	١
	ديرب نجم	مستشفى ديرب نجم	١	١	١	١
	الحسينية	مستشفى الحسينية		٢		٢
	الابراهيمية	مستشفى الابراهيمية		٢		٢
المجوع			١٦	١٨	١٠	٢٠

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
سوهاج	سوهاج	م سوهاج العام	٧		٣	٢
	سوهاج	رعاية طف سوهاج		٤	١	٣
	سوهاج	المركز الطبى بسوهاج	٢	٢	١	٣
	طما	م طما العام	٣	٢	١	
	طما	رعاية طفل طما	١	٣		٤
	دار السلام	م دار السلام	٢	٢	١	٤
	المنشاه	رعاية طفل المنشاة	١	٣	١	٣
	جرجا	م جرجا المركزى	١	٣		٣
	جرجا	رعايةطف جرجا	١	٣		٤
	جهينة	م جهينة	١	٣	١	٤
	المراغة	م المراغة		٤		٣
	طهطا	م طهطا		٤		٤
	البلينا	م البلينا		٤		٤
	اخميم	م اخميم		٤		٤
	ساقلتة	م ساقلتة		٤		٤
المجوع			١٩	٤٥	٩	٤٩

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الجيزة	البدرشين	م البدرشين المركزى	١		١	
	الصف	م الصف المركزى	١		١	
	العجوزة	م امبابة العام	٢			١
	اطفيح	م اطفيح	١		١	
	الحومدية	م الحومدية	١	١	١	
	جنوب	م ام المصرين	٢		١	
	العياط	م العياط	٢		١	
	الهرم	م ٦ اكتوبر		١		١
	اوسيم	م اوسيم	١		١	
	شمال	م التحرير العام	١		١	
المجوع			١٢	٢	٨	٢

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
كفر الشيخ	كفر شكر	م كفر الشيخ العام	٢		١	
	كفر شكر	المركز الطبى العام		١		١
	كفر شكر	مستشفى التكامل سيدى غازى		١		١
	كفر شكر	مستشفى التكامل باريمون	١			١
	دسوق	مستشفى دسوق المركزى	١	١	١	
	دسوق	م شباس الشهداء التكامل		١		١
	بلطيم	مستشفى بلطيم المركزى	١		١	
	بلطيم	التكامل برج البرنس	١		١	
	سيدى سالم	سيدى سالم المركزى	١		١	
	سيدى سالم	التكامل ابابو غنيمة		١		١
	سيدى سالم	رعاية طفل سيدى سالم		١		١
	الرياض	م الرياض المركزى	١		١	
	الرياض	المركز الطبى بالريض		١		١
	بيلا	م بيلا المركزى	١		١	
	بيلا	التكامل بالجرايدة	١			١
	قلين	م قلين المركزى	١			١
	الحامول	الحامول المركزى	١	١		٢
	فوة	رعاية طفل فوة	١		١	
	فوة	مستشفى فوى العام	١	١		١
	مطوبس	مطوبس المركزى		١		١
المجوع			١٤	١٠	٨	١٣

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
قنا		مستشفى قنا العام	٥	١	٢	١
		المركز الريفى للمشروع الاروبى		١		٢
		م ابو تشب المركزى	٢	١		٢
		م فرشوط المركزى	١	١	١	١
		م نجع حمادى	٢	١	٢	
		م دشنا المركزى	١	١		٢
		م الوقف المركزى	١	١		٢
		م قوص المركزى	٢		١	١
		م نفادة المركزى	١	١		٢
		م ارمنت المركزى	٢			٢
		م اسنا المركزى	٢	١	١	١
المجوع			١٩	٩	٧	١٦

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
السويس	السويس	مستشفى السويس	٥		٥	
	عتاقة	مستشفى العبور	٢		١	٢
	الاربعين	مستشفى الصباح		٢	١	٢
	الجناين	مستشفى الشروق		٢		٢
	عيادة متنقلة	الجناين		٢		٢
	عيادة متنقلة	السويس		٢		٢
المجوع			٧	٨	٧	١٠

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
القليوبية	شبرى الخيمة	مستشفى النجا المركزى	٣	١	١	٣
	كفر شكر	مستشفى كفر شكر المركز	٢	٤	٢	٤
	الخانكة	التكامل الصحى بالقلج	١	٧		٨
	بنها	دار الولادة النموزجى	٢	١٢	٢	١٢
	طوخ	المستشفى المركزى	٥		٢	١
	قليوب	المستشفى المركزى	٢	١	١	٢
	القليوبية		١			
المجوع			١٥	٢٥	٨	٣٠

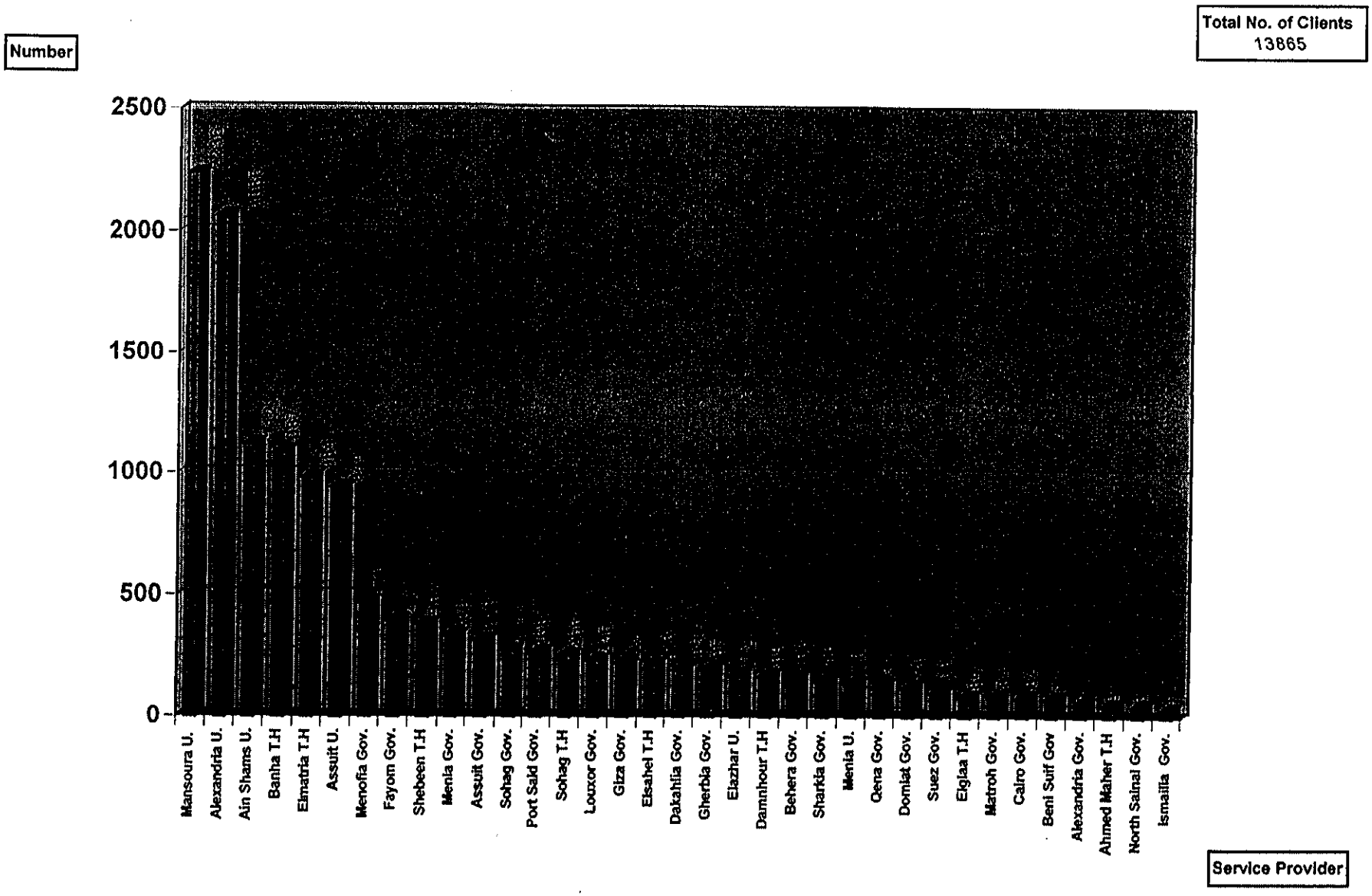
الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
بني سويف	بنى سويف	م .بنى سويف العام	٤		١	٣
		م .الوسطى المركزى	٢	١	١	١
		م .ناص المركزى	١	٢	١	١
		م. اهناسيا المركزى	١	٢		٢
		م. الفشن المركزى	٢	١	١	١
		م. سمطة المركزى	١	٢		٢
		م. ببا المركزى	١	١	١	١
		ع .م .٧٢١		٢		٢
		ع .م .٧٣٢		٢		٢
المجوع			١٢	١٣	٥	١٥

الموقف من التدريب على مستوى المحافظات ومراكز تقديم خدمة النور بلانت

المحافظة	الادارة	مركز تقديم الخدمة	ط .مدرب	ط .غير مدرب	م .مدربة	م .غير مدربة
الوادى الجديد	الخارجة		٧	٧	٤	٦
	الداخلة		٢	٢	٢	٤
المجوع			٩	٩	٦	١٠

Norplant Users Distributed According to Service Delivery Point
From 01 / 10 / 1995 To 31 / 12 / 1999



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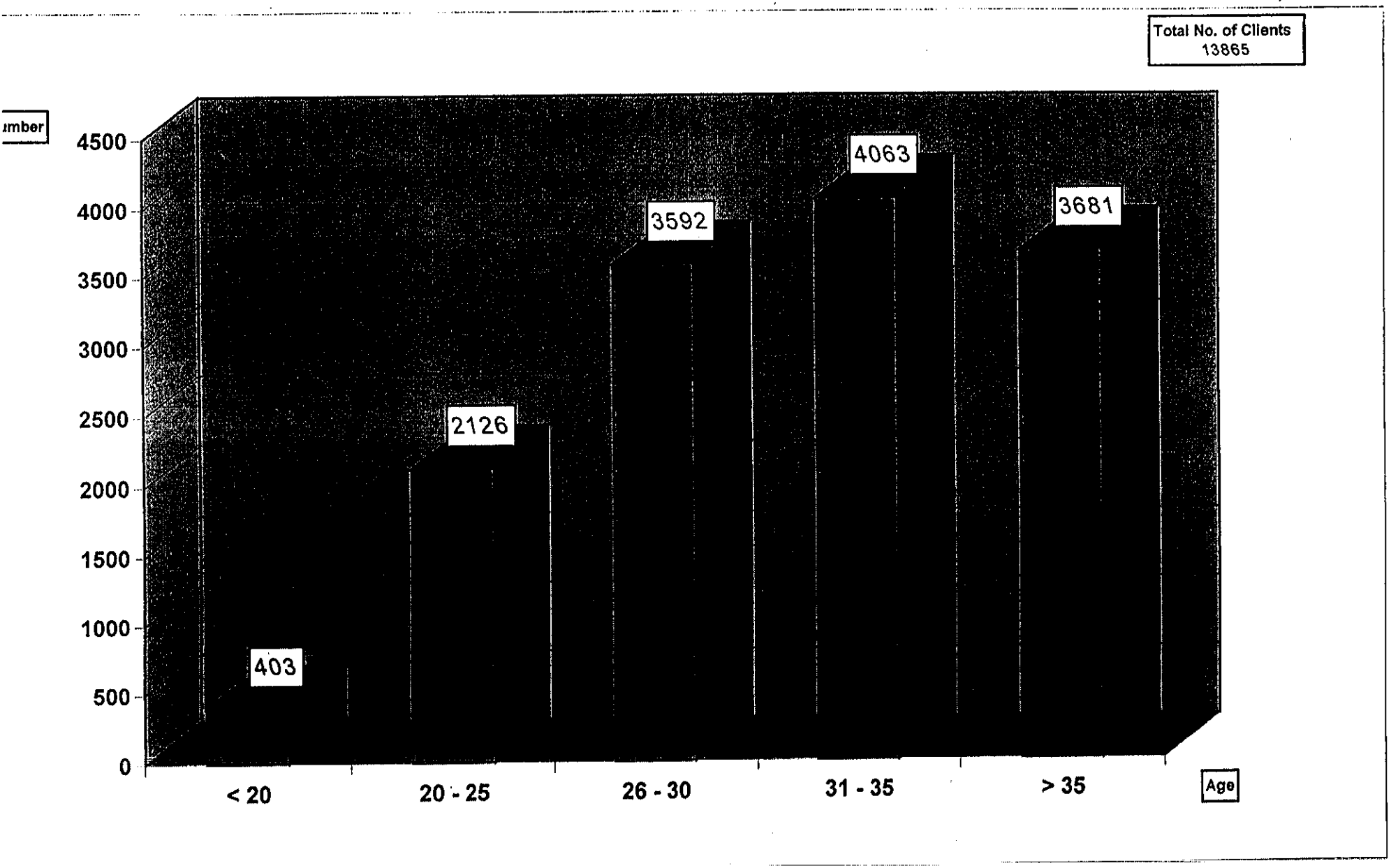
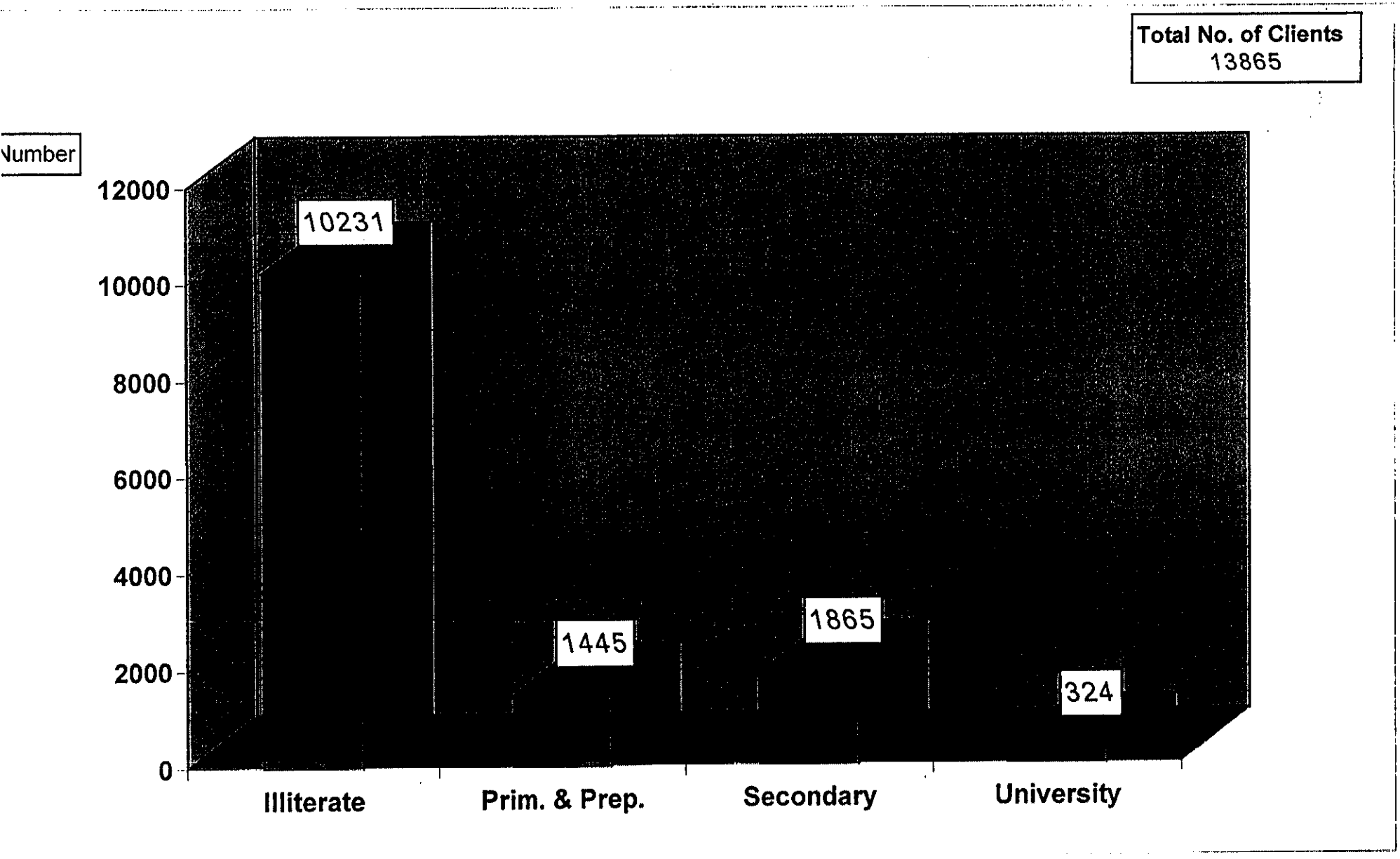
Norplant Users Distributed According to Age
From 1 / 10 / 1995 To 31 /12 / 1999



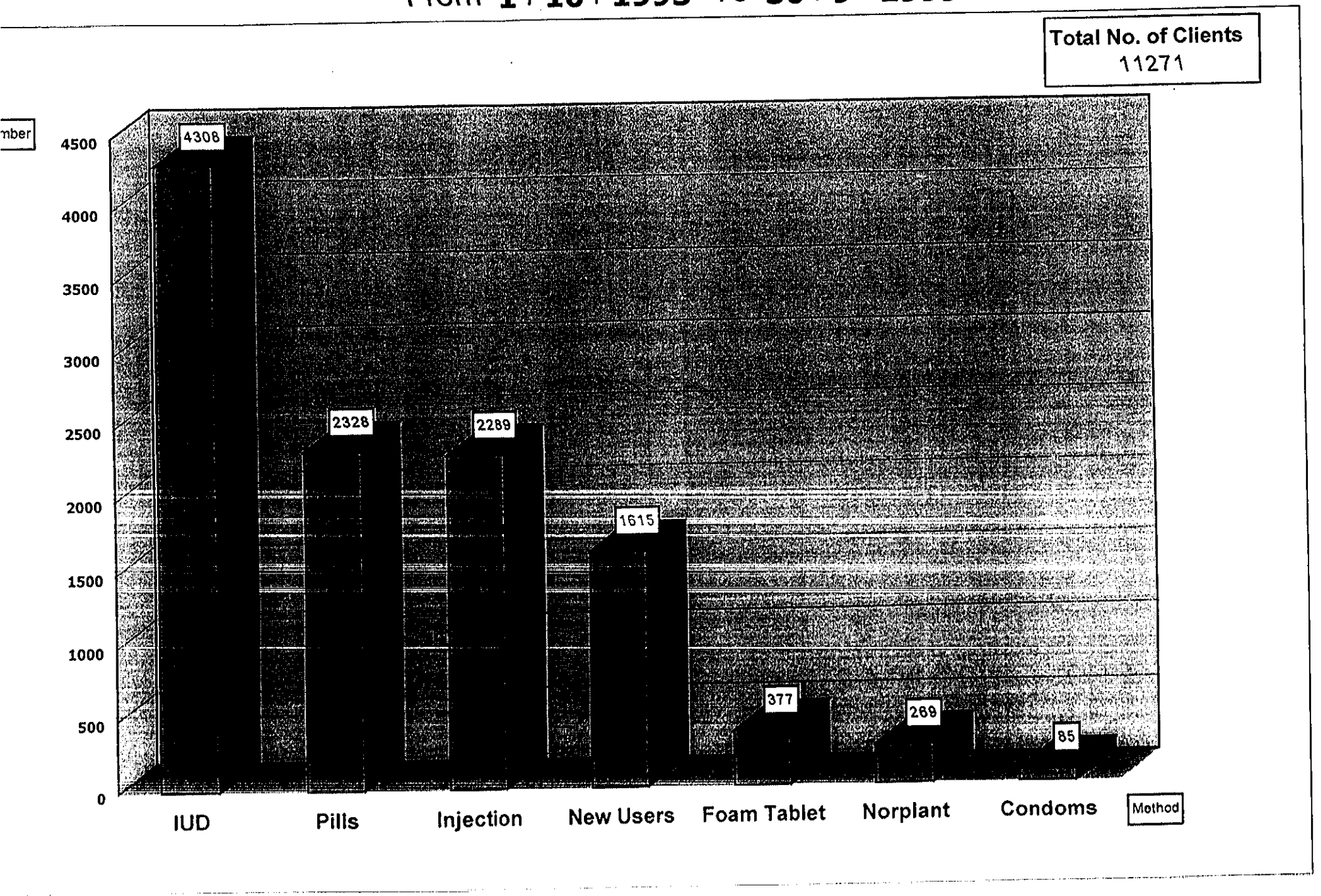
285

Norplant Users Distributed According to Education
From 1 / 10 / 1995 To 31 / 12 / 1999



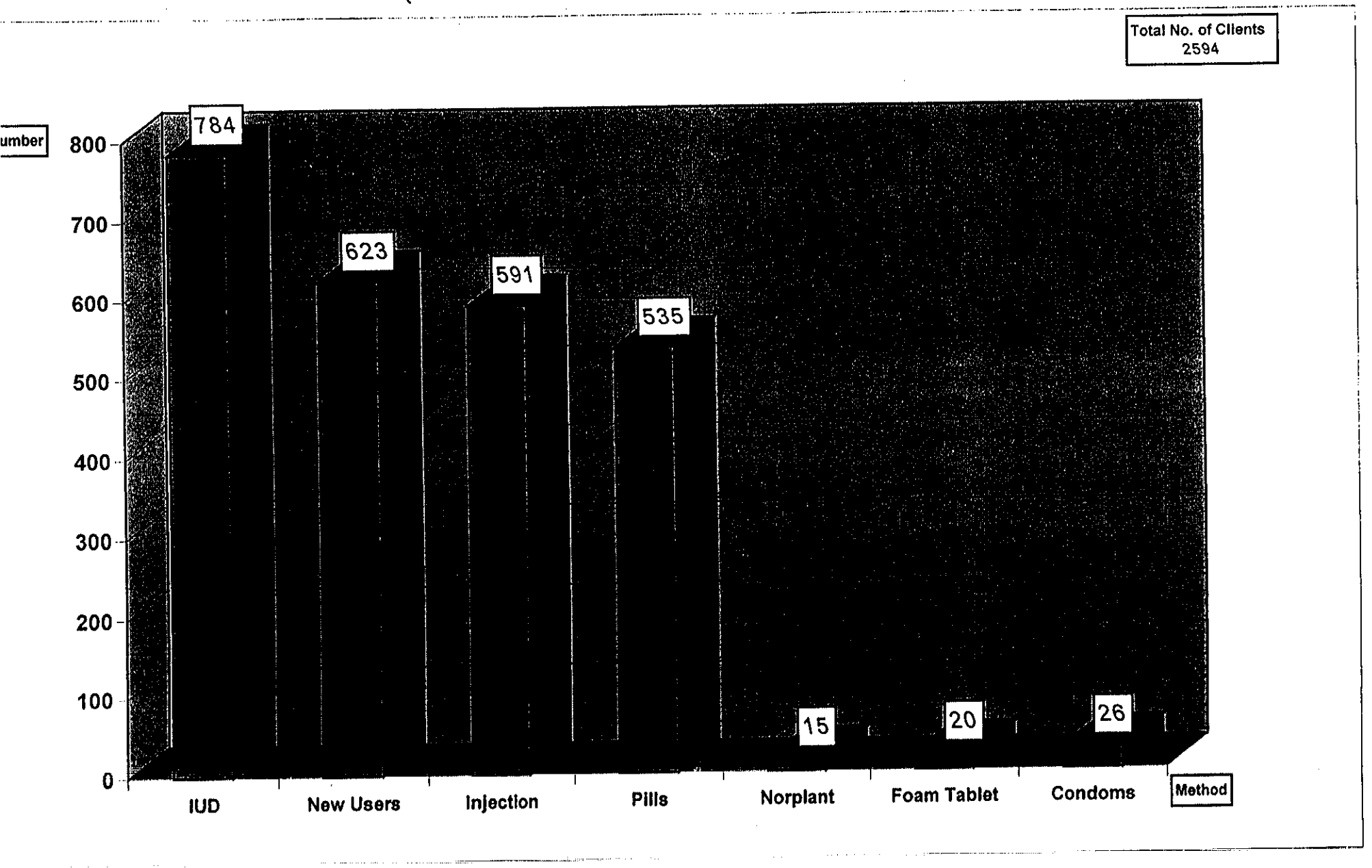
286

Norplant Users Distributed According to Last Method
From 1 / 10 / 1995 To 30 / 9 / 1999



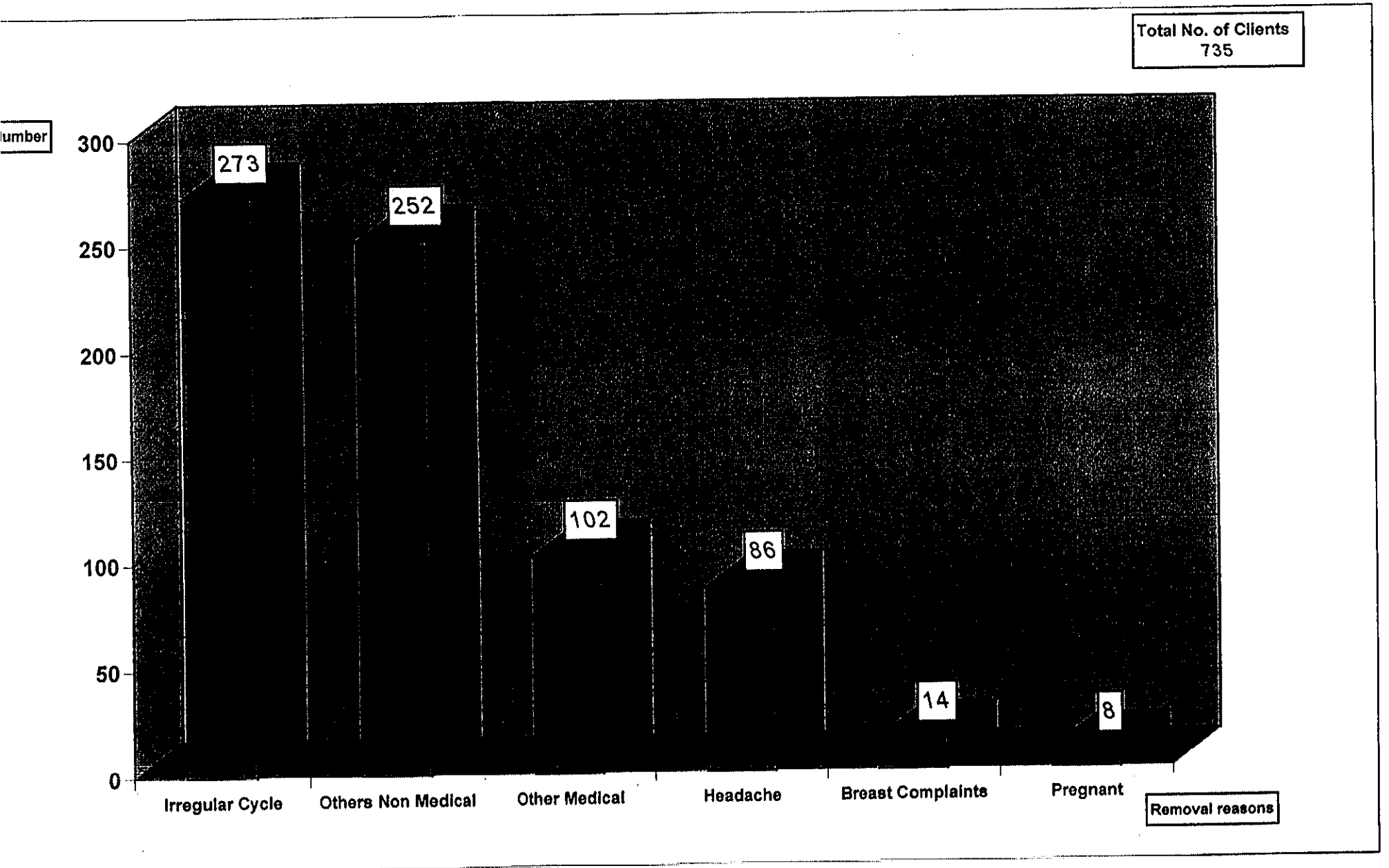
287

Norplant Users distributed According to Last Method
(From **1 / 10 / 1999** To **31 / 12 / 1999**)



288

Norplant Removal Distributed According to Reasons for Removal
From 1 / 10 / 1995 To 31 / 12 / 1999



2pp

اسم العيادة: ..... رقم ترخيص العيادة: .....

إسم الطبيب (ثلاثي): ..... رقم الطبيب للتوريدات: .....

اسم المنطقة (ثلاثي): ..... رقم المنطقة: ..... السن: .....

الحالة التعليمية: امية: ☐ ابتدائي/اعدادي: ☐ ثانوي: ☐ جامعي: ☐ عدد الأبناء .....

الحالة العملية: تعمل خارج المنزل نعم: ☐ لا: ☐

اسم الزوج (ثلاثي): ..... وظيفته: .....

عنوان المنطقة: ..... المدينة/القرية: .....

القسم / المركز: ..... المحافظة: .....

عنوان دائم لأحد الأقارب: ..... المدينة/القرية: .....

القسم / المركز: ..... المحافظة: .....

نتيجة اخر حمل: ولادة: ☐ اجهاض: ☐ تاريخ اليوم الاول لآخر دورة شهرية : ..../..../....

الوزن لأقرب كيلو: ..... كجم ضغط الدم: ..... رضاعة طبيعية: نعم: ☐ لا: ☐

هل سبق استخدام وسيلة منع حمل: نعم : ☐ لا: ☐ في حالة نعم: ماهي آخر وسيلة مستعملة لمنع الحمل:

حبوب منع الحمل فمية: ☐ لولب: ☐ حقن منع الحمل: ☐ اخرى: ☐

تاريخ زرع الكبسولات: ..../..../.... التاريخ المفروض لاستخراج الكبسولات: ..../..../....

مكان زرع الكبسولات: الذراع الايمن: ☐ الذراع الايسر: ☐

هل حدثت مضاعفات اثناء الزرع: نعم: ☐ لا: ☐

في حالة نعم: نزيف شديد: ☐ صعوبة في الزرع: ☐ فتحة كبيرة: ☐ مضاعفات اخرى: ☐

اسم القائم بكتابة البيانات (ثلاثي) (اذا لم يكن الطبيب المسئول):

.....

بطاقة استخراج كبسولات الذكريات

اسم العيادة: ..... رقم تركيب الكبسولات: .....

اسم الطبيب (ثلاثي): ..... رقم الطبيب للتوريدات: .....

اسم المنطقة (ثلاثي): ..... رقم المنطقة: .....

اسم الشارع التي بها الزرع: ..... رقم المنطقة في شارع الزرع: .....

اسباب استخراج الكبسولات:

اعطاء اثبات بالتوقيع الطبي: ☐ [illegible]: ☐ تكرار موعد بالعيادة: ☐

[illegible]: ☐ [illegible]: ☐ الرغبة في [illegible]: ☐

اسباب اخرى : .....

تاريخ استخراج الكبسولات: ..../.....

مضاعفات اثناء الاستخراج: لا يوجد: ☐ يوجد: ☐ في حالة يوجد:

نزيف خفيف: ☐ نزيف شديد: ☐ كسر الكبسولات: ☐ نقل موضع كبير: ☐

الالتهاب الى طرف خط عناية لاستخراج الكبسولات: ☐

تم استخراج جميع الكبسولات: نعم: ☐ لا: ☐ في حالة لا: عدد الكبسولات التي لم يتم استخراجها: ☐

الاستعداد لاستخراج باقي الكبسولات : ..../..../....

هل حالة تم لاستخراج وحيدة مع هل تم استخراج الكبسولات: نعم: ☐ لا: ☐

في حالة نعم: [illegible] مع هل فقط: ☐ لا يمكن: ☐ [illegible]: ☐ اخرى: ☐

اسم القائم بكتابة البيانات (ثلاثي) (اذا لم يكن الطبيب المسئول): .....

* يجب ارسال كارت استخراج مع هذه استخراج باقي الكبسولات

إرشادات وتوجيهات لاستعمال بطاقه

إستخراج كبسولات النوربلانت

١- يجب إرسال بطاقة استخراج الكبسولات الى المركز الرئيسى لمشروع تنمية النظم بوزارة الصحة فور الانتهاء من عملية إستخراج الكبسولات على العنوان التالى:

وزارة الصحة – مشروع تنمية النظم

د. حسن الجبالى – المدير التنفيذى للمشروع

شارع مجلس الشعب – القاهرة – جمهورية مصر العربية

٢- يتم الحصول على هذه البطاقات من المركز الرئيسى لمشروع تنمية النظم بوزارة الصحة

٣- الموعد المحدد لاستخراج باقى الكبسولات هو التاريخ المحدد لعودة المنتفعة لاستخراج باقى الكبسولات

٤- يجب ملء هذه البطاقه كامله لكل حالة استخراج كبسولات النوربلانت بالاضافة الى تسجيل عملية الاستخراج في استمارة المنتفعة المستخدمة في خدمات تنظيم الاسرة .

٥- يجب تسجيل اسم الطبيب القائم بإستخراج الكبسولات ورقم النوربلانت الممنوح له لتأدية خدمة النوربلانت وجميع البيانات الخاصة بالمنتفعة بدقة لضمان المتابعة الجيدة .

٦- رقم المنتفعة على البطاقه هو نفس الرقم المسجل فى بطاقة التعريف لمستعملة النوربلانت.

إرشادات وتوجيهات لاستعمال بطاقة التعريف

لمستعملة النوربلانت

١- يجب إرسال هذه البطاقات الى المركز الرئيسى لمشروع تنمية النظم بوزارة الصحة بمجرد الانتهاء من عملية إدراج الكبسولات فور الانتهاء من عملية الادراج على العنوان التالى :

وزارة الصحة – مشروع تنمية النظم

د. حسن الجبالى – المدير التنفيذى للمشروع

شارع مجلس الشعب – القاهرة – جمهورية مصر العربية

٢- يتم الحصول على هذه البطاقات من المركز الرئيسى لمشروع تنمية النظم بوزارة الصحة

٣- يجب ملء هذه البطاقه كاملة لكل مستعملة النوربلانت بالاضافة الى استمارة المنتفعة المستخدمة في خدمات تنظيم الأسرة .

٤- يلزم عمل المنتفعة كشف طبى دورى بعد مرور ثلاثة أشهر من إدراج الكبسولات وكذلك بعد ثلاثة أشهر من تاريخ استخراج الكبسولات بعد خمس سنوات من تاريخ الادراج.

٥- يجب تسجيل عنوان المنتفعة (الأول والثانى) والاسم الثلاثى للمنتفعة وزوجها بمنتهى الدقة لضمان المتابعة الجيدة.

٦- يسجل اسم الطبيب القائم بإدراج الكبسولات ورقم النوربلانت الممنوح له لتأدية خدمة النوربلانت بدقة لضمان المتابعة الجيدة.

٧- رقم المنتفعة المسجل على الكارت هو نفس الرقم المسجل على استمارة المنتفعة المستخدمة في خدمات تنظيم الأسرة.

محافظة :

مركز تقديم الخدمة :

وزارة الصحة والسكان

السكان وتنظيم الاسرة

سجل قيد منتفعات النوربلانت خلال شهر ..... سنة

تاريخ الزيارة date	اسم المنتفعة ♀ Name	اسم الزوج ♂ name	عنوان المنتفعة address	عنوان احد اقارب المنتفعة add. relative	سبب الزيارة Reason for visit				ملاحظات comments
					زرع insert.	استخراج Remov			
					تاريخ الزرع date	التاريخ المرتقب للاستخراج calc date for removal	تاريخ الاستخراج date actual remov.	جهة التركيب place of insertion	

يعتمد طبيب الوحدة

Sig. Physician

التوقيع :

م الممرضة :

Sig. nurse

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EXPANDING ACCESS AND IMPROVEMENT OF QUALITY OF SERVICES FOR NORPLANT

By

Prof. Ezzeldin Osman Hassan

May 2000

EXPANDING ACCESS AND IMPROVEMENT OF QUALITY OF SERVICES FOR NORPLANT

INTRODUCTION

Research and development programs that ended in the production of Norplant started in 1966 in the Center for Biomedical Research, the Population Council. Results showed that various steroid hormones can be released continuously from silicone rubber (Silastic) tubes placed under the skin maintaining fairly constant blood levels for long periods of time, over five years. These results formed the basis of the Norplant concept i.e. placing levonorgestrel, a progestagen used in many combined and progestagen only pills, within silicone rubber capsules. When placed under the skin, these capsules can provide effective contraception for many years thus, a single act of contraceptive acceptance could replace more than 1800 days of pill taking.

Over the next 20 years, implants were subjected to extensive research to select the most suitable progestagen, determine the appropriate dosage, assess the metabolic and pharmacological effects, evaluating efficiency, side-effects, acceptability and elucidating the mechanism of action. Thus, at the time of its initial marketing, Norplant was a thoroughly investigated and tested novel method of contraception. Clinical studies involved over 55,000 women, resulted in more than 400 articles on Norplant appearing in peer-reviewed scientific journals, fulfilled requirements for registration in more than 60 countries and ended by the method being used by over six million women worldwide.

As currently marketed, Norplant (the Population Council trademark) consists of six small Silastic capsules, each is 34 mm long and 2.4 mm in diameter and contains 36 mgm levonorgestrel. The capsules are inserted in a fan shaped manner under the skin of the inner aspect of the upper arm under local anaesthesia through a trocar. Release of levonorgestrel by diffusion through the Silastic starts immediately after

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insertion and reaches mean concentration in the first day, thus the contraceptive effect is achieved soon after insertion. The Norplant system of six capsules is effective in preventing pregnancy for up to 5 years, after which the capsules should be removed. However, the capsules can be removed at anytime during their effective life if the user or the service provider decides to do so.

CLINICAL FEATURES OF NORPLANT

Norplant prevents pregnancy by inhibition of ovulation, interference with sperm transport through the female genital tract, particularly through the cervix and by inadequate development of a secretory endometrium that can prevent implantation in the rare occasions when fertilization may have occurred. The cumulative 5-year pregnancy rate for Norplant, 1.1%, is one of the lowest failure rates of currently available methods for reversible contraception.

The major side effect is an irregular pattern of uterine bleeding. Changes in the duration and amount of bleeding are common, but overall, the blood loss is scanty, with a tendency for the mean haemoglobin concentration to rise slightly during the first 3 years of Norplant use. Irregular and prolonged bleeding tend to be more pronounced in the first years of use, after which some women experience a more regular pattern. During the first year of Norplant use, about 1/4 of the cycles are regular, 2/3 are irregular and 7% of women have no bleeding. By the fifth year, 2/3 of the cycles are regular, 1/3 are irregular and amenorrhea is very uncommon. Other non-menstrual side effects include headache, weight and mood changes, vaginal discharge, mastalgia and acne. Most studies have shown that Norplant has no adverse effects on bone density, liver and thyroid function, blood cortisol, lipoproteins or blood coagulation parameters. There is no evidence that prolonged use of Norplant impairs subsequent fertility. Once the implants are removed, the contraceptive effect ceases almost immediately with prompt return to previous fertility.

At the end of 5 years, about 1/4 of Norplant users will have requested removal of the implants because of a bleeding problem and another 15% discontinue because of a medical problem such as headache and weight gain. About 1/4 of all implant removals occur because the women wishes to become pregnant.

Counseling, a key element of Quality Care in Family Planning, is of paramount importance for Norplant implants. This is because starting and stopping the method are not under the user's control and require minor surgical procedures, and also because early removal is undesirable because of the high initial cost. Pre-insertion counseling should address the advantages and disadvantages of the method,

including the adverse effects to be expected with particular emphasis on bleeding disturbances. Before reaching a decision, the client should consider the relative merits of implants and other available contraceptive choices.

Post-insertion counseling is also necessary. Women often need to be reassured about adverse events and they need support when they approach the limit of tolerability. The training of health providers should not be limited to insertion and removal but should extend to develop their communication and counseling skills that will improve the self-selection of users who will be satisfied with progestagen implants, reducing discontinuation rates.

THE EGYPTIAN RESEARCH EXPERIENCE

Egypt shared many other countries in providing worldwide experience with Norplant use. This was achieved by (1) conduct of two sets of pre-introductory clinical trials. The first was in the early 1980s and supported by the Rockefeller Foundation and the Population Council and the second was in 1988, coordinated by the Egyptian Fertility Care Society with support from the United States Agency for International Development (Appendix 1). The second study had (2) an integral acceptability component to complement the clinical data on the safety and efficiency of the method (Appendix 2). As well, Egypt shared seven other countries between 1987 – 1997 in the conduct of (3) The Post-Marketing Surveillance Study of Norplant, the first large scale long-term prospective drug surveillance project in developing countries, whose data were analyzed at the World Health Organization in Geneva (Appendix 3).

(1) THE PRE-INTRODCUTORY CLINICAL TRIAL

The second clinical trial on Norplant was conducted in 5 University Hospitals between 1988 – 1994 to assess its efficiency and to evaluate its safety and acceptability. Side effects were the same as reported in international literature, however, the cumulative 5-year discontinuation rates were about 15% for menstrual problems and complications were encountered during 0.4% of insertions and 0.8% of removals. The capsules were removed for all participating 1536 cases before the end of the clinical trial. Proper selection of women, appropriate pre-insertion counseling, a meticulous follow-up schedule, high quality service and attention to adequate training in insertion and removal were behind achieving these results.

(2) THE ACCEPTABILITY STUDY

The study used both focus group discussions and a survey to measure the acceptability of Norplant among participants of the second pre-introductory clinical trial. In Egypt, where childbearing begins early, and closely spaced pregnancies are the norm, the long duration of Norplant effectiveness, its

reliability and reversibility were – among others – the main reasons behind high satisfaction with Norplant.

(3) THE POST-MARKETING SURVEILLANCE STUDY

This 5 year follow-up study in which women were closely followed up every 6 months irrespective of change of contraceptive method, showed that the 5 year continuation rates for Norplant and the CuT 380A IUD were nearly similar (67.3% and 65.4% respectively) and that the incidence of difficult removals was about 1%). Results also confirmed the very high efficacy of Norplant (pregnancy rate 0.26 per 100 woman/year) and there were no significant excess of malignant neoplastic disease or cardiovascular events such as stroke, myocardial infarction or venous thromboembolism in women using Norplant compared with that in women using non-hormonal methods. In the light of this Post-Marketing surveillance of Norplant, the method appears to be safe, well tolerated, and a highly effective method of contraception.

ITERNATIONAL EXPEREINCE AND LESSONS GAINED FROM NORPLANT USE IN THE RESEARCH AND FAMILY PLANNING SERVICE CONTEXT

Experience of all countries in which Norplant had been used in research and/or family planning clinics worldwide show that the quality of the service provided is a major determinant of the successful use of Norplant and of the subsequent degree of satisfaction among users. It is essential that potential Norplant users are given adequate information about the various contraceptive methods available. The quality of follow-up care, access to removal, and the skills and attitudes of service providers are also critical (Appendix 4).

(a) INFROMED CHOICE AND PROPER SELECTION OF CANDIDATES

Women should receive information about all available contraceptives in order to be able to make an informed choice. For Norplant, potential users should receive information about the effective life of the method, how it is inserted and removed, the necessity to remove the capsules after 5 years, the common side effects, the follow-up schedule and the problems that need prompt unscheduled visits to the clinic. The World Health Organization Medical Eligibility Criteria for contraceptive use should be applied if the woman has any pre-existing health condition.

The reproductive needs and intentions of the couple should also be taken into consideration, as Norplant is not the ideal contraceptive for short-term contraception. A woman may use Norplant if she is in need for a long- term reversible contraception while having difficulty with taking a daily contraceptive action e.g.: pill intake. A suitable candidate is a woman who has completed her family but does not want to use a permanent method.

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(b) COUNSELING

Counseling women is essential when prescribing Norplant. The critical aspects of counseling are:

1. That the most common side effect of Norplant is a change in the menstrual bleeding pattern.
2. That the capsules are inserted and removed by a minor surgical procedure under local anaesthesia.
3. That the capsules should be removed 5 years after insertion, however, she can remove them at anytime before that if she wishes. Removal is a simple surgical intervention but must be undertaken by a physician specially trained in that procedure.

(c) EASY ACCESS TO REMOVAL SERVICES

Women should understand clearly what to do and where to go if she wants to remove the Norplant. Service providers should understand the woman's right to have the capsules removed if she insists to do that after proper counseling that should be an integral part of an established clear follow-up system. They should be advised to do that whenever there is a medical indication for removal. There should be no unsatisfied user of Norplant, removal should be promptly undertaken without hesitation whenever it is clear that a woman is not satisfied with the method.

(d) TRAINING AND SKILLS OF SERVICE PROVIDERS

Providers need training in counseling, insertion and removal, and in the management of side effects and medical problems. The quality of insertion is crucial to ensure that all capsules are placed in a superficial plane immediately under the skin, as this is essential to ensure easy removal. In general, removal is a more difficult procedure than insertion. Unfortunately, removal is the most difficult component of training mainly because of lack of a sufficient caseload in most training sites.

(e) Programs need to provide campaigns to remind women using Norplant in whom removal is delayed past 5 years, and to advise them to use a supplemental contraceptive method while awaiting Norplant removal.

NORPLANT INTRODUCTION IN EGYPT

Research demonstrated the acceptability and safety of Norplant to the satisfaction of the Government of Egypt and it was registered and given regulatory approval in February 1993. A Norplant Task Force was formed to develop an Implementation Plan for its 5 years Introductory Program (1994 – 1999) based on the MOHP strategy paper. The plan provided broad guidelines for expanding the use of Norplant beyond the University Hospital environment of the 1988 clinical trials, taking into consideration the experience and lessons extracted from Norplant use in Egypt and in Family Planning programs in other countries and the strengths of the Health System in Egypt. The Introductory Program aimed at expanding the choice of available contraceptive methods through the provision of Norplant as part of the cafeteria of methods provided in the Egyptian Family Planning Program mainly by attracting new contraceptive clients and providing an alternative for the high percentage of women with poor compliance to oral hormonal contraceptives. The five year period was considered an opportunity to develop the management capacity for ensuring the smooth operation of the clinical and programmatic subsystems that support the provision of this new contraceptive, and to study the effect of adding Norplant to the family planning program.

The following three principles guided the development of the Norplant Introductory Program Implementation Plan: (Appendix 5)

(1) Ensuring a high quality service during the step-wise horizontal expansion in University hospitals, MOHP teaching hospitals, general hospitals, and health insurance hospitals.

(2) Understanding use dynamics through systemic monitoring and evaluation.

(3) Examining the impact of introducing Norplant on the services delivery systems through limited vertical introduction in some District hospitals, Urban Health centres, MCH centres and some major centres of the Clinical Service Improvement Program.

Thus the horizontal introduction will provide highly qualified Ob/Gyn specialists in leading institutions throughout Egypt with an experience in providing the new contraceptive while the restricted vertical introduction in two governorates will provide adequate programmatic experience that ensures quality service particularly in training, logistics, information system, IEC and follow-up.

The major features of the implementation plan are:

(1) Update the MOHP National Standards of Practice for Family Planning Clinical Services delivery with a supplement containing full and complete references on Norplant that should emphasize in particular:

a- Informed Choice and counseling before insertion and during a clear schedule of follow-up visits, especially about side effects and the necessity of removing the capsules after 5 years.

b- The importance of training in insertion and also in removal

c- The importance of access to removal on request and encouragement to choose another method, after removal of the capsules.

d- The importance that client records and clinic registries should include clear information particularly in relation to name, address, date of insertion, expected date of removal and actual date of removal.

(2) An IEC strategy to (a) identify target audience and reach them to increase awareness of those matching the selection criteria and to dispel rumors (b) expand upon teaching material to service provider.

(3) Upgrade the existing Management information system to incorporate adequate information to enable the tracking of Norplant clients as well as monitoring and evaluation.

(4) Address logistic issues to forecast demand, estimate needs, develop plans for receiving, storage and distribution of Norplant sets.

In short, the Implementation plan of the Norplant introductory program emphasized two important issues: choice of the appropriate candidate for Norplant insertion and providing high quality service being the two important elements for maintaining client acceptability and sustaining satisfaction.

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PRESENT STATUS OF NORPLANT SERVICES

Norplant is imported by Schering for Sale on behalf of Leiras to governments at a subsidized price (23 US$ per set). The cost reaches about 25 US$ after inclusion of costs for shipping, etc. However, the price is expected to be much higher if Norplant is sold to the private sector.

At present, USAID donate Norplant free of charge to the Ministry of Health and Population. The population sector send the Norplant sets to the Egyptian pharmaceutical Trading Company (EPTC) that have the responsibility of its distribution according to instructions from the population sector. The EDHS (1997 – 1998) show that Norplant contributes to CPR by 0 - 0,1% and during the first quarter of the year 2000, Norplant was estimated to contribute by 1.3% for the CYP.

According to the agreement between USAID and the Egyptian MOHP, EPTC distributes the Norplant sets free of charge to the MOHP Teaching Hospitals and Family Planning units. EPTC distributes Norplant sets to University Hospitals for a nominal fee of 2 LE per set. These hospitals charge their clients 20 LE for the insertion of one set. The difference of 18 LE compensates relevant insertion expenses and also incentives for service providers. Since August 1999, Norplant being provided free of charge in MOHP units, service providers receive no incentives for inserting or removing Norplant. With increasing demand on Norplant over the last years, MOHP purchased 10,000 sets that were immediately distributed to the units in the beginning of April 2000. Another 10,000 sets were purchased and expected to be received in 2 – 3 months.

According to the records of the MOHP, 40000 Norplant sets were received from USAID between the beginning of Norplant service in 1994 and January 2000. (Appendix 7). A total of 34414 sets were distributed (6100 to Teaching Hospitals, 1149 to University Hospitals, 600 to the Regional Training Center [RCT] and 15765 to MOHP service delivery units). Only 460 sets remained in stock because 5010 sets were sent to Colombia at a time when insertion of Norplant was slowly coming up and their Expiry date was approaching and 116 sets were used by the Drug Regulatory procedures.

In the 24 Governorates in which Norplant service is provided, in addition to University hospitals, 273 MOHP centers provide that service. These are teaching, general and some regional hospitals. According to MOHP records, a total of 659 physicians work in these units, 348 (52.8%) of whom are trained in Norplant insertion and removal. These are mainly Ob/Gyn specialists and few general practitioners in some governorates to cope with increased demand. The corresponding number for nurses is 559, 213 (38.1%) are trained in Norplant services provision. (Appendix 8).

In addition, mobile teams of trained service providers used to visit places in which service is not provided to insert Norplant sets particularly in the early phases of initiation of service. Now the role of mobile clinics is mainly to help Potential Norplant users reach the service units.

In addition to clinic based service provision, Norplant started to be provided by mobile clinics since November 1999 in some governorates. El-Menia Governorate is especially active with this mode of service delivery. It is believed that the role of mobile clinics is now declining in service provision after the horizontal expansion in service sites. Health educators (Raidat Rifiyat) and the I & E specialists inform women of the service beforehand. Insertions are being recorded in the clinic records in which the trained service provider work. Women are instructed to report to that clinic for follow-up.

Again, according to MOHP MIS records, 13865 sets had been inserted between 1/10/1995 till 31/12/1999 *. (Appendix 9) Two university centers inserted about one third of total insertions, Mansoura 16% and Alexandria 15%. Ein-Shams and Assiut Universities, Banha and El-Matarria Teaching Hospitals, each inserted about 7.5%.

* Based on statistics received by Norplant officer from the governorates, 6534 insertions were performed between 1st of August 1999 and 31 December 1999 and 12031 sets were inserted from 1st of August 1999 until 30 April 2000. (Appendix 9a)

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A big discrepancy exists between the 34414 distributed and the 13865 inserted sets because of under-registration. Only 40% of distributed sets could be traced by the MIS records. The remaining 26135 are not in the pipe-line. The System Development Project in MOHP admit irregular receipt of insertion cards and that this number of inserted Norplant sets is not realistic and does not reflect the real situation particularly in Teaching and University Hospitals. SDP realizes that the present system of MIS (Appendix 14 forms to be sent by service delivery units to central MIS system for every insertion and removal) does not serve the purpose because some user cards are not received, some are received with bad handwriting that cannot be read, some with missing data and there is no monthly reports from the units on Norplant use or information on the inventory system.

It appears that there is a great discrepancy between the number of insertions as recorded by the MIS system based on insertion cards being sent from the governorates and that reported to the Norplant officers as monthly activity statistics. This can be partially due to the very low reporting of insertions and removals by some University Centers. As well, it appears that the number of monthly insertions had greatly increased starting from August 1999.

Realizing these difficulties, MOHP is currently changing the MIS system. A logbook is to be kept in the unit recording information needed for follow-up of Norplant clients (Appendix 15). Identification of Norplant users for removal of the capsules will be the responsibility of the service units. These will send only the number of insertions and removal centrally to the MOHP for the purpose of calculating the CYP. This is a simple recording system that need to be complemented to monitor the quality of service in the Norplant service delivery points.

82% of inserted Norplant sets are in women aged 26 – 35 years, nearly equally distributed between age categories 26 – 30, 31 – 35 and more than 35. Only 3% are inserted in women less than 20years old. (Appendix 10). Most Norplant users (74%) are illiterate (Appendix 11). This is due to the fact that services are provided only in Public sector service units, whose clients are usually from the lower social and

economic strata. No mass media campaigns had been done to reach potential acceptors from educated higher socio-economic classes.

Distribution of Norplant users by last contraceptive method used show that 36.7% were using IUDs, 20.8% injectables, 20.6% Oral Contraceptive pills and 16% were new contraceptors. Thus 57.5% were pulled from the pool of long-acting methods and only 36.6% were new contraceptors or using oral contraceptive pills. (Appendix 12)

Also, according to the MOHP records (Appendix 13), only 735 Norplant sets had been removed. The overall removal rate being 5.3% over a period of more than 4 years (1/10/1995 – 31/12/1999). The removal rate was 53.5% in Galaa hospital probably because they remove Norplant sets not inserted in the hospital, 13.3% in Mansoura University, 13.2% in Assiut University, 7.3% in Banha Teaching Hospital and 5.6% in El-Matarria Teaching hospital, 3% in Ein-Shams University and only 0.5% in Alexandria University. This low removal rate has to be looked into. It can be due to under-registration of removals but it can also be due to lack of access to removal.

37% of removals were due to menstrual causes, 34% to non-medical reasons, 13.9% to non-menstrual medical reasons, 11.7% because of headache, 1.9% due to breast complaints and only 1% because of the occurrence of pregnancy.

Complication during insertion and removal do not appear in the provided statistics although they should have been recorded in the insertion and removal cards sent to MIS.

INCREASED DEMAND ON NORPLANT SERVICE

MOHP believe there is an increased demand on Norplant inspite of lack of mass media campaign.

Now, Norplant is distributed neither by a pull or a push system, the increased demand absorb all distributed Norplant sets immediately. The MOHP attributes this increased demand to (1) Increased accessibility of services, increased number of service units providing Norplant in addition to the mobile clinics (2) IEC activities done at the governorate level by the Ministry of Health IEC officers (3) Free Norplant. The increase in demand on Norplant apparently is met with increase in service delivery points rather than by a clear well defined referral system for those willing to use Norplant from the service units who do not provide Norplant to those who provide that service.

NORPLANT TRAINING

Training needs for Norplant is being assessed at the governorate level. There is a 3 monthly training plan in each governorate to cope with increased service units and staff turnover. Nomination is being sent from the governorates on a monthly basis to the Regional Center for Training (RCT) who coordinate for training courses to be conducted in 5 university hospitals namely Ein-Shams, Al-Azhar, Mansoura, Alexandria and Assiut. Five physicians or 10 nurses are being trained at a time in one training course. Based on RCT records, 937 physicians and 934 nurses had been trained in 177 courses for physicians and 99 courses for nurses. Mostly trained physicians are Ob/Gyn specialists but some are general practitioners. The differences between these figures and those provided by MOHP may be due to turnover of service providers.

Some governorates had realized – through the observation of medical supervisors who are mostly trained in Norplant – lack of practical training among trained physicians. Individual efforts are being done by some governorates (particularly Alexandria and Suez) to re-train trained physicians in MOHP centers with a heavy caseload in the governorate. Efforts are underway to generalize this procedure i.e. to complement the training done in the five University centers by the RCT by a local practical course for training at the governorate level so that physicians can acquire the necessary skills in insertion and removal.

Up till now, refresher courses for training, particularly in removal is not being done. The MOHP requested RCT to formulate and conduct re-training courses in removal for two days but RCT insist that the duration of such courses should be 4 days.

RCT has no technical control on training in Norplant that is being conducted in the 5 university training centers, its responsibilities are only administrative and financial. RCT cannot monitor or evaluate training in the university centers. RCT had noticed evidence of inadequate training particularly in skills among those trained by the universities. They are convinced that most trainees do not satisfy the

accreditation criteria of trainees inserting 3 Norplant sets and removing at least one set. RCT see a need to re-train trained physicians particularly in removal.

This issue of need for trained providers in different techniques for removals should be addressed urgently because service started late in the year 1994. Now, there are Norplant users who are already had used Norplant since more than one year. The number is still small because the insertions in year 1994 and the few years after are not that great. However, the increased need should be anticipated with increasing caseload in the coming years.

RCT see that the following are needed in the area of training:

- Revision of Norplant training curriculum
- External technical evaluation for training conducted in the universities.
- Conducting re-training courses particularly in removal.

In that respect, RCT agree on widening the base of training centers in MOHP teaching hospitals or other hospitals with a high caseload. A mechanism should be established to identify centers with good load of removal, optimize utilization of removal cases to serve training purposes and to provide service providers in these centers with TOT courses.

INFORMATION, EDUCATION, COMMUNICATION EFFORTS FOR NORPLANT

MOHP distributes a leaflet having information about Norplant to FP clinic clients. However, the first pamphlet did not stress clearly the need for removal of Norplant sets 5 years after insertion. The MOHP produced a second pamphlet by the "Gold Star" initiative that replaced the first one and contains information on the need for removal of Norplant capsules after 5 years. Some service units have posters that show Norplant among other family planning methods.

The Center for Education, Information and Communication (state information services) produced a pamphlet containing questions and answers on family planning methods including Norplant (Appendix 16). It also included Norplant in the chart it produced for counseling (Appendix 17). However, they did not produce special leaflets or posters on Norplant and did not conduct mass media campaigns on the Radio and Television, which they attribute to lack of knowledge on the part of those who introduce the programs.

They recommend the following:

(1) Service units should try to locate those who inserted Norplant before 5 years (when time comes) if they do not present for removal.

(2) Produce a poster to be hanged in the service units solely for reminding users with Norplant removal.

(3) Utilize the regular meetings that the IEC center conduct with the public to inform them about Norplant among other methods, to dispel rumors and to stress the need for removal after 5 years, and the need to use another method of contraception until removal is done.

(4) To mention "as an insert" need for Norplant removal after 5 years in Radio and Television programs talking about family planing method.

However, they warned against a concentrated campaign to encourage removal convinced that this may cause a lashback, people thinking there is something wrong with Norplant and the government is urging people for removal.

INTRODUCTION OF NORPLANT IN CURRICULAE AND TRAINIG PROGRAMS

The Egyptian Fertility Care Society is currently undertaking activities to conduct coordination between all the Egyptian universities to adopt a unified teaching Curriculum for undergraduates and Training Program for House Officers in the area of FP/RH. It is intended to include Norplant in the corresponding curriculum and training.

INTRODUCTION OF NORPLANT IN THE PRIVATE SECTOR

Norplant in its current six-rod system is the only approved implant available in Egypt. There are so many questions that have to be answered if one think of introducing Norplant in the private sector. Whom to train? Physicians working in FP units in MOHP or others? Who will bear the cost for training? Where to train potential services providers? Logistics to supply them with Norplant? And lastly the prospects for other implants: Javelle and Implanon? (Appendix 6)

Another constraint is the cost. Schering estimates that Norplant will cost about 200 US$ if it is to be provided in the private sector so as to cover the cost of training.

There are no plans in the year 2000 to promote any type of implant for the private sector, Schering and Leiras have no plans to promote or sell Norplant in the private commercial sector. Their preference is to wait for the simpler two-rod system (Javelle) currently making its way through development and the regulatory process in other countries.

Implanon, Organon new one rod-system is not yet approved but currently in its early stage of approval in Egypt. There are no plans to promote this product through the private sector given the necessary training support required to insert and remove the rod. However, it might be a good candidate for the NGO sector.

SUGGESTIONS TO EXPAND THE AVAILABILITY AND ACCESS OF NORPLANT –A follow-up on Introduction Plan for Norplant

At this phase of Norplant introduction in the Family Planning program, it may be of help to evaluate the experience gained from previous efforts and to look forward for procedures that can help in expanding the access and to improve the quality of services provided to Norplant clients.

(1) Appropriate training to ensure skilled providers and high quality service particularly in the area of counseling and easy access to removal are the two pillars for Norplant acceptability. Hence, it is important to evaluate current ongoing training of service providers particularly in the areas of appropriate counseling provided to clients to ensure that women are provided with adequate information about Norplant particularly its surgical nature, expected side-effects and the need for surgical removal at the end of five years or whenever requested before that period. It would be appropriate to emphasize the choice of Norplant users from new contraceptors or COC users rather from those using other safe long acting methods except if this is the client choice. Practical training in insertion should emphasize subdermal and not subcutaneous placement of the Norplant capsules so as to avoid difficulties during removal.

With the approach of five years since the start of Norplant services and the expected increase in the demand on removal, there is a need for refresher courses for service providers in the removal process. Training sites should be chosen to include those centers with a heavy caseload for removals, preferably utilizing the expertise of experienced staff in the 5 universities in which the clinical trial was conducted viz: Ain-Shams, Assiut, Al-Azhar, Mansoura and Alexandria.

(2) As well, there is a need to remind Norplant users about the necessity to remove the Norplant capsules from those who used it for a complete 5 years. This can be achieved at a low-key in order to avoid any lash-back or rumors by:

- A poster to be put in the family planning clinics.
- As inserts in mass-media programs discussing contraceptive methods.
- As messages during home visits by "Raedat Reefeyat".
- Providing clients with a card that carry the necessary information may also be of help.

(3) It appears that the recording system for Norplant need some modifications as the present system did not serve the expected purposes. A simple logbook in the service delivery units to identify clients from whom Norplant need to be removed is a logical solution. However, as the quality of service is a crucial factor in maintaining high acceptability of Norplant, information is needed to monitor and evaluate the services. This can be achieved by filling a more simplified card for clients, whose data can be entered on the same software of the already available system.

(4) The chapter on Norplant in the National Standards of Practice for Family Planning and Reproductive Health clinical services delivery needs to be updated to include more information necessary for counseling and service provision.

(5) At the moment, the Norplant 6-rod system is the only implant registered in Egypt. Training of physicians and cost are the two important constraints for its introduction in the private sector. Manufacturers have no intention to introduce Norplant in the private sector.

In the light of new forms of implants, the use of the six rod Norplant system in the private sector may be postponed, waiting for the availability of Jadelle (the two rod Norplant system) or Implanon (the one rod in a preloaded inserter).

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- Dr. Safaa El-Baz, Executive Director, Regional Center for Training (RCT)
- Dr. Ibrahim Ismail, Deputy Executive Director, RCT
- Dr. Hafez El-Hawan, Director, El-Obour Hospital, Suez
- Dr. Mahmoud Abdel-Karim, Director, Family Planning Department, Suez Governorate.

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11. Norplant users distributed according to education.
12. Norplant users distributed according to last method.
13. Norplant removal distributed according to reasons for removal.
14. Insertion and removal cards from service delivery units to central MIS in MOHP (Arabic).
15. Proposed logbook to be kept in service delivery units (Arabic).
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17. Flip chart for counseling developed by Center for IEC, SIS (Arabic).