AN EVALUATION OF NORPLANT
AT THE UNIVERSITY TEACHING HOSPITAL

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DEDICATION

To my dear wife, Mwangelwa, without whose patience this piece of work would not have been possible.

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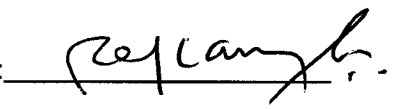
STATEMENT

I HEREBY STATE THAT THIS DISSERTATION IS ENTIRELY THE RESULT ON MY OWN PERSONAL EFFORT. THE VARIOUS SOURCES TO WHICH I AM INDEBTED HAVE BEEN CLEARLY INDICATED IN THE BIBLIOGRAPHY AND ACKNOWLEDGEMENTS

SIGNED: 

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I HEREBY DECLARE THAT THIS DISSERTATION HEREIN PRESENTED FOR THE DEGREE OF MASTER OF MEDICINE (OBSTETRICS AND GYNAECOLOGY) HAS NOT BEEN PREVIOUSLY SUBMITTED EITHER WHOLLY OR IN PART FOR ANY OTHER DEGREE AT THIS OR ANY OTHER UNIVERSITY NOR IS IT BEING CURRENTLY SUBMITTED FOR ANY OTHER DEGREE.

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APPROVAL

This dissertation of **Dr. Reuben Kamoto Mbewe** is approved as fulfilling part of the requirements for the award of the degree of Master of Medicine in Obstetrics and Gynaecology by the University of Zambia.

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ABSTRACT

A nine year review of NORPLANT was conducted at the University Teaching Hospital (UTH) in Lusaka to evaluate NORPLANT as a method of fertility control in Zambian women. The study was designed to investigate acceptability, side effects, and reasons for discontinuation. Based on the evaluation, to make recommendation for use in the National Family Planning Programme.

Case records were reviewed from March 1986 to March 1994 for 390 clients. Data was collated for the following variables: age, marital status, level of education attained, occupation, parity, previous contraception, date of insertion, date of removal, duration of use, complications and reasons for removal.

The mean age and parity were 32.7 years and 4.9 respectively. Out of 390 clients 14% completed the five year term, 45% discontinued, 31% included those who were either continuing with the method or those who had reinsertions, 9% were lost to follow up, and 1% died. Continuation rate at 1 year was 90% and 3 of the 390 clients (0.7 %) got pregnant. The commonly reported side effects were menstrual problems, weight change, site complications, dizziness, headache and raised blood pressure. Common reasons for discontinuations were menstrual problems (35%), desired pregnancy (10 %) and weight changes (10%) followed by, to a lesser extent, site complications, switched to bilateral tubal ligation, raised blood pressure and headache.

NORPLANT appear to be highly effective and a highly acceptable contraceptive method for selected Zambian women.

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INTRODUCTION AND BACKGROUND

Overview of Contraceptives and Family Planning

In the broadest sense, the term "Family Planning" could be viewed as a means by which patients are assisted in either achieving or preventing pregnancy. However, family planning is generally defined more narrowly to include only those methods by which couples defer or prevent pregnancy. Family planning methods include temporary contraception, permanent contraception and even induced abortion by some.

Family Planning has broader connotations than the needs of the individual family. Those who are concerned with public health, particularly with maternal and child health, view family planning as an important factor in avoiding the aftermath of unintended pregnancy and unwanted children, preventing excessive parity in high risk women with its negative effect of maternal health and also of reducing perinatal mortality. Those concerned with stabilizing population growth find family planning a critically important component in these efforts and they are especially concerned with its availability, accessibility, safety and utilization. Finally, those concerned with improving the status of women view contraceptive effectiveness and safety as important issues in allowing women to regulate their fertility and to participate in societal activities that previously had been precluded by excessive and frequent pregnancies.

There are numerous of contraceptive methods e.g. hormonal, intrauterine, barrier, sterilization and periodic abstinence natural family planning. These are outlined in Table 1. In addition, the lactational amenorrhoea method can be effectively used in the postnatal period.

Background of Family Planning in Zambia

The concept of family planning is not new in Zambia. Traditional methods were used as strict unquestionable rules. These included abstinence, polygamy and abortion. These were overtaken by western values, thereby promoting contemporary scientific and western oriented methods of contraception.

In 1972, Zambia began offering institutional family planning services and dissemination of population and family planning related information through the Planned Parenthood Association of Zambia (PPAZ).

Politicians maintained that there was no need for family planning because Zambia was a vast unoccupied land with a wealth of natural resources and they called on the Zambian people to answer the Biblical call of multiplying and filling the land. Churches, the Catholic faith in particular, regard family planning as unethical and sinful, and discouraged church members from using it. Traditionalists interpreted the programme as a direct attack on the socio-economic security of the elderly because it is children that care for the aged parents. Other groups also feared that family planning would erode the morals of Zambia by encouraging promiscuity. With time, resistance and hostility waned and individuals and non-governmental organizations (NGOs) began engaging in family planning activities. In 1980, the Family Life Movement of Zambia was formed to educate the public on scientific natural family planning methods. It is also interesting that in 1972 the Termination of Pregnancy Act (CAP 554) was passed in Zambia.

Population Trends in Zambia

The population in Zambia has been increasing rapidly over time. Results from the past four national censuses indicate that the population increased from 3.5 million in 1963 to 4.1 million in 1969, 5.7 million in 1980 and 7.8 million in 1990. The population had thus almost doubled itself in size during the 21 years between 1969 to 1990 (1). The rate of growth of the population has also been high and increasing over time. Between 1963 and

1969, the rate of growth was 2.6% per annum, this increased to 3.1% per annum in the 1969 - 1980 and to a projected 3.7% per annum in the 1985 - 1990 periods, respectively. The level of fertility in the country has remained persistently high for several past decades and is likely to remain so in future, unless some concrete interventions are undertaken. The crude birth rate (CBR) was approximately 50 per 1000 person in the 1950 -1955 period and remained virtually unchanged since then (49 per 1000 persons in 1988) (1). The total fertility rate had been high in Zambia. It was reported at 7.2 after the 1980 census and estimates based on that census suggested it would be 7.0 in 1990. However the 1992 Zambia Demographic and Health Survey (1992 ZDHS) (2) reported it to be 6.5 - a slight decrease, while the 1996 Demographic and Health Survey (1996 ZDHS) reported it to 6.1 (3). Maternal mortality rate (MMR) still remains high. The 1996 ZDHS estimated the national maternal mortality ratio to be 670 per 100 000 livebirths (3). Similarly the infant mortality rate (deaths up to 1 year) and under 5 mortality were noted from the ZDHS to be 109 and 197 per 1000 livebirths respectively (3). These figures have increased over previous years.

Fertility preferences and contraception knowledge in Zambian women

According to the 1996 ZDHS, over one quarter (28.5 %) of currently married women do not want any more children and an additional 39 % of women want to wait at least 2 years before having another child. Moreover, the 1996 ZDHS data shows that spacing births can potentially reduce childhood mortality levels; children born less than two years after a preceding birth were almost three times more likely to die during their first year of life than children born at least four years after a preceding birth. A high proportion of married women report knowing a modern method (95.1 %) and 64.8 % of them have some knowledge of traditional methods. The most widely known methods are the Condom, pill and female sterilization, known by 91.5, 86.4 and 66.1 % of all women respectively. Following these, injectables and IUD are the most commonly known methods (reported by 53.2, and 42.4 % of all women respectively). As regards the traditional methods, 53.8 and 43.8 % of all women know of withdrawal and periodic abstinence (3).

There are some factors which may have negative effects on the adoption of family planning, and particularly modern methods of family planning. These include: preference for large families; ignorance of the benefits; fear of side effects, fear of reaction of husbands, especially in rural areas, and other cultural factors. Other factors have to do with their cost, availability and access to health centres providing family planning.

NORPLANT as a Family Planning Method

In order to increase contraceptive efficacy without considerable dose increases, non-oral systems that gradually release the progestin have been developed which include vaginal rings, injectables and subdermal implants (NORPLANT) (4). (See also Appendix 1 for Norplant product profile including mode of action). Depo provera and Noristerat are precursors of NORPLANT. These progestin only contraceptives were developed in order to avoid certain side-effects and risks associated with oestrogens in combined oral contraceptives.

The first implantable contraceptive system was levonorgestrel implant (NORPLANT). Recently there have been trials of single Implants - Uniplant. Other implantable contraceptives which may be available to family planning programs within this decade are NORPLANT II, capronor, fused pellets and implantable contraceptive releasing the progestin desogestrel.

NORPLANT implants are effective long lasting reversible subdermal implants that provide protection against pregnancy for up to 5 years.

Norplant use in Zambia and worldwide

A research and development programme began in the laboratories of the Population Council's centre for Biochemical research in 1966. The first clinical experience was of a progestin released from silastic capsules was reported in Santiago, Chile, in 1968. From 1980, pre-introductory trials began in Brazil, Chile, Denmark, Dominican Republic, Finland and Jamaica. Several other countries followed suit so that by December 1990

more than half a million women had used the method in 17 countries where it had received regulatory approval (5).

Women's satisfaction with NORPLANT implants have been evaluated in several countries. In China a study was done to assess the efficacy, safety and acceptability of NORPLANT (6). The 5-year average annual pregnancy rates was 0.3 per 100 women years of use, with a minimal ectopic pregnancy rate at 0.09 per 1000 women. Younger women experienced higher pregnancy rates than did older users. Headache, myoma, dizziness and weight gain led more frequently to discontinuation that did other adverse events apart from menstrual disturbances. Seventy-two per 100 initial acceptors used the implants continuously for five years. A similar study in Bangladesh and Pakistan suggested that the NORPLANT system is highly effective, safe and acceptable among women (7).

Levonorgestrel implants have been found to be well tolerated by most young patients and recommendations have been made to clinicians involved in the care of adolescents to consider NORPLANT as an appropriate option of birth control for this population (8).

On the African continent, Egyptian women were favourable to NORPLANT usage because of the long duration of effectiveness, the site of insertion, the ease of use and their relative lack of perceived side effects compared to the pill and IUD. A high percentage (93%) of the women expressed satisfaction with the method (9).

NORPLANT implants have already been approved for use in Kenya, Madagascar, Rwanda, Tanzania, Mauritius and South Africa. NORPLANT implants are in pilot phase in Botswana, Ethiopia and Zimbabwe.

In neighboring Zimbabwe, the initial experience indicated that NORPLANT IMPLANTS continuation rate was much higher than for any other reversible method of contraception and is highly acceptable as a long term contraceptive (10).

The implantable contraceptive method NORPLANT implants have been available in Zambia for approximately 9 years. In 1986, a pre-introductory clinical trial was started at the University Teaching Hospital (UTH), Lusaka. 242 clients were recruited into the study and followed up for two years. The main objective of this trial was to gain first hand experience with the method and to assess acceptability among the Zambian women (11).

The study showed that the method was well accepted by clients at UTH. However, this was limited by the fact that the study of NORPLANT usage had only assessed experience in clients who had used the method for 2 years only. Experience on its use up to 5 years and beyond is important.

Accordingly this current study looks at nine years experience with the method (from 1986 to 1995). The author has been involved in the NORPLANT introduction project since 1988.

STUDY JUSTIFICATION

NORPLANT IMPLANTS are a new contraceptive and therefore, there is need to study factors which may affect the incorporation of the method in the National Family Planning Programme.

It is important to document the experience of NORPLANT users beyond 5 years to be able to fully describe acceptance, discontinuation and repeat usage. This would complement the previous study at UTH by Dr Chikamata et al (11) and allow for an in-depth and more comprehensive evaluation of NORPLANT usage by clients at UTH.

AIMS AND OBJECTIVES

To evaluate NORPLANT as a method of fertility control in Zambian women attending the family planning clinic at UTH.

Objectives

1) To document usage of the method from the beginning of the Norplant Programme at UTH in 1986 to 1994, by:

   (a) establishing numbers of users

   (b) demographics of clients

2) To investigate acceptability of NORPLANT among users.

3) To examine side effects of NORPLANT.

4) To document reasons for discontinuation of the method.

5) Based on the evaluation, make suitable recommendations for NORPLANT in the National Family Planning Programme.

METHODOLOGY

In order to achieve the stated objectives, case records of all women who had accepted NORPLANT at the Department of Obstetrics and Gynaecology, University Teaching Hospital (UTH), in Lusaka over the period 1986 - 1994 were scrutinised.

Ethical considerations

Permission was sought and granted from the Research Ethics committee to evaluate the trial using case records in an anonymous manner. The Research Ethics Committee of the University Teaching Hospital had previously approved the original protocol in February 1986 for the actual introduction trial of NORPLANT at UTH.

Client Protocol

Clients to the Family Planning clinic were counseled on all methods. Those who expressed interest in NORPLANT were recruited if they met the inclusion criteria and signed a volunteer agreement.

The product profile for NORPLANT describing the product, indications, contraindications, mode of action, complications and use is outlined in Appendix 1.

Before NORPLANT were inserted, their inclusion criteria specified that each subject had to be between 18 and 40 years old, previously pregnant as evidenced by at least one living child, not breast-feeding, not having used injectable contraceptives in the six months prior to admission, readily accessible and willing to return to the clinic regularly and not using other contraceptive methods simultaneously during the study. A few inclusions of younger clients and those not having had a previous pregnancy were made by the Consultants involved. Insertion of the NORPLANT was to be done within the first seven days of the menstrual cycle.

On admission to the study, the clients had a complete history taken and a physical examination including breast and pelvic examination were done.

Follow up visits were scheduled for the first, third, sixth and twelfth month and thereafter every six months until removal of the implants At each visit, the clients were given a physical examination and side-effects and client reactions to NORPLANT assessed. Women were encouraged to return to the clinic for any problems that occurred, regardless of the next scheduled follow up visit.

Data collection

Case records of all clients recruited between 1986 to 1994 were reviewed. Data was entered into Epi Info for the following variables: age, marital status, level of education completed, occupation, parity, previous contraception, date of insertion, date of removal, duration of use and complications experienced by clients. This database was subjected to descriptive and comparative statistics.

RESULTS

(All Tables and Figures are included in APPENDIX 2)

Number of Clients

Since the beginning of the programme 390 clients were recruited. Figure 1 outlines the breakdown of clients continuing, those with removals, lost to follow up and others.

Years of insertion are shown in Table 2 and Figure 2. Over 50% of insertions (203 out of 390) were between 1986 and 1988.

Demographics of clients

The descriptive statistics of the ages, parity, occupation, marital status and level of education of clients is outlined in Tables 3,4,5,6 & 7 and Figure 3,4,5,6 & 7 respectively.

The last contraceptive method used by clients before accepting NORPLANT is outlined in Table 8 and Figure 8.

Acceptability of NORPLANT

Acceptability was defined as those clients who continued to use the method for more than one year. Table 9 and Figure 9 outlines the numbers of clients and duration of use.

Of the 390 clients, 129 were either continuing or lost to follow up (includes 4 who died). Of the other 257, 53 had discontinued before 1 year and 204 discontinued after 1 year.

Side-effects

The side-effects have been reported within the intervals of 0 - 3 months, 3 - 6 months, 6 - 12 months, 1 - 2 years, and 2 years onwards.

For each interval the number of clients who did not complain, the number of clients who had complaints and the number of clients who did not turn up were recorded. Also recorded are the cumulative totals of removals. For each interval this is reported in Tables 10,12,14,16 & 18 and Figures 10,12,14,16 & 18.

Similarly the descriptions of complaints for each interval is reported in Tables 11,13,15,17 & 19 and Figures 11,13,15,17, & 19. Note that the number of complaints is more than the number of complainants. This is because some complainants reported more than one complaint.

A consolidated list of all the side effects from all complainants is outlined in Table 20 and Figure 20.

Reasons for discontinuation / removal

229 of the 390 clients (59%) had removals. 55 did so because of term expiry. The other 174 had removals because of complaints. Menstrual disturbances were the commonest reasons for discontinuation in this group of 174 (61 clients). The primary reason for discontinuation in all 174 clients with complaints is tabulated in Table 21 and shown in Figure 21.

Discontinuation due to menstrual problems

To assess when those 61 clients with menstrual problems discontinued, the cumulative discontinuation rate is tabulated in Table 22 and illustrated in Figure 22.

Discontinuation with respect to previous contraceptive method

The previous contraceptive history of the 174 clients who discontinued is tabulated in Table 23. Also shown is the history of those who desired pregnancy, those who discontinued for menstrual disturbances and those who discontinued for other reasons.

Discontinuation with respect to parity and age

The parity and age of those who discontinued and those who continued were evaluated and presented in Table 24 and Table 25 respectively.

DISCUSSION

Years of insertion

The highest number of insertions were done between 1986 and 1988 compared to the 1989 to 1994 period. This was due to erratic supply of NORPLANT. If this contraceptive method is to be effectively introduced, it is imperative that continuous supply of NORPLANT is established.

Occupation

With respect to occupation, almost 50% of the clients were full time housewives. The next largest group of clients were "others" who comprised telex operators, radio producers, small scale businesswomen etc. This could be due to the fact that most women are not in employment. It does not imply that housewives liked the method more than the rest of the clients.

Marital Status

Most of the clients were married as observed in other studies. There was a large number of clients (13% - the second largest group of clients) whose marital status was not indicated. This should be emphasised in data collection for future studies. The fact that over three quarters of the clients had some education (primary school education or higher) would make counselling easier. The significance of education was not mentioned in other studies.

Acceptability

The data presented in this study indicate that NORPLANT may be acceptable to Zambian women. NORPLANT users showed a high degree of continuation after one year (90%).

The study also shows a high degree of effectiveness in preventing pregnancy. Only three pregnancies were reported. One client was pregnant at time of insertion and the other two conceived after four years of NORPLANT use. The weights of the clients who conceived were 63.8 kg and 77 kg respectively. Most studies show that there is an increase in pregnancies in clients who are over 70 kg at insertion. These pregnancies could be explained by the fact that concentration of levornorgestrel in the capsules decrease towards fifth year of use. Hence one of the clients (77 kg) had an ectopic pregnancy after four years and nine months of use. Therefore it is important to counsel clients who are over 70 kg about the possibility of conceiving before term expiry.

Side effects

The dominant side effects other than menstrual problems were headache, site complications, dizziness and weight change. The headache, dizziness and weight change were possibly associated with steroid use.

Discontinuation

61 (35%) of the 174 removals in the five years of NORPLANT use were due to menstrual problems. In most of the other studies, menstrual problems were the commonest reasons for removal though some reported higher percentages.

An unanticipated high incidence of site complications was reported. It would appear the insertion technique may be responsible. Therefore it would be important to review technique to ensure that the implants are not deeply inserted.

The significance of last contraceptive method used in this study is doubtful because it appears most of the clients use the pill as it is the most available contraceptive rather than by choice. Nevertheless, it is difficult to determine if last contraceptive method influenced the choice to use NORPLANT or to discontinue. Nevertheless, this study shows that the last contraceptive used did not influence discontinuation (see Table 23) . It is interesting to note that other studies show that clients without recent experience with hormonal

contraceptive were likely to continue NORPLANT use compared to those with recent hormonal contraceptive experience (12).

As with other studies (12), the age group discontinuing for desired pregnancy was younger. A similar difference with lower parity at insertion correlating with a higher discontinuation rate. This is because those who are young and those with low parity will use NORPLANT for spacing as opposed to a long-term method.

Lost to follow-up

Nine percent of the clients lost to follow up. A study reported by Maimbolwa (12) at UTH and conducted between December, 1991 and January, 1992 to find out why clients delayed in coming for NORPLANT removal. Twenty clients were interviewed, five experienced no problems, another five said there was no doctor to attend to them, four had social problems, two feared getting pregnant after removal, one was busy at work and another was told by the doctor to be sterilised before removal. In-fact two respondents had started using alternative methods. This information indicates the importance of staff training, particularly in counselling. Also, providers need to be well trained in insertion and removal. To avoid loss to follow-up, accurate record keeping is important. Each client should have the date of insertion and removal on a card which she should keep as a reminder. It would also be helpful to have a mailing address of the client and next of kin so that the client can be reminded by mail, preferably two years after insertion when clients stop coming for review because they have less side effects then.

Summaries of Case records of deaths

First death was in a 29 year old woman who had NORPLANT inserted and reinserted after 5 years. The client died two and half years after reinsertion. No reason could be determined for the death.

Second client was a 28 year old widow who had NORPLANT in situ. The exact date of death was not known. She only made one visit 5 months after insertion at which time she had no complaints.

Third death was reported in a 39 year woman. She was reviewed three months after insertion with complaints of spotting, fever and general malaise. The client died with NORPLANT in-situ. The cause of death was tuberculosis.

Fourth death was reported in a 28 year. Full details were not available.

It was felt important to ensure proper documentation of deaths be recorded in future.

STUDY LIMITATIONS

The main limitations were of poor and incomplete record keeping. For instance, data was missing on age, and parity on some of the clients. There was no proper documentation of economic status of the clients.

CONCLUSION

The study suggests that NORPLANT is highly effective and a highly acceptable contraceptive method for Zambian women. However, since the method is provider dependent, the providers should be adequately trained to counsel, insert and remove the NORPLANT IMPLANTS.

RECOMMENDATIONS

It has been said that a wide range of choice of contraceptive methods encourages acceptance and sustained use; each additional method appears to contribute independently to overall prevalence of contraceptive use. Therefore, we should take advantage of this opportunity and introduce this contraceptive method. However, the success of this study can be attributed in part to the services and infrastructure available at an urban facility such as the University Teaching Hospital. Sterile procedures can be assured; medical staff can be available for immediate removal if requested; and follow-up can be facilitated because transport and communication facilities are present. If NORPLANT services are to be expanded beyond the current introductory programme, this should be done only where access to facilities with appropriate follow-up procedures and trained providers can be assured.

REFERENCES

1. Central Statistical Office (CSO) Republic of Zambia, 1995. 1990 Census of Population, Housing and Agriculture : Demographic Projection 1990-2000. Lusaka, Central Statistical Office.

2. Gaisie K, Cross A, Nsemukila G. Zambia Demographic and Health Survey, 1992. Columbia, Maryland, Macro International Inc, 1993.

3. Central Statistical Office (Zambia) and Ministry of Health and Macro International Inc. 1997. Zambia Demographic and Health Survey, 1996. Calverton Maryland: Central Statistical Office and Macro International Inc.

4. Leiras Pharmaceuticals : Norplant Contraceptive Implants. Product Information. Helsinki, Leiras, 1989.

5. The Population Council : Norplant a Summary of Scientific Data. New York, New York, The Population Council. 1990.

6. Gu SJ, Du MK, Zhang LD, Liu YL, Wang SH, Sivin I. A five year evaluation of Norplant contraceptive implants in China. *Obstetrics and Gynaecology,* p673 - 8, 1994.

7. Akhter H., Dunson TR., Amatya RN., Begum K., Chowdhury T., Dighe N., Krueger SL., Rahman S. A five year evaluation of Norplant contraceptive subdermal implants in Bangladeshi acceptors. *Contraception,* p569 - 82, 1993.

8. Berenson A.B., Wiemann CM. Patient satisfaction and side effects with Levonorgestrel implant use in adolescents 18 years of age or younger. *Paediatrics* 92 (2) : 257 - 60, 1993

9. Hassan ED., Kafafi L., el Husseini M., Hardee-Cleaveland K., Potter L. Acceptability of Norplant in Egypt. *Advances in Contraception* 8 (4): 331 - 48 , 1992.

10. Kasule J., Chipato T., Zinanga A., Mbizvo M., Maigurira J. Norplant in Zimbabwe : preliminary report. *Central African Journal of Medicine.* 38 (8): 321 - 4, 1992.

11.Chikamata D., Labanya G., Sikazwe C., Mwamba M., Mulenga F. Pre-introductory clinical trial of Norplant contraceptive subdermal implants. A report on the Zambian experience 1990. (unpublished) Department of obstetrics and Gynaecology, University teaching Hospital, Lusaka.

12.Grubb GS, Moore D, Anderson NG. Pre-introductory clinical trials of Norplant implants: a comparison of seventeen countries' experience. *Contraception* 52(5):287-296, 1995

13.M.C. Maimbolwa Factors contributing to failure of NORPLANT clients to return for scheduled removal at the University Teaching Hospital. Departmental Report, Department of Obstetrics and Gynaecology, University Teaching Hospital, Lusaka.

APPENDIX 1

PRODUCT PROFILE OF NORPLANT

(Adapted from Summary of Scientific Data) (reference 5)

NORPLANT is an effective, long lasting reversible contraceptive that provides protection for five years.

Six thin flexible capsules made of a soft rubber-like material each measuring 34mm long and 2.4mm wide and contains 36mg of Levonorgestrel, a synthetic progestin widely used in combined oral contraceptive and in the "Minipill" (progestin only pill). This hormone continuously diffuses through the walls of the capsule in low doses. They are inserted and removed just under the skin of a woman's upper arm in a minor surgical procedure. If the woman wishes to continue using NORPLANT, a new set of implants can be inserted at the same time as the old set is removed.

NORPLANT become effective within a few hours of insertion and will provide contraceptive protection for five years. Pregnancy is prevented through a combination of mechanisms; mainly involving inhibition of ovulation and thickening of the cervical mucus. Other mechanisms may add to these contraceptive effects.

The product literature claims that NORPLANT has undergone more than 20 years of extensive research and testing both in developing and developed countries. It has been found to be one of the most effective reversible contraceptive method. For every 100 women who use NORPLANT for a year, less than one will be pregnant.

NORPLANT may be used by almost any woman in her fertile years who wants to avoid getting pregnant. It is particularly suited for women who are seeking continuous contraceptives or want to space their children. Women who cannot use methods that contain oestrogen or who do not want to be sterilized and women who desire a method that is convenient and not related to sexual intercourse could opt for NORPLANT.

Contraindications include women who have active thromboembolic disorders; undiagnosed abnormal genital tract bleeding; acute liver disease or benign or malignant liver tumors or known or suspected carcinoma of the breast. Implants should be removed immediately, if a woman becomes pregnant.

Functional ovarian cysts sometimes occur in NORPLANT users. They usually disappear spontaneously and should not require surgery unless, as occurs rarely, they twist or rupture.

Ectopic pregnancy may occur although pregnancy is rare. Also, studies have shown no increase in the number of ectopic pregnancies per year among NORPLANT users as compared with users of no method or IUDs. The risk of ectopic pregnancy may increase with duration of NORPLANT and possibly with increased weight of the user.

Cigarette smoking increases the risk of serious cardiovascular side effects from use of combined oral contraceptives. This is believed to be an oestrogen - related effect. It is not known whether a similar risk exists with progestin only methods such as NORPLANT. However, NORPLANT users are advised not to smoke cigarettes.

In lactating women, studies have shown no significant effects on growth or health of infants if implants are inserted six weeks after childbirth.

Most side effects of NORPLANT are not serious. The most frequently reported side effect is change in the menstrual bleeding pattern. Other complaints include headache, nervousness, nausea, dizziness, adnexal enlargement, dermatitis, acne, change of appetite, mastalgia, weight gain, hirsutism and hair loss. Some drugs may affect the metabolism of the hormones delivered by NORPLANT to make the implants less effective in preventing pregnancy. These include rifampicin, barbiturates and phenytoin.

To make sure the woman is not pregnant NORPLANT are inserted within seven days after the onset of menstrual bleeding or immediately post-abortal. Once the implants

are removed, the contraceptive effect ceases within 24 hours and the woman can become pregnant as rapidly as women who have not used the method.

APPENDIX 2

TABLES AND FIGURES

Table 1 Summary of current methods, their mode of action side effects and efficacy.
(Adapted from Norplant Fact Sheet. August 1988, Population Council)

METHODS	1st YEAR PREGNANCY RATE (PER 100 USERS)	FREQUENCY OF ADMINISTRATION	WHAT IT IS/ HOW IT WORKS
HORMONAL NORPLANT[R] IMPLANTS	0.0 - 0.5	Once every 5 years	6 silicone rubber capsule filled with a progestin are inserted under skin of arm/often suppresses ovulation, thickens cervical mucus
COMBINED ORAL CONTRACEPTIVES	0.1 - 3	Daily	Combination pill contains a progestin and estrogen/suppresses ovulation, thickens cervical mucus
PROGESTIN ONLY PILLS	0.5 - 3	Daily	Minipill contains only a progestin/thickens cervical mucus, often suppresses ovulation
INJECTABLES (DEPO-PROVERA, NET-EN,)	0.3 - 0.4 (3 months)	Once every 3 and months respectively	Progestin is injected into muscle/thickens mucus, often suppresses ovulation
INTRAUTERINE DEVICE (COPPER T380A)	0.3 - 1	Once every 4 years	Plastic device inserted in uterus prevent fertilization/copper increases effectiveness
BARRIER DIAPHRAGM, CERVICAL CAP	3 - 18	Prior to sexual intercourse	Flexible rubber dome, or thimble-shaped cap, inserted into vagina to cover cervix. Used with spermicide.
VAGINAL CONTRACEPTIVES (SPERMICIDES)	3 - 28	Prior to sexual intercourse	Spermicide (foams, jellies, creams) inactivate sperm, prevent entry into uterus.
CONDOM	3 - 12	Prior to sexual intercourse	Thin rubber sheath put on man's erect penis, collects semen.
MALE STERILISATION	0.1 - 0.15	Once	Vas deferens are cut so sperm cannot enter the semen; minor surgery under local anesthetic.
FEMALE STERILISATION	0.2 - 0.4	Once	Fallopian tubes are closed so eggs cannot travel to be fertilized; can be dine under local or general anesthetic
PERIODIC ABSTINENCE	2 - 20	Abstinence for one-third to one-half of menstrual cycle	Couple refrain from intercourse when woman is ovulating; requires use of various measurements to determine fertile period.

Table 1 (continued) Summary of current methods, their mode of action side effects and efficacy.

METHODS	REVERSIBILITY/ RETURN TO FECUNDITY	SIDE EFFECTS
HORMONAL NORPLANT[R] IMPLANTS	Immediate upon removal	Bleeding irregularities include prolonged menses, spotting between periods, amenorrhea. Other side effects may include headaches, dizziness, nervousness, weight gain, ovarian cyst, acne and other skin and hair disorders, infection of implant site.
COMBINED ORAL CONTRACEPTIVES	Immediate to short delay	Side effects of combined pill include nausea, headache, weight gain, gastrointestinal complaints. Increased risk of stroke, cardio-vascular disease, particularly for women over 35 who smoke.
PROGESTIN ONLY PILLS	Immediate to short delay	Minipill users have menstrual irregularities, increased risk of ectopic pregnancy.
INJECTABLES (DEPO-PROVERA, NET-EN,)	Delayed 4 - 8 months	Heavy menstrual bleeding and amenorrhea
INTRAUTERINE DEVICE (COPPER T380A)	Immediate upon removal	Increased bleeding, often with pain, may make some women anemic. Infection and perforation of uterus possible at insertion. Risk of pelvic inflammatory disease. Recommended for women who have had at least one child and are in a stable, monogamous relationship.
BARRIER DIAPHRAGM, CERVICAL CAP	Immediate	Some women have pelvic conditions that rule out use. Diaphragm may be dislodged during intercourse. May interfere with spontaneity; some find it messy. May increase chance of bladder infection.
VAGINAL CONTRACEPTIVES (SPERMICIDES)	Immediate	Chemicals in sponge may cause irritation.
CONDOM	Immediate	Condoms may disrupt sexual pleasure for some.
MALE STERILISATION	Reversible in some cases	Temporary pain, swelling are common. Risk of operative and post-operative complications.
FEMALE STERILISATION	Reversible in some cases	Tubectomy has risk of operative and post-operative complications requiring medical care.
PERIODIC ABSTINENCE	Immediate	High failure rates, particularly if woman's cycle is not regular or she is ill. Requires monitoring of menstrual cycle, body temperature, cervical mucus. Not useful during lactation.

Table 1 (continued) Summary of current methods, their mode of action side effects and efficacy.

METHODS	ADVANTAGES	SPECIAL CHARACTERISTICS
HORMONAL NORPLANT[R] IMPLANTS	Can be used to delay of space pregnancies by most healthy women. Breast feeding women can use starting 6 weeks after child birth. Not related to intercourse, convenient. Has no estrogen and low amount of progestin, avoiding daily hormonal surges.	Very effective reversible method. Less effective aft years in women over 70Kg. Inserted and removed i minor surgical procedures by trained providers. Insertion during menses preferable to ensure woman not pregnant.
COMBINED ORAL CONTRACEPTIVES	Not related to intercourse. Convenient, easy to use. Combined pill protects against pelvic inflammatory disease, ectopic pregnancy, endometrial cancer, ovarian cancer, common menstrual disorders.	Highly effective when used regularly. Must be take daily. Levels of hormones fluctuate. Women can switch formulations to adjust intermenstrual bleedin
PROGESTIN ONLY PILLS		
INJECTABLES (DEPO-PROVERA, NET-EN,)	Does not interfere with lactation. Not related to intercourse, convenient.	Women must return regularly to clinic for injections. Levels of progestin fluctuate quarterly.
INTRAUTERINE DEVICE (COPPER T380A)	Long-term method, not related to intercourse, convenient	Woman has to check regularly, to make sure device h not been expelled. Insertion and removal by trained provider. Requires careful patient selection. Must b removed if woman becomes pregnant. Insertion duri menses preferable to ensure woman is not pregnant.
BARRIER DIAPHRAGM, CERVICAL CAP	Comes in different sizes. No apparent health risks. Barrier methods, including condom, and spermicides provide best protection against sexually transmitted diseases, including AIDS.	Diaphragm must be left in place 6 hours after intercourse. Cervical cap can be in place for 2 days v additional application of spermicide. Must be fitted b provider and refitted after pregnancy or marked weig change. Must be kept clean.
VAGINAL CONTRACEPTIVES (SPERMICIDES)		Polyurethane sponge must be kept in place 6 hours af intercourse, should be removed within 24 hours.
CONDOM		Condoms are available in variety of sizes, thickness, colors, texture, and with or without spermicide.
MALE STERILISATION	No impairment of sexual functioning. Not related to intercourse.	Sterilization is only method of permanent contracepti Should be selected only if no more children are desire
FEMALE STERILISATION	No long-term health or safety risks with either procedure.	Tubectomy is usually arranged in advance, maybe performed after childbirth or abortion or combined w other surgery.
PERIODIC ABSTINENCE	No health risks, except high pregnancy rate.	Careful instruction required. Depends on commitmer of couple to methods and on ability of woman to lear symptoms of ovulation and keep records.

FIGURE 1

CURRENT STATUS OF ALL CLIENTS

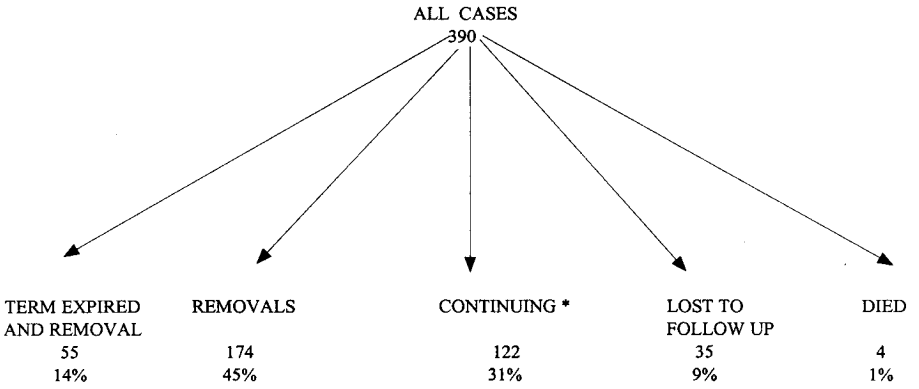

TABLE 2: YEARS OF INSERTION

YEARS OF INSERTION	NUMBER	PERCENT
86-88	203	52.1
89-91	88	22.6
92-94	99	25.4
TOTAL	**390**	**100**

FIGURE 2

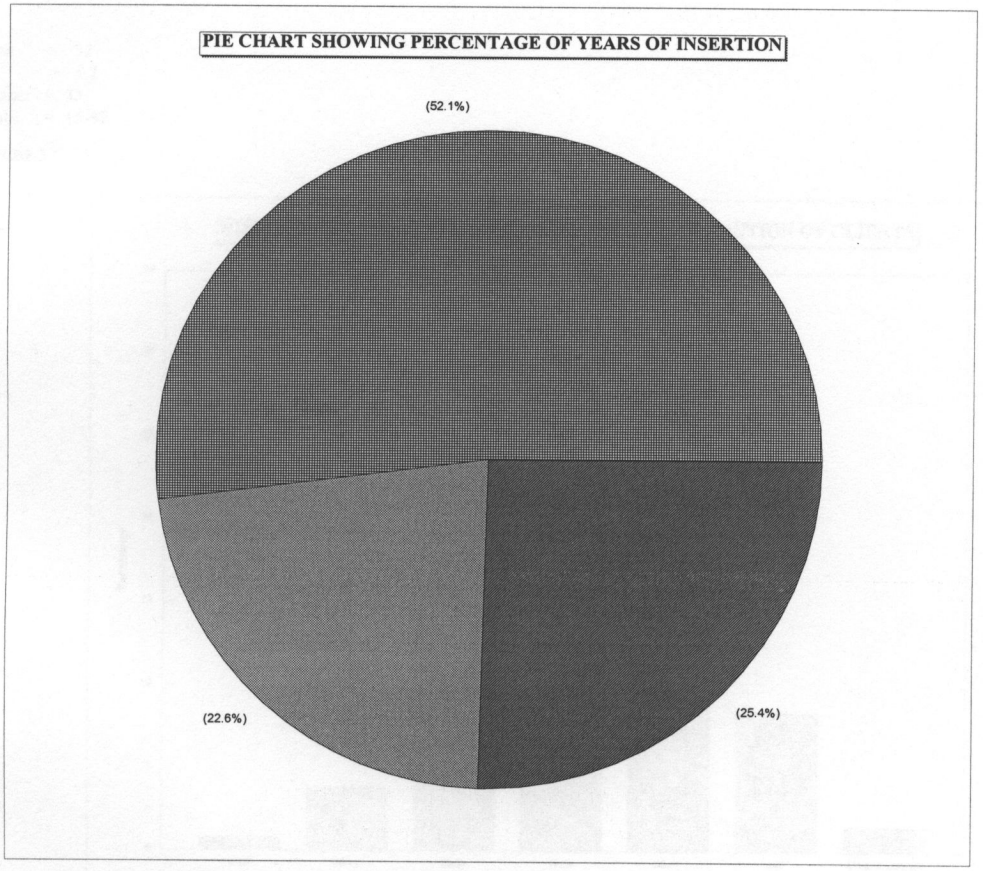

TABLE 3: AGE DISTRIBUTION OF CLIENTS

AGE (Years)	NUMBER	PERCENT
< 20	3	0.8
20-24	15	3.8
25-29	96	24.6
30-34	117	30.0
35-39	120	30.8
>40	33	8.5
UNSPECIFIED	6	1.5
TOTAL	**390**	**100**

Mean = 32
SD = 5.2
Median = 33
Range = 15-47

FIGURE 3

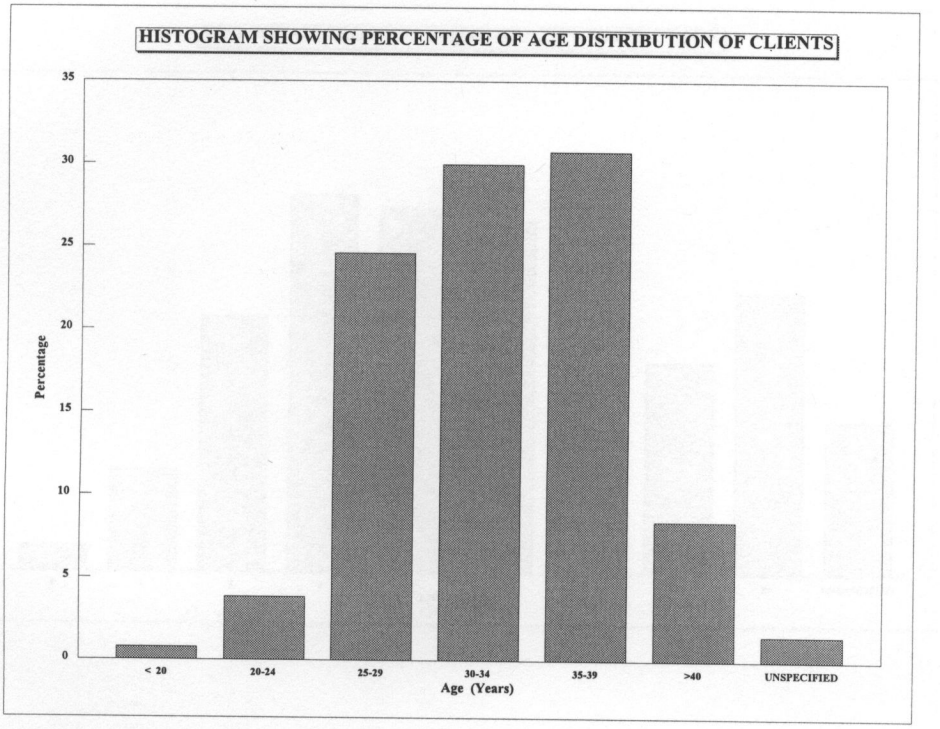

TABLE 4: PARITY OF CLIENTS

LIVE BIRTHS	NUMBER	PERCENT
0	4	1.0
1	16	4.1
2	40	10.3
3	59	15.1
4	57	14.6
5	55	14.1
6	58	14.9
7	33	8.5
8+	44	11.3
UNSPECIFIED	24	6.2
TOTAL	**390**	**100**

FIGURE 4

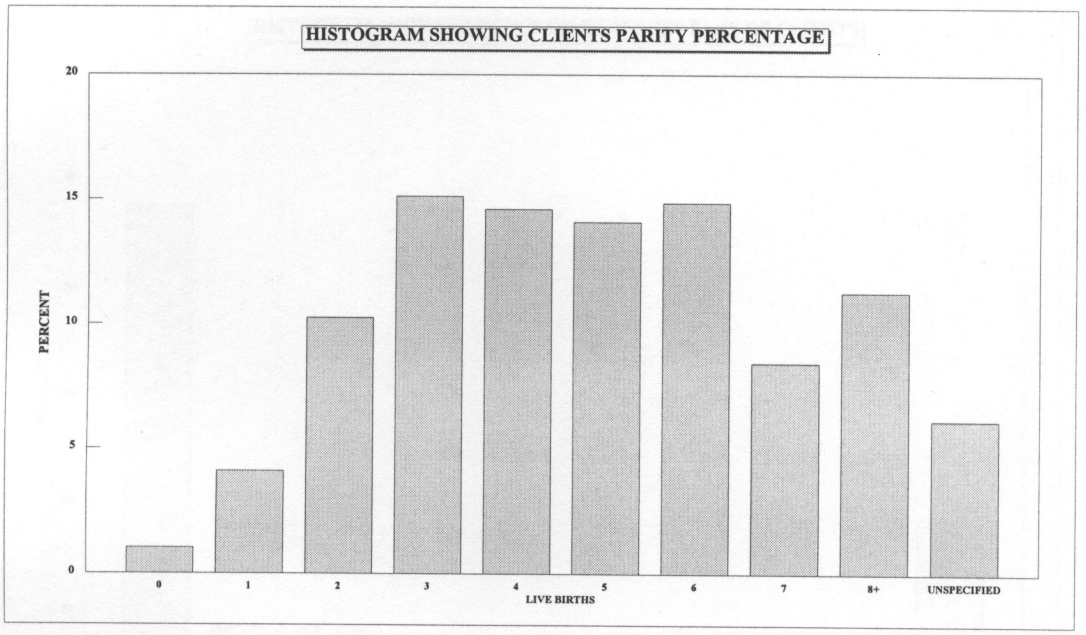

TABLE 5: OCCUPATION OF CLIENTS

CATEGORY	NUMBER	PERCENT
HOUSE WIFE	186	47.7
SECRETARY	33	8.5
NURSE	33	8.5
DOCTOR	5	1.3
CLEANER	10	2.6
TEACHER	16	4.1
CLERK	8	2.1
BANKER	9	2.3
TYPIST	18	4.6
OTHERS	72	18.5
TOTAL	**390**	**100**

FIGURE 5

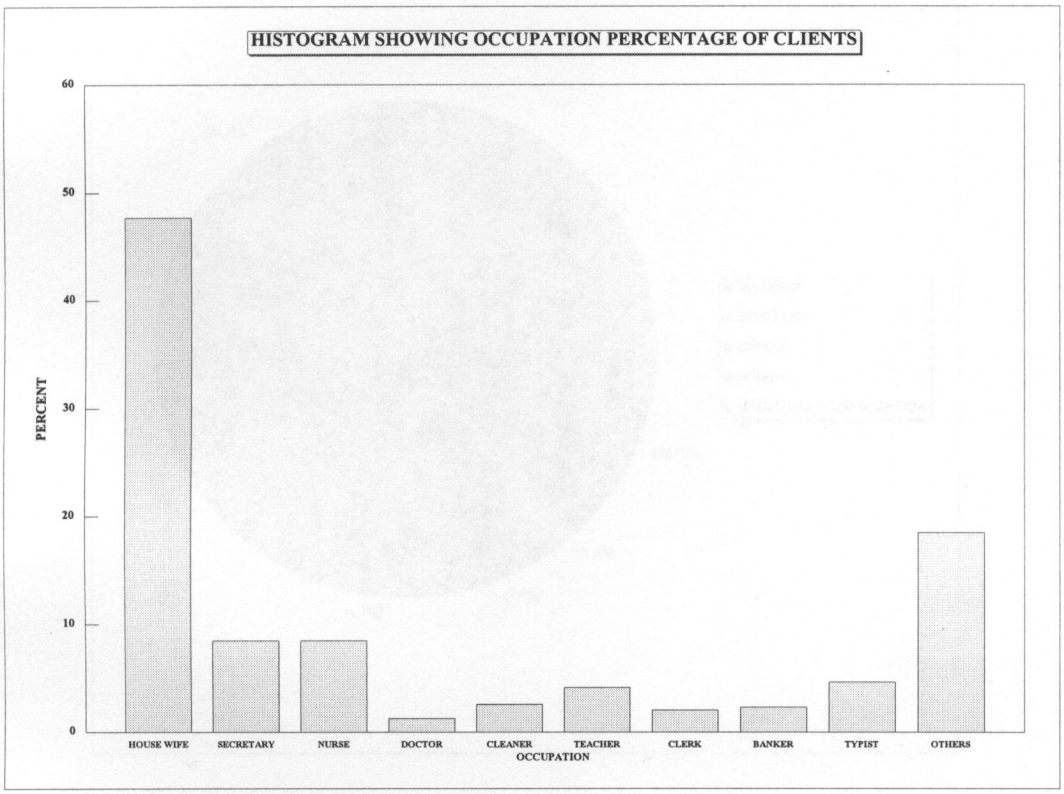

TABLE 6: MARITAL STATUS OF CLIENTS

MARITAL STATUS	NUMBER	PERCENT
MARRIED	274	70.3
DIVORCED	26	6.7
SINGLE	31	7.9
WIDOW	8	2.1
UNOBTAINED INFORMATION	51	13.1
TOTAL	**390**	**100**

FIGURE 6

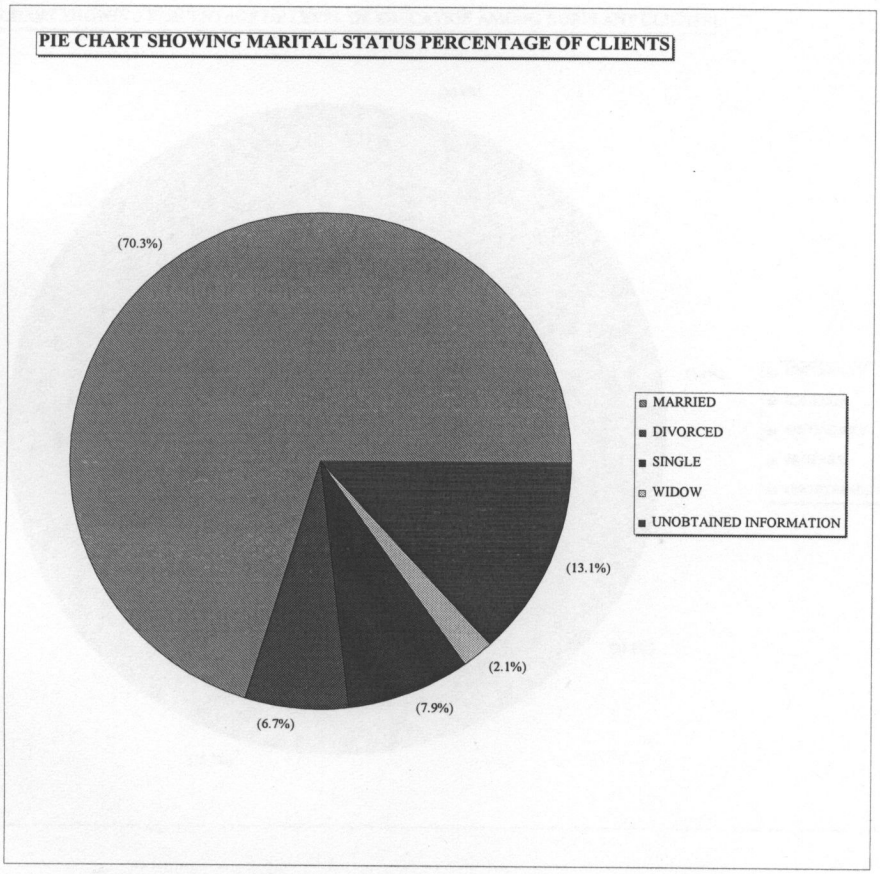

TABLE 7: LEVEL OF EDUCATION AMONG NORPLANT CLIENTS

LEVEL OF EDUCATION	NUMBER	PERCENT
UNIVERSITY	20	5.1
COLLEGE	120	30.8
SECONDARY	103	26.4
PRIMARY	63	16.2
UNOBTAINED INFORMATION	84	21.5
	390	**100%**

FIGURE 7

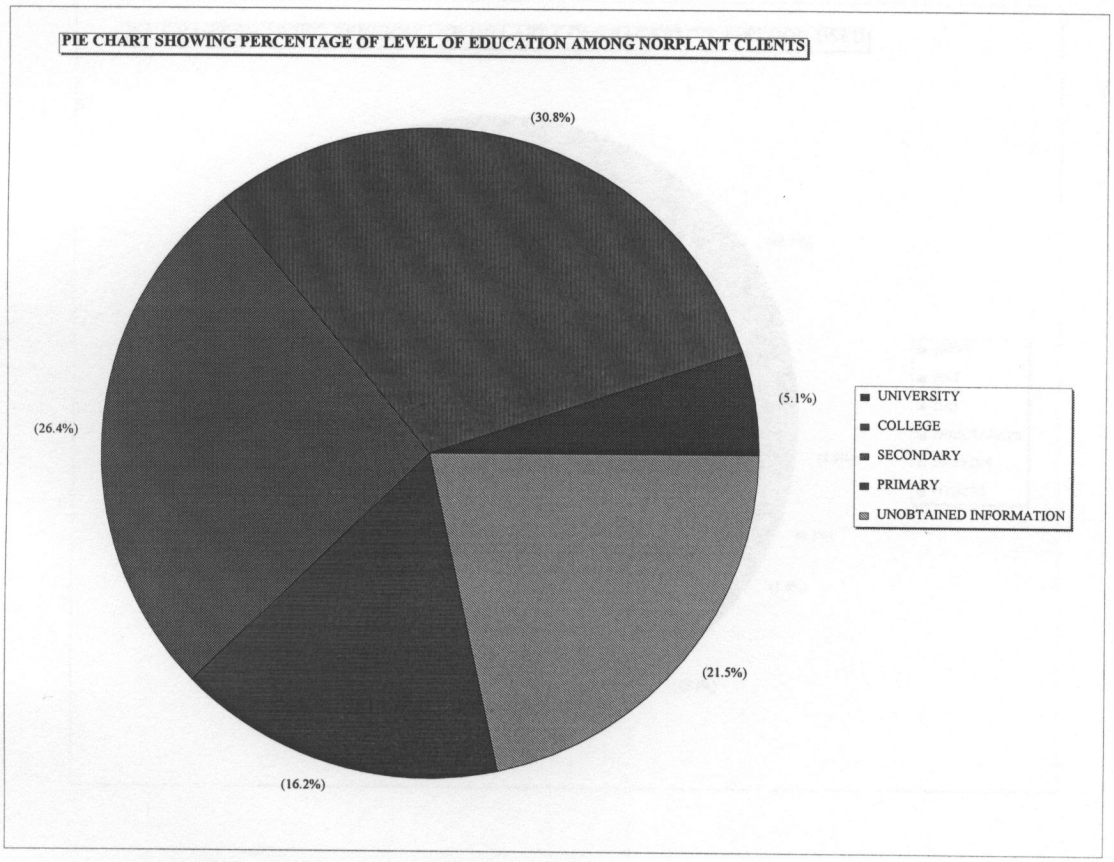

TABLE 8: LAST CONTRACEPTIVE METHOD USED

CONTRACEPTIVE	NUMBER	PERCENT
NONE	72	18.5
PILL	234	60.0
IUD	47	12.1
INJECTABLES	6	1.5
BARRIER	16	4.1
OTHERS	15	3.8
TOTALS	**390**	**100**

FIGURE 8

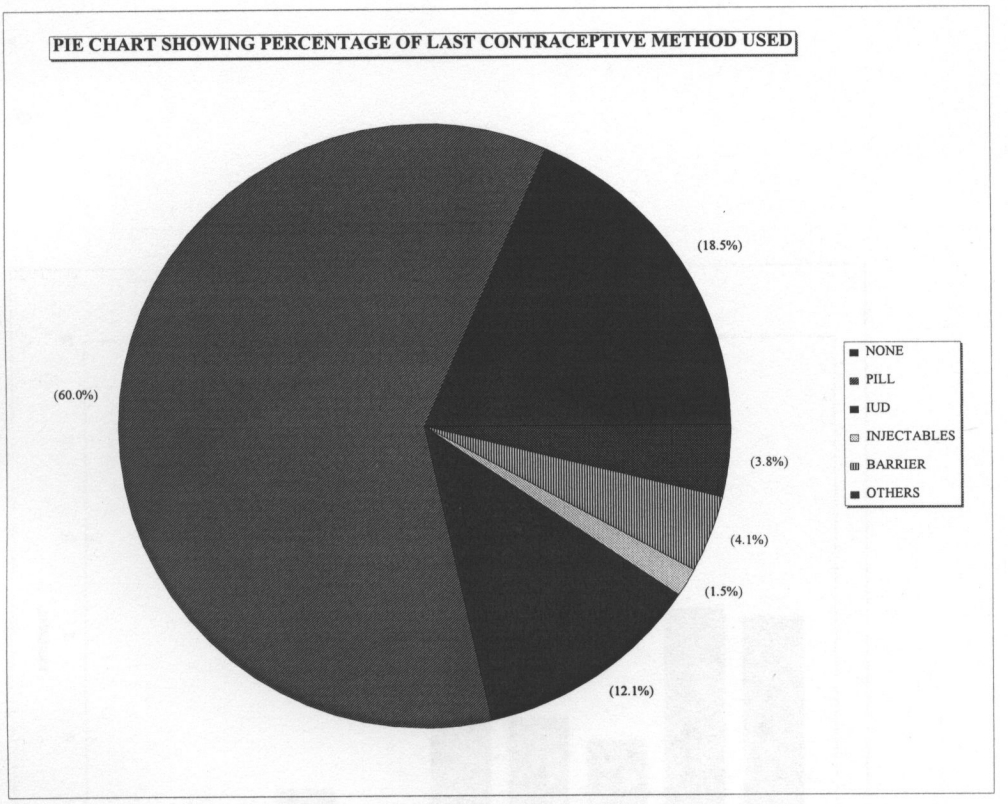

TABLE 9: DURATION OF USE OF NORPLANT

PERIOD (MONTHS)	NUMBER	PERCENT
<3	9	3.5
4-6	10	3.9
7-9	19	7.4
10-12	15	5.8
13-24	68	26.5
25-36	28	10.9
37-48	25	9.7
49-60	42	16.3
>60	41	16.0
TOTAL	**257**	**100**

FIGURE 9

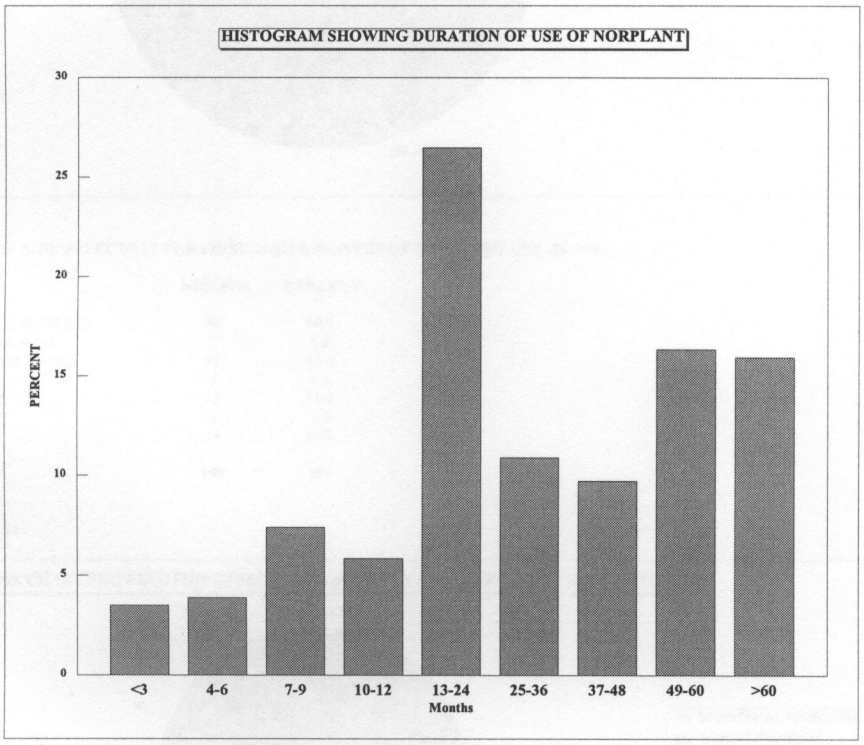

TABLE 10: NUMBERS OF CLIENTS BY COMPLAINT IN THE FIRST THREE MONTHS

CATEGORY	NUMBER	PERCENT
NO COMPLAINTS	145	37.2
CLIENTS WITH COMPLAINTS	96	24.6
DID NOT TURN UP	140	35.9
REMOVALS	9	2.3
TOTAL	**390**	**100**

FIGURE 10

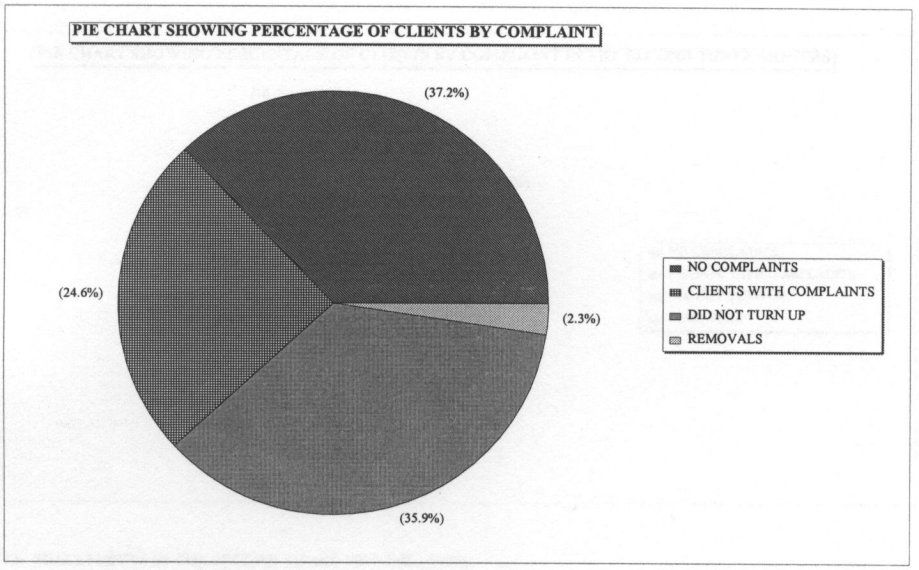

TABLE 11: SIDE EFFECTS IN THE FIRST THREE MONTHS OF NORPLANT USE (N = 96)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	54	49.5
WEIGHT PROBLEM	2	1.8
SITE COMPLICATIONS	17	15.6
DIZZINESS	5	4.6
HEADACHE	12	11.0
RAISED BP	5	4.6
OTHERS	14	12.8
TOTAL	**109**	**100**

FIGURE 11

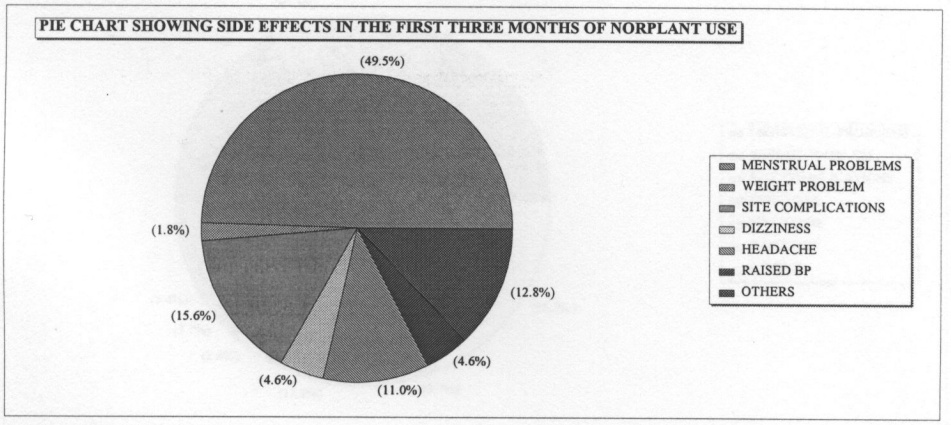

TABLE 12: NUMBERS OF CLIENTS BY COMPLAINT IN THE SECOND THREE MONTHS (N = 390)

	NUMBER	PERCENT
NO COMPLAINTS	70	17.9
CLIENTS WITH COMPLAINTS	73	18.7
DID NOT TURN UP *	235	60.3
REMOVALS	12	3.1
TOTAL	**390**	**100**

*INCLUDES 2 DEATHS

FIGURE 12

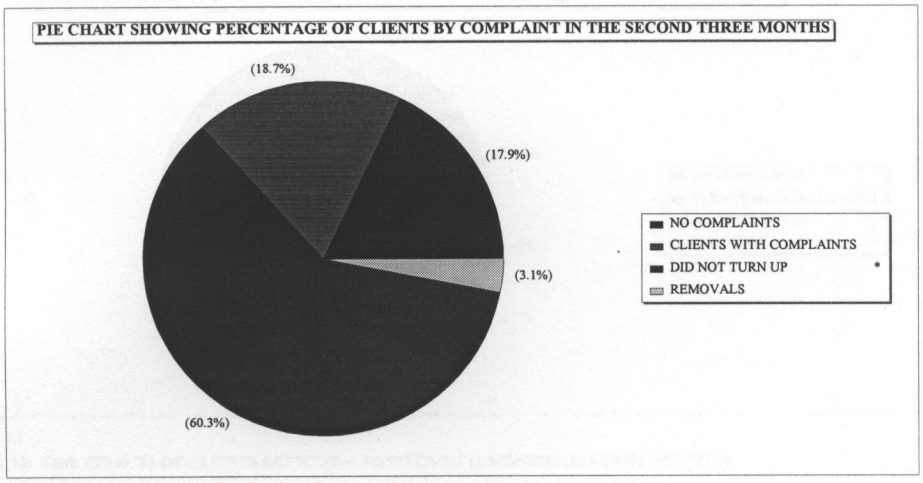

TABLE 13: SIDE EFFECTS IN THE SECOND THREE MONTHS (N=73)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	47	57.3
WEIGHT PROBLEM	2	2.4
SITE COMPLICATIONS	3	3.7
DIZZINESS	2	2.4
HEADACHE	10	12.2
RAISED BP	3	3.7
OTHERS	15	18.3
TOTAL	**82**	**100**

FIGURE 13

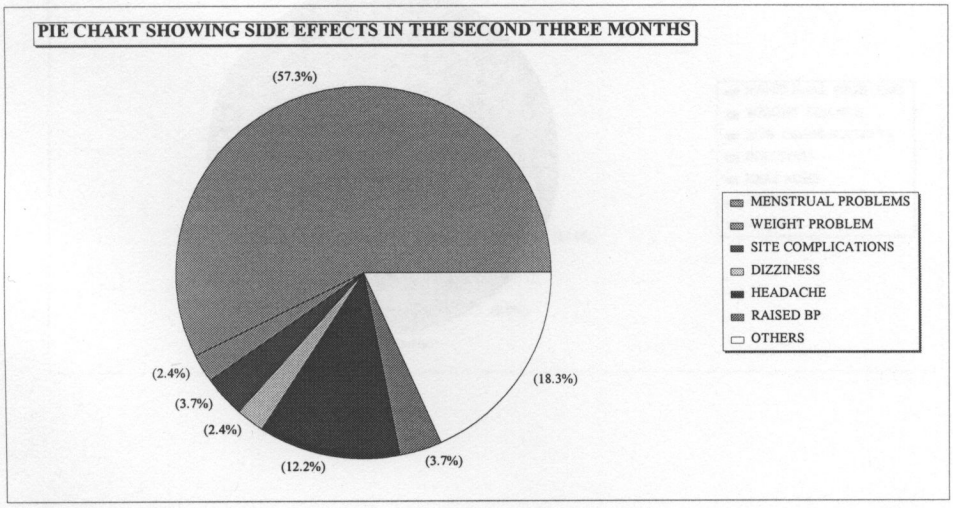

TABLE 14: NUMBERS OF CLIENTS BY COMPLAINT BETWEEN 6 AND 12 MONTHS (N=390)

	NUMBER	PERCENT
NO COMPLAINTS	41	10.5%
CLIENTS WITH COMPLAINTS	82	21.0%
DID NOT TURN UP	242 *	62.1%
REMOVALS	25	6.4%
TOTAL	**390**	**100%**

* Includes 2 deaths

FIGURE 14

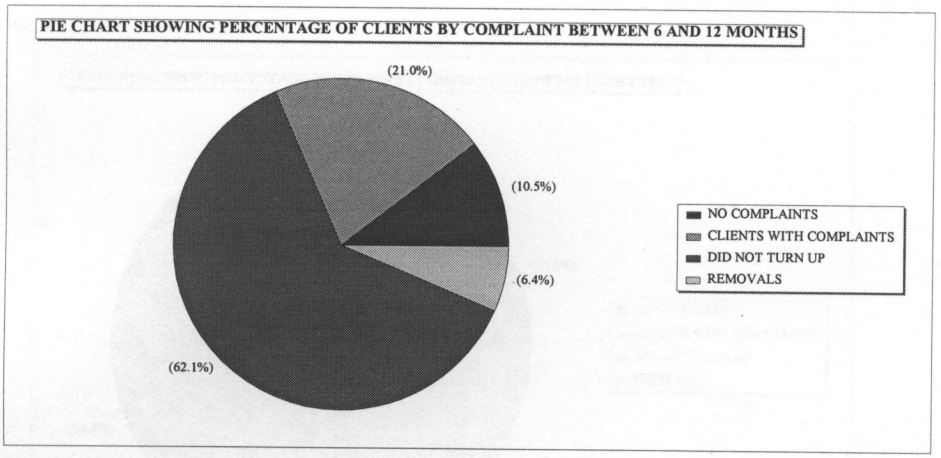

TABLE 15: SIDE EFFECTS OF CLIENTS BETWEEN 6 MONTHS TO 12 MONTHS (82 COMPLAINANTS)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	62	54.4%
WEIGHT CHANGE	7	6.1%
SITE COMPLICATIONS	3	2.6%
DIZZINESS	5	4.4%
HEADACHE	18	15.8%
HIGH BP	3	2.6%
OTHERS	16	14.0%
TOTAL	114	100%

FIGURE 15

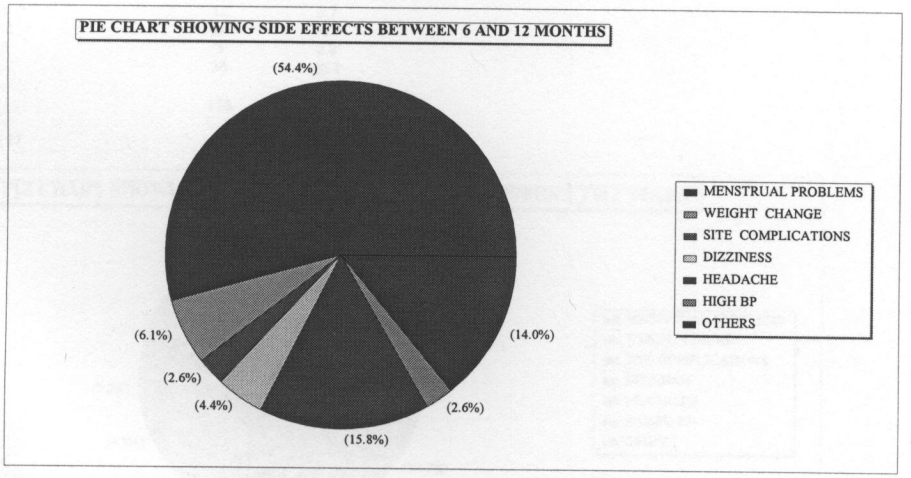

TABLE 16: NUMBER OF CLIENTS BY COMPLAINT BETWEEN 1 AN 2 YEARS (N=390)

	NUMBER	PERCENT
NO COMPLAINTS	45	11.5%
CLIENTS WITH COMPLAINTS	84	21.5%
DID NOT TURN UP	183	46.9%
REMOVALS	78	20.0%
*Includes 3 deaths	**390**	**100**

FIGURE 16

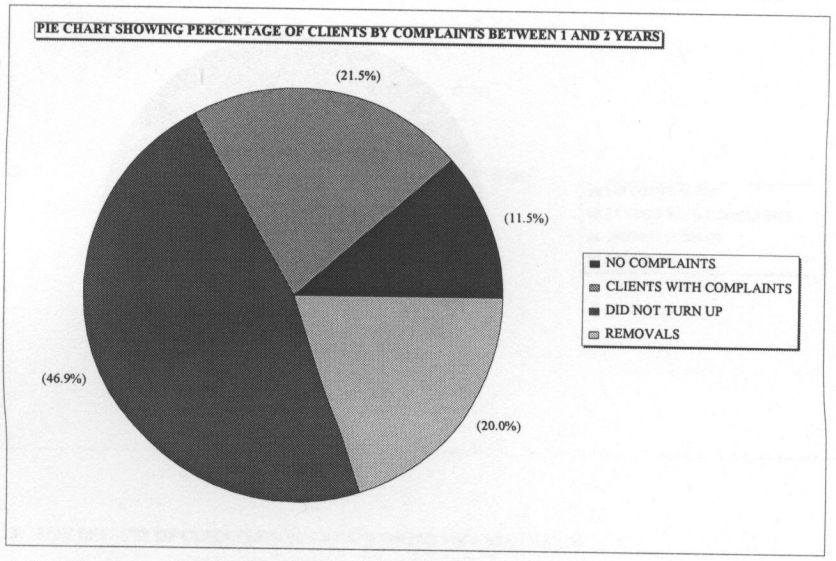

TABLE 17: SIDE EFFECTS OF CLIENTS BETWEEN 1 TO 2 YEARS (N=84)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	85	47.8
WEIGHT CHANGE	13	7.3
SITE COMPLICATIONS	8	4.5
DIZZINESS	12	6.7
HEADACHE	19	10.7
RAISED BP	5	2.8
OTHERS	36	20.2
TOTAL	**178**	**100**

FIGURE 17

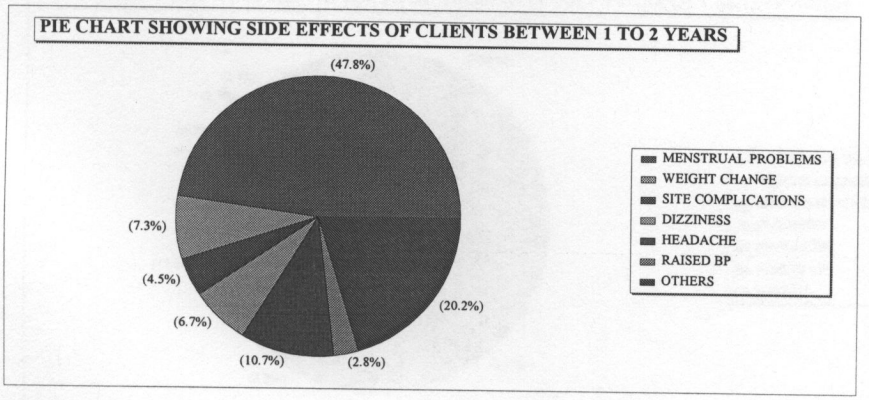

TABLE 18: NUMBER OF CLIENTS BY COMPLAINT FROM 2 YEARS ONWARDS (N=390)

		NUMBER	PERCENT
NO COMPLAINTS		29	7.4
CLIENTS WITH COMPLAINTS		30	7.7
DID NOT TURN UP	*	102	26.2
REMOVALS	**	229	58.7
TOTAL		**390**	**100**

FIGURE 18

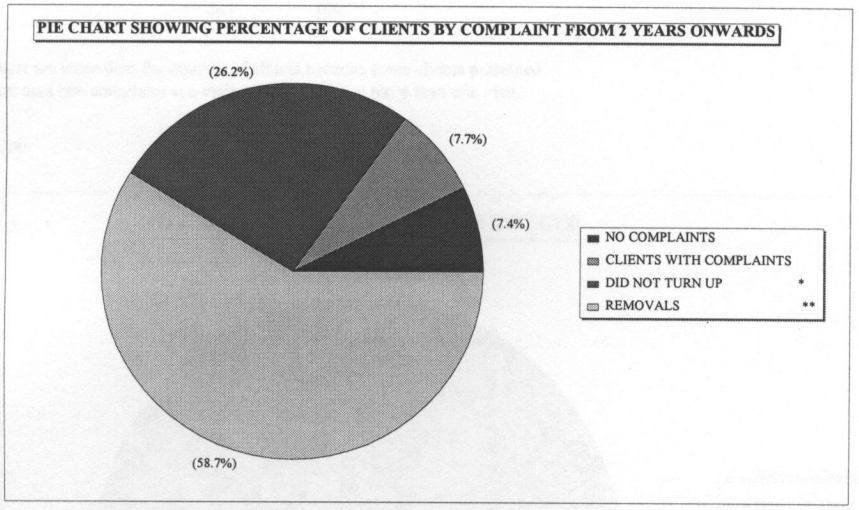

TABLE 19: SIDE EFFECTS OF CLIENTS FROM 2 YEARS OF USE ONWARDS (N=30)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	37	34.3
WEIGHT CHANGE	4	3.7
SITE COMPLICATIONS	1	0.9
DIZZINESS	7	6.5
HEADACHE	19	17.6
RAISED BP	9	8.3
OTHERS	31	28.7
	108	**100**

FIGURE 19

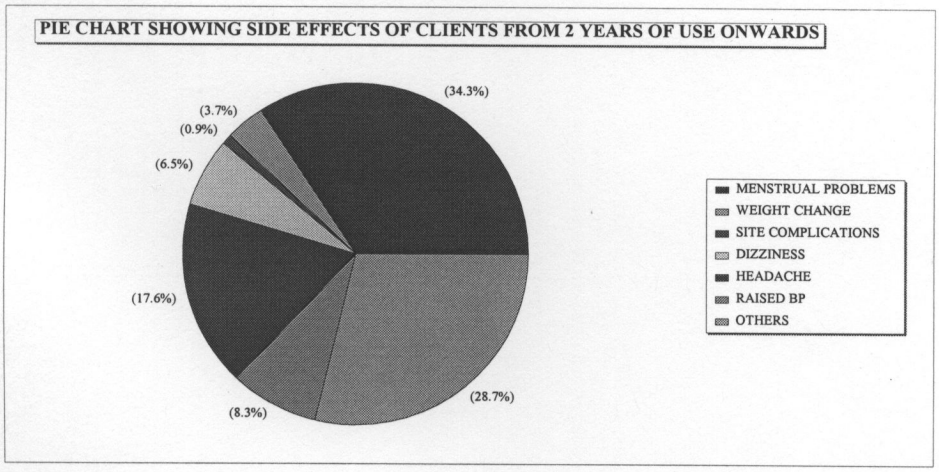

TABLE 20: TOTAL NUMBER OF SIDE EFFECTS FROM ALL CLIENTS (N=390)

	NUMBER	PERCENT
MENSTRUAL PROBLEMS	285	48.4
WEIGHT CHANGE	28	4.8
SITE COMPLICATIONS	32	5.4
DIZZINESS	29	4.9
HEADACHE	78	13.2
RAISED BP	25	4.2
OTHERS	112	19.0
TOTAL	**589**	**100**

Side effects are more than the number of clients because some clients presented with more than one complaint at a visit or complained at more than one visit.

FIGURE 20:

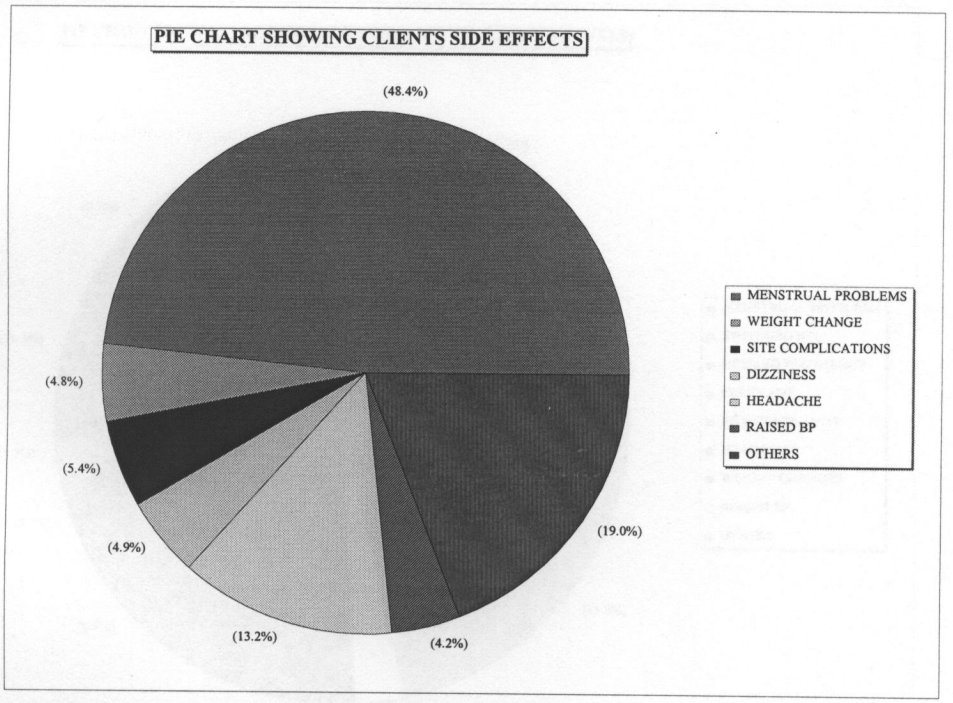

TABLE 21: PRIMARY REASON FOR NORPLANT IMPLANT REMOVAL (n=174)

COMPLAINT	NUMBER	PERCENT
MENSTRUAL PROBLEMS	61	35.1
SWITCHED BTL	10	5.7
DESIRED PREGNANCY	18	10.3
PREGNANT	3	1.7
SITE COMPLAINTS	10	5.7
HEADACHE	12	6.9
WEIGHT CHANGES	18	10.3
RAISED BP	5	2.9
OTHERS	37	21.3
TOTAL	**174**	**100**

FIGURE 21

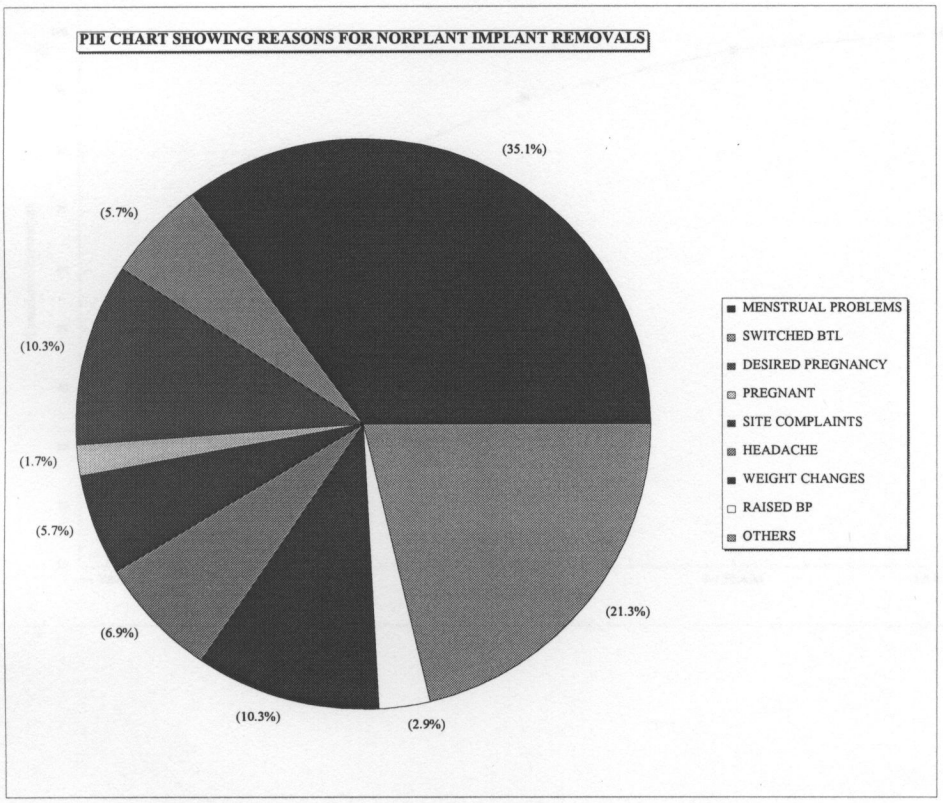

TABLE 22: DURATION OF USE BY CLIENT WITH MENSTRUAL PROBLEMS (n = 61)

DURATION	NUMBER	PERCENT	CUMULATIVE
>1 YEAR	14	23.0	22.0
1-2 YEARS	31	50.8	74.0
2-3 YEARS	8	13.1	87.0
3-4 YEARS	6	9.8	97.0
4-5 YEARS	2	3.3	100
	61	**100**	

FIGURE 22

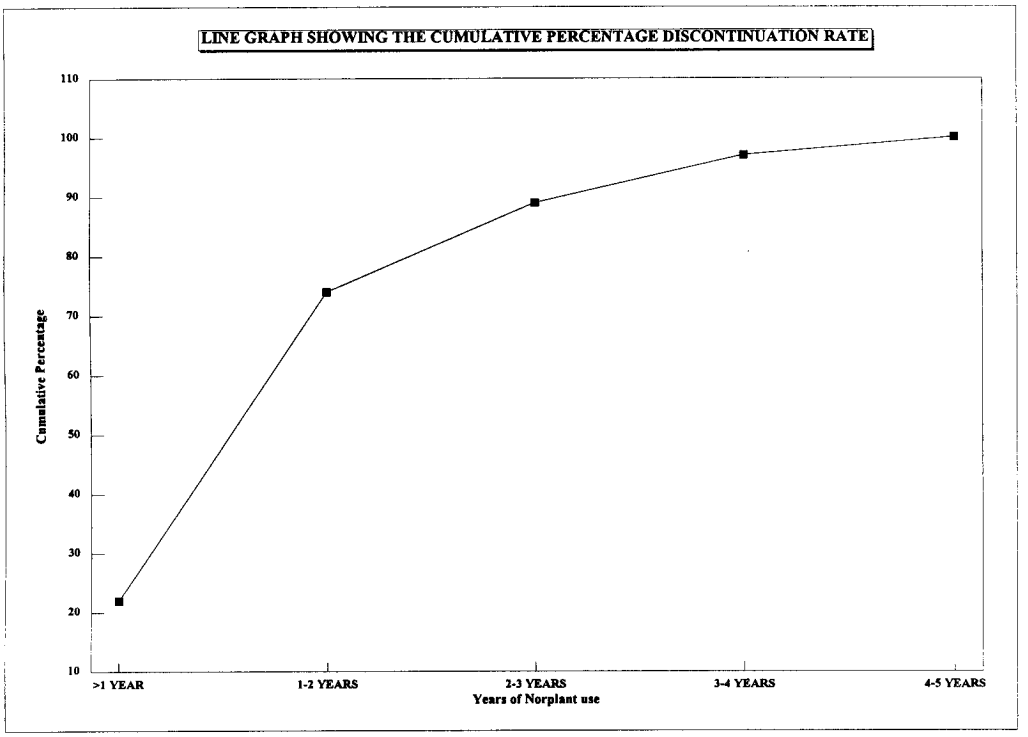

Table 23. DISCONTINUATION WITH REGARD TO LAST CONTRACEPTIVE USED.

METHOD n=174	DESIRED PREGNANCY n=18	MENSTRUAL DISTURBANCES n=61	OTHER COMPLAINTS n=95
NONE	(4) 23%	(7) 11%	(14) 14%
NON-HORMONAL	(3) 15%	(14) 22%	(33) 35%
HORMONAL	(11) 62%	(40) 67%	(48) 51%
Totals	100 %	100 %	100 %

TABLE 24. COMPARISON OF CLIENTS WHO DISCONTINUED WITH RESPECT TO PARITY

	The rest of the clients(216)	Clients who discontinued (174)	
		Desired pregnancy (18)	Other Complaints (156)
Mean Parity	4.9	3.3	4.8
Parity Range	1 - 13	2 - 7	1 - 14

1. There was significant difference in the mean parity when the rest of the clients were compared to those who discontinued for desired pregnancy.
   (4.9 vs 3.3, sig, $p < 0.0001$) (students 't' test)

2. When the mean parity of those who discontinued because the desired pregnancy was compared to those clients who discontinued due to complaints, there was significant difference. (4.8 vs 3.3, sig, $p < 0.005$)

3. There was no significant difference between the mean parity of the rest of the clients and those who discontinued due to complaints.
   (4.9 vs 4.8, sig $p < 0.9$)

TABLE 25. COMPARISON OF CLIENTS WHO DISCONTINUED WITH RESPECT TO AGE.

	The rest of clients (216)	Clients who discontinued (174)	
		Desired Pregnancy (18)	Other complaints (156)
Mean Age (years)	32.7	28.4	33.1
Age Range (years)	15 - 45	20 - 35	23 - 47

1. There was significant difference in the mean age when the rest of the clients were compared to those who desired pregnancy. (32.7 vs 28.4 $p < 0.0001$)

2. When the mean age of those who discontinued because their desired pregnancy was compared to those clients who discontinued due to complaints, there was significant difference. (28.4 vs 33.1 $p < 0.0001$)

3. There was no significant difference between the mean age of the rest of the clients and those who discontinued due to complaints. (32.7 vs 33.1 $p = 0.443$)