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EXPERIENCE WITH NORPLANT AT A NIGERIAN TEACHING HOSPITAL

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ABSTRACT

Objectives: To determine the acceptance of Norplant implants while it was in use and share our experience with other Norplant providers.

Design: Retrospective descriptive study.

Setting: The family planning clinic of the Jos University Teaching Hospital, Jos, Nigeria.

Results: During the 21-year period, January 1985 to December 2005, a total of eighteen thousand, two hundred and ninety one (18,291) new clients accepted various modern contraceptive methods in the family planning clinic of Jos University Teaching Hospital, Nigeria. Norplant was accepted by 1,333 clients (4.9%) as against the intrauterine devices (IUDs) 25.4%, and Oral Contraceptive Pills (OCP) 22.9%. Female sterilisation was a contraceptive method of choice in 21.2%, the injectables in 13.9%, and the male condom in 9.3%. Failure rate was 0.37% and continuity rate was high among users. The Norplant contraceptive implant was accepted by women of mean age of 29.6 years and women of all parity. The acceptance pattern demonstrated a multi-nodal pattern from the time of introduction in 1985 to December 2005 when supply came to an abrupt stop. The greatest barriers to Norplant use were non-availability and high cost of the commodity.

Conclusion: Norplant implants provided contraceptive protection with high reliability, safety, independence from user compliance, rapid return of pre-existing fertility after removal, good tolerability, and relatively simple and quick insertion and removal. The capsules will definitely be used as a reference for similar contraceptive products in the contraceptive market.

INTRODUCTION

The development of levo-norgestrel implants (Norplant) was aimed at meeting the contraceptive need for a long-term reversible contraceptive free from estrogen side effects (1). Implant development began in 1966 with the pioneering research work of Segal and Croxatto (2,3). The development of subdermal contraceptive implants was made possible by the introduction of silicone rubber in the late 1940s. The original sub-dermal implants developed by the Population Council provided safe, convenient, reversible, long term and highly effective method of contraception for women (4). Norplant[®] is the trademark of the Population Council for levo-norgestrel subdermal implants. The six-capsules system released approximately 30 mcg /day of levo-norgestrel, and was said to be effective for at least five years. Each capsule was about 34mm by

2.4mm and contains 36 mg of free crystals of levo-norgestrel. The continuation rates are good in many acceptors, and over half of the acceptors used the method by three years, while discontinuation rates were up to 14.1/100 users at four years (5). Medical reasons for the discontinuation included headaches, weight changes, and skin problems amongst others. Discontinuation prior to the recommended removal time of five years is likely to be among younger women desiring to be pregnant again. The return of fertility after removal is rapid and almost comparable to that of the normal population (5). About 76% of Norplant acceptors become pregnant 12 months after discontinuation, and 90% within 24 months (5). Pre-introductory clinical trial in Nigeria was between 1985 and 1990 (6,7), and Jos University Teaching Hospital participated in the trial. The implants were introduced into clinical settings in 1989, overlapping with the pre-clinical introductory clinical trial (6).

Norplant got registered for use in Nigeria with National Agency for Food and Drug Administration and Control (NAFDAC), in 1998, with the registration number of 04-110 (8).

Jos University Teaching Hospital provides wide range of family planning methods. It commenced Norplant services to desiring clients in 1985 (9) but supply came to an abrupt end in November 2005 following the stoppage of further manufacture and distribution of the contraceptive. Most women who have had Norplant liked it for its effectiveness, convenience and lack of serious complications (10), however few women had unacceptable problems warranting their removal before time.

The study was to determine Norplant acceptance compared with other methods, the trend, effectiveness, and side effects among the users during the period that it was in use.

MATERIALS AND METHODS

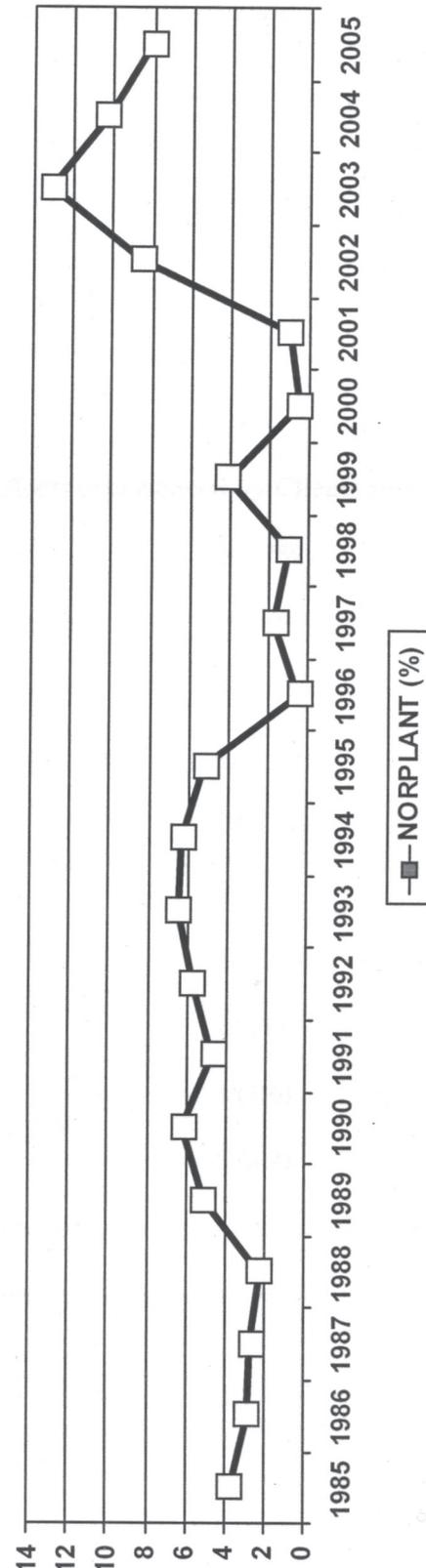
This was a retrospective descriptive study aimed at sharing our experience of over two decades of use of the Norplant implant, a long term contraceptive method, in our Family Planning clinic setting. The period covered in the study was January 1985 to December 2005; 21-year duration of use in the clinic. The records of all clients that used the implant and clients that used other modern methods of contraception were retrieved and analysed. The information extracted from the case notes of implant users included their age, parity, number of living children and weight at insertion. The duration of use of the implants, indication for removal, complications and side effects were also collated. The total yearly acceptance of Norplant and other methods of modern contraception accepted by clients were also computed from the register.

RESULTS

A total of eighteen thousand, two hundred and ninety one (18,291) new clients accepted various modern contraceptive methods in the family planning clinic. Norplant was accepted by 1,333 clients (4.9%) as against the intrauterine devices (IUDs) 25.4%, and Oral Contraceptive Pills (OCP) 22.9%. Female sterilisation was a contraceptive method of choice in 21.2%, the Injectables in 13.9%, and the male condom in 9.3% cases. The acceptance of the method demonstrated a multiple modal pattern from introduction in 1985, until it came to an abrupt end in December 2005, Figure 1. The peak period of acceptance was between 2003 and 2004, during which large consignment of the implants were received.

Figure 1

The yearly distribution of Norplant acceptors, in percentages, compared with other modern contraceptive methods in Jos University Teaching Hospital between 1985 and 2005 when supplies stopped



The socio-demographic parameters are as shown in Table 1. The clients were women of the reproductive age, with a mean age of 33.2 ± 5.7 years. The women were of mean parity 3.8 ± 1.7 and about 31.5% were of parity five and above. Their mean weight at insertion was 66.6 ± 10.9 kg and the mean of the duration of use of the implants was 38.4 months.

Table 1
Socio-demographic Characteristics of the Clients

	Range	Mean
i. Age of Women (years)	18 - 48	33.2 ± 5.7
ii. Weight (kg)	32 - 95	66.6 ± 10.9
iii. Parity	0 - 10	3.8 ± 1.7
iv. Duration of use (months)	1 - 120	38.4

The common side effects were as seen in Table 2. These included disruption of the menstrual cycle 117 (62.9%), headaches 38 (20.4%), weight gain 22 (11.9%) and infection of the insertion site in three (1.6%). Disruption of the menstrual cycle manifested as prolonged menstrual cycle 52, menorrhagia 17, spotting between periods 43 and amenorrhoea five.

Table 2
Reported Side Effects experienced by Clients (n = 186)*

Reported Side Effect	No.	(%)
i. Disruption of the menstrual cycle	117	(62.9)
- Prolonged menstrual cycle	52	
- Spotting between periods	43	
- Menorrhagia	17	
- Amenorrhoea	5	
ii. Headaches	38	(20.4)
iii. Weight gain	22	(11.9)
iv. Infection	3	(1.6)
v. Others	6	(3.2)

(*Not all the side effects were indications for removal of the Norplant as many clients still kept the implants despite the side effects)

The most common indication for the removal of Norplant was the desire for another pregnancy (37.1%) and closely followed by expiration of the implants in the client's arm (36.4%). Menstrual disruption constituted 13% of the indications for removal, Table 3. Norplant was the most expensive of all available methods of contraception in the facility costing about twice the next costly method namely bilateral tubal ligation, Table 4. Norplant cost about N2,000 (\$ 13) while bilateral tubal ligation cost N 1,000 (\$ 7) .

Table 3
Indications for Removal of Norplant Implants during Study Period

Indication for removal	Number (%)
i. Desire for pregnancy	208 (37.1)
ii. Expiration <i>in vivo</i>	204 (36.4)
iii. Menstrual disruption	73 (13.0)
iv. Headaches	22 (3.9)
v. Change to BTL	13 (2.3)
vi. Spousal disapproval	12 (2.1)
vii. Weight gain	7 (1.3)
viii. Death of spouse	5 (0.9)
ix. Infection/partial expulsion	3 (0.5)
x. Others	13 (2.3)
Total	560 (100.0)

Table 4
Comparative costs of the commonly used contraceptives in Jos

Contraceptive method	Cost per Service in \$US (Naira)
Bilateral tubal ligation	7 (1,000)
Injectables	0.5 (60)
Intrauterine Devices	1.3 (200)
Oral Pills	0.1 (15)
Female Condom	0.1 (20)
Male Condom	< 0.01 (1)
Norplant	13 (2,000*)

(\$1 is equivalent to about 150 Naira; *Method therefore not affordable to many intending users of Norplant)

DISCUSSION

Norplant implants were accepted by about 5% of clients using modern methods of contraception during the period of study. Norplant implants occupied the fifth position among other contraceptive methods in Jos and fourth place in Enugu (11). The relatively low acceptance was partly due to scarcity and cost of the implants (12); and the long term action of the implants for the clients. The cost of about \$13 (N2,000) per set made it un-affordable to some clients desiring the use of Norplant.

Norplant was used by clients of all parity including the nullipara, to postpone a first pregnancy, or to 'space' pregnancies in those still desirous of

children; while yet in others to provide reversible, long-term contraception when the desired family size had been reached.

The implants required little or no motivation following adequate counselling (13,14). Continuation rates for implant use were high among those who had adequate pre-insertion counselling because the perceived advantages or benefits greatly outweighed the nuisance effects. One year following its introduction, Norplant was found to be highly effective, safe and acceptable among Nigerian women of different ethnic groups. It was associated with a high degree of client satisfaction with a pooled continuation rate of 90.1 % after 12 months, 84.9% after 14 months and 77.1 % after 36 months (15).

The return of fertility after removal was rapid and almost comparable to that of the normal population. The failure rate was low and therefore found to be highly efficacious among our clients. Pregnancy occurred in five women out of 1,333 (0.37%). Two (2) additional women became pregnant at one year and 1.5 years after expiration of the capsules *in situ*, and not included in the cases of failure. Thus the method was adjudged to be very effective, preventing unwanted pregnancies in users.

The institution provided training in Norplant insertion and removal for about 200 service providers, namely Gynaecologists, Family Physicians, General Practice Doctors and Midwives. Norplant service provision was institutionalised in the department of Obstetrics and Gynaecology as all resident doctors in the department were trained to insert and remove the implant. Clients were provided the service between 7.30 hours and 15.0 hours daily from Monday to Friday after adequate counselling.

The supply was epileptic to the centre thereby affecting the acceptance rate. The continuous use of Norplant was hampered by inconsistent supply and availability of the commodity. The main barriers to Norplant use were therefore non-availability of the commodity between 1996 and 2001, and the high cost. Supplies totally depended on external sources and therefore affected availability and acceptance. Continuity of service was not guaranteed as the provision of the service stopped abruptly within the country in November 2005.

Inconsistent supply and availability of the commodity/capsules, interrupted supply, logistics, ready access, cost (capsules and consumables) and menstrual disturbances were the main drawbacks to the use of Norplant during the period. The low incidence of subjective side effects experienced by Norplant users meant that it was safe. This was similar to the side effects of other progestogen-only contraceptives. The change in bleeding pattern during Norplant use was tolerated by clients as its acceptance was comparable to other progestogen-only methods. The Norplant implants had little impact on metabolic

parameters (16). However, in the short term, there was a tendency to significant prolongation of ECG intervals in Norplant users (17).

Clinical as well as metabolic changes are known to be the attendant consequences of Norplant implants and steroidal contraception. The total serum triglycerides were found to be reduced in our clients using the implants (16).

Norplant provided five (5) years of contraceptive protection, high reliability, independence from user compliance, rapid return of pre-existing fertility after removal, good tolerability, and relatively simple and quick insertion and removal if the instructions for these were followed correctly (18-20).

As in many other parts of the country, Norplant was found to be safe and free from major side effects, effective, acceptable, suitable and reversible long acting progestin-only contraceptive method. The side effects were few, tolerable and menstrual changes were the most common side effect (21). Norplant definitely had a place in the prevention of unplanned and high risk pregnancies, one of the reproductive health elements of the millennium development goals (MDGs).

The continuation rate was high among users, and contributed a significant portion of the contraceptive armamentarium in Jos. The issue of availability however remained unresolved because of several factors such as logistics and high cost. These had serious inhibitory effects on the availability and hence the use/acceptance of the implants. While many workers recommended for Norplant to be made easily available, accessible and affordable to clients (18), it took about three years to get the implants from the manufacturers to the service delivery point, and two years to be used before expiration.

In conclusion, Norplant implants have come and gone, at least in Nigeria. Women that used this method of contraception found it useful and effective. Institutions found it an addition in their armamentarium of contraceptive methods. In its own way, it had a positive impact on the contraceptive arena. Few women found Norplant not very helpful and discontinued its use within three months of insertion. Majority (89.0%) of the women used it for one term of about five years, while few used it for three terms of five years (15 years) in its 21-year sojourn in Nigeria.

We anxiously look forward to 'substitutes', 'replacements', 'reliefs', or 'surrogates', that will beat the record of this long acting progestin-only contraceptive implant that stood the test of time in a little over two decades of clinical use in our setting. The development of the one (Implanon) and two-rod (Jadelle) implant systems it is hoped would greatly simplify the insertion and removal of the contraceptive implants. Norplant has made its mark as a method of contraception among many women

and will not be forgotten easily by those who used it. Norplant has left an indelible imprint or mark in the sands of contraceptive history. Norplant implant will definitely be used as a reference product for similar products in the contraceptive market. Norplant will also be remembered as an important, effective, and long-term contraceptive implant. Adieu Norplant, Adieu!

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