Final Report of the Project

Acceptability and Continuation Rates of 2 Monthly Injectable Contraceptive Norethisterone Enanthate

Protocol Amendment – DEXA Study

(Funded by Department of Family Welfare, MOHFW, Govt. of India)

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Table of Contents

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Summary

The Family Planning Programme of India offers limited contraceptive choices like IUCD, oral pills, male condom, tubal ligation and vasectomy. There is substantial unmet need of 13% for contraception of which about 50% is for spacing methods (NFHS 3, 2005-06). It is essential to increase the range of contraceptive choices to fulfil this unmet need. Long acting injectable Contraceptives viz. 2 monthly - Norethisterone Enanthate (Net-En) and 3 monthly - Depot Medroxyprogesterone Acetate (DMPA) are available in Indian market since 1993, but have not been introduced in the National programme because of opposition from women's health group. In view of this, at the initiative of the Government of India, the Institute had carried out a multi centre study to obtain more recent data on 2 monthly injectable contraceptive (Net-En). A total of 1209 healthy women aged between 20-40 years with proven fertility and at least having one living child were enrolled across India. The objectives were: i) to assess acceptability/continuation rates of Net-En; ii) to evaluate the incidence of side effects like menstrual irregularities and weight gain; iii) to study women's attitude/perceptions towards injectable and iv) to study return of fertility following discontinuation of injection. The injections were offered under cafeteria approach giving balanced information about all the contraceptive methods available in the National Family Welfare Programme (NFWP). The major emphasis in this study was on good counselling by qualified staff providing quality contraceptive services, ensuring informed choice and consent. The duration of injection Net-En in this study was two years. At discontinuation of the injection, women were interviewed to know their perceptions towards this method. Women who desired pregnancy following discontinuation of injection were followed up for 1 to 2 years for return of fertility. The observations based on 17268 women months of injection use show cumulative continuation rates of 65%, 53.6% and 48.3% at the end of 12,18 and 24 months respectively. The major discontinuations were due to personal reasons, lost to follow-up and migration because of floating population. The method related discontinuations like menstrual disruptions; weight gain and pregnancies were observed in 15.5% of women at the end of study period of two years. The method was found to be very effective since there were only three pregnancies reported during 2 year of injection use. About 89% women said that injections should be made available through National programme, since the method is more convenient compared with daily intake of oral pills, does not have effect on breast

milk, offers a wider choice of Family Planning (FP) methods etc. The method was well accepted by majority of the women, thus can fulfil the unmet need for contraception. Over 79% were satisfied with the use of this method and also recommend this method to their friends and relatives. About 39% requested to provide them further injections after completion of the study. Based on these study findings, the Government of India will consider introducing injectable in the programme.

A total of 150 women desired to conceive following discontinuation of injection. Of these, 75.33% conceived within 9 months whereas 24.67% conceived between 10 to 23 months respectively after the washout period of the drug. There were 135 full term deliveries with healthy newborns at birth, 12 women underwent pregnancy termination with tubal ligation and 3 women had first trimester spontaneous abortion.

Injectable and Bone Mass Density (BMD):

Some recent reports have shown that the bone mineral density (BMD) decreased in adolescent women aged 14 to 18 years who used the 3 monthly injectable contraceptive - Depot medroxyprogesterone acetate (DMPA). However, after stopping the injection, BMD increased (Arch Pediatr Adolesc Med. 159(2): 139-44, 2005). It is not yet known whether bone loss due to use of DMPA leads to osteoporosis and risk of fracture in later life. Based on these reports, Pfizer Company, manufacturer of injection DMPA in agreement with USFDA inserted 'Black Box' warning label on the use of injection DMPA in November 2004. The warning suggests that the use of DMPA causes a significant loss in BMD, which is greater with increasing duration of drug. Therefore, injection DMPA should be used as a long-term birth control method (more than two years) only if other birth control methods are inadequate/unacceptable and in this case the woman should be evaluated while taking the drug long term.

In May 2005, the issue of 'Black Box' warning with DMPA use was raised by the "All India Democratic Women's Association" and was communicated to the Health Secretary and also in the media. In view of this an urgent meeting of the Institute's Ethics Committee (IEC) was held on 17th May 2005. The ethics committee discussed all these issues and available literature reports on BMD,

which mainly reported on injection DMPA. The committee also emphasized that the duration of injection Net-En use in the study is for 2 years. The committee approved the following plan of action:

i. The additional parameter of DEXA for assessing bone density be carried out as soon as possible in all the women who are still using injection Net-En.

ii. The DEXA investigation will be repeated every six months during injection Net-En use and one year after stopping.

iii. These amendments were for all the participants at all the centers where DEXA was done locally.

Though the baseline levels of the BMD in these women (prior to initiation of injection Net-En) are not available, this will reassure the women about their bone density status.

Accordingly, a total of 142 women still using injection Net-En underwent BMD evaluation by DEXA at hip and lumbar spine. Of these, 73 women underwent repeat DEXA scan at 6 months interval after receiving 3 more injection. Similarly, 109 women had DEXA scan done one year after stopping the injection.

Healthy women (n=59), who did not use hormonal contraceptives and were matched with respect to age and parity comprised the control group for DEXA study. The findings showed that with the increasing use of injection there was no decrease in mean BMD. Similarly, there was no significant change in mean BMD observed among injection users compared with control group. These findings are reassuring.

The findings of this study have shown that skilled counseling by qualified staff, quality of services in the family planning clinics helped clients to continue injections in spite of menstrual disruptions. There were inter-centre variations in continuation rates of injections. There was no significant decrease in BMD observed among injection users compared with control group. The other factors like Body Mass Index (BMI) had significant effect on BMD as observed in the study.

Introduction and Rationale:

Contraception is an integral part of services provided to improve the health of the family. Although, the contraceptive prevalence rate has increased in the recent years, there is however a substantial unmet need of 13.2% for contraception, of which about 50% is for spacing methods among eligible couples (NFHS-3, 2005-06). The fact that annually 78% conceptions are unplanned and 25% are unwanted is the good indicator of this unmet need. About 18% maternal morbidity/ mortality is related to the induced abortions. All efforts should be made to meet the unmet need of contraception of the eligible couples by expanding the contraceptive choices in our National Family Welfare Programme (NFWP). It is necessary to maximize access and quality of services to increase contraceptive use to make the programme more effective.

At present, in the cafeteria approach within the NFWP, the spacing contraceptive methods offered are intra-uterine contraceptive device (CuT 380), combination oral pills and male condoms. Injectable contraceptives like 3 monthly, Depo medroxyprogesterone acetate (DMPA) and 2 monthly Norethisterone Enanthate (Net-En), have been registered in 179 and 91 countries respectively. Globally, about 32 millions of women are using injectable contraceptive (Population Reports: Series K, Jan-Feb. 2007, Fig.1).

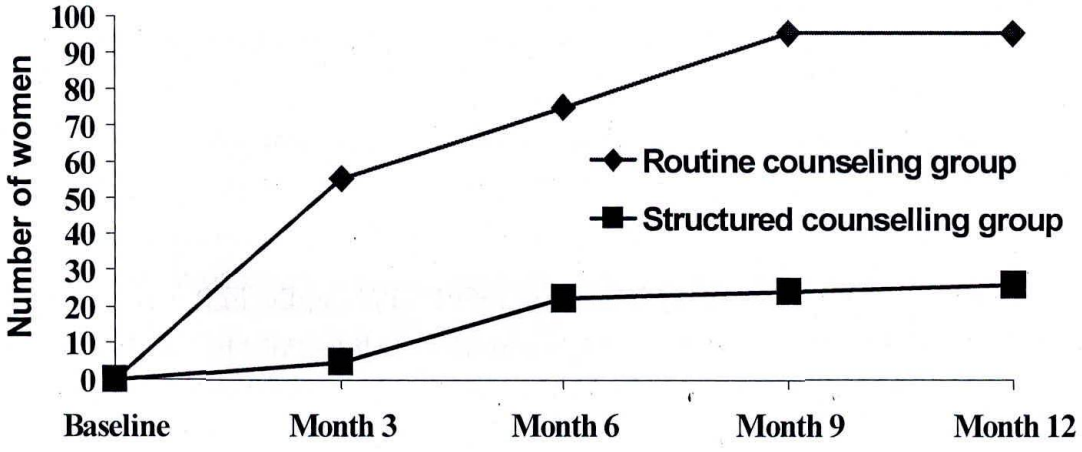
The Indian Council of Medical Research (ICMR) had generated considerable data on these injections in mid 1970s and early 1980s. Both these injectables (DMPA & NET-EN) are available in the Indian market since 1994 after USFDA approved injection DMPA for contraceptive use in the United States in 1992. At present some of the private sectors and social marketing agencies provide 2 monthly and 3 monthly injections to women at subsidized cost. These injections have not been introduced into our NFWP due to the issues raised by women's health group.

In view of prevailing concerns, a workshop was jointly convened by the Institute and Government of India in December 1998. The objective of the workshop was to review the status of injectables (2 monthly and 3 monthly) in the neighboring Asian countries vis-à-vis that in India and to debate the pros and cons of their introduction into the NFWP. A majority of the delegates were in favour of introducing injectables into the NFWP. However, in the Indian context it was emphasized that injectables should be introduced gradually in a *phased manner*

with emphasis on *good clinical practices* and *counseling issues,* suitably in well equipped centers.

A Chinese study (Lei Zhen-WU 1996) has shown that structured counseling before initiation of injectable contraceptive substantially increased the continuation rate of the method as shown in the following figure.

Termination rates of DMPA (Chinese study)



Cumulative termination rates - 11% (23/204) and 42% (92/217) respectively (p< 0.0001), Source: Contraception. 53, 1996

The idea of offering injectable contraceptive as a method of contraception is to widen the choices of contraceptives available for women. None of the available contraceptives is 100% effective, or completely free from side effects. However the side effects are more of an inconvenience than life threatening. The risk of morbidity and mortality associated with unwanted pregnancies must always be weighed against the side effects of contraceptive methods, which are much less.

Injectable contraceptives can be used as a long-term or short-term (2-3 months) method. They can be of use to women whose spouses visit them for short duration. They can be ideal contraceptive after vasectomy when contraception is required for 2 to 3 months till husband's sperm count becomes zero. Women who are breast-feeding, and cannot take oral pills or use intrauterine contraceptive devices can use injectable contraceptives.

With this background information, at the initiative of the Government of India, the Institute had undertaken a multicentre study on "Two monthly injectable contraceptive Norethisterone Enanthate (Net-En)". The major emphasis of this study was on counseling by qualified staff.

The objectives were :

i. To assess user acceptability/continuation rates of injectable contraceptive NET-EN

ii. To evaluate the incidence of menstrual irregularities and other side effects

iii. To assess user's attitudes/perceptions towards injectable contraceptive

iv. To study return of fertility in eligible women

Formulation and Injection Schedule :

Norethisterone Enanthate (Net-En) is a two monthly injectable contraceptive containing a synthetic hormonal progestrogen, which resembles the natural female progesterone. Each dose contains 200 mg of hormone in an oily base. The injection is marketed as Noristerat in a 1ml ampoule and manufactured by Schering AG. The drug is released at a relatively constant rate into the blood stream from the site of injection after an initial peak level (serum levels between 10-20 mg/ml) and provides the users with a safe and highly effective from of birth spacing method.

NET-EN is a highly effective contraceptive method. The 200mg dose of NET-En is most commonly used in a 2-month schedule. The range of efficacy quoted for NET-EN is 0.01-1.3 per 100 women years. The drug has to be inject deep intramuscularly.

Mechanism of action :

- Primarily stops ovulation (release of eggs from ovaries).
- Effect on endometrium - decreases receptivity to blastoclyst/fertilized ovum.
- Thickens cervical mucus, making it difficult for sperms to pass through.

Injection schedule:

First injection :

1. Regular menstrual cycle: upto 7 days (days 1 through 7) of the menstrual cycle.
2. Post-partum, breast feeding women after 6 weeks from delivery.
3. 1st trimester spontaneous or induced abortion immediately or upto 5 days.
4. 2nd trimester abortion, after 6 weeks
5. Change of contraceptive method :
   i. Intra-uterine contraceptive device users-immediately if removed during menses (1-7 days), otherwise women were advised to come after next period.
   ii. Combination oral pills - the interval between last active pill and injection should not exceed 7 days.

Grace period for subsequent injections :

Net-En can be given upto 1 week late or early. Ideally women should be encouraged for re-injections on scheduled time. If given during grace period, provider should be reasonably sure that woman is not pregnant. Pregnancy needs to be excluded by history, pelvic examination or urine pregnancy test if necessary.

Study Design:

This is a multicentre study, which was initiated at 9 centers in June 2002 after having extensive review by the Institutional Ethics Committee (IEC). Each participating centre was asked to obtain local Ethics Committee approval and to enroll a minimum of 120 women participants over a period of 12-18 months. Women attending the family welfare clinics/gynaecological OPDs in public hospitals and requesting for spacing methods were given balanced presentation on all available contraceptive methods in the programme including 2- monthly injection Net-En. Healthy women between 20-40 years of age, having at least one living child, willing to sign an informed consent form and accessible for follow-ups, and who met eligibility criteria were given detailed written information on injection Net-En including its advantages and disadvantages *(please see information and informed consent for the participants pages 28-30).* The women with following medical conditions were excluded from the study.

Exclusion Criteria:

Breast feeding women < 6 weeks post-partum
Known or suspected pregnancy
Unexplained/abnormal vaginal bleeding
Active liver disease and h/o Jaundice within 6 months of enrollment
Known or suspected malignancy
Cardio-vascular disease
H/o cerebro-vascular stroke
Focal migraine headaches
Any chronic medication including corticosteroids (except nutritional supplements)
Known allergy to any hormonal preparation

The major emphasis in this study was on good counseling by qualified staff and quality care services. All the health providers from the participating centers were trained to strengthen counseling and motivational skills through pre study and midterm workshops conducted at the Institute. The nurses were trained for the injection technique and safe injection practices. Counseling guidelines were prepared for implementation at various stages of use i.e. at initiation, during treatment and after discontinuation of the method and also management of common side effects (see pages 22-27 for counselling issues and management of side effects).

Enrollment and Follow-up Procedures:

The information for the participants included all the advantages and disadvantages of injectable contraceptive. Thus a total of 2352 women after screening for inclusion and exclusion criteria were found to be eligible for injection Net-En, of these 1209 (51.4%) women accepted injection under the cafeteria approach after signing an informed consent form (Fig.2). The remaining 1143 (48.6%) women desired other available spacing methods in the programme (Please see flowchart for recruitment (Fig. 3). The reasons for refusal of this method are listed in table 1. The commonest reasons were, frequent visits to the clinic for repeat injections (27.8%) and anticipated side effects like irregular menstrual periods and weight gain (17.4%). Some women also expressed fear of developing male characteristics (0.5%). The women were interviewed at discontinuation of injection/termination of the study by the qualified staff to know their views and

attitudes towards this method. This is essential to determine the needs of the potential users before the method is introduced into the National Programme.

A thorough physical and pelvic examinations were done at enrollment including weight, height, blood pressure, haemoglobin, routine urine sugar and albumin. Pap smear was done at enrollment and thereafter at 1 to 2 years wherever facility existed. They received injection Net-En 200mg deep intramuscularly every 2 months, with a grace period of 7 days was permitted (either early or late). They were given menstrual diary card to record symbols for menstrual bleeding as instructed. The dates of subsequent injections were mentioned at the back of the menstrual card. One menstrual card was also kept with the case record form and information from the menstrual card given to the woman was transcribed into the card kept in the clinic.

Follow-up Procedures:

i. Each woman was followed up for scheduled injections as mentioned under injection schedule for a duration of 2 years.
ii. At each follow-up visit the menstrual diary card was completed and symptoms related to method recorded and appropriate counseling was given.
iii. Blood pressure, weight record, breast and pelvic examinations were done every 6 months and as relevant.

In case of amenorrhoea, (> 6 weeks) pregnancy was excluded by symptoms, pelvic examination and urine pregnancy test if necessary before administering subsequent injection.

All women participants were interviewed at discontinuation of the injection. Thereafter women who wished to conceive or did not accept contraceptive method in the respective clinics were followed up every 3 months for upto 2 years to study return of fertility.

Database Management and Statistical Analysis:

The data entry and verification of the data has been carried out before tabulation and analysis. The statistical methods used were: descriptive statistics for the variables like age, weight, haemoglobin, body mass index, and bone mass density etc. Life table technique was used for calculation for continuation rate as described

in the book entitled "Epidemiologic approach to reproductive health" CDC Atlanta Georgia, USA FHI and WHO Geneva, Switzerland, WHO/HRP/EPI/1994. Chi square statistical test was applied to observe the centerwise continuation rates of injection and the educational status of the women.

The definition, classification and analysis for menstrual pattern was followed by the methodology adopted by Dr. S. Datey (ICMR) and Dr. Belsey et al. WHO. The proportions among various groups has been shown in the bar diagram for comparing the difference between the various groups.

Correlation analysis is used to test the significant relationship between Bone Mass Density (BMD) and Body Mass Index (BMI), changes in body weight, haemoglobin estimation and other related variables.

Unpaired t-test is used to test the significance of mean difference of BMD between the variables like age group, breast feeding status, number of children etc. and control group vs. injection users.

Paired t-test (before and after) is used to study the significant difference of mean BMD at femoral neck and lumbar spine between injection users compared with injection discontinuers. Descriptive statistics were used for the data of return of fertility.

Results:

Socio Demographic Profile of the Participants:

The women were from low-mid socio-economic strata. The demographic profile of these women is shown in table 2 and figures 4a, 4b and 4c respectively. The mean age of the participants was 24.97 and body mass index (BMI) ranged between 13.6 to 38.7. About 71% women attended secondary and higher secondary schooling while 15.4% of the participants were graduate and postgraduate. The family income of the study participants per month ranged between <Rs.1000/- to >Rs.10,000/-. Of the 1209 women participants enrolled, 518 (42.8%) received their first injection within 7 days of the regular menstrual period (interval group), whereas 438 (36.2%) received 6 weeks after delivery (post partum group) while remaining 253 (20.9%) received their first injection concurrent with surgical abortion (post MTP group).

Contraceptive Use prior to Participation in this Study:

Of the 1209 women acceptors, 721 (59.64%) women had used one or more contraceptive methods prior to accepting Net-En, whereas 488 (40.36%) women accepted injection Net-En as their first contraception (Fig. 5a). The methods of contraception used in the past were, intra-uterine contraceptive device (34.26%), condoms (31.8%), Oral pills (25.9%), Injectable/Norplant (4.3%), withdrawal /Natural Family Planning (3.5%), failure of tubal sterilization (0.28%), as seen in Fig. 5b. It was interesting to note that women who used injectable in the past accepted injection Net-En. They could not continue using injections because of the high cost.

The number of women who had received between 1 and 12 injections during a 2-year study period is shown in histogram (Fig.6). The observations are based on 17268 women months of use of injection Net-En. Cumulative continuation rates of injection Net-En using a life table technique at the end of 12,18 and 24 months were 65%, 53.6% and 48.3% respectively (Fig.7). There were significant inter-center variations in continuation rates as seen in Table 3. Continuation rate of injection at 1 year was significantly higher ($P<0.05$) at the centers from Nagpur and Chennai compared to other centers. Similarly 1 year continuation rate of the injection at the center from Jaipur was significantly higher ($P<0.05$) compared to the centers at Baroda, Mumbai and New Delhi. A 2 year continuation rate at Chennai and Nagpur was significantly higher compared to other remaining centers. Within the 3 FP clinics of NIRRH, although the settings and staff structure is similar, there were inter-clinic variations in continuation rates. These differences could be due to the counseling skills of the providers, presence of medical doctors to look into the side effects of the method and also cultural/ethnic differences. In one of the Institute's Family Welfare clinics, the counseling was so effective that in spite of irregular menstrual pattern/frequent bleeding, some of these women had no complaint and there were few discontinuations for menstrual irregularity.

The education of the women did not have impact on a 1 year continuation rate of the injection as seen in table 4 whereas a 2 year continuation rate was signicantly higher ($p<0.05$, Chi Square) among women having upto secondary schooling compared to those who were graduates and post graduates.

The various reasons for discontinuation of injection in a 2-year study are depicted in table 5. The majority of the discontinuations were due to personal reasons and lost to follow-up/migration because of floating population. These were mainly reported during first 6 months of the injection because these women requested for 1 or 2 injections. It was interesting to note that 5.95 of women who were waiting to undergo tubal ligation had accepted this method and postponed surgery for tubal ligation. About 4% of women had suffered from other medical illnesses like Tuberculosis, Hepatitis A, Skin rash, Headaches, Malaria etc, and were discontinued from the study. There were 2 accidental deaths not related to injection, reported during first 6 months of study from 2 centres (KEM hospital, Mumbai and Chennai). Only 15.54% of women discontinued due to method related causes like menstrual disruption, weight gain and method failure. A total of 3 pregnancies (method failures) were reported from the centers at NIRRH Mumbai (1 pregnancy) and Baroda (2 pregnancies). The woman participant from NIRRH Mumbai, probably conceived during 2nd injection since her pregnancy was detected at the time of 3rd injection. The remaining two pregnancies reported from Baroda, who had their 1st injection following medical termination of pregnancy. The pregnancies were detected at the time of 3rd injection.

Menstrual Pattern among Injection Net-En Users:

"A bleeding/spotting episode is defined as requiring the use of a pad or other protection".

Each woman had maintained the record of bleeding episodes on menstrual diary card as instructed. A sample menstrual diary card is shown below.

National Institute for Research in Reproductive Health

Menstrual Diary Record

Name : Centre No. Serial No.

Year	Day ▶ Month ▼	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
									I									•	•	•	•	•	•									
											X	X	XX	XX																		

Symbols : B-bleeding, P-profuse bleeding, S-spotting, I-injection, to be transferred on to the menstrual card from subjects diary card
Symbols for Subject : X-bleeding, XX-profuse • spotting

Checked by Dr. _____ Signature _____

For the analysis of the menstrual pattern, a 90 days reference period was considered and the statistical programme was developed based on the WHO guidelines by Belsey et al (1986) and modified as per Datey et al (1995). The following definitions were considered. Prolonged and frequent bleeding patterns were clubbed together for the analysis purpose.

Definitions of Bleeding Patterns:

a) Prolonged bleeding : At least one bleeding/spotting episode lasting more than 14 days

b) Frequent bleeding : More than four bleeding/spotting episodes during the reference period.

c) Infrequent bleeding : One or two bleeding or spotting episodes.

e) Amenorrhoea : No bleeding /spotting days during the reference period

f) Regular pattern : Three to four episodes of bleeding or spotting each lasting about five to seven days.

Thus a total of 5666 reference periods were studied during a 2 year injection use. It was observed that through out the study period the infrequent bleeding (oligomenorrhoea) pattern was most commonly seen whereas regular or acceptable bleeding pattern was observed among 13.4% and 12.9% of women during the reference period at 1 and 2 years respectively. The frequent and prolonged bleeding pattern was observed only in 6.2% and 4.8% of women during these reference periods respectively. There was increase in amenorrheic pattern at the end of 2 years of injection use (37.7%) compared to 27.2% during the reference period at 1 year (Fig.8). It was observed in this study that infrequent bleeding pattern was well accepted by the women after counseling.

Changes in Body Weight observed during Injection Use:

A total of 709 participants had repeat weight record at the end of 1 year while 417 women had at the end of 2 years of injection use respectively. Although majority of the women (62.9%) had weight gain at 1 year of injection use, there was no significant increase in mean body weight compared to their body weight recorded

before initiation of injection. The weight loss was also observed in about 16% of women although it was not significant compared to their body weight before injection use. Similarly, the increase in mean weight was observed in 76.5% cases at two year of injection use, although it was not significant (Fig.9a & 9b). ***The increase in body weight was perceived as positive health effect by some of the women who were having low weight prior to injection use.***

Overall Effect on General Well-Being:

At the discontinuation of injection, a total of 968 women were asked direct questions pertaining to certain side effects of the injection, although none of them directly complained about these side effects since they were well informed and counseled prior to participation. About 55.7% of women had some of the following side effects like weight gain (21.6%), lethargy (20.6%), bloatedness (18.9%), irritability (15.2%), mood changes (13.7%), backache/leg pain (6.5%) and breast tenderness (3.5%) although there were no discontinuations for these effects (Fig.10).

Changes in Cervical Cytology (Pap Smear) observed during a 2 Year Study Period:

Repeat cervical cytology observations were available in 550 women at 1 or 2 years of injection use. There was no significant change in the cervical cytology observed during the study period compared to their pre-injection cytology (Table 6).

Haemoglobin Status Of Net-En Users:

The haemoglobin (Hb) of the participants was done before initiation of injection and repeated at 1 or 2 years of injection use wherever it was feasible. Most of the women refused to have their haemoglobin done at follow up visits to avoid second prick (pricks for injection and Hb estimation) as informed by the centres. Therefore, the repeat haemoglobin values were available in 229 women. The observation shows that there was increase in mean Hb in most of the women (56.77%) whereas decrease in Hb was observed in 16.59% women although these were not significant. There was no change in Hb observed in 26.64% of women (Fig.11).

Women's Attitudes/ Perceptions towards Injectable Contraceptive:
(Please see table 7 for questionnaire and responses)

All the participants were interviewed at admission to assess their knowledge, perceptions & attitudes towards injectable contraceptive.

Knowledge about Injectable Contraceptive:

Of the 1209 women enrolled, 723 women (59.8%) had not heard or knew about injectable prior to participation in this study, whereas 486 (40.2%) heard about this method from their friends or relatives who had used injectable (54.8%), health personnel (41.2%), private doctor (14.8%) and media (5.6%) as shown in Fig.12a & 12b. Surprisingly many of the health care providers were not knowledgeable about the method. When women were asked about their concerns regarding this method after having read full information on injectable, 25% of women feared about the effect of injection on future fertility, quantity of breast milk, effect on blood pressure, HIV transmission through repeated needle pricks and fear of genital cancer. This reflects the need for good counseling, alleviation of fears, information, education and knowledge about injectable contraceptive.

At discontinuation/termination of the study, a total of 968 women were personally interviewed by the qualified social staff through structured questionnaire. The majority of the participants (79.6%) were satisfied with the injectable contraceptive, while 20.4% were not satisfied because of the menstrual disruption they experienced during injection use. Over 80% of the women found two monthly injection schedule convenient to take as against like taking daily pills. It is important for users to remember the dates of subsequent injections. In this regard 51.1% of women referred to menstrual cards on which the dates of subsequent injections were written. When asked about **whether women will like to take 2 monthly or 3 monthly schedule** of the injection. Majority of the women (59.4%) said that they would like to take 2 monthly schedule because of the experience of this injection during the study (Fig.13). In response to question on "change in menstrual pattern", 89.9% of users had experienced change in menstrual pattern, still majority of them continued using injections after good counseling and this change was acceptable to both the spouses (74%).

It is reported that hormonal contraception particularly oral pills decreases libido in women. In this study 88.3% of women reported no change in sexual behavior

particularly coital frequency as many couples abstain from sexual intercourse during menstrual bleeding.

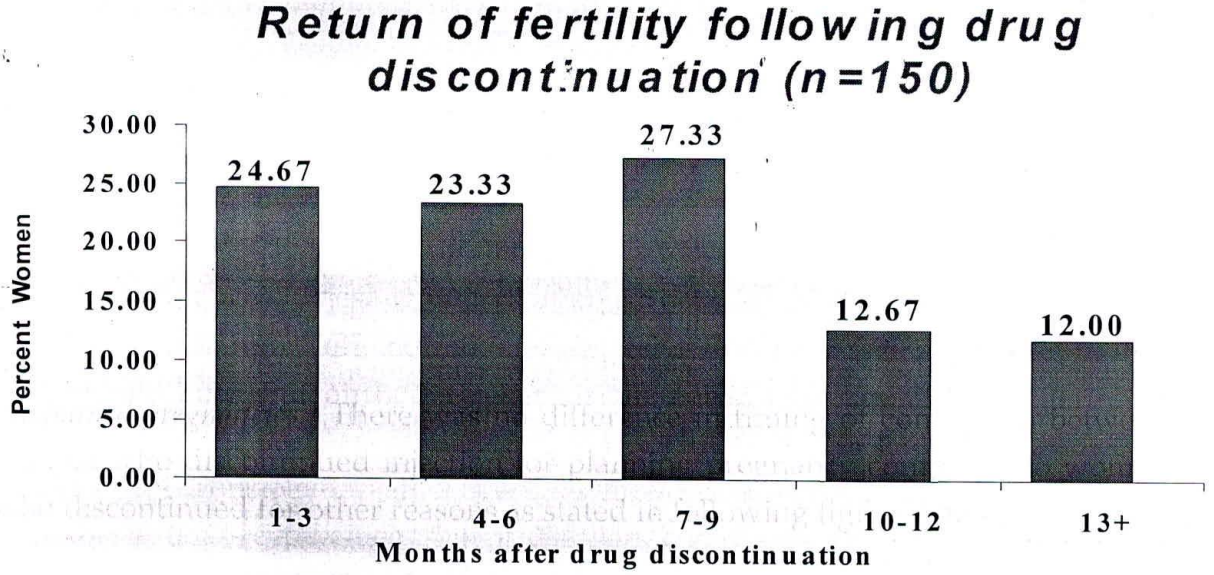
Over 89% of women expressed that injection should be available through National Family Welfare Programme because of the convenient schedule and everyone can afford and access the method and also it will widen the choices of contraceptives (Fig.14). Majority of the participants (79.4%) also said that they would recommend this method to their friends/relatives. The reasons were "one is carefree for 2 months" and do not have to memorize to take daily pills. Some of them also felt that the method is private, it causes less pain during menses and this can be viewed by women as positive health effect (Fig.15). About 60.4% said that they would be able to pay for the injection if the method cannot be made available free of cost (Fig.16).

It was interesting to note that about 3?% of women requested to provide them injections beyond the study period of 2 years (Fig.17). In this regard the matter was discussed with the Chairman of our IEC and they recommended that the participants should be provided injections on service basis. Subsequently some women received additional 3-4 injections depending on its availability at each centre.

Return of Fertility following Drug Discontinuation:

Women desiring pregnancy or who did not accept contraceptive in the clinic after discontinuation of injection (after the wash out period of drug) were followed up every 3 months for return of fertility over a period of 2 years. Thus a total of 150 women who desired pregnancy were eligible. The pregnancies were confirmed either by urine pregnancy test or ultrasonography. Over 74% of the women reported pregnancy within 9 months of drug discontinuation. Although, conception was delayed in about 12% of women beyond 1 year following discontinuation of injection, no woman had requested for the investigations of delayed pregnancy. These women conceived between 13 to 23 months following drug discontinuation. Of the 150 women, 135 continued pregnancy till term and had normal babies at birth, 3 women had first trimester spontaneous abortion, whereas 12 women underwent surgical abortions (MTP). These women wanted to continue injections beyond study period hence did not accept other contraceptives available in the programme. They underwent concurrent tubal legation following abortion. *Had we continued injections in these women, they would not have had*

unplanned pregnancies. There was no difference in timing of conception between women who discontinued injection for planning pregnancy compared to women who discontinued for other reasons as stated in following figure & table.



Full term deliveries – normal newborns : 135
Induced abortions with tubal ligation : 12
Spontaneous abortions : 3

Return of fertility compared with reasons for discontinuation of injection Net-En (n=150)

Reasons for discontinuation	Number (%)	Return of fertility in months following drug discontinuation
Desired pregnancy	109 (72.67)	1 to 23*
Personal reasons	18 (12.00)	1 to 19
Irregular / Prolonged bleeding	8 (5.33)	1 to 9
Other medical reasons	6 (4.00)	1 to 9
Amenorrhoea	4 (2.67)	1 to 19
Late for injection	3 (2.00)	7 to 19
Weight loss / Weight gain	2 (1.33)	4 to 9

* One woman conceived 23 months after drug discontinuation

Counselling Issues and Management of Irregular Menstrual Bleeding:

The workshops were conducted by the Institute for the health care providers from participating centers to strengthen motivational and counseling skills pertaining to injectable contraceptive. The training was focused on the following key points on counseling. Nurses were trained for injection technique and safe injection practices.

Key Points on Counseling for Injectable Contraceptive :
Initial Visit:

What clients expect?

- Composition of injectable contraceptive
- How it acts
- Efficacy and safety
- Who can take
- When to initiate
- How often (interval)
- Privacy
- Side effects of the method

Advantages of the method: (providers should inform)

- No daily intake e.g. pills
- Very effective & safe
- Privacy can be maintained
- Not coitus dependent
- Can be used at any age
- No effect on quantity and quality of milk, can be used by nursing mothers as early as 6 weeks after delivery.
- Can be used by women with certain medical diseases since no estrogen component in the drug.

Non Contraceptive Benefits :

- May prevent pelvic inflammatory diseases / ectopic pregnancy
- May prevent endometrial cancer, sickle cell crisis
- May prevent iron deficiency anaemia (refer to menstrual changes)

Disadvantages of the Method:

Inform clients about common side effects (assure that these are not a sign of disease)

- Changes in menstrual cycles are unpredictable for individual woman
- Initial light/heavy menstrual bleeding and subsequent amenorrhoea
- Weight gain, headache, breast tenderness
- Delay in return of fertility

Counselling during Use of the Method:

- Assurance for irregular menstrual bleeding, which is expected during first 6 months of injection use.
- Medicines are available for heavy bleeding
- Amenorrhoea – Inform about advantages e.g. improvement in anaemia, can be compared with lactational / post partum amenorrhoea, no medication is required, assure that woman is not pregnant and regular menstrual flow is not necessary for good health.

Training for Injection:

- Aseptic conditions
- Site of injection, no massage/ fomentation since this will reduce the efficacy of the injection.
- Disposable syringes and needles
- Storage of drug / ampoules
- When to initiate
- Grace period/flexibility of subsequent injections

Health care providers need to become skilled at counselling and disseminating information, effective communication at each follow-up visit of the client taking into consideration cultural differences. Women considering injectable contraceptive, need to understand that her menstrual bleeding pattern may change and the precise changes she may experience cannot be predicted, however they are transient and reversible.

The rationale for the management of menstrual irregularities is as follows:

- Rebuilding endometrium with estrogen/ combined oral contraceptive pills.
- Non-Steroidal Anti-inflammatory Drugs (NSAIDs), which block prostaglandin synthesis and decrease uterine bleeding temporarily.

Counseling women for contraceptive assists in having the full and correct information of all available methods and selecting an appropriate method. Proper counselling strongly influences long-term continuation rates of the contraceptive as seen in Chinese study (pl. see figure on page 9).

General Considerations in Counseling:

In describing the balance between benefits and risks with use of injectable contraceptive, it is helpful to individualize both sides of equation for each woman. Prepare the client for likely side effects and let her know that there are ways to minimize these side effects. It is equally important to explore women's attitudes, myths and fears towards any particular side effect.

Management Options for Bleeding Irregularities induced by Injectable Contraceptive:

Several research studies have been undertaken to understand the causes of menstrual bleeding irregularities induced by long acting progestin only contraceptives. The exact cause and treatment is not yet understood. The various management options are based on clinical experiences of the providers. The counseling and education of clients are the mainstay of management and certainly influence continuation rates.

Management of Spotting or Slight Bleeding:

This is lesser than regular menses and it does not affect health even if prolonged for sometime. Counseling and reassurance is needed. A pelvic examination to rule out other causes of bleeding will further reassure the woman.

Management of Prolonged/ Heavy Bleeding:

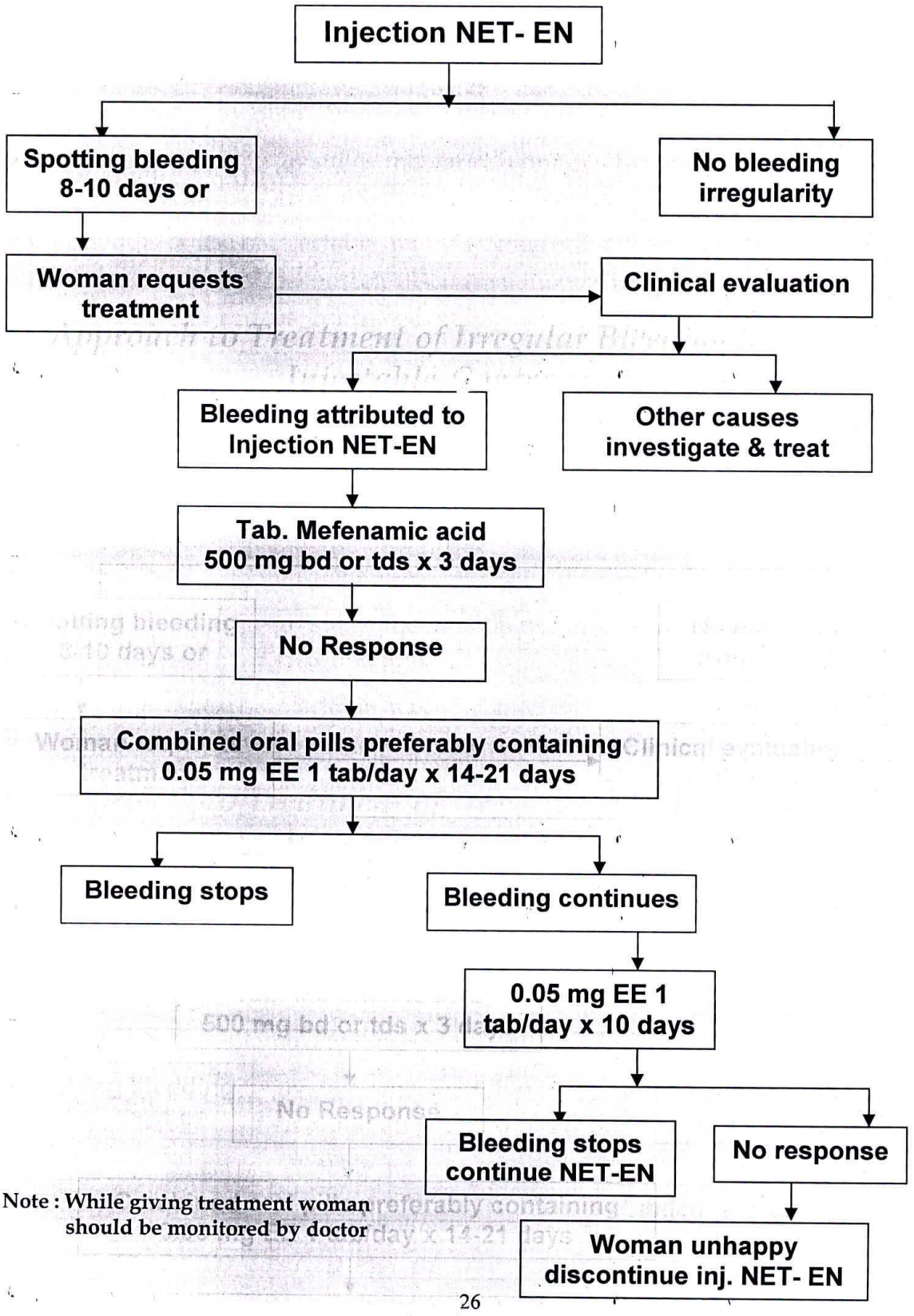
If a woman has bleeding more than twice as long as her normal menstruation, she should be assured that this is normal and expected in some of the women in the first 6 months of injection use. Bleeding episode becomes shorter over a period of time even with continued injection use.
Supportive treatment and counseling of the woman is required and assurance that this bleeding is not a sign of disease. Iron and calcium supplements including styptic drugs should be prescribed (please see flowchart on page 26).

Management of Amenorrhoea:

By 12 months of use of injectable, many women will experience amenorrhoea. This is the most common reason for discontinuation. If woman is concerned about amenorrhoea she can be counseled about the advantages e.g. improvement in anemia and can be compared with lactational amenorrhoea. There are no harmful effects of amenorrhoea induced by injectable contraceptive and regular menstrual flow is not required for good health. If woman is worried, assure her about the pregnancy and it should be ruled out by doing pregnancy test. Avoid use of hormones to induce withdrawal bleeding Advise woman to wait for return of menstruation.

The flowchart on page 26 states the various options for management of irregular menstrual bleeding.

Approach to Treatment of Irregular Bleeding induced by Injectable-Contraceptive



Note : While giving treatment woman should be monitored by doctor

Thus a 233 women participants requested to provide them medicines for frequent bleeding. They were given drugs as shown in the following table.

All these women required to take medicines at subsequent follow up visits. This treatment helped women in stopping/reducing bleeding episodes temporarily and further continuation of injections.

Drugs given for irregular/frequent menstrual bleeding (n = 233)

Sr. No.	Drug Particulars	No. of subjects	Frequency
1	Mefenamic acid	65	79 times
2	Styptic	92	111 times
3	Styptic and Antiprostaglandin	24	31 times
4	Combined Oral Pills	52	63 times

Acceptability and Continuation rates of 2 monthly Injectable contraceptive Norethisterone Enanthate

Information for the participants

(If the woman is illiterate, the investigator should read this information to the woman)

Injectable contraceptives are safe, effective family planning methods that protect women from unwanted pregnancies. All over the world about 14 million women use progestin only injectable contraceptive. In India two types of injectable contraceptives are available, one of which is administered every 2 months. This is marketed as Injection Noristerat.

The idea of offering this injection is to increase the choice of family planning methods. If you select this method for family planning, we would collect some information from you like your acceptance and views regarding this method. Please read the following information about this injection.

How does this injection prevents pregnancy?

- It stops release of eggs from the ovaries.
- It also causes thickening of cervical secretions/fluids at the entrance of womb making it difficult for the sperm to pass through.

Who can use this method?

- It can be used by women of any age or parity who want to space births.
- It provides effective and safe contraception after delivery and abortion.
- It is suitable for nursing mothers since it does not have effect on quality and quantity of milk.
- Suitable for women who may have side effects related to use of oestrogen containing contraceptive eg. Oral pills.
- Women with certain medical diseases, who can not use other contraceptives eg. Combination oral pills, can use injectable contraceptive.

When is the first injection given?

- The first injection can be given anytime provided you are not pregnant, preferably during first 7 days of your normal menses.
- Immediately after an abortion.
- 6 weeks after delivery if you are breast feeding.

What are the benefits of using this injection?

- It is very effective (99.6%) and reversible.
- It is a convenient method and will ensure/maintain privacy.

- Once you take this injection, you will be carefree about contraception for 2 months. You will not need to take every day like for the pills.
- In some women it may reduce painful periods.
- The regular visits for injection offer an additional advantage of regular medical check up.

What are the likely disadvantages with this method?

- You may experience irregular periods like spotting, delayed menses, prolonged bleeding and rarely heavy bleeding.
- You may gain weight .
- You may experience headache.
- Once you take this injection, the effect will last for 2 months.
- If you wish to plan pregnancy you may conceive within 12 months after stopping injection (i.e. 4 to 9 months after the effect of the last injection).

What you need to do if you take this method?

- You will be given choice of all the contraceptive methods available and will have choice for yourself.
- If you choose this method you will have to undergo general and gynecological examination.
- You can choose to take this injection either in the buttock or arm.
- You have to visit the centre for repeat injection after 2 months.
- You will be given a diary card and explained to enter information on bleeding/menses. You have to bring this card at repeat visits to show us.
- We will offer this method for the duration of 2 years. You may decide to stop this method any time you wish.

What happens if I have any problem?

- If you have concerns or questions about this injection, please come to the centre. You may contact clinic doctor (_____) or any other staff at this address.

_____

_____

Telephone No.

Please Note:

- Injectable contraceptive does not provide protection against HIV/AIDS.
- Treatment for any side effects due to this injection will be given at the centre free of cost.
- Only health providers at the centre will have access to your records. Your name or identity will not be revealed in any data reports.

Acceptability and Continuation Rates of 2 Monthly Injectable Contraceptive - Norethisterone Enanthate

INFORMED CONSENT

I _____(full name) have been made to understand that Institute for Research in Reproduction conducts clinical trials of various contraceptive methods I have been fully informed about the aim of this study. I have been explained all the advantages and disadvantages including menstrual irregularities that can occur with the use of injectable contraceptive method. I have been also informed about the benefits and risks of other spacing methods like Cu-T 200, oral pills and condoms available in the National family planning programme. I have selected 2 monthly injectable method **Noristerat** willingly for spacing children. I have had all my questions and doubts about this method answered and clarified.

I am willing to undergo physical examination, come for follow-up. I am also aware of my right to withdraw from this study at any time without having to give any reason for doing so, without loss of benefits or utilizing the services of the clinic. I will not have to pay for the injections.

Signature / thumb impression of acceptor

Date:

Doctor's Name & Signature

Protocol Amendment – DEXA Study

Background Information:

Some recent reports from United States have shown that the bone mineral density (BMD) decreased in adolescent women aged 14 to 18 years who used the 3 monthly injectable contraceptive-Depot medroxyprogesterone acetate (DMPA). The decrease in BMD is dependent upon the duration of use, being maximum in first one to two years. However, after stopping the injection, BMD increased (Arch Pediatr Adolesc Med. 159(2): 139-44, 2005). It is not yet known whether bone loss due to use of DMPA leads to osteoporosis and risk of fractures in later life. A recent study carried out in Africa (March 2005), in women using injection DMPA, Net-En, Oral pills and non-users were reported to have no effect on BMD.

In November 2004, Pfizer company manufacturer of injection DMPA in agreement with the United States Food and Drug Administration (USFDA) issued revised labeling on the use of DMPA on BMD (Black Box warning). ***The warning suggests that the use of injection DMPA causes a significant loss in BMD which is greater with increasing duration of drug. Therefore injection DMPA should be used as a long- term birth control method (more than two years) only if other birth control methods are inadequate/ unacceptable. In this case, women should be evaluated while taking the drug long term.*** However, currently World Health Organization (WHO) recommends that women of 18-45 years of age can use DMPA and Net-En, if they are eligible (WHO Category 1, Medical Eligibility Criteria for Contraceptive use, 2005).

The issue about DMPA use and decrease in BMD was raised by "All India Democratic Women's Association" (May 2005). In view of this, an urgent meeting of the Institute's Ethics Committee (IEC) was held on 17th May 2005. The ethics committee discussed all these issues and available literature reports on BMD, which mainly reported on injection DMPA. The committee also emphasized that the duration of Net-En use in the ongoing study is for 2 years. The committee approved the following plan of action and the amendment was made as follows:

- The additional parameter of DEXA for assessing bone density be carried out as soon as possible in all the women who are still using injection Net-En.
- The DEXA investigation will be repeated every six months during injection Net-En use and one year after stopping the injection.

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- These amendments will be for all the participants at all the centers, where DEXA can be done locally.

Though, the baseline levels of the BMD in these women (prior to initiation of injection Net-En) are not available, this will reassure the women about their bone density status. DEXA will not be done for women who are planning to be pregnant. Before doing DEXA, pregnancy will be excluded, if necessary. Accordingly the participant information sheet and consent forms were amended and women were requested to re-consent for the additional DEXA investigation during further participation.

Study Findings:

Following IEC approval and protocol amendment, the study was initiated at 6 centres where DEXA facility was locally available. Three participating centres viz. Nagpur and Cuttack were excluded for DEXA study because of unavailability of the DEXA machine in these cities. The centre at Kolkatta could not participate because they had very few active women using injection. A total of 142 active users of injection Net-En underwent initial DEXA scan. The use of injection varied between 14 to 22 months (DEXA-1). Of these, 73 eligible women still using injection Net-En underwent repeat DEXA at 6 months interval (DEXA-2, Net-En use 20 to 30 months). The final DEXA scans were done one year after stopping the injection (n=109).

The observations showed that there was increase in mean BMD at both femoral neck and lumbar spine between first and second DEXA scans (Fig.1). It was observed that after taking more injections there was no decrease in mean BMD. The relative increase in mean BMD was also observed among women who underwent DEXA scans 1 year after discontinuing injection, compared to the BMD during injection use. There was positive correlation between BMD and Body Mass Index (BMI). These observations are reassuring (Fig.2).

Since the baseline values (before initiation of injection) of BMD could not be assessed in these women, it was necessary to compare BMD with those who did not use any hormonal contraceptives in the past. Therefore, it was proposed to enroll 59 healthy women matched with respect to age and parity with those of injection users comprised the control group. An IEC approval was obtained in November 2007. The participants for control group were selected from the

Institute's family welfare clinics who did not use any hormonal contraceptive methods in the past five years preceding DEXA scan. Lactating women were excluded from the study. A written informed consent was obtained before taking DEXA scan. The women planning pregnancy were excluded from the study.

Observations:

The mean BMD of women in the control group was compared with mean BMD of 73 women who had DEXA scan done while using injection (injection use 20 to 30 months). The findings showed that there was no significant difference in mean BMD between control group and injection users (Fig.3).

Salient Observations of DEXA Study :

There was no correlation between duration of injection use and mean BMD. There was positive correlation between BMI and BMD. Women with BMI of 25 and above had significant ($p<0.001$) higher BMD at both the sites compared to women having low BMI of less than 20. There was inverse correlation between parity and BMD. Mean BMD was significantly higher (0.886gm/cm^2 $P<0.05$) among women having 1 or 2 children compared with women having 3 or more children (0.769gm/cm^2). There was no significant difference in mean BMD among injection users compared with control group.

Conclusion of the Study:

The study findings showed that the skilled counseling and quality of services at every stage of injection use, presence of medical doctor to look into the problems/side effects induced by the injectable contraceptive, training of nurses for injection technique and safe injection practices are necessary. There were inter-centre variations with regard to continuation rates of injection. The educational status of the women did not have impact on 1 year continuation rate of the injection. There was no decrease in mean BMD observed among injection users compared with control group. Comprehensive training of health care providers pertaining to injectable contraceptive is necessary. Training through workshops/role-play is more effective as observed during the study.

The findings of this study will be useful in programme implementation of the injectable contraceptive.

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General Assistance: DCR, NIRRH

Mr. Anand Hankare, Mrs. Akshaya Rathod

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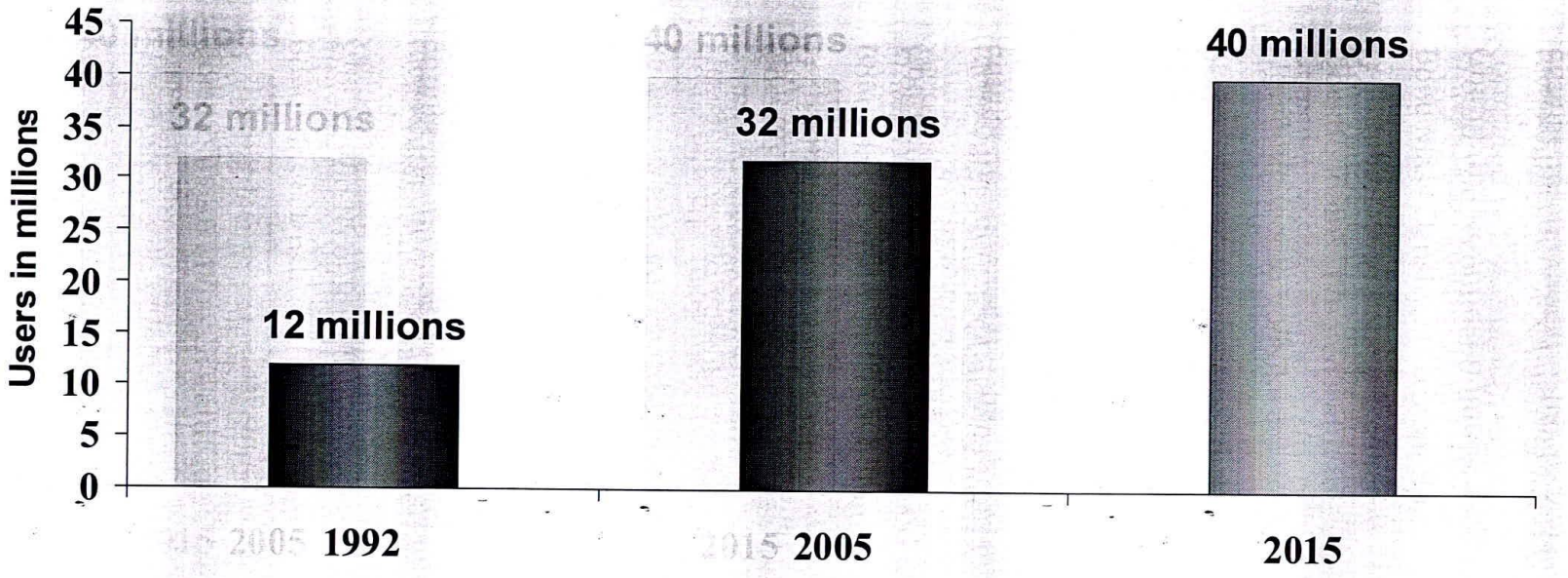
List of Figures & Tables

Fig. 1: Worldwide use of injectable contraceptive



Most popular method in Sub Saharan Africa, 38% women use inj.

Source: Population Reports,
(Series K, no. 6, Jan-Feb 2007)

Fig. 2: Number of eligible women attended & enrolled for Net-En

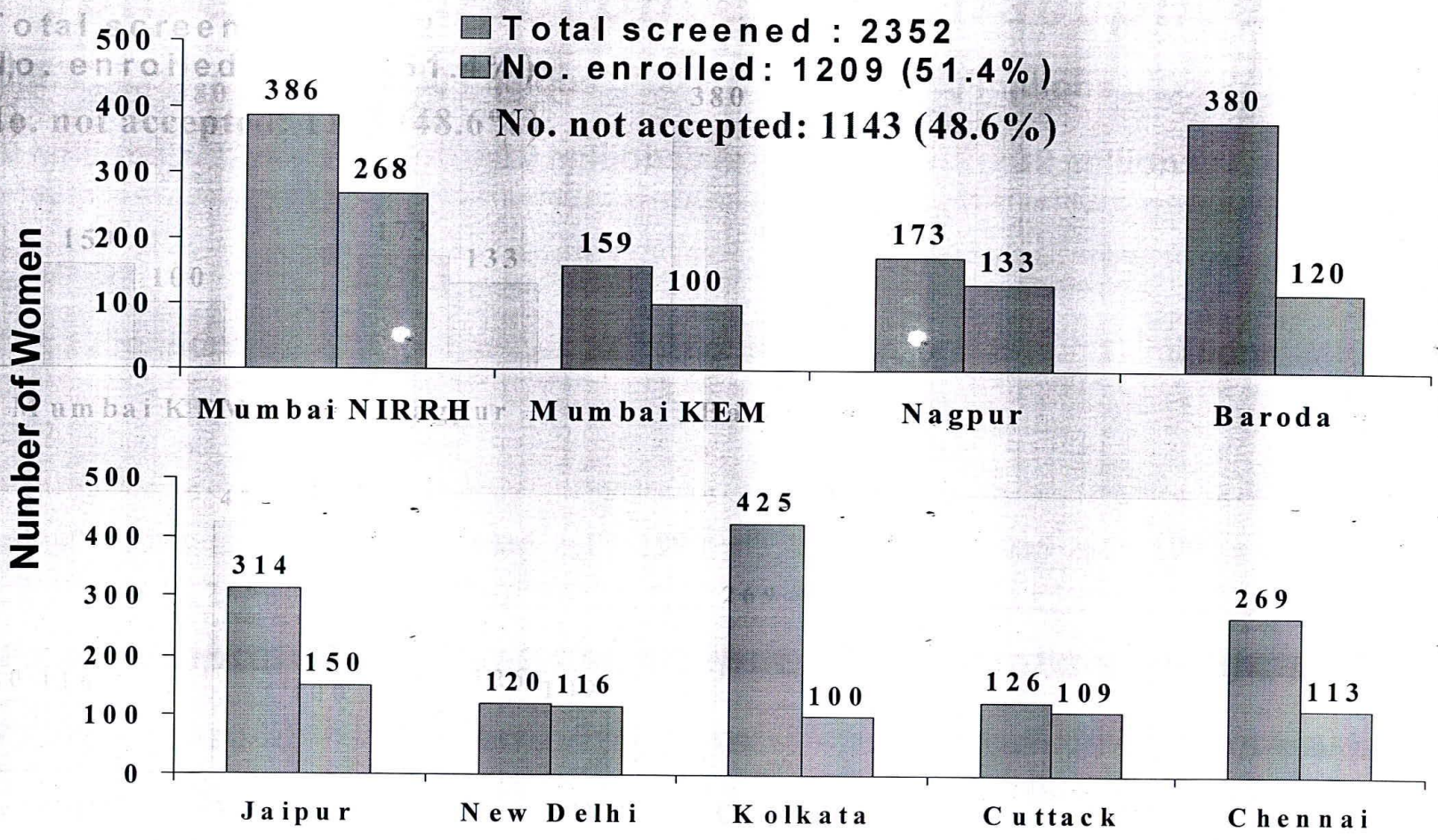


Fig.3:
Recruitment Process

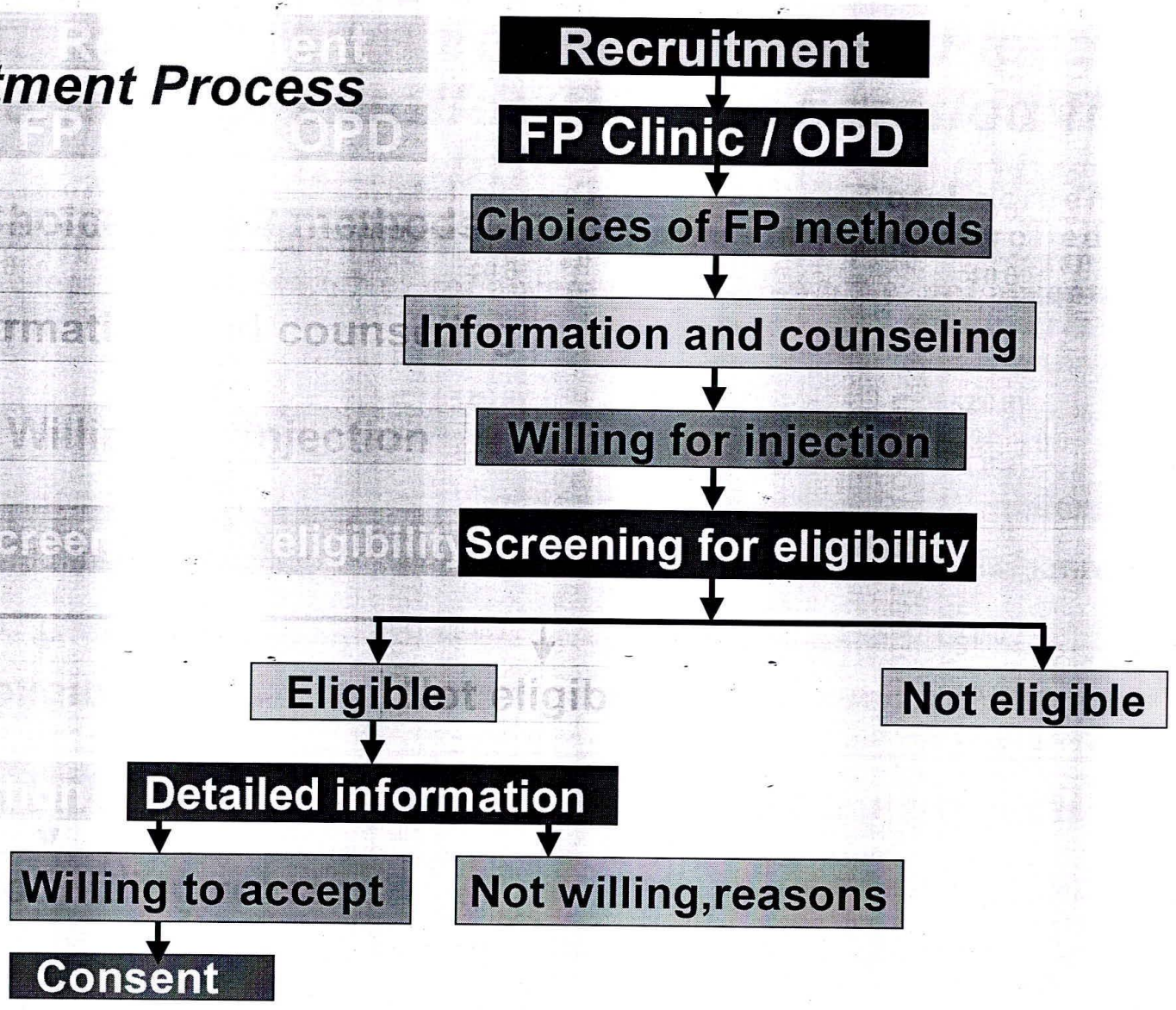


Table 1: Eligible women - reasons for not accepting injection (n = 1143)

Reasons	Numbers	%
Frequent visits for repeat injection	318	27.8
Prefers IUCD	201	17.6
Fear of side effects(menstrual irregularity & weight gain)	198	17.4
Family members' objection	132	11.5
Scared of Injection prick	120	10.5
Prefers permanent method	59	5.2
Prefers Oral Pills / Condom	49	4.3
Likely to migrate	31	2.7
Regular contraception not required	20	1.7
New method	9	0.8
Fear of developing male characteristics	6	0.5

Table 2: Socio demographic profile of the participants (n=1209)

Parameters	Mean (± SD)	Range
Age (years)	24.97 (3.8)	19 - 40
Parity	1.53 (0.7)	1 - 6
BMI (kg/ m^2)	20.54 (3.6)	13.6 – 38.7

Other Characteristics	Number	Percent
Interval cases	518	42.8
Post Partum cases	438	36.2
Post MTP cases	253	20.9

Fig. 4a: Education of the participants (n = 1209)

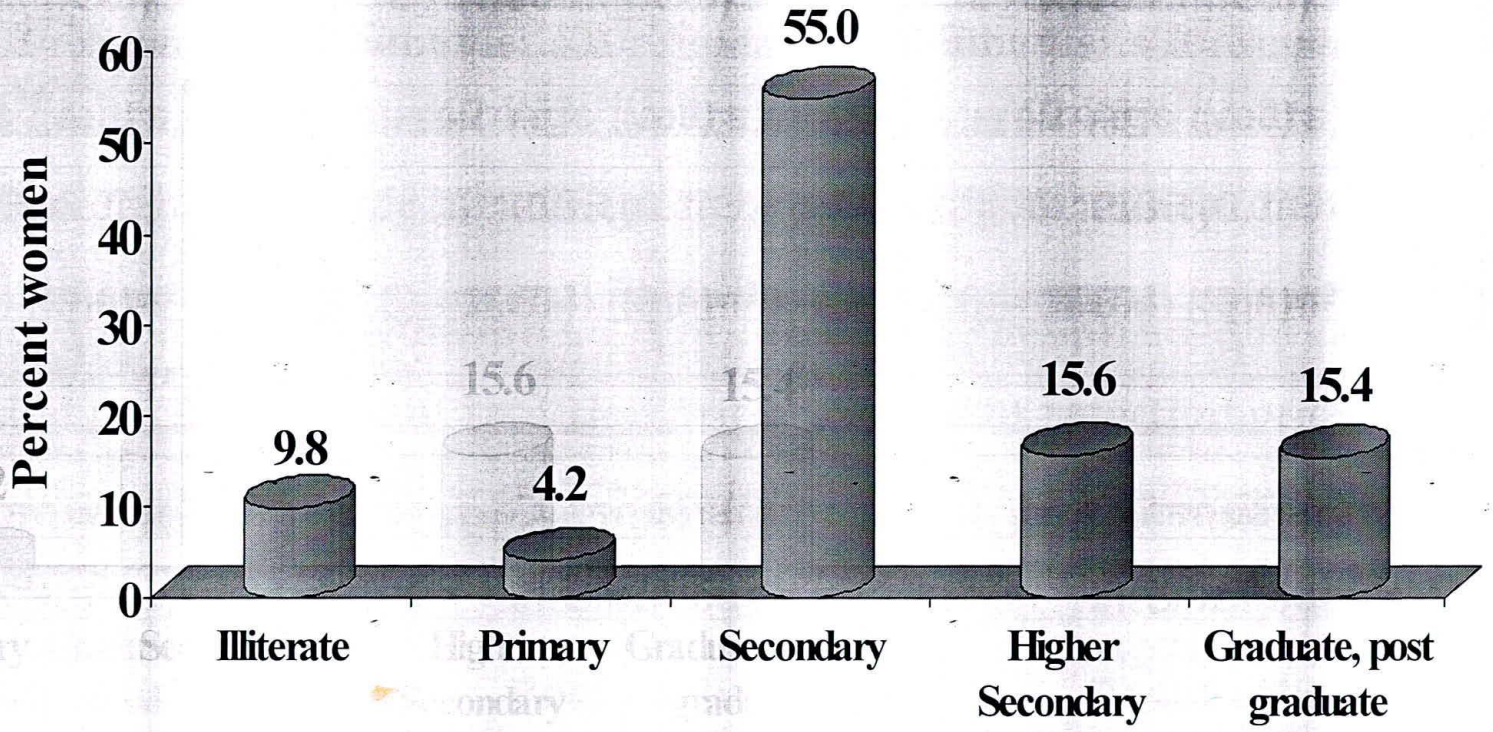


Fig. 4b: Family income per month of the participants (n=1209)

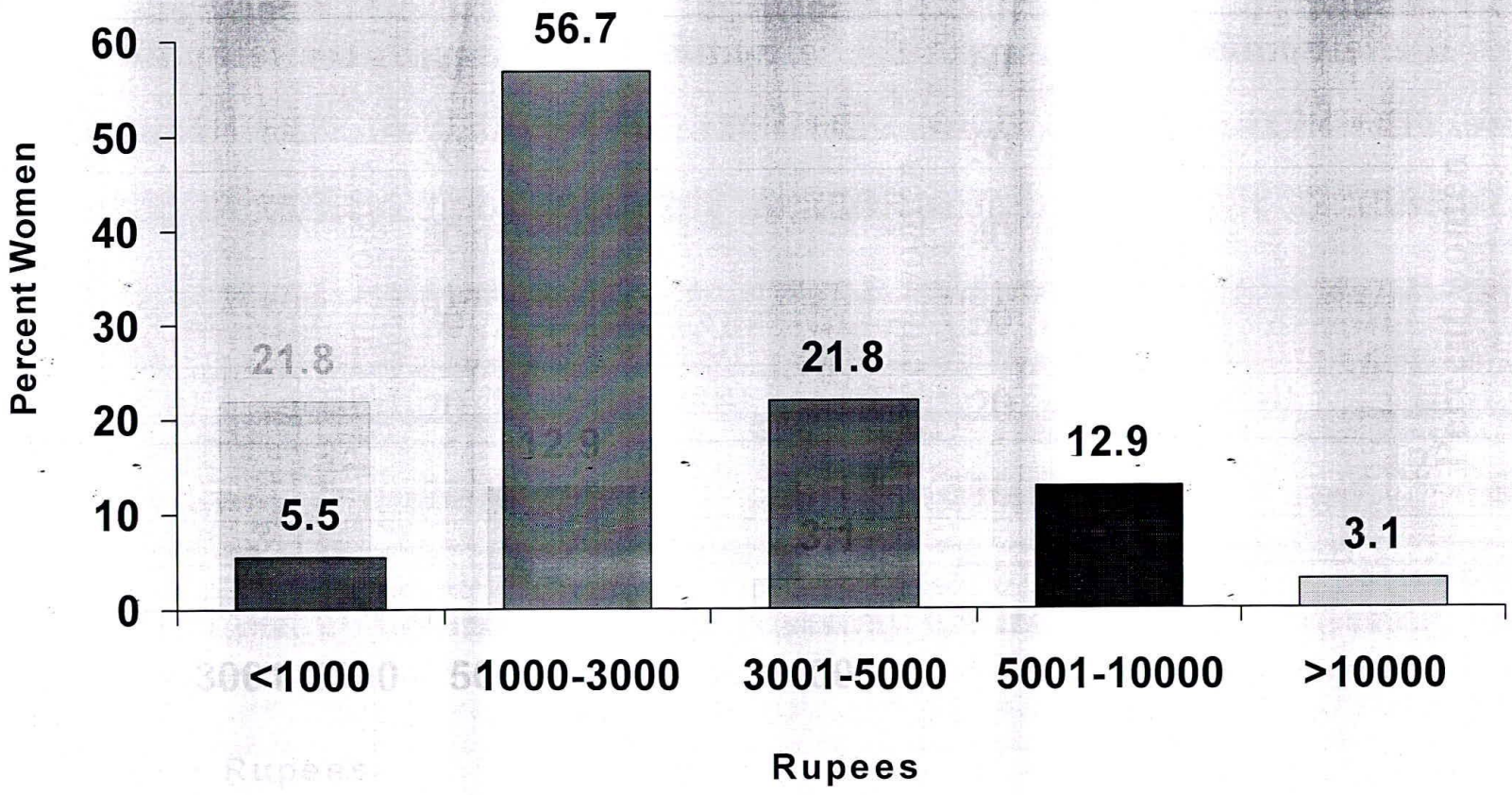


Fig. 4c: Religion of the participants (n=1209)

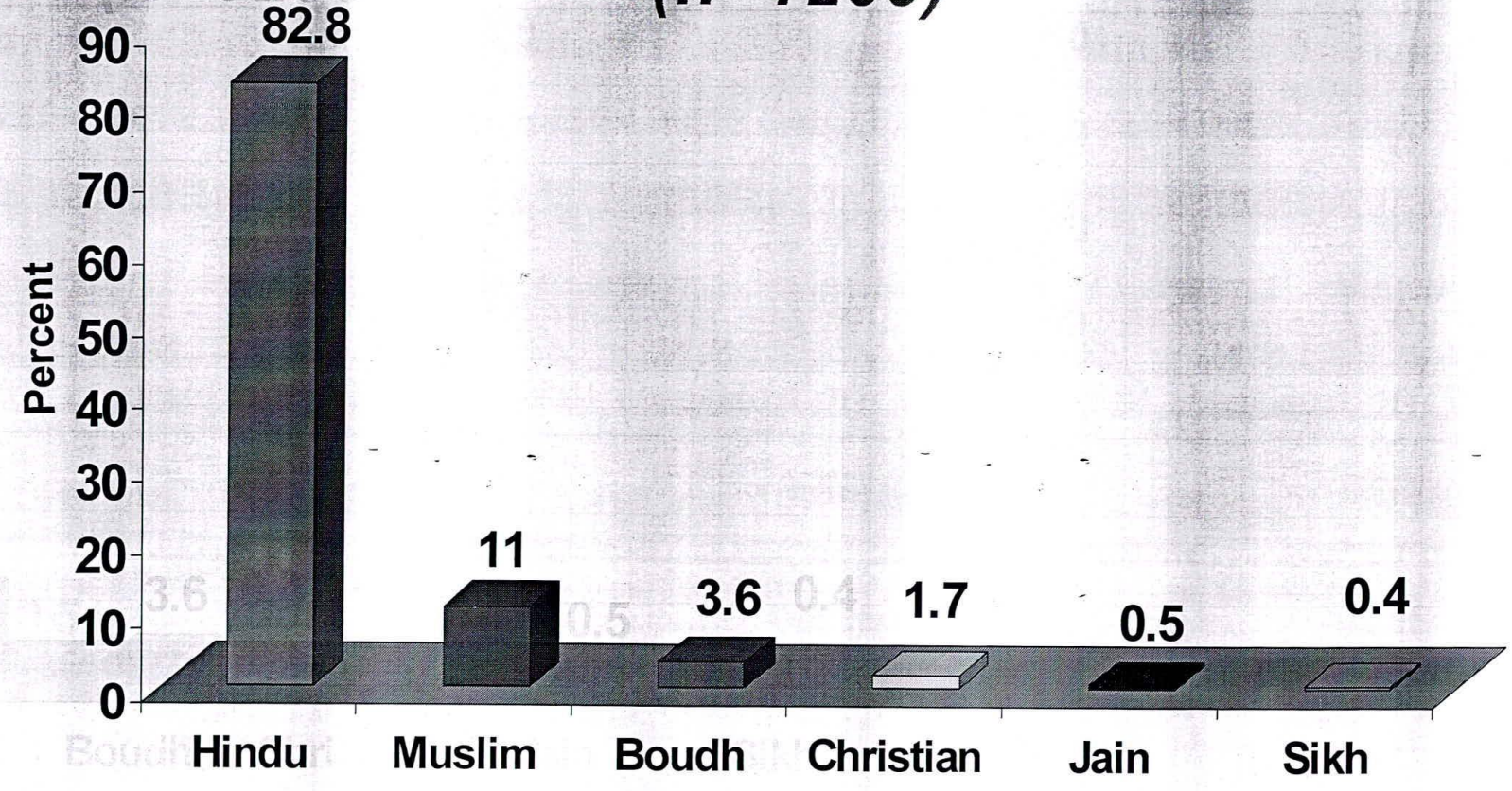


Fig. 5a: Contraceptive use prior to participation in this study (n=1209)

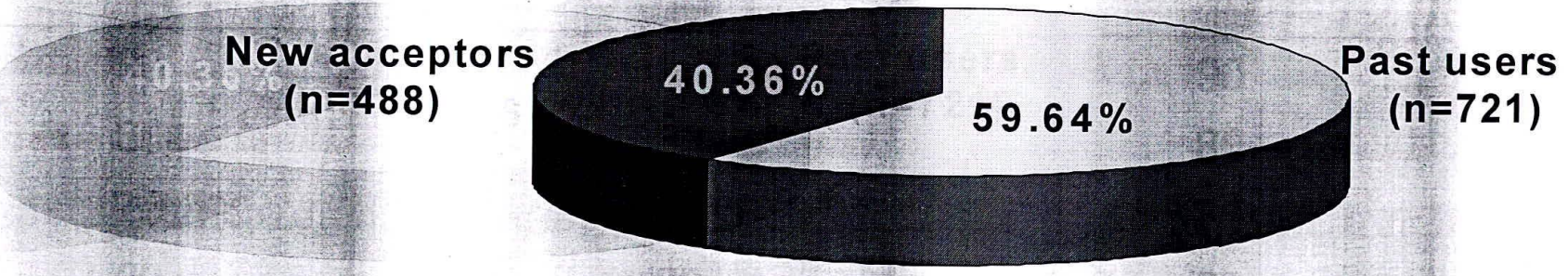


Fig.5b: Contraceptives used (n=721)

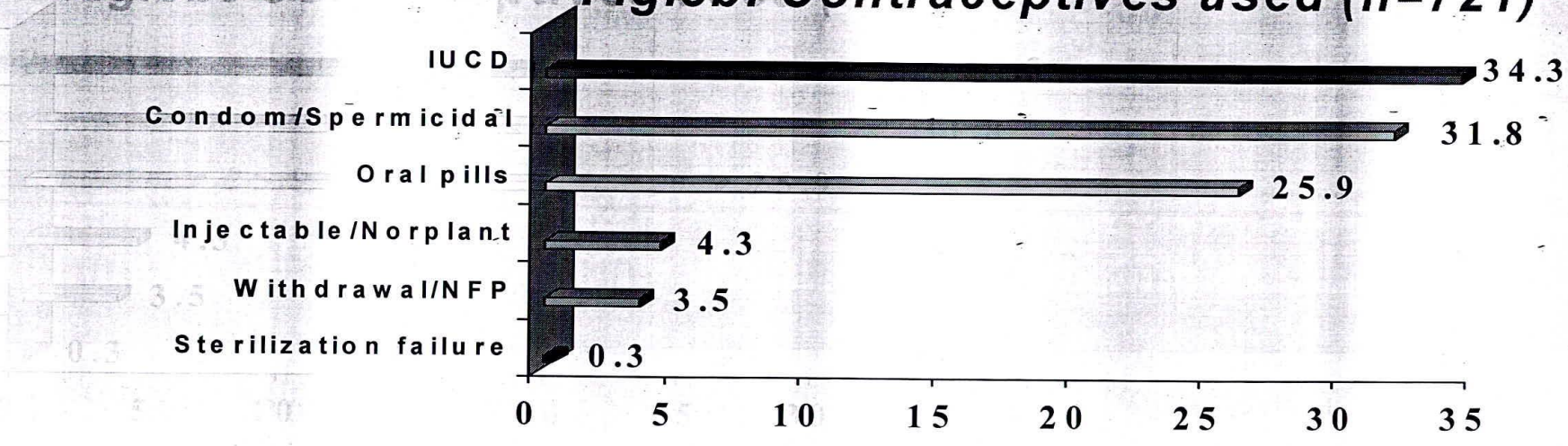


Fig. 6: Number of injections received by the women during a 2 year study period

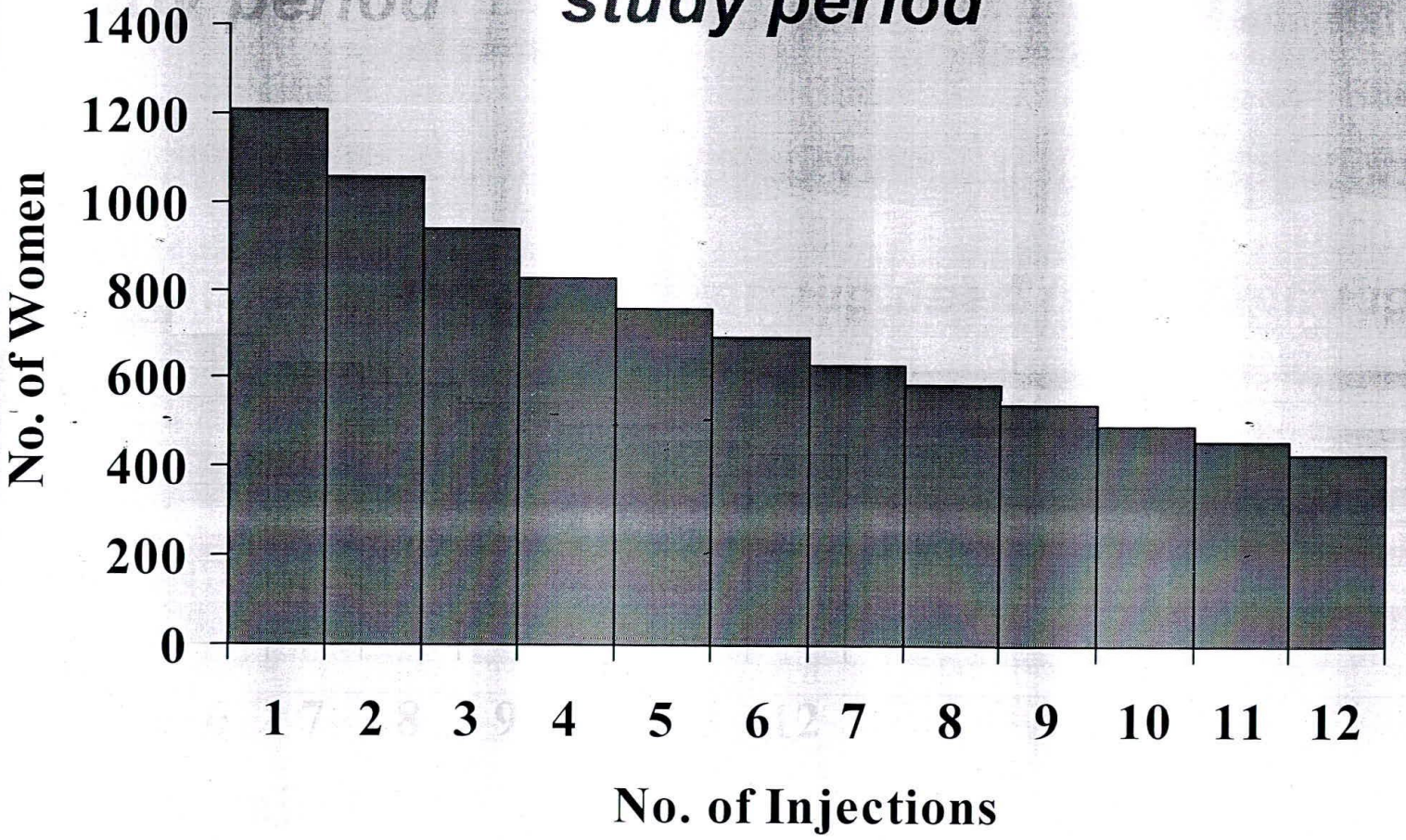


Fig. 7: Cumulative continuation rates of Net-En (women months of use=17268)

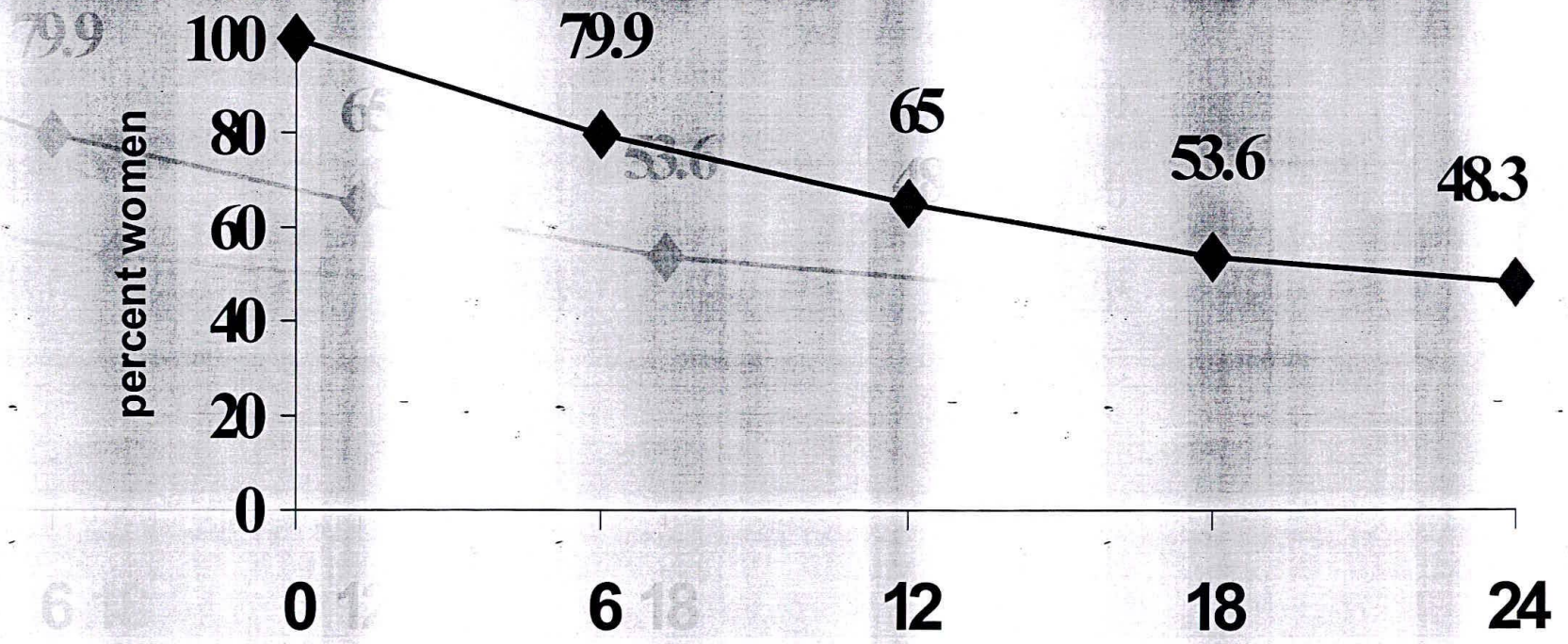


Table 3: Centre wise cumulative continuation rates of injection Net-En

Centers	Net-En use in months			
	6 months	12 months	18 months	24 months
Baroda	68.33	47.5	34.16	28.33
Kolkata	75.99	56.05	44.56	41.68
Chennai	89.32	74.14	61.63	54.48
Cuttack	66.78	47.39	37.7	33.39
Jaipur	82.00	65.12	46.12	40.02
NIRRH, Mumbai Three FP Clinics	68.83	45.55	35.42	31.38
	67.44	46.51	34.88	32.55
	71.58	57.75	50.43	43.11
KEM Hospital	59.82	54.85	49.45	42.5
Nagpur	91.00	84.45	56.7	53.66
New Delhi	67.94	51.66	48.5	41.88

Table 4: Cumulative continuation rates of Net-En Vs education status of the participants (n=1209)

Education Status	6 mths %	12 mths %	18 mths %	24 mths %
Illiterate (n=115)	75.54	55.96	46.11	40.1
Primary (n=121)	70.30	61.14	48.17	39.83
Secondary (n=595)	77.28	60.59	48.75	43.91
Higher Secondary (n=189)	71.95	55.50	42.76	36.65
Graduate & above (n=189)	71.53	54.02	39.33	35.16

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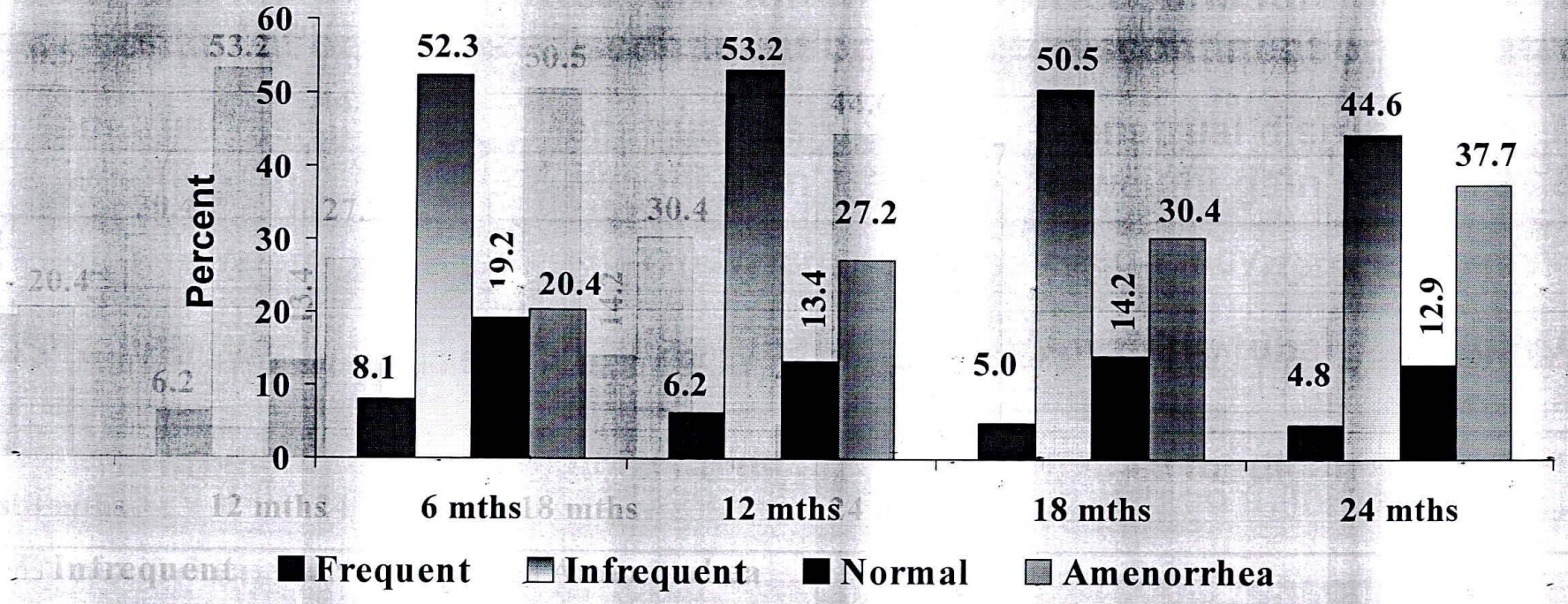
Table 5: Reasons for discontinuations of Net-En (women enrolled - 1209)

Reasons for discontinuation	6 mths %	12 mths %	18 mths %	24 mths %	Total %
Menstrual disruption & weight gain	8.4	4.2	2.2	0.4	15.3
Pregnancy	0.16	0.0	0.08	0.0	0.24
Awaiting tubal ligation	1.6	1.9	1.5	0.9	5.9
*Other medical reasons	1.9	1.1	0.33	0.66	3.9
Personal reasons	6.2	5.1	4.8	1.9	18.0
Lost to follow up/ Migration	10.9	2.9	2.2	0.7	16.7

* TB, Hepatits A, Skin allergy, Headache, Accidental deaths, Malaria

Fig.8: Percentage of different Menstrual Pattern in a two year study period

(Total Reference Period – 5666)



WHO guidelines (Belsey et al., 1986),

Frequent Bleeding – More than 4 bleeding/spotting episodes during the ref. period
Infrequent Bleeding- 1- 2 bleeding or spotting episodes
Regular Pattern – 3- 4 episodes of bleeding or spotting each lasting about 5-7 days
Amenorrhea - No bleeding / spotting days during the reference period

Fig. 9a: Change in body weight among Net-En users during 1 year of injection use (n=709)

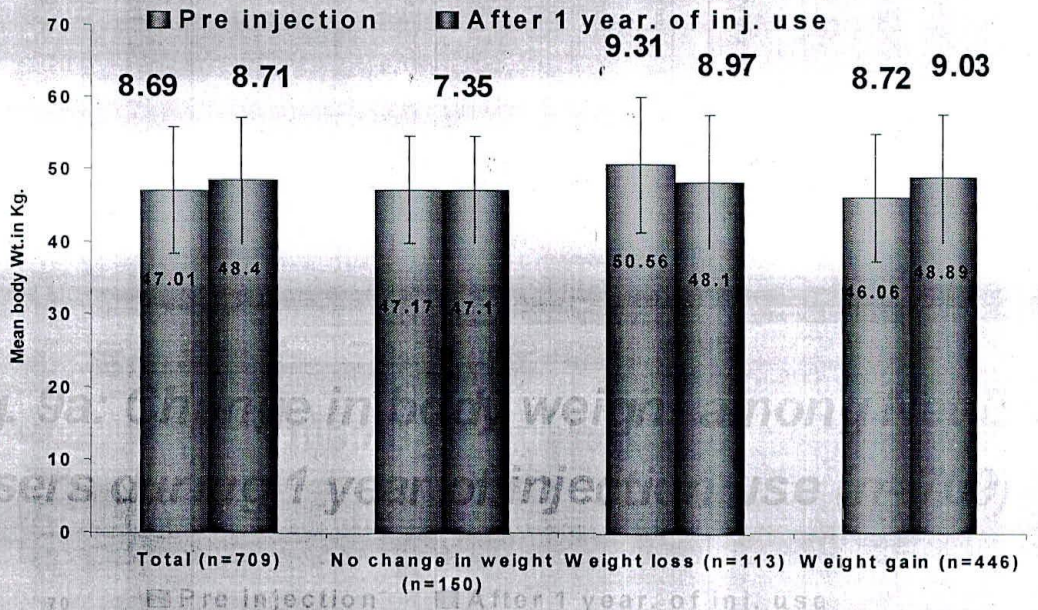


Fig. 9b: Change in body weight of Net-En users during 2 year of injection use (n=417)

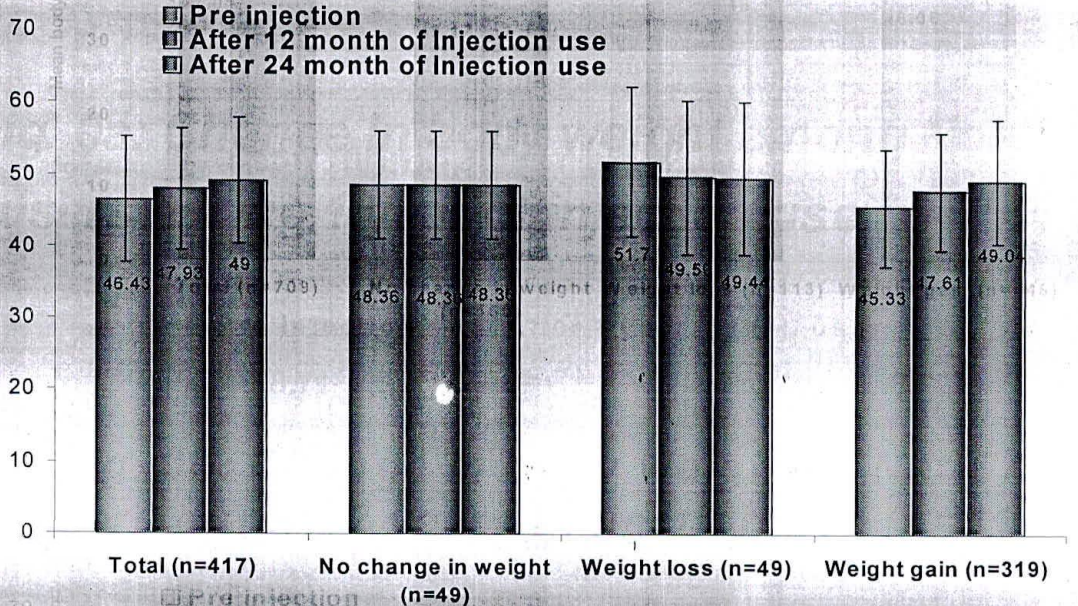


Fig.10: Overall effect on general well being/ health (n=539/968)

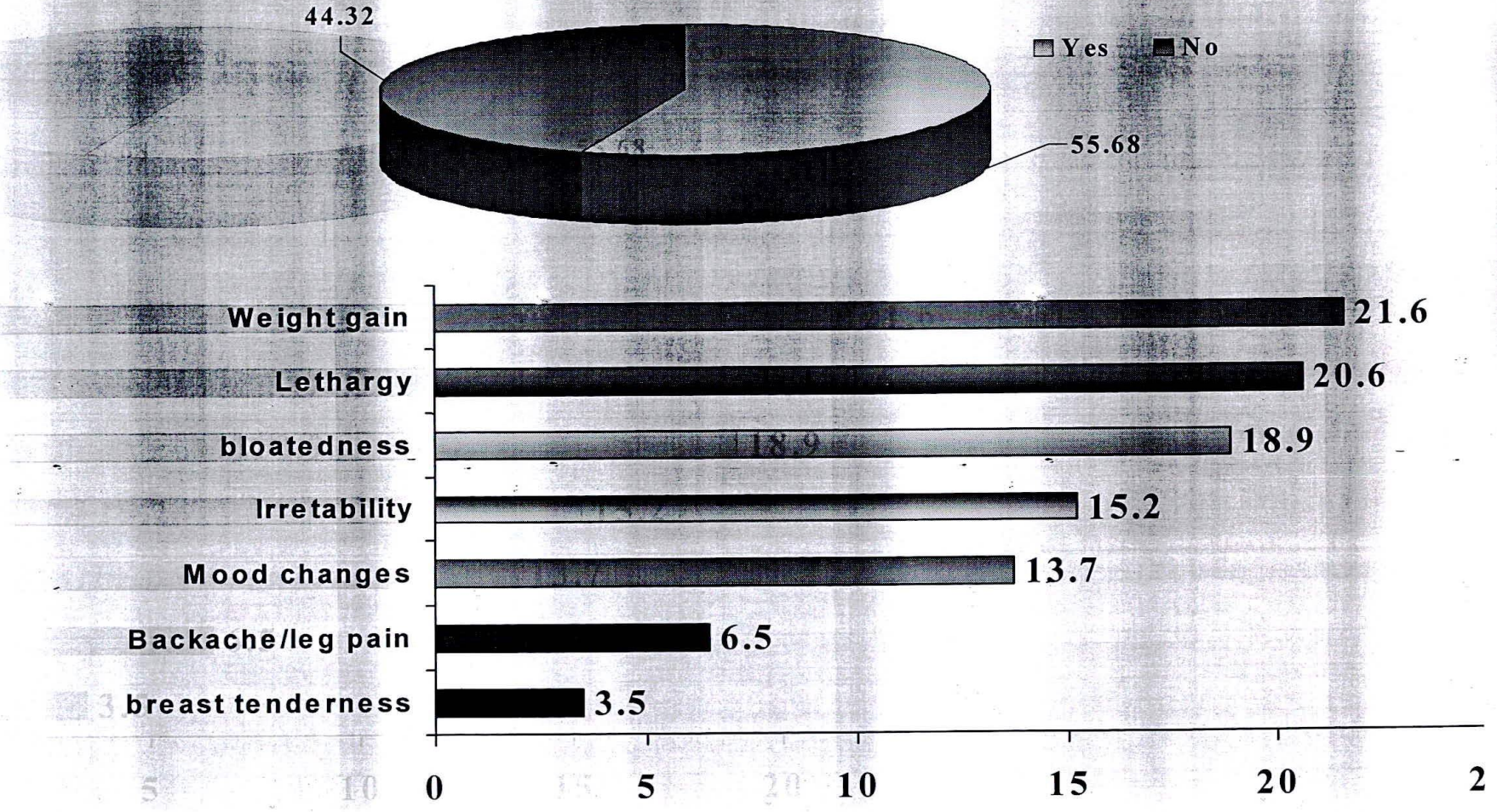


Table 6: Cervical cytology (Pap smear) during injection Net-En use (n=550)

Admission/ Pre-injection Pap	Number	Post injection Pap (1 or 2 yrs.)	Number	Percentage
Negative	382	Negative	382	69.45
Inflammatory	64	Inflammatory	64	11.64
Inflammatory	59	Negative	59	10.73
Negative	43	Inflammatory	43	7.82
Inflammatory	1	CIN I	1	0.18
Negative	1	CIN I	1	0.18

Fig. 11: Haemoglobin status of Net-En users before and after 1 or 2 years of injection

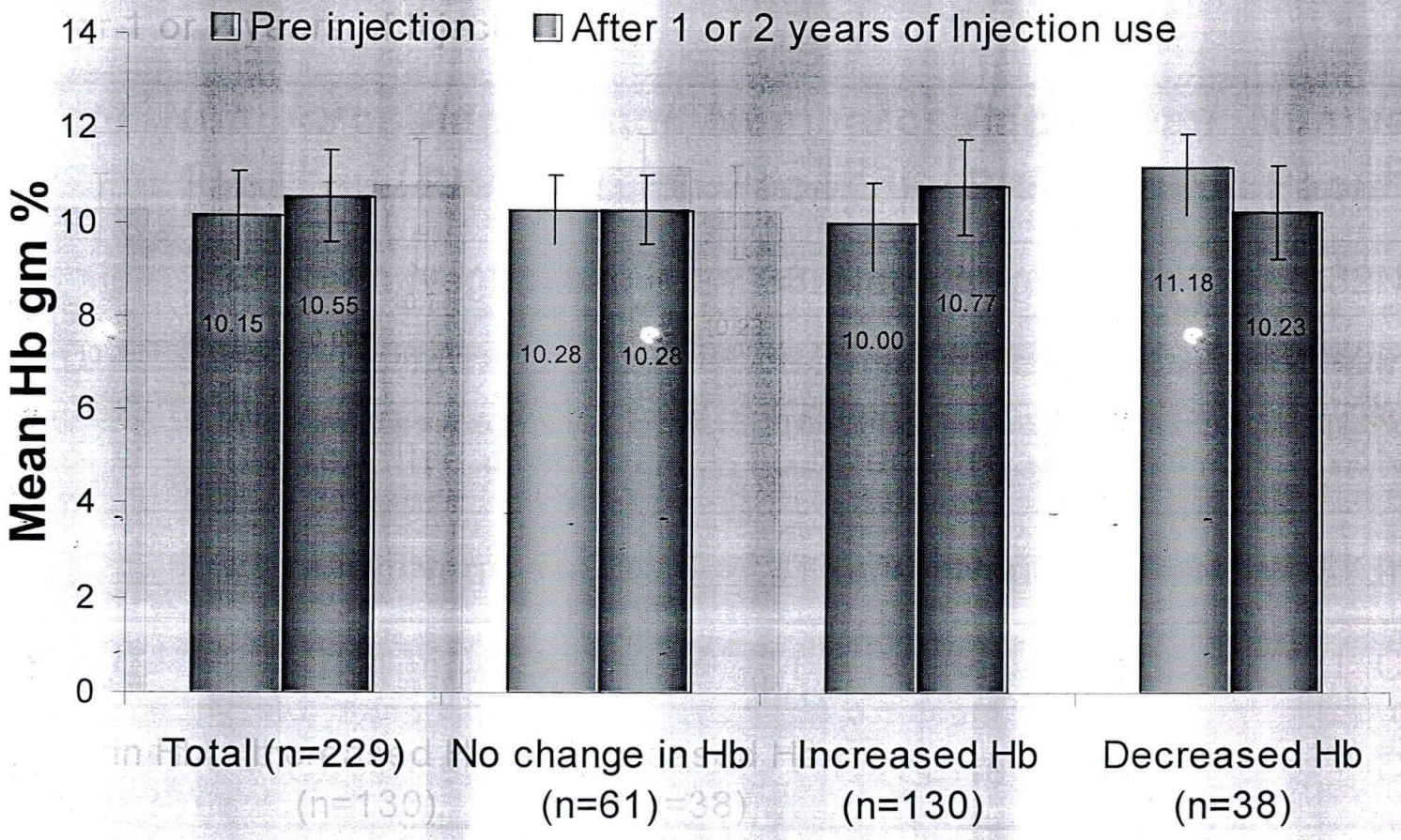


Table 7: *Women's attitudes/ perceptions towards injectable contraceptive* (n=968)

Questions	Responses	Number	%
1. Did you know injectable contraceptive prior to this study? if yes – sources (n=1209)	Yes	486	40.2
	No	723	59.8
2. How did you find this method?	Satisfied	578	59.7
	Very satisfied	193	19.9
	Not satisfied	197	20.4
3. Was it convenient for you to take injection?	Yes	857	88.5
	No	111	11.5
4. Would you like to take injection every 2 months or 3 months?	2 months	575	59.4
	3 months	291	30.1
	Can not say	102	10.5
5. How did you remember the dates of these injections?	Written on menstrual card	495	51.1
	I could memorize	343	35.4
	Reminded by clinic staff	123	12.7
	Husband reminded	7	0.7
6. Did you experience change in menstrual periods?	Yes	870	89.9
	No	98	10.1
7. Was it acceptable to you and your spouse?	Yes	644	74.0
	Neither	226	26.0
8. Change in sexual behavior during injection use	Yes	113	11.7
	No	855	88.3
9. Did this method interfere with your social/routine activities?	Yes	204	21.1
	No	764	78.9
10. Do you think this injection should be available in NFWP?	Yes	864	89.3
	No	54	5.6
	No opinion	50	5.2
10 a. If yes? Why?	Convenient, no daily intake like pills	435	50.2
	Everyone can afford and access through NFWP	220	25.4
	Wider choices of FP methods	151	17.4
	Non coital dependent	36	4.2
	No effect on breast milk	18	2.1
	No response	4	0.5

Women's attitudes/ perceptions towards injectable contraceptive ctd....

Questions	Responses	Number	%
11. Would you be able to pay for injection?	Yes	585	60.4
	No	351	36.3
	Can not say	32	3.3
11 a. If yes, how much for each injection?	Rs.10-25	100	17.1
	Rs.26–50	284	48.5
	Rs.51-75	39	6.7
	Rs.76-100	103	17.6
	More than Rs.100	59	10.1
12. How long would you like to take this injection?	At least one year	261	27.0
	One to two years	330	34.1
	More than two years	377	38.9
13. Would you recommend this method to your friends/relatives?	Yes	769	79.4
	No	62	6.4
	No opinion	137	14.2
13 a. Reasons for recommending	Care free for two months, no hassle like taking daily pills.	502	65.3
	Better than IUCD as it is invasive procedure.	132	17.2
	Non-coital dependent.	27	3.5
	Effective method.	41	5.3
	Suitable for breast-feeding women.	32	4.2
	Privacy can be maintained.	16	2.1
	Less pain during menses.	4	0.5
	No response.	15	2.0
14. User's concerns/fear about injectable	**No concerns**	726	75.0
	Concerns	242	25.0
	Effect on future fertility , quantity of breast milk, effect on blood pressure, HIV transmission through repeated needle pricks and fear of genital cancer		

Fig.12a: Did you know injectable contraceptive prior to participation in this study (n=1209)

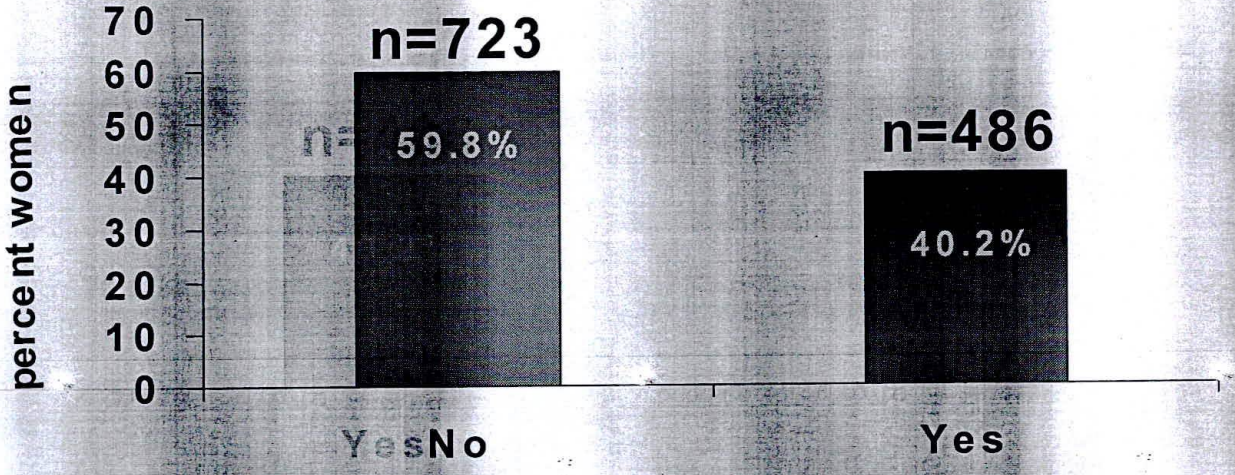
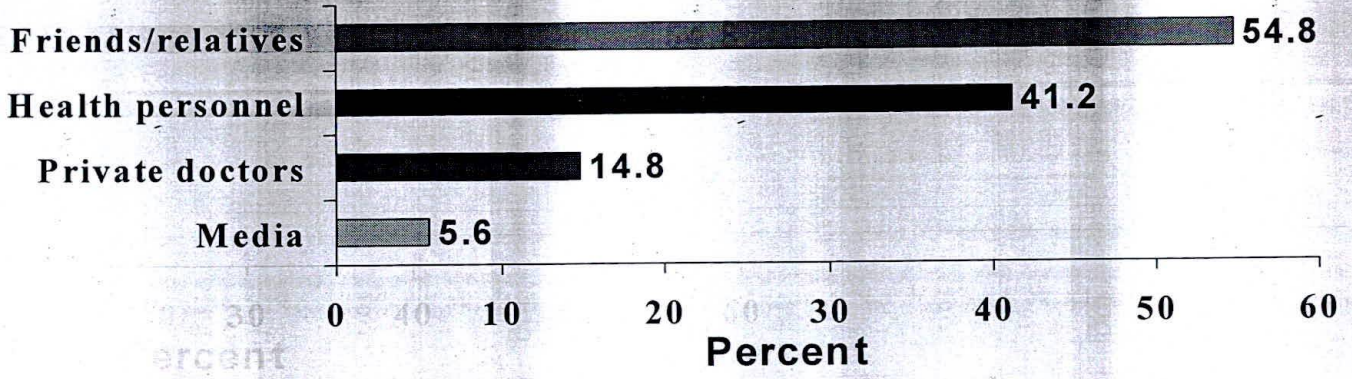
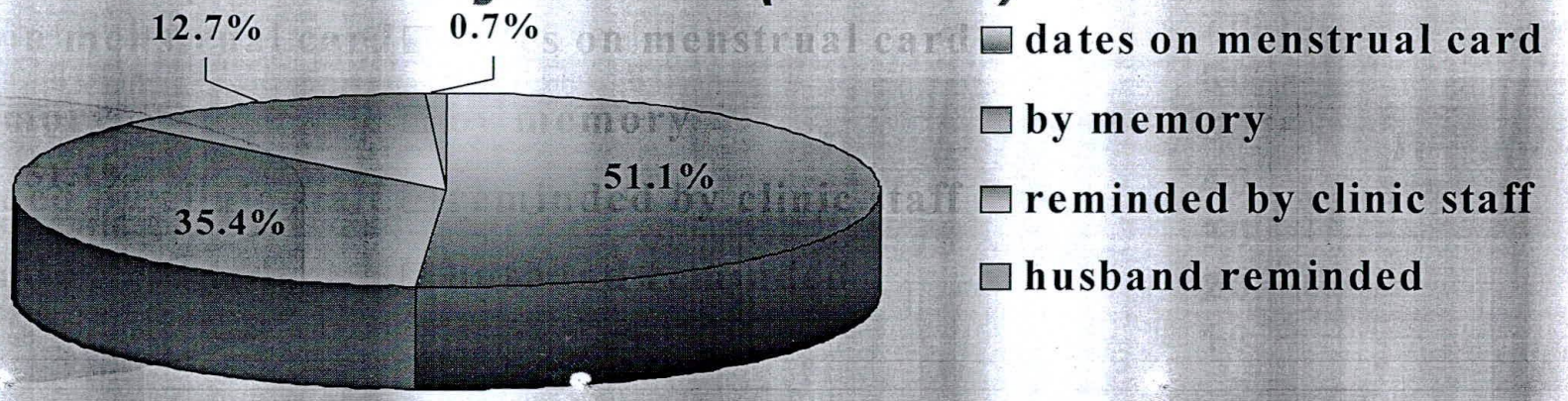


Fig.12b: Sources of information (n = 486)



Percentages do not add up to 100 due to multiple responses

Fig.13: How did you remember dates of injection (n=968)



Would you like to take injection every 2 or 3 months (n=968)

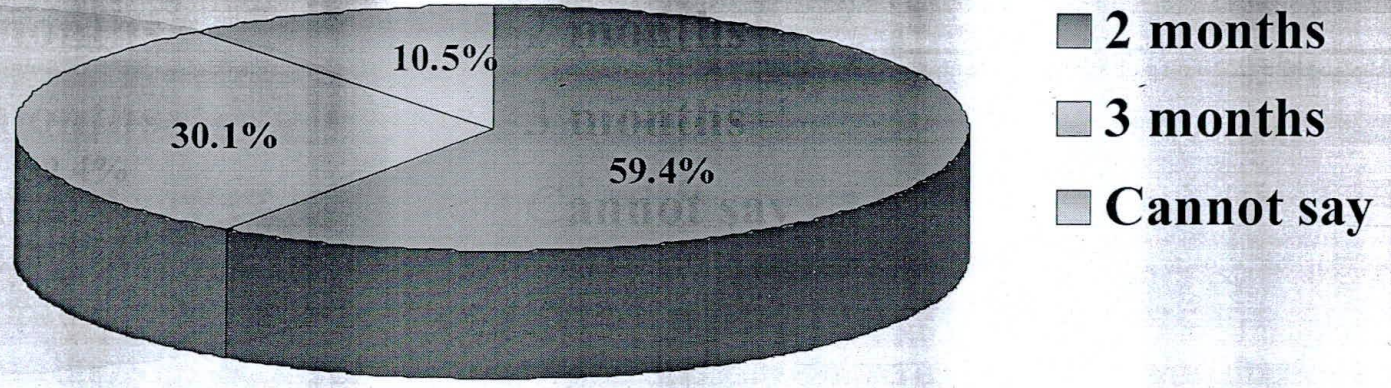
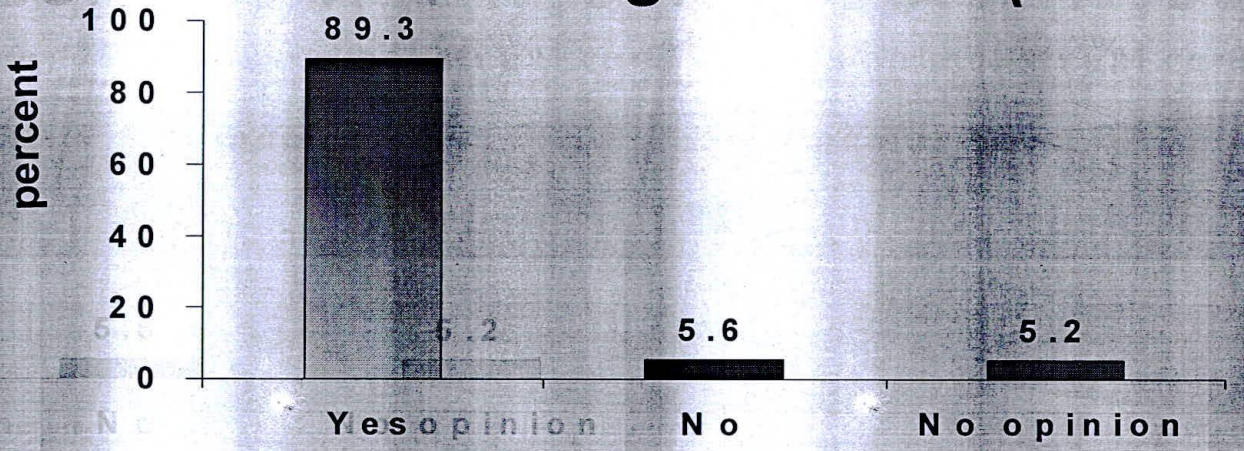


Fig. 14: Should injection be available through NFWP (n=968)



If yes, why (n=864)

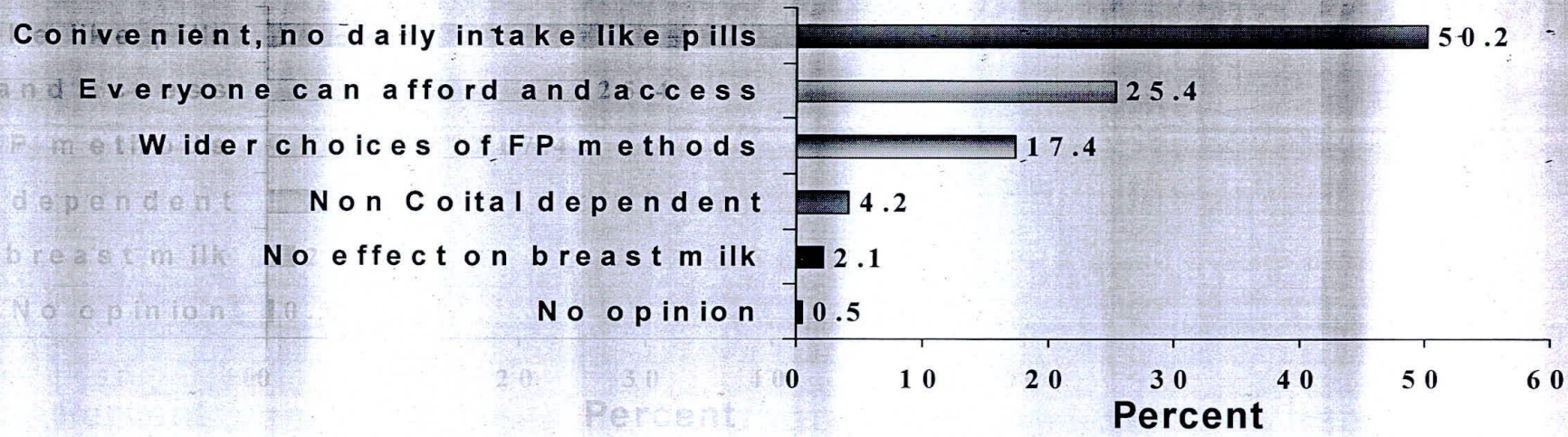
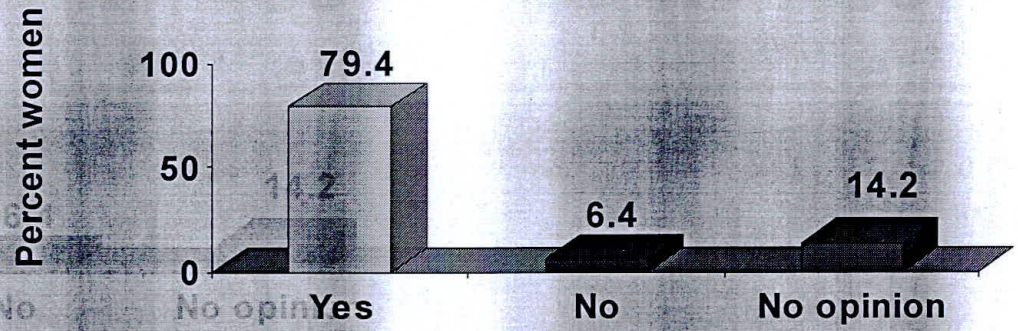
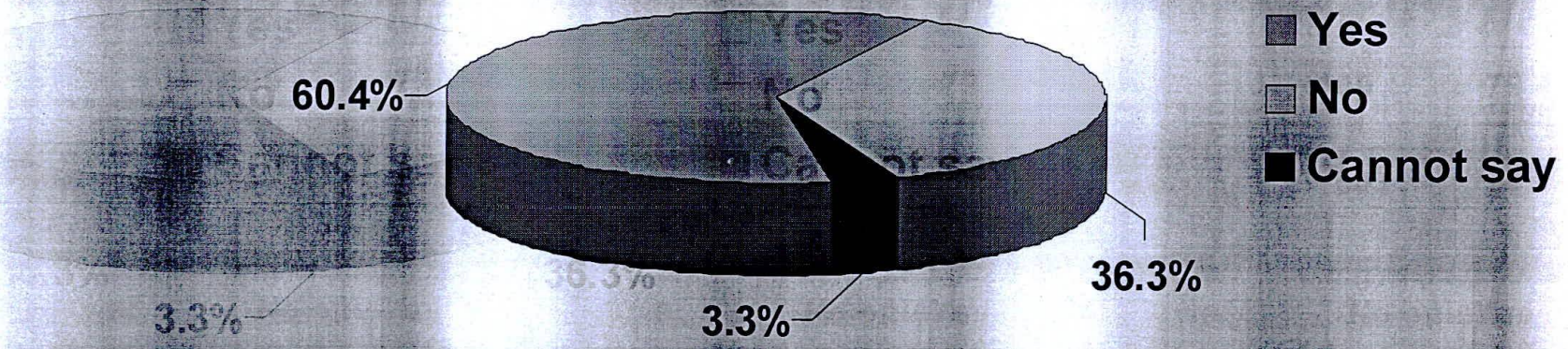


Fig. 15: Would you recommend this method to your friends and relatives (n=968)



If Yes, Why?	Number	Percent
Care free for two months	502	65.3
Better than OC/ IUD	132	17.2
Non Coital dependent	27	3.5
Effective Method	41	5.3
Suitable for breast feeding women	32	4.2
Privacy can be maintained	16	2.1
Less pain during menses	4	0.5
No opinion	15	2.0
Total	769	100

Fig. 16: Affordability for injection (n=968)



How much would you be able to pay for each injection (n=585)

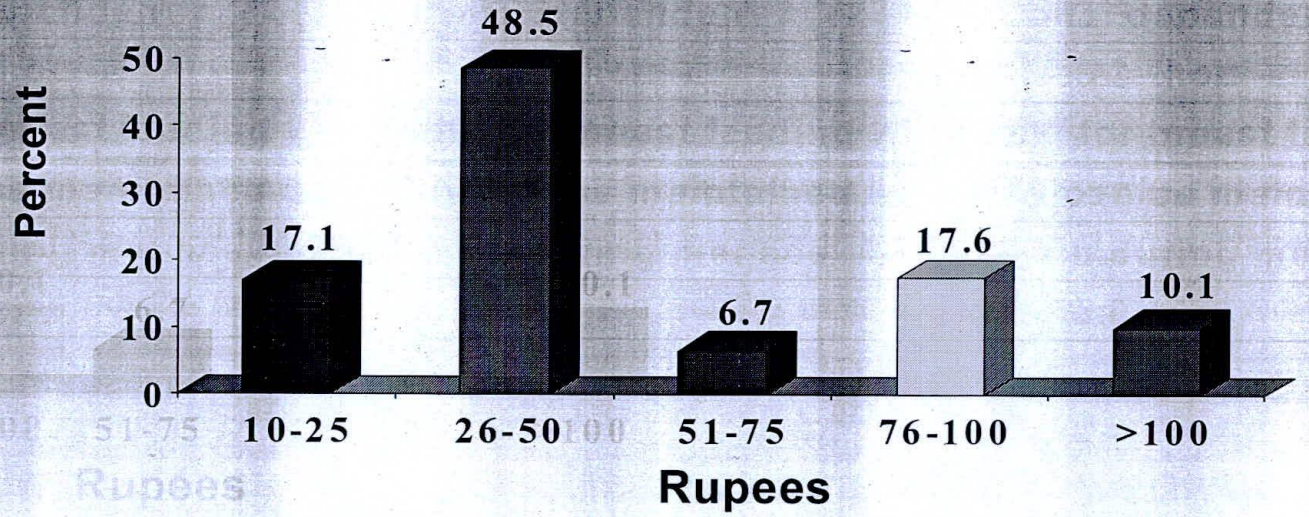


Fig. 17: How long would you like to take this Injection (n=968)

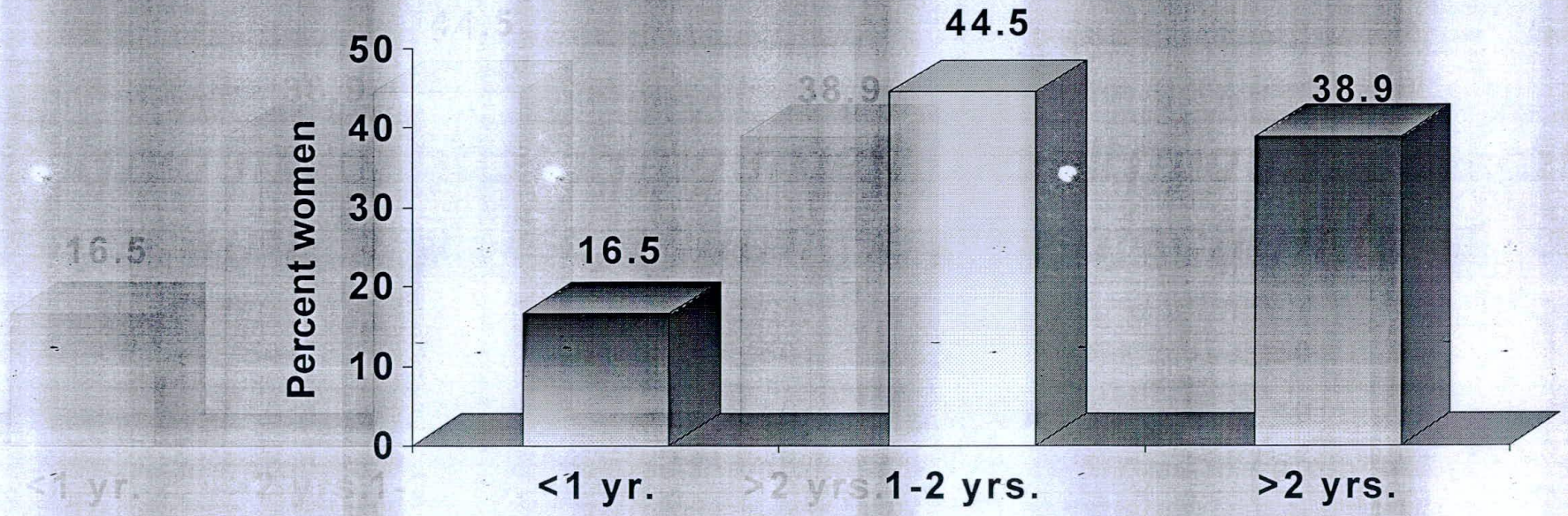


Fig. 1: BMD values by DEXA among Net-En users (n=73)

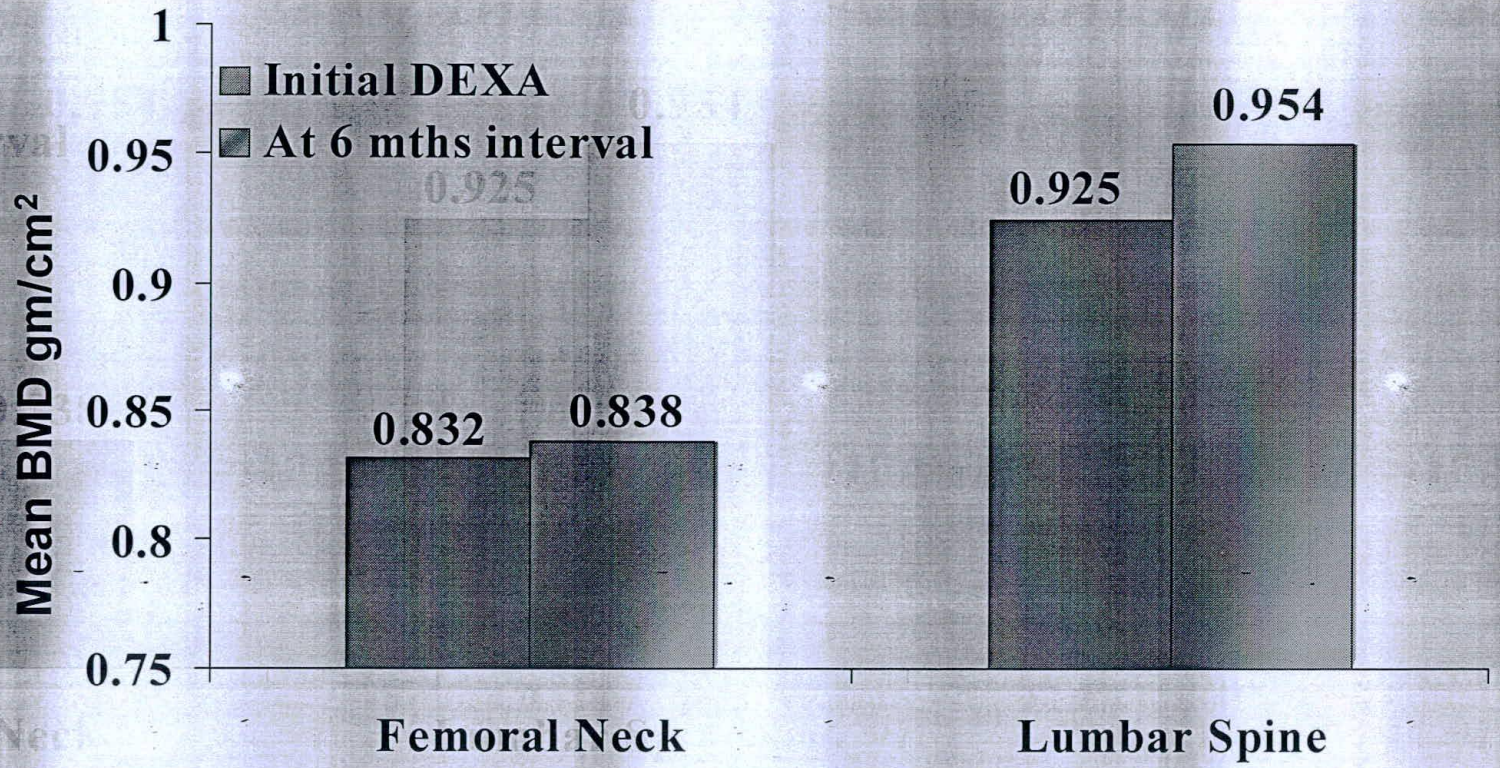


Fig. 2: BMD values by DEXA among injection Net-En users compared with injection discontinuers (n=109)

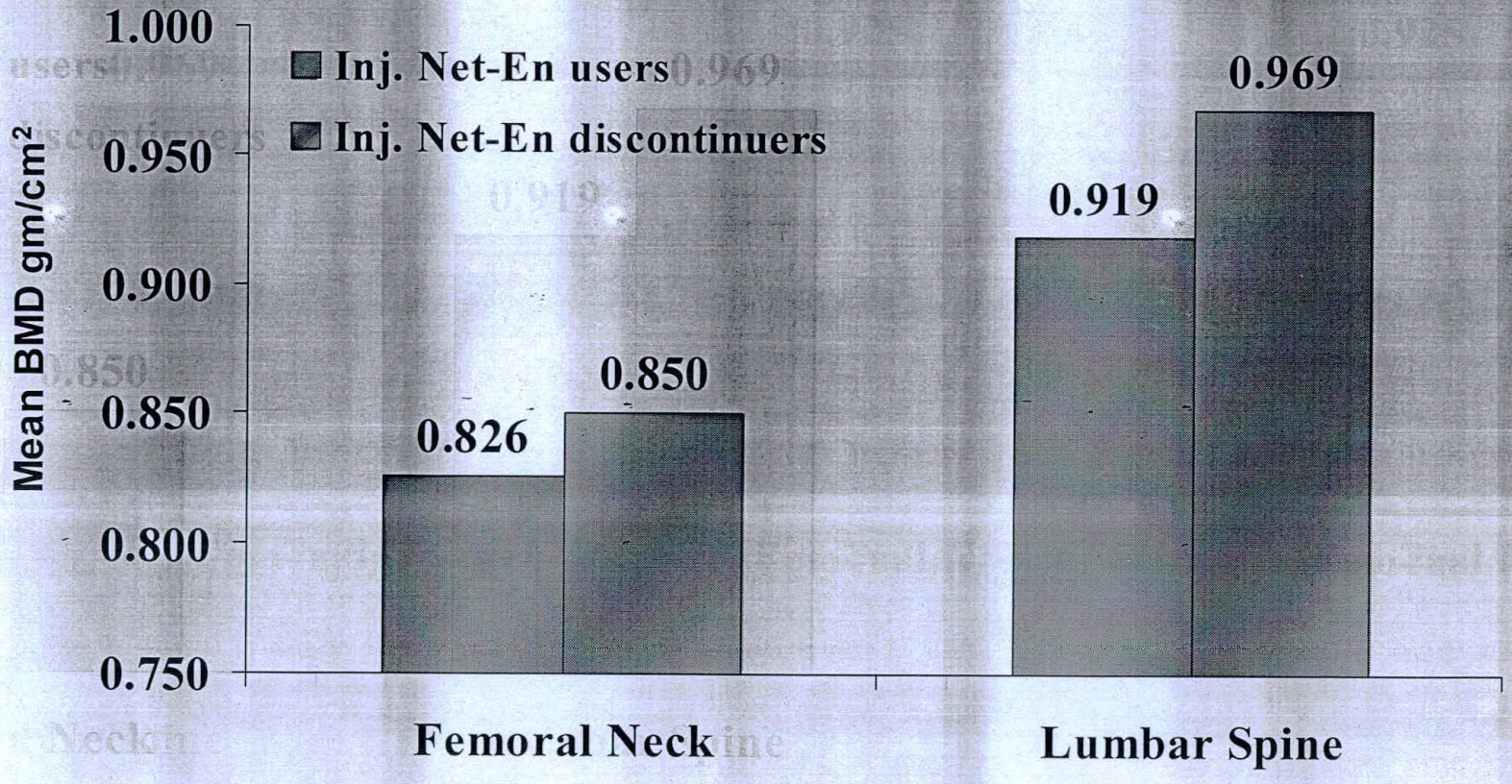


Fig. 3: BMD values by DEXA among injection Net-En users compared with Control (n=59)

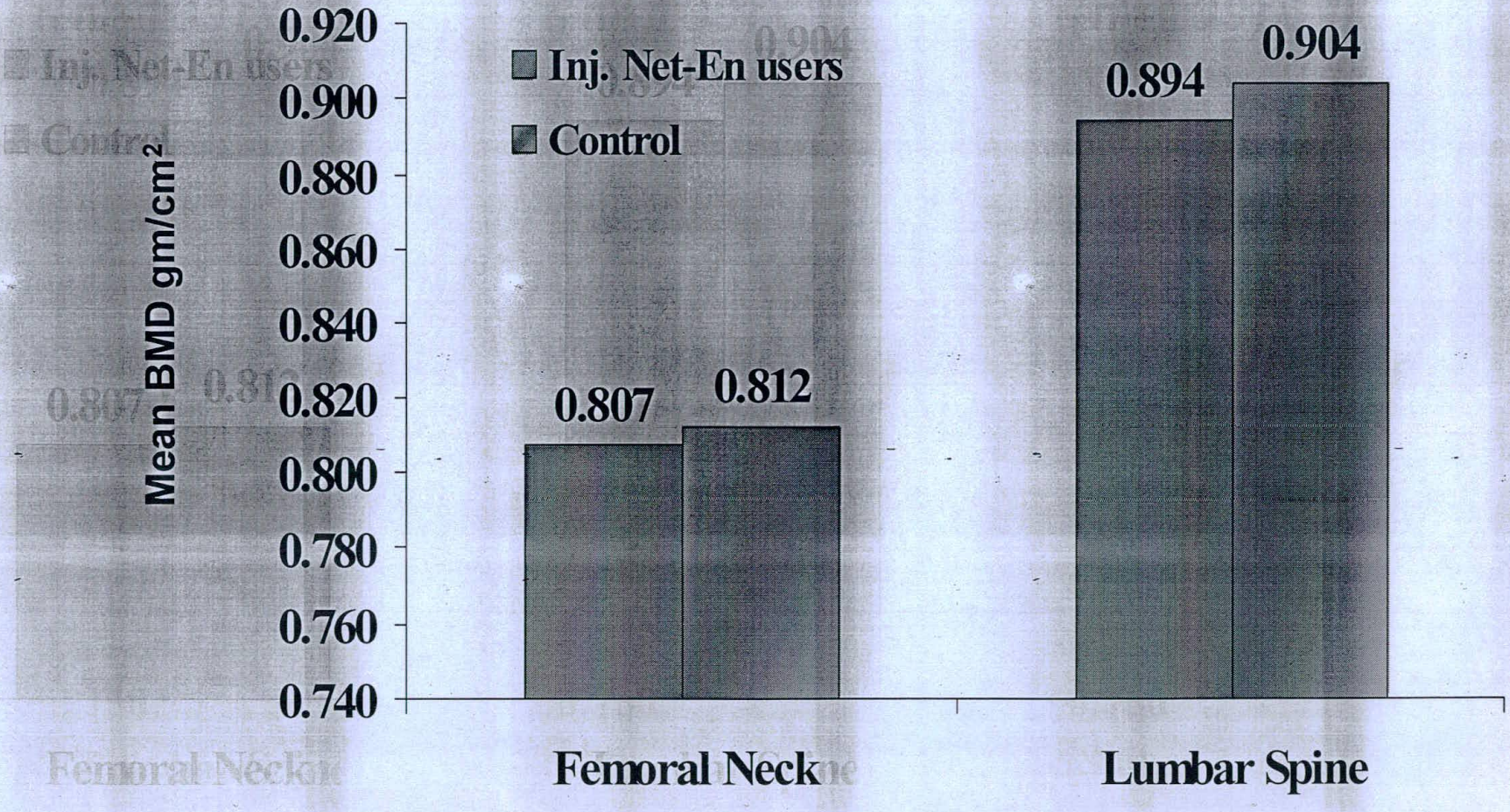


Fig. 4a: Bone mass density at lumbar spine compared with body mass index (n=142)

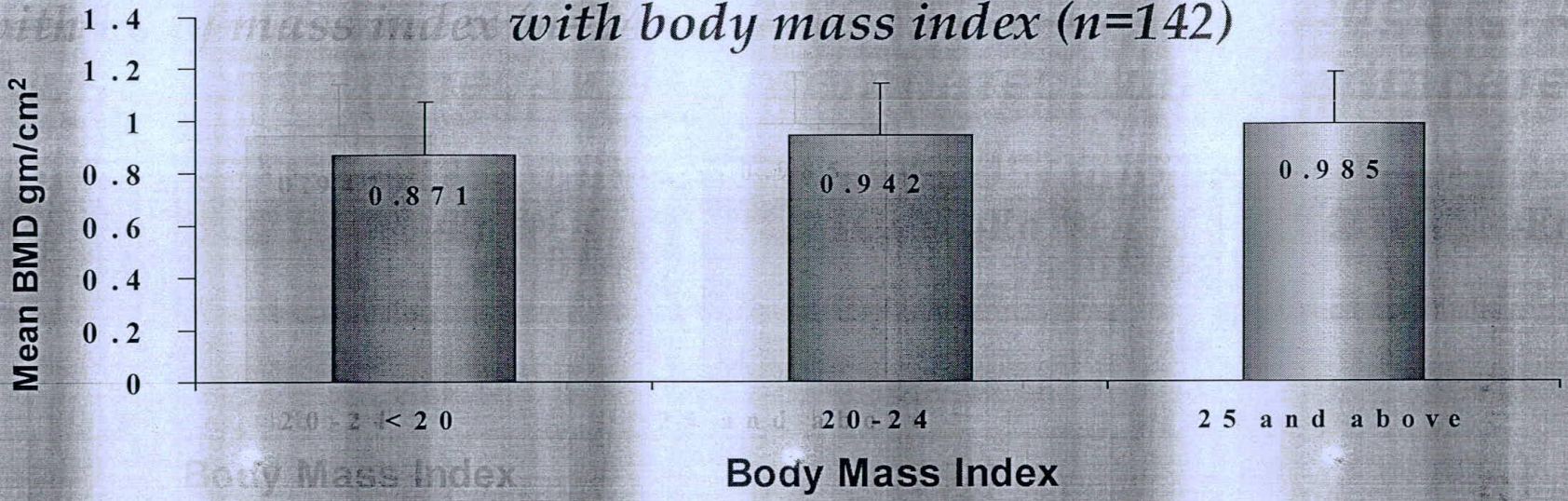


Fig.4b: Bone mass density at femoral neck compared with body mass index