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**under**

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**"Pre-Introduction Clinical Trial**

**NORPLANT<sup>®</sup> Contraceptive Subdermal Implants"**

**(September 15, 1985 to April 30, 1988)**

**THE POPULATION COUNCIL  
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**Pre-Introduction Clinical Trial**  
**NORPLANT® Contraceptive Subdermal Implants**  
**Report on the One-Year Experience in Kenya**  
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## **I. Background**

NORPLANT<sup>®</sup> contraceptive subdermal implants provide an alternative to oral and injectable contraceptives for women who want long-acting, steroidal contraception. Unlike oral contraceptives, and to a lesser extent the vaginal ring and injectable methods, implants do not require daily or monthly motivation. Furthermore, the method is reversible since the implants can be removed any time the woman wishes. After removal of the implants, the woman can attempt a pregnancy immediately during the next menstrual cycle.

NORPLANT<sup>®</sup> is the registered trademark of the Population Council for contraceptive subdermal implants. The NORPLANT<sup>®</sup> six-capsule system has received approval for marketing in Finland, where it is manufactured by Leiras Medica; it has also been approved in Chile, China, Colombia, Dominican Republic, Ecuador, Indonesia, Peru, Sri Lanka, Sweden, Thailand and Venezuela.

This implant system consists of six Silastic<sup>®</sup> capsules, each of which is approximately 3.4 cm in length and contains 36 mg of levonorgestrel, a synthetic progestin that is widely used in oral contraceptives. The total release rate of steroid into the bloodstream is about 50 mcg per day during the first year of use and 30 mcg per day in subsequent years. The capsules are designed to be implanted subdermally in the upper arm. Both placement and removal are performed as minor surgical procedures through a single 2 mm incision under local anesthesia.

In clinical trials based on over 50,000 woman-months of use, the effective lifetime of the NORPLANT<sup>®</sup> capsule system has been determined to be five years. Contraceptive effectiveness has been determined to be less than 0.5 pregnancies per 100 continuing users of NORPLANT<sup>®</sup> over the first three years of use and a total of 2.7 pregnancies per 100 users after five years.

The side effects most often reported are: frequent and longer menstrual bleeding episodes, increased spotting, a reduction in total menstrual blood loss and sometimes amenorrhea. Since this system contains no estrogen, some of the major complications and side effects that have been associated with the estrogen component of combined oral contraceptives would not be expected to occur with these implants.

## **II. STUDY OBJECTIVE**

In 1984, as part of an overall program for the worldwide introduction of NORPLANT<sup>®</sup>, the Population Council initiated a series of pre-introduction clinical trials of the NORPLANT<sup>®</sup> method in selected countries. The principal objectives of these studies were to introduce the NORPLANT<sup>®</sup> implant system into countries with no previous experience with the method, to provide proper training to physicians in the insertion and removal techniques and in client counseling, and to determine overall acceptability of the implants in different populations. A second objective of the studies was to provide regulatory authorities and population/family planning policymakers in each country the opportunity to review the local clinical data and decide on the appropriateness of the NORPLANT<sup>®</sup> method for more wide-scale distribution. A third objective, particular to this study, was the opportunity to design and test the requirements necessary to take this clinic-based method to a rural area while maintaining aseptic standards.

## **III. SITE SELECTION**

In early 1985 a proposal was submitted by the Department of Obstetrics and Gynaecology, University of Nairobi to the Population Council to conduct a pre-introduction evaluation of NORPLANT<sup>®</sup> Contraceptive Subdermal Implants in order to test acceptability and to familiarize leading clinicians and government officials in Kenya with the method.

The site selected for the study was in the Northern Division of Machakos district. The study area covers a total of 172 sq. kms with 10 sublocations which are divided into 64 villages. This area has a total population of 51,000. Of these, 12,000 are women aged 15-49 years. The study area is divided into two regions separated by a ridge into East and West. The Western side of the study area, with better soil and rainfall, is economically better off than the Eastern side. The Western side also has a higher population and population density compared to the Eastern side. These factors have had an effect on contraceptive prevalence, with the Western side having a higher prevalence of use of all methods. The overall modern contraceptive prevalence is 17% in the study area among women of reproductive age.

The area is served by a total of six clinics and one subdistrict hospital. Four of the six clinics are research clinics for a major ongoing project funded by the WHO/HRP on the Impact of Integrated Maternal/Child Health and Family Planning Services on family planning use. These four clinics, located in simple buildings in the market places in this rural setting. They are run by a team of community nurses, field workers and a postgraduate student in the Department of Obstetrics and Gynaecology. The clinics are operated on a one day per week basis. The other two clinics and sub-district hospitals are operated by the Ministry of Health.

The NORPLANT® study was carried out at these four research clinics involving only women who were residents within the study area.

#### **IV. STUDY APPROVAL**

The study protocol was prepared by the University of Nairobi Dept. of Obstetrics and Gynaecology and the Population Council, and was approved by the Council's Human Investigation Committee on 10 July 1985, as well as the Kenyatta National Hospital Ethics Committee. Local institutional review approval was obtained by the research committee.

## **V. TRAINING OF PERSONNEL**

Since NORPLANT® provides protection over five years and since use of the method requires a minor surgical procedure, training in proper placement and removal of implants, and motivation and counseling of clients was carried out.

Professor Mati and Dr. Sinei attended training sessions in Jyvaskyla, Finland in September 1985 prior to the initiation of the study. They, in turn, trained the physicians who were to be involved in the study. To date, four obstetrician/gynaecologists and four postgraduate students in obstetrics/gynaecology have received training in insertion and removal techniques locally. The training of these physicians took place in the study area and each had to insert at least five implants under supervision during the training.

Mrs. Mungai, the study coordinator, traveled to Brazil and attended a training session in a well-established clinic where NORPLANT® had been used for a long time.

Also, prior to initiation of the study, the field nurses and field workers were trained in motivation, counseling, client selection, and maintenance of equipment.

## **VI. STUDY INITIATION**

This study was formally initiated during a site visit by a representative of the Population Council in April 1986. The study protocol and data collection procedures were reviewed during this visit.

This study was conducted according to the standard Population Council protocol entitled "Pre-Introduction Evaluation of NORPLANT® Implants," dated July 1985. Standardized, computer-readable data collection forms were used to record information about each acceptor at admission and at regularly scheduled follow-up visits.

## **VII. ADMISSION**

### Subject Enrollment and Informed Consent

A total of 292 acceptors were recruited into this ongoing clinical trial. There were 97 acceptors at Kinyui clinic, 142 acceptors at Katwanyaa clinic, 40 acceptors at Kathama clinic and 13 at Katheka clinic. Enrollment at all four clinics began in April of 1986 and, at the time of this report, is continuing.

This report is based on clinic visits through January 1988 and on data processed through March 1988. Data reported for menstrual irregularities are based on the first 250 acceptors. Acceptability and follow-up data are based on continuing enrollment.

Women were admitted to the study only if they met all the selection criteria outlined in the Selection Criteria Checklist attached to the protocol. These criteria specified that each subject had to be: between 18 and 40 years of age, sexually active, previously pregnant, not breastfeeding, not using injectable contraceptives in the six months prior to admission, within the first seven days of the menstrual cycle, and readily accessible and willing to return to the clinic for regularly scheduled follow-up visits. Women with a history of liver disease, jaundice, or herpes gestationis were excluded from consideration. Prior to insertion of the implants, physical and pelvic examinations were performed on each woman. Those with evidence of thromboembolic disease, hypertension, pelvic inflammatory disease, undiagnosed vaginal bleeding, cancer, pregnancy or contraindication to use of hormonal contraception were excluded from the study.

Women who met all the criteria were fully informed about the purpose of the study, and the risks and benefits associated with the use of this contraceptive method. Each woman who volunteered to participate in this study was required to give informed consent by signing a Volunteer Agreement.

There were some protocol violations. Most of these related to the insertion of NORPLANT® within seven days after the onset of menses. This was generally because the women were postpartum. There were eleven violations for women over the age of 40: three were in Kinyui, eleven at Katwanyaa, and one at Kathama.

## VIII. RESULTS

### Sociodemographic Characteristics of Acceptors

Selected sociodemographic characteristics of the women are presented in Table I. Mean age of the entire group was 27.5 years with a mean parity of 3.7 live births. There were no notable sociodemographic differences among the four clinics.

### Pregnancies

For the 292 women reported here (2,771.5 woman-months of use) there were no pregnancies.

### Previous Contraceptive Use

The primary method used at admission was oral contraceptives (43.2%), but a significant number (34.6%) were using no contraception. Injectables were used by 12.3%, and 7.9% used IUDs. Barrier methods accounted for only 2.1%.

### Follow-up

Follow-up visits for all acceptors were scheduled at 1,3, 6 and 12 months after admission to the study. However, women were encouraged to return to the clinic for any problems that occurred, regardless of the next scheduled follow-up visit. Follow-up of all women will continue every six months until removal of the implants. Follow-up rates for the first 12 months of use are listed in Table II.

## IX. MEDICAL PROBLEMS

A medical problem is defined as any complication or complaint, of a medical nature, reported by the client, any unanticipated event, or a serious medical condition or hospitalization that occurred during the study. A listing of medical problems reported by the women during any follow-up visit appears in Table III. As indicated below, most of these cases did not require removal of the implants. They were treated and followed-up as the clients continued in the study. Since each NORPLANT® acceptor could have reported more than one medical problem at any one visit or at different visits, that the total number of events in this table exceeds the total number of women with medical problems.

Other than menstrual irregularities there were a total of 100 medical problems that were reported by 67 women during the first year of use. Thirty-five problems were reported by 23 acceptors at Kinyui, 39 problems by 32 women at Katwanyaa, 15 problems by 9 women at Kathama and 11 problems by 3 acceptors at Katheka.

The most frequently reported medical problem was general malaise, which may include symptoms of malaria (32 cases). The second most frequently reported medical problem was abdominal pain (12 cases) and the third most frequently reported medical problem was lower abdominal pain with vaginal discharge (11 cases).

### Weight and Blood Pressure Changes

Changes in mean body weight, and blood pressure at the one-year follow-up visits are shown in Table IV. The average weight was essentially unchanged at Kinyui, Katwanyaa and Katheka; Kathama reported a decrease of about 1 kg.

All four clinics reported a decrease in systolic blood pressure (up to 4 mm Hg) and a decrease in diastolic blood pressure (up to 3 mm Hg).

The mean for all four clinics for each parameter proved to be negligible.

### Continuation Rates

The one-year cumulative lifetable rates are presented in Table V. Kathama had the highest continuation rate of the four clinics (95.5). The continuation rates at Kinyui, Katwanyaa and Katheka were 91.5, 94.4 and 88.9, respectively. The 15 removals resulted in a pooled net termination rate of 6.7 per 100 women at one year, and a pooled continuation rate of 93.3. There was a total of 2,771.5 accumulated woman-months (231 woman-years) of use for the four clinics.

## **X. MENSTRUAL CHANGES**

The menstrual patterns of the first 250 women using NORPLANT® over an 18-month period of use are shown in Table VI. At insertion, 77.55% of the women reported having regular periods, while 18.9% had amenorrhoea, and only 3.7% had spotting. Six of the women did not have their menstrual pattern recorded at the initial visit, but their menstrual patterns following insertion have been followed. Only those women who returned for the follow-up visits are reported. The table also excludes those women who had terminated use of the method as their menstrual patterns would not be known after removal. This explains the different totals used in the table to calculate the percentages. There were 26 removals among these 250 women by the 18th month of use. If these are excluded, a follow-up rate of 79% at 18 months of use was achieved.

The NORPLANT® acceptors over the first three months went through patterns of amenorrhoea, irregular periods, spotting, and other menstrual problems as shown in Table VI. However, after three months of use, the women progressively regained their regular cycles with 51.5% achieving this by 18 months of use. Increased bleeding, which could have been just an increase in number of bleeding days, occurred in 1.1% - 3.8% of the women through the 18 months of use. Decreased bleeding was reported by 3.7%-19.5% of the women. This pattern, however, was reported maximally at 6 months of use and thereafter tended to disappear. Spotting did not show any particular pattern

and was reported by 3.7% - 10.6% of the women. Menstrual irregularities were experienced by 3.8% of the women at 1 month of use and rose to 24.2% at 18 months of use. This progressive increase may be explained by the number of women who went from amenorrhoea to regular cycles with irregular cycles in between.

Table VII shows the incidence of new menstrual changes reported by women during a 12-month period of use. A total of 332 new menstrual changes were reported by these women. This table shows a progressive decrease in the new changes reported with the duration of use. The majority of these were reported after one month of use. After six months of use, onset of amenorrhoea was not reported. Spotting was also reported mostly after one month of use, but thereafter the incidence remained low. Data from table VII suggests that most of the menstrual changes develop during the first month of use. Thereafter, incidence drops or remains low.

Table VIII shows the duration of 283 menstrual changes that were accurately recorded over 12 months follow-up. The majority of these menstrual changes lasted for 1-3 months from the first time that they were reported regardless of the duration of use. Of these, 250 changes lasted for 1-3 months. Considering that 200 of the 330 were reported in the first three months (see Table VII) it can be concluded that most of the menstrual changes developing during the use of NORPLANT® do so in the first three months and may dissipate within the next three months.

## **XI. REMOVALS**

### Reasons for removal

A total of 15 removals were reported in the first year of use: seven at Kinyui, six at Katwanyaa, one at Kathama and one at Katheka (Table V). There were no removals for pregnancy during the first year of use (2,771.5 woman-months of use).

Desire for pregnancy was cited as the primary reason for seeking removal by seven acceptors (three at Kinyui, three at Katwanyaa and one at Kathama). These removals occurred between seven and ten months post-insertion.

There were three removals for other personal reasons (two at Kinyui and one at Katwanyaa). Two occurred in the fifth month and one in the tenth month post-insertion. Clinic counselors consider that these three removals and the majority of removals for desire of pregnancy were due to family pressure for fertility.

There were three removals for menstrual problems (one at Kinyui and two at Katwanyaa). Two removals were due to medical problems. The client at Kathaka discontinued at three months because of recurrent chest pain and pain at insertion site. The client at Kinyui discontinued after six months of use because of what appeared as pellagra (depression due to niacin deficiency) although previous notes indicate social pressure from the mother-in-law.

#### Follow-up of women who terminated use of NORPLANT®

The various reasons for removal are shown in Table X. Of the 17 women who terminated the method in order to become pregnant, 11 (65%) subsequently have become pregnant and four of them have delivered full-term infants. Of the women who had NORPLANT® removed the mean duration from the time of removal to the time of conception was 3.45 months (range 1-10 months). The high rate of return to fertility is promising. Of the remaining six women, only two did not conceive within a 12-month period. Of the 11 women who terminated use of NORPLANT® for other reasons, two of them conceived and seven of them changed to other methods. Four are using Depo-Provera, two are using IUDs and one changed to pills. The remaining two are not using any method but have not conceived as yet. Follow-up of the 17 women is still continuing and any resulting pregnancies and the infants will be monitored.

## **XI. ACCEPTABILITY OF NORPLANT®**

An adjunct study of the acceptability of NORPLANT® was initiated in August 1987. The study involved those women seeking termination of use of NORPLANT® as the index population. Three controls (women not seeking discontinuation) for each woman seeking termination were interviewed. The criteria for selecting the controls included age, parity, date of last delivery and duration of use of NORPLANT®. The women selected for the study were then interviewed using the "sense making technique" (see Dervin Brenda, 1983). The technique is used to collect qualitative data using in-depth interviews without the use of preset questions, thus allowing the women to discuss their problems or situations.

Preliminary results of this study are presented in Tables IX and X. These results cover the first 28 removals that had taken place by 18 January 1988 and 74 controls. Table IX shows that 54% of the women seeking termination had originally accepted NORPLANT® because of dissatisfaction with another method. This compares with 36% of controls who originally accepted NORPLANT® because of dissatisfaction with another method of contraception. This suggests that women who keep on changing methods are likely to discontinue use of any method, in this case NORPLANT®. This may be due to a lack of satisfaction with contraception in general.

Marital status at time of insertion differed greatly between the removals and controls. Only 17.1% of controls were single at the time of insertion compared to 35.5% of the removals. At time of removal, the situation had changed drastically with only 9.7% of the removals being single, suggesting that with marriage there was a high demand for termination of the method in order to have a child to fulfill a requirement of marriage.

Table X shows the situations leading to termination of the method. It can be seen that only 29% of women who had NORPLANT® removed said they did so because of side effects. This suggests that side effects may not be a major reason for seeking removal,

possibly because of proper counseling regarding information on side effects offered to the clients before insertion. It may also be due to the fact that when these side effects occurred they were not serious and lasted for a short period. Table X shows that the major reason for removals is the desire to have another child (61% of all removals). This outcome may relate to the changing marital status among this group of women mentioned in the preceding paragraph.

### **XIII. CONCLUSION**

The findings presented in this one-year report on the pre-introductory clinical trial experience with NORPLANT® contraceptive subdermal implants at four clinic sites in Kenya suggest that the NORPLANT® system is a highly effective and acceptable method among Kenyan women. There were no pregnancies or serious or unanticipated adverse experiences. As demonstrated in other international trials, the method's main disadvantage is its effect on a woman's menstrual cycle; however, even though 263 (96.3%) women mentioned bleeding irregularities, only 3 women discontinued use for this reason. This would indicate that most women seemed willing to tolerate menstrual changes for the first six months of NORPLANT® use, when data show that most women return to their normal menstrual patterns and the menstrual problems were short-lived in most women.

This study has also shown for the first time, that even though the NORPLANT® system is a clinic-based method it can be delivered to rural communities that do not have all available services, provided that attention is paid to provision of sterilized materials and aseptic procedures. Of the 292 admissions reported here, there were no infections at the insertion site, demonstrating that with proper techniques, the NORPLANT® subdermal contraceptive implant method can be delivered safely in a rural environment.

#### **XIV. FUTURE PLANS**

##### Follow-up of study clients in a rural setting

To date a total of 315 women have accepted NORPLANT® and 33 have had the implants removed.

There is need to continue following these clients to learn the long-term experiences of women who continue using the method. There is also the need to follow-up those women who have the implants removed to study the return to fertility in a larger sample, and in those who become pregnant, the pregnancy outcome. It would be important also to study the infants born to women who have used NORPLANT®. Study protocols to cover these aspects are being developed.

##### Extension of the NORPLANT® study to Kenyatta National Hospital (KNH)

This study will now be initiated at an additional site, KNH. This site will provide three opportunities:

1. an urban experience with the method in terms of acceptability, and follow-up of the clients living in an urban setting;
2. opportunity to train additional doctors and nurses in provision of the NORPLANT® method. (KNH serves as both a national referral hospital and teaching hospital for the medical and nursing schools);
3. a broader experience upon which to evaluate the needs for introduction of NORPLANT® into the Kenyan Family Planning Program.

**Table I**  
**Selected Sociodemographic Characteristics**  
**NORPLANT® Pre-Introductory Clinical Trial**

	<u>Kinyui</u> (N=97)		<u>Katwanyaa</u> (N=142)		<u>Kathama</u> (N=40)		<u>Katheka</u> (N=13)		<u>Total</u> (N=292)	
<u>Age</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
<20	10	10.3	10	7.0	2	5.0	0	0.0	22	7.5
20-24	32	33.0	35	24.6	16	40.0	4	30.8	87	29.8
25-29	31	32.0	43	30.3	13	32.5	3	23.1	90	30.8
30-34	15	15.5	39	27.5	8	20.0	3	23.1	65	22.3
35-39	5	5.2	8	5.6	0	0.0	2	15.4	15	5.1
40+	3	3.1	7	4.9	1	2.5	0	0.0	11	3.8
Mean	26.9		28.3		26.2		27.8		27.5	
<u>Parity</u>										
0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
1	18	18.6	20	14.1	2	5.0	2	15.4	42	14.4
2	20	20.6	22	15.5	14	35.0	1	7.7	57	19.5
3	14	14.4	23	16.2	8	20.0	5	38.5	50	17.1
4	17	17.5	28	19.7	6	15.0	1	7.7	52	17.8
5	15	15.5	18	12.7	5	12.5	2	15.4	40	13.7
6	4	4.1	11	7.7	3	7.5	0	0.0	18	6.2
7	3	3.1	8	5.6	1	2.5	0	0.0	12	4.1
8+	5	5.2	12	8.5	1	2.5	2	15.4	20	6.8
Mean	3.4		4.0		3.4		3.8		3.7	
<u>Last Contraceptive Method Used</u>										
None	37	38.1	46	32.4	14	35.0	4	30.8	101	34.6
IUD	6	6.2	13	9.2	3	7.5	1	7.7	23	7.9
Pill	43	44.3	61	43.0	19	47.5	3	23.1	126	43.2
Injectables	7	7.2	21	14.8	4	10.0	4	30.8	36	12.3
Barriers	4	4.1	1	0.7	0	0.0	1	7.7	6	2.1
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Unspecified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

**Table II**  
**Follow-up Rates\***  
**NORPLANT® Pre-introduction Trial**

<b><u>Follow-up Interval</u></b>	<b><u>Clinic</u></b>				
	<b><u>Kinyui</u></b> (N=97)	<b><u>Katwanyaa</u></b> (N=142)	<b><u>Kathama</u></b> (N=40)	<b><u>Katheka</u></b> (N=13)	<b><u>Total</u></b> (N=292)
1 month	97.9	95.1	80.0	76.9	93.2
3 months	92.8	91.5	72.5	69.2	88.4
6 months	87.5	85.2	65.0	66.7	82.4
12 months	81.1	70.6	53.8	66.7	71.5

\* Follow-up rate is defined as the percentage of women not previously terminated who return for follow-up.

**Table III**  
**Medical Problems Reported at Follow-up Visits**  
**NORPLANT<sup>®</sup> Pre-Introductory Clinical Trial**

<u>PROBLEM</u>	<u>CLINIC</u>				<u>Total</u> (N=292)
	<u>Katheka</u> (N= 13)	<u>Kathama</u> (N= 40)	<u>Katwanyaa</u> (N=42)	<u>Kinyui</u> (N=97)	
<u>General symptoms</u>					
Abdominal pain	1	1	6	4	12
Chest pain/coughing	1	0	3	2	6
General malaise, body aches, fever (Malaria)	3	8	14	7	32
Eye/Ear/Throat	1	0	2	2	5
<u>Cardiovascular</u>					
Arrythmia	0	0	0	1	1
Hypertension	0	0	1	0	1
<u>Insertion Site</u>					
Infection	0	0	0	0	0
Pain	1	0	2	1	4
<u>Musculoskeletal System</u>					
Pain in Joints	2	0	2	1	5
Pain in Legs	0	0	0	1	1
<u>Nervous System</u>					
Headache	2	2	2	2	8
<u>Skin and Appendages</u>					
Irritation	0	1	1	1	3
Acne	0	0	0	1	1
<u>Urogenital System</u>					
UTI (clinical impression)	0	0	2	3	5
Lower abdominal pain with vaginal discharge	0	1	3	7	11
Vaginitis	0	2	1	2	5
<b>Total # of Problems</b>	<b>11</b>	<b>15</b>	<b>39</b>	<b>35</b>	<b>100</b>
<b>Total # of Women</b>	<b>3</b>	<b>9</b>	<b>32</b>	<b>23</b>	<b>67</b>

**Table IV**

**Changes in Clinical Measures at One-Year  
NORPLANT® Pre-Introductory Clinical Trial**

<b><u>Clinical Measure</u></b>	<b><u>Kinyui</u> (N=142)</b>	<b><u>Katwanyaa</u> (N=40)</b>	<b><u>Kathama</u> (N=13)</b>	<b><u>Katheka</u> (N=97)</b>	<b><u>Total</u> (N=292)</b>
Weight (kg.)	0.3 (95)*	-0.1 (134)	-1.1 (32)	-0.8 (10)	-0.1 (271)
Systolic blood(mmHg) Pressure (monthly)	-0.4 (94)	-1.7 (135)	-4.2 (32)	-3.0 (10)	-1.6 (271)
Diastolic blood(mmHg) Pressure (monthly)	-0.4 (94)	-1.1 (135)	-1.3 (32)	-3.0 (10)	-0.9 (271)

\* Number in parentheses represents the number of cases with valid data at both the last follow-up and at admission.

Table V

One Year Cumulative Lifetable Rates (per 100 women)  
 NORPLANT® Pre-Introductory Clinical Trial

	<u>Kinyui</u> (N=97)	<u>Katwanyaa</u> (N=142)	<u>Kathama</u> (N=40)	<u>Katheka</u> (N=13)	<u>Total</u> (N=292)
	<u>Rate</u>	<u>Rate</u>	<u>Rate</u>	<u>Rate</u>	<u>Rate</u>
Pregnancy	0.0	0.0	0.0	0.0	0.0
Removal for:					
Menstrual Problems	1.1 (1)*	1.8 (2)	0.0	0.0	1.3 (3)
Infection/expulsion	0.0	0.0	0.0	0.0	0.0
Desired Pregnancy	3.9 (3)	2.9 (3)	4.5 (1)	0.0	3.3 (7)
Other Personal	2.4 (2)	1.0 (1)	0.0	0.0	1.4 (3)
Medical	1.3 (1)	0.0	0.0	11.1 (1)	0.8 (2)
Continuation	91.5	94.4	95.5	88.9	93.3
Woman-Months	982.0	1380.5	307.0	102.0	2771.5

\* Number of events reported in parentheses.

**TABLE VI**  
**Prevalence of Menstrual Patterns Among NORPLANT®**  
**Users at Various Months of Use**

Menstrual Pattern	Months							
	0	1	3	6	9	12	15	18
Regular Periods	77.5%	23.3%	15.9%	18.1%	29.6%	43.3%	49.7%	51.5%
Spotting	3.7%	10.6%	6.2%	9.3%	10.6%	6.1%	3.7%	6.1%
Not Menstruating	18.9%	48.7%	49.1%	42.3%	28.6%	20.0%	17.2%	16.4%
Menstrual Irregularities	*	3.8%	9.7%	7.4%	16.4%	22.2%	23.3%	24.2%
Increased Bleeding	*	3.8%	2.7%	3.4%	2.1%	1.1%	2.5%	1.8%
Decreased Bleeding	*	9.7%	16.5%	19.5%	13.2%	7.2%	3.7%	*
Total (N)	244	236	226	215	199	180	163	165

\* Information not obtained at admission

**TABLE VII**

**Number of New Menstrual Changes Reported for the First Time by Women Using NORPLANT<sup>®</sup> at Various Months of Use (Incidence)\***

Menstrual Problems	Months					TOTAL.
	1	3	6	9	12	
Menstrual Irregularities	*	18	13	19	16	66
Increased Bleeding	*	4	7	3	1	15
Decreased Bleeding	*	33	21	13	6	73
Spotting	24	7	7	8	9	55
Not Menstruating	90	24	0	0	0	114
<b>Total</b>	<b>114</b>	<b>86</b>	<b>55</b>	<b>43</b>	<b>32</b>	<b>330</b>

\* The incidence could not be calculated as the prevalence of these changes was not recorded for all clients at the time of insertion.

**TABLE VIII**

**Duration of Menstrual Changes  
Occurring for the First Time During the Use of NORPLANT®  
From the Time They Were Reported**

<b>Menstrual Changes</b>	<b>Months</b>			<b>TOTAL</b>
	<b>1-3</b>	<b>4-6</b>	<b>&gt;6</b>	
<b>Spotting</b>	<b>46</b>	<b>1</b>	<b>0</b>	<b>47</b>
<b>Not Menstruating</b>	<b>70</b>	<b>15</b>	<b>12</b>	<b>97</b>
<b>Menstrual Irregularities</b>	<b>61</b>	<b>3</b>	<b>0</b>	<b>64</b>
<b>Increased Bleeding</b>	<b>14</b>	<b>0</b>	<b>0</b>	<b>14</b>
<b>Decreased Bleeding</b>	<b>59</b>	<b>2</b>	<b>0</b>	<b>61</b>
<b>Total Reports</b>	<b>250</b>	<b>21</b>	<b>12</b>	<b>283</b>

**Note:** This table covers only those changes that were observed from time of onset to the time they disappeared. This excludes those reports among women seen only once during the duration of the menstrual change

**Table IX**

**Original Reason for Accepting the Use of NORPLANT®**

<b>Original Reason for Accepting NORPLANT®</b>	<b>Removals</b>	<b>Control</b>
<b>Wants Change of Method</b>	<b>15 (54%)</b>	<b>27 (36%)</b>
<b>No Previous Method Wants Contraception</b>	<b>13 (46%)</b>	<b>47 (64%)</b>
<b>Total</b>	<b>28 (100%)</b>	<b>74 (100%)</b>

**Table X**

**REASON TERMINATION OF NORPLANT® USE**

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<b>SITUATION</b>	<b>REMOVALS</b>
<b>Side Effects</b>	<b>8 (29%)</b>
<b>Desired Pregnancy Wants Child</b>	<b>17 (61%)</b>
<b>Husband/Relative Object</b>	<b>3 (10%)</b>
<b>Total</b>	<b>28 (100%)</b>

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