PN-ABE-532
65078

TECHNICAL REPORT

PROJECT TITLE: NORPLANT(R) Pre-introduction Evaluation in the Dominican Republic.

AWARD No. : I84.18e. and I86.26A

PERIOD : September 1, 1984 - December 31, 1987.

The principal objective of the project was to expand the contraceptive options available to Dominican women with a focus on ensuring that medical staff develop the necessary competence in insertion and removal skills and in counseling techniques that are considered essential to successful use of this method.

Emphasis was placed on:

- Providing adequate training in insertion and removal skills as well as in the counseling techniques required to ensure that potential acceptors make an informed choice based on an understanding of the risks and benefits of this method in comparison with other available methods.

- Establishing an experience in a few initial clinics that could serve as bases for future extension of training to personnel in other clinics on a broader scale after regulatory approval.

- Disseminating information on the method to government officials, clinicians, paramedical personnel and potential acceptors.

- Developing a data base on which to evaluate acceptability, training and service delivery requirements in the Dominican Republic.

The first task of the coordinators was to select clinics able and willing to participate in the study. Once the centers were selected, at least two physicians of each were trained at the Hospital Moscoso Puello, institution that had a great experience on NORPLANT(R) use for having participated in clinical trials.

The list of the clinics participating and the principal investigators in each clinic is as follows:

1.- Hospital Moscoso Puello, Santo Domingo; Dr. Frank Alvarez.

2.- Maternidad Nuestra Señora de la Altagracia, Santo Domingo; Dr. Esther Portes.

3.- Hospital San Lorenzo de los Mina, Santo Domingo; Dr. Douglas Mendes Leger.

4.- Hospital José María Cabral y Báez, Santiago; Dr. Pedro Pichardo.

Clinical activities were initiated in December 1984, when physicians were trained at Hospital Moscoso Puello. It was decided not to include women who received the implants during that training period. Officially, insertions were initiated in January 1985.

In order to adequately monitor the data on this new contraceptive method, ensuring adherence to clinical study protocol and monitoring clinical performance when the method is used in larger populations, the Population Council provided technical assistance through Ms. Joanne Spicehandler who acted as the project monitor and Dr. Aníbal Faúndes, senior representative in Brazil.

Data from this project were incorporated to the LAC regional database in Campinas and from Campinas will be sent to the worldwide data base in FHI Computer facilities. Monitoring of the clinical activities and data collection procedures was temporarily affected by the administrative changes in CONAPOFA in 1986, but became normal after a short transition period.

Results

The number of insertions of NORPLANT(R) are sufficiently big to allow life table analysis separated by clinics.

On the contrary the number of NORPLANT(R)-2 insertions is too small, reason why we compiled all the NORPLANT(R)-2, insertions in one file and were analyzed as a single clinic.

In the tables, clinics are identified by their code number:

Clinic 3 Hospital Moscoso Puello.

Clinic 5 Hospital San Lorenzo de Los Mina

Clinic 6 Hospital Cabral y Báez

Clinic 9 Hospital de Nuestra Señora de la Altagracia.

Description of the population studied.

Table 1 shows the number of insertions by clinic of both systems of implants. As expected, clinic 3, that already had participated in clinical trials enrolled a greater number of subjects to the study. The acceptance of the method in that clinic is comparable with the acceptance of Copper IUDs.

As stated earlier, the number of insertions of NORPLANT(R)-2 is small in all clinics.

Table 2 shows the dates of first and last insertions of both methods by clinic.

Table 3 shows the distribution by age of NORPLANT(R) users in the four clinics.

In all the clinics, 90% or more of the acceptors are 29 years age or younger. This fact was a little surprising because it was though that NORPLANT(R) would have a higher acceptance in women over 30 wanting to use a long action method.

The parity distribution shows that the percentage of women of parity 4 or more is very low (Table 4). This is consistent with the age distribution. Apparently women of high family and over 30 do not attend family planning clinics because a high percentage have been already sterilized.

Age and parity distribution in NORPLANT(R)-2 users present the same pattern (Table 6).

Analysis of performance.

NORPLANT(R) performance was analyzed up to 24 months of use. Table 7 shows net cumulative discontinuation rates by reason and cumulative continuation rate in the four clinics up to 12 months.

Effectiveness was very high. No pregnancies occurred during the first year of use. Three pregnancies were detected during the first year of use, but these pregnancies occurred before the insertion of NORPLANT(R).

The infection/ expulsion rate was also very low (0,2-07%) and as observed in other studies, removals for infection/ expulsion accurred during the first months of use.

As observed in other studies, the main reasons for discontinuation are related to bleeding problems. The removal rate for these reasons ranged from 5,2 to 8,1 per 100 women. The removal rate for other medical reasons, item that includes all complaints not related to bleeding problems, related or not to NORPLANT(R) use is equivalent to the rate for menstrual problems. Only clinic 6 presented a significantly lower rate for this reason.

Continuation rates at 12 months in the four clinics, are within the ranges usually reported in previous studies. The highest continuation rate was obtained in clinic 6 that also has the lowest LFU rate. This rates, plus the 0,0 rate of infection suggest that the standard of quality of this clinic is higher than the others but, of course, other factors may be also contributing to these differences.

Cummulative pregnancy rates at 24 months were very low, ranging from 0,0 in two clinics to 0,7 in clinic 9.

Removals for bleeding problems continued to be the most frequent. Cumulative rates for this reason ranged between 13,6 and 28,0. In all but one clinic removal rate for bleeding problem was higher than removal rate for other medical.

Cummulative continuation rate at 24 months ranged between 51,0 to 64,4 per 100 women. The very high LFU rates makes the results not completely reliable. Two clinics presented LFU rates of 60% up to 24 month. (Table 8).

The performance of NORPLANT(R)-2 is shown in Tables 9 and 10.

In the first year, no pregnancies were detected and the removal rates were within the expected ranges. LFU rate was relatively low, giving reliability to the data. In the second year, LFU rate increased sharply making the results less reliable. No pregnancies were detected up to 24 months.

Comments.

The acceptability of NORPLANT(R) in the participitin clinics was very good. In general, clinics did not meet the demand for the method, due to administrative limitations and and strikes, lack of personnel, etc.

Physicians and other health workers felt comfortable working with the method and think that this method should be included as another option in regular FP programs.

Analysis of performance shows good results, mainly high effectiveness. Unfortunately, the high LFU rate makes the results less reliable. The method has been already approved by the MOH for clinical use and began to be used as a routine in the clinics that participated in the study.

The proposal is to continue the introduction the method slowly, taking care of giving very good training to all new physicians beginning to use the method.

TABLE 01 - INSERTIONS BY CLINIC

	NORPLANT (R)	NORPLANT - 2	TOTAL
CLINIC 3	580	53	633
CLINIC 5	458	40	498
CLINIC 6	189	40	229
CLINIC 9	444	40	484
TOTAL	1671	173	1844

TABLE 02 - DATES OF FIRST AND LAST INSERTION BY CLINIC AND MODEL

	NORPLANT (R)		NORPLANT - 2	
	First	Last	First	Last
CLINIC 3	07.01.85	01.04.87	03.01.86	26.05.86
CLINIC 5	17.12.84	23.01.87	29.11.85	14.04.86
CLINIC 6	15.02.85	31.03.87	02.04.86	26.09.86
CLINIC 9	30.01.85	29.04.87	28.11.85	24.04.86

NORPLANT (R)

TABLE 03 - DISTRIBUTION OF THE USERS BY AGE AND CLINIC

	CLINIC 3	CLINIC 5	CLINIC 6	CLINIC 9
UP TO 19	14.8	14.2	11.1	14.9
20 - 24	49.5	60.7	51.9	57.2
25 - 29	29.0	20.5	27.0	24.1
30 - 34	6.0	4.4	9.5	3.2
35 and more	0.7	0.2	0.5	0.7

NORPLANT (R)

TABLE 04 - DISTRIBUTION OF THE USERS BY PARITY AND CLINIC

	CLINIC 3	CLINIC 5	CLINIC 6	CLINIC 9
Nulliparous	0.0	2.4	0.0	2.0
1	34.3	41.5	34.4	33.3
2	42.6	38.4	43.4	41.4
3	18.4	12.0	15.3	17.6
4 and more	4.7	5.7	6.9	5.6

NORPLANT - 2

TABLE 05 - DISTRIBUTION OF THE USERS BY AGE

UP TO 19	12.7
20 - 24	53.8
25 - 29	24.9
30 - 34	8.7
35 and more	0.0

NORPLANT - 2

TABLE 06 - DISTRIBUTION OF THE USERS BY PARITY

Nulliparous	0.0
1	38.7
2	38.7
3	15.6
4 and more	6.9

TABLE 07 - NET CUMULATIVE DISCONTINUATION RATES BY REASON AND CUMULATIVE CONTINUATION RATE UP TO 12 MONTHS OF USE BY CLINIC

NORPLANT (R) USERS

	CLINIC 3	CLINIC 5	CLINIC 6	CLINIC 9
Pregnancy	0.0	0.0	0.0	0.0
Preg. before insertion	0.4	0.0	0.0	0.2
Expulsion/infection	0.2	0.7	0.0	0.2
Bleeding problems	6.6	5.2	5.2	8.1
Other Medical	8.0	5.1	1.1	5.7
Planning Pregnancy	1.4	2.0	1.1	0.4
Other Personal	5.0	2.8	0.6	8.4
Continuation Rate	78.5	84.1	92.0	76.9
Completed the period	311	242	145	197
First Insertions	580	458	189	444
L.F.U.	29.7	34.1	13.8	41.0

TABLE 08 - NET CUMULATIVE DISCONTINUATION RATES BY REASON AND CUMULATIVE CONTINUATION RATE UP TO 24 MONTHS OF USE BY CLINIC

NORPLANT (R) USERS

	CLINIC 3	CLINIC 5	CLINIC 6	CLINIC 9
Pregnancy	0.3	0.0	0.0	0.7
Preg. before insertion	0.4	0.0	0.0	0.2
Expulsion/infection	0.2	0.7	0.0	0.2
Bleeding problems	13.6	13.9	28.0	14.3
Other Medical	14.8	9.4	6.9	9.6
Planning Pregnancy	7.3	4.9	3.6	2.0
Other Personal	12.6	6.7	4.6	16.1
Continuation Rate	51.0	64.4	56.9	56.9
Completed the period	114	74	52	76
First Insertions	580	458	189	444
L.F.U.	45.0	60.5	36.0	60.4

TABLE 09 - NET CUMULATIVE DISCONTINUATION RATES BY REASON AND CUMULATIVE CONTINUATION RATE UP TO 12 MONTHS OF USE BY CLINIC

NORPLANT - 2 USERS

Pregnancy	0.0
Preg. before insertion	0.0
Expulsion/infection	0.0
Bleeding problems	5.1
Other Medical	6.3
Planning Pregnancy	1.3
Other Personal	1.9
Continuation Rate	85.4
Completed the period	128
First Insertions	173
L.F.U.	12.7

TABLE 10 - NET CUMULATIVE DISCONTINUATION RATES BY REASON AND CUMULATIVE CONTINUATION RATE UP TO 24 MONTHS OF USE BY CLINIC

NORPLANT - 2 USERS

Pregnancy	0.0
Preg. before insertion	0.0
Expulsion/infection	0.0
Bleeding problems	24.2
Other Medical	13.5
Planning Pregnancy	13.3
Other Personal	16.4
Continuation Rate	32.5
Completed the period	5
First Insertions	173
L.F.U.	64.2