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FINAL SUBSTANTIVE REPORT

Award № 184.21A

Project title: Pre-introduction evaluation of NORPLANT(R) contraceptive sub-dermal implants in Ecuador.

Background.

The Ecuadorian Association for Family Wellbeing (APROFE) participated in the Phase III Clinical Studies on NORPLANT(R) since 1981.

This first study, with financial and technical support from the Population Council was undertaken in two clinics, Guayaquil and Cuenca.

The protocol asked for 300 NORPLANT(R) insertions and 300 T-Cu 200B, because this study was designed as a prospective clinical comparative study.

The results of this study were encouraging. The analysis of the performance of the first year was published in studies in Family Planning in 1983.

A second cohort of NORPLANT(R) users was studied and the results were also very good. The most remarkable facts of these first studies were the very high effectiveness of the method and the high acceptability. During the enrollment period of these two studies, more than 15% of all new acceptors chose NORPLANT(R).

In 1983, NORPLANT(R) received regulatory approval in Finland, where it is manufactured. This fact triggered the initiation of pre-introduction studies, coordinated by the Population Council as part of a strategy for introducing the method in other countries. The objective of these studies was to obtain local experience in each country, that may be used for obtaining regulatory approval and to implement centers that can be used as training centers after regulatory approval is obtained.

Before initiating the pre-introduction study, Leiras Pharmaceuticals, through a local representative, with the collaboration of APROFE, began the regulatory approval process. NORPLANT(R) was approved for clinical use and commercial distribution in 1986. Ecuador was the third country in the world and the first in the developing world in giving regulatory approval to the method.

Results of the pre-introduction study.

This study was initiated in March 1985, with the participation of ten clinics and nine private physicians. Insertions were completed by May 1986. The list of insertions by clinic is presented in Annex 1. A total of 1422 insertions were performed, 1274 in the ten clinics belonging to APROFE and 148 by the nine private physicians. Five clinics inserted 100 sets or more: Guayaquil, 459; Cuenca, 209; Puerto Viejo, 100; Milagro, 100 and Chone 100.

Follow-up of all continuing users is ongoing and will continue until the last NORPLANT(R) is removed.

The clinical experience was very good, almost as good as in the Phase III studies, but the LFU rate was higher. The results, by clinic, analyzed by life table method, are presented in annex 2.

All the clinics having 100 or more insertions were analyzed individually. APROFE's clinics having less than 100 insertions were pooled and analyzed as an individual clinic.

The data from the nine private physicians are not presented because the great LFU rate, or missing information, in this group, makes the analysis not valid. One hundred and thirty women out of 148 insertions (87,8%) were LFU up to six months of use. This experience shows that, at least in Ecuador, private physicians are not adequate for collaborative clinical trials. They did not perform adequate follow-up and refused monitoring.

Conclusions.

The experience obtained through the pre-introduction study confirmed the results of the clinical studies. NORPLANT(R) presented very high effectiveness and high continuation rates. As occurred in clinical studies, menstrual disturbances are, by far, the main reason for discontinuation. Clinics having better counseling have less discontinuation rates for menstrual problems and other medical reasons.

The acceptance of the method was very good in all the participating clinics. If widely available at a reasonable price, NORPLANT(R) would have an important place among other contraceptive methods.

Adequate training of more physicians and counselors would be necessary for the correct introduction of the method into the Family Planning Programs, both in the public and private sector.

ANNEX 1

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR
INSERTIONS BY CLINIC

CLINIC	NUMBER
01 Guayaquil	459
02 Cuenca	209
03 Quito	39
04 Machala	89
05 Porto Viejo	100
06 Babahoyo	50
07 Milagro	100
08 Ambato	45
09 Loja	83
10 Chone	100
13 Dr. J. López	8
16 Dr. G. Vaca	22
17 Dr. Nalo M.	15
19 Dr. Chamba	1
21 Dr. Vásquez	5
26 Dr. Zuñiga	40
27 Dr. León	45
28 Dr. Vizqueta	3
29 Dr. Víctor	9

ANNEX 2

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinic No 1.

Net cumulative termination rates by reason and continuation rate at 36 months of use.

REASON	RATES
Pregnancy	1.1
Menstrual problems	5.0
Other medical	6.9
Planning pregnancy	13.5
Other personal	13.7
Continuation rate	59.6
Women/years	874.6
Total insertions	459

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinic No 2.

Net cumulative termination rates by reason and continuation rate at 36 months of use.

REASON	RATES
Pregnancy	0.8
Menstrual problems	20.8
Other medical	13.2
Planning pregnancy	0.6
Other personal	7.1
Continuation rate	49.5
Women/years	337.5
Total insertions	209

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinic No 5.

Net cumulative termination rates by reason and continuation rate at 36 months of use.

REASON	RATES
Pregnancy	0.0
Menstrual problems	18.5
Other medical	16.0
Planning pregnancy	9.1
Other personal	7.1
Continuation rate	49.3
Women/years	187.6
Total insertions	100

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinic No 7.

Net cumulative termination rates by reason and continuation rate at 36 months of use.

REASON	RATES
Pregnancy	0.0
Menstrual problems	16.6
Other medical	17.0
Planning pregnancy	4.0
Other personal	3.8
Continuation rate	58.6
Women/years	179.1
Total insertions	100

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NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinic No 10.

Net cumulative termination rates by reason and continuation rate at 36 months of use.

REASON	RATES
Pregnancy	0.0
Menstrual problems	33.4
Other medical	7.3
Planning pregnancy	12.7
Other personal	9.5
Continuation rate	37.1
Women/years	156.6
Total insertions	100

NORPLANT(R) PRE-INTRODUCTION STUDY IN ECUADOR.

Clinics having less than 100 insertions (pooled)
Net cumulative termination rates by reason and
continuation rate at 36 months of use.

REASON	RATES
Pregnancy	1.5
Menstrual problems	16.6
Other medical	14.3
Planning pregnancy	8.7
Other personal	5.2
Continuation rate	53.7
Women/years	538.0
Total insertions	306
