

TECHNICAL REPORT

Award No. I85.32A, I87.57A, I88.30A

Project title : Regional database for the pre-introduction evaluation of NORPLANT(R) contraceptive implants in Latin-America.

Project period: December 1, 1985 - May 31, 1989.

This project was initiated in December 1985 with the general objective of contributing to the establishment of a global database for monitoring the world wide experience of NORPLANT(R).

The specific objectives were defined as:

1. To establish at CEMICAMP a database for the LAC region
2. To provide guidance to participating clinics in good clinical research practices.
3. To provide assistance to participating clinics in establishing methods of record keeping and data management.

4. To facilitate the capture of data from pre-introduction trials in the region and its transfer to the global database in North Carolina.
5. To collaborate in data analysis with participating researchers.

CEMICAMP, with the technical assistance of the Population Council through two consultants, established the regional database, receiving all the data from the seven countries of the region participating in the pre-introduction study.

The first task was to define the mechanisms through which the data would be included in the data base.

All the studies used different clinical records, so our first task was to define a record format able to capture all the information common to all countries (This record format is included in annex 1).

After that, depending on local capacity, the countries began sending the data to the regional database.

Ecuador, the Dominican Republic and Brazil sent the forms to be completely processed by CEMICAMP. Chile, Colombia, Mexico and Peru sent their data in diskettes.

Several problems derived from the differences of the forms and data entry systems had to be solved before including the data in the regional database. Currently the system is working without problems and all data of all the countries of the region are stored and available for analysis.

- Transference of data to the world wide database:

This process also required adjustments before obtaining a good flow of data. Currently the system is working without problems and the data of all countries are being incorporated to the world wide database.

- Analysis of data and reports:

CEMICAMP has given assistance to local projects for preparing reports and papers for publication and for congresses. Several papers have been presented to several meetings and Congresses, based on analysis of data performed by CEMICAMP.

- Technical assistance to local countries.

CEMICAMP has collaborated with the local coordination of the projects in implementing data collection procedures in order to make the data compatible with the database.

- Monitoring of the studies.

The activities were not limited to a formal review of the correctness of the data.

Several monitoring visits were performed to all the participating countries to ensure not only the formal correctness of data but also ensure uniformity of procedures and high quality standards of clinical procedures.

The monitoring visits were extremely useful because they contributed to increase the quality of the studies and to ensure that the data collected are reliable and representative of the real experience with the method.

Monitoring of some studies, initiated by the end of this project will continue beyond the end of this project.

- Contribution to the preparation of the NDA.

Data collected in the LAC database were used to prepare the NDA for USFDA already presented by the Population Council.

Comments:

This project greatly contributed to the quality of the NORPLANT(R) introduction process. Besides its influence in increasing the quality through monitoring, stimulated the communication between investigators of different countries, making possible to use the experience of all the investigators in improving the studies.

This data collection system should be used as a model for future introduction programs. The experience gained through this project will make possible to improve some aspects in order to make it more efficient.

NORPLANT(R) IMPLANTS DATABASE PROJECT LAC REGION
FORMAT OF THE DATA FILES.

ADMISSION FORM

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#	VARIABLE	SIZE	FIELD POSITION	CODES
01	Identification of the region	01	01	always 3
02	Identification of the country	02	02-03	01= Brazil 02= Chile 03= Colombia 04= Dominican Republic 05= Ecuador 06= México
03	Clinic Number	04	04-07	0001 thru 0021
04	Patient number	07	08-14	0000001 thru 9999999
05	Age	02	15-16	completed years
06	Number of Births	02	17-18	00 thru 99
07	Date last pregnancy ended	06	19-24	ddmmyy 999999= Never pregnant
08	Outcome of last pregnancy	01	25	0= Never pregnant 1= Live birth 2= Stillbirth 3= Ind. Abortion 4= Spont. Abortion 5= Ectopic Pregnancy 8= Other 9= Unknown
09	Last contraceptive method used	01	26	0= None 1= IUD 2= Pill 3= Injectables 4= Barriers 8= Other 9= Unknown
10	Date of last Menses	06	27-32	ddmmyy 999999= unknown 888888= no menses in last three months
11	Date of insertion	06	33-38	ddmmyy

#	VARIABLE	SIZE	FIELD POSITION	CODES
12	Impant type	01	39	1= 6 capsules 2= 2 covered rods
13	Weight (Kg)	03	40-42	999= unknown (not done)
14	Blood pressure			
	Sistolic	03	43-45	999= unknown (not done)
	Diastolic	03	46-48	999= unknown (not done)
15	Remarks	31	49-79	always blanks
16	col 80	01	80	always 1

FOLLOW-UP FORM

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VARIABLE -----	SIZE -----	FIELD POSITION -----	CODES -----
Identification of the region	01	01	3 always
Identification of the country	02	02-03	Same codes of admission form
Clinic number	04	04-07	0001 thru 0021
Patient number	07	08-14	0000001 thru 9999999
Date of visit	06	15-20	ddmmyy
Date of last menses	06	21-26	ddmmyy 999999= unknown 888888= no menses since last contact
Weight (Kg)	03	27-29	999- unknown (not done)
Blood pressure:			
Systolic	03	30-32	999- unknown (not done)
Diastolic	03	33-35	999- unknown (not done)
Implants removed	01	36	0= No 1= Yes
Reason for removal	01	37	*1= pregnancy 2= menstraul 3= infection or expulsion 4= desired pregnancy 5= other personal 6= other medical 7= end of estudy 8= end of study 9= not removed
* Reason 1 includes 12 insertions in pregnant patients.			
Date of removal	06	38-43	ddmmyy 9999999= not removed
Complications of removal	01	44	9- unknown
Specif. of complic.	02	45-46	99- unknown
Menstrual irregularities	01	47	0= No 1= Yes 9= unknown

VARIABLE

FIELD
SIZE POSITION

CODES

4	Remarks	32	48-79	always blanks
5	Col80	01	80	always 2