NORPLANT IN BRAZIL: IMPLANTATION STRATEGY IN THE GUISE OF SCIENTIFIC RESEARCH

ANA REGINA GOMES DOS REIS
Rede em Defesa da Especie Humana, Av. Oceanica 3009/Ap 401, Ed. Solarius—Ondina 40201, Salvador BA, Brazil

Synopsis—The Brazilian Ministry of Health gave permission for the testing of the long-acting implantation contraceptive Norplant on Brazilian women in 1984, at a time when the country was living under a military dictatorship and the public had no opportunity to participate in, or even be informed of, many government decisions. The following year, political changes allowing more democratic participation enabled feminist groups to exert an influence on government actions regarding fertility control. A Committee for Studies of Human Reproductive Rights was formed in the Brazilian Ministry of Health, composed of representatives of the Ministries of Education, Foreign Affairs, and Social Welfare, and the National Council for Women's Rights, the Federal Medical Council, as well as feminists and congresswomen. Once this committee evaluated the Norplant trials, finding many irregularities, contradictions, and methodological errors, the Medicaments Division of the Brazilian Ministry of Health cancelled its authorization of the Norplant trials in January 1986.

> "Ah, se eu pudesse não cantar essa absur-da melodia."
>
> —Chico Buarque de Hollanda

In Brazil, although the government has not officially admitted the adoption of a birth control policy, between 1970 and 1985 the fertility rate fell by 25%. In 1986, according to the Brazilian Institute of Geography and Statistics, 27.5% of women who had married or common-law status were sterilized. Since the 1960s, more than 100 private birth control agencies, financed by foreign capital, have operated in the country.

The Population Council is one of the international agencies that works through universities to implement birth control policies. New contraceptives such as Norplant, developed in the United States, are tested on low-income women who attend the medical schools' health services. Teachers and students are trained and motivated to promote those birth control techniques and by this means the method is introduced in the country. A close relationship exists between universities and international population control agencies. For example, the president of the University of Campinas (UNICAMP), at the time Norplant tests began, Jose" Pinotti, was a former member of the board of trustees of the Population Council.

Norplant is a long-lasting hormonal contraceptive developed by the Population Council. It consists of six capsules 34 mm in length with a diameter of 24 mm containing levonorgestrel. The capsules are surgically inserted in the woman's arm under the skin, with local anesthesia. It is, therefore, a birth control method that depends on providers to insert and remove the capsules.

The project to test Norplant in Brazil was presented to the health authorities in the name of the Centro de Pesquisa e Controle das Doenças Materno-Infantis (Mother-Child Disease Control and Research Centre) at the University of Campinas (Cemicamp-UNICAMP), in 1984.

A "prospective clinical study" was proposed to "increase the options of fertility control methods." Another aim mentioned was the "need for Brazilian scientific testing to be able to judge whether Norplant should or should not be used in Brazil" (Faundes, 1989, p. 2).

The Medicaments Division of the Brazilian Ministry of Health gave authorization to test the implants, although the request hadnot met all the legal conditions, such as informed consent. At that

I wish to thank Regina Barbosa for her valuable discussions on research methodology and also Rita Arditti and Gena Corea for their helpful suggestions.

time (1984) the country was still under the authoritarian regime of the military government, when decisions were taken without the public being informed or able to influence the policies adopted. In this context, favourable ground was prepared in Brazil for not only experimenting with drugs, but also with techniques and surgical procedures.

The Norplant case is an example of how these practices are carried out. It is also an unprecedented example of what can be done when the public is informed, able to discuss and demand that the authorities fulfil their obligation, which is to care for the welfare of the population. Although the problem has not been fully resolved, a big step forward has been taken.

THE INTRODUCTION OF THE TEST

The Norplant study was presented to the health authorities as a prospective clinical appraisal that would involve seven clinics and a total of 2,000 women over a three-year period. In the 1984 annual report of the Population Council however, tests like this were called pre-introductory. In other words, the tests do not concern so much detailed analysis of each reaction of the woman to a new drug, but rather concern forming strategies for establishing the method, encouraging it to be accepted by women, and motivating doctors and nurses to recommend it. They are tests that use marketing techniques rather than clinical and epidemiological ones.

Although a product cannot be advertised in this country before it has been approved, the Population Council representative in Brazil, Dr. Anibal Faundes, promoted Norplant on the highest audience-rated programme on Brazilian television, "Fantastico", as well as in the magazine *Veja,* a weekly magazine of large middle-class circulation (Veja, 1985). Dr. Faundes, the technical advisor of the study, is a professor in the Tocogynecological Department, University of Campinas. Coordinator of the Norplant project with Dr. Juan Diaz, Faundes has already had prior experience with the implants in other countries, such as Chile (he and Diaz are native Chileans) and the Dominican Republic (Faundes, 1989).

In a clear allusion to the strategy for implementating the method, it was proposed that a "reference centre be established for training and information on the use of the method; develop collaborative study in several states of Brazil; offer technical assistance to the participating clinics" (Brazilian Health Ministry Working Group to Re-Evaluate Norplant Research, 1987, p. 3).

The project's clinical activities began in August 1984. Three months later, on 31 October, 313 women in nine clinics from different parts of the country were already using the method. By 31 March 1985, eight months after the start, the sample group had grown to 1,329 women; by October, 3,103 women; and finally, by January 1986, 3,589 women.

This sample group's fast growth is quite apparent. After the fourth month, in the busiest clinic, Norplant was the method chosen by 20% of the women who had begun some kind of contraception, a puzzling percentage for a method that is undergoing tests. The researchers themselves had defined the women to receive Norplant as being restricted to those with the following characteristics: "need for a prolonged action, but reversible, contraceptive; women who wish to be sterilised but are not quite sure about taking this step; during immediate postpartum; women who are not candidates for other contraceptive methods; and women for whom the use of estrogen is not recommended" (Brazilian Health Ministry Working Group, 1987, p. 2). Without discussing these criteria in too much detail, I wish to call attention to the fact that, of the 3,589 women using the implants, there were seven girls under the age of 14 and 301 between the ages of 15 and 19.

THE EVALUATION OF THE TEST

When the government officially adopted family planning in health programmes in 1983, serious debates occurred throughout the country. Women's groups were exerting pressure in an effort to ensure safe contraception and to prevent the use of risky contraceptives like the Dalkon Shield intrauter-ine devices and the injectables, such as Depo-Provera, already banned in other countries. In 1985, when there was a more democratic outlook that enabled feminist groups to participate in official debates on the policies regarding the medical, ethical, and legal aspects of fertility control methods, a Committee for Studies of Human Reproductive Rights was formed in the Ministry of Health.

The committee assembled representatives of the Ministries of Education, Foreign Affairs, Social Welfare, as well as the National Council for Women's Rights and the Federal Medical Council. Feminist group members and congresswomen also formed part of the committee. The committee requested a review of the Norplant study. In response, a work group was designated by the Health Minister to evaluate the development of the tests.

Once the Norplant project and its procedures were analyzed the Medicaments Division *cancelled* its authorization for the Norplant trials 22 January 1986.

REVIEWING THE DATA

A detailed analysis of irregularities, contradictions, and methodological errors encountered in the Norplant process would be exhausting. I shall only mention the most significant. I shall use as a reference base the reports of the work group of the Ministry of Health, the Federal Medical Council, and the interim and final reports of the researchers. Two studies will also be mentioned that were carried out by interviewing women who had received the implants: one in Rio de Janeiro, by researchers from the National School of Public Health, at the request of the Ministry of Health (Koifman report) and the other in Campinas, Fortaleza and Curitiba, by Cemi-camp researchers (Hardy report) for the Population Council.

The first irregularity that called attention during the review was the number of women and the clinics involved in the tests. The project had planned for 2,000 women over a three-year period in seven clinics. At the end of 1985, one year and a half after the first implant was made, 3,589 women had received Norplant and 21 clinics were inserting the capsules.

Questions on the conditions in which Norplant was offered were also raised in the review. Statements taken by feminists groups have revealed that several women did not know that they were taking part in research and that the method was given as an alternative form of contraception; the clinics did not fulfill the criteria for test participation and very often the method was imposed on the women (Brazilian Health Ministry Working Group, 1987).

In addition to the accusations from feminist groups, the greatest surprise in the review was the fact that, instead of signing a document legally declaring knowledge of risk, internationally known as informed consent, the women were given a *term of responsibility* in an attempt to pass to them the onus of possible harm caused by Norplant (Appendix). To show that the method was offered as an option the first paragraph of this term of responsibility reads: "I have freely decided (sic) to use Norplant (R) implants after having received detailed explanations about all contraceptive methods in the clinic." Yet, as we will see, we have testimony that in at least one clinic "all contraceptive methods available in the clinic" were Norplant and the IUD. Diaphragms, condoms, or the Billings method were not options at all.

The scarce information as to possible harm caused by Norplant is clear in paragraphs 4 and 5: "I understand that the Norplant (R) implants are in general well tolerated but it is probable that I present significant alterations in my menstrual cycle, which include irregularity, intermenstrual bleeding or even periods of no menstruation at all. It is possible that other side effects may also occur, such as headaches, weight gain, acne and other symptoms related to the use of hormones."

Paragraph 6 strongly suggests that the women were induced to commit themselves to long term use of the implants, which would increase the continuation rates of the methods: "Although I am planning to use Norplant (R) implants for *one year or more* (my underlining), I am aware that I could request that they be removed at any time."

Maria Almeida, who received Norplant in a clinic in Brasilia, illustrates the situation experienced by women. When asked about the term of responsibility, she replied: "I thought it meant that I was only signing a kind of commitment to them, a document explaining what it is, that I assume responsibility. I know that I was assuming it all, and the woman asked me to have a look at it, but when I began to read, she took it away, there was no time."

When asked about the circumstances under which she was offered Norplant she said that "friends told me about it."

> Q: So you went along and said that you wanted to implant Norplant?

A: No, you don't need to say anything, you just go there and get the card and choose: Norplant or the IUD.

Q: They don't have the pill? Nor the diaphragm?

A: No, only the IUD or Norplant.

Q: Did they give you some kind of class about it before?

A: They give you a talk.

Q: And did you understand everything about it in the first class?

A: What they mostly said was that the most important thing was not to have children. I think they chose poor people because they imagined that we are badly informed and don't try and find out more about it. What's important is not to have any more children. (Personal communication, 1985)

Maria Almeida, who was breastfeeding at the time, was advised to stop nursing.

In Hardy's study, 47.1 % of the women in Fortaleza said that they had not seen the implants before insertion. (Hardy, Coutinho, Goodson, & Rodriguez, 1986).

According to the Federal Medical Council's report, the register did not include criteria for women to take part in or leave the sample group. The tests to take part in the research (such as general physical examination, gynecological examination, weight, height, blood pressure measurements, and wherever possible (sic) recording the plas-matic haemoglobin) and for follow-up (weight and blood pressure control and an annual counting of the haemoglobin level) were regarded as being "too few when dealing with the clinical control of a drug that has multiple side effects on various organs of the human body" (Mello, 1986, p. 16).

The pathological alterations presented by women during the uninterrupted exposure to implanted levonorgestrel are not explained by the researchers. The change in body weight, for example, was a variable that showed wide fluctuations at the clinics under study. The proportions of women with body weight alterations varied from 40% to 81%. At one clinic, 32% of the women gained more than 5 kg during the first year of implant, while at another, this same figure dropped to 5%. The reason for these fluctuations is not known, and lack of a control group is a hindrance to understanding the real meaning of these data (Faundes, 1989).

According to the study done by Koifman and colleagues, the women in Rio de Janeiro showed "dramatic" changes in weight. One woman gained 38 kg in 9 months and then started to drink too much, the study noted. Another had an immediate weight gain of 2 kg in the first week, 3 kg in the second, and also developed depression and respiratory problems. A third woman gained 26 kg after Norplant was removed. In a fourth, the extra 27 kg was gained over a four-month period (Brazilian Health Ministry Working Group, 1987).

These dramatic alterations in women's bodies are minimized by the way they are shown in the researchers final report, where the following categories are used: Alterations in weight:

Drop 5 kg or more
from 3 to 5 kg
no change
Gain 3 to 5 kg
more than 5 kg (Faundes, 1989)

Thus, the wide variations do not appear.

"Menstrual irregularities" are treated in the same way. Behind the term *increased bleeding* are hidden blood losses that would be considered pathological if the classic gynecological terms and concepts, such as menorrhea and hypermenorrhea were used.

Interviews with Norplant users taped by feminist groups reveal that many women had continuous bleeding lasting for 20 or even 30 days. The impact of these "irregularities" on these women's day-to-day life and health was ignored. When the women complained about this, they were informed that this was "normal" and if they waited, the symptoms would eventually disappear. The change in menstruation is, however, the main cause for removal of the implants, which demonstrates that this is not a "normal" biological behavioural pattern for women.

According to the final report, "it is important to stress that all removals for this reason were made at the woman's request and not because of a clinical situation that would make removal necessary" (Faundes, 1989, p. 15).

Many other serious reasons were causes for removal. Among them were severe alterations

regarding the central nervous system. Those symptoms called the attention of Koifman and his colleagues in Rio, who stated that

> "it would be worth discussing the role played by irritability in this group of women. Besides being a highly prevailing feature, characterized by intolerance in the different social spheres (family, work, emotional, etc.), this was frequently accompanied with behavioural changes referred to not only by the interviewees, but also by relatives and neighbours, which can be confirmed throughout the research."

They continue their analysis

> "This condition, not yet described in Norplant's literature, surprised the authors both by its frequent occurrence and effects: absentmindedness, loss of memory, inability to adapt to her group of origin—neighbourhood children began to throw stones at one woman, another lost her way, a third began to beat her children for no reason whatsoever—besides frequent comments by the interviewees of their feeling different, almost mad, and when Norplant was removed these effects ceased." (Brazilian Health Ministry Working Group, 1987, p. 12-13).

These researchers found 17% of the Norplant users experienced reduced libido, which they considered an underestimation due to the difficulties in approaching the subject.

Symptoms like those cannot be considered as occasional and of little importance. They are serious enough to demand careful investigation. For the Population Council researchers, however, those symptoms are only "causes for removal," factors reducing the method's continuation rates.

In their final report, a long list of local and general symptoms is reduced to medical reasons, personal reasons, and irrelevant reasons. The medical reasons are listed as follows:

- Pregnancy
- Increased bleeding
- Hypomenorrhea/amenorrhea
- Infection/expulsion
- Weight gain
- Alteration of the skin
- Another medical cause (Faundes, 1989)

It would be difficult, if not impossible to know what those other medical reasons are, if we didn't read an interim report, where they were quoted as foot note to a table:

Table 1. Removal of Norplant, by Cause—July 1984 to February 1986

Causes for Removal	No.	%	Accumulated
Increased bleeding	155	26.3	26.3
Headaches	73	12.4	38.7
"Personal reasons"	67	11.4	50.1
Desire for child	52	8.8	58.9
Influence of television	35	5.9	64.8
Amenorrhea	35	5.9	70.7
Dizziness	17	2.9	73.6
Weight gain	15	2.5	76.1
"Other complaints"	14	2.4	78.5
Insertion in pregnancy	13	2.2	80.7
"Doesn't need contraceptives"	10	1.7	82.4
Irritability	07	1.2	83.6
Menstrual irregularity	05	0.8	84.4
Husband's request	05	0.8	85.2
Moved towns	05	0.8	86.0
Nauseas	04	0.7	86.7
Localised infection	04	0.7	87.4
Other reasons*	74	12.6	12.6
Total	589	100	100

Source for basic data: CEMICAMP/UNICAMP, February 1986.

* drop in libido (3); breathlessness (3); partner's vasecto-my (3); cardiologist recommendation (2); religious reasons (2); allergy (2); high blood pressure (2); abdomen cramps (2); ovarian cyst (2); intermenstrual staining (2); insomnia (2); weight loss (2); brain disturbance (2); one time occurrences: labyrinthitis, vomiting and dizziness; dizzy turns; prediabetes; weight loss; mastalgia and cramps; "medical reasons"; sebaceous cyst; hair loss; heavy sweating; cardiomegalia; epilepsy; numbness of hands and foot; increase in varicose veins; cramps and menstrual irregularity; pain in the right illiac region and influence of television[1]; body pains; salpingectomy; headaches and amenorrhea: husband's decease; woman murdered.

When pathologies such as ovarian cyst or epilepsy or enlargement of the heart (cardiomegalia) are present, one should ask what kind of attention is planned during the long term follow-up, and what kind of health care will be offered to women when Norplant will be used in large-scale population control programmes?

The problem of follow-up in so-called controlled researches is indicative of how difficult it is to assure that women will receive appropriate medical assistance. The fight for survival obliges people from poor classes to be constantly on the move, migrating several times during their lives over long distances, which makes any kind of long term follow-up unfeasible. They should never be included in tests of this type precisely for this reason.

Hardy and colleagues, in their Population Council study about women's experiences with Norplant found it difficult to interview women in the Campinas, Fortaleza, and Curitiba clinics, *less than one year after the start of the pre-introductory test.* Chosen from the register cards from a total of 584 files studied, 71 women had to be substituted "basically because their whereabouts was unknown" (Hardy et al., 1986, p. 4).

It is not known whether these women have already removed the implants or not. If they continue as carriers, who is going to remove Norplant? Only the clinics involved in the research are trained to handle the implants. One of those clinics presented 21.07% follow-up loss in the third year (Hardy, 1986).

Hardy's study intended "to learn from women who were using or had used Norplant what their experience had been, what side effects they had had, what were the method's features that they liked and did not like, how their husbands react to the change in menstrual flow, etc." (Hardy, 1986, p. 1).

When discussing the results, the paragraph referring to experience using the implant, reads: "The women were asked if there had been any problem while using the implant. The interviewer was given specific instructions not to go too deeply into this question" (Hardy, 1986, p. 9).

The pre-introductory test, the purpose of which is to study the acceptability of the method, provides little information regarding the social-economic characteristics of the women's sample group. Such data as education, marital status, and income level that would enable an assessment of possible internal motives or outside pressures interfering in the choice of contraceptive methods, were not considered significant variables when evaluating Norplant's performance. The choice of variables to be analyzed in clinical studies when introducing any new method is fundamental in the design of the project and replies obtained, and is a direct portrayal of the political and ideological interests of the researchers and institutions involved.

Thus the study and its results, as a whole, suffered from the lack of variables studied. Norplant's performance in general is simply reviewed in terms of the number of removals, reasons for removal, and rate of continued usage and pregnancies. Acceptability is simply defined in terms of the number of implants. Both women and services are ignored as the subjects under study and analysis, while the method and its performance are considered above everything else.

The probability of a woman continuing to use the method after the first year varied from 40% to 82.3%. After the second year, it varied from 24.4% to 67.7% and, lastly, after the third year of use, this probability oscillated between 18% and 54%, depending on the clinic studied. These fluctuations vary considerably and the questionable performance of the method with regard to its rates of use continuity do not justify the risk of side effects and harm to the menstrual cycle inherent to the method (Faundes, 1989).

The need for contraception methods over long periods (for example, to space children or to prevent more births) does not mean that the method must be of long duration.

Norplant requires surgical intervention, which involves the problems of asepsis that are serious in underdeveloped countries. But additionally, Norplant hands over to doctors fertility control power, an inalienable prerogative of women throughout the world, no matter the rates of population growth.

According to the researcher's final report "when the enthusiasm (sic) of some investigators, or failure of the clinics to undertake implants removals, led to problems in removing the implants from some women, these problems were quickly identified and corrected" (Faundes, 1989, p. 31).

A mountain of women's experiences lies buried beneath this simple sentence. What are the stories of women who suffered from the implant, tried to have it removed, and were sent away from clinics with the hormone cylinder still buried in their arms, still pumping into their bloodstreams? What were the women's actual experiences with "enthusiastic investigators" and were all the

problems really quickly "corrected"? And if enthusiastic investigators and clinics succeeded in establishing the use of Norplant on a wide scale throughout the Third World, who will control women's fertility—the women or enthusiastic physicians?

When some women in Rio de Janeiro asked how safe Norplant was, the reply given at the clinic was: "That is your problem, the method is still being tested." To another woman the reply was—"It's such an expensive investment better you try and get used to it." To a third woman, worried about the safety of an implant in her arm, the following reply was given: "It's better you lose an arm than your uterus" (Brazilian Health Ministry Working Group, 1987, p. 14).

Koifman and colleagues's conclusions, after interviewing 175 Norplant users, are summarised as follows:

> "The issues mentioned from the experience of the Rio de Janeiro group of women bring together a solid set of evidence on the risks in using Norplant and even when not statistically significant, they do mention that it is not harmless, bearing in mind the above mentioned repercussions. Thus, it seems to us prudent and advisable to contact all women at present using Norplant to have it removed." (Brazilian Health Ministry Working Group, 1987, p. 13–14)

Another opinion on Norplant, given in the name of the Regional Medical Council of Rio de Janeiro, concluded that:

> "I can guarantee that Norplant is harmful to the physiology of the woman's menstrual cycle and I am absolutely sure that this kind of research should be completely abandoned as soon as possible, and steps be taken to remove the ill-fated Norplant from all Brazilian women who are using it, who should be followed-up with a certain frequency, since the interference caused to the menstrual cycle normally remains for some time as a result of the endocrine imbalance produced by Norplant." (Lago, 1987, p. 7)

The final conclusion of the work group designed by the Health Minister to analyze the Norplant project endorsed Koifman's report and recommended that public health services should follow-up the women using Norplant and ensure the removal of the implants.

The political situation within the Ministry of Health, however, changed and a new Minister took over. The case was suspended. It remains for the women's movement here in Brazil and abroad to continue providing information on the danger to which women are exposed and to continue demanding reliable research to clarify innumerable obscure points about Norplant's side effects.

It will not be necessary to further expose women's health to unnecessary risks in continued clinical trials. An honest evaluation of the experience of those women who had already had Norplant implanted is enough. When clinical and not political criteria are taken seriously, then it will be seen that Norplant is a method for population control and not a method that women can use for fertility control.

ENDNOTE

1. "TV influence" given as a reason refers to the impact of statements by women who talked about their negative experiences with the implants on the programme "Fantastico." Since "Fantastico" had announced the method's advantages at the start of the research, it was committed, according to the values of good journalism, to also announce its negative side. In the first programme, we remember that it was only Dr. Faundes who spoke, but in the second, women told of their actual experience with the implants.

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APPENDIX TERM OF RESPONSIBILITY

I _____, the undersigned will use the subdermic implants, a reversible hormonal contraceptive method, that is being tested in this clinic.

1) I have freely decided to use the subdermic implants, after having received detailed explanations about all contraceptive method available in the clinic.
2) I was informed that there two subdermic implant systems: NORPLANT(R) which consists of inserting 6 3cm long capsules, and N0RPLANT(R)-2 which consists of inserting 2 4cm long cylinders. The capsule and cylinder diameters are the same (2.4 mm).
   I accept the use of either one of the systems, according to the aleatory choice made by the clinic.
3) I am aware that, although there is a very low possibility of pregnancy while using NORPLANT(R) or N0RPLANT(R)-2, (less than 1 % as observed in other countries), I could become pregnant while using it. If this occurs, the implants will be removed.
4) I understand that the NORPLANT(R) and NORPLANT(R)-2 implants are, in general, tolerated well. It is, however, probable that I present significant alterations in my menstrual cycle, which include irregularity, intermenstrual bleeding, or even periods of no menstruation at all.
5) It is possible that other side effects may also occur, such as headaches, weight gain, acne and other symptoms related to the use of hormones.
6) Although I am planning to use the NORPLANT(R) or NORPLANT(R)-2 implants for one year or more, I am aware that I could request that they be removed at any time. On the other hand, I also know that the doctor may decide to remove the implants at any moment, for reasons that he considers necessary.
7) After the implant removal, I may choose any other contraceptive methods available at the clinic.
8) I promise to return to the clinic for check-ups and I understand that I have the right to be attended whenever I need assistance, in addition to specific appointments.
9) I will receive no compensation whatsoever for my participation in this study, except for the use of a highly efficient contraceptive method and the satisfaction of collaborating in the progress of science.

Patient's signature_____
Name of Patient

Doctor's signature_____
Doctor's name ,

Date:_____