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NEW CONTRACEPTIVES

NORPLANT AND POOR WOMEN

EDITED BY
Sarah E. Samuels, Dr. P. H.
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The Henry J. Kaiser Family Foundation, based in Menlo Park, California is one of the nation's largest private foundations devoted exclusively to health. Established in 1948 by industrialist Henry J. Kaiser and his wife Bess, the Foundation now has assets of approximately $400 million. It is not associated with Kaiser hospitals or Kaiser Permanente.

The Foundation makes more than $23 million in philanthropic expenditures each year, focusing its grantmaking on government's role in health, on the health of low-income and minority groups, and on developing a more equitable and effective health care system in South Africa. The Foundation also has an interest in promoting innovation and policy change in its home state of California.

Norplant® is a registered trademark of The Population Council for levonorgestrel-releasing subdermal implants.

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INTRODUCTION

Long-acting contraceptives pose an unusual challenge for the health field. These contraceptives, of which Norplant® is the first, promise women ease in effectively protecting themselves against unintended pregnancies over a span of years. But they also raise concerns: How will public programs pay for this costly contraceptive? Will women using these contraceptives forego condoms, and thus increase their risk of sexually transmitted diseases? Will society attempt to coerce poor women into using these contraceptives as a way of limiting welfare roles?

To explore these issues, the Foundation brought together researchers, contraceptive experts and policymakers in a two-day forum on Norplant and low-income women. The forum was one of an on-going series the foundation is sponsoring to bring together the leading minds in health care to tackle some of the field's most difficult problems.

The six papers collected in this book address what forum participants considered the most critical issues surrounding long-acting contraceptives: the impact of this form of birth control on the health of poor women, the threat of coercion, the great need to evaluate societal and medical effects of long-term contraceptives, and the ways in which this new contraceptive fits into the development of other new devices.

We hope this publication will help others address the complex issues inherent in long-acting contraceptives. And we intend, as a foundation concerned about both reproductive rights and the general health of poor women, to continue examining the benefits and drawbacks of such birth control.

Based, in part, on this forum, the Foundation has, so far, funded three grants focusing on long-term contraceptives: The Alan Guttmacher Institute will set up a national system to monitor and analyze legislative, judicial and administrative decisions affecting Norplant availability, including watching for coercive policies pressuring low-income women to use Norplant.

The University of California at San Francisco will track teenagers who choose or who reject Norplant, to measure whether this contraceptive is acceptable to young women and whether it's use encourages or discourages condom use to protect against STDs.

The Association of Maternal and Child Health Program Directors will study how to integrate family planning into existing health services for women, through a survey of state maternal, child health and family planning directors.

It is our hope that this forum, and the studies that resulted from it, will inform others concerned with long-acting contraceptives, and encourage effective, equitable, policies.

Drew E. Altman
President

EXECUTIVE SUMMARY

Norplant,®* approved in 1990 by the FDA for use in the U.S., has been hailed as the most significant new contraceptive device since the introduction of oral contraceptives in the 1960s. Levonorgestrel releasing subdermal implants, whose trade name is Norplant, is the first of several new long-acting implantable contraceptives expected to be available in the next decade. Extensively tested, primarily in the developing world, it has been very well received. In Indonesia more than 1 million women have used the device since the early 1980s. While nearly all women using Norplant there have kept the implant for the full five years, early studies in the U.S. have shown that almost one-quarter have requested early removal. Side effects that frequently occur during the first year, such as irregular bleeding, headaches, acne, and weight gain are a major reason to discontinue use of Norplant. The introduction of Norplant into the U.S. market has also been hampered by its high price and concerns of some groups about potential coercive uses of the product.

It was in this climate that the Kaiser Family Foundation hosted a Forum on the Dimensions of New Contraceptive Technologies: Norplant and Low Income Women, in November 1991. The introduction of Norplant into the U.S. market served as the catalyst for this meeting. At the time of the Forum, states were deliberating reimbursement rates, judges were considering punitive uses for Norplant, and state elected officials were considering incentives for Norplant use as a way to reduce births to women on

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[Norplant's] ... current costs, $350.00 for the product and a minimum provider's fee of $150.00 each for insertion and removal, is much more expensive than any other method.

welfare. Independently, women, particularly low-income women, were eager to try Norplant and the waiting lists at family planning clinics were growing. Yet providers were unprepared for the demand. Few were trained for insertions and even fewer for removals. And at a time of limited public funds, states have been forced to limit eligibility for Norplant. The introduction of Norplant serves as a good example to learn from, since it is the first of several long-acting contraceptives planned for the U.S. market.

The Foundation convened this Forum to initiate a dialogue on the policy and ethical issues that surround Norplant. Experts in contraceptive technology, family planning providers, administrators, researchers, consumer advocates and policymakers focused their attention over two days on the acceptability, the delivery, and the uses and abuses of this new contraceptive, particularly for low-income women.

The background papers published in this volume were commissioned in advance of the meeting. The presentation of the papers was supplemented by reactions from providers, state health officials, and consumer activists. At the heart of the discussion were controversies surrounding the appropriate uses and abuses of this new product, sensitivities to the needs of consumers and special population groups, and policies that promote access, quality of care, and minimize cost. The following is a summary of several important topics that emerged from the discussion.

High cost Norplant, manufactured and sold in the U.S. by Wyeth-Ayerst Laboratories, is expensive. Current costs, $350.00 for the product and a minimum provider's fee of $150.00 each for insertion and removal, are much more expensive than any other method. The manufacturer has not agreed to a discount price for

public health programs, which exists for all other contraceptive methods. However, they have established a foundation that distributes Norplant to poor women, uninsured or ineligible for publicly subsidized programs. A representative from the U.S. manufacturer said that the company feels justified in their pricing policy because of the risk they have incurred in bringing Norplant to market. The same product, manufactured in Europe, is marketed elsewhere in the world for under $100.00. This high "up-front cost" has significant implications for consumers, insurers, and public providers and may make it difficult to justify early removal. A woman who changes her mind because of unpleasant side effects, a change in marital status or in birth-spacing plans may be discouraged from having Norplant removed. Limited state funds for family planning services have forced states to establish strict eligibility requirements and set priorities for who receives Norplant through publicly sponsored programs.

Technical expertise Norplant insertion and removal requires access to trained medical providers able to perform the procedures. Once Norplant is inserted, a woman is then dependent on the medical system for removal. At the time of this meeting, 26,000 physicians had been trained for insertion, but few of those had experience with removal. An absence of trained providers that serve low-income women in rural and urban areas ultimately restricts access.

Removal upon request Removal upon request may present additional problems. Like any drug, there are risks and benefits. The side effects associated with the use of Norplant, such as bleeding and spotting, headaches, acne, and others may be outweighed by its reversibility, when compared to sterilization. Yet these same side effects may seem more severe to a woman familiar with other forms of contraception and she may choose to have Norplant removed prematurely. Insurers or third-party payers may question the cost-effectiveness of the product if it is not used for the full 3–5 year time period. The inability to pay for removal

Some have concerns that coercive policies could be instituted that may require poor women to keep Norplant in for a minimum period of time as a method of population control.

may also stand in the way. One conference participant reported that one physician charged his patients $75.00 per tube for removal. If the patient only had $75.00 then only one tube would be removed at a time. Consumer groups have expressed concern that poor and geographically isolated women may not have easy access to trained providers able to remove Norplant. A Native American woman activist reported that many reservations were as far as 200 miles from a trained provider. Some have concerns that coercive policies could be instituted that may require poor women to keep Norplant in for a minimum period of time as a method of population control. There is only one known case of a judge sentencing a woman to mandatory use of Norplant. But several state legislatures have considered paying women on welfare to use Norplant to prevent future pregnancies. Some state government policies have set priorities for who should receive Norplant and who should not. The use of Norplant and other long-acting contraceptives as a tool of social policy is one that needs to be closely monitored. Women need comprehensive pre-insertion counseling on the potential side effects, the costs, and removal process. New policies need to be explored that will insure that women unable to pay will be able to have Norplant removed upon request.

STDs and HIV Norplant is not protective against the transmission of human immunodeficiency virus (HIV) or other sexually transmitted diseases. Condoms need to be used to offer protection. The features that make Norplant attractive, in contrast to condoms, are—it is not a coitus-dependent method, it does

not require daily compliance, and it does not require partner cooperation. Yet, women who use Norplant, and are sexually active, need also to consider using condoms to protect themselves and their partners against STDs. Little research data is available on how Norplant use effects sexual behavior, condom use, and exposure to STDs. More research is particularly needed on teens, substance abusing women, and incarcerated women.

As a result of the Forum, the Foundation has made several grants. A grant to the Alan Guttmacher Institute will monitor legislative, judicial, and administrative policies affecting Norplant distribution, pricing, and availability, including any decisions that may be perceived as coercing the behavior of low-income women. A grant to the University of California, San Francisco Department of OB/GYN will study the acceptability and use of Norplant among teens.

Upon reflection on what went on in the two-day forum, we felt that there was a need for some guiding principles for everyone to adhere to in the development of policies and programs that will make Norplant widely available to women. We think most of the discussion reflected general agreement on the following seven points.

Principles on Norplant Availability

1. Norplant, as with all other contraceptives, should be made widely available to all women seeking contraception. Marketing practices to any population should abide by a woman's right to fully informed choice. Norplant should be offered along with all other available contraceptives.
2. All women seeking contraception must freely consent to its use, be fully informed of their contraceptive options, and receive complete information on Norplant and contraceptive alternatives. This should be applied to all women, including teens and incarcerated women seeking family planning.

3. No harm should be done to any woman seeking Norplant. Risks and benefits of Norplant should be weighed carefully for each individual woman. Medical contraindications should be considered when Norplant is prescribed.
4. Norplant should be prescribed only when there are clear benefits to the individual. The needs of the society can be considered but should not outweigh the needs or the rights of the individual. Perceived social benefit is not a sufficient condition for prescribing Norplant.
5. All women receiving Norplant should have access to medically indicated health care required for the safe usage of the product.
6. All women should have the right to the removal of Norplant upon request, regardless of reason. Publicly funded programs should establish a reserve of funds or alternative mechanisms to guarantee access to removal. Payers have no obligation to reinsert Norplant after it has been prematurely removed.
7. Economic incentives should not be so great as to be coercive. While incentives are not in themselves unethical or inappropriate, they should not violate a woman's right to autonomy.

The conclusions drawn from this Forum are far-reaching. The needs of consumers—especially low-income and minority women—require special attention and sensitivity. For example, the culturally sensitive needs of minority populations must be addressed to overcome fears of genocide, exploitation and victimization that have been associated with the introduction of sterilization and earlier forms of contraception. Efforts to use Norplant to prevent teenage pregnancy must be considered in the context of the unique interests of teens seeking to prevent unwanted pregnancies, maintaining confidentiality, and protecting themselves emotionally and physically from harm. The needs of substance abusing women, incarcerated women, mentally ill and dependent women also need to be considered. For

all of these populations, Norplant use does not reduce the risk of HIV and STDs. Alternative protection must be encouraged.

Additional resources need to be allocated to train providers how to inset and remove Norplant, particularly those providers serving poor women in rural areas, on Indian reservations, and in medically underserved communities. These providers need to be trained in the unique needs of the populations they serve.

Policies need to be considered that will lead to universal access to Norplant, access to removal on demand, a public sector pricing structure, and state policies that will adhere to a woman's right to fully informed choice.

Policies need to be considered that will lead to universal access to Norplant, access to removal upon request, a public sector pricing structure, and state policies that will adhere to a woman's right to fully informed choice.

Finally, more research is needed on the acceptability of Norplant among low-income, minority, and teenage women. Research should look for factors that influence women to choose or to remove Norplant. Also needed is information on changes in sexual behavior and condom use among women using Norplant.

The introduction of Norplant into the U.S. market provides an opportunity that has not been seen for the last 25 years. We are likely to see in the future a variety of long-acting contraceptives, "morning after" pills and other new approaches added to the current mix of available contraceptives. Therefore the experience with Norplant and its impact on fertility patterns, reproductive choices, and social policies will provide us with many lessons for the future.

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NORPLANT CLINICAL TRIALS

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Continuous release of levonorgestrel into the bloodstream from the six-capsule implant system Norplant® prevents pregnancy for five years. By providing an effective dose systemically for so long a period, Norplant capsules represent the first major innovation in contraception in 20 years. Implant contraception is convenient as well as effective. From a day after placement until removal, a woman need take no further measure yet will be protected against unwanted pregnancy. Annual pregnancy rates average below 1 per 100. By providing the lowest dose compatible with contraceptive effect, Norplant capsules minimize side effects and may confer minor health benefits, such as modest increases in hemoglobin.

Effectiveness

The effectiveness and safety of Norplant capsules have been established in several well-monitored prospective clinical trials.[1,2,2-4] Effectiveness and health effects are currently being more minutely analyzed in an international collaborative postmarketing

Table 1. Annual Pregnancy Rates Per 100 Users of NORPLANT

Country or Study	1[A]	1[B]	2	3	4	5	N
Population Council	0.2	0.1	0.5	1.2	1.5	0.8	2,470
China	0.1	<0.1	0.1	0.3	0.5	0.5	10,718
Indonesia	0.4	0.0	0.2	0.3	0.0	1.8	813
Egypt	1.3	0.0	0.0	0.0	0.0	0.9	250

A. Includes women pregnant at time of placement.

B. Excludes women pregnant at time of placement.

surveillance study conducted jointly by the Population Council, the World Health Organization, and Family Health International. In the first year of Norplant use the accidental pregnancy rate has been on the order of 2 per 1,000 (Table 1). This rate includes women whose preexisting pregnancies were missed at the time of the physical examination preceding placement. Indeed, preliminary data from the Norplant postmarketing surveillance study suggest that Norplant implants may have a lower first-year pregnancy rate than that associated with sterilization. Sterilization serves as a concurrent control in the postmarketing surveillance study.

A comparison of pregnancy rates during the first year of use of Norplant with those of other methods show it to be the most effective reversible method, and not less effective than sterilization[1, 5, 6] (Table 2). With the passage of time, pregnancy rates

Table 2. Pregnancy Rates Per 100 During First Year of Contraception

Method	15 Developing Countries[A]	United States[B]
Sterilization	0.1[C]	<0.1
NORPLANT	0.2[D]	<0.1
Pill	5.9	3
IUD	3.4	3
Rhythm	19.9	20
Withdrawal	12.5	18
Condom	NA	12
No Method	NA	85

A. L. Moreno and N. Goldman, *Fam. Plan. Persp.* 1991; 17:44–49.

B. J. T. Trussell et al. *Stud. Fam. Plan.* 1990; 21:41–54.

C. Preliminary 1-Year Data from the Norplant® Postmarketing Surveillance, 1991.

D. I. Sivin, *Stud. Fam. Plan.* 1988; 19:81–94.

increase during Norplant use to about 5 per 1,000 users in the second year, and to an average of about 10 per 1,000 per year in the third through fifth year of use. These pregnancy rates remain, on average, below those of the pill, because the pill requires strict adherence to the prescribed regimen of daily ingestion of tablets. The penalty for omission of two to three tablets in the first week of each cycle often is unintended pregnancy.

Table 3. Estimated Average Annual Failure Rates of Contraceptives (U.S.) By Age

	All	<25	25–34	35–44
Sterilization[A]	0.2	NA	0.3	<0.1
IUD (Copper T 380)[B]	0.5	0.8	0.4	<0.1
Norplant®[C]	0.8	1.1	0.8	<0.1
Pill[A]	1.9	3.4	1.2	0.3
Condom[A]	2.9	8.0	1.6	1.4
Rhythm[A]	7.3	20.0	5.6	4.6
Vaginal Methods[A]	10.0	22.7	9.4	2.7
No Method[A]	32.0	53.5	31.0	7.1

A. C. Westoff, *Fam. Plan. Persp.* 1988.

B. I. Sivin andJ. Stern, *Stud. Fam. Plan.* 1979.

C. This paper.

On the other hand, when long-term use is considered, the effectiveness of Norplant has been less than that of sterilization and, by current estimates, less than that of medicated IUDs with copper surface areas of 380 mm^2 (Table 3). In Population Council studies, the five-year cumulative pregnancy rate of Norplant has been about 4 per 100, while that of the copper T 380 has been 2 per 100.[2, 7, 8] A report from China, however, indicates that in a very

large, well-monitored study, the five-year pregnancy rate among Norplant users was about 2 per 100 (Gu, personal communication, 1991).

The Chinese noted that pregnancies among women under the age of 25 were at twice the rate of other women. Despite the massive size of the Chinese study, 10,718 women, only 300 of them were under the age of 25 at admission, and the five-year rate for the young women does not differ from the rate for the entire group. Similar observations of higher rates of pregnancy for women under the age of 25 in Population Council studies have been made, but these, too, were not statistically significant. Nevertheless the Chinese and the Population Council experiences parallel that observed with most forms of contraception. Regardless of method, younger women experience higher contraceptive failure rates than do others, in large part because coital frequency is higher. When age is taken into consideration implants have been more effective than pills for women under the age of 35. At 35 to 44 years, the average annual pregnancy rates of implants and pills[9] are about the same (Table 3) but may be somewhat above the rate associated with IUD use in that age group.

Increased pregnancy rates observed among Norplant users in the third through fifth years correspond to a decreased rate of levonorgestrel release from the capsules. Further decreases in release rates have been noted in six-year trials. In these, the annual pregnancy rate rose above 2 per 100, a value comparable to that associated with combined oral contraceptives (Table 2).

Increased pregnancy rates with greater duration of use have been more marked in heavier women than in lighter women. In Population Council studies, women weighing 70 kg or more first experienced an annual pregnancy rate above 1 per 100 in the second year of use; women weighing 60–69 kg first recorded a 1 per 100 pregnancy rate in the third year; those weighing 50–59 kg reached this level in the fourth year. Women who weighed less than 50 kg at admission did not quite reach a 1 per 100 pregnancy rate even in the fifth year, the rate being 8 per 1,000.

Increased pregnancy rates with time and weight have been confirmed in the large-scale Chinese studies carried through five years, according to Gu Sujuan, coordinator of the Chinese studies. The five-year cumulative pregnancy rate for women weighing less than 50 kg was less than 1 per 100, rising in direct correlation with weight to about 4 per 100 at five years for women weighing 70 kg or more. The difference in overall pregnancy rates between the Chinese and the Population Council studies reflects a marked difference in the proportions of women in each weight group in the two studies. It is likely that women who weigh more than 80 kg have higher pregnancy rates than have been observed in other groups. We believe the phenomenon represents a dose decreased by dilution. Blood concentrations of levonorgestrel measured by radioimmunoassay significantly differ by weight and by ponderal index as early as one month after placement of implants.

Menstrual Pattern Effects

Because drug release and levonorgestrel blood levels are highest in the initial year of use, both contraceptive effects and side effects are strongest then. The effect of progestin-only medication is most notable in menstrual cycle alterations, which are experienced by the majority of women. Some of these alterations, such as reduced bleeding, have proved attractive to users and have been associated with high continuation rates. Other alterations such as prolonged spotting or prolonged bleeding, are principal reasons for terminating use of the method.

In the initial months of use, the number of onsets of bleeding exceeds the norm, but after four quarter-years of a gradually diminishing number of events, the average number of onsets of menses throughout the second and third years of use are normal, about 13 per year.

Days of bleeding and spotting tend to be more numerous than average during the first four quarter-years of implant use, but they diminish in the second and third years. After the first year, bleeding has averaged between 17 and 19 days per quarter-year, near or slightly above normal limits.

Excess bleeding can be manifested in a number of ways. One manifestation is the occurrence of more than eight consecutive days of bleeding or spotting. In the first quarter-year after placement, fully 57 percent of Norplant users had such lengthy bleeding episodes. The proportion steadily decreased during use, so that by the last quarter of the third year only 19 percent experienced so prolonged an episode.

Another manifestation of excess bleeding is frequent onset of bleeding. Forty-eight percent of Norplant users experienced five or more onsets of bleeding or spotting in the first quarter-year after placement. By the middle of the second year, the percentage had dropped to 14, and in the third year, there was a further diminution to 9 or 10 percent.

I have elsewhere[1] demonstrated that these changes result principally from alterations in the menstrual patterns of continuing users. Some changes in means and percentages do derive from discontinuation by women with the most profoundly disturbed menstrual patterns. In most studies, however, substantially less than 10 percent of women discontinue use in the first year because of bleeding patterns. Indeed, in some countries, less than 10 percent discontinue the method in the first year.

About 20 percent of women experienced markedly reduced bleeding during Norplant use. This percentage tends to stay relatively constant after the first 90 days in Population Council Norplant studies, where the definition of reduced bleeding was 60 or more consecutive days without bleeding or spotting in each quarter-year. These women tended to be amenorrheic. Similar or slightly higher proportions had two or fewer onsets of bleeding or spotting each quarter.

Side Effects Other Than Menstrual Pattern Changes

The Population Council's submission for regulatory approval of Norplant in the United States provided data from two large multicentered studies in which Norplant capsules were compared with Copper T IUDs, as well as several studies without such controls. All studies, in accordance with FDA regulations, were analyzed to provide detailed information on side effects, whether or not these effects led to termination. That is to say, the annual incidence of each of several hundred conditions was computed, as was the annual rate of termination attributable to the condition. We noted that complaint rates, as well as the corresponding termination rates, usually decreased after the first year. Such change after year one has three components. First, blood concentrations of levonorgestrel are highest in the first year, especially in the first quarter-year, generally producing the most marked side effects. Second, as with menstrual disturbances, women experiencing the most severe side effects have the implants removed. Third, as use continues to a third, fourth, or fifth year, effects that have been felt but tolerated for so long a period may no longer be voiced, though objectively they may be as severe or as mild in the fifth as in the second year.

Side effects were noted at each clinic visit, scheduled at 1, 3, 6, and 12 months after admission and semiannually thereafter through the five years of use. Some clinics required volunteers to visit clinics quarterly throughout the five years. The incidence of recorded side effects is somewhat higher at these sites than at other centers. At a visit, each woman was asked how she had been feeling since her last visit. Statements other than that she was well were probed, then recorded and coded. All conditions found upon physical examination at visits were also recorded. In recording terminations, when a woman reported both a personal reason and a complaint or condition as a reason for termination, the condition or complaint was always recorded as the primary reason for

Table 4. Conditions Deemed to Occur at Higher Rates Among Implant Users Than Among Copper IUD Users

Condition	Percentage with condition in first year	
	Norplant	IUD
Headache	18	10
Dermatitis	8	2
Nausea	8	4
Acne	7	3
Nervousness	6	2
Change in appetite	6	2
Weight gain	6	1
Mastalgia	6	5
Ovarian enlargement	3	3
Hair conditions	3	<1

termination. This was the case whether it was the woman or the physician who made the decision to remove implants.

In the two Population Council studies that used copper IUD controls, there were ten conditions (Table 4) that were reported at a significantly higher rate ($P<.05$) among Norplant users in both studies or when the data from the two studies were combined.

Table 4 compares the incidence of these ten conditions in the more recent of the two studies. This was a study with a U.S. component and began in 1982. Three of the listed conditions, nausea, mastalgia, and ovarian enlargement, were observed at frequencies similar to the IUD in the second study but under the above rules were deemed, from the combined data, to occur at a higher rate than among IUD users.

In the first year of contraception, Norplant users reported headache at the rate of 18 per 100 woman-years (WY) as opposed to 10 per 100 of IUD users. Headache was the most commonly occurring first-year side effect that may be attributed to Norplant. Headaches were mentioned about 80 percent more frequently by Norplant users as by IUD users.

Complaints of dermatitis, the second most common attributable condition, at 8 per 100 WY in the first year, were about four times as frequent as found among IUD users. Nausea, at 8 per 100 WY in the first year, and acne, at 7 per 100, occurred about twice as frequently to implant users as to IUD users. Nervousness, change in appetite, and weight gain were each reported at 6 per 100 WY by implant users but at a rate of 1 or 2 per 100 WY by women with IUDs. At some centers in the Population Council studies, as well as in preintroduction trials, substantially more women complained of weight loss than of weight gain.[1] Generally this occurred in areas where the mean weight was below 55 kg. In the Population Council study, mastalgia and ovarian enlargment were not elevated above rates observed among IUD users. Hair problems, including hirsutism, hypertrichois, and hair loss (alopecia), were more frequent among the implant accepters.

Dermatitis, acne, and hair conditions indicate androgenic properties of levonorgestrel and are thought to be dose-related. Table 5 traces changes over time in the incidence of the ten conditions that currently are deemed attributable to Norplant use.

Rates of termination for conditions attributable to implants have been very much lower than the rates of occurrence. For example, only 1.9 percent of women, not 18 percent, stopped use of

Table 5. Incidence Per 100 Woman-Years: Population Council Study 21/25

Condition	Year 1	2	3	4	5
Headache	17.8	13.3	5.3	10.0	5.2
Dermatitis	5.6	3.7	3.9	5.5	2.6
Nausea	7.6	3.4	2.8	1.0	2.6
Acne	8.8	4.2	5.0	5.5	1.7
Nervousness	5.8	3.7	3.2	3.5	0.0
Change in appetite	5.1	2.5	0.7	1.0	1.7
Weight gain	6.7	5.6	4.6	5.5	0.0
Mastalgia	5.8	3.4	4.6	6.5	5.2
Ovarian enlargement	2.3	3.7	3.6	3.5	6.0
Hair conditions	2.0	2.3	2.1	1.5	0.0

N=474

Norplant during the first year because of headache. The annual rate fell to 1.0 percent in the second year and continued to fall in the third year and after (Table 6) An exception to the pattern of decreased medical termination rates after the first year was weight change, with a higher removal rate in the second year (Table 6). Undoubtedly, many women deferred removal to such time as they felt certain the change would not reverse direction during use of Norplant.

Table 6. Women Terminating Implant Use as Percentage of Those Who Started the Year

	Year 1	2	3	4
Headache	1.9	1.0	0.3	0.0
Weight change	0.2	2.3	0.6	0.0
Ovarian Conditions	0.2	0.3	0.0	0.0
Skin Conditions	0.6	0.0	0.3	0.0
Breast conditions	0.0	0.0	0.3	0.0
Placement-related problems	0.6	0.0	0.6	0.0
Depression	1.1	0.3	0.6	0.4
Other mood changes	0.4	0.8	0.0	0.0
All circulatory, cardiovascular problems	0.4	0.3	0.3	0.4
Total medical	6.1	5.9	3.8	1.3

Altogether 6.1 percent of women sought removal of the implants in the first year for a medical reason (Table 6). A similar percentage, 5.9, of those who started the second year stopped that year for medical reasons. Weight changes accounted for 39 percent of all second-year medical terminations. Medical reasons for removal of implants were given by 3.8 percent of women entering the third year of use and by 1.3 percent of women starting the fourth year.

Placement-related problems have precipitated removal. These problems include expulsion, infection, or reaction to materials used in bandaging or placements leading to sensations of numbness or pain in the arm or hand with the implants. These reasons were cited by 0.6 percent of women in the first and third years of use and by none in the second and fourth years.

A small percentage of women have experienced difficulties that relate directly to the skill and training of the providers who placed or removed the implants. Removal problems have been engendered when implants have been placed too deeply, have been severed in placement, or have been spread too far apart in placement. The consequences of these problems have been removal times longer than the 10–15 minute average or the necessity of making two visits for removal or, on occasion, the necessity of making two incisions rather than one to remove all six capsules.

Acceptability and Continuation

The first multicenter study of Norplant implants identified several factors that contribute to their acceptability.[10] Subsequent studies have confirmed these attributes,[11–14] and have demonstrated, through high continuation rates, that, for those who begin contracepting with Norplant, it is a highly acceptable method.

The principal qualities that contribute to Norplant's acceptability are four: ease of use, long-lasting protection against pregnancy, relative freedom from side effects, and high efficacy.[10] Of these, ease of use was cited more than twice as frequently as any other feature (Table 7) in the first survey.

The primary feature of Norplant contraception that women have disliked is the disruption of the menstrual cycle caused by the method. In the early survey, menstrual problems were cited as the principal negative feature four times as frequently as were all other side effects (Table 8). In this study, rather large proportions of women in a Jamaican center objected to the appearance of the implant in their arms and also to the feel of the implant. At that time, the six Norplant capsules were placed in the palmar aspect of

Table 7. Attributes Enhancing Norplant Acceptability

Features liked most	Implant Norplant	IUD Copper T 200
Ease of use	42	33
Freedom from side effects	17	25
Effectiveness	19	24
Long-lasting	9	2
Other	11	9
No feature liked	2	7

I. Sivin et al., 1980.

the forearm and were frequently visible. The forearm location also provided more frequent opportunity to put pressure on the set of implants, thereby increasing the chances the women would sense their presence. The strong objection to this placement location in Jamaica led the Population Council to search for other placement sites. Placement in the scapular area of the back, the buttock, or the thigh—other areas where implants were placed or suggested—all required partial disrobement and entailed removal difficulties. The inner aspect of the upper arm, first used in Finland, has proved highly acceptable and has been recommended since 1980.

The initial comparative study of the system now called Norplant was of one year's duration. This study was a randomized comparison with a second implant with a concurrent IUD

Table 8. Attributes Militating Against Acceptability

Features disliked most	Implant Norplant	IUD Copper T 200
Menstrual problems	41	25
Pain	6	9
Other side effects	10	13
Appearance of implant	7	—
Feel of implant	4	—
Other	10	14
No feature disliked	24	39

I. Sivin et al., 1980.

comparison group as well. Investigators voted to remove all implants after a year, when the pregnancy rate of the second implant increased to unacceptable values. In that study, the one-year continuation of the Norplant accepters was 77 per 100, somewhat but not significantly below the continuation rate of IUD accepters enrolled in parallel at the clinics. In most subsequent studies, in which investigators had an empirical basis for counseling women about the effectiveness and duration of action of Norplant, and about side effects associated with its use, continuation rates have, generally, been higher. In several countries, the first-year continuation rates have been 90 per 100 or higher

Table 9. Estimated One- and Five-Year Continuation Rates

	1	5
Chile	90	55
China	94	72
Dominican Republic	79	25
Egypt	90	58
Indonesia	95	78
Scandinavia	76	33
United States	81	30

(Table 9). In the United States, the continuation rate has been comparable to the highest rates observed for modern methods in clinical trials. Five-year continuation rates exhibit great heterogeneity by country (Table 9). They reflect different proportions of women that have adopted Norplant to space births or to stop childbearing. They also reflect differential availability or lack of other convenient, effective, reversible methods in different countries.

Conclusion

In the United States, primary acceptability, the willingness of women to start use of the method, will be strongly affected by two exogenous variables. First is the price, the perception of which will

be conditioned by the "up-front" payment demanded for both the product and the provider's services. The second extrinsic factor will be providers' attitudes. Advertisements in gynecological journals promote contraceptive steroidal methods that regulate menstrual bleeding and have minimal "breakthrough" bleeding of spotting. Many gynecologists, impressed by 30 years of such advertisements, are unlikely to recommend Norplant as the contraceptive of first choice.

When women initiate use of Norplant, they will make their own evaluation of its acceptability. Price, provider attitudes, and the cost to governments and public-sector providers may prevent many from initiating use.

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NORPLANT AND POOR WOMEN

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Background

American women and men have high levels of unintended pregnancy—high relative to other Western, developed countries[1] and relative to our own childbearing plans. More than half of all pregnancies each year are unintended.[2] Thus, concerns about availability and accessibility of contraceptives are not only issues of satisfying different tastes or preferences among methods but also of helping meet some of our unfilled needs and of reducing unintended pregnancy rates.

Statistics consistently show that women (almost no data are available for men) with lower family incomes have higher levels of unintended pregnancy than others, indicating greater difficulty in meeting their childbearing goals. The abortion rate among women with annual family incomes under $11,000 is roughly twice that of women with incomes of $11,000–$24,999 and four times that of higher-income women.[3] During the late 1980s, 58 percent of births to women under 100 percent of the federal poverty level (equivalent in 1988 to an annual family income of $11,611 for a

family of four) were unintended, compared with 43 percent of births to women at 100–199 percent of poverty and 32 percent of births to higher-income women. The largest differences by poverty status were in the proportions of births to women after they had had all the children they had intended to. That proportion among those under 100 percent of poverty (25 percent) was twice the level among women at 100–199 percent of poverty and three times the level among those at 200 or more percent of poverty.[4]

Thus, though levels of unintended pregnancy, abortion, and unplanned birth indicate that Americans as a whole do not do as well as we could in achieving our childbearing goals, women and men with lower family incomes have greater difficulties than others. Some of the difficulties regarding access to contraceptive methods are not new, and programs have been set up to help deal with them. Some issues have been raised again or anew in the context of the introduction of contraceptive implants, Norplant®, that require other solutions if the special needs of lower-income women and men are to be met.

Low-Income Women

At any given time, a sizable proportion of women of reproductive age, that is, between ages 15 and 44, are poor or near poor. According to the 1988 National Survey of Family Growth (NSFG), for example, 14 percent of women 15–44 had incomes below 100 percent of poverty, and a total of one-third were below 200 percent of poverty. Women are most likely to be poor when they are young, unmarried, and if they are black or Hispanic. The proportion below 200 percent of poverty decreases steadily from 49 percent of those aged 15–19 to 22 percent of women aged 45–44. Some 52 percent of formerly married women and 44 percent of never-married women (who are not currently in a cohabiting relationship) fall below 200 percent of poverty, compared with 30 percent of cohabiting and 23 percent of currently married women. In the United States, over half of all black and Hispanic women aged 15–44 have family incomes below 200 percent of poverty (56 and

51 percent, respectively), compared with 28 percent of white and other non-Hispanic women.[4]

As a result of the patterns of poverty, lower-income women as a group are younger, less likely to be married, and more likely to be black or Hispanic than higher-income women. Forty-three percent of women aged 15–44 who are under 200 percent of poverty are aged 15–24, compared with only 26 percent of higher-income women. A minority of poorer women (34 percent) are currently married; a majority (58 percent) of women at or above 200 percent of poverty are married. Although most poorer women are non-Hispanic whites, more than one in three are black (21 percent) or Hispanic (15 percent), compared with about one in six higher-income women, 9 percent and 7 percent, respectively.[4]

These sociodemographic characteristics of lower-income women suggest that they may have special needs or concerns compared with those with higher incomes. Less money available means they will have greater difficulty paying for contraceptive services and supplies. Because more of them are young and unmarried, the concomitant risk of sexually transmitted disease (STD) may be of greater concern, and they are more likely to need methods that offer both pregnancy and STD prevention. Their disadvantaged economic position as well as the fact that more are from racial and ethnic minority groups raises special concerns about obtaining their informed consent to method use and guaranteeing protection against coercion from others.

Risk of Unintended Pregnancy

Though most women between the ages of 15 and 44 are able to get pregnant, they are not at risk of unintended pregnancy throughout all these years. Some 12 percent of women 15–44 have not yet had intercourse, and another 7 percent are not currently sexually active (i.e., haven't had sex within the last three months). Six percent are sterile for reasons other than contraceptive sterilization, and 5 percent are pregnant or have recently had a baby. At any given time 4 percent of women aged 15–44 are trying to

Among all women at risk of unintended pregnancy, more than one-third rely on contraceptive sterilization of themselves (25 percent) or of their partner (11 percent)

become pregnant. The other two-thirds of women of reproductive age are considered to be at risk of unintended pregnancy; that is, they are having sex, would be physically able to become pregnant if they used no contraceptive, but do not want to have a child at the present time.[4]

Further tabulations from the 1988 NSFG indicate that slightly fewer lower-income women aged 15–44 are at risk of unintended pregnancy than those at and above 200 percent of poverty, 64 percent versus 69 percent, respectively. This is primarily because poorer women— younger and less likely to have been married—are more likely to not yet have had intercourse, 16 percent of those aged 15–44 under 200 percent of poverty compared with 9 percent of higher-income women.

Most of the women at risk of unintended pregnancy report they intend to have no (more) children, and the proportions are similar by poverty status, 57–58 percent. Yet, poorer women reach this point at earlier ages than those with higher incomes. Seventeen percent of lower-income women aged 15–19, 29 percent of those aged 20–24, and over half of those aged 25–29 who are at risk of unintended pregnancy say they intend to have no children in the future. Among women at or above 200 percent of poverty, by contrast, only one-third of women at risk aged 25–29 say they plan no more children.

The relatively high numbers among lower-income women of younger women who intend no children in the future, as well as of births that occurred after women had had all the children they wanted, suggest that the availability of a highly effective contraceptive method in addition to contraceptive sterilization might be especially attractive to some poorer women.

Contraceptive Use

Among all women at risk of unintended pregnancy, more than one-third rely on contraceptive sterilization of themselves (25 percent) or of their partner (11 percent), and over half (55 percent) use a reversible contraceptive. At any given time, however, one in ten uses no method of contraception.[4]

Those women at risk with incomes under 200 percent of poverty are as likely as higher-income women to rely on contraceptive sterilization, 36 percent versus 35 percent, respectively. Yet, the patterns of contraceptive sterilization are quite different, partly because lower-income women are so much less likely to be married. Poorer women are much more likely than others to have had a tubal sterilization, 30 percent versus 22 percent, but they are only half as likely to have a partner who has had a vasectomy than are higher-income women, 6 percent versus 13 percent.

In general, poorer women at risk of unintended pregnancy are less likely than those at or above 200 percent of poverty to be using a reversible method of contraception, 50 percent versus 57 percent, respectively. Here again, the patterns of use vary by economic status. Although the differences are small, lower-income women are slightly more likely than others to use oral contraceptives or the IUD (32 percent versus 29 percent, respectively). They are slightly less likely, however, to be using the condom and much less likely to use the diaphragm or other methods.

The net result of the differences in contraceptive use, differences primarily in use of those methods that are linked to time of coitus and generally have higher use-failure rates, is that poorer women at risk of unintended pregnancy are about twice as likely to use no contraceptive than are higher-income women, 15 percent versus 8 percent.

The patterns of use and differences by poverty status apply whether women are trying to delay having (more) children until a later date or want no more children at all. In both cases, lower-income women are about twice as likely to be using no contracep-

tive method at all, 22 percent versus 11 percent among those who might want to have children later and 10 percent versus 5 percent of those who intend no more children.

Pregnancy and Contraceptive Failure Rates

If a fertile woman has intercourse but uses no contraceptive, her chance of becoming pregnant is very high. About 85 percent of such women will be pregnant within 12 months. The use of any contraceptive method reduces this risk substantially, but the likelihood of an unintended pregnancy while using a contraceptive varies by method and with how correctly and consistently it is used. Contraceptive failure rates are highest among those using the barrier and spermicide methods, periodic abstinence, and withdrawal, that is, the methods that require a good deal of user control and must be used around the time of intercourse. Oral contraceptives have an extremely low failure rate when used correctly and consistently. In actual use they have higher levels of unintended pregnancy, but are still on average much more effective than coitus-related methods.

Among women using the pill or coitus-related methods, failure rates are two times as high among lower-income women as among those with higher incomes, even after controlling for differences between groups in age and marital status. The difference by poverty status remains almost as large within racial and ethnic groups as it is for all women together, indicating that both family income and minority group status are markers for difficulty in effective method use.

Reversible methods that require little user input, methods like IUDs, contraceptive implants, and long-acting hormonal injections, and surgical sterilization have extremely low failure rates that vary little by user.[2] Until recently, the primary such option available to women and men in the United States has been permanent—surgical sterilization. Only a small proportion of American women at risk of unintended pregnancy use the IUD[6].

Contraceptive injections—Depo-Provera—were approved by the FDA in October 1992, although they were available from some clinicians before then. The introduction of Norplant in the United States in early 1991 therefore greatly expanded the method options in the category of highly effective reversible contraceptives.

Factors in Contraceptive Method Choice

Though the proportion of women at risk of unintended pregnancy using no contraceptive method is low at any given time, they account for a high proportion of all unintended pregnancies because their chance of becoming pregnant is so high. In fact, the 10 percent of all women at risk currently using no method of contraception account for 53 percent of all unintended pregnancies.[2] Thus, it is important to understand the reasons for periods of nonuse.

When women at risk of unintended pregnancy who are not using a contraceptive are asked why they are using no method, the most frequent response is that they are concerned about side effects; the next most frequent response is that they do not like or believe in birth control.[7] Nonuse is affected by levels of motivation to avoid pregnancy, by the partners' influence, and by other personal and socioenvironmental factors.[8] Some of these factors are independent of the available methods; others interact with methods. For example, methods differ in frequency and types of side effects, in the levels of motivation needed for beginning and continuing to use the method, and in the extent of partner interaction or even awareness.

Cost is seldom mentioned as the reason for not using any contraceptive method at all. Among nonusers at risk of unintended pregnancy in 1982, 2 percent of those aged 15–24 and 1 percent of women 25–44 said the reason for nonuse was that they could not afford contraceptives.[7] In a 1986 survey of low-income women aged 18–35 at risk of unintended pregnancy in four areas of the United States, 4 percent said they were using no contraceptive because of cost.[9]

Women may be less concerned about some side effects with Norplant than with oral contraceptives ...

Although, as shown above, high proportions of lower-income women use oral contraceptives or the IUD, about four out of every five of those who either use other reversible methods or none at all claim it is because of concerns about side effects and method safety. One percent or fewer say cost is a reason for their not using these methods.[9]

Those low-income women surveyed in 1986 who had ever previously used oral contraceptives or the IUD, a barrier or spermicide method, or either periodic abstinence or withdrawal were also asked why they had switched away from that method. Again, cost was almost never mentioned as the reason for changing methods. Those who switched from using the pill or IUD were most likely to have done so because of concerns about side effects (58 percent) or health (18 percent). Women switched from the condom, the diaphragm, or spermicides primarily because of their lower effectiveness (48 percent) and because they interfered with intercourse or were a hassle to use (25 percent). Concern about effectiveness was the primary reason women changed from periodic abstinence or withdrawal (86 percent).[7]

Although many factors influence whether a woman uses a contraceptive at any given time and which method she and her partner use, method characteristics are obviously important to those choices. Women may be less concerned about some side effects with Norplant than with oral contraceptives, but the most common side effect of such progestin-only methods as Norplant is altered bleeding patterns, and many women who discontinued its use during clinical trials did so because they did not like this side effect. At the same time, Norplant offers another option to those women especially concerned about method effectiveness and who want to use a method that does not interfere with intercourse and presents little hassle for them.

So far, most studies show cost not to be a method choice factor for most women, even for poorer women. At the current time, this may not be the case when it comes to including Norplant or IUDs as method options.

Factors in Contraceptive Provider Choice

Although cost has, up to now, seldom been found to be an important factor in the decision to use any contraceptive or which method to use, it has been crucial for many lower-income women in determining where they obtain contraceptive services. For example, 96 percent of low-income women surveyed in 1986 reported that whether a provider had sliding fees was important to them, and 89 percent said cost was important. For most of these women, these factors were "very important."[7]

The preferred source of medical care for most people in the United States is a private physician. The 1988 NSFG shows that three-quarters of women at or above 200 percent of poverty who use oral contraceptives, the most common reversible method and one that requires a medical visit to obtain the prescription, go to private physicians. Lower-income women also generally would prefer to get their contraceptive care from a private physician. Yet, only four in ten lower-income women go to private physicians when they make a family planning visit. The main reason for the discrepancy between lower-income women's preferences and where they actually obtain care is the lower cost of being served in a clinic.[7]

Because family planning clinics are subsidized by federal and state funds, they are able and often required to provide contraceptive care, both medical care and contraceptive supplies, free or on a sliding scale to low-income women. For example, most clinics receive some funding through Title X of the Public Health Service Act, which requires that clients under 100 percent of poverty be served at no charge and that those between 100 percent and 250 percent be charged on a sliding scale relative to their ability to pay. Medicaid, which covers a sizable minority of poor women,

reimburses providers directly for services to women who are covered by it.

Data from 1983, the most recent available, illustrate the impact of both Title X policies and the sliding scales in effect even in most non–Title X–funded clinics. In that year, for a woman at 75 percent of poverty, the median charge for an initial contraceptive visit and three months of oral contraceptives was zero in a Title X-funded clinic and $14 in a non–Title X–funded clinic. Women at 125 percent of poverty were asked to pay a median of $15–$23, depending on whether the clinic they went to had Title X funding. The median fee for a woman at 250 percent of poverty was about $50 in both types of clinics.[10] In contrast, in 1982, the average private physician fee for an initial contraceptive visit alone was $42. Only 17 percent of private physicians serving contraceptive clients would reduce fees for those who could not pay the full amount, and 56 percent would accept Medicaid.[11] Today an initial office visit costs more than $60 from an obstetrician/gynecologist, who provides most contraceptive care, and more than $40 from a general or family practitioner.[12]

Not only is the cost of private physician care more than many lower-income women can afford, but the need to purchase contraceptive supplies adds substantially to the cost of private care. Though women going to a private physician may receive some free sample packs of oral contraceptives, they generally must purchase pills at pharmacies. Prices vary by store and by brand, but the average annual cost for 13 cycles of pills is probably at least $200. Low-income women going to family planning clinics obtain pills at no cost if they meet income criteria or at a reduced price that is substantially less than if they purchased them from a drugstore.

How much contraceptive supplies cost depends to a great extent on the time frame, how long a woman will use the method and whether one looks at initial, short-term, or long-term costs. For a woman going to a private physician, the cost of contraceptive supplies, independent of the physician's charge for prescription or for insertion and removal, is lowest initially for oral contraceptives,

which can be purchased one pack at a time. In terms of one year of use, supply costs are lowest for the Progestasert and ParaGard IUDs (approximately $84–160, respectively) and highest for Norplant ($350). However, the ParaGard is now approved for up to eight years of continuous use, Norplant for five years, and the Progestasert for one year. If one assumes each method would be used continuously for five years, oral contraceptives are by far the most expensive, followed by the Progestasert, Norplant, and the ParaGard.

... for every $350 available for contraceptive supplies in one year, a program can serve about 25 pill clients, 4 IUD clients, or 1 Norplant client.

Wide differences in the cost of the most effective reversible methods now available are faced not only by women relying on private providers but by family planning clinics as well. In fact, for them, the cost differences are even wider. It is common for family planning clinics to be able to purchase oral contraceptives at reduced public-sector prices. Although the average price all clinics pay for pills is not known, the public programs probably supply a patient with a year's supply of pills for under $15,[13] compared with costs of about $79–$84 for an IUD and $350 for Norplant for one patient. Thus, for every $350 available for contraceptive supplies in one year, a program can serve about 25 pill clients, 4 IUD clients, or 1 Norplant client. If every client used her selected method continuously for five years, 5 pill clients could be served for the entire period compared with 4 ParaGard clients and 1 Norplant client. The five-year cost of Progestasert would be higher than even Norplant, however.

The primary purpose of publicly funded contraceptive service providers was to provide poor women and others without access to private physicians with equal access to contraception. Though all access problems have not been solved by the public program, up until now poor women were able to report that the

... the average amount of public funding available per contraceptive patient increased from $75 in 1980 to $100 in 1990, but that funding had the equivalent purchasing power in 1990 of only $46.

cost of getting care was not a major factor in their method choice. Many and probably the overwhelming majority, of the public-sector family planning providers are not able to offer equal access to IUDs or, especially, to Norplant because they are so costly.

Even though clinic clients may want access to these methods, the funding available to publicly funded providers has not expanded to cover the higher supply costs. Instead, funding has decreased by about one-third since the early 1980s in terms of actual buying power. In addition, clinics are being called on to serve women with more complicated medical needs than in the early 1980s, in part, but not entirely, because of expanded needs for STD screening and treatment.[14] If family planning clinics are serving as many contraceptive clients as in 1983, the last year for which data are available, the average amount of public funding available per contraceptive client increased from $75 in 1980 to $100 in 1990, but that funding had the equivalent purchasing power in 1990 of only $46.[15]

Even before the introduction of Norplant to the U.S. market at a fixed price of $350, the price of IUDs may have contributed to their being less available than other methods through family planning clinics. At current levels of public funding for clinic services, there are questions about maintaining existing services, much less providing a wider range of method choices. Without increased funding, perhaps specifically for purchase of contraceptive supplies, and/or drastic reduction in the price public-sector programs must pay for these methods, it is likely that they will continue either not to offer them at all or to make them available

only to those who can afford to pay for them themselves or who are covered by some third-party insurance mechanism.

Potential Reach of Third-Party Coverage

The companies marketing IUDs and Norplant have undertaken to get these methods included in state Medicaid programs and in private insurance policies. The cost of IUDs is covered under the Medicaid programs in the majority of states and Norplant is now covered under the Medicaid programs in all states. The cost is covered in a number of private insurance policies and health maintenance organizations as well. A foundation has been set up by Wyeth-Ayerst to provide Norplant at no cost for specific low-income clients of private physicians who agree to provide their own services for free. Though variations in the level of reimbursement for the concomitant physician services will affect provider willingness to offer Norplant to covered women, these actions help provide access to many poor women. The key question is the extent to which this restores equal access to all contraceptive choices for poor women.

According to the 1988 NSFG, only 6 percent of women aged 15–44 at risk of unintended pregnancy were on AFDC. Because being on welfare is the key way nonpregnant women can become covered by Medicaid, most of those on Medicaid are not only poor but also unmarried and already have at least one child. Even among very poor women, a minority have Medicaid coverage. Among those women under 100 percent of poverty, only one in three is covered by AFDC and Medicaid, dropping to less than 10 percent of those between 100 and 149 percent of poverty.

Medicaid provided payment for only 7 percent of the most recent family planning visits among women surveyed in the 1988 NSFG who had made a visit in the past 12 months. About one-quarter of those under 100 percent of poverty had their visit paid for by Medicaid, compared with 10 percent of

those at 100–149 percent of poverty and 4 percent of women at 150–199 percent of poverty.

Four in ten women used insurance to pay for all (24 percent) or for some (17 percent) of their visit costs. Higher-income women are more likely to have medical insurance, even though the majority of insurance policies probably do not cover nonsurgical contraceptive care.[12] Only 14 percent of women under 100 percent of poverty used insurance for any portion of the costs of their last family planning visit, but this level rose with income. Still, even among women at 200 percent of poverty or more, only 51 percent had insurance coverage for their contraceptive care.

Roughly four in ten women under 100 percent of poverty are covered for contraceptive care, at least in part, by either Medicaid or by private insurance. Among women with slightly higher family incomes, between 100 percent and 149 percent of poverty, only 31 percent have third-party coverage. Their lower level of Medicaid coverage is not completely made up for by their greater chance of having private insurance that covers contraception. Even among women at and above 200 percent of poverty, only 53 percent appear to have any third-party coverage for contraceptive services and supplies.

Women who are covered by Medicaid as well as by private insurance may not even then have equal access to all contraceptive methods if the reimbursement levels are not enough to induce physicians to provide the concomitant care. Comparison between individual physician charges in 1982 and Medicaid reimbursement levels in their state for an initial contraceptive visit indicated that for every dollar the Medicaid reimbursement level was below their customary charge, physicians were 1 percent less likely to accept Medicaid reimbursement at all.[16]

Medicaid and private insurance coverage of Norplant as well as of other contraceptive options can provide access for many women who otherwise would not be able to afford these methods. Yet, most poor women and almost half of higher-income women are not reached by this coverage. In addition, unless reimburse-

ment levels are high enough to persuade providers to accept them, even these covered women will not have equal access to all methods.

Conclusion

Lower-income women have special needs for improved contraceptive access. They have higher levels of unintended pregnancy, abortion, and unintended births, due both to lower levels of contraceptive use when they are at risk of unintended pregnancy and to higher levels of failure while using contraceptive methods.

The publicly funded family planning clinic program has helped equalize access to contraceptive methods by subsidizing the cost of services. As a result, cost has been a factor in poor women's decisions about where to get services, but seldom in the choice of methods to use.

The high initial cost of IUDs and of Norplant and the high long-term cost of Norplant and of the Progestasert make them too expensive for subsidized family planning clinics to make available to all clients who might be interested in them. Instead, unless additional funding and other funding mechanisms are made available, they will be limited to women with adequate third-party coverage through Medicaid or private insurance and to women who can afford them. As a result, we are moving much farther from, rather than closer to, closing the income gap in equal access and in reproductive outcomes.

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NORPLANT AND WOMEN OF COLOR

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The National Black Women's Health Project (NBWHP) is a self-help and health advocacy organization that is committed to improving the overall health status of black women. The core program of the NBWHP is based on the concept and practice of self-help and the inclusion of all African American women, with a special focus on black women living on low incomes.

The NBWHP began in 1981 as a pilot program of the National Women's Health Network, and was incorporated as a nonprofit organization in 1984. Since that time, it has become an internationally recognized grass roots advocacy organization run by black women for black women, comprising over 2,000 members participating in more than 150 self-help chapters in 31states. The NBWHP national office is located in Atlanta, Georgia, with local offices in New York City; Philadelphia, Pennsylvania; and Oakland, California; there is a newly opened National Public Policy and Education office in Washington, D.C.

The Washington, D.C., office was established in 1990 to provide a national forum to share the information, data, and

perspectives of the NBWHP self-help networks in a way that will ensure an impact on policy discussions regarding African American women's health issues. The initial focus of this office is on reproductive health and rights.

The importance of reproductive health choices and rights, and the necessity for hearing African American women express their own agenda and speak in their own voices with regard to these rights, must be recognized. We will be speaking out and developing policy statements regarding a wide range of critical health issues affecting African American women. A major focus of our work will be to collaborate and work in coalition with other organizations to develop and promote a comprehensive health policy agenda.

One of the primary responsibilities of the D.C. office is to monitor legislation and to advocate for the kind of health policies and funding that will benefit African American women and women of color. We are advocating for remedies to issues, policies, and practices that affect women of color—all women, and we would argue, all citizens of our nation—issues such as the punitive or racially motivated use of Norplant,® a recent technological advance in female contraception.

Norplant is manufactured in Finland and repackaged and distributed domestically by the Wyeth-Ayerst pharmaceutical company. After almost 25 years of research and development by the Population Council, Norplant was approved by the Food and Drug Administration for distribution and public use in December, 1990, amid much fanfare and excitement. Norplant's appeal is that it is a time-lapsed, long-term contraceptive—designed to perform for up to five years. According to Population Council research, it is very effective—resulting in less than one pregnancy for every 100 women tested during the first year of use. And it is reversible.[1] We will discuss its limitations later.

Norplant contains the synthetic hormone progestin which inhibits ovulation and thickens the cervical mucous. Norplant is inserted under the skin, usually in a woman's upper arm, in six rubberlike capsules the size of matchsticks.[2]

We at the National Black Women's Health Project welcome the development of subdermal implants because it is a much needed and long overdue addition to the meager menu of contraceptive options currently available to women. It also represents the first scientific breakthrough geared specifically to women in over 25 years.

Before examining some of the broader implications of Norplant, I must strongly state that although this contraceptive is an advancement, it is not for every woman. As with most other medications, Norplant has side effects—women report having severe abdominal pain, headaches, and mood or weight changes. The area where Norplant is implanted can become infected, and up to 70 percent of new users experience irregular bleeding.[3]

In particular, women who smoke heavily, who experience abnormal vaginal bleeding, blood clots, or any circulation or heart problems or liver disease, or who have had breast cancer or any condition for which they were treated with hormones are strongly advised against using Norplant.[4]

Also, women with health histories that include diabetes, high cholesterol or high blood pressure, migraines or frequent headaches, depression, epilepsy, or gall bladder or kidney disease should consider Norplant use with extreme caution.[5]

All of the health conditions that I just mentioned, that warrant close medical supervision and could mediate against Norplant use, dramatically and disproportionately affect African American women and women of color. Women of color have a shorter life expectancy, higher maternal and infant mortality, and higher incidence of chronic disease and lack access to regular, high-quality health care information and services.[6]

We at the National Black Women's Health Project support medical research and development, as well as applications of new technology that can improve the health and reproductive choices of women and their families. But we are also appealing to the women's community, to health providers, to legislators, and to the public at large to examine some very critical issues associated with

Norplant that impact women of color. Consideration must be given to Norplant's safety and accessibility and to potentially punitive, coercive, or racially discriminatory applications of the drug. These are issues that seem to be overshadowed by the general exuberance generated by the availability of this new product.

Safety

Women using Norplant do not have natural cycles and experience irregular and frequent bleeding. Many health providers don't take this side effect seriously. They argue this is just a "nuisance factor" that will eventually wear off, probably after the first year or so of use. But irregular bleeding is also one of the early symptoms of endometrial or cervical cancer.[7] If its occurrence is treated whimsically and is attributed solely to Norplant, there is a serious risk of missed or delayed diagnosis of much more serious conditions.

Norplant also may pose a serious health risk to the child of an implanted mother who is breast-feeding, as studies indicate that the concentration of infants' sera reaches 5–10 percent of that of mothers' sera. Because data so far available don't follow exposed infants beyond three years, we do not know the long-term effects for exposed children.[8]

For African American women, Norplant raises specific concerns. Its effectiveness decreases for women who weigh 155 pounds and more[9]—and the surgical insertion and removal procedure can result in keloid formation, or thick, permanent scarring, in African American women.

But one of our biggest concerns about the safety of Norplant is its long-term impact. The Population Council says that since 1975 it has conducted five-year Norplant studies of over 55,000 women in 46 different countries.[10] But very few of those women have been monitored or studied 10 to 15 years after Norplant use.

We have a right to know now what, if any, long-term effects Norplant may have on women and the children they bear after using Norplant. We do not want to repeat the tragedy of another

generation of drastically affected children and shattered families that resulted from the prescription drug DES to find out about the long-term impact of Norplant. We understand long-term safety data will be collected as part of the postmarketing surveillance program coordinated by the World Health Organization, the Population Council, and Family Health International, but funding for this has not been secured for more than five years as of fall 1990.

We have a right to know now what, if any, long-term effects Norplant may have on women and the children they bear after using Norplant.

Access

Regarding the question of access—at least 15 million women in this country have little if any chance of using Norplant because they have no health insurance. African American women and women of color experience the greatest difficulties in accessing affordable, responsive, high-quality health care.[11] Women of color who may be considering a Norplant implant probably do not have access to the kind of health care they need to assess their medical histories to determine if they should be a candidate for the hormone implant.

Also, the cost of Norplant is prohibitive, ranging from $300 to $500 for the implant and another $150 to $200 for removal. Even if a woman of color has health insurance and access to a health provider, what if by the five-year removal deadline she has lost her health benefits, or what if she wants Norplant removed early and does not have the money for the removal process?

While Norplant may pose fewer problems and fewer short-term risks than birth control pills and injectables, it does require a delivery system that is responsive to women's needs and able to offer fairly high-quality care. Many women, especially poorer women and women of color, who have had difficulty

obtaining high-quality, responsive care in the past, are justifiably skeptical.[12] The prospect of the health and medical care system's suddenly becoming reliable, that is, that care givers actually will be trained adequately in insertion and removal techniques, and that all requests for implant removals will be immediately honored, requires a blind leap of faith.

Punitive/Coercive Use

It seems the search for scapegoats for the country's economic problems has converged with conservative and punitive attacks on sexually active women. Thus, by far the most troubling impact of the new subdermal contraceptive is its potential for forced use on unwilling or uninformed women. The women who are targeted are most often poor women and women of color.

For example, two days after the FDA approved Norplant for public use, a *Philadelphia Inquirer* editorial suggested the implant should be used as "a tool in the fight against black poverty."[13] That some policymakers and opinion leaders see this drug as a potential tool to be "used" against the poor and those victimized historically by racism, sexism, unequal pay, discrimination, and other injustices is not only inhumane, it is unconscionable.

To add insult to injury, some states are suggesting that women of color be forced, in some instances, and enticed financially, in others, to be implanted with Norplant. One form of coercion is the "incentive plan" strategy first proposed by a conservative prolife Kansas state representative, who wrote a bill authorizing that welfare mothers be paid $500 to get the implant. The implant procedure would be paid for, plus the mother would receive an annual checkup and a $50 check each year. This strategy not only imposes an antichoice agenda, it also targets the poor and is racially motivated.

Louisiana's David Duke also proposed an "incentive plan" to cover the costs of the implant and to pay women on welfare extra money to have Norplant inserted. Fortunately, these bills

died in committee. The majority of other states have authorized use of Medicaid funds to pay for Norplant for low-income women.[14]

Though "incentives" are not in themselves a bad thing, in these instances, the line between incentive and coercion is fuzzy. The incentives are only being offered for one contraceptive—Norplant—to one class of women—poor, single mothers on welfare, who are more than likely women of color. What ever happened to choice?

Several states are considering Norplant legislation that would mandate that women convicted of certain crimes be forced to have Norplant implants as a condition of sentencing or parole. Some examples of legislation under consideration bear discussion. In Ohio, Senate Bill 82 would amend the definition of a neglected child to include children born drug-addicted as a result of a mother's drug use during pregnancy. The bill would make it a second-degree aggravated assault to cause a child to be born addicted to drugs. In Ohio, punishment for this crime for any woman not previously convicted of child neglect would be to either complete a drug addiction program or to undergo a Norplant implant and agree to abstain from drugs for five years.[15]

For a woman previously convicted of child neglect, the Norplant implant would be mandatory, and the woman would have to pay for it herself, unless she was indigent, in which case she would have to convince the Ohio Department of Human Services to pay. Senate Bill 82 was sent to the Judiciary Committee, and a vote before the full Ohio General Assembly is pending.[15]

South Carolina Senate Bill 986, on the other hand, would require a physician to test a newborn for drugs if he or she suspected the mother used a controlled substance during her pregnancy. Positive test results would be considered prima facie evidence that the infant had been abused and grounds for family court to order the mother to undergo reversible sterilization or Norplant implantation. An additional sinister feature of this proposed legislation is that it would provide immunity from civil or criminal liability for

... when women of color are convicted of child abuse or drug use while pregnant, and are subsequently forced to use Norplant, the decision is very likely to be racially motivated.

any consequences of state actions pursued, allowed, or required under the bill. Senate Bill 986 will be considered in the Judiciary Committee of the South Carolina Senate when it reconvenes in January of 1992.[15]

Regarding Norplant litigation, a case occurred less than one month after FDA approval of Norplant. In this case, a California judge sentenced a 27-year-old pregnant African American mother of four to have Norplant inserted for three years for reported child abuse. The mother, Darlene Johnson, was convicted of beating her children.

Without denying or diminishing the seriousness or responsibility of the charges, we must recognize that Ms. Johnson's prosecution and sentence were very likely influenced by her race. A recent Florida study found that black women are ten times more likely than white women to be referred for prosecution for substance abuse while pregnant, even though a comparable percentage of women of both races have been documented as using harmful drugs. Child abuse prosecutions are similarly influenced by race. It follows, therefore, that when women of color are convicted of child abuse or drug use while pregnant, and are subsequently forced to use Norplant, the decision is very likely to be racially motivated.

Ms. Johnson is appealing the forced Norplant sentence, saying that when she initially agreed to the procedure as a condition of her probation, she did not understand what the implant was and she feared a stiffer sentence if she did not comply. In addition, it was recently revealed that Ms. Johnson is a diabetic and thus susceptible to serious health risk because of that condition. Diabetes is considered a condition that warrants extreme caution regarding Norplant use.

As in the case of Darlene Johnson, some women should simply *not* use it. And no judge or jury should be allowed to impose or prescribe a medical application like Norplant that they are in no position to assess the impact of, even if a woman *is* willing.

Once again, we see the imposition of an over simplistic and one-dimensional remedy for complex social issues and problems. In the case of Ms. Johnson, rehabilitation and support programs that help families learn nonviolent approaches to problem solving and conflict resolution would have been a far more appropriate and effective remedy than forced contraception.

And so with the availability of Norplant, we are witnessing the aggressive imposition of punitive birth control measures on poor women and women of color in the United States, just as sterilization and other so-called population control measures have been forced upon African American women and new immigrants in this country historically and continue to be imposed on women of color in developing or so-called third world countries around the world.

When women in Indonesia were tested for Norplant, they reported not being properly informed about the drug. They say they were pressured into choosing Norplant over other contraceptives and were discouraged from seeking early removal if they needed or wanted it.[16] Indeed, at the November 1990 Sixth International Meeting on Women and Health, women from twelve Third World countries wrote a letter to the U.S. AID concerning the lack of adequate information regarding Norplant's risks and benefits and difficulty in obtaining implant removal on request. It seems that universally, the development of contraceptive technology is being guided by population control policies rather than a woman's health needs. Education, counseling and access to comprehensive services are not funded, but Norplant use is.

Given this country's history—of population control strategies and experiments, the eugenics movement, and sterilization abuses—and the policies and practices of our high-priced and racist health care system, it should come as no surprise that women

of color are not embracing Norplant "incentive plans" and are instead viewing them with great suspicion. After all, women of color have had to bear the brunt of these dehumanizing practices. For example, while white women were fighting for the right to have access to voluntary sterilization in the 1950s and 1960s, low-income women and women of color were sterilized without their consent, or often their knowledge. And in some instances poor women have been forced to choose between forced sterilization and eligibility for some benefits and services.

Protests organized by the women's health movement and other women of color activists forced adoption of written consent regulations and requirements for a 30-day waiting period for sterilizations and similar federally funded procedures; comparable measures should be instituted to ensure that women who are Norplant candidates are making truly voluntary, uncoerced decisions about their own bodies and their own futures.

We at the National Black Women's Health Project are not suggesting that Norplant is inherently bad. It is relatively maintenance-free and 99 percent effective in deterring pregnancies in optimal conditions, if a woman does not weigh over 155 pounds, is in near-perfect health, and is well informed and assertive about her health options.

Our concerns, as were stated earlier, are about Norplant's safety and accessibility and about public policies that punitively and forcibly impose use of the implant on poor women and women of color.

What can you do about questionable uses of Norplant? We cannot emphasize enough the importance of state-based legislative battles involving Norplant policy. Increasingly, state legislatures are becoming the forums in which Norplant safety, access, and coercive use and incentive policies are being discussed. Bills involving Norplant are currently pending in Hawaii, Ohio, and South Carolina, among other states. If Norplant legislation has already been enacted in your state, you should initiate a process to reexamine it. You should also take the lead to guarantee that very careful consideration and examination is conducted of any

pending Norplant legislation that might establish so-called incentive plans for low-income women or might impose Norplant implants as a term of a woman's sentence or parole, and that all women's voices are registered and heard, regardless of race or income.

We also encourage women's groups and health advocates to establish local and state-based watchdog and clearinghouse organizations to identify and document Norplant abuses.

We also encourage women's groups and health advocates to establish local and state-based watchdog and clearinghouse organizations to identify and document Norplant abuses. These same groups should encourage pharmaceutical manufacturers and contraceptive research and development enterprises to establish task forces and advisory groups composed of diverse groups of women to ensure that women's voices and views are considered in new product development and distribution.

The ultimate solution to potential misuses of Norplant and drugs like it is development of health delivery policies and systems that focus on the medical and health care needs of women, the poor, children, young people, and citizens of greatest need first, rather than on ways to limit their reproductive freedom. Population control is not the answer. The provision of the kind of comprehensive and high-quality health services that each citizen deserves, regardless of gender, sexual preference, economic circumstances, ethnicity, or country of origin *is*.

Because ethical and medical responsibility and accountability for administration of Norplant rests with the current health care system, we must make it reliable and responsible. We must advocate for the proper training of health care providers to assess whether women are good candidates for Norplant and to insert and remove the implants safely. We must advocate for the health care delivery system to fill all requests to have implants removed immediately, without judgment.

Because we must rely on the health care delivery mechanisms that currently exist, we must address the deficits in that system to ensure that all citizens, especially women of color and those in greatest need, have access to health care that is affordable and responsive.

We must also vigorously advocate for a health care system that includes responsible education and counseling as a vital component of its comprehensive services.

Education is sorely needed to inform women about all their options—especially for poor women and women of color, who characteristically may not question authority or be aware of all their rights. Education is important to let women know about the pros and cons of Norplant and its limitations. Education is critical to let women, especially sexually active young women, know that because Norplant does not provide protection against sexually transmitted diseases, like HIV infection, condoms are a necessary protection and must be used in combination with Norplant.

Only our advocacy can help to make sure judges and doctors and other health care practitioners will not force a woman to agree to a Norplant implant because it is the current drug of choice of the medical profession or because it is mistakenly seen as a cure for social ills.

We are, frankly, concerned, however, because although more progressive organizations, such as the National Women's Health Network, have spoken out, the traditional women's reproductive rights and health community have been oddly silent on these issues concerning the potential misuses of Norplant. Of these groups only the Planned Parenthood Federation of America and the originator of the implant contraceptive have gone on public record and spoken out quickly and forcefully against the coercive and punitive use of Norplant.

Although punitive Norplant judicial rulings seemed to catch by surprise, our colleagues of the reproductive rights, women's, and health communities, months prior to FDA approval of Norplant, we at the National Black Women's Health Project, other

women of color groups, and the National Women's Health Network predicted abuses would occur and that poor women of color would be the prime targets.

We at the NBWHP claim no pride at being able to second-guess such atrocities. Our history over the past decade of documenting the health abuses and systemic shortcomings that punish women of color have helped us to identify trends in legislation and policy.

We hope that our advice and counsel will be heeded in the future, and that women and men everywhere, both our traditional supporters and those who have not historically been active in the women's and health community, will become active participants in a campaign of information and advocacy. We welcome efforts to mobilize and activate communities of interest other than our defined constituents—to inform and educate legislators, other policymakers, and their staffs so that our voices are aggregated and resonate from town halls to state halls to the halls of Congress. We all have and should exercise the responsibility to contribute to the crafting of nonpunitive, nonrace- and nongender-discriminatory legislation that addresses the real problems—the economic, educational, and health needs of poor women and women of color.

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NORPLANT: POTENTIAL FOR COERCION

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In December, 1990, the FDA approved the use of Norplant, the highly effective and exciting new long-acting contraceptive implant developed by the Population Council. It was met with much enthusiasm by the reproductive health field as the first really new contraceptive to be introduced since the introduction of oral contraceptives and IUDs some thirty years ago.

Less than one year later, however, three instances of potentially coercive use of the contraceptive have come to national attention. Two states, Kansas and Louisiana, have proposed legislation that would provide financial incentives to women who receive public assistance to have Norplant inserted and kept in place over time. The third case is that of a California woman convicted of child abuse who was ordered to have Norplant inserted as a condition of her probation.

Thus the introduction of this highly effective new contraceptive option has led to controversy—predicted by some, but underestimated by most workers in the field of reproductive health. To better understand how such potential abuse could come to be considered, one has to review the historical precedent of potential

and actual sterilization-related abuse. In addition, it is important to note a political climate within the current administration in Washington and in the federal court system that places a low priority on a woman's reproductive choice and rights.

The History of Sterilization Abuse

Contraceptive sterilization used coercively has been a concern since the option of sterilization for contraceptive purposes became a reality in the twentieth century. The potential for sterilization abuse was first realized at the time of the eugenics movement in the early part of the century.[1] The concept of eugenics was established by a small group of individuals who articulated neo-Malthusian principles about the negative consequences of overpopulation among the "socially unfit," which included the poor. This concern led to the belief that active and invasive measures taken to control population growth among groups deemed "inferior" was not only acceptable but in society's best interest.

Surgical sterilization was one of the measures considered appropriate to help achieve this goal. Compulsory sterilization laws were common in the majority of states, and in 1927, the Supreme Court upheld such laws with their decision in the well-known *Buck* v. *Bell* case (which, incidently, still remains unchallenged).[2] As many as 45,000 people in the United States were sterilized between 1907 and 1945, and many of them were poor.[3] Despite the fact that eugenics-based sterilization policies were widespread, they did not seem to reflect prevailing public opinion.[4, 5] Rather, a few influential individuals were able to have a significant impact on public policy.

Compulsory sterilization was commonly practiced throughout the first half of this century; however, for all intents and purposes, sterilization as a voluntary contraceptive option did not exist for many women. Those who sought sterilization as a means

to prevent further pregnancies were routinely denied the procedure unless they met suggested requirements developed by the American College of Obstetrics and Gynecology, in which age multiplied by parity should equal 120, two additional physicians (often including a psychiatrist) had to concur that the procedure was indicated, and spousal consent had to be obtained.[1] Such restrictions were supported by the American Medical Association and the American Public Health Association. Denial of access to this procedure as a contraceptive option constituted another, more subtle form of sterilization abuse.

By the early 1970s, the professional organizations began to lift their restrictions. This was due to improved surgical procedures, as well as changed attitudes and demand among the public for more contraceptive options.[6] Federal funds that had been available for other types of family planning services were extended to include voluntary surgical sterilization in this period as well. Sterilization had presumably evolved from a procedure reserved for controlling the fertility of the "unfit" to a voluntary contraceptive option available to all members of society.

Despite this liberalization of sterilization policies, a few proposals for compulsory sterilization continued to be introduced in the 1960s and 1970s in a number of states. Although they were never passed into law, the majority of these proposals were aimed primarily at low-income women. Even more disturbing is that some physicians were in favor of such proposals.[7]

In 1973, a highly publicized case of involuntary sterilization of two black teenagers in Montgomery, Alabama, shocked many in the field of family planning who did not believe that coercive sterilization was an issue. It resulted in the reporting of similar abuses elsewhere; several other cases were reported of persons sterilized without their knowledge or consent.[3] In almost every case, the victims of the abuse were poor or minority women. Individual providers were not alone in this practice. It appears that coercive sterilization also occurred in teaching hospitals and other settings that served large numbers of public patients.[3]

It is not difficult to see direct parallels between past occurrences of sterilization abuse and today's possibility for coercive uses of Norplant.

Because of the reported cases of sterilization abuse among minorities and the poor and the potential for additional cases, the then Department of Health, Education, and Welfare (now the Department of Health and Human Services) issued its first set of national guidelines to regulate *federally funded* sterilizations in 1974. These guidelines, which were revised and updated and in 1978 became federal law, require the following: informed consent in the person's native language, extensive counseling and information regarding the procedure, a prohibition of consent at times of stress or duress, a 30-day waiting period between consent and procedure, and a ban on sterilizations for persons under the age of 21. Though these guidelines do not eliminate all possibility of abuse, they do serve to protect those most vulnerable to potential coercion or abuse.

At the same time, there is also the potential for another form of abuse. On occasions a woman who desperately wants a sterilization procedure arrives unexpectedly at the hospital and undergoes a laparotomy for another purpose (e.g., an ectopic pregnancy), or a woman has had no prenatal care because of access problems and requires a cesarean section. In both types of cases it would be desirable if there were some appeals process to meet the needs of the individual woman who might not be able to easily return 30 or more days later. In addition to the inconvenience, entry into the peritoneal cavity a second time carries some increased risk.

It is not difficult to see direct parallels between past occurrences of sterilization abuse and today's possibility for coercive uses of Norplant. The proposals in Louisiana and Kansas indicate that attitudes toward poor and minority women by some in positions of power have not changed. Some within the anti-abortion movement apparently have little difficulty with the concept of mandated use of a contraceptive like Norplant.

The Current Assault on Reproductive Rights

The ability to freely and responsibly choose the number and spacing of children is a basic right. The United Nations has proclaimed it to be a basic human right in a variety of documents, most importantly in the Convention on the Elimination of All Forms of Discrimination Against Women; states that sign the convention are legally bound to recognize the rights of women, on an equal basis with men, to decide on childbearing and to have access to the information and means to exercise the right.[8]

Within the United States, however, the right to reproductive choice has been a source of extraordinary debate. Part of the controversy stems from the fact that the right is not explicitly articulated in any part of the Constitution. To some, this absence reduces it to a position of lower priority relative to rights that are specifically protected, such as freedoms of speech and religion.

For the past ten years the assault on reproductive rights in the United States has been especially acute. Two Republican presidents have supported overturning *Roe* v. *Wade* and have used the powers of the executive branch to fill the federal judiciary, including the Supreme Court, with those who share their beliefs on women's reproductive rights. Policies from the executive branch itself have aimed at doing anything to undermine abortion choices, as evidenced by the recent "gag rule" upheld by the Supreme Court in *Rust* v. *Sullivan* and its far-reaching implications for patient-provider relationships and freedom of speech.

The assault on reproductive rights has continued at the state and local levels. Some judges, frustrated by the increasing incidence of drug abuse among women, with its negative health consequences on their newborns, have begun allowing prosecution of pregnant, drug-addicted women for child abuse or for passing drugs to minors. The justification is that the state has the right to protect the fetus from the actions of its mother. Such judicial actions directly result from a political climate in which women's reproductive rights are held to be either nonexistent or of secondary importance.

The California judge who sentenced a young woman to Norplant® insertion has taken the argument one step further. He asserts that the state has a vested interest in protecting the rights of any of the woman's future children (including those not yet conceived). He contended that these rights far outweigh her right to privacy and reproductive choice. The rapid descent down the "slippery slope" is well under way.

Incentives have been used in family planning programs in some parts of the world, and there is much debate among population and human rights experts as to how society's need to effect fertility change is outweighed by the couple's and the individual's right to freely choose the number and spacing of their children. Most agree, however, that population policies do not violate individuals' human rights as long as they are "not coercive, discriminatory or contrary to recognized human rights".[9] The incentives proposed in Louisiana and Kansas clearly violate this standard. Because they are aimed at mothers on public assistance, they are most clearly coercive, discriminatory, and a violation of those women's reproductive rights.

Norplant and Coercion

As has been discussed above, Norplant is not the first contraceptive to have the potential for involuntary and coercive use, but it is important to consider what makes it potentially amenable to coercion. In the first place, Norplant is reversible, allowing some to argue that its involuntary insertion is not necessarily a violation of a woman's right to privacy because it allows a rapid return of fertility after removal.

Secondly, Norplant is similar to other highly effective methods that require little user compliance, such as sterilization. The relationship between a user's control over a method and the method's efficacy is inverse; that is, the more power and motivation a method requires of a user, the less effective it is likely to be.[8] The invasive nature of the most effective methods unfortunately increases the potential for coercion, because the user becomes

Three Ways Norplant Could Be Used Coercively

1. Decisions by clinicians to violate principles of informed consent.
2. Legislative endeavors to target specific groups for insertion, either through incentive or disincentive plans.
3. Judicial actions that require insertion as an element of sentencing, a condition for parole or probation, or to prevent "unfit mothers" from having more children.

dependent on the professional ethics and motivations of an outsider. Norplant is a clear example because it requires insertion and removal by a trained health professional.

In the first case, a provider could either consciously or subconsciously violate principles of informed consent. These principles are full and complete disclosure to the patient of both the available method choices and the benefits and potential risks of each method. The provider would most probably be acting independently and according to personal values and beliefs. Studies show that many doctors assume poor women are not capable of using methods that require high user compliance, such as oral contraceptives, despite the fact that such assumptions are not founded on fact.[10] Such beliefs seriously call into question the health care provider's capacity to present accurate, unbiased information to the patient.

Legislation aimed at controlling the fertility of particular segments of society is a second way in which Norplant could be used coercively, as has already been proposed in Kansas and Louisiana. In those two states mothers on public assistance have been targeted by the proposed legislation, which offers them significant financial incentives to have the birth control device inserted and left in for the full five-year period. Other segments of

Norplant is reversible, allowing some to argue that its involuntary insertion is not necessarily a violation of a woman's right to privacy because it allows a rapid return of fertility after removal.

the female population could be potential targets of such legislation, such as those who are HIV positive or mentally handicapped or are prisoners.

Proponents of such legislation argue that society has the right to protect itself from the unnecessary costs that may (or may not) occur when specific segments of the population have children, and that such "tough love" tactics are also beneficial to the targeted women.[11] However, the argument clearly ignores the fact that large financial incentives to the poor make real choice unlikely because of the short-term financial gain offered. This becomes coercive because such incentives would be of little, if any, interest to women of means.

A third way in which Norplant can be used coercively is through the judicial system. In the recent case in California of a woman convicted of child abuse, the judge suggested that Norplant could be inserted as a condition of punishment and/or rehabilitation of women convicted of a crime and in particular one involving the well-being of their children. The justification is that society has the right to protect future children from abuse or neglect and itself from the future social and economic costs that such abuse entails. These rights purportedly outweigh the mother's individual right to privacy and reproductive choice. It is not impossible to imagine that such judicial acts may be aimed at other women who expose their fetuses and children to risk, such as substance abusers and anyone considered an "unfit mother."

Though a full discussion of the legal implications are beyond the scope of this paper, it is important to point out a double standard indicated by such actions. Men who abuse or neglect their children are not legally prohibited from having more children.

One could argue correctly that such prohibition does not occur because reversible methods that do not require user compliance are not available for men. Yet that argument ignores the fact that men are often not held accountable for their actions relating to their children, as demonstrated by the weak enforcement of payment of child support.

Conclusions

The introduction of Norplant in 1990 was a significant breakthrough in contraceptive technology. It is potentially the most important contraceptive development since the introduction of oral contraceptives and IUDs in 1960. Though in the vast majority of private and clinic-based practices this contraceptive method will be used properly with careful informed consent, the issue of potential coercion is complex and merits serious consideration if the abuses of the past are to be prevented. As health providers, we have a special obligation to ensure that uses of all family planning methods are voluntary. The effective training of health care personnel dealing with Norplant will play a vitally important role in decreasing the likelihood of coercion. Counselors and/or health care providers are ultimately responsible for educating and informing the patient about all aspects of the method. Furthermore, they are responsible for presenting all contraceptive options, without preconceived notions of the patient's capacity to comply with any one method. The process of informed consent is designed to protect the patient but can only be effective when the power balance between patient and provider is as equitable as possible.

It is essential that very clear guidelines are established, with the goal to ascertain that all women wishing to consider Norplant as a contraceptive option are fully informed about the method—its benefits and its risks—so as to be able to make an informed decision. Barriers to access must be decreased while, at the same time, ascertaining that the opportunity for coercion is removed.

As health providers, we have a special obligation to ensure that uses of all family planning methods are voluntary.

The guidelines used for federally funded voluntary sterilization may provide a basis for Norplant guidedlines but certainly need alteration. For example, the 30-day waiting period and ban on those younger than 21 are not warranted. Such guidelines will not prevent the legislative and judicial actions we have seen thus far, but they will address the issue of the patient-provider relationship and the potential for coercion.

Despite the attractiveness to some politicians and judges of limiting the childbearing ability of some women because of their past and/or present behavior, every effort should be mounted to oppose this infringement of a basic human right. Such use of this new contraceptive method would be disproportionately against the poor, particularly against women of color. It is only a short additional step to other forms of discrimination, discrimination that must be opposed at all costs. When a David Duke starts to talk about the forced use of a contraceptive method, we had all better be particularly alert and on the offensive against such action.

Finally, we would be remiss were we not to mention one other concern that many of us have concerning availability. The pharmaceutical company with marketing rights in the United States, Wyeth-Ayerst Laboratories, has established what to us is an unconscionable pricing structure. Levonorgestrel, developed by the company in the early 1960s and used in oral contraceptives for years, was donated to the Population Council for the development of the system. All other costs of the 25-year development phase was covered by public-sector funding (from the U.S. government and from a number of private foundations).

Though the company did have both training and marketing costs, these simply do not justify the current pricing structure—particularly because no public-sector pricing was made available. The creation of a "foundation" to provide Norplant kits for

individual women proven to be of need is a token solution, limited in amount and difficult for clinics and patients. Each kit must be ordered individually, thus not allowing the clinic to stockpile a small supply so as to be able to respond when a woman requests the method. We urge that pressure be brought to bear on Wyeth to change their current policy and make this method as readily available to the poor as it will be to the better off—but, as above, available only for voluntary use, with full informed consent.

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ISSUES IN EVALUATING NORPLANT

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Introduction

Norplant® is an innovative addition to the array of contraceptive methods available in the United States. It is the first truly new method of contraception marketed for widespread use in the United States in the last two decades. Norplant is being introduced in the United States in a time period that differs socially, politically, and scientifically from the period when oral contraceptives and IUDs were introduced. These differences dictate an approach to evaluation that is more careful and more comprehensive than were evaluations of oral contraceptives and the IUD. Advances in the methodology of evaluation allow evaluations that are more informed.

This paper will do three things. First, it will sketch the background of evaluations of other contraceptives introduced in the United States, describe the problems with these evaluations, and delineate the lessons to be learned from past experience. Second, it will review broadly what appears to be known based on evaluations of Norplant that are ongoing here and in other countries and describe evaluations that are in progress here and in

other countries. Third, it will describe the components of a comprehensive program of evaluation, and, for each component, it will identify specific questions that need to be addressed for Norplant with a high priority.

Background and Lessons

Oral contraceptives were first marketed for use as contraceptives in the United States in 1960. At that time, they had been evaluated in several field trials, but the total number of women who had used them was probably not more than several thousand. Intrauterine contraceptive devices (IUDs) were first marketed in the United States at a time when marketing of medical devices was not subject to review and approval by any federal agency. It is difficult to reconstruct the number of women who had used IUDs at the time that they were marketed, but this number was probably also not more than several thousand.

There was no formal plan for evaluating either oral contraceptives or IUDs at the time these methods were introduced in the U.S. market. In fact, the recognition that drugs and devices should be carefully scrutinized to identify unexpected effects was not widespread. The notion of "postmarketing surveillance," which is defined to be the systematic evaluation of new drugs and devices after their approval for marketing, had not yet evolved. The need for comprehensive evaluation of these methods of fertility control was a concept not in the fore, at least for funding agencies.

The lack of a formal plan for evaluation cannot be seen as a failure of a specific individual or group of individuals. It did, however, have unfortunate consequences. Most important, the growth of knowledge about many of the noncontraceptive health effects of oral contraceptives and IUDs was slow and haphazard. The haphazardness in the accumulation of knowledge meant that anecdote and innuendo took the place of information.

For example, the observation that some women on oral contraceptives suffered strokes and venous thrombosis was made

in reports of cases to drug regulatory agencies and to medical journals. The importance of these anecdotal reports and the validity of a purported association with use of oral contraceptives was essentially impossible to evaluate in the absence of data on the prevalence of use of oral contraceptives and the incidence of stroke and venous thrombosis in healthy women. For several years after these case reports, discussions of the possibility of an association were characterized by several things. First, physicians and many scientists were incredulous, because precedent for an effect of exogenous hormones on stroke and thrombosis was absent and because clotting abnormalities in oral contraceptive users could not be demonstrated with laboratory tests then available. Second, oral contraceptive users were fearful because of the absence of knowledge. Last, because there were no good studies, poorly conducted studies were given enormous media play. The public, especially women using oral contraceptives, was put on a roller coaster of constantly changing opinion based on constantly changing pseudofact. It was not until the mid- and late 1960s that real data on these issues became available.

The attempt to unravel the truth about the association of IUDs with pelvic inflammatory disease was no less haphazard and no less dominated by rapidly polarized opinions, an early dearth of good data, and media-driven hysteria. The question of an association of IUDs with pelvic inflammatory disease remains clouded to this day, over 25 years after the modern IUD was developed.

The health evaluations of oral contraceptives and IUDs that were done even well into the 1970s were often narrowly framed. They focused prominently on identifying adverse physical effects on health. The noncontraceptive benefits of oral contraceptives, in particular, were ignored to a considerable extent even in the 1970s. The explicit weighing of health risk and health benefits, including the benefit from avoiding childbirth, was a latecomer to discussions about both oral contraceptives and IUDs. It was not until the late 1970s that a balanced view of the health risks and health benefits of contraceptives was presented to the public.

The societal effects of the revolution in fertility control brought about by modern methods of fertility control, especially for women, is evident everywhere, yet little evaluated.

Even today, our knowledge of the mental health effects of the various currently available methods of fertility control and of fertility control per se is limited. The societal effects of the revolution in fertility control brought about by modern methods of fertility control, especially for women, is evident everywhere, yet little evaluated.

Experience with oral contraceptives and the IUD teaches us that evaluation should be proactive, explicit, comprehensive, and broadly focused. Evaluation should be multidisciplinary and multifaceted.

Status of Norplant Knowledge and Ongoing or Planned Evaluations

Status of Knowledge

The number of women who have already successfully used Norplant, at least 280,000,[1] is much greater than was the number of women who had used oral contraceptives when they were introduced into the United States in 1960. Norplant has been evaluated in more than 44 countries outside the United States[1] as well as in preintroduction clinical trials in the United States. Experience abroad and in preintroduction trials in the United States has gathered information that documents the acceptability of Norplant to women and physicians, the feasibility of introducing Norplant into national family planning programs, the high effectiveness of Norplant, and the lack of major short-term adverse effects. Because Norplant has been used by so many women here and abroad, it seems highly unlikely that surprising and serious adverse health effects will come to light with early widespread use

of the method in the United States, as they did when oral contraceptives were first marketed.

Moreover, Norplant uses a drug, levonorgestrel, that has been used widely in oral contraceptives without documented special problems. Progestin-only contraceptives in forms other than Norplant (such as the minipill and injectable DMPA) have also been used, although not on a widespread basis except in a few settings. The experience with levonorgestrel in other forms and with other progestin-only contraceptives provides a backdrop of information that allows greater reassurance about the safety of Norplant than was possible about oral contraceptives when they were first introduced.

It would, however, be a mistake to assume that there is a large published knowledge base for Norplant. A search of Medline for the period 1980–1991 revealed only 130 (118 English-language) publications that used the term *Norplant* in the title or abstract. These publications deal mostly with effectiveness, acceptability, and short-term adverse effects of the method, such as infection at the insertion site. However, at least one published study on the effect of Norplant exists for each of the following physiologic parameters: lipids, carbohydrate metabolism, hemoglobin, ferritin, hemostasis, prolactin, cortisol, and thyroid hormone.

Norplant is distinguished from other methods in several important ways. It is a method potentially subject to involuntarism because of the difficulty of self-removal after insertion. The method requires a fairly high level of technical skill in both insertion and removal. The method is expensive. Each of these unique traits has implications for recommendations about evaluation.

Ongoing and Planned Evaluations

In many places, follow-up of women using Norplant continues. These studies will provide information on the long-term effectiveness and discontinuation rates of Norplant and on problems that may be encountered with removal.

Under joint sponsorship and with involvement of the World Health Organization, the Population Council, and Family Health International, a cohort study involving 8,000 Norplant accepters and a comparison group of 8,000 women undergoing sterilization is underway in eight countries (Bangladesh, Chile, China, Colombia, Egypt, Indonesia, Sri Lanka, and Thailand). This study aims to ascertain short- and medium-term side effects of Norplant that might not have been detected in preregistration trials. Women choosing Norplant and sterilized women will be followed for five years with six-monthly interviews and, if needed, medical examinations. Occurrence of hospitalization and of death will be ascertained and then compared between Norplant users and women who have been sterilized.

The state of Florida has plans to initiate a study that will evaluate Norplant in the context of a demonstration program that will make it available free to low-income, high-risk women in selected counties in the state. Eligible to receive Norplant in the Florida program will be poor women aged 15–34 who are defined as high risk because of use of alcohol or drugs, infection with syphilis or HIV, or violent family environment, or because of diabetes, pyelonephritis, hypertension, or multiparity and requesting sterilization at age less than 21. Approximately 3,700 of these high-risk women will be enrolled in this study along with a comparison group comprising the same number of high-risk women who seek Norplant but cannot be offered Norplant because of lack of funds. The evaluation will assess attitudes toward Norplant, removal rates, and failure rates; characteristics of women likely to accept and continue Norplant as a method of fertility control; and the cost-effectiveness of Norplant in comparison with other methods of contraception.

The Demographic and Behavioral Science Branch of the National Institutes of Health has issued a request for applications for studies to investigate the decision process leading to consideration, adoption, and discontinuation of Norplant and the incidence and prevalence of side effects and their effect on decisions to

A Comprehensive Evaluation of Norplant

A comprehensive evaluation of Norplant will include four components, which are listed in Table 1. Evaluation must consider carefully whether Norplant is reaching those who want it and is being used in the ways envisioned, including most importantly whether it is being used coercively. The effectiveness of Norplant in the United States must be evaluated. Some of the noncontraceptive effects of Norplant on health need further evaluation, especially as long-term use accumulates. Last, the cost of Norplant and its cost-effectiveness in relation to alternatives must be considered.

continue or discontinue use. Several follow-up studies comparing accepters of Norplant with users of other contraceptive methods are likely to be funded under this solicitation.

Plan of Comprehensive Evaluation

Use as Envisioned

Many consider that Norplant will be most "suitable" for women who want reversible, long-term contraception who are opposed to surgery or who cannot use other forms of contraception, women who require long-term contraception that does not require regular compliance, and women in whom estrogen is contraindicated.[2] However, this conference highlights the importance of making Norplant widely available and allowing for free and independent choice of the method by well-informed consumers. Thus, the vision of Norplant as a highly effective, *voluntary*, reversible form of contraception that is widely available to women in need must supplant the vision of Norplant as a method that should be "targeted" to certain populations based on the values of

Table 1. Components of a Comprehensive Evaluation of Norplant

- Is Norplant available to those who want to use it? Is Norplant being used in the ways envisioned?
- How effective is Norplant in the United States?
- What are the noncontraceptive effects of Norplant on health?
- How much does Norplant cost? What are the costs of Norplant relative to its benefits and its alternatives?

program planners. Within this framework, it is critical to evaluate whether Norplant is being used in accordance with the vision of it as a method that allows women more and better contraceptive choices.

The problems of coerced use of Norplant have appropriately figured prominently in this conference. These discussions lead to the conclusion that the most important immediate issue in evaluation of Norplant probably is ongoing evaluation of the existence of coercion in the use of Norplant and of policies, both direct and indirect, that foster and allow coercive use.

Presuming there will be much demand for Norplant, it is also very important to evaluate the ability of the medical care system to meet this demand and to identify barriers to use among those who desire the method? Will all suitably qualified providers be able to offer the method. Will issues of "turf" inappropriately compromise widespread availability of the method? Will family physicians, for example, provide this service? Specific critical questions in this topic area are given in Table 2.

Table 2. Important Questions Related to Program Use to Be Addressed in a Comprehensive Evaluation

Is Norplant available to women who want to use it?

Is Norplant being used in the ways envisioned?

Women

- Who uses Norplant?
- What affects the choice of Norplant?
- Do Norplant users understand the method?
- Is there coercion in the use of Norplant, either direct or indirect?

Providers

- Do issues of "turf" compromise the widespread availability of Norplant?
- Is the training adequate to assure high-quality service and a low rate of complications?

Program

- How does provision of Norplant affect the availability of other family planning methods?

Table 3. Important Questions Related to Effectiveness to Be Addressed in a Comprehensive Evaluation

How effective is Norplant in the United States?

- What is the continuation rate for Norplant in the United States?
- What are the reasons for discontinuation, and how do these differ from those of women in other settings?

Effectiveness

Norplant has very high theoretical effectiveness, but its use effectiveness will be dependent on continuation. Continuation is likely to be affected by the acceptability or lack of acceptability of the irregular patterns of bleeding that accompany use of the method, particularly in the first year of use. Women in the United States, who have access to a variety of other methods of fertility control, may be less willing to tolerate the minor bleeding effects of Norplant than women in countries where alternatives are less available. Even though effectiveness has been studied elsewhere, it is critical that it be defined for populations of users outside the highly structured environment of the preintroduction trial. Some specific questions are listed in Table 3.

Noncontraceptive Effects on Health

Experience with oral contraceptives and, to some extent, with injectables provides a frame of reference for deciding what adverse and what beneficial effects should be the focus of evaluation in users of Norplant. Table 4 lists the diseases and conditions for which oral contraceptive use has been shown to have a definite

Table 4. Conditions Associated with Definite or Putative Increase in Risk in Oral Contraceptive Users

- thrombotic stroke
- venous thromboembolism
- acute myocardial infarction
- breast cancer
- cervical cancer

or putative adverse effect.[3] Table 5 shows the diseases and conditions for which oral contraceptives have been shown to have a beneficial effect.[3] Among these conditions, six are of particular interest for Norplant (Table 6).

First, the continuing uncertainty about the effect of oral contraceptives on breast cancer.[4] The importance of breast cancer in the United States as a disease affecting women dictates that breast cancer be high on the agenda for evaluation.

Second, oral contraceptive use decreases the risk of ovarian cancer.[5] The mechanism for the effect of oral contraceptives on ovarian cancer is not known with certainty, but suppression of ovulation is considered to be the most likely explanation. Use of DMPA as an injectable contraceptive does not decrease the risk of ovarian cancer,[6] even though it suppresses ovulation. Because Norplant suppresses ovulation in at least some cycles, it seems possible that it may decrease the risk of ovarian cancer. The possibility of this effect as a benefit of Norplant should also be a high priority on the agenda for evaluation because ovarian cancer is an important cause of cancer morbidity and mortality in the United States.

Table 5. Conditions Associated with Definite or Putative Decrease in Risk in Oral Contraceptive Users

- ovarian cancer
- endometrial cancer
- pelvic inflammatory disease
- iron deficiency anemia
- benign breast disease
- functional ovarian cysts
- menstrual problems

Oral contraceptive use also decreases the risk of endometrial cancer,[5] most likely by causing uterine atrophy. DMPA has a similar association with a lower risk of endometrial cancer.[7] Although the public health effect of a lowering in the risk of endometrial cancer is less than the public health implications of a lowering of the risk of ovarian cancer, documenting the similarity or lack of similarity of association with Norplant is nonetheless an important goal.

The effects of Norplant on these cancers, if indeed there are effects, will certainly not be immediate effects. An evaluation of these cancers in Norplant users should be planned for a time in the future when a sufficiently large percentage of U.S. women has used Norplant so that the study can be done within a reasonable budget. Table 7 shows the number of cases of a disease that would

Table 6. Noncontraceptive Health Effects with a Priority for Evaluation

- What is the risk of breast cancer in users of Norplant?
- Does Norplant reduce the risk of ovarian cancer?
- Does Norplant reduce the risk of endometrial cancer?
- Does Norplant reduce the risk of pelvic inflammatory disease?
- Does Norplant affect the time that it takes to become pregnant and the ultimate likelihood of becoming pregnant after use is discontinued?
- What proportion of pregnancies with Norplant are ectopic pregnancies?
- What is the effect of Norplant on libido, sexual behavior, and a sense of well-being?

be required in a case-control study with three controls per case to rule out a doubling in risk (or a halving of risk) for several estimates of the prevalence of long-term use (four-plus years) of Norplant. At prevalences less than 4 percent, the number of cases needed to rule out a twofold increase in risk, or to establish a halving in risk, is very high. For this reason, evaluations of these cancers in Norplant users cannot reasonably be expected until the twenty-first century.

Oral contraceptives decrease the risk of pelvic inflammatory disease.[8] It is believed that they do so by changing the cervical mucus and by decreasing the motility of the fallopian tube, thus

Table 7. Number of Cases of Breast Cancer Needed to Detect a Twofold Difference in Risk for Several Estimates of Prevalence of Use[1,2]

Prevalence of Use	Number of Cases Needed
0.01	1977
0.02	1010
0.03	688
0.04	527
0.05	430
0.08	287
0.10	239

1. Assuming a study design with 3 controls per case.

2. At alpha=0.05, two-tails; beta=0.90.

altering the likelihood that a lower genital tract infection will ascend. Published information on DMPA and pelvic inflammatory disease is not available. Because Norplant is likely to be used in women who are otherwise at high risk of PID and because it may attract at least some women who would otherwise be protected from PID by use of oral contraceptives, assessing the effect of Norplant on PID is also a high priority for evaluation. This question can be answered more easily and in less time than the question of Norplant and cancer; for this question, a prospective cohort study might be the more suitable study design.

Table 8. Sexually Transmitted Pathogens of Interest in Relation to Norplant

Nonviral

- gonorrhea
- syphilis
- trichomonas
- monilia
- chlamydia

Viral

- HIV
- herpes

The relationship between use of Norplant and other sexually transmitted pathogens (Table 8) also will be of interest, particularly the effect of the method on the likelihood of transmission of HIV. This latter question would require very large numbers of subjects, because of the relatively low likelihood of exposure in U.S. populations. Other methodologic problems inherent in the nonexperimental study of contraceptive use and sexually transmitted diseases are liable to make evaluations difficult to carry out and very expensive, although interest in their results is unquestionably high.

There is information on return to fertility after discontinuation of Norplant, but this information is quite limited. Dr. Sivin has

mentioned some data on this topic that will be published soon, and these data are of great interest. Notwithstanding the existence of studies elsewhere, additional studies that establish with certainty that return to fertility and eventual success at achieving pregnancy are not affected by Norplant are important. Such studies probably will not be initiated in the United States for several years, because the majority of women choosing Norplant now will likely be beginning use with the intention of using it for five years.

Norplant is a highly effective contraceptive, and there are few pregnancies among users. However, Norplant does not completely suppress ovulation. The question of whether the pregnancies that occur in Norplant users are more likely to be ectopic is a legitimate question and one that should be a priority for research.

Evaluation of Norplant should also include evaluation of its effects on libido, sexual behavior, and sense of well-being. These issues have been much neglected in the study of other fertility control methods and may be more important determinants of use and discontinuation than is generally recognized.

The possibility of doing a prospective cohort study of Norplant users and a comparison group of women using other forms of contraception, such as sterilized women, IUD users, or users of oral contraceptives, modeled after the study by the World Health Organization, the Population Council, and Family Health International should be considered. The aim of such a study would be to assess short-term effects, discontinuation, and the overall risk/benefit of the method when compared with other methods, because the number of women who would need to be studied to address questions about breast cancer, ovarian cancer, endometrial cancer, and cardiovascular disease is large (Table 9). The cost of large cohort studies of contraception done in the United States tends to be very high, and studies in the specific areas described above are probably of higher priority than a cohort study.

Table 9. Number of Norplant Users Aged 35–44 Needed in a Cohort Study Designed to Detect a Twofold Difference in Risk[1,2]

Disease	Average Incidence[3]	Follow-up 5 years	Follow-up 10 years
acute MI	0.20	17,800	8,900
thrombotic stroke	0.06	59,000	29,500
venous thrombosis	0.15	23,700	11,800
breast cancer	0.54	6,600	3,300
ovarian cancer	0.14	25,400	12,700
endometrial cancer	0.08	44,500	22,250

1. Assuming a comparison group of equal size.

2. Alpha=0.05, one-tail; beta=0.20.

3. Per 1,000 women-years based on incidence in the Walnut Creek Contraceptive Drug Study.

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NEW CONTRACEPTIVE TECHNOLOGIES

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Norplant® is the first of many long-acting contraceptives expected on the U.S. market in the coming 10 years. How does it fit into the broader contraceptive picture? How important will it be in a decade, when other advances in contraceptives are available?

Dr. Gary S. Grubb, Associate Medical Director of the Clinical Trials Division of the Family Health International, took a hypothetical leap 10 years into the future, and looks backs at new contraceptive technologies of the 1990s. This is a fictional account, based on what is already in development or use abroad, about innovations Americans can expect in contraceptives this decade.

Introduction

As we look back in 2000 as the 1990s have just ended, we see that contraceptive choices expanded in the United States after a decade of constriction of choices. The 1980s discouraged the development of new contraceptive technologies primarily because of concerns about product liability litigation.[1] This problem almost removed intrauterine contraceptive devices (IUDs) from the United States. It threatened the production of spermicides, and

it discouraged U.S. manufacturers from further research and development in the area. These events led to claims that the United States was regressing in contraceptive choices, and there were multiple conferences and calls for reform of product liability laws. With a new IUD and the imminent approval of Norplant in the late 1980s, the tide of contraceptive development seemed to be turning toward increasing of options. U.S. manufacturers continued to look for companies overseas to develop new contraceptives and then license them for distribution in the United States. However, the long-term outlook for research in the United States was stimulated in 1991 by the funding by the National Institutes of Health of two centers to develop new contraceptives, particularly vaccines.

Though the 1990s started off with the introduction of Norplant, the rest of the decade saw many other long-acting steroid contraceptives introduced that had a shorter duration of action than Norplant. Clinicians required much less training for providing these methods compared to the training needed for Norplant insertion and removal. Because of their shorter duration of action and improving technology, the later long-acting contraceptive systems cost less than Norplant to initially purchase, but the cost per year of use (if used to the maximal duration of action) was higher than for Norplant.

Norplant Introduction

When Norplant was approved in the United States in August 1990, it was hailed as the first "new" contraceptive since oral contraceptives were introduced in the early 1960s. In fact, there had been several new contraceptives introduced in the interim, including the cervical cap and the vaginal sponge. There had been wide international experience with Norplant for ten years prior to its approval in the United States. Despite its wide acceptability and success overseas, the future of Norplant in the United States was uncertain even at the time of its introduction. Pharmaceutical companies estimated that the market for long-acting

steroid contraceptives in the United States would be about 1–2 percent of the private sector and possibly 3–5 percent of the public sector. The acceptance of Norplant in its first year marketed in the United States was far beyond the expectations of Wyeth-Ayerst, the distributor of Norplant in the United States. Waiting lists for women to receive Norplant persisted well into the second year of its availability.

Clinicians also gained expertise in screening potential Norplant users by having them use other progestin methods.

Clinicians gained valuable experience with Norplant that would help in the later provision and acceptance of other long-acting steroid contraceptives. Experience with Norplant also improved the ability of clinicians and their staffs to effectively counsel women on the expected side effects and how to cope with them when they occurred. When progestin-related effects did occur, providers learned how to treat common side effects, such as irregular menstrual bleeding, with safe but effective therapies. Clinicians also gained expertise in screening potential Norplant users by having them use other progestin methods, such as progestin-o9nly oral contraceptives or depo-medroxyprogesterone acetate (DMPA), to see how the women would tolerate irregular menstrual bleeding.

Contraceptives Introduced in the Early 1990s

New Progestin-Containing Oral Contraceptives

Oral contraceptives (OCs) containing third-generation progestins had been available in Europe for over five years before being marketed in the United States. The three progestins, desogestrel, gestodene, and norgestimate, were combined with an estrogen in both monophasic and triphasic OCs. These were an improvement over existing OCs primarily because they had

Norplant was the first compliance-free, temporary method available for women who were not candidates for IUDs.

much less effect on blood cholesterol levels. The U.S. companies marketing the OCs put a good deal of effort into drawing attention to these new products in the early 1990s; however, the differences in safety and effectiveness between the OCs with the three new progestins were marginal—but marketable.

Depo-Provera®

In response to several large epidemiologic studies of depot medroxyprogesterone acetate (DMPA) which showed no clinical evidence of carcinogenicity, the FDA encouraged the manufacturer of Depo-Provera to resubmit the drug for approval as a contraceptive. After approval was given, DMPA was used as a steroid contraceptive intermediate in duration of action and incidence of intermenstrual bleeding between OCs and Norplant. The avoidance of a high initial cost for a medium-acting contraceptive was attractive to individuals and third-party payers unsure about the duration of use of a long-acting method like Norplant. The prevalence of use of DMPA eventually approximated the prevalence of Norplant.

Female Condoms

Norplant was the first compliance-free, temporary method available for women who were not candidates for IUDs, particularly women who were not in a stable sexual relationship. For many of these women, concern about sexually transmitted diseases (STDs) was of paramount concern to pregnancy protection; therefore, condoms were still needed as the preferred preventive for STD transmission. Spermicides used alone or with a diaphragm were not considered as effective as condoms to prevent STDs and particularly to prevent HIV transmission. To provide an additional option and allow women to have more control over STD

prevention, female condoms were introduced in the early 1990s. The female condoms are large, thin, (usually) plastic cylinders about 6 inches long that resemble a large male condom covering most of the vulva and extending to the cervix. The closed end of the female condom is inserted in the vagina like a diaphragm, and the open end remains outside the vagina. Although a female condom is more expensive than a male condom, it provided the first opportunity to women to have control over a reliable means of preventing the transmission of STDs.

Plastic Condoms

The use of condoms increased markedly in the late 1980s, spurred by concern about STDs and AIDS and by more public education encouraging condom use. However, people who had a personal experience with condom breakage or heard stories about the consequences of condom breakage wanted a more reliable condom. In the early to mid-1990s, several types of stronger condoms made from different kinds of plastics were marketed. The plastic types felt almost as soft and pliable as the latex condoms. Some of these plastic condoms were loose-fitting (like natural skin condoms) except at the base, so the condom would not slip off. Couples chose to use latex, natural skin, or plastic condoms based on personal preference (e.g., penile sensitivity) and the degree of their concern about breakage.

Sterilization

It had been over 15 years since the last tubal sterilization device had been introduced when the Filshie Clip was approved in the early 1990s. This small metal clip with a plastic lining occluded only 3 mm of the fallopian tube. The only other kind of tubal sterilization clip that had been marketed previously, the Hulka Clip. had not been widely used[2] because application of the clip to the tube was somewhat more difficult than were procedures for other methods of sterilization.

The advantage of occluding a small portion of the fallopian tube is that the chances for successful reversal of the sterilization are

improved. The primary limitation to a successful reconnecting of a ligated or occluded fallopian tube had usually been an insufficient length of healthy tube to sew together. Though physicians continued to counsel women that the sterilization would be irreversible, the improving skill of microsurgeons (who did the sterilization reversal) and the use of the tubal sterilization clips improved the success rates for sterilization reversal. For women wanting no more children who were vacillating between continuing temporary contraception (including Norplant) and having a sterilization, the increased chance for reversal sometimes helped their decision to have a sterilization with a clip device.

Other Implants

By the time the first accepters of Norplant in the United States had completed five years of use and were ready for a second set, the Norplant II® implants were available.[3] The Norplant II implants now can be used for five years but were initially approved for three years of use until more data became available. The Norplant II was an improvement over the six-capsule Norplant system because the Norplant II has only two rods, which are therefore easier to insert and remove. Clinicians had a little more difficulty locating the Norplant II implants for removal, but their skill in inserting Norplant gained through years of experience improved the ease of Norplant II removals. Women also liked having Norplant II implants because they were less likely to be seen or felt.

Following the introduction of Norplant II, a thinner, single-capsule subdermal implant was marketed in the United States. It releases the progestin desogestrel and lasts two years. Desogestrel was one of the new progestins introduced in the United States in the early 1990s as an OC. By that time, desogestrel OCs had been the most successfully selling OCs in Europe for many years, in part because they did not cause adverse changes in women's blood cholesterol levels. Before its introduction in the United States, the desogestrel implant had been marketed in Europe as Implanon.®[4]

In the mid-1990s, an intrauterine implant was introduced that was derived from the Norplant II system.

The small differences between Norplant II and the desogestrel implant in insertion and removal were usually not deciding factors for women deciding which one to use. Because Norplant II lasts five years and the desogestrel implant lasts two years, the latter was used more as a birth-spacing method. Its shorter "life span" also meant the up-front cost was less than for Norplant II. The two products therefore tended to be used by women with different contraceptive needs without direct competition for the same market. The small reductions in the cost of the two products over the rest of the decade was due more to increasing concerns about rising health care costs than to price competition between the two products.

In the mid-1990s, an intrauterine implant was introduced that was derived from the Norplant II system. With the incorporation of a levonorgestrel-releasing rod into the stem of an IUD, a low level of steroid is released, and the intrauterine implant is replaced after seven years of use.[5] Although it was first marketed in the early 1990s in Europe as the Levo-Nova® IUD, the term *intrauterine implant* is a more apt term than *intrauterine device* for this contraceptive method. This is because the local effects of the steroid on thinning the endometrium and thickening the cervical mucus are more important in determining its clinical performance than the plastic "device" part of the contraceptive. Compared with IUD users, who had increased menstrual bleeding and cramping, intrauterine implant users had less than the usual amount of bleeding and cramping they had before insertion of the intrauterine implant. The thickened cervical mucus theoretically could prevent STDs such as pelvic inflammatory disease (PID), but the clinical evidence to support this was not strong.[5] Therefore women who were not in a mutually monogamous relationship were not prescribed the intrauterine implant, in part because of concerns about litigation.

The intrauterine implant is easier to insert and remove than a subdermal implant, it costs about the same as IUDs on the market, and it lasts at least two years longer. This longer period of use was attractive to women who wanted no more children. As the older of these women became perimenopausal and were given estrogen replacement for menopausal symptoms, they began using the implant as a source of a progestin delivered most effectively by direct contact with the endometrium. The progestin prevents the overgrowth of endometrium (sometimes leading to endometrial cancer) that can occur with estrogen replacement.

IUDs

The copper IUD marketed in 1988 (after all but one IUD was removed from the market by the manufacturers) was slowly accepted by U.S. women in the late 1980s and early 1990s. It was so effective that it was difficult to develop an IUD with a significantly lower failure rate. Other IUDs that were introduced tried to avoid some of the side effects of existing IUDs, notably the increased menstrual bleeding and cramping. Previous IUDs had tried to reduce these side effects by making IUDs smaller, less rigid, and conforming more closely to the shape of the uterine cavity, thereby limiting contact with the endometrium.

To create an IUD that would minimally disturb the endometrium, a series of six copper "sleeves" (i.e., hollow cylinders) were strung together as a flexible tube on a nylon string.[6] The top part of the string was inserted into the top of the uterine wall, and the copper sleeves were freely suspended in the uterine cavity. Other IUDs were researched that avoided the rigidity of existing IUDs, but the high standard of effectiveness of the existing copper IUDs was difficult to equal.

Contraceptives Introduced in the Late 1990s

In the late 1990s two new types of long-acting steroid contraceptives were marketed that made three significant improvements over the available implants:

1. They avoided the most common problem with the implants, irregular menstrual bleeding.
2. A woman could stop using them whenever she wanted to, without the need for removal by a trained health care provider.
3. They cost less with the initial purchase.

Vaginal Rings

Steroids are absorbed as readily from the vaginal mucosa as from subdermal tissue, so many of the research groups developing subdermal implants also shaped one of the implant capsules into a ring to be worn in the vagina. Several different kinds of these progestin-only vaginal rings were tested beginning in the early 1980s.[7] In later versions of the vaginal rings, a section of the ring was filled with an estrogen to help control irregular menstrual bleeding. The timing of use of the vaginal ring is similar to that of oral contraceptives containing three weeks of active pills and one week of inactive pills. The progestin-estrogen rings are worn for three weeks and then removed for a week to induce menstrual bleeding. The same ring could be used for usually three months. Despite having a lower "up-front" cost than implants, the relatively short "life span" made the vaginal ring one of the least cost-effective of the long-acting steroid contraceptives.

A disadvantage of the vaginal rings was the small risk of dislodging or expelling the vaginal ring, most commonly during defecation. Though the rings could be removed for an hour or two, removal for much longer resulted in a decrease in contraceptive protection. The vaginal rings do not need to be removed during sex or for any other activity.

The vaginal ring appealed to some women because of its convenience of use. Women who wanted regular cycles without having to take an oral contraceptive every day only had to remember to remove and insert the vaginal ring once a month. Women who wanted more immediate control over a long-acting steroid contraceptive than was possible with a subdermal or intrauterine implant also favored the vaginal ring.

Transdermal Contraceptives

Drugs that were absorbed through skin patches became common in the 1980s. Examples of drugs released from patches include nitroglycerin for cardiac pain, an antihistamine for motion sickness, and estrogens for menopausal symptoms. The technology of transdermal delivery of drugs improved in the 1990s, and the patches could be made smaller and less irritating to the skin. In the late 1990s, progestin-estrogen contraceptive patches were introduced. The patch is applied on almost any part of the trunk (to minimize abrading or bending of the patch), and for the longest acting of the patches, each patch lasts a week. Three patches are worn in succession over three weeks, and then a fourth week without a patch allows menses to occur.

A Look Around Us

Many of the contraceptives introduced to the United States in the 1990s were developed in Europe and used in other parts of the world for years before being marketed in the United States. This remains true today in the year 2000 for contraceptives developed by European companies and by nonprofit contraceptive research organizations.

Though the major research groups in the United States submit the contraceptives that they develop for FDA approval, the World Health Organization (WHO) rarely does this with the contraceptives that it develops, partly because of the time and expense involved in satisfying FDA submission criteria. Two of WHO's products, the monthly injectables containing either DMPA or norethindrone enanthate and an estrogen, have been used widely around the world.[8] The monthly injections allow regular menstrual bleeding and have a rapid return of fertility once a women stops having injections. In many parts of the developing world, the injection can be bought over-the-counter as a one-use-only injection device. It can be either self-injected at home or injected by the pharmacist. This means that a clinic visit is often

not necessary for a woman to use an injectable contraceptive. Perhaps the overriding concern for selecting an injectable over other long-acting methods in less developed countries is cost. At less than a dollar per injection, it has a lower initial cost than any other long-acting steroid contraceptive.

Drugs that were absorbed through skin patches became common in the 1980s.

A Look Ahead

The 1990s saw contraceptive choices expand through improvements in available methods and the delivery of steroids via long-acting systems. As we look ahead to the next ten years, we will probably see some new contraceptives that work differently from existing methods.[9]

Oral contraceptives prevent ovulation by disrupting (at one point) a hormonal biofeedback loop that controls hormone release from the ovaries, the pituitary gland, and the brain's hypothalamus. This hormonal biofeedback loop can be disrupted at other points either by blocking the effect of a hormone or hormone-stimulator (with an antagonist) or by inducing lowered production of a hormone or its stimulator (with an agonist). Several of these types of contraceptives should be available within ten years.

The long search for a "male pill" may be fulfilled in some unusual forms. A synthetic testosterone analog released from an injection or implant will gradually stop sperm production in a majority of men. Men will have to have their sperm counts checked for several months to know if their sperm production has ceased. A "vasectomy" procedure that has a high rate of reversibility should make vas sterilization a more popular contraceptive. An injection of liquid silicone into a confined area of the vas hardens to form an intravas plug in a few minutes. The plug can be removed years later,

and a high percentage of men who have it removed have their fertility restored.[10] The male has a biofeedback loop controlling reproductive hormones analogous to the female's. There may be a vaccine developed that induces antibodies against one of the male's hormone-stimulators, thereby preventing sperm production.

The other birth control vaccines in development are for use in women. In the United States, vaccines that cause antibodies to attack sperm or unfertilized eggs are being refined to ensure high effectiveness and safety.[11] Overseas, an anti-hCG vaccine against an essential hormone for the growth of the fertilized egg is in use in a few countries. In a more direct approach to immunocontraception, a vaginal device that releases manufactured antibodies against sperm may soon be available.

Just as when the IUD and oral contraceptives were introduced in the 1960s, we will have to wait to see if there are any unusual but important side effects of the new types of contraceptives introduced in the next ten years. Though the 1900s produced some interesting and useful variations in the existing types of contraceptives, the new types of contraceptives introduced in the first decade of twenty-first century could have a greater impact on contraception for women and men.

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APPENDIX I SAMPLE NORPLANT PROTOCOL

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Sample Norplant Protocol

I. Introduction

Norplant is a continuous release contraceptive system that provides highly effective birth control for up to five years. Because of the cost of the system, it should not be used routinely as a short term contraceptive, that is, when use of the system is anticipated to be less than 2 years. Because continuation rates of Norplant appear to be highly dependent upon detailed counseling and follow-up, clinicians will need to maintain an up-to-date knowledge of the use of this method.

II. Client Selection

A. Norplant is indicated for clients who prefer this method over others and who do not have absolute contraindications as listed in Section IIB. Optimal candidates are women who:

1. Have not yet completed childbearing but desire long-term birth spacing.
2. Have completed childbearing and are considering surgical sterilization, but who want to avoid surgery or an irreversible procedure.
3. Have experienced serious or minor estrogen-related side effects with OC's.
4. Have had problems with episodic (intercourse-related) contraceptives, other hormonal methods, or IUD's.

B. Contraindications:

1. Absolute contraindications:
   a. Active thrombophlebitis or thromboembolic disorders
   b. Undiagnosed abnormal genital bleeding
   c. Known or suspected pregnancy
   d. Active liver disease
   e. Benign or malignant liver tumor
   f. History of known or presently suspected breast cancer
2. Relative contraindications: the following conditions may increase the medical risks for women who use Norplant. If a client has any of the conditions listed below, consultation with a physician is advised and should be documented in the client's chart:
   a. History of heart attack or stroke
   b. History of a clotting or bleeding disorder
   c. History of ectopic pregnancy

d. Migraine headaches
e. Severe endogenous depression
f. Seizure disorder with current use of anticonvulsants
g. Allergy to or intolerance of available local anesthetics.
h. Cardiovascular risk factors; see Appendix A.

III. Pre-Insertion Evaluation
A. Counseling:
1. Counseling and written informational material regarding all available methods of contraception must be provided.
2. Method specific counseling regarding Norplant must include the following topics:
a. General description of the device; duration of action
b. Mechanisms of action
c. Effectiveness rates in comparison with other methods.
d. Comparison of the advantages and disadvantages of Norplant vs. other methods of contraception.
e. Review of side effects with emphasis on common bleeding patterns.
f. Method of insertion and removal, including timing, technique, sensations, and potential complications. Dummy implants should be used to demonstrate the size of the capsules and the placement site of implantation.
g. Indications for Norplant removal, in addition to advice regarding the selection of a medical provider should the client move to another locale.
h. Initial and long-term financial costs, including a comparison to the costs of using other methods for equivalent periods of time.
i. Absence of protection from sexually transmitted diseases and the necessity for the coincident use of a barrier contraceptive, if there is potential exposure to a STD.
j. Concerns regarding the interaction of Norplant and cigarette smoking. This discussion should include a description of the increased risk of cardiovascular complications, such as heart attack and stroke, in

OC users who are over 35 years old and who smoke cigarettes. While it is not yet known whether such an interaction occurs with Norplant, women who use Norplant should be advised not to smoke, but should not be excluded from use.

3. Allow time for a discussion of the client's concerns and questions. Development of realistic expectations is critical if long continuation rates are to be achieved.
4. If the client opts to have Norplant inserted.
   a. Provide reading level and language-appropriate Norplant informational literature.
   b. Supply a copy of the FDA approved manufacturer's written information pamphlet.

B. Consent:
   1. The client must read and sign a written consent for Norplant insertion which will be retained in the medical record. A copy of this form also may be given to the client.

C. History, physical examination, and pap smear are performed in a manner identical to that of a OC user.
   1. If a previously registered client requests Norplant insertion, a completed initial or annual examination and pap smear within the past year represents an adequate data base. Interval historical information must be entered on the Norplant Insertion Record.
   2. If a new client requests Norplant insertion, an initial history, physical exam, and pap smear must be completed and findings recorded.

IV. Insertion and Removal

A. General guidelines:
   1. If the client has not been using continuous contraception in the preceding cycle, insertion should be performed in the first 7 days after the onset of the menses. In this case, contraceptive levels of hormone are reached within 24 hours of insertion.
   2. If the client presently is using a continuous method of contraception (e.g., OC's of IUD), Norplant insertion may be performed at any time of the month. OC's should be continued until the end of the present Pill cycle. If the client has missed any Pills in the present cycle, a negative highly sensitive pregnancy test should

be documented and a back up method used until the present pack is completed. IUD's should be removed with the onset of the next menses.

3. Although not advisable, insertion may be necessary beyond day 7 in a woman who has not used continuous contraception in the present cycle. In this case, a negative highly sensitive pregnancy test must be documented before insertion and a back-up method of contraception used for the next 2 weeks.
4. Postpartum women who are not lactating or women who have undergone therapeutic abortion may have Norplant inserted immediately after completion of the pregnancy. Insertion in postpartum lactating women should be delayed for 6 weeks to allow for the establishment of lactation.

B. Insertion technique (for right handed clinicians; reverse hand instructions if left-handed).
   1. Supplies:
      a. Norplant insertion kit. It is advisable to have one extra kit on site should a capsule become contaminated during insertion and the use of a substitute sterile capsule becomes necessary.
      b. Sterile gloves. Most clinicians prefer to use a specific hand size in order to increase tactile sensitivity rather than using generic "small" or "large" sized gloves.
      c. Skin antiseptic (e.g., Betadine or Hibiclens solution)
      d. Local anesthetic solution:
         1. The "standard" anesthetic agent used is lidocaine 1% solution.
         2. Many clinicians prefer lidocaine 1% with 1:100,000 epinephrine, since it causes local vasoconstriction and may decrease skin bruising.
         3. In order to decrease the burning induced by the anesthetic agent, it may be buffered with 1 meq of sodium bicarbonate per 10 cc. of lidocaine (this combination is unstable and must be discarded if not used within 24 hours).
      e. Optional extra needles (see 4d below): 25 gauge 1" and 18 gauge 1 1/2" needles.

2. The client's non-dominant arm is most appropriate for insertion.
   a. Stabilize the elevate the upper arm relative to the table, so that the surface of the upper arm is at the same level as the chest. This may be done easily with a 2" thick book.
   b. The incision site should be chosen at a point 8–10 cm from the medial epicondyle of the elbow.
   c. Pre-insertion skin marking with a template is very helpful in achieving an optimal insertion pattern. A surgical skin marker must be used to mark the points.
3. Cleanse the skin with an antiseptic to include the insertion field to the level of the elbow.
4. Administer local anesthesia:
   a. Using a 22 gauge needle, raise a skin wheal with 1/2 cc. of anesthetic solution.
   b. Anesthetize the field of insertion with 5 cc of anesthetic. Approximately 3/4 cc. of solution should be placed into each track, with care to deposit the anesthetic track as the needle is being withdrawn.
   c. The location and depth of the channels made by the needle are critical as they are the same used for placement of the Norplant capsules in the subdermal plane.
   d. Some clinicians prefer to use an alternative choice of needles during anesthetic placement:
      1. Since a smaller caliber needle tends to cause less pain at insertion, a 25 gauge needle is used to place the initial skin wheal.
      2. Subsequently, an 18 gauge 1 1/2 inch needle is used for placement of the anesthetic tracks, owing to the observation that a wider anesthetic track may facilitate trocar placement.
5. Make a 2 mm. incision with the scalpel OR use the trocar to puncture the skin.
6. Insert the trocar with the right hand and advance subdermally with the bevel UP and the obturator held in place by the fourth finger. Stop advancement when the second mark (nearest the hub) reaches the incision. The key to accurate subdermal placement is adequate

skin tenting, which is achieved by levering the trocar upwards with 2 fingers under and the thumb on top of the trocar hub.

7. Once fully positioned, remove the obturator from the trocar with the right hand and load one capsule into it. While tenting the bevel of the trocar upwards, replace the obturator, and with gentle pressure advance the capsule to the end of the trocar. Never forcefully push the obturator.
8. Holding the obturator in a stationary position with the right thumb and while levering the trocar upward with the left, withdraw the trocar to the first mark (nearest the bevel), allowing the implant to drop from the tip of the trocar.
9. After reversing hand position, use the right hand to redirect the trocar 15 degrees from the first implant and advance to the second mark (nearest the hub). Simultaneously use the index finger of left hand to laterally retract the previously placed capsule. Repeat this process until all 6 capsules have been placed.
10. Palpate the implantation site and note the distribution of the capsules relative to one another and to the skin incision. All tips should be at least 5 mm above the skin opening.
11. Close the incision with a small steristrip and wrap the insertion site with the pressure dressing included in the insertion kit. This should be left in place overnight and the steristrip left on for 3–4 days. Advise the client to keep the bandage dry for 24 hours. If the area becomes sore, the client may use an ice pack at 20 minute intervals within the first 2–4 hours, and thereafter should use warm moist heat once the pressure dressing has been removed. Limit strenuous exercise for 24 hours after insertion.
12. Complete documentation, including a diagram of the location of the capsules in relation to each other and to the incision site, degree of bruising, and an assessment of client toleration of the procedure. Record the lot number of the implant set in the medical record, on the client's post-insertion instruction booklet or sheet, and in the Norplant insertion log.

13. Provide and review written post-insertion instructions, advise regarding discontinuation of previous contraceptive method, emphasize warnings, and review follow-up plans.

C. Follow-up:
   1. The Norplant user should be advised to return to the clinic in 1 year for an annual exam and pap smear.
   2. Many clinicians also prefer to schedule a 2–3 months post-insertion visit in order to evaluate menstrual patterns and provide ongoing counseling. At this time:
      a. Briefly review interim history for symptoms of intolerance, infection, or expulsion.
      b. Examine insertion site for signs of infection, expulsion, hematoma, or superficial phlebitis.
      c. Record blood pressure.
      d. Review bleeding patterns and inquire about the presence of other side effects.
      e. Provide any necessary follow up reminders.
   3. Clients should be advised to return for episodic visits should any of the following develop:
      a. Arm pain; pus or redness at the insertion site.
      b. Expulsion of an implant
      c. Onset or worsening of episodes of migraine or severe headaches.
      d. Concern for pregnancy; amenorrhea for longer than 6 weeks after experiencing regular cycles.
      e. Heavy or persistent genital bleeding

D. Removal:
   1. When a client requests removal before completion of the five year life-span of Norplant, discuss the user's reason for this decision and provide any necessary counseling.
   2. Removal may be attempted at any time in the cycle, although it is critical to inform the client that she will return to baseline fertility within 24 hours of removal. An alternative method of contraception will be necessary immediately, unless the client is seeking pregnancy or is not sexually active.
   3. Technique:
      a. Palpate the area to identify the location of each capsule.
      b. Inject 3 cc. of local anesthetic under the implant tips.

Never deposit anesthetic over the tips of the capsules, as this will push them deeper and obscure them.

c. Using a #11 scalpel, make a skin incision 3–5 mm long and equidistant from the tips of the capsules.

d. Remove the capsules that are easiest to reach first, using the extrusion technique. If fibrous tissue surrounds the capsule, rub the end with gauze or scrape carefully with a straight mosquito clamp or a #11 scalpel to open.

e. If a capsule cannot be worked toward the incision easily with the index finger and thumb of one hand, introduce curved mosquito forcep (tips up) into the incision and gently dissect the tissue while pushing the capsule toward the incision.

f. Do not take extraordinary measures to remove the last one or two capsules if they are difficult to reach. The client should be advised to return in 4–6 weeks at a time when a clinician most experienced in Norplant removal is available.

g. Once all six of the implants are removed, close the incision with a steri-strip and apply a pressure dressing. Count the capsules for the client and document a complete removal in the medical record.

h. New implants may be inserted through the same incision if requested subsequent to successful use. In this case, the fan-shaped distribution of capsules can be done toward the elbow. If the fibrous capsule is judged to be too thick to accommodate a second insertion at the original site, the opposite arm should be used.

4. Provide and review written post-removal instructions, advise regarding start-up of a new contraceptive method (if desired), and emphasize warnings regarding complications.

V. Management of Side Effects and Complications

A. Irregular bleeding patterns:

1. Irregular bleeding patterns are due to two factors: fluctuation of estrogen levels leading to estrogen withdrawal bleeding and endometrial hypoplasia with consequent breakdown.

2. While 70% of Norplant users will have alteration of bleeding patterns in the first year of use, including possible changes in menstrual spacing, duration, and volume, bleeding patterns tend to regularize after this time.
3. Management:
   a. Obtain interval history, with focus on the possibility of pregnancy or genital tract infection.
   b. Perform a pelvic examination, as indicated, to exclude pregnancy, infection, or an anatomic lesion.
   c. Laboratory tests:
      1. Highly sensitive pregnancy test, if indicated.
      2. If history suggests prolonged or heavy bleeding, perform homatocrit. If <28%, seek physician consultation.
      3. If cervical or upper tract infection is suspected, obtain a cervical gonorrhea culture and a chlamydia test.
   d. If no obvious cause of bleeding is found, reassure the client that the bleeding patterns are not dangerous and may resolve with time.
   e. If intermenstrual bleeding becomes problematic, use:
      1. Ibuprofen 800 mg PO TID for 5 days (OR)
      2. Ethinyl estradiol (Estinyl) 20 mcg or conjugated equine estrogen (Premarin) 2.5 mg. once daily for 21 days.

      Counsel the client that while this regimen may temporarily improve her bleeding pattern, there is a substantial possibility that the irregular pattern will return after discontinuation of treatment.
   f. Women who do not respond to either regimen and who continue to find the bleeding bothersome may require Norplant removal.

B. Possible pregnancy:
   1. While Norplant failures are rare, prompt diagnosis of pregnancy is desirable both to facilitate client decision and to indicate the need for Norplant removal. Women who experience a Norplant failure have a 25% risk of an ectopic pregnancy.

2. Pregnancy is most likely in women who have had regular cycles followed by amenorrhea for >6 weeks and who experience pregnancy symptoms.
3. Management:
   a. Interim history update, focusing on pregnancy symptoms.
   b. Pelvic examination to evaluate uterine softening or enlargement, adnexal tenderness or mass.
   c. Highly sensitive urine pregnancy test.
   d. If the pregnancy test is positive,
      1. Remove the Norplant capsules as soon as possible.
      2. Evaluate for symptoms and signs or ectopic pregnancy; begin work-up or refer immediately if suspected.
   e. If the pregnancy test is negative, counsel and reassure the client that amenorrhea while using Norplant is an expected side effect and not dangerous.

C. Headache:
1. Headache is a relatively common complaint in Norplant users, although not all headaches are necessarily related to the hormone in the device.
2. Obtain a headache history in an attempt to differentiate tension headache from migraine headache. If the headaches seem to be of the tension variety, explain that Norplant removal is unlikely to change the pattern.
3. If the headaches are mild and without neurologic changes, attempt treatment with Ibuprofen or other analgesic.
4. If Ibuprofen fails or neurologic signs are present, consider Norplant removal.

D. Weight change:
1. Weight gain may occur in the Norplant user as a result of the anabolic effect of l-norgestrel and its resultant impact on appetite. Of women who experience weight change, one-third have weight loss.
2. Women with excessive weight gain should be counseled that this may be an effect of the Norplant, but can be controlled with adequate exercise and moderate dietary restriction. Many women notice weight stabilization or improvement with time.

3. If these measures fail and weight gain becomes problematic, Norplant removal may become necessary.

E. Infection or bleeding at insertion site:
   1. Infection and bleeding are rare complications of Norplant use, each seen in fewer than 1% of clients.
   2. When the client returns to the Center for examination, evaluate for acute infection, hematoma, or localized superficial thrombophlebitis. Examination must include temperature and inspection of the insertion site, proximal and distal arm, and axillary lymph nodes.
   3. Bleeding usually can be treated with a steri-strip and reapplication of an elastic bandage to the insertion site.
   4. If the insertion site appears to be infected:
      a. Clean the site with a skin antiseptic (eg, Betadine or Hibiclens.)
      b. Provide a prescription for dicloxacillin or cephalexin 500 mg PO QID for 7 days. Suggest the use of moist warm compresses or a heating pad at home.
      c. Ask the client to return in 3–4 days to evaluate her progress.
      d. If the infection does not appear to be responding, removal of the Norplant by an experienced clinician may be necessary.

F. Expulsion:
   1. Expulsion is a rare complication and is related to infection or placement of a capsule too close to the insertion site.
   2. If a client presents with a partial capsule expulsion, gently remove it with a mosquito forcep. Do not attempt reinsertion of the same capsule.
   3. Clean the area of the incision with antiseptic and close the incision with a steristrip. If bleeding is present, a pressure dressing may be used.
   4. Advise the client to use another method of contraception until a replacement capsule has been inserted.
   5. After the old incision site is well healed and evidence of infection is absent, a replacement capsule must be inserted. A new incision site should be used and a sterile capsule placed at either end of the fan pattern.

VI. Personnel

A. Only clinicians who have been credentialed to insert and remove Norplant should be authorized to perform this procedure.

B. Credentialing:

1. Clinicians are advised to attend a Norplant practicum session which includes didactic training and supervised experience with a model training arm.
2. Once this has been completed, the clinician must be proctored during human insertion(s) by an experienced clinician. Most experts feel that 2 or more proctored insertions are necessary as a requisite to credentialing.
3. When "insertion proctoring" has been completed, a credentialing form should be placed in the clinician's personnel file.
4. Separate credentialing is necessary for Norplant removal. Only clinicians who are credentialed in Norplant insertion and who have been proctored during removal(s) may apply for Norplant removal credentials.

VII. Quality Assurance

A. Storage of Norplant

1. The shelf life of a package of Norplant capsules is two years. Stock must be rotated so that the units with the earliest expiration dates are used first. Expired units or packages which are found to be open before insertion may be returned to the manufacturer for a credit.
2. The Norplant insertion kits must be stored under appropriate conditions and protected from excessive heat, direct sunlight, dirt, and excessive moisture.

B. Because of the unlikely event of a drug recall, the lot number of each Norplant set must be recorded in 3 locations:

1. In the client's medical record
2. In a Norplant insertion log book, which contains the client's name, date of insertion, and Norplant lot number.
3. In the client's copy of the Norplant post-insertion instruction sheet or booklet. She should be advised to keep this information with other valuable documents.

C. If an incident reporting system is used, the following conditions may be used as criteria for generating a report:

1. Hematoma requiring treatment beyond direct pressure, analgesics and local heat.
2. Pregnancy unrecognized at the time of insertion or occurring while the implants are in place.
3. Any Norplant related hospitalization, including ER management of hematoma or surgical management of irregular vaginal bleeding
4. Cardiovascular complications such as stroke, heart attack, thrombophlebitis, or pulmonary embolism.
5. Any event, complication, or deviation from medical protocol that could result in a claim or lawsuit.

C. Audit: appropriate use of Norplant may be monitored in two ways:
   1. Clinician-specific retrospective chart review which includes a sampling of Norplant clients. Some clinics may opt for physician co-signature of the charts of some or all Norplant insertion and removal procedures which are performed by mid-level clinicians.
   2. Focused audit: periodic audit of a sample of Norplant clients, with assessment of the degree of compliance with specified clinical indicators.

Appendix A:

Considerations Regarding Screening for Cardiovascular Disease Risk Factors:

A. While it is well established that Norplant use does not have an adverse effect upon lipoprotein levels or clotting factors, little data exists regarding the impact of Norplant use in women with preexisting cardiovascular disease risk factors and the consequent risk of heart attack. Because Norplant releases much less progestin than OC's and contains no estrogen, it should not be assumed that the cardiovascular risks associated with higher dose OC's necessarily will be seen with Norplant users. However, based upon experience with higher dose oral contraceptives, the following risk factors are synergistic in increasing the short-term risk of a myocardial infarction in combined OC users:
   1. Age greater than 35 years old
   2. Cigarette smoking >10 cigarettes/day
   3. Hypertension (BP >160 systolic, 95 diastolic)

4. Diabetes mellitus or abnormal glucose tolerance
5. Abnormally elevated cholesterol levels

B. Until more long-term clinical experience with Norplant is obtained, some experts believe that screening for cardiovascular risk factors is advisable. Others believe that screening is unnecessary, since they feel that the presence of one or more risk factors will not contraindicate Norplant use. Since there is not a national consensus on this subject, each clinic/provider will need to evaluate this issue and formulate their own individual policy.

C. If cardiovascular risk factor screening is opted, the following represents a widely used approach in screening OC users:
   1. Age, smoking history, and a history of hypertension will be determined during review of the medical history; undetected high blood pressure may be discovered at physical examination.
   2. A client at risk for undetected hypercholesterolemia should have a random cholesterol level performed if she has a:
      a. Previous history of elevated cholesterol
      b. Family history of premature parental death from heart attack or stroke at <55 years old.
   3. A client at risk for undetected diabetes should have a fasting blood sugar performed if she has a:
      a. Personal history of glucose intolerance
      b. Personal history of gestational diabetes
      c. Personal history of glucosuria
      d. Family history of medically-treated diabetes

D. Once risk factor screening is completed, the client's risk profile may be evaluated. Since each risk factor is synergistic (multiplicative), the more risk factors a woman has, the less appropriate she may be as a Norplant candidate.

E. Quality Assurance
   1. Storage of Norplant
      a. Stock must be rotated so that the units with the earliest expiration dates are used first. Expired units or packages which are found to be open before insertion may be returned to the manufacturer for a credit.
      b. The Norplant insertion kits must be stored under appropriate conditions and protected from excessive heat, direct sunlight, dirt, and excessive moisture.

2. Because of the unlikely event of a drug recall, the lot number of each Norplant set must be recorded in 3 locations:
   a. In the client's medical record
   b. In a Norplant insertion log book, which contains the client's name, date of insertion, and Norplant lot number.
   c. In the client's copy of the Norplant post-insertion instruction sheet or booklet. She should be advised to keep this information with other valuable documents.
3. Audit should be performed periodically to insure consistent and appropriate use of Norplant.

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APPENDIX III
PROGRAM

WEDNESDAY, NOVEMBER 20, 1991

7:00 Dinner at Hotel

Drew E. Altman, Ph.D.
Henry J. Kaiser Family Foundation

THURSDAY, NOVEMBER 21, 1991

8:15–9:00 Continental Breakfast at Quadrus

9:00–9:15 **Overview of the Conference**

Mark D. Smith, M.D., M.B.A.
Henry J. Kaiser Family Foundation

9:15–10:15 **Summary of Worldwide Clinical Experience with Norplant**

Irving Sivin, M.A
The Population Council

Philip D. Darney, M.D.
UCSF/San Francisco General Hospital

New Contraceptive Technologies: An Historical Perspective

Gary Grubb, M.D.
Family Health International

10:15–10:30 Break

10:30–11:30 **Access and Minimum Standards of Care**

Mike Policar, M.D.
Planned Parenthood of San Francisco/Alameda

11:30–12:30 **The Economics of Norplant**

Marc W. Deitch, M.D.
Wyeth-Ayerst Laboratories

Cost-effectiveness of Norplant—Comparison with Other Methods of Contraception

Eugene Washington, M.D.
Center for Reproductive Policy, UC-San Francisco

12:30–1:30 Buffet Lunch

1:30–2:00 **The Emerging Regulatory Environment for New Contraceptive Technologies**

Philip A. Corfman, M.D.
Food and Drug Administration

2:00–3:00 **Utilization of Contraceptives by Low-Income Women and Barriers to Care**

Jacqueline D. Forrest, Ph.D.
The Alan Guttmacher Institute

Gail Wyatt, Ph.D.
Neuro-Psychiatric Institute, UCLA

3:00–3:15 Break

3:15–4:30 **Norplant—Double-edged Sword for Low-Income Women and Women of Color?**

Julia Scott
National Black Women's Health Project

Charon Asetoyer
The Native American Women's Health Education Resource Center

Judy Norsigian
Boston Women's Health Book Collective

Long-term Contraceptives and the Threat of Coercion

Allan Rosenfield, M.D.
Columbia University School of Public Health

Janet Benshoof, J.D.
American Civil Liberties Union

5:00–6:00 Social Hour

6:15 Shuttle departs for hotel

FRIDAY, NOVEMBER 22, 1991

7:30–8:30 Continental Breakfast at Quadrus

8:30–9:30 **Critical Issues in Evaluating Norplant in the U.S.**

Diana Pettiti, M.D.
University of California, San Francisco

9:30–10:45 **Case Studies of State Introductions of Norplant**

1. Florida

   Carla Schmidt
   State Health Office/Family Health Service

2. California

   Stephen W. Kessler, M.B.A.
   State of California Department of Health Services

3. North Carolina

   Margie Rose, J.D., M.P.H.
   Division of Maternal and Child Health

10:45–11:15 **Wrap Up and Summary of Conference**

Sarah E. Samuels, Dr.P.H.
Kaiser Family Foundation

11:45 Informal lunch for participants who remain