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Family Planning Digest

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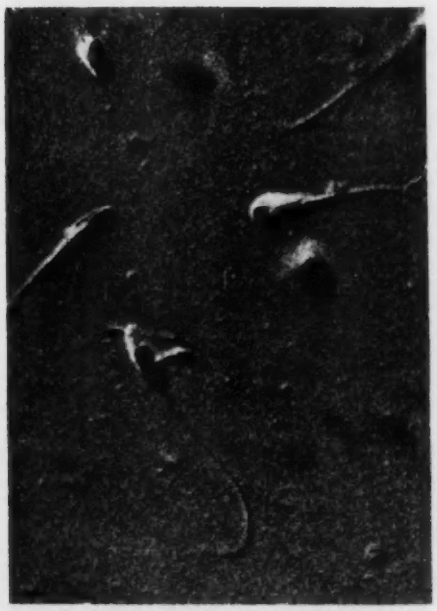
Male Contraception

Combination of Hormones Seems Promising As Male Contraceptive in Human Trials

Reports of a new male contraceptive combining two different hormones and administered experimentally to a small group of men are cautiously optimistic, as they were about earlier animal studies. The approach involves using a combination of a progestogen and testosterone. Each substance has been shown, when administered separately, to suppress sperm production in animals and man; but each, taken by itself in doses sufficient to interfere with gonadal function, has also proven to produce undesirable and even dangerous side effects. Thus, progestogens can cause reversible suppression of sperm production and of hormone production (and, therefore, loss of libido) and, sometimes, overdevelopment of the male mammary glands (gynecomastia). Elevated levels of testosterone cause increase in the weight of the sex glands, may be associated with the development of cancer of the prostate and have also been suspected as a cause of heart attacks in men.



Living human sperm cells, magnified 3,000 times.

In combination, however, it appears that sperm production may be suppressed without the undesirable side effects caused by either drug when taken alone: libido and blood testosterone levels are normal, there is no irreversible testicular damage, and no gynecomastia. The effects of the combined dose appear to be totally reversible.

Human trials, however, have been limited to a very few men. Results are not entirely consistent. No universally effective minimum dosage level has yet been determined. And long-term side effects, if any, have not been investigated.

Human trials carried out in Austria, Brazil and Sweden involve 51 men, and illustrate the difficulties of finding appropriate dose levels and delivery systems. Testosterone, since it is metabolized by the liver if taken orally, must be given either through injection or via small Silastic implants. The progestogen may be delivered orally or by other routes.

Dr. J. Frick, a urologist at the University of Innsbruck, Austria, succeeded in suppressing spermatogenesis in 16 of 37 subjects using a variety of approaches. For all of them, testosterone was given by a Silastic capsule (less than an inch long and one-tenth of an inch in diameter) implanted under the skin on the chest, and containing enough hormone to supply about 45 mcg daily for 13 months. Progestogens were delivered by implant or pill.

In five men, treated only with testosterone, no decrease in sperm count was observed. The same was true for six subjects who received three testosterone implants and four implants of the progestogen, megestrol acetate. One man received an extra progestogen implant, and spermatogenesis was curbed in 10 weeks, without any reported change in libido. Four months after implantation, this

patient remained sperm free. Six weeks after the implants were removed, his sperm count returned to its pretreatment level. Another five subjects were treated with three testosterone implants and 30 mg of megestrol acetate orally each day. In three men, no live sperm were observed after eight weeks, while two subjects had very low sperm counts (one of two million per ml and the other of one million per ml), well below generally accepted fertile levels. One man was observed for a longer period. After five weeks without live sperm, his sperm count began to rise, exceeding pretreatment level 16 weeks after the trial began.

Seven subjects received three testosterone implants and six norethindrone implants and, in addition, took 25 mg of norethindrone orally each day. After 12 weeks, four men had no live sperm in their semen and two had sharply reduced counts, while, one showed only a moderate reduction. Seven older men, aged 62-77, were treated with two testosterone implants and six norethindrone implants. Biopsies 10-12 weeks later demonstrated a considerable reduction in the number of seminiferous tubules showing active sperm production. Finally, six older men received three testosterone and six norethindrone implants, along with 25 mg of norethindrone orally each day for three weeks. After five weeks, five subjects had no live sperm, while the sixth was extremely subfertile, as measured by sperm output.

Dr. Frick noted that even in the cases where spermatogenesis was suppressed, libido was unaffected and the levels of testosterone in the blood plasma were normal during the treatment. "This important finding suggests that it may be possible to devise a male contraceptive method based on hormonal suppression of spermatogenesis combined with testosterone replacement therapy," he noted, although "the entire spectrum of potential toxicity issues need to be thoroughly considered. . . ."

Drs. E. M. Coutinho and J. F. Melo of the Federal University of Bahia, in Brazil, reported a marked reduction in sperm count in eight of 12 men who were treated with testosterone implants plus 50 mg of either norgestrienone, norethindrone, or R2323 (all progestogens) orally twice a week, with no loss of libido or potency. All subjects were normal, healthy men, 35-45 years old, with at least three children. Each subject received two or three testosterone implants and also three or four progestogen implants. No effect was observed until oral progestogen treatment was also started. The addition of oral progestogens caused a cessation of spermatogenesis in the four norgestrienone patients and three of the four R2323 patients (the fourth received no oral therapy). Little effect was seen with the norethindrone patients, however, even when the oral dose was doubled. For one man, the dosage was increased to 50 mg daily. This reduced the sperm count to one million per ml, but treatment was stopped because the subject developed gynecomastia. Two patients on R2323 reported delayed orgasm, two men on norgestrienone reported increased libido; all four on R2323 reported increased weight (2.2-4.4 pounds per month), with smaller increases for the other progestogens.

Drs. Elof D. B. Johansson and Karl-Gosta Nygren of the University Hospital in Uppsala, Sweden, also treated two subjects (only one of whom had testosterone implants) with norethisterone, but only a moderate decrease in sperm count resulted.

The work reported was part of the program of the Population Council's International Committee for Contraceptive Research (ICCR) and the preliminary results appeared in *Contraception*.

While the new approach appears promising, "it should be evident that many issues remain to be investigated before expanded field trials with a male combination method can be initiated," noted Sheldon J. Segal, chairman of the ICCR and director of the Population Council's Biomedical Division. "Identification of the most advantageous progestational and androgenic compounds will be required. The optimal progestin-androgen dosages must be established, and alternate routes of administration require further study."

Animal Trials

Extensive trials on rats of several progestogens in combination with testosterone propionate, another component of the Population Council-supported programs to develop a male contraceptive, were conducted by Charles Terner and Julia MacLaughlin of Boston University's Biological Science Center. Reporting in the *Journal of Reproduction and Fertility*, the investigators noted that they originally tried eight different progestogens (one mg a day, given by injection along with the testosterone), and two, Provera and ethynodiol diacetate, were selected for further trials. The one mg progestogen dose is similar to that in most combination oral contraceptives. Spermatogenesis was prevented, with no effect on the rats' mating behavior. Sperm production returned within a few weeks after treatment was stopped.

With Provera, only 10 mcg of testosterone propionate were needed daily to prevent atrophy of the prostate gland and seminal vesicles (which progestogens tend to cause). With ethynodiol diacetate, which has a slight estrogenic side effect, 100 mcg a day were needed. At autopsy, after at least four weeks of treatment, the section of the epididymis nearest the testis was "virtually free from spermatozoa" in all cases.

Chemical Sterilization

Another approach to permanent male contraception has been taken by two Johns Hopkins researchers, Dr. Coy Freeman, a urologist, and Donald S. Coffey, a pharmacologist, who reported on their work at the annual meeting of the Federation of American Societies for Experimental Biology held in Atlantic City last April. They have successfully sterilized rats by injecting ethyl alcohol and other sclerosing (hardening) agents directly into the vas deferens.

They noted that all 32 rats injected with 50 mcl of a 95 percent ethanol solution in both vasa became sterile, and remained so for 12 months of follow-up. During that time, they were continuously mated, but no offspring were produced. There was "no histological evidence of regeneration or recanalization" of the epithelium lining the vas, the investigators reported.

In the sterilized rats, the vas was scarred and closed for several centimeters. Granular clumps of spermatozoa and sperm fragments were found, similar to those seen after surgical vasectomy in other animals, and the lining of the vas was "completely absent." Rats injected with dilute salt solutions did not become sterile. Trials are under way using other agents, including silver nitrate, formaldehyde, sodium tetradecylsulfate and acetic acid.

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Premarital Sex

Poll Finds Americans Now More Tolerant

Americans have grown increasingly tolerant about premarital sex, according to a Gallup poll taken in August 1973. Fewer than half (48 percent) of all Americans say that sex before marriage is wrong; while 43 percent assert that it is *not* wrong. (The remainder were undecided or did not answer.)

There has been a 20 percent decline in disapproval since 1969, when a Gallup poll showed that 68 percent of Americans believed that sex before marriage was wrong. Increasing tolerance of premarital sex was tied to an increase in approval of birth control education and services to teenagers by Judith Blake, University of California demographer. [See: "Contraceptive Education for All Teens, and Services on Request Favored by Most Adults," *Digest*, Vol. 2, No. 5, p. 4.]

Most of the general trends seen in the 1969 poll remained evident in 1973:

- More women than men found premarital sex wrong in 1969 (74 percent vs. 62 percent) and continued to do so in 1973 (53 percent vs. 42 percent).
- Younger persons disapproved less in both years than did older persons. Thus, 29 percent of those under 30 years disapproved in the 1973 Poll compared with 49 percent in 1969; 44 percent between 30 and 45 years disapproved in 1973, compared with 67 percent in the earlier poll; and 64 percent of those 50 and over disapproved in 1973, compared with 80 percent in 1969.
- While persons with higher education continued to be less likely to disapprove of sex before marriage than those with less education, the largest decline in disapproval was found among those with only a high school education (24 percentage points, compared with 17 percentage points among those with a grade school education and 15 for college-educated persons.)
- Regional differences remained substantial. Southerners disapproved most of premarital sex in both years (78 percent in 1969 and 58 percent in 1973). However, Easterners replaced Westerners as least disapproving. (Sixty-five percent of Easterners disapproved in 1969, compared to 38 percent in 1973; and 55 percent of Westerners disapproved in 1969, compared to 41 percent in 1973.)

Married people, the 1973 poll showed, were almost twice as likely (51 percent) to disapprove of premarital sex than single men and women (27 percent).

The increase in approval of premarital sex has been steady since 1969. In a Gallup survey in that year, 19 percent of white Americans said premarital sex was not wrong, Blake has reported. This figure increased to 30 percent of whites in another Gallup survey taken for Blake in 1972, and to 41 percent of whites in the 1973 survey.

While younger Americans showed much less disapproval of premarital sex than their elders, another Gallup survey shows that they are more conventional than European youth. Twenty-three percent of U.S. youths aged 18-24 said premarital sex should be avoided "under any circumstances," compared to four percent in Sweden, six percent in West Germany, eight percent in Switzerland, 10 percent in France, 14 percent in Britain and 18 percent in Yugoslavia.

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Contraceptive Research

Progestogens Work As Precoital Pill

Recent research suggests that progestogens do not need to be taken continuously to prevent conception, but may work if taken just prior to sexual intercourse.

In an article in the *Journal of Reproduction and Fertility*, Drs. J. Zañartu and S. Manzor of the University of Chile Medical School in Santiago report on preliminary research with three different progestational hormones. The investigators had observed that the effectiveness of progestogen-only minipills seems "to be related to the hour of the day when the tablets are ingested." Taking the pills at midday produced "better effects" than taking them early in the morning, and "results were even better when the dose was taken late in the evening by subjects who usually had intercourse at night."

This apparent increase in contraceptive effectiveness achieved by moving the time of pill taking closer to the time of intercourse led the researchers to investigate the precoital effectiveness of progestogens. Some 136 fertile women participated in the study, all for at least four months. The average incidence of coitus was twice a week.

Forty women took 40 mg doses of retroprogestogen for a total of 305 woman-months of treatment. There were four preganancies during this time. The other two progestogens produced better results during the brief trials. Of the 74 women who took one mg doses of clogestone (407 woman-months of treatment), one became pregnant, and she was uncertain whether she had missed a tablet just before intercourse. Some 13 women took 0.5 mg doses of norgestrienone and nine took 0.7 mg doses of the same hormone, for a combined total of 102 woman-months of treatment. None became pregnant.

"The acceptability of the method was surprising," the investigators commented. "Users reported that it was easier to follow and remember than the daily intake of pills." Of the 55 women who dropped the method in order to become pregnant, 51 conceived in the first two cycles. Nearly two-thirds of the cycles recorded lasted 25 to 35 days. When the pill was used "for more than three to four days a week, the incidence of prolonged irregular cycles, amenorrhea, and/or scanty uterine bleeding increased," however, so women using the method four or more times a week were advised to use another method.

The researchers urged further investigation of the precoital approach.

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Midtrimester Abortion

New Techniques Sought to Reduce High Complication Rate Linked to Late Abortion

Although most women seeking legal termination of pregnancy are doing so in the first trimester when risks to health and life are extremely low, considerable numbers still delay the decision until the second trimester when complications are more frequent and more serious, and mortality rates are from three to 10 times higher. [See: "Mortality, Morbidity in Legal Abortions Drop as Women Learn Early Procedures Safer," *Digest*, Vol. 2, No. 3, 1973, p. 8.] A recent report by Dr. Christopher Tietze and Sarah Lewit on early complications associated with the use of saline, the most common method employed in the United States to terminate second trimester pregnancy, based on data from the Joint Program for the Study of Abortion (JPSA), highlights the problems of late abortion and why investigators are seeking alternative methods which will be both safer and less traumatic.

Analysis of the 14,690 saline abortions performed between July 1, 1970 and June 30, 1971 in the 60 hospitals participating in JPSA shows that complications are associated with one in four of the procedures, and about one in 50 are major in nature. (The complication rate was calculated for the 13,946 patients who did not have preexisting health conditions which might have led to complications and who did not undergo concurrent sterilization.) Among the major JPSA findings were the following:

- The complication rate increased with patient age, from a rate of 20.0 per 100 women for those aged 19 or younger to 30.4 per 100 women for those 30 or older.
- The complication rate increased with parity — from 19.0 for nulliparous women to 34.6 for those with three or more prior births.
- The complication rate decreased with gestational age, dropping from 29.5 for 14 or fewer weeks to 21.2 for 21 weeks or more.
- Private patients had strikingly fewer complications than nonprivate patients, 15.1 compared with 28.9; while inpatients had more complications than outpatients, 24.9 compared with 17.7.
- The complication rate increased as the relative amount of saline instilled increased, and as the time to abortion increased.
- The time to abortion decreased as the amount of saline instilled increased.
- The success rate (on first instillation) decreased as parity and maternal age increased, but rose as gestational age increased; the rate was higher for private patients and inpatients, with the overall success rate for first instillation 94.2 percent. The median time to abortion for successful first instillation was 32.0 hours.

The most common complication was hemorrhage (including bleeding caused by retained placental tissue), which occurred in 14.1 percent of the cases. Pelvic infection was reported for about one woman in 50. The rate of major complications (those involving unintended major surgery, one or more blood transfusions, three or more days of 100.4° F fever, or similar dangerous situations) was 1.7 per 100 women.

[The incidence of hemorrhage may be reduced by surgically removing the placenta within the first hour after delivery of the fetus if the placenta has not been expelled spontaneously, according to a study of 2,170 women who underwent saline abortion at Park East Hospital in New York City. Dr. Gary S. Berger, formerly abortion surveillance officer with the Center for Disease Control and now associated with the International Fertility Research Program of the Carolina Population Center, reported that 2.7 percent of the women hemorrhaged who delivered the placenta and fetus simultaneously, compared to 5.7 percent of those who expelled the placenta later, but within the first hour after delivery. The hemorrhage rate rose to 16.2 percent after one hour. However, he noted in a paper presented at the 1973 meeting of the American Public Health Association in San Francisco, 7.2 percent of those women who had the placenta surgically removed within one hour hemorrhaged — a rate higher than if the placenta were expelled spontaneously within one hour, but lower than if the placenta were retained for a longer period and then expelled.]

Three deaths were reported to JPSA: a 37-year-old woman who developed hypernatremia (excess sodium in the blood) and cerebral edema after instillation, and died 10 days later; a woman treated under an assumed name, as an outpatient in New York City, who never returned after instillation and died the next day of a severe hemorrhage; and a psychiatric institution patient who committed suicide a month after her abortion. "The association of this death with the abortion is highly questionable," the authors said.

Results with Oxytocin

In the hospitals participating in the JPSA study, oxytocin, a hormone which causes the uterus to contract and is used to induce labor, was employed in addition to the saline instillation only if the woman did not abort within a specified length of time (such as 48 hours). But other institutions have begun to use oxytocin regularly from the start of the procedure in order to reduce the time to abortion and the complication rate.

In a series of 5,000 consecutive midtrimester saline abortions performed by Dr. Thomas D. Kerenyi and associates in New York City, between February 1971 and February 1972, the average instillation-abortion time was 25 hours (compared to 32 hours in the JPSA study). The patients received a maximum of 50 milliunits of intravenous oxytocin per minute, administered by slow drip, beginning four to six hours after instillation (except for women with extensive uterine surgery or of high parity, who received no oxytocin stimulation), according to a report in the *American Journal of Obstetrics and Gynecology*.

The failure rate on first instillation was lower in the New York series — where all abortions were done on an inpatient basis— than in JPSA (1.4 percent in the last 1,000 women in the series, for whom a lower oxytocin dose was used, compared with 4.0 for salines performed as an inpatient procedure reported by JPSA) ; only 0.4 percent of these 1,000 women failed to abort after either one or two instillations, compared with 1.8 percent in the JPSA inpatient group. There were no maternal deaths in this series. Dr. Kerenyi attributes this to the slow-drip infusion method used, which avoids the often-fatal complication, hypernatremia. The complication rates in the two series were not markedly different.

A more direct analysis of the effects of oxytocin was performed by Drs. Charles A. Ballard and Edward G. Quilligan of the University of Southern California Medical Center. Some 200 consecutive saline patients were randomly divided into two groups — one receiving 67 milliunits of oxytocin per minute, starting within one to two hours after instillation, the other not receiving oxytocin unless abortion had not occurred within 48 hours. While there was one failure in each group, according to a report in *Obstetrics and Gynecology*, the mean time to abortion for the oxytocin group was 22.1 hours, compared with 37.9 hours for the control group. "There was no difference in the incidence of infection, hemorrhage or patients returning with complications in the two groups," according to the authors, who concluded that addition of oxytocin "does not seem to increase the hazards of the procedure."

The time at which the oxytocin is started has an effect on time to abortion, according to another study. Drs. Niels H. Lauersen and Joseph D. Schulman of the New York Hospital-Cornell Medical Center reported on a study of 682 women in the *American Journal of Obstetrics and Gynecology*. Some 202 patients who received no oxytocin aborted in an average of 35.6 hours after instillation; 221 women who began receiving oxytocin (100 ml per hour) within two hours of instillation aborted in an average of 20.4 hours. The study also demonstrated that the sooner oxytocin treatment was instituted the

shorter the period to abortion. The complication rate was also significantly lower following early oxytocin treatment, and patients receiving it within two hours of instillation had the best record, 15 complications of all varieties, compared with 43 among the no-oxytocin group and 54 in the group who received oxytocin after 24 hours or more.

Adding Laminaria

The addition of laminaria tents for cervical dilatation further shortens time to abortion, according to a report by Drs. Jon H. Lischke and Robert C. Goodlin of the Stanford University School of Medicine in the *American Journal of Obstetrics and Gynecology*. Without laminaria, and beginning oxytocin (50 to 300 milliunits per minute) six hours after instillation or at the onset of uterine cramping, the average time to abortion at the medical center was 23.4 hours. But in the first 100 patients in whom one or two laminaria tents were inserted immediately after instillation, the average time dropped to 17.5 hours. The tents were removed if abortion did not occur within 12 hours to reduce the possibility of infection. [For more on laminaria, see: "Laminaria Tents Dilate Cervix Gently," *Digest*, Vol. 2, No. 5, 1973, p. 7.]

Prostaglandins

Because of the high complication rate associated with saline abortions, researchers are attempting to develop alternative methods for midtrimester abortions. The agents under most intensive study are the prostaglandins, especially prostaglandin E_2 (PGE_2) and prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$). [See: "Prostaglandins: New Birth Control Hope or Headache?" Vol. 1, No. 2, 1972, p. 11.] Several routes of delivery (principally intraamniotic or intravaginal) have been tried, as well as assorted dose schedules, alone or in combination with other agents such as oxytocin, laminaria and urea. While the occasional life-threatening side effects associated with saline appear to be either absent or less common with the prostaglandins, recent research reports indicate that the prostaglandins seem to produce a high rate of incomplete abortions (retained placental tissue) and frequent nausea, vomiting and diarrhea.

Dr. William E. Brenner and his colleagues at the University of North Carolina School of Medicine have studied the use of intraamniotic $PGF_{2\alpha}$ with nine different dose schedules administered to 204 women: three single dose levels, three multiple dose treatments augmented with laminaria, and three multiple treatments alone. The investigators found that as the amount of prostaglandin given in a single dose was increased, the time to abortion decreased significantly. However, about half the abortions were incomplete. With multiple doses in various amounts, even more women aborted in less time, but again, there was a high rate of incomplete abortions. When laminaria was added to the multiple dose schedules, abortion time was further reduced. However, vomiting and diarrhea occurred frequently with prostaglandin administration, whatever the protocol.

Doctors at The John Hopkins Hospital also studied several dose schedules of intraamniotic $PGF_{2\alpha}$ for midtrimester abortion. While almost 95 percent of the 132 women in the group studied aborted, almost 30 percent of these abortions were incomplete, the investigators reported in the *American Journal of Obstetrics and Gynecology*. In addition, 70 percent of the women vomited, 14 percent had a fever of greater than 100°, and two cases of cervical laceration were seen. The researchers concluded that the method "does not appear to offer significant advantage in the areas of safety, convenience or reliability."

Researchers from the University of Colorado Medical Center added oxytocin to a single 15 mg dose of $PGF_{2\alpha}$ along with laminaria, and produced a very low mean time of injection-to-abortion of seven hours and 25 minutes in 20 women. But 30 percent of the patients suffered from repeated episodes of vomiting. The placenta was immediately removed manually in all cases, followed by curettage if there was a possibility of retained tissue.

Dr. Ronald J. Bolognese and his colleagues at the University of Pennsylvania School of Medicine tried 20 mg PGE_2 vaginal suppositories on 64 women (repeated every two to three hours, and augmented with oxytocin after membrane rupture). The average time to abortion, they reported at the 1973 annual meeting of the American College of Obstetricians and Gynecologists, was 11.9 hours, with one failure. But nearly half the abortions (30 of 63) were incomplete, even when oxytocin was used. Fifty-two of the women suffered from vomiting or diarrhea, with repeat episodes in 36 patients; 39 women also had elevated temperatures.

Despite the problems associated with their use, some investigators believe prostaglandins have important potential. Dr. Leon Speroff, of Yale University School of Medicine and a pioneer in the investigation of prostaglandins, writes in a forthcoming book: "The use of prostaglandins for midtrimester abortions has produced results . . . superior to those with hypertonic [saline] solution." He also thinks they are safer.

While these and other studies show that much more work needs to be done before prostaglandins can be used routinely in the United States (as they are now in Britain) for midtrimester abortion, Australian researchers have reported an observation they believe worthy of further investigation. The University of Sydney team, working with intraamniotic $PGF_{2\alpha}$, noted that the time to abortion varies sharply with the time of day at which the injection is given. In a paper in *Nature*, they reported that 14 patients injected at 6 p.m. aborted in an average of 10.4 hours; while 76 patients injected at all other hours between 8 a.m. and 10 p.m. took an average of 26.2 hours to abort. The cause and significance of this unexpected example of circadian rhythm are unknown.

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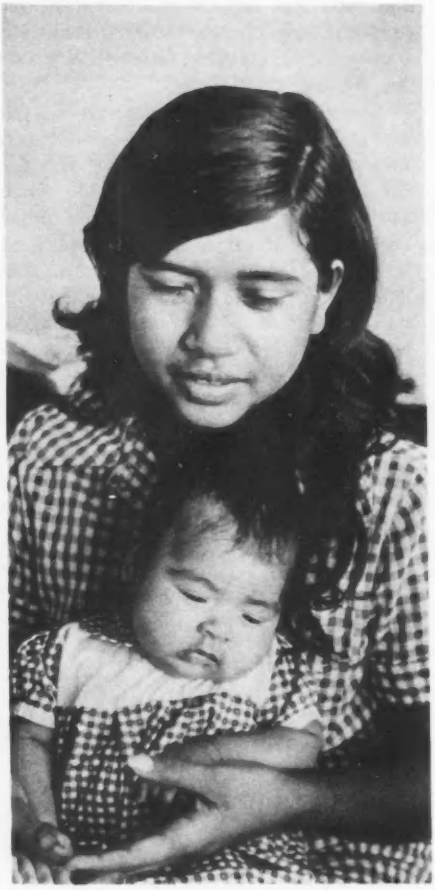
1970 National Fertility Study

Contraceptive Failure Linked to Age, Intent Although Pill, IUD Most Effective Methods

The pill continues to be by far the most effective contraceptive in actual use over time, followed by the IUD; the condom and the diaphragm are associated with moderate success in averting unintended pregnancy; but couples using foam, rhythm and the douche have much higher failure rates, according to an analysis of data from the 1970 National Fertility Study by Princeton sociologist Norman B. Ryder.

Couples who intend to delay a wanted pregnancy are generally less successful whatever method they use than couples who seek to prevent an unwanted pregnancy; and couples who become pregnant at a relatively young age are far more likely to have future contraceptive failures than those who are old relative to the number of pregnancies they have had. When intention (to delay or prevent) and relative age are controlled, there is no systematic variation in failure rates by education, religion or the number of prior pregnancies. While intent and relative age at pregnancy *do* affect contraceptive success with any method, the pill and IUD remain by far the most effective methods when these factors are standardized (see Table 1).

These are some of the findings reported by Ryder, who with Charles F. Westoff is codirector of the National Fertility Study, in a recent number of *Family Planning Perspectives*. Data for the study, which was conducted under contract with the National Institute of Child Health and Human Development, were based on interviews conducted in late 1970 and early 1971 with a national sample of 6,752 married or formerly married women of reproductive age. These data, the author points out, reflect experience during the 1950s, when the pill and the IUD were not yet available to U.S. women, as well as the 1960s. Data were analyzed only for intervals between pregnancies or since the last pregnancy for which the couples used contraception. Intervals preceding a woman's first pregnancy were not included because



of the indeterminate time she was at risk of becoming pregnant, and intervals after the fifth and higher order pregnancies were excluded because of their small numbers.

Table 1. Percent of contraceptors who had an unintended pregnancy in the first year of exposure to risk by contraceptive method used (standardized for intent to delay or prevent pregnancy and relative age at previous pregnancy)

Method	*Percent failing*
Pill	6
IUD	12
Condom	18
Diaphragm	23
Foam	31
Rhythm	33
Douche	39

Contraceptive Success

More than a third of couples who used contraception because they wanted no more children reported that they had an unwanted pregnancy within five years, and a "substantially larger" proportion may be expected to have an unwanted pregnancy eventually. Within one year, 14 percent had an unwanted pregnancy, while 24 percent failed to delay a wanted pregnancy.

Ryder noted that with all methods, couples whose goal was to prevent further pregnancies had a lower failure rate than couples whose objective was to delay a wanted pregnancy. In some cases this difference was exceptionally large: For example, only five percent of couples who wanted to prevent pregnancy had an IUD failure within 12 months, compared with 15 percent of those whose aim was to delay. Use of the condom was associated with a 21 percent failure rate among those wanting to delay a pregnancy, but just a 10 percent failure rate when prevention was the goal.

Ryder also pointed to evidence that "one of the consequences of past contraceptive failure is increase in the probability of future contraceptive failure." Thus, women who were youngest relative to the number of pregnancies they already had were twice as likely to become pregnant within one year as women in the oldest age groups if their objective was to delay a pregnancy, and four to five times more likely to fail if the goal was preventing any further pregnancies.

Among the other findings reported were the following:

- The rate of contraceptive failure has declined by half over the past 10 years for unwanted, and over the past 15 years for mistimed pregnancies, according to a comparison of women from different marriage cohorts. Some 53 percent of the decline in prevention failures and 57 percent of the decline in delay failures "were attributed to adoption of the pill." The remainder of the improvement came from more effective use of all methods.
- There was little difference between Catholics and non-Catholics — essentially none when prevention was the goal, and only slightly fewer failures for non-Catholics when delay was the objective.
- Blacks had a higher failure percentage for all age categories than whites. When the aim was to delay pregnancy, blacks had more than 50 percent more failures proportionately than whites; when the goal was prevention, they had nearly three times as many failures. This was partially accounted for by the fact that blacks began their pregnancy experience at a relatively younger age.

Commenting on the implications for family planning programs of Ryder's findings in an article in the same number of *Family Planning Perspectives*, Frederick S. Jaffe, director of Planned Parenthood's Center for Family Planning Program Development, noted that the findings raise doubts about the 'cafeteria' approach to dispensing birth control methods used by some programs. Programs should be sure to give patients accurate information about the relative use-effectiveness of the different methods. He emphasized the importance of reaching young, nulliparous or low-parity women before they get into the failure cycle described by Ryder, as well as the need for developing "new methods of conception control more effective and more acceptable than the pill."

Sources

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F. S. Jaffe, "Commentary: Some Policy and Program Implications of 'Contraceptive Failure in the U.S.'," *Family Planning Perspectives*, 5:143, 1973.

National Health Service

Free Family Planning Under British Plan

Family planning services will become an integral part of Britain's National Health Service (NHS) on April 1 when a major reorganization plan for the NHS goes into effect. The estimated eight million women at risk of an unwanted pregnancy in England, Scotland and Wales will be able to obtain free counseling and medical examination either through their own family doctors or in specialized clinics. Contraceptive supplies will be free, but a majority of the women will be required to pay prescription charges.

Under the old NHS system, a woman could obtain family planning services without charge from her general practitioner only if she had a certifiable medical need for such care (for example, if her health would be seriously endangered by pregnancy; most other medical care was provided without charge). Some local health authorities, which are similar to local health departments in the United States, provided family planning services to women residing in their areas. In some instances, examination, counseling and supplies were available free of charge. Services could also be obtained from clinics operated by the Family Planning Association (FPA), a voluntary nonprofit organization. When the FPA was acting as agent of local health authorities its services were also sometimes without charge.

Under the new arrangement, consultation, advice and examination will be free to everyone, but the usual 20 pence (50 cents) charge for each prescription will apply to contraceptives. The same charges apply to all drugs and devices secured through the NHS. Earlier, the House of Lords had unsuccessfully sought to amend the law so that contraceptives would be free for all. Some women will be exempt from all charges, however, including those receiving aid similar to welfare in the United States, those under 15, women who are pregnant, women who have given birth or have had an abortion within the past year, and those requiring contraception for medical reasons. [For a discussion of this aspect of the plan, see: "Expansion Plan Calls for Free Contraception for All Pregnant Over the Previous Year," *Digest*, Vol. 2, No. 2, 1973, p. 13.]

Abortion and sterilization will be included in the new NHS plan as it had been in the old. Clinics established by local health authorities will be absorbed by the NHS; those run by the FPA, which serve over 900,000 women, will also be integrated into the NHS system over a period of two to three years beginning April 1, 1975. Some of the locally run programs provided free contraceptives to some 1,250,000 women, many of whom will have to pay the standard prescription charge beginning April 1.

While welcoming the new plan, the Family Planning Association warned that there were weaknesses in it that could undermine its proper functioning. Among these:

- ". . . family planning services are not to have a clear identity in the huge and complex machine of the National Health Service and, therefore, their effectiveness is likely to suffer."
- No provision has been made for senior administrators on the national level who would devote full time to the administration, development and projection of family planning services.
- Many different bodies, rather than one coordinated body, will be responsible for various aspects of the family planning program with, for example, the Department of Health and Social Security being responsible for service delivery, while two other departments will have responsibility for manpower training and family planning education.

"Clearly there is to be no visible and accountable central authority or person at national, Area or District level whose sole responsibility it is to coordinate and extend the work of the various bodies," the FPA observed, concluding: "The Association is concerned particularly that the standards of patient care which it has developed . . . must at least be maintained, if not improved upon."

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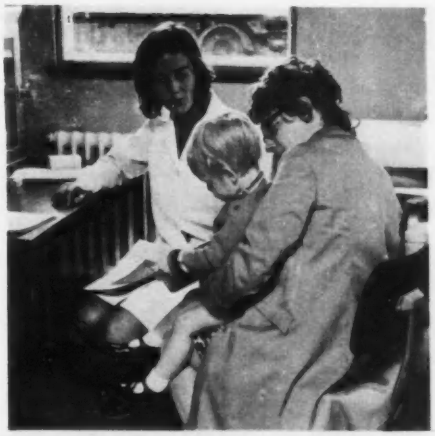


Mother and child visit NHS clinic in London.

Rural Program

Outreach Should Aim At Younger Women

The question of how best to use family planning outreach resources, including money and manpower, was highlighted by a recent report on a rural family planning program in Georgia published in the Center for Disease Control's *Annual Summary of Family Planning Services, United States 1971*.

There were an estimated 379 women in need of subsidized family planning services in Crawford County as of December 1971, of a total population of 5,700, according to the report. More than 300 women had been patients at some time since the health department started a family planning clinic in 1967. The study focused on the clinic and contraceptive use continuation of 168 women admitted from June 1, 1967 to May 31, 1970.

Of these, 149 (88.7 percent) accepted IUDs, 10 (six percent) the pill and nine (5.3 percent) other methods. At 12 months, both the clinic continuation rate and the contraceptive use continuation rate were about 80 percent. Both dropped to 65 percent at 24 months, while at 36 months the program continuation rate was 48 percent with the use continuation rate 58 percent.

Those women remaining in the program for extended periods of time tended to be older and to have more children; while those entering the program had an average age of 26.3 and a parity of four, at 24 months the average age was 28.7 with parity five, and at 36 months 31.3 years with a parity of six.

Of the 52 percent of women not continuing in the program after three years, nearly half were no longer in need of the clinic's services (17.4 percent of the total group had moved, six percent were sterilized and 0.7 percent had become menopausal or had died). Of the 41.8 percent who had discontinued contraceptive use at three years, three in five were no longer in need of the clinic's services — 19.2 percent had moved, 6.3 percent had been sterilized and 0.7 percent were menopausal or deceased.

Therefore, since most dropouts no longer needed the clinic's services, the report concluded, outreach should concentrate on recruitment — especially of younger women. "The high average age and number of living children among the active patients suggests that many of the unserved women are younger and that outreach efforts may be most efficiently directed toward recruiting these individuals."

Source

P. S. Armstrong, P. Prior and F. J. Romm, "Special Study — Crawford County Family Planning Program," in Center for Disease Control, *Annual Summary of Family Planning Services, United States, 1971*, March 1973.

Resources in Review

By Dorothy L. Millstone

High motivation, good reading comprehension and disciplined study habits are prerequisites for the successful use of programmed learning texts. For those who possess these attributes, such books have some advantages over traditional classroom learning: They permit each student to advance at his own speed; understanding can be checked at every level; at any point after the study has been completed, effective review is easily within grasp — something even the best of note-takers at lectures would covet.

Two recently published programmed texts open doors to family planning self-instruction.

● *Human Reproduction and Family Planning: A Programmed Text* (1972), was specifically prepared for health and education professionals seeking to review their knowledge of human reproduction and the mechanisms of action of contraceptives. However, it seems probable that this 128-page course could also be used by students who never had tackled the body of material previously. Hospital or clinic staff courses directed to nonprofessionals may find it useful as reinforcement of classroom teaching and lectures. Authors Elizabeth Murphy Whelan's and Michael C. Quadland's discussion of contraceptives is objective and generally adequate. Illustrations are clear, with new matter highlighted in color. Quizzes at the end of each chapter permit the reader quickly to check memory and comprehension of the material presented. Appendices include a brief glossary, bibliography and a list of contraceptive side effects and contraindications.

Purchase price: $5. Orders in volume earn discounts; 50 or more cost $2.25 each. Order from Syntex, Stanford Industrial Park, Palo Alto, Calif. 94304.

● *Methods of Conception Control (originally* published in 1965 and revised in 1972 by two medical school professors of obstetrics and gynecology is beamed at the medical profession, and will fit comfortably into related courses at schools of public health and nursing. Its 211 teaching units or "frames" assume a level of prior knowledge which would preclude the text for most nonprofessionals. But those planning training courses would do well to look it over.

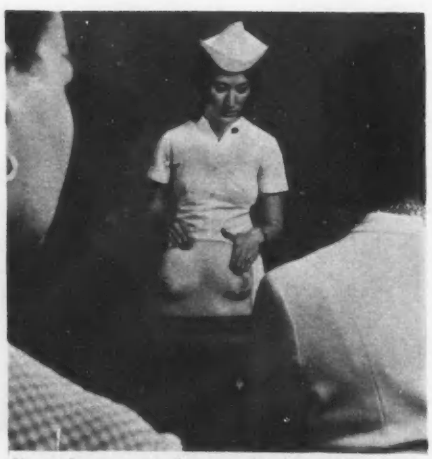
Authors Donald P. Swartz and Raymond L. Vande Wiele cover the physiology of the menstrual cycle and interrelations among the ovarian hormones and the endometrium, the modern methods of birth control, including contraindications and precautions in connection with their use as well as warnings of possible adverse reactions. Method effectiveness is also assessed. Visuals are interestingly combined in this text: Charts fold in and out from a back-of-the-book section, putting them in easy reach as specific frames call for them. A final examination permits the student to check mastery of the material; an answer sheet keys questions to pages where correct replies can be found.

In teaching about intrauterine devices, only the "loop" is referred to specifically or shown in illustrations although the text states that IUDs are available in different shapes. No distinctions are made between open and closed devices, and this reviewer found no teaching about problems in removing IUDs. Although a selected bibliography suggests further avenues of study, it is a shortcoming that the text concentrates solely on the product manufactured by the drug company which publishes the manual.

Single copies, $4.75 each; in volume of 40 or more, the unit price drops to $4.25. Order from Department of Educational Services, Ortho Pharmaceutical Corp., Raritan, N.J. 08869.

Teaching With Plastic

"Gynny" is a pelvic teaching model developed by the Indiana University School of Medicine which is already proving to be of special value in training family planning professionals. This close-to-life-size vinyl prototype makes it possible for the student to observe family planning methodology and to practice it in a classroom setting. With this model, the student can learn to fit and insert a diaphragm, insert and check the positioning of intrauterine devices and learn and practice such diagnostic procedures as taking a pap smear. On the whole, this is a professional teaching tool, and may be too medically sophisticated and too expensive for most clinics to use to teach consumers. But those health services specializing in heightening patient awareness of medical practice (like some women's clinics) may find "Gynny" very helpful in teaching consumers what to expect in the way of a gynecological examination in a birth control facility or in a doctor's office.



Nurse demonstrates breast palpation on 'Betsi'.

Two other new teaching models make it possible to broaden family planning clinics' service to consumers without substantially increasing the payroll or overhead. The purpose of each is to teach women to check their own breasts for lesions, but one is for use in training professionals and the other for direct use with clinic patients. Both are marketed under the name "Betsi." "Betsi C," designed for patient education, makes it possible to answer the question, "What does a lump feel like?" Each of Betsi's breasts contain different lesions and, with the help of a trained staff counselor, clinic patients can be taught quickly how to check for them. The package for teaching professionals contains two models whose diverse lesions make it easier for instructors to demonstrate specific palpation techniques.

The breast models, like the pelvic prototype, are Ortho products. Arrangements to view all three can be made through Ortho representatives locally or by writing to the national office at the address given above. Price of the professional breast model teaching packet is $214; the consumer version costs $107; the pelvic model costs $230.

A Professional IUD Guide

Of exceptional interest because of its comprehensiveness and detail is *Intrauterine Devices — A Manual for Clinical Practice* (1973), a 28-page 6½" x 9½" booklet by Aquiles J. Sobrero, M.D., and Alfredo Goldsmith, M.D. It is comprehensive in the aspects examined rather than in the IUD types and shapes under discussion. Only those in widest use are explicitly referred to, and the booklet's one illustration shows Lippes Loop D, Dalkon Shield, Double Coil and T-Cu 200 (Copper T). Its single table, covering evaluation, reviews the comparative pregnancy, expulsion and removal rates only of these. However, distinctions are made between open and closed devices and a substantial reference list guides the reader to additional related source materials.

In a section discussing insertion procedures, the authors stress the importance of testing for gonorrhea at the time IUD preparations are being made. For a young unmarried clientele, this is more important even than a pap smear, they contend, adding: "Missing the opportunity for uncovering venereal infections cannot easily be justified in our times." Among its six appendices are one devoted to techniques of IUD insertion, another to sterilization of the devices and instruments used to insert them, and one which instructs the professional on what to tell the woman about the IUD. This booklet was published by the Pathfinder Fund largely for the guidance of family planners overseas and its original edition (in Spanish, Italian and French as well as English) was in early heavy demand.

Copies may be obtained without charge from the Pathfinder Fund, 850 Boylston St., Chestnut Hill, Mass. 02167, while the dwindling supply lasts. Pathfinder is placing copies in all Department of Health, Education and Welfare regional family planning offices for consultation.

For Men Only

The Man's World (1972), a 14-page, 3¼" x 9" folder, is distinctive and may be unique in that it assembles special sex education and family planning materials of male interest in just one publication. All the methods of birth control, including vasectomy, are listed and briefly described. As might be expected, this pamphlet places major emphasis on the condom. More detail is provided about this method of birth control than is usually found in manuals. The most common shapes are pictured, but no trade names are given. Male adolescents, especially, but young girls, as well, may find this an instructive publication. There is a table of contents. Besides the condom, subjects discussed briefly in the booklet include male and female sex organs, conception, venereal disease and birth control. A mailing to a selected group of high school athletic coaches recently produced orders for 20,000 copies, indicating a strongly favorable response.

For a free copy, write Population Services International, 105 N. Columbia St., Chapel Hill, N.C. 27514. Single copies cost 15¢ each and in volume of 500 or more the unit price drops to 10¢.

Reaching Teenagers

• Inviting materials for young people continue to turn up in movies, books and booklets. Bound to be popular is *How About You?* a 25-minute black and white teaching film concerned with family planning and sexuality. Regrettably, its candor, the essence of its teaching method, will almost certainly bar it from most schools. High school students, mostly girls, are shown frankly rapping about birth control and sex; the camera comes in close and their talk is recorded. The photography is not perfect; occasionally it is even blurred. But the young people filmed are so candid, unrehearsed, knowledgeable and interesting that it doesn't matter. The young women, especially, seem to know a lot about birth control. They expect to take responsibility for themselves. They desire — and seem to expect — equality with men in friendship, in lovemaking and in sex. The few young men shown have a secondary role, suggesting that their inclusion was a formality, perhaps even an afterthought. This heightens the main focus well. Perhaps a later film will center on the adolescent male. Meantime, this gives insight into adolescent female thinking. Two group leaders, both women, look and dress much like the students, and their authority just faintly comes through. The film's best use is probably as an introduction to a family planning or sex education class, a rap session, or a training course for youth leaders.

Pandora Films made this movie. Purchase price is $290. It may be rented for one day for $35, more for longer periods. Order from Texture Films, Inc., 1600 Broadway, New York, N.Y. 10019.

• Young people might well be the audience for the 16 mm film, *Purposes of Family Planning* (15 minutes, color), made in Canada. It is a pleasant, fast-moving introduction to the health and economic rationale for spacing and limiting births. The movie stresses that each couple should make its own decisions about when to have babies and how many to have and that family planning makes this possible. In an opening scene, a doctor is checking with a mother who has just delivered a baby. "I don't have to worry about family planning," she says. "I'm nursing." This leads the doctor to explain that lactation is not always a protection and that she might need help. Methods are not discussed in this movie. The one reference to a diaphragm is quite casual. Instead, health considerations, such as age of mother, intervals between babies, economic pressures, career ambitions, and other factors in family planning are humanized and pictured. As in many of the new health education films, the cast is interracial. The mother who doesn't know what to do is white and her well-informed, calm and helpful neighbor who provides much of the teaching, is black. This film can be recommended for school use from the fourth grade up. Adult audiences would find nothing objectionable, but most of what it has to say has become so widely known that it might be difficult to hold viewer interest.

The film may be bought for $210 or rented for $25 from Oxford Films, Inc. 1136 N. Las Palmas, Los Angeles, Calif. 90038.

Family Planning Newsletters

• U.S. family planning programs and communications techniques are often discussed in the bimonthly *IEC* (Information, Education, Communications) *Newsletter*, distributed by the East-West Communications Institute in Hawaii. Recent issues reviewed U.S. mass media educational campaigns and efforts to bring condoms into wider use.

To receive this newsletter regularly, without charge, write to Assistant Director, Communications Institute, East-West Center, 1777 East-West Rd., Honolulu, Hawaii 96822.

• Information on efforts to introduce population issues into formal school curricula, especially at middle and high school levels, is assembled regularly in *Inter-change*, a Population Reference Bureau newsletter distributed to educators and centers of potential population education activity.

To subscribe, address PRB at 1755 Massachusetts Ave., N.W., Washington, D.C. 20036.

• National and international news on population and family planning is published in *Intercom*, a monthly newsletter issued by Population Services International. Judged by early issues, *Intercom* promises to be of interest to U.S. family planners.

Digest readers can obtain a free sample by writing *Intercom*, 1012 14th St., N.W., Washington, D.C. 20005. Subscription costs $30 a year to organizations; $24 a year to individuals and $18 to students.

• Combining selective quotations regarding family planning, sterilization, abortion and demographic developments with editorial comment and "action line" directives, the *Pro-Life Reporter*, newsletter of the U.S. Coalition for Life, is a roadmap of the direction in which this movement is travelling in its opposition to specific aspects of family planning such as the IUD, contraceptive sterilization and postcoital contraceptives. The newsletter makes clear that the right-to-life groups have broadened their interest from opposition to abortion to concern with every aspect of family planning, including government policy and funding, and scientific research. Aimed at educators, government administrators, physicians and population agencies, in addition to its own constituency, the newsletter should be helpful to those in family planning concerned with what this well-organized and committed group is saying and doing.

Individual subscriptions cost $5 a year, the group rate is $25. Bulk orders may earn a reduction in price. Query direct as discounts may vary. The newsletter is published quarterly with occasional supplements. A free sample is available on request. For subscriptions write to *Pro-Life Reporter*, Box 315, Export, Pa. 15632.

Note — Readers are urged to send their own materials for review. Send two copies of each item; define the intended audience and goal; state the price and how *Digest* readers may obtain copies. Contributions should be addressed to:

Resources in Review
Family Planning Digest
Room 12A-33
5600 Fishers Lane
Rockville, Md. 20852

Credits

p. 1: Population Council; pp. 3, 6, 10, 12: Ken Heyman; p. 7: British Information Services; p. 8: Ortho Pharmaceutical Corp.

Attitudes

Women Accept Some Sex Stereotypes But also Favor Greater Equality with Men

The changing role of women and the effect these changes might have on fertility patterns have recently come under scrutiny by social scientists. The Commission on Population Growth and the American Future recommended that in the United States certain changes in the status of women were desirable, not only to increase "the freedom of women to seek alternative roles [which] may reduce fertility" but also because "the limitations on the rights of women abridge basic human liberties that should be guaranteed to all. . . ." It recommended modifying sex and family roles, eliminating discrimination based on sex, assuring equal access for women to all jobs, and altering educational programs that foster sexual stereotypes.

Knowing how women feel about traditional sex roles is relevant to these issues. A preliminary analysis of responses to 17 questions on sex role attitudes included in the 1970 National Fertility study by Karen O. Mason of the University of Michigan and Larry L. Bumpass of the University of Wisconsin indicates that most women do not conform either to the traditional "patriarchal" model or to the "egalitarian" feminist viewpoint. Rather, the investigators reported at the 1973 annual meeting of the American Sociological Association in New York, many women held "what are from the point of view of either of these models, a mixture of beliefs and outlooks."

On the one hand, almost 80 percent of the 6,740 ever-married women under age 45 who were queried said that "it is much better for everyone involved if the man is the achiever outside the home and the woman takes care of the home and family." Nearly all respondents, however, stated that women should get equal pay for equal work. Considerable numbers accepted some sex stereotypes, but rejected others. The investigators emphasized that respondents were surveyed at a particular point in time and the data do not measure changes in opinion over time. However, they believe the composite picture which emerges suggests that women are retaining several key aspects of the traditional sex role ideology but are adopting apparently liberalized views in other areas.

In general, women over 30 had only marginally more traditional views than those under 30. On many, but not all questions, more black women than nonblacks rejected the traditional position. The authors had originally conjectured that this might be attributable to economic and social, rather than racial influences. But an analysis of responses standardized for differences in background and socioeconomic status showed that where there were racial differences, these remained in all cases except for the statement that "women are happier if they stay at home and take care of their children." Blacks appeared to agree more than whites with this statement, but when responses were standardized, about 40 percent of both groups were found to agree.

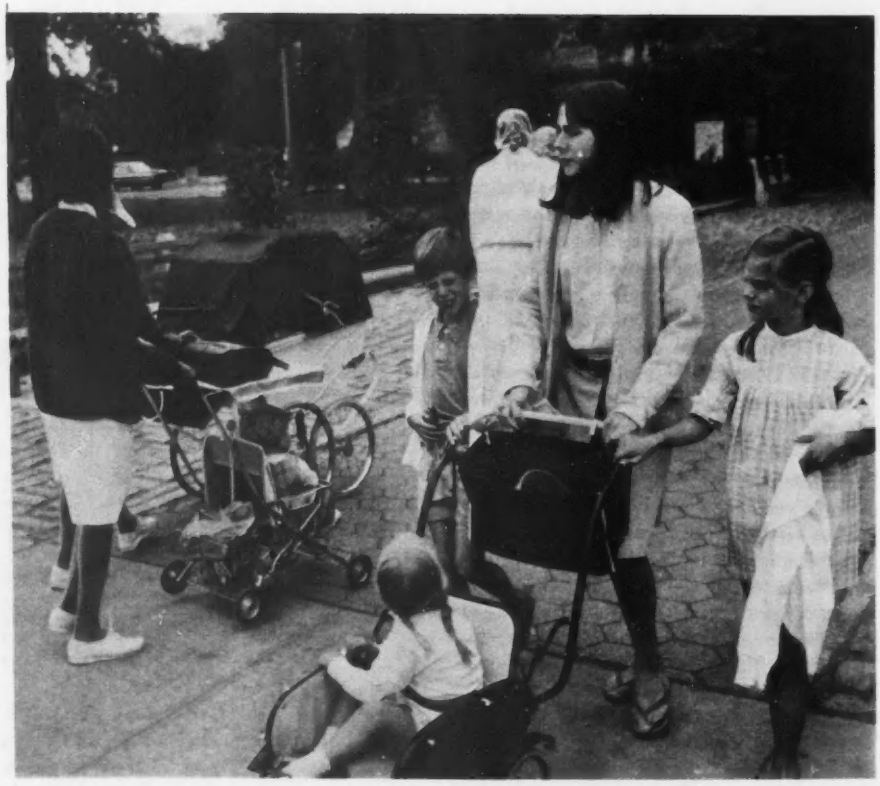
On questions concerning sex-based division of labor, responses were mixed. As noted, there was "continuing strong support for the segregation of basic roles by sex;" however, nearly half the women interviewed felt a woman should not let children "stand in the way of a career if she wants it." Younger black women gave stronger support to this view than nonblacks under 30. On the question of whether men should share the housework, there was a significant difference by color. Seven in 10 black women agreed that men should share household chores, against just over half of others.

Slightly more than six in 10 women agreed that "a woman should have exactly the same job opportunities as a man" — with somewhat more blacks than whites supporting this view — while more than seven in 10 believed that men should not refuse to work under women bosses. On the crucial question of whether "women should be considered as seriously as men for jobs as executives or politicians or even President," somewhat fewer women agreed than on either of the other two issues — but still more than half.

The authors observe that there is evidence that probably the most significant cause for sex differences in earning comes from unequal occupational placement and promotion of women, rather than from simple wage discrimination. The fact that barely a majority of those surveyed believe that women should be considered for the best-paying and most responsible jobs suggests, the authors believe, that the female public may still tolerate considerable differences in the treatment of women and men workers.

Two related issues drew much heavier support from black women than from white women — four in five blacks supported both child care centers and maternity leave, but only half as many whites supported child care centers and only two-thirds as many agreed that "a woman's job should be kept for her when she is having a baby."

Three questions on the role of mothers drew two mixed responses and one traditional outlook. Nearly half the women agreed that "if anything happened to one of the children while the mother was working, she could never forgive herself," with greater support among blacks than whites. The same was true for the statement that "a working mother can establish just as warm and secure a relationship with her child as a mother who does not work." The strongest support for a traditional position was in response to the statement that "a preschool child is likely to suffer if his mother works."



Seven in 10 whites agreed with this view, as did six in 10 blacks.

Only about one-sixth of the women agreed that "sex seems to exist mainly for the man's pleasure" (with blacks agreeing twice as often as whites), and fewer than a third felt that men can make long-range plans but women must "take things as they come." However, a majority (but only four in ten blacks) believed that many women's rights activists were "unhappy misfits."

The one variable which is most strongly associated with a woman's responses, the investigators noted, is her educational level, with more education correlated with a more egalitarian position. Work status also is noticeably correlated with women's basic sex role attitudes, but not with their attitudes about women's employment rights. The overall effect of religiosity, marital status and husband's income does not appear to be particularly large. Age at first marriage had no apparent relationship to attitudes.

While among these women, surveyed in late 1970 and early 1971, there was no strong support for the radical feminist view, neither was there a sizable proportion who held "a full-blown, traditional patriarchal ideology." Mason and Bumpass speculate that there might therefore be a greater potential for fairly rapid change in the future, than if there were a majority of women whose entire spectrum of sex role attitudes were consistently Victorian in nature, although this depends on factors not explicitly considered in their analysis.

Sources

Commission on Population Growth and the American Future, *Population and the American Future*, New American Library, New York, 1972, p. 152.

K. O. Mason and L. L. Bumpass, "Women's Sex Role Attitudes in the United States, 1970," paper presented at the annual meeting of the American Sociological Association, New York City, Aug. 27-30, 1973.

Table 1. Net cumulative termination rates per 100 woman-years of use, TCu-200 and Lippes loop D (first 12 months of use)

Reason for termination	*TCu-200*			*Lippes loop D*
	Parous only	*Nulli-parous only*	*Nulli-gravid only*	*Parous only**
Pregnancy	2.2	1.3	0.8	2.6
Expulsion	8.3	10.7	8.7	10.8
Removals:				
Bleeding/pain	6.4	9.4	9.6	11.8
Other medical	2.6	2.3	2.2	3.1
Planned pregnancy	2.1	1.1	0.8	1.2
Other personal	2.0	1.9	2.0	2.1
Total removals	13.1	14.7	14.6	18.2
Total event rate	23.6	26.7	24.1	31.6
Continuation rate	76.4	73.3	75.9	68.4
Insertions	4,127	2,099	1,585	7,533
Woman-months of use	26,760	11,436	8,598	66,777

*Adjusted for age-parity distribution of women using TCu-200.

Contraception

Copper IUD Protects The Never-Pregnant

Continuing clinical trials with the Copper T IUD (TCu-200) prove it to be effective in preventing pregnancy among women who have never had a child (nulliparae), especially if they have never been pregnant. However, differences between the TCu-200 and the Lippes loop D in levels of protection among parous women are now minimal; the advantage of the TCu-200 over the loop D in total removals remains, however, confirming results reported earlier. [See: "Shield Pregnancies Higher Than Loop's; TCu, Cu 7 Reviewed," *Digest*, Vol. 2, No. 1, 1973, p. 6.] Expulsion rates were also lower with the TCu-200. However, differentials between the TCu-200 and the loop D among parous women for expulsions and removals continued to narrow with more experience.

As may be seen in Table 1, fewer women in each pregnancy group discontinued use for any reason (except planned pregnancy) of the TCu-200 (a T-shaped polymer device with 200 sq. mm of copper wire around the stem) than did parous women using the loop D. This latter device is seldom used among nulliparous women because of difficulty of insertion. Among those adopting the TCu-200, the continuation rate was 76.4 per 100 woman-years of use after one year for parous women, 75.9 for nulligravidae and 73.3 for nulliparae, compared with 68.4 for parous women adopting the loop D.

The nulligravid women utilizing the TCu-200 enjoyed by far the greatest protection against pregnancy, with pregnancy rates of 0.8 per 100 woman-years compared to 1.3 for nulliparae and 2.2 for parous women on the TCu-200 and 2.6 for parous women on the loop D. (This differential, however, could be related to the fact that never-pregnant women may have less exposure to the risk of pregnancy.)

These findings were reported by Sarah Lewit of the Population Council, and the data are based on information from 27 investigators (all but two in the United States), and include 6,733 first insertions of the TCu-200, accounting for 45,723 woman-months of use (40,404 for the first 12 months).

The rate for expulsion declined as the age and parity of the user increased, Lewit noted. These rates were higher for nulliparous and nulligravid women probably because of their smaller uteri and narrower cervical canals, she said. Removals for bleeding and pain were lowest for women with two previous pregnancies and women aged 25-29, Lewit said, although the reason is "unexplained."

Among parous women, pregnancy rates were two times higher if the TCu-200 was inserted 29-90 days postpartum than if insertion was delayed to more than three months after delivery. Expulsion rates were also higher when insertions were made in the late postpartum period, although there was little difference in total removal rates.

Dr. Daniel R. Mishell, Jr., and his colleagues at the University of Southern California School of Medicine report similar pregnancy and medical removal but somewhat different expulsion rates than Lewit in a study of the TCu-200 in 471 nulliparous women. At 12 months (and 4,430 woman-months of use), the pregnancy rate of the women in the Los Angeles study was 1.7, compared to 1.3 found in Lewit's survey and the rate of removals for bleeding and pain was 10.7 compared with 9.4 in Lewit. The expulsion rate, however, was markedly lower — 5.4 in Mishell's study vs. 10.7 in Lewit's. The one-year continuation rate was about the same (74.2 for Mishell and 73.3 for Lewit). Some 343 of the patients were nulligravid. The results compare favorably with other IUDs used by multiparae and, Mishell notes, the pregnancy rate "is lower than that reported by others in adolescent clinics with the oral contraceptives."

Sources

S. Lewit, "Two Years of Experience with the Copper-T: A Research Report," *Studies in Family Planning*, **4**:171, 1973.

D. R. Mishell, Jr., R. Israel and N. Freid, "A Study of the Copper T Intrauterine Contraceptive Device (TCu-200) in Nulliparous Women," *American Journal of Obstetrics and Gynecology*, **116**:1092, 1973.

Communications

Direct Mail Improves Knowledge of Methods But Fails to Recruit Women to Clinics

How effective is direct mail as a communications tool? Is it successful as a patient recruitment device? Does it improve knowledge of family planning? Can it diffuse information about services to a larger audience than the immediate target of the mailing?

A controlled study of one campaign, aimed at a sample of low-income mothers in Tennessee, found that direct mail seems to have a minimal effect on recruitment, but is successful in educating the recipient and in spreading word. It is also a relatively inexpensive communications effort, according to Paul J. Placek, a graduate student in the Department of Sociology at Vanderbilt University in Nashville, who conducted the study.

Methodology

A random sample of 300 mothers aged 15-44, receiving welfare assistance in Davidson County, Tennessee, under the Aid to Families with Dependent Children (AFDC) program, were included in the study. (They represented a 7.5 percent sample of the 4,000 AFDC families in the county.) Half the group, chosen at random, received no communication; the remaining half, the experimental group, received a mailing which included:

- a cover letter pointing out that free birth control services (including examination by a physician and free supplies to women of any age, married or single), were available at 14 clinics in the county. The recipient was asked to talk about the services with a friend, neighbor or relative and to distribute a supply of booklets to interested persons. Extra booklets were enclosed.
- a list of the 14 clinics. A phone number was also provided to enable the recipient to make an appointment if she wished.
- three packets of patient-level birth control booklets, each packet containing *ABCs of Birth Control, Questions and Answers about the Pill* and *Questions and Answers about the IUD*. On the back of each booklet was the message, "'Have Your Children by Choice. Not by Accident.' For information on the free birth control clinics call [number]." Two of the three packets had the notice, "Please give these extra booklets to a friend, relative, or neighbor."

From one to three weeks following the mailing, all 300 women were interviewed by trained interviewers who asked questions concerning birth control knowledge, attitudes and practice. They were also asked about their family planning communications with others.

Findings

The data show that about the same proportions of both groups were active clinic users before as after the direct mailing. "We must conclude that the direct mailing had no discernible effect on clinic use based on a comparison of the experimental and control groups," Placek said. Thus, clinic recruitment appeared unaffected by the direct mail appeal, confirming the experience of other researchers in the field, according to the investigator.

Some 93 percent to whom the mailing had been sent (139 of 150) remembered receiving it, although the interviews occurred on an average of 20 days after the mailings were sent. Half the recipients reported that they read the booklets a "lot," suggesting, says Placek, that they were filling a real need. About 17 percent of the recipients had read none of the booklets because they felt they had no need for the information, because they already knew what they wanted to know or didn't have time to read them.

The mailing did seem to improve the family planning knowledge of many of the recipients. Four out of five who read the booklets said they found them helpful because they provided additional information, told them how the different methods work or told them about birth control for men.

The interviewers asked all the women five open-ended questions about contraception and related physiology. While their answers, Placek said, showed an "appalling" lack of knowledge about family planning, the data showed a consistent trend for recipients of the direct mailing to have more correct or partially correct answers than the nonrecipients. More than half the experimental group could verbalize how pregnancy occurs, compared to less than one-third of the controls; more of the women in the experimental than the control group answered correctly questions concerning ovulation and the various methods. "The booklets seem to have significantly contributed to the family planning knowledge among women who were sent the direct mailings," Placek observed. In the total sample, however, less than half the women in both groups knew specifically how pregnancy occurs; less than one-fifth knew when ovulation occurs or how the pill works; fewer than one in 20 knew how the IUD works. Nearly half could not answer even one question correctly (one-third of the experimental and 57 percent of the control group) and one-third could answer only one. Only three women of the 300 answered all five questions correctly. "It is likely," Placek says, "that this ignorance about contraception and related physiology contributes significantly to the unwanted and accidental pregnancies which these women experience." (Of the 1,190 pregnancies experienced by these 300 women, 606 — 51 percent — were unwanted by the mother at the time of conception.)

The direct mailing also had an impact upon diffusion of information. It was found that 84 of the 139 respondents contacted 155 different persons, giving them booklets, discussing clinics with them or both. Thus, a greater number of women were reached indirectly by respondents than were reached directly through the mailing.

To find out whether some or all of these discussions would have taken place without the stimulus of the mail campaign, all the respondents were asked about the total number of persons with whom they had discussed family planning recently. Those who had received the mailing talked with twice as many people about the clinics as those who had not. On the assumption that without the mailing women in both groups would have talked with about the same number of people, the investigator concludes that women in the experimental group communicated with significantly more people as a result of the mailing.

The total cost of the direct mailing to 150 women was $115.50, or 77¢ per person. Included in the cost is the price of the booklets, three of which were enclosed; the printing of letterheads, envelopes and clinic lists; third class postage; and labor for stuffing, addressing and stamping the envelopes.

Source

P. J. Placek, "Direct Mailing to AFDC Welfare Mothers: Their Impact on Clinical Recruitment, Family Planning Knowledge, and Informal Communications with Others," unpublished paper.

Program Evaluation

Larger Caseload Lowers Per Patient Cost; Outreach Expenditures Influence Continuation

A study of federally financed family planning projects shows that projects with larger patient volume and larger budgets tend to have comparatively low per patient costs, that continuation rates are directly related to the proportion of a project's budget spent on outreach activities, and that patients are, in general, satisfied with the services they receive.

The study, performed by National Analysts, Inc., for the Office of Economic Opportunity (OEO) and the National Center for Family Planning Services (NCFPS) of the Department of Health, Education and Welfare (DHEW), investigated cost characteristics of 30 OEO-financed sites and 15 DHEW-funded programs. Based on samples drawn from lists of patients who first entered the projects between October 1968 and March 1969 at 16 of the OEO projects and all the DHEW clinics, some 2,256 women were interviewed about their reaction to the clinics and changes in their fertility and contraceptive behavior since entering the program. Each woman had first enrolled in a program about three years prior to the interview.

The average annual cost per patient for the 45 projects was $53 in 1968-1969. This per patient cost, when adjusted for inflationary increases in accordance with DHEW estimates, comes to about $61 in 1971, very close to the $66 per patient figure reported for that year in an analysis of costs of 24 DHEW family planning projects made by the Westinghouse Population Center. [For details of the Westinghouse study, see: "$66 a Patient Annual Family Planning Cost," *Digest*, Vol. 1, No. 5, 1972, p. 7.] The average project had operating costs of $135,000. The projects ranged in budget size from $27,323 to $443,555, and economies varied directly with patient volume: The cost per patient for high-volume projects (3,000 or more patients) was about 25 percent lower than the average per patient cost for all projects; while low-volume projects (with 950 patients or fewer) spent nearly two times as much as the average. A breakdown of how the money was spent showed that most of the savings made by high-volume projects were accounted for in nonmedical areas.

Budget size also had an important effect on costs. Large-budget programs (over $150,000 a year) had a per patient cost of about 10 percent below average; while small projects (under $60,000) had per patient costs one-third more than the average.

For all projects combined direct medical services accounted for 44 percent of total costs. Recruitment, follow-ups and community education accounted for 20 percent of the total and management and administration costs were 36 percent of the total. Medical expenditures, however, accounted for nearly 49 percent of the costs in high-volume projects but only 35 percent of the cost in low-volume projects. Support and management costs, however, were higher in low- than in high-volume projects. The differential between high- and low-volume projects was greater for support costs — only six percent of the budget in high-volume projects but 16 percent in low-volume programs.

Another factor which affected per patient costs was the length of time a project had been in operation. The 11 projects surveyed that were less than two years old had an average per patient cost of nearly twice the average; while the eight programs three to five years old cost 40 percent less than the average. (The 18 projects in operation more than five years, however, cost a little more than the average for all patients.) Initial capital expenditures, plus higher costs for recruitment and community education, were contributing factors to the high costs in the younger projects. Similar results were reported in the Westinghouse study.

Age and Size Affect Cost

A compounding problem was the fact that the younger programs tended to be smaller: those under two years averaged 762 patients; those two to three years old averaged 1,382 patients; those three to five years old averaged 5,603 patients. Those in operation more than five years averaged just 2,596 patients, accounting for the higher per patient cost for this group compared with projects in operation three to five years.

Both the clinic setting and the geographic setting also affected project costs. Costs were lowest for projects based in hospitals—about 40 percent less than average — while costs were about ten percent less than average for those based in general health clinics, 13 per cent more than average for those operating as free-standing locations; nearly 60 percent more than the average when services were delivered by private physicians, and highest — almost two times higher than average — for projects which delivered their services in several different types of setting. Per patient costs in projects in major urban areas (population over 250,000) were only about three-quarters as costly as those delivered in nonmetropolitan and rural settings.

Other findings included the following:

- The higher the ratio of physicians to other medical staff, the higher the per patient cost.
- The larger the proportion of costs spent on medical services, the lower the per patient cost; conversely, the larger the proportion spent for administrative costs, the higher the per patient cost.

Other factors investigated, such as overall comprehensiveness of service, proportion of resources spent for support services, and use of contract services had no clear effect on per patient cost.

The National Analysts survey found that the amount spent on outreach activities was a major factor contributing to patient continuity. When measured by dollars spent per patient, programs with high expenditures for outreach had only about one-half as many dropouts (8 percent) during the first year as did projects with low outreach expenditures (15 percent). This effect was even more pronounced when the yardstick was percent of total direct costs allocated to outreach activities: projects with a high proportion of total direct costs going to outreach had only seven percent dropouts in the first year, with 48 percent of the patients remaining for three or more years; projects with low outreach expenditures had a 17 percent one-year drop-out rate, with only one-fourth of the patients still participating after three years.

Total cost per patient and patient volume apparently did not affect the continuation rate. Many of those who dropped out of the projects did not stop effective contraception, however. Forty-one percent of the women interviewed were clinic dropouts, and some gave multiple reasons for discontinuing; thus, the percentages that follow are not additive. Fourteen percent said that either they or their husbands had been sterilized. About 15 percent said they left because they preferred going to their personal physician, and six percent added that they could now afford their own personal physician. More than 10 percent dropped out because they had become pregnant or wanted to become pregnant. Only 10 percent said they were dissatisfied with the clinic, and six percent were dissatisfied with the contraceptive method advised by the clinic. Among other reasons given for discontinuation were that the clinic was not convenient or was no longer accessible because they had moved.

The greatest loss of patients was after the first visit (13 percent of all dropouts). There was no significant difference in age, marital status, parity, education, religion or income between dropouts and continuing patients.

Patient Knowledge

While the amount spent on outreach had a significant effect on patient continuation, the amount spent on patient education did not seem to affect their understanding of elementary human reproduction and contraceptive effectiveness. The patients were asked at what point in the menstrual cycle a woman had the greatest chance of becoming pregnant. Only one out of five knew the correct

answer. Although women from projects where the percent of direct costs going to education was highest had a slightly better record than other patients, there was no significant or systematic relationship found. Most women had an accurate understanding of the contraceptive effectiveness of the pill as compared to rhythm and douching. But there was little or no difference between projects with high and low expenditures for patient education.

Patient Satisfaction

In general, the patients interviewed by National Analysts said they were satisfied with the services they were receiving. There was little relationship, however, between satisfaction and any of the various project characteristics studied. Each woman was asked to rate several items — such as competence of medical staff, ability to see the same doctor, ability to tell the staff exactly what kind of help she wanted, and waiting time — on a scale of one (least favorable) to five (most favorable); these were then combined into a general "satisfaction index."

The overall score was 3.5. Asked to rate their general satisfaction with their care at the clinic, 95 percent of the patients said they were either satisfied or very satisfied. There was a very slight trend towards greater satisfaction in projects with lower patient volume, more emphasis on outreach and education, and higher per patient costs.

The principal authors of the report were Jack Schwartz, associate director of National Analysts' Social Science Division, and Suzanne Hathen, at the time a research assistant with National Analysts.

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Insurance

Full Coverage Urged For Maternity Care

The American College of Obstetricians and Gynecologists has proposed a model law requiring that complete maternity care coverage be included in all health insurance policies. Such coverage would apply to both single and family policies, and would not be affected by the marital status of the insured.

Among the areas that would be covered, according to the 15,000-member organization's proposal, are the following:

- normal obstetrical care and all obstetrical complications;
- all treatment "associated with voluntary control of reproduction," including sterilization and legal abortion;
- prenatal care, including care of the unborn infant;
- labor, delivery, and the period of confinement during and after delivery; and
- "newborn care from the moment of birth through the first year of life."

Any pregnancy beginning while the policy is in force would be covered, and coverage would be equal to that for other areas of health care (i.e., deductibles and coinsurance — where the insured pays a percentage of the costs — would be allowed only in proportion to deductibles and coinsurance for other types of medical and surgical care covered by the policy). Copies of the model bill have been sent to the sponsors of the numerous national health insurance programs now before Congress.

A similar proposal previously had been made by Herbert S. Denenberg, Pennsylvania Insurance Commissioner, in testimony before Congress' Joint Economic Committee. In discussing the elimination of sex discrimination in insurance, Denenberg proposed a 10-point "Woman's Insurance Bill of Rights," including "the right to adequate health insurance coverage for all needs, including comprehensive maternity benefits for all conditions of pregnancy regardless of age or marital status."

Most insurance is inadequate in this area, even when pregnancy is covered, Denenberg noted. "In some plans, particularly commercial health insurance, maternity expenses are subject to a flat maximum payment for both medical-surgical and hospitalization expenses. This flat maximum . . . may be completely inadequate to pay the true cost of a normal childbirth," he said. In addition, maternity benefits are usually restricted to married couples enrolled in family plan contracts. Not only are single women and dependents often excluded, Denenberg commented, but so are married women workers whose husbands are not covered by the same plan.

Normal pregnancy as well as "all complications of pregnancy" are typically excluded from disability policies, Denenberg said, on the assumption that pregnancy is usually "a planned event." But "certainly not all pregnancies are planned and most certainly complications of pregnancy are not planned. . . . Working women must not be forced to choose between having a job and having a family. Disability insurance would help women to do both, and to do so, it must recognize the wage loss associated with pregnancy."

Sources

American College of Obstetricians and Gynecologists, press release, October 2, 1973.

H. S. Denenberg, Pennsylvania Insurance Commissioner, testimony before the Joint Economic Committee of Congress, July 12, 1973.

IUD, Pill Use-Effectiveness Found Similar; Pregnancy Rates Linked to Age, Parity

Contraceptive discontinuation and pregnancy rates among lower income women adopting contraception in a postpartum clinic were only marginally lower — or even higher—for those choosing the IUD as their first contraceptive method than for those selecting the pill, according to a long-term study at a New York City hospital. These results, reported by Dr. Robert E. Hall in the *American Journal of Obstetrics and Gynecology*, differ from earlier investigations which indicated that the use-effectiveness rates with the IUD were significantly better than those with oral contraceptives.

Dr. Hall noted that discontinuation and pregnancy rates for IUDs and orals were both "disappointingly high" in his study: Within two years, more than four in 10 women had stopped using any contraception and one-fourth of the subjects had had an unplanned pregnancy. A contributing factor was the "almost cursory care" given the women, the investigator noted, typified by the fact that follow-up visits were not scheduled until 15 months after a patient had started in the program.

This long follow-up period was deliberate, Dr. Hall explained. "This study was not designed for the common purpose of maximizing results by either careful patient selection or ideal medical supervision but rather for the pragmatic purpose of discovering the results of including all eligible patients and providing minimal doctor participation," he noted. "By permitting the patients to select their contraceptive method and offering follow-up care by the resident staff every 15 months, in other words, an attempt was made to duplicate the type of service thought to be available in other hospital clinics of similar size."

All of the 8,642 women who gave birth on the ward service of Sloane Hospital for Women in 1966-1969 were offered contraception, and 6,641 (72.7 percent) of them adopted one of four methods:

- 4,396 (50.9 percent), the oral contraceptive,
- 1,511 (17.5 percent), the IUD,
- 372 (4.3 percent), the diaphragm,
- 162 (1.9 percent), rhythm.

In addition, just over five percent underwent sterilization and almost two percent selected methods not offered by the clinic. Al-

Table 1. Net cumulative discontinuation rates per 100 women (including planned pregnancies) and gross cumulative pregnancy rates (unplanned only), during use of first method and all methods, for Sloane Hospital and for clinics in Atlanta, Brooklyn and Buffalo*

Months of use, method and clinic	*Discontinuation rates*		*Pregnancy rates*	
	First method	*All methods*	*First method*	*All methods*
Six months				
Orals				
Sloane†	27.2-32.2	15.9-20.9	3.5-0.0	8.2-4.8
Atlanta	30.6	27.1	7.2	10.9
Brooklyn	22.3	16.9	3.2	6.3
Buffalo	19.6	13.5	1.5	3.0
IUDs				
Sloane	22.3	11.1	3.2	6.2
Atlanta	16.8	10.1	3.3	5.6
Brooklyn	12.6	3.3	1.8	2.5
Buffalo	9.0	5.9	2.0	3.1
Diaphragm				
Sloane	29.4	14.9	3.9	6.1
Twelve months				
Orals				
Sloane†	38.5-(45.7)	25.8-(32.3)	6.5-4.1	13.3-12.3
Atlanta	45.5	40.3	16.1	24.3
Brooklyn	38.3	31.2	6.0	13.4
Buffalo	33.6	25.3	2.0	8.4
IUDs				
Sloane	36.8	22.3	7.3	12.6
Atlanta	26.3	16.8	6.0	10.1
Brooklyn	24.4	7.9	4.4	6.1
Buffalo	17.6	10.6	3.5	4.8
Diaphragm				
Sloane	41.8	25.1	10.6	13.6

* Sloane Hospital data from R. E. Hall, "Continuation Rates with Four Contraceptive Methods," *American Journal of Obstetrics and Gynecology*, **116**:671, 1973; data for other clinics from C. Tietze and S. Lewit, "Use Effectiveness of Oral and Intrauterine Contraception," *Fertility and Sterility*, **22**:508, 1971.

† First rate given is for women using a sequential pill; second rate is for women using a combination pill. Figures in parentheses based on fewer than 100 cases.

most eight percent of the total group failed to appear at the six-week postpartum visit (when the contraceptive method chosen was provided) and another 11 percent refused contraception.

Of the 6,441 women who chose one of the four methods, 1,498 were randomly selected for follow-up; 82 percent were successfully followed. Within six months of initiating contraception, 27.2 percent of the women had stopped using the first method they chose (for all methods combined), while 15.5 percent had terminated contraception altogether. Within 12 months, 40 percent had stopped using their first method and 25.9 percent were no longer using any contraception. At 18 months, 50.6 percent had stopped using the first method, while 33.1 percent had terminated contraception. The record continued to worsen so that after two years 58.8 percent were no longer using the initial method they chose, while 40.9 percent had discontinued contraception altogether.

There was little difference in discontinuation rates between women who first chose oral contraceptives and those who began with IUDs, while the rates were slightly higher for those who initiated contraception with the diaphragm. For example, after one year, 36.8 percent of those who began with the IUD had stopped using their first method and 22.3 percent discontinued all methods; while of those who started on the pill, 38.5 percent had stopped taking orals and 25.8 percent had terminated all methods. Those who started with diaphragms were more likely to have stopped using them (41.8 percent at one year), but many evidently switched to other methods, since 25.1 percent had discontinued all methods at 12 months.

The difference in contraceptive termination and pregnancy rates between those who began contraception with the IUD and the pill reported by Dr. Hall are much smaller than those reported in 1971 by Dr. Christopher Tietze and Sarah Lewit of the Population Council in a study of extended use-effectiveness based on patients from clinics in three cities. The discontinuation rates were also greater at Sloane than at two of the other clinics. (See Table 1 for a comparison of six- and 12-month termination rates.)

Gross cumulative pregnancy rates showed similar trends. Dr. Hall reported that for all methods combined, the rate for those continuing with their first method was 3.2 per 100 at six months, 7.7 at one year, 10.0 at 18 months, 12.1 at two years and 14.6 at 30 months; for all methods (including women who switched to methods other than the one they first adopted), the rates were 6.6, 13.5, 18.4, 23.9 and 29.7 for the same time periods. Again, there was little difference between women who started with the pill or those who began with the IUD, while those who began with the diaphragm had marginally higher pregnancy rates (see Table 1).

Less Discontinuation Among Blacks

Dr. Hall noted that discontinuation rates for blacks (who made up 46.5 percent of the sample) were consistently lower than for Spanish-speaking women (who composed 38.4 percent of the sample), with all other ethnic groups falling in between (but nearer the black women). Discontinuations with changes to another method were about the same for blacks and Spanish-speaking women, he observed, but the blacks less frequently stopped all contraception. As for the effect of age, "[method] termination rates were slightly higher and pregnancy rates were strikingly higher among women in the younger age groups." This was not so much true for women who began on the pill as for those who first adopted IUDs or diaphragms. Both discontinuation and pregnancy rates declined markedly with increasing parity.

The principal difference between this study and others, Dr. Hall observed, is that the discontinuation and pregnancy rates with IUDs are higher in his report. "At least part of the explanation for these differences must lie in the longer (15 month) interval between follow-up appointments," he notes. Some 41.9 percent of the pregnancies in IUD acceptors took place "with the location of the device unknown at the time of conception," much higher than in other studies—including an earlier one of his own — he adds. Socioeconomic and educational differences are also probable contributing factors to the higher pregnancy and discontinuation rates found in the study.

The lack of a substantial difference in rates of pregnancy and contraceptive termination between acceptors of IUDs and orals has been reported by others, Dr. Hall notes, and these additional data dispute the theory that adoption of the IUD necessarily results in lower contraceptive termination and pregnancy rates than the pill. In addition, "one must unavoidably conclude . . . that, in addition to the age, parity, and ethnic origin of

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the patient and her initial choice of contraceptive method, the intensity of follow-up care determines to a significant extent the overall success of a contraceptive program."

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FDA Okays Limited Depo-Provera Use

The Food and Drug Administration (FDA) has announced its decision to approve Depo-Provera (the progestogen, medroxyprogesterone acetate) for contraceptive use under several limited and sharply defined circumstances. Numerous trials of the injectable hormone (manufactured by the Upjohn Company) during the past decade have shown that 150 mg doses every three months provide effective contraception, "but also clearly demonstrated that the regimen can cause prolonged and possibly permanent infertility," according to the FDA.

Both Depo-Provera and diethylstilbestrol (DES), an estrogen which was also recently approved by the FDA for use as a "morning-after" contraceptive pill, will be required to have special package inserts for the patient as well as for the doctor. The only other drugs required to have an insert in the package sold to the patient are oral contraceptives. Final approval of Depo-Provera has been delayed until an insert can be approved.

Depo-Provera's contraceptive effect was first noted while it was being used to treat endometriosis, threatened and habitual miscarriage, and cancer of the uterus. Women who received such therapy were found to remain infertile for long periods after discontinuing the medication. In clinical trials of the drug as a contraceptive, irregular bleeding patterns were a common side effect, and ranged from amenorrhea in some women to very heavy bleeding in others. It was feared by some investigators that, in women with poor nutrition, the heavy bleeding might lead to anemia. But the side effects which delayed approval by the FDA are the possibility of permanent sterility and the possible increased risk of breast tumors. A report by investigators from Emory University School of Medicine and the Center for Disease Control noted that in a study of 723 patients, normal menses had not resumed within a year after discontinuation in 24 percent of the women. The researchers recommended that Depo-Provera be used by "women who do not plan to have more children."

Upjohn researchers Dr. Paul C. Schwallie and J. Robert Assenzo, summarizing work by 54 clinical investigators with 3,857 women in an article in *Fertility and Sterility*, noted that it took an average of 5.8 months (with a maximum of 28 months) for fertility to return in 245 subjects. (They also noted that 15 women, or 0.25 per 100 woman-years, became pregnant while on the injectable. The maximum duration of treatment in this group was 70 months.

The FDA pointed out that "animal tests have raised the question of a possible increase in breast tumors when Depo-Provera is used as a contraceptive. Tumors of the breast were observed in tests on dogs given low and high doses." At high dose levels, some of the tumors were malignant, and metastasized. The relevance of these experiments to humans is "not known, but at the present time there is no evidence that breast cancers occur more often in women receiving the drug," according to the FDA.

The package insert will advise both the woman and her doctor that Depo-Provera should be used only by "those patients who accept the possibility" that they may not be able to become pregnant after discontinuing contraception, an FDA spokesman told *Digest*. The FDA also declared that, for a woman to use Depo-Provera, she must:

- refuse or be "unable to accept the responsibility demanded by other contraceptive methods," or
- be "incapable or unwilling to tolerate the side effects of conventional oral contraception," or
- have had "repeated" failures with other contraceptive methods.

The dangers of using Depo-Provera will be detailed in the package insert. The same will be true for the DES insert, which will also emphasize that the FDA "does not consider the drug safe for routine or repeated contraceptive use because of the relatively large amounts of estrogen taken over a short period of time." The increased risk of future cervical and vaginal cancer to a female fetus if the woman is already pregnant will also be noted. In such an instance, the "FDA is recommending that the patient consult with her physician on the question of continuing any pregnancy." [For details on DES approval, see: "FDA Approves DES, Urges Limited Use," *Digest*, Vol. 2, No. 3, 1973, p. 12.]

Sources

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