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Family Planning Digest

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Female Sterilization

Hysteroscopic Technique Appears Promising; Improvements in Laparoscopy Investigated

Research continues to find a method of female sterilization which is simpler, safer and less traumatic than conventional surgery. Enthusiasm for laparoscopic sterilization [for details see: "Simpler Sterilization Boosts Public Acceptance," *Digest*, Vol. 1, No. 3, 1972, p. 4] has been tempered somewhat by recent reports of some serious complications associated with its use, and Planned Parenthood's National Medical Committee last May advised the agency's affiliates to consider laparoscopic sterilization a hospital rather than an outpatient clinic procedure, to be performed under general anesthesia only by experienced physicians.

Another endoscopic technique, hysteroscopy, seems promising as yet another way to perform female sterilization without even the minimal surgery into the peritoneal cavity required by laparoscopy.

Opening of fallopian tube seen through hysteroscope.

Hysteroscopic Sterilization

In hysteroscopy, the combined fiberoptic endoscope and cautery device is inserted through the cervix into the uterus, where the openings into the fallopian tubes can be visualized. The cautery is inserted into the tubes, one at a time, and the tubes are burned; scar tissue then forms over the injury, blocking the tubes. Various mediums have been used by different investigators to distend the uterus—carbon dioxide, dextran, and a distilled water and glucose solution. Reports of experience in the United States, Mexico, Thailand and Germany give a preliminary picture of the current state of hysteroscopy.

The major problem with the method so far appears to be a high failure rate. Dr. Robert Neuwirth, Professor of Clinical Obstetrics and Gynecology at Columbia-Presbyterian Medical Center in New York City, reported on 17 hysteroscopic sterilizations performed in New York and 44 done in Bangkok, at the annual meeting last May of the American College of Obstetricians and Gynecologists. In the New York group, he used a 32 percent solution of dextran to distend the uterus. Dextran is a viscous fluid which does not mix easily with blood, a problem that can cause poor visualization through the hysteroscope. Of the 16 patients he was able to follow up with hysterograms (x-ray of the uterus), one woman had bilateral patency and three had unilateral patency—a 25 percent failure rate.

Of these four women, two underwent another hysteroscopic sterilization, both successful, and two had laparoscopic procedures performed. Two women, it was later discovered, were already pregnant when the hysteroscopy was performed. Both were aborted two weeks after their first missed period. One of them was found to have unilateral patency, and she underwent laparoscopic sterilization concurrent with her abortion. The other woman showed no patent tubes when checked three months after the operation (the standard follow-up time for all the women in

Table of Contents **Page**

the series). Six months later, however, she became pregnant and another hysterogram, following abortion, revealed unilateral patency (evidently due to recanalization, according to Dr. Neuwirth). The hysteroscopic procedure was repeated on her.

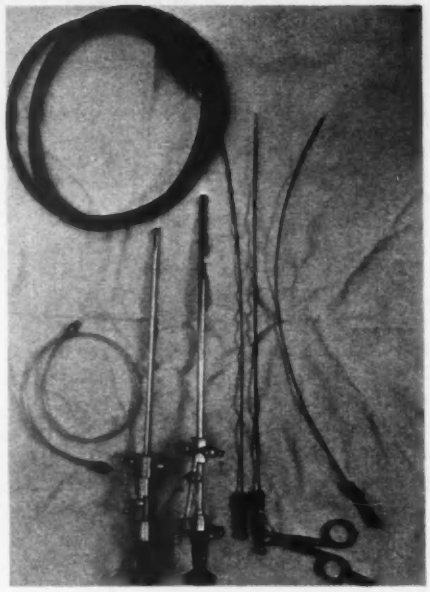
"All patients reported normal menstrual function postoperatively," Dr. Neuwirth said. "There was no fever, pain, or other morbidity noted." The same is true for some 30 patients operated on more recently in New York, he added, who were not included in the report because they had not yet been analyzed for tubal patency. The tubal closure rate was not improved by inserting teflon or polyester mesh plugs after cautery, which was attempted (in another study) with several patients at the Chulalongkorn Hospital Clinic in Bangkok. Dr. Neuwirth noted that of 20 patients who had teflon plugs inserted, there was an 85 percent rate of bilateral closure; for 14 women with polyester plugs inserted, a 64 percent rate; and for nine women with no plugs inserted, an 89 percent rate. (One woman on whom only cautery was performed was lost to follow-up.) The Thai women were given Depo Provera as a contraceptive until closure was confirmed; the New York women were put on a regimen of oral progestins.

The failure rate has been decreasing with experience, Dr. Neuwirth said, as the protocol for the timing of the procedure (now done as soon after menstruation as possible for easy visualization of the tubes), and the amount of diathermic energy used has been refined. Ease of locating the opening of the fallopian tube and inserting the cautery has also been a factor, he reported. For the last 44 cases done in Bangkok and New York, the bilateral closure rate was only 61 percent when the doctor noted some difficulty in identifying the tubes, while the rate was 94 percent "in cases which went easily." While more work is needed to refine the method, such factors as the "minimal morbidity," the short operative time ("usually less than 15 minutes"), and the "rapid, two to four hour" recovery time indicate "that hysteroscopic tubal cautery will shortly be useful in routine clinical practice," Dr. Neuwirth declared.

Dr. Rodolfo Quinones Guerror of the National Medical Center in Mexico City found his experience with hysteroscopic sterilization "most acceptable." He reported at the annual meeting of the American Fertility Society in San Francisco last April that he had performed 115 procedures using a five percent solution of glucose in distilled water to distend the uterus. This, he claimed, worked as well as dextran but required somewhat more pressure. There was no morbidity in the 114 cases he was able to follow up, but there were eight pregnancies. Of the first 34 hysterosalpingograms (x-rays of the uterus and the tubes) made three months after hysteroscopic sterilization, six, or nearly 18 percent, showed unilateral patency three months after the operation. In a series of 71 women, 14, or nearly 20 percent, had a patent tube three months postoperatively. Local anesthesia (paracervical block) was used in all cases.

Because the tubes occlude at different rates in different women, careful follow-up is essential, Dr. Quinones emphasized. The women were maintained on oral contraceptives (or, if the pill was contraindicated, vaginal contraceptives; never IUDs) until closure was confirmed. While the women are released only 15 minutes after the procedure is completed, Dr. Quinones said, they must return for examinations one day, one week and three months later, and then every three months for a year, with hysterograms taken from three months onward.

Dr. Hans-Joachim Lindemann, of the Elizabeth Hospital in Hamburg, Germany, outlined his operating techniques at the American Fertility Society, and described his results (as of June) in a special communication to *Digest*. He has performed more than 130 hysteroscopic sterilizations using carbon dioxide to distend the uterus. He told *Digest* that there were no complications in his series, but warned that "complications might occur when using higher values of gas pressure and volume" than he uses. Dr. Lindemann recommends a flow of 80 ml of gas per minute at a pressure of 200 mm of mercury, and a coagulation temperature of 80-90 degrees centigrade delivered for about 90 seconds. He uses an adapter on the hysteroscope, "which fixes itself automatically by vacuum to the cervix" to prevent gas from escaping from the uterus, a problem sometimes encountered.



Hysteroscopic instruments: (top) fiberoptic tube; (l. to r.) dextran tube, scopes, cautery, scissors, knife.

There have been no pregnancies in the series. Complete closure of the tubes, the physician said, has occurred in the 53 women on whom the procedure was performed in the proliferative stage of the menstrual cycle (just after menstruation). Some incomplete closures were observed when hysteroscopy was performed in the secretory stage of the menstrual cycle (after ovulation), or when higher temperatures were used to achieve coagulation of the tubes or when sterilization was done concurrently with abortion. A total of 87 women have thus far been checked three months after sterilization by hysterosalpingography (x-ray of the uterus) and hysteroscopy for tubal patency.

Lindemann found that it takes about 12 weeks for the tubes to close completely. At the beginning of the series, he recommended that contraception be used during this period. Now, however, he believes this is unnecessary because of the technique he employs (described above). Even in the 20 women in whom a tube was not completely closed, the physician reported "functional sterility [was] achieved." This is because the cauterization destroys the spincter muscle of the tube, he explained, so that the fertilized ovum can no longer remain in the tube for the four days it needs to mature before implantation.

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At the present time, the procedure is performed under local anesthesia (paracervical block) on an outpatient basis. Originally, all patients were hospitalized. The typical patient in the series was 31 years old, and had two children.

In a phone interview, Dr. S. Jan Behrman, Professor of Obstetrics and Gynecology and Director of the Department of Reproductive Biology at the University of Michigan School of Medicine, told *Digest* that he regards hysteroscopic sterilization as an experimental method by no means ready for general use. One of its limitations, he points out, is that the technique can be used only on multipara since the cervical canal must be dilated to seven mm. Another problem, he feels, is that the technique is more difficult than laparoscopy, requiring a longer training period for the requisite skills to be developed by doctors. Dr. Behrman has performed 12 hysteroscopic sterilizations, using glucose and distilled water, as Dr. Quinones does, believing that this method is superior to carbon dioxide which requires twice the amount of equipment and may be accompanied by untoward complications. His own findings are too preliminary to be reported at this time, he says. Dr. Behrman believes that the advantage of hysteroscopy over laparoscopy is that the former is "probably less traumatic" as an outpatient procedure under local anesthesia.

Laparoscopic Sterilization

Despite the cautions concerning laparoscopic sterilization, there is a consensus that if a skilled physician performs the procedure complication rates can be kept low. Two recent reports highlight this observation.

Laparoscopic sterilization can be performed successfully and safely on an outpatient basis in a freestanding clinic, according to Dr. A. J. Penfield, Medical Director of the Planned Parenthood Center of Syracuse, New York, where some 200 women have undergone the procedure since July 1972. There were no perforations, burns or hematomas and only one technical failure in the series he reported at the 1973 annual meeting in Houston of the American Association of Planned Parenthood Physicians (AAPPP). Only local anesthesia was used.

"Increasing numbers of women are requesting this procedure because of its effectiveness, its convenience and its relatively low cost," Dr. Penfield said. The clinic uses a sliding fee scale up to $300, based on income for the procedure; and the demand is so high that there is currently a waiting list, he added.

The Syracuse center decided to add the service, Dr. Penfield noted, because "patients, in increasing numbers, are requesting sterilization, and many are unwilling to accept the expense and delay of a hospital admission." The Planned Parenthood affiliate already offered contraception, sex education, vasectomy and abortion services.

Each patient—who must be 21 or over—is given "at least one month to think over her decision" after she first requests sterilization. If she is married, her husband's consent is "welcomed" but not required. Patients with heart disease, convulsive disorders, multiple previous laparotomies or gynecological disorders whose correction would take precedence over sterilization are excluded.

The woman is told exactly what she should expect to feel during the operation. She is informed that only local anesthesia will be used and "that she will feel very full" when the 1.8 to two liters of carbon dioxide are introduced into her abdominal cavity. And she is also told to expect "three seconds of sharp pain" as each of her tubes is cauterized with electric current.

The technique for the operation is standard, using the single-incision method. [See: "Outpatient Female Sterilization Is Found Effective," *Digest*, Vol. 1, No. 4, 1972, p. 6.] The only failure occurred with a woman who had "unusually thick tubes," Dr. Penfield said. She became pregnant two months later. The pregnancy was terminated at her request and laparoscopic sterilization was again performed (using five mm grasping forceps instead of the three mm forceps that were used originally), this time successfully.

After the sterilization is performed, the woman rests in a recovery room for an hour where she is observed for any developing complications, before being sent home with a companion. She is informed she may have abdominal or shoulder discomfort (from trapped gas bubbles) for a day or two, and told not to worry about any "slight oozing from the incision" (which is closed with two sutures and covered with a bandaid) or discoloration. "She may have intercourse at any time but we advise waiting one week so that all her discomfort is gone," Dr. Penfield said. "Most of our patients told us after the procedure that they were glad to have it done that way."

While the one failure was the only complication in the Syracuse series—where all the laparoscopies have been performed by Dr. Penfield—the complication rate has been a problem elsewhere. Dr. Julius Butler, of the University of Minnesota School of Medicine reported at the AAPPP meeting on what two clinics in Washington State did to reduce their unacceptably high rate of complications from laparoscopic sterilization.

The Mason Clinic in Seattle began a laparoscopic sterilization program (using the two-incision method) in February 1970, and a similar program was started that December at the Harborview Medical Center, also in Seattle. But when, by October 1971, 13 complications had occurred in 93 cases at Mason and 11 complications were associated with 106 cases at Harborview for a total complication rate of 12 percent, the two institutions held a combined conference, conducted by Drs. Butler and Richard M. Soderstrom, to try to ascertain why the rate was so high and what could be done about it. The complications included nine cases of bleeding, five failures, four round ligament resections, two resections of the ileum, one cauterization of the bowel, one case of umbilical splitting, one instance of gas trapped in subcutaneous tissues and one spasmodic closure of the larynx. They found that all but one instance of operative or postoperative bleeding could be attributed to defective cautery equipment, and 12 of the remaining 16 complications occurred when an "inexperienced" physician performed the operation. (Only those individuals who had received postgraduate training in laparoscopy and had performed at least 10 such operations were considered "experienced.")

As a result, a rigid protocol was established for the operation, Dr. Butler explained, equipment maintenance was improved and "a laparoscopy committee was formed to establish criteria for operation privileges of all involved surgeons." Trainees, before performing voluntary laparoscopic sterilizations, were advised "to practice tubal sterilization and other operative laparoscopy procedures in a minimum of ten patients already scheduled for benign laparoscopy such as hysterectomy." A "sidearm" was obtained for the laparoscope so students could observe experienced surgeons performing the procedure. Part of the protocol was to have the cautery equipment connected only when cauterization was to be done and disconnected immediately afterwards.

As a result of the strict controls introduced, in the next year there were only three complications in 294 operations—one percent of the cases—performed at the two clinics.

New Clips

In an effort to reduce trauma from electrocautery, investigators at the University of North Carolina are using a new clip, made of inert plastic, to achieve severing of the tubes without cauterization. The clip consists of two jaws, each about half an

inch long and narrower than a paper match, Dr. Jaroslav F. Hulka told *Digest*. The jaws are placed around the tube and are held together with a small gold-plated stainless steel spring designed to let the jaws seal off the tube and gently divide it over a few days. The initial laparoscopic procedure remains the same, Dr. Hulka said, with nitrous oxide used to distend the abdomen. Instead of the cautery equipment, the clips are applied with a clip-applying laparoscope which is about as big around as a fountain pen. Once the clips are on, the instruments are removed, the nitrous oxide is let out, a suture is applied to the abdominal opening and the patient leaves soon afterward. The suture dissolves a few days after surgery. Since September 1972, 185 sterilizations using these new clips have been performed, with the following results: In two instances, the clips could not be applied because obesity of the patients made it impossible to visualize the tubes. Two pregnancies have occurred. In one case, a clip was placed too far laterally and it didn't extend across the channel. This was seen by hysterosalpingogram x-ray after the patient aborted spontaneously. Another woman was already pregnant when the clips were placed. She requested and received a legal abortion. X-ray after the abortion revealed both tubes to be closed. One woman had unsuspected pelvic inflammatory disease (PID), when the clips were applied, and the procedure activated the infection. The patient received treatment and the PID is now under control. All other patients have been carefully followed and are free of complaints and pregnancy.

Although the precise complication rate associated with laparoscopic sterilization is not yet known, a recent report by the Complications Committee of the American Association of Gynecological Laparoscopists, based on replies from 49 physicians to a questionnaire on their experience for the year ending June 1972, found the following: They had performed 12,182 laparoscopic procedures, about 7,000 of them sterilizations. Electrocoagulation accidents occurred in 16 cases, for a complication rate of 2.3 per 1,000 cases. There were four pregnancies, including two where fertilization occurred after surgery, and two where sterilization probably followed implantation, for a total failure rate of 0.5 per 1,000 sterilizations, an incidence described by the committee as "equal, if not superior to, the standard Pomeroy technique of interval sterilization." There was one death of peritonitis caused by bowel cautery and later perforation unsuspected at surgery.

The results which can be obtained by an experienced surgeon were demonstrated by Dr. Patrick Steptoe, pioneer British laparoscopist. He reported that of a total of 3,000 laparoscopic sterilizations, 1,840 had been followed up for from 18 months to six years. There were no deaths and two pregnancies unrecognized at the time of sterilization. There were also two ectopic pregnancies. In commenting on who should do laparoscopic sterilizations, Dr. Steptoe said, "It is appalling to me that anyone should think of attempting to train people in laparoscopy, particularly for sterilization, in a course lasting a few days. Only the principles can be taught, and several months of guided experience in diagnostic uses is paramount."

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Polling Americans

Contraceptive Education for All Teens, and Services on Request Favored by Most Adults

More than 70 percent of white adult Americans would "approve . . . of having nationwide programs of birth control education in public high schools" and 54 percent would approve of "health programs that gave birth control free to teenage girls who requested it." Approval for both items rose sharply between 1970 and 1972. These were the major findings of a 1972 nationwide Gallup survey as reported by Judith Blake, professor in the Graduate School of Public Policy and Research Demographer at International and Urban Research at the University of California (Berkeley), at the annual meeting of the Population Association of America held in New Orleans in April.

The August 1972 survey is the most recent of four commissioned by Blake; the earlier polls were conducted in January and October 1969 and July 1970. All asked the same two questions about educating and serving teenagers: "Would you approve or disapprove of having nationwide programs of birth control education in public high schools?" and "What about health programs that gave birth control free to teenage girls who requested it? Would you approve or disapprove?" The most striking change in attitude occurred between 1970 and 1972, with a 10 percentage point increase in the proportion of respondents approving education and a 14 percentage point increase in approval of services, as Table 1 shows. Approval among women increased even more dramatically, by 12 percentage points for education and by 18 percentage points for provision of services upon request. The size of the 1972 sample was 1,345, similar to the previous ones.

While the earlier polls showed that more non-Catholics than Catholics and more men than women favored both educational programs and free services, these differences virtually disappeared by the time of the most recent survey. There was still a marked difference in response according to age and education, however, with younger and better educated respondents more likely to favor such programs.

In the January 1969 survey, 69 percent of the men (63 percent of Catholics, 71 percent of non-Catholics) and 58 percent of the women (49 percent of Catholics and

62 percent of non-Catholics) favored birth control education in public high schools. By August 1972, this had increased to 71 percent of men (70 percent of Catholics and 72 percent of non-Catholics) and women (69 percent of Catholics and 72 percent of non-Catholics). The attitude toward free services for teenage girls who request them showed a similar pattern: In January 1969, 46 percent of men (34 percent of Catholics, 50 percent of non-Catholics) and 30 percent of women (23 percent of Catholics, 32 percent of non-Catholics) supported this idea, while in August 1972 the figures were 55 percent of men (54 percent of Catholics, 56 percent of non-Catholics) and 53 percent of women (56 percent of Catholics and 52 percent of non-Catholics).

While support for free services was lower than support for education, "the responses concerning services may even have been biased in a positive direction because the question was asked after respondents had committed themselves concerning birth control education in high schools," Blake said. "Moreover, the question did not specify the birth control methods to be dispensed." Expanding on her prepared paper, she pointed out that her research showed less readiness to dispense the pill to teenagers on request than nonspecified contraception. "Counterbalancing these sources of positive bias," she said, "is the fact that the question referred to girls alone. Many respondents may be more positive toward services for teenage boys (services that, for example, dispense condoms)." However, she said, health programs are most likely to offer "the most effective methods," pills and IUDs. "Only casuistry would allow one to suggest that the actual targets of teenage birth control services are or will be in the near future, teenage boys."

Differences in the wording of questions can produce different results, Blake noted, referring to a Gallup survey commissioned by Planned Parenthood in June 1972, two months before the most recent one in Blake's series. In that survey, 73 percent of whites and 63 percent of blacks agreed that "professional birth control information, services and counseling should be made available to unmarried teenagers who are sexually active." The figures for men and women were almost identical (73 and 72 percent, respectively) while Catholics showed only slightly lower support (68 percent) than Protestants (73 percent).

Blake asserted that "by placing the issue of services between birth control information and counseling in one question, Planned Parenthood did not tap attitudes toward services independently of attitudes toward birth control education. She, on the other hand, used two separate questions for education and services. Moreover, she pointed out, the Planned Parenthood question "did not specify which sex was under consideration." Blake added, in response to questions, that use of the term "sexually active" could also enlarge the proportion approving, although teenagers who request contraception might be presumed to be sexually active.

A question similar to Blake's statement on birth control education was included in a survey made for the Commission on Population Growth and the American Future by the Opinion Research Corporation in May and June 1971. In response to the question, "would you be for or against high schools offering information on ways of avoiding pregnancy?," 62 percent said they favored such education, 25 percent said they opposed it, eight percent said it depended on other factors, and five percent had no opinion. These results show close correspondence with Blake's 1969 and 1970 surveys.

Blake compared the support for free birth control services to teenage girls with attitudes toward premarital sex. Respondents were asked in July 1969 and August 1972 whether they thought "it is wrong for a man and a woman to have sex relations before marriage, or not?" In both years there was significantly less approval of premarital sex than of birth control services for teenage girls (19 percent vs 39 percent in 1969 and 30 percent vs 54 percent in 1972). More respondents in all categories answered both questions positively in 1972 than in 1969. While differences between Catholics and non-Catholics on the question of sexual permissiveness essentially disappeared between the two polls, the difference between men and women who thought premarital sex was not wrong remained (23 percent vs 14 percent in 1969 and 37 percent vs 23 percent in 1972).

Blake concluded that "moral reservations about premarital relations exert a downward pressure on the proportions willing to make birth control services available to teenage girls." Even in those groups who least support premarital sex, there is moderate support for birth control services to teenage girls, Blake said. Thus, only 10 percent of women over 45 said premarital relations were not wrong in 1969, and 12 percent in 1972, but 32 percent in 1969, and 45 percent in 1972 supported birth control services for teenage girls. "The public has thus not allowed its normative feelings to color in all cases its views about protecting teenage girls from pregnancy. We may expect that future changes in popular approval of birth

Table 1. Percent of white adult Americans who would approve nationwide birth control education programs in public high schools and of health programs that gave free birth control to teenage girls who request them; July 1970 and August 1972

Respondents	*Percent favoring education*		*Percent favoring free services*	
	July 1970 (N= 1,393)	*Aug. 1972* (N= 1,345)	*July 1970* (N= 1,393)	*Aug. 1972* (N= 1,345)
Total	**61**	**71**	**38**	**54**
Men	**64**	**71**	**46**	**55**
Catholic	62	70	46	55
Non-Catholic	65	72	46	56
<30	81	83	62	66
30-44	67	75	39	58
≥45	57	63	43	48
Grade school	45	56	41	42
High School	67	72	43	52
College	75	77	55	65
Total men	(680)	(663)	(680)	(663)
Women	**59**	**71**	**35**	**53**
Catholic	58	69	42	56
Non-Catholic	59	72	32	52
<30	78	88	48	65
30-44	64	77	29	57
≥45	47	58	33	45
Grade school	32	58	19	36
High school	63	72	36	55
College	65	75	46	57
Total women	(713)	(682)	(713)	(682)

control services for teenage girls will be affected not only by changes in attitudes toward premarital relations but also by changes in the degree to which the public is willing to take a purely pragmatic view of the teenage birth control issue."

Proportion Sexually Active

Blake's finding that most adults approve giving free birth control services to teenage girls who request them, and the Planned Parenthood survey finding that there is overwhelming approval for giving birth control services to "sexually active" teenagers lead to the question of what proportion of girls who *request* contraceptive services have already *had* sexual experience.

A study of 502 girls younger than 18 years of age, who for the first time sought professional help to obtain contraceptive services at five Los Angeles clinics in 1972-1973, reveals that 96 percent were previously sexually active—92 percent of them for longer than one month and 61 percent for more than a year. Drs. Diane S. Fordney Settlage, Sheldon Baroff and Donna Cooper of the Los Angeles County-University of Southern California (USC) Medical Center reported that only 39 percent of the sexually experienced girls had ever used any form of contraception prior to seeking professional birth control help. These data were presented at the 1973 annual meeting of the American College of Obstetricians and Gynecologists in Bal Harbor, Florida.

A breakdown of the girls by age, sexual activity and contraceptive use shows the following:

- Nine were 13 years old, all of whom were sexually active; seven for between one month and one year, one for less than one month and one for more than one year. None had ever used contraception.
- Twenty-five were 14 years old, and 23 of them had prior sexual experience. Two of those who had intercourse had been sexually active for less than a month, 13 for between one month and one year, and eight for more than a year; 22 of those sexually active had never used contraception.
- Fifty-five of the 63 15-year-olds were sexually active. Of those with sexual experience, seven had been sexually active less than a month, 22 for between one month and one year and 26 for more than one year. Only 19 had ever used any form of contraception—even improvised methods such as withdrawal.
- Of the 176 16-year-olds, 174 were sexually active—eight for less than one month, 70 for one month to one year and 96 for more than one year. Of those sexually active, 111 had never used contraception.

- Of the 229 17-year-olds, 221 were sexually active; three less than one month, 57 for one month to one year and 161 for more than one year. One hundred and eighteen of those sexually active had never used contraception.

Dr. Settlage noted that the 20 girls who were not sexually active said they had boyfriends and expected to have sexual intercourse shortly.

Since all of the Los Angeles girls were seeking professional birth control help for the first time, it is not surprising that the proportion sexually active who had never used contraception was markedly higher than for girls of similar age and sexual experience in a national study by Johns Hopkins sociologists John F. Kantner and Melvin Zelnik. Kantner and Zelnik found that only 32, 20 and 12 percent of sexually experienced 15-, 16- and 17-year-olds, respectively, had never used contraception, compared with 61, 63 and 52 percent in this Los Angeles sample.

Contraceptive Use

Among those who had ever used contraception, the condom was the most popular method (employed by 42 percent of those ever using contraception and 16 percent of all sexually active). More surprisingly, the second most often used method was the pill (used by 26 percent of users and 10 percent of the sexually active), obtained from friends or other nonmedical sources or from a doctor for treatment of irregular menstrual cycles. Use of withdrawal (eight percent of users) and douche (less than one percent) was much lower than that reported in the Johns Hopkins study—another surprising finding, considering that none of the girls had previous professional help in obtaining contraception. Eight percent of users had used rhythm, and four percent some combination of methods. As might be expected, none had used the IUD.

The older the girl, the more likely she was ever to have used contraception, Dr. Settlage found. However, of those who had never used contraception, the oldest were more likely than the younger to have been sexually active for more than a year (70 percent of noncontracepting 17-year-olds, compared with 47 percent of similar 16-year-olds, 50 percent of 15-year-olds, 36 percent of 14-year-olds and 11 percent of 13-year-olds).

Family income ranged from welfare level to over $20,000 a year, but the study found no difference in prior contraceptive use among the various income levels. The five clinics included a Planned Parenthood clinic in a middle-class area (60 percent of those girls studied), the teen and pediatric gynecology clinics at the USC Medical Center (which had 25 percent of the girls, mainly from middle and lower socioeconomic groups), a free clinic (five percent, who were either local high school students or transients), the John Wesley County Hospital (which had five percent, from a working-class black area), and Children's Hospital (which had five percent, mainly upper and middle class).

One-fourth of the girls were black, 70 percent white and five percent Mexican-American. One difference that was noted among the racial groups was that blacks tended to make up larger proportions of the younger age groups—78 percent of the 13-year-olds were black, with the rest white; while 22 percent of the 16- and 17-year-olds were black, with 69 and 75 percent, respectively, white and nine and three percent Mexican-American.

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Social Norms

Family, Peers Apply Pressure for Kids

Despite the fact that American fertility performance is now at the level consistent with replacement, and that younger Americans say they expect only about two children, there appears to be greater social pressure to have a first and second child than to refrain from having five or more, Janet Griffith, of The Johns Hopkins University, reported to the 1973 annual meeting of the Population Association.

Among couples themselves, she found that two children is a "normative" lower limit on family size, while the upper limit is "less clear." Her conclusions were based on responses to questions asked of 990 men and 1,050 women in a survey of a national sample conducted by the Opinion Research Corporation in July 1972. When respondents were asked whether families with different numbers of children were "too small," she found "a sharp break between two children and one child." While only seven percent of women and five percent of men assert that two or more children make a family too small, 74 percent of women and 63 percent of men believe that a family as small as one child isn't large enough.

On the other hand, only 12 percent of men and six percent of women believe that three children make a family "too large." One-fourth of the respondents (28 percent of men and 20 percent of women) say that four children make too large a family, and less than half (48 percent of men and 44 percent of women) think that five children are too many. A majority (61 percent of both men and women) believe that six children make a family too large. "Overall," Griffith said, "women appear somewhat less tolerant than men of one-child or childless families, and perhaps somewhat more tolerant of three- to five-child families."

Those ever-married respondents aged 18-39 (310 men and 415 women) were asked whether they would expect pressure from family, peers and others if they remained childless, had only one child or were expecting a fifth child. Seventy-eight percent of both men and women believe that parents or other relatives would definitely or probably "urge [them] to have a child" if they had none, while 62 percent of men and 69 percent of women said that friends would do so. Not surprisingly, women feel more pressured about childbearing than men: If they already had one child, 62 percent of the men, but 76 percent of the women would expect relatives to urge them "to have another child," and 52 percent of men and 66 percent of women would expect a similar reaction from friends. If a couple were expecting its fifth child, 54 percent of the men and 72 percent of the women would expect relatives to urge them "to think about limiting [their] family," while 51 percent of the men and 62 percent of the women think friends would do so. Higher proportions—58 percent of the men and 72 percent of the women—think "people would say [they] were wrong to have so many children."

Women more than men expect to feel "out of place" in social situations if they remain childless. While 54 percent of the women would feel out of place when getting together with other married women, only 33 percent of the men would feel that way with other married men. Some 43 percent of the women and 34 percent of the men would feel out of place when meeting with relatives; while 51 percent of the women and 40 percent of the men think "people would say [they] were being selfish." Nearly the same proportion of women and men (81 and 83 percent, respectively) believe people would say that their child "would be spoiled" if they had only one. However, 71 percent of the women, compared with just 57 percent of the men, said they would worry that being an only child "would be bad for the child." Griffith points out:

> Many women give up employment and remain at home, particularly after the birth of the first child, which tends to bring them into contact with neighbors and others who have children and who thus constitute a 'social audience' for the evaluation of parental behavior. The combination of responsibility for producing a 'good' family life and 'good' children, the absence of clear criteria for evaluating this performance, and the woman's primary structural position in the family and neighborhood rather than in occupational activities, would be expected to, and apparently does, make these pressures considerably greater on women than on men.

There is a difference between young (18-24) and older (25-39) wives in the sample, she notes. A smaller proportion—but still "above 60 percent"—of the younger group expect peer pressure to have a first child, while two-thirds think "it would be bad for the child if they had an only child." There is no significant difference in expected pressures between women employed full-time and those who are not.

"These kinds of data, in combination with data on expected family size and on the employment of women, point to the continued tension among economic, technical, demographic, and normative factors in the development and acceptance of different role alternatives within and outside marriage and in the making and implementing of family size decisions," Griffith concluded.

Source

J. Griffith, "Contemporary U.S. Family Size Norms and Deviant Family Sizes," paper presented at the annual meeting of the Population Association of America, New Orleans, La., April 27, 1973.

Dilatation

Laminaria Tents Dilate Cervix Gently

A hundred-year-old method of cervical dilatation is slowly coming back into use in the United States after some 60 years of disfavor. Laminaria tents—dried, rounded stems of the seaweed *Laminaria digitata*, five to seven cm long and one mm or more in diameter—were once widely used when dilatation was necessary for obstetrical or gynecological procedures, but the method was generally abandoned because of problems with infection. Improved sterilization methods have stimulated renewed interest in laminaria as a means of averting the uterine and cervical damage which sometimes occurs when standard methods are used.

In a series of 500 curettage abortions performed at the University of Oregon Medical School, with laminaria tents used for cervical dilatation in all cases, the method was so effective that a nine to 12 mm curette could be inserted in all but two cases, according to a report by Burritt W. Newton, M.D., in the *American Journal of Obstetrics and Gynecology*. There were no uterine perforations, and only three cases of minor cervical lacerations, including the two in which insufficient dilatation took place.

The average age of the patients was 22.2 years, with a range of 14-43: 127 were under 20 years of age; 339 were 20-29 years old; and 34 were 30 or older. Sixty-eight percent had no children; and just under nine percent had three or more. The length of gestation ranged from two to 18 weeks, with 90 percent pregnant for less than 10 weeks. Fifty patients were more than 12 weeks pregnant.

The laminaria tents, which were presterilized by irradiation and then resterilized by ethylene oxide gas prior to use, were inserted after sterilization of the vaginal and cervical area one day prior to the abortion (except for eight insertions on the day of the abortion and nine two days before). During the time the tents were in place, they slowly absorbed cervical fluids (since they are hygroscopic), and expanded to several times their original size—thereby dilating and softening the

cervix. "Except in rare instances," Dr. Newton found, conventional cervical dilators were used only for calibration, rather than dilatation. In 212 cases, the actual abortion was performed in the hospital operating room; 288 were performed in a clinic examining room.

Complications due to laminaria or abortion arose in eight percent of the cases and included fever, infections, bleeding and trauma. The infection rate attributable to laminaria was 2.2 percent. "Prior to the use of laminaria at this institution," Dr. Newton wrote, "there was an infection rate of five percent in a series of 246 abortions." Bleeding was not a "serious problem," he reported, since "no patients required transfusion, and none required overnight hospitalization. . . . Delayed bleeding was a complication in one patient who was admitted for curettage." There were no uterine perforations and the rate of all cervical damage was 0.6 percent, compared with five percent prior to the use of laminaria. "It is apparent," he observed, "that the slow dilatation and cervical softening accomplished by laminaria tent should save considerable trauma, with attendant decrease in blood loss, and possibly preservation of childbearing capability." The overall incidence of hospital admission for complications in this series was 1.2 percent.

The tents, which were reused as many as 20 times after resterilization, were also used to soften the cervix prior to induction of labor near term and for placement and removal of IUDs. A cord through one end permits easy removal.

Doctors in London have used laminaria tents for second-trimester abortions, and found the method "very useful and safe." In these cases, since greater dilatation was needed, two or three tents were inserted at a time, and used in combination with standard dilatation techniques, according to Drs. Immanuel Bierer and Victor Steiner, reporting in *Medical Gynecology and Sociology*. In 390 cases, there was only one perforation of the uterus recorded, and cervical lacerations occurred in five percent of the cases. Occasionally, when the cervix was very rigid or the fetus very large, as many as five or six tents were used at once. In this series, 126 patients were 14-19 years of age, 203 were 20-29, 55 were 30-39 and six were 40 or over.

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B. W. Newton, "Laminaria Tent: Relic of the Past or Modern Medical Device?" *American Journal of Obstetrics and Gynecology*, **113**:442, 1972.

Resources in Review

By Dorothy L. Millstone

Many family planning manpower needs can best be met by inservice training. The field is still so new that few traditional schools have identified its career opportunities, much less set down curriculum. That is why it is heartening to be able to report the advent of several new and good training guides.

Drawn from Experience

Patient Services Training Manual (1973), an 83-page 8½" x 11" paperback, is beamed specifically at qualifying staff and volunteers to teach classes in birth control methods, and to become interviewers, medical aides, 'rap' leaders in teen clinics and pregnancy counselors; but it has additional virtues, as well.

Published by Planned Parenthood of Alameda-San Francisco to meet its own needs, the contents, drawn from experience, have the ring of reality. It could also be used as a general text to teach family planning in a variety of settings. Content is indicated by the chapter headings, listed here in order of their appearance in the manual: human reproductive systems, birth control methods, psychological aspects of contraceptive use, guidelines for leaders teaching birth control methods, the pelvic exam, the clinic interview, clinic information and guide for medical aides, teen services, pregnancy counseling, venereal disease, sterilization and human sexuality (including selected bibliography). Rare in such guides is the brief, factual resume of U.S. population issues and Planned Parenthood policies. This could make wholesome background reading for any clinic staff.

Other commendable guide attributes include medical illustrations of high professional quality comprehensible to nonmedical readers; and direct and clear language with scientific terms and popular synonyms smoothly combined. Stress is placed throughout on respect for patients and concern for their privacy, their right to complete information about the service and the confidentiality of the records. There are many evidences of lessons learned from the women's movements; the patient should be told what to expect, rather than be taken by surprise; her method of choice is to be explained, rather than just given.

Purchase price, $4 for a single copy; $3.50 for orders in volume of 10 to 50 copies, from Planned Parenthood-World Population of Alameda-San Francisco, 476 MacArthur Blvd., Oakland, Calif. 94609.

Telling the Same Story

Do patients in your clinic get a different answer to their questions depending on which staff member they happen to ask? A way out of this embarrassing and confusing situation is inservice training for staff at all levels to assure that the same correct information is provided to patients no matter to whom they address their queries. A bonus of inservice training is that it permits a sharing of experience among members of the clinic team. To meet the need for inservice training materials, Dr. Robert A. Hatcher, of Emory University Medical School's Department of Obstetrics and Gynecology, has prepared a set of 30 courses entitled *Family Planning Inservice Training Programs*, which is now being used experimentally in seven medical schools as part of an American Public Health Association (APHA)-sponsored project.

The courses cover various administrative and biomedical aspects of clinic service organized around central questions. For example, an introductory session designed for all staff levels asks: Is it medically appropriate to give a sexually active 12-year-old oral contraceptives? Does an IUD cause infection? Should IUD patients be counseled to use foam or condoms on days 10-17 of the menstrual cycle? Can a never-pregnant woman use an IUD? Do you believe a 15-16-year-old should be able to get contraception without parental consent? In group classes should withdrawal, condoms and rhythm be mentioned routinely?

Another session, on patient privacy and treatment, asks how long patients wait before they see a doctor, whether they are adequately draped during examinations, how they are addressed by staff, whether pregnancy test results are delivered confidentially and at what point the purpose of their visit (whether contraception, infertility therapy or other) is determined.

Although keyed to the 54-page textbook *Contraceptive Technology* (1972) which is out of print (a 1973 edition is in preparation), any standard contraceptive manual or text will provide correct answers.

A free copy of the inservice courses may be obtained from Bennett Terry, APHA, ninth floor, 1015 Eighteenth St., N.W., Washington, D.C. 20036.

For Junior High Schools

There is no shortage of sex education materials for schools. What is in short supply are texts which can evoke high pupil interest and at the same time be acceptable to the "gatekeepers"—the principals, teachers, boards of education,

and community custodians of taste and morality. Now, a St. Paul, Minnesota schoolteacher, Jean Coryllel Lipke, who is also a wife and mother, has produced a set of nine *Being Together* books which just may win a place on this rare book list.

The author designed five books in her set for grades below junior high—an unusual example of books which actually follow the recommendation educators have often made—to get sexual information to pupils *before* the onset of puberty. Interestingly, the one volume that introduces family planning concepts—*Conception and Contraception*—is one of the five.

This 54-page volume (hardcover, colorfully illustrated like the whole 8¾" x 6¼" set) is a factual teaching text discussing physical readiness for conception, how conception takes place and how it may be prevented. Pregnancy and sterility are examined, and a brief section on the chromosomes reviews their role in determining heredity.

A 16-page family planning chapter, the book's last, explains: "Most couples want children and if they can choose when each child will be born, they will have a healthier, happier family." Birth control is defined and the pill, the intrauterine device, rhythm and other methods (including sterilization) are introduced objectively.

The other volumes recommended for elementary levels are *Puberty and Adolescence*, *Pregnancy*, *Birth* and *Heredity*. None of these is excessively simple. All are suitable for higher levels. Children with poor reading comprehension would probably find them hard to follow, and it is likely all would require teacher assistance in classroom situations.

Family planning is mentioned in two of four books designated for junior and senior high school levels. In *Marriage*, a four-page section on contraception cites specific methods and indicates their mechanism of action. A cross-reference directs the student to the fuller presentation in *Conception and Contraception*. In *Sex Outside of Marriage*, a general paragraph mentions contraception. As might be expected, this book highlights negative aspects of premarital sex. The other two junior/senior high school texts are *Loving* and *Dating*, and both seem informative, straightforward and noncontroversial. The nine volumes are enhanced by unusually attractive illustrations, the work of Patricia Bateman and Robert Fontaine.

Two additional texts from the same publisher touch on family planning as they instruct in demography.

The Economics of Underdeveloped Countries by Michael Belshaw discusses population growth as a factor in under-

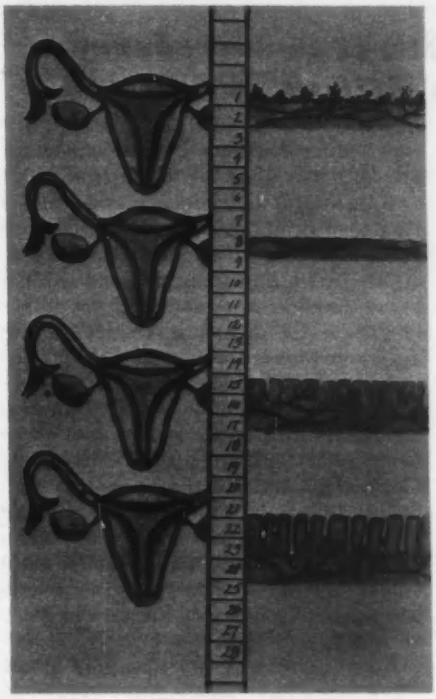


Illustration from "Conception and Contraception."

development and refers specifically to government-sponsored national family planning programs designed to limit growth. *Population: The Population Explosion*, by Claire Jones, Steve J. Gadler and Paul H. Engstrom, uses much the same approach. Principles of demography are introduced, the reality of runaway population growth in some countries is discussed, the U.S. problem is examined, and family planning is briefly reviewed. The U.S. family planning postage stamp is one of many illustrations. The tone of both books is objective, nonadvocative and free of crisis orientation.

The price of all of these books is $3.95 each. Order from Lerner Publications Co., 241 First Ave. North, Minneapolis, Minn. 55401.

A More Flamboyant Approach

A different path to educating young people is taken in *What's Happening*, a 32-page, 8½" x 11", magazine-style booklet dealing with sex, drugs and family planning. This publication, issued by the Emory University School of Medicine and prepared by student interns attending a family planning program summer session, is aimed at helping parents grapple with these issues in the home. But adolescents could quite easily read it themselves. Cartoons, photographs and headlines combine to give this a freewheeling atmosphere.

A lavish use of slang and fast-moving dialogue appeals to young readers. The writing level varies so widely from article to article that it suggests a runaway elevator. On facing pages, for example, are to be found an article entitled, "How to Say 'No'" which reads like minutes from a rap session and another article with the title "Methods of Birth Control," styled like a traditional methods guide. Copies of an experimental edition of *What's Happening* will be sent free to the first 500 *Digest* readers who write for them. In return, Emory invites *Digest* readers to evaluate the booklet, suggest improvements and spell out their suggestions for a national edition.

Purchase price: 35¢ a copy, $15 for 50, $25 for 100 and $200 for 1,000. For a free sample, write to Sheryl Richardson, Training Center, Emory Family Planning, Room 805, Hartford Building, 100 Edgewood Ave., Atlanta, Ga. 30303.

From Co-op Extension

Another welcome addition to education beyond the schoolroom comes from the Cooperative Extension Service of Indiana. Mardel Crandall, a graduate student in child development and family life, created this attractive, cheerful and straightforward series. *Planning for Parenthood* contains the family planning information. The others are *Sex and the Married Couple* and *On the Care and Feeding of Your Marriage*. Each is 20 pages, 6" x 9", imbued with a warm, friendly spirit and a touch of wit. In addition to birth control methods, which are named and assessed, *Planning for Parenthood* discusses birth control philosophy, infertility therapy, pregnancy, and parental roles.

The three publications don't overlap. *Sex and the Married Couple* is a fast-paced popularization distilled from modern studies, shorn of academic references. Common problems are addressed and some solutions suggested. In the *Care and Feeding of Marriage*, the emphasis is on flexibility and adaptability, and the desirability of not expecting perfection. Family planners might consider giving all three in a single packet. Out-of-Indiana requests for free copies should be addressed to Mailing Room, Agricultural Building, Purdue University, West Lafayette, Ind. 47907.

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

IUD Research

Progesterone, Fluid Filled IUDs Introduced; Congressional Hearings Held on IUD Safety

Intrauterine devices came under scrutiny in a variety of settings recently: Two experimental models were discussed at the annual meeting of the American College of Obstetricians and Gynecologists last May, and a Congressional committee held hearings soon afterward to consider whether IUDs (as well as other medical devices) should be regulated by the Food and Drug Administration (FDA) as are the oral contraceptive and other drugs. In a related action, the FDA ordered the Majzlin spring, an IUD made of metal, seized because of complications association with its use.

The Progesterone T

One of the experimental IUDs is a T-shaped polymer device which continuously releases a minute dose of progesterone into the uterus. It is based on the observation, reported Dr. Antonio Scommegna, of the Michael Reese Hospital and Medical Center of Chicago, that after a blastocyst forms progesterone produced by the corpus luteum transforms the lining of the uterus into the decidua, characteristic of early pregnancy; once the decidua forms, another implantation cannot occur. The progesterone released by the T causes premature development of the decidua, thus preventing implantation.

The plain T was chosen as the device to contain the progesterone because of its reported low expulsion and medical removal rates, the physician said, and because the T by itself has a high pregnancy rate (18.3 per 100 woman-years). Therefore, Dr. Scommegna noted, "any contraceptive effect of the added progesterone would become readily apparent." The device, containing a six-month supply of progesterone, was inserted in 249 volunteers 16-41 years of age. The mean daily progesterone release was 128.6 mcg (250 mcg per day at the beginning, down to 65 mcg per day by the end of the six months).

In 1,662 woman-months of use, there were no pregnancies "while a device releasing adequate amounts of progesterone was present in the uterine cavity. Two pregnancies occurred after IUD expulsion (one complete, the other after cervical displacement)." In a third pregnancy, the IUD "was removed and found to be empty because of an improper seal," according to Dr. Scommegna.

The expulsion rate (including cervical displacement) of the progesterone T of 7.9 per 100 woman-years was higher than that reported for the plain T (6.3), as was the rate of removal for medical reasons (6.4 vs 3.2 per 100 woman-years) and removal for personal reasons (12.9 vs 3.9). Many of the expulsions, Dr. Scommegna noted, occured at the beginning of the study when the researchers were not using the proper technique for inserting the device. He attributed the high removal rate to the clinical procedure which included replacement every six months and reevaluation at five-week intervals for the first three months of use, usually with an endometrial biopsy. Half of the medical removals were because of pelvic inflammatory disease (more than seven percent of the women in whom the device was inserted were found to have gonorrhea). Only two women had the device removed because of pain, he noted.

These tests were "not intended as an effectiveness and acceptability study" of a new IUD, since the frequent checkups and replacement may have decreased patient acceptance, Dr. Scommegna noted. But another version of the progesterone T—a polymer device made by the Alza Corporation which releases 50 mcg of progesterone a day for a year—is currently being tested in 14 clinics in the United States, Canada and Mexico. Preliminary results reported by Dr. W. Paul Dmowski, also of the Michael Reese Hospital and Medical Center, show that there have been two pregnancies (one with the device in place, the other in the cervical canal) after insertions in 764 parous and 286 nulliparous women, for 1,181 and 460 woman-months, respectively. The one pregnancy with the device in situ (a rate of 0.7 per 100 woman-years) occured in a multiparous woman whose "uterine cavity was large and presumably progesterone delivery was not adequate." There were 47 device-related discontinuations among parous patients and 40 among nulliparous women. The overall expulsion rate was 2.3 percent of all insertions; the removal rate for all reasons was 8.1 percent of all insertions.

Fluid-Filled IUD

Dr. Jack M. Futoran of San Francisco reported on preliminary work with a non-rigid IUD filled with saline after insertion to "custom fit" to the uterus. The pouch, made of a silastic polymer reinforced with dacron mesh, is in the shape of an inverted isosceles triangle, measuring 28 mm along its base and 35 mm along each leg. A thin silastic tube runs out from the point, and is used to inject the saline—up to a maximum of 0.6 cc. The device is wrapped around a plastic uterine sound (held in place by a small gelatin capsule, which quickly dissolves). After insertion, the saline is injected until the device fills the uterine cavity. Usually the full amount is needed, but filling is stopped if the patient complains. This happens only with some nulliparous women, Dr. Futoran said. After filling, a knot is tied in the tube.

A very low pregnancy rate should be associated with use of the device, the investigator maintained, because of the large proportion of endometrial surface it covers; there should be a low removal rate for pain and bleeding, since the fluid distributes pressure evenly throughout the device, and therefore no pressure points are created. Early results seem encouraging, the physician said. In a total of 207 insertions for 661 woman-months (including 114 nulliparous women for 390 woman-months), there were no pregnancies with the device in place. One woman, who had the device inserted immediately postpartum, expelled it without realizing it, and later became pregnant.

There were five expulsions and five removals for medical reasons, including two expulsions and two removals among the nulliparous patients. In addition, there was one removal for personal reasons in a parous woman. No dilatation, analgesia or paracervical block was used in any insertion. The device should be "easily and painlessly" inserted, Dr. Futoran said, although occasionally a nulliparous patient "may have some cramping."

Congressional Hearings

The question of whether the FDA should regulate IUDs, as it does oral contraceptives, was the subject of hearings by the Subcommittee on Intergovernmental Relations of the House Committee on Government Operations last May and June. The Population Council, Planned Parenthood, the American College of Obstetricians and Gynecologists, as well as two practicing gynecologists, urged that such control be instituted.

Presently, only IUDs which provide contraceptive action through the use of chemicals or heavy metals—such as the copper T or progesterone T—are under premarketing control by the FDA because they are classified as drugs.

In a joint statement, the three Population Council representatives—Sheldon J. Segal, Vice-President and Director of the Biomedical Division; Dr. Christopher Tietze, Associate Director of the Biomedical division; and Dr. Daniel R. Mishell, a consultant to the Council and Professor

of Obstetrics and Gynecology at the University of Southern California—urged "effective regulation and surveillance" and recommended that the following "minimum standards" should be met before an IUD is permitted on the market:

- Clinical trials, on which claims of pregnancy rates, continuation rates and removal and expulsion rates are based, should include a minimum of 1,000 women and 12,000 woman-months of use—including at least half the women for a full year. If claims are made for special subgroups, like nulliparous women, the same criteria should apply to this one group.
- There should be at least five different clinical investigators studying the device. Only studies with at least an 80 percent one-year follow-up should be included.
- Claims for short-term safety must be based on as many women and woman-months of use as other data and should include incidence of syncope (fainting) at insertion, pelvic inflammatory disease, uterine perforation and injury related to removal of the IUD. Reports on long-term safety should describe all information on which claims are based. Information on menstrual blood loss should be based on at least 100 women for 600 cycles, and should include varying lengths of IUD use.
- IUD design should "avoid the risk of bowel entrapment," and have a low risk of breaking while in the uterus. Proof of quality control and sterilization should be provided.

They told the subcommittee that such guidelines would "assure the availability of adequately tested devices . . . while preventing the distribution of potentially harmful or ineffective" ones. They expressed their confidence in those "adequately tested" IUDs already in use, noting that the Population Council has been involved in studying the safety and effectiveness of such devices through its Cooperative Statistical Program.

PP-WP Favors FDA Regulation

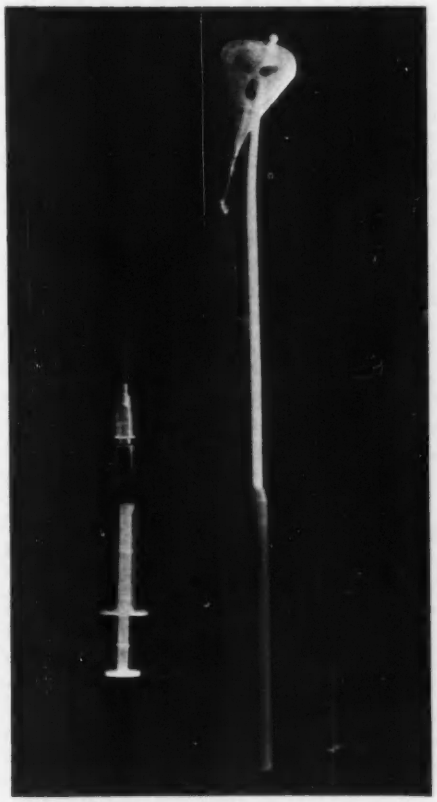
Dr. Ralph Woolf, Medical Director of Planned Parenthood-World Population, stated his agency's support for legislation "to enable FDA to regulate the safety and effectiveness" of inert as well as noninert IUDs, including the obligation of the agency to clear new devices for marketing and to "require registration of manufacturers of IUDs, complete disclosure of complaints and clinical studies of safety and efficacy."

Earlier, two gynecologists described their own experience with IUDs. Major Russell J. Thomsen of the Department of Obstetrics and Gynecology of the U.S. Army Hospital at Fort Polk, Louisiana, discussed "hidden costs" of IUDs—such as increased need for tampons, iron pills, visits to the doctor and, if the IUD string is not in place, x-rays. He chastised IUD manufacturers for their "misleading advertising" to doctors. He was especially critical of the manufacturers of the Majzlin spring and the Dalkon shield—the former for never mentioning the difficulties many doctors have encountered in removing the device, and the latter for basing major advertising campaigns on studies which had "a pathetic average insertion time of only 5.4 months," and burying in a "small print footnote" at the bottom of their ads the recommendation that an additional contraceptive should be used for the first three months after insertion of the shield.

Dr. John Gray Madry, Jr., of Melbourne, Florida, decried the lack of data on morbidity and mortality associated with IUD use, and called for the FDA to develop a package insert for IUDs—similar to the one currently included with all oral contraceptives—describing all complications associated with the devices. He urged the agency to send a letter to physicians including the same information.

Sherwin Gardner, Acting Commissioner of Food and Drugs of the Public Health Service, described the FDA's authority with regard to medical devices. The FDA may seize or ban the import of "misbranded" or dangerous devices, he noted. But whereas the drug manufacturer must prove his product is safe and effective, the burden of proof for devices is on the FDA, which "must accumulate evidence sufficient to assure that it can sustain a court action." Legislation to provide "more effective regulation" by the FDA was submitted to Congress in December 1971 and has been reintroduced in the current Congress, but no action has been taken on it. The question of regulating IUDs, he said, involves regulation of all devices. Flexibility is needed in such regulation, he said, because merely reclassifying such devices as drugs would create an overwhelming administrative burden and raise "difficult legal issues . . . about our authority to allow them to remain on the market pending approval."

Several days before the hearings began, the FDA did use its limited power over medical devices to act against one it considered dangerous—the Majzlin spring. On the FDA's recommendation, the U.S. Attorney for the Eastern District of New York seized more than 30,000 springs from the manufacturer, Anka Research, Ltd., of Jamaica, New York. The FDA cited complications such as cramps and bleeding, uterine perforations, imbedding in the walls of the uterus and the possibility that surgical removal may be needed. Additional seizures have been made from doctors, hospitals, and supply houses.



Fluid-filled IUD.

Sources

Testimony presented before the Subcommittee on Intergovernmental Relations, May 24-June 12, 1973:

S. Gardner, Acting Commissioner of Food and Drugs, Public Health Service, Department of Health, Education and Welfare.

J. G. Madry, Jr., Melbourne, Fla.

D. R. Mishell, S. J. Segal and C. Tietze, The Population Council.

R. J. Thomsen, Department of Obstetrics and Gynecology, U.S. Army Hospital, Fort Polk, La.

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Stroke, High Blood Pressure, Changes in Blood Sugar, Milk Are Pill-Related; No Association with Benign Breast Disease, Mood

Ongoing investigations into side effects of oral contraceptives confirm previous reports that pill use appears to have no association with benign breast disease. It is, however, associated with increases in stroke, blood pressure and blood sugar, but has no apparent effect on mood. The pill appears to be responsible for decreases in the amount of protein, fat and calcium in the milk of nursing mothers. One investigator suggests that matching the various pill formulations to the specific needs of individual women may be one way to reduce or eliminate some side effects. Another way may be by reducing the amount of estrogen in the pill, and a new pill containing 20 mcg of the hormone compared with the previous low of 50 mcg has recently been approved by the FDA for general use.

Breast Disease Risk Found Not Increased

A study by Johns Hopkins University researchers confirms findings by British investigators showing no association between the use of oral contraceptives and the presence of benign breast lesions. (Several studies have suggested that women who have benign tumors are at a greater risk of later developing breast cancer.)

For each of 416 women admitted to Johns Hopkins Hospital with benign lesions from 1969 to 1972, the investigators, headed by Dr. Philip E. Sartwell, found a control (among women admitted to the hospital for different reasons) matched for age, race, parity, ever-married status and payment status in the hospital. As in the British study, headed by Dr. Martin P. Vessey, slightly more women in the control group had used oral contraceptives than women with breast lesions. [See: "British, U.S. Studies Find No Link Between Pill Use and Breast or Cervical Cancer," *Digest*, Vol. 2, No. 1, 1973, p. 3.]

Among patients with chronic cystic disease, the report, in the *New England Journal of Medicine* notes, 266 women had never used oral contraceptives, compared with 261 controls. In Dr. Vessey's study, 78 of 117 patients had never used orals, while only 67 controls were never-users. The differences were greater among those women who were currently using the pill and had been doing so for two years or more. There were only five such women among the cystic disease patients in Dr. Sartwell's study, and 10 among the controls; Dr. Vessey found four patients with such a history, compared with 15 controls. This marked difference led Dr. Vessey and his coworkers to suggest there was some evidence that orals may even protect the user against benign breast disease. The Hopkins group however, write that their "data do not seem to us to allow such an inference, but they do provide further evidence that oral contraceptives or other female hormones are not causative factors in this group of conditions."

Among women with fibroadenoma (a tumor, usually benign, containing fibrous tissue), slightly more controls than patients (44 and 41) out of 71 in the Hopkins study had never used orals. In Dr. Vessey's study, the opposite was true, with 60 patients and 43 controls (out of 86) never having used the pill. The number of long-term (two years or more) current users was the same among patients and controls in the Hopkins study, while Dr. Vessey found only one patient and 10 controls in this category. The Hopkins study included women aged 20-70, while the British survey focused on women 16-39 years old. Use of estrogens (chiefly among postmenopausal women) was slightly less common in the patients in the Sartwell series than among the controls.

Stroke Risk Higher Among Pill Users

A retrospective study of stroke in 598 women of childbearing age, conducted at 12 university medical centers (with support from the National Institutes of Health) across the country, has shown that the risk of thrombotic stroke in women who use oral contraceptives is about nine times greater than for women who do not use the pill. The risk of stroke from hemorrhage is twice as high for pill users, the study also found, but there is apparently no increased incidence of other types of stroke among women using oral contraceptives. The investigators also note a much higher percentage of cigarette smokers or former smokers among the women who had strokes than in control groups. All these effects were more pronounced among white women than among blacks.

The report by the Collaborative Group for the Study of Stroke in Young Women, published in the *New England Journal of Medicine*, extends earlier research by British investigators into the relationship of oral contraceptives to thromboembolism. (Five years ago, Drs. W. H. W. Inman and Martin P. Vessey concluded "that a small but definite risk [of cerebral thrombosis] exists" for women using the pill.) Institutions participating in the project included Duke, Johns Hopkins, Wayne State, Case Western Reserve, Washington and Emory universities and the universities of Illinois, California, Minnesota, Washington, Maryland, Alabama and Kansas.

Despite the increased risk of stroke among these women (all between 15 and 44 years of age, with more than half 35 or older), Dr. Vessey, in an editorial accompanying the report, notes that "it must be remembered that the absolute risk to the individual woman is extremely small."

Methodology

For each of the stroke patients, the investigators selected two controls matched for age and race—one discharged from the same hospital with a condition other than cerebrovascular disease, and one from the patient's neighborhood. Efforts were made to obtain interviews with each of the 182 thrombotic stroke patients and matched controls. But some of the patients had died, others were unavailable for interview and some refused to be interviewed. In some cases a relative supplied the data. Information was obtained from both patients and their hospital controls in 98 pairs, and from both patients and their neighborhood controls in 106 pairs. For hemorrhagic stroke patients, 141 patient-hospital control interviews were obtained, and 155 patient-neighborhood control interviews. Overall, interview data were obtained for 73 percent of the women.

In the 98 matched comparisons between thrombotic stroke patients and their hospital controls, the investigators note that in 38 pairs only the stroke patient used oral contraceptives, while in only four pairs did the control use the pill while the patient did not—a ratio of 9.5:1. In 50 pairs, neither woman was a pill user, and in six pairs both women were. For the 106 patient-neighbor control matchings, there were 44 pairs where only the patient used the pill, compared with five pairs where only the control was on oral contraceptives—a ratio of 8.8:1. In 55 pairs, neither woman used the pill, and in two pairs both women did.

For 141 hemorrhagic stroke patient-hospital control pairings, in 26 instances

only the patient used the pill, and in 13 only the control did—a 2:1 ratio. Neither used the pill in 95 pairs, and both did in seven match-ups. For the 155 patient-neighbor control comparisons, in 30 cases only the patient was a pill user, while in 13 only the control used oral contraceptives—a ratio of 2.3:1. In 107 pairs, neither woman used the pill, while in five pairs both did. In "other" types of stroke, there were 64 patient-hospital control pairings. In 44 pairs neither used the pill, and in three both did. In nine cases, only the patient was a pill user, and in eight only the control used oral contraceptives. In the 71 patient-neighbor control comparisons, the number of pairs in which only the patient or only the control used the pill were equal—16 each. In 35 match-ups, neither woman used the pill, and in four pairings both women did.

The association between thrombotic stroke and pill use was not surprising, according to the investigators. The pill had previously been implicated as a factor which increases the risk of thromboembolism. If such a blood clot broke loose from its source and lodged in the brain, a stroke could occur. The investigators suggest that the weaker association between the pill and increased risk of hemorrhagic stroke might be associated with the fact that the pill apparently causes an increase in blood pressure in some women. An increase in blood pressure would increase the chance that a blood vessel in the brain will hemorrhage.

Thrombotic strokes accounted for 30.4 percent (182) of the 598 cases; nine percent (16) of the patients died. Some 46 percent (276) of the cases involved hemorrhagic strokes, and 44 percent (181) of these women died. The remaining 140 stroke cases were attributed to other causes.

The researchers note that the association between the pill and stroke was much less pronounced among blacks (who made up 36 percent of the cases). In fact, no statistically significant difference between black pill users and nonusers was found for hemorrhagic stroke, nor was the difference significant for thrombotic stroke when the black patients were compared with their neighborhood controls.

They also found that 74 percent of the women who had strokes smoked cigarettes regularly at some time, compared with 43 percent in the control group. Even for nonsmokers, however, the risk of stroke was increased if they used oral contraceptives, the investigators say.

No data are presented—although promised for the future—on the differential effect of different types of oral contraceptives. Dr. Vessey had previously reported that pills with the lowest dose of estrogen—50 mcg—produced a significantly lower incidence of thromboembolism. "Low-dose preparations should therefore be used whenever possible," he notes in his editorial. "It also seems important that women taking oral contraceptives should have their blood pressure checked at regular intervals so that any who show an appreciable rise can be changed to an alternative method of birth control." Dr. Vessey observes that a shortcoming of the study is that the investigators failed to consider "the types of oral contraceptives used, the duration of use, and the possible confounding effect of disorders such as hypertension, diabetes and migraine, which may both predispose to the development of stroke and influence the decision whether or not to use oral contraceptives." Despite these reservations, he adds, "it seems hard to escape the conclusion that oral contraceptives are a cause of thrombotic strokes. . . ."

Slight Blood Pressure Rise Now Confirmed

A continuing long-term prospective study by Kaiser-Permanente investigators (supported by the National Institutes of Health) into side effects of the pill has resulted in reports on the association of the pill with high blood pressure, elevated blood sugar levels and emotional depression. Data gathered from several thousand women who are members of the Kaiser Foundation Health Plan were analyzed by the organization's Contraceptive Drug Study in Walnut Creek, California.

Blood pressure tests on 7,605 women aged 18-60 showed "slight" increases for women on the pill as compared to other women, confirming previous reports. The prospective study included 1,941 current users, 1,593 former users, 2,189 who had never taken oral contraceptives, 953 women in early pregnancy, 247 postpartum subjects (examined one to three months after delivery) and 682 older women taking estrogenic hormones other than the pill for a variety of indications. The investigators analyzed all data age-specifically, since age, they point out, has a significant effect on blood pressure. The statistics, presented by Dr. Irwin R. Fisch, Shanna H. Freedman and Dr. A. V. Myatt in a report in the *Journal of the American Medical Association*, show a smaller increase in blood pressure attributable to pill use than to age. They observed that while the effect of aging on blood pressure is marked, "the point at which a rise occurs is earlier among current oral contraceptive users."

While the proportion of women with elevated blood pressure was higher among pill users than among nonusers, especially in younger women, "the fact that severe hypertension is probably an unusual occurrence can be reassuring to the great majority of women taking these compounds," the investigators write. "Whether or not a minimal elevation of blood pressure is ultimately detrimental to these women is unknown at this time." Because former users exhibited no difference in blood pressure from those who never took pills, the increase in pressure "appears to be reversible." Comparison of blood pressure among women taking pills with different dosages of different hormones failed to show any effect caused by these factors.

Although weight is known to affect blood pressure, the investigators find that oral contraceptive users in this study weighed less than nonusers at every age level. Parity had no affect either.

Despite the fact that "oral contraceptives may simulate a pseudopregnant state," women in their first or early second trimester of pregnancy had blood pressure readings markedly lower even than those of the nonuser group. The researchers note that this may change later in pregnancy, but they have no data on this effect. Women taking estrogenic hormones other than the pill (80 percent of whom were over 45) had average readings near those in the same age group who had never used the pill. Women in the postpartum period (who did not receive hormones to cause cessation of lactation or who were not taking oral contraceptives), also had readings similar to nonusers.

Blood Sugar

One-hour glucose tolerance tests—to determine blood sugar levels one hour after being given an oral dose of glucose—on 4,815 nonpregnant women, aged 20-44 undergoing multiphasic health checkups at Kaiser-Permanente showed that pill users had elevated serum glucose levels (an average of 145 mg per ml for users, compared with 134 mg per ml for nonusers), Nancy Phillips and Dr. Thomas Duffy reported in the *American Journal of Obstetrics and Gynecology*. Glucose tolerance tests are used to determine the presence of and predilection toward diabetes.

As with blood pressure, there was no difference between former users (who made up 31 percent of the group) and never-users (32 percent) so the effect seems to be reversible. The normal factors which affect glucose tolerance—age, weight and a family history of diabetes—were also found, but the effect of the oral contraceptives was added on to those parameters. Thus, a graph of serum glu-

cose levels (one hour after taking 75 grams of glucose in six ounces of lemon-lime flavored water) versus age showed two parallel lines increasing with age—with the levels for users steadily above those for nonusers. When different pill formulations were compared, "no specific estrogen-progestogen combination produced a mean one-hour value significantly different from any other."

The researchers found the same elevation in users of sequential pills as in women taking combination oral contraceptives. There was no correlation between elevation in one-hour serum glucose level and the length of time a woman had been taking the pill. Similarly, there was no statistically significant difference among former users who had been off the pill for different lengths of time—from four months to more than five years.

Diabetic Risk

Approximately one-third of the study subjects, the investigators pointed out, reported diabetes in one or more blood relatives. As a group, these women tended to have somewhat higher one-hour values than others. "The magnitude of the difference between women with and without a positive family history was the same for both users and nonusers of contraceptive drugs," they observed, so that "when users with a positive family history were compared with similar nonusers, the difference between them in one-hour serum glucose was no greater than that observed between users and nonusers with negative family histories."

While the increase in one-hour serum glucose levels found in pill users "is not a clinically significant increase . . . , it implies that the one-hour glucose tolerance of women taking oral contraceptives has been lowered, on the average, to that of women seven to eight years older. Whether or not this alteration might accelerate the development of atherosclerosis or other degenerative processes is a question which needs to be investigated."

Although glucose tolerance varies with time of day and time since last meal, these differences were represented equally in each of the three groups (users, former users and never-users), and therefore did not affect the results.

In summing up, the investigators made the following points:

- The elevation in one-hour serum glucose which accompanies the use of oral contraceptives remains constant over time.
- The data suggest that the pill's effect on glucose tolerance is "probably completely and permanently reversible."
- The effect of the drugs on one-hour glucose tolerance is "merely additive to the effects of age, obesity, and a family history of diabetes."
- If the pills were diabetogenic their effect should be most marked in women likely to have subclinical diabetes. The reverse appears to be true.

The Pill and Depression

In an effort to establish whether there is an association between the use of the oral contraceptive and depression, a variety of psychological tests were administered to 5,151 Kaiser Health Plan subscribers, of whom 33.5 percent had never used the pill, 27.9 percent were former users and 38.6 were current users. Investigators S. Jerome Kutner and Dr. Willard L. Brown, reporting in the *Journal of Nervous and Mental Disease*, found no difference in the average measure of depression or general moodiness among the groups. Contrary to previous reports, current users showed less premenstrual moodiness and irritability than either the never-users or past users (who had a slightly higher incidence of these symptoms than never-users). The incidence of severe symptoms was also higher among past users than among the other two groups.

While oral contraceptives seem associated with reduced premenstrual moodiness, they seem to have no particular effect on users who have a previous history of depression, the investigators report. Furthermore, "'the pill' does seem to exacerbate this history," they write. The study showed, however, that women who discontinued use of the pill had had a significantly greater history of depression during previous pregnancies than did women in the other groups. This predilection to depression during or after pregnancy may be linked with whatever reasons the women had for discontinuing use of the pill, the authors write.

The investigators found that the dosage of progestin taken seems to have an important effect. When users were broken down according to low (0.5-1.0 mg), medium (2.0 mg) and high (2.5-10.0 mg) doses of progestin, the average amount of premenstrual moodiness and irritation declined to a statistically significant degree as progestin dosage increased. The same was true for the percentage of women reporting severe symptoms and clinical (severe) depression. This observation was confirmed by comparing users of sequential pills (which contain progestin for only six days each cycle) and combination pills (which have progestin throughout the cycle).

However, progestin seems to have no dose effect when users have had a history of depression. In a study of several hundred women with such histories, the investigators found no correlation between the amount of the progestin dose and the four measures of moodiness and depression they used. They dismiss the possibility that the reason current users exhibit fewer premenstrual symptoms, while former users have more of them, is that women who became depressed while using the pill might tend to stop using it. They also note that premenstrual irritability and moodiness is low for former users during the first few months after discontinuing the pill, and does not rise until after three months or so. Therefore, they urge that "consideration should be given to progestin replacement for patients presenting depressive reactions to withdrawal from oral contraceptives." [For more information about effects of oral contraceptives, see: "New Findings: Liver, Libido, Breasts, Vitamin A," *Digest*, Vol. 1, No. 2, 1972, p. 14.]

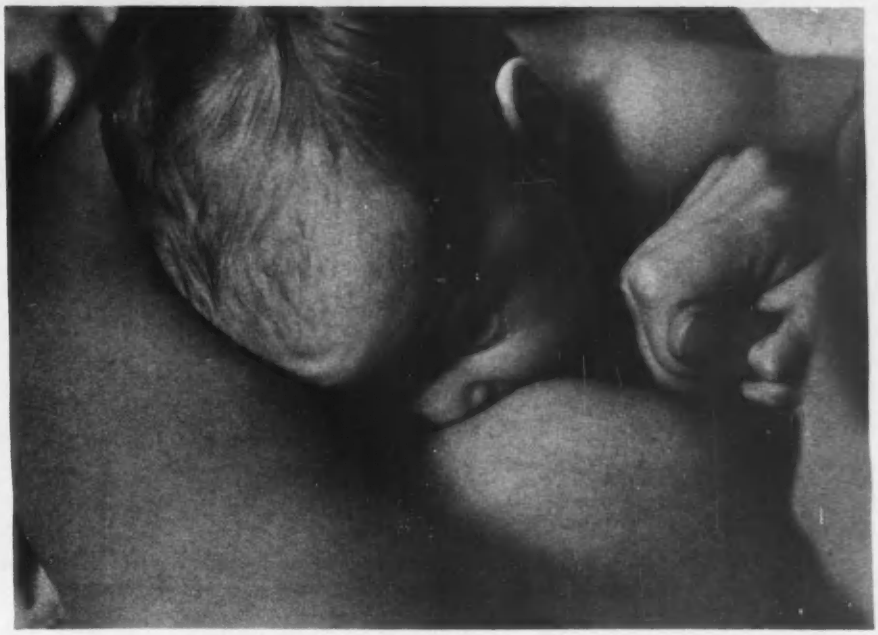
Milk Nutrients Lower In Women Using Pill

Oral contraceptives containing estrogen and progestogen markedly reduce the amount of protein, fat and calcium in the milk of a nursing mother, Villi M. Barsivala and Dr. Katayun D. Virkar of the Institute for Research in Reproduction in Bombay report in *Contraception*. They also found that while the amount of these constituents also declined in women taking progestin-only minipills, the decrease was not statistically significant.

The 39 women studied (eight controls, 16 on combination oral contraceptives and 15 on minipills) were all 20-30 years old, were regularly lactating, had babies one to nine months old, had two or more children and had previously nursed their

infants. They were tested before beginning oral contraceptive therapy, and after one and three cycles of treatment. No significant changes were found in the control group, the investigators reported. Among women taking progestin-only pills the protein content of the women's milk dropped from 1.88 to 1.69 grams per 100 ml after three cycles, while fats declined from 2.5 to 1.9 grams per 100 ml and calcium dropped from 26 to 22 mg per 100 ml.

The change was greater for women on combination pills. Protein content fell from 1.86 grams per 100 ml before starting treatment to 1.16 grams per 100 ml after three months. Fats fell from 2.8 to 1.7 grams per 100 ml, while calcium declined from 25 to 16 mg per 100 ml. "It can be seen that gestagens clearly interfere with the vital function of lactation. The adverse effect of gestagens seem to be specifically directed on the important constituents of milk-proteins, fats and calcium—which are essential for the growth, vitality and general well-being of the baby," the investigators conclude. "Therefore, clinicians prescribing combination oral contraceptives to women . . . interested in breast feeding their infants should exercise restraint before recommending this particular mode of contraception, especially during the first six to nine months of lactation. Continuous low-dose progestogens are recommended for use in the post-partum period."



Fitting Pill to Patient Reduces Side Effects

Many side effects of the pill could be eliminated and the risk of thromboembolism reduced if prescribing physicians were aware of the differences in the various formulations of oral contraceptives and selected the appropriate one for each patient, observes Dr. Richard P. Dickey, of the Louisiana State University Medical Center, reporting at the American Medical Association Clinical Meeting in Cincinnati last fall.

Noting that the various estrogens and progestins commonly used in oral contraceptives vary in potency, Dr. Dickey emphasized that, "The structure of the progestins is more important than milligram dosage in determining the clinical potency of pills." Using the delay of menses test (which measures how long a substance will delay onset of menstruation), he notes 0.5 mg of norgestrel (contained in Ovral) is as potent as 1.0 mg of ethynodiol diacetate (Ovulen, Demulen), or 10 mg of norethindrone (Ortho Novum, Norinyl), or 160 mg of dimethisterone (Oracon). One mg of norethindrone is only one-tenth as potent as 0.5 mg of norgestrel. Therefore, the doctor who prescribes the latter, in the belief that its lower progestin content will reduce such side effects as fatigue, increased appetite and weight gain, is not achieving the desired result. He is actually giving his patient a progestin dose 10 times more potent.

Some progestins also have an estrogenic effect. Therefore, the total estrogenic effect of any compound cannot be calculated from the estrogen content alone. While dimethisterone, norethindrone and norgestrel have no estrogenic effect, he noted:

- norethindrone acetate has a very small effect,
- ethynodiol diacetate a somewhat greater effect (although "usually manifest only at high dosage of progestins while at lower doses it is antiestrogenic"),
- norethynodrel ("the first progestin to be used in oral contraceptives and a component of Enovid"), has significant estrogenic activity, "which potentiates the effect of the estrogen component of Enovid."

Therefore, according to Dr. Dickey, a physician who prescribes Enovid 5 (which has 5.0 mg of norethynodrel) because he wants only a 75 mcg dosage of estrogen is actually giving his patient a compound with more than five times the estrogen potency of Ortho Novum 1 + 80 or Norinyl 1 + 80, each of which has 1.0 mg of norethindrone and 80 mcg of mestranol (also used in Enovid). (See Table 1 for side effects associated with estrogen or progestin excess or deficiency.)

The androgen or masculinizing potency of the progestins "can be useful in selecting the best pill for . . . a patient with mild hirsutism who wants to use oral contraceptives." Norgestrel has the most androgenic activity, Dr. Dickey notes, followed in decreasing order by norethindrone acetate (with only 30 percent of norgestrel's potency), norethindrone and ethynodiol diacetate, while dimethisterone and norethynodrel have no androgenic activity. He concludes:

> Many of the minor side effects of birth control pills can be eliminated by a better choice of initial pill or a change to a pill with a better estrogen and progestin potency for a particular woman's needs. This can occur only if physicians

Table 1. Side effects associated with excesses and deficiencies of estrogen and progestin

Estrogen excess Nausea and vomiting; edema and leg cramps; mucorrhea (excessive discharge of mucus); fibroid growth; cystic breast changes; visual changes; hypermenorrhea (excessive menstrual bleeding); dysmenorrhea (painful menstruation); vascular headache; hypertension.

Progestin excess Increased appetite; weight gain; fatigue; depression; change in libido; breast tenderness and swelling; dilated leg veins; moniliasis (a vaginal infection); oily skin and scalp; postpill amenorrhea and galactorrhea; acne.

Estrogen deficiency Bleeding before day 14; scant or absent flow; hypoplastic uterus (defective or incomplete development of tissue); decreased vaginal secretion.

Progestin deficiency Bleeding starting after day 14; heavy flow and clots; dysmenorrhea; decrease in weight and breast size.

Estrogen excess if on pills—progestin excess if between cycles Premenstrual symptom: Edema; bloating; cyclic headache; irritability; leg cramps; breast tenderness.

Source: R. P. Dickey.

Family Planning Digest
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are better informed about the pharmacological differences among the 14 pills presently available by prescription in the United States. . . . There must be a more active effort on the part of physicians to inform themselves about oral contraceptives and on the part of professional organizations, professional journals and medical institutions to help the individual physician obtain this information.

FDA Approves Pill With Least Estrogen

The FDA recently approved a combination oral contraceptive with the lowest estrogen content of any combined pill on the market, Loestrin 1/20. The pill, manufactured by Parke-Davis, contains one mg of norethindrone acetate (a progestin) and 20 mcg of ethinyl estradiol (an estrogen). Clinical trials of this and other low-estrogen pills had been reported by Dr. Stephen N. Preston at the annual meeting of the American Fertility Society last year. [See: "Half of Estrogen Dose Prevents Pregnancy," *Digest*, Vol. 1, No. 5, p. 9.]

While the low estrogen level theoretically will reduce the risk of serious side effects attributed to estrogen, such as thromboembolic events, the rate of pregnancies and bleeding complications is significantly higher for Loestrin 1/20 than for pills with 50 mcg of estrogen—the lowest dose previously available. In clinical trials of Loestrin 1/20 on 1,336 women for 12,241 cycles, Parke-Davis reported three pregnancies attributed to method failure (0.29 per 100 woman-years) and seven attributed to patient error (0.69 per 100 woman-years), for a total of 0.98 pregnancies per 100 woman-years of use.

In clinical trials, the pregnancy rate for 50 mcg pills was lower—no pregnancies for Norinyl-1 and Ortho-Novum 1/50 in more than 16,000 and 7,000 cycles, respectively, and a rate of 0.16 pregnancies per 100 woman-years for Ovral in more than 84,000 cycles. For all pills, the FDA's Advisory Committee on Obstetrics and Gynecology reported in 1969 a method failure rate of 0.1 per 100 woman-years and a total pregnancy rate (method and user failure) of 0.7 per 100 woman-years. (The pills in general use at that time contained between 50 and 100 mcg of estrogen.)

While side effects common to pills with higher estrogen dosages—such as weight gain, nausea, breast tenderness, headaches, vomiting and edema—are reported to be less common with Loestrin 1/20, irregular bleeding patterns are more frequent, and are a major cause of discontinuation. Dr. Preston had reported that more than one-third of the women who took the Loestrin 1/20 formulation during trials of four low-dose pills had either irregular bleeding or no bleeding during their first cycle on the pill. This dropped to 22 percent after one year, and 15 percent after 15 months.

Low-estrogen pills are being tested by other pharmaceutical manufacturers as well. P.G.T. Bye and M. Elstein reported in the *British Medical Journal* that tests by Schering of a pill with 30 mcg of ethinyl estradiol and 0.5 mg of d-norgestrel on 1,085 women for 7,323 cycles resulted in one pregnancy (attributed to patient error), a rate of 0.16 per 100 woman-years. They reported an overall rate of 2.24 percent for amenorrhea, 8.8 percent for spotting and 5.2 percent for breakthrough bleeding—a total of 16.2 percent for all irregular bleeding patterns. The latter two complications were more common in early cycles, and then declined in frequency, they noted. The pill, called Eugynon 30, went on the market in Britain in June.

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Credits

Pp. 1, 2: Dr. Robert Neuwirth, Columbia-Presbyterian Medical Center; pp. 5, 14, 15: Ken Heyman; p. 6: Constantine Manos, Magnum; p. 8: Robert Fontaine, from "Conception and Contraception"; p. 11: Dr. Jack Futoran.

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