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Family Planning Digest

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Table of Contents

	Page
British Report on Oral Contraceptives Finds Risks Few, Benefits Great	1
No Need to Choose Between Family Planning and Development	7
Resources in Review	8
APPP—1974	
Synthetic Steroid Holds Promise As New Male Contraceptive	10
Pediatric Family Planning Clinic Aimed at Never-Pregnant Girls	11
Only One-Third Are Pregnant When Period Is Five Days Late	12
DHEW Abortion Report Finds Fewer Out-of-State Procedures	12
Steroid Injection Reduces Postvasectomy Pain, Swelling	13
Say Most IUDs Safe, Effective; Shield Shelved Pending Safety Resolution	14
Credits	16

Royal College Report on Oral Contraceptives

8-Year Prospective Study of 23,000 Users Finds Serious Risks Few, Benefits Great

The largest prospective study of the side effects of oral contraceptive use, conducted by Great Britain's Royal College of General Practitioners, confirms many of the earlier reports of beneficial and adverse effects of the pill, and the authors of the study point out that of several thousand morbidity categories which have been assessed in the course of the study " . . . perhaps the most dramatic observation is the very small proportion of diseases which are materially affected by oral contraceptive usage. Not a single previously unsuspected important adverse effect of the pill has been revealed . . . so far, and several suspected risks have been shown to be small or non-existent." They conclude that the risk of developing "serious" illness because of the pill is small and is "one that a properly informed woman would be happy to take."

Data for the study, which began in 1968, were gathered by 1,400 general practitioners on more than 23,000 oral contraceptive users and an equal number of controls. Women taking the pill were observed during more than 35,000 woman-years of use, while nonusers were followed for a total of nearly 60,000 woman-years, the difference caused by the fact that many women discontinued pill use during the study. [The only comparable study in the United States is the Kaiser-Permanente Contraceptive Drugs Study, funded since 1967 by the Center for Population Research of the National Institute of Child Health and Human Development. Some 18,000 women — half using the pill, and half not — are being followed through regular multiphasic health screening, with more than 200 separate standardized physical and laboratory tests administered to all or some of the women.]

Pill users in Britain reported six episodes of illness every three years, compared with five for nonusers. But the authors of the report feel that "this does not mean that the extra episode of illness reported in takers is due to the pill. It is almost certainly the result of over-reporting by oral contraceptive users" for several reasons, including more frequent doctor visits by pill users and a greater tendency by pill users to mention minor ailments because they were worried about the effects of oral contraceptives. Therefore, the authors conclude, while users report more illness, "the evidence suggests . . . that oral contraceptive users suffer in total no more episodes of illness than non-users, and they may actually have less."

Among the study's major findings are the following:

- Previous reports that oral contraceptive use protects against benign breast lesions were confirmed, while no evidence was found

that pill use increases the risk of developing any form of malignancy.

- Hypertension is more common in pill users than in nonusers after the first year of use, and this effect increases with longer pill use. Hypertension in users may be related to the progestogen dosage of the pill.
- Further evidence of an increased risk of thromboembolism in pill users was reported. The data on coronary thrombosis were too few to draw a definite conclusion, although there was an indication of increased risk to pill users; and information on stroke was insufficient to estimate the increased risk. The incidence of deep vein thrombosis of the leg is five to six times higher in users than in nonusers, although the risk is 25 percent lower with pills containing only 50 mcg of estrogen than with higher dose pills.
- The pill probably protects users against ovarian cysts (confirming a recent U.S. report).
- No adverse effects of pill use on subsequent pregnancies were found, although a delay of about three months in conceiving after stopping pill use was not uncommon.
- No association was found between the pill and any endocrine disorder, including diabetes.
- Reports of a small increased risk of gallbladder disease among users were confirmed; this effect may be related to progestogen dosage as well as to the estrogen component of the pill.
- More urinary tract infections among pill users were reported, an effect that is probably related to estrogen dosage.
- Pill users have a markedly lower rate of iron deficiency anemia than nonusers, largely because of "markedly reduced menstrual [blood] loss."
- There is some indication that pill users may be more susceptible to certain common viral infections, especially chicken pox, than nonusers — possibly because of some effect on the body's immune system.
- Among the new users in the study (those who had never taken orals before the study began), the one-year continuation rate was 65.6 percent. Nearly 72 percent of those who started a second year of use completed that year, and 81 percent of those women who completed two years continued for a third year. The pregnancy rate for women using the pill (not including those who discontinued) was 0.34 per 100 woman-years; for those who discontinued pill use while still at risk of an unintended pregnancy, the pregnancy rate was 20 per 100 woman-years.
- Pill users report far fewer menstrual disorders, such as dysmenorrhea (painful menstruation) and menorrhagia (excessive bleeding), than nonusers. Reports of depression and headache are more common in pill users, but this difference may be due to reporting bias.
- Photosensitivity and chloasma (yellowish-brown discoloration of the skin, often appearing on the face) are more common in pill users, but no association with alopecia (hair loss) was found. Acne and sebaceous cysts were seen less frequently in users, while certain other skin diseases appear to be more common in users.

Figure 1 shows the comparative likelihood that pill users will develop beneficial or adverse side effects as a result of their pill-taking.

Methodology

Some 1,400 general practitioners participated in the study, which began in 1968. The British health system permits such a massive, long-term study to be conducted because almost every person in the United Kingdom is registered with his or her own general practitioner under the National Health Service. Each such doctor is paid on a per capita basis for the patients under his care, and has the medical records of each individual for whom he is professionally responsible. Patients can go for treatment *only* to the physician with whom they are registered (except in emergencies) and, the study's authors point out, "once registered it is unusual for patients to change their doctor, unless they move to another district. Thus, long-term continuity of patient care is characteristic of most British general practices."

Pill takers and controls were recruited over a 15-month interval. Participating doctors were instructed to recruit into the study the first two women for whom they wrote oral contraceptive prescriptions each month, who were married or living as married (so as to standardize exposure to the risk of pregnancy). Controls were selected from the doctors' other patients — for each pill taker, the first eligible woman, in alphabetical order after the taker, among the physicians' patients who had never used the pill and whose age was within three years of the pill taker, was entered into the study.

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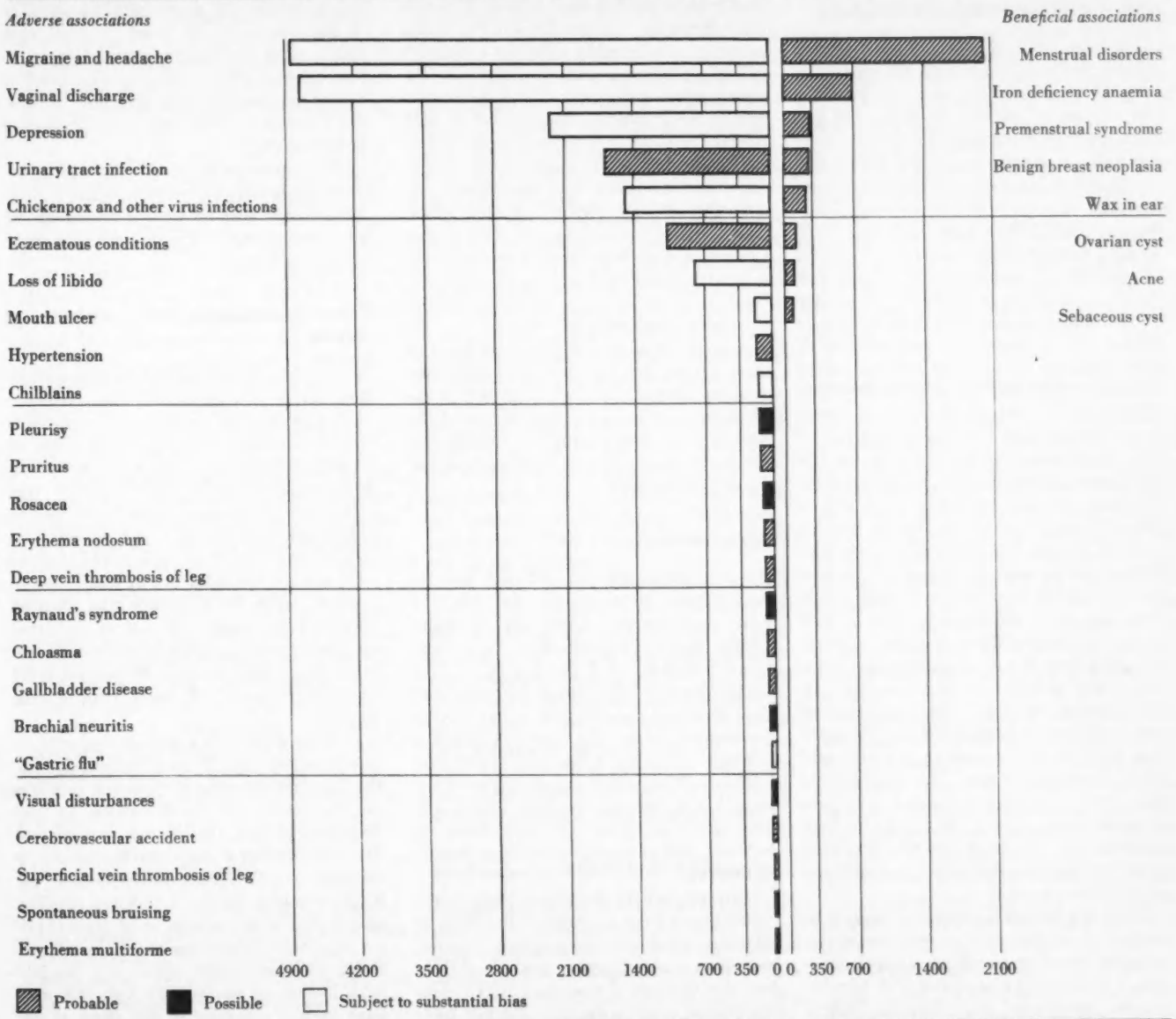
While the pill users and controls were matched only for age and marital status, the two groups were fairly similar. Pill users tended to be somewhat younger at recruitment (average age 28.8 years for users, against 29.3 for controls) — and while this difference is statistically significant, it was not considered clinically significant. The pill users also tended to be of slightly higher parity (average 2.0, against 1.6 for the controls). The distribution of both users and controls by social class was almost identical, and all classes were well represented.

Cigarette smoking was significantly higher among pill users than among controls — an average of 6.45 cigarettes a day for users compared to 5.28 for controls. In all age, parity and social class groups, pill users smoked more than controls. Only 20 percent of users received their first prescription for oral contraceptives upon enrollment in the study — 62.4 percent had been continuous users for varying lengths of time, and 17.1 percent were intermittent users, with a total of 25,590 woman-years of use. Almost all (98 percent) of the women in the study were white.

To control for these variations in age, parity, social class and cigarette consumption, morbidity data (for the various diseases investigated) were adjusted, using the pill users as the standard. One factor not controlled was the women's previous medical history. For most of the diseases considered — such as tuberculosis, diabetes, stroke, thromboembolic events, heart disease, varicose veins and liver disease — a higher proportion of controls than of pill users reported a prior history of each illness.

While the largest proportion of pill users were taking combination pills containing estrogen doses greater than 50 mcg when the study started, low dose pills soon began to predominate. This was spurred by a report by the Committee on the Safety of Drugs in December 1969 linking the pill to thromboembolism and suggesting that lower estrogen doses would lower the risk of thromboembolism. By 1971, high dose pills (over 50 mcg) were used by fewer than five percent of the women.

Figure 1. Adverse and beneficial associations of various diseases with pill use, per 100,000 users per year



Source: The Royal College of General Practitioners, *Oral Contraceptives and Health*, Pitman Medical, London, 1974, Fig. 13.1, p. 84.

For all women enrolled in the study, the general practitioners reported on diagnosed illnesses every six months for as long as the women were under their care. If a woman discontinued pill use, she was continued in a special category for former users. Controls who later started pill use were then shifted to the pill-user category from that point on. Some 34,000 women were still being followed when the data were analyzed.

The investigators examined all data submitted by the doctors for bias in reporting, since pill users tended to see their doctors more often (to renew their prescriptions, if nothing else) and, thus, were more likely to mention less serious problems that otherwise would not have been brought to the physicians' attention.

Cancer and Nonmalignant Neoplasia

"Understandably, no aspect of pill usage has caused greater concern than the possibility that . . . long-term use might increase the risk of cancer," the report notes. The two main types of cancer that have come under study are malignancies of the breast and cervix. Several previous investigations found no correlation between pill use and breast cancer. [See: "Data Link Pill with Gallbladder Disease, Blood Changes; Confirm Embolic Risk, No Cancer Link," *Digest*, Vol. 2, No. 6, 1973, p. 6.] The Royal College study confirms these earlier reports: The incidence rates in users and controls were almost identical. The data on cervical cancer (invasive) were too few to evaluate; only eight cases were observed — two in users, two in former users and four in controls.

As for benign growths of the breast, the pill apparently protects women against these neoplasms, at least after two years of use. [See: "Breast Disease Risk Found Not Increased," *Digest*, Vol. 2, No. 5, 1973, p. 12.] These growths were diagnosed 20 percent less often in pill users than in controls, while there was little difference between former users and controls. When analyzed by duration of pill use, the investigators note that a "materially reduced incidence on the pill only becomes apparent after two years of continual usage," dropping to slightly more than half that of controls in the fifth and subsequent years of use. The investigators also found an inverse association with progestogen dosage, that is, the higher the progestogen dose, the lower the rate of benign breast disease. This observation had not been previously reported.

Two other benign neoplasms — uterine fibroids and ovarian cysts — were found significantly less often in pill users than in controls. The negative association with fibroids was not unexpected, since fibroids lead to lowered fertility or infertility, so women with fibroids would be less likely to take the pill (five times as many controls as users had fibroids prior to recruitment into the study). "The beneficial effect" [with reference to ovarian cysts] "is probably related directly to the suppression of ovulation," the report notes, confirming the findings of a recent U.S. study. [See: "Pills May Protect Against Type of Cyst," *Digest*, Vol. 3, No. 3, 1974, p. 14.]

One important question concerning the pill is not answered by the study — the effect of oral contraceptives on cervical cytology. While 5.2 percent of pap smears from users and former users were abnormal (showing dysplasia) compared to 4.5 percent of smears from controls, this difference was not statistically significant and possibly was biased by several factors. The first is the fact that users had 70 percent more smears (per thousand woman-years of observation) than controls. Secondly, standardization for sexual behavior — believed to influence a woman's risk of developing cervical dysplasia (abnormal cells) and cancer — was impossible. Finally, the dysplasia rates recorded for both groups are about four times the rate previously estimated for the general population of the United Kingdom. The investigators observe that although the participating physicians were told to include only cases of dysplasia and to exclude cases of inflammation in reports of abnormal smears, the data were "contaminated with a substantial number of reports of inflammatory changes. . . . No convincing evidence has been published so far to suggest that the use of oral contraceptives predisposes to an increased risk of the development of pre-cancerous lesions of the uterine cervix. Regrettably it is unlikely that this study will be able to contribute definitive data in this field."

Hypertension

The association between pill use and increased blood pressure has been made by many investigators. [See, for example: "Slight Blood Pressure Rise Now Confirmed," *Digest*, Vol. 2, No. 5, 1973, p. 13.] The incidence of hypertension increases with duration of pill use, the data reveal. During the first year of use, the rate in pill users is little more than double that of the controls — a difference that could be caused by more frequent blood pressure readings among pill users. However, by the fifth year of use, the incidence rate is nearly three times that in the first year.

[Investigators for the Kaiser study in the United States have also studied the effect of pill use on the development of hypertension. According to a preliminary analysis of their data, the incidence of new cases of hypertensive disease is approximately 385 per 100,000 users per year, compared with 56 cases per 100,000 women per year for never-users and 69 per 100,000 women per year for former users. The women in the study were at most 46 years old when enrolled, and were overwhelmingly white and middle class. Different populations might have different incidence rates.]

Because of the increase with prolonged use found in Britain, the data raise "once more, the question of whether women would benefit from a break from pill usage every few years. There is no evidence at present available that is directly relevant to this problem, and this study may be unable to provide this information even after many more years of observation."

One difficulty of evaluating the incidence of hypertension in the study sample is the fact that no specific criteria for defining high blood pressure were given the participating doctors (so as not to focus attention on this one particular item). Instead, each doctor made the diagnosis according to his own criteria. Pill users were diagnosed as having hypertension more than two-and-one-half times more often than either controls or former users.

There appears to be a relationship between incidence of hypertension and progestogen dosage, with the highest rates observed for women using pills with more than three mg of progestogen.

Thromboembolism, Heart Disease and Stroke

Since venous thromboembolism is more common during pregnancy, after an operation or if a person has experienced a previous thromboembolic event, only first cases of thromboembolism in subjects with no predisposing cause were considered. Deep vein thrombosis of the leg — which can lead to pulmonary embolism if a clot breaks loose and lodges in the lung — was found to occur 5.66 times more often in pill users than in controls, while no difference was reported between former users and controls. A related and less dangerous illness, superficial thrombosis of the leg, occurred 48 percent more frequently among pill users than among controls.

Because there was a greater disparity in incidence rates for the more serious disease, the investigators believe reporting bias was not responsible for the difference. In confirmation of this, they found an apparent dose relationship of deep vein thrombosis to estrogen — with higher incidence rates for higher estrogen doses. No apparent relationship to progestogen dosage or duration of pill use was found. There was an increased incidence with increasing age — and possibly with increasing parity, although this may have been a reflection of the effect of age alone, the investigators note.

For the study population, the investigators

estimate that, for women using oral contraceptives with 50 mcg or more of estrogen, the pill would cause an additional 30 cases of superficial thrombosis ("a relatively trivial condition") per 100,000 women per year. An additional 112 cases of deep vein thrombosis per 100,000 women per year would be caused by pills with high estrogen doses, they estimate, and 81 cases per 100,000 women by 50 mcg pills.

[The Boston Collaborative Drug Surveillance Program estimates that, in the United States, 60 cases of venous thromboembolism requiring hospitalization per 100,000 users per year are attributable to pill use.]

Pill users showed much higher incidence rates for coronary artery disease than controls, but the numbers involved were too small for the difference to be statistically significant (since heart disease is extremely rare in young women). Nevertheless, users had an incidence rate for myocardial infarction more than five times that of the controls. [For another report associating the pill with myocardial infarction, see: "More Heart Attacks in High Risk Users?," *Digest*, Vol. 3, No. 2, 1974, p. 11.]

The relationship between the pill and stroke has been shown by several other studies. [See, for example: "Smoking and High Blood Pressure Increase Stroke Risk among Oral Contraceptive Users," *Digest*, Vol. 3, No. 2, 1974, p. 6; and "Stroke Risk Higher among Pill Users," *Digest*, Vol. 2, No. 5, 1973, p. 12.] The Royal College study found that pill users had more than four times the risk of developing cerebrovascular disease of all forms than did nonusers. This relative risk is somewhat smaller than that found in other studies, but includes a wider group of diseases.

A relationship was also found between pill use and three diseases involving circulation in small blood vessels—Raynaud's syndrome (a circulation defect causing blueness or extreme pallor of the extremities), chilblains (painful itching and redness of the fingers, toes or ears caused by a disease of the small blood vessels of the skin) and spontaneous bruising. "Taken together," the investigators observe, "these results suggest that the pill may have an action on the walls of small vessels. . . . It is interesting to speculate whether such a change could have a bearing on the aetiology of hypertension and vascular thrombosis during oral contraceptive usage."

Pregnancy and Fertility

Analyses of the outcomes of 2,583 pregnancies among women who had formerly been pill users and 7,405 pregnancies among controls reveal "no evidence that the pill has any adverse effect on the outcome of subsequent pregnancies." This confirms the results of a recent U.S. study. [See: "No Link Between Pill, Chromosome Damage," *Digest*, Vol. 3, No. 4, 1974, p. 1.] The abortion rate (including both spontaneous and induced abortions, since the investigators were unable to differentiate between the two from the data available) was higher in former pill takers (21.0 percent of pregnancies vs. 12.3 percent for controls). However, they found that former pill users who desired their pregnancy had an abortion rate of only 13.4 percent, while those not wanting to become pregnant had a 30.6 percent rate.

"It is likely that amongst women who choose the pill there is a substantial number who demand a highly effective contraceptive because they have strong reasons for wishing to avoid pregnancy," the report explains. "If these women subsequently conceive, it would be expected that a high proportion of induced abortions, whether self-induced or surgically terminated, would occur." Among 86 women who conceived while still taking the pill, 26 percent of the pregnancies ended in abortion. The stillbirth rate was slightly lower among former users than among controls (although the difference was not statistically significant), and the proportion of babies with abnormalities was essentially the same in both groups.

While it was not possible to determine the incidence of secondary amenorrhea among women who stopped using the pill (because reported diagnoses of amenorrhea included cases where only one period was missed), a delay in return to full fertility after stopping the pill could be demonstrated using monthly conception rates. Conceptions were low in the first month after discontinuing the pill, rose in the second month, and peaked in the third. To the investigators' surprise, they also found two other smaller peaks in conception rates — in the sixth-seventh month, and again in the tenth month after pill discontinuation. They could offer no explanation for this phenomenon.

The data "undoubtedly indicate a delay in conception in women who have used the pill. In spite of the delay, however, it must be emphasised that in the whole group of 2,291 couples [desiring pregnancy] at least 85 percent of nulliparous, and 93 percent of parous women had conceived by the end of two years after stopping the pill." These rates are minimum estimates, they note, since some women may have conceived after leaving the care of their original doctor.

Endocrine and Gallbladder Diseases

No increase in diseases of the thyroid were seen in pill users and, despite numerous reports of altered carbohydrate metabolism among oral contraceptive users, there was no greater incidence of diabetes among women on the pill than among controls.

An increased incidence of gallbladder disease and gallstones among pill users, previously reported in a U.S. investigation, was also observed in this study. Although the number of cases was not large enough to reach statistical significance, the investigators felt this was a definite side effect of pill use for two reasons. First, a relationship to progestogen dosage was found, with increasing incidence of gallbladder disease accompanying increased progestogen dosage. Secondly, users did not appear to have a higher rate of developing gallstones for their first two years of pill use but, after four years of use, had twice as many gallstone incidents as nonusers. Since gallstones take some time to develop, such a pattern would be expected if the pill was causing the increase. The investigators estimate that the pill is responsible for an extra 68 cases of gallbladder disease per 100,000 users per year.

[The Boston Collaborative Drug Surveillance Program estimates that, in the United States, pill users experience 158 cases of "surgically proven" gallbladder disease per 100,000 women per year — twice as many cases as nonusers.]

While jaundice was not found to be more common among pill users (in fact, the incidence rate was slightly lower in users than in controls), pruritus (itching), which is often associated with jaundice, occurred 75 percent more often in pill users. A slight relationship to estrogen was seen, with the incidence rates increasing with estrogen dosage.

Genitourinary Disorders and Anemia

Urinary tract infections were reported 20-50 percent more often in pill users (depending on the type of infection), confirming the findings of a recent U.S. study. [See: "Pill Use Linked to Urinary Infections," *Digest*, Vol. 3, No. 4, 1974, p. 4.] The infection rate increased with increased estrogen dosage. This association with pill use "seems firm though the mode of action is less clear. The increased sexual activity of pill users may be a factor, since most doctors believe that coitus can precipitate an attack of urinary infection."

Numerous gynecological disorders were seen less often in pill users, but this was attributed to selection — the disorders are generally associated with subfertility or infertility, and women with such conditions would have little need for oral contraceptives. Pill users had higher incidence rates for various vaginal infections which are also associated with sexual activity. Only one disorder—cervicitis — showed any dose relationship, with higher incidence rates accompanying increased progestogen dosage. In addition, cervicitis "generally increases in incidence with the length of time the pill is used. The rate

in the first six months . . . is no higher than that in the controls, but it has increased threefold by the sixth year."

The investigators note that pill users "probably have more pelvic examinations than the controls, and since discussion of contraception inevitably focuses attention on the genital tract, minor gynecological disorders are particularly likely to be subject to biased observations."

Menstrual disorders were generally less common among pill users, except for scanty menstruation, which was seen three times as often in users as in controls. Menorrhagia (heavy bleeding) was seen only half as often, and dysmenorrhea (painful menstruation) was seen 63 percent less often in users. Irregular menstruation was reduced 35 percent and intermenstrual bleeding by 28 percent.

Pill users have significantly lower rates of iron deficiency anemia and anemia of unspecified origin (much of which is probably due to iron deficiency). "This lower incidence . . . has long been recognised and is to be expected from the markedly reduced menstrual loss experienced by oral contraceptive users." Among pill users, there is a strong association between anemia and social class — the lower the class, the higher the incidence of anemia. Among controls, "there is only a weak correlation. . . . The likely explanation is that menstrual loss is the predominant cause of anemia in the controls, while in the takers the menstrual loss is low, and a social factor, presumably diet, assumes greater significance."

Viral Infections

Higher incidence rates among pill users than controls were observed for a large group of infectious diseases. For some of the milder types, this could be explained as an example of reporting bias. For some diseases — rubella, herpes simplex (a viral disease marked by groups of watery blisters on the skin and mucous membranes), and chicken pox—the differences reached statistical significance. For chicken pox (but for none of the other diseases) a dose relationship was seen, with the incidence of the disease rising with increased estrogen dosage.

"The curious association of chicken pox with pill usage requires confirmation," the investigators noted, "but could be due to a suppression of immunity by the pill. The evidence with regard to other virus infections—though far from conclusive at this stage of the study — suggests that such a change could occur more generally. . . . The effect of such a suppression, if it exists, is, however, unlikely to be of clinical importance."

Many common respiratory ailments were reported more often in users, but the investigators note that such diseases are prone to reporting bias — since pill users see their doctors more often, they are more likely to mention such minor problems. Thus, users were reported as having 29 percent more acute nasopharyngitis (the common cold) than controls, 36 percent more chronic nasopharyngitis, 36 percent more chronic sinusitis, 89 percent more influenza accompanied by gastric upset, 21 percent more acute laryngitis and tracheitis, and 33 percent more hay fever and allergic rhinitis.

While for many of these, the differences were dismissed as examples of reporting bias, a relationship to estrogen dosage was found in a few cases: the incidence of hay fever and allergic rhinitis, chronic nasopharyngitis, and influenza with digestive upset all increased with increasing estrogen dosage. The investigators consider no relationship as proven. In the case of "gastric influenza," however, they note that several other viral infections were reported more often in pill users — also with a relationship to estrogen dosage — and this whole group of infections might be more common in pill users because of some adverse effect on the body's immune response system.

Continuation and Pregnancy Rates

Since most of the users had been taking the pill for some time before recruitment into the study, continuation rates could be calculated only for the 6,324 new users. Nearly two-thirds (65.6 percent) were still on the pill after one year; nearly four-fifths of those who discontinued were still in need of contraception. Continuation rates improved with time, however — 71.7 percent of those who started the second year of use completed that year, and 81.2 percent of women completing two years of use continued for a third year. Use-effectiveness for the group as a whole (new and continuing pill users) was high: the pregnancy rate for women using the pill was 0.34 per 100 woman-years of use.

More than 11,000 women stopped using the pill during the study. The main reason for stopping (cited by one-third of the women, with some giving more than one reason) were episodes of morbidity which the women felt were associated with the pill — depression, headache, menstrual disorders, thromboembolism, hypertension, cramps, and loss of libido, among many others. One in five discontinued because they wanted to become pregnant, and 15 percent cited anxiety about side effects.

About 14 percent stopped pill use on their doctors' advice, to take a break from continuous use. The investigators point out that there is "no evidence . . . [that] this policy is likely to be of any benefit to the patient. . . . [But] the practice may be harmful unless the doctor ensures that the patient willingly accepts an alternative method of contraception. In women who stopped the pill while still requiring contraception, there was a pregnancy rate of about 20 per hundred woman-years and 30 percent of these pregnancies aborted."

Mental Disturbances and Depression

There was no significant difference found in the proportion of users who developed psychotic conditions as compared to controls. There were differences, however, with some neurotic conditions. Phobic neuroses were seen only half as often in pill users, a difference "almost certainly due to selection. It is unlikely that a woman with phobic tendencies would choose the pill as a method of contraception." Neurotic depression was diagnosed 30 percent more often in users, although there was no difference in the proportion of such cases which required hospital admission. This 30 percent increase is a "maximum," the investigators note, since substantial reporting bias may be operating in this category. "There is no convincing evidence that oral contraceptive users have more severe depression than non-users," they add.

Loss of libido was reported much more frequently among pill users — four-and-a-half times more often, in fact. There are several possible sources of bias here, the investigators observe. First, "it is much easier for a woman to talk about her sexual feelings when she is discussing contraception with her doctor than at other times." There is no dose relationship seen, and reports are most common in the first year of use, and then decline. This "could reflect the fact that many women start the pill soon after a pregnancy. Loss of libido experienced at that time may reflect the influence of the recent birth more than the effect of the pill. A further factor is that oral contraceptive users may have greater expectations of sexual satisfaction than non-users." Thus, while pill users "certainly *complain* of loss of libido more than non-users, . . . they have many reasons and opportunities to do so which are unconnected with the pharmacological action of the pill."

Skin Disorders

"There is fairly strong evidence here that oral contraceptive usage is associated with increased reactivity of the skin, particularly in response to external irritants," according to the report. The greatest increase was seen for photosensitivity, which was reported more than four times as often among users than among controls. The condition is rare, however, and "a pill-associated reaction might be expected, at the most, in one in 2,000 users each year."

For two skin disorders, the pill had a pro-

tective effect, however. There were fewer cases of acne and sebaceous cysts among pill users than controls, and "at least one in 500 users per year should benefit" from this effect. The investigators also noted a 24 percent lower incidence of wax in the ears among pill users than among controls. They attribute all these effects to the reduction of sebum (fatty) secretions, which has been well-documented during pill usage, and which is usually credited to the estrogen component.

The incidence rates for all forms of eczema (an inflammatory skin disease characterized by scales and crusts, watery discharges, itching and burning) were higher in pill users. Although no relationship to dose or duration of use was found, "this does not exclude a pharmacological effect of the pill." Localized neurodermatitis (a chronic itching eruption in the axillary and pubic regions) was found 59 percent more often in pill users, and the incidence increased with increasing progestogen dosage.

Previous reports have linked chloasma and alopecia to pill use. The Royal College study confirmed the association for chloasma (which was diagnosed 44 percent more often in users), but not for alopecia. The increased risk of chloasma for the study population was estimated at 70 cases per 100,000 users per year.

Other conditions analyzed include:

- *Premenstrual syndrome.* This phenomenon — which can include nervousness, depression, restlessness, headache, and fluid retention — occurred 29 percent *less* often in users than in controls. "However, in this morbidity category the exceptional situation occurs where there may be a bias due to *under*-diagnosis and reporting in takers, since neither the observing doctors nor their patients expect pre-menstrual symptoms to occur. Thus, the pharmacological beneficial effect of the pill may be less than these data indicate."
- *Pleurisy.* Pleurisy and chest pains were reported significantly more often among users than controls. But "since pleurisy can be clinically indistinguishable from pulmonary embolism, it is tempting to attribute the difference in rates to contamination of the data with occurrences of pulmonary embolism. . . . There is no evidence which can confirm or refute this suggestion." No correlation with dosage or duration of use was found. The increased incidence of pleurisy, as reported, was 120 cases per 100,000 users a year.
- *Neurological disorders.* An increased incidence of epilepsy was found among pill users, but the number of cases was too small for statistical significance. The investigators indicated "the need for further controlled trials and retrospective studies." Headache and migraine were both reported more often in pill users than in controls, but both symptoms are susceptible to a high degree of reporting bias. "Thus, though an adverse effect of oral contraceptives cannot be excluded, any such effect is likely to be small."
- *Sense organs.* No increased incidence of any disease of the eye or ear was seen in users that could not be attributed to reporting bias.
- *Ulcers.* Women using oral contraceptives developed duodenal ulcers less frequently than controls, but the investigators do not feel this was a protective effect of the pill.

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Family Planning or Development *Which Comes First?*

The choice "between family planning and social development as preferred routes to lower fertility . . . is a false choice," according to Dr. K. Kanagaratnam, director of the Population and Nutrition Projects Department of the International Bank for Reconstruction and Development. "What we are faced with is a challenge to mesh the two," he said in a paper presented at the annual meeting of the Population Association of America.

While reductions in population growth are more apparent in industrialized countries — with high literacy, low infant mortality, women participating in nonagricultural labor, and high per capita income — family planning programs have had important influences in many countries where these social changes have not occurred to the same degree, Dr. Kanagaratnam said.

- In South Korea, the birthrate has fallen from 40 live births a year per 1,000 population in 1962 (when a nationwide family planning program began) to fewer than 30 per 1,000 in 1971.
- In Taiwan, the country's family planning program "began offering IUDs, oral contraceptives and condoms to couples on an island-wide basis" in 1964. The rate of population growth fell from three percent annually in 1963 to two percent in 1972.
- In Hong Kong, where services are primarily provided by the local family planning association, the crude birthrate fell from 36 per 1,000 in 1960 to fewer than 20 per 1,000 in 1972.
- The fertility of women of reproductive age in Singapore fell by more than 30 percent after an official family planning program was begun in 1966.
- In Jamaica, fertility remained at about 40 per 1,000 from 1960 to 1966 — at which time an official family planning program was instituted. The birthrate then fell from 40 per 1,000 in 1960 to 34.5 per 1,000 in 1970.

Changes in fertility are not the only effect of the introduction of family planning programs in less developed nations, however, Dr. Kanagaratnam observed:

- In Singapore, there was "extensive use of the mass media to support the family planning program" after its introduction. This "brought open discussion on a range of population questions." Increased knowledge about contraceptive failure and "accurate documentation of abortion experience" led to the reform of abortion laws in 1969. There soon followed changes in many social policies aimed at encouraging small families, including changes in tax laws, housing regulations, maternity leave and educational benefits for children.
- During the first 10 years of Korea's family planning program, the average age of women at first marriage rose from age 20 to age 23. While changes in taxation, housing policy and maternity leave, as enacted in Singapore, have not yet been made, they are "being discussed and may be enacted in the near future."

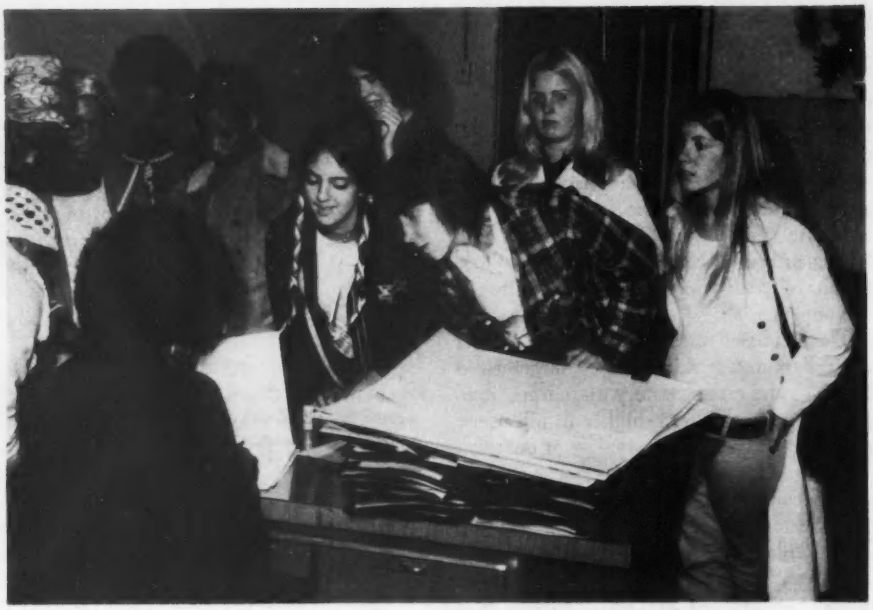
These observations, Dr. Kanagaratnam pointed out, indicate that family planning programs may make important contributions to lowered birthrates and modernization even if comparatively little social and economic progress has previously occurred.

Source

K. Kanagaratnam, "Realistic Pathways to Fertility Reduction in Less Developed Countries—The Prospects from the Viewpoint of Family Planning Programs," paper presented at the annual meeting of the Population Association of America, New York City, April 19, 1974.

Resources in Review

By Dorothy L. Millstone



Participants in the YWCA workshops described in Attention Is Needed, Action Is Called For.

While laws and policies concerning family planning have been liberalized in recent years, those involved in family planning programs are well-advised to keep informed in this area both to see what legal obstacles remain, which have disappeared, and what new restrictions may be in the winds. Policy makers will find something of interest in two major resources which complement each other.

● *Family Planning, Contraception, and Voluntary Sterilization: An Analysis of Laws and Policies in the United States, Each State and Jurisdiction* (7¾″ x 10¼″). This data-packed volume was prepared by the Center for Family Planning Program Development, Planned Parenthood's technical assistance division, for the Department of Health, Education and Welfare. Its 337 pages assemble and analyze federal, state and territorial laws, policies and regulations governing the subjects listed and the conditions under which minors may receive these services as of September 1971 (although an addendum adds developments which took place up to June 1973). In addition to the 50 states, it combs the laws of the District of Columbia, American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands. A brief review of artificial insemination's legal status, the issues involved and sources of further information are also included.

Catalogers may at first glance mark this for lawyers and legislators, but program developers and planners might be added since they, too, will want to know what is permitted and what is forbidden. Most program planners who have to make decisions concerning expanding services will want to know that such a book exists and probably will need to consult it. With this volume, the city or state policy maker can check on what other people do, how they find the money to pay for their services, and how they determine eligibility, among other important subjects. A copy is like a Seeing Eye dog to guide you through the legislative labyrinth.

The book, DHEW Publication (HSA) 74-16001, costs $3.50 and may be ordered from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. The stock number is 1731-0002.

● However, laws keep changing. The way to keep up-to-date is to receive and file the bi-monthly periodical, *Family Planning/Population Reporter,* which reports regularly on legislative and policy developments in birth control and provides a legislative record of all bills introduced, along with their progress in the legislatures.

Subscribe to *Reporter* without charge by writing: *Family Planning/Population Reporter,* Center for Family Planning Program Development, 1666 K Street, N.W., Washington, D.C. 20006. Add a $2.50 check for a binder for filing, if desired. Each issue is prepunched for a three-ring binder.

For Professionals

● Those concerned with making services available to teenagers will gain insight into how young people regard family planning by studying *Attention Is Needed, Action is Called For,* a 1974 (6″ x 9″, 86 pp.) publication of the National YWCA Resource Center on Women.

To find out the concerns and priority needs of teenage women in representative sections of the country, the YWCA queried more than 1,100 teens and conducted intensive workshops attended by 118 young people. This booklet summarizes what these 15-19-year-olds told them. Sex education ranked first among needs not met, and second only to job training among needs most often mentioned.

Family planning was high on the teens' list of sex education topics, as is evident in the direct quotes taken from workshop discussion. Some examples:

"They don't tell you about birth control until the last two weeks in school."

"That's how it is in school! When you have hygiene and you finish your course, in the last two days they tell you about birth control, venereal disease and all that. But they won't teach you about it in the whole year!"

In addition to their attitudes on sex education, teenagers were queried about jobs, recreation, drugs, child care, counseling, racism and women's changing roles.

There is nothing didactic about the way this material is presented. It is told as drawn from the young people. It could be a good tool in building support among policy makers for better family planning programs for teenagers.

The booklet costs $2 a copy, plus 10 percent for postage and mailing. Order from Communications, National Board, YWCA, 600 Lexington Ave., New York, N.Y. 10022.

● Judged by title alone, *Guidelines for Self-Evaluation of Programs Serving Adolescent Parents* might be reviewed principally by agencies working with pregnant teenagers. However, this 156-page (9″ x 11″) book in soft-cover binder, published (1973) by the Maternity Care Research Unit of the University of Pittsburgh Graduate School of Public Health, has much broader value than its name suggests.

This is one of the rare items on evaluation which is literally and effectively set in the framework of the programs to be assessed. A major asset is its careful review of the germane literature and its incorporation of much of the significant related research into the various chapters.

Family planners will find helpful suggestions throughout this volume. The subsection on needs and resources, in particular, contains concretely useful guidelines and references. Factors supporting the health rationale for family planning for adolescents are synthesized in the section on medical aspects.

Although the book as a whole gives little emphasis to prevention of repeat pregnancies as a measure of program effectiveness, there are many references to the role of family planning. The bibliographies are representative and well-keyed to the associated subject matter. A bonus of uncommon interest is a paper by Tony Larry Whitehead, based on a 1964 Urban League of Pittsburgh study, entitled "A Consumer Evaluation of an Educational Medical Program for Pregnant School-Age Girls." One hundred and thirty-seven girls were interviewed and their comments about sex and family planning education in the schools are extraordinary. Elsewhere, there is much of factual and statistical value to family planners, and sources are clearly indicated.

Digest readers may obtain a free copy by writing to Edward R. Schlesinger, M.D., Department of Public Health Practice, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pa. 15261.

● *Family Planning Handbook for Doctors* (1974) is the retitled fourth edition of International Planned Parenthood Federation's *Medical Handbook.*

While family planners in countries with low doctor-to-patient ratios may be a prime audience for this soft-cover, 5¾″ x 8¼″, 173-page book, there is much to recommend this manual for a prominent place in every family planning clinic or study library. The introduction moves directly into substance, much of it new in approach. For example, merchandising, promotion and distribution are discussed, and adaptation of some of the techniques of marketing is recommended as part of the delivery of services. The use of paraprofessionals as part of the doctor's team is spelled out in a way potentially germane to rural America. "The problem of the role and responsibility of nondoctor health personnel is *not* a problem of how to substitute a less highly trained person to undertake a doctor's work, although it is sometimes seen in these terms," notes the text. The problem, it continues, "is of how to build up a working team in such a way that the doctor has the maximum freedom to perform those tasks for which his long and expensive training has prepared him." The *Handbook* emphasizes throughout opportunity for such teamwork in family planning.

In medical aspects of family planning, the *Handbook* is remarkable for its comprehensiveness, its detail and its care to present latest research findings. Material covered is indicated by chapter titles: coitus interruptus; induced abortion; condoms; systemic contraception; intrauterine contraception; male and female sterilization; the rhythm method; caps and spermicides; subfertility; cervical and vaginal cytology; and equipping and running family planning clinics.

The price of the *Handbook* is $3.75. Order from IPPF Western Hemisphere Region, Inc., 111 Fourth Ave., 8th Floor, New York, N. Y. 10003.

A Movie with Possibilities

● *Young, Single and Pregnant*, an 18-minute, color, 16mm film might, if thoughtfully used to stimulate discussion, fit well into the counseling programs Miss Mitchell's monograph recommends and it might be used in community programs for adolescents as well. Presented just as a one-time film showing, this could be a waste of time or, worse, it could discredit adult sponsors in the eyes of young viewers. Quite simply, the movie permits four unmarried teenagers to tell how they solved the problem of unwanted pregnancy. One gave her child for adoption; one married; the third had an abortion and the fourth carried the pregnancy to term and voluntarily became a single parent. The tone is matter of fact, nontragic and nonpunitive, free of breast-beating flashbacks, guilt or self-pity. Each is thoughtful but each could easily be imagined (and this may be a flaw rather than a virtue) as telling someone else's story rather than her own, so objective is the narration. Moreover, each is (unbelievably) quite satisfied with her decision. If there were no adequate teaching lead into the showing and postviewing discussion, such noncredible one-dimensional thinking could not be classified as education. The teenager who gave her baby up for adoption after holding the child in her arms for several days is so comfortably sure it's all for the best that the painful remainder of the untold story pounds silently but inevitably into the viewer's mind. So it is with all four. As is, they are "lies" — incomplete, shallow and naggingly annoying. But it is exactly this that could stir serious thought and debate and yield sensible, meaningful teaching. In mixed groups, some fine results could be obtained by sensitive discussion. Throughout, the role of the male is limited. The pregnancy is seen chiefly as the girl's problem in all four cases, although the young father is usually mentioned and quoted and, occasionally, even heard. There is not a word about how the pregnancy came about and how future pregnancies might be delayed or prevented. Family planning should be a natural part of postviewing discussion, reproductive physiology a part of the preparatory lesson. Several other movies on the theme of unwed teenage pregnancy are on the market, but they are not as likely to stimulate thought. One of them, *Phoebe*, made by the Canadian Film Board, portrayed the heroine suffering from guilt, fear and shame; flashbacks told how Phoebe got 'caught' and how bad it was. Students were to discuss what Phoebe did and what she ought to do. Essentially, the message of the film was that sex is a no-no for teens; such messages have more often turned young people off than they have won adherents to the viewpoint. (*Phoebe* may be rented for $8 from Contemporary Films, 330 West 42 St., New York, N.Y. 10036.) *Young, Single and Pregnant* might be somewhat more useful.

Young, Single and Pregnant costs $265. It may be rented for $35 for three days. Write to See-Saw Films, P.O. Box 262, Palo Alto, Calif. 94302 to inquire or order.

At the Patient Level

For the client to consult after a visit to the clinic, the Midwest Family Planning Association in Chicago has published *Conception: How it Occurs, How to Prevent It* (5½″ x 9″, 20 pp., 1973). It explains conception and contraception briefly. Birth control methods are reviewed from the point of view of advantages and disadvantages. "Methods that don't work very well" get a page of their own on which withdrawal, vaginal tablets and douching are listed. Male and female sterilization and abortion are also included. This is being sold for 30 cents a copy. For a free sample, write the Association at 5952 W. Addison, Chicago, Ill. 60634.

Materials in Spanish

The Harlem Hospital (New York City) teaching film, *A Matter of Choice* [reviewed and recommended in *Digest*, Vol. 2, No. 3, 1973, p. 11], has just been produced in Spanish under the title, *Una Question de Preferencia.*

The price of a 16mm print is $150. A free preview may be arranged. Address inquiries to The Albany Medical College, Family Planning Education Program, 628 Madison Ave., Albany, N. Y. 12208.

DHEW Publication

DHEW has issued a second edition (October 1973) of the booklet, *Guide to Audiovisual Aids for Spanish-Speaking Americans.* This catalog (42 pp., 5¾″ x 9″) of health-related films, filmstrips and slides includes family planning materials.

For a free sample, write Public Inquiries, Health Services Administration, 5600 Fishers Lane, Rockville, Md. 20852.

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-27
5600 Fishers Lane
Rockville, Md. 20852

Discrimination Persists

Equal Pay Not Yet Achieved by Women

An end to discrimination in employment, which shunts women into low-paying, low-status jobs, "may effectively compete with childbearing and have the effect of lowering fertility," the Commission on Population Growth and the American Future concluded in its report to the President and Congress. Yet, despite efforts during the 1960s to end sex discrimination in employment and concomitant wage differentials, the inequality in pay between men and women did not decrease over the decade and, in fact, grew larger for younger women, reported Howard M. Iams of the Department of Sociology of Hope College, Holland, Michigan, at the annual meeting of the Population Association of America. Wage differences were not as great for never-married women as for ever-married women, and were smaller for women working in the public sector than for those employed by private companies.

These findings are based on an analysis of data from one in 1,000 samples from both the 1960 and 1970 U.S. Censuses. Data on white, full-time, civilian, nonagricultural wage earners were used. For the analysis, the women were divided into three age groups — those 20-34 in 1960, women 35-44 in 1960 and women 45-54 in 1960.

To determine whether these unequal wages were due to different qualifications, Iams used the data to calculate a formula to estimate a woman's and man's hourly wages based on three factors — age, education and type of occupation. He then applied the formula for one sex to the average characteristics of the other. The results showed that if the men had been paid on the same basis as the women, they would have earned even less than the women in the majority of categories, and that if women had been paid on the same basis as men, their wages would have been nearly equal. This indicates, Iams said, that "the lower wages of women appeared to reflect an inability to translate characteristics into wages at a rate as high as men rather than discrepancies in mean levels of education, age, and occupational prestige. . . . In the main, women seemed to earn less because they were paid less than men for their characteristics in both 1960 and 1970."

Sources

H. M. Iams, "The Earnings of White Women Relative to White Men," paper presented at the annual meeting of the Population Association of America, New York City, April 18, 1974.

Commission on Population Growth and the American Future, *Population and the American Future*, U.S. Government Printing Office, Washington, D.C., 1972, p. 93.

Progress in Family Planning

Male Contraceptive, Pioneer Pediatric Clinic, Vasectomy Improvement Reported at APPP

Among the 40 papers presented at the twelfth annual meeting of the Association of Planned Parenthood Physicians (APPP) held in Memphis on April 16-17 were several of special interest to *Digest* readers, including reports on:

- trials with a new combination of hormones to achieve reversible male contraception;
- a pediatric family planning clinic for girls younger than 16 years of age;
- an analysis of the probability of pregnancy when a menstrual period is delayed one or two weeks;
- the 1972 abortion experience summarized by DHEW's Center for Disease Control and preliminary figures for 1973 (after the Supreme Court decisions) which indicate that most women are now obtaining legal abortions in their home states instead of obtaining them out of state; and
- the injection of steroids into the vas deferens and scrotum at the time of vasectomy to reduce swelling and discomfort.

More than 300 physicians and other professionals active in the family planning field attended the meeting.

Male Contraceptive

Synthetic Steroid Holds Promise

Current efforts to develop a systemic contraceptive for men — in effect, a male "pill" — focus on testosterone-progestogen combinations. [See: "Combination of Hormones Seems Promising as Male Contraceptive in Human Trials," *Digest*, Vol. 3, No. 1, 1974, p. 1.] Progestogens can suppress sperm production, but have certain undesirable effects — such as loss of libido and gynecomastia (overdevelopment of the male mammary glands) — which must be offset by doses of the androgen (male hormone) testosterone. Progestational effects on metabolism, noted in women using estrogen-progestogen combination pills and progestogen-only 'mini-pills' are not offset by the use of testosterone.

Studies with a new synthetic steroid, danazol, which has no estrogenic or progestational activity and only a weak androgenic effect, suggest that this drug also has potential as a male contraceptive agent used in combination with testosterone, Dr. C. Alvin Paulsen of the University of Washington School of Medicine reported.

Several different danazol dosage levels and two types of testosterone were administered to 100 volunteers; Dr. Paulsen reported that one combination produced azoospermia (absence of live sperm) in one-fourth of the subjects and oligospermia (very low concentrations of sperm in the ejaculate) in an additional 60 percent of the men.

Danazol, which does not occur naturally in the body, is a testosterone derivative which has an inhibitory effect on the production of gonadotropins (substances which stimulate the sex glands) in both animals and humans. Recent reports have shown it to be useful in treating endometriosis (growth of tissue resembling the uterine endometrium in anomalous places in the pelvic cavity). Other preliminary research has indicated that 200 mg of danazol daily can suppress ovulation in humans and rhesus monkeys.

In searching for compounds that could be used as a male contraceptive, Dr. Paulsen found that danazol administration caused a "sharp" reduction in the production of testosterone, but "very little change in sperm concentration," although there was a downward trend. He thought that administering extra testosterone would eliminate this effect, but "to our surprise," he told *Digest*, he and his coworkers found that the testosterone potentiated the effect of the danazol, producing a sharp reduction in sperm count.

Six different danazol-testosterone combinations were used in the first trials: danazol at 400 or 600 mg orally each day, or a placebo (as a control) combined with either 10 or 25 mg of methyl testosterone orally each day, or 200 mg of testosterone enanthate by injection each month. Poor results were achieved with the oral testosterone, since it is metabolized by the body too quickly to have the desired effect in most men (only one-third of the 18 subjects treated with 600 mg of danazol and 25 mg of methyl testosterone achieved oligospermia). But better results were observed with testosterone injections: 11 of 13 men who received 600 mg of danazol daily and 200 mg of testosterone enanthate monthly achieved oligospermia during a six-month trial, including three who were azoospermic.

The volunteers were told that their wives or sexual partners should not abandon other forms of contraception until a "safe" sperm count of less than five million per cc was achieved. Although the investigators do not know how many of the couples relied solely on the danazol-testosterone combination for contraception, there were no pregnancies in couples where the man had become oligospermic. (The one pregnancy in the series was planned, when a man receiving a danazol placebo dropped out of the trial.)

The combination was remarkably free of side effects, according to the physician. There

was no liver or kidney toxicity, no change in cholesterol level, no loss in libido, and recovery of sperm count to the pretreatment level occurred within five months in all subjects who supplied sufficient semen samples for analysis, Dr. Paulsen said. The only side effect so far is a small weight gain, averaging three pounds per man over the six-month testing period.

Whether or not a sperm count below five million is a true indication of infertility is an unanswered question. "Based on my experience," Dr. Paulsen commented, "fertility with a very severe decrease in sperm count is very unlikely." He added that, in the course of treating infertile men, he had never seen a pregnancy achieved with a sperm count below five million.

Further trials are planned with danazol-testosterone and other combinations (including several progestogens) with another 150 men who have already volunteered for the project.

Pregnancy Prevention

Youngsters Served By Pediatric Clinic

In an effort to reach sexually active girls under 16 years of age before they have their first pregnancy, a pediatric family planning clinic was established at Grady Memorial Hospital in Atlanta in September 1972. In the clinic's first year of operation, 191 new patients were served (including five males), nine out of 10 of them with parental consent. Most were referred by parents, the pediatric emergency clinic or other medical sources. Eight out of 10 (166) patients were between the ages of 13 and 15. A total of 161 of the girls seen were sexually active and at risk of an unwanted pregnancy. All but one accepted a contraceptive method from the clinic; nevertheless, at least 12 pregnancies occurred among this group as of March 1974. One of the main reasons for this poor record, according to the investigators, was lack of an adequate follow-up program. These findings were presented by Dr. Audrey Forbes Manley, who headed a team which also included Dr. Robert A. Hatcher, Kristine Staffa and Claire D. Brindis, all associated with the clinic.

The clinic was established because most teenagers receiving family planning services in Atlanta entered the program after their first pregnancy, Dr. Manley said. Nine in 10 of the 186 girls who were referred to the clinic during its first year of operation had never been pregnant; in contrast, nine in 10 of the girls under 16 attending conventional family planning clinics in the Atlanta area had already been pregnant. Three-fourths of the girls in the pediatric family planning clinic were sexually active, and two-thirds of these girls had never used contraception.

The clinic meets once a week for three hours, and all supplies and services are provided without charge. Staff includes a pediatrician with experience in a family planning program, a pediatric nurse, a patient counselor and an outreach worker assigned from the regular family planning program, a nurse's aide, and junior medical students and students in a physician's assistant program who have the option of working in the clinic as part of their training.

Each clinic session begins with a 24-minute film, *About Sex*, which shows a Planned Parenthood counselor leading an ethnically mixed group of teenagers in a rap session on sexuality and related topics. [For more information on this film, see: "Resources in Review," *Digest*, Vol. 1, No. 6, 1972, p. 7.] The nurse, counselor and outreach worker then conduct a rap session with both new and returning patients. Contraceptive methods are discussed and displayed, and the procedure for a pelvic examination is described in detail, since most of the patients have never had one. The tests provided include a urinalysis, hematocrit, pregnancy test, sickle cell test, pap smear, gonorrhea screening culture and, where indicated, hemoglobin analysis.

Of the 191 patients seen in the first year, 186 were girls; and all but six were nonwhite. Sixteen of the 186 girls had been pregnant. Six of these were pregnant when referred to the clinic; four had previous deliveries; five had one previous abortion; and one had two previous abortions. Three of the ever-pregnant girls were 13 years old, three were 14, nine were 15 years of age and one was 16. The average age of all the clinic patients was 13.9 years. Nearly 80 percent were between 13 and 15 years old, and the range in age was from four to 16 years. The six patients younger than 11 years had been referred by the hospital's Pediatric Emergency Clinic because of positive gonorrhea cultures (sexual assault was identified as the cause in two cases). More than three-quarters (143) of the total group reported that they had previously experienced sexual intercourse. The average age of first sexual exposure was 13.5 years, with the average length of sexual activity before coming to the clinic just under one year (ranging from one month to three years).

Nine in 10 patients, Dr. Manley said, "claimed to have parental or guardian's consent for contraceptive services. Many of these patients came with a parent or guardian. Only 19 of them . . . wished to keep this information from their parents." Twenty-eight percent (54) of the patients were referred to the clinic by parents or guardians; another 17 percent (33) were referred by the Pediatric Emergency Clinic and an equal number came from other medical sources. The remainder came on their own, were referred by friends or other relatives, or the referral source was not known.

Twelve of the 186 girls were aged 11 or younger — none of these were sexually active, and none were given contraception at the clinic. Of the other 31 girls who had no prior sexual activity, 12 were not anticipating sexual activity and no contraception was prescribed for them. Those girls who were neither sexually active nor anticipating sexual activity, and had not been referred because of a positive gonorrhea culture, fell into three groups: girls brought by parents who thought they might be at risk and wanted them to have contraception; patients who came with older siblings; and girls referred for dysmenorrhea, Dr. Manley told *Digest*. Of the six girls pregnant when referred to the pediatric clinic, one decided to continue the pregnancy to term and, therefore, was not at risk. The other five had abortions and were later given IUDs. Of the 161 girls at risk (either currently sexually active or expecting to be sexually active in the near future), 160 accepted a contraceptive method: 142 chose the pill, eight were given IUDs, three girls reported as mentally retarded were put on Depo-Provera (a long-acting progestational agent given by injection), while the other seven chose the condom, foam or a combination of the two methods.

Venereal Infection Common

Examination showed that 78 girls had various infections, including 50 cases of gonorrhea. Among the other problems diagnosed were mental retardation, obesity, breast masses and seizures; two children were victims of child abuse.

One problem noted by the authors was that only 43 follow-up visits were made by the 191 patients by the end of the clinic's first year of operation. This highlights the need, they maintained, "for a public health nurse or an outreach worker to provide follow-up contact for this age group." Parental involvement is also important, they observed, since many of the girls selected the pill and "this age group is not the most reliable for pill taking." They noted that the recent approval by the Food and Drug Administration of a copper-bearing IUD, which can be used in nulliparae, "may offer a more reliable form of contraception for the young, never-pregnant female than oral contraceptives."

They recommended that "family planning training and contraceptive technology become an integral part of pediatric training and that a routine first pelvic examination become part of normal pediatric care." In addition, "the need to involve the adolescent male in such services must become a top priority."

Delayed Menses

35% Pregnant When Period 5 Days Late

Two-thirds of women whose menstrual periods are five days late and one-third whose periods are two weeks late are not pregnant. Thus, the likelihood of pregnancy in a woman with a regular menstrual cycle increases with the length of time she is amenorrheic, according to Dr. Elton Kessel, director of the International Fertility Research Program (IFRP) of the University of North Carolina. Dr. Kessel added that during the first two weeks beyond a missed menstrual period a parous woman is about seven percent more likely to be pregnant than a nulliparous one, and a woman more than 25 years old is about 10 percent more likely to be pregnant than one 25 years of age or younger.

These findings are based on data from 1,440 cases of endometrial aspiration (also known as menstrual regulation) performed at 23 centers, with data sent to the IFRP for analysis. [For more information on endometrial aspiration, see: "Menstrual Induction Safe, But Many Women Not Pregnant," *Digest*, Vol. 2, No. 4, 1973, p. 13.] A pathologist examined the aspirated uterine contents for products of conception in each case, and reported whether the woman was actually pregnant or not. No clear diagnosis could be made in 132 cases (9.2 percent), while 647 women were pregnant and 661 were not. The pathological findings were also compared with a commonly used pregnancy test (the Pregnosticon Dri-Dot test) given to each woman before the procedure was performed. The test detects, in a urine sample, high levels of human chorionic gonadotropin produced during pregnancy.

Only 35 percent of the women whose menses were delayed five days were pregnant, Dr. Kessel reported. This proportion rose steadily to 65 percent pregnant at 14 days after a missed period. There was a marked difference between women whose preliminary pregnancy test was positive (407) and those whose test was negative (1,009). At four days, 80 percent of the women with a positive pregnancy test were found to be pregnant by the pathologist's examination; this rose to 93 percent at 14 days. For those with a negative test, however, the proportion pregnant was generally between 25 and 30 percent and showed little change over time.

Therefore, "if the pregnancy test is positive it is very likely the woman is pregnant: this likelihood increases with increasing days delayed menses," Dr. Kessel observed. On the other hand, "a negative test is . . . not very useful for excluding pregnancy" in this time period.

He noted that using "days delayed menses" — based on the woman's own estimate of when her period was due — rather than days since last menstrual period minus 28 (which assumes a four-week menstrual cycle) produced higher probabilities of pregnancy because it helped control for variations in cycle lengths.

Older and parous women were probably better able to judge when their periods were overdue since their periods were more regular than those of younger and nulliparous women, Dr. Kessel hypothesized. This might explain why, for the same number of days beyond expected menstruation, about seven percent more of the multiparas than of the nulliparas were pregnant, and why 10 percent more of the women over 25 years of age than of the women 25 or younger were pregnant.

DHEW Report

Fewer Out-of-State Abortions in 1972

In 1972, the last year before the Supreme Court decisions removing most restrictions on abortions, 586,760 legal abortions were reported to DHEW's Center for Disease Control (CDC) — an increase of 100,000 over 1971 — Jack C. Smith of the CDC's Family Planning Evaluation Division told the APPP meeting, citing the CDC's 1972 abortion surveillance report. Data from the 27 participating states and the District of Columbia show patterns similar to 1970 and 1971:

- Approximately seven in 10 abortions were performed on unmarried women.
- The ratio of abortions to live births was highest for women under 20 years of age or 35 or more years of age.
- More than three-fourths of all procedures were performed in the first trimester.
- More than two-fifths of all reported abortions were performed outside the woman's home state (with 90 percent of these procedures concentrated in four states).
- More than three-fourths (76 percent) of the women receiving abortions were white (including Spanish surnamed). The abortion ratio (number of abortions per 1,000 live births) was 161 for whites, compared to 225 for blacks and others.

In addition, the abortion surveillance report noted that 71 maternal deaths related to abortion were reported in 1972 — 19 associated with legal abortions — by the 50 states and the District of Columbia. Based on the number of legal abortions reported (albeit from only 27 states and the District of Columbia), this means that there were 3.2 deaths per 100,000 legally induced abortions; 1.7 deaths per 100,000 were related to suction and sharp curettage procedures, 13.2 to amniotic fluid exchange and "at least" 66 per 100,000 to hysterotomy.

A preliminary survey of data for 1973, Smith noted, shows that the Court's decisions apparently were having a marked effect on the proportion of out-of-state abortions, with the degree of change depending upon how restrictive an attitude toward abortion each state maintained after the rulings. New York State, for example, where three-fifths of all abortions in 1972 were performed on out-of-state women, reported "92,000 fewer abortions in 1973 than in 1972, a 30 percent decrease."

One change from previous years in the 1972 data was increased reliance on suction curettage, with a concomitant decrease in use of all other principal abortion methods, especially dilatation and curettage (D&C). For the six states reporting abortions by type of procedure in 1970, 1971 and 1972, 77 percent were by suction curettage in 1972, an increase from 41 percent in 1970. The proportion of abortions performed by sharp curettage fell from 34 percent in 1970 to seven percent in 1972.

The proportion of procedures performed during the first trimester held fairly steady during the three years, increasing from 76 percent in 1970 to 79 percent in 1972. The state of Washington reported the highest proportion of abortions performed in the first trimester in 1972 (95 percent) while Colorado reported the lowest (50 percent).

Almost one-third of all abortions reported in 1972 were performed on teenagers, according to data from 17 states supplying information on abortion by age. Women aged 20-24 accounted for another third, with women 25 or older making up the remaining third, Smith noted. This division was fairly constant for the three years for which data are available, according to the CDC report, although there was a small increase in the proportion of abortions of 15-19-year-olds and a small decrease in the proportion performed on 20-24-year-olds from 1970 to 1972. The mean age of women undergoing abortions was 22.7 in 1972, down from 23.0 in 1971.

Abortion ratios were highest in all three years for the youngest (under 15) and oldest (over 40) age groups. For the eight states with data for all three years, the only age group to show more than a small increase in the abortion ratio from 1971 to 1972 was the youngest, where the ratio nearly doubled, from about 1,200 to about 2,300 abortions per 1,000 live births. Ten of the 17 states with 1972 data reported more abortions than live births for girls under 15. The lowest abortion ratio was for women aged 25-29, according to the CDC report.

The percentage of abortions performed on married women dropped slightly, from 34 percent in 1970 and 33 percent in 1971 to 31 percent in 1972. All of the 17 states reporting abortions by marital status had higher abortion ratios for unmarried women

than for married women in 1972. The abortion ratio (which was 180 per 1,000 live births for all women) was 18 times higher for unmarried than for married women, Smith said. In eight of the 17 states, unmarried women had more abortions than live births. Related to these data is information in the report on abortions by number of living children (reported by 13 states). In three states and New York City, more than half of the abortion patients for whom the number of living children was known had no living children. Overall, 46 percent of the women who had abortions had no living children; 17 percent had one child; 12 percent had two; 13 percent, three or four; five percent, five or more; and seven percent, unknown. Abortion ratios were highest for women with no living children and lowest for women with one child.

In 1972, the abortion ratio (by the woman's state of residence, rather than state of occurrence) was highest in New York (397 per 1,000 live births) and Washington State (378), and lowest in Idaho (one per 1,000 live births) and South Dakota (11). The five Pacific states had the highest ratio of any region (318); nearly all of these abortions were performed in the woman's home state. The four East South Central states (Kentucky, Tennessee, Alabama and Mississippi) reported the lowest ratio (45); nearly nine in 10 of these procedures were performed outside the woman's home state.

This geographic pattern of abortions apparently changed somewhat in 1973, Smith said, following the Supreme Court decisions. While the data are not complete, they indicate different responses by various states depending on the type of abortion reform law present or enacted in 1973, and on the proportion of abortions performed on out-of-state residents in 1972.

"Some states experienced little or no change in the trend previously established for the yearly number of abortions performed," Smith explained. Typical were states with reform laws in effect before the Court decisions and not subsequently modified, and those in which fewer than five percent of abortions in 1972 were performed on out-of-state women. Such states (Alaska, Hawaii, Maryland and Oregon) showed a change of less than 10 percent in abortions performed between 1972 and 1973.

States with preexisting reform laws, and no subsequent change, but which reported large numbers of nonresident abortions in 1971 and 1972, reported fewer abortions in 1973. New York's 30 percent drop was "the most dramatic example" of this response. The mechanics of this change can be seen by examining abortions performed on residents of Georgia, Smith noted. In 1972, an average of more than 400 abortions were performed on Georgia residents each quarter in upstate New York (outside New York City). Georgia enacted an abortion reform law "patterned after the Supreme Court rulings" in April 1973. In the first quarter of 1973, 248 abortions were performed in upstate New York on Georgia residents, dropping to 68 in the second quarter, nine in the third and one in the fourth quarter, according to preliminary statistics. But despite an almost "50 percent decrease in out-of-state abortions" performed in upstate New York from 1972 to 1973, the number of abortions on instate residents "remained almost constant for each quarter of 1973."

States such as Georgia, which enacted legislation in 1973 in accordance with Court rulings, reported an increase in the number of abortions performed over 1972. "Dramatic" changes of this nature also occurred in Tennessee, Nebraska and South Dakota, which first legalized abortion in 1973, and North Carolina which, like Georgia, liberalized earlier reform laws. The increase was not caused by an increase in abortions to out-of-state residents. Rather, "the increase was due to a larger number of residents of the state receiving abortions in their home state," Smith observed.

States with no abortion reform law (either before or after the Court decisions) were "the most difficult group of states" to analyze. Responses varied greatly, ranging from Texas, whose law was specifically voided by the Court rulings and in which "more than 20 hospitals and clinics around the state are now performing abortions," to North Dakota, which passed a restrictive law (permitting abortion only if needed to preserve the life of the mother) *after* the Supreme Court decisions.

Vasectomy

Swelling, Discomfort Cut by Steroid Shot

Injecting steroids into the vas deferens and scrotum during vasectomy can sharply reduce the number of patients who experience swelling and discomfort following the procedure, Dr. Robert S. Gould of Marlborough, Massachusetts, reported. In a group of 210 patients who underwent vasectomy with local anesthesia but without the steroid treatment, 54 percent of the men responding to a written questionnaire and direct interview reported moderate or severe discomfort lasting for five-seven days after the procedure, and 63 percent had moderate or severe swelling. But in the last 800 patients in the series, all of whom were given the steroid Depo-Medrol, only 10 men (1.25 percent) experienced more than mild postoperative discomfort or swelling.

Depo-Medrol, a long-acting corticosteroid, is normally used as an antiinflammatory agent for such conditions as bursitis and localized forms of arthritis. In connection with vasectomy, 20 mg of the drug was mixed with an anesthetic and injected into the scrotum and each vas prior to making an incision. In all but the first 110 patients in the series, tetracycline was given prophylactically for five days, but this regimen did not appear to produce a lower rate of infection, Dr. Gould said.

In the first group of 210 patients, who did not receive Depo-Medrol, 48 percent of the men used the prescriptions for codeine which were routinely given to all patients. While 54 percent reported discomfort, only 10 percent of the men said the discomfort was "severe." Of the next 100 patients — the first to receive the steroid — only two percent used their codeine prescriptions while eight percent had moderate or severe swelling. In the final group of 800, only 10 men reported significant pain and discomfort and six of these had obvious causes for their problems. Three of the men had hematomas (swelling caused by the collection of blood), one had a sperm granuloma (an inflammatory lump), one an inflammation of the vas and one an inflammation of the epididymis. Of the other 790 men in this third group, three-fourths reported no discomfort at all, and the rest reported only mild discomfort. "This is in marked contrast with the earlier" group, Dr. Gould noted.

While the use of Depo-Medrol reduced the incidence of postvasectomy discomfort and swelling, "it is not a substitute . . . for very careful operative technique and small incisions," Dr. Gould declared. The question of pain and swelling after vasectomy is "a very sensitive area for patients, and we've got to go overboard in our attempts to make [the procedure] simple, safe and pain free."

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IUD Hearing

IUDs Praised as Generally Safe, Effective, But Shield Shelved Pending Safety Resolution

The IUD was generally acknowledged to be a relatively safe and effective method of contraception by some three dozen biologists, physicians, social scientists and members of the general public who testified August 21 and 22 before a special OB/GYN Advisory Committee hearing convened by the Food and Drug Administration (FDA). Witnesses were divided, however, on the relative advantages and risks associated with one type of device, the Dalkon shield. Distribution and sale of the shield was suspended by its manufacturer, the A. H. Robins Company, June 27 following consultation with the FDA, after reports of sometimes fatal midtrimester spontaneous abortions of women who became pregnant while wearing the shield, and release of the results of a nationwide survey of doctors made by DHEW's Center for Disease Control (CDC) which suggested that a higher incidence of complications of pregnancy occurred among women wearing the shield than among those wearing other devices. FDA Commissioner Alexander M. Schmidt stated on July 12 that it was the agency's "interim judgement" that physicians "suspend further prescribing of this particular IUD until the safety issue can be resolved," but that "the evidence now in hand does not warrant recall of the Dalkon shield to the user level." Dr. Schmidt said that, "depending on his own judgment, the physician may or may not choose to replace the shield in women wearing it successfully." He added that the "FDA does not feel that action in such cases is required," but recommended that "the physicians consider action at the point that any patient wearing the Dalkon shield reports she has missed a menstrual period." Physicians were informed of the FDA interim recommendations in the July *FDA Drug Bulletin*, and were asked to report to the FDA on their experience with the various types of IUD from July 1, 1973 to July 1, 1974, including number of insertions, removals, medical complications and deaths associated with an IUD.

Following the August 21 hearing, the Advisory Committee concluded that IUDs "have been shown . . . to be a safe and reliable means of contraception and they compare favorably with . . . oral contraceptives." The Committee recommended that sales and distribution of the Dalkon shield, however, continue to be suspended, but agreed that its removal from asymptomatic women did not appear to be necessary.

A special subcommittee was appointed to recommend to the FDA a more "definitive" position for the agency on the shield. An updated FDA report on all IUDs is now in preparation and is expected to be completed in about a year.

[*Further details of FDA action on the IUD are expected to be reported in a forthcoming number of Digest.*]

Dr. R. A. Skufca, of the FDA's Bureau of Medical Devices, reported at the open hearing that, as of August 21, the FDA had received a total of 241 case reports of septic spontaneous abortion occurring to women who had become pregnant while wearing IUDs; the outcome of 18 of these cases was fatal. The great majority of the infected abortions reported, he said, apparently occurred during the second trimester of pregnancy, described by several witnesses and members of the advisory committee as a previously "very rare" event. Dr. Skufca pointed out that 209 of the cases of septic abortion—88 percent of the total—occurred with a shield in place; 21 cases were reported with the Lippes loop; eight with the Saf-T-Coil, and three with other devices. Eleven of the 18 deaths were associated with shield use; five with the loop; one with the Saf-T-Coil, and one with the Birnberg bow (since discontinued). These case reports came from a variety of sources, including the A. H. Robins company, and responses to the FDA's request for reports published in the *Drug Bulletin*. (At the time distribution of the shield was suspended, June 27, just 107 cases had been recorded of septic spontaneous abortion—seven of them fatal—associated the shield.)

One hypothesis as to why the shield may be more likely than other devices to cause infection when a pregnancy occurs with the device in place was advanced by Drs. Howard Tatum of the Population Council and M. McCarty of Rockefeller University. The two scientists said that in in vitro experiments which they conducted, the multifilament tail of the shield acted as a wick, up which bacteria could travel all the way to the upper end; while the bacteria did not travel up the monofilament tails of the other devices tested. Since the tail of the device is often retracted past the cervix some weeks after the onset of pregnancy, it could act as a reservoir of infection once inside the uterus, with the cervix opening virtually plugged up.

Based on a randomized comparative study of nearly 800 women, Dr. Daniel R. Mishell of the University of Southern California School of Medicine, reported that the shield appeared to be associated with a higher incidence of uterine perforation compared to the loop (1.3-1.4 per 1,000 insertions, compared to less than one per 1,000 with the loop); but, more important, he said, severe inflammatory reactions appear to occur when the shield perforates through to the abdominal cavity. As a result, he said, he has been recommending removal of all perforated shield devices.

A number of witnesses testified that the shield was a safe, effective, highly acceptable device in their practice. Typical was the testimony of Dr. R. Snowden, of the University of Exeter in England, who reported on 6,000 Dalkon shield fittings followed in 20 United Kingdom centers over the past two years. Dr. Snowden reported that the pregnancy rate associated with all devices ranged from two to four per 100 women years of use, and that associated with the shield was 2.8. Removal for bleeding and pain and expulsion were found to be lower for the shield than other devices. He cautioned against "undue haste" in reducing the choice of methods by removing the shield from use, and called for larger and more systematic studies of IUD safety and effectiveness independent of manufacturers and distributors of IUDs, as well as of physicians who fit them.

Dr. D. Seigel of the National Institute of Child Health and Human Development, indicated that the Institute's Center for Population Research (CPR) was about to embark on studies of the safety of the IUD comparable to those made of the oral contraceptives' relationship to breast cancer and thromboembolism. The CPR studies, he said, would involve: interviews of hospital admissions for complicated pregnancy; interviews of hospital admissions for complications thought to be associated with IUD use (such as pelvic inflammatory disease); and interviews of hospital admissions for complications not generally associated with IUD use. Respondents will be asked, he said, if they were using an IUD and, if so, what type.

Dr. Seigel was critical of the CDC doctor survey because it relied on self-reporting by physicians; the response rate was low (about 50 percent); there was no satisfactory control group; and the duration of IUD use was not taken into consideration. Dr. Seigel's criticisms were taken up and amplified by several other witnesses; while others supported the study as "reasonable." Thus, Dr. Charles Anello of the FDA's Bureau of Drugs, found that the CDC study provided support for the hypothesis that there *is* an association between the Dalkon shield and complications of pregnancy.

The results of the survey were presented at the hearing by Dr. Henry Kahn, of Emory University, who had directed the survey when he was a CDC epidemiologist. The main findings of the study, made by the CDC's Family Planning Evaluation Division in conjunction with the American Medical Association's Committee on Maternal and Child Care and the American Osteopathic Association, were first made public at a press conference held July 5.

CDC Study Results

Of about 3.2 million women who were wearing an IUD in the first six months of 1973, an estimated 7,900 were hospitalized for device-related complications. At least five women died as a result of such complications. Four of the reported deaths involved severe infections, two relating to pregnancies that occurred with the device in place. One death was the result of thromboembolism that occurred after surgical removal of a device which had perforated the uterus. One death involved the Dalkon shield, two the Lippes loop and two the Saf-T-Coil. The shield death occurred following a septic second trimester spontaneous abortion.

Nearly 17,000 physicians — about half of the 34,544 sent mail questionnaires as part of the CDC study — reported 3,502 unduplicated hospitalizations during the first half of 1973 that they considered related to IUD use. Interviews conducted with a one percent sample of nonrespondent physicians demonstrated that their experience was not much different from that of the respondents, permitting a projected total estimate of about 7,900 hospitalizations related to IUD use for the six-month period, Dr. Kahn explained. For a full 12 months, therefore, nearly 16,000 hospitalizations could be expected.

Table 1. Distribution of IUD-related hospitalizations for which type of IUD is known, by diagnosis and type of IUD

Diagnosis	*Total*	*Dalkon shield*	*Lippes loop*	*Saf-T-Coil*	*Other*
Total					
No.	2,947*	1,431*	1,062*	233*	221*
%	100.0	48.6	36.0	7.9	7.5
Complicated pregnancy					
No.	874	538	259	60	17
%	100.0	61.6	29.6	6.9	1.9
Pelvic infection					
No.	991	494	323	76	98
%	100.0	49.8	32.6	7.7	9.9
Other infections					
No.	63	32	19	6	6
%	100.0	50.8	30.2	9.5	9.5
Uterine perforation					
No.	715	325	296	57	37
%	100.0	45.5	41.4	8.0	5.2
Intestinal obstruction					
No.	15	8	3	2	2
%	100.0	53.3	20.0	13.3	13.3
Hemorrhage					
No.	449	190	161	42	56
%	100.0	42.3	35.9	9.4	12.5
Other diagnoses					
No.	401	140	170	31	60
%	100.0	34.9	42.4	7.7	15.0
Unknown diagnoses					
No.	15	6	3	3	3
%	100.0	40.0	20.0	20.0	20.0

* Column totals are not additive since some women were hospitalized for more than one complication. Totals represent number of hospitalizations, rather than number of complications.

Note: Percents may not add to 100 because of rounding.

Based on sales figures supplied by the manufacturers and continuation rates from clinical studies, the CDC estimated that about 3.2 million women were wearing IUDs during the first six months of 1973. Thus, the rate of IUD-related hospitalizations was about five per 1,000 IUD wearers for the year 1973. Since not all of these hospitalizations were necessarily attributable to the IUD, Dr. Kahn indicated that these rates "compare relatively well with the pill" (based on a CDC estimate of net attributable hospitalizations for pill-related complications of one per 1,000 users per year).

As to the five reported deaths, Dr. Kahn said that, if the same number were reported for the second half of 1973 as for the first half, the mortality rate would be approximately three deaths per million wearers per year. He indicated that this was a "minimum estimate" since there may have been some underreporting of deaths. "However," he said, "our survey of independent data sources has not revealed any other [deaths] that are clearly attributable to the IUD in the same [six-month] time period." The CDC concluded that "the overall rate of IUD-related mortality appears to be low compared with the mortality rates associated with pregnancy and other forms of modern contraception."

A large proportion of the hospitalizations — especially those for pregnancy-related complications —were experienced by women wearing the Dalkon shield. Table 1 shows that, of the 2,947 hospitalizations for which the type of IUD was known, nearly half involved shield wearers; 36 percent were of women using the loop; eight percent, the Saf-T-Coil; and eight percent, other devices (including IUDs such as the Majzlin Spring that have since been taken off the market as unsafe).

Based on the same analysis of sales figures and continuation rates from which they estimated a total of 3.2 million IUD wearers in 1973, the CDC estimated that in that year the shield was worn by 39 percent of all IUD users, the loop by 43 percent, the Saf-T-Coil by 16 percent, and other devices by two percent. If these market estimates are correct, the rate of hospitalization for IUD-related complications was nearly 50 percent higher for women wearing Dalkon shields than for women using all other devices.

A considerably larger proportion of hospitalizations for pregnancy-related complications was accounted for by shield users than for other types of complications. Sixty-two percent of all pregnancy-related complications where the type of IUD was known were associated with shield use, compared to 45 percent of hospitalizations for nonpregnancy-related complications. Complications of pregnancy accounted for nearly three in 10 (29 percent) of all IUD-related hospitalizations and, along with pelvic infections (with which they are often associated), are the leading cause of such hospitalizations.

Table 2. Percent distribution of complications of IUD-related pregnancies requiring hospitalization, by type of IUD and specific diagnosis of complication, where diagnosis is known*

Complication	*Total (N= 444)*	*Dalkon shield (N= 245)*	*Lippes loop (N= 129)*	*Other (N= 30)*	*Unknown (N= 40)*
Infection (including septic abortion)	100	63	22	6	9
Ectopic pregnancy	100	44	42	3	11
Spontaneous abortion	100	51	32	8	10
Uterine perforation	100	49	38	10	3
Hemorrhage	100	59	22	10	8
Incomplete abortion	100	80	5	0	15
Other†	100	44	33	11	11

* Based on information volunteered by physician respondents. Specific diagnoses were volunteered only for 44 percent of all cases, including about half of all hospitalizations associated with the shield and the loop.

† Includes abruptio placentae, placenta praevia, induced abortion and premature delivery.

Note: Percents may not add to 100 because of rounding.

Analyzing these proportions by a method similar to that used in retrospective case control studies, Dr. Kahn said that the CDC study showed that a woman hospitalized with a pregnancy-related complication was two times more likely to be wearing the shield than if she were hospitalized for a nonpregnancy-related complication — a statistically significant difference for the number of cases observed. (Based on the sample of nonrespondent physicians, the likelihood was found to be eight times as great, "establishing," the CDC reported, "that a statistical association between the Dalkon shield and complicated pregnancies also existed in the experience of these physicians.")

Incomplete information is available on types of IUD-related pregnancy complications, based on volunteered information by physician respondents for 44 percent of all such reported complications. As can be seen from Table 2, the shield appears to be associated with more than its market share (39 percent) of each type of complication of pregnancy — notably, the leading type: infections, including septic abortions. The

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shield is associated with 63 percent of such infections which, in turn, account for about one-third of all known diagnoses of IUD-related complications of pregnancy.

The large proportion of pregnancy-related complications associated with the shield remains when the data are standardized for age, race and region of residence, Dr. Kahn pointed out. Data on socioeconomic variables were not available, he said. Possible explanations for the relatively high rates, the CDC indicated, could be "an elevated rate of pregnancy with this device, . . . an increased rate of complications once a pregnancy is established, or . . . a combination of these postulated factors."

The CDC study did not examine these questions. However, other research suggests that the shield may well have a high pregnancy rate compared to other devices. One study of nulliparae found shield pregnancies three times higher than those associated with loops. [See: "Shield Removals High among Nulliparae," *Digest*, Vol. 3, No. 3, 1974, p. 9.] A study by Indiana University gynecologists Robert M. Shine and Joseph F. Thompson found that, of 303 women with an IUD in situ for 12 months, 46 experienced a pregnancy — seven percent of those who were wearing loops and 17 percent of those wearing shields. A recent study of 291 patients, 30 percent of them nulliparae, by Dr. Johanna F. Perlmutter of Harvard Medical School found the shield to be associated with a pregnancy rate of 10.1 per 100 woman-years of use, after 2,143 woman-months of use, with no reduction with time over a two-year period. (This is the rate utilizing the Pearl Index. Calculated according to the life-table method, Perlmutter reported a pregnancy rate of 7.8 per 100 woman-years of use.)

In May, based on reports of four septic second trimester abortion deaths associated with the shield, the A. H. Robins Company, the manufacturer of the device, sent a letter to 120,000 U.S. physicians warning them of the potential danger to women who become pregnant with the device in place. The letter reported that in addition to the four deaths, 32 women had suffered septic abortions, but apparently these were not fatal.

Doctors were advised in the Robins letter that any woman using the shield who missed a period should have a pregnancy test. If she is found to be pregnant, the device should be removed, if possible by traction on the string of the IUD. If the device cannot be "readily removed" because of embedding, "serious consideration should be given to offering the patient a therapeutic abortion." Because of the swift onset of generalized fatal infection, the letter advised that if a shield wearer decides to continue a pregnancy — whether or not the shield is in place — "the patient should be *followed very closely* for early signs which will alert the physician to potential severe complications. The time limit for initiating treatment may be very short following the appearance of symptoms." This warning from the manufacturer led the National Medical Committee of Planned Parenthood Federation of America to call upon all its affiliates, which operate 700 clinics, to stop prescribing shields and, in addition, to "advise all their patients who are already wearing the shield to report to the clinic, at which time they should be advised of a serious risk to their health in the event that they should become pregnant with the IUD in place and choose to continue that pregnancy." The women should be given the opportunity at that time to select another contraceptive method, including a different IUD, Planned Parenthood recommended.

Details of the four deaths associated with the shield, referred to in the Robins letter, and one with a "loop-type device" are described by Dr. C. D. Christian of the University of Arizona in the *American Journal of Obstetrics and Gynecology*. Dr. Christian points out that "the greatest concern is the rather insidious yet rapid manner in which these patients become ill. In three of the five noted maternal deaths, the first symptoms, which were disarmingly innocuous in and of themselves [painless dark brown spotting, sore throat, earache, or flu], occurred 31 to 72 hours of death from sepsis and sequelae of sepsis. It appears that the infection becomes generalized at about the same time as or before there are any localizing signs and therefore the margin of safety that time ordinarily provides in treating such infections is not present."

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