VOLUME 2, NUMBER 1, JANUARY 1973

Family Planning Digest

A Publication of the National Center for Family Planning Services, Health Services and Mental Health Administration, U.S. Department of Health, Education and Welfare.

Minority Communities

Family Planning Programs to Stress Quality, Comprehensiveness, Community Participation

The central objective of family planning in minority communities must be to help build strong families, Dr. Lloyd C. Elam, President of Meharry Medical College, and Marjorie A. Costa, Director of the National Center for Family Planning Services (NCFPS), told some 300 physicians, health administrators, social workers and others concerned with the health needs of minorities at a family planning workshop held in Atlanta on October 20.

In explaining the federal government's position on family planning, Costa told the meeting, "I see family planning services not as a birth control program, not as population control, not limited to contraception. I see family planning as part of a comprehensive health service for anyone who wants and needs it and has not had access to it." The aim of the NCFPS, the public health educator explained, "is to get quality health care programs in family planning all over the country." She defined quality programs as those to which people who have a choice would return voluntarily because they are satisfied with the services provided. People would not only use the services in such programs themselves, she said, but would want them for their daughters as well. Such programs would be dignified in their physical setting and in their attitude toward those they serve. They would strive to maintain the self-respect of clients and would be more, she emphasized, than a collection of examining tables and hospital gowns. Costa told her audience, which included a substantial number of family planning workers, most of them black, that programs funded by NCFPS not meeting the standards of comprehensiveness, quality and dignity would be "defunded."

Marjorie A. Costa

Comprehensive service, she said, includes a complete and thorough check-up, referral to an appropriate facility when necessary, and follow-up to make certain that the referral has achieved its objective. "If you don't follow through, you have not provided comprehensive care," she added.

The government's family planning program objective, she said, "is not geared to limiting the size of anyone's family—it is to build strong families." She said that programs should include and involve men as well as women since men are an integral part of strong families. Information and education will be "heavily emphasized" for all levels of the population, she stressed, with particular effort to educate and inform so-called "unreachables." She explained that she takes great exception to the term and concept "unreachable" because she believes there are no such people. Those hard to reach must be offered quality comprehensive family planning care, she said, and

Table of Contents **Page**

Meeting on Minorities and Family Planning Hears Objectives Defined 1
No Evidence that Pill Causes Cancer 3
9 in 10 Mid-Atlantic Colleges Have No Contraception; Boston Is Better 5
Shield Pregnancies Higher than Loop; TCu, Cu7 Effectiveness Analyzed 6
Do Spermicides Prevent VD? 8
Prostaglandins in U.K. 8
Seven New Genetics Centers 9
Despite Higher Risks, Some Doctors Prefer Hysterectomies to Ligations 9
Bleeding, Pregnancy among Problems Found in Five Minipills Tested 10
Resources in Review 12
What Constitutes "Informed Consent" In Contraceptive Clinical Research? 13
Family Planning Forum Sets Goals 14
9 in 10 New Mothers Adopt Birth Control Method in Hospital 15
Credits 15
Job Opportunities 16

NCFPS will support efforts in this direction. It just takes a little more effort and commitment to reach them.

A keystone of all programs to be funded by NCFPS is consumer participation, Costa emphasized, pointing out that such participation is mandated by the Center's guidelines. Proposals for funding will be required to define consumer participation in detail and how it will be achieved.

Costa, whose personal experience with consumer participation is extensive, explained that it takes a long time and profound commitment to achieve true consumer participation. It is more, she said, than simply having an auditorium full of people. Consumer participants must communicate with each other as well as with the program operators. When consumers are organized as boards or councils, their advice should be respected and accepted. "I cannot think of anyone who can evaluate a family planning clinic any better," Costa pointed out, "than someone who is familiar with the family planning services. Consumers have the right to find out what the services are and to make them what they want them to be." If consumers do not take the opportunity to make the services responsive to their needs, they do not have the right to complain about the services, she said.

Replying to the charge sometimes made that family planning for minorities is genocidal, Costa said that it is up to the minorities to make such programs what they want them to be. In this effort, she said, NCFPS pledges its full cooperation.

She concluded by pointing out that family planning is part of general health care and should properly be offered in a variety of settings designed to meet the health needs of all the people. She added that it is her aim as Director of NCFPS to help establish a single standard of health care in place of the dual system which now exists and which she described as "deplorable."

Dr. Elam, a psychiatrist, explained that the challenge of family planning is "not to avoid overpopulation, not to conserve scarce resources, not to avoid pollution—as important as these are—but the overriding challenge is the need to build strong families." He maintained that there is a "concerted attack" on black families and black people in some high places, and that there has been an effort by official agencies to take over for the family. Dr. Elam attacked this effort, observing that "no agency can substitute for the family, whose main function is to provide emotional support for all family members."

Birth control is one important element of family planning because it makes possible the "enhancement of sexual pleasure, personal fulfillment, and the opportunity to build economic strength." He observed: "We cannot measure the success of family planning by the number of devices provided, but rather by the individual's pleasure in being part of a strong united family."

It is not the business of the providers of service to ascertain whether others are actually using family planning, he added. Rather, it is their business to see that it is made available and to make certain that no one is interfering with the dissemination of information and service. Dr. Elam pointed out that family planning has long been supported by black Americans. In February 1935, Meharry Medical College opened its first contraceptive clinic, at the initiation of a bacteriologist. Partly because it was opposed by religious leaders who were hostile to the clinic and partly because the clinic was not associated with other health services and made no referrals for care, attendance remained "undramatic" until the 1940s, when it began to provide more extensive care. Since then, he said, attendance has expanded.

He pointed out that organizations such as the National Urban League, the National Medical Association and the National Association for the Advancement of Colored People endorse family planning and urge that it be made available to anyone who wants it because of its importance as a health service. On the question of whether family planning is being made available to the poor primarily to keep their numbers down, Dr. Elam said: "The key to the answer is how the service is offered. If it is isolated from the people to be served it is suspect. If blacks help plan the programs, serve on the boards, work as professionals, it will help guarantee that its purpose is truly to guarantee to every woman the right to control her own fertility and of the child to be wanted." Dr. Elam maintained that "those blacks who stay outside the system perpetuate what is negative."

It is not the business of the professional, he said, to tell people how many children to have or when to have them. If a family wants 10 children, it should be free to have them, provided it really has a choice. It makes a "mockery of rights," he maintained, to deny information and services to all who want them.

Dr. Elam emphasized the urgent need for research of all kinds to enhance the quality of services. Biomedical research is needed to develop better and safer contraceptives; social research is necessary to understand the human motivations regarding family building.

He criticised the concept of the minority person as a "recipient," a concept which, he said, reflects the American attitude that minorities are not "up" to whites in their ability to give as well as to receive. Minority persons can also be donors, he said, can provide education and leadership that are vital to program success. They must be involved on boards, in key positions, so that they won't be only recipients.

A large part of the hostility of black men toward family planning stems from the fact that they are not seen as contributors to family planning, Dr. Elam said. He noted that virtually all family planning literature talks about the rights of women and children and implies that men have no rights and belong on the sidelines. "It is not possible to achieve stronger families unless men are also perceived as an essential unit of the family. When men are included in family planning, it will become as widely acceptable to them as it is to women."

Conference participants attended six concurrent workshops which examined such issues as: why family planning for minorities; family planning as total health care; manpower needs; financing community-based family planning services; legal and legislative aspects of family planning and the consumer's view of family planning. Out of the workshops came a series of recommendations, including the following:

- Consumers should be part of the planning committees of all programs, and minority people should be among the consumers on such committees.

Family Planning Digest

Volume 2, Number 1, January 1973

A Publication of the National Center for Family Planning Services, Health Services and Mental Health Administration, U.S. Department of Health, Education and Welfare. Prepared bimonthly by the Center for Family Planning Program Development, the Technical Assistance Division of Planned Parenthood-World Population.

Editor: Lynn C. Landman
Assistant Editor: Richard Karp
Copy Editor: Trudy Raschkind

Editorial Offices, Center for Family Planning Program Development, 515 Madison Avenue, New York, N.Y. 10022.
Director of Publications: Richard Lincoln

The Project upon which this publication is based was performed pursuant to Contract No. HSM 110-71-176 with the Health Services and Mental Health Administration, Department of Health, Education and Welfare.

The views expressed herein do not necessarily reflect the views of the National Center for Family Planning Services, Health Services and Mental Health Administration, DHEW.

- Family counseling should be an important aspect of family planning.
- Training programs should be established to develop a pool of manpower to work at every level in family planning programs. Provision should be made for upward mobility, and standards and certification should be established.
- More physicians should be encouraged to participate in family planning.
- Informed consent forms must be written in direct, simple, easily understood language.
- Emergency funds should be available to care for patients who suffer as a result of their participation in research.
- Family planning programs which dispense contraceptives without a complete physical examination should be warned against this practice and, if it persists, should be defunded.
- Abortion and sterilization should be readily available as options but should not be substituted for family planning.
- Nurse-clinicians are an acceptable part of the family planning medical team but should not substitute for the physician.
- Voluntarism should be emphasized in all family planning programs. The obligation of the counselor is to make known all possible options; the decision to accept or reject family planning must remain the patient's.
- Sex education should be encouraged.

The diverse participants at the conference seemed united behind the view expressed by Rev. Andrew Young, Chairman of the Atlanta Community Relations Commission (and newly-elected Georgia Congressman), that family planning is not genocidal "if the same choices are available to all." The minister, a long-time associate of the late Rev. Martin Luther King, Jr., commented on the question of the motivation of those offering family planning to minorities: "The devil may have meant it for evil, but the Lord made it for good."

The workshop, "Family Planning in Minority Communities," is the first of four to be held in various parts of the United States. They are a project of the John Hale Medical Society of San Francisco. All are cosponsored by the National Medical Association and by Howard and Meharry Medical Colleges, and are funded by NCFPS.

Erratum

The paper by Dr. Zigmund Lebensohn, referred to on pp. 14 and 15 of *Digest*, Vol. 1, No. 4 ["Health, Social Impact of Legalized Abortion"], was delivered at the meeting of the American Psychiatric Association, not the American Psychological Association.

Cancer

British, U.S. Studies Find No Link Between Pill Use and Breast or Cervical Cancer

There is no suggestion that use of oral contraceptives is associated with increased risk of breast cancer, cancer of the cervix or precancerous cervical lesions. Indeed, pill use—especially long-term use—may have a protective effect against the development of benign breast disease. These are the conclusions of two major retrospective (case control) studies conducted by teams of U.S. and British investigators and published recently in the *British Medical Journal* and *Obstetrics and Gynecology*, and of a report delivered last summer at a conference on contraceptives sponsored by the National Academy of Sciences.

In a related development, Britain's Committee on Safety of Medicines (England's equivalent of the U.S. Food and Drug Administration) reports, on the basis of six years of studies with rats and mice, that it has found no evidence that pill use by women constitutes a cancer hazard.

In the British breast cancer study, which is still under way, 345 ever-married women aged 16-39 who were admitted to five London hospitals between December 1, 1968 and December 31, 1971 for diagnosis and treatment of breast disease were interviewed in the hospitals by experienced medical social workers who assembled complete medical, obstetric, menstrual, contraceptive and social histories of each woman. For each of the 90 patients with breast cancer, two controls were selected from among women in the same hospitals who were suffering from an acute medical or surgical condition or had been admitted for a routine elective operation. They were matched for age (within five years), marital status and parity with the cancer patients. In the same way, one matched control was selected for each of 255 women with benign breast disease. All the controls were interviewed, and the same data elicited as from the patients. Each hospital provided histological material for review by a member of the investigating team, which was headed by Dr. Martin P. Vessey, whose previous research had established the association between the oral contraceptive and increased risk of thromboembolism. The contraceptive history of each woman with breast disease was taken as of the time she first noted the presence of a lump; the matched control's history corresponded.

The investigators report that of 90 patients with breast cancer, 31—about one-third—had used oral contraceptives. Among their 180 controls, 73—about four in 10—had used them. Of the 255 patients with benign breast disease, 85—again one-third—had taken pills, compared with 116—nearly six in 10—of the matched controls. "The use of the [oral] preparations," the investigators note, "was less in both series of patients with breast disease than in the corresponding matched controls." The data also show that smaller percentages of those with breast disease, whether benign or cancerous, were users of oral contraceptives for periods ranging from four to more than 25 months than were their matched controls. What is more, investigators note, the longer the use of oral contraceptives, the less likely the appearance of breast disease—especially benign breast disease. Thus, when controlled for marital status and social class, 3.7 percent of patients with benign disease were long-term users (more than 24 months), compared with 11.8 percent of controls; when age at first pregnancy was the constant, 3.4 percent of those with benign disease were long-term users, compared with 11.1; and when past history of breast biopsy was the constant, the proportions were 3.6 and 10.7.

The tissues from patients with breast disease were divided into five categories, two of which accounted for more than 80 percent of the benign lumps. In both these categories the data show "a deficiency of current long-term users of oral contraceptives in comparison with the matched controls." No such difference was observed in the remaining 20 percent of cases. Histological review of tissues from patients with breast cancer showed no differences in the lesions from patients who had used oral contraceptives and those who had not.

From this most recent data (preliminary findings from this ongoing study have

been reported previously) the investigators conclude:

> There is no suggestion that the use of oral contraceptives is related in any way to the risk of breast cancer in women under the age of 40, while there is some evidence that their use may actually protect against benign breast disease in this age group. . . . Our data indicate that this protective effect is largely confined to women who continue to use oral contraceptives and have used them altogether for more than two years. Such women appear to have only about 25 percent as great a risk of being admitted to hospital for a breast biopsy as women who have not used oral contraceptives at all.

After reviewing other findings regarding the pill and breast cancer, they observe: "It is likely to be many years before the question of the possible relation between oral contraceptives and breast cancer is finally settled, but the available data are reassuring."

Cervical Cancer and the Pill

Also reassuring is the observation of a team of investigators headed by Dr. J. G. Boyce, who, after studying almost 400 women, half of whom had cervical cancer and half of whom were free of the disease, report that their data "do not confirm an increase in cervical carcinoma among women who use oral contraceptives."

The investigators reached this conclusion after a study of 196 consecutive patients with cancer of the cervix treated at Downstate Medical Center in New York City and 196 controls who were free of the disease and were matched with the patients for age, ethnic background, age at first coitus, age at first pregnancy and socioeconomic status. "These factors were selected," they write, "because they are known to be the most reliable and important influences on the prevalence of cervical carcinoma." Information was obtained by interviews, each lasting about 40 minutes. All the controls had recent normal cervical smears, 190 of them within three months, five within one year and one within two years. Pathologic specimens from all patients with cancer of the cervix were reviewed by one of three pathologists, none of whom knew the patient's contraceptive history.

The median age was about 31 for both patients and controls, and 188 patients were matched within 12 months. The greatest difference in age was 20 months. Seventy-seven percent of both controls and patients were black, 13 percent were white, 10 percent were of Latin American origin. About 90 percent of both controls and patients had had coitus and almost two-thirds had experienced their first pregnancies by age 20.

Both controls and patients were poor, with 44 percent of the former and 48 percent of the latter on welfare; about 60 percent of both groups had at least a high school education. Both controls and patients had a median of four pregnancies.

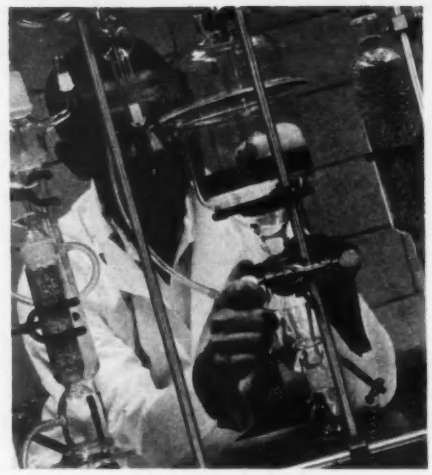
One hundred and sixty-nine controls and 167 patients used oral contraceptives for 2,262 and 2,239 months respectively—for an average of 22 months. The data demonstrate that, in matched populations, oral contraceptive use does not appear to be significant in the etiology of cervical carcinoma.

Another report presented at a National Academy of Sciences Workshop in San Francisco last July by Dr. M. R. Melamed, of Memorial Hospital in New York City, appears to confirm this finding. Dr. Melamed reported on an ongoing investigation of nearly 8,000 women over a three-year period, all of whom were new family planning patients when they entered the study. All were free of cervical disease, as shown by repeated cytological tests in the first year. A small number of the women developed borderline or precancerous tissue changes (dysplasia) subsequently, Dr. Melamed reported, but there was no significant statistical difference between women using the IUD, oral contraceptives or the diaphragm. "It is very clear," he said, "that at least over a three-year period we are not seeing any kind of explosive increase in carcinoma in relation to any of the three contraceptive modalities."

On the basis of earlier, more preliminary, study, Dr. Melamed and a team of Memorial Hospital researchers reported in 1969 a small but apparently significant increase in the prevalance of precancerous lesions of the cervix in women who had been using pills as compared to those using the diaphragm.

Rats and Mice

Although certain forms of cancer can be produced in various strains of rodents by prolonged administration of very high doses of estrogenic and progestogenic preparations, "this evidence cannot be interpreted as constituting a carcinogenic hazard to women when these preparations are used as oral contraceptives." This is the main conclusion of the British Committee on Safety of Medicines in its long-awaited report on *Carcinogenicity Tests of Oral Contraceptives*, published October 28. The report deals with experiments in some 7,000 mice and 6,500 rats. Each group of 240 mice was observed for 80



weeks and fed daily with low, medium and high doses of progestogens, estrogens and combinations of the two. The low doses were reported to be equivalent to from two to five times, the medium dose, 50-150 times, and the high dose, 200-400 times the contraceptive dose recommended for humans. The same procedure was observed for the rats in the study, except that each group was observed over 104 weeks. On the basis of its experiments, the Committee has come to a number of conclusions about the relationship of the pill to tumors, benign and malignant, in various organs:

- *Liver*. The Committee finds that its "extensive tests do not support the previous work showing liver damage progressing to nodular hyperplasia [abnormal cell multiplication] and an increased incidence of hepatomas [liver tumors] from prolonged administration of oral contraceptive preparations to rats. The results are in conformity with the clinical evidence that no constant or persistent disturbance of liver function occurs in women from the prolonged use of oral contraceptive preparations."
- *Lung*. No difference was observed in the incidence of long tumors between treated and untreated rats and mice.
- *Breast and Pituitary*. The incidence of breast tumors, both benign and malignant, was elevated by administration of dosages "several hundred times the human contraceptive dose" and "over a major portion of the [rodents'] life span." The Committee finds that at "two to four times the human dose these effects are not observed." Similar conditions, the report states, apply to higher incidence of pituitary tumors (adenoma). What is more, both effects are found to be "predominantly related to the estrogenic activity of the compounds." The report points out that "the oral contraceptives currently in use are progestagen dominant preparations." (Following publication of the Com-

mittee report, the British licensing authority approved a number of applications for oral contraceptives containing new substances. Such new licenses had been withheld pending completion of these rodent studies. Among the new preparations approved were three progestogen-only 'mini-pills', two containing microdoses of norethisterone and one containing a microdose of ethynodiol diacetate.)

Because the most common tumor found in these animal experiments was pituitary adenoma, and because of the observed common finding of amenorrhea of varying duration after pill use, the Committee indicates that its findings "raise the possibility that there might sometimes be an anatomical basis [for amenorrhea] in the pituitary." It calls for "careful documentation, investigation and follow-up of all cases of amenorrhoea following hormonal contraception" and promises that "a full study will be undertaken." The Committee also states that "careful monitoring should be maintained" of women using the pill, and promises that it will continue its own work, as well as study all new information from longterm U.S. studies with primates and beagle bitches.

In an editorial, the *British Medical Journal* is critical of the report. The editorial charges that the report does not indicate whether ovulation was suppressed in the treated female animals, that benign and malignant tumors occurred with such frequency in some of the control animals that it is questionable whether such experiments "can throw useful light on the carcinogenicity of any compound for man," and that it does not provide data on early deaths of the experimental rodents which might have reduced the incidence of dose-related tumors. The *BMJ* editorial concludes: "The studies now reported neither incriminate oral contraceptives as carcinogens nor exonerate them. We shall simply have to wait and see what the epidemiologists learn from prospective studies."

Sources

J. G. Boyce, T. Lu, J. H. Nelson and D. Joyce, "Cervical Carcinoma and Oral Contraception," *Obstetrics and Gynecology*, **40**:139, 1972.

Committee on Safety of Medicines, *Carcinogenicity Tests of Oral Contraceptives*, Her Majesty's Stationery Office, London, SBN 11 320490 6, 1972.

M. R. Melamed, presentation at Cancer Workgroup, National Academy of Sciences, San Francisco, Cal., July 29, 1972.

M. Potts, "Oral Contraceptives and the British Committee on Safety of Medicines," International Planned Parenthood Federation, Nov. 1972 (mimeo).

"Tests on the Pill for Carcinogenicity," *British Medical Journal*, **4**:190, 1972.

M. P. Vessey, R. Doll and P. M. Sutton, "Oral Contraceptives and Breast Neoplasia: A Retrospective Study," *British Medical Journal*, **3**:719, 1972.

Colleges

Nine in 10 Mid-Atlantic Colleges Offer No Contraception; Boston Schools Do Better

Colleges and universities in the Middle Atlantic states are lagging in providing contraceptive information and services to college students, according to a 1971 survey of institutions in Maryland, Delaware, Washington, D.C., Pennsylvania and New Jersey. Another report, on birth control information and medical services for college students in the greater Boston area, showed somewhat more colleges establishing such on-campus services.

The Middle Atlantic region survey of four- and two-year institutions, made by Tingle C. Barnes of the Graduate School of Public Health of the University of Pittsburgh, revealed that 83 of 187 colleges, universities and junior colleges replying to questionnaires provide no contraceptive *information* on campus, while 162 of the 187 offer no contraceptive *services* through student health services now functioning on campus. Only five percent said they planned to initiate such services in the future.

The greater Boston area report, presenting a plan by the Planned Parenthood League of Massachusetts (PPLM) to develop a program of birth control education and services for college students, was prepared by Janice Bumstead, Director of the Planned Parenthood College Student Health Project. The effort to build the program was spurred by reports that five to 10 percent of coeds had unplanned pregnancies and by the increase in venereal disease (10,000 new cases in Massachusetts in 1971).

An informal survey of Boston area colleges made in January 1971 revealed that only the University of Massachusetts (with 5,000 students) showed any interest in a birth control program for college students. Other schools were reported to exhibit responses ranging from "guarded to openly antipathetic." By January 1972, eight Boston area schools had enrolled in the PPLM-sponsored college birth control project, with faculty and administration sanction. Only three of the institutions, however, provided birth control services in their own facilities; the others referred students to private physicians with long waiting lists and sometimes stiff fees.

At the University of Massachusetts the University Health Service organized peer group counseling which provided 10 hours of service a week. The students organized weekly discussion groups, and a noncredit course in human sexuality was developed by a student-faculty committee; 140 students registered for it as well as for a teach-in on venereal disease. In addition, the health service hired a gynecologist to provide contraceptive services. PPLM's college director is now a half-time employee of the university, charged with organizing credit courses on human sexuality, operating a full-time counseling service, and organizing an evening gynecological clinic to serve students in small Boston area colleges without their own health services. At Boston State College, which has 5,000 students, the PPLM project hired a full-time counselor-organizer in January, and by March she was counseling 50 students. At Boston University, with 18,000 students, the health service was not willing to participate in the program, but the student union provided money, space and a telephone for an information and referral center in March 1972; 30 students were trained and a human sexuality center was opened in September.

Fifty-six percent of the institutions in the Middle Atlantic Region (60 percent of the four-year colleges but only 46 percent of the two-year colleges) provided contraceptive information to students on campus. Many of those who did not offer such information stated that they believed such data were not necessary. Of the 73 four-year institutions which provided birth control information on campus, the sources of information most frequently cited were student health services (49 institutions) and counselors (25 institutions), with 19 providing it through college courses and 15 through student groups. Of the 31 two-year institutions which offered on-campus information, 21 said it was offered through the student health service, 20 through a college course, 17 through a counselor, and only two through a student group.

The reluctance of some institutions to bring contraceptive information to the students' attention is indicated by the fact

that of the 73 four-year institutions where such information was said to be available on campus, 37 percent made no effort to inform the students of this fact. Of the 48 four-year institutions with no contraceptive information available, only five said students had requested that such information be made available on campus.

Although student health services would seem to be natural sources for contraceptive services, only 13 percent of all respondent colleges provided these services through on-campus student health facilities.

Some of the institutions imposed restrictions on providing contraceptive services. Seven of the 25 institutions providing services through on-campus student health facilities required parental consent if the student was neither married nor over 21. The other 18 — just 10 percent of respondents — offered contraceptive services to all students. All but three of the institutions said they made the availability of the services known to students.

Reasons most frequently given by the institutions for the absence of such services were lack of facilities or funds, administration, alumni or parent opposition, and opposition of the medical community. Because of the dearth of contraceptive services in many of the institutions, the survey also showed, many of the college students are seeking help at local Planned Parenthood, hospital and health department clinics and from private doctors in the community.

Many institutions which do not provide contraceptive services on campus refer students to local agencies; of the 162 institutions with no contraceptive services on campus, 100 (62 percent) refer students elsewhere. The most frequently mentioned local agencies or resources were local doctor (53 four-year and 15 two-year colleges), local Planned Parenthood clinic (41 four-year and 24 two-year colleges), local hospital clinic (11 four-year and six two-year colleges) and local health department clinic (four four-year and five two-year colleges).

Various problems are mentioned in connection with referrals to the local physician and the local Planned Parenthood clinic, according to the survey. Students have complained that local doctors often "moralize rather than give constructive advice and services," and some students say the doctor's fee is too high. Another source of difficulty is the fact that the Planned Parenthood clinics have become increasingly more crowded, and that there has been conflict between the older patients and the college student patients in some clinics. The survey notes that "older patients have objected to the appearance and actions of these students."

Sources

T.C. Barnes, "The Availability of Contraceptive Services and Information at Colleges, Universities and Junior Colleges in the Middle Atlantic Region of the United States," survey jointly sponsored by Planned Parenthood's Mid-Atlantic Region and the Population Division, Graduate School of Public Health, University of Pittsburgh, 1971.

J. Bumstead, Progress Report of the College Student Health Project, Planned Parenthood League of Massachusetts, 1972.

IUDs

Shield Pregnancies Higher than Loop's; TCu, Cu7 Reviewed

The first large-scale study of the Dalkon Shield intrauterine device in the United Kingdom shows an annual pregnancy rate more than three times higher than that found in American studies—higher, indeed, than those reported for the traditional Lippes loop and the Saf-T-Coil. While the British study found that expulsions and removals for bleeding and pain were less than for the first-generation IUDs, these rates also were higher than reported in U.S. studies of the device.

The new report was made by the Family Planning Research Unit in the University of Exeter, in collaboration with the British Family Planning Association. The British study was based on reports over 14 months from 11 principal clinics in England and Scotland, involving 1,039 insertions in parous women and 6,669 woman-months of use.

The Dalkon Shield was developed by Dr. Hugh J. Davis, a gynecologist, and Irwin S. Lerner, a bioengineer at The Johns Hopkins University School of Medicine. Clinical trials of the device were begun at Johns Hopkins in 1968, and are continuing there and elsewhere. Most of the U.S. studies have reported pregnancy rates of about one per 100 users at 12 months of use—about one-third those which have been reported for the more standard devices. Previously reported rates of expulsion and removal of the shield for bleeding and pain have also been far below those reported for the standard devices (see Table 1). The antifertility effects of the shield have been credited by its developers to the large amount of uterine endometrium in surface interaction with the device, which is said to attract white cells and produce secondary changes in the uterine milieu capable of destroying sperm and ova. The low expulsion and removal rates are said to be due to its shape and composition.

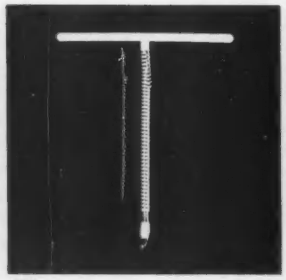
Table 1 shows that the cumulative pregnancy rate obtained in the United Kingdom—3.8 pregnancies per 100 women during the first year of use—"is significantly higher than the American figures and . . . gives no advantage to the shield over the two sizes of Lippes loop and Saf-T-Coil as reported in Tietze's Cooperative Statistical Programme."

As to expulsions, the table shows a cumulative net expulsion rate of 3.9 per 100 woman-years of use, well below the 12.7-19.1 rates reported for the more standard devices, although higher than reported for the shield in the American trials. The British investigators credit the comparatively low expulsion rate to "the flexible lateral 'fins' on the device which give [it] a fundal seeking characteristic. . . ."

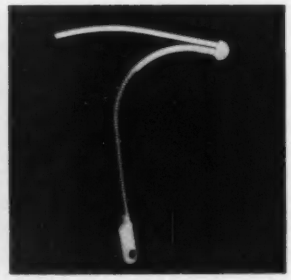
The table also shows a rate of removal for bleeding and pain (4.6 per 100 woman-years), considerably below that reported for the standard devices. This, the investigators hold, may be due to the "flexibility afforded by the polyvinyl acetate with which the Dalkon Shield is manufactured. . . ."

The investigators found an average pregnancy rate of 1.0 per 100 users every three months, about the same as U.S. investigators found at 12 months, with "no sudden decrease in the pregnancy rate with time," they stated. They conjecture that "the difference . . . may, in part, be due to the use of adjunctive methods of contraception by the women in the American studies. . . . The pregnancy rate in the American studies may well be measuring the rate associated with the Dalkon Shield plus a spermicide, whereas the

Dalkon Shield



TCu



Cu7

United Kingdom rates refer to the Dalkon Shield alone." [See: "2nd Generation IUDs Prove Most Effective," *Digest*, Vol. 1, No. 4, 1972, p. 8.]

The British investigators stated that if other independent studies support their findings that the antifertility effect of the shield is no better than for the standard linear devices, "the view that the effectiveness of an IUD is related to the area of endometrial contact may lose much force, and the concept of the 'macrophage' [destruction by white cells] theory of the IUD mode of action may have to be reconsidered." They point out that in the British study there is variation relating to pregnancies, expulsions and removals among the clinics. Thus, the London clinic reports a cumulative pregnancy rate 10 times higher than the Birmingham clinic, and an expulsion rate about 40 percent higher, with no obvious explanations based on age or parity of the patients, or follow-up record of the clinics involved.

Summarizing clinical impressions of British doctors using the shield, the investigators point to "some difficulty in the insertion." They report that the rigidity of the inserter not only "creates difficulty at insertion" but also "increased danger of uterine perforation." They add that the notch on the inserter "does not always hold the device securely during insertion." Some difficulties, they say, are also encountered in removing the shield, noting that "a fairly hard 'pull' is required."

They find, nevertheless, "few complaints of cramp, heavier periods or intermenstrual bleeding. Overall, the lack of side effects is said to be noticeable and encouraging."

Table 1. Net Cumulative Rates per 100 Users for Pregnancy, Expulsion and Removal for Bleeding/Pain, for Selected IUDs at 12 Months of Use

Device	*Event*				
	Pregnancy	*Expulsion*	*Removal*	*Number of Insertions*	*Woman-Months of Use*
Loop C*	3.0	19.1	11.0	3,489	31,032
Loop D*	2.7	12.7	11.7	7,553	72,016
Saf-T-Coil*	2.8	19.0	14.7	2,463	17,636
Dalkon Shield					
Davis 1970 + 1972†	1.1	2.3	2.0	640	3,549
Ostergard & Broen 1971‡	1.1	1.0	9.7	1,242	5,415
Earl 1971§	0.5	0.2	2.7	536	
U.K. 1972**	3.8	3.9	4.6	1,031	6,669

*C. Tietze and S. Lewit, "Evaluation of Intrauterine Devices: Ninth Progress Report of the Cooperative Statistical Program," *Studies in Family Planning*, No. 55, 1970.

†H.J. Davis, "The Shield Intrauterine Device—A Superior Modern Contraceptive," *American Journal of Obstetrics and Gynecology*, **106**:455, 1970. (The same rates, apparently based on the same 1968-1969 study, appear also in H.J. Davis, "Intrauterine Contraceptive Devices: Present Status and Future Prospects," *American Journal of Obstetrics and Gynecology*, **114**: 134, 1972); H.J. Davis, *Intrauterine Devices for Contraception. The IUD*, Williams & Wilkins, Baltimore, 1971; H.J. Davis and I.S. Lerner, "Experience with a Shield Design Accommodative Intrauterine Device," *Advances in Planned Parenthood, Vol. 4*, Excerpta Medica, I.C.S., **224**:85, 1970; H.J. Davis and J. Lesinski, "Mechanism of Action of Intrauterine Contraceptives in Women," *Obstetrics and Gynecology*, **36**:350, 1970.

‡D.R. Ostergard and E.M. Broen, "The Dalkon Shield: A Clinical Evaluation," *Contraception*, **4**:313, 1971.

§J.E. Earl, "The Shield Intrauterine Device," *American Family Physician*, Vol. 4, No. 3, 1971, p. 93.

**R. Snowden and M. Williams, *The Dalkon Shield*, Family Planning Research Unit, The University of Exeter, Devon, England, 1972 (offset).

Table 2. Net Cumulative Rates per 100 Users for Pregnancy, Expulsion and Removal for Bleeding/Pain, for Selected IUDs at 12 Months of Use, 1972

Device	*Event*				
	Pregnancy	*Expulsion*	*Removal*	*Number of Insertions*	*Woman-Months of Use*
Loop D*	3.0	13.0	9.0	750	5,760
TCu-200*	2.2	7.2	5.6	785	6,727
Copper-7					
(U.K.)†	1.1	6.7	3.0	342	1,197
(U.S.)‡	1.1	4.1	12.4	186	1,693
Shield (U.K.)§	3.8	3.9	4.6	1,031	6,669

*C. Tietze and S. Lewit, "Comparison of the Copper-T and Loop D: A Research Report," *Studies in Family Planning*, **3**:277, 1972 (first segment only).

†J. Newton, J. Elias and J. McEwan, "Intrauterine Contraception Using the Copper-Seven Device," *Lancet*, **2**:951, 1972 (first segment only, based on nine months of use).

‡G.S. Bernstein, R. Israel, P. Seward and D.R. Mishell, Jr., "Clinical Experience with the Cu-7 Intrauterine Device," *Contraception*, **6**:99, 1972.

§R. Snowden and M. Williams, *The Dalkon Shield*, Family Planning Research Unit, The University of Exeter, Devon, England, 1972, offset (all segments).

The Copper T

Dr. Christopher Tietze and Sarah Lewit of The Population Council recently compared the Copper TCu-200 device with the Lippes loop D on the basis of reports from nine clinics participating in a double-blind study in the United States and Canada, involving 945 and 750 insertions, and 7,749 and 5,760 woman-months of use, of the TCu-200 and the loop D, respectively. The data showed considerably lower expulsion rates for the copper device than for the loop, but no "conclusive" evidence "that event rates for other causes were much different." The overall termination rate for one year of use was 23.5 per 100 first insertions for the TCu-200, and 29.8 for the loop D. (The overall comparable termination rate for the shield found in the British study was 20.9.) If the experience of one clinic which accounted for two-thirds of the pregnancies is discounted, however, the pregnancy rate for the remaining investigators was less than one per 100, and rates for expulsion and removal for pain and bleeding in the eight remaining clinics were close to one-half the comparable rates for the loop D.

The Copper 7

Preliminary reports on clinical experience in Britain and the United States with another IUD using copper—the Cu-7—have been published in *Lancet* and *Contraception* on event rates over the first nine months of use for 342 women in whom the copper 7 was inserted. The pregnancy rate reported over 1,192 woman-months of use is somewhat lower than Tietze and Lewit found for the copper T in all nine clinics (1.1 for the '7', as compared to 2.2 for the 'T'), but a little higher than Tietze and Lewit found for the 'T' in eight clinics (excluding the clinic which reported unusually high pregnancy rates).

The expulsion rate reported for the '7' (6.7) is similar to that reported by Tietze and Lewit for the 'T', while the rate of removal for bleeding and pain is lower for the '7' than the 'T' (3.0 compared to 5.6).

The U.S. study reports on event rates for the first 12 months of use for 186 women in whom the Cu-7 was inserted. The pregnancy rate found in the U.S. study is the same as that reported by the British (1.1). The expulsion rate is somewhat lower (4.1, compared to 6.7); while the medical removal rate is considerably higher (12.4, compared to 3.0). It should be noted, however, that while only 32 percent of the patients in the British study were nulliparae, 59 percent in the U.S. study had no previous births.

Table 2 compares the cumulative net rates of pregnancy, expulsion and removal for bleeding and pain as found by Tietze and Lewit for the copper T and loop D in the nine clinics, with the British and U.S. data on the copper 7, and with the British data on the shield.

Sources

G. S. Bernstein, R. Israel, P. Seward and D. R. Mishell, Jr., "Clinical Experience with the Cu-7 Intrauterine Device," *Contraception*, **6**:99, 1972, Table 2.

J. Newton, J. Elias and J. McEwan, "Intrauterine Contraception Using the Copper-Seven Device," *Lancet*, **2**:951, 1972.

R. Snowden and M. Williams, *The Dalkon Shield*, Family Planning Research Unit, The University of Exeter, Devon, England, 1972, offset (all segments).

C. Tietze and S. Lewit, "Comparison of the Copper-T and Loop D: A Research Report," *Studies in Family Planning*, **3**:277, 1972 (first segment only).

VD

Do Spermicides Block Syphilis, Gonorrhea?

Clinical trials have begun for the first time to determine whether currently marketed contraceptive foams, creams and jellies also provide effective protection against syphilis and gonorrhea, as well as trichomoniasis and candidiasis, common vaginal infections which are sometimes transmitted venereally. The field trials in a large U.S. urban health department's venereal disease clinic follow several years of laboratory research which indicated that spermicides *are* effective in immobilizing or destroying the various venereal disease organisms. The trials are directed by John C. Cutler, M.D., Professor of International Health and Director of the Population Division of the University of Pittsburgh's Graduate School of Public Health, and a member of the team of researchers which established the laboratory findings.

Dr. Cutler told *Digest* that all the participants in this experiment have enrolled voluntarily in the program after receiving a detailed explanation of the nature of the research and its objectives. All are sexually active women over 21 years of age who have been patients of the VD clinic, where they have been cured of two bouts of gonorrhea within the past year. It is assumed that they are at high risk of incurring venereal disease again in the normal course of their lives, Dr. Cutler said. All use the oral contraceptive or the IUD, and continue to use them, or have been sterilized.

According to the protocol, approved by the State Department's Agency for International Development, which supports the research, the women are divided on a randomized basis into two groups. The controls as well as the subjects receive a complete physical examination when they enroll in the program, but only the subjects receive a supply of spermicides individually packaged (like tampons) in a standard single dose; they are instructed to insert it routinely before each act of coitus. The spermicide is a cream which can be purchased over the counter at pharmacies around the country. Although specially labeled, the formulation is one of the standard spermicides. The controls and the subjects, both free of disease when enrolled, agree to return to the clinic twice a month for a physical checkup and culture. They are paid five dollars for each visit in addition to their carfare. Any woman in either group who contracts a venereal disease while in the study will, Dr. Cutler explained, be treated for the infection. All the participants have been instructed to report the use of any medication other than the spermicides to avoid the possibility that therapy for another condition might affect the outcome of the experiment.

The objective of the clinical trials is to determine whether the spermicides behave in human subjects as they do in the laboratory. Under experimental conditions, and using a variety of testing techniques, investigators found that many of the 21 contraceptive preparations, in a variety of concentrations, immobilized or destroyed the bacteria, fungi or parasites which cause venereal disease within five to 10 minutes. The experiments show, the investigators reported, that the preparations act directly on the microorganisms, contrary to the widely held assumption that spermicides achieve their affect by altering the acid-alkaline (pH) environment of the vagina.

They warned that although these laboratory findings are encouraging, it remains to be seen whether or not the spermicides will be equally effective as VD prophylactics in human beings. They concluded: "Any preparation that would simultaneously provide prevention of conception and protection against . . . genital infections would be a most useful adjunct to public health programs. . . ."

Work with rabbits has shown, according to Dr. Cutler, that the spermicides are effective against syphilis. Gonorrhea, however, is not transmissible to any laboratory animal, making it necessary, he said, to do clinical investigation directly with human subjects. If it had been necessary to expose women deliberately to either disease, the experiment would have been of dubious ethical propriety, the physician explained. In the investigation described, however, the women are continuing to live as they usually do, but are receiving ongoing medical care of a quality and intensity not normally available to them. The risks of infection are no greater than the risks to which the women usually are subjected, Dr. Cutler said, while the odds are that any infections they do contract will be cleared up more expeditiously than previously in their experience.

The investigator believes that it will be at least two years before the clinical trials now under way produce definitive results. He hopes to extend the investigation to other urban and rural settings in the United States and abroad.

Sources

J. C. Cutler, personal communication.

J. C. Cutler, H.M.D. Utidjian, B. Singh and R. C. Arnold, "Studies on Development of a Vaginal Preparation Providing Both Prophylaxis Against Venereal Disease, Other Genital Infections, and Contraception. I. Venereal Disease Prophylaxis, Past Experience, Present Status and Plans for Future Studies," *Military Medicine* (in press).

B. Singh, J. C. Cutler and H.M.D. Utidjian, "Studies on the Development of a Vaginal Preparation Providing Both Prophylaxis Against Veneral Disease and Other Genital Infections and Contraception," *British Journal of Venereal Diseases*, **48**:57, 1972, and "Studies on Development of a Vaginal Preparation Providing Both Prophylaxis Against Venereal Disease, Other Genital Infections and Contraception. III. *In Vitro* Effect of Vaginal Contraceptive and Selected Vaginal Preparations of *Candida Albicans* and *Trichomonas Vaginalis*," *Contraception*, **5**:401, 1972.

Prostaglandins in U.K.

In September 1972, Great Britain became the first country in the world to permit the sale of prostaglandins to physicians for use in abortion and the induction of labor in women at term. The drugs approved for marketing by the British government's Department of Health and Social Security are Prostin E_2 and Prostin F_2-alpha, which are manufactured by The

Upjohn Company. By terms of the marketing license, the drugs may be sold only for intravenous infusion for the induction of labor at term and for intravenous infusion and intrauterine extra-amniotic administration to terminate pregnancy.

Because prostaglandins have many effects on various body systems which are not yet fully understood [see: "Prostaglandins: New Birth Control Hope or Headache?" *Digest*, Vol. 1, No. 2, 1972, p. 11], the two compounds will be made available for use only in selected hospitals and clinics where patients can be closely monitored. According to Upjohn, this policy of limited marketing will continue through extensive clinical trials.

In the past two years, there have been several clinical investigations of the E_2 and F_2-alpha prostaglandins as birth control agents in Sweden, Uganda, the United Kingdom and the United States. The results of these investigations were uncertain, in terms of the drugs' effectiveness and safety, and all investigators warned that a great deal more research is needed.

Sources

"Upjohn Introduces World's First Commercial Prostaglandin Products in the U.K.," news release, The Upjohn Co., Kalamazoo, Mich., Oct. 12, 1972.

T. G. Kelly, public relations associate, The Upjohn Co., personal communication.

Genetics Centers

The National Institutes of Health of DHEW began funding seven new Genetics Research Centers last June in a major effort to achieve a better understanding of the causes of genetic diseases. The $3.9-million-a-year federal program will bring together a variety of medical specialists to investigate genetic disorders, including bone and structural abnormalities, blood and circulatory disorders, chromosomal abnormalities and various metabolic deficiencies.

Specific projects at the centers will include genetic mapping of human chromosomes, identification of carriers of genetic diseases, studying control mechanisms of genetic expression in man, and use of a central repository of human cell lines at the Institute for Medical Research at Camden, New Jersey. [See: "Genetic Counseling, A Practical Family Planning Service?" *Digest*, Vol. 1, No. 1, 1972, p. 4.]

Source

Office of Information, National Institutes of Health (NIH), Public Health Service, DHEW, "NIH Opens Seven Genetics Research Centers in New $3 Million Program," *NIH feature service*, NIH, Bethesda, Md., June 1972.

Sterilization

Despite Higher Risks, Some Doctors Still Prefer Hysterectomy to Tubal Ligation

Although the complication rate resulting from hysterectomy is 10 to 20 times higher than that associated with tubal sterilization, and although hysterectomies are about five times more expensive and require six weeks' convalescence as compared to a few days at most following tubal ligation, there has been a considerable increase in the past few years in the number of elective hysterectomies performed on nonpregnant, healthy young women for the sole purpose of accomplishing sterilization in at least one major California hospital, according to Dr. Lester T. Hibbard, in an article appearing in the *American Journal of Obstetrics and Gynecology*. The physician reports that during a recent two-and-one-half-year period, the number of all types of sterilizations at the Women's Hospital of the Los Angeles County-University of Southern California Medical Center increased by 282 percent; while the number of hysterectomies performed as a contraceptive sterilization procedure increased by 742 percent. Dr. Hibbard observes that "the charge that this operation is overexploited appears to have considerable substance."

Prior to 1967, hysterectomies for the primary purpose of sterilization were "rarely performed" at Women's Hospital, the physician notes, but between July 1968 and December 1970, 316 women, most of whom were normal and healthy, and none of whom were pregnant, were sterilized by having their uteri removed. Over one-third of these women (116) had originally asked for tubal sterilization, but were "persuaded to accept hysterectomy either because of the enthusiasm of the attending physician" or because of secondary minor pelvic complaints that would not ordinarily require this major operation. "Taken by themselves," Dr. Hibbard notes, "these indications had not been sufficiently troublesome to require an operation." They included mild to moderate degrees of pelvic relaxation, stress incontinence, benign ovarian cysts and history of dysfunctional bleeding.

Past restrictions against hysterectomy based on the woman's age, parity and marital status were relaxed as the number of hysterectomies increased over the period. In 1968, 16 percent of the patients receiving hysterectomies were not married, nine percent were under 26 years of age and none had fewer than three children. By 1970, 31 percent were unmarried, 25 percent were under 26 years and 19 percent had fewer than three children. "Presumably," the author writes, "some of these women will come to regret this irrevocable decision."

By an examination of the operative complications experienced by the hysterectomy patients in comparison to 1,360 patients who underwent tubal surgery during the same period, Dr. Hibbard observes, "By any yardstick, hysterectomy is significantly more hazardous than tubal sterilization":

- Using temperature as a measure of postoperative morbidity, the author found that 54 percent of the hysterectomy patients suffered from fever in excess of 100 degrees, and 17 percent had temperatures greater than 101 degrees. This occurred despite the fact that 31 percent of the patients were given antibiotics prophylactically before the operation and 40 percent after the operation.
- Another measure of postoperative complications was prolonged hospital stay. Because most of the patients were young and reasonably healthy, the usual plan was for discharge by the fifth postoperative day. In actuality, 37 percent remained in the hospital for more than five days and 11 percent remained for more than eight days.
- While the operative complication rate for tubal sterilization ranged from one to two percent, the complication rate for hysterectomy ranged from 22 to 34 percent.

The author concludes, "In our experience, the case for routine elective hysterectomy for sterilization has not been made."

Dr. Hibbard's admonition against utilizing hysterectomy for contraceptive sterilization drew strong support in an editorial in *Obstetrics and Gynecology* signed by Dr. Harold Schulman of Albert Einstein Medical College. Dr. Schulman said that national statistics from the Commission on Professional and Hospital Activities reveal a mortality rate from hysterectomy of 16.4 per 10,000 patients, while the risks for tubal ligation alone do not appear to be "much greater than those associated with the anesthetic." (Until recently, tubal ligation was considered a postpartum, not an interval, procedure, so that definitive results from large-scale studies are not yet available.) Also decrying the use of hysterectomy for abortion, Dr. Schulman said: "It would appear rather conclusive that when a hysterectomy or hysterotomy is substituted for simple tubal ligation, suction abortion or saline abortion, the physician should inform his patient that he is recommending a proce-

dure which increases her risk of dying at least 20 times."

Dr. Schulman singled out for criticism those who performed the procedure: for "convenience"; to "protect the patient from herself" ("she may be of low economic status, will not return for follow-up and therefore hysterectomy will eliminate a source of future uterine pathology"); for resident training; for research; or to spare women "the drudgery of the menses." All of these reasons, Dr. Schulman pointed out, have been given by physicians to justify contraceptive hysterectomies and hysterotomies for abortion in recent articles published in *Obstetrics and Gyncecology* and the *American Journal of Obstetrics and Gynecology*. Vaginal hysterectomy for sterilization of "selected patients" was recommended in the November 1st number of the *American Journal of Obstetrics and Gynecology* by Dr. C. J. Roach and his colleagues from the Fitzsimmons General Hospital in Denver. The Denver team reported on 100 consecutive cases of vaginal hysterectomy of whom 29 developed 33 complications ranging from peritonitis to urinary tract infections. Seventy-eight percent of patients went home within five days after the operation. The investigators held that sterilization is an "accepted indication for vaginal hysterectomy" for patients with long-standing benign gynecologic complaints, for patients who are unreliable about follow-up or contraception, and for those who want to be certain that sterilization will not fail. The investigators said that hysterectomy mortality is not "at issue," quoting 10-year-old figures from a Johns Hopkins study comparing mortality rates for tubal ligation and vaginal hysterectomy. They did not point out, however, that these mortality figures are not applicable to the newer laparoscopic and culdoscopic methods of tubal ligation, but only to the traditional sterilizations performed in conjunction with other events (such as delivery) and involving major surgery, such as laparotomy. Other articles advocating hysterectomy or hysterotomy as sterilization or abortion procedures cited by Dr. Schulman include: S. M. Atkinson and S. M. Chappell, "Vaginal Hysterectomy for Sterilization," *Obstetrics and Gynecology*, **39:**759, 1972; L. E. Laufe and A. K. Krentner, "Vaginal Hysterectomy: A Modality for Therapeutic Abortion and Sterilization," *American Journal of Obstetrics and Gynecology*, **110:**1096, 1971; J. A. Morris, G. L. Haswell and R. F. Hustead, "Research in the Human Mid Trimester Fetus," *Obstetrics and Gynecology*, **39:**634, 1972; J. R. Van Nagel and J. W. Roddick, "Vaginal Hysterectomy as a Sterilization Procedure," *American Journal of Obstetrics and Gynecology*, **111:**703, 1971. [For a further discussion of hysterectomy for contraceptive sterilization, see: "Preventive Medicine?" *Family Planning Perspectives*, Vol. 4, No. 1, 1972, p. 5.]

Mortality risk for hysterectomy said to be 20 times that for tubal ligation (above).

Sources

L. T. Hibbard, "Sexual Sterilization by Elective Hysterectomy," *American Journal of Obstetrics and Gynecology*, **112:**1076, 1972.

C. J. Roach, J. D. Krolak, J. L. Powell, A. S. Llorens and K. F. Deubler, "Vaginal Hysterectomy for Sterilization," *American Journal of Obstetrics and Gynecology*, **114:**670, 1972.

H. Schulman, "Major Surgery for Abortion and Sterilization," editorial, *Obstetrics and Gynecology*, **40:**738, 1972.

Progestogens

Bleeding, Pregnancy Problems Found in Five Minipills Tested

Because the estrogen component in the combined oral contraceptive has been identified as the cause of numerous metabolic effects not necessary for contraception, and has been associated with increased risk of sometimes fatal thromboembolic disease, researchers continue to explore the effectiveness and acceptability of presumably more benign progestogen-only preparations. (New drug applications for two such preparations, chlormadinone acetate and medroxyprogesterone acetate, were withdrawn in the United States after the drugs were found to produce malignancies in beagles.)

A recent, carefully controlled one-year clinical investigation in Yugoslavia of several of these drugs confirms previous reports, however, that current progestogen-only preparations are less effective in preventing pregnancy than the combined pill. Method failure rates ranged from 2.4 pregnancies per 100 woman-years for norgestrel and norethisterone acetate to 13.2 for megestrol, compared to a theoretical method failure rate, according to the U.S. Food and Drug Administration, of 0.1 for the combined pill. Moreover, the progestogen-only preparations continue to demonstrate a tendency to disrupt the menstrual cycle and cause abnormal bleeding in a large proportion of users, leading the investigators to conclude that it seems "unlikely that any currently available progestogen will be found to be capable of preventing conception without interfering with the menstrual cycle." Menstrual irregularities, especially short cycles, in this as in previous studies, caused large numbers of women to discontinue this method of contraception.

The investigation also confirmed previous research regarding the antifertility mechanism of microdoses of progestogen-only preparations: a reduction in sperm penetrability of the cervical mucus, an alteration in the histology of the endometrium, impairment of luteal function and, in some cases, inhibition of ovulation.

The Yugoslav investigation was conducted at the Family Planning Institute of Ljubljana under the direction of M. P. Vessey, of Britain, whose earlier research associated the combined estrogen-progestogen pill with increased risk of thromboembolic disease. The Yugoslav study involved 307 healthy women of proven fertility, aged 18-44, in a randomized double-blind trial comparing four progestogen-only oral contraceptives: norgestrel (0.075 mg), megestrol acetate (0.7 mg), norethisterone acetate (0.3 mg) and chlormadinone acetate (0.5 mg).

A fifth group of 71 women received the combined oral contraceptive, nuvacon (ethinyl estradiol, 0.1 mg; megestrol acetate, 2.0 mg). The 378 women were followed up for one year.

The progestogen-only tablets were specially manufactured to be identical in appearance, so that neither researchers nor participants knew which preparation was taken by whom. At the first visit, after a complete medical examination, the women were given randomly selected bubble packs of the progestogen-only pills, and were told to start taking them on the first day of the next menstrual period, to continue to take one tablet every day even when bleeding occurred, and to return to the clinic five weeks later.

They were asked to take the tablets at the same time each day, and were provided with personal record cards on which to keep day-by-day records of tablets taken and any vaginal bleeding which occurred.

After the first follow-up visit at five weeks, the women returned to the clinic at four, seven, 10 and 13 months. At each visit the personal record card was checked and recorded on a special form. Endometrial biopsy specimens were taken from some women. Because progestogen-only oral contraceptives disrupt the normal menstrual pattern, the researchers asked the women to record as menstrual bleeding only bleeding sufficient to require the use of sanitary protection. Any lesser degree of bleeding was regarded as "spotting."

Twenty-eight percent of the women discontinued taking pills for reasons not connected with treatment (equal proportions of those taking the progestogen-only preparations and those taking the combined pill); 29.6 percent discontinued taking the pills because of accidental pregnancy, menstrual disturbances or other pill side effects. Nearly one-third (31.9 percent) of those taking the progestogen-only preparations withdrew for treatment-related reasons, compared to 19.7 percent of those taking the combined pill.

Menstrual Problems

Menstrual irregularities were the main cause of withdrawal, accounting for 20.8 percent of all progestogen-only users and 5.6 percent in the nuvacon group. In this respect, norgestrel was the least satisfactory progestogen-only preparation, with a rate of 5.4 withdrawals for menstrual disturbance per 100 woman-months of use, compared to a rate of 0.7 for nuvacon. Norethisterone was the best of the progestogens, with a withdrawal rate of 1.6 per 100 woman-months, and megestrol and chlormadinone were intermediate, with rates of 2.7 and 2.1, respectively.

The investigators took a "rough measure" of menstrual regularity by calculating the range of variation in cycle length for every woman completing six or more cycles of treatment. The combined pill was the most satisfactory preparation in this respect; women on the progestogens were, at best (with norethisterone), a little more than 50 percent more irregular and, at worst (with norgestrel and megestrol), close to 100 percent more irregular than those on nuvacon.

Progestogen-only users experienced a high frequency of short cycles of 17 or fewer days duration. While only 3.8 percent of those in the nuvacon group had short cycles, from 11.3 to 20.7 percent of those on progestogens experienced such cycles. Norgestrel proved the least satisfactory of the progestogens and norethisterone the most satisfactory in this regard.

Duration of flow was also less satisfactory with the progestogens than with the combined pill: 11.7 percent of women on nuvacon experienced seven or more days of bleeding, compared to 17.0-31.0 percent of progestogen users. The least satisfactory progestogen in this connection was norgestrel.

Other Side Effects Minimal

With regard to other side effects such as headache, nausea or vomiting, breast tenderness, and back or abdominal pain, all four progestogens were found to be more acceptable than the combined pill. Norethisterone had the lowest rate of withdrawal for such other side effects (0.6 per 100 woman-months), compared to nuvacon with the highest (1.6 per 100 woman-months). The rate for chlormadinone was 1.0; for norgestrel, 1.2; and for megestrol, 1.5.

The rate of withdrawal because of accidental pregnancy among the progestogen-only users was lowest for norethisterone and norgestrel (0.2 per 100 woman-months), and compared favorably with nuvacon (also 0.2 per 100 woman-months), although the researchers point out that the one pregnancy in the nuvacon group followed irregular taking of tablets, while all of those who became pregnant on the progestogen-only tablets appeared to have taken them regularly. The withdrawal rate because of pregnancy was 1.1 for megestrol and 0.3 for chlormadinone.

In assaying the acceptability of the four progestogen preparations compared to nuvacon by calculating the total withdrawal rates for all treatment-related reasons, the researchers found norethisterone as acceptable as nuvacon—2.4 withdrawals per 100 woman-months for norethisterone, compared to 2.5 per 100 woman-months for nuvacon. The treatment-related withdrawal rates for the other progestogens were higher: chlormadinone, 3.4; megestrol, 5.3; and, least satisfactory, norgestrel, 6.8.

Only in relation to weight-gain was norethisterone less satisfactory than the other progestogen preparations. After 10 months of treatment the mean change in weight for norethisterone users was a gain of 2.6 pounds; for nuvacon users, a gain of 0.4 pounds; for norgestrel users, a gain of 0.9 pounds; for megestrol users and chlormadinone users, a loss of 0.4 and 1.8 pounds, respectively.

The Yugoslav clinicians therefore concluded that norethisterone acetate emerges "as the most promising of the four progestogens" in this trial.

A clinical investigation of low-dose norgestrel (.075 mg), conducted in Great Britain under the direction of P. Eckstein, arrived at results similar to those found in the Yugoslav study. The British study involved the administration of norgestrel to 144 healthy women of proven fertility over a period of 30 months in 12 clinics in the United Kingdom.

With regard to menstrual disturbance, the British investigators found the same high proportion of irregular and generally short bleeding intervals, 20.6 percent of the cycles lasting less than 17 days, compared to 20.7 percent in the Yugoslav study. Similarly, the British reported a high rate of discontinuation because of menstrual disturbance for norgestrel users: thirty-six women (or about 63 percent of all those who withdrew for treatment-related problems) withdrew from the trial for that reason. With regard to the effectiveness of norgestrel in preventing pregnancy, the British clinicians found the accidental pregnancy rate similar to that of the Yugoslav study, but came up with a lower method-failure rate—1.3 per 100 woman-years.

The British study also found that norgestrel did not interfere with the return of fertility after completion of treatment. Six women at one clinic stopped the medication in order to conceive and all succeeded, two within one cycle and the others in from two to six months. In addition, the British clinicians found a significantly lower concentration of cholesterol during norgestrel treatment, as well as a slight lowering in the concentration of blood glucose, in contrast to a tendency for serum cholesterol to rise in women taking combined pills.

The British concluded that norgestrel, while not as effective against pregnancy as the combined pill, "compares favourably with . . . other progestogen-only preparations and intrauterine devices" and "appears to be a useful alternative to the combined type of pill. . . ."

Sources

M. P. Vessey, E. Mears, L. Andolsek and M. Ogrinc-Oven, "Randomised Double-Blind Trial of Four Oral Progestogen-Only Contraceptives," *Lancet*, **1**:915, 1972.

P. Eckstein, M. Whitby, K. Fotherby, C. Butler, T. K. Mukherjee, J. B. C. Burnett, D. J. Richards and T. P. Whitehead, "Clinical and Laboratory Findings in a Trial of Norgestrel, A Low-Dose Progestogen-Only Contraceptive," *British Medical Journal*, **3**:195, 1972.

L. M. Hellman, "Chairman's Summary," in Advisory Committee on Obstetrics and Gynecology, Food and Drug Administration, DHEW, *Second Report on the Oral Contraceptives*, U.S. Government Printing Office, Washington, D.C., 0-362-666, 1969, p. 3.

Resources in Review

By Dorothy L. Millstone

Family planning program staff, especially those in new programs, will find useful an attractive, handy, durable kit of materials produced for the U.S. Department of Housing and Urban Development by the Health Services Division of Westinghouse Learning Corporation. Its four brief booklets (entitled *Family Planning)* are brightened by warmly human pen-and-ink sketches, and are backed up by resource lists. Booklet No. 1, *The Concept*, covers the philosophy, history, rationale, attitudes and basic components of a family planning program. No. 2, *Program Planning*, summarizes organization of the planning effort, need assessment, resource identification and mobilization and financing. The third booklet, *Getting and Keeping Your Program Going*, describes staffing, clinic layout, purchase of equipment and supplies, record-keeping and communications. Booklet No. 4, *Improving Your Existing Program*, concerns evaluation, consumer participation, services for men and teenagers, and strengthening boards and committees.

Kit of four books costs $4.50. Order from the Superintendent of Documents (Stock No. 2300-1197), U.S. Government Printing Office, Washington, D.C. 20402.

Hospital Programs

Family Planning in Hospitals consists of the distilled wisdom of 122 health specialists representing 25 hospitals around the country who met last May in Battle Creek, Michigan, to discuss the role of hospitals in delivering family planning services. The booklet contains useful discussion of experience in some key hospital programs, discussion of rationale for such programs, and recommendations to improve and extend them.

Available free from Johan W. Eliot, M.D., Center for Population Planning, Room 3047a, School of Public Health, Ann Arbor, Mich. 48104.

Training Paramedical Personnel

• Film—*Family Planning: More Than a Method*. 27 minutes, black and white. This New Careers film shows paramedical staff in training and at work teaching family planning. Filmed on location in a large county health department, the people and the situations come across as real. The film identifies obstacles to effective use of family planning and problems patients face, and portrays both strong and weak points in training. A discussion guide is provided. The movie, produced under a grant from the Office of Economic Opportunity, is suitable for the general public, community groups, educators and potential patients as well.

Purchase price, $61.25, from the National Audio-Visual Center, Washington, D.C. 20409. Rental $10, from PP-WP Film Library, 267 West 25 Street, New York, N.Y. 10001.

• Film Strip—*Interviewing, Family Planning Style*, 10 minutes, color, includes record. Witty cartoons and narration used for training family planning workers for outreach and clinic services. Topics covered—most in dialogue between worker and patient—include how to: listen to a patient and establish rapport, acquire patient information, deal with typical situations met in home visiting. The accompanying training manual on intake and outreach interviewing describes training techniques and includes the film's script. Produced for Office of Economic Opportunity by Planned Parenthood-World Population Training Department.

Purchase price, $25; rental $5, from Planned Parenthood Audio-Visual Department, 810 Seventh Ave., New York, N.Y. 10019.

The Pregnant Teenager

• *Pregnant Adolescents* reviews and abstracts nearly 200 articles published between 1960 and 1970 on this subject. The articles are divided into five sections: definitions of the problem and recommendations for action; existing services; health research; psychological, psychiatric and social work research; and research on pregnant teenagers in the public schools. Each section's findings are summarized in brief overviews.

A free copy may be obtained from the Consortium on Early Childbearing and Childrearing, Research Utilization and Information Sharing Project, Suite 709, 1145 19th St., N.W., Washington, D.C. 20036.

• *If You Are Single and Pregnant. . .* , a simple four-page folder addressed to the pregnant teenager herself, packs valuable information in short, clear sentences. "Don't Panic," the folder advises, asking key questions such as: "Can I stay at school or at work?" "Do my parents have to know?" Not all questions are answered, but the young girl is guided to where the answers can be found. The pamphlet is sponsored by Vermont Catholic Charities, Planned Parenthood, Children's Aid Society, and a shelter for unwed pregnant girls, the Elizabeth Lund Home.

Available free from Helen King, Superintendent, Elizabeth Lund Home, 76 Glen Road, Burlington, Vt. 05401.

Patient Recruitment

Popular interest in astrology and the lure of games furnish themes for two pocket-sized booklets which, with bold art and simple copy, focus on the benefits of birth planning. *The Horoscope for Family Planning* is addressed to women and mentions only the pill.*Every Man's Guide to Being Lucky in Love*, for the other half, discusses only the condom. Both include simple diagrams of the female reproductive organs, and the men's book also includes a diagram of the male organs.

Price, six cents for each in quantities up to 5,000; a small reduction for larger quantities, from Neighborhood Concepts in Family Planning, 427 Ocean St., Jacksonville, Fla. 32202.

Vital Statistics

• *We the Americans—Who We Are* is a colorful, succinct summary of demographic statistics drawn from the 1970 Census. Statistics on population growth, density, migration, ethnicity and urban-rural makeup are made more accessible and attractive by well-designed charts and diagrams.

Price, 35 cents, from the Superintendent of Documents (Stock No. 0324-0006), U.S. Government Printing Office, Washington, D.C. 20402, or any Department of Commerce Field Office.

• *Spanish Language Health Communication Teaching Aids*, is a HSMHA-DHEW annotated bibliography (56 pp.) of health interest items ranging from "Accidents" to "Whooping Cough," and including a number of entries on family planning. Easy-to-use subject index and source index.

Free sample copy available from Public Inquiries, OCPA, Health Services and Mental Health Administration, Room 5B-29, 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-33
5600 Fishers Lane
Rockville, Md. 20852

Contraceptive Research

Acceptance of Risk by Patient Said to Be "Essence" Of Informed Consent for Research

The question of what constitutes adequate explanation to a patient of the possible risks involved in medical or surgical procedures, before he gives his consent to have a procedure performed, is being discussed increasingly in medical and lay circles. Two physicians explored the question at a meeting of the American College of Legal Medicine in Miami, emphasizing the responsibility of the physician to inform patients of the possible risks in diagnostic, therapeutic and experimental procedures. The problems involved in applying the principle of informed consent are also highlighted in two recent reports involving contraceptive modalities.

Acknowledging that informed consent — routinely required today for clinical investigation in hospitals and institutions — hampers experimentation, Dr. Shields Warren, of the Cancer Research Institute of New England Deaconess Hospital in Boston, declared that such restrictions "are probably without too great social cost for the protection afforded." Dr. Sam D. Rhem of Pasadena, Texas, agreeing with his colleague, held that physicians *must* be educated as to the legal necessity "to inform the patient properly."

Discussing the question of elective procedures, such as vasectomies and abortions, Dr. Warren said there are risks which should be explained. "For example, vasectomy has long been thought to be a safe and effective means of male sterilization, but [researchers] have reported cases of sperm reappearance in the ejaculate some weeks . . . after vasectomy, and spontaneous recanalization of the vas is a possibility," he pointed out. There is also a "psychosexual casualty rate." Risks should be "fully explained," he maintained, even though the procedure has been sought out by the patient.

Dr. Warren said that informed consent is rarely considered in abortion, "as the act is usually eagerly sought by the pregnant woman . . .," but, he added, "the inevitable risks and the contraindications tend to be glossed over." Dr. Warren noted that while "the risk of a properly performed early abortion is slight, it is nevertheless real, and it is essential that the risks should be properly presented."

Chile IUD Study

An example of the problems involved in double-blind studies — in which neither the subject nor the doctor is "informed" nor gives "consent" for research — is demonstrated by a recent report from Chile on a research project designed to ascertain whether IUDs could be safely inserted immediately after induced or spontaneous abortion. Following admission to a hospital for treatment of incomplete abortion (either spontaneous or illegally induced), 584 women were given instruction in family planning and elected to have an IUD inserted. The women were then randomly assigned to one of two study groups. As reported in the *IPPF Medical Bulletin*, "although all the women thought they had received an IUD, one group had a Lippes loop D inserted immediately after curettage and the other group had no insertion." The study was "double-blind," with the attending doctor also having no prior knowledge about which women received the device. The patients were requested to return to the hospital in 30 days for a checkup, and at this time those women who had not received an IUD were given one. The authors of the report in the *IPPF Medical Bulletin* said it would have been desirable to continue the study beyond one month, but "the study was only undertaken with the knowledge that the probability of conception is very small in the first month after abortion and, therefore, the women were exposed to little pregnancy risk even without the IUD." [In fact, at least one other study has indicated that ovulation usually takes place less than a month following abortion, see: "Six-Week Check Late for Contraception?" *Digest*, Vol. 1, No. 6, 1972, p. 12.]

What is Consent?

Dr. Rhem emphasized that "acceptance of risk by the patient is the essence of informed consent." Analyzing the legal pitfalls, he declared that "the consent form which exists in most modern hospitals today is so *vague* and *unrevealing* that the courts have stated that such blanket consent forms were almost completely worthless." Court decisions seeking to outline the physician's duties have been confusing, he added.

He said that the problem "lies not so much with the fault of the law as it does with the physician population and their reticence to burden a patient with what appears to them to be needless and unnecessary details. . . ." He maintained that physicians must "get over the antiquated notion that the procedure they feel necessary for the patient must invariably be accepted by the patient. The patient must be looked upon as a legally competent person, capable of giving a legally defensible informed consent." The physician, Dr. Rhem said, "must not proceed . . . until all the risks have been disclosed."

An attempt to disclose "all" risks can be seen in connection with use of an experimental injectable contraceptive, Depo-Provera, which needs to be administered only four times a year.

A consent form approved by the Food and Drug Administration (FDA) tells a woman considering use of the drug that:

- Dogs developed breast tumors when given the drug. It warns that such tumors, possibly cancerous, might also develop in the woman's breasts.
- She must confirm that all non-experimental contraceptives (including surgical sterilization) have been described to her, with the effectiveness, advantages and disadvantages of each explained.
- She must "read and understand" pamphlets about the oral contraceptive prepared by the American Medical Association, the American College of Obstetricians and Gynecologists and the FDA, which detail many possible side effects of the pill because "Depo-Provera is similar to the pill in that I may have some of the same problems. . . ."
- She may experience "unexpected vaginal bleeding, completely irregular menstrual cycles or no menstrual bleeding" at all while on the drug and her hormonal balance may be altered. The possibility of temporary or permanent sterility is noted.

She then has to state that she cannot or will not use any other form of birth control, and voluntarily agrees to the use of Depo-Provera.

The investigator may also, if he chooses, obtain the consent of the husband. The consent form requires the physician to state that he has explained all the risks and alternatives, and the patient accepts the experimental drug for one or more specific reasons, also given.

Sources

Papers presented at meeting of the American College of Legal Medicine, Miami Beach, Fla., May 1972:

S.D. Rhem, "Informed Consent — The Surgeon's Last Hurrah."

S. Warren, "Informed Consent as Related to Clinical Investigation and Practice."

Other sources:

A. Goldsmith, R. Goldberg, H. Eyzaguirre and L. Lizana, "IUD Insertion Immediately after Incomplete Abortion," *IPPF Medical Bulletin*, Vol. 6, No. 2, April 1972, p. 1.

"Depo-Provera Written Informed Consent Form for Contraceptive Studies," form #95-1945, Upjohn Co., Kalamazoo, Mich.

Program Development

National Family Planning Forum Sets Program, Reporting, Manpower Goals

Renewal and expansion of the federal family planning project grant programs, better and speedier reporting by the National Family Planning Reporting System, more effective consumer participation in program policy making, earlier communication to organized programs of proposed new or revised project guidelines, a standardized family planning terminology, development of a system for evaluating program effectiveness, and a greater federal investment in manpower training and development were among the goals and recommendations adopted by representatives of the nation's major family planning programs meeting October 4-6 in Los Angeles.

Representatives of more than 220 of the 238 member organizations from 42 states which comprise the National Family Planning Forum met to hammer out program goals for this fiscal year and to consider reports by key program committees. The Forum was formally established in March to "originate, promote, improve and coordinate the distribution and availability of family planning" throughout the nation.

Marjorie A. Costa, Director of the National Center for Family Planning services (NCFPS), emphasized in the keynote speech that agency's commitment to obtaining consumer participation in family planning programs. She called for meaningful family planning programs for teenagers, as well as the introduction of effective health and sex education programs in the schools. She emphasized the importance of quality services, services "good enough for you, for me, your mother, your daughter, your son to come back to when we have a choice of places to go," and for dignified services. "I don't want to see a room where they have three or four examining tables, and expect a woman to come in, strip and jump up on the table and spread her legs for a pelvic examination."

Forum members adopted as a priority program goal for the current fiscal year the attainment of greater consumer participation in Forum affairs. Other program objectives adopted for FY 1973 included:

- Development of a mechanism whereby the Forum is "routinely and promptly" informed by federal agencies of new or revised guidelines affecting family planning service delivery "so that the Forum may make its views known regarding the content of such guidelines." (Immediate clarification was called for concerning treatment of pathology detected in the course of delivering family planning services, liability protection for family planning workers, and NCFPS federal and regional "roles and responsibilities" relating to project grantees, as well as to subcontractors who may actually provide the family planning services.)
- Development of some "major measurable points" for evaluation of family planning services (such as "patient-months of nonpregnancy") which could be utilized in an overall family planning program evaluation system.

Standardized Definitions

The Forum adopted a "Glossary of Family Planning Terms," consisting of definitions of nearly 50 terms commonly used in family planning, compiled from more than two dozen published reports, studies and planning documents. A Committee on Terminology compiled the standardized glossary to assure comparability of data within and among programs, and thus facilitate program management, monitoring and evaluation, cost analysis and accounting. At the present time, it was pointed out, terms such as "active patient," "outreach" and even "family planning services" are often used by different programs to mean different things. The glossary definitions adopted by the Forum are now being used by the University Research Corporation in its evaluation of family planning programs made for NCFPS. Adoption of the glossary has also been proposed to the membership of the American College of Obstetricians and Gynecologists (ACOG), and it may be obtained from Dr. Louise B. Tyrer, Director of the Division of Family Planning, ACOG, One East Wacker Drive, Suite 2700, Chicago, Ill. 60601.

The Forum adopted the report of its Committee on Manpower Training and Development, which called for considerable upgrading by NCFPS of staff and funds for manpower purposes. The report held that current allocations for manpower training—about three percent of total estimated federal family planning expenditures—were inadequate. Such short-changing of training, the report said, risks inefficient use of expenditures for service. Late release and "limitations and ambiguities" of policy guidelines, it added, further "decrease [the] availability and utility" of manpower funds (e.g., the guidelines' disallowance of training programs leading to academic degrees, and their lack of clarity as to whether costs of training of volunteers and part-time trainees are covered). The Committee also called for more and better data on family planning manpower needs. It concluded: "The lack of a clear federal statement regarding manpower priorities represents a serious constraint to the development of traditional policies in this area."

The Forum adopted a resolution urging Congress to extend the project grant program under Title V of the Social Security Act and Title X of the Public Health Service Act for at least three years beyond the current fiscal year, and to authorize expenditures over and above currently authorized levels (more than $110 million is authorized under Title X for FY 1973), so that the national family planning program can achieve the objectives outlined in the DHEW Five-Year Plan. [See: "DHEW Five-Year Plan: Serve 6.6 Million, Spur Research for New Contraceptives by 1975," *Digest*, Vol. 1, No. 2, 1972, p. 1.]

Forum members also called upon the National Center for Health Statistics (NCHS) to report back to the family planning projects regularly, promptly and systematically. Members complained that while projects were required to report demographic and visit data to NCHS, computerized reports often came back to them too slowly and were not complete enough to be useful in program administration and evaluation.

Robert Parke, Jr., who was Deputy Director of the Commission on Population Growth and the American Future, reported on the recommendations made by that Commission to the President and the Congress last March. [See: "Population Commission: Welcome and Plan for Stabilization Now," *Digest*, Vol. 1, No. 4, 1972, p. 3.] Dr. John P. Marshall, Professor of Obstetrics and Gynecology of the University of California-Los Angeles School of Medicine, spoke on new directions and needs in contraceptive research.

A panel reported on program evaluation, management and cost studies being made of local projects for NCFPS and the Office of Economic Opportunity. Program evaluation, medical standards, manpower, funding problems (especially negotiation of Title IV-A and Medicaid reimbursement), consumer participation, sickle cell testing and counseling, and "new directions" (such as services to teenagers who are not from low-income families) were subjects of Forum workshops.

The next meeting of the Forum will be held May 1-3 at the Ramada Inn, Key Bridge, Washington, D.C.

Postpartum Program

Nine in 10 of 3,500 Newly Delivered Mothers Adopt Birth Control in Hospital

Largely as a result of family planning counseling by specially trained paraprofessionals, nine out of 10 of more than 3,500 women who delivered babies or had abortions in 1970-1971 at Temple University Health Sciences Center in Philadelphia, Pennsylvania, and were offered family planning services accepted contraception before leaving the hospital, according to a report by Dr. Jerry J. Shulman, in *Obstetrics and Gynecology*. As part of an expanded family planning program, begun late in 1969, almost all the patients were offered a choice of contraceptives to be provided immediately after abortion or delivery. The counselors, all neighborhood women, informed patients about family planning and acted as liaison among the community, the patients and the hospital staff.

Six counselors were recruited from among previous patients who had demonstrated a sustained interest in family planning or through advertisements in local newspapers. The only requirements were belief in the benefits of birth control, a sympathetic attitude toward other women, and the ability to communicate easily. They were trained for six weeks in interviewing techniques and in the various contraceptive methods, including their benefits and possible side effects.

Prenatal Counseling

A counselor sees each patient at her second or third prenatal visit to the hospital, and offers information about contraception or sterilization. The patient is asked to discuss family planning with her husband or any other person she chooses. She is interviewed again at the next prenatal visit and, if necessary, is given further counseling. If the patient chooses immediate postpartum contraception, the counselor notes the fact on the patient's prenatal record. If a patient did not come to the hospital for prenatal care, but only for delivery or abortion, she is interviewed immediately following the procedure, and contraception or sterilization is offered if interest is expressed.

Surgical sterilization is performed immediately after delivery and, if there are no contraindications, Dr. Shulman explained, the selected contraceptive method is prescribed and provided immediately or an IUD fitted before the patient is discharged. Two tubes of foam or a two months' supply of pills are provided to those selecting either of the two methods. Dr. Shulman emphasized that "all patients are encouraged to return for a postpartum visit whether or not they have accepted a contraceptive method. . . ."

Of the 3,792 women treated between November 1969 and August 1971, 3,554 (94 percent) were interviewed by the counselors; of these, 3,213 (90 percent) accepted contraception before leaving the hospital. According to the physician, "the use of trained counselors recruited from the community itself was a major contributory factor in the success of the project."

Medical Bias?

Of the 10 percent who did not accept inhospital contraception, some had personal reservations about family planning, but a number may have rejected it because of "a medical, social or moral" reluctance on the part of the resident physician to prescribe contraception in the immediate postpartum or postabortal period. "It is possible," Dr. Shulman observed, "that some physicians have an emotional conflict in prescribing contraception to prevent pregnancy during a period in which they advise abstinence from sexual intercourse."

The reluctance on the part of many physicians to prescribe immediate postpartum contraception was also ascribed by Dr. Shulman to what he regarded as exaggerated fears regarding the possibilities of infection, perforation or thromboembolic or other complications associated with the IUD or the oral contraceptive. He noted that in the program described there have been very few complications.

Table 1. Contraceptive Methods Accepted before Hospital Discharge for Various Program Periods

Method	*July-December 1970*		*January-August 1971*	
	No.	*%*	*No.*	*%*
Pill	495	48.0	677	53.5
Foam	233	22.6	183	14.5
Sterilization	174	16.9	216	17.1
IUD	128	12.5	189	14.9
Total	**1,030**	**100.0**	**1,265**	**100.0**

Source: J.J. Schulman, "Contraceptive Provision in the Immediate Postpartum Period," *Obstetrics and Gynecology*, **40**:405, 1972.

Among the more significant findings are the following:

- Between July 1970 and August 1971, the largest proportion of acceptors, approximately 51 percent, chose the pill. About 17 percent underwent sterilization (usually within an hour after delivery or at cesarean section), 14 percent were fitted with intrauterine devices and about 19 percent selected foam. As the program progressed there was an increase in the acceptance of the more effective methods and a decrease in the selection of foam (see Table 1). "This is an indication," Dr. Shulman said, "of the counselor's ability to help patients choose a more reliable method, as she gained experience and assurance."
- About 60 percent of all the patients returned to the hospital for checkups, and the return rate did not differ between those who delivered and those who had abortions, or between those who accepted inhospital contraception and those who did not. This was significantly higher than the previous return rate of 44 percent at the hospital, Dr. Shulman noted, but not as high as that reported for other family planning programs. He commented: "These latter . . . provide contraceptive measures only at the postpartum visit and this is undoubtedly an incentive for the patient to return. It may be that our patients who do not return view contraceptive provision as a substitute for the postpartum or postabortion visit."
- The return rate tended to decrease, among acceptors and nonacceptors, as the age of the patients increased. According to the author, this was probably because more older women chose sterilization and were therefore less likely to return for a postdelivery visit. Young girls, on the other hand, are eager to resume their education and, in order to do so, are required to present a letter from a physician, which they obtain when they return for the postpartum examination.

Among nonacceptors, the greatest percentage return—83.4-100 percent—was registered among those aged 35-39 and 40 and over, probably because, the physician believed, of a strong determination to limit family size at these age levels.

Source

J. J. Shulman, "Contraceptive Provision in the Immediate Postpartum Period," *Obstetrics and Gynecology*, **40**:403, 1972.

Credits

p. 1: National Center for Family Planning Services; p. 3: Planned Parenthood-World Population; p. 4: Wide World; p. 5: Ken Heyman; p. 6: G. D. Searle, David Amundsen; p. 10: Alvin M. Siegler, M.D.

Family Planning Digest
National Center for Family Planning Services
Health Services and Mental Health Administration
Department of Health, Education and Welfare
5600 Fishers Lane, Room 12A-33
Rockville, Maryland 20852

Postage and Fees Paid
U.S. Department of H.E.W.

Family Planning Job Opportunities

Family planning agencies are invited to send job opportunity statements for professional positions to:

National Center for Family Planning Services
HSMHA, DHEW
5600 Fishers Lane, Room 12A-33
Rockville, Maryland 20852

The National Center for Family Planning Services, HSMHA, does not necessarily support the agencies seeking to fill positions.

All openings listed below are with Equal Opportunity employers.

●

Position: Clinic Consultant
Agency: Family Planning Council of Greater St. Louis
Location: St. Louis, Mo.
Salary Range: $12,000-$16,076
Job Description: Under the general direction of the director of program operations, assist in the training of new clinic personnel for the participating agencies; provide short-term, on-site supervisory assistance to newly organized clinic programs; give technical assistance to family planning clinics as requested, in order to improve program effectiveness and efficiency; develop acceptable, efficient clinic and medical forms that may be used by the participating agencies; maintain a working knowledge of current family planning methods and procedures and advise on the practical clinic applications of this knowledge; assume an in-service orientation role with other nurse specialists and professional staff, as requested; replace clinic physicians of participating agencies on a short-term or emergency basis, as requested; assist the director of program operations in the negotiation of service contracts and agreements; represent the Council with segments of the medical community; participate in the Council's community education programs; perform related duties at the request of the Council's director of program operations.
Qualifications: Registered nurse with a current state license, holding a diploma or B.A. from an accredited nursing school. M.A. preferred. Must successfully complete either an authorized nurse-clinician program in family planning or a midwifery course which includes special training in family planning before functioning in this position. A minimum of three years of hospital, clinic or military experience in family planning, program development, counseling and/or public health preferred.
Contact: Executive Director, Family Planning Council of Greater St. Louis, 915 Olive Street, Suite 815, St. Louis, Mo. 63101

●

Position: Associate Director for Service Information
Agency: Los Angeles Regional Family Planning Council, Inc.
Location: Los Angeles, Calif.
Salary Range: $14,400-$17,500, negotiable depending upon experience
Job Description: Responsible for collection, processing, analysis and reporting of information on the delivery of services under LARFPC contracts with its delegate agencies. Provide guidance and direction to the delegate agencies in implementing the centralized patient reporting system and resolve problems of implementation as they arise. Direct technical consultants and support personnel involved with implementation of the system. Interface with National Center for Health Statistics regarding national reporting requirements. Prepare regular reports and analyses of patient service statistics for the Executive Director, Board of Directors and delegate agencies. Perform related duties and prepare special studies at the request of the Executive Director.
Qualifications: Extensive experience in statistical analysis; project management, including directing of service contractors; and information processing systems, as well as medical records management. Ability to supervise support personnel and direct efforts of consultants, as well as to organize and write reports are important.
Contact: Joyce R. Henderson, Executive Director, Los Angeles Regional Family Planning Council, Inc., 1636 West 8th Street, Suite 205, Los Angeles, Calif. 90017

●

Position: Director of Information, Education and Communications
Agency: Family Planning International Assistance, Planned Parenthood-World Population
Location: New York, N.Y.
Salary Range: $23,000-$28,000
Job Description: Manager of all information, education and communications project activities; design, plan and direct development and implementation of program assistance for local family planning programs in developing countries worldwide.
Qualifications: Extensive experience in management of information, education and communications activities; strong interpersonal and cross-cultural skills, available for international travel.
Contact: John Palmer Smith, Family Planning International Assistance, 810 Seventh Avenue, New York, N.Y. 10019

●

Position: Executive Director
Agency: Planned Parenthood of Metropolitan Washington
Location: Washington, D.C.
Salary: $16,000, or commensurate with experience
Job Description: Responsible for supervising program and staff. Submit budget and policy recommendations to the Board of Directors and implement its decisions. Represent the agency with other community agencies; responsible for public relations, and involved in fund-raising activities.
Qualifications: B.A.; graduate education desirable, but not a prerequisite. A minimum of five years of professional employment, preferably in administration, community organization, public health, social welfare, family planning or education.
Contact: Mrs. Joseph L. Rauh, Jr., 3625 Appleton Street, N.W., Washington, D.C. 20008

●

Position: Assistant Director
Agency: Mid-Atlantic Regional Office, Field Department, Planned Parenthood-World Population
Location: Philadelphia, Pa.
Salary: Open
Job Description: Provide support to the Regional Director in program and affiliate matters, in coordination with the activities of the Regional staff as a whole. As assigned by the Director, this may include consultation in specific affiliate program areas: service delivery systems, government-funded projects, short- and long-range planning, board development, as well as regional planning. Act for the Regional Director in delegated program areas.
Qualifications: Minimum of two-and one-half years' experience (preferably both rural and urban) with Planned Parenthood affiliates or other voluntary health agencies. Some experience with federal programs also valuable. Some planning, training, and/or M.A. or M.S. desirable, but not required.
Contact: Mrs. Helen P. Stanford, Mid-Atlantic Regional Office, 1505 Race Street, Suite 902-904, Philadelphia, Pa. 19102

U.S. GOVERNMENT PRINTING OFFICE: 1973 O—735-097(1)

DHEW PUBLICATION NO. (HSM) 73-16000