CONTRACEPTION I

IUD's: Approval of a renaissance

The idea of placing an object in the uterus to block conception is mentioned in the writings of Hippocrates and was investigated extensively by scientists during the nineteenth century. In 1929 the German scientist Ernst Grafenberg inserted silver rings into the uteri of 2,000 women, and reported a pregnancy rate of only 1.6 percent.

Despite this history, the use of intrauterine devices, or IUD's, was not generally accepted. Reports of IUD-related infection and other suspected adverse reactions kept gynecologists chary of the devices, and wholly suitable materials for making IUD's had not been developed. The idea lay dormant for nearly thirty years.

In 1959 there was a revival of interest in Grafenberg's work. Devices made of stainless steel and plastic were employed, and methods of insertion in the uterus were devised that did not involve dilation of the cervix and a concomitant risk of infection. Successes in this renaissance of the IUD stimulated further investigation. Though eclipsed somewhat by the advent of oral contraceptives, the IUD now has an estimated six to eight million users worldwide, about a million of them in the United States.

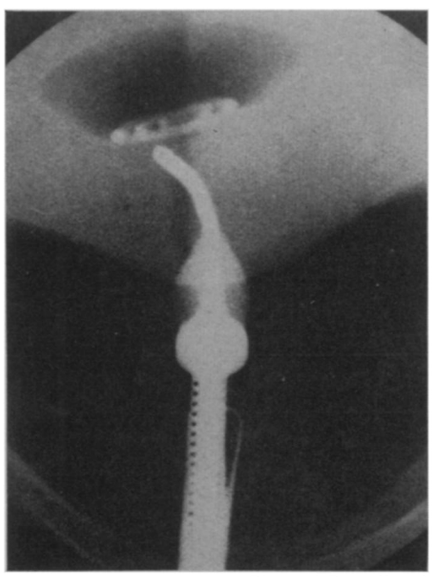
Because of the expanding use of IUD's, the U.S. Food and Drug Administration a year ago began a study of the devices. A report made public last week by the FDA's Advisory Committee on Obstetrics and Gynecology concludes that, while it doesn't know how they work, it finds IUD's to be safe and effective in blocking conception.

Under controlled conditions IUD's have proved to be slightly less effective than birth control pills. However, in the field the effectiveness of the two contraceptive methods is comparable, because many women fail to take the pills as directed. Population control authorities note that only temporary motivation is required to get people to use the IUD; once it's in it can be forgotten. Pills on the other hand require a daily decision in favor of family planning, on top of fairly extensive education in the method.

As yet scientists have no concrete evidence to explain the way IUD's work. There are two popular theories. One is that the device speeds the transport of the egg through the reproductive tract, preventing implantation. The other theory holds that an IUD prevents proper maturation of the lining of the uterus, again preventing implantation of a fertilized ovum.

So far there is very little theory governing the design of IUD's. The devices now are being used in some 30 different shapes, ranging from springs to bows to loops to coils to Maltese crosses. Basically, however, they are either closed designs (originating from a circle) or open designs (originating from a straight line.) The most popular device is the Lippes loop, an open device in the form of a double S. Far more open devices are used than closed, though there is a greater variety of closed devices on the market.

The FDA committee concludes that presently available closed devices are "not to be used except in specially indicated circumstances." The committee reports several instances of intestinal obstruction following perforation of the uterus by a closed IUD. Such accidents have not been reported with open devices.



Planned Parenthood

Inserter and spiral device in place.

Speaking generally of the safety of the IUD's, the committee verifies some of the adverse reactions reported previously by individual physicians. "The insertion of IUD's carries a definite, albeit small, risk of infection and uterine perforation," the report says. The incidence of perforation, the committee believes, can be reduced by more careful sounding of the depth of the uterine cavity before insertion, since most perforations apparently are the result of injury caused by the introducing device.

Infection is largely attributed to lack of proper sterile procedures during insertion. Many IUD's are sold nonsterile in bulk. They have to be sterilized before insertion. The introducer also is often sold nonsterile and must be autoclaved. The problem is that the plastic device must be folded into the tubelike introducer for insertion. This cannot be done before autoclaving since the plastic would lose its ability to spring back into shape. Therefore the physician must scrub up, don sterile gown, and follow careful sterile procedures to place device into introducer and introducer into uterus. Dr. Louis M. Hellman, chairman of the committee, says all this is a complex operation that often is not properly performed.

The committee in its report endorses proposed legislation which would require that manufacturers prove the safety of medical devices such as the IUD before placing them on the market. At present it is up to the FDA to prove any suspect medical device unsafe or ineffective before sale can be blocked. The FDA is interested, for instance, in requiring that IUD's be sold sterile with disposable introducers. It seeks similar control over all medical devices.

CONTRACEPTION II

Dangers of the pill

Nearly 13 million women throughout the world use the eight types of oral contraceptives popularly lumped as the pill; several thousand of them may be expected to suffer for it.

The extent of the hazard is unknown; many physicians still will not prescribe the regimen for most patients; many more will. Meanwhile millions of dollars continue to be spent on research concerning hazards of present use, as well as on the search for substitutes.

Dr. Louis M. Hellman, chairman of the Food and Drug Administration's Advisory Committee on Obstetrics and Gynecology, says there is no ideal contraceptive available, even though the element of risk with the presently used birth control pills is small.

The most serious hazard seems to be with blood clots. A thrombo-embolism, for example, can travel to the lungs, heart or brain, obstructing a major blood vessel. The numbers of affected women, however, are small. The death rate in a recent British study was three per 100,000 per year. This would indicate that in 20 years 60 pill users per 100,000 would risk death from this cause in comparison with about 20 nonusers.

Dr. Roy Hertz, one of the members of the Advisory Committee, formerly with the National Institutes of Health and now a professor of obstetrics and gynecology at George Washington University, takes the most sober view of