IUDs Reassessed—A Decade of Experience

Rings, loops, spirals, coils, bows, M’s, Dalkon Shields, Copper Ts, Cu-7s, intrauterine membranes, and fluid-filled devices—an almost infinite variety of intrauterine devices are now available in different parts of the world in a vast array of sizes, shapes, and materials. How many IUDs are now in use? Which is best for the individual woman? Which is best for national family planning programs? What are the main problems in clinical use? What are the most significant improvements in IUD design? In short, what is the present role and future potential of the intrauterine device in the management of fertility? Now, a little more than a decade after intrauterine devices were reconsidered as medically acceptable these questions remain.

Undoubtedly, intrauterine devices have become important elements in modern contraception. If they do not quite live up to their original promise as “the ideal contraceptive”, they are nevertheless highly effective and widely used.

15 Million IUDs

It is estimated that about 15 million IUDs are presently in place, about twice as many as in 1969 (197,210). Approximately one-half are used in developed and one-half in developing countries. In the USA, nearly nine million devices have been distributed and it is estimated that about three to four million women were using them in 1974 (104,209,210).

Intrauterine devices are the principal contraceptive method in at least 10 countries—including Korea and Taiwan, two of the most successful programs in Asia. IUDs were not found to be as satisfactory as originally expected in India or Pakistan where it was hoped that they would offer a simple, inexpensive “one-time” method. On the other hand, they are proving more valuable than expected in Latin American programs where medical follow-up is available and where women often start with other methods and shift to IUDs for continuing protection.

In all countries, the main difficulty with intrauterine devices is not the pregnancy rate of about 2 to 4 per hundred women at one year, or the expulsion rate of about 3 to 15, but rather the continuing rate of removal for medical reasons, especially excessive menstrual bleeding or pain. These rates range from 5 to 20 per hundred women at one year. Unlike expulsions, removals for bleeding or pain are not usually followed by successful reinsertion. In developing countries, excessive or intermittent menstrual bleeding is especially serious since many women are already malnourished and anemic.

Lippes Loop the Standard

Of all the models devised, the Lippes Loop designed by Dr. Jack Lippes of Buffalo, N.Y. in the early 1960s has best stood the test of international experience. It remains the standard against which other devices are usually judged. Loop D, the largest size, is most common. In two recent extensive international studies—one based on data from five different clinical research centers and the other based on ten years of experience in a single center—Lippes Loop D, inserted either postmenses or postabortion, offered the best or near-best performance (see Figs. 1 and 2). Smaller sizes may be needed for women with small uteri and especially women who have never been pregnant.
On the whole, the IUD and especially the Lippes Loop is most appropriate for older multiparous women who tend to have lower pregnancy and expulsion rates and to tolerate the problems of excessive bleeding or discomfort more readily. For younger women, women who have never been pregnant, or women using contraception to space rather than terminate births, oral contraceptives are usually the method of choice. The new IUDs with copper added, however, have been used successfully in nulliparous women. These devices, especially the Copper T and Cu-7, are not difficult to insert, produce less bleeding than inert devices, but may need to be replaced after several years of use if the copper is depleted (141).

Over the last decade the performance rates of IUDs have gradually improved. As physicians and health workers have gained more experience with the devices and their insertion, perforations and infection have declined. IUD insertion after abortion has also proved a safe and effective way to provide contraceptive protection at a time when motivation to prevent pregnancy is high.

Low Mortality and Morbidity
Mortality or serious morbidity related to the IUD has been low in developed countries. One device, however, the Dalkon Shield which may be associated with a higher incidence of septic abortion, has been placed under closer surveillance in the USA. On the whole, IUD-associated deaths in the USA are estimated at 1-10 per one million woman years of use and complications serious enough to require hospitalization occur at a rate of 0.3 to 1.0 per 100 woman years of use (77,209). These rates compare with maternal mortality in developed countries of about 20 per 100,000 births. In developing countries, there are no data on IUD-related mortality or serious morbidity, but maternal death rates are often as high as 400 per 100,000 births. Under these circumstances, IUDs are clearly much safer than pregnancy.

Improving Devices and Programs
The long-term protection against pregnancy which IUDs offer can undoubtedly be made even safer, more effective.

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**Fig. 1.** One-Year Net Event Rates Ranked by Termination Rate for 10 IUDs Used at Selected IFRP Clinical Research Centers, 1968-1972.

<table>
<thead>
<tr>
<th>Device</th>
<th>Country</th>
<th>Women in Study (woman-months of use) and year of initiation</th>
<th>Termination, Pregnancy, Expulsion, and Removal Rates per 100 Users</th>
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<tr>
<td>Loop D</td>
<td>New Guinea</td>
<td>222 (2132) 1968</td>
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<td>751 (8189) 1970</td>
<td>Expulsion rate: 3.7</td>
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<td>Egypt</td>
<td>100 (1125) 1973</td>
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<td>457 (4501) 1968</td>
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<td>M-213</td>
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<td>Dalkon Shield</td>
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<td>Egypt</td>
<td>100 (1069) 1972</td>
<td>Removal rate (for pain and bleeding) 9.2</td>
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</table>

SOURCE: Kessel (90).
and more acceptable by continuing research. Much IUD research has focused on new configurations and variations in size, thickness, and material. Bioactive substances such as copper and/or progesterone have been added either to enhance contraceptive action or to reduce unwanted side effects or both. Also under investigation, are flat and flexible devices with large surface areas and soft fluid-filled devices that adjust to the contours of the uterus.

Extensive clinical research with inert IUDs over the last decade, however, has shown that the apparent differences in performance between one device and another are often not as great as the differences between one clinical center and another. In other words, the skill of the person performing the insertion, the quality of counseling, reassurance, and follow-up and the cultural setting of the program may be more important than minor changes in the device. This means more effort is needed to simplify insertion techniques, to train paramedical workers, including rural village midwives, and to extend follow-up care throughout rural areas.

## HISTORY

There is considerable debate as to when and where intrauterine devices were first used. One well circulated but unconfirmed story describes the first intrauterine device as a small pebble placed in the uterus of the camel to prevent pregnancies during long caravan journeys. Hippocrates is credited with using a hollow lead tube or sound to insert medication or pessaries into human uteri but translations differ as to whether the process was intended for contraception or other purposes (44,194).

The immediate antecedents of the modern IUD were the cervico-uterine stem pessaries used in the 19th and early 20th centuries. These were small buttons or caps which covered the opening of the cervix and were attached to stems extending into the cervical canal. In some models the stem extended even further into the uterine cavity in the form of a bulb or flexible arms or wings (44). Made from a variety of materials such as ivory, wood, glass, silver, gold, ebony, pewter, and diamond-studded platinum, these pessaries were ostensibly used for many different purposes including support of the uterus, prevention of irregular or delayed menses, and a cure for dysmenorrhea and infertility (195). Before 1890 there is no published reference to the contraceptive effect of pessaries although they were very likely also used for that purpose (200).

In 1902 a wishbone-shaped pessary which extended into the uterus was patented by Dr. Carl Hollweg in Germany. Although the patent application made no mention of contra-
ception, Hollweg reported elsewhere that the pessary had been inserted in 700 women for the prevention of pregnancy (72).

One of these pessaries, known as the "Sterllette", was advertised for regulation of menstruation and was sold complete with instructions for self-insertion (44). Many of these early stem pessaries were apparently used not only as contraceptives but also in some cases as abortifacients. This use caused serious medical complications such as hemorrhage and pelvic infection sometimes resulting in death (184). In a period when antibiotics were not available, the hazards of infection were great. Cervico-uterine pessaries were therefore promptly condemned by the medical community. This early condemnation retarded medical acceptance of other intrauterine devices introduced later.

The first completely intrauterine device designed specifically for contraception was a ring made of silkworm gut. Richter, a German physician, described the device in a two-page article in the Deutsche Medizinische Wochenschrift in 1909 (see Fig. 3) (44,165).

Pust designed a cervical button attached by a stem to intrauterine silkworm threads in the 1920s (see Fig. 4). It combined Richter's silkworm ring and the older stem pessary. No pregnancies or serious complications occurred among the 453 women in whom he inserted the device. He distributed over 23,000 of these devices for insertion by other interested physicians (155), but many still protested their use, claiming that the devices would cause pelvic infection (184).

Graefenberg and Ota Rings

A significant event in IUD history occurred in the late 1920s when Ernst Graefenberg developed a silver ring to be placed entirely within the uterus (62). Highly effective in preventing pregnancy, the Graefenberg ring became popular first in Germany and then elsewhere. In 1934 Ota, working in Japan, introduced the ring that bears his name. Ota claimed that his gold or gold-plated silver ring, which had a small disc attached in the center of the ring by three spokes, yielded fewer failures (one pregnancy among 73 users) than Graefenberg's (five pregnancies among 51 users) (147). Both the Graefenberg and Ota rings are still being used today.

The enthusiasm which these IUDs produced in the early 1930s was followed by another wave of protest which branded them inefficient and dangerous. In 1936 the Japanese government prohibited their use (131) — a ban which was not lifted until July 1974 (8,128). Although Graefenberg claimed his ring had a pregnancy rate of only 1.6 percent, European physicians who had no practical experience with the devices but opposed them on theoretical grounds forced Graefenberg to abandon his device. When
At this conference Dr. Jack Lippes of Buffalo, New York, described his experience with the now well-known Lippes loop (109) (see Fig. A1). Like the Margulies Coil, it was usually inserted without cervical dilation through a narrow, easily threaded tube and extruded from the inserter into the uterus where it resumed its original shape. Lippes attached a marker thread or tail to his device, making it easy for the user to confirm its presence and for the physician to remove it. Manufactured entirely from an inert plastic, polyethylene, rather than the metals used in Ota and Graefenberg rings and equipped with a single filament thread, the Lippes loop appeared to offer both cost and safety advantages over the earlier metal rings.

Early Evaluation Efforts

Following the 1962 Conference, a Cooperative Statistical Program (CSP) for the evaluation of IUDs was established by the Population Council under the direction of Dr. Christopher Tietze. The data from about 30 public and private IUD programs in the USA and several other countries were pooled and analyzed by life table methods, an actuarial technique adapted for use in evaluating contraception by Tietze and Robert G. Potter (206) (see page B-31). A second international conference was held in 1964. The Ninth Progress Report of the CSP, published in 1970, compared the Lippes Loop (A, B, C, and D models), Margulies Spiral, small and large Birnberg Bows, steel ring, double coil, and several other IUDs after approximately 27,000 insertions and almost 470,000 woman months of use. In a conclusion that remains valid after a decade of IUD research Tietze observed:

No single type of IUD has consistently lower rates than the others for all types of events (pregnancies, expulsions, and removals), nor does any one IUD have consistently higher rates than the others (206).

The Ninth Progress Report indicated that smaller devices were associated with higher pregnancy and expulsion rates than were larger models, but with lower rates of removal for bleeding, pain and other medical reasons. Some 60 percent of the women were still using IUDs two years after insertion. On the whole, the evaluation showed that the IUD was a safe and effective means of contraception. It was considered appropriate for use in national family planning programs that were just being initiated (206).

Since then, a number of other organizations have also developed and refined both clinical and program evaluation of IUDs, including experimental models. In December 1974 a third international conference on IUDs, attended by participants from 38 countries, was convened in Cairo by the Population Council with cooperation and support from the World Health Organization, the Pathfinder Fund, the International Development Research Centre (Canada), the Ford Foundation, the International Planned Parenthood Federation (IPPF), and the International Fertility Research Program (IFRP).

At the Cairo conference, attention focused primarily on second-generation devices. About one-third of the papers dealt with devices to which copper had been added. These perform well and are particularly appropriate for nulliparas but it is not yet clear how long the copper remains effective or which IUD configuration provides the best vehicle or carrier for copper or other active substances. Approximately one in six of the papers dealt with the Daikoh Shield, which has low expulsion rates but may be associated with a higher risk of life-threatening septic abortions (see p. B-36). Although many refinements are under investigation, leading to the hope that it may one day be possible to select the device most suited to each individual woman, at present the extensive international studies conducted by the Population Council and the IFRP indicate that the Lippes Loop, size D, still has not been surpassed in overall performance by newer models (15,90,185) (see Figs. 1 and 2).

MODE OF ACTION

Although IUDs are now used by millions of women throughout the world, there is still no single accepted explanation of exactly how they work in human beings.

In different animal species IUDs have been proven to affect different phases of the reproductive process. In the sheep, for example, IUDs apparently prevent fertilization by stimulating phagocytosis and/or cytolysis which destroys sperm in the uterus before fertilization. Also in the sheep, IUDs prevent surviving sperm from moving through the fallopian tubes by reversing the direction of uterine contractions (68). In the rabbit, IUDs may prevent the implantation of fertilized eggs by stimulating a higher concentration of prostaglandins in the uterus (175). In the cow and the pig, IUDs have been shown to prevent embryo survival even after fertilization and implantation have occurred (57, 69).

Since mechanisms of action vary from species to species, it is difficult to extrapolate the results of animal experimentation to humans. During the last decade intensive research has ruled out some hypotheses while reinforcing others. In humans, IUDs apparently do not suppress ovulation, interfere with the corpus luteum, or completely inhibit sperm transport or fertilization. Researchers have shown this by recovering viable sperm, and both fertilized and unfertilized ova from the fallopian tubes of women with IUDs (22,60,125,136,137). Generally, IUDs seem to interfere in some manner with the implantation of the fertilized egg in the endometrium—possibly through a nonspecific inflammatory cell reaction occurring within the uterine cavity (42,126,127,174). This is the most widely accepted theory at present. At the same time, in postintercourse uterine fluid removed from women with IUDs, “colossal numbers of macrophages” have been found phagocytizing or devouring intact spermatozoa—a further defensive cell reaction activated by the foreign body in the uterus (173).

Reinforcing this inflammatory reaction hypothesis, Kar has found that the characteristics and content of uterine fluid are changed in women with IUDs. This renders the uterus inhospitable to survival of the blastocyst even before implantation (80,83,84). Wynn and Tamada showed that IUDs cause an early, asynchronous development of the endometrium thereby preventing implantation (79,201,226). Others have observed abnormal, pre-laborlike activity in the presence of IUDs at the time during the menstrual cycle when a fertilized ovum would normally implant (17,124). Several investigators have suggested that this uterine activity may be caused by increased intrauterine prostaglandin levels (29,30,79).

NATIONAL FAMILY PLANNING PROGRAMS

During the mid-1960s, the IUD appeared to have many advantages when first introduced into large scale national
family planning programs in developing countries. It offered contraceptive protection that was:

- highly effective
- long lasting
- inexpensive to manufacture
- independent of coitus
- completely reversible upon removal of the device.

Moreover, the use of IUDs seemed in most instances to require only a single decision on the part of the woman and a single procedure by trained health personnel.

While some of these expectations were fulfilled, it soon became apparent that IUDs alone were not a panacea for the world's population growth problems. Although different conditions prevailed in different regions and in individual countries, the data from Table 1 on IUD acceptors in 22 developing countries with adequate records show that the total number of IUD insertions increased from 1968 through 1973, whereas the proportion of women using IUDs as compared with other methods decreased slightly. During this six-year period, the number of IUD acceptors increased by 40 percent, from 890 thousand to almost 1.3 million. The proportion, however, decreased from 23 to about 17 percent of total acceptors as oral contraceptives, sterilization, and pregnancy termination became more widely available.

India and Pakistan

A review of program experience in several specific countries reveals the many different factors which influenced the distribution and popularity of intrauterine contraception in family planning programs. For example, India and Pakistan, the first of the developing nations to establish national family planning programs, introduced the IUD in the mid-1960s. In India, the highest number of IUD insertions (almost one million) occurred in 1966 and in Pakistan the highest number (865,000) occurred in 1968 (133). Since their introduction in the two countries approximately eight million devices have been inserted; however, it is now estimated that no more than 25-30 percent of these are still in situ (66,134,223).

Besides the increasing availability of other methods, the decrease in use of IUDs in India and Pakistan has been explained in various ways, for example:

- Lack of proper sterile technique for insertion leading to subsequent complications and infection (38).
- Higher than anticipated rates of pregnancy and expulsion made the device less than completely effective.
- Side effects of bleeding and pain were unacceptable to the individual wearer.
- Inadequate numbers of trained health personnel for insertion and follow-up care among large rural populations (197).

Bleeding and/or pain accounted for 50 percent of IUD removals in Asian studies (45,78,172,217,223). As Soonawala and others have observed, Indian women, who are generally anemic and whose cultural beliefs prohibit participation in normal family rituals or even preparation of food while they are bleeding, can ill afford a contraceptive method which increases menstrual flow or produces intermenstrual spotting (14).

Because rural women in these countries are not mobile due to cultural restraints or inadequate transportation, IUD insertion services were for the most part provided by temporary or mobile clinics. When these were withdrawn, there were no medical facilities or personnel to deal with the problems which arose and to reassure village women.

Another major factor was the shortage of trained female physicians and paramedical personnel. Generally women in this region will not accept male physicians for any gynecological procedure. In Pakistan paraprofessionals called Lady Health Visitors and Lady Family Planning Visitors were trained to insert IUDs, but there were too few to meet the needs for both insertion and follow-up counseling (176). Moreover, the program threatened the livelihood of local village midwives who were often hostile and encouraged women to have their IUDs removed.

Hong Kong and Singapore

Hong Kong and Singapore, although more developed than India and Pakistan and largely urban, also had unfortunate experiences with the IUD despite the easy availability of medical facilities and personnel. In Singapore, a family planning program based primarily on the Lippes Loops was initiated in the mid-1960s. When an unusually high uterine perforation rate—7.0 to 8.7 per 1,000 insertions as compared with 0.7 per 1,000 for the Lippes Loop in the CSP (206)—aroused rumors and hostility against the method, program emphasis rapidly shifted to oral contraceptives (82,162).

The reason for the high perforation rate in Singapore is not fully established. Faulty insertion technique was probably an important factor. Higher perforation rates occurred when insertions were done by part-time general practitioners and house officers (35,161). In some cases, IUDs were inserted immediately postpartum without either sounding or stabilizing the uterus. Also, some IUDs were loaded into inserters hours before insertion which distorted the shape, thus increasing the risk of perforation (149). The steady but less abrupt decline of IUD use in Hong Kong has been attributed to some of these same problems, as well as to a lack of popularity among young, low parity women (49).

Korea and Taiwan

In two small countries, Korea and Taiwan, on the other hand, the use of IUDs in family planning programs has had significant impact on fertility. Private physicians are trained and subsidized by the government to provide family planning services in both countries. Potential family planning clients are recruited and referred to physicians by a well-trained cadre of fieldworkers who receive higher incentive payments for motivating women to accept IUDs than for other methods (65,168). Oral contraceptives were not provided in either country until the late 1960s and then primarily for IUD dropouts.

In Taiwan there were almost twice as many new Lippes Loop acceptors in 1973 as oral contraceptive acceptors; three times more couples chose IUDs than condoms (10) (see also Table 1). For IUD acceptance in Taiwan, 1968-1973). In a 1968 sample of almost 5,000 Taiwanese IUD acceptors, 67 percent were still using the device one year after insertion and 36 percent after four years (27). Reinsertions and increased experience with IUDs have improved these rates. Among a sample of 5,832 Taichung women who initially accepted an IUD in the early 1960s, a 1974 study found that 52 percent of the women at risk of pregnancy were still using the device five years after the first insertion and 48 percent after eight years (31,154).
Table 1—Acceptors* of IUDs in 22 Countries with National Family Planning Programs, 1968-1973

<table>
<thead>
<tr>
<th>Country &amp; Year</th>
<th>Total Acceptors (thousands)</th>
<th>Acceptors of IUDs (thousands)</th>
<th>Acceptors of IUDs as Percent of Total Acceptors</th>
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*Primarily new or first-time acceptors.
Includes Postpartum Program acceptors.
Includes private association acceptors.
Nonsovereign territory.
Data for fiscal year beginning April 1 of indicated year.
Includes acceptors in private clinics now part of national program.

SOURCE: From Norton (134, 135).
The Korean IUD program has produced similar results. A comprehensive evaluation of the Taiwan and Korea programs, however, revealed a basic weakness: when the group of older, higher parity women selecting IUDs was depleted, new acceptors were difficult to recruit. Thus, further declines in fertility were hard to achieve without introducing additional methods with a greater appeal to younger women (182).

The effect of these IUD-oriented programs in reducing age-specific fertility rates among older women in Taiwan and Korea has been well documented (52, 163). To attract young women, however, who are both less likely to select IUDs and more likely to discontinue use, oral contraceptives have gradually been introduced in both countries (65, 86). Abortion also remains an important factor in the declining birth rates of Taiwan and Korea since women who discontinue IUDs or oral contraceptives often resort to abortion if they become pregnant (32, 65, 86).

From Asia, national family planning programs have spread slowly to other regions. Latin American governments, often influenced by the Roman Catholic Church, have until recently not supported or actively promoted family planning work, but have permitted private family planning associations to provide limited clinical services, mainly in urban areas. Oral contraceptives, which are usually available without prescription for those who can afford to pay, have been the most popular method in Latin America, but private and national programs are giving increasing emphasis to IUDs (214).

In Chile, for example, because family planning was authorized by the government as a response to the widespread maternal morbidity and mortality from illegal abortions, the program began as one of postabortion and postpartum IUD insertion. Oral contraceptives have subsequently been added to the national program; however, they are reserved primarily for use by women with contraindications or intolerance to IUDs. In 1968, approximately 60,000 women (60 percent of all family planning acceptors and 3 percent of the total female population aged 15-44) received IUDs through specialized units within the National Health Service. In that same year, however, the Chilean government decreed that the program could serve no more than 15 percent of all Chilean women of fertile age. The specialized family planning units were further restricted in mid-1970 when the government ordered that they be combined with the understaffed and overworked maternal and child health services. As a result the critical and immediate health needs of mothers and children took precedence over family planning. New acceptors of contraception in Chile declined by almost 50 percent since 1968 and new acceptors of IUDs by about the same amount from 59,800 in 1968 to 31,200 in 1973 (61, 215, 216) (see Table 1). Since mid-1973, however, Zipper notes a preference among patients and physicians for IUDs which between June 1973 and June 1974 amounted to about 73 percent of the contraceptives provided by the National Health Service (228).

Because IUD-oriented family planning programs usually depend on extensive, specially trained government-sponsored units capable of IUD insertion and available for some follow-up, these programs may be especially vulnerable to political changes at high levels of government and to budget cuts in periods of national financial crisis.

Improving Delivery Systems

To improve IUD performance and to facilitate use of IUDs in national programs, several approaches are being tried. On the one hand, bioengineering research is still underway to develop IUD configurations with minimal pregnancy, expulsion, and medical removal rates (see page B-38). On the other hand, increasing attention is being focused on the need for better training of paramedical personnel so that they can assume major responsibility for IUD insertion and follow-up.

Studies from both developed and developing countries show that nurses, paramedical personnel, and even rural village midwives, can perform routine IUD insertions as well as physicians (166, 167). In counselling women, reassuring them about side effects, and providing sympathetic follow-up care, nurses or indigenous health workers can do a better job than busy physicians. In controlled studies continuation rates are generally higher when IUD insertion and follow-up care are provided by nonphysicians (18, 43, 148, 146, 166, 168, 187, 212).

Within the last few years, paramedical personnel have been specifically trained and authorized to insert IUDs in a number of developing countries, including Barbados, Haiti, India, Indonesia, Jamaica, Korea, Nigeria, Pakistan, the Philippines, Mexico, Senegal, and Uganda (46). In the USA, additional training in IUD insertion for midwives from developing countries was initiated in 1966 at the Downstate Medical Center in New York (96). Also, Harbor General Hospital in California now provides training in IUD insertion for experienced midwives and others who have had little or no previous medical training (144, 146).

Clearly the present trend is toward greater use of paramedical personnel and health care teams, but the reluctance of some doctors to delegate responsibility for IUD insertion and the lack of adequate training programs for nonphysicians have delayed action in some areas. A review of family planning training programs for midwives and other nonphysicians will appear in a forthcoming Population Report.

INSERTION PROCEDURES

Meanwhile, since paramedical personnel are taking on a greater role in IUD and other family planning programs, new efforts are being directed to devise simple techniques and equipment for IUD insertion to improve overall IUD performance. Meshell emphasized at the recent Cairo conference:

Since insertion technique and correct intrauterine positioning of an IUD are probably more important for effectiveness than design of the device per se, more attention should be directed toward development of optimal IUD inserters than changes in IUD design... the IUD which will yield the best performance under field conditions will be the one that is easiest to insert into the correct intrauterine position by personnel who have not had extensive experience with this contraceptive technique (118).

Besides the skill and experience of those inserting the device, successful IUD insertion depends on:

- the size and type of device and inserter
- the timing of the insertion
- the insertion technique employed

Because IUD-oriented family planning programs usually depend on extensive, specially trained government-sponsored units capable of IUD insertion and available for some follow-up, these programs may be especially vulnerable to political changes at high levels of government and to budget cuts in periods of national financial crisis.
Size and Type of Device

Most IUDs are made in graduated sizes corresponding with variations in uterine size. The Lippes Loop, for instance, ranges from a length of 22.5 mm for size A to 30 mm for size D. In general, the smaller the device, the easier the insertion. At the same time, "the larger the device, the lower the expulsion rate; therefore the largest device that the uterus can accommodate should be inserted" (94). Both for ease of insertion and for other performance characteristics, smaller IUD sizes are usually recommended for nulliparous women.

IUDs in use today may be characterized first as either inert or bioactive, and then by configuration, rigidity, surface area, and nature of the material from which they are made. Configuration and rigidity are perhaps the most important qualities for IUD design from the point of view of insertion. IUD configurations are classified as either open and linear or closed and basically ring-shaped. Linear devices, such as Lippes Loops, Saf-T-Coils, and the copper IUDs (see Figs. A1, A3, A6, and A7) can be stretched or folded into a narrow tube for relatively easy insertion. Open or linear devices offer less risk of organ injury or bowel obstruction if the device perforates the uterus and migrates within the abdominal cavity (93,94).

Closed devices, on the other hand, such as the Zipper or Ragab Rings and several of the Chinese and Japanese IUDs (see Figs. A4, A5, A11, and A20), are usually inserted with somewhat more difficulty, utilizing an instrument similar to a uterine sound which has a hooked tip for carrying the ring into the uterus. Several modifications of the closed device have decreased the risk of bowel obstruction by incorporating a membrane which covers the open area of the ring (see Figs. A2 and A18), but this in turn has made the device more rigid and thus somewhat more difficult to insert (93,94).

Size and Type of Inserter

The size and type of inserter is also important. In general, because most IUDs are passed through the cervix within a tube-like inserter and released inside the uterus, the narrower the diameter of the inserter, the easier the insertion process. Most devices introduced in recent years have had their own specially designed inserters which, including the loaded device, vary in width from about 0.3 to 2.5 cm (see Fig. 5). The Cu-7 inserter with a width of 0.3 cm and the Saf-T-Coil, which is only slightly larger, are among the easiest to use. On the other hand, the standard Dalkon Shield, which measures 2.5 cm at its widest point, is not inserted through a tube. Although the device collapses or folds somewhat during passage through the cervical canal, it is relatively difficult to insert properly.

For the new Progestasert device, the Alza Corporation has tested various inserters, determining that even a slight reduction in the diameter of the inserter reduced the incidence of bleeding and pain at the time of insertion by 50 percent (23). With the newest Alza inserter, reported expulsion rates of the Progestasert were reduced from 17 to 5 per 100 insertions in nulliparous women (6). Inserter design is especially important in devices for nulliparas since their cervical canals are narrower and less elastic than those of multiparas.

One innovation now incorporated on most inserters is a flange or cuff to mark uterine depth and to minimize the danger of perforations caused by forcing the IUD too high into the uterus. Since the length of the cervical canal varies in different women, however, a technique for marking the distance between the internal, rather than the external, os of the cervix and the fundus of the uterus might also contribute to more successful IUD fitting (67,90).

Timing of Insertion

Timing of the IUD insertion influences its performance, especially the rates of pregnancy and expulsion. IUDs inserted immediately after delivery, for example, tend to yield lower pregnancy rates because of immediate postpartum infertility but higher expulsion rates because of uterine involution.

From both the physiological and psychological standpoints, the ideal time for IUD insertion seems to be immediately after abortion. Insertion is easier through a dilated cervix, and complications and expulsions are reduced (13). Moreover, after an abortion, women are strongly motivated to prevent another pregnancy and as a result are more willing to tolerate minor discomfort or bleeding irregularity. Recent studies in Sweden and Poland confirm that IUD insertion immediately after abortion can play an important role in family planning (73,139).

For women who have not recently delivered or aborted, the best time for IUD insertion is during the last few days of menstruation. At this time the cervix is somewhat softer than usual and slightly open. Bleeding which may be caused by insertion is less noticeable and the chance of inserting an IUD in an already pregnant uterus is reduced. Rigid adherence to this recommendation, however, may discourage a prospective IUD candidate or force her to go without effective contraception through the fertile part of the cycle (189).

IUDs are also frequently inserted postpartum. This can be done immediately, while the woman is still in the delivery room, or at some later time before she leaves the hospital. In the International Postpartum Family Planning Program sponsored by the Population Council, more than 16,500 immediate postpartum insertions were performed in 13 participating hospitals. Expulsion rates decreased steadily from a high of 26.6 percent for devices inserted within 24 hours of delivery to 10.4 percent for those inserted from 7 to 10 days postpartum (227).

If IUD insertion is delayed more than a week after delivery, it may be wise to postpone it "for at least eight weeks", according to an IUD working group for the International
Planned Parenthood Federation, European Region (74). This recommendation was based on an exceptionally high perforation rate noted in Singapore for IUDs inserted between four and eight weeks postpartum. On the other hand, rigid adherence to this advice can also present practical problems in developing countries since postpartum hospital visits are not routine practice and there is always some danger of an intervening pregnancy.

**Insertion Technique and Equipment**

Descriptions of optimal IUD insertion equipment and technique have been prepared by the Population Council, the Pathfinder Fund, the IPPF, and various training centers. Most of these differ only slightly. The equipment provided to developing countries by the US Agency for International Development is shown in Figure 6. The instructions given below represent a composite of basic procedures plus recent refinements (94, 170, 189, 190).

- Sterilize device and instruments. Unless provided in a sterile package, the device and inserter should be soaked for 24 hours in 1:750 aqueous benzalkonium chloride solution or for 10 to 15 minutes in 1:2500 iodine solution (3, 210).
- Perform a careful bimanual pelvic examination to establish position, size and regularity of the uterus.
- Visualize the cervix with a speculum.
- Grasp the cervix with a tenaculum or vulsella forceps and swab the cervix and vaginal walls with antiseptic solution such as betadine.
- Straighten the cervical canal and uterine cavity by applying gentle traction on the forceps.
- Use a uterine sound to determine depth and direction of the uterus.
- Load the device into or onto the applicator and gently insert into the uterus.
- Release the IUD in the transverse plane of the uterine cavity in a high fundal position (see the variations in release procedures described later).
- Remove the inserter.
- Check and trim the marker tails (if present) to within two to three cm of the external os.

**Placement in the Uterus**

The mechanism by which the IUD is released from the inserter varies according to the model used. Some IUDs, such as the Dalkon Shield and some ring-shaped models, are carried into the uterus on an inserter with a hooked end (see Fig. 5 and A2). The inserter is then revolved in order to disengage the device—a procedure not always readily accomplished. Another device, the Antigon (see Fig. A18), is inserted by extruding the folded device through the cervical canal with the inserting apparatus remaining at the external cervical os (94). For most IUD models, however, the inserter consists of a plunger within a thin tube (see Fig. 5). The IUD is either pulled or folded manually and pushed into the tube immediately prior to insertion.

There are two basic methods of insertion, a "push-out" and a "withdrawal" technique. In the "push-out" technique, used for the Lippes Loop and Saf-T-Coil, the tube bearing the IUD is inserted just beyond the internal os and the plunger is moved forward until the IUD is pushed out of the inserter. Then the plunger and tube are withdrawn together. In the "withdrawal" technique, used for the Cu-7, Copper T, and Soonawala's Y (193), the tube bearing the IUD is inserted right up to the fundus of the uterus and then the outer tube is withdrawn while the plunger maintains the IUD in the proper position. The plunger is then withdrawn.

A newer device, the Spring Coil (see Fig. A13), employs a unique insertion technique. Following its insertion through a tube by a combined "push-out" and "withdrawal" method (205), this device is further adjusted to its proper uterine placement by manipulating an auxiliary set of cervical threads attached towards the middle of the device. This simulates the curved center part of the device over the internal os thus reducing the chances for expulsion (157). This manipulation is described by those who have used the device as being perhaps "too complicated for general use" (89, 99).

**Pain during Insertion**

As a rule, general anesthesia or local, paracervical block, or even analgesia are not required for pain during or after IUD insertion, although they may be used. With the Cu-7, reported to be the easiest of all IUDs to insert, about 83 percent of nulliparous and 94 percent of multiparous acceptors experienced no pain at all (6). Caraway reported that in preliminary tests with 273 women using the nulliparous model of the Saf-T-Coil, insertion was "easy and virtually painless." There was no need for anesthesia, and no syncope was noted after insertion (25). With the Lippes Loop and Margules Coil, Webster reported that "lower abdominal pain and backache similar to the patient's normal menstruation were experienced by the majority." Simple analgesia was usually sufficient to relieve this discomfort (218).

A few women do experience severe pain and syncope, however. Conrad found that six women in a series of 7,140 IUD acceptors in Atlanta, Georgia, had acute neurovascular sequelae including convulsions and syncope (sometimes termed cervical shock) following IUD insertion or removal (40). Syncope occurs most often upon insertion of the rigid devices, with a frequency of up to 10 percent among nulliparous women. This reaction can be treated by placing the woman in a horizontal position and administering aromatic spirits of ammonia (189).

**Perforation**

The most frequent complication of IUD insertion is perforation of the uterus. A range from 0.01-0.12 perforations per 1,000 insertions in the CSP (206) to a high of 7.0-8.7 per 1,000 in a Singapore study (82, 162) has been reported. Actually, the true incidence of perforation may be higher because some perforations are asymptomatic and never identified. Although IUDs may migrate or be dislodged at any time, it is generally agreed that perforations most commonly occur or at least begin at the time of insertion.

Perforations probably occur more often with the "push-out" rather than the "withdrawal" technique of insertion (74). Persons who have less experience in IUD insertion or who neglect to use a forceps for straightening and stabilizing the uterus and a sound for determining uterine depth and direction before insertion are also more likely to cause perforations (119, 161, 170, 179).

It is not always easy to determine whether a perforation has occurred. Pain is sometimes but not always a symptom of perforation. If the tail of the IUD is not visible and the
woman has not noticed that the device was expelled vaginally, perforation should be suspected. If, after probing, the device is not found within the uterus, Mishell recommends lateral X-rays with contrast medium in the uterus (119). Other investigators advocate lateral and postanterior X-rays of the pelvis after a second IUD of a different configuration has been inserted as a uterine marker. If two IUDs appear in different planes in these X-rays, perforation of the uterus by the first IUD may be assumed. A hysterosalpingogram (X-ray with contrast medium in the uterus) is recommended only if further questions remain concerning the X-rays (4, 179).

There is little argument that closed devices (e.g., ring, bow, and other nonlinear shapes) should be removed promptly when perforation is discovered because of the danger of bowel strangulation (170). Copper IUDs should also be removed because inflammation and adhesions may form around these active devices in the peritoneal cavity (95).

There is some disagreement, however, as to whether open or linear devices should be removed after perforation. Both Rudel and Mishell see little reason for removal (119, 170), but other investigators recommend that all devices which have perforated be removed (28, 34, 48). Recent reports suggest that removals be attempted where feasible by laparoscopy or culdoscopy and otherwise by laparotomy or culpotomy (34, 97, 119).

**MEASURING IUD PERFORMANCE**

IUD performance is usually assessed by the Tietze-Potter life table method. Based on actuarial techniques of calculating life expectancy, this approach measures the probability of a defined risk or event such as pregnancy, expulsion, or removal occurring in each successive month following IUD insertion. Cumulative event rates per 100 users can be calculated for given time periods of IUD use, such as six or twelve months, and these rates for one clinic or IUD model can then be compared with others regardless of calendar time of insertion. The inverse of the combined net event rates* is known as the continuation rate; it provides a rough measure of how long an IUD can be expected to remain in situ. In other words, if the net pregnancy rate after 12 months is 3, the net expulsion rate 8, and the net removal rate is 18, the continuation rate after 12 months would be 71.

*Net event rates measure incidence of each type of event taking into consideration intervention of all other types of events. These rates may be added to give the total event rate. Gross rates, on the other hand, exclude other intervening events and therefore, are usually slightly higher than net rates. These rates cannot be added to obtain total event rates.
Table 2—Comparison of One-Year Net Pregnancy, Expulsion, Removal, and Continuation Rates for Selected IUDs in Major Studies, 1968-1974.

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<th>Type of Device</th>
<th>Country</th>
<th>Author &amp; Date</th>
<th>Ref. No.</th>
<th>Number of Insertions</th>
<th>Woman-Months of Use</th>
<th>Parity Status</th>
<th>Net Event Rates per 100 Women</th>
<th>Continuation Rate*</th>
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<tr>
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<td>31,032</td>
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<td>Progestasert USA</td>
<td>Place 1974</td>
<td>152</td>
<td>1,145</td>
<td>8,275</td>
<td>N</td>
<td>1.4</td>
<td>8.7</td>
<td></td>
</tr>
<tr>
<td>OTHER DEVICES USA</td>
<td>Fuchs 1972</td>
<td>56</td>
<td>1,480</td>
<td>8,093</td>
<td>N &amp; P</td>
<td>1.8</td>
<td>16.9</td>
<td></td>
</tr>
<tr>
<td>OTHER DEVICES Egypt</td>
<td>Ragab 1969</td>
<td>158</td>
<td>3,650</td>
<td>39,297</td>
<td>N/A</td>
<td>1.1</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>OTHER DEVICES USA</td>
<td>Burdick 1973</td>
<td>24</td>
<td>466</td>
<td>N/A</td>
<td>N/A</td>
<td>3.7</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>OTHER DEVICES Yugoslavia</td>
<td>Rendic 1974</td>
<td>160</td>
<td>309</td>
<td>3,117</td>
<td>P</td>
<td>0.0</td>
<td>9.2</td>
<td></td>
</tr>
<tr>
<td>OTHER DEVICES Brazil &amp; USA</td>
<td>Syntex 1974</td>
<td>41</td>
<td>3,527</td>
<td>N/A</td>
<td>N &amp; P</td>
<td>2.9</td>
<td>3.9</td>
<td></td>
</tr>
</tbody>
</table>

N/A—Not available
N—Nulliparous
P—Parous
†—All postabortion
*Continuation rates are given as reported and do not always equal the total of net events presented here subtracted from 100 because of reinsertions, loss to follow-up, and exclusion of nonmedical removals in some studies.
Life table analysis was first applied in the mid-1960s to determine which type or configuration of device was most effective. Pertinent events which are ordinarily included in the life table evaluation of IUDs are (1) pregnancy, whether occurring with the IUD in situ or after an unnoticed expulsion; (2) involuntary expulsion; and (3) removal for medical reasons, primarily excess or irregular bleeding and pain. Removal for personal reasons, such as the desire to have another child or the husband's disapproval, removal as a choice of the investigator, and loss or release from follow-up can be, but are not usually, considered in life table evaluations of IUD performance (see Table 2).

The principal factors that influence these pertinent events can be categorized as device-related, center- or clinic-related, culture-related, and user-related. But as more research is performed to evaluate different devices, the relationships and interrelationships among these factors appear to increase in complexity.

Early research focused on device-related factors to identify the best IUD for general use. It soon became evident that improvements in one parameter produced difficulties in another. For example, as Fig. 7 shows, the greater the surface area of the device, the lower the pregnancy rate, but the higher the rate of removal for bleeding and pain (90). Rigid devices, like the Dalkon Shield, have lower expulsion rates but are harder to insert and may cause serious problems if pregnancy occurs. Copper-bearing devices produce less bleeding and fewer pregnancies early in use, but these benefits may diminish over time.

International multiclinic studies soon revealed that some clinics, health centers, or individual physicians invariably performed better than others regardless of the device tested (21). Small studies by the developers of a particular device or by highly experienced physicians usually involve the kind of meticulous care that produces low termination rates. Investigators are now suggesting that valid comparisons between devices should be made only on data from the same insertion center (118). For example, the 10-year comparison by Andolsek from the Family Planning Institute at Ljubljana, Yugoslavia, ranks IUDs by specific performance characteristics (see Fig. 2). In those studies the Copper T and Lippes Loop D performed best (15).

Larger studies and particularly the use of a device in a national family planning program tend to produce higher termination rates (or lower continuation rates) than smaller studies (compare Tables 2 and 3). Even in the carefully monitored clinical research of the International Fertility Research Program (IFRP), larger study groups seem to produce higher termination rates than smaller groups (see Figs. 1 and 2). In the Ljubljana clinic, for example, the top ranked Copper T was used in only 93 women (15). In the multiclinic IFRP studies, most of the IUDs tested in small groups of women, such as the Spring Coil, performed better than most of the IUDs tested in larger groups (90).

Cultural factors, including reactions to profuse or intermittent bleeding and unwillingness to allow examination or consultation with a male physician, also show up in multiclinic studies. An exceptionally high rate of removal for bleeding, for example, occurred among Orthodox Jewish women in Ashkelon, Israel, as compared with rates for non-Orthodox women in the same town (20).

User-related factors include the obvious characteristics of age and parity. In general, the higher the age, the lower the pregnancy, expulsion, and removal rates. Low parity and especially nulliparity is associated with high expulsion rates and high removal rates (206). The copper devices and the Dalkon Shield have performed somewhat better in nulliparous women than did devices introduced earlier. The motivation of the user, whether to terminate or merely to space childbearing, is important in affecting the removal rate but motivation is clearly interrelated with age and parity (168,171). Other factors relevant to the individual woman, such as menstrual history, uterine size, nutritional status, frequency of intercourse, use of adjunctive contraceptives (such as foam), also appear to have some effect but their impact has not been quantified or analyzed with respect to different devices. Also, as previously noted, the timing of IUD insertion in relation to an individual's reproductive pattern—postmenstrual, postabortion, or postpartum—influences performance (see p. B-29).

Reviewing the overall status of IUD research and experimental devices, the Workshop on IUDs organized by the Scientific Committee of the VIII World Congress on Fertility and Sterility concluded:

- None of the experimental inert devices have yet been demonstrated to have significant advantages as compared to devices presently available.
- From the results of studies of copper-containing devices, it appears that the T-Cu-200 and the 7-Cu-200 are as good, if not better, than presently used inert devices.
- There is no conclusive evidence that any of the drug-releasing IUDs have any significant advantage over available IUDs (60).

### Table 3—Recent IUD Continuation Rates at 12 and 24 Months in National Family Planning Programs of Nine Developing Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hong Kong</td>
<td>66</td>
<td>49</td>
</tr>
<tr>
<td>Korea, Republic of</td>
<td>57</td>
<td>38</td>
</tr>
<tr>
<td>Malaysia, West</td>
<td>68</td>
<td>52</td>
</tr>
<tr>
<td>Pakistan, East</td>
<td>74</td>
<td>66</td>
</tr>
<tr>
<td>Pakistan, West</td>
<td>56</td>
<td>N/A</td>
</tr>
<tr>
<td>Philippines</td>
<td>77</td>
<td>49</td>
</tr>
<tr>
<td>Singapore</td>
<td>69</td>
<td>N/A</td>
</tr>
<tr>
<td>Taiwan</td>
<td>67</td>
<td>53</td>
</tr>
<tr>
<td>Turkey</td>
<td>62</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Non sovereign territory

bNational follow-up survey

Prior to independence of Bangladesh

N/A — Not available

SOURCE: Ross (168).

There is no question that IUDs are more effective in preventing pregnancy than any other nonsurgical method except oral contraceptives. Net pregnancy rates for the devices most commonly used range from 0.0 to 5.6 per 100 women for the first year after insertion (see Table 2) compared with rates of 1 to 3 for orals, 3 to 36 for condoms and over 5 for other methods.
As previously noted, large devices are more effective in preventing pregnancy than small ones, and older women, being less fertile, are less likely to become pregnant with IUDs in situ. Regardless of age and parity, inert IUD pregnancy rates decline with successive years of use. Thus, in the CSP the gross annual pregnancy rate for Lippes Loop D during the first year after insertion is 3.2 per 100 users; during the second year, 2.1; during the third, 1.3; and after six years the rate further declines to 0.9 (206). For copper devices, on the other hand, the decline in pregnancy rates during the second year is not so marked (141).

A common cause for pregnancy with IUDs in situ is displacement of the device. IUDs which have slipped down into the cervical canal or are dislodged or imbedded are often associated with pregnancies (219). This displacement may be caused by insertion that is not sufficiently high in the uterine fundus (156).

Ectopic Pregnancy and Spontaneous Abortion

The relative frequency of ectopic pregnancy and spontaneous abortion is higher for women who become pregnant with IUDs in situ than for others. It is estimated that IUDs reduce uterine implantation by about 95.9 percent, tubal implantation by about 95 percent and do not reduce ovarian implantation at all (103). In other words, IUDs do not cause ectopic pregnancies but rather, because they sharply reduce the likelihood of uterine implantation, those pregnancies which do occur are much more likely to be extrauterine.

Anecdotal evidence suggests that IUDs do not cause ovarian pregnancy. In a study of 320 women, 54 percent of the pregnancies in women wearing IUDs ended in spontaneous abortion compared with 17 percent in women using other methods, a threefold difference (213). In a similar US study including 46 women who became pregnant with an IUD in situ, 49 percent experienced spontaneous abortions (183). This rate compares with a general spontaneous abortion rate of about 15 percent (92).

Although it was originally thought that IUDs should be left in situ if pregnancy occurs (110, 189, 224) the current trend is toward removal. A technical bulletin issued by the American College of Obstetrics and Gynecology in August 1974 suggested that "because of this increased risk of septic abortion, the IUD should be removed if the string is visible, or if trouble should be considered or offered as an option" (208). Some reinforcement of this position may be found in the earlier CSP data which showed that if a device in situ during pregnancy had a cervical thread, the likelihood of spontaneous abortion was reduced by its removal. On the other hand, if a device had no cervical threads, the likelihood of spontaneous abortion was increased by its removal (105).

EXPULSION

IUD expulsion rates in large studies range from 0.7 to 19.3 per 100 first insertions during the first year of use (see Table 2). Like pregnancy rates they decline with age and to a lesser degree with parity. Expulsion rates also decline over successive months of use. The highest incidence is in the first three months after insertion. Expulsion occurs most often at the time of menstruation.

If discovered promptly, expulsion is not a serious problem for women with access to a physician or clinic. Another device can usually be inserted and retained. For example, with a Lippes Loop D a woman has about an 87 percent chance of not expelling, her original device within six years after the first insertion. In the CSP, two out of three women experiencing a first expulsion had a second IUD inserted, and almost one-half of these wore a Loop for at least six years after reinserter (206). Somboonsuk found that over 90 percent of Thai women who expelled the Lippes Loop had reinsertions (192). Tietze recommends replacing an expelled device with a larger size of the same configuration (206).

A more serious problem, however, is that a woman may not notice the IUD expulsion. Tietze reported in 1970 that about 20 percent of IUD expulsions went unnoticed, putting the woman at risk of pregnancy (206). It has been estimated that approximately one-third of the pregnancies among IUD users occur after an unnoticed expulsion (119).

Cervical threads or "tails" are useful in reducing the number of unwanted pregnancies that can follow expulsion. Women can normally locate the threads themselves and are advised to do so often, at least after each menstrual period. Although threads are present on most of the IUDs in use today, several models manufactured in Japan and China do not have them (see Figs. A4, A5, A8-A10). Some investigators argue that if problems arise, devices without tails are less likely to be removed by a woman herself or by a village midwife and therefore insure continued contact with health personnel (85).
REMOVAL FOR BLEEDING AND PAIN

It is generally agreed that the major difficulty with IUDs is the high incidence of bleeding, pain, infection, and other side effects that lead to removal. The rate of voluntary removal for all reasons ranges from 3.6 to 34.8 per 100 users during the first year of use (see Table 2). Removal rates for bleeding and pain where available as a rate apart from other medical reasons range from 4.0 to 14.7 per 100 users (see Table 2).

There is no doubt that IUDs substantially increase the amount of menstrual flow in most women and women should be told to expect this. Moreover, after IUD insertion, the general pattern of menstruation changes somewhat: the flow usually begins earlier (79,138), and ends later, extending the average menstrual period by two to four days (145). Increased bleeding, often accompanied by pain, occurs in both nulliparous and multiparous women (145,153), with the greatest loss usually experienced by women whose periods were scanty before IUD insertion (64). Menstrual bleeding does not return to pre-IUD levels, at least within the first six months of use (64).

The severity of bleeding may vary according to the type of IUD used. In two similar studies the exact amount of blood loss during menstruation was determined by measuring the amount of hemoglobin present in the tampons and/or pads used by each woman during her menstrual period. Among 145 Egyptian women who used no contraception Hefnawi found that the mean volume of blood lost at menstruation was 37 ml. In 91 women who used either the Copper T or Cu-7, the mean blood loss was 50 ml, and in 50 who used the Lippes Loop, blood loss was 78 ml (71). A similar US study yielded a mean blood loss of 20 ml for controls, 30 ml for women wearing Cu-7s, 45 ml for those wearing Saf-T-Coils, and 62 ml for those with Dalkon Shields (101).

Excessive blood loss can exacerbate existing health problems. In developing countries anemia has been found to occur in from four to five times more common in IUD users than in nonusers (64). Shaw has noted that although only 10–20 percent of women may be forced to discontinue currently available IUDs within two or three years of insertion because of excess uterine bleeding, many more who continue to wear such devices may develop iron deficiency during additional years because of a chronically increased loss of menstrual and intermenstrual blood. Although this problem appears significant for all women, it is most significant to those nationalities or groups of women having poor diets and existing in areas where exposure to parasitic infection is high (181).

Despite findings that associate iron deficiency with IUD use, iron therapy is not usually given, and in fact is mentioned only infrequently in clinical reports.

Removal rates for bleeding and pain are strongly influenced by the attitude of those who insert the IUD and provide follow-up care. Although a number of Yugoslav clinics utilized the same model of IUD to serve women of similar age, parity, and socioeconomic status, each clinic had a different physician. During the first six months after insertion, the rate of expulsion was the same—below 1 percent—in all of the clinics. Removals for bleeding and pain, however, ranged from zero to 10 percent. Physicians who were enthusiastic about the IUD and encouraged women to continue despite early problems had consistently lower removal rates (20).

Apart from variations from one clinic to another, the record and attitude of individual clinicians often changes with experience (21). Murayama, for instance, explained: "I readily removed the IUD following slight complaints in the early days." Later, after more experience, he was less likely to remove the device at the first complaint and reported higher continuation rates among later patients (129).

Finally, individual motivation and determination to avoid pregnancy as well as the availability of alternative methods of contraception are important factors in determining how much inconvenience women will tolerate in return for contraceptive protection. For example, in a US study indigent clinic patients were more likely to tolerate increased bleeding than were affluent private ones. Observing that 5 percent (28 of 623) of the clinic patients had the Lippes Loop removed because of bleeding, compared with 14 percent (96 of 706), of the private patients, Wilson speculated that:

Fewer clinic than private patients reported persisting spotting because they were afraid we would remove the device, thereby eliminating the single practical method they had found to protect themselves against pregnancy. The private patients reported even small amounts of bleeding because they were more concerned about the possible implications of the bleeding than over the possibility of our removing the loop (222).

Evidence from both clinical studies and mass family planning programs indicates that reinsertion seldom follows removals of IUDs for bleeding and/or pain (27,206).

INFECTION

Infection, usually pelvic inflammatory disease (PID), is second only to bleeding and pain as a cause of IUD removal. As previously noted, pelvic infection or the fear of it discredited IUDs in the early 20th century. To a certain extent antibiotics and improved insertion techniques have alleviated this problem, particularly if pregnancy is not involved.

In the CSP the removal rates for pelvic inflammatory disease ranged from 1.3 to 2.5 per 100 users after two years of use. Pelvic infection among IUD wearers decreased over time from a high of 7.7 per 100 women during the first 15 days to 0.9 per 100 women from the fourth through the sixth years (206). Mishell has shown that even when bacteria are introduced by IUD insertion into the normally sterile uterus, the uterus becomes sterile once again within 30 days. (120).

Diagnosis of PID varies considerably, depending on the description or reaction of the woman and the judgment of examining personnel. Wright has suggested the following criteria for diagnosis: oral temperature of 99.8°F (37.7°C) or higher and at least two of the following symptoms—tenderness in the lower abdomen, tenderness upon cervical manipulation, or adnexal tenderness (230). A discharge is sometimes also present.

Whether IUDs actually increase the risk of PID is unclear because there are no valid statistics on the incidence of PID among nonusers. In a retrospective case-control study
comparing one group of women who experienced a first episode of PID and a matched group who were free from PID, Wright found that 48 percent of the PID group (24 women) had IUDs compared to only 9 percent of the control group. Twenty-two of the 24 developed PID more than six months after IUD insertion (225).

**Prevention and Treatment of PID**

To prevent infection following IUD insertion, special care should be taken to use proper sterile technique. IUD and insertion equipment should be thoroughly sterilized. Women who have or who have recently had pelvic infections should avoid IUD insertion until the infection is completely cured. If possible, women should also be screened by culture for asymptomatic gonorrhea (102,119,120,123).

There is general agreement that PID which occurs later than the first month following IUD insertion is usually due to venereal or intercourse-related causes (94,119,120,123,199). Gonorrhea symptoms are more severe among women who have an IUD (132,199). PID and gonorrhea often flare up in the days immediately following menstruation (92). Wright has hypothesized that normal vaginal defenses against the ascent of bacteria may break down with uterine bleeding, thus exposing IUD wearers to a greater risk of PID because of more frequent and prolonged bleeding (224).

To treat infection in women wearing IUDs, antibiotics are normally used. Some investigators recommend removing the device (59,199); others recommend leaving it in place (112,119,120,123) or removing it only in cases of confirmed gonorrhea (170). The current practice is, whenever possible, to retain the device, thus ensuring contraceptive protection, while at the same time administering drug therapy (39).

**IUD-Related Infection and Mortality in USA**

Infection has been the main cause of serious IUD morbidity and mortality in the US. In a 1967 survey of the Fellows of the American College of Obstetricians and Gynecologists, 369 of the 561 cases of critical IUD illness reported were related to PID. Moreover, seven of the 10 deaths associated with IUD use at that time involved pelvic infection; four occurred within one month of insertion and three occurred later. Of the remaining three deaths, one was caused by a postoperative infection probably unrelated to the IUD; the other two were caused by amniotic fluid embolism following a second trimester delivery. These two could not be definitely attributed to the IUD although uterine perforations had taken place (178).

A 1973 survey of US physicians likely to insert IUDs showed that of all IUD complications requiring hospitalization, infection was the most common. During the first six months of 1973, there were 3,502 cases of IUD-related hospitalization, or 0.3 to 1.0 per 100 women years of use. Of these, 1,198 or 34 percent, were attributed to pelvic infection and another 2 percent to "other major infection" (81,207,209). Recent data suggest that infection associated with pregnancy with an IUD in situ poses the greatest danger. Since intrauterine devices were introduced in 1965, the US Food and Drug Administration (USFDA) has identified 39 deaths that were attributable to IUD use (77). Of these 39 deaths, 35 were related to sepsis in some form. Eighteen of the 35 were associated with pregnancy. These were primarily cases of second trimester septic abortion. The pat-

ttern noted in most of these cases is that the patient first experiences a septicemia without pelvic or uterine symptoms. Spontaneous abortion occurs as a late phenomenon in the course of sepsis (33).

The USFDA has estimated that:

The mortality rate from the intrauterine device is between 1 and 10 deaths per million women years, while with oral contraceptives it is 22 to 45 per million women years. The hospitalization rates with intrauterine devices are in the same order of magnitude as with oral contraceptives, 3 to 1.0 per 100 women years of use (77,209).

In general, after an extensive review, the USFDA found that IUDs are:

- a safe and reliable means of contraception and they compare favorably with the standard in this field—namely, oral contraceptives (77).

**Dalkon Shield and Septic Abortion**

Of the various IUD models used in the USA, the Dalkon Shield seems to pose the greatest dangers related to septic abortion. In reviewing septic deaths attributable to IUDs, the USFDA noted 15 deaths associated with the Lippes Loop, six of which involved pregnancy; 14 associated with the Dalkon Shield, 13 of which involved pregnancy; and six with all other devices, one of which involved pregnancy (77) (see Table 4). Morbidity during pregnancy was "219 infected abortions with the Dalkon Shield, 50 with the Lippes Loop, 14 with the Saf-T-Coil, and 6 cases with all other intrauterine devices" (77).

It is not clear, however, how many Dalkon Shields were newly in situ (when pregnancy is most likely) during the period when these septic complications occurred or whether Dalkon Shields were in fact disproportionately associated with these complications. In any case, the USFDA Advisory Committee suggested that several features of the Dalkon Shield, particularly the multiple filament tail might be associated with the increased incidence of septic abortion. Several investigators have noted that the multiple filament tail can act as a wick to carry bacteria into the uterus (122,203).

Because of the problem, the A. H. Robins Co., distributor of Dalkon Shields, temporarily suspended commercial distribution of the device in summer 1974. The National Medical Committee of Planned Parenthood (USA) stated in June 1974 that "Dalkon Shields should not be utilized for new

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Dalkon Shield</th>
<th>Lippes Loop</th>
<th>Saf-T-Coil</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not pregnant</td>
<td>1</td>
<td>8</td>
<td>1</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Sepsis</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Perforation with sepsis</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Embolism</td>
<td>13</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Septic abortion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>17</td>
<td>4</td>
<td></td>
<td>35</td>
</tr>
</tbody>
</table>

SOURCE: Jennings (77).
patients" and that "all patients who are known to be using
the Dalkon Shield should be contacted or informed of the
potential risk involved if they should become pregnant with
the device in place" (36). In December 1974 the USFDA
announced the resumption of Dalkon Shield sales under a
controlled distribution and reporting system. A monofilament
thread will replace the multifilament thread (211). Nevertheless, Planned Parenthood recommends "no further
insertions" of the existing device but will review
research protocols for the new device with multifilament
tail (37). USAID does not plan to purchase additional sup­
plies of Dalkon Shields for overseas use nor to distribute
those still in the warehouse.

## CONTINUATION RATES AND DEMOGRAPHIC IMPACT

An IUD continuation rate identifies the percentage of
women having IUDs inserted who retain the device after a
given period of time, usually one or two years (see Tables 2
and 3). In other words, it is the percentage remaining after
all the net rates for pregnancy, expulsion, and removal
during the specified time period have been subtracted.

Continuation rates provide a useful way to compare the
overall acceptability of one type of IUD with another type—
provided both IUDs are used with similar populations and
preferably within the same clinic. On the other hand, they
are less useful in comparing the IUD with other forms of
birth control, such as oral contraceptives, condoms, or
sterilization, or in evaluating the demographic impact of
family planning programs.

A major limitation of continuation rates as a measure of
contraceptive or program effectiveness is that these rates
do not usually take account of users' age and parity. Since
IUD users are consistently older than oral contraceptive
users, and since fecundity declines with age, the demogra­
phic impact of IUD use by a woman in her late thirties is less
in terms of births averted than the demographic impact of
oral contraceptive use by a woman in her early twenties.

Oral contraception is frequently chosen for child spacing,
whereas IUDs are frequently chosen by women who have
completed their families. This further limits the use of
continuation rates for comparing different contraceptives in
family planning programs.

Method prevalence, that is, the number of users in a
community at a particular time is also relevant. As Speidel
and Ravenholt have noted:

> An increased acceptance rate can make up for a decreased
> continuation rate. For example, two women using a method
> for six months each will have essentially the same demogra­
> phic impact as a single user of the method of 12 months
duration (196).

The availability of other methods of family planning and of
abortion often introduces family planning to women who
might be reluctant to start with an IUD if it involves a pelvic
examination or other unfamiliar clinical procedures. Studies
in Taiwan showed that when other methods were available, many of the women who discontinued using an
IUD were utilizing some method of contraception or abortion
to prevent further births (51). A successful program
provides multiple methods. It should include IUDs and
sterilization which have high continuation rates but which
require special skills and health facilities, but it should also
include methods for intermittent use which can be distrib­
uted through nonmedical channels.

## DISTRIBUTION

IUDs have an advantage over oral contraceptives and
condoms in that they can be manufactured readily in
developing countries either by hand, using simple molds for
small quantities, or machine molds for mass production.
The Population Council grants licenses for manufacture of
the Lippes Loop and has supplied molds and materials to
national family planning programs in developing countries.
The Ortho Pharmaceutical Corporation produces the Lippes
Loop for use in the private sector of the developed countries
(26).

Since 1966, the leading manufacturers of IUDs in the USA
(primarily the Ortho Pharmaceutical Corporation, Julius
Schmid, Inc., and the A.H. Robins Company) have sold
approximately 8.8 million IUDs for use in the USA. From
1966 through 1971, when the IUD market in the USA was
dominated by the Lippes Loop and the Saf-T-Coil, approxi­
mately 3.54 million devices were sold. Since 1971, when the
Dalkon Shield was introduced, approximately 5.24
million IUDs have been sold in the USA (77).

Table 5-US Distribution of Currently Marketed IUDs*,
1966-October 1974

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of IUDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1966</td>
<td>577,933</td>
</tr>
<tr>
<td>1967</td>
<td>436,446</td>
</tr>
<tr>
<td>1968</td>
<td>491,296</td>
</tr>
<tr>
<td>1969</td>
<td>856,756</td>
</tr>
<tr>
<td>1970</td>
<td>1,185,231</td>
</tr>
<tr>
<td>1971</td>
<td>1,670,504</td>
</tr>
<tr>
<td>1972</td>
<td>1,473,919</td>
</tr>
<tr>
<td>1973</td>
<td>1,327,783</td>
</tr>
<tr>
<td>1974</td>
<td>775,161</td>
</tr>
<tr>
<td>TOTAL</td>
<td>8,795,002</td>
</tr>
</tbody>
</table>

* Leading IUD Manufacturers

SOURCE: Jennings (77).

Many of the IUDs used in developing countries have been
purchased from US manufacturers in bulk packages by the
US Agency for International Development (AID). Such
packages contain 100 IUDs and ten inserters as well as
written instruction for sterilization of the devices. IUDs
packaged and purchased in bulk range in price from $.36 to
$.46 (US) each, including the reusable inserters. In con­
trast, the IUDs used by the private sector in both developed
and developing countries are usually sold to physicians
in prestereilized packages containing individual disposable
inserters. These range in price from $3.26 to $4.00 (US)
for the same devices. Whether this cost differential is justified
by the convenience and safety of individual packaging is not

From fiscal year 1969 through 1974, USAID distributed
almost 5.3 million IUDs either directly or through other
organizations to developing countries. Most of these have
been the Lippes Loop (four sizes). The Dalkon Shield
was distributed for research purposes and on request from 1970
until 1974, and the Saf-T-Coil was provided for the first time
in 1974. Of the 3.2 million IUDs distributed directly to
governments by USAID during the last six years, 47 percent
have gone to the Latin American region, 31 percent to Asia
and 22 percent to Africa (1) (see Table 6).
In 1970 Scemmegna reported on 34 women who used a Lippes Loop containing a silastic capsule of progesterone. Ovulation and menstruation were not affected, but there were consistent changes in the endometrium which prevented implantation (177). Pandya in the US also tried various shapes of progesterone-releasing IUDs with similar promising results (148).

Although progesterone-bearing IUDs are still in the experimental stages, the Alza Corporation of California is seeking approval of the USFDA to market its Progestasert. The Alza device is a flexible plastic T-shaped device with a hollow vertical stem containing progesterone which is released gradually into the uterus (see Fig. A14). The Progestasert must be replaced at the end of one year when the active ingredient is exhausted.

Clinical evaluation by Alza based on 3,121 insertions yielded a pregnancy rate after one year of 1.0 per 100 parous women and 1.4 per 100 nulliparous women (151,152) (see Table 2). At first, expulsions and removals were relatively high but modifications of the inserter design to release the device higher in the uterine fundus have reduced these problems among both parous and nulliparous women (150). With the cooperation of the World Health Organization, clinical testing of the Progestasert is continuing in several countries (114,169).

**Expulsion Resistant Devices**

Some research has been directed toward designing an IUD which, by virtue of its shape, configuration, or spring-loaded action, would resist expulsion. Three such devices—the Majzlin Spring, the M device, and the Dalkon Shield—have been developed but all present other problems such as perforation, difficulty in removal, bleeding, pain, and infection should pregnancy occur.

The Majzlin Spring and the M, which were made entirely from stainless steel without a covering material, incorporated a spring type action which provided a constant outward pressure on the uterine walls. This prevented expulsion, but both models were discontinued because of high perforation rates and difficulties in removal (16,149,187). The Dalkon Shield also has a low expulsion rate—less than 4 per 100 users during the first year (see Table 2)—but difficulties with insertion and removal and more recently a possible association with septic second trimester abortions leave its future in doubt (see page B-36).

A spring type action comparable to the M and Majzlin devices is used in a new Ypsilon device to be marketed by the Syntax Corporation (see Fig. A15). In the Ypsilon, the stainless steel spring is completely covered by silicone rubber. In preliminary tests with 4,500 nulliparous women,
the Ypsilon caused no perforations (6). Soichet, who developed the device, reported pregnancy and expulsion rates of 0.3 per 100 users after two years in a study of 310 women using the device for a total of 5,412 months (191). Fuchs reported slightly higher but still promising rates for the same device (54,55).

Other New Devices

Another IUD in the experimental stage is the Intrauterine Membrane (IUM) (see Fig. A16). Designed by the Battelle Population Study Center under contract with the US Agency for International Development, the IUM is not formed by injection molding like other plastic IUDs but rather by a pressing process. The IUM has deep corrugations, a large surface area and soft lateral pliancy not found in other IUDs. Preliminary results from clinical trials which began in May 1973 are encouraging but inconclusive (220).

A somewhat similar IUD which has produced good preliminary results is the Latex Leaf (see Fig. A17). Developed by Dr. Ian Anderson in Australia the device is now undergoing clinical trials in Indonesia, Israel, Thailand and other countries. This soft flexible silicone rubber device, like the IUM, has no pointed ends, protrusions, or sharp edges. The Latex Leaf releases minute quantities of copper and zinc which may interact chemically within the uterus, thereby enhancing its antifertility effect (12). Data on approximately 5000 Latex Leaf IUDs are being collected and analyzed by the IFRP.

Another IUD currently being evaluated by the IFRP is the Spring Coil (see Fig. A13). This device is made of polyethylene and is used either alone or as a carrier for active substances. Ragab reported no pregnancies at the end of two years among 344 Egyptian women who used the plain coil for a total of 5,465 months (157). Kessel noted that for prevention of pregnancy this "is probably the highest efficacy reported for any independently tested device." He pointed out, however, that continuation rates with this device vary greatly depending on the skill of the inserter (see p. 5-28). Although high removal rates for bleeding have occurred in some centers, preliminary data suggest that the addition of 700 sq mm copper, progesterone, or mestranol to the coil may reduce this problem (99,159).

Information on other models of IUD are given in Table 2 and in the Appendix.

Drug Therapy for Bleeding and Pain

Some researchers have tried to identify or develop drugs which can be administered to reduce the bleeding or pain which sometimes accompany IUD insertion and use. Already two drugs are being used: amincaproic acid, a fibrolytic inhibitor which reduces postinsertion bleeding (2,798); and naproxen, a nonsteroid anti-inflammatory compound which minimizes cramps and pain (5,115). The Workshop on IUDs at the VIII World Congress on Fertility and Sterility in November 1974 observed that "evidence is inconclusive as to whether long-term systemic administration of supplementary drugs with any IUD is advantageous" (60).

Research Priorities

In spite of extensive clinical study of many IUD configurations and a "reasonably good" evaluation methodology, the effort to improve intrauterine contraception has proved "expensive and frustrating" (87). Research priorities identified by various IUD investigators include:

- better understanding of exactly how IUDs function so that design changes can be made on the basis of knowledge rather than random experimentation.
- better criteria for evaluation of bleeding and pain since removal rates may be influenced by factors not related to the device such as attending personnel and cultural inhibitions.
- additional randomized comparative studies of IUD models conducted in single clinic settings and including reinsertions and experience over extended time periods.
- field trials directed toward hypothesis testing, that is, altering individual IUD characteristics to investigate their effects on changing performance.
- better identification of cultural, racial, anatomical, nutritional and other factors that may influence IUD performance so that where possible the appropriate IUD can be chosen for each woman.
- establishment of an international data bank compiling and analyzing IUD data from clinical research centers throughout the world.
- development of simpler IUD insertion techniques—and training in these techniques—so that nonphysicians with minimal education, including rural village midwives, can safely and effectively insert devices.

BIBLIOGRAPHY
APPENDIX: IUD PHOTOGRAPHS AND DATA

The IUDs in the following photographs are pictured actual size on sq cm grids. Devices for which 12-month life table data are available have been listed in Table 2. Effectiveness data for other devices are given in the caption below the photograph. Addresses for the agencies which have conducted major IUD evaluation programs are on p. 48. Excluded from this Appendix are several devices which were extensively tested but are no longer manufactured — the Majzlin Spring, the M, and the Gynskoii.

Fig. A1. Lippes Loop
Description: Injection molded of alathon-20 polyethylene with barium sulfate added for radiopacity; two nylon cervical threads; available in four sizes, smallest size A (left) and largest size D (right).
Developer: Jack Lippes, USA.
Distributor: Ortho Pharmaceutical Corporation, Raritan, N.J. 08869, USA. (Also available for developing countries form the Population Council).
Evaluation Programs: Numerous (see Table 2).
Areas of major use: More than 70 countries in North and South America, Asia, Africa, and Europe.

Fig. A2. Dalkon Shield
Description: A membrane-type device made of ethylene vinyl acetate (EVA) with barium sulfate added for radiopacity; has fundal-seeking lateral fins; a single cervical thread is made of multifilaments bound within a thin plastic sheath; available in two sizes, nulliparous Shield (left) and standard multiparous Shield (right).
Developer: Hugh Davis and Irwin Lerner, USA.
Distributor: A. H. Robins Co., 1407 Cummings Drive, Richmond, Virginia 23220, USA.
Evaluation Programs: Numerous (see Table 2).
Areas of major use: 40 countries in Asia, Europe, and North America.

Fig. A3. Saf-T-Coil
Description: Injection molded of ethylene vinyl acetate (EVA) copolymer with barium sulphate added for radiopacity; two nylon cervical threads; available in three sizes, smallest model 25S (left) and largest model 33S (right).
Developer: Ralph R. Robinson, USA.
Distributor: Schmid Laboratories, Inc., Rt. 46 W, Little Falls, N. J. 07424, USA.
Evaluation Programs: Numerous (see Table 2).
Areas of major use: North and South America, Asia, and Europe.

Fig. A4. Yusei Ring
Description: Three models, each of different composition — one made entirely of polyethylene (left), one made of polyethylene except for the center ring, which is metal (center), and the third made entirely of polyethylene with wire core in the upper and center parts (right); no cervical threads.
Developer: Onagi Ikemi, Japan.
Distributor: Yusei Ring Sogokenkyushu, 2-8-14 Shinbashii, Minato-ku, Tokyo, Japan.
Evaluation Program: Status unknown.
Areas of major use: Japan.
Note on effectiveness: The following event rates apply for the ring in the center: pregnancy—1.8 percent; expulsion and descent—0.8 percent; and medical removal—3.9 percent among 133 insertions and 266 woman-years of use (229).
Fig. A5. Ota Ring
Description: Four models—two made entirely of polyethylene (left), two made of gold-plated silver (right); no cervical threads.
Developer: Tenrei Ota, Japan.
Distributor: The model on the far left is distributed by: Ohta Rings Kenkyu-sho, 2-1 Ogawa-machi kanda, Chiyoda-ku, Tokyo, Japan.
The other three by: Yuseiriing Sogokenkyusho, 2-8-14 Shinbashil, Minatoku, Tokyo, Japan.
Evaluation program: Status unknown.
Areas of major use: Japan and Taiwan.
Note on effectiveness: Although there is little information on the effectiveness of Japanese IUDs, the most authoritative statement available indicates a “failure rate” of the Ota polyethylene ring of approximately 2.5 per 100 woman years (117). This conforms with Ishihara’s figure of a pregnancy rate of 2.5 percent (76) and that of Fuchi of 2.7 percent (83). Data for the Ota metal ring appear to be more fragmentary than those for the polyethylene ring; however, identification of type ring (metal or polyethylene) is not always stated in published reports.

Fig. A6. Cu-7 (Gravigard)
Description: Injection molded of polypropylene homopolymer with barium sulphate added for radiopacity; has 200 sq mm copper wire wound around the vertical stem; a single polypropylene cervical thread.
Developers: Jaime Zipper and Harvey Abramson, Chile.
Distributor: G.D. Searle and Co., Box 5110, Chicago, Illinois 60680, USA.
Evaluation Programs: G.D. Searle and Co. and others (see Table 2).
Areas of major use: North and South America, Asia, and Europe.

Fig. A7. Copper T
Description: Injection molded of polyethylene with barium sulphate added for radiopacity; has 200 sq mm copper wire wound around vertical stem; two nylon cervical threads.
Developers: Howard Tatum, USA, and Jaime Zipper, Chile.
Distributor: Outokumpu Oy, Pori Works, Pori 10, Finland; Ab Kabi, Medical Department, S-104 25 Stockholm, Sweden; the Population Council.
Evaluation Programs: The Population Council and others (see Table 2).
Areas of major use: Taiwan, Thailand, United Kingdom, USA, and various other countries in Asia, Europe, and Latin America.
Fig. A 8. Spira Ring
Description: A polyethylene device with no cervical threads.
Developer: Tenrei Ota, Japan.
Distributor: Ohta Rings Kenkyu-sho, 2-1 Ogawa-machi Kanda, Chiyoda-Ku, Tokyo, Japan.
Evaluation Program: Status unknown.
Area of major use: Japan.
Note on effectiveness: A single incomplete study reported in a secondary source indicated a pregnancy rate of 0.5 percent and a removal rate of 4.1 percent among 196 insertions over an unspecified time period (76).

Fig. A 9. K.S. Wing
Description: Stainless steel wire core covered with molded natural rubber; available in four basic shapes, in different sizes; no cervical threads.
Developer: Kiyoo Kurokawa, Japan.
Distributor: K.S. Wing Laboratory, 123 Hase, Kamakura, Kanagawa, Japan.
Evaluation Program: Status unknown.
Area of major use: Japan.
Note on effectiveness: A secondary source reported that among 15 insertions with a total of 180 cycles of use, 13.3 percent of the wearers became pregnant; 6.6 percent of the IUDs were expelled; and 6.5 percent were removed for medical reasons (76).

Fig. A 10. Flower of Canton
Description: Injection molded of polyethylene; these have an opening in the lower segment through which a cervical thread could be attached; however, available samples do not include threads; the older model (left); the newer model (right)
Developer: Unknown
Distributor: Unknown
Evaluation Program: Status unknown.
Area of major use: Peoples Republic of China.
Note on effectiveness: A secondary source indicated pregnancy and expulsion rates of 0.5 and 4.0 percent, respectively, with an unknown number of insertions and an unstated period of time for the “old” model (19). There are no known evaluations of the “new” model.

Fig. A 11. Stainless Steel Ring
Description: Stainless steel; available in two models, single ring (left) or double twisted ring (right); two nylon cervical threads.
Developer: Unknown
Distributor: Unknown
Evaluation Program: Status unknown.
Area of major use: Peoples Republic of China.
Note on effectiveness: A secondary source indicated a pregnancy rate of 1-4 percent per year and expulsion rate of 10-15 percent per year with an unknown number of insertions and an unstated number of months of use (19).
Fig. A12. Szontagh
Description: Two models—one of polyethylene with two cervical threads (left), the other of polyethylene coated with 0.1 mm copper (right).
Developers and Distributor: Dr Zoltan Szereday and Dr Lajas Zelenka developed this device under the supervision of Professor F. R. Szontagh; WHO Clinical Research Center of Human Reproduction, Department of Obstetrics and Gynecology, University Medical School, Semmelweis utca 1, H-6725 Szeged, Hungary.
Evaluation Program: IFRP.
Area of major use: Hungary.
Note on effectiveness: One report indicated the following event rates for 419 insertions and 7,433 months of use for the copper Szontagh calculated by the Pearl formula for two years of use: pregnancy—2.6 percent; expulsion—0.8 percent; medical removal—5.8 percent (142).

Fig. A13. Spring Coil
Description: Molded alathomon-20 polyethylene coil; has four monofilament nylon cervical threads, two attached to the end of the device for identification and removal, and two others attached higher for situating the device in the uterus during insertion. This coil has been tested as a carrier for copper or hormones.
Developer: Elton Kessel, Pathfinder Fund, USA.
Distributor: Not available commercially.
Evaluation Program: IFRP (see Table 2).
Areas of major use: Egypt, Hungary, and Yugoslavia.

Fig. A14. Progestasert
Description: A membrane-mediated drug delivery system. The vertical section of the T contains a core reservoir of progesterone, dispersed in silicone oil, surrounded by a rate-limiting membrane of ethylene vinyl acetate copolymer. The horizontal cross arms of the T are solid copolymer. The device has two monofilament cervical threads.
Developer: Alza Corporation, USA.
Distributor: Alza Corporation, 950 Page Mill Road, Palo Alto, California 94304, USA.
Evaluation Programs: Alza Corporation and World Health Organization (see Table 2).
Areas of major use: Brazil, Germany, Hong Kong, Hungary, Mexico, Sweden, Thailand, United Kingdom, USA.

Fig. A15. Ypsilon
Description: Stainless steel V-shaped core covered by silicone rubber membrane; single cervical thread is an extension of the silicone rubber.
Developer: Samuel Solchet, USA.
Distributor: Not available commercially.
Evaluation Program: World Health Organization (see Table 2).
Areas of major use: Brazil, Thailand, USA.
Fig. A 16. Intrauterine Membrane
Description: Alathon-20 polyethylene sheet press-formed into corrugated membrane with barium sulphate V-shape piece injection molded to the base for radiopacity and support of the membrane; a single cervical thread is attached to the V.
Developer: Battelle Laboratories, USA.
Distributor: Not available commercially.
Evaluation Program: IFRP.
Areas of major use: USA, Yugoslavia.
Note on effectiveness: Life table event rates after three months for approximately 100 women using this device are reported as follows: pregnancy—2.1/100 users; expulsion—1.5; and medical removal—4.4 (220).

Fig. A 17. Latex Leaf
Description: Stamped from sheet of silicone rubber which contains small quantities of copper and zinc particles; has two cervical threads.
Developer: Ian Anderson, Australia.
Distributor: Not available commercially.
Evaluation Programs: IFRP.
Areas of major use: Australia, India, Indonesia, Malaysia, Singapore, Thailand, and Republic of Vietnam.
Note on effectiveness: One year life table rates for insertions in 354 Indonesian women were 3.2, 6.2, and 8.2 per 100 women, respectively, for pregnancy, expulsion, and removal. The continuation rate was 70 per 100 (11).

Fig. A 18. Antigon-F
Description: Injection molded of high pressure polyethylene; a magnetic strip is built into one of the longer sides for detection by a galvanometer; two nylon cervical threads. Original device was closed ring type; the modified Antigon-F has a membrane covering the opening.
Developers: Original Antigon developed by Paul E. Lebech and Mogens Osler, Denmark. Modified Antigon-F developed by Fritz Fuchs, USA.
Distributor: Svend Schroder, 112 Bjerlingbrovej, Rodovre, Denmark.
Evaluation Programs: World Health Organization and Family Planning Research Unit (see Table 2).
Areas of major use: Europe, India, Thailand, and USA.

Fig. A 19. Massouras Duck’s Foot
Description: Polyethylene or silicone with a fine stainless steel and/or polyester core; barium sulphate added for radiopacity; the horizontal appendages may be cut to fit uterus.
Developer and Distributor: H. G. Massouras, 93 Michalacoulou Avenue, Athens 611, Greece.
Evaluation: By the developer only.
Areas of major use: Greece.
Note on effectiveness: Although this device has been used primarily for the prevention of intrauterine adhesions, no pregnancies or expulsions occurred during "up to one-year follow-up" among 50 insertions for contraception (118), poses (000).
Fig. A 20. Ragab Ring
Description: Handmade device of nylon filaments wound into a circle and bound at several points; two filaments left unbound to serve as cervical threads.
Developer: M. I. Ragab, Egypt.
Distributor: M. I. Ragab, 13 Midan Tahrir, Cairo, Egypt.
Evaluation: By the developer (see Table 2).
Area of major use: Egypt.

Fig. A 21. Shamrock
Description: A closed polyethylene ring, twist-folded and heat-set with 20 percent barium sulphate added for radiopacity; has two cervical threads; the five available Shamrocks vary in size and pliancy.
Developer: C. Lator Burdick, USA.
Distributor: C. Lator Burdick, The Lator Foundation, 4400 Lancaster Pike, Wilmington, Delaware 19805, USA.
Evaluation: By the developer (see Table 2).
Area of major use: USA.

Fig. A 22. Dana
Description: Ethylene vinyl acetate (EVA) with 25 percent barium sulphate added for radiopacity; available in two models—the Dana Super Lux (four sizes, one shown at left); and the Dana Cor (three sizes, one shown at right); two nylon cervical threads.
Distributor: State Textile Research Institute, Centre for the Application of Radioactive Isotopes in the Textile Industry, Brno-Vaclavska 6, Czechoslovakia.
Evaluation Program: Status unknown.
Areas of major use: Czechoslovakia and Democratic Republic of Germany.
Note on effectiveness: A secondary source gives one-year rates per 100 users as 3.9, 4.5, and 3.1 for pregnancy, expulsion, and medical removals respectively (44).

Fig. A 23. D.I.U, Pharmatex
Description: Made of tisan with a barium sulphate filament embedded for radiopacity; available in four sizes; has two cervical threads.
Developer: Laboratoires Fandre, France.
Distributor: Laboratoires Pharmelac, 40 rue de Paradis, Paris 75010, France.
Evaluation Program: Status unknown.
Area of major use: France.
Note on effectiveness: There is no information available about the effectiveness of this device.
Fig. A 24. Omega
Description: Molded plastic with barium sulphate added for radiopacity; numerous shapes and sizes available; has two cervical threads made of nylon; copper Omega is being tested currently.
Developer: Rene Cournot, France.
Distributor: Sodermec, 32, Rue Gambetta, 46 200 Souillac, France.
Evaluation Program: Status unknown.
Area of major use: France.
Note on effectiveness: The following event rates, based on 6601 insertions and 85,829 woman-months of use, have been computed from data received by mail from 400 French physicians. Rates are expressed as percentages: pregnancy—2.8; expulsion—8.5; medical removal—6.5 (47).

Fig. A 25. Spiram W
Description: Made of alkathene WNG-14 with no cervical threads.
Developer: Andrezej Reszczynski, Poland.
Evaluation Program: Status unknown.
Area of major use: Poland.
Note on effectiveness: The following event rates, based on usage by 800 women during an unstated period of time, were received in a personal communication from the developer. Rates are stated as percentages: pregnancy—3 (including 3 ectopic pregnancies); expulsion—5; medical removal—6.

Agencies which have conducted major IUD evaluation programs:

International Fertility Research Program (IFRP)
Carolina Population Center
NCNB Plaza
Chapel Hill, N. C. 27514 USA

The Family Planning Research Unit
Department of Sociology
The University of Exeter
Devon, England

The Population Council
245 Park Avenue
New York, N.Y. 10017 USA

Human Reproduction Unit
World Health Organization
1211 Geneva 27, Switzerland