Sir Theodore Fox (1964) stated in a recent Lancet "Perhaps more urgently than anything else, the world needs a safe and effective method of contraception which will cost very little!" The question is, have we found it?

The idea of intra-uterine contraception seems to have been known to the ancient Arabs who still employ the method to prevent conception in saddle camels used for long journeys by a nomadic tribe of the Sahara, Touareg, and also in the Sudan. The practice consists of introducing a round smooth stone, the size of a kidney bean or a chick pea, into the uterus of the camel, which then repulses the advances of the male, as if she were pregnant. Cauvet (1925) writes: "Through this technique, one is always able to count upon a saddle animal; otherwise one is disagreeably surprised to find the day on which he is going to start on a long journey that his camel is pregnant and unable to render the services demanded. During the first 4 or 5 months of pregnancy it is necessary to rest the saddle animal frequently for short periods. Then too, a pregnant camel often becomes difficult and stubborn; she lies down refusing to get up and leave the pack."

Cauvet introduces the topic by saying that beginning with Aristotle it has been repeatedly stated that one may castrate a female camel. Cauvet concludes that this cannot mean ovariectomy as in heifers today, but some artificial method such as an intra-uterine device. He implies that female sterilization was too formidable a procedure for that epoch.

On consulting Aristotle, I see no grounds for Cauvet's interpretation. We read: "Female camels are mutilated when they are wanted for war purposes, and are mutilated to prevent their being got with young... they run in consequence of the length of their stride, much quicker than the horses of Nisaea. As a general rule, mutilated animals grow to a greater length than the un-mutilated."

The above material quoted from Aristotle is taken from a section of the History of Animals (Thompson, 1910) dealing with the technique and effects of castration in the males and females of different species. The lines preceding the quoted reference to the female camel discuss the 'mutilation' of the sow, "the ovary grows, adhering to the two horns of the womb; they cut off a little piece and stitch up the incision". It is obvious to me that, by discussing 'mutilation' of the female camel in the very next sentence, the same procedure of ovariectomy is implied. Then, too, Aristotle discusses the somatic advantage of the castrated

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* Delivered at the London School of Hygiene and Tropical Medicine, 26th November 1964.
† President, Planned Parenthood Federation of America, Inc.
state—'greater length'. It is unlikely that an intra-uterine contraceptive device could create eunuchoid growth stimulation. I conclude that intra-uterine contraception was not known in antiquity and therefore the intra-uterine contraceptive devices (IUCDs) represent one of those rare medical entities which did not originate with Hippocrates or Soranus. Apparently, however, IUCDs have been used in folk medicine, possibly for a long time; I have recorded elsewhere a remarkable account of their use among tribes in Battavia (Guttmacher, 1965).

Early IUCDs in Europe

The medical aspects of intra-uterine contraception apparently stem from about 1878. At this time cervical intra-uterine devices were largely used to treat dysmenorrhea, uterine displacements, amenorrhea and sterility. But from about 1878 they were introduced to prevent pregnancy or to produce abortion. During the nineteenth century the literature is full of both the use and abuse of these devices. Complications are described, contra-indications are stated, patents for various devices were claimed and issued. As early as 1916 Dr Robert Latou Dickinson foresaw that a wholly intra-uterine pessary would eventually be adopted for the prevention of conception. Dr Gräfenberg, beginning in 1928, published many articles, particularly in the German literature, about various types of intra-uterine devices. His devices were made of silver, gold and silkworm-gut and were completely intra-uterine. His experience with them apparently was quite satisfactory, both in the prevention of conception and in the paucity of complications. However, when the practice passed from the hands of the masters to the ordinary physician in obstetrics and men in general practice, complications multiplied (see Southam, 1964) and the whole method fell out of favour; but there were still some physicians, in Europe particularly, who continued to use intra-uterine contraceptives. Dr Margaret Jackson, who is in this audience, and others employed these devices—though perhaps on a small scale—with reasonably good results. Chapter 13 of Norman Haire's book, Birth Control Methods, published in 1937 is captioned 'Intra-uterine devices'. So intra-uterine contraception did not disappear, it merely became dormant.

In 1957 or 1958 Mr Daniel O'Connor came to see me, referred by Robert Cook of the Population Reference Bureau. O'Connor, an economic advisor to the Government of Puerto Rico, had become concerned with the population explosion. He talked to me about the use of intra-uterine devices, but having been indoctrinated with the fear of intra-uterine contraceptives my ear was not attuned to this topic, and I therefore paid little attention. In 1958 Dr Margulies at the Mount Sinai Hospital tried to interest me in allowing him to carry on some clinical contraceptive experiments with polyethylene intra-uterine devices; I was still too deaf or timid to hear.

Development of modern IUCDs

In 1959 Oppenheimer from Israel published a very excellent study on 329 cases in whom he had used Gräfenberg intra-uterine contraceptive devices for as long as 18 years with extraordinarily good results. His contribution co-
incided with a paper from Ishihama (1959) which described in the *Yokohama Medical Journal* the excellent results that they had had in Japan, mainly with Ota intra-uterine rings. After this many physicians changed their attitudes and became more tolerant toward the concept of intra-uterine contraception. Dr Margulies at Mount Sinai, Dr Zipper in Chile, Dr L IPPes at the University of Buffalo, Dr Charles Birnberg at the Brooklyn Jewish Hospital, all at about the same time began again to experiment with intra-uterine contraception. At the Mount Sinai Hospital Dr Margulies worked very effectively; I worked with him in a very minor capacity and we were pleased and excited by our first 500 cases.

**The Population Council study of 1962**

At about this time I was asked by the Population Council conjointly with the International Planned Parenthood Federation to undertake a journey to study efforts at conception control around the world. Mrs Guttmacher and I made the trip during January and February 1963. When I returned to New York I advised the Population Council that, in my opinion there were broadly three possible methods of controlling the great upsurge of population, namely, oral chemicals and hormones, immunization, and intra-uterine contraception. I believed that the orals were being so actively investigated and distributed by pharmaceutical manufacturers that I could see no reason for the Population Council to become deeply involved in their study. I felt that immunization would not be able to contribute very much in the near future, since many years of basic research would first have to be done; it was, therefore, my opinion that the best chance for immediate success lay in work with intra-uterine contraception.

**Conferences on IUCDs**

The Population Council followed this advice and held the first IUCD conference on the 30th April and the 1st May 1962. It was chaired by the late Dr Warren Nelson and myself. Eleven countries were represented with forty participants.

Following this a film on intra-uterine contraception was made by the Population Council which was shown all over the world. The Population Council decided to back heavily its gamble on intra-uterine contraception and has spent, in the interval, between the spring of 1962 when they first became involved and the autumn of 1964, about a million and a half dollars in its study.

The National Committee of Maternal Health (NCMH) is a subsidiary of the Population Council and almost wholly supported by its funds. One of its functions is to act as a clearing house for the world literature on contraception, sterilization and abortion. Full bibliographic listings in each field are published by NCMH periodically. In addition NCMH collects and analyses the data on important clinical studies on various contraceptive techniques. Its most important project is a comparative study of five different IUCDs. Dr Tietze, Director of NCMH research, collects and collates data from thirty-eight different clinical trials, thirty-three of them located in the United States and most in University hospitals. Of the five abroad, one is in England, Dr Margaret Jackson's clinics in Devon and Cornwall; others are in Fiji, Puerto Rico, Hong Kong and Sweden. To-date Dr Tietze has accurate statistical data on 114,630 women who
have used the five devices for a total of 12,343 years. The Population Council recently held its second International Conference on Intra-uterine Contraception in New York, on the 2nd and 3rd October 1964. Instead of forty representatives attending from eleven countries, as was the case in 1962, over 500 participants representing forty-four countries gathered at the 1964 meeting. I believe it is safe to say that never in history has any contraceptive method received such exhaustive and prompt study. The fifty-eight papers read and discussed at the conference form the groundwork for my discussion today.

Five intra-uterine devices are photographed in Plate 1. Three of them, the Margulies spiral (a), the Lippes loop (b), and the Birnberg bow (c) are fashioned from polyethylene plastic to which a barium salt has been added to render it radio-opaque. Being fashioned from plastic tubing, each can be stretched into linear form and threaded into a teflon tube. This catheter-like tube, with the bore of a soda straw, is passed through the cervical canal just beyond the internal os, then a plunger is inserted to force the device into the uterine cavity. Since moulded plastic has 'memory', the device after being discharged into the uterus reshapes itself into its original form. The fourth device (d), the Hall ring (about the size of a sixpence), is a coil spring fashioned from stainless steel wire. The fifth (e), the Zipper ring, is much like the old Gräfenberg ring, but instead of being formed by interlaced strands of silkworm-gut is made from nylon fishing-line. All the materials, polyethylene, stainless steel and nylon are non-reactive with human tissue and well tolerated by it. Three, the spiral, the loop and the coil, have tails which protrude from the external os of the cervix. The tail bestows two advantages, it permits the patient to palpate the tail with her finger or the doctor to see it on speculum examination and thus determine that the device is still within the uterine cavity and has not unknowingly been ejected. The other advantage from a protruding tail is that the device can be very easily removed, simply by making traction on the tail. The tail of the spiral is polyethylene plastic, being a moulded portion of the device itself; while the tail of the loop is a nylon thread tied to the plastic. The nylon coil leaves a long end of one of its threads uncut to act as a tail. The two tailless devices, the stainless steel ring and the polyethylene bow, must be hooked out, a button-hook-like instrument being used. In most parous patients the spiral, loop and coil can be inserted and removed without either preliminary cervical dilatation or fixation of the cervix by a tenaculum. Some parous patients require cervical dilatation for the insertion and removal of the bow and the ring.

Methods of Insertion

Doctors who insert an IUCD are gynaecologists. It is not yet known whether the use of IUCDs will be safe in the hands of the general practitioner, if not, their use would be severely limited. The actual insertion is not difficult, so that it is anticipated that, eventually, midwives can be taught to use them; if this proves impossible, widespread use will be denied to countries like Pakistan and India. One of the things, therefore, which must be done in the next few years is to carry out comparative studies of results between IUCDs inserted by physicians and those inserted by para-medical personnel.
The five IUCDs being intensively studied by the National Committee of Maternal Health (three-quarters actual size): (a) Margulies plastic spiral or coil; (b) Lippes plastic loop; (c) Birnberg plastic bow; (d) Hall steel ring; (e) Zipper nylon ring.

(Facing p. 118)
Mode of action

Their mode of action in preventing pregnancy is still far from clear. It seems to be essentially different in various animal species. Extensive studies on the mechanism of action have been done in the rat, rabbit, cow and monkey.

Rats

In the rat, one uterine horn was kept as a control and a thread placed through the other horn, so that the knots are on the outside of the uterus and the thread itself inside the uterine cavity. In the operated animal, ova are ovulated from both ovaries, are fertilized and pass down the Fallopian tubes normally on both sides, but as soon as they reach the uterine cavity on the side with the thread the ova disappear. Ova on the control side implant and develop normally. Something therefore happens to the ovum between the time that it leaves the tube and implants in the uterus. Perhaps nidation is impossible because of an endometrial cellular factor. The usual decidual cell reaction, which occurs on irritating the endometrium of the rat, cannot be obtained on the side which carries the thread (Doyle & Margolis, 1965; Marston & Chang, 1965a; Chaudbry, 1965; Parr, 1965; Schuchner & Davidson, 1965).

Dr Chang believes that there is some specifically-timed local trigger mechanism in the rat, possibly a bio-chemical substance or a neuro-endocrine reaction necessary for the initiation of implantation. He suggests that this particular biochemical substance or neuro-endocrine reaction is exhausted or used up by the presence of a foreign body, such as a thread.

It is also possible that the foreign body produces a toxic substance which prevents development of the fertilized ovum (Marston & Chang, 1965a)

Rabbits

In the rabbit, when a thread is sewn in one uterine horn, ovulation takes place, the eggs pass down the tubes and normal blastocysts are found in the uterus up to Day 7 (day of implantation). After Day 7 many degenerated blastocysts are found in the experimental horn, moreover a few implant but none develop beyond Day 14, after which the dead embryos are resorbed. Thus in one species there is no implantation, and in the second there is implantation of a small proportion of the fertilized ova (Marston & Chang, 1965b). No ova continue to develop beyond the middle of pregnancy (Marston & Chang, 1965b; Eckstein & Adams, 1965).

Cows

At the U.S. Government Animal Breeding Station they have been anxious to study cows with intra-uterine contraceptive devices in the hope of helping India solve her sacred cattle problem, for, in India, sacred cattle, which may not be killed, compete with humans for food. It would be immensely helpful if something short of slaughter could be done to reduce the cattle population. An intra-uterine contraceptive device has been developed for the cow which is inserted into each uterine horn and is extraordinarily effective. At the research station eighteen cows with an IUCD inserted in each uterine horn were serviced by artificial insemination. From these sixty services, no pregnancies resulted.

Twenty-one control animals were serviced thirty-eight times using semen
from the same bull and each cow was impregnated by these thirty-eight services.

In the cow with an iucd in place the investigators determined that usually the ovum is discharged; four of the eighteen experimental cows had cystic follicles and were anovulatory. The other fourteen ovulated normally; however, the corpus luteum did not develop sufficiently to become the usual discrete solid ovarian body which can be palpated on rectal examination. The reason that eggs are transplanted normally through the tube but do not implant in experimental cattle, may be because progesterone is withdrawn when the corpus luteum atrophies prematurely on the 3rd day, at the critical implantation phase (Hawk, Conley, Brinsfield & Righter, 1965).

The monkey

Mastroianni of the University of California, Los Angeles, has done some fascinating experimental work in the monkey. He fitted six macaque Rhesus monkeys with intra-uterine coils, of the Margulies type, which can be inserted *per vaginam* through the cervix into the uterine body, just as in the human. Then he hyper-ovulated his coil animals with a 6-day course of human urinary gonadotrophin (Pergonal) followed by a 3-day course of human chorionic gonadotrophin. Approximately 8 hr after ovulation should have taken place he laparotomized his six animals. He identified fifteen corpora lutea in the ovaries which indicated fifteen ova had been shed into the Fallopian tubes, but on washing the tubes none of the fifteen was recovered. He treated eight control monkeys similarly, that is, monkeys without an iucd and got twenty-one ovulation points. Eleven ova were washed from the tubes of these controls. Then he put a ligature at the utero-tubal junction in six additional coil animals so that the ova could not pass into the uterus. He superovulated them and recovered half the ova. This proved that the coil animals not only ovulated but also the ova found their way into the Fallopian tubes. From these experiments Mastroianni hypothesizes that an iucd in the monkey causes the whole smooth muscle tract to undergo such hypermotility that instead of eggs taking a 3-day leisurely trip down the tube and finally getting into the uterus, they rush down in a few hours. Either they are not fertilized in their rapid passage, or they reach the uterus in such an immature state after fertilization that they cannot implant or perhaps the lining of the uterus is not sufficiently prepared this early in the cycle to permit implantation (Mastroianni & Hongson and, 1965).

Humans

There is evidence that in women fitted with an iucd something happens to the egg between the time of its ovulation and nidation. There is no evidence of implantation; menstrual cycles are usually shorter, not longer. Whether the egg becomes fertilized is not yet established; spermatozoa have been recovered from the tubes in great abundance. Some evidence that the tubal hypermotility theory may be applicable to the human is furnished by the fact that tubal pregnancy has rarely been observed in women wearing an iucd: in them ectopic pregnancy has been encountered with less than one-tenth the expected frequency (Tietze & Lewit, 1965).
**RESULTS**

**Effectiveness**

IUCDs have an occasional failure with pregnancy resulting. Pregnancy either occurs with the device in situ or after the device has been expelled and the patient fails to notice the expulsion. Obviously under this latter condition any coitus is unprotected against impregnation.

Table 1 is slightly modified from a similar table compiled by Tietze & Lewit (1965).

The hypothetical pregnancy rate assumes that all unnoticed expulsions are invariably followed by pregnancy before expulsion is detected. This is probably not true and therefore the true pregnancy rate is probably more than the reported rate and less than the hypothetical rate.

**Table 1**

<table>
<thead>
<tr>
<th>Type of device</th>
<th>No. of patients</th>
<th>Woman-months of use</th>
<th>Per 100 patients during 1st year after insertion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiral</td>
<td>4044</td>
<td>33467</td>
<td>1.1, 2.9</td>
</tr>
<tr>
<td>Loop</td>
<td>4100</td>
<td>27772</td>
<td>1.3, 3.3</td>
</tr>
<tr>
<td>Bow</td>
<td>1606</td>
<td>7899</td>
<td>5.5, 6.5</td>
</tr>
<tr>
<td>Steel ring</td>
<td>1880</td>
<td>29340</td>
<td>3.6, 6.2</td>
</tr>
<tr>
<td>Nylon ring</td>
<td>3000</td>
<td>49644</td>
<td>4.5, 11.3</td>
</tr>
<tr>
<td>Total</td>
<td>14630</td>
<td>148122†</td>
<td></td>
</tr>
</tbody>
</table>

*Assuming no routine visit and all unnoticed expulsions invariably followed by pregnancy, ergo, reported pregnancies plus all unnoticed expulsions.
† 12,343 woman years.

The reported pregnancy rates, particularly for the spiral and the loop, are excellent and compare favourably with that observed in a similar class of patients on the oral progestagens. The hypothetical pregnancy rates are probably not as low as those met with when using oral contraceptives, but, except for the nylon ring, probably better than would be found in the same patients using intravaginal methods.

**Expulsions and removals**

The first column of Table 2 depicts the numbers of each device which were recognized to have been expelled during the first year per 100 patients. Column 2 gives the number in the first column to which is added those who became pregnant and in whom it is unknown whether the device has been expelled or still remains in utero. It is obvious that the spiral and the nylon ring have inferior rates in respect to expulsion.

Removals by a physician were either performed for medical or personal reasons. The symptom necessitating removal on medical grounds was largely bleeding; abdominal cramps and backache were of lesser importance. The bleeding was intermenstrual in type, though profuse menses after iucd insertion were also encountered. Intermenstrual staining or bleeding is very frequent.
during the first 10 days after insertion and it is not uncommon for it to persist for a month or two; it then usually disappears. Many patients wearing an iucd note freer bleeding during the menses, rarely it may be sufficiently intense to dictate removal. Abdominal cramps or backache for \( \frac{1}{2} \) to 2 hr after insertion is not uncommon. In the very exceptional instance, insertion of an iucd is followed by temporary mild syncope. Also infrequently, cramps or backache may be sufficiently severe or protracted to necessitate removal within the first 24 hr. Personal reasons causing a patient to seek removal are many—fear of cancer, desire for pregnancy, lack of confidence, husband's command, etc.

Combining the adverse reactions of failure (pregnancy), expulsion and removal one is led to conclude that the stainless steel ring, bow and loop are, in overall results, superior to the spiral and nylon ring.

Much experimentation is being carried on currently, particularly in the United States, to improve the iucds now in use by varying their size and consistency and, in addition, studies involving new devices and principles. Davis and Barnes at the Johns Hopkins are investigating a plastic device incorporating a small piece of magnetized iron. The latter permits its detection in utero by deflecting the needle of a compass placed over the pubis.

<table>
<thead>
<tr>
<th>Type of device</th>
<th>Expulsions</th>
<th>Removals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Excluding pregnancies with device undetermined</td>
<td>Including pregnancies with device undetermined</td>
</tr>
<tr>
<td>Spiral</td>
<td>17-6</td>
<td>17-9</td>
</tr>
<tr>
<td>Loop</td>
<td>9-0</td>
<td>9-5</td>
</tr>
<tr>
<td>Bow</td>
<td>3-8</td>
<td>7-3</td>
</tr>
<tr>
<td>Steel ring</td>
<td>8-7</td>
<td>10-8</td>
</tr>
<tr>
<td>Nylon ring</td>
<td>17-2</td>
<td>19-6</td>
</tr>
</tbody>
</table>

**Effect of parity on expulsion and removal**

The five devices studied by Tietze each show lower expulsion and removal rates for patients who have borne two or more children than nulliparae or mothers of one child, (see Table 3). The size, position or shape of the uterus has no prognostic significance as to which patient will expel an iucd or which will develop side effects. Furthermore, the condition of the cervix bears no relationship to the retention of a device or the occurrence of side effects.

**Tolerance to an intra-uterine device**

Expulsion is most frequent within the first 3 months, commonly during the menses. After the 3rd month, likelihood of expulsion is relatively slight. The occurrence rate total during the next 15 months (Months 4 to 18) being less than the total during the first 3 months.

The removal rate follows the same pattern, but to a lesser degree. One third of the removals took place in the first 3 months and two-thirds in the next 15 months.
### Table 3

**Expulsion and Removal Rate by Parity Per 100 Patients Per Year**

<table>
<thead>
<tr>
<th>Type of device</th>
<th>Expulsion</th>
<th></th>
<th></th>
<th></th>
<th>Removal</th>
<th></th>
<th></th>
<th></th>
<th>Total removal and expulsion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0*</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4 and +</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Spiral</td>
<td>21.9</td>
<td>23.6</td>
<td>16.0</td>
<td>16.5</td>
<td>16.4</td>
<td>12.3</td>
<td>16.5</td>
<td>14.3</td>
<td>13.7</td>
</tr>
<tr>
<td>Loop</td>
<td>12.1</td>
<td>10.5</td>
<td>8.2</td>
<td>6.9</td>
<td>—</td>
<td>—</td>
<td>14.6</td>
<td>13.4</td>
<td>11.0</td>
</tr>
<tr>
<td>Bow</td>
<td>7.5</td>
<td>7.0</td>
<td>1.6</td>
<td>0.8</td>
<td>—</td>
<td>—</td>
<td>13.8</td>
<td>7.6</td>
<td>8.3</td>
</tr>
<tr>
<td>Steel ring</td>
<td>5.0</td>
<td>13.8</td>
<td>9.7</td>
<td>5.4</td>
<td>8.9</td>
<td>2.9</td>
<td>3.9</td>
<td>7.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Nylon ring</td>
<td>26.4</td>
<td>18.9</td>
<td>13.6</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>8.5</td>
<td>6.3</td>
<td>7.1</td>
</tr>
</tbody>
</table>

* Para.
Infections

Table 4 demonstrates that 1-2% patients/year developed pelvic inflammatory disease (PID) subsequent to the insertion of an intra-uterine device. The figure is rather meaningless since we do not know the rate of pelvic infection to be expected in a similar sample of women not wearing an intra-uterine device. The fluctuation of rate from 0-3 to 2-7 between different devices is difficult to interpret. Does this mean that in this particular respect the steel ring is greatly superior to the spiral? Probably not, since the steel ring series was heavily weighted by private patients and the spiral group by slum clinic patients from New York and Philadelphia, a segment of the population which naturally shows a high incidence of pelvic inflammation. Then, too, diagnostic criteria vary from clinician to clinician.

About one-third of the infections in the Tietze series were described as severe by the individual investigator, or the patient was ill enough to require hospitalization. Eleven per cent occurred within the 1st week after insertion. It is not known whether these represented a new infection, perhaps acquired with the insertion of a device, or the recrudescence of an old pelvic inflammatory infection.

There is no need to remove an intra-uterine device when pelvic inflammatory disease occurs for the condition is equally amenable to antibiotic therapy with the device in position or removed.

Uterine perforation

In a total of more than 16,000 patients seven cases of uterine perforation have been reported either while attempting to insert or remove a device. In each instance the device was extruded into the peritoneal cavity. Six remain in the peritoneal cavity where they appear to cause no harm, one was removed surgically, probably without necessity. A patient in Dr Lehfeldt’s clinic at Bellevue Hospital in New York shows a remarkable x-ray, a loop in the uterine cavity and another loop in the mid-abdomen. Several weeks after a symptomless uterine perforation in the process of inserting a loop, another loop was placed in the uterine cavity where it belongs and where it appears to be protecting the patient against impregnation.

Table 4

<table>
<thead>
<tr>
<th>Type of device</th>
<th>Pelvic inflammation per 100 patients per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiral</td>
<td>2.7</td>
</tr>
<tr>
<td>Loop</td>
<td>1.2</td>
</tr>
<tr>
<td>Bow</td>
<td>0.6</td>
</tr>
<tr>
<td>Steel ring</td>
<td>0.3</td>
</tr>
<tr>
<td>Nylon ring</td>
<td>1.0</td>
</tr>
<tr>
<td>Average</td>
<td>1.2</td>
</tr>
</tbody>
</table>
Pregnancy with the device in situ

Occasional pregnancies occur with an intra-uterine device in its proper position. Many of them proceed to term with the birth of a normal infant. The device is always extraovular and is delivered with the placenta and membranes. The abortion rate, not the prematurity rate, is somewhat higher in these cases. It is impossible to determine whether the increase in abortions is due to the presence of the device or whether patients with a pregnancy and an IUCD in situ are more prone to seek and achieve an induced abortion.

Obviously there are no grounds for therapeutic abortion on the basis that pregnancy occurs in a patient wearing an IUCD. The device can be left undisturbed in such a situation or, if tailed and easily withdrawn, it can be removed. There is no justification for attempting to withdraw an untalled device by a hook in these cases.

Carcinogenicity

There is no evidence on the basis of either reported cases, uterine biopsies or vaginal cytology, that an IUCD is carcinogenetic. Many studies are being conducted on this problem and uniform negative results have been reported. To be sure studies with the five new devices are not yet sufficiently long term (maximum 6 years) to rule out all possibilities of malignant influence.

Since the devices have little contact with the cervix or cervical canal—some have none at all—one would expect an IUCD to affect the occurrence of endometrial carcinoma, not cervical carcinoma. Dr Howard C. Taylor, Jr., when discussing this topic at the recent New York conference, pointed out that endometrial carcinoma is rarely encountered before the menopause. And the IUCD is not used post-menopausally. He also stated that the genesis of endometrial carcinoma seems in some way to be associated with an endocrine dyscrasia and not an irritative phenomenon.

Endometrial changes

In approximately 20% of cases endometrial changes are produced by intra-uterine devices, changes which are seldom clinically significant. The changes noted were submucosal oedema, localized haemorrhage and an associated increase in vascular channels in the superficial layers of the endometrium. There may be a diffuse sprinkling of plasma cells and lymphocytes with an occasional polymorphonuclear leucocyte. Endometrial changes are more frequently encountered in patients with symptomatic inter-menstrual bleeding. However endometrial changes seem to bear no relationship to the length of time the device has remained in position. The endometrium probably returns to normal after each menstrual period (see Willson, Ledger, Andros & Bollinger, 1965).

Fertility after removal

It has been widely observed that after its removal the previous use of an IUCD has no effect on subsequent fertility. In support of this Willson gives the data on seven patients who had worn spirals from 3 to 25 months. Five of the seven conceived within the 1st month, one in 2 months and one in 9 months.

E
Two of the five who conceived the first month had worn a spiral for 13 and 25 months respectively (Willson et al., 1965). Tietze (1965) states that in his cooperative study series 109 women had the IUCD removed in the hope of achieving pregnancy. Seventy per cent conceived within 6 and 90% within 9 months. This appears normal for a population of proved fertility.

**Use of IUCD for population control**

Intra-uterine devices are being used in many parts of the world to reduce the rapid growth of population. Pilot programmes are being carried on in Tunisia, Egypt, Chile, Pakistan, India, Puerto Rico, etc. Other areas are in the process of initiating programmes: Jamaica, Barbados, Turkey, Mexico, etc. The three regions with the most extensive programmes are Hong Kong, South Korea and Taiwan. Reports from South Korea state that 38,000 have been inserted within the past 6 months and it is planned by the Government to insert one million in a population of 30 million within the next 5 years. Taiwan with a population of 12 million plans to introduce 600,000 before 1970.

The advantages of an IUCD for population control are several. (1) A patient requires only sufficient motivation to have the device inserted. Thereafter no effort is necessary, since an IUCD works regardless of the individual patient's cooperation or even her wishes. (2) An IUCD is inexpensive. The cost of manufacture for the loop in the United States is 5.5 cents, less than sixpence. An introducer, which can be used for twenty loops costs 60 cents to make, the equivalent of 4 shillings. It is believed that in Hong Kong or some other cheap labour market the price will be one-fourth or one-fifth the U.S. manufacturing cost. (3) An IUCD does not inhibit lactation as do the oral contraceptives in some nursing women. (4) They have a very high rating of acceptability by patients.

In conclusion I should like to make several points. Some very simple clinical questions remained unanswered. Several were alluded to in the body of this address. How do you train doctors and how long does it take? What is the role of the general practitioner? Can one use para-medical personnel in the full, or even partial, conduct of an IUCD programme with safety? How early in the post-abortal or post-partum period can these devices be safely and effectively inserted? Are there contra-indications for their use? Should they be tailed or untailed? What is the best material from which to fashion them—polyethylene, stainless steel, nylon or one of the many other materials against which the body shows no tissue reaction? What is the most effective size and shape? How does an IUCD prevent pregnancy in the human female?

Then, too, questions remain on the administrative side. How many intra-uterine devices can a qualified person insert in the course of a day? Which is better in the field, to use a mobile unit or a fixed clinic to which patients come?

Much stress has been laid in my discussion on side effects—bleeding, menorrhagia, infection, perforation, etc., but I should like to point out that, as far as I am aware, of the 100,000 women or more supplied with modern IUCD devices, none has died therefrom. In all matters medical one must create a value equation. One has to equate with the side effects and dangers of both IUCDs and oral contraceptives the danger which would occur to the woman if one of these two highly effective methods were not used and she became pregnant.
Maternal mortality is very high in much of the world and having a child is not without real danger. Furthermore, some of the women impregnated would undoubtedly seek abortion. If you add the danger of viable pregnancy and delivery to the danger of abortion in that group of women who would seek it, their sum is far greater than the several potential dangers observed and theorized through the use of IUCDs or oral contraceptives.

People unqualified in this field, are prone to say, "Use some method other than the IUCD or the oral contraceptive and avoid all danger". They say, "let the man use a condom or the woman a cap or some other vaginal method". They fail to realize that many women—literally millions who will use an intra-uterine device or the pill—will not and perhaps cannot use any other contraceptive method. The great attraction of these two methods is that neither is applied at the time of intercourse; they are coitus independent.

I have a strong sense of optimism. I feel we can now talk about controlling a population through contraception. Much has been accomplished in two short years. When we observe the progress of the 2 years behind us and look forward to the even greater progress of the next 2 years my sense of optimism appears justified.

This address has been singularly free of levity so if you will allow me one more minute I should like to close with an anecdote.

I entered my office several months ago and as I passed my secretary she said, "Dr Guttmacher, something remarkable has happened". I said, "What do you mean?" She replied, "A man has been waiting 2 hours for you without an appointment". I said, "That's simple, he must be a process server". I had never been served with a process before in a long medical life, but I couldn't imagine anyone waiting that long unless he be a process server. I said "Show him in". A rather nondescript man ambled in; he was in no great hurry. He was a careful man, carried an umbrella and rubber shoes. He presented me with a paper, a process. Some woman had unfortunately died of cardiac arrest at a hospital with which I had been associated before I became President of Planned Parenthood and the heirs were suing every name on the hospital letter-head, a common American activity. Since I had never met a process server, I said to the careful chap, "Are you in a hurry?" He replied, "No", so I bade him sit down and chat. I plied him with many questions: "Do you enjoy your work? How much do you make? The chances for advancement?" His answers were unspirited and dull. I was bored, so I got up and began shaking his hand violently, as much as to say: get out. He rose, looked at me and said, "Doc, I like you". I replied, "You're crazy, you're daft. I don't like you nor do I dislike you. We have only spoken together for 2 minutes. You don't like or dislike me". He said, "Doc, you got me wrong. My wife's got one of your rings in and they're just wonderful".

REFERENCES


