Evaluation of a Plastic Intrauterine Loop in a Post Partum Family Planning Program

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THE WIDESPREAD use of plastic intrauterine devices in the national family planning programs of several developing countries is convincing evidence of a growing professional confidence in their acceptability, effectiveness, and relative safety (*1*). Because of the particular relevance of the intrauterine method to the family limitation or planning needs of underprivileged women in the United States, the method has achieved growing acceptance in public health clinics and hospitals where these women receive medical care (*2–5*). Prompted by favorable early reports (*6*), the Emory University Family Planning Program added the large size D loop (*A*) to the other available birth control methods in September 1964.

Clinic Setting

The loop was introduced into a post partum clinic serving the returning 50–60 percent of the 6,500 low-income women delivering each year at Grady Memorial Hospital, Atlanta, Ga. Added to these women were self-referred indigent mothers from the eligible community whose pregnancies and deliveries occurred more remotely. The referral potential of this group in the Atlanta area approaches 50,000 women. Family planning is an integral part of this clinic; the main emphasis is on providing contraceptive service. The women who, after a thorough class presentation of available methods, chose the loop and had it inserted were asked to report back routinely at the end of a year. Each woman was encouraged to report to the family planning nurse by phone any problems occurring in the meantime. If necessary, she could return to the clinic or, during nonclinic hours, to the emergency room.

The only contraindications to insertion were active pelvic inflammatory disease, a history of an undiagnosed menstrual disorder, and pregnancy. Cervicitis was not considered a contraindication; nor was a past history of pelvic inflammatory disease. Insertion was not restricted to women of high parity or to married women living with their husbands (*7*). Almost all the women were parous. A Papanicolaou smear was routinely taken, but insertion was not delayed until the test results were known.

Method

I took a 20 percent sample (every fifth name in the insertion register) of all women who had first insertions of the size D loop between September 1, 1964, and November 30, 1965. Women whose insertions had been made before the 6-week post partum visit were excluded. From the patients who had had the loop inserted 6

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weeks or more after termination of the last pregnancy, I selected 721 women. All their pertinent hospital records were reviewed, and if inconclusive, incomplete, or missing, the patient was telephoned or received a letter. A few home visits were made when other methods of collecting the pertinent information failed. The data were reviewed from 3 to 5 months after the study's closing date of November 30, 1965, thus allowing the inclusion of women with loop-related pregnancies who came late for prenatal care.

Followup to the termination date of November 30, 1965, was completed for 677 women by one or more of the review methods. An additional six women contributed to the group experience but could not be followed to the termination date. The 35 women (5.3 percent) who could not be traced at all after insertion have been excluded from the calculations. The group experience was calculated by a life table method for the first segment of use. The method and terminology have been described by Tietze (*8*).

Study Sample

Table 1 shows the distribution of the sample population by age, parity, and marital status. The median age was 24 years and the median parity was four. The sample was 91.8 percent Negro. Insertions of loop D at 6 weeks from termination of the last pregnancy totaled 560 (81.9 percent). The 123 remaining women in the sample had insertions at various longer intervals from the termination of last pregnancy. The general characteristics of the sample faithfully reflected the total population of some 3,600 women who had loops inserted during the 15-month study period.

Table 1. Age, parity, and marital status of patients in first-insertion sample

Characteristic	Number of patients	Percent of patients
Total	683	100.0
Age (years):		
15–19 [1]	146	21.4
20–24	216	31.6
25–29	155	22.7
30–34	105	15.4
35–39	43	6.3
50 and over	18	2.6
Parity:		
0	6	.9
1	113	16.5
2	125	18.3
3	104	15.2
4	111	16.3
5	71	10.4
6 or more	153	22.4
Marital status:		
Married	441	64.6
Single	148	21.7
Separated	78	11.4
Divorced	7	1.0
Widow	9	1.3

[1] Includes 3 patients under age 15.

Results

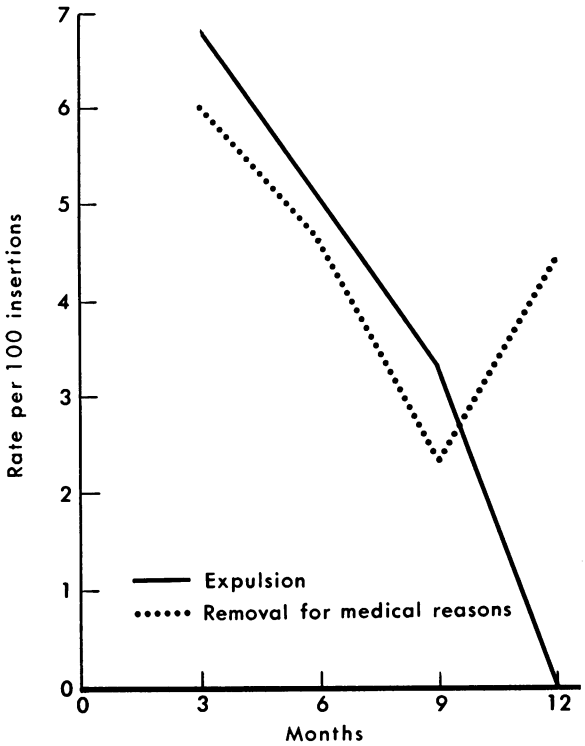
The cumulative net rates (with standard errors) for termination of use of loop D by women in our sample—per 100 first insertions—by the reasons for termination were as follows:

Type of termination	*Cumulative net rates*
Pregnancy	3.2±1.1
Expulsion	15.1±2.2
Removal:	
Medical reasons	17.4±2.3
Personal reasons	0.4±0.4
Nonrelevant reasons	5.5±1.4

Pregnancy. Seven intrauterine pregnancies occurred in the sample. Three of these took place after unnoticed expulsion of the loop and three others with the loop in situ. Whether the loop was present in one patient was undetermined. At the completion of the record review in May 1966, three patients had not delivered, three had experienced nonseptic abortions, and one had delivered a normal term infant. There were no extrauterine pregnancies. The pregnancy rate of 3.2±1.1 is not significantly different from that in other reports calculated in a similar manner (*9*, *10a*). Careful supervision might have lowered the rate by the detection of unnoticed expulsions, but requirements of professional time in a large public clinic prohibited frequent followup visits.

Expulsion. Sixty-one first segments were terminated by expulsion. Figures 1 and 2 show the relationship of expulsion to elapsed time since insertion. The decline in the rate of expulsion with time is in agreement with the decline noted in other reports (*9*, *10a*). The fact that no expulsions occurred in months 10 through 12 is probably related to the relatively small number of aggregate months of experience in those months. Of the 61 women who expelled the loop, 41 returned to the clinic—29 for reinsertion and

Figure 1. Net rates for expulsion [1] and medical removal of loop D by 3-month periods from insertion



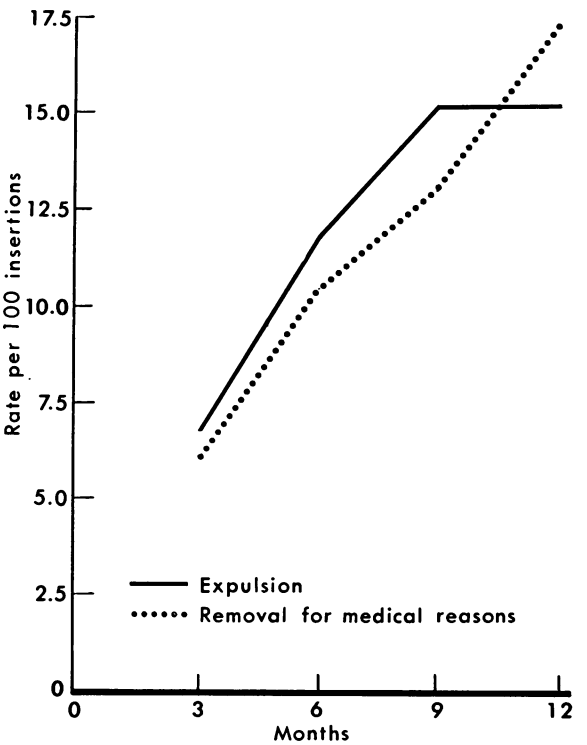
[1] No expulsions in months 10 through 12.

12 to try another contraceptive method. All but two of these women returned within a month of the expulsion. The 20 other women noticed the expulsion but did not return for a variety of reasons, including disenchantment, loss of clinic eligibility, and loss of interest. The three, and probably four, unnoticed expulsions leading to pregnancy are by definition not included with the expulsions. It is clear from this experience that the women in this unsupervised population noticed most of the expulsions. Clinical histories and examinations suggested that most of the expulsions occurred around the time of the menses and were complete rather than partial. In the orientation session, the women are strongly urged to examine themselves. Many anxious women were reassured by the fact that relatively few expulsions go undetected by the women affected. The use of a tailed device was particularly helpful to these women.

The cumulative net expulsion rate of 15.1 ± 2.2 is higher, but not significantly higher, than other reported rates (*9*, *10b*). The youthful age distribution and the time of insertion in relation to the previous pregnancy favored a higher expulsion rate in this population. On the other hand, its high parity favored a lower rate. Tietze, in an analysis of first insertions 3 months post partum or later, showed an inverse relationship between parity and age to expulsion rates for loop D. The age of the women, however, appeared to be the stronger factor. Expulsion rates for loop D according to the time of insertion approach differences that are significant when the interval of 5 to 8 weeks post partum is compared with 12 weeks or more (*10b*). The combined effect of the predominance of the younger patient and of insertions at 6 weeks post partum may well have been responsible for the somewhat higher expulsion rate in the Atlanta sample.

The effect of experience in the technique of insertion on expulsion rates was explored in the study sample. Two physicians inserted the bulk of the loops over the 15 months, although many other physicians were trained in the technique

Figure 2. Cumulative net rates for expulsion and medical removal of loop D by 3-month periods from insertion



during this time. No relationship was found between expulsions and the calendar month of insertion. Furthermore, no relationship was apparent between expulsion and the ease or difficulty of the insertion procedure as recorded by the two inserting physicians. Finally, expulsion apparently was not related to uterine position at the time of insertion.

Removal. The largest number of loop removals were for medical reasons. Figures 1 and 2 show the relationship of medical removal to elapsed time since insertion. Except for the increase at 10 through 12 months, when the aggregate months of experience with the loop were relatively small, the rate appeared to decline in time, a tendency which corresponds with that in other reports (*9*, *10a*). The reasons for the 56 medical removals varied, but in 38 cases they included irregular bleeding and cramps, separately or in combination. Sixteen removals were performed in connection with a diagnosis of infection, and two patients whose removals were classified as medical were pregnant at the time of insertion. One of these women delivered a normal term infant, and the other had not yet delivered at the conclusion of the study. In contrast to expulsion, medical removal was much less likely to be followed by reinsertion of a loop. Of the 56 women who had the loop removed for medical reasons, only four had loops reinserted, 30 changed to another method, and 20 did not return to the clinic after the removal.

Irregular bleeding is common following insertion. Lippes has estimated that 90 percent of the women having an insertion will experience some alteration in their menstrual pattern, typically a 2-day "warning" discharge or transient menorrhagia, or both (*9*). Members of the sample reported similar problems, which sometimes lasted many months if the woman hesitated to return to the clinic for fear her protection would be removed. Willson and co-workers also noted this hesitation among clinic patients (*11*). Although irregular bleeding and cramps were equally common reasons for removal, cramps was much more likely to be the presenting complaint.

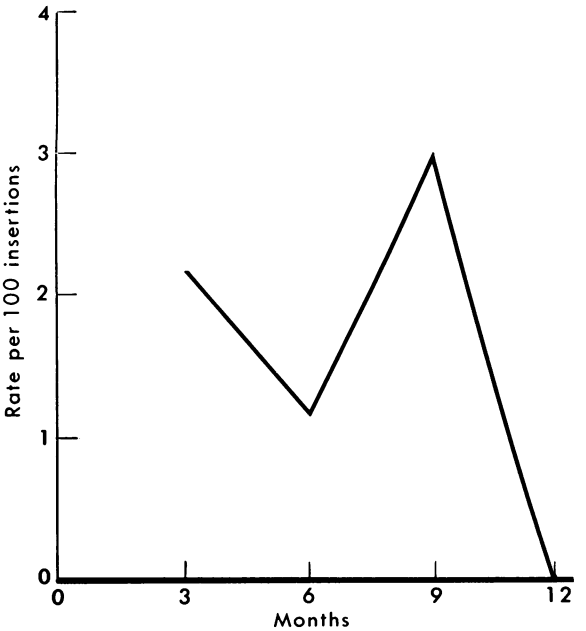
Table 2 presents, by complaint, the pattern of return visits following insertion. Cramps emerges as the most repetitive complaint in the sample and the one least likely to lead to removal of the loop. Of the 683 women in the sample, 262 (38.4 percent) made at least one revisit, usually unscheduled, before the termination date of the study or before individual termination of use of the loop. Sixty-five women (9.5 percent of the total) made more than one revisit to the various hospital clinics for loop-related complaints. Women in the sample made 424 revisits over the study period. The fact that only two of these 424 recorded visits were to private practitioners suggests the reliance of the study group on Grady Memorial Hospital.

The cumulative medical removal rate of 17.4 $\pm$2.3 is higher, but not significantly higher, than that reported by others (*9*, *10a*). Tietze has shown that the medical removal rate for loop D because of bleeding or pain declines with increasing age and parity (*10b*). Another factor in elevating the medical removal rate of this sample was the variety of clinics and physicians

Table 2. Complaints of study women on visits to clinic or emergency ward subsequent to insertion of loop D and before termination date of study, by number of times complaint was made on revisits

Complaint	Revisits					Total visits
	1st	2d	3d	4th	5th	
Cramps	68	25	11	2	3	174
Bleeding	55	7	5	0	1	89
Routine checks	72	7	0	0	0	86
Expulsion of loop (presumed or actual)	47	1	0	0	0	49
Bleeding and cramps	10	3	0	0	0	16
Other and unknown	10	0	0	0	0	10
Total	262	86	48	8	20	424

Figure 3. Rates for acute pelvic inflammatory disease [1] by 3-month periods from insertion of loop D



[1] No cases in months 10 through 12.

within Grady Memorial Hospital to whom patients may present complaints. Only 45 percent of all revisits were made to the clinic where the orientation had been given and the insertion performed. The patient found it simpler to go to the emergency room which operates around the clock and where no appointment is necessary. Although attempts were made to instruct all the rotating emergency room physicians, a number of loops were removed unnecessarily. A number of other avoidable removals were done in connection with the diagnosis of infection. Such occurrences became more rare as house officers were encouraged to treat the infection but refer the patient back to the family planning clinic. The experience with removals for medical reasons did not suggest that experience in the technique of insertion, subjective impressions of ease or difficulty of insertion, or the uterine position at insertion were significant.

Only twice were loops removed for personal reasons. One spouse objected, and another patient feared cancer. Both patients selected another birth control method. The cumulative rate of removal for personal reasons in our sample is lower than that reported elsewhere (*10a*). This low rate probably reflects the population's confidence in the method and a tenacious desire for effective birth control.

Twenty-five loops were removed for reasons not relevant to acceptability of the loop. Twenty-two of these removals were incidental to surgery, usually in the first 3 months after insertion. In 20 instances, the operation was a hysterectomy and in two instances, minor procedures. Two patients died of unrelated causes, one of rupture of a congenital cerebral aneurysm and another of cirrhosis with erosive esophagitis and gastrointestinal hemorrhage. The remaining patient requested removal so that she could become pregnant. Removal for desired pregnancy will probably remain infrequent because the majority of these women are more interested in family limitation than in family planning.

Pelvic inflammatory disease. To evaluate carefully the occurrence of acute pelvic inflammatory disease, I studied all putative cases and included only those satisfying the following clinical criteria: an oral temperature of 99.8° F. or greater; both cervical motion tenderness and unilateral or bilateral adnexal tenderness on physical examination. Adnexal masses were not a requirement. Laboratory tests were also not required and were not performed in most of the clinics where this diagnosis was made. The value of cervical cultures and smears for detecting gonococci is doubtful in any case because of frequent false-negative results. Furthermore, there is no evidence that all cases of acute pelvic inflammatory disease are etiologically related to one organism (*12–14*).

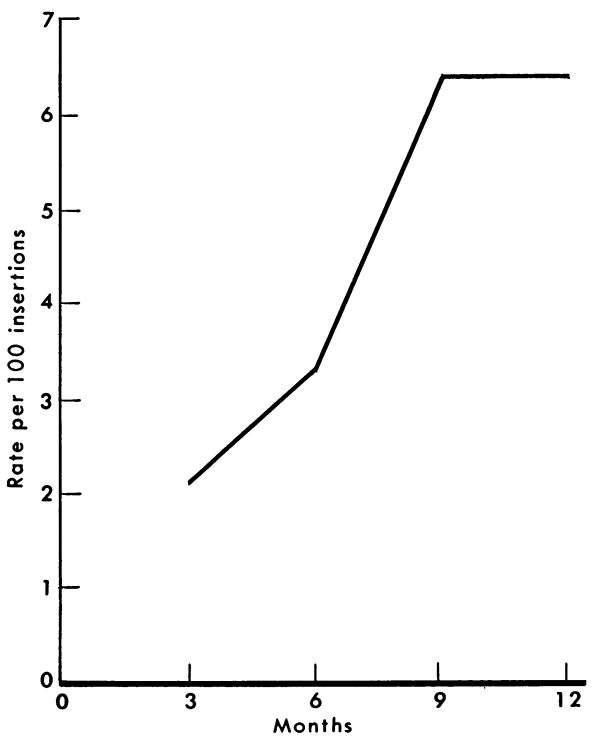
Based on these criteria, 59 episodes diagnosed as acute pelvic inflammatory disease were reduced to 22 "definite" acute episodes in 22 patients. The annual cumulative rate per 100 first insertions was 6.7 ± 1.5. The monthly rates in figures 3 and 4, in contrast to the rates for expulsion and medical removal, were not highest near the time of insertion. None of the 22 definite episodes required hospitalization of the patient, and all but five patients were successfully treated with the loop in place.

Although the rate for acute pelvic inflammatory disease in the study sample is greater than in other studies, rates cannot be compared without uniform clinical criteria and sharper

definitions of socioeconomic status. In reports including substantial numbers of private patients or which exclude patients with a past history of pelvic inflammation, the rates are less than 1.5 percent (*7, 9, 11*). In the pooled data of the Cooperative Statistical Program for the Evaluation of Intrauterine Contraceptive Devices, the rate for loop D is somewhat higher—2.1±1.2. For populations similar in socioeconomic status to our sample, Willson and coworkers reported 43 upper genital tract infections in 623 women who wore plastic coils for 5,606 months, or a rate of 7.7 percent (*6a*).

It is not known whether the rate reported for our sample is identical with, or represents an increase or decrease over, the expected rate of acute pelvic inflammation in this population. The occurrence of acute episodes of pelvic infection appears to be randomly distributed in time, and it is hard to make a case for increased risk at the time of insertion on the basis of this sample. Almost all acute episodes can be treated with the loop in situ, and the clinically severe case is unusual.

Figure 4. Cumulative rates for acute pelvic inflammatory disease by 3-month periods from insertion of loop D



Discussion

A cumulative net continuance rate for our sample at 1 year, excluding nonrelevant removals and patients lost to complete followup, was 63.8±2.9 per 100 first insertions of loop D. This figure understates the effective continuance rate, since there were reinsertions of the loop. The main reasons that this rate is lower than that reported by Tietze (*10a*) for loop D are the higher rates for expulsion and medical removal in the Atlanta sample. The higher expulsion rates appear to be due to the younger age distribution and the generally earlier insertion time with respect to the most recent termination of pregnancy. The higher medical removal rates appear to be due to removals that might have been avoided if all patients had come back to the clinic where the loop had been inserted. Thorough orientation of all hospital physicians is necessary in the charity hospital setting. Nevertheless, the cumulated continuance rate for the Atlanta sample exceeds the 1-year oral contraceptive continuance rate of 51 percent which characterized a smaller sample of the Grady Memorial Hospital population in 1964–65 (*4*).

Even though offering family planning to women at 6 weeks post partum results in a higher expulsion rate for those accepting the loop, the post partum setting has many advantages. The risk of conception rises rapidly after the first menstrual period following delivery (*15*). Motivation to accept a family planning method is high at this time; family planning services can increase the rate of return of patients for post partum treatment. Finally, the cost of adding a service oriented toward the intrauterine method in the post partum setting is less than for establishing a separate setting for the service (*4*).

It is disconcerting that 20 of the 61 women experiencing expulsions and 20 of the 56 having removals (5.9 percent of the total sample) did not return for further contraceptive counseling. Some of the 40 women who did not return may have lost their hospital eligibility after the first insertion, but more frequent followup than at 1 year from insertion might have helped these women. Routine followups do not require medical consultation unless special research procedures must be performed. White has suggested

the use of public health nurses with disposable specula for string checks and to provide general motivational support to the patient in her home (*16*). Such a procedure, although desirable, multiplies operating expenses. No medical hazards appeared to be attributable to the clinic's policy of routine 1-year followup with other visits as needed. In the absence of medical indications for close followup, the staff considered that the administrative simplicity and low costs possible in a large clinic justified continuation of the followup procedure.

During the 15 months of the review, 70 percent of all the women in the program who chose contraception chose the loop. Later, however, the loop acceptance rate began to fall, reaching 35 percent by July 1966. The reasons for the decline are not obscure. A pregnant woman with a loop in situ is most conspicuous, particularly since prenatal and post partum clinics are held at the same time and place. Group discussions at the clinic, informal talk in the community (like I overheard on a city bus), and interaction on the delivery ward are all damaging to loop acceptance. In the initial orientation, care must be taken not to stimulate unreasonable expectations of success. The statistical effectiveness of the loop, its simplicity and economy, and the lack of the need for intensive continuing motivation once it is inserted recommend the method in the public health setting. Mothers who have already exceeded a desired number of births cannot be expected to think statistically, comparing the few failures with the many successes. Further improvements in design, however, may be expected to improve future acceptance by minimizing expulsions and side effects.

Summary

In a sample of a low-income, fertile population in Atlanta, Ga., pregnancy rates per 100 first insertions of an intrauterine plastic loop (size D) were 3.2±1.1, and expulsion rates were 15.1±2.2. The net rate of removal per 100 first insertions was 17.4±2.3 for medical reasons and 5.5±1.4 for reasons not relevant to the acceptability of the loop. The cumulated net continuance rate at 1 year was 63.8±2.9 per 100 first insertions. This rate underestimates effective continuance because reinsertions were made during the study period, but it still exceeds the 51 percent continuance rate for oral contraceptives in the same population.

Although acceptance of intrauterine contraception decreased in time, it remains the most effective method of birth control offered to this population. Continued refinements in the design of intrauterine devices so that side effects will occur less frequently should increase the acceptance and prolong the use of these devices in the future. More intensive followup of the women accepting the devices, wherever possible, might also prolong use.

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EQUIPMENT REFERENCE

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Continued Decline in Infant Mortality Rate

The nation's infant mortality rate—the number of deaths under 1 year of age per 1,000 live births—continued to decline in the first half of 1967, reaching a new low of 22.9.

Data compiled by the National Center for Health Statistics, Public Health Service, show a decline in the infant mortality rate for every year since 1958, except for 1962, which had the same rate as 1961 (25.3). From 1958 to 1966 this rate declined from 27.1 to 23.4 per 1,000, a drop of 13.7 percent.

The rate for the first 6 months of 1967 was lower than for the corresponding period in 1966. Since the full-year rate for 1966 was the lowest ever recorded in the United States, it is hoped that a new low can be achieved in infant mortality in 1967.

A number of factors will have the effect of continuing to lower the infant mortality. The factors include increased family income with better nutrition and health care, increased emphasis on early access to high-quality medical care, greater availability of prenatal medical services, the spread of family planning services, and a higher level of education.

Influenza and pneumonia (except pneumonia of the newborn) were the only causes of death among infants that declined markedly during the first half of 1967, compared to the same period in 1966. This undoubtedly reflects the fact that there has been no influenza outbreak this year comparable to the outbreak in the late winter in 1966. With this exception, the decline from almost every other cause of death appears to have been a slight but general one. The decline has been approximately the same for the white and nonwhite population, but the rate for the nonwhite group is still nearly double that of the white population.

The United States ranks only 15th (tied with Canada) among the major nations of the world in 1965, the latest year for which a ranking is available. The United States thus has a higher infant mortality rate than Sweden (12.4), the Netherlands (14.4), and Norway (16.8).