CLINICAL EXPERIENCE WITH INTRA-UTERINE DEVICES: PREGNANCIES, EXPULSIONS AND REMOVALS

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Summary. Clinical experience, mostly in the United States, with five major types of intra-uterine devices, computed under the Cooperative Statistical Program of the Population Council, covered 27,575 women with 477,157 months of use as of mid-1967. The devices studied were: the loop, spiral, bow, stainless steel ring and the double coil. The principal reasons for discontinuation of use were removals for bleeding or pain, and expulsion, with the highest risk in the 1st year of use. Declines in expulsions and pregnancies were more closely associated with increasing age than with parity, while removal rates declined moderately with increasing parity.

The data presented in this report cover clinical experience with intra-uterine devices (IUDs), largely in the United States, for 27,575 women with an aggregate of 477,157 woman-months of use. The statistics are based on individual case records submitted to the Cooperative Statistical Program for the Evaluation of Intra-uterine Devices (CSP) by thirty investigators, twenty-six institutional and four in private practice, over a 4-year period, from July 1963 to June 1967.

The CSP was initiated in mid-1963 by the National Committee on Maternal Health at the request and with the financial assistance of the Population Council. On 1st January 1967 the functions of the National Committee on Maternal Health were transferred to the Council's Bio-Medical Division, under whose auspices the operation of the CSP continues.

Five major types of IUDs in ten sizes are being studied in the CSP: the Lippes loop in four sizes, A, B, C and D, from smallest to largest; the Margulies spiral (Gynekoil) and Birnberg bow, in two sizes each; and the stainless steel ring of Hall and Stone and the double coil (Saf-T-Coil) in a single size. The larger loops (C and particularly D) were the most frequently used devices, accounting for 46% of all insertions (Table 2). Loop D was the only device for which sufficient data were available for tabulations involving extended durations, annual rates and detailed cross-tabulations (Tables 7 and 9). A residual group of 'other devices' (Tables 2 to 4) includes experimental models abandoned after a period of trial and new devices recently added to the programme.

As shown in Table 1, two out of three women were under 30 years of age at the time of their first insertion, and most of the remaining third were under 40 years. The overwhelming majority (97%) had given birth to one or more children, with an average of 3.1 live births per mother.

The number of first insertions and re-insertions and aggregate woman-months of use are presented in Table 2. Of the 27,575 women with first insertions, 22,230 had one insertion only and 5245 women had at least two insertions. The 6756 re-insertions represented 4192 cases with two insertions, 773 cases with three insertions and 280 cases with four or more insertions.

TABLE 1
NUMBER OF WOMEN BY AGE AND PARITY AT
FIRST INSERTION

<i>Age (years)</i>	<i>Number</i>	<i>Parity</i>	<i>Number</i>
15-19	2,552	0	910
20-24	8,830	1	5,088
25-29	7,620	2	7,283
30-34	4,799	3	5,566
35-39	2,608	4	3,704
40-44	993	5	2,077
45-49	173	6 or more	2,947
Total	27,575		27,575

TABLE 2
FIRST INSERTIONS AND RE-INSERTIONS AND WOMAN-
MONTHS OF USE, BY TYPE AND SIZE OF DEVICE

<i>Device</i>	<i>Insertions</i>			<i>Woman- months of use</i>
	<i>First</i>	<i>Later</i>	<i>Total</i>	
Loop A	1,022	265	1,287	22,367
Loop B	1,361	128	1,489	13,896
Loop C	3,858	1,306	5,164	67,485
Loop D	8,305	2,413	10,718	170,858
Small spiral	452	98	550	7,663
Large spiral	2,223	313	2,536	39,010
Small bow	1,482	172	1,654	22,540
Large bow	2,276	659	2,935	52,769
Steel ring	1,739	376	2,115	38,134
Double coil	2,804	321	3,125	14,586
Other	2,053	705	2,758	27,849
Total	27,575	6,756	34,331	477,157

Of the 27,575 women in the CSP, 11,520 were classified as active users as of 30th June 1967, of whom one out of two had more than 2 years of experience; 3603 had been released from observation as users at earlier dates; and 12,452 were classified as non-users or inactive cases. Of the last group, 8723 were closed because of pregnancy, expulsion, or removal of the IUD, and 3729 were lost to follow-up.

Numbers of events and closures

Numbers of events (pregnancies, expulsions, removals), by type and size of IUD, are shown in Table 3. Removals for medical reasons (5353) accounted for more than one third of all events (15,479). Bleeding or pain, often reported together (3942), was the most frequent cause for removal of the IUD. Other medical reasons for removal (1411) cover a miscellany of complaints, some of which are not related to the device.

The second most frequently reported event was expulsion (4818). Complete expulsion into or from the vagina made up 85% of the reported expulsions; an additional 15% were partially or completely in the cervical canal and had to be removed. About 80% of the expulsions were noted by the women and 20% were unnoticed.

TABLE 3
EVENTS BY TYPE OF TERMINATION, BY TYPE AND SIZE OF DEVICE

Device	Pregnancies	Expulsions	Reasons for removals					All events
			Bleeding and/or pain	Other medical	Planning pregnancy	Other personal	Investigator's choice	
Loop A	93	255	128	66	49	63	340	994
Loop B	39	225	144	54	13	34	10	519
Loop C	143	897	552	182	111	117	20	2,022
Loop D	332	1,414	1,447	462	287	335	121	4,398
Small spiral	23	174	53	23	24	54	11	362
Large spiral	48	605	429	250	75	119	40	1,566
Small bow	192	74	182	49	43	74	775	1,389
Large bow	197	83	407	148	84	96	176	1,191
Steel ring	141	353	183	58	91	60	32	918
Double coil	36	362	214	56	7	27	8	710
Other	92	376	203	63	52	77	547	1,410
Total	1,336	4,818	3,942	1,411	836	1,056	2,080	15,479

Investigator's choice (2080) covers, mainly, removals involving research procedures or the replacement of a device by another considered more effective. Removals for personal reasons (1892) include 836 for planning pregnancy and 1056 for other personal reasons, including fear, lack of confidence, objection of husband or of family physician, separation from husband, and similar reasons.

Of the 1336 pregnancies reported, two out of three occurred with the IUD *in situ*, and the remaining one third with the position of the device at the time of conception undetermined.

Closures because of pregnancy, expulsion or removal, by type and size of device, are shown in Table 4. The numbers of closures are smaller than the numbers of corresponding events (Table 3), especially for removals at the investigator's choice and for expulsions, because many events were followed by re-insertions. One out of two closed cases was terminated for medical reasons; one out of five, for expulsion; and about one in eight, for pregnancy.

TABLE 4
CLOSURES BY TYPE OF TERMINATION, BY TYPE AND SIZE OF DEVICE

Device	Pregnancies	Expulsions	Reasons for removals					All events
			Bleeding and/or pain	Other medical	Planning pregnancy	Other personal	Investi- gator's choice	
Loop A	76	84	85	36	32	52	6	371
Loop B	36	69	135	42	13	32	1	328
Loop C	127	285	496	141	95	109	4	1,257
Loop D	285	487	1,275	331	227	301	21	2,927
Small spiral	16	53	36	17	18	45	2	187
Large spiral	39	192	280	131	62	95	4	803
Small bow	158	17	110	35	33	64	9	426
Large bow	160	38	343	121	67	82	18	829
Steel ring	126	121	154	52	71	56	10	590
Double coil	34	140	205	52	7	27	1	466
Other	73	148	162	47	38	67	4	539
Total	1,130	1,634	3,281	1,005	663	930	80	8,723

Event rates and closure rates

All of the rates shown in this report are net rates of events and closures computed by means of multiple decrement life table procedures. The application of life table methods to contraceptive behaviour was developed jointly by Robert G. Potter and the senior author (C.T.) in the United States, and independently by Benjamin Viel in Chile.

The great majority of the rates shown here is based on the entire experience with each type and size of IUD following first and later insertions; one table is limited to experience following first insertions only (Table 10), and one table to later insertions only (Table 11). In all tables, the notation 0·0 indicates a rate of less than 0·05, including a zero rate. Rates based on less than 1200 woman-months of use are not shown. Insertions during the first 4 weeks after a delivery or abortion are excluded from all tables except Table 10 and nulliparous women are excluded from Tables 8 to 10 (Potter, 1963, 1966, 1967; Tietze, 1965, 1967; Viel, 1966).

Cumulative event and closure rates by type and size of device and type of termination, after 1 year of use and after 2 years, are shown in Tables 5 and 6. Closure rates are consistently lower than event rates because, as has been stated, there are fewer closures than events. For instance, by the end of the 2nd year, 11·5% of all women wearing Loop D had experienced a first expulsion, but only 3·6% had discontinued its use for this reason. By subtracting the closures (3·6%) from the events (11·5%) it can be seen that 7·9% of the women wearing Loop D (more than two out of three women with a first expulsion) had the loop re-inserted after a first expulsion. Since only 2·3% of all cases were closed after a later expulsion, it follows that 5·6% of the women, or one half of those with a first expulsion, continued to wear the loop after one or more re-insertions for at least 2 years after the first insertion.

At the end of the 2-year period, as well as after 1 year, pregnancy rates and expulsion rates were higher for the smaller devices than for the larger ones of

TABLE 5
CUMULATIVE RATES OF EVENTS AND CLOSURES PER 100 USERS, BY TYPE OF TERMINATION: ALL DEVICES BY TYPE AND SIZE, 1 YEAR OF USE

Type of termination	Loops				Spirals		Bows		Steel ring	Double coil
	A	B	C	D	Small	Large	Small	Large		
<i>Events:</i>										
Pregnancies	5.4	3.0	2.7	2.6	4.2	1.5	10.8	4.7	6.6	2.3
Expulsions:										
First	20.0	16.8	14.0	9.6	29.4	19.9	3.4	1.6	14.8	14.1
Later	4.0	2.0	4.8	3.1	8.8	5.8	0.9	1.0	3.2	3.8
Removals:										
Bleeding and/or pain	8.1	10.9	10.9	11.6	9.3	14.3	9.5	10.2	7.6	13.2
Other medical	4.1	4.2	3.2	3.5	4.0	8.0	2.7	4.1	2.0	3.0
Planning pregnancy	2.0	0.9	1.0	1.1	1.4	1.0	1.3	0.9	1.5	0.4
Other personal	4.3	2.2	1.9	2.2	9.1	3.9	3.4	1.6	1.4	1.2
<i>Closures:</i>										
Pregnancies	4.9	2.8	2.4	2.4	2.9	1.3	8.8	3.9	6.2	2.2
Expulsions:										
First	5.7	4.3	4.2	2.9	8.6	6.1	0.9	0.6	4.6	5.8
Later	2.1	1.1	1.8	1.8	3.6	1.8	0.1	0.4	1.7	2.0
Removals:										
Bleeding and/or pain	5.5	10.3	9.8	10.3	7.0	9.6	6.1	8.8	6.7	12.8
Other medical	2.2	3.4	2.2	2.5	2.7	4.2	1.8	3.7	1.9	2.9
Planning pregnancy	1.1	0.9	0.7	0.7	0.8	0.9	0.9	0.6	1.2	0.4
Other personal	3.6	2.1	1.8	1.9	7.0	3.1	2.9	1.3	1.4	1.2
Total closures	25.1	24.9	22.9	22.5	32.6	27.0	21.5	19.3	23.7	27.3
Continuation rate	74.9	75.1	77.1	77.5	67.4	73.0	78.5	80.7	76.3	72.7
Woman-months of use	8,742	9,436	30,397	70,990	3,786	18,744	14,827	24,637	15,091	12,015

TABLE 6
CUMULATIVE RATES OF EVENTS AND CLOSURES PER 100 USERS, BY TYPE OF TERMINATION: ALL DEVICES
BY TYPE AND SIZE, 2 YEARS OF USE

Type of termination	Loops				Spirals		Bows		Steel ring
	A	B	C	D	Small	Large	Small	Large	
<i>Events:</i>									
Pregnancies	9.6	6.0	4.4	4.2	5.0	2.4	16.2	7.7	9.1
Expulsions:									
First	23.0	20.7	17.1	11.5	33.2	23.6	4.8	1.9	18.3
Later	4.9	4.0	7.1	4.4	10.5	7.1	1.3	1.2	4.6
Removals:									
Bleeding and/or pain	13.0	18.3	16.4	17.5	13.1	21.1	16.1	16.3	11.9
Other medical	7.1	5.7	5.5	5.9	5.9	11.8	4.4	5.9	3.4
Planning pregnancy	4.0	1.7	3.2	2.9	3.6	3.1	4.1	2.7	4.5
Other personal	6.8	4.0	3.4	3.8	12.0	5.8	7.3	3.4	3.3
<i>Closures:</i>									
Pregnancies	8.1	5.5	4.0	3.6	2.9	1.9	13.1	6.2	8.0
Expulsions:									
First	6.9	6.3	5.1	3.6	9.7	7.4	1.2	0.8	5.4
Later	2.5	2.2	2.9	2.3	4.0	2.1	0.3	0.5	2.3
Removals:									
Bleeding and/or pain	8.5	16.6	14.9	15.4	8.7	13.8	9.2	13.6	10.0
Other medical	3.4	4.6	4.2	4.3	4.2	6.4	3.5	4.8	3.1
Planning pregnancy	2.1	1.7	2.6	2.1	2.0	2.4	3.3	2.0	3.6
Other personal	5.4	3.8	3.1	3.3	9.5	4.5	6.2	3.0	3.1
Total closures	36.9	40.7	36.8	34.6	41.0	38.5	36.8	30.9	35.5
Continuation rate	63.1	59.3	63.2	65.4	59.0	61.5	63.2	69.1	64.5
Woman-months of use	13,407	12,126	49,277	118,986	5,915	29,324	19,500	41,454	25,790

the same type, while removal rates were not significantly associated with size of device, except for the spiral. The experience with the smaller devices has resulted in a general limitation of their use to nulliparous women only. Among the larger IUDs, and those of a single size, the spiral had the lowest pregnancy rate, followed by the double coil and the loop, and the steel ring and the bow had the highest. The expulsion rate was lowest for the bow, followed by the loop (Loop D) and, at some distance, by the double coil and steel ring. The spiral had the highest expulsion rate. The steel ring had the lowest removal rate for medical reasons, followed by the bow, loop and double coil; the spiral had the highest. Continuation rates were quite similar for the various devices with about two out of three women remaining users at the end of the 2-year period.

Annual and cumulative rates of events and closures for a period of 5 years by type of termination are shown for Loop D in Table 7. The annual rates per 100 users at the beginning of each year decreased with each year of use for most events and closures, especially for such major reasons for termination as expulsions and removals for medical reasons, while the rates of removal for planning pregnancy increased through the 4th year. The result was that annual closure rates declined each year; from 22.5% for the 1st year to 7.1% for the 5th year. The cumulative closure rates, up to the end of each successive anniversary of first insertion increased from 22.5% for the 1st year to 53.9% for the 5th year; and its complement, the continuation rate, declined from 77.5% to 46.1% over the same period of time.

Age and parity

Cumulative rates of events by age and parity of women at first insertion are shown in Table 8 for a 2-year period for five major devices: Loops C and D, the large spiral, the large bow and the steel ring. Expulsion rates and, to some extent, removal rates tended to decline for each device with both age at insertion and with parity. Some decline in pregnancy rates was observed with age, as might be expected, but no association was observed with parity. Closure rates declined sharply with increasing age at insertion for each device, and almost as sharply with increasing parity. About three out of four older women and women of high parity were continuing users after 2 years compared with about one out of two of the young women and of those of low parity.

In spite of the large differences in expulsion rates between younger women and older women, standardization for age had little effect on the levels of the rates for each type and size of IUD, because the age distribution of the women was quite similar between devices. The following figures show cumulative event rates of first expulsion at the end of 1 year and after 2 years, adjusted for age, which can be compared with the rates in Tables 5 and 6.

<i>Device</i>	<i>1st year</i>	<i>2nd year</i>
Loop C	14.5	17.7
Loop D	10.0	11.9
Large spiral	21.5	25.5
Large bow	1.6	1.9
Steel ring	15.5	19.0
Double coil	13.5	—

TABLE 7
ANNUAL AND CUMULATIVE RATES OF EVENTS AND CLOSURES BY TYPE OF TERMINATION, PER 100 USERS:
LOOP D, 5 YEARS

Type of termination	Annual rates					Cumulative rates				
	1st year	2nd year	3rd year	4th year	5th year	1st year	2nd year	3rd year	4th year	5th year
<i>Events:</i>										
Pregnancies	2.6	2.0	1.1	1.3	0.8	2.6	4.2	5.0	5.7	6.1
Expulsions:										
First	9.6	2.5	1.6	0.7	0.2	9.6	11.5	12.5	13.0	13.1
Later	3.1	1.7	1.1	0.4	0.0	3.1	4.4	5.1	5.3	5.3
Removals:										
Bleeding and/or pain	11.6	7.6	7.5	4.5	2.2	11.6	17.5	22.4	24.9	26.0
Other medical	3.5	3.0	2.1	1.2	2.6	3.5	5.9	7.3	7.9	9.2
Planning pregnancy	1.1	2.4	2.5	2.7	2.2	1.1	2.9	4.6	6.1	7.2
Other personal	2.2	2.1	1.8	2.3	1.5	2.2	3.8	5.0	6.3	7.0
<i>Closures:</i>										
Pregnancies	2.4	1.6	0.9	1.2	0.3	2.4	3.6	4.2	4.9	5.0
Expulsions:										
First	2.9	0.9	0.5	0.5	0.2	2.9	3.6	3.9	4.2	4.3
Later	1.8	0.6	0.5	0.2	0.0	1.8	2.3	2.7	2.8	2.8
Removals:										
Bleeding and/or pain	10.3	6.5	6.5	4.1	1.6	10.3	15.4	19.7	21.9	22.7
Other medical	2.5	2.3	1.4	0.8	1.6	2.5	4.3	5.2	5.7	6.5
Planning pregnancy	0.7	1.8	2.3	2.7	1.9	0.7	2.1	3.6	5.1	6.1
Other personal	1.9	1.8	1.7	2.3	1.5	1.9	3.3	4.5	5.7	6.5
Total closures	22.5	15.5	13.8	11.8	7.1	22.5	34.6	43.8	50.3	53.9
Continuation rate	77.7	84.5	86.2	88.2	92.9	77.5	65.4	56.2	49.7	46.1
Woman-months of use	70,990	47,996	31,310	11,424	3,130	70,990	118,986	150,296	161,720	164,850

A cross-tabulation by age by parity after 2 years of use for Loop D is shown in Table 9. Pregnancy rates declined sharply with age within each parity group and increased somewhat with prior parity within most age groups. A well-defined decline in expulsion rates was noted with age within each parity group and some decline with parity at the younger ages. Removal rates declined moderately with parity within each age group and showed no association with age within parity. All in all, age emerged as a more important factor than parity.

Interval since last confinement

Cumulative rates of events by type of termination by interval between first insertion and most recent confinement are shown for Loops C and D, the large spiral, the large bow and the steel ring in Table 10. Expulsion rates were highest for insertions during the early *post partum* period (first 10 days); this information is available for the loops only. For all devices, expulsion rates were slightly higher for insertions during the late *post partum* period (5 to 12 weeks), than after 3 months *post partum*. Pregnancy rates and removal rates were not significantly associated with the interval between insertion and confinement.

Re-insertions

Net cumulative rates of termination at the end of 2 years are shown separately per 100 first re-insertions following expulsion and those following removal for selected devices (Table 11). The expulsion rate was much higher for women who had experienced a previous one than for women with no previous expulsion. Expulsion rates following removal were quite low. About two out of five women with a previous expulsion retained the device for at least 2 years after re-insertion. For each device, there was little difference between the removal or

TABLE 8

CUMULATIVE RATES OF EVENTS BY TYPE OF TERMINATION AND OF CLOSURES, PER 100 USERS, BY AGE AND BY PARITY AT FIRST INSERTION: SELECTED DEVICES, 2 YEARS OF USE

Termination of events and total closures	Age at insertion				Parity		
	15 to 24	25 to 29	30 to 34	35 to 49	1 or 2	3 or 4	5 or more
<i>Loop C</i>							
Pregnancies	5.6	4.9	4.1	1.3	5.3	3.9	3.5
Expulsions:							
First	25.4	15.9	11.1	6.4	20.9	14.8	12.2
Later	12.3	6.1	3.3	1.2	9.0	6.4	4.3
Removals:							
Bleeding and/or pain	18.8	15.4	15.1	12.8	20.1	14.8	9.4
Other medical	6.3	6.3	4.6	4.1	5.4	6.0	5.6
Planning pregnancy	5.4	2.9	1.0	0.2	5.9	0.9	0.7
Other personal	4.0	2.5	3.9	2.0	3.9	3.0	2.0
Total closures	47.4	34.9	30.4	20.1	45.9	31.6	23.2
Continuation rate	52.6	65.1	69.6	79.9	54.1	68.4	76.8
Woman-months of use	17,121	13,945	8,801	8,723	20,570	18,456	9,564

TABLE 8 (continued)

Termination of events and total closures	Age at insertion				Parity		
	15 to 24	25 to 29	30 to 34	35 to 49	1 or 2	3 or 4	5 or more
<i>Loop D</i>							
Pregnancies	5.7	4.7	2.9	1.6	4.4	4.2	3.9
Expulsions:							
First	17.4	9.9	7.1	5.4	14.4	10.2	7.2
Later	7.5	4.1	2.3	0.7	5.6	4.2	2.3
Removals:							
Bleeding and/or pain	18.0	17.5	16.7	16.6	19.5	16.9	13.6
Other medical	6.6	5.7	4.8	5.6	5.9	6.1	5.4
Planning pregnancy	5.0	2.7	1.0	0.6	5.4	1.5	0.4
Other personal	4.7	3.6	3.5	2.5	3.9	3.5	4.5
Total closures	42.3	33.1	28.4	25.4	40.8	31.3	26.1
Continuation rate	57.7	66.9	71.6	74.6	59.2	68.7	73.9
Woman-months of use	40,885	33,815	23,558	19,372	48,046	45,060	24,524
<i>Large spiral</i>							
Pregnancies	2.3	3.0	1.8	2.0	1.7	2.7	2.7
Expulsions:							
First	33.9	23.4	21.5	9.3	26.0	22.7	21.5
Later	10.8	6.2	5.5	3.1	7.9	7.2	5.3
Removals:							
Bleeding and/or pain	23.6	21.4	21.4	16.3	25.6	22.1	13.2
Other medical	12.1	12.6	11.4	10.9	13.1	10.0	12.0
Planning pregnancy	4.4	3.5	2.6	0.7	6.3	1.4	0.7
Other personal	8.8	4.9	5.2	2.9	6.6	5.2	5.3
Total closures	47.1	37.9	34.9	29.3	45.9	36.5	30.6
Continuation rate	52.9	62.1	65.1	70.7	54.1	63.5	69.4
Woman-months of use	8,172	7,996	6,736	5,572	10,550	9,836	8,090
<i>Large bow</i>							
Pregnancies	8.4	8.2	6.2	6.2	8.2	6.8	8.5
Expulsions:							
First	2.2	0.8	3.0	1.7	2.7	1.3	1.2
Later	1.9	0.6	1.1	0.0	1.3	1.2	1.0
Removals:							
Bleeding and/or pain	19.0	15.6	14.2	9.5	20.0	14.6	12.0
Other medical	6.7	4.8	5.6	5.5	5.7	5.5	7.0
Planning pregnancy	3.8	2.2	1.3	1.1	5.0	1.3	0.5
Other personal	3.7	3.3	3.3	2.1	3.5	3.4	3.0
Total closures	37.0	27.4	27.5	18.9	37.1	26.6	26.2
Continuation rate	63.0	72.6	72.5	81.1	62.9	73.4	73.8
Woman-months of use	7,1902	11,930	6,767	4,753	16,338	15,681	9,333
<i>Steel ring</i>							
Pregnancies	12.6	8.4	6.7	4.9	10.3	9.1	7.3
Expulsions:							
First	29.6	14.4	9.5	8.0	25.4	13.7	9.1
Later	7.4	3.1	3.5	2.8	6.5	3.9	1.4
Removals:							
Bleeding and/or pain	12.8	13.2	9.1	13.0	12.9	12.4	10.5
Other medical	4.5	4.2	1.8	1.9	3.2	3.5	5.6
Planning pregnancy	5.2	4.4	2.0	0.6	6.0	2.2	0.0
Other personal	4.1	2.1	3.7	2.8	2.8	3.5	4.9
Total closures	47.0	34.4	22.6	23.9	41.4	33.5	25.0
Continuation rate	53.0	65.6	77.4	76.1	58.6	66.5	75.0
Woman-months of use	9,121	7,114	4,551	3,111	12,043	8,131	3,713

TABLE 9
CUMULATIVE RATES OF EVENTS BY TYPE OF TERMINATION AND OF CLOSURES, PER 100 USERS, BY AGE AND PARITY AT
FIRST INSERTION: LOOP D, 2 YEARS OF USE

Type of termination	15 to 24 years			25 to 29 years			30 to 34 years			35 to 49 years		
	Para 1 or 2	Para 3 or 4	Para 5 or more	Para 1 or 2	Para 3 or 4	Para 5 or more	Para 1 or 2	Para 3 or 4	Para 5 or more	Para 1 or 2	Para 3 or 4	Para 5 or more
Events:												
Pregnancies												
Expulsions:												
First	5.5	5.5	8.1	4.7	4.7	4.9	2.7	3.4	2.5	0.6	1.2	3.0
Later	18.5	15.9	13.6	12.4	9.1	7.5	8.4	6.9	6.3	5.0	5.4	5.8
Removals:	7.7	7.6	3.7	4.5	4.3	3.1	3.5	1.0	2.7	0.3	1.1	0.6
Bleeding and/or pain	20.0	15.0	10.7	18.5	18.3	14.2	20.2	16.3	14.2	18.6	18.2	13.1
Other medical	5.9	7.8	8.2	5.8	6.4	4.2	4.4	3.6	6.6	7.7	4.9	4.3
Planning pregnancy	7.0	1.7	0.0	5.1	2.1	0.5	2.4	0.5	0.5	0.7	0.6	0.4
Other personal	4.9	3.9	7.5	3.1	4.2	3.4	2.7	2.3	5.6	1.5	2.6	3.3
Total closures	46.1	36.0	34.8	39.1	33.5	23.2	33.3	24.5	28.3	26.9	25.4	24.0
Continuation rate	53.9	64.0	65.2	60.9	66.5	76.8	66.7	75.5	71.7	73.1	74.6	76.0
Woman-months of use	25,151	13,612	2,122	10,816	15,255	7,744	6,344	9,291	7,923	5,735	6,902	6,735

Type of termination	Para 1 or 2			Para 3 or 4			Para 5 or more		
	15 to 24 years	25 to 29 years	30 to 34 years	15 to 24 years	25 to 29 years	30 to 34 years	15 to 24 years	25 to 29 years	30 to 34 years
Events:									
Pregnancies									
Expulsions:									
First	5.5	4.7	2.7	5.5	4.7	3.4	8.1	4.9	2.5
Later	18.5	12.4	8.4	15.9	9.1	6.9	13.6	7.5	6.3
Removals:	7.7	4.5	3.5	7.6	4.3	1.0	3.7	3.1	2.7
Bleeding and/or pain	20.0	18.5	20.2	15.0	18.3	16.3	10.7	14.2	14.2
Other medical	5.9	5.8	4.4	7.8	6.4	3.6	8.2	4.2	6.6
Planning pregnancy	7.0	5.1	2.4	1.7	2.1	0.5	0.0	0.5	0.5
Other personal	4.9	3.1	2.7	3.9	4.2	2.3	7.5	3.4	5.6
Total closures	46.1	39.1	33.3	36.0	33.5	24.5	34.8	23.2	28.3
Continuation rate	53.9	60.9	66.7	64.0	66.5	75.5	65.2	76.8	71.7
Woman-months of use	25,151	10,816	6,344	13,612	15,255	9,291	2,122	7,744	7,923

TABLE 10
CUMULATIVE EVENT RATES BY INTERVAL BETWEEN INSERTION AND
LAST CONFINEMENT, PER 100 FIRST INSERTIONS: SELECTED DEVICES,
2 YEARS OF USE

<i>Device and event</i>	<i>First 10 days</i>	<i>2 to 4 weeks</i>	<i>5 to 8 weeks</i>	<i>9 to 12 weeks</i>	<i>3 months or more</i>
<i>Loop C</i>					
Pregnancies	5.2	2.7	4.8	3.0	3.0
Expulsions	56.9	20.9	20.0	21.0	13.9
Removals:					
Bleeding and/or pain	7.4	8.3	14.2	9.3	14.7
Other medical	2.3	5.9	4.5	4.4	4.7
Planning pregnancy	2.1	—	2.5	3.0	3.1
Other personal	1.1	2.3	2.0	4.3	3.0
Total events	75.0	40.1	48.0	45.0	42.4
No events	25.0	59.9	52.0	55.0	57.6
Woman-months of use	1,330	1,382	12,106	3,590	23,379
<i>Loop D</i>					
Pregnancies	1.7	—	4.5	6.3	3.2
Expulsions	45.2	—	15.0	13.6	9.5
Removals:					
Bleeding and/or pain	8.9	—	15.8	12.5	16.5
Other medical	0.4	—	5.2	3.5	4.9
Planning pregnancy	1.2	—	2.0	2.7	2.9
Other personal	1.6	—	2.7	3.8	3.6
Total events	59.0	—	45.2	42.4	40.6
No events	41.0	—	54.8	57.6	59.4
Woman-months of use	3,368	—	17,781	11,643	65,004
<i>Large spiral</i>					
Pregnancies	—	—	1.9	2.8	1.3
Expulsions	—	—	25.3	27.5	19.3
Removals:					
Bleeding and/or pain	—	—	14.8	16.1	18.2
Other medical	—	—	9.5	5.7	9.9
Planning pregnancy	—	—	1.3	3.7	2.5
Other personal	—	—	4.5	5.8	5.0
Total events	—	—	57.3	61.6	56.2
No events	—	—	42.7	38.4	43.8
Woman-months of use	—	—	4,452	3,275	16,202
<i>Large bow</i>					
Pregnancies	—	—	9.4	4.5	7.1
Expulsions	—	—	2.3	2.1	1.9
Removals:					
Bleeding and/or pain	—	—	14.8	13.6	17.6
Other medical	—	—	6.9	1.7	3.7
Planning pregnancy	—	—	2.3	2.1	3.0
Other personal	—	—	3.3	3.9	3.2
Total events	—	—	39.0	27.9	36.5
No events	—	—	61.0	72.1	63.5
Woman-months of use	—	—	11,096	4,614	17,661
<i>Steel ring</i>					
Pregnancies	—	—	11.4	6.5	5.5
Expulsions	—	—	25.5	21.8	15.0
Removals:					
Bleeding and/or pain	—	—	12.9	12.2	9.8
Other medical	—	—	2.6	1.8	2.9
Planning pregnancy	—	—	1.5	2.2	3.1
Other personal	—	—	2.2	4.9	2.8
Total events	—	—	56.1	49.4	39.1
No events	—	—	43.9	50.6	60.9
Woman-months of use	—	—	3,189	2,989	12,389

TABLE 11

CUMULATIVE RATES OF EVENTS BY TYPE OF TERMINATION, PER 100
FIRST RE-INSERTIONS, AFTER EXPULSION AND AFTER REMOVAL:
SELECTED DEVICES, 2 YEARS OF USE

Type of termination	Loop C	Loop D	Large spiral	Large bow	Steel ring
<i>After expulsion:</i>					
Pregnancies	4.2	4.8	2.5	5.7	—
Expulsions	41.1	33.7	58.3	9.5	—
<i>Removals:</i>					
Bleeding and/or pain	10.1	11.1	9.6	12.2	—
Other medical	1.1	3.8	4.5	6.6	—
Planning pregnancy	0.9	3.4	2.2	1.7	—
Other personal	2.3	3.0	1.2	1.6	—
Total events	59.7	59.8	78.3	37.3	—
No events	40.3	40.2	21.7	62.7	—
Woman-months of use	4,239	6,972	1,348	3,322	—
<i>After removal:</i>					
Pregnancies	2.6	3.1	—	9.2	10.5
Expulsions	8.7	7.3	—	0.9	13.8
<i>Removals:</i>					
Bleeding and/or pain	17.4	13.1	—	12.8	15.3
Other medical	5.7	6.4	—	8.5	4.0
Planning pregnancy	5.3	2.8	—	5.2	1.8
Other personal	5.0	4.3	—	3.3	2.6
Total events	44.7	37.0	—	39.9	48.0
No events	55.3	63.0	—	60.1	52.0
Woman-months of use	6,107	15,700	—	4,323	2,878

TABLE 12

LOW AND HIGH ESTIMATES OF CUMULATIVE CONTINUATION RATES: ALL DEVICES, 2 YEARS OF USE, AND LOOP D, 1 TO 5 YEARS OF USE

Devices and Years of use (Loop D)	Low	High
<i>All devices</i>		
Loop A	60.4	64.8
Loop B	41.8	71.3
Loop C	47.8	72.1
Loop D	55.8	70.4
Small spiral	54.5	62.1
Large spiral	54.2	66.2
Small bow	57.9	66.3
Large bow	62.4	72.2
Steel ring	52.3	71.1
<i>Loop D</i>		
1 year	70.8	79.4
2 years	55.8	70.4
3 years	46.5	63.9
4 years	40.3	59.2
5 years	36.5	57.5

TABLE 13

LOWER AND UPPER CONFIDENCE LIMITS (95%) FOR ANNUAL AND 1-YEAR CUMULATIVE RATES, BY LEVEL OF RATE AND WOMAN-MONTHS OF USE

Rate/100 women	Woman-months of use											
	1,200		2,400		6,000		12,000		24,000		60,000	
	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
0.0	0.0	3.7	0.0	1.9	0.0	0.8	0.0	0.4	0.0	0.2	0.0	0.1
0.1	0.0	3.9	0.0	2.1	0.0	1.0	0.0	0.6	0.0	0.4	0.0	0.3
0.2	0.0	4.1	0.0	2.3	0.0	1.2	0.0	0.8	0.0	0.6	0.1	0.4
0.5	0.0	4.6	0.0	2.8	0.0	1.6	0.2	1.2	0.2	1.0	0.3	0.8
1.0	0.0	5.5	0.1	3.6	0.3	2.4	0.4	1.9	0.6	1.6	0.7	1.4
2.0	0.2	7.1	0.5	5.1	1.0	3.6	1.2	3.1	1.4	2.7	1.6	2.4
5.0	1.6	11.3	2.4	9.1	3.2	7.3	3.7	6.6	4.0	6.1	4.4	5.7
10.0	4.9	17.7	6.2	15.1	7.5	13.0	8.2	12.1	8.7	11.4	9.1	10.9
15.0	8.6	23.6	10.3	20.8	11.9	18.5	12.8	17.4	13.4	16.7	14.0	16.1
20.0	12.6	29.2	14.6	26.3	16.5	23.8	17.5	22.7	18.2	21.9	18.9	21.2
25.0	16.8	34.7	19.2	31.6	21.2	29.1	22.3	27.9	23.1	27.0	23.8	26.3
30.0	21.2	40.0	23.7	36.9	26.0	34.3	27.1	33.0	28.0	32.1	28.7	31.3
40.0	30.3	50.3	33.1	47.2	35.6	44.5	36.9	43.2	37.8	42.2	38.6	41.4
50.0	39.8	60.2	42.8	57.2	45.5	54.5	46.8	53.2	47.7	52.3	48.6	51.4

LL = Lower limit; UL = Upper limit.

pregnancy rates after re-insertion, and the removal or pregnancy rates after a first insertion.

Low and high estimates of cumulative continuation rules for Loop D for 5 years and all other devices for 2 years are shown in Table 12. In most other tables (Tables 5 to 11) the assumption is that pregnancies, expulsions, removals and re-insertions occur with the same frequency among women lost to follow-up as they do among those who remain under observation. The low estimates in this table are based on the assumption that all cases lost to follow-up were closed; and the high estimates, that all of these cases remained users.

The order of magnitude of sampling errors is illustrated in Table 13 for annual and 1-year cumulative rates from 0.0 to 50 per 100 women, based on samples from 1200 to 60,000 woman-months of use. The lower and upper limits shown are approximations, derived by interpolation and rounding from the tables of Mainland, Herrera & Sutcliffe (1956). The maximum risks of over-estimating the upper limit are 2.5% each.

It is obvious that rates based on small samples, especially low rates, should be interpreted with great care, taking into account any similarities and dissimilarities in the patterns of rates for different types and sizes of IUDs. Confidence limits for N-year cumulative rates approximate those based on the number of woman-months divided by N for 1-year rates.

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