

AGENCY FOR INTERNATIONAL DEVELOPMENT WASHINGTON, D. C. 20523 BIBLIOGRAPHIC INPUT SHEET	FOR AID USE ONLY <i>Batch 83</i>
-----------------------------------------------------------------------------------------------------	-------------------------------------

1. SUBJECT CLASSIFICATION	A. PRIMARY Population	PC00-0000-0000
	B. SECONDARY Family planning	

2. TITLE AND SUBTITLE
IUD performance patterns; tables, charts and comments prepared for investigators, Oct. 1969

3. AUTHOR(S)
(100) Bernard, R. P.; Compton, Helen; Fukuda, Esther; (101) Pathfinder Fund. Family Planning Evaluation Ctr. Boston, Mass.

4. DOCUMENT DATE 1969	5. NUMBER OF PAGES <i>70p. 710.</i>	6. ARC NUMBER ARC
--------------------------	----------------------------------------	----------------------

7. REFERENCE ORGANIZATION NAME AND ADDRESS
Pathfinder

8. SUPPLEMENTARY NOTES (Sponsoring Organization, Publishers, Availability)
(In Yugoslavia multi-clinic IUD trial)
(In Geographic ser.-NR.1)
(Prepared for European Cong.on Sterility. 2d. Dubrovnik, Yugoslavia, 1969)

9. ABSTRACT

10. CONTROL NUMBER <i>PN-AAF-552</i>	11. PRICE OF DOCUMENT
-----------------------------------------	-----------------------

12. DESCRIPTORS Contraceptives Data Data processing Intrauterine device	13. PROJECT NUMBER
	14. CONTRACT NUMBER CSD-1573 Res.
	15. TYPE OF DOCUMENT

PREPARED FOR THE SECOND EUROPEAN CONGRESS ON STERILITY
DUBROVNIK, YUGOSLAVIA (OCTOBER 8-11, 1968)

IUD PERFORMANCE PATTERNS

GEOGRAPHIC
SERIES-NR. 1

October 1969

TABLES, CHARTS AND COMMENTS
PREPARED FOR INVESTIGATORS

BY
ROGER P. BERNARD, MD, MSPH

WITH ASSISTANCE FROM
HELEN COMPTON and ESTHER FUKUDA



DATA COLLECTION AND PROCESSING: RESEARCH DEPARTMENT THE PATHFINDER FUND BOSTON, MASS., U.S.A. R.P. BERNARD AND H. COMPTON-NEMER

DATA COMPUTATION: SOCIOLOGY COMPUTER LABORATORY BROWN UNIVERSITY PROVIDENCE, R.I., U.S.A. J.M. SAKODA, R.G. POTTER AND P.S. CHI

COMPUTED ACCORDING TO THE TIETZE-POTTER MULTIPLE SEGMENT-DECREMENT LIFE-TABLE APPROACH (OCT.-1968 VERSION)

THE INTERNATIONAL IUD PROGRAMME OF THE PATHFINDER FUND IS SUPPORTED BY
THE AGENCY FOR INTERNATIONAL DEVELOPMENT (CONTRACT AID/CSD - 1673)

RESEARCH DIRECTOR, THE PATHFINDER FUND, CHESTNUT HILL, MASS. 02167 U.S.A.

**THE PATHFINDER FUND
RESEARCH DEPARTMENT
INTERNATIONAL IUD PROGRAMME**

Roger P. Bernard
Helen Compton
Esther A. Fukuda
Zipora Pazner
Christine Colven
Marlene Dwyer
Joan McConnell
Sadie Factor
Doris Ziskend
Mary Ann Williams
Dorothy Woodberry

Research Director
Research Assistant
Research Secretary
Research Librarian
Field Secretary
Keypuncher
Keypuncher
Coder
Coder
Coder
Coder

CONSULTANTS ON EVALUATION

Sidney Goldstein
Robert Potter
James Sakoda
Christopher Tietze

Brown University
Brown University
Brown University
The Population Council

MEDICAL ADVISORY COMMITTEE

Samuel J. Behrman
John Craig
Aquiles Sobrero
Thomas Lardner
Luigi Mastroianni, Jr.
Stuart Mudd
John Rock

University of Michigan
Harvard Medical School
Margaret Sanger Research Bureau
Massachusetts Institute of Technology
University of Pennsylvania
University of Pennsylvania
Harvard Medical School

P R E F A C E

This is the first number of a *Geographic Series* supplemental to *IUD Performance Patterns*, which was published by Dr. Roger Bernard in preliminary editions as Volume 1 in January 1969 and Volume 2 in July 1969. Volume 1 provided baseline data from the INTERNATIONAL IUD PROGRAMME of *The Pathfinder Fund* on experience with the Lippes Loop in widely placed and differing cultural settings, as well as preliminary information on a few experimental designs of IUDs.

In Volume 2 of *IUD Performance Patterns*, the first serious field testing of a new device is reported and some of the difficulties of this task indicated. The concept of "pertinent events" was introduced to include pregnancy, first expulsion and removal for bleeding and/or pain, as the most useful for evaluating newer developments in IUD technology. The double-blind approach was fully exploited and fitted into an overall scheme to evaluate both a new IUD design, the M device, and two modifications of this device — namely, two different thicknesses of the device and teflon-coated and uncoated versions. "Center-specific" and "device-specific" events were differentiated. Some evidence that center specificity may hold over time was suggested. The relative importance of age and parity was studied for both first expulsion and removal for bleeding and/or pain.

In this first regional number, Dr. Bernard goes into further depth in developing his epidemiologic strategy for the evaluation of IUDs. The effect of age-parity and calendar time of insertion is investigated, as well as the effect of history of abortion on first expulsion.

With this publication, one might say that the descriptive epidemiology of IUD performance has reached a degree of sophistication to permit formulation of hypotheses and experimental studies to test them. Such hypotheses would relate to the physical and chemical characteristics of IUDs and their effect on pertinent events. Experimental studies would be designed to investigate one changed IUD characteristic at a time in a carefully controlled manner.

To muster a critical mass of talent to perform these tasks well, *The Pathfinder Fund* is developing cooperative arrangements with major research centers in biological, physical and social sciences. With this help and Dr. Bernard's energy and epidemiologic skills, I believe a new generation of IUDs will emerge very soon.

Boston
October 6, 1969

Elton Kessel, M.D.
President

NOTE:

The Editor of this manual wishes in no way to impose his views concerning these data on the generators thereof. He has therefore chosen the present format of data presentation to serve as accessible background material for the contributor's own local scientific publication . . .

**R. P. Bernard, M. D.
Research Director**

NOTES

This opening number of the *Geographic Series of IUD Performance Patterns* is an interesting blend of old and new. It brings to fruition years of labor on the part of both the Yugoslavian contributors and the staff of *The Pathfinder Fund's* Research Department. Both old and new studies have yielded crucial information toward better understanding of the yet-existent shortcomings of the IUD method of contraception. This information is very young, as all studies have been computed over the last three months. It has been our endeavour not only to speed out professional evaluation, but also to accelerate broad diffusion of the findings.

Here is a skeleton of the assembled material:

A. LONG RANGE (study start: 1964 through 1967)

THE YUGOPOOL

- Center
- Age
- Parity
- Abortion
- Cohort (Time)

B. SHORT RANGE (study start: 1968)

DOUBLE-BLIND TESTING

- New Prototypes
- Post-Menses - Post-Abortum
- Study Design for Practitioners

Highlights of this collection are:

1. Neat untangling of the association web among age/parity, expulsion and abortion
2. A 70% three-year continuation rate.
3. The double-blind testing scheme.
4. Confirmation of virtual unexpellability of the M-device in a short-range assessment.
5. Demonstration of a center-effect on removal for bleeding and/or pain.

While the figures of the double-blind scheme have been borrowed from Vol. 2 of *IUD Performance Patterns (July 1969)*, those of the YUGOPOOL and its constituents have been extracted from *IUD Performance Patterns, Vol. 1* - definite edition - presently in press.

To both the contributors in the field and my staff at home, I am indebted for their commitment and seriousness in their work.

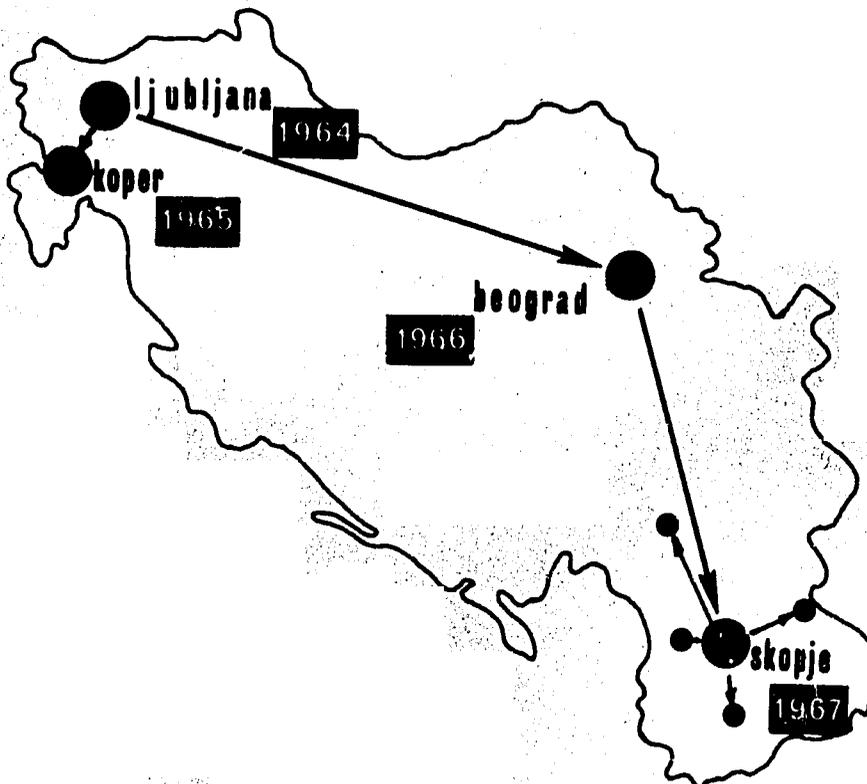
Boston
October 6, 1969

Roger P. Bernard, M.D.
Research Director

THE YUGOPOOL

1. Presently, there are five Loop C studies from four centers at hand. They have been conducted in places as far north as Ljubljana (capital of Slovenia) and as far south as Skopje (capital of Macedonia). The method has, in fact, been spread with this device from north to south, via Beograd. The investigators are of above average commitment and all do meticulous reporting, so that the studies are really "at hand" in Yugoslavia and Boston.

SPREAD OF THE IUD METHOD OF CONTRACEPTION
THROUGHOUT YUGOSLAVIA



2. The five studies have been analyzed individually by *center* and collectively as a *pool* of 1,438 primary insertions. This YUGOPOOL – with a one-year follow-up of 95% – has been submitted to successive analyses and computations of pertinent event rates by such variables as age, parity and abortions, treated hereafter.
3. The format of presentation will be to give first the pertinent statistical tables followed by "comments." Both are conceived in such a way that they may be partially absorbed into the contributor's own local scientific publication.
4. Comments of a theoretical nature have been interspersed sporadically, as it is believed that they will be of some didactic value to the contributor while preparing his publication.

CONTRIBUTORS:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behilovic
Dr. L. Antonovski/ A. Nikolovski

1

CENTER

COHORT

Comments:

(The Yugoslavia IUD Baseline – Study Center and Time After Insertion)

1. The table gives net cumulative pertinent event rates (single and combined) per 100 Loop C users, together with standard errors, at three points in time after insertion: 4, 12 and 24 months. De facto discontinuation and continuation are also given. The lower half of the table gives for each corresponding cell residual and cumulative woman-months of use, together with the proportion of patients lost to follow-up. This mode of presentation – whereby *pertinent* and *de facto* rates are contrasted to a corresponding *cell of logistics* – will be adhered to.
2. There is remarkable homogeneity in result outcome for the five studies analyzed. All one- and two-year continuation rates are very close to 85 and 80%, respectively – though the study centers are as far as 750 kms. apart, and considerable differentials in race, religion and culture are known to exist.
3. The 4-, 12- and 24-month expulsion rates were 6.1, 8.9 and 10.2% – with a minimal variation between centers. Corresponding net cumulative rates of removals for bleeding and/or pain were astoundingly low, when compared to international figures – 3.6, 5.2 and 8.6% – whereby some greater variation was encountered between the individual studies. At 4 months, already, the extreme BI/P removal values are 5.6 against 0.7 per 100 Loop C insertions. At one year, the extremes are 7.8 against 2.9%, with an average of 5.2 per 100 primary insertions. This center-effect on BI/P removals is of particular interest, as it appears even in studies of rather low BI/P removal.
4. The two Koper studies have been conducted by the same physician, with the same device, but were initiated three years apart, as is seen at the bottom of the table. Corresponding removal for bleeding and/or pain rates are 4.9% against only 0.7% at the fourth month after insertion. It is interesting to note this (calendar) time (at insertion)-effect on BI/P removals which may well have to do with experience.
5. The relative homogeneity in outcome of these five studies has permitted the use of the combined patient-pool as one entity, toward further analysis. The 1,438 cases – the YUGOPOOL – have been followed up to 24 months at a 95% level, which will lend additional meaning to the findings. The 4-, 12- and 24-month rates are based on aggregates of 5,280.5, 14,095 and 21,932 woman-months of use.

CONTRIBUTORS:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behilovic
Dr. L. Antonovski/ A. NIKODVSKI

2

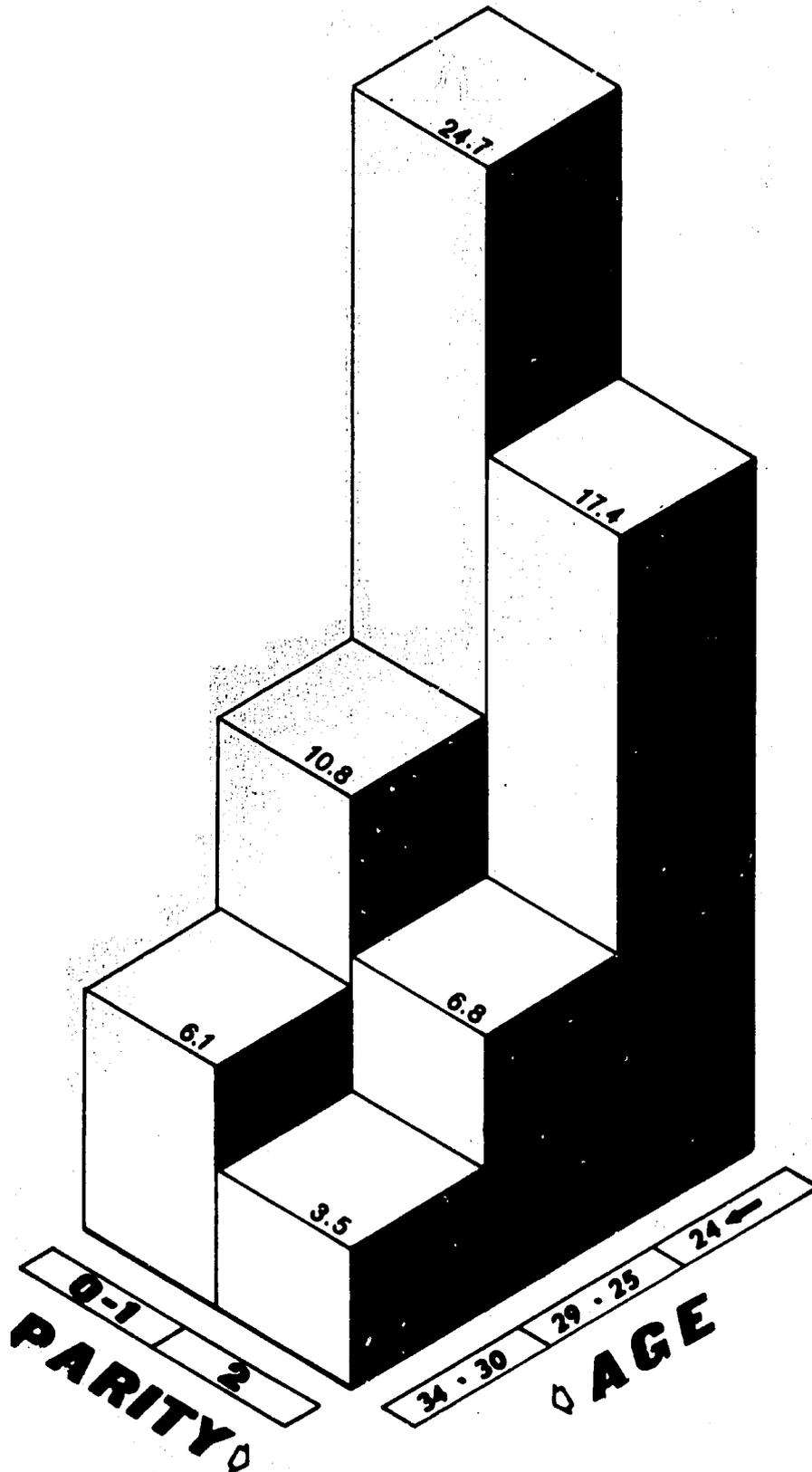
AGE

PARITY

AGE- AND PARITY DEPENDENCE OF EXPULSION

Six-month rates of loop G expulsions

YUGOSLAVIA 1969-BASELINE DATA



YUGOSLAVIA LOOP C THREE-MONTH BASELINE DATA

3 MONTHS

THREE-MONTH CUMULATIVE PRIMARY EXPULSIONS
AND REMOVALS FOR BLEEDING AND/OR PAIN
BY AGE AND PARITY
PER 100 LOOP C USERS

2

PARITY

AGE

	0-1	2	3	4+	All Parities
-24	(117) 18.0 ± 3.6 0.0 ± 0.0 1.0%	(72) 14.3 ± 4.2 1.4 ± 1.4 1.5%	8	3	(200) 16.6 ± 2.7 1.0 ± 0.7 1.1%
25-29	(97) 8.6 ± 2.9 4.2 ± 2.1 3.3%	(261) 5.5 ± 1.4 0.8 ± 0.6 2.8%	(50) 4.2 ± 2.9 4.1 ± 2.9 4.1%	25	(433) 6.0 ± 1.2 2.1 ± 0.7 3.4%
30-34	(68) 1.5 ± 1.5 9.0 ± 3.5 3.1%	(234) 3.1 ± 1.1 2.6 ± 1.1 1.3%	(95) 3.2 ± 1.8 5.4 ± 2.3 1.1%	(76) 4.1 ± 2.3 1.4 ± 1.4 2.7%	(473) 3.0 ± 0.8 3.9 ± 0.9 1.8%
35-39	31	(118) 1.7 ± 1.2 2.6 ± 1.5 2.6%	(62) 3.4 ± 2.4 3.3 ± 2.3 4.9%	(66) 0.0 ± 0.0 10.9 ± 3.9 3.1%	(277) 1.8 ± 0.8 4.4 ± 1.2 2.9%
40+	5	16	17	17 FIRST EXPULSION REMOVAL BI/Pn LOSS FUP	(55) 1.9 ± 1.8 3.7 ± 2.6 1.8%
All Ages	(318) 9.8 ± 1.7 3.2 ± 1.0 2.0%	(701) 4.8 ± 0.8 1.9 ± 0.5 2.1%	(232) 4.5 ± 1.4 4.0 ± 1.3 2.7%	(187) 2.2 ± 1.1 6.1 ± 1.8 3.8%	(1438) 5.5 ± 0.6 3.1 ± 0.5 2.4%

CUMUL. Q-MOS. OF USE

4018

YUGOSLAVIA LOOP C HALF-YEAR BASELINE DATA

6 MONTHS

SIX-MONTH CUMULATIVE PRIMARY EXPULSIONS
AND REMOVALS FOR BLEEDING AND/OR PAIN
BY AGE AND PARITY
PER 100 LOOP C USERS

2

PARITY

AGE

	0-1	2	3	4+	All Parities
- 24	(117) 24.7 ± 4.1 2.9 ± 1.2 2.7%	(72) 17.8 ± 4.8 1.4 ± 1.4 1.5%	8	3	(200) (21.7) ± 3.0 2.7 ± 1.2 1.8%
25 - 29	(87) 18.8 ± 4.1 4.2 ± 2.1 5.5%	(281) 8.8 ± 1.8 2.8 ± 1.1 3.8%	(50) 4.2 ± 2.9 6.3 ± 3.5 8.8%	25	(433) 7.5 ± 1.3 3.6 ± 0.9 5.5%
30 - 34	(68) 6.1 ± 2.9 9.0 ± 3.5 3.1%	(234) 3.5 ± 1.2 3.7 ± 1.1 1.8%	(95) 4.3 ± 2.1 6.5 ± 2.8 1.1%	(76) 5.5 ± 2.7 1.4 ± 1.4 2.7%	(473) 4.4 ± 1.0 4.3 ± 0.9 2.0%
35 - 39	31	(118) 4.4 ± 1.9 2.6 ± 1.5 4.5%	(62) 3.4 ± 2.4 3.3 ± 2.3 4.9%	(66) 0.0 ± 0.0 10.9 ± 3.9 3.1%	(277) 3.0 ± 1.0 4.8 ± 1.3 3.8%
40 +	5	16	17	(17) FIRST EXPULSION REMOVAL B/P/P LOSS FUP	(55) (1.9) ± 1.8 9.3 ± 3.9 1.8%
All Ages	(318) (13.5) ± 2.0 4.6 ± 1.2 3.1%	(701) 6.2 ± 0.9 3.0 ± 0.7 2.9%	(232) 4.9 ± 1.4 5.8 ± 1.6 3.7%	(187) (3.4) ± 1.4 6.1 ± 1.8 5.0%	(1438) 7.3 ± 0.7 4.2 ± 0.5 3.3%

CUMUL. Q-MOS. OF USE 7686.5

YUGOSLAVIA LOOP C ONE-YEAR BASELINE DATA

12 MONTHS

ONE-YEAR CUMULATIVE PRIMARY EXPULSIONS
AND REMOVALS FOR BLEEDING AND/OR PAIN
BY AGE AND PARITY
PER 100 LOOP C USERS

2

PARITY

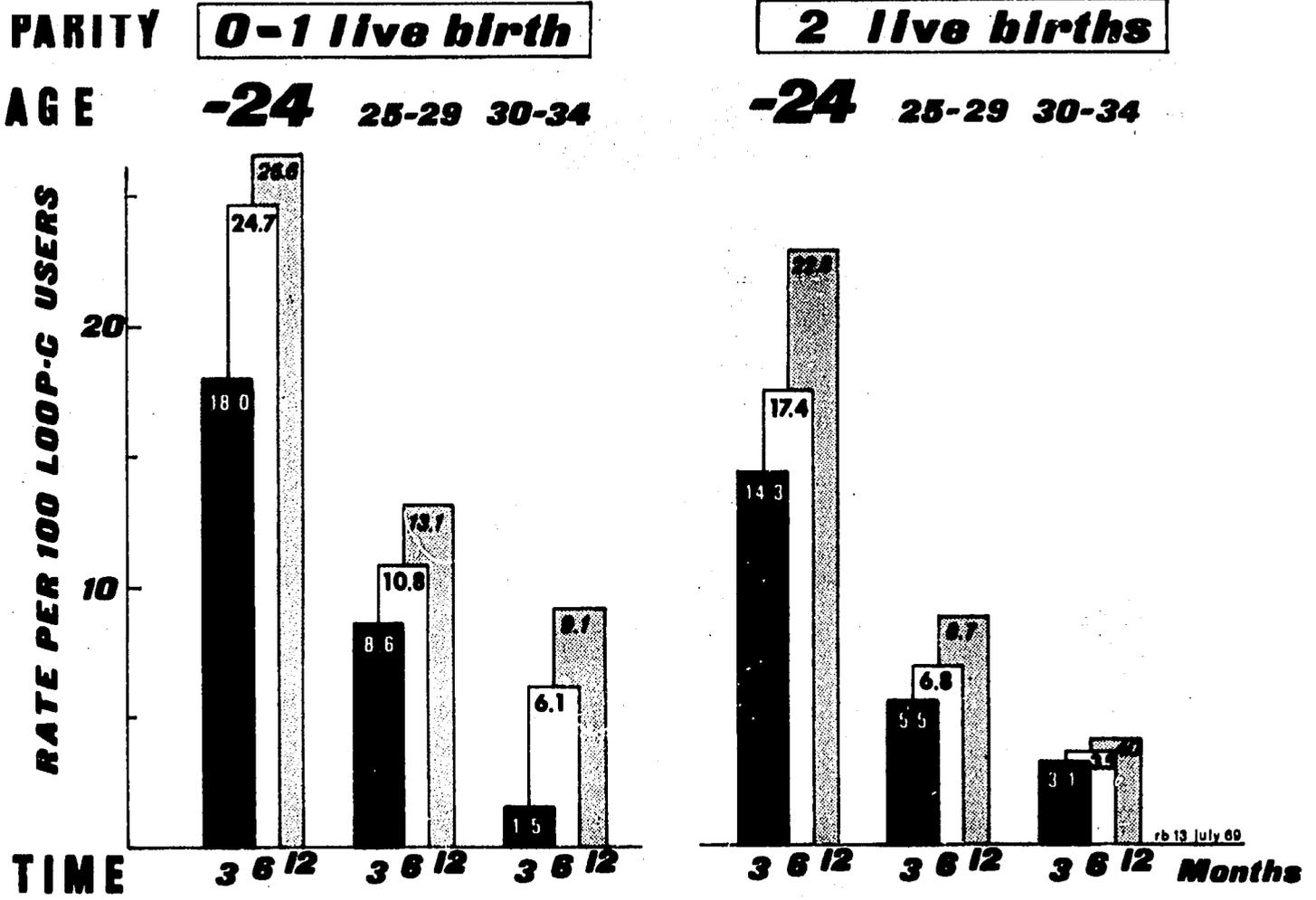
AGE

	0-1	2	3	4+	All Parities
-24	(117) 26.6 ± 4.3 3.8 ± 1.9 2.2%	(72) 22.8 ± 5.3 1.4 ± 1.4 1.5%	8	3	(200) 24.7 ± 3.2 3.3 ± 1.3 1.8%
25-29	(97) 13.1 ± 3.5 6.5 ± 2.8 8.2%	(261) 8.7 ± 1.8 3.8 ± 1.2 4.6%	(50) 4.2 ± 2.9 6.3 ± 3.5 11.2%	25	(433) 9.2 ± 1.4 4.7 ± 1.1 6.9%
30-34	(68) 9.1 ± 3.6 10.6 ± 3.8 4.8%	(234) 4.0 ± 1.3 4.7 ± 1.3 2.4%	(95) 5.5 ± 2.4 7.6 ± 2.8 4.9%	(76) 8.5 ± 3.3 1.4 ± 1.4 2.7%	(473) 5.8 ± 1.1 5.3 ± 1.1 3.3%
35-39	31	(118) 4.4 ± 1.9 3.6 ± 1.8 5.7%	(62) 3.4 ± 1.4 3.3 ± 2.3 4.9%	(66) 3.5 ± 2.5 14.1 ± 4.4 3.1%	(277) 3.9 ± 1.2 6.5 ± 1.5 4.2%
40+	5	16	17	(66) FIRST EXPULSION REMOVAL BI/Pn LOSS FUP	(55) 1.9 ± 1.8 9.3 ± 3.9 1.8%
All Ages	(318) 15.9 ± 2.1 6.4 ± 1.2 4.4%	(701) 7.6 ± 1.0 3.8 ± 0.8 3.7%	(232) 5.4 ± 1.5 6.3 ± 1.8 5.8%	(187) 5.8 ± 1.8 7.3 ± 1.9 5.0%	(1438) 8.9 ± 0.8 5.2 ± 0.8 4.3%

CUMUL. Q-MOS. OF USE

14095

**PRIMARY EXPULSION BY AGE, PARITY AND TIME
AFTER INSERTION**



Comments:

(The Yugoslavia IUD Baseline – Age and Parity)

1. The 1,438 cases of the homogenous YUGOPOOL, with a one-year follow-up of 95%, were submitted to an Age/Parity analysis in time after insertion (3, 6 and 12 months). Twenty-two computer runs were done on July 10 and generated the material hereafter.
2. For each point in time after insertion, a composite table was constructed, giving four information bits for each subclass by age and parity: number of women, primary expulsion rate, removal rate for bleeding and/or pain and the cell-specific loss to follow-up. Row- and column-totals give corresponding values for all parities and all ages, respectively.
3. The two graphic illustrations are based on figures of the three previous tables. Figure 1 dramatizes the following findings:
 - a. Loop C expulsion increases dramatically with decreasing age and parity. One-in-four women of an age less than 25 and parity less than 2 had lost their C loop during the first half year after insertion. If the patient was ten years older, that risk was four times smaller (6.1% down from 24.7%). This *inverse age-effect on expulsion* is of such strength that it can be used as a delineator of success for prospective IUD candidates.
 - b. The inverse age-expulsion association is stronger than the still important negative parity-expulsion association. Indeed, while expulsions plummeted from 21.7% for women less than 25 years to 1.9% for women in their forties, the expulsions decreased from 13.5% for women with up to 1 live birth to 3.4% for women with at least 4 live births. This *inverse parity-effect on expulsion* is thus weaker than the corollary age-effect.
4. Figure 2 introduces in an optically accessible fashion the *element of time* which has elapsed since primary insertion. It clearly shows that the age-parity pattern is being fully established *during the immediate post-insertion period* (up to 4 months). This *time (after insertion)-dependent age-parity-effect on expulsion* allows speculative thinking into the reasons for such rapid and age-parity-bound rejection of the device by the uterus.
5. Removals for bleeding and/or pain are positively related to age, as to read from the 12-month composite table's summary column. Here are the values:

AGE	-24	25-29	30-34	35-39	40+
Expulsion, 1st	24.7	9.2	5.8	3.9	1.9
Removal, BI/P	3.3	4.7	5.3	6.5	9.3
SUM	28.0	13.9	11.3	10.4	11.2
	BELOW 30		THIRTIES		FORTIES

On the other hand, no relationship of BI/P removal with parity could be established. This apparently *parity-independent age-effect on BI/P removals*

becomes particularly exacerbated for women in their forties and seriously counterbalances the very low expulsion rate of that advanced age category of IUD wearers. It would appear that women under thirty have twice as many troubles with IUDs (or 20%) as do those in their thirties (or 10%) and that those over forty encounter serious bleeding (and/or pain) problems. Practically speaking, women in their thirties seem to be the best Loop C candidates, as expulsion and BI/P removal – the two most crucial pertinent event categories -- are both very low.

6. Glancing at any one of the three *cellular tables* giving frequencies by age and parity, a strong association between the two variables becomes apparent immediately, as the cells with substantial frequencies appear in a diagonal arrangement. It is worthwhile to quantify this relationship by computing percentage distributions for both rows and columns.

		P A R I T Y				
FREQUENCIES		0-1	2	3	4+	POOL
AGE	-29	214	333	58	28	633
	30+	104	368	174	159	805
	Composite	318	701	232	187	1438
ROW PERCENTAGE (Age = constant)						
AGE	-29	33.8	52.6	9.2	4.4	100.0
	30+	12.9	48.7	21.6	19.8	100.0
	Composite	22.1	48.8	16.1	13.0	100.0
COLUMN PERCENTAGE (Parity = constant)						
AGE	-29	67.3	47.5	25.0	15.0	44.0
	30+	32.7	52.5	75.0	85.0	56.0
	Composite	100.0	100.0	100.0	100.0	100.0

As to read from the row-percentage table, whereas only 13.0% of the women below thirty had had at least 3 births, the corollary value for women above 29 was 41.4%. Or, said the other way around, as to read from the column-percentage table: the proportion of older women increases dramatically with number of live births. It passes from 32.7% for a maximum of one live birth to 85% for women with at least 4 live births.

7. This expected strong association between age and parity points to the way in which this twin couple of basic demographic variables will have to be treated to lend its maximal dissociative power for events related to IUD insertion.

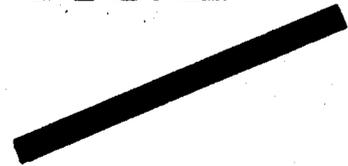
CONTRIBUTORS:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behlilovic
Dr. L. Antonovski/ A. Nikolovski

3

AGE



PARITY

as

DISCRIMINATOR

INTERNATIONAL IUD PROGRAMME — THE PATHFINDER FUND

TABLE 1
MONTHLY NET EVENT RATES*
BY ORDINAL MONTH FROM FIRST INSERTION
PER 100 IUD USERS

Month from insertion:	MONTHLY						CUMULATIVE
	1	2	3	4	5	6	1-6
Type of Termination:**	NUMBER						
PREGNANCY p	3	5	4	3	5	1	21
EXPULSION							
First Expulsion p	34	27	16	8	8	8	101
Later Expulsion	0	1	1	1	5	0	8
REMOVAL							
Bleeding/Pain p	24	16	3	7	6	2	58
Other Med. Reas.	0	2	0	1	1	1	5
Planning a Baby	1	0	0	0	2	1	4
Other Pers. Reas.	1	1	0	1	0	1	4
TOTAL	63	52	24	21	27	14	201
PERTINENT EVENTS **	61	48	23	18	19	11	180
ADJ. NO. OF WOMEN ***	1416.5	1348.5	1298.5	1270.5	1232	1187.5	

		RATES						
PREGNANCY p		0.2	0.4	0.3	0.2	0.4	0.1	1.5 ± 0.3
EXPULSION								
First Expulsion p		2.4	2.0	1.2	0.6	0.6	0.7	7.3 ± 0.7
Later Expulsion		—	0.1	0.1	0.1	0.4	—	0.6
REMOVAL								
Bleeding/Pain p		1.7	1.2	0.2	0.6	0.5	0.2	4.2 ± 0.5
Other Med. Reas.		—	0.1	—	0.1	0.1	0.1	0.4
Planning a Baby		0.1	—	—	—	0.2	0.1	0.3
Other Pers. Reas.		0.1	0.1	—	0.1	—	0.1	0.3
COMB. RELEVANT RISKS		4.4	3.8	1.8	1.6	2.2	1.2	14.6
PERTINENT EVENTS		4.3	3.6	1.7	1.4	1.5	1.0	13.0
LOSS TO FOLLOW-UP		1.4	0.7	0.2	0.2	0.2	0.5	3.3
WOMAN-MOS. OF USE		1398	1330	1290	1262.5	1223.5	1182.5	7686.5

* Tietze-Potter life table approach (multiple segment-decrement); conditional net monthly probabilities

** The numerator

*** The denominator

.. It is felt that pregnancies, first expulsions and removals for bleeding and/or pain (grouped as pertinent events) are of prime importance to the basic goal of rapid development of superior IUDs (Σp)

FINDINGS WORTHY OF DISCUSSION IN YOUR PAPER:
(see also other tables)

1. Monthly expulsions at the 2% level drop to less than 1% in the second quarter after insertion.
2. Low B/P removal.
3. Excellent FUP.

PHYSICIAN PLACE
Yugo-Quadrum-Virat
Skopje, Beograd, Ljubljana, Koper

DEVICE at first insertion
Loop C

STUDY START
June 1965

COMPUTATION-CUTOFF
March 1969

STUDY SPAN
46 Months

TOTAL LOST TO FOLLOW-UP
4.9% (70/1436)

AVERAGE ANNUAL LFUP
1.3%

COMPUTATION DATE
10 July 1969

243

4-8-69

INTERNATIONAL IUD PROGRAMME - THE PATHFINDER FUND

TABLE 2

CUMULATIVE NET RATES OF EVENTS AND CLOSURES
BY TYPE OF SEGMENT TERMINATION AND
INTERVAL AFTER FIRST INSERTION
PER 100 IUD USERS

Months after insertion:	6	12	18	24	30	36
						Rates available up to 42 months
			<u>E V E N T</u>			
Type of Termination:						
PREGNANCY p	1.5	3.1	3.5	3.9	5.4	6.5
EXPULSION						
First Expulsion p	7.3	8.9	9.9	10.2	10.5	10.9
Later Expulsion	0.6	0.8	0.9	0.9	0.9	0.9
REMOVAL						
Bleeding/Pain p	4.2	5.2	6.9	8.6	10.5	11.9
Other Med. Reas.	0.4	1.0	1.3	1.6	1.9	3.0
Planning a Baby	0.3	0.9	1.4	1.6	2.1	3.0
Other Pers. Reas.	0.3	0.4	0.5	0.6	0.8	1.1
TOTAL TERMINATIONS	14.6	20.2	24.4	27.4	32.0	37.2
PERTINENT EVENTS*	13.0	17.2	20.3	22.7	26.4	29.3
PERT. CONTINUATION**	87.0	82.8	79.7	77.3	73.6	70.7
			<u>C L O S U R E</u>			
PREGNANCY	1.2	2.5	2.7	3.2	4.6	5.7
EXPULSION						
First Expulsion	3.5	4.5	5.0	5.1	5.4	5.7
Later Expulsion	0.4	0.6	0.7	0.7	0.7	0.7
REMOVAL						
Bleeding/Pain	3.8	4.7	6.2	8.0	9.9	11.3
Other Med. Reas.	0.3	1.0	1.1	1.4	1.7	2.9
Planning a Baby	0.3	0.9	1.4	1.6	2.1	3.0
Other Pers. Reas.	0.3	0.4	0.5	0.6	0.8	1.1
DISCONTINUATIONS***	9.7	14.6	17.7	20.6	25.2	30.4
CONTINUATIONS**	90.3	85.4	82.3	79.4	74.8	69.6
LOSS TO FOLLOW-UP	3.3	4.3	4.8	5.2	7.4	7.4
RESIDUAL Q-MOS. OF USE†	1182.5	964.5	649	440.5	251.5	165
CUMUL. Q-MOS. OF USE††	7686.5	14095	18743	21932	23854.5	25056

* Grouping of 3 out of 7 termination categories ($\sum p$)

** Complement

† Aggregate woman-months of use during that ordinal month (last computed) after first insertion

†† Cumulation of aggregate woman-months of use, from the first through that ordinal month (last computed) after first insertion

*** Discontinuation is the sum of all closures (events not followed by reinsertion)

Besides the three pertinent termination categories, it includes:

Later Expulsions (all except the primary)

Removals for Other Medical Reasons (all except Bleeding and/or pain;

Removals for Planned Parenthood

Removals for Other Personal Reasons

FINDINGS WORTHY OF DISCUSSION IN YOUR PAPER:
(see also other tables)

1. After 6 months, expulsions level off toward 10% plateau.
2. Dynamic reinsertion policy (1 in 2 expulsions).
3. Low B/P removal, to reach 12% after 3 years.
4. Excellent FUP.

PHYSICIAN PLACE
DEVICE at first insertion

STUDY START
COMPUTATION-CUTOFF
STUDY SPAN

TOTAL LOST TO FOLLOW-UP
AVERAGE ANNUAL LFUP
COMPUTATION DATE

Yugo-Quadrum-Virat
Skopje, Beograd, Ljubljana, Koper

June 1965
March 1969
46 Months
4.9% (70/1438)
1.3%
10 July 1969

Loop C

243

4-8-69

INTERNATIONAL IUD PROGRAMME – THE PATHFINDER FUND

TABLE 3

FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF EVENTS AND CONTINUATION BY TERMINATION TYPE AND AGE/PARITY PER 100 IUD USERS

Months after insertion: Age in years: Number of live births:	FOUR			TWELVE		
	Composite	-25 or 0-1 L	26+ and 2+ H	Composite	-25 or 0-1 L	26+ and 2+ H
Number of cases:	1438	= 454	+ 984	1438	= 454	+ 984
Type of Termination:						
PREGNANCY p	1.1 ± 0.3	0.5	1.4	3.1 ± 0.5	1.7	3.7
EXPULSION						
First Expulsion p	6.1 ± 0.6	10.3	> 4.2	8.9 ± 0.8	15.4	> 5.9
Later Expulsion	0.2	0.5	0.1	0.8	1.2	0.5
REMOVAL						
Bleeding/Pain p	3.6 ± 0.5	2.9	= 3.9	5.2 ± 0.6	5.4	= 5.2
Other Med. Reas.	0.2	0.2	0.2	1.0	0.5	1.3
Planning a Baby	0.1	0.2	—	0.9	2.0	0.4
Other Pers. Reas.	0.2	0.5	—	0.4	1.0	0.1
TOTAL TERMINATIONS	11.5	15.0	9.9	20.2	27.2	17.0
PERTINENT EVENTS*	10.8	13.7	9.5	17.2	22.5	14.8
PERT. CONTINUATION**	89.2	86.3	90.5	82.8	77.5	85.2
DISCONTINUATIONS***	7.7	10.2	6.5	14.6	20.0	12.0
CONTINUATIONS**	92.3	89.8	93.5	85.4	80.0	88.0
LOSS TO FOLLOW-UP	2.6	2.4	2.7	4.3	4.1	4.5
RESIDUAL Q-MOS. OF USE†	1262.5	= 384	+ 878.5	964.5	= 293.5	+ 671
CUMUL. Q-MOS. OF USE††	5280.5	= 1627.5	+ 3653	14095	= 4308	+ 9787
DURATION IN MONTHS	46	46	46	46	46	46
COMPUTATION START	6/65	6/65	6/65	6/65	6/65	6/65
COMPUTER RUN	243	326	327	243	326	327

* Grouping of 3 out of 7 termination categories (Σ p)

** Complement

† Aggregate woman-months of use during that ordinal month (last computed) after first insertion

†† Cumulation of aggregate woman-months of use, from the first through that ordinal month (last computed) after first insertion

L: "low" age-parity group; H: "high" age-parity group

*** Discontinuation is the sum of all closures (events not followed by reinsertion) Besides the three pertinent termination categories, it includes:

Later Expulsions (all except the primary)

Removals for Other Medical Reasons (all except Bleeding and/or pain)

Removals for Planned Parenthood

Removals for Other Personal Reasons

FINDINGS WORTHY OF DISCUSSION IN YOUR PAPER:
(see also other tables)

- At both points in time after insertion, expulsions for the "low" age-parity group are about 2.5 times that of the "high."
- In contrast, there is no age-parity differential for BL/P removals.
- Excellent FUP.

PHYSICIAN PLACE
DEVICE at first insertion

STUDY START
COMPUTATION-CUTOFF
COMPUTATION SPAN

TOTAL LOST TO FOLLOW-UP 4.9% (70/1438)
AVERAGE ANNUAL LFUP 1.3%
COMPILATION DATE 10 July 1969

Yugo-Quadrum-Virat
Skopje, Beograd, Ljubljana, Koper

Loop C

June 1965
March 1969
46 Months

COMP.

DATA COLLECTION AND PROCESSING RESEARCH DEPARTMENT
THE PATHFINDER FUND
BOSTON, MASS., U.S.A.
R.P. BERNARD AND M. COMPTON-MEMER

DATA COMPUTATION SOCIOLOGY COMPUTER LABORATORY
BROWN UNIVERSITY
PROVIDENCE, R.I., U.S.A.
J.M. SAKODA, R.G. POTTER AND P.S. CHU

CCTON = YLGC - QUARLMVIRAT
PLACE = SKCP.RECG.LJLBL.MCP.
DEVICE = Y L G C C-BASELINE

STUDY START = JUNE, 1965
CUTOFF DATE = MARCH, 1969
STUDY SPAN = 46 MONTHS

COMPUTATION SPAN = 46 MONTHS
COMPILATION PLACE = PROVIDENCE
COMPILATION DATE = 10 JULY 1969 BRISTOL

CUMULATIVE NET AND GROSS RATES OF EVENTS AND CLOSURES, BY TYPE OF TERMINATION AND INTERVAL AFTER FIRST INSERTION PER 100 IUD USERS 1)

MONTHS	PREGNANCY	EXPLLSION FIRST	EXPLLSION LATE*	REMOVAL BLEEDING AND PAIN	REMOVAL C.MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL C.PERSONAL REASONS	T O T A L TERMINATIONS	WOMAN MONTHS OF USE RESIDUAL CUMULAT
1	C.2-+C.1	2.4-+C.4	C.C-+C.C	1.7-+C.3	0.0-+0.0	0.1-+0.1	0.1-+0.1	4.4-+0.5	1398.0 1398.0
2	C.6-+C.2	4.4-+C.5	0.1-+C.1	2.8-+C.4	0.1-+0.1	0.1-+0.1	0.1-+0.1	8.2-+0.7	1330.0 2728.0
3	C.9-+C.2	5.9-+C.6	C.1-+C.1	3.1-+C.5	0.1-+0.1	0.1-+0.1	0.1-+0.1	10.0-+0.8	1290.0 4018.0
4	1.1-+C.3	6.1-+C.6	C.2-+C.1	3.6-+C.5	0.2-+0.1	0.1-+0.1	0.2-+0.1	11.5-+0.9	1262.5 5280.5
5	1.5-+C.3	6.7-+C.7	C.6-+C.2	4.0-+C.5	0.3-+0.1	0.2-+0.1	0.2-+0.1	13.5-+0.9	1223.5 6504.0
6	1.5-+C.3	7.3-+C.7	C.6-+C.2	4.2-+C.5	0.4-+0.2	0.3-+0.1	0.3-+0.1	14.6-+1.0	1187.5 7686.5
7	2.6-+C.4	8.0-+C.7	C.8-+C.2	4.7-+C.6	C.7-+0.2	0.5-+0.2	0.3-+0.1	17.7-+1.0	1093.5 11045.0
12	3.1-+C.5	8.9-+C.8	C.8-+C.2	5.2-+C.6	1.0-+0.3	0.9-+0.3	0.4-+0.2	20.2-+1.1	964.5 14095.0
18	3.5-+C.5	9.9-+C.8	C.9-+C.3	6.9-+C.7	1.3-+0.3	1.4-+0.4	0.5-+0.2	24.4-+1.2	649.0 18743.0
24	3.9-+C.6	10.2-+C.9	C.9-+C.3	8.6-+C.9	1.6-+0.4	1.6-+0.4	0.6-+0.2	27.4-+1.4	440.5 21932.0
30	5.4-+C.8	10.5-+C.9	C.9-+C.3	10.5-+1.1	1.9-+0.5	2.1-+0.6	0.8-+0.3	32.0-+1.7	251.5 23854.5
36	6.5-+1.0	10.9-+1.0	0.9-+C.3	11.9-+1.3	3.0-+0.8	3.0-+0.8	1.1-+0.4	37.2-+2.1	165.0 25056.0
42	6.5-+1.0	11.5-+1.1	C.9-+C.3	11.9-+1.3	3.0-+0.8	3.0-+0.8	1.1-+0.4	37.8-+2.1	51.0 25742.5

MONTHS	DISCONTINUATION	CONTINUATION								
1	C.1-+C.1	0.9-+C.3	C.C-+C.C	1.4-+C.3	0.0-+0.0	0.1-+0.1	0.1-+0.1	2.6-+0.4	97.4	1398.0
2	C.5-+C.2	2.0-+C.4	C.1-+C.1	2.4-+C.4	0.1-+0.1	0.1-+0.1	0.1-+0.1	5.3-+0.6	74.7	2728.0
3	C.8-+C.2	2.7-+C.4	0.1-+C.1	2.6-+C.4	0.1-+0.1	0.1-+0.1	0.1-+0.1	6.5-+0.7	93.5	4018.0
4	C.9-+C.3	3.0-+C.5	C.2-+C.1	3.2-+C.5	0.1-+0.1	0.1-+0.1	0.2-+0.1	7.7-+0.7	92.3	5280.5
5	1.1-+C.3	3.2-+C.5	C.4-+C.2	3.6-+C.5	0.2-+0.1	0.2-+0.1	0.2-+0.1	9.0-+0.8	91.0	6504.0
6	1.2-+C.3	3.5-+C.5	0.4-+C.2	3.8-+C.5	0.3-+0.1	0.3-+0.1	0.3-+0.1	9.7-+0.8	90.3	7686.5
7	2.2-+C.4	4.1-+C.5	C.6-+C.2	4.3-+C.5	0.6-+0.2	0.5-+0.2	0.3-+0.1	12.7-+0.9	87.3	11045.0
12	2.5-+C.4	4.5-+C.6	C.6-+C.2	4.7-+C.6	1.0-+0.3	0.9-+0.3	0.4-+0.2	14.6-+1.0	85.4	14095.0
18	2.7-+C.5	5.0-+C.6	C.7-+C.2	6.2-+C.7	1.1-+0.3	1.4-+0.4	0.5-+0.2	17.7-+1.1	82.3	18743.0
24	3.2-+C.5	5.1-+C.6	C.7-+C.2	8.0-+C.9	1.4-+0.4	1.6-+0.4	0.6-+0.2	20.6-+1.2	79.4	21932.0
30	4.6-+C.8	5.4-+C.7	C.7-+C.2	9.9-+1.1	1.7-+0.5	2.1-+0.6	0.8-+0.3	25.2-+1.6	74.8	23854.5
36	5.7-+1.0	5.7-+C.8	C.7-+C.2	11.3-+1.3	2.9-+0.8	3.0-+0.8	1.1-+0.4	30.4-+2.0	59.6	25056.0
42	5.7-+1.0	6.3-+1.0	C.7-+C.2	11.3-+1.3	2.9-+0.8	3.0-+0.8	1.1-+0.4	31.0-+2.1	59.0	25742.5

G R C S S

MONTHS	LOSS TO FOLLOW-UP								
1	C.2-+0.1	2.4-+C.3	0.0-+C.0	1.7-+C.3	0.0-+0.0	0.1-+0.1	0.1-+0.1	1.4-+0.3	1398.0
2	C.6-+0.2	4.4-+C.4	0.1-+0.1	2.9-+C.4	0.2-+0.1	0.1-+0.1	0.1-+0.1	2.7-+0.4	2728.0
3	C.9-+0.2	5.6-+C.4	0.2-+C.1	3.1-+C.4	0.2-+0.1	0.1-+0.1	0.1-+0.1	2.4-+0.4	4018.0
4	1.1-+0.3	6.2-+C.5	0.2-+0.1	3.6-+C.5	0.2-+0.1	0.1-+0.1	0.2-+0.1	2.6-+0.4	5280.5
5	1.5-+0.3	6.9-+C.5	C.6-+C.2	4.1-+C.5	0.3-+0.1	0.2-+0.1	0.2-+0.1	2.9-+0.5	6504.0
6	1.6-+0.3	7.5-+C.5	0.6-+C.2	4.3-+C.5	0.4-+0.2	0.3-+0.2	0.3-+0.2	3.3-+0.5	7686.5
7	2.9-+0.4	8.3-+C.6	C.8-+C.2	4.9-+C.6	0.7-+0.2	0.6-+0.2	0.3-+0.2	3.8-+0.5	11045.0
12	3.3-+0.5	9.2-+C.6	C.8-+C.2	5.4-+C.6	1.1-+0.3	1.0-+0.3	0.4-+0.2	4.3-+0.6	14095.0
18	3.8-+0.5	10.5-+C.6	0.9-+C.3	7.2-+C.7	1.5-+0.3	1.6-+0.4	0.5-+0.2	4.8-+0.6	18743.0
24	4.3-+0.6	10.8-+C.7	0.9-+C.3	9.2-+C.9	1.8-+0.4	1.8-+0.4	0.7-+0.3	5.2-+0.7	21932.0
30	6.1-+0.9	11.1-+C.7	0.9-+C.3	11.5-+1.3	2.2-+0.5	2.5-+0.7	0.9-+0.4	7.4-+1.0	23854.5
36	7.5-+1.2	11.6-+C.9	0.9-+C.3	13.2-+1.5	3.7-+1.1	3.6-+1.0	1.4-+0.6	7.4-+1.0	25056.0
42	7.5-+1.2	12.4-+1.2	C.9-+C.3	13.2-+1.5	3.7-+1.1	3.6-+1.0	1.4-+0.6	7.4-+1.0	25742.5

MONTHS	TOTAL LFU ANNUAL MEAN ADMISSIONS								
1	C.1-+0.1	0.9-+C.3	C.C-+C.C	1.4-+C.3	0.0-+0.0	0.1-+0.1	0.1-+0.1	4.9	1398.0
2	C.5-+0.2	2.0-+C.4	C.1-+C.1	2.5-+C.4	0.1-+0.1	0.1-+0.1	0.1-+0.1	1.3	2728.0
3	C.8-+0.2	2.7-+C.4	C.2-+C.1	2.7-+C.4	0.1-+0.1	0.1-+0.1	0.1-+0.1	1438	4018.0
4	1.0-+0.3	3.0-+C.5	0.2-+0.1	3.2-+C.5	0.2-+0.1	0.1-+0.1	0.2-+0.1	1398.0	5280.5
5	1.1-+0.3	3.3-+C.5	C.5-+C.2	3.7-+C.5	0.2-+0.1	0.2-+0.1	0.2-+0.1	6504.0	6504.0
6	1.2-+0.3	3.6-+C.5	0.5-+C.2	3.9-+C.5	0.3-+0.2	0.3-+0.2	0.3-+0.2	7686.5	7686.5
7	2.4-+0.4	4.3-+C.6	0.7-+C.2	4.4-+C.6	0.7-+0.2	0.6-+0.2	0.3-+0.2	11045.0	11045.0
12	2.7-+0.5	4.8-+C.6	0.7-+C.2	4.9-+C.6	1.1-+0.3	1.0-+0.3	0.4-+0.2	14095.0	14095.0
18	3.0-+0.5	5.2-+C.6	C.8-+C.3	6.6-+C.7	1.3-+0.3	1.6-+0.4	0.5-+0.2	18743.0	18743.0
24	3.5-+0.6	5.4-+C.7	C.8-+C.3	8.6-+C.9	1.6-+0.4	1.8-+0.4	0.7-+0.3	21932.0	21932.0
30	5.3-+0.9	5.7-+C.7	0.8-+C.3	10.9-+1.3	2.0-+0.5	2.5-+0.7	0.9-+0.4	23854.5	23854.5
36	6.7-+1.2	6.2-+C.9	0.8-+C.3	12.6-+1.5	3.5-+1.1	3.6-+1.0	1.4-+0.6	25056.0	25056.0
42	6.7-+1.2	7.0-+1.2	0.8-+C.3	12.6-+1.5	3.5-+1.1	3.6-+1.0	1.4-+0.6	25742.5	25742.5

1) COMPLETED ACCORDING TO THE TIETZE-POTTER MULTIPLE SEGMENT-DECREMENT LIFE-TABLE APPROACH (OCT.-1968 VERSION)
2) RECOMMENDED FOR INTRA-STUDY COMPARISON
3) RECOMMENDED FOR INTER-STUDY COMPARISON

**LOW
A/P**

DATA COLLECTION AND PROCESSING • RESEARCH DEPARTMENT
THE PATHFINDER FUND
BOSTON, MASS., U.S.A.
R.P. BERNARD AND H. COMPTON-NEMER

DATA COMPUTATION • SOCIOLOGY COMPUTER LABORATORY
BROWN UNIVERSITY
PROVIDENCE, R.I., U.S.A.
J.M. SAKODA, R.G. POTTER AND P.S. CHI

FACTORY = YUG - QUACRLPVIRAT STUDY START = JUNE, 1965 COMPUTATION SPAN = 46 MONTHS
PLACE = SKCP.BEOG.LJLPL.KCP. CUTOFF DATE = MARCH, 1969 326 COMPILATION PLACE = PROVIDENCE
DEVICE = YUG.C-PASEL. 25-1 LC STUDY SPAN = 46 MONTHS COMPILATION DATE = 4 AUGUST, 1969 DUBRO

CUMULATIVE NET AND GROSS RATES OF EVENTS AND CLOSURES, BY TYPE OF TERMINATION AND INTERVAL AFTER FIRST INSERTION PER 100 IUD USERS (1)

MONTHS	PREGNANCY	EXPLSION FIRST	EXPLSION LATER	REMOVAL BLEEDING AND PAIN	REMOVAL O.MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL O.PERSONAL REASONS	T O T A L TERMINATIONS	WOMAN MONTHS OF USE RESIDUAL CUMULAT
1	C.C.+0.C	3.6+0.9	0.C+0.C	1.8+0.6	0.0+0.0	0.2+0.2	0.2+0.2	5.8+1.1	439.5
2	C.2+0.2	7.5+1.2	0.2+0.2	2.9+0.8	0.2+0.2	0.2+0.2	0.2+0.2	11.5+1.5	411.5
3	C.5+0.3	9.6+1.4	0.5+0.3	2.9+0.8	0.2+0.2	0.2+0.2	0.2+0.2	14.1+1.7	392.5
4	C.5+0.3	10.3+1.4	0.5+0.3	2.9+0.8	0.2+0.2	0.2+0.2	0.5+0.3	15.0+1.7	384.0
5	C.7+0.4	11.9+1.6	0.7+0.4	3.6+0.9	0.2+0.2	0.5+0.3	0.5+0.3	18.1+1.8	372.0
6	C.7+0.4	13.1+1.6	0.7+0.4	4.1+1.0	0.2+0.2	0.7+0.4	0.7+0.4	20.3+1.9	357.5
9	1.4+0.6	14.4+1.7	1.2+0.5	4.6+1.0	0.5+0.3	1.2+0.5	0.7+0.4	24.3+2.1	332.5
12	1.7+0.6	15.2+1.8	1.2+0.5	5.4+1.1	0.5+0.3	2.0+0.7	1.0+0.5	27.2+2.2	293.5
18	2.C+0.7	16.7+1.8	1.5+0.6	7.3+1.3	0.8+0.4	3.3+1.0	1.0+0.5	32.5+2.4	213.0
24	2.4+0.8	17.4+1.9	1.5+0.6	8.5+1.5	0.8+0.4	3.7+1.0	1.0+0.5	35.2+2.5	162.5
30	3.6+1.2	17.4+1.9	1.5+0.6	10.7+1.9	0.8+0.4	5.1+1.4	1.0+0.5	40.0+2.9	93.0
36	4.5+1.5	18.4+2.1	1.5+0.6	10.7+1.9	1.8+1.1	6.1+1.7	1.0+0.5	44.0+3.3	62.0

CLOSURE	DISCONTIN UATION	CONTIN UATION								
1	C.C.+0.C	1.8+0.6	C.C.+0.C	1.8+0.6	0.0+0.0	0.2+0.2	0.2+0.2	4.0+0.9	96.0	439.5
2	C.2+0.2	3.8+0.9	C.2+0.2	2.9+0.8	0.0+0.0	0.2+0.2	0.2+0.2	7.7+1.3	92.3	851.0
3	C.5+0.3	5.2+1.1	0.5+0.3	2.9+0.8	0.0+0.0	0.2+0.2	0.2+0.2	9.5+1.4	90.5	1243.5
4	C.5+0.3	5.7+1.1	0.5+0.3	2.9+0.8	0.0+0.0	0.2+0.2	0.5+0.3	10.2+1.4	89.8	1627.5
5	C.7+0.4	6.4+1.2	0.7+0.4	3.6+0.9	0.0+0.0	0.5+0.3	0.5+0.3	12.4+1.6	87.6	1999.5
6	C.7+0.4	6.9+1.2	0.7+0.4	4.1+1.0	0.0+0.0	0.7+0.4	0.7+0.4	13.8+1.7	86.2	2357.0
9	1.4+0.6	8.2+1.3	1.2+0.5	4.6+1.0	0.2+0.2	1.2+0.5	0.7+0.4	17.6+1.8	82.4	3380.0
12	1.7+0.6	8.7+1.4	1.2+0.5	5.1+1.1	0.2+0.2	2.0+0.7	1.0+0.5	20.0+2.0	80.0	4308.0
18	2.C+0.7	9.6+1.5	1.5+0.6	7.C+1.3	C.5+0.4	3.3+1.0	1.0+0.5	24.9+2.2	75.1	5766.0
24	2.4+0.8	10.0+1.5	1.5+0.6	8.2+1.4	0.5+0.4	3.7+1.0	1.0+0.5	27.3+2.3	72.7	6888.5
30	3.6+1.2	10.0+1.5	1.5+0.6	10.4+1.9	0.5+0.4	5.1+1.4	1.0+0.5	32.1+2.8	57.9	7608.5
36	4.5+1.5	10.9+1.8	1.5+0.6	10.4+1.9	1.6+1.1	6.1+1.7	1.0+0.5	36.1+3.3	53.9	8057.0

G R O S S

EVENT	LOSS TO FOLLOW-UP								
1	C.C.+0.C	3.6+0.6	C.C.+0.C	1.8+0.6	0.0+0.0	0.2+0.2	0.2+0.2	0.7+0.4	439.5
2	0.2+0.2	7.6+0.9	0.2+0.2	3.0+0.8	0.2+0.0	0.2+0.2	0.2+0.2	2.1+0.7	851.0
3	0.5+0.4	9.8+1.1	0.5+0.4	3.0+0.8	0.2+0.0	0.2+0.2	0.2+0.2	2.1+0.7	1243.5
4	0.5+0.4	10.5+1.1	0.5+0.4	3.0+0.8	0.2+0.0	0.2+0.2	0.5+0.3	2.4+0.7	1627.5
5	C.8+0.4	12.3+1.2	C.8+0.4	3.8+0.9	0.2+0.0	0.5+0.4	0.5+0.3	2.6+0.8	1999.5
6	0.8+0.4	13.6+1.3	0.8+0.4	4.3+1.0	0.2+0.0	0.8+0.4	0.8+0.4	2.9+0.8	2357.0
9	1.6+0.7	15.2+1.4	1.4+0.6	4.9+1.1	0.5+0.3	1.4+0.6	0.8+0.4	3.7+1.0	3380.0
12	2.C+0.7	16.1+1.4	1.4+0.6	5.8+1.1	0.5+0.3	2.3+0.8	1.1+0.6	4.1+1.0	4308.0
18	2.3+0.8	17.6+1.5	1.7+0.7	8.1+1.4	0.9+0.5	4.0+1.1	1.1+0.6	4.5+1.1	5766.0
24	2.9+1.0	18.5+1.6	1.7+0.7	9.5+1.7	0.9+0.5	4.4+1.2	1.1+0.6	4.5+1.1	6888.5
30	4.5+1.5	18.5+1.6	1.7+0.7	12.4+2.3	0.9+0.5	6.3+1.8	1.1+0.6	6.8+1.7	7608.5
36	5.8+2.0	19.8+2.0	1.7+0.7	12.4+2.3	2.5+1.6	7.8+2.3	1.1+0.6	6.8+1.7	8057.0

CLOSURE	TOTAL LFU ANNUAL MEAN ADMISSIONS								
1	0.C+0.C	1.8+0.6	0.0+0.0	1.8+0.6	0.0+0.0	0.2+0.2	0.2+0.2	4.4	439.5
2	0.2+0.2	3.9+0.9	0.2+0.2	3.0+0.8	0.0+0.0	0.2+0.2	0.2+0.2	1.2	851.0
3	C.5+0.4	5.4+1.1	0.5+0.4	3.0+0.8	0.0+0.0	0.2+0.2	0.2+0.2	454	1243.5
4	0.5+0.4	5.9+1.1	0.5+0.4	3.0+0.8	0.0+0.0	0.2+0.2	0.5+0.3		1627.5
5	C.8+0.4	6.6+1.2	0.8+0.4	3.8+0.9	0.0+0.0	0.5+0.4	0.5+0.3		1999.5
6	0.8+0.4	7.2+1.3	0.8+0.4	4.3+1.0	0.0+0.0	0.8+0.4	0.8+0.4		2357.0
9	1.6+0.7	8.5+1.4	1.4+0.6	4.9+1.1	0.3+0.3	1.4+0.6	0.8+0.4		3380.0
12	2.C+0.7	9.1+1.4	1.4+0.6	5.5+1.1	0.3+0.3	2.3+0.8	1.1+0.6		4308.0
18	2.3+0.8	10.2+1.5	1.7+0.7	7.8+1.4	0.7+0.5	4.0+1.1	1.1+0.6		5766.0
24	2.9+1.0	10.6+1.6	1.7+0.7	9.2+1.7	0.7+0.5	4.4+1.2	1.1+0.6		6888.5
30	4.5+1.5	10.6+1.6	1.7+0.7	12.1+2.3	0.7+0.5	6.3+1.8	1.1+0.6		7608.5
36	5.8+2.0	11.9+2.0	1.7+0.7	12.1+2.3	2.2+1.6	7.8+2.3	1.1+0.6		8057.0

1) COMPUTED ACCORDING TO THE TIETZE-POTTYR MULTIPLE SEGMENT-DECREMENT LIFE-TABLE APPROACH (OCT.-1968 VERSION)
2) RECOMMENDED FOR INTRA-STUDY COMPARISON
3) RECOMMENDED FOR INTER-STUDY COMPARISON

DATA COLLECTION AND PROCESSING* RESEARCH DEPARTMENT
THE PATHFINDER FUND
BOSTON, MASS., U.S.A.
R.P. BERNARD AND H. CUMPTON-NENER

DATA COMPUTATION* SOCIOLOGY COMPUTER LABORATORY
BROWN UNIVERSITY
PROVIDENCE, R.I., U.S.A.
J.M. SAKODA, R.G. POTTER AND P.S. CHI

CCCTOR = YJGC - QUACHPVIRAT STUDY START = JUNE, 1965 COMPUTATION SPAN = 46 MONTHS
PLACE = SKCP-BEUG-LJLEL-KCP. CUTOFF DATE = MARCH, 1969 327 COMPILATION PLACE = PROVIDENCE
DEVICE = YUG-C-BASEL.26-2 PLS STUDY SPAN = 46 MONTHS COMPILATION DATE = 4 AUGUST, 1969 DUBRO

CUMULATIVE NET AND GROSS RATES OF EVENTS AND CLOSURES, BY TYPE OF TERMINATION AND INTERVAL AFTER FIRST INSERTION PER 100 IUD USERS 1)

MONTHS	PREGNANCY	EXPLSION FIRST	EXPLSION LATER	REMOVAL BLEEDING AND PAIN	REMOVAL MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL PERSONAL REASONS	TOTAL TERMINATIONS	WOMAN MONTHS OF USE	NET
1	C.3-+C.2	1.9-+C.4	C.C-+C.0	1.7-+C.4	0.0-+0.0	0.0-+0.0	0.0-+0.0	3.8-+0.6	958.5	958.5
2	C.7-+C.3	2.9-+C.5	C.C-+C.0	2.8-+C.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	6.7-+0.8	918.5	1877.0
3	1.1-+C.3	3.7-+C.6	C.C-+C.0	3.1-+C.6	0.1-+0.1	0.0-+0.0	0.1-+0.1	8.1-+0.9	897.5	2774.5
4	1.4-+C.4	4.2-+C.6	C.1-+C.1	3.9-+C.6	0.2-+0.2	0.0-+0.0	0.1-+0.1	9.9-+1.0	878.5	3653.0
5	1.8-+C.4	4.3-+C.7	0.5-+C.2	4.2-+C.7	0.3-+0.2	0.1-+0.1	0.1-+0.1	11.4-+1.0	851.5	4504.5
6	1.9-+0.4	4.6-+C.7	0.5-+C.2	4.2-+C.7	0.4-+0.2	0.1-+0.1	0.1-+0.1	12.0-+1.1	825.0	5329.5
9	2.2-+0.6	5.0-+C.7	C.5-+C.2	4.8-+C.7	0.8-+0.3	0.2-+0.2	0.1-+0.1	14.6-+1.2	761.0	7665.0
12	3.7-+0.6	5.9-+C.8	0.5-+C.2	5.2-+C.7	1.3-+0.4	0.4-+0.2	0.1-+0.1	17.0-+1.3	671.0	9787.0
18	4.7-+0.7	6.8-+C.9	C.5-+C.2	6.6-+0.9	1.6-+0.4	0.5-+0.3	0.2-+0.2	20.6-+1.4	436.0	12977.0
24	4.6-+C.8	6.8-+C.9	0.5-+C.2	8.7-+1.1	2.0-+0.5	0.5-+0.3	0.5-+0.3	23.7-+1.6	278.0	15043.5
30	6.7-+1.1	7.3-+1.0	C.5-+C.2	10.4-+1.4	2.5-+0.7	0.5-+0.3	0.8-+0.4	28.2-+2.0	158.5	16246.0
36	7.3-+1.4	7.3-+1.0	C.5-+C.2	12.7-+1.8	3.7-+1.1	1.2-+0.7	1.3-+0.7	34.1-+2.6	103.0	16999.0
42	7.4-+1.4	7.3-+1.0	C.5-+C.2	12.7-+1.8	3.7-+1.1	1.2-+0.7	1.3-+0.7	34.1-+2.6	32.0	17421.5

MONTHS	PREGNANCY	EXPLSION FIRST	EXPLSION LATER	REMOVAL BLEEDING AND PAIN	REMOVAL MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL PERSONAL REASONS	TOTAL TERMINATIONS	WOMAN MONTHS OF USE	NET
1	C.2-+0.1	0.5-+C.2	C.C-+C.0	1.2-+0.4	0.0-+0.0	0.0-+0.0	0.0-+0.0	2.0-+0.4	98.0	98.5
2	0.6-+C.3	1.1-+C.3	C.C-+C.0	2.2-+C.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	4.2-+0.6	95.8	1877.0
3	C.9-+C.3	1.5-+C.4	C.C-+C.0	2.5-+C.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	5.1-+0.7	94.9	2774.5
4	1.2-+0.3	1.7-+C.4	0.1-+C.1	3.3-+C.6	0.2-+0.2	0.0-+0.0	0.1-+0.1	6.5-+0.8	93.5	3653.0
5	1.3-+0.4	1.7-+C.4	0.3-+C.2	3.6-+C.6	0.3-+0.2	0.1-+0.1	0.1-+0.1	7.4-+0.9	92.6	4504.5
6	1.4-+0.4	1.9-+C.4	C.3-+C.2	3.6-+C.6	0.4-+0.2	0.1-+0.1	0.1-+0.1	7.9-+0.9	92.1	5329.5
9	2.6-+C.5	2.3-+C.5	0.3-+C.2	4.2-+C.7	0.8-+0.3	0.2-+0.2	0.1-+0.1	10.4-+1.0	89.6	7665.0
12	2.8-+0.6	2.6-+C.5	0.3-+C.2	4.5-+C.7	1.3-+0.4	0.4-+0.2	0.1-+0.1	12.0-+1.1	88.0	9787.0
18	3.1-+0.6	2.8-+C.6	C.3-+C.2	5.8-+C.8	1.4-+0.4	0.5-+0.3	0.2-+0.2	14.2-+1.2	85.8	12977.0
24	3.5-+0.7	2.8-+C.6	0.3-+C.2	7.9-+1.1	1.9-+0.5	0.5-+0.3	0.5-+0.3	17.4-+1.5	82.6	15043.5
30	5.1-+1.0	3.2-+C.7	0.3-+C.2	9.6-+1.4	2.3-+0.7	0.5-+0.3	0.8-+0.4	21.9-+1.9	78.1	16246.0
36	6.3-+1.3	3.2-+C.7	0.3-+C.2	11.9-+1.8	3.5-+1.1	1.2-+0.7	1.3-+0.7	27.8-+2.5	72.2	16999.0
42	6.3-+1.3	3.2-+C.7	C.3-+C.2	11.9-+1.8	3.5-+1.1	1.2-+0.7	1.3-+0.7	27.8-+2.5	72.2	17421.5

GROSS

MONTHS	PREGNANCY	EXPLSION FIRST	EXPLSION LATER	REMOVAL BLEEDING AND PAIN	REMOVAL MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL PERSONAL REASONS	TOTAL TERMINATIONS	WOMAN MONTHS OF USE	NET
1	0.3-+0.1	1.9-+C.2	C.C-+C.0	1.7-+C.4	0.0-+0.0	0.0-+0.0	0.0-+0.0	1.8-+0.4	958.5	958.5
2	0.7-+0.3	3.0-+C.4	C.C-+C.0	2.8-+C.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	2.2-+0.5	918.5	1877.0
3	1.1-+0.3	3.7-+C.4	C.C-+C.0	3.2-+C.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	2.5-+0.5	897.5	2774.5
4	1.4-+0.4	4.3-+C.4	0.1-+C.1	3.9-+C.6	0.2-+0.2	0.0-+0.0	0.1-+0.1	2.7-+0.5	878.5	3653.0
5	1.9-+0.4	4.4-+C.4	0.6-+C.2	4.3-+C.6	0.3-+0.2	0.1-+0.1	0.1-+0.1	3.0-+0.6	851.5	4504.5
6	2.0-+0.4	4.8-+C.5	0.6-+C.2	4.3-+C.6	0.5-+0.2	0.1-+0.1	0.1-+0.1	3.5-+0.6	825.0	5329.5
9	3.4-+0.6	5.1-+C.5	0.6-+C.2	4.9-+C.7	0.8-+0.3	0.2-+0.2	0.1-+0.1	3.8-+0.6	761.0	7665.0
12	3.9-+0.6	6.1-+C.6	0.6-+C.2	5.3-+C.7	1.4-+0.4	0.4-+0.2	0.1-+0.1	4.5-+0.7	671.0	9787.0
18	4.5-+0.6	7.2-+C.6	0.6-+C.2	6.9-+0.9	1.7-+0.4	0.6-+0.3	0.3-+0.2	5.0-+0.7	436.0	12977.0
24	5.0-+0.7	7.2-+C.6	0.6-+C.2	9.2-+1.2	2.2-+0.6	0.6-+0.3	0.5-+0.3	5.5-+0.8	278.0	15043.5
30	6.8-+1.1	7.7-+C.8	0.6-+C.2	11.1-+1.5	2.8-+0.8	0.6-+0.3	0.9-+0.5	7.7-+1.3	158.5	16246.0
36	8.3-+1.5	7.7-+C.8	0.6-+C.2	13.8-+2.0	4.4-+1.4	1.4-+0.9	1.6-+0.8	7.7-+1.3	103.0	16999.0
42	8.3-+1.5	7.7-+C.8	C.6-+C.2	13.8-+2.0	4.4-+1.4	1.4-+0.9	1.6-+0.8	7.7-+1.3	32.0	17421.5

MONTHS	PREGNANCY	EXPLSION FIRST	EXPLSION LATER	REMOVAL BLEEDING AND PAIN	REMOVAL MEDICAL REASONS	REMOVAL PLANNING PREGNANCY	REMOVAL PERSONAL REASONS	TOTAL TERMINATIONS	WOMAN MONTHS OF USE	NET
1	0.2-+0.1	0.5-+C.2	C.C-+C.0	1.2-+0.4	0.0-+0.0	0.0-+0.0	0.0-+0.0	2.0-+0.4	98.0	98.5
2	0.8-+0.3	1.2-+C.4	C.C-+C.0	2.2-+0.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	4.2-+0.6	95.8	1877.0
3	1.0-+0.3	1.5-+C.4	0.0-+C.0	2.5-+0.5	0.1-+0.1	0.0-+0.0	0.1-+0.1	5.1-+0.7	94.9	2774.5
4	1.2-+0.4	1.7-+C.4	0.1-+C.1	3.3-+C.6	0.2-+0.2	0.0-+0.0	0.1-+0.1	6.5-+0.8	93.5	3653.0
5	1.3-+0.4	1.7-+C.4	0.3-+C.2	3.6-+C.6	0.3-+0.2	0.1-+0.1	0.1-+0.1	7.4-+0.9	92.6	4504.5
6	1.4-+0.4	2.0-+C.5	0.3-+C.2	3.6-+C.6	0.5-+0.2	0.1-+0.1	0.1-+0.1	7.9-+0.9	92.1	5329.5
9	2.7-+0.6	2.3-+C.5	0.3-+C.2	4.3-+C.7	0.8-+0.3	0.2-+0.2	0.1-+0.1	10.4-+1.0	89.6	7665.0
12	3.0-+0.6	2.7-+C.6	0.3-+C.2	4.7-+C.7	1.4-+0.4	0.4-+0.2	0.1-+0.1	12.0-+1.1	88.0	9787.0
18	3.3-+0.6	2.9-+C.6	0.3-+C.2	6.1-+0.9	1.6-+0.4	0.6-+0.3	0.3-+0.2	14.2-+1.2	85.8	12977.0
24	3.8-+0.7	2.9-+C.6	0.3-+C.2	8.4-+1.2	2.0-+0.6	0.6-+0.3	0.5-+0.3	17.4-+1.5	82.6	15043.5
30	5.6-+1.1	3.5-+C.8	0.3-+C.2	10.3-+1.5	2.6-+0.8	0.6-+0.3	0.9-+0.5	21.9-+1.9	78.1	16246.0
36	7.1-+1.5	3.5-+C.8	0.3-+C.2	13.0-+2.0	4.2-+1.4	1.4-+0.9	1.6-+0.8	27.8-+2.5	72.2	16999.0
42	7.1-+1.5	3.5-+C.8	0.3-+C.2	13.0-+2.0	4.2-+1.4	1.4-+0.9	1.6-+0.8	27.8-+2.5	72.2	17421.5

1) COMPUTED ACCORDING TO THE TIETZE-POTTER MULTIPLE SEGMENT-DECREMENT LIFE-TABLE APPROACH (OCT.-1968 VERSION)
2) RECOMMENDED FOR INTRA-STUDY COMPARISON
3) RECOMMENDED FOR INTER-STUDY COMPARISON

Comments:

(The Yugoslavia IUD Baseline – Optimal Age/Parity Discriminator for Expulsion)

1. Studying the 12-month composite table of expulsion and BI/P removal, one recognizes a rather abrupt decrease in expulsion with increasing age and parity. There was an interest to cut the YUGOPOOL into two subsamples, along a line of maximal discriminatory power, with regard to primary expulsion. After considerable trying, the following two samples were delineated:

Low Age-Parity Group: Women through 25 years or up to 1 live birth
 High Age-Parity Group: Women above 25 years and at least 2 live births

2. Three standard tables have been constructed and used as the *basic analysis tool* for all studies around the world sponsored by the INTERNATIONAL IUD PROGRAMME.

Table 1:

Short-range IUD use-effectiveness. Monthly net event rates by ordinal month from first insertion per 100 IUD users. Numerator and denominator have been given so that the reader may verify the rates given in the lower half of the table. For instance, the fact that 34 out of 1416.5 (adjusted) women expelled during the first post-insertion month leads to a 2.4% expulsion rate for that first ordinal month. Note the definition of the denominator (C. Tietze): adjusted number of women entering current month = number of women entering a given ordinal month after first insertion, adjusted for the numbers who remain at risk for part of the month only. The table gives in the framed, right-hand bottom column half-year net cumulative event rates, the combined relevant risk, the pertinent events (bold) with standard errors – to set them apart from the 7 “relevant termination categories,” as defined by C. Tietze. It gives, furthermore, the loss to follow-up percentage and the estimate of the aggregate women-months of use through that ordinal month. One would thus read: based on a cumulative aggregate of 7685.5 women-months of use and on a follow-up of 96.7% through the 8th ordinal month after primary insertion, 7.3 per 100 Loop C wearers had lost their device during the first half-year after insertion in the statistical universe defined as YUGOPOOL. The corresponding BI/P removal figure was 4.2% and the corollary genuine pregnancy rate was 1.5%. Note the difference between combined relevant risk (14.6), the sum of the seven “relevant” (C. Tietze) termination categories, as opposed to the pertinent events (13.0) delineated here. The six-month column leads to the second table.

Table 2:

Long-range IUD use-effectiveness. Cumulative net rates of events and closures by type of (time-) segment termination and interval after first insertion per 100 IUD users. Cumulative rates are given at half-year intervals so far as the residual women-months of use (= estimate of aggregate women-months of use during and at that ordinal month) will permit. The computer has been instructed to shut off where less than thirty “segments remain under observation as of the midpoint of a given ordinal month” (Tietze). As to read from standard Table 2: the 36-month rates are still given, as 166 women remained under observation at the 36th ordinal month after insertion. The table also indicates that rates are available up to 42 months (based on a residual number of 51). One would thus read: based on a cumulative aggregate of 25,056 women-months of use and on a follow-up of 92.6% through the 36th ordinal month after primary Loop C insertion, 10.9 per 100 IUD wearers had lost their device during the subsequent three-year period in the universe defined as YUGOPOOL. Corresponding 3-year net cumulative rates of BI/P removal and genuine pregnancy failure were 11.9 and 6.5%, respectively. Note the now greater discrepancy between total termination (= combined relevant risks) and the termination due to the three pertinent event categories: 37.2 against 29.3%. The complement of the latter is being referred to as *pertinent continuation* and is perhaps coming closest to the *theoretical effectiveness* of a given IUD still within a given universe. It neglects the following termination categories: later expulsion, and removal for all reasons other than bleeding and/or pain. Besides crystallization of the theoretical IUD effectiveness, it is also possible to give a realistic picture of the local program’s success, by taking into account both the IUD termination categories dropped above and the reinsertion policy – known to be locale-specific. Any event not followed by reinsertion is defined as a closure (of the patient history) and any event category will produce a corollary lower or equal closure rate. The sum of the

net rates of the seven "relevant" termination categories not followed by reinsertion (= closure) is defined as the discontinuation rate (Tietze). Its complement is the (IUD program) continuation rate, probably the best indicator of the local program's success. This *de facto continuation* does not vary much in the YUGOPOOL (69.6), when compared to the theoretical continuation (70.7). This is essentially due to a virtual balancing of the two opposite forces molding the de facto continuation rate: reinsertions (up) and occurrence of non-pertinent events (down). Let us retain that a 3-year continuation (whether *de facto* or *theoretical*) of 70% is an outstanding achievement, in light of American and Asian figures.

Table 3:

Short- and mid-range IUD use-effectiveness by age-parity.

Four- and twelve-month cumulative net rates of events and continuation by termination type and age-parity per 100 IUD users. As previously mentioned, the densely stratified age-parity analysis of the YUGOPOOL has led to a distinction between a low and a high age-parity group, already defined. Table 3 is constructed by making two further computer runs, after having sorted the "composite" sample into its two "low" and "high" age-parity constituents. Four and 12 months after insertion have been chosen as points in time of particular propitiousness toward interpretation of potential age-parity differentials. The findings are framed by three equations, guaranteeing the computer's perfect performance. Naturally, the frequencies of women enlisted together with the residual and cumulative women-months of use should add perfectly. The crucial finding of this table is interpreted in the left-bottom frame: (1) At both points in time after insertion, expulsions for the "low" age-parity group are about 2.5 times that of the "high." (2) In contrast, there is no age-parity differential for BI/P removals. (3) Excellent follow-up. The 85.4% one-year de facto continuation rate (= sum of closures¹) splits into 80.0% for the low age-parity group against one of 88% for the high group. It is easily recognized that this differential is almost essentially due to the differential in primary IUD expulsion. In other words: age-parity is a critical discriminator for successful IUD retention, as already determined by Christopher Tietze² in his USA experience and by Robert Potter³ in the IUD experience of Formosa.

3. Table 3 is based on the *computer summary outputs* terminating the presently used computer program developed by J.M. Sakoda, R.G. Potter and P.S. Chi at Brown University. To round out the background information, they have been reproduced here for both the composite and the age-parity groups.

The lower half gives the *gross* rates which, though at hand for each study, have not been given here. They are slightly higher than the corresponding net rates, but lack the crucial quality of additivity to calculate total discontinuation (theoretical and de facto). They are thus literally kept in storage at headquarters, in case a crucial comparison between several studies around the world for a given event category should be in order. For most comparison, however, *net* rates are sufficient and shall therefore remain the statistical language of the INTERNATIONAL IUD PROGRAMME. They provide the unique advantage of simultaneous assessment both of *theoretical IUD effectiveness* and *program success*. The contributor who is being fed back the statistical results of the local study can thus incorporate in his local scientific publication two important aspects of the study — simultaneously preserving the basic criterion of international comparability.

CONTRIBUTORS:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behlikovic
Dr. L. Antonovski/ A. Nikolovski

- ¹ Tietze, C., 'Intra-uterine contraception: Recommended procedures for data analysis.' *Studies in Family Planning, XVII, April, 1967*, suppl. 1-6.
- ² Tietze, C., 'C.S.P. for the Evaluation of Intra-uterine Devices.' *Eighth Progress Report, June, 1967*, tables 9 and 10.
- ³ Potter, R., 'Effectiveness of the IUD'. In: *Family Planning in Taiwan: An Experiment in Social Change* by Freedman, R. and Takeshita, J. Chapter 10. Princeton University Press, New Jersey, 1969.

4

ABORTION

AGE / PARITY

THE YUGOSLAVIA IUD BASELINE
(LOOP C - 1438 CASES)

4

FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY ABORTION AND AGE/PARITY
PER 100 LOOP C USERS

ABORTION

AGE / PARITY

L
OW
H
igh
C
omp
L
OW
H
igh
C
omp

RATE PER 100	0	1	2	3	4	5+	pool	MONTH
PREGNANCY, Gen.	0.9 ± 0.9	0.7 ± 0.7	—			—	0.5 ± 0.3	4
EXPULSION, 1st	13.1 ± 3.2	11.3 ± 2.7	12.8 ± 4.2			5.8 ± 3.3	10.3 ± 1.4	
REMOVAL, BI/P	2.6 ± 1.5	2.0 ± 1.2	3.2 ± 2.2			—	2.9 ± 0.8	
PERTIN. EVENTS	16.6	14.0	16.0			5.8	13.7	4
DISC./CONTIN.	9.6 90.4	10.5 83.5	16.0 84.0			3.9 96.1	10.2 89.8	
PREGNANCY, Gen.	0.7 ± 0.7	2.3 ± 1.0	0.5 ± 0.5	—	1.4 ± 1.4	2.8 ± 1.2	1.4 ± 0.4	
EXPULSION, 1st	8.6 ± 2.3	3.7 ± 1.3	2.9 ± 1.2	2.3 ± 1.3	4.3 ± 2.4	3.9 ± 1.6	4.2 ± 0.6	
REMOVAL, BI/P	2.6 ± 1.3	2.7 ± 1.1	5.3 ± 1.6	5.4 ± 2.0	7.1 ± 3.1	2.2 ± 1.1	3.9 ± 0.6	
PERTIN. EVENTS	11.9	8.7	8.7	7.7	12.8	8.9	9.5	12
DISC./CONTIN.	7.3 92.7	5.1 94.9	5.3 94.7	7.0 93.0	7.2 92.8	8.4 91.6	6.5 93.5	
PREGNANCY, Gen.	0.8 ± 0.5	1.7 ± 0.7	0.4 ± 0.4	—	1.0 ± 1.0	2.2 ± 1.0	1.1 ± 0.3	
EXPULSION, 1st	10.6 ± 1.9	6.7 ± 1.3	5.2 ± 1.2	2.4 ± 1.2	5.1 ± 2.2	4.3 ± 1.3	6.1 ± 0.6	
REMOVAL, BI/P	2.6 ± 1.0	2.5 ± 0.8	4.8 ± 1.3	6.5 ± 1.9	6.1 ± 2.4	7.7 ± 0.9	3.6 ± 0.5	
PERTIN. EVENTS	14.0	10.9	10.4	8.9	12.2	8.2	10.8	12
DISC./CONTIN.	8.3 91.7	7.2 92.8	7.8 92.2	8.3 91.7	7.1 92.9	7.4 92.6	7.7 92.3	
PREGNANCY, Gen.	2.0 ± 1.4	2.2 ± 1.3	—			—	1.7 ± 0.6	
EXPULSION, 1st	20.2 ± 3.9	16.6 ± 3.2	14.4 ± 4.5			7.8 ± 3.8	15.4 ± 1.8	
REMOVAL, BI/P	3.5 ± 1.7	6.7 ± 2.2	8.1 ± 3.5			—	5.4 ± 1.1	
PERTIN. EVENTS	25.7	25.5	22.5			7.8	22.5	12
DISC./CONTIN.	18.7 81.3	22.7 77.3	20.9 79.1			8.1 91.9	20.0 80.0	
PREGNANCY, Gen.	3.0 ± 1.5	4.4 ± 1.5	3.6 ± 1.4	2.4 ± 1.4	2.9 ± 2.0	4.6 ± 1.6	3.7 ± 0.6	
EXPULSION, 1st	11.1 ± 2.6	6.6 ± 1.8	3.4 ± 1.3	3.1 ± 1.5	4.3 ± 2.4	6.3 ± 1.8	5.9 ± 0.8	
REMOVAL, BI/P	5.6 ± 1.9	4.9 ± 1.5	5.9 ± 1.6	5.4 ± 2.0	8.8 ± 3.4	2.8 ± 1.2	5.2 ± 0.7	
PERTIN. EVENTS	19.7	15.9	12.9	10.9	16.0	13.7	14.8	12
DISC./CONTIN.	13.4 86.6	11.7 88.3	9.6 90.4	13.5 86.5	10.4 89.6	13.7 86.3	12.0 88.0	
PREGNANCY, Gen.	2.6 ± 1.0	3.6 ± 1.0	2.8 ± 1.0	3.1 ± 1.4	2.1 ± 1.5	3.6 ± 1.2	3.1 ± 0.5	
EXPULSION, 1st	15.1 ± 2.3	10.6 ± 1.7	6.0 ± 1.4	5.5 ± 1.8	6.2 ± 2.5	6.6 ± 1.7	8.9 ± 0.8	
REMOVAL, BI/P	4.7 ± 1.3	5.6 ± 1.3	6.4 ± 1.5	6.5 ± 1.9	7.2 ± 2.6	2.2 ± 1.0	5.2 ± 0.6	
PERTIN. EVENTS	21.4	19.8	15.2	15.1	15.5	12.4	17.2	12
DISC./CONTIN.	15.7 84.3	16.1 83.9	12.2 87.8	16.4 83.6	13.8 86.2	12.4 87.6	17.7 82.3	

STUDY START 6/65
 COMPUTATION-CUTOFF DATE 3/69
 STUDY SPAN (in mos.) 46
 COMPUTATION DATE 1-10/89
 Physicians: Dr. L. Andolsek, Dr. M. Kolenc, Dr. B. Behilovic, Dr. L. Antonovski/A. Nikolovski

	L	H	C
Age in Years	25 or C-1	26+ and 2+	Composite

**Background Data To
THE YUGOSLAVIA IUD BASELINE
(LOOP C - 1438 CASES)**

4

**FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY ABORTION AND AGE/PARITY
PER 100 LOOP C USERS**

A B O R T I O N

AGE | PARITY

		0	1	2	3	4	5+	pool	MONTH
L OW	LOGISTICS								
	NO. C. RUN	120 830	148 831	66 832			52 835	464 326	4
	RESID. Q-Mos. of Use	98.5	123.5	53			48	384	
CUMUL. Q-Mos. of Use	421	529	226.5			198	1627.5		
LOSS to FUP	1.8%	3.7%	-%			3.9%	2.4%		
H igh	NO. C. RUN	157 840	226 841	214 842	132 843	73 844	182 845	984 327	
	RESID. Q-Mos. of Use	137.5	+ 199	+ 194.5	+ 121.5	+ 63.5	+ 162.5	= 878.5	
	CUMUL. Q-Mos. of Use	574.5	+ 837.5	+ 802.5	+ 503	+ 265	+ 670.5	= 3653	
LOSS to FUP	2.7%	4.6%	1.9%	1.5%	1.4%	2.8%	2.7%		
C omp	NO. C. RUN	277 850	374 851	279 852	173 853	101 854	234 855	1438 243	
	RESID. Q-Mos. of Use	236	+ 322.5	+ 247.5	+ 166.5	+ 89.5	+ 210.5	= 1262.5	
	CUMUL. Q-Mos. of Use	995.5	+ 1366.5	+ 1029	+ 660	+ 371	+ 868.5	= 5280.5	
LOSS to FUP	2.3%	4.2%	1.5%	1.8%	1.0%	3.1%	2.6%		
L OW	NO. C. RUN	120 830	148 831	66 832	41	28	52 835	464 326	12
	RESID. Q-Mos. of Use	67	87	46.5			45.5	293.5	
	CUMUL. Q-Mos. of Use	1088	1338.5	628.5			576	4308	
LOSS to FUP	5.3%	4.8%	-%			5.9%	4.1%		
H igh	NO. C. RUN	157 840	226 841	214 842	132 843	73 844	182 845	984 327	
	RESID. Q-Mos. of Use	86	+ 137	+ 157	+ 101.5	+ 52	+ 137.5	= 671	
	CUMUL. Q-Mos. of Use	1443.5	+ 2146	+ 2213	+ 1390.5	+ 724.5	+ 1869.5	= 9787	
LOSS to FUP	4.4%	6.3%	2.4%	1.5%	3.0%	7.2%	4.5%		
C omp	NO. C. RUN	277 850	374 851	279 852	173 853	101 854	234 855	1438 243	
	RESID. Q-Mos. of Use	153	+ 224	+ 203.5	+ 128	+ 73	+ 183	= 964.5	
	CUMUL. Q-Mos. of Use	2529.5	+ 3484.5	+ 2841.5	+ 1775	+ 1019	+ 2445.5	= 14095	
LOSS to FUP	4.6%	5.6%	1.9%	2.4%	2.2%	6.9%	4.3%		

STUDY START 6/65
 COMPUTATION-CUTOFF DATE 3/69
 STUDY SPAN (in mos.) 46

COMPUTATION DATE 1-10/69
 Physicians: Dr. L. Andoleak, Dr. M. Kolenc, Dr. B. Behilovic, Dr. L. Antonovski/A. Nikolovski

	L	H	C
Age in Years	-25 or 0-1	26+ and 2+	Composite
No. of Live Births			

Comments:

(The Yugoslavia IUD Baseline – Abortion and Age/Parity)

1. The same YUGOPOOL has been analyzed for the same two broad age-parity classes by number of abortions (spontaneous and/or induced) *prior* to primary Loop C insertion. The same format of presentation has been adhered to. In particular, a *logistics* table has been prepared to check into corresponding frequencies (use this for construction of your frequency tables) and loss to follow-up proportions.
2. Naturally, abortion is age-parity related, as can be read from the following percentage distributions, giving row and column values.

		A B O R T I O N						
		0	1	2	3	4	5+	POOL
FREQUENCIES								
A-P	Low	120	148	65	41	28	52	454
	High	157	226	214	132	73	162	964
	Composite	277	374	279	173	101	234	1438
ROW PERCENTAGE (Age/Parity = constant)								
A-P	Low	26.4	32.6	14.3	9.0	6.2	11.5	100.0
	High	16.0	23.0	21.7	13.4	7.4	18.5	100.0
	Composite	19.3	26.0	19.4	12.0	7.0	16.3	100.0
COLUMN PERCENTAGE (Abortion = constant)								
A-P	Low	43.3	39.6	23.3	23.7	27.7	22.2	31.6
	High	56.7	60.4	76.7	76.3	72.3	77.8	68.4
	Composite	100.0	100.0	100.0	100.0	100.0	100.0	100.0

As to read from the row-percentage table, whereas the majority of the low age-parity group had had up to one abortion only (59%), the majority of the high age-parity group (61%) had undergone at least two abortions *prior* to primary Loop C insertion. Note also that 35.3% of the YUGOPOOL had suffered at least 3 abortions; 23.3%, at least 4, and 16.3%, at least 5! It is interesting also that only 1 in 4 (26.4%) of the low age-parity women was registered as never having had an abortion. In another country's pool situation the corollary relation is 3 in 5 (58.3%).

The same association can be read from the column-percentage table in the *low abortion frequency range*: the proportion of the high age-parity group increases with number of abortion. It climbs from 56.7% for nil abortions to readily reach a plateau at 2 abortions, with 76.7%. Note, thus, that in the *high abortion frequency range*, 1 in 4 patients belonged to the low age-parity group, independent of the number of abortions experienced. To recapitulate:

up to 2 abortions	expulsion is related to age-parity
for 2 abortions upwards	expulsion is independent of age-parity

This loss of dependency at such a low abortion frequency is a remarkable facet of the YUGOPOOL.

3. Still, the obvious triangular association of age-parity and abortion asks for fixing — to the extent possible — two variables when investigating the third. Given the very strong association between age and parity — previously demonstrated with the YUGOPOOL — two age-parity groups of potent differentiation capacity have been crystallized and previously defined — the low and high age-parity groups. In a sense, it is abandoning valuable qualitative information by shrinking a multi-point scale of two basic demographic variables into two broader and all-inclusive ranges. On the other hand, it allows — at least, in part — one to compensate for the relatively small sample (1438) which we are trying to classify by several variables.

4. The overall one-year *pertinent discontinuation* rate — already known as being 17.2% — decreases with increasing abortion, from 21.4 for 0 abortions to 12.4% for 5 or more abortions. Looking at the bottom row of cells, pregnancy failures do not vary by abortion. Neither do BI/P removals — with the exception, perhaps, of the 5+ abortion cell (2.2% against the POOL value of 5.2%). In contrast, primary expulsion decrease with abortion — exclusively so in the *low abortion frequency range, 0-2* (the sole range already known to be positively associated with age-parity!) The one-year expulsion rate of 15.1% for women without abortions decreases to 6% for women with 2 abortions. Further increase of abortion, however, does not influence the expulsion rate any further. To recapitulate:

up to 2 abortions	expulsion is related to abortion
for 2 abortions upwards	expulsion is independent of abortion

Obviously, up to now, the association of expulsion with abortion has been fully explained as being of an indirect nature:

expulsion is associated with abortion via age-parity

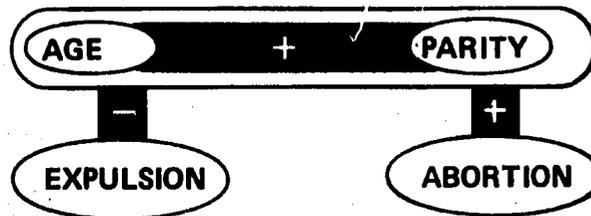
5. Furthermore, in the low abortion frequency range, the expulsion rates dissociate into a high rate for the low age-parity group (20.2, 16.6 and 14.4 for 0-2 abortions) against a low rate for the high age-parity group (11.1, 6.6 and 3.4, respectively). Thus could be further verified an *abortion-independent age-parity-effect on Loop C expulsion* for the very abortion range (0-2) known to be strongly related to age-parity.

6. Of particular interest is the sequence of ratios, by abortion, for the expulsion rates in the low age-parity groups.

		A B O R T I O N		
		0	1	2
A-P	Low.	20.2	16.6	14.4
	High	11.1	6.6	3.4
	Ratio	1.8	2.5	4.3

The expulsion ratio between the two contrasting age-parity groups increases with abortion (read now: with age-parity, given the low abortion frequency range). Within the defined age-parity groups, expulsions decrease less in the low age-parity group – with increasing age-parity – than they do in the high. This is a further way of refining information about the existent *age-parity-effect on Loop C expulsion*

7. Here is the relation scheme found up to now, whereby the abortion link is only verified in the *low abortion frequency range*:



8. Further inquiry should go into the high abortion frequency range. Given that 0-2 abortions (for which abortion-independence, but age-parity-dependence for expulsion has just been described), is rather associated with young women, it would make sense to focus on the high age-parity group as a *next* step toward untangling the association web. This is the next stage of inquiry.

CONTRIBUTORS:
 Dr. L. Andolsek
 Dr. M. Kolenc

Dr. B. Behilovic
 Dr. L. Antonovski/ A. Nikolovski

5

ABORTION

AGE

INTERNATIONAL IUD PROGRAMME — THE PATHFINDER FUND

5

THE YUGOSLAVIA IUD BASELINE

[LOOP C — 1436 CASES]

FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY AGE (WITHIN "HIGH" AGE/PARITY GROUP)
AND ABORTION (NIL VERSUS 4+)
PER 100 LOOP C USERS

A G E

A B O R T I O N

0

4+

B
oth

0

4+

B
oth

	26-29	30-34	35-39	40+	ALL
RATE PER 100					
PREGNANCY, Gen.	—	1.8 ± 1.7			0.7 ± 0.7
EXPULSION, 1st	11.0 ± 3.9	8.4 ± 3.6			8.6 ± 2.3
REMOVAL, BI/P	4.6 ± 2.6	1.8 ± 1.7			2.6 ± 1.3
PERTIN. EVENTS	15.6	12.0			11.9
DISC./CONTIN.	7.8 92.2	8.6 91.4			7.3 92.7
PREGNANCY, Gen.	5.2 ± 2.9	1.0 ± 1.0	2.8 ± 1.9		2.4 ± 1.0
EXPULSION, 1st	1.7 ± 1.7	5.0 ± 2.2	4.1 ± 2.3		4.0 ± 1.2
REMOVAL, BI/P	3.5 ± 2.4	5.0 ± 2.2	2.7 ± 1.9		3.6 ± 1.2
PERTIN. EVENTS	10.4	11.0	9.6		10.0
DISC./CONTIN.	8.7 91.3	8.1 91.9	8.2 91.8		8.0 92.0
PREGNANCY, Gen.	2.5 ± 1.4	1.3 ± 0.9	2.1 ± 1.4		1.8 ± 0.7
EXPULSION, 1st	6.6 ± 2.3	6.3 ± 1.9	4.1 ± 2.0		5.8 ± 1.2
REMOVAL, BI/P	4.1 ± 1.8	3.8 ± 1.5	2.0 ± 1.4		3.2 ± 0.9
PERTIN. EVENTS	13.2	11.4	8.2		10.8
DISC./CONTIN.	8.2 91.8	8.3 91.7	7.1 92.9		7.8 92.2
PREGNANCY, Gen.	1.7 ± 1.7	3.9 ± 2.7			3.0 ± 1.5
EXPULSION, 1st	12.7 ± 4.2	10.3 ± 4.0			11.1 ± 2.8
REMOVAL, BI/P	7.9 ± 3.4	1.8 ± 1.7			5.6 ± 1.9
PERTIN. EVENTS	22.3	16.0			19.7
DISC./CONTIN.	14.5 85.5	10.8 89.2			13.4 86.6
PREGNANCY, Gen.	5.2 ± 2.9	3.1 ± 1.8	5.6 ± 2.7		4.1 ± 1.3
EXPULSION, 1st	5.6 ± 3.1	6.1 ± 2.4	5.5 ± 2.7		5.8 ± 1.5
REMOVAL, BI/P	3.5 ± 2.4	6.1 ± 2.4	4.2 ± 2.4		4.5 ± 1.3
PERTIN. EVENTS	14.3	15.3	15.3		14.4
DISC./CONTIN.	12.5 87.5	14.4 85.6	11.1 88.9		12.8 87.2
PREGNANCY, Gen.	3.4 ± 1.7	3.4 ± 1.5	5.3 ± 2.3		3.7 ± 1.0
EXPULSION, 1st	9.4 ± 2.7	7.7 ± 2.2	6.4 ± 2.5		7.7 ± 1.4
REMOVAL, BI/P	5.8 ± 2.1	4.6 ± 1.7	5.3 ± 2.3		4.9 ± 1.1
PERTIN. EVENTS	18.6	15.7	17.0		16.3
DISC./CONTIN.	13.7 86.2	13.3 86.7	12.6 87.4		13.1 86.9

MONTH

4

12

STUDY START
COMPUTATION-CUTOFF DATE
STUDY SPAN (in mos.)

6/65
3/69
46

COMPUTATION DATE

30-9/69

Physicians:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behlikovic
Dr. L. Antonovaki/A. Nikolovski

INTERNATIONAL IUD PROGRAMME - THE PATHFINDER FUND

Background Data To
THE YUGOSLAVIA IUD BASELINE
[LOOP C - 1438 CASES]

5

FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY AGE (WITHIN "HIGH" AGE/PARITY GROUP)
AND ABORTION (NIL VERSUS 4+)
PER 100 LOOP C USERS

AGE

ABORTION

		26-29	30-34	35-39	40+	ALL	MONTH
0	LOGISTICS NO. C. RUN	67 861	61 862	26 863	3 864	157 865	
	RESID. Q-Mos. of Use	57.5 +	53 +	[24] +	[3]	137.5	
	CUMUL. Q-Mos. of Use	239 +	224 +	[99.5] +	[12]	574.5	
	LOSS to FUP	1.6%	3.6%	3.8%	not avail.	2.7%	
4+	NO. C. RUN	59 871	102 872	75 873	19 874	255 875	4
	RESID. Q-Mos. of Use	53 +	89.5 +	66.5 +	[17]	226	
	CUMUL. Q-Mos. of Use	220.5 +	369.5 +	275.5 +	[70]	935.5	
	LOSS to FUP	1.7%	2.1%	2.7%	not avail.	2.4%	
B oth	NO. C. RUN	126 881	163 882	101 883	22 884	412 885	
	RESID. Q-Mos. of Use	110.5 +	142.5 +	90.5 +	[20]	363.5	
	CUMUL. Q-Mos. of Use	459.5 +	593.5 +	375 +	[82]	1510	
	LOSS to FUP	1.6%	2.7%	3.0%	4.5%	2.5%	
0	NO. C. RUN	67 861	61 862	26 863	3 864	157 865	
	RESID. Q-Mos. of Use	36.5 +	31 +	[16] +	[2.5]	86	
	CUMUL. Q-Mos. of Use	603.5 +	546 +	[258.5] +	[35.5]	1443.5	
	LOSS to FUP	5.7%	3.6%	3.8%	not avail.	4.4%	
4+	NO. C. RUN	59 871	102 872	75 873	19 874	255 875	12
	RESID. Q-Mos. of Use	44 +	75.5 +	54 +	[16]	189.5	
	CUMUL. Q-Mos. of Use	593 +	1039.5 +	757 +	[204.5]	2594	
	LOSS to FUP	7.5%	4.5%	7.3%	not avail.	6.0%	
B oth	NO. C. RUN	126 881	163 882	101 883	22 884	412 885	
	RESID. Q-Mos. of Use	80.5 +	106.5 +	70 +	[18.5]	275.5	
	CUMUL. Q-Mos. of Use	1196.5 +	1585.5 +	1015.5 +	[240]	4037.5	
	LOSS to FUP	6.5%	4.3%	6.5%	4.5%	5.5%	

STUDY START 6/55
COMPUTATION-CUTOFF DATE 3/80
STUDY SPAN (in mos.) 46
COMPUTATION DATE 30-9/80
Physicians: Dr. L. Andolsek
Dr. M. Kolenc Dr. Bahilovic
Dr. L. Antonovsk/A. Nikolovski

Comments:

(The Yugoslavia IUD Baseline – Age and Abortion – WITHIN THE "HIGH" AGE/PARITY GROUP)

1. The "high" age-parity group (known to be associated with fewer expulsions than its low counterpart – which, in turn, showed clearly an abortion-independent age-parity-effect on expulsion) has been subclassified by age groups for the two most distant abortion categories still practical for statistical reasoning on this subsample: 0 versus 4+.
2. The issue is: is there still an (strong enough) association (left) between age and abortion, within the high age-parity group which would essentially explain away the apparent association between abortion and expulsion.
3. Let us start out by computing row- and column-percentages of this restricted universe comprising 412 women, a number barely large enough for the task ahead.

		A G E				
		(WITHIN THE "HIGH" AGE/PARITY GROUP)				
		26-29	30-34	35-39	40+	SUBSAMPLE OF "HIGH" AGE/PARITY
ABORTION	FREQUENCIES					
	0	67	61	26	3	157
	4	59	102	75	19	255
	Comb.	126	163	101	22	412
	ROW PERCENTAGE (Abortion = constant)					
	0	42.7	38.8	16.6	1.9	100.0
	4	23.1	40.0	29.4	7.5	100.0
	Comb.	30.6	39.6	24.5	5.3	100.0
	COLUMN PERCENTAGE (Age = constant)					
	0	53.2	37.4	25.7	13.6	38.1
4	46.8	62.6	74.3	86.4	61.9	
Comb.	100.0	100.0	100.0	100.0	100.0	

4. As to read from the two (extreme) abortion rows: in the 26-29 age bracket, women with 0 abortions (42.7) were twice as frequent as women with at least 4 abortions (23.1). For women over 34, that ratio was reversed: for each woman with 0 abortions (18.5), there were two with at least 4 (36.9)! Certainly, even in this subsample abortion remains associated with age. Or, reading this association the other way around from the column percentage table: the proportion of women falling into the high abortion group (4+) increases steadily with age. It climbs from 46.8% at age 26-29 to 86.4% for women in their forties (it should be clearly stated here that the column percents have been exacerbated, as the intermediate abortion values [1, 2, 3] have been neglected for the sake of accrued contrasting).

5. The cellular table is now lacunary, as the numbers have decreased dramatically with age. Still, some interesting features can be read therein. The one-year *pertinent continuation rate* of this subsample is 16.3% and does not vary much with age. Looking at the bottom row of cells, pregnancy failures do not vary with age, as do neither BI/P removals. In contrast, there is a slight decrease in primary expulsion with age. Women between 26-29 exhibited a 9.4 primary expulsion rate, against 6.4 for the 35-39 age group. At best, a slight

age-effect on expulsion could be discerned even within the high age-parity group.

6. Perhaps of more importance here is to check into the potential differentials of expulsion between the two abortion extremes, within narrow age categories. The expulsion rates dissociate into a high rate (12.7, 10.3) for women who have never aborted, and a much lower rate (5.6, 6.1, 5.5) for women who have aborted frequently. In short, independent of age, the 0-abortion women exhibited twice as high a probability of primary expulsion (11.1) as did the 4+ abortion women (5.8) -- which can be read from the right-hand bottom column. Demonstration of this

age-independent *abortion-effect on expulsion* is a basic contribution straight out of the YUGOPOOL and is the first* European confirmation of Robert Potter's finding in Asia. ¹ Particular significance is attached to this finding, as it emerged from a sample followed at a 95% level, through the 12th ordinal month after primary insertion.

CONTRIBUTORS:

Dr. L. Andolsek
Dr. M. Kolenc

Dr. B. Behilovic
Dr. L. Antonovski/A. Nikolovski

* A similar association has been found simultaneously in the ISRAEL POOL -- subject of the second number of the *Geographic Series of IUD Performance Patterns*.

¹ Potter, R., 'Effectiveness of the IUD'. In: *Family Planning in Taiwan: An Experiment in Social Change* by Freedman, R. and Takeshita, J. Chapter 10. Princeton University Press, New Jersey, 1969.

6

ABORTION

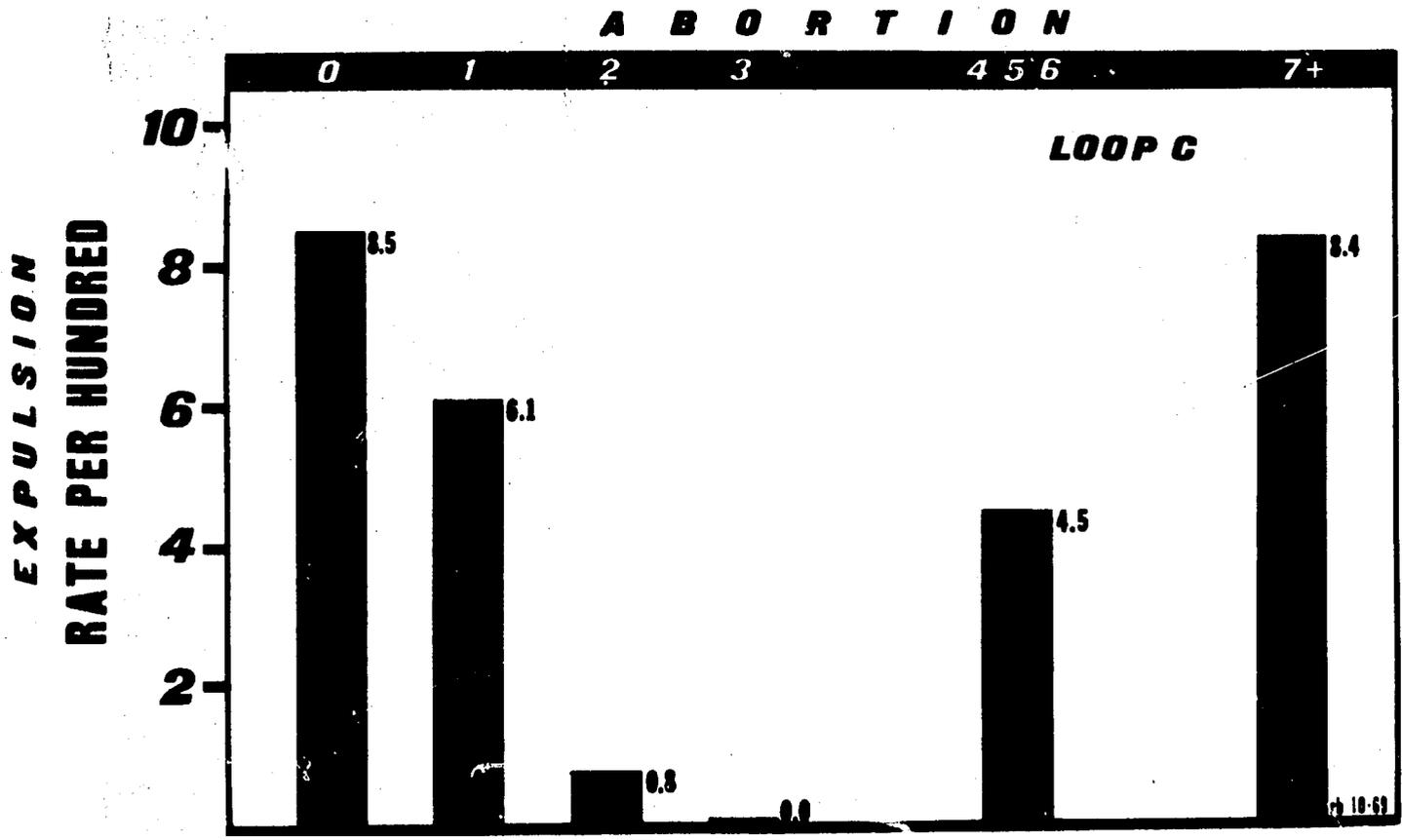
***AGE and PARITY
restricted***

EXPULSION BY ABORTION

In women: age 30-39

YUGOPOOL

parity 2-3



INTERNATIONAL IUD PROGRAMME – THE PATHFINDER FUND

THE YUGOSLAVIA IUD BASELINE
[LOOP C – 1436 CASES]

6

FOUR- AND TWELVE-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
FOR THE SUBSAMPLE: AGE 30-39 AND PARITY 2 OR 3 (509 CASES)
BY ABORTION
PER 100 LOOP C USERS

ABORTION	0	1	2	3	4,5,6	7+	ALL		
Insertions	73	+ 113	+ 120	+ 74	+ 67	+ 62	= 509		
PREGNANCY	p	–	0.9±0.9	–	–	3.1±2.1	–	4 MONTH	
FIRST EXPULSION	p	7.0±3.0	3.7±1.8	0.8±0.8	–	4.5±2.6	6.7±3.2		
BI/Pn REMOVAL	p	1.4±1.4	3.6±1.8	4.3±1.9	4.2±2.4	3.0±2.1	5.0±2.8		
PERTINENT EVENTS		8.4	7.2	5.1	4.2	10.6	11.7		
RESID. Q-MOS. OF USE		65.5	+ 103	+ 113	+ 68.5	+ 59.5	+ 53.5	= 463	12
CUMUL. Q-MOS. OF USE		275	+ 428	+ 458.5	+ 281	+ 247	+ 220.5	= 1910	
LOSS TO FOLLOW-UP		2.9	1.9	1.7	2.7	–	5.0	2.2	
PREGNANCY	p	3.5±2.4	2.9±1.6	2.8±1.6	1.5±1.5	7.9±3.4	–		
FIRST EXPULSION	p	8.5±3.3	6.7±2.4	0.8±0.8	–	4.5±2.6	8.4±3.6		
BI/Pn REMOVAL	p	3.2±2.2	5.9±2.4	4.3±1.9	4.2±2.4	4.8±2.7	5.0±2.8		
PERTINENT EVENTS		15.2	14.9	7.9	6.7	17.2	13.4		
PERTINENT CONTINUATION		84.8	85.1	92.1	93.3	82.8	86.6	88.1	
RESID. Q-MOS. OF USE		38.5	+ 69.5	+ 91.5	+ 59.5	+ 47	+ 49	= 355	
CUMUL. Q-MOS. OF USE		674.5	+ 1071.5	+ 1276.5	+ 784.5	+ 677.5	+ 622.5	= 5107	
LOSS TO FOLLOW-UP		2.9	1.9	2.6	2.7	3.7	10.5	3.9	
Computer Run		781	782	783	784	785	786	780	
STUDY START		7/85	7/85	8/85	7/85	8/85	3/86	6/85	
COMPUTATION-CUTOFF DATE					3/89				
STUDY SPAN (in mos.)		46	46	46	46	44	37	46	
COMPUTATION DATE					1-10/89				
Physicians:		Dr. L. Anđelić Dr. M. Kolenc			Dr. B. Behilović Dr. L. Antonovski/A. Nikolovski				

Comments: (The Yugoslavia IUD Baseline – Abortion in Subsample: age 30-39 and parity 2-3)

1. After having crystallized an age-independent abortion effect on expulsion, it is of interest to quantify – to the extent possible – that relationship. Given the association of expulsion with age-parity, which literally overshadows – if not entirely masks – the association with abortion, it will be essential to choose a subsample restricted enough both in the age-parity range and in the ensuing expulsion variation. On the other hand, the number should remain large enough to permit an inquiry into the pertinent events for women with increasing abortion, prior to IUD insertion. In short, looking at the three cellular age-parity tables of the YUGOPOOL, one should choose an area where expulsion was clearly independent of age and parity.
2. Such a “field” is clearly at hand. Here are the 12-month rates and frequencies:

		P A R I T Y			
		2	3		
A G E	30-34	234 4.0 ± 1.3	95 5.5 ± 2.4	=	
	35-39	118 4.4 ± 1.9	62 3.4 ± 2.4		
		509			=
		4.3 ± 0.9			

The remarkable homogeneity of the expulsion rates allowed the welding of these four cells into a subsample of the YUGOPOOL: 509 women in their thirties and having had two or three live births mustered a one-year expulsion rate of only 4.3%.

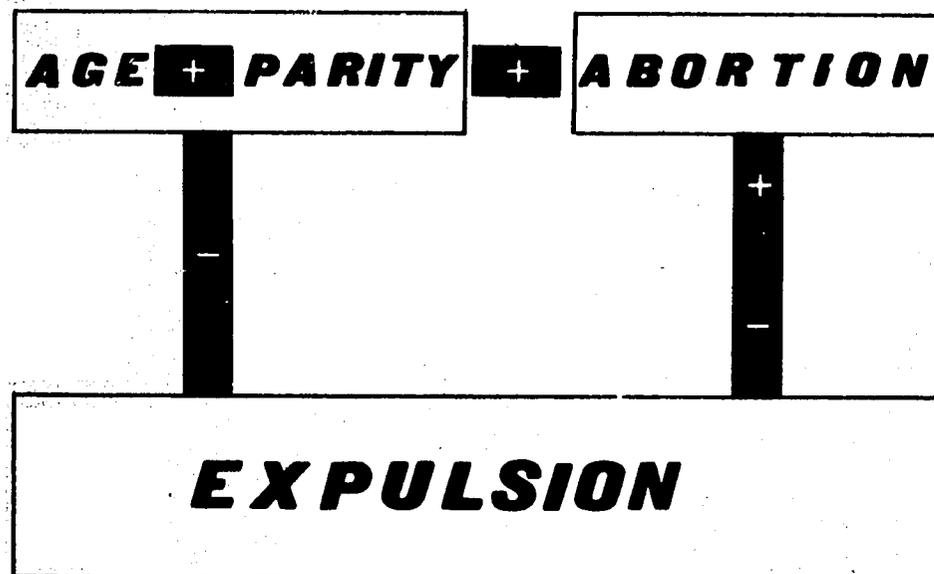
3. If pertinent event rates are computed by number of abortions prior to primary IUD acceptance, a startling picture presents itself. An important negative gradient emerges for primary expulsions as abortions increase. 8.5 percent of the 73 “2 or 3 children women in their thirties” having had *no* abortion had lost their device within one year after primary insertion – contrasting with a total absence of expulsions among the 74 women of both 2 or 3 live births and 3 abortions. A variation in reading this table would be: the 73 “2 or 3 parity women” who presented themselves in their thirties for an IUD insertion lost their device 10 times more frequently if they had had *no* abortion than did the 194 women who had had 2 or 3 abortions besides their 2 or 3 children. No doubt, we are confronted here primarily with a **negative** age and parity-independent *abortion-effect on expulsion in the low abortion range (0-3)*, so to speak.
No such effect can be demonstrated for the two other pertinent event categories.
4. This negative association, however, reverses itself in the high abortion range. Whereas the 194 women in their thirties with both 2 or 3 live births and (only!) 2 or 3 abortions did virtually not expel the device (1 in 194), the 129 women with 4 or more abortions exhibited a ten-fold expulsion probability over the previous group (8 in 129). This

positive

age and parity-independent *abortion-effect on expulsion*
in the high abortion range (4+)

opens speculative thinking into the mechanism underlying abortion-bound expulsion.

5. It should be noted that this age and parity-independent V-shaped *abortion-effect on expulsion* is being wrought during the earliest post-insertion period, as at the 4th ordinal month after insertion, the V-relation is already fully established.
6. The YUGOPOOL of less than 1500 well-followed-up women gave the occasion to demonstrate each of the following association links to exist independently of the others. Intuitively, age and parity are strongly positively associated as the twin pair is also with abortion. The negative association of expulsion with age-parity on the one hand, and with abortion in the low abortion range, on the other – as well as the reversal of the latter link in the higher abortion range – should be retained. End of YUGOPOOL analysis – October 5, 1969.



CONTRIBUTORS:

Dr. L. Andrišek
 Dr. M. Kolenc

Dr. B. Behilovic
 Dr. L. Antonovski/ A. Nikolovski

THE DOUBLE-BLIND MULTI-CLINIC TRIAL SCHEME

1. In June and July, 1968 a series of double-blind trials were initiated in Yugoslavia with the help of Dr. Eugene Silbermann, New York Medical College — who had been actively involved in testing precursory prototypes — and Dr. Ljubomir Antonovski, a relatively recent but dynamic contributor to the INTERNATIONAL IUD PROGRAMME.
2. While the already established axis — Ljubljana-Beograd-Skopje — was adhered to, some further valuable contributors joined this venture in Beograd (University Clinic) and Skopje (University Clinic and City Hospital). Kosovska-Mitrovica joined in July of that year.
3. The idea was to field test several variants of the M device "at one hit and spot" (time and space introducing thus minimal variability) in a double-blind way, so as to exclude, furthermore, personal bias (doctor *and* patient). Of particular importance was to link the M with a well-known prototype in a setting where a study of old standing would permit a comparison with the new device's performance quite rigorously. Centre-I in Beograd was chosen to compare the M with Loop C* (Link A).
4. Ljubljana accepted to test two variants of the M with different widths (Link B). Again, the advantage being that within a single center the new experience could be compared with the old and still ongoing one.
5. In Skopje (Link D) and Kosovska-Mitrovica (Link C), double-blind studies were initiated for the assessment of the merits of a teflonized version.
6. The double-blind technique was one of cluster-sampling, whereby day-loads of patients were randomly allocated (coin-flipping immediately before session start by another person than the physician who would make the insertions) to one of the two devices — thus randomly generating a sequence of device-specific days (M-days, MS-211 days).
7. An intensive consulting supervisory dialogue is maintained between the field and headquarters.
8. The tables hereafter contain findings of new and old studies, to form a local IUD baseline so important as to be established to become closer to the genuine IUD problems. The "comments" are most recent notes prepared at headquarters for the local contributor which should be fully used together with the tables while preparing local scientific publications or reports.
9. Seven centers participated in the venture involving 15 physicians. 4,553 primary insertions with 8 devices are being reported on by way of giving center and device-specific 3- and 6-month net cumulative rates of pertinent events, based on a grand aggregate of 21,636 woman-months of use (6 mos.). 2,295 primary insertions belong to the double-blind category, while the other half are live studies of old standing and permit, thus, a particularly meaningful intra- and inter-study comparison.

* A more extensive comparison scheme for linking new with old had been set up one week earlier in Israel. This is reported in *IUD Performance Patterns, Vol. 1 — July, 1969.*

THE DOUBLE-BLIND MULTI-CLINIC TRIAL SCHEME

(2)

The range of follow-up is 95.6 to 99.5%. Of further interest is the possibility of comparison between three study kinds: post-menses, post-D & C abortion and post-vacuum abortion.

10. It was felt that whatever is presently available in a digested form should be released under one cover without delay. That this coincides with the Second European Congress on Sterility held this week in Dubrovnik is indeed fortunate, as all Yugoslavian contributors to this testing scheme will be reporting on their individual studies, united hereafter.

CONTRIBUTORS:

LINK A:	Dr. B. Behilovic	Beograd
LINK B:	Dr. L. Andolsek	Ljubljana
LINK C:	Dr. D. Dragovic Dr. Z. Parovic	Kosovska-Mitrovica
LINK D:	Dr. L. Antonovski Dr. A. Nikolovski	Skopje
	Dr. K. Curclev Dr. M. Stankowski	
	Dr. M. Belopeta Dr. K. Janev	
STUDY E:	Dr. B. Mitosevic Dr. R. Mikić Dr. Z. Tucovic	Beograd

A

LOOPC



M 213

THE BEOGRAD MEDICAL CENTER - I IUD PROJECT
(2 DEVICES - 675 CASES)

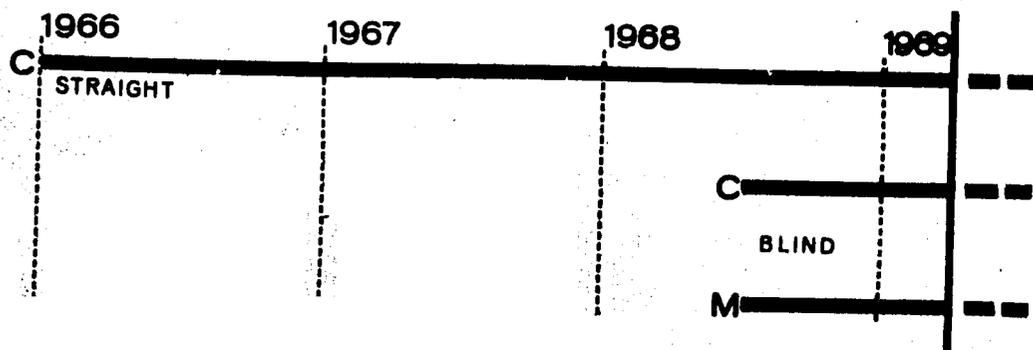
A

**THREE- AND SIX-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY DEVICE AND STUDY TECHNIQUE
PER 100 IUD USERS**

Place	CENTER-I, BEOGRAD			1
	POST-MENSES			
Study kind	LOOP C M-213			1
Device				2
Insertions	390	140	145	675
PREGNANCY	<i>p</i>			3
FIRST EXPULSION	<i>p</i>			
BI/Pn REMOVAL	<i>p</i>			
PERTINENT EVENTS				
RESID. ♀-MOS. OF USE	358.5	91	77	526.5
CUMUL. ♀-MOS. OF USE	1109	337.5	301	1747.5
LOSS TO FOLLOW-UP	1.3	2.2	6.5	
PREGNANCY	<i>p</i>	BLIND		6
FIRST EXPULSION	<i>p</i>			
BI/Pn REMOVAL	<i>p</i>			
PERTINENT EVENTS				
PERTINENT CONTINUATION	88.2	88.9	89.8	
RESID. ♀-MOS. OF USE	341	44.5	40.5	426
CUMUL. ♀-MOS. OF USE	2152.5	514.5	462.5	3129.5
LOSS TO FOLLOW-UP	2.8	2.2	6.5	3.5
Computer Run	167	166	165	
STUDY START	1/68	6/68	6/68	
COMPUTATION-CUTOFF DATE	3/69	3/69	3/69	
STUDY SPAN (in mos.)	30	10	10	
COMPUTATION DATE	3-7/69	3-7/69	3-7/69	
STUDY TECHNIQUE	STRAIGHT	BLIND		
Physician: Dr. B. Behllovic				

1. The results are based on 675 primary insertions of two devices (Alathon loop and stainless steel narrow-band M), administered at the Medical Center-I of Beograd. Insertions were made between January 1966 and March 1969 and ensuing six-month life-table rates (Tietze-Potter approach) are based on a grand aggregate of 3129.5 woman-months of use.
2. The six-month genuine pregnancy failures ranged from 0 to 2.5% – well within the limits of expectation, based on values established around the world.
3. While the M showed no expulsion, the two C studies (carried on “straight” and “blind”) showed an overall six-month expulsion rate of 8% – independent of study technique.
This study technique- independent device effect on expulsion is the most salient early finding of this long-range project.
4. In contrast, removals for bleeding and/or pain were not statistically different among the three studies. This might change, however, as the M study grows in size and duration. The short-range analysis, though, does not permit the exclusion of a study technique- and device- independent center effect on BI/P removals. Time will tell. Present BI/P removals are quite low, when compared with those of other baseline data.
5. An important observation in this project is that two Loop C studies – both of different onset (2½ years apart) and different design (straight series against the homonymous C-portion of a blind study) – generated similar pertinent event rates. This study technique- and time- independent pertinent event effect for a given device
i.e. pregnancy effect
BI/P removal effect
Expulsion effect, all for a given device, is important insofar as it suggests that at least in a single-doctor study and operating within the same population – meaningful comparison of *different* IUD models tested at different calendar points in time are not necessarily below statistical rigor. Under the present ideal circumstances, the Loop C portion of the recent blind study served as a *bridge* between two studies of different IUD models as well as of different testing times (calendar).

THE MEDICAL CENTER-I STUDY DESIGN



MEDICAL CENTER-I STUDIES

Device type	Loop C	Loop C	M-213
Calendar time	1966	1968	1968
Study design	Straight	Blind	Blind

Indeed, by borrowing one qualitative trait from the two other studies with respect to device type and calendar time of testing (Loop C as in the older study but of recent design as the M study), it was possible to demonstrate *time-independence* for result outcome of identical devices (both studies showed *similar* expulsion) on the one hand, and *device-independence* for result outcome at identical testing time and equal testing design on the other hand (both devices recently tested exhibited a *similar* BI/P removal rate).

6. Having demonstrated by way of this *central study* the existence of a device- and time-independence for a given pertinent event category (expulsion independent of calendar-time of study conduct; BI/P removal independent of device type tested), it was also possible to crystallize the genuine differences in pertinent events among the three studies. Clearly, the high expulsion rate of Loop C (independent of calendar-time of study conduct) contrasts with an M-specific zero-expulsion rate; whereas BI/P removals in both recent studies (independent of device type) do not contrast with study-time-specific (old study) lower BI/P removal rate.
7. It should be realized that these findings (differential expulsion by device against similar BI/P removal for the two devices tested) would have been factually identical *in the absence of this bridge-study*. Non-incorporation of this study in the original design, however, would have possibly lowered the weight of the results produced. It is exceptional that within the framework of a service-program such an ideal and simple study-design is feasible in these hectic times of ours. The very outcome of this step-by-step Beograd Project, then, allows one to skip one justifying intermediary of time and device type — as everyday circumstances would anyhow generally dictate.
8. In a sense it is encouraging that — within a service program situation — considerable evidence has been produced for the theoretical feasibility of study-time-and-technique-independent comparison of IUD use-effectiveness. Still, another consideration should be kept in mind. What is the crucial event-category being compared for two devices being tested? The three pertinent event categories (expulsion, pregnancy failure and BI/P removals) define quite well the success of an IUD project. Their sum's complement may be understood as the locale-specific, theoretical use-effectiveness — which is expressed as the *local pertinent continuation rate for a given device*. Naturally, this continuation rate will be strictly dependent on three constituents thereof.
9. The fact is that each pertinent event category has its own dependency array. The following table is an attempt to list the event categories in sequence of increasing dependency upon milieu characteristics.

RELATIVE DEPENDENCY OF PERTINENT EVENTS UPON THE LOCALE

	DEVICE		PATIENT		DOCTOR	
	Shape	Size	Uterus	Attitude	Skill	Attitude
<i>Primary Expulsion</i>	+	+	+	-	(-)	-
<i>Pregnancy Failure</i>	+	+	+	+	-	-
<i>Bleeding/Pain Removal</i>	+	+	+	+	+	+

L O C A L E

The least involved category is expulsion, whereas removal for Bleeding/Pain is the most obnubilated and least understood category.

10. To come back to the Beograd Center-I Trial: for event categories primarily characterized by non-involvement with the locale (such as expulsion) comparison of studies carried on at different points in time and with different devices is a powerful approach toward development of low-expulsion devices. By extension, this approach is justified to be undertaken *between* centers, as long as one deals within the biological confines of one racial group. Nevertheless, comparison between racial groups of device-specific expulsion rates is also desirable, as race would be the controlled and only changed variable. In fact, this is the only neat way to uncover race-specific expulsion traits. Local findings on account of expulsion have furthermore a considerable potential for generalization.
11. Not so with findings concerning BI/P removals, as the locale's entire range of influences will have brought about that result. To cite only three spheres expulsions would completely be independent of — in contrast to BI/P removals: the doctor's attitude toward expected early side effects, the patient-doctor relationship and the doctor's skill at IUD insertion. Naturally, only by holding this whole constellation of influencing factors — both constant and equally distributed in the universe in which two devices are being compared for their Bleeding/Pain potential — will it be possible to make indicative conclusions. Such a situation was created in Beograd, where the two different devices had been compared in the same clinic, by the same doctor, by way of the double-blind approach.

To sum up the gist of this intellectual excursion: expulsion's being rather locale-independent justifies comparative exploitation of somewhat independent and solitary studies for the search toward a high-retention model, whereas inquiry into Bleeding and/or pain has to be carried on within one center to control for the whole gamut of extraneous factors.

CONTRIBUTOR
Dr. B. Behlilovic

B

M 211



M 213

INTERNATIONAL IUD PROGRAMME - THE PATHFINDER FUND

B

LJUBLJANA IUD BASELINE DATA
 SIX DEVICES - 1,446 CASES
 THREE- AND SIX-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
 AT THE LJUBLJANA CENTER
 BY DEVICE
 PER 100 IUD USERS

Place FAMILY PLANNING INSTITUTE, LJUBLJANA
 Study kind POST-MENSES

Device **SPIRAL ANTIC** **D LOOP C** **211 M 213**
 Insertions 223 114 506 220 195 187

1
 1
 6
 1445

	SPIRAL ANTIC	D LOOP C	211 M	213	
PREGNANCY	-	0.9 ± 0.9	0.6 ± 0.4	1.9 ± 0.9	0.6 ± 0.6
FIRST EXPULSION	5.0 ± 1.5	1.8 ± 1.3	9.5 ± 1.3	6.0 ± 1.6	-
BI/Pn REMOVAL	1.8 ± 0.9	0.9 ± 0.9	1.4 ± 0.5	2.8 ± 1.1	2.4 ± 1.2
PERTINENT EVENTS	6.8	2.6	11.5	10.7	0.8

MONTH
3

RESID. ♀-MOS. OF USE 205.5 109.5 455 201 97.5 126.5
 CUMUL. ♀-MOS. OF USE 632.5 335.5 1413 623.5 405.5 433
 LOSS TO FOLLOW-UP 0.5 2.7 0.4 0.5 2.8 3.1

1195
 3843

	SPIRAL ANTIC	D LOOP C	211 M	213	BLIND
PREGNANCY	0.5 ± 0.5	0.9 ± 0.9	2.5 ± 0.7	2.4 ± 1.0	0.6 ± 0.8
FIRST EXPULSION	7.4 ± 1.8	5.4 ± 2.1	13.1 ± 1.5	8.4 ± 1.9	-
BI/Pn REMOVAL	2.3 ± 1.0	0.9 ± 0.9	2.3 ± 0.7	3.3 ± 1.2	5.6 ± 3.3
PERTINENT EVENTS	10.2	7.2	17.9	14.1	3.6

6

PERTINENT CONTINUATION 90.3 92.8 82.1 85.9 93.8 95.8

RESID. ♀-MOS. OF USE 195.5 102.5 427 191 29.5 61
 CUMUL. ♀-MOS. OF USE 232 649 2723.5 208 533.5 678.5
 LOSS TO FOLLOW-UP 0.5 3.6 0.6 1.0 2.8 5.5

1006.5
 7024.5
 2.5

Computer Run 182 173 176 179 174 175

STUDY START 9/84 8/86 9/84 8/85 8/88 8/88
 COMPUTATION-CUTOFF DATE 3/89 3/89 3/89 3/89 3/89 3/89
 STUDY SPAN (in mos.) 55 32 55 46 10 10

COMPUTATION DATE 5-7/88 3-7/88 4-7/88 5-7/88 3-7/88 3-7/88
 STUDY TECHNIQUE STRAIGHT BLIND

Physician: Dr. L. Andolsek

Comments:

(Yugoslavia IUD Baseline Data -- Study Technique and Device)

1. The results are based on 1,445 primary insertions of six various models inserted between September 1964 and March 1969, at the Ljubljana Family Planning Institute. Six-month life-table rates are based on a grand aggregate of 7024.5 woman-months of use.
2. The patient histories on the six devices are presently being recorded on the PROGRAMME's data-collection system and the table gives corresponding three- and six-month rates, side-by-side. This single-center (Ljubljana) single-yardstick (life table) evaluation approach of six live studies permits particularly meaningful comparison of the various devices' performance.
3. The genuine pregnancy failure rate at six months lay between 0.6 and 2.8% -- well within the confines of international values. Comparing these results with the potential results of women not protected by a device, one may thus refer to a
type-independent device-effect on pregnancy
4. Spiral L, Loop C and Antigon showed similar levels of expulsion. On the other hand, the larger loop model (D) was apparently expelled more frequently (13.1 against 8.4). The corresponding six-month M expulsions are nil. Clearly, there emerges a
device-effect on expulsion
5. Checking into the relatively high expulsion rate for the larger loop model, one finds that the six-month rate of 13.1 dissociates into 20.4 against 10.2 for corresponding low and high age-parity women, thus revealing the already known
age-parity-effect on expulsion
6. Removal rates for bleeding and/or pain are *low* in Ljubljana, independent of the device tested. Below 1% are Antigon and M-213. When comparing this to BI/P removal rates of other centers, one may discern very clearly a
device-independent center-effect on BI/P removal
7. The highest pertinent continuation rate was attained with M-213 (95.8), the lowest with Loop D (82.1). More generally, the C and D Loop wearers had a 10-point-lower six-month pertinent continuation rate (84%) than did the M device wearers (94%).
8. Short-range results on the double-blind testing of the two M models differing in width yielded -- besides a total absence of expulsion -- the following rates for BI/P removal:

Broad (M-211)	5.6 ± 3.3
Narrow (M-213)	0.8 ± 0.8
9. Though the difference goes in the direction anticipated, namely that the broad-band might be associated with more removals for bleeding and/or pain, no statistically significant difference could be ascertained at this point in time ($p = 0.15$). The study is progressing in building up and with increasing numbers the variance will decrease and potential differences may become apparent.

CONTRIBUTORS:

Dr. L. Andolsek
Miss M. Oven (statistical assistant)



M 211



MS 211

THE TWO KOSOVSKA-MITROVICA DOUBLE BLIND TRIALS OF M-211 vs. MS-211
 [2 DEVICES - POST-MENSES AND POST-ABORTUM (D&C) - 536 CASES]

THREE- AND SIX-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY STUDY KIND AND DEVICE
PER 100 BROAD-M USERS
(RANDOM ALLOCATION WITHIN STUDY KIND)



Place	WOMEN-HEALTH PROTECTION CENTER, KOSOVSKA-MITROVICA									1
	POST-MENSES			POST-ABORTUM			POST MENSES/ABORTUM			
Study kind	M MS 211			M MS 211			M MS 211			2
Device	M MS 211			M MS 211			M MS 211			
Insertions	88 + 112 = 200			181 + 155 = 336			269 + 267 = 536			MONTH
PREGNANCY p	-	-	-	1.2	-	0.7	0.9	-	0.5 ± 0.3	
FIRST EXPULSION p	1.4	1.0	1.1	-	-	-	0.4	0.4	0.4 ± 0.3	
BI/Pn REMOVAL p	-	1.0	0.6	1.1	1.4	1.2	0.8	1.3	1.0 ± 0.5	
PERTINENT EVENTS	1.4	2.0	1.6	2.3	1.4	1.9	2.1	1.7	1.9	
RESID. ♀-MOS. OF USE	47.5+ 78 = 125.5			166 + 127 = 293			213.5+ 205 = 418.5			418.5
CUMUL. ♀-MOS. OF USE	176.5+ 262.5 = 439			515.5+ 427 = 942.5			662 + 689.5 = 1381.5			1381.5
LOSS TO FOLLOW-UP	4.4	5.1	4.8	0.6	-	0.3	1.6	2.0	1.8	
	BLIND			BLIND						
PREGNANCY p	-	-	-	1.8	0.9	1.4	1.4	0.5	1.0 ± 0.8	6
FIRST EXPULSION p	1.4	1.0	1.1	-	-	-	0.4	0.4	0.4 ± 0.3	
BI/Pn REMOVAL p	-	2.9	1.7	1.1	5.2	2.9	0.8	4.4	2.5 ± 0.8	
PERTINENT EVENTS	1.4	3.9	2.8	2.9	6.1	4.3	2.6	5.3	3.9	
PERTINENT CONTINUATION	98.6	96.1	97.2	97.1	93.9	95.7	97.4	94.7	96.3	
RESID. ♀-MOS. OF USE	24.5+ 36.5 = 61			92.5+ 63 = 155.5			117 + 99.5 = 216.5			216.5
CUMUL. ♀-MOS. OF USE	275 + 419.5 = 694.5			882.5+ 693.5 = 1576			1157.5+1113 = 2270.5			2270.5
LOSS TO FOLLOW-UP	4.4	5.1	4.8	0.6	-	0.3	1.6	2.0	1.8	1.8
Computer Run	202	205	208	203	206	209	201	204	207	

STUDY START
 COMPUTATION-CUTOFF DATE
 STUDY SPAN (in mos.)

6/88
 3/89
 10

COMPUTATION DATE
 STUDY TECHNIQUE
 Physicians:

6-7/88
 BLIND
 Dr. D. Dragovic
 Dr. Z. Parovic

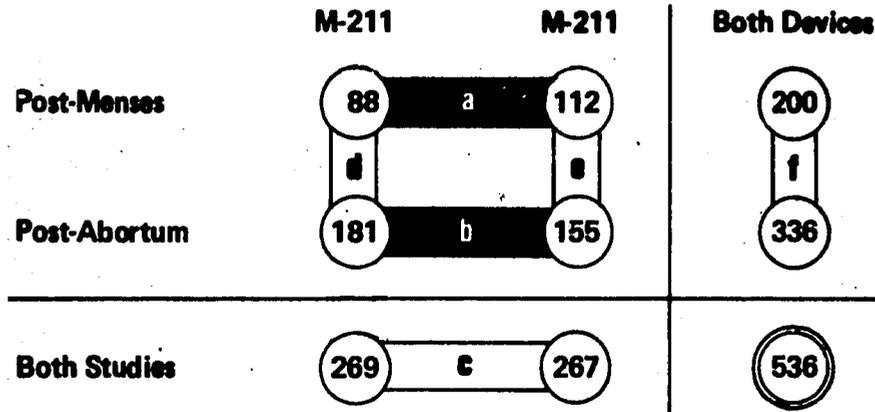
Comments: *(The Kosovska-Mitrovica Broad-Band M IUD Project – Study Kind and Device)*

1. The results are based on 536 primary insertions of identically-shaped devices (broad-band M) of different materials (raw medical-grade stainless steel against its teflon-coated version), performed at the Kosovska-Mitrovica Women Health Protection Center between June 1968 and March 1969. Six-month life-table rates (Tietze-Potter approach) are based on a grand aggregate of 2270.5 woman-months of use. Within a study kind (post-menses and post-abortion (D&C)), women were randomly allocated daily to either one of the two models tested (double-blind).
2. The six-month genuine pregnancy failure ranged from 0-1.8% – well within the limits of expectation, based on values established around the world. The overall six-month pregnancy rate was 1.0%. Though the events are rare, the overall pattern suggests, thus, a
study-kind-and-type- independent device effect on pregnancy.
3. No expulsion in the post-abortum series and 1.1% expulsion in the post-menses series (for both device-makes) generated a 0.4% six-month expulsion rate for the broad-band M device, thus confirming the very low expulsion trend for this device. Though Kosovska-Mitrovica has no Loop C baseline of its own, comparison of this very low expulsion rate (0.4 ± 0.3) with the Loop C expulsion rate generated in the All-Yugoslavia IUD Baseline* (7.3 ± 0.7) on the one hand, and with the very low M-expulsion produced in other centers in and beyond Yugoslavia, permits the tagging of the local finding as an
M-kind, study kind and center- independent device effect on expulsion.
4. Inquiry into removals for bleeding and/or pain has been one of the mobiles for setting up this double-blind study. It was thought that teflonization of the raw-steel, broad-band version might cut down on bleeding. Removals were low, perhaps a bit higher for the teflonized version – though the unexpected differential remains submarginal: 0.8 ± 0.6 versus $4.4 \pm 1.5 = 2.5 \pm 0.8\%$. At six months, then, teflon coating of the stainless steel broad-band M had no demonstrable effect upon BI/P removals. It should be retained also that an overall six-month rate of 2.5% is to be considered very low. Several M studies in and out of Yugoslavia (testing both the narrow and broad versions) had reached a 10% level at the sixth ordinal month. It is therefore appropriate to retain above findings as an
M-kind, study kind and device- independent center effect on BI/P removal.
5. Thus, then, six months after administration of the broad-banded M device (M-“11”), no significant difference in the outcome of the three pertinent event categories could be detected between the two materials (M-211, steel versus MS-211, teflonized steel) for either study series (post-menses and post-abortum).
6. Along the same line, post-menses and post-abortum insertions (study kind) furnished statistically confoundable results. That the M inserted immediately after Dilation and Curettage would give as encouraging results as insertion after menstruation is a finding worthy of retention.

* See “IUD Performance Patterns, V.2, July, 1969” – The Pathfinder Fund, Boston, Mass.

7. Up to now, then, the broad-banded M model did extremely well in Kosovo, as to read from the grand-total column. Indeed, the six-month rates of genuine pregnancy failure, primary expulsion and BI/P removals add up to a dramatically low *pertinent event rate* of 3.9%, generating a *half-year local pertinent continuation rate* of 96.1% — the local *theoretical continuation*.
8. The *de facto continuation* was even higher: 96.6%. It is the complement of all closures (events *not* followed by reinsertion). Besides the three pertinent termination categories, it includes:
 - Later expulsion (all except the primary)
 - Removals for other medical reasons (all except bleeding and/or pain)
 - Removals for planned parenthood
 - Removals for other personal reasons
9. In this miner-town project, the two sole expulsions confined to the very early post-insertion period (1st month), were followed by reinsertion; similarly, 3 out of the 10 removals for bleeding and/or pain were followed by reinsertion. These 5 events are accounted for in the pertinent event and continuation rates, but are excluded from the *de facto continuation rate* as *subsequent reinsertion* saved them from being closures. Thus, remedial intervention at the Service level boosted the continuation rate to 97.1%. However, two further, non-pertinent removals were recorded — one for "medical reasons other than bleeding and/or pain" and one for "planning a pregnancy." As they were not followed by reinsertion, they constituted genuine *closures* and thus lowered the continuation rate by 0.5%, from 97.1% to the six-month *de facto continuation rate* of 96.6%.
10. This exercise in detailing was primarily a movement toward understanding the prevailing *opposite forces* (reinsertion: up, non-pertinent events: down) shaping the *de facto continuation rate* out of the *theoretical rate* of continuation. The term of "pertinent continuation" was in fact introduced quite recently, as it covers those events of prime importance to the INTERNATIONAL IUD PROGRAMME's basic goal — the rapid development of superior IUDs. It was a deliberate attempt to escape the up and down forces molding the factual continuation rate, forces which are highly *center-dependent* as they are projections of such elements as local reinsertion policy, patient's and doctor's attitude toward the IUD method of contraception, and medical conditions unrelated to IUD. Removal toward intended pregnancy is also deleted as it is again highly center-dependent. Indeed, the program now has studies which could be labelled typical *stopper-projects*, and others, typical *spacer-projects*.
11. It should be realized that the Kosovo *study design* was geared toward six next statistical comparison steps (a-f) in a two-by-two contingency scheme of two pairs of qualitative data. The following table gives an overview of this statistical approach:

THE KOSOVSKA-MITROVICA STUDY DESIGN
(6 COMPARISON LINKS; 2 DOUBLE BLIND)



By holding constant (or not) one qualitative variable at a time (device type or study type), the following six possibilities were envisaged for comparison of pertinent events.

STEP	TRIAL	● VARIABLE HELD CONSTANT				FREQUENCY
		COMPARISON	M-211	MS-211	P. MENS P. ABOR	
		[DEVICE TYPE]	[STUDY TYPE]			
a	STEEL versus TEFLON-COATING	■ a ■	●	—	200	
b	"	■ b ■	—	●	336	
c	"	— c —	Study type not fixed		536	
d	POST-MENS versus POST-ABOR	●	—	— d —	269	
e	"	—	●	— e —	267	
f	"	Device type not fixed		— f —	536	

The main purpose of the Kosovo study was to compare the two material-makes of the broad-banded M with respect to its impact on removal for bleeding and/or pain. Therefore, the comparison steps "a" and "b" were set up in a double-blind approach, whereby neither doctor nor patient would be aware of the make of the device having been inserted. Furthermore, cluster sampling was chosen for random allocation of dayloads of patients to one of the two devices — thus generating "C-days" or "M-days" at the very onset of the daily clinic. This scheme was adhered to for a post-menses and post-abortum (D&C) series.

12. The results, that is the pertinent event rates attained at a given point in time after primary insertion, were rearranged according to the study design. The following nine-cell table gives the six-month cumulative pertinent event rates, together with the identifying computer run number, the aggregate woman-months of use and the loss to follow-up. Corresponding frequencies may be read from the study design table. Standard errors are given.

**THE KOSOVSKA MITROVICA M-211
SIX-MONTH PERTINENT EVENT RATES**

		DEVICE			
		STEEL M-211	TEFLON-COATED MS-211	BOTH DEVICES	
STUDY	POST-MENSES	(275) 202 — 1.4 ± 1.4 — 4.4%	(419) 205 — 1.0 ± 1.0 2.9 ± 2.1 5.1%	(694) 208 — 1.1 ± 0.8 1.7 ± 1.7 4.8%	
	POST-ABORTUM (D&C)	(882) 203 1.8 ± 1.0 — 1.1 ± 0.8 0.6%	(693) 206 0.9 ± 0.9 — 5.2 ± 2.1 —%	(1576) 209 1.4 ± 0.7 — 2.9 ± 1.0 0.3%	
	BOTH STUDIES	(1157) 201 1.4 ± 0.8 0.4 ± 0.4 0.8 ± 0.6 1.6%	(1113) 204 0.5 ± 0.5 0.4 ± 0.4 4.4 ± 1.5 2.0%	(2270) 207 1.0 ± 0.5 0.4 ± 0.3 2.5 ± 0.8 1.8%	Q-Mos. C. Run Pregnancy First Expulsion BI/P Removal Loss FUP

13. The surprising dimension is that *all* events turned out to be *rare* in Kosovska -Mitrovica — independent of the variables incorporated in the study design. While this outcome is to be valued as important, the study design's potential for discrimination of differentials by type of study and device goes mainly unexploited, as the frequencies at this early stage of trial are too small to cope with comparison of still rare events. From the use-effectiveness point of view, however, the better: up to now, Kosovska-Mitrovica revealed that the M can be very advantageously administered post-menses as well as post-abortionum and that the two makes of the broadband M do not reveal any difference in the *short-range analysis*; furthermore, the Women Health Protection Center is, up to now, one of the low BI/P removal centers registered with the INTERNATIONAL IUD PROGRAMME. The excellent FUP of 98% lends additional meaning to the Kosovo findings.

CONTRIBUTORS:

Dr. D. Dragovic
Dr. Z. Parovic

D

M213



MS 213

INTERNATIONAL IUD PROGRAMME – THE PATHFINDER FUND

D

THE SKOPJE COOPERATIVE IUD PROJECT

(3 DEVICES – 1597 CASES)

THREE- AND SIX-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY STUDY PLACE, STUDY KIND AND TYPE OF DEVICE
PER 100 IUD USERS

Place	POLICLINIC BUCHAREST			CITY HOSPITAL	OB-GYN CLINIC	3		
	POST-MENSES				P-ABORT.		2	
Study kind	LOOPC M 213 MS			M 213	M 213	3		
Device	505			340	280	238	234	1597
Insertions	505			340	280	238	234	1597
PREGNANCY	p	0.6 ± 0.4	—	0.9 ± 0.6	1.5 ± 0.8	0.5 ± 0.5	3	MONTH
FIRST EXPULSION	p	5.2 ± 1.0	0.4 ± 0.4	0.4 ± 0.4	0.9 ± 0.6	0.5 ± 0.5		
BI/Pn REMOVAL	p	5.0 ± 1.0	6.7 ± 1.5	7.2 ± 1.6	1.4 ± 0.8	7.6 ± 1.8		
PERTINENT EVENTS		10.8	7.1	8.5	3.8	8.6		
RESID. ♀-MOS. OF USE		439.5	233	201.5	186.5	200.5		1261
CUMUL. ♀-MOS. OF USE		1377	807.5	689.5	619.5	631.5		4125
LOSS TO FOLLOW-UP		3.1	4.7	4.9	0.0	6.1		
		BLIND					6	
PREGNANCY	p	1.7 ± 0.6	0.6 ± 0.6	0.9 ± 0.6	1.5 ± 0.8	1.0 ± 0.7		
FIRST EXPULSION	p	6.3 ± 1.1	0.4 ± 0.4	0.4 ± 0.4	0.9 ± 0.6	0.5 ± 0.5		
BI/Pn REMOVAL	p	6.7 ± 1.1	9.4 ± 1.8	8.8 ± 1.9	3.1 ± 1.3	9.7 ± 2.1		
PERTINENT EVENTS		14.7	10.4	10.1	5.5	11.2		
PERTINENT CONTINUATION		85.3	89.6	89.9	94.5	88.8		
RESID. ♀-MOS. OF USE		411	156	125.5	93	18.5		804
CUMUL. ♀-MOS. OF USE		2635.5	1363.5	1137	1001.5	901		7038.5
LOSS TO FOLLOW-UP		4.2	5.1	4.9	0.0	6.1		4.4
Computer Run		170	151	152	520	521		
STUDY START		3/67	6/68	6/68	6/68	10/68		
COMPUTATION-CUTOFF DATE		3/69	3/69	3/69	3/69	3/69		
STUDY SPAN (in mos.)		26	10	10	10	6		
COMPUTATION DATE		3-7/69	29-6/69	29-6/69	1-9/69	1-9/69		
STUDY TECHNIQUE		STRAIGHT			DOUBLE-BLIND			
Physicians:		Dr. L. Antonovski Dr. A. Nikolovski			Dr. M. Belopeta Dr. K. Janev		Dr. K. Curciov Dr. M. Stankowski	

Comments:

(The Skopje Cooperative IUD Project – Place, Study Kind and Device)

1. The results are based on 1,597 primary insertions of three devices (Alathon-loop, stainless steel narrow-band M and its teflonized version), done in three Skopje centers between March 1967 and March 1969. Six-month life-table rates (Tietze-Potter approach) are based on a grand aggregate of 7038.5 woman-months of use.
2. With all devices, genuine pregnancy failure at six months oscillated around the 1% level, demonstrating a type-independent device effect on pregnancy.
3. Primary expulsion of the Loop C was about 10 times higher than that of the narrow-band M device (6.3 against 0.6%) – independent of study kind (post-menses and post-abortum) and study place. This study kind and center-independent device effect on expulsion is the most striking early finding of this multi-clinic trial in Macedonia.
4. Removals for bleeding and/or pain at one center were relatively high for the three devices tested post-menses. Contrasting confirmation of this device-independent center effect on BI/P removal comes from another city-center, where BI/P removals for one of the previous models tested was low (six-month levels of 3% and 9%, respectively).
5. It is not possible, at this moment, to tag the relatively high BI/P removals of the third center as an effect of the center and/or the study-kind (post-vacuum abortion insertions).
6. Short-range comparison of three devices by way of one study kind at a single center – and particularly the double-blind method used for comparing two narrow-band M models – allowed the observation of no difference in effectiveness for the three pertinent event categories (pregnancy, expulsion and BI/P removal) within the M-family tested. On the other hand, the above-mentioned device effect on expulsion was clearly established in the same center.

CONTRIBUTORS:

Dr. L. Antonovski
Dr. A. Nikolovski
Dr. M. Belopeta
Dr. K. Janev
Dr. K. Curclev
Dr. M. Stankowski

E

M 213

INTERNATIONAL IUD PROGRAMME – THE PATHFINDER FUND

E

THE BEOGRAD OB-GYN CLINIC IUD PROJECT
[M-213 – POST-MENSES AND POST-ABORTUM (VAC) – 500 CASES]

THREE- AND SIX-MONTH CUMULATIVE NET RATES OF PERTINENT EVENTS
BY STUDY KIND
PER 100 M-213 USERS

Place	BEOGRAD UNIVERSITY OB-GYN CLINIC		1
	POST-MENSES	POST-ABORTUM	
Study kind	M - 213		2
Device			1
Insertions	250	250	500
PREGNANCY	<div style="border: 1px solid black; padding: 5px; text-align: center;"> - - - - </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> - - - - </div>	3
FIRST EXPULSION			
BI/Pn REMOVAL			
PERTINENT EVENTS			
RESID. ♀-MOS. OF USE	194	191	385
CUMUL. ♀-MOS. OF USE	672.5	672	1344.5
LOSS TO FOLLOW-UP	-	0.4	
PREGNANCY	<div style="border: 1px solid black; padding: 5px; text-align: center;"> - - - - </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> - - - - </div>	6
FIRST EXPULSION			
BI/Pn REMOVAL			
PERTINENT EVENTS			
PERTINENT CONTINUATION	100.0	100.0	
RESID. ♀-MOS. OF USE	108	109	217
CUMUL. ♀-MOS. OF USE	1090.5	1082.5	2173
LOSS TO FOLLOW-UP	0.7	0.4	0.5
Computer Run	522	523	
STUDY START	5/68	6/68	
COMPUTATION-CUTOFF DATE	3/69	3/69	
STUDY SPAN (in mos.)	11	10	
COMPUTATION DATE	1-6/69	8-9/69	
STUDY TECHNIQUE	STRAIGHT	STRAIGHT	
Physicians:	Dr. R. Mikić Dr. Z. Tucović	Dr. B. Mikošević	

Comments:

(The Beograd Ob-Gyn Clinic IUD Project – Study Kind)

1. The results are based on 500 primary insertions of the narrow-band, stainless steel M device (M-213), done at the University Ob-Gyn. Clinic between May 1968 and March 1969. Six-month life-table rates (Tietze-Potter approach) are based on a grand aggregate of 2,173 woman-months of use.
2. The genuine pregnancy failure at six months was nil – a finding still consistent with other models tested around the world.
3. Neither were expulsions reported at this half-year assessment of the M-213's use-effectiveness – the single most important finding, as it holds for both post-menses and post-abortum (vacuum) insertions.
4. The single most intriguing aspect of the Ginekolosko-akuserska klinika studies is the total absence of removals for bleeding and/or pain, for both IUD-retention studies, though coupled with a perfect follow-up. Given the major interest of this surprising dearth of removals, the authors should endeavour to describe precisely the doctor-patient relationship, as it might serve as a clue to centers known to be associated with high removals for bleeding and/or pain.
5. As both study kinds were associated with total absence of bleeding and/or pain removal, and as other places with M studies showed up to 10% removal, one should retain this information primarily as a study kind-independent center effect for BI/P removals.
6. Thus, then, short-range comparison of the theoretical M-213 effectiveness (the three pertinent event categories) as a result of post-menses and post-abortum (vacuum) insertion of the tested device revealed a total absence of events, and thus, no difference for both study kinds. This 100% continuation rate – both theoretical and factual – still one half year after primary insertion is undoubtedly to be interpreted as an effect of the center, which, in turn, merits careful description.

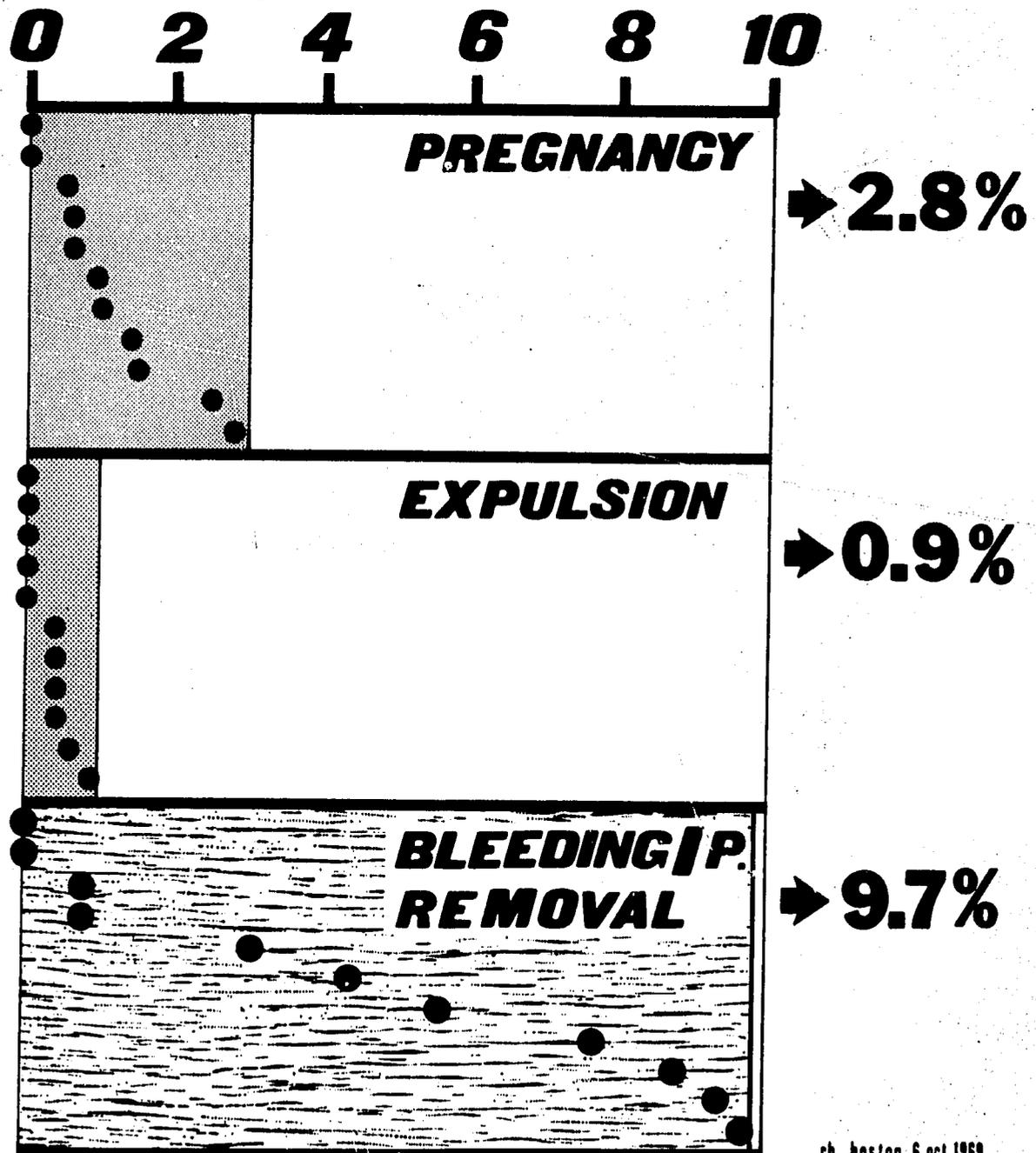
CONTRIBUTORS:

Dr. B. Milosevic
Dr. R. Mitic
Dr. Z. Tucovic

SPREAD OF PERTINENT EVENTS FOR 11 M-STUDIES PROGRESSING IN YUGOSLAVIA

6 MONTHS

RATE PER HUNDRED



A B S T R A C T

Submitted for the Conference Proceedings

INTERNATIONAL IUD PROGRAMME: The Yugoslavia Multi-Clinic Trial Bernard, R.P. The Pathfinder Fund, Boston, Mass. U.S.A.

The single most important all-out effort to fight the overt abortion epidemic in Yugoslavia was the creation of IUD-clinics all over the country. The Pathfinder Fund has assisted such since 1963.

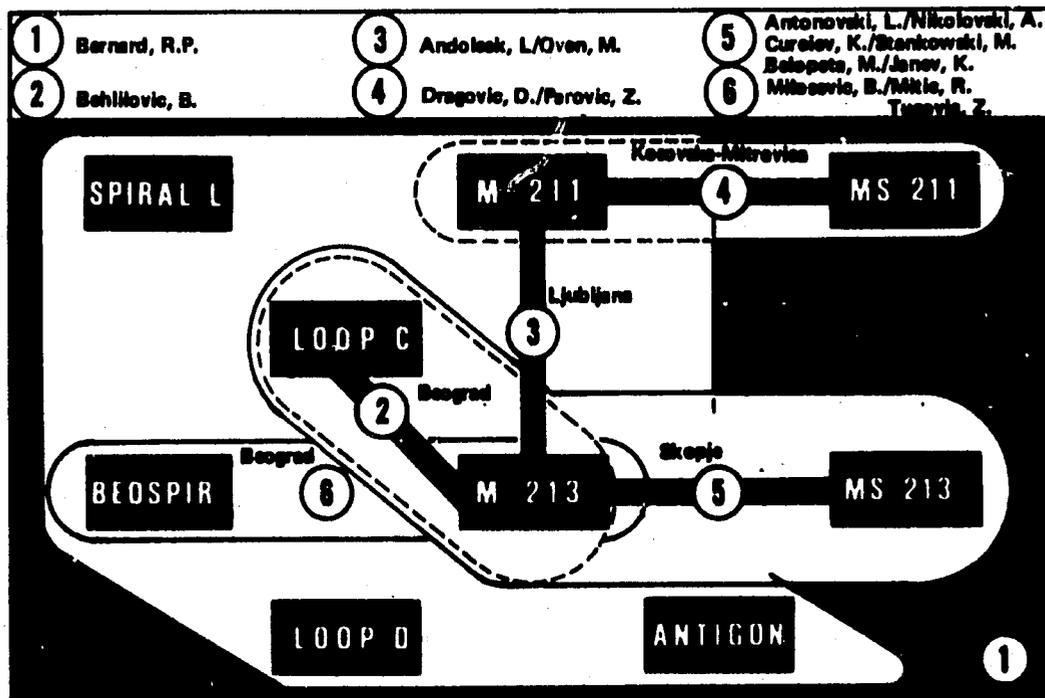
Central evaluation of the use-effectiveness of 9 devices was possible in 1969, by way of processing a standard record of admission and follow-up.

In June, 1968, double-blind studies had been initiated in Skopje, Kosovska-Mitrovica, Beograd and Ljubljana to field-test the family of M devices. The next five papers will give results on this still young multi-clinic trial. One paper will report on a post-abortion series (Kosovska-Mitrovica), another on 7 devices inserted in 2,000 women over the last 5 years (Ljubljana).

The three most important findings in the Yugoslavia scheme are:

1. Existence of centers with few, and others with many, *removals* as a consequence of bleeding and/or pain complaints.
This DEVICE-INDEPENDENT CENTER EFFECT ON REMOVAL makes meaningful comparison of various models within the same center mandatory.
2. In all centers, the M-prototype had an *expulsion* rate much lower than that of the other models discussed here.
This CENTER-INDEPENDENT DEVICE EFFECT ON EXPULSION may be exploited toward the construction of a more ideal device.
3. Five Loop C studies of old standing (Ljubljana, Koper, Beograd and Skopje) were analyzed together. The 1,438 cases of this homogeneous YUGOPOOL (97% follow-up) showed Age and Parity to be inversely associated with *expulsion*. 25% of the women up to 24 years of age and/or having had up to 1 live-born baby had expelled their Loop C during the first 6 post-insertion months. In contrast, only 3.5% of those between 30-34 years of age and having had 2 children had lost the device.
This CENTER-INDEPENDENT AGE/PARITY EFFECT ON LOOP C EXPULSION (stronger with age) should be used to delineate the best candidate for successful Loop C wearing in particular.

The testing strategy for the following 5 papers is given below.



TO: Contributors to the INTERNATIONAL IUD PROGRAMME Who Are Testing the M Device
RE: Assignment of Next Computation-Cutoff Date, Toward Global Evaluation of M Projects

Dear colleague:

October 7, 1969

You have been involved in serious testing of the M device, which — up to now — has shown an extremely low expulsion rate in Europe and in one study in Asia. On the other hand, we are not so clear on BI/P removals, as there is considerable variation *among centers* — not only for the M device but also for the Lippes Loop. Furthermore, we do not have enough information on problems arising beyond the short-range period of observation.

In an attempt to make, within this academic year (before July 1970), a neat statement concerning the relative merits of this device — in comparison with others around the world — we have set an

▶ **October 31, 1969 computation-cutoff date**

There is a handful of studies with an assigned computation-cutoff date of December 31, 1969, so that they may furnish at least six-month rates.

It is rather crucial that you try to reschedule all the patients between November and January, and

▶ **send in all new sheets, by air, at the end of each month**

We shall prepare the first Overdue List in November and indicate, at that time, which of the patients must be seen once more. This is a very big enterprise. You are participating in the most important international field testing of its kind and I ask from you the same commitment and professional conscientiousness that you have offered up to now. In return, you can count on our professional skills at the evaluation center. Above all, I am sure that each contributor to the INTERNATIONAL IUD PROGRAMME has now fully realized that the value of the project is a function of the weakest links in this testing scheme.

We shall adhere to the well-established rule: the loss to follow-up must be less than 1 in 10, so that computed rates will be meaningful and can claim international comparability.

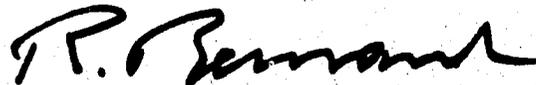
We anticipate uniting all M studies in a single volume, *IUD Performance Patterns, Vol. 2*, and giving one-year rates for some 20 projects and six-month rates for some ten others.

▶ **please anticipate your needs in follow-up pads**

At our end, this will be much simpler than having to wait up to the moment that you have the patient in front of you.

It is my pleasure to tell you that the INTERNATIONAL IUD PROGRAMME presently enjoys remarkable international prestige, because of the very high commitment you — the contributor — have been offering so spontaneously. Together we will succeed!

Very sincerely yours,



Roger P. Bernard, M.D.
Research Director

RPB:eaf