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PREPARED FOR THE SECOND EUROPEAN CONFERENCE ON STERILITY  
DUBROVNIK, YUGOSLAVIA OCTOBER 8 - 11, 1969

# IUD PERFORMANCE PATTERNS

GEOGRAPHIC  
SERIES-NR. 1

October 1969

TABLES, CHARTS AND COMMENTS  
PREPARED FOR INVESTIGATORS

BY  
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WITH ASSISTANCE FROM  
HELEN COMPTON and ESTHER FUKUDA

 <p><b>THE YUGOSLAVIA MULTI-CLINIC IUD TRIAL</b></p>	<b>supplement 1A</b>
	<b>DUBROVNIK WORKING - LUNCHEON  10 October 1969</b>

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COMPUTED ACCORDING TO THE TIETZE - POTTER MULTIPLE SEGMENT - DECREMENT LIFE - TABLE APPROACH (OCTOBER - 1969 VERSION)

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**TO: Contributors to the INTERNATIONAL IUD PROGRAMME**

Dear contributor:

January 16, 1970

You have, in the meantime, received *IUD Performance Patterns, October 1969 – Geographic Series No. 1*, entitled, *The Yugoslavia Multi-Clinic IUD Trial*. On the basis of that October 1969 statistical material, six papers were presented at the 2nd European Congress on Sterility at Dubrovnik, Yugoslavia, on October 10, 1969. The papers will appear in the Proceedings – to be issued this year.

After the presentations some 35 people – a great number of them contributors to the INTERNATIONAL IUD PROGRAMME – came together for a working luncheon to discuss, in medias res, the findings which had just been so uniformly computed and published, as well as to review the INTERNATIONAL IUD PROGRAMME in its present stage. Emphasis was placed on analysis concept and the topic of removals for bleeding – the present limitation of this IUD method of contraception.

The current *Supplement IA to Geographic Series No. 1* is a re-worked magnetic transcript in the sense that each contributor was given the chance to re-edit his statements. Very few changes have, in fact, been made. However, some graphical illustrations were added to clarify concepts and findings.

Women inserted with M devices are presently being carefully followed-up. One-year rates on many studies around the world are anticipated this summer. With such projected publication, it will be possible to make a fair assessment of the M device's mid-range performance.

At this crucial evaluation stage, we count more than ever on your following-up carefully the patients included in the trials.

Very cordially yours,



Roger P. Bernard, M.D.  
Research Director

RPB:eaf

**"Thought Exchange on the Latest Findings in the Yugoslavia Multi-Clinic IUD Trial -  
With Emphasis on Bleeding/Pain Removal"**

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**THOUGHT EXCHANGE ON THE LATEST FINDINGS  
IN THE YUGOSLAVIA MULTI-CLINIC IUD TRIAL**

**DUBROVNIK WORKING LUNCHEON, 10 OCTOBER 1969  
2ND EUROPEAN CONGRESS OF STERILITY, DUBROVNIK, YUGOSLAVIA (OCTOBER 8 - 11, 1969)**

**[Bernard, R.]**

Ladies and gentlemen — I think we are very honored that so many people could and would attend.

First of all, my congratulations to the five Yugoslavian contributors to the INTERNATIONAL IUD PROGRAMME for their excellent morning presentation. As you have realized, it left an impression of unity in study design, presentation of the findings and was an attempt toward meaningful interpretation

I am convinced that Clarence Gamble would very much have enjoyed listening to you this morning. I have the privilege to extend to you the most cordial greetings of all at The Pathfinder Fund, in Boston — from Board to staff. Two delegates are attending this Congress: Dr. Werner Bustamante, from Santiago, Chile — Director of the Latin American region — and I, serving for 27 months as Research Director.

I am glad to welcome an advisor to our program — Dr. Aquiles Sobrero, Director of the Margaret Sanger Research Bureau in New York. We are also honored by the presence of our friend, Dr. Benjamin Viel, Professor of Preventive Medicine in Santiago, Chile — to whom I owe a broad spectrum of advice, and who is coordinating for us a field trial with the M Device. Greetings also to Dr. Obolensky, a dynamic Swiss contributor. It would be time consuming to individually greet all present here; each one has identified himself and should know that we so much appreciate being honored by his presence.

How can we make this luncheon meaningful? I think that it should be a give-and-take operation. I shall endeavour to give you an overview as succinct as possible of what has happened during the last two years with the INTERNATIONAL IUD PROGRAMME. Together with the six papers delivered this morning, it may hopefully represent a trampoline for the thought exchange on your mode of action, when faced with a patient complaining of bleeding or pain, during the early or the later post-insertion period.

When I joined The Pathfinder Fund 27 months ago, I had been given a very broad assignment by Dr. Kessel, then Executive Director, now the Fund's President. The challenge was to try to bring some order into the disorder of international IUD evaluation.

Dr. Clarence J. Gamble had started, in 1963, to distribute a — at that time — potential panacea for humane population control — the intrauterine device — by way of a kind of Madison Avenue approach. He thought that spreading this method by mail to as many doctors as possible would possibly represent a remarkable acceleration in the diffusion of this revitalized method. Within three years, 1,500 doctors in

82 countries were in correspondence with Clarence Gamble on this very method of family planning.

After consultation with Dr. Christopher Tietze, presently Associate Director of the Biomedical Division of The Population Council in New York, the pink admission record was systematically added to Dr. Gamble's mailings. He had thus set the rule of educating the doctors to report back on the first few insertions before sending them a larger supply of loops. In this way, he laid the foundation for possible later statistical analysis of information being collected around the world.

A Field Studies Office was created, headed by Dr. David Burtleson — now with the North Carolina Population Center at Chapel Hill. This was essentially an ever-expanding service operation and a period of laying further grounds for possible later statistical analysis. The first study had reached the coding stage at the time at which Clarence Gamble passed on, in summer of 1966. Naturally, this sorrow meant a further delay in systematic statistical exploitation, as the Fund had to find itself after the loss of such an outstanding personality — who, in fact, incarnated the Fund.

Dr. Tietze was so kind as to give me some intensive basic training for my task ahead. His Cooperative Statistical Program for the Evaluation of Intra-uterine Devices was in full swing at that time, and I felt that with such advice, it should be possible to bring this world operation under control.

By January 1968, we had found out that 628 doctors from 82 countries had entered a kind of regular records dialogue with the Fund in Boston. One month later, already 490 doctors had been shifted to the newly-created Service Department, while the work of the remaining doctors was held in the newly-created Research Department for possible later analysis.

Let me confess here a secret. Had it not been for some very few studies of extremely high quality reporting, we probably would not have continued the Research operation at that time. I discovered in our files in Boston that Beograd and Ljubljana did extremely complete and Swiss clock-like reporting through Dr. Behlilovic and Dr. Andolsek. It is because of these two studies I discovered in the files that I decided to build up the format of the present operation now called INTERNATIONAL IUD PROGRAMME. I felt that if we were able to crystallize, from Clarence Gamble's operation, one or two scores of such high quality studies, we would certainly be able to make a world assessment on IUD effectiveness at large. Already at that time, I sensed that the INTERNATIONAL IUD PROGRAMME might well develop into an international clearing house for newer developments in IUD technology.

Five months after my joining the Fund, we had computed one-year rates for the Dr. Behlilovic study and found a most significant difference in medical removals between the Beograd study and the Cooperative Statistical Program figures, released one year earlier by Dr. Tietze in New York. Frankly, the difference was appalling. The American experience gave a 14 percent one-year bleeding/pain removal rate, against the 2 percent one-year rate of Beograd. It was instantly clear to me that the material accumulated in some 30 file cabi-

nets in Boston would constitute a real gold mine toward extracting clean evidence on why such dramatic differences in bleeding/pain removal occur in different programs, though with the same device. However, I knew also that a tremendous task lay ahead of systematic handling of data.

I appealed to the contributors and asked them to take their work extremely seriously, because the very method of intrauterine contraception may stay or fall with their quality of work. I must say that the response was beyond any expectation. It was the contributors who essentially made me dare to set higher and higher standards for our evaluation operation. It is only through your unequalled commitment that it was possible today to report on so many studies such meaningful data. You know that your overall one-year follow-up is 95 percent and you have sweated for it.

By May 1968, we had computed seven Israeli studies and found again a much lower removal rate for bleeding and/or pain, when compared to Asian and American figures.

During summer, 1968, Robert Potter, James Sakoda and Christopher Tietze joined forces to elaborate the computer program so skillfully written by Peter S. Chi of Brown University. Concomitantly, my Assistant, Helen Compton, organized — in a remarkably short time — the practical coding operation of many studies of high quality onto a single-sheet case-history code which we had worked out together with the Brown University consultation team. As you know, in October 1968 — to be exact, one year ago to the day — the computer program was functional.

Within one year, then, three volumes of IUD performance patterns were created — the latest having been released this morning. No doubt, it will remain a tribute to the Yugoslavian contributors and I am particularly grateful to you, because you made me feel at home on all my flash-trips, even if I were to leave you virtually before I had correctly landed.

I am sure that you will forgive me on this score, as besides all the responsibilities at home, I had engaged upon ten trips of consultation with physicians working with the INTERNATIONAL IUD PROGRAMMI

Let me say a word on methodology. There was a reason why I decided very early in the game to stick to the life table method. This method would in fact take into account the factor of time, which is completely neglected by the Pearl Formula, still used — unfortunately — by so many people around the world. I started to refer, in 1967 already, to the Tietze-Potter life table method. Later, I had to learn that Professor Viel had, in fact, worked on the same method quite independently and each time I encounter him, I have a kind of guilt feeling. No doubt, the single yardstick we are presently propounding for use-effectiveness evaluation should be called today the Tietze-Potter-Viel life table approach. So, Benjamino, I now got rid of my guilt complex. You realize that I had not expected that you would act as my psychiatrist.

Before even being in possession of a smooth computer program, we had sensed that we should try to demonstrate, on a world scale, the feasibility of serving as a clearing house for newer developments in IUD

technology. We felt able to take on the task of coordinating a multi-clinic field trial of a new family of devices which had been developed on the basis of a hypothesis stipulating virtual absence of expulsion. This is how we set up, in May and June of 1968, many studies in Israel and Yugoslavia — but now, under rather controlled conditions. Dr. Tietze advised us of the double-blind method of comparison, which has been adhered to in both countries since.

It should be realized that for the first time in this operation some rigorous planning had been introduced. Thus, we could project the release of clean six-month rates by early July, 1969 — which some of you have reported at the Bristol Meeting in England. Naturally, it was in Bristol that we felt we should focus this very day on the bleeding/pain removal problem, as a dramatic discrepancy in removals for bleeding and/or pain was encountered for the same device. These findings certainly stood, perhaps for the first time, on most solid ground. The double-blind approach allowed the clear enucleation of the fact of the very existence of device-independent high removal centers, contrasting another series of device-independent low removal centers. In retrospect, naturally, one would expect such to be true by intuition. Let us, however, clearly state that it was the first time that this was found via the double-blind method, thus excluding the patient's and doctor's bias.

Before we give our views on this tremendous variability in bleeding/pain removals, let me perhaps sketch in some sentences how we think to proceed with the material accumulated. Above all, I maintain these studies are yours and that the high-speed, high-quality computer feedback should serve as a solid basis for your own scientific publication. You certainly have demonstrated this morning how well you would pick up the ball. There are, however, further dimensions to be exploited. First of all, such findings should be systematically collected into master manuals and then, be put at the disposal of anybody interested in the field. As only high-quality studies are entering such manuals, we systematically associate the contributor's name to his work. The aim is to cross-fertilize discussion on this very method, now based on rates coming ever-closer to the never-attainable claim of total international comparability.

Perhaps as important — and this is surely a dimension where the Fund is now breaking tough ground — a duplicate of the computer summary output goes straight to the M.I.T. IUD Laboratory, most recently created and sponsored by the INTERNATIONAL IUD PROGRAMME. The sole aim of this systematic feedback into two directions is to speed up both dissemination of most recent information on this method and exploitation of all findings, toward construction of a better and better device.

Naturally, we are also willing to incorporate into future study designs devices of significant promise which have been developed around the world. However, I should like to state it once and for all — and this is my personal point of view — it is long overdue that most careful evaluation of the prospective merits of any new model offered for testing should precede its introduction into the present evaluation scheme. Cer-

tainly, it is in line with Clarence Gamble's thinking that the best and cheapest method of contraception should be developed the fastest possible way.

Thus, then, the stage is now set — and you certainly appreciate now the dynamic role you are playing in this venture — on which a team of IUD creation and one of evaluation harmoniously join to form a dynamic and efficient cycle of IUD improvement.

A final word on format of data release. Statistical material, after having been fed to the individual contributors, is being bound into volumes of *IUD Performance Patterns*. Blue stands for studies initiated under the leadership of Clarence J. Gamble, whereas Red stands for studies having been built up in the wake of his departure. When enough material is accumulated for an area, regional volumes are being constituted. We have witnessed today the birth of the first Green volume — which, naturally, will be composed of a Blue and a Red part.

All this orderly accumulated statistical material is, then, a challenge to both the contributors in the field and to us at headquarters. Both will publish papers. You, the way you did this morning; we, in Boston, aiming at some broad overviews which, naturally, are much more sparse in appearance than are the publications from the field. We feel that this strategy will allow to bring some order into the field of the IUD method of contraception. Thank you for having borne with me.

[Sobrero, A.]

As a corollary to such an exquisite meal, it was most pleasant to listen to the informative exposé so brilliantly given to us by Dr. Bernard. As one of the Advisors to The Pathfinder Fund, I would like to join my voice in praise of the Yugoslavian experience. I think that this is probably a unique experience and you should be very proud of being able to produce such solid data which, as you know, is not The Pathfinder Fund's data, but your own. We should keep in mind that Dr. Bernard could not have spoken so eloquently if you had not made such a conscientious effort here in Yugoslavia.

I think that the time has come in which we must recognize that in modern contraception — contraceptive methodology — effectiveness is no longer a problem. We have the tools now — through intrauterine devices, through oral contraceptives, through injectable contraceptives — for which effectiveness is no longer our concern. It is the continuation rate which, at the present time, remains our concern: how long these women will remain using contraception; how long they will postpone the not-wanted pregnancy; and how far we can go in fulfilling the wish of every woman of having a pregnancy when she wants it and when she wants no pregnancy, of having access to means for preventing it.

So, in coming back to the intrauterine method of contraception, which is the immediate concern at this working luncheon, I would say that our problem lies in the disparity in the removal rates that we see all over the world — and the Yugoslavian experience is no exception, as we have heard in six presentations this morning. Medical removal is the real core of the problem we are facing now, here in Dubrovnik and all over

the world.

I think it is just to pull ourselves from the clouds that Dr. Bernard took us a little bit closer to the ground in saying that we should try seriously to discuss the matter and to find the answer -- if there is any -- for the disparities encountered in removals for bleeding and/or pain. The question is highly relevant, as it is not how successful we are in inserting 300, 3,000 or 300,000 IUDs, or, for that matter, in prescribing any other method of contraception. It is rather how long the people who have received contraceptive service will stick to the method that we have chosen for them.

[Bernard, R.] Thank you very much Dr. Sobrero for this capsule overview of some real problems we are facing today in the application of present contraceptive means. Professor Viel from Santiago is manifesting interest to speak to us. Please, Dr. Viel.

[Viel, B.] Just to emphasize the international usefulness of the kind of comparison the INTERNATIONAL IUD PROGRAMME seems now to be aiming at, I would like to say that in Chile, in a series of 15,000 cases of women inserted with Lippes Loop size "D", we find exactly the same as what was so clearly stated in the morning session on the Yugoslavian experience.

There is, however, one apparent difference and I would like to very shortly focus on it. Removal for bleeding and/or pain on women having been inserted beyond age 40 is much higher in the Yugoslavian experience than in that recorded in Chile. This difference seems to find an immediate explanation. At a glance, it appears that the composition of the two populations is very different. The Chilean women having reached 40 years is almost exclusively made up of great multipara. In Yugoslavia -- if I understood correctly -- the corollary population segment having asked for contraceptive devices contains many women of relative low parity, so, probably, this could explain the difference in bleeding/pain removals between the two national experiences. At any rate, this is definitely a field for a study and it is a field that should be studied deeply.

I would like to emphasize also, as Dr. Sobrero has said, that our removal for bleeding and pain varied from one clinic to another, the extremes being 3 versus 15 percent after three years. It seems to me that there is a definite personal difference in attitude of the doctors facing a patient complaining of bleeding or possibly pain. This problem complex asks -- I think -- for a sort of international advice of how to behave in front of the women who are complaining of bleeding and/or pain.

[Bernard, R.] Thank you, Benjamino, for your wonderful comparison and expression of the need for an international expertise on bleeding/pain removal problems. Dr. Obolensky, you ask for the microphone -- you have it!

**[Obolensky, W.]** The bleeding and pain problem, which is usually only a bleeding problem – at least with our material in Liestal, Switzerland – is a very tricky affair. If you work in a community, as we do, where people may or may not come to you – and if they are not satisfied, they will not come any more – you have to remove devices for bleeding much more often than if you work in a place where you can offer to the women two alternatives only: “either you have the device and you may bleed, or you will have the baby.” This is a rather important consideration. I think, from this point of view, it will be extremely difficult to make any international comparison. In fact, I was very concerned with my feedback which I just got out of the computer some days before taking off for this Dubrovnik Meeting. It is true, it is not an M study, it is a study we have carried on for over two years. But that is not the point. I just would like to warn to compare internationally bleeding and pain.

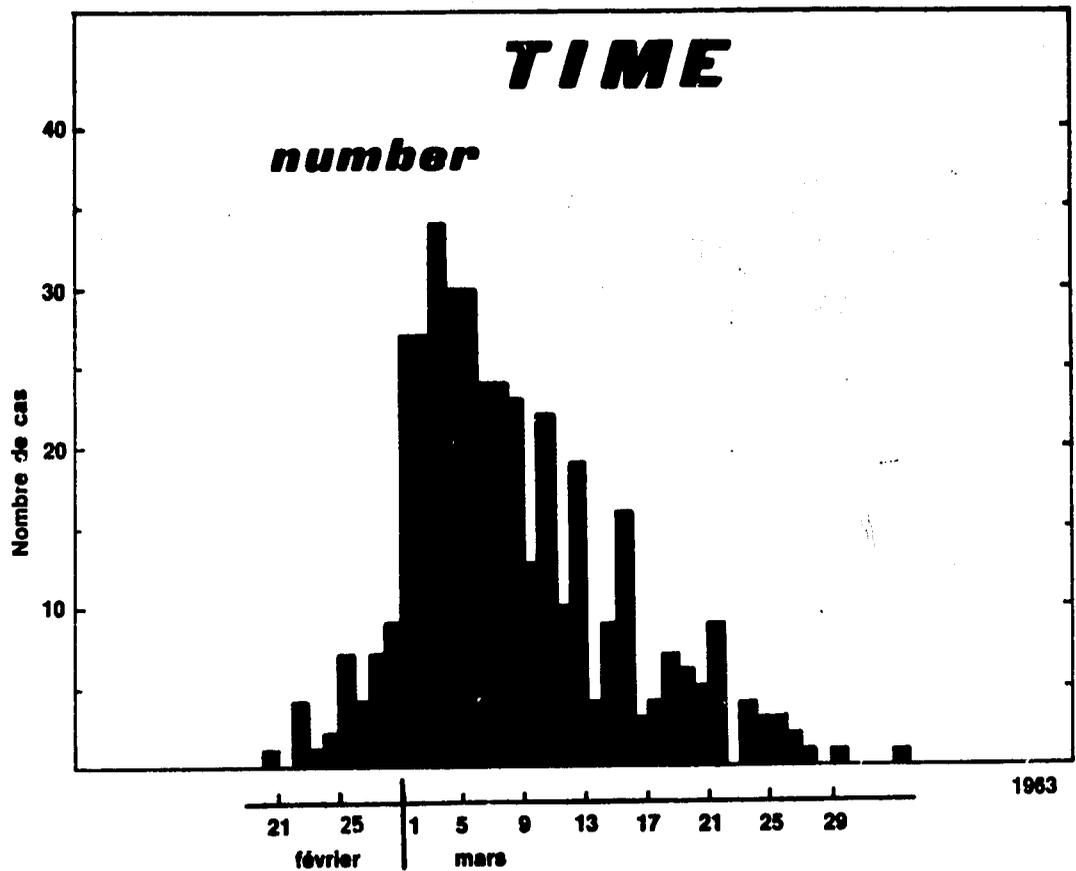
**[Bernard, R.]** May I perhaps reply to this rather pertinent statement. I think we should define very clearly some terms. There is a watershed difference between bleeding and/or pain and removals for bleeding and/or pain. The first term involves the patient only, involves only its own gammut of problems of objective measurement, which has not been solved to this day. The second term adds another gammut of variables, so difficult to define. The doctor’s attitude towards reported bleeding and/or pain is as variable as the pains reported by a woman giving birth to a child without anesthesia.

By international comparability, we do not mean that we can, in fact, compare different experiences in attitude. But what we can compare are the resulting rates of removals thereof. Once those rates are at hand, we have to go backwards and ask each contributor, ‘How come that, in fact, in your case you had a much higher bleeding/pain removal rate than others?’ By international comparability of results, we strictly mean that we apply one and single yardstick of evaluation to all studies which have met certain basic criteria, such as, good follow-up, completeness, consistency, regularity in reporting, etc. Discovering, then, substantial differences for a given event rate in various settings obliges us to inquire retrospectively. We would say to a colleague, for instance, ‘Now look. In your case you are testing a given device and you have a 0 bleeding/pain removal rate. Seventy miles from your clinic, we have computed a 10 percent removal rate for the same time span and the same device. Can you tell us the problems you are facing with bleeding/pain complaints? What is your attitude? How do you solve problems related to it?’ Asking these questions of each center will gradually help to associate broad classes of answers with a given level of removal for bleeding and/or pain. You will sense that this is the simple technique of retrospective epidemiological inquiry. It is true, we play it a bit the Scotland Yard way. Epidemiological reasoning, is, today, an all-pervading tool of analysis in public health and population control. Let me give you an example, so that we really understand each other. Dr. Obolensky, when I investigated the 1963 Zermatt Typhoid Epidemic in Switzerland, it was this kind of retrospective study which led finally to accumulate enough evidence to substan-

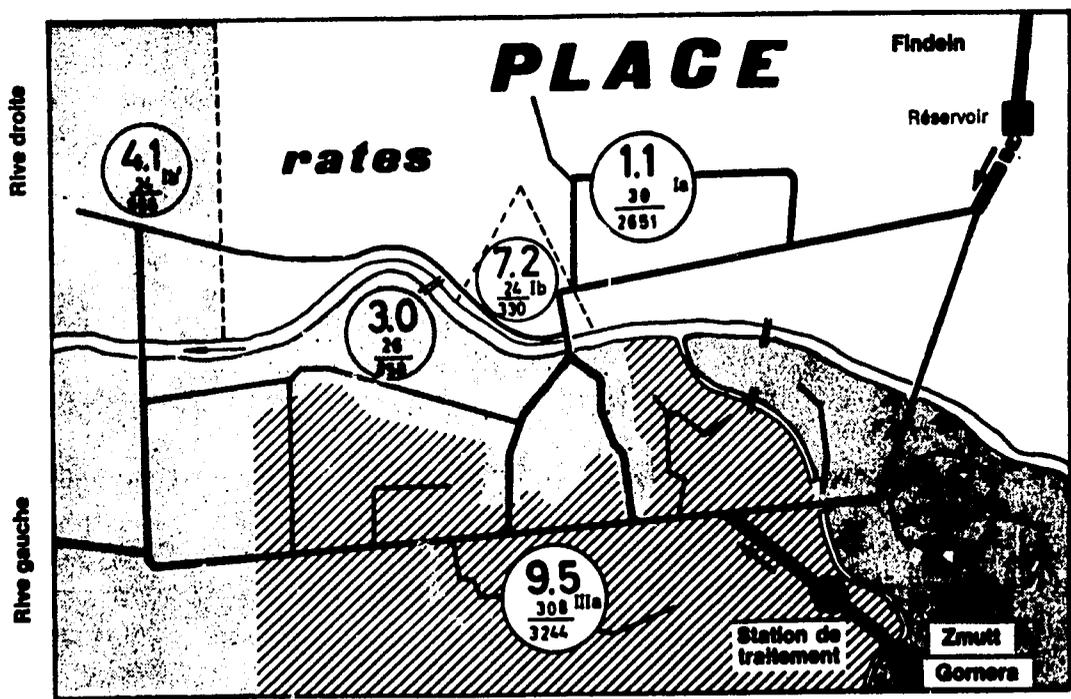
tiate a hypothesis explaining the whole debacle that plush resort station had to go through. In that case, one took some simple variables such as age, date of arrival and departure at that Ski Resort center, date of onset of the illness (some 200 became ill after they had returned home, name it any place around the world), and exact residence by vacationing in Zermatt. As you recognize, inquiry went essentially into place and time. The hypothesis, naturally, was that the water system had distributed the bug in a rather explosive manner in that very community. The trick now was to compute sectional attack rates, which could be associated with peculiarities of that very water system. This meant, naturally, that a rather precise census had to be taken, so that a clean denominator of inhabitants in given sections of Zermatt could be established. Thus, it was possible to compute "Local Attack Rates." Overlaying an attack rate chart onto the water engineer's water-distribution chart, one became aware that a given region had a typhoid attack rate ten times higher than did another one. The crucial thing now was to go back and to inquire into the differences in water supply in the two regions where such a dramatic differential in attack rate was found, by way of the retrospective epidemiological inquiry. To simplify the findings, it came essentially into light that one of the two water systems had been infected at a given point in time, which could be nailed down to one particular weekend: 16 - 17 February, 1963, if I recall correctly.

I gave this example because it is the calculation of local (attack) rates which allowed giving the clean answer to the problem. It is the same local rates which will help us to find the problems associated with the IUD method of contraception at large. One-hundred years ago, cholera was traced back — by computation of local rates — to a very specific origin giving rise to a slaughtering epidemic, for people who relied on the Broad Street pump for their water consumption. In all these retrospective investigations, a single yardstick was applied for measurement of local event rates. In the case of the cholera outbreak in the Golden Square section of London, Dr. Snow did that computation himself and published a classic paper, 'On the Mode of Communication of Cholera.' Some 120 years later, a new element had to be taken into consideration. The world had meanwhile grown small. In the case of Zermatt, facts had to be gathered from all over the world — as happy or unhappy tourists had returned to four continents, mostly by jet plane. Still, a single yardstick was applied to all the data collected. In fact, the analysis of the Zermatt Typhoid Epidemic was not made in Switzerland, but in Paris, while I was with the Pasteur Institute. In the case of IUD evaluation, we have quite a parallel from the methodological point of view. Although individual studies are being carried on on the five continents, the doctors report on what they do and observe by way of a standardized multi-lingual record system to a central agency which, in turn, applies a single yardstick — in this case, the Tietze-Potter multiple segment-decrement life table approach. Certainly, the yardstick has grown so complex that it can only be applied efficiently via computer, that high-speed

**Courbe épidémiologique**

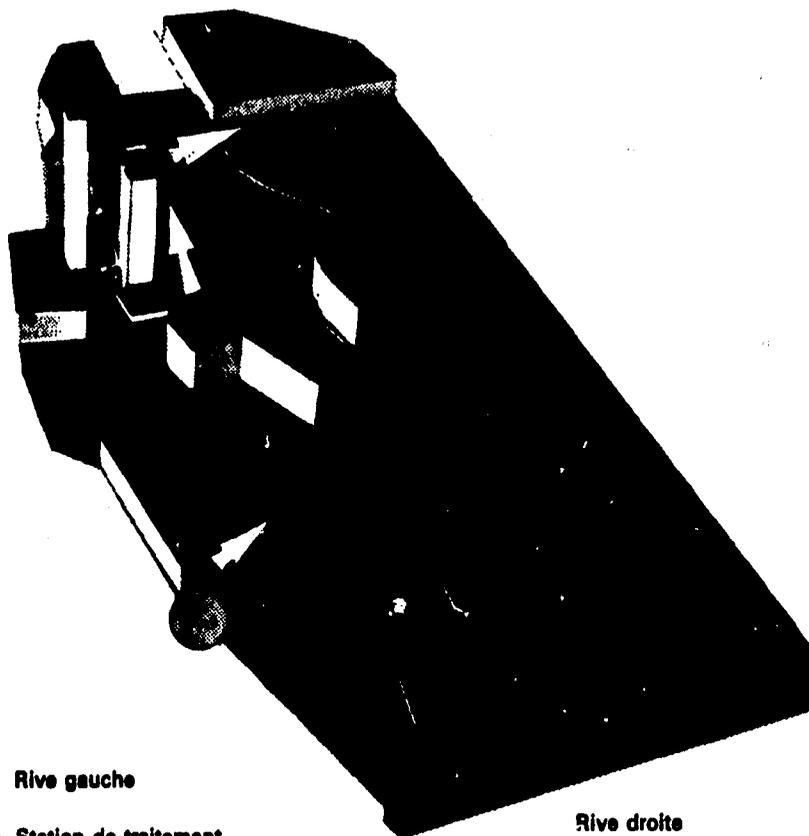


**Taux de morbidité par zones en fonction du système d'alimentation en eau**



# RATES

## Les faits



Rive gauche

○ Station de traitement  
de l'eau potable

Viège

Rive droite

*On reconnaît aisément le trajet emprunté par les bacilles qui ont donné naissance aux taux de morbidité régionaux représentés ici en relief. Les plus hautes morbidités ont été enregistrées aux bas de la rive gauche.*

imbecile who certainly will not do more than what you ask him to do.

This, then, is the answer I give to Dr. Obolensky. By international comparability, we mean applying a single and unique yardstick, as of yet applied at one data collection center. Why a unique data collection center? If several centers were to compute rates not using an identical code and coding strategy, it might well be that differences encountered between rates for a given event category might well be explained by just that difference in technique. If, on the other hand, one single center does the evaluation, any bias will run systematically through the whole evaluation, and differences will have a much bigger meaning. Thank you, Dr. Obolensky.

[Dr. Obolensky was so kind as to think about the problem associated with bleeding/pain removals and asked us to incorporate the following text in this discussion] :

#### REMOVALS FOR BLEEDING AND/OR PAIN

In our Liestal experience, pain is of no practical importance as a reason for removal, except in rare cases immediately after insertion. Slight pain while palpating the adnexa may arise from the end of the loop lying at the tubal orifice. Bleeding, then, is the major reason for removal. The removal rate is center-dependent, as it depends both on the physician's policy to recommend other contraceptive measure and the patient's willingness to accept bleeding for the sake of not becoming pregnant. Furthermore, the patient may or may not have at her disposal other means of contraception — this latter being certainly a function of her socioeconomic status.

Nevertheless, two points in time after primary IUD insertion must be differentiated, with regard to complaints for bleeding, as they necessitate two ways of approach on the part of the physician facing such a patient:

1. *Early post-insertion bleeding or spotting.* Here, a conservative attitude is mandatory. To state it clearly, already at the insertion session, the patient must be informed on the prospective possibility of this untoward effect during the first one-to-three cycles, as well as about increased menstrual flow. Should the spotting *persist* for a longer time, however, the patient should be dealt with as if she belonged to the next group.
2. *Bleeding During a Later Period of IUD Wearing (Late Bleeding).* If, after a symptom-free time span of wearing, bleeding or only spotting, for that matter, occurs, the IUD should be removed immediately and reinsertion performed at the next menstrual period, while other means of contraception may be used during the uncovered interval. This dynamic approach is mandatory, as spotting or bleeding might be the first sign of internal displacement of the intrauterine device. Although the displacement is initially only intra-

uterine, we believe, from our experience, that this very first symptom of internal displacement is an alarming signal announcing a dramatic shift in the probability of expulsion, and what is worse and of parallel occurrence, a signal also of dramatic increase in genuine pregnancy failure — that is, the IUD being still recorded as anatomically 'in situ.' Therefore, I recommend to distinguish between early and late spotting/bleeding and to retrospectively evaluate the data for a possible correlation between late bleeding and the occurrence of genuine pregnancy failure with device in situ in old data. New studies should incorporate feasibility of this comparison in a prospective statistical design.

[Chmelik, V.] I would like to congratulate the pioneers of this organization. It will not take too long that the method of intrauterine contraception will be one of the practical solutions to the abortion epidemic and will thus, above all, protect the health of these poor women.

[Bernard, R.] Thank you, Dr. Chmelik. We are very happy to have you — coming from Czechoslovakia — among us today. Indeed, very good IUD work is being done in your country. I wonder whether Dr. Stambolovic from Lazarevac would perhaps relate his IUD experience at the Obstetrics-Gynecology Clinic near Beograd.

[Stambolovic, B.] Unser Wirkungskreis stellt die Gemeinde Lazarevac mit circa 50 Tausend Einwohnern dar. Der Zuwachs der Bevölkerung beträgt 6 pro mille und ist in gelindem Abfallen. Auf Grund von anamnestischen Angaben unserer Patientinnen haben wir ausgerechnet, dass in unserer Gemeinde 2,25 Abtreibungen auf 1 Geburt entfallen. Natürlich, selbst für unsere Verhältnisse in Jugoslawien ist dies sehr viel.

Als Verhütungsmassnahmen gegen unerwünschte Schwangerschaft verwenden hier die Ehepaare den Coitus interruptus mit wenig Erfolg. Unsere Beratungsstelle für Kontrazeption empfiehlt den Frauen verschiedene kontrazeptive Mittel in Form von oralen und vaginalen Tabletten, vaginaler Salbe, Schaum und IUD.

Bis jetzt haben wir 35 Lippes Loop C und 176 M-213 (insgesamt 211) appliziert und zwar 183 unmittelbar nach der Curettage bei legaler Abtreibung und 28 in den letzten Tagen der Menstruation.

17 IUDs (8%) haben wir herausgenommen und zwar 6 (2.8%) wegen Metrorrhagia profusa und Adnexitis, 4 (1.8%) wegen Residua post abortum, 3 (1.4%) wegen Schwangerschaft, 3 (1.4%) wegen psychologischen Faktoren (Cancerophobia, Eifersucht des Gatten) und 1 (0.4%) wegen dem Wunsch nach noch einem Kind.

12 Frauen wurden im Krankenhaus wegen mässiger Uterusblutung mit Erfolg behandelt ohne dass man gezwungen war die IUD herauszunehmen.

Die Blutungen traten meist in den ersten Monaten als Endometritis und Adnexitis bei Frauen welche Antibiotica als Präventivmassnahme nicht eingenommen haben und welche psychischen und physischen Strapazen ausgesetzt waren auf obzwar sie vom Arzt sowohl das Rezept für die Antibiotica, als auch den Rat drei Tage im Bett zu bleiben bekommen haben.

Wir haben insgesamt bei 211 IUDs 18 (8.5%) Uterusblutungen gehabt, was uns im Allgemeinen keine grosse Sorge bereitet hat. Unserer Meinung nach die Hauptsache um den Uterusblutungen zu entweichen besteht darin, den Frauen mit Adnexitis oder Parametritis, auch wenn es sich um die leichteste Form handelt, keine IUD zu geben und die Frauen welche IUD bekommen haben zu verpflichten in den ersten Tagen Antibiotica einzunehmen und sich Ruhe zu gönnen.

[Bernard, R.]                      Vielen Dank, Dr. Stambolovic, für Ihre feinen Erläuterungen. Gehen wir zurück zur nördlichen Adriatika. Dr. Kolenc aus Koper, Sie haben sehr feine Arbeit geleistet in den letzten zwei Jahren. Möchten Sie vielleicht Ihre Erfahrungen, die im YUGOPOOL eingeschmolzen wurden, uns jetzt erläutern.

[Kolenc, M.]                      Ich muss mich in erster Linie bedanken dass ich ein Mitarbeiter in diesem Pathfinder Program geworden bin. Ich verdanke dies Frau Dr. Andolsek. Sie war einmal meine Schülerin – jetzt aber bin ich ihr Schüler geworden.

Die Pathfinder Stiftung hat uns eigentlich gezwungen die statistischen Daten seriös und anständig zu sammeln. Das ist es, was wir von Dr. Bernard erlernt haben. Wir waren zuerst etwas schlampig aber sie haben uns sicher gelehrt bessere Arbeit zu leisten und ich hoffe dass Dr. Bernard mit uns mehr zufrieden ist als vor zwei Jahren. Jedenfalls haben wir jetzt einen ganz persönlichen Profit von den statistischen Daten die wir so systematisch kriegen. Wir wissen ja alle wie schwer es ist gute statistische Daten zu sammeln und auch welche enorme Arbeit damit verbunden ist. Dr. Bernard hat uns aber gezeigt wie solche Arbeit durch den Komputermöglich und wertvoll wird. Natürlich wissen wir auch, dass viele Leute in Statistik nicht glauben. Was wir aber nun von Boston bekommen ist tatsächlich glaubwürdig. Ich war sehr beeindruckt – wie alle meine Kollegen – als wir gestern im grünen Buch unserer Studien studieren konnten. Welche Ordnung in diesen Zahlen!

Noch eine Bemerkung. Bis vor kurzem, habe ich die Stellung eingenommen – wie andere Kollegen in Jugoslavien – dass intra-uterine Einlagen nur solchen Frauen gegeben werden sollten, die zum mindesten zwei Kinder geboren haben. Der Grund für dies war vielleicht ein gewisses Misstrauen, dass nämlich diese Kontrazeptionsmethode doch irgendwie schädlich sein könnte auf das Endometrium und dass es daher nicht so gut wäre den Frauen die noch weitere Kinder haben wollen solche Einlagen zu verschreiben. Jetzt aber dass wir die Datenbewertung von Boston bekommen haben ist ja die Lage ganz anders. Verschiedene Studien haben gezeigt dass Einlagen sofort nach Abortus legalis artificialis und auch in primipara gegeben werden können. Ferner, die M-Einlage scheint viel weniger Ausstossungen zu haben. Besonders wichtig scheint mir dass 'bleeding/pain removals' mehr mit dem Studien-ort als mit dem Einlage-typus zu tun haben.

Obwohl Koper eine sehr geringe Natilität hat, sind wir froh dass unsere kleine Adriatische Stadt einen Beitrag leisten durfte. Ich danke Dr. Bernard für alle Arbeit die er für uns getan hat bis zur heutigen wissenschaftlichen Sitzung.

[Bernard, R.]

Vielen Dank, Dr. Kolenc, ich werde Ihr Lob meinen Mitarbeitern in Boston

zuleiten.

Sie haben einen Punkt aufgegriffen, den ich weiter erläutern möchte: 'In wie weit sind Statistiken glaubwürdig?' Da ich die Grundelemente in medizinischer Statistik in Paris bekommen habe, und da Professor Dalsace uns heute mit seiner Anwesenheit beehrt, werde ich französisch sprechen.

Il y a une grande différence entre les statistiques et la méthode statistique comme disait mon maître le Professeur Daniel Schwarz a Paris, qui m'a introduit à l'art de la méthode statistique. Les statistiques, effectivement on peut les truquer. On peut en faire ce qu'on veut. La méthode statistique, au contraire, ne permet pas de truquer. Les résultats sortent du computer. Nous sommes l'esclave de la méthode. Vous recevez les résultats comme ils sortent du computer, par un "output imprimé". Nous ne pouvons pas changer une virgule. La seule chose que la méthode statistique permet c'est d'essayer de grouper les données en certaines combinaisons pour faire mieux apparaître une tendance de toute façon contenue dans l'ensemble du matériel collectionné selon un protocole bien établi. C'est effectivement après maints essais de combinaison que nous avons clairement établi la relation entre avortement et expulsion. Il est néanmoins essentiel de retenir que le statisticien travaille avec un univers très défini et une fois que l'information est sur les cartes IBM il n'y a plus de possibilité de changer ces données. C'est certainement une loi fondamentale en exploitation statistique. C'est même une question d'esthétique professionnelle. Voici donc la différence entre les statistiques et la méthode statistique.

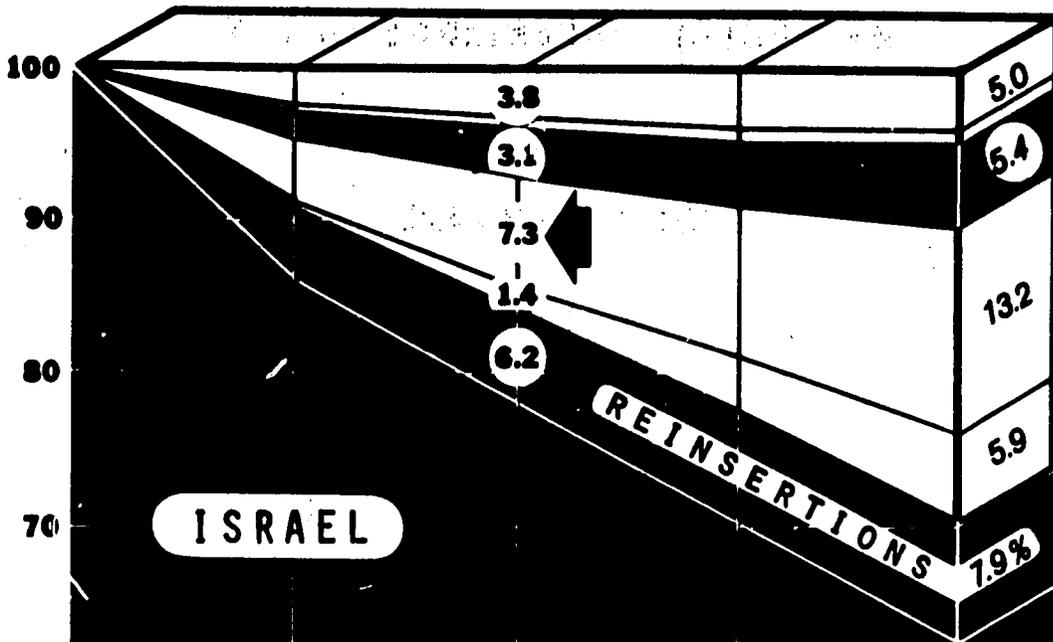
A typical example of how we dig out trends hidden in a given statistical universe — of how, furthermore, rates can be dissected and thus be made highly specific, i.e., found to be associated with a given factor — is the fascinating story we lived over the last eighteen months, with the Israel Multi-Clinic IUD Trial.

The one-year bleeding/pain removal rate following some 1,800 primary Loop C insertions had been found to be 7.3 percent — which impressed us as being very low in comparison with figures reported from Asia and the United States. There was a whole chain of questions which arose.

First of all: how great would be the variation between the 7 centers which had contributed to the ISRAEL POOL? Practically, this meant running the IBM cards in seven individual stacks — that is, center-specifically — through the computer. It was found that there was a rather narrow spread of the bleeding/pain removal rate among centers — with one exception, though, which showed a removal rate twice as high (15 percent) as the national average. Naturally, you sense, that is where epidemiological reasoning has to dictate further action. One is now presented with a lead and one must get an answer to why there is one

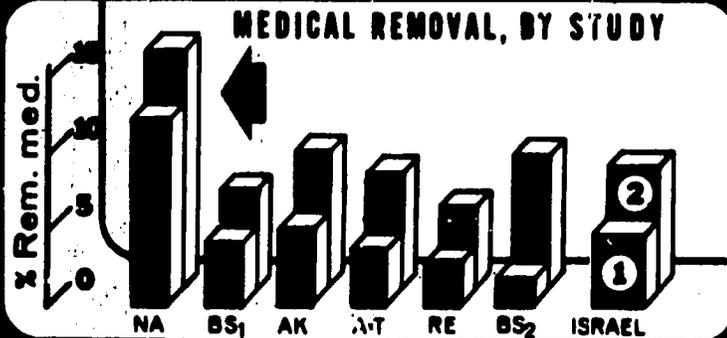
# INTERNATIONAL IUD PROGRAMME — THE PATHFINDER FUND

## DISCONTINUATION PROBABILITIES



**EXPULSION  
PREGNANCY**

**REMOVAL  
-medical  
-personal**



1100	609	212	73
8210	13212	15242	15992

PHYSICIANS Heading Seven Studies  
 PLACE Israel  
 DEVICE Lippes Loop C  
 STUDY START (earliest) November 1964  
 COMPUTATION-CUTOFF DATE December 1967  
 STUDY SPAN 38 Months  
 TOTAL LOST TO FOLLOW-UP 5.4% (97/1798)  
 AVERAGE ANNUAL LFU 1.7%  
 COMPUTATION DATE 24 April 1968

② SEMESTER  
 ①  
 • 0-MONTHS AT SEMESTER END  
 • CUMULATIVE 0-MONTHS OF IUD-WEARING

**CONTINUATION % ↑**

① ② ③ ④  
**1 year 2 years**

# REMOVAL RATES FOR BLEEDING/ PAIN BY DOCTOR EXPERIENCE IN TIME

STUDY: 022 loop C

NUMBER CASES **97213 116**

NUMBER REMOVALS **15 19 4 2 3 1 1 4 3**

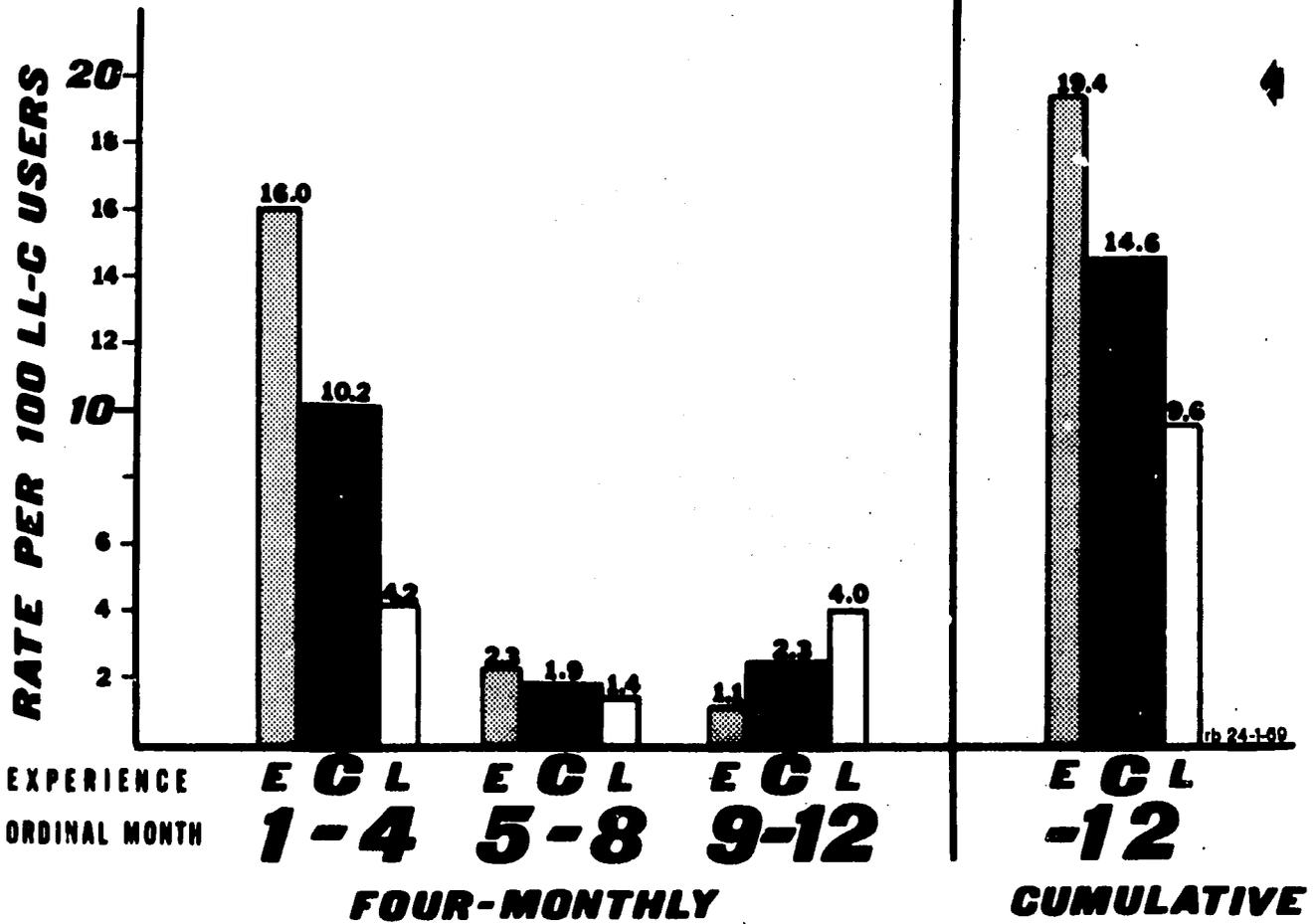
**C: COMPOS.**

**E: EARLY**  
**L: LATE**

START

11-64

9-66



center in seven of much higher medical removal. No doubt, the local situation must be particular.

'Which span of the doctor's experience in time is involved?' is certainly the next question. Practically, it amounted to taking the perhaps 200 IBM cards — each one representing an entire patient history — to split them into two stacks of, say, 100 cards before running them individually through the computer. So it was found that the center-specific one-year bleeding/pain removal rate of 15 percent split into 20 percent for the doctor's first 100 insertions, against 10 percent for the later acceptor cohort. This information was naturally gratifying to epidemiological reasoning, as it meant to convey that in that center, the very beginning of the doctor's IUD insertions — that is, while he essentially learned to apply a method still new to him — was associated with many removals for bleeding and/or pain. And perhaps as important, that — as time went by and implicitly, thus, his experience increased — bleeding/pain removals were cut in half. But one can pinpoint further.

Which point in time after the first 100 insertions — that is, for the patients representing the doctor's apprenticeship period — is in fact associated with a high removal rate? Did these first clients complain early after insertion, or only as time had gone by? It was found that most removals had occurred during the very early post-insertion period (the first 4 months). In particular, also, for each medical removal (4 percent) among patients belonging to the doctor's more advanced experience, the computer printed out four such removals (16 percent) for patients identified as having been inserted during the doctor's apprenticeship time.

It should be borne in mind that all this information can be gained without necessarily discussing such with the physician. You understand why epidemiological reasoning has become such an important tool in public health at large. Still, there comes a moment where the "epidemic intelligence officer" has to make contacts to discuss his findings, and particularly, to obtain confirmatory explanations and interpretations from, say, the defendant — always a professionally honest defendant.

It was a happy end — the meal we shared together in Northern Israel. The gynecologist spontaneously declared that only as time went by did she become more conservative concerning bleeding/pain removals, as she literally had gone through an apprenticeship of her own. She implied at least two basic elements bearing on the removal rate: the doctor's insertion skill, on the one hand, and his rapport with the patient, on the other. In her case, both improved over time, she affirmed.

I traced this story a bit more in detail, because it demonstrates how systematic application of simple statistical reasoning has allowed the obtainment of some crucial information on bleeding/pain removals — information initially drowned in a national figure of low removal. Thank you, Dr. Kolenc.

Je vois que le Professeur Dalsace semble être désireux de prendre la parole.

[Dalsace, J.] Vous m'excuserez tous de parler français mais je me suis aperçu avant le déjeuner que tout le monde parlait français comme tout le monde parlait l'anglais. Il me sera donc plus facile de parler français.



Dr. Bernard gratulieren.

Das grösste Problem das gelöst werden muss ist nach meiner Meinung unsere Verhaltensart gegenüber unregelmässige Blutung, die nach Einlage von IUDs früher oder später auftreten kann. Wir sind überzeugt, dass Dr. Bernard auch diese Klippe zu überbrücken helfen wird.

[Bernard, R.] Thank you so much, Dr. Behlilovic. Perhaps a remark on the spread of this method of contraception throughout Yugoslavia. Dr. Behlilovic is the first physician in Beograd who picked up the ball from Dr. Andolsek, in January of 1966. He at that time started a Loop C study, following Dr. Andolsek by two years. One year later, in 1967, Dr. Antonovski in Skopje picked up the ball from Dr. Behlilovic. Shortly thereafter, the method was spread back northward, when Dr. Dragovic started IUD work in the miners' town of Kosovska-Mitrovica. A very interesting spread, indeed.

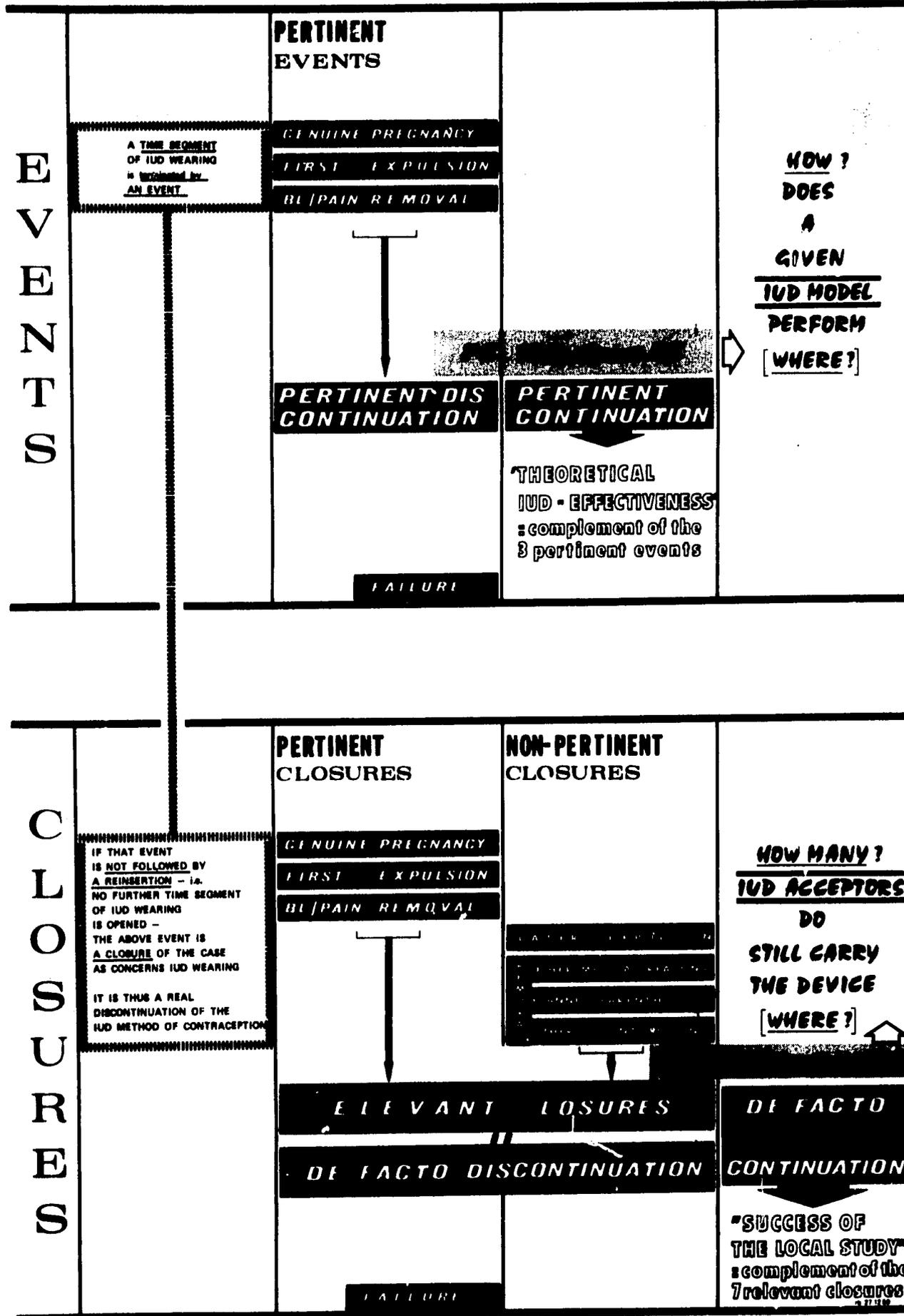
Before we narrow down our thought exchange to the discussion of bleeding/pain removals, it may be of interest to give some – hopefully – clarifying remarks on the terminology being used in our program.

We are facing a challenge of methodology when we try to feed you back results from the computer. On the one hand, we would like to give you figures which orient you on the success of your local IUD program while on the other, the assessment of the theoretical IUD effectiveness remains a must. The program's success is certainly what interests you most for your publication, as it does us also in the long run. Nevertheless, if we want possibly to assess the real merits and limitations of a given method, we should try to find some relatively simple measure for objectively expressing its efficacy. In short, we would like to offer you, in one stroke, two kinds of figures: figures evaluating the contraceptive method you have dispensed, and, concomitantly, figures on the local program you have carried on with that very method.

To make our figures compatible with those used by another agency in population, we essentially abided by the terminology introduced by Dr. Christopher Tietze – who distinguished seven relevant event categories: pregnancy failures, first and later expulsions, medical removals, and those for personal reasons. The two removal categories underwent, in that scheme, a further simple dichotomy into bleeding/pain removals and those for other medical reasons, on the one hand, and into removals for pregnancy desire and those for other personal reasons, on the other. Several of these relevant event categories do not, however, necessarily call for discontinuation of this method of contraception. In fact, if there is reinsertion of an IUD, that case remains open, and does not represent a closure of the patient history. Therefore, then, it is the sum of the relevant closures and not that of the relevant terminations which is used toward a simple expression of the study's success. The complement, then, of the sum of all the closures relative to the seven event categories represents the rate of the de facto continuation.

This measure of the program's success takes naturally into account – among other things of importance – the local doctor's attitude. There are doctors who reinsert whenever possible – and this is very laud-

# CONCEPTS BEHIND THE TERMINOLOGY TOWARD ANSWERING THE FOLLOWING QUESTIONS



I wonder if Dr. Andolsek, the first Yugoslavian contributor to the INTERNATIONAL IUD PROGRAMME and whose Family Planning Institute in Ljubljana is classified as a typical low removal center, would not like to start off with her specific comments.

[Andolsek, L.] I cannot say exactly why we are a low removal center. But I guess that our doctors have a positive approach to the bleeding problem. I mean, they never would remove firstly the device. When a patient presents herself with bleeding, we always try to give some conservative treatment. We would, for instance start out with an antibiotic. In thirty percent of the cases where bleeding did not recede with antibiotic treatment, glandular-cystic hyperplasia of the endometrium could be found under the microscope. We prescribe in those cases Anovlar for 2-3 cycles, or some other estrogens. Only if these two approaches would not lead to improvement of the bleeding situation would we consider removal of the device.

Perhaps another element favors us in Ljubljana. We are very lucky that we work in a relatively small city, where all the doctors — who work also in the outpatient department — depend on their unique school of medicine and send all these women to the University Clinic Hospital. So, all the women are treated in the same way. I do not think we do something special.

Perhaps another important aspect is that we select the women carefully before we insert the device. We never insert the device in women with a history of either hypermenorrhea or hypermenorrhagia, or a combination thereof. Neither in women who have some other troubles with coagulation, or for that matter also, are anemic.

Besides the treatment consideration, one should perhaps also consider the cultural milieu in which one is working. We in Ljubljana do not have a whole array of problems such as exist in some other countries. In Israel, and probably in some parts of our country — where the population has some problem with religion — we know of a much higher removal rate for bleeding and/or pain. As you know perhaps, there are some religions where it is not very well taken that the woman bleed beyond the normal monthly cycle, because bleeding would exclude intercourse, and that is a rather important reason why many devices in these countries are being removed. In particular, I know the situation in Israel, as it has been reported in a recent meeting, and as far as I know, Pakistan and India are facing an identical problem.

[Bernard, R] Lidija, do you in fact instruct the patients on what they have to expect, that is, that they might have increased bleeding in both time and quantity?

[Andolsek, L.] Yes we do, systematically.

[Bernard, R.] Dr. Andolsek has just introduced a specific factor — the element of religion — as a center-dependent variable. This may be the propitious moment to say some words on creed.

Three months ago, early testors of more recent devices in Yugoslavia, Israel, UAR and Hong Kong

joined the British colleagues to report and discuss rates which had just been released, in time to reach the Annual Conference of the Society for the Study of Fertility. This was the release of the first Red Book.

As a working luncheon – the forerunner of our present gathering – I inquired into the high local bleeding/pain removal rate produced at one of the three Israeli centers – which were testing – in a double-blind approach – the M versus the Loop C. In fact, for both devices tested, that particular center had a twice as high six-month removal rate as the two other centers had obtained – again, independent of the device type. Dr. Vago, a fine contributor to the INTERNATIONAL IUD PROGRAMME, answered with a prediction: 'If you were to take our cases and subdivide them by religious adherence, namely, Orthodox versus Non-Orthodox, I think you would find many more bleeding/pain removal among the Orthodox Jews.

So we did, and that we found, for a study series of Loop C begun in May of 1967. The one-year 9 percent bleeding/pain removal rate split into 15 percent for Orthodox women, against 3 percent for the Non-Orthodox women.

To my knowledge, this is the first time that in a single center a creed-effect on bleeding/pain removals has been demonstrated and internationally related. The finding takes particular weight, also, as it resulted from a prediction. It takes, thus, a confirmatory dimension of a hypothesis. Thank you, Dr. Andolsek, for putting us onto still another center-dependent variable.

[Dr. Andolsek has thought a bit further about this bleeding/pain removal problem and has sent us the following overview on both bleeding associated with IUD wearing and the conservative treatment plan, such as that adhered to at the Ljubljana Family Planning Institute]:

I would divide the bleeding due to IUD wearing into:

1. *Early bleeding* – following nearly each insertion of IUD – of different intensity: from spotting to severe bleeding, which may last for a time interval of variable length.
2. *Late bleeding* – which may appear several months or years after the insertion. Considering our patient materials, these bleedings take place at the time of ovulation and in the second part of the menstrual cycle, in the form of spotting. The reasons for these bleedings, as well as their treatments, have been described in many articles.

The local IUD removal rate for bleeding as a consequence of IUD wearing depends on the treatment of it in a given center and on the doctor's approach toward this problem, in general. Since we are classified by the INTERNATIONAL IUD PROGRAMME as a center with low removal rates for any device we have inserted, I should like to sketch our own way of treatment:

#### ROUTINE TREATMENT AT INSERTION :

After any insertion, the woman will receive – routinely – Cevicalcit for the three cycles following insertion. Cevicalcit is a preparation of vitamin C and calcium.

Simultaneously, she is being informed about the possibility of stronger and protracted bleeding, which so often occurs during, say, the first three months after insertion.

After three months, every woman comes to a mandatory control visit, during which she would state the whole bleeding status since IUD insertion.

We have observed that the patients do not complain about bleeding problems as much as they would before we initiated routine Cevicalcit treatment. However, we do not think that this is a consequence of the use of Cevicalcit, but rather, a psychological effect.

#### TREATMENT OF LATE BLEEDING

First we prescribe calcium in high doses, in the form of intravenous injections.

Sometimes, we may add some small quantity of estrogens or wide-spectral antibiotics.

if the antibiotic therapy has no effect and no signs of clinical endometritis are perceived, biopsy is performed. In the great majority of the cases, glandular-cystic hyperplasia was found, so we prescribed Anovlar for 2-3 cycles.

If this therapy is not successful, then finally, we remove the IUD permanently or temporarily, only.

This way of treatment is also used by other doctors in the Ljubljana area. At any rate, the doctor would somehow automatically refer bleeding problem cases to our Institute, where they will get standardized therapy, on an individual basis. With such cooperation, we succeeded in lowering the removals towards the smallest possible number.

Let us add that we live in a society where women are mostly educated without any major religious problems.

We are preparing an article on bleedings and hystological findings and on the influence of the above-outlayed therapies on bleeding.

[Bernard, R.] I wonder if we should not pass the microphone to another contributor, Dr. Behlilovic. Could you perhaps try to give us your personal feelings on the doctor's attitude toward bleeding in your Center I experience in Beograd? As everybody knows by now, you have a very low removal rate for bleeding and/or pain. How, in fact, do you reach such?

[Behlilovic, B.] Ich glaube, dass das Wichtigste der Kontakt zwischen dem Patienten und dem Arzt ist. Ausserdem ist wichtig, dass immer derselbe Arzt die Frau kontrolliert.

In meiner ersten Serie habe ich sehr wenig Removal gehabt, in der zweiten Serie leider etwas mehr, weil die Frau und ich waren etwas mehr nervös und ungeduldig.

[Bernard, R.] Ein sehr interessantes Element. Sie sagen, 'Sie waren auch sehr nervös,' könnten Sie vielleicht ein wenig weiter ausholen in dieser Richtung?

[Behlilovic, B.] Man muss viel Geduld haben, ja sehr viel Geduld und man muss immer wis-



with Drs. Curciev, Belopeta, Janev, Nikolovski and Dragovic, from Kosovska-Mitrovica) the removal problem, and we think that we can divide it essentially into two categories:

1. *Removals Depending on the Attitude of the Doctor.* As Professor Viel from Santiago, Chile, told us earlier, the opinion and attitude of the doctor is a most important element in judging local removal rates. Fifteen days ago, after our Skopje Symposium on Contraception – in which Prof. Dr. Sukarow spoke about organization, Prof. Dr. Lazarev about the abortion problem in Macedonia, Prof. Dr. Stankowski about oral contraception – and in light of the summary and the conclusion of this Symposium, we may now say that we must start to have a better relationship between all gynecologists offering this contraceptive service, as well as with the general practitioners. Above all, we have to inform each other on how to treat patients who are positively bleeding after insertion of IUDs. Unfortunately, we have not yet one unique plan of means and methods of treatment, as has Dr. Andolsek in Ljubljana, to which other doctors adhere now. We started with giving Secale Cornutum, which we do not anymore, as we have meanwhile learned that it is contraindicated. I cannot underscore enough the importance of this collaboration between all gynecologists, to follow one worked out plan of treatment on removal for bleeding and/or pain.
2. *Anamnestic Removals for Bleeding and/or Pain.* What do I mean by this? Many women are coming into our ambulance, asking to have the intrauterine device removed because of bleeding. After examination, we can see that bleeding probably does not present a major problem. We then would inform the woman that we do not see any particular reason for having the device removed, because we could not diagnose a particularly heavy bleeding pattern. A stereotype answer would be, 'Yes, but I have been bleeding a great amount this night and particularly, last night.' Naturally, we have to suspect that this patient is under the influence of an anti-IUD propaganda, so to speak, led either by laity or – yes, I am sure about that – by medical persons, too – yes, even by some local gynecologists.

If we are honest, we must admit we are a bit guilty ourselves, as Dr. Curciev told me some days ago. At the bottom of the yellow follow-up records, we are invited to make remarks. In many cases, we are told by the patient that she has heavy bleeding and we decide to remove because of bleeding and/or pain. And we would certainly record this in the 'Doctor's Remarks' place on the sheet, writing: **Personal Reasons – the patient insists to remove IUD. Aware of consequences. It is a fact that we are often mistaken.**

**We very well know that after insertion of IUD, as after initial prescription of oral contraception,**

there are psychological and neurological changes in the patient. We, in fact, often consult with neurologists and psychiatrists, because of these changes. Sometimes, we have problems to recognize the patient after having initiated the treatment. She is afraid. No doubt, every case in the future must be treated individually, and not just in a group of twenty-to-thirty patients to receive an IUD, as we had done earlier when there had been a very great interest in IUDs. We have now become more selective and would speak to each woman, according to her education and her intellectual development. Thank you.

[Bernard, R.] Thank you, Dr. Antonovski, for your informative remarks on frequent bleeding/pain removals. Let us now switch to a low removal center in that capital of Macedonia. Please, Dr. Belopeta.

[Belopeta, M.] Tout d'abord, j'aimerais remercier le Dr. Bernard qu'il ait bien voulu accepter l'hôpital de ville de Skopje comme un centre contribuant à ces statistiques mondiales.

La méthode est relativement facile, ce qui est très important parce que nous avons beaucoup d'Analphabètes auxquelles on ne pourrait guère offrir une autre méthode de contraception à l'heure actuelle. Nous avons évidemment aussi beaucoup de femmes qui ne savent pas parler le Macédoine — surtout des Albanaises et autres minorités de notre pays.

Mais comment avons-nous réussi à avoir si peu d'extractions de DIUs pour cause de saignement? Tout d'abord nous sommes en consultation avec les deux autres centres, soit la Policlinique et la Clinique Universitaire de Skopje. En plus chaque patiente qui visite notre Clinique et qui se plaint de saignements est systématiquement canalisée vers le même docteur — en l'occurrence moi-même. Ainsi nous arrivons à être conservatif.

J'ai effectivement pas mal de femmes qui saignent initialement — mais seulement passagèrement et notre traitement conservatif avec des médicaments permet de garder la plupart des femmes au régime anti-conceptionnel de DIU.

Tout récemment encore nous avons eu une femme hospitalisée avec endométrite et nous avons traité cette patiente avec une méthode conservatrice sans retirer le DIU. L'endométrite passa et le DIU resta en place sans autre complication.

[Bernard, R.] Merci, Docteur Belopeta. Nous avons tous vos commentaires sur bande magnétique. Dépêchons-nous de donner la parole au Professeur Stankowski. A la Clinique Universitaire de Skopje il y a eu pas mal de retrait médicaux.

[Stankowski, M.] Our recent experience with intrauterine devices is based on some 230 M-213 insertions after vacuum abortion. The number of cases seems to us, at this moment, quite small to make any definite statements on complications — particularly those of bleeding and pain. We had had 10 percent removals for bleeding and/or pain at the sixth ordinal month after primary insertion of the M device. I think that the bleeding is much more frequent in our clinic, because the insertion was made immediately after abortion. The uterus is in a non-physiological state and the uterus must, in fact, revert to normal conditions after the IUD has already been inserted.

**INTERNATIONAL IUD PROGRAMME – THE PATHFINDER FUND**

**THE SKOPJE COOPERATIVE IUD PROJECT**

(3 DEVICES – 1897 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
Study kind	POST-MENSES				P-ABORT.	2
Device	LOOPC M 213 MS			M 213	M 213	3
Insertions	505	340	280	238	234	1597
<b>PREGNANCY</b>	0.6 ± 0.4	—	0.9 ± 0.6	1.5 ± 0.8	0.5 ± 0.5	<b>3</b>
<b>FIRST EXPULSION</b>	5.2 ± 1.0	0.4 ± 0.4	0.4 ± 0.4	0.9 ± 0.6	0.5 ± 0.5	
<b>BI/Pn REMOVAL</b>	5.0 ± 1.0	6.7 ± 1.5	7.2 ± 1.6	1.4 ± 0.8	7.6 ± 1.8	
<b>PERTINENT EVENTS</b>	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				
<b>PREGNANCY</b>	1.7 ± 0.6	0.6 ± 0.6	0.9 ± 0.6	1.5 ± 0.8	1.0 ± 0.7	<b>6</b>
<b>FIRST EXPULSION</b>	6.3 ± 1.1	0.4 ± 0.4	0.4 ± 0.4	0.9 ± 0.6	0.5 ± 0.5	
<b>BI/Pn REMOVAL</b>	5.7 ± 1.1	6.9 ± 1.8	6.8 ± 1.6	2.1 ± 1.3	2.7 ± 2.1	
<b>PERTINENT EVENTS</b>	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.)	25	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		STRAIGHT	STRAIGHT	
Physicians:	Dr. L. Antonovski Dr. A. Nikolevski			Dr. M. Bolepata Dr. K. Janov	Dr. K. Carelev Dr. M. Stanowski	

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

**DEVICE**

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

● VARIABLE HELD CONSTANT

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

On the other hand, there is the disparity between the size of the uterine cavity and that of the device.

It is very important that in the present series of insertions we have not observed any spontaneous expulsion.

The reason should be found not only in the special condition of the cavum uteri after vacuum abortion, but also because of the particular kind of the device. I hope that the further follow-up of the patients will give us much more information on the relatively high bleeding/pain removal rate at the present early stage of the study, and also on the kinds of complications.

[Bernard, R.] Thank you, Dr. Stankowski; it will indeed be of considerable interest to watch the developments in the University Clinic IUD study carried on with women having post-vacuum abortion insertions. I count on the fact that Dr. Kurciov will keep up his fine work. In Kosovska-Mitrovica, a miners' town in the autonomous area of Kosovo, Dr. Dragisa Dragovic has also inserted M devices, particularly immediately post-curetage abortion. Please, Dr. Dragovic, although our time is running out.

[Dragovic, D.] We have inserted at the Kosovska-Mitrovica Women Health Protection Center some 800 M Devices since July 1968. We have put them in post-menses, post-abortum (D&C) and post-partum.

Complaints for bleeding and/or pain have been very rare in the post-menses and post-abortum series. We have six-month removal rates of about 2½ percent. In the post-abortum series, I think — and this is my opinion — the reasons could be either endometritis, decidua post-abortale, or dysfunctio ovarialis. On the other hand, I have no explanation for the low bleeding rate in the post-menses series.

The post-partum series had not yet been evaluated by the INTERNATIONAL IUD PROGRAMME. We have, at this moment, some 110 cases and I recall that up to now we have no expulsion and no removals for bleeding and/or pain. We will have, next Spring, one-year rates for two studies and six-month rates for the post-partum series. Thank you.

[Bernard, R.] Thank you very much, Dr. Dragovic. It will be exciting to watch your one-year rate concerning removal for bleeding and/or pain, for your three study kinds.

We're running short of time. Still, I feel that we should get some insight into a most peculiar study situation, at least from the statistical point of view. At the University Clinic of Beograd, where Professor Milosevic Dr. Mitic and Dr. Tucovic — all present here — have produced a total absence of pertinent events at the sixth ordinal month after insertion, in both a post-menses and a post-abortum series. Many people were surprised that there was no event whatsoever — the page in the Green Book has empty rate boxes.

I perceive some smiling faces now in the audience — which brings me to a remark of principle. From the statistical point of view, this can happen. It would be a rather rare occurrence, but still, I cannot exclude it. Variation in statistics follows its own laws.

Be advised that in one of the British studies, there was also a 0 expulsion and a 0 bleeding/pain removal rate. We have investigated that study rather carefully and must accept the explanation given by the local study director as plausible.

What is important here is that we get an independent statement from the Beograd clinic group as to how they, in fact, achieved that six-month 0 bleeding/pain removal rate in 500 patients followed-up at a 99 percent level. To me, there is no doubt that these studies will possibly lead to a much better understanding of what is involved in the whole removal complex.

Professeur Milosevic, la parole est à vous.

[Milosevic, B.] Je vous remercie Dr. Bernard, de vos compliments. Je peux vous dire que les résultats que nous avons obtenus sont dû à un contact très serré entre les femmes et les médecins. C'est surtout le Dr. Mitic qui tient une consultation depuis 15 ans et qui — à part son expérience et une intime connaissance de chaque femme — s'occupe des complications d'une manière très systématique.

En matière de complications, je peux dire que nous en rencontrons également. Cependant, nous sommes en contact permanent avec nos patientes, car la méthode de travail que nous avons adoptée l'exige.

Tout d'abord, l'étude détaillée des antécédents de la patiente à la Consultation nous conduit à lui proposer, si rien ne s'y oppose, un moyen anticonceptionnel intra-utérin. Nous conseillons ce moyen aux femmes ayant déjà eu une ou plusieurs interruptions de grossesse volontaires et légales. A la Consultation nous pratiquons un examen bactériologique et un contrôle cytologique des sécretions vaginales. Nous prévenons la patiente des complications et effets secondaires qui peuvent survenir. De plus, elle est tenue de se présenter à l'examen médical un mois après insertion initiale, afin que nous puissions répéter l'examen des sécretions vaginales ainsi que le contrôle de l'état des organes génitaux. La patiente est demandée, en outre, de se présenter avant ce délai, au cas où cela lui semble nécessaire. De cette façon nous sommes en mesure d'évaluer le degré des complications. S'il s'agit de cas plus ou moins graves, avec hausse de température, douleurs, saignement important, nous pouvons hospitaliser ces cas pendant 2 ou 3 jours, ou davantage au besoin, afin de les soigner et de les soumettre au contrôle des médecins mêmes qui ont initialement procédé à l'introduction du dispositif intra-utérin. Les docteurs Mitic et Toucovic, s'occupent en particulier, à côté de moi des patientes de cette catégorie à la Clinique.

Cette façon de procéder nous a permis de traiter conservativement les rares complications sans qu'il ait été nécessaire d'extraire le dispositif. Retenons, cependant, que la complication est l'exception à la Clinique Universitaire de Belgrade. Des centaines de femmes, que nous contrôlons tous les 3 ou 6 mois, sont extrêmement satisfaites des deux types de dispositifs intra-utérins (Beospir et M-DIU) que nous étudions présentement et qui ne semblent présenter aucune complication détectable. Ceci est certainement le résultat d'un contact étroit et continu entre la femme et son médecin. Je vous remercie de votre attention.

[Bernard, R.]

Dr. Milosevic, Dr. Mitic — to whom you referred — told me that Prof. Mladeno-

vic, from the City Hospital, is systematically consulted on the difficult cases. We would certainly appreciate his addressing us now. Professor Mladenovic, please.

[Mladenovic, D.] I shall take up only some few minutes, because my experience in IUD insertions is not as extensive as that of those who have spoken before me.

Above all, it was a great privilege for me to be invited to this meeting and to listen to such learned commenting on problems related to the IUD method of contraception.

Still, I can tell you frankly that I worked at the University Clinic of Beograd and I could have removed many of these IUDs just referred to by Prof. Milosevic, because of bleeding. I collaborated with Dr. Mitic, but I never would counsel removal. I always would call Dr. Mitic to take care of the bleeding and, in common consultation, we decided in each case — I recall — to treat the bleeding conservatively. This is my first comment.

Secondly, I have presently taken on responsibilities in the City Hospital, after the death of Professor Kostic. As many of you know, as previous director of that hospital, the late Dr. Kostic had started such an IUD study. There were, I am told, some 200 insertions. Unfortunately, the material is presently not consolidated enough to give figures here.

Still, I hope that we will continue our work in the City Hospital of Beograd. Particularly so now, as Dr. Grcic, who works in Sremska-Mitrovica in this very field has a new appointment with the City Hospital. I think we will continue studies along the lines Dr. Bernard has done in Yugoslavia, and I feel that they will be of great help to us in Beograd, in particular, and to Yugoslavia, in general. Thank you very much.

[Bernard, R.] Thank you very much, Professor Mladenovic and Professor Milosevic. Your complementary comments will certainly help us to look at the 0 removal rate produced at the University Clinic at Beograd from a new angle. Still, it would be of some interest to the profession to learn more about the conservative treatment resulting in the total absence of removal for bleeding and/or pain.

I think Dr. Grcic, from Sremska-Mitrovica — an ancient Roman town — would like to give some of his impressions on bleeding/pain removal. I recently visited his model center, while setting up a new study. Dr. Grcic, please feel free to speak in Serbo-Kroatisch. We will translate your remarks, so as to reach a broader international audience.

[Grcic, R.] "Because one of the official languages of this Congress is Serbo-Croatian, I will take the opportunity to use it, because the majority of the people here are Yugoslav.

With the kindness of Dr. Mojic, I am the first in Yugoslavia who has used M-213 and have had, with those 26 loops, excellent results. This experiment I have done with the help and cooperation of the wives of my good friends. At the beginning, we thought that the M device was the best one, considering that it had better adaptability than the Lippes Loop, intra-utero.

Great patience must be sustained by both patient and doctor, as Dr. Behlilovic said in his discussion.

The results are negative if the patients are depressed. This is noticed, particularly during the summer vacation, when another doctor is on duty, and in the case of bleeding, simply removes the device.

We insert the device after induced abortion and after menses.

In conclusion, I can say that we are very satisfied with the M-213 device."

[Bernard, R.] Thank you very much, Dr. Grcic. You can be sure that I have not understood a single word, but I will learn about it when I return to Boston — after my planned Eastern European trip.

Still, I think I have understood some mimic expressions, when mentioning Dr. Angelina Mojic, and we might perhaps terminate this give-and-take session in being told how the entire M testing started in Yugoslavia.

Indeed, it is not The Pathfinder Fund who started the M testing. We have been oriented on the M device by another agency in population, which itself did not take it on in its testing program.

Before Dr. Angelina Mojic speaks to us, let me perhaps make a point.

From the first day to now, I have encountered an outstanding spirit of collaboration with just about everybody I contacted in connection with the INTERNATIONAL IUD PROGRAMME. Let me just cite the three major places of our activity: Ljubljana, Beograd and Skopje. In Ljubljana, it was Dr. Andolsek who opened the doors wide, so that a working mood could be established, literally within minutes; in Beograd, without any doubt, it was Dr. Angelina Mojic who acted as a most skillful impresario, and in Skopje, it was Dr. Antonovski at the Polyclinic "Bucharest" who opened the way to the University Clinic and the City Hospital. No doubt, without this professional entente, we would not have achieved one-tenth of what we commonly communicated today.

Dr. Angelina Mojic, the Director of the Service for Mother and Child Protection for so many years, will now give us the beginning of the M testing in Yugoslavia.

[Mojic, A.] I am not quite sure if it is very important to know how testing of the M device was in fact started in Yugoslavia. Still, here are the developments. During my visit to the United States three years ago, Dr. Silbermann of the New York Medical College asked me to take some samples of the M-211 device to Yugoslavia for possible testing. So I brought them and showed them to Dr. Grcic and Dr. Behlilovic. Dr. Grcic showed considerable enthusiasm. He was, in fact, very fond of it and he asked me more and more. So I wrote back to Dr. Silbermann and two years later Dr. Silbermann would accompany Dr. Bernard from The Pathfinder Fund on a demonstration trip through Yugoslavia, as clinical advisor with regard to M insertions. The Pathfinder Fund then set up, within a month, many studies, ranging from Ljubljana to Skopje. Still, it must be said that Dr. Grcic was initially most enthusiastic about the device.

A further point I would like to make, I am very grateful to Dr. Sobrero and Dr. Bernard, to help us to switch from one method of family planning — I mean, from abortion — to family planning by contraception, because abortion is a very great problem in our country. We have more than 300,000 abortions a year. So, if

you help us not only to test out a method in Yugoslavia, but perhaps also help us to organize some evaluation function in this country — I mean, particularly, statistical evaluation to which we are not very used. If you help us to train our people for professional evaluation, we would be certainly very grateful. In the name of our Service for Mother and Child Protection, I have dared to suggest this.

[Bernard, R.] Thank you very much, Dr. Mojic. In fact, an answer to what you said — we have decided to invite Dr. Antonovski as the first Pathfinder fellow to come to the United States, and Dr. Soltero — one of our medical advisors — will, initially, take him under his wings. I can tell you he will have a very fine formation and after that, he will stay perhaps two months with us at The Pathfinder Fund. Then, he will return to Skopje. We believe that he can make a basic contribution in Macedonia toward lowering the abortion epidemic. Perhaps some closing remarks — very short.

On the last slide I projected this morning, you have witnessed a remarkable spread of removals for bleeding/pain already during the early post-insertion period (Yugoslavia Half-Year M Baseline). However, not only in Yugoslavia but also in England exists now at least one study with a zero half-year bleeding/pain removal rate for the same M device, whereby each study is based on at least 500 patients most carefully followed-up. On the other hand, both countries have studies with around 10 percent bleeding/pain removal after six months (10% and 9.7%). Furthermore, the few Israel M studies fall into the same range. Thus, then, we are confronted with three independently-established and strictly-superimposable “national” IUD performance ranges — of impressive spread, however. This may perhaps point to the possible limitations to this method of contraception.

It is reasonable to project that IUD technology will now quite rapidly reach — say, within a few years — that optimal shape and configuration . . . without, necessarily, solving the major problem associated with this method of contraception. Practically speaking, the local IUD continuation rate’s success will lie with the doctor, as you have so nicely demonstrated today.

Certainly, aside from the major challenge facing the doctor around the world now, there remains one for the bioengineer and the laboratory man. The idea will always be to reduce — singly or combined — one of the three pertinent event categories.

For instance, considerable work is presently underway in at least three places to add megestrol-acetate to the device. It may well be that the future IUD will be an “elegant bastard” — as I call it — between the mechanical and the hormonal approach. It is thought that the slow release of a hormone from an IUD may have a beneficial effect in lowering both genuine pregnancy and bleeding. Furthermore, certain ions seem also to be pregnancy-depressing, and another agency in population is presently spear-heading in that direction.

Your contribution was twofold. Not only have you shown in your multi-clinic trial that expulsion of the IUD may be something of the past, but you have also demonstrated that the doctor will remain a key element in the success of the IUD method of contraception. It is my contention that this will apply to almost the same degree, even if IUD technology were to improve.

As you see, the dream now is to hurriedly continue toward the construction of not only an unexpel-  
lable, but also both totally pregnancy- and bleeding-preventing Super-IUD. Naturally, if this can be developed,  
many performance factors connected with the doctor and the patient will be eliminated. Meanwhile, however,  
the IUD method of contraception is in real jeopardy, because limitations which have strictly to do with the  
doctor are being projected onto the mechanical device. I know you will help through your most conscientious  
work to ward off that very threat to which the IUD method of contraception is presently exposed.

The Pathfinder Fund is considering the launching of an international multi-clinic, multi-IUD trial as  
soon as progress in IUD technology, along the lines just sketched, will have been made. As Yugoslavia has per-  
formed so well, and as you have now a baseline founded on both Clarence Gamble's and later work, this country  
will remain a first choice candidate for such a double-blind scheme.

I thank you very much on behalf of the Board of The Pathfinder Fund, and the entire staff, for the genu-  
ine collaboration and commitment you have generated. On my part, I promise you that I will continue this  
line of action and shall, over the next two or three years, try to compile internationally all figures which can  
scientifically justify entering the International IUD Baseline. Again, thank you and we know, also, that in the  
future we can count on you as much as you can count on us.

Dr. Sobrero asks for the microphone. Let us close with his words this fine working luncheon.

[Sobrero, A.]

This has been a most productive gathering. I think all of us should feel quite  
satisfied with the frankness of the discussion and the concern shown for a serious and unprejudiced analysis of  
the problems faced in the conduct of the clinical studies reported. I want to commend you all for this extra-  
ordinary achievement and for this show of scientific maturity.

As I was listening to the remarks made by different speakers I started to sense why the level of "panic  
threshold" may vary at different locations, motivating prompt removals in one place, while perhaps not in  
another. To what causes may these different levels of "panic threshold" be due? They may be motivated by  
the general uncooperative atmosphere created by the medical staff of the hospital or by the prevailing feel-  
ing in favor of or against contraception in the country; it may be generated by the unspoken coldness to the  
program of the chief of service; it may also be due to the personal experience and the medical standing of  
the physician conducting the program, as well as to the cultural level and maturity of the patients or the re-  
ligious attitude and the approval or resistance of local political and religious leaders, etc.

All this can be summarized perhaps in a single statement: regardless of the level of professional medi-  
cal competence and self-confidence, the physician does not work in a vacuum. There is a powerful interplay  
between him, his work and his patients on the one side, with the social and professional environment, on the  
other. This is why our work is not completed either by just performing it or only serving our patients. We —  
physicians working in family planning — must interact with the milieu in which we live and work. We should

~~not~~ work in secret, but should publicize our work. We should discuss it openly with our colleagues and with ~~people~~ who form social opinion, and thus educate professional and public opinion, making our program ~~better~~ understood and more acceptable to all. Thank you.

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