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INTERNATIONAL IUD PROGRAMME - THE PATHFINDER FUND \*

REPORT 1967

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\* THE REVITALIZED IUD PROGRAMME IS A PROJECT ADMINISTERED BY THE PATHFINDER FUND'S FAMILY PLANNING EVALUATION CENTER, ESTABLISHED UNDER THE DIRECTION OF DR. ELTON KESSEL, EXECUTIVE DIRECTOR, WITH SUPPORT FROM THE AGENCY FOR INTERNATIONAL DEVELOPMENT (CONTRACT AID/CSD - 1573)

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This report would not have flowed into its present cast had it not been for Helen Compton Nemer's tenacious and creative work since she joined the Fund twenty-months ago and for Esther Fukuda's multifarious skills

# INTRODUCTION

## FACETS

Dr. Clarence J. Gamble's IID distribution and study began in Fall of 1962. When he died in the Summer of 1966, his work had become a world-wide operation.

There is no certainty concerning his intentions on exactly how to exploit the data which were flowing in at an ever-increasing rate. However, this pioneer believed very strongly that an excellent way to ensure the growth of a new method would be the use of the local medical journal. The contributing physicians would receive statistical feed-back on their studies for publication; their experiences would then reach colleagues, serving the purpose of not only spreading and promoting the new method, but also of increasing their professional stature. C. J. Gamble was an activist who wanted above all to put his convictions into action. Thus, he made it his personal challenge to propagate at that time another highly-promising means of birth control.

Fortunately, he established the kernel of an infrastructure for possible later analysis of the material by imposing Dr. Christopher Tietze's record system as a means of feeding back data from the field. To a certain extent there was some screening of the incoming material. The rule of educating the doctor to report back on the first few insertions before sending him a larger supply of loops was just one facet of his foresight.

Unfortunately, there was not a systematic follow-through on compulsory high-quality reporting. At the time of C. J. Gamble's death, the operation had reached an almost unmanageable size for the limited staff in his FIELD STUDIES office. Cautiously, Dr. David Burleson, then Director of the Field Studies, began to set quotas--adapted to the contributor's quality of reporting, density of follow-up and the overall size attained--beyond which additional insertions were not to be reported on the long form. He thought that circumscribing the original series would be an invitation for continued high-quality reporting on that segment.

Naturally, several possibilities arose as to the fate of the studies.

1. Several highly-motivated physicians disregarded the proposed quota limit and continued their studies unabated.
2. Many studies were "discontinued" at a relatively young stage and were thus definitely lost to exploitation.
3. Several physicians did exactly as requested: stopped reporting on new admissions but kept on sending a relatively dense follow-up for the circumscribed series. Of these, studies with a large enough admission total will be thus exploitable. Furthermore, those doctors will be possible candidates for the testing of new devices in the very near future.
4. The language barrier was surely responsible for many total interruptions. Some doctors must have misconstrued the directions to mean that the headquarters wished no further reporting of any kind. This created a certain pool of "dead studies."
5. More important is the effect that this message obviously had on the follow-up of cases still reported on long forms. Many contributors had apparently never fully grasped the meaning of the requested densely-linked follow-up chain. Freezing the number of admissions to a quota probably induced a further relaxation on the follow-up reporting. This presented a real threat to the intrinsic value of many studies.

Many physicians who sent in the records during 1966 and the greater part of 1967 probably felt more and more that their work was not being closely followed. This situation, however, does not apply to some fifty "good" studies, for which overdue-lists for check-up visits were not only established for a tentative cut-off date, but also revised two to four times per year. This was indeed a basic educational approach to the doctors of those studies most likely to reach the stage of statistical exploitability. Unfortunately, only about one-third of those studies were nurtured up to mid-1967.

Staff limitation imposed, furthermore, a rather succinct treatment of many studies meriting better following. The best that could be done was to screen the incoming material from time to time and to send out an important batch of white "query sheets" with missing positions circled in red. (Appendices 1 & 2) This kind of return follow-up must have had a demoralizing effect on many contributors, the more because no concrete statistical feed-back could be sent out.

For approximately fifteen months, the Field Studies were administered essentially by one person, Helen Compton Nemer, who is now in charge of the Processing

Department. Her imaginative way allowed her to somehow keep many studies from dying-off entirely. Their dynamic start, nevertheless, was followed by an unpreventable slowing down.

#### GOAL

The task ahead was to not only save as much as possible for pertinent analysis, but also to embark together with that experience and the world-wide network of active Pathfinder contributors into the rapid testing of new devices; the latter was surely in C. J. Gamble's spirit. With this broad definition, I joined the Fund in July of 1967.

## REORGANIZATION

#### BECOMING ACQUAINTED

The information collected by C. Tietze's record system afforded the very means of becoming most rapidly acquainted with the entire problem area to be faced. I should like to express at this point my personal gratitude and that of the Fund for the fine orientation I received from C. Tietze, now Associate Director, Biomedical Division, in his Population Council office in New York during July and August of 1967. Without that condensed learning period, I do not think that at this time we would have accomplished half of what we did trying to place the whole Pathfinder IUD operation on a firmer footing. The month of September brought me closer to the operation and marked the beginning of the building up of the internal system.

#### MAIL POLICY

By October, the following points were adhered to strictly:

1. Each mailing related to the IUD operation would demand an immediate appraisal together with the study on file. Furthermore, the physician's correspondence file would serve to re-define the entire image of the study.

2. A specific air mail reply, ideally within forty-eight hours of arrival, would be composed on the basis of the two mentioned sources of information. An optically-striking instruction sheet would be systematically added to the letter. (Appendix 3)
3. Incomplete records would be immediately returned for completion, enclosed in a personal letter, rather than to transcribe the identification on a white query sheet and to send that form to the doctor, sometimes months later. The contributor's reaction would be a valuable criterion for the assessment of both the prospective exploitability of his ongoing study and his potential as a candidate for testing a new device. A further bonus obtained from this approach was the freeing of the processing teams so that they might devote their attention to screening for error and inconsistency, a considerably more involved task. It would also allow us, in the not-too-distant future, to phase-in concomitant coding on consistently filled-in records.

#### REVITALIZATION ACTION

This method of handling incoming mail had, surprisingly, a remarkable effect. Within weeks an improvement in reporting was perceived by the staff in the Processing Department. Mailing became more dense and ever more contributors condescended to send their new records by air. The inflow of both records and letters grew very rapidly to an almost unmanageable load. The letters embodied both an eagerness to learn and a friendly attitude. It became necessary to incorporate a new secretary in the IUD operation.

These procedures rapidly gelled into what we refer to as the "revitalization action." More and more doctors were written to, independent of their having sent in a recent mailing. (Appendix 4) The selection of names was based on a common agreement between the Records Librarian and myself as to possible exploitation of the data. By mid-December, an active dialogue had been established with some two-hundred doctors.

RECORD-KEEPINGMeans of Data Conveyance

Along with the revitalization action had to go a systematic probing into the record system itself. It had become apparent that the classical C. Tietze "long form" (Appendices 5 & 6) was not ideally suited for the pioneering work that Clarence Gamble was doing world-wide, though there were some remarkable exceptions. The sheets had been primarily geared for institutions with trained and highly-motivated personnel and were presenting quite a challenge to many doctors in less-developed countries and some in the more-developed ones! At the Boston headquarters it became apparent that many Pathfinder contributors wanted to abandon that long form in favor of a shorter version.

A basic decision was thus pending when I first arrived at the Fund. Were we going to cease requesting an information core, to which many doctors had been conditioned over the years, in favor of a roster-type questionnaire? The answer was crystal-clear and would decide the very feasibility of statistical exploitation of the past and the future. The data would not have been fully exploitable and the possibility of swift revitalization questionable had we taken the path of least resistance. Thus, we embarked upon a venture which would yield an attractive arrangement of C. Tietze's basic information core. It became now a question of selling the ware. The color and size remained unchanged, but the sheet was made self-explanatory for easier completion.

Most of our energy was channeled into the rearrangement of the Follow-up Record, the ninth draft of which constitutes the presently-finalized version.

The ideas of many helpers such as Sarah and Christopher Tietze, Aquiles Sobrero, Gerald Zatuchni, Jack Feldman, Elton Kessel and Dick and Walter Gamble, to mention only a few, were incorporated and I am very grateful for their constructive criticism. The overall responsibility for any deficiency, however, lies with the present reporter.

Pre-testing in five countries by devoted Pathfinder contributors allowed us to obtain a further insight as to the improvement of many details. Very constructive suggestions came from B. Viel (Chile), A. Stewart (Iran), W. Obolensky (Switzerland), H. G. Neumann (East Germany) and B. Behlilovic (Yugoslavia).

Though the questionnaire looks quite technical (Appendix 7), it is completed in half the time required by the previous one. The real bonus we were striving for, however, would be a higher degree of accuracy and completion and a simplification of coding. How?

1. In scrutinizing the new yellow sheets, one is aware of the fact that the grey area will not be applicable in, say, three out of four cases. The segment-coding strip, an idea brought to my attention by Aquiles Sobrero, Director of the Margaret Sanger Research Bureau, is always left blank. Thus remains a relatively reduced space with which the doctor and the interviewer have to cope, the minimum information core being arranged in a kind of question column. Each answer should serve as a signpost for the next relevant question. A basic endeavour was to group negative and affirmative answers in a systematic way. We expect to condition some basic reflexes in the contributing doctors; hence the pattern will be fixed and they will obtain the full benefit of increasing ease in coping with the sheet.
2. A real switchboard situation has been thought through in order to guide the coder into making the right decision concerning the treatment of the incoming records. If there is no event (the screener-coder will also receive the benefit of pattern-fixation; he should recognize the applicable situation at a

glance!), thus no termination of a time segment of IUD-wearing and no re-insertion, such a situation applying to some seventy-five percent, the coder will circle the two "no"s in the bottom-right-hand corner, thus reading the instruction: "do not code." The three other possibilities are also self-explanatory. The aim is to create a clear-cut and automatic decision-making procedure and to simultaneously cut down on the grinding work of processing the data. It is hoped that the idea will be practical, though many detailed facets have yet to pass the test imposed by experience.

The Admission Record (Appendix 8) has remained more classical in its many aspects, even though the core has been grouped more systematically. In fact, since the original admission record was more easily completed correctly, we justifiably spent less time with it.

Many contributors are desperately struggling with the problem of systematic check-ups. Several have found their own way of keeping track of their patients. Some few discussed the matter seriously with us and in a discussion I had with Dr. Staackmann, Jefe de Clinica, Asociacion Pro-Bienestar de la Familia de Guatemala, while visiting his clinic in November of 1967 for possible revitalization of a study which had been suddenly interrupted in 1966 (Appendix 9), I was surprised by the concrete solution he had imagined for his problem. Though the method is a classical one, it is a fact that the Pathfinder Fund had never proposed it to the contributors. We are just now beginning to distribute the Follow-up Master File (Appendix 10) to contributors who replied to our offer. What benefit will stem from it remains to be seen. It is already apparent, however, that a motivated nurse will, as well as the physician, accept it as a valuable tool to keep track of the patients in both time and space.

Office Handling of Data Upon Arrival

(written by Helen Compton Nemer)

Background: In April of 1966 I, Helen Compton Nemer, took over the Pathfinder Fund's Scanning Department (then consisting of two part-time persons) as Records Librarian. At that time, incoming records were listed in a sort of notebook, handled mainly by one of the two record-scanners and each batch then crossed off as it was scanned and queried, more or less in the order that it arrived. There was, however, no concept of priorities and indeed the scanned batches of records were added to the files without their being compared to the rest of the study records; there was no clear view on the actual completeness of the follow-up chains, since setting-up of records into case-folders had been discontinued some time earlier. Moreover, there was no Master List or any other effective means of correct categorization of data.

During the following year, 1967, a Master List was established and periodically revised; intercommunication was increased between the Scanning and Service units, so that response to physicians' requests for materials was at least partly based on their performance as data-contributors. Moreover, incoming data was registered by me in two forms: individual Physician Report Sheets (which registered study growth and sketched details revealed by the scanning) and a Master Calendar-Log (on which incoming data was registered and which showed the growth of these studies comparatively by country.) By the autumn of 1966 each study was handled completely and an overdue list was issued every three to four months.

Certain essentials, however, were yet lacking. There was no inventory on "dead" studies, as there was on those still growing, hence no master chart

on which all data could be seen in perspective and assessed according to a single set of standards. Furthermore, the establishment of tri-monthly scanning allowed for communication with physicians about their studies every three months, at best.

Present State of Internal Record-Keeping: Transferral of responsibility for priority assignments and communication with the physicians from myself to the Research Director was facilitated by the advent of a First Inventory in July of 1967; all material in the files was entered in a ledger, with positions for quality, study onset, device types, total number of records, etc. This allowed for the information dispersed among my various calendars and reports to be centralized in a form which put all studies, dead, dormant and growing into a single perspective. It also allowed, for the first time, a grouping of the entire material by continent and country, demanding a three-fold increase of the file cabinets.

From this July-1967 inventory, a first concept of priorities emerged. This became more crystallized with the establishment of the alluded-to one-to-one contact with physicians on the basis of record arrivals. This necessitated a briefing system which would allow me to keep the Research Director abreast of study growth by means of the following:

1. The 1968 Records Flow Sheet. This is a daily ledger of records receipts, set up by country, doctor and series. Numbers of new and returned (corrected) admission, follow-up and query sheets are entered, together with outgoing sheets for studies just processed. (Appendix 11) It provides an overview for any point in time.
2. The 1968 Fact Sheet. This is a rearranged version of the old Master Calendar-Log, which allows the monthly growth of studies to be viewed as it is organized by country and on which the Records Librarian keeps track of frequency of processing and compilation of overdue lists. (Appendix 12)
3. The Action Sheet. This is the brief, on which the entire dialogue is revealed: that between physician and Records Librarian as mater-

ial is received and scanned and that between the Records Librarian and the Research Director as he views progress, transmits directions and makes suggestions to the physician; it furthermore informs the Processing Department of priority decisions. (Appendix 13)

4. The Processed-Study Brief. This is a more-detailed page, which reflects the feelings and perceptions of the Processing Department, now grown to five full- and one part-time person, besides myself, concerning each study, informs the Research Director of lost-to-follow-up cases and consequently also attests to the response of the physician to the increased and more personal dialogue established by the Research Director toward higher study quality (Appendix 14).

## ASSESSMENT OF THE PRESENT STATUS

### POLICY FOR MAKING A FAIR ASSESSMENT

There is no doubt that it was of advantage to attempt the revitalization of many doctors before making a tentative assessment of the exploitability of their studies. Speaking in retrospect, it probably meant the difference between the success and the failure of the entire past Research operation; but also--and this is of further importance--it projected our more recent speculative reasoning toward possible future IUD testing on a solid network of presently-active and highly-motivated doctors.

By mid-December, however, it was felt that an end-of-year assessment would permit us not only to review the past, but also to create the first baseline against which any development during the following years might be measured. Two approaches were thought to best define the Pathfinder Fund's IUD studies as a whole:

1. A daily reckoning of the inflow and outflow during the last consecutive four-week span before the cut-line inventory would well-define the present vitality of the entire operation.
2. A cut-line inventory would immediately follow the flow-inventory. This approach is by definition more static. Thanks to the creative

and methodical work of the Records Librarian, however, systematic figures for each study were at hand for both mid-1967 and the end of 1967. Thus, it was possible to introduce a facet of dynamics.

What follows, therefore, will provide insight into:

1. The Pathfinder Fund's IUD activity, as measured by the entire pool of reported insertions.
2. The possibly-analyzable studies, as of the present time.
3. The last six-month increase thereof.
4. The Pathfinder Fund's last-month record flow.

#### THE DECEMBER 1967 FLOW INVENTORY

To assess the current inflow of documents related to IUD insertions, a daily count of countries, doctors and their admission and follow-up records was made for four consecutive weeks (December 11, 1967 - January 7, 1968). For purposes of documentation, both a Day-by-Day List and a rearrangement by Area and Country have been generated (Appendices 15 & 16).

As can be seen in the overview of that influx in Table 1, 163 mailings from 96 doctors representing 43 countries contributed 1,600 admissions and 4,730 follow-up records. The lower half of the table gives the relative proportions of the world areas from whence the mailings came. One-third of both admission and follow-up records originated in Latin America, followed by Africa and Europe with one-fifth each. The area-independent follow-up load, three times that of admissions, reflects intensive global follow-up activity.

Table 2 lists the previous information for the seven-out-of-forty-three countries thought to have been most active during that month: Peru, Guatemala, Rhodesia, England, France, Israel and the Philippines. Half of all doctors mailing during that month lived in those seven countries and had sent in two-

thirds of the total admission and follow-up records.

#### THE DECEMBER 1967 CUT-LINE INVENTORY

Up to the end of 1967, there was an uncertainty as to exact numbers in any category related to the IUD studies. All letters to contributing doctors, during the last six weeks of 1967, contained a request that they send in by air all new admission and follow-up records before Christmas. Allowing two extra weeks for mail travel time, the strenuous task of compiling an inventory of all IUD files was accomplished between January 6 and January 14, 1968.

#### The Concomitant First-Referral Round

Each study was judged individually and tagged with one or two of the following red stamps: "referred," "two months grace" or "active-1968." It is very difficult to give an account of the precise criteria which served as a basis for classification. Frequency of mailing, density of follow-up records, reply to specific letters of inquiry and quality of reporting contributed to the overall impression. There was a concensus of opinion between the Records Librarian and me concerning most of the decisions and we tried to take a conservative stand whenever possible. Many studies could not be judged ideally at the present time, however, and were consequently tagged: "active-1968, two months grace," or "referred-two months grace." Some two-hundred air mail letters were sent off during the inventory week, many bearing the title, "Important Message Concerning Your IUD Study." The letter contained inventorial information relative to the particular study (Appendix 17), as well as the short statement: "We will postpone any decision concerning the relative priority assignment for the evaluation of your study until the end of February." Naturally, the response to those letters will in the very near future decide the fate of many a study.

The Pathfinder Fund's Recorded Past IUD Activities

A summary-extraction from the voluminous inventory lists is given in Table 3 and represents all registered IUD insertions and contributors, by area, to the Pathfinder Fund's Field Studies. A further built-in consideration is the definitely-referred part of those data at the present time. The following points are worthy of citation:

1. Up to the end of 1967, the Pathfinder Fund had provided IUD assistance to the 628 doctors in 82 countries with whom we had established a records dialogue. There were on record 71,910 first insertions, fifteen percent of which (10,892) had arrived at our headquarters during the last six months.
2. Africa comprised one-third (27 per cent) of all countries assisted, followed by Latin America and Far East and Oceania, approximately one-fourth each.
3. Though four areas share approximately equal proportions of countries and doctors, there is one notable exception: Europe. It is easily seen from the left-middle box that twice as many doctors (21.4 percent) had been served in that area than was to be expected from the proportionate area-participation (9.8 percent). One finds that this is essentially due to the ninety-five French doctors representing 15.1 percent of all doctors having reported to Boston; their proportionate country-participation, however, is only 1.2 percent.
4. The studies of 198 doctors (from 57 countries as read in Table 4), with a total of 45,496 insertions on record in Boston, are presently held for possible analysis, pending the stipulation mentioned above.
5. While the studies of 68.5 percent of all reporting doctors have been definitely referred, 63.3 percent of all practiced insertions stem from studies still possibly analyzable. Referrals are presently highest for the Far Eastern studies (50.9 percent) and, surprisingly, lowest for the African studies (22.6 percent). Those proportions, however, are transient, as the second referral round projected for March 1, 1968 will definitely eliminate many studies presently "on probation."
6. Of interest is that almost 95 percent (10,265) of all admissions having reached the headquarters during the last six months are still prospectively analyzable and constitute 22.6 percent of all possibly analyzable insertions, a sign of relative vitality. As the doctors have been recently followed more closely, the probability of bringing their younger studies to fruition is increasing.

7. A remarkable dynamism is perceived in the Middle East, judging from the comparative proportions insertions had reached during the last six months (9.1 percent) against the entire past (5.7 percent). In contrast, the reverse pattern applies to the Far East and Oceania.

#### Presently-Continuing IUD Projects

Possibly-exploitable studies have been extracted from the overall inventory list and grouped by world area, country, doctor, study onset and cumulative insertions attained at two points: June 1967 and December 1967 (Appendix 18). Furthermore, to make an assessment of our end of the dialogue with those doctors, all outgoing letters from the Executive Staff (Elton Kessel, William Strong and myself) during the second half of 1967 were counted. This listing is summarized in Table 4, an overview of the possibly-exploitable material and brings to light the following facts:

1. During the last six months the number of admissions of now possibly-analyzable studies had grown by 29 percent, as indicated in ratio-5.
2. Judging from the frequency ratio of outgoing mail during the third quarter to that during the fourth (1:4.6), one may state that there has been a considerable intensification of dialogue.

Adding together the 200 inventory letters, the 675 previously-written letters and those addressed to presently "referred" doctors, it is a conservative *estimate* <sup>guess</sup> that 1,000 letters dealing with IUD studies were written over the last six months, more than three-quarters of which went out over the last three months.

The lower part of Table 4 is a proportionate breakdown by area of the positions mentioned.

3. While one-third of the correspondence was carried on with Europe, it is interesting to note that its relative contribution of admission records amounted to only one-sixth of the total. The Far East and Oceania, in contrast, received only one-eighth of the correspondence load but contributed almost one-fourth of all admissions.

This reflects quite accurately one aspect of our present dilemma. Many small studies were being dragged along in France (95 doctors!) and inter-communication had not been very consistent. Thus, a considerable effort was recently exerted in developing a means of deciding on the value of their statistical exploitation (Appendix 19). In contrast, studies done in the Far East and Oceania, particularly in the Philippines, are even less well-defined than those from other areas. Batches from the Planned Parenthood Movement in the Philippines come in at random, in bulk and without any systematic pre-triaging of the material so as to arrange it by doctor and study (Appendix 20). I doubt very much that significant value can be derived from either source, some notable exceptions withstanding.

4. The Middle East recently shows the most dynamic studies, judging from the six-month relative insertion increase (9.4 percent) compared to the relative admission totals by mid-1967 (4.8 percent). No doubt responsible for this are the presently very dynamic Israeli studies (Appendix 21).

The 247 presently-continuing and possibly-exploitable studies conducted by 198 doctors have been broken down by the area in which they are conducted, as well as by their inception date. Table 5 reveals that:

1. More than half of the active studies have begun during the last two years (complement of 46.6 percent).
2. New studies have apparently increased during 1967, where they decreased during the second half of 1966.

Interpretation of this trend is difficult, as the probability of referring studies increased with duration. Seventeen percent of the studies presently being considered for later analysis, however, have begun over the last six months and this proportion will probably increase as many older studies will have to be referred by March 1968. Relatively speaking, this would indicate a trend of actual and prospective growth of the Pathfinder Fund's IUD new-cooperator roster.

3. One-third of the possibly-analyzable studies, at the present time, are African and almost one-fourth are European.

Table 6 contains an identical breakdown, with the exception that the studies proper are replaced by their total number of first admissions reported up to the end of 1967. The following pattern emerges:

1. Almost one-fourth (complement of 76.7 percent) of all possibly-analyzable first insertions were reported to us from studies with onset during the last two years. Because of the relative recency involved, these studies have a higher chance to reach a state of statistical exploitability than have the older studies in general. The former statement is justified by the fact that, for the recent studies, our guidance was offered at an earlier stage of growth than was it, if ever, in the older ones.
2. Though merely one-twentieth (2.6 percent) of all possibly-analyzable admissions were reported to us from studies with onset during the last six months, no pessimistic inference should be made. It seems both more realistic and more practical to consider the portion these recent insertions constitute of those reported by studies with onset during the last two years. One-ninth (1,197/10,606 or 11.3 percent) of all insertions from the latter category belong to the former. Thus, one can observe the existence of most-recently begun, good-quality studies that have a fair chance of growing into analyzable entities.
3. Almost three-fifths (58.6 percent) of the first insertions stemming from studies begun over the last six months may be attributed to African projects, whereas the corollary studies from other areas showed a remarkable decrease during the second-half of 1967, judging from the 1967 columns in Table 6.

It would be interesting to compute figures which would allow one to observe the relative growth of projects in time. The inventory provided for this thought, though practical possibilities were limited. Table 7 tries to sketch this growth pattern by area. It is essentially a reproduction of the top and bottom parts of the previous table, but gives in addition a categorized time-span frequency count for 1967. The crystallization of certain facts alone justifies this table.

The ellipses indicate the number of first insertions which reached our headquarters from studies initiated during a given six-month period. From the bottom-left box one observes that 814 first insertions reached the headquarters during the first-half of 1967 and originated from studies begun during the same time-span. During the next six months, however, the same studies produced a considerably higher yield, as they contributed 2,167 first insertions during the second-half of 1967. While providing interesting information, the table does have its limitations because the calendar-log sheet system was begun only in January of 1967. The studies presently believed to be analyzable and having begun during the second half of 1966 had grown to a cumulative total of 660 insertions by June 1967 and contributed another 798 insertions during the second-half of 1967. What then can be sensibly extracted from this table?

1. Were it not for Africa, whose most recent studies had yielded 701 admissions, the Pathfinder Fund's July-December yield would have lagged behind that of the January-June 1967 studies. In computing the four complementary areas' yield for both halves of 1967, one observes a ratio of 782:496 (first-half to second half). In contrast, Africa's first insertion-load had multiplied twenty times, from 32 to 701 insertions.

The Pathfinder Fund's IUD operation was surely facing a serious crisis, as in most areas less insertions were being performed in new studies. Computation was not necessary to reveal that truth. The fact at hand is that Africa's 701 insertions reflect a most-recent revival. A spearhead field trial has been launched in the U.A.R., beginning a second era in the Fund's operation.

Though our Service function will continue unabated, emphasis is now being placed on the rapid testing of new devices. Dr. Ismail Ragab's project in the U.A.R. (Appendix 22) is the first link of a projected longer chain of trials which will have as their object the experimenting with more-recent

models of IUDs.

2. While 14.0 percent (6,352) of the analyzable admission records reaching Boston during the last six months were obtained from studies beginning during the last two years, another 8.6 percent (3,913) were obtained from studies initiated prior to 1966. Thus, 22.6 percent of the possibly-analyzable material arrived very recently.

It is discouraging that much of this recent, better material will be lost because the older studies were not followed systematically in their early stages; simultaneously encouraging is the fact that recent quality improvement in reporting was made by contributors who had pulled-along essentially low-quality studies. Presently, many co-operators have been invited to propose a later segment of their studies for pertinent analysis. Several agreed and stated that the first "x" cases were a kind of apprenticeship. That alone is notable. It is furthermore believed that several of those malleable physicians will become excellent candidates for the testing of new devices.

3. The above-mentioned global proportion of 26.6 percent is hiding a considerably higher corresponding figure for the Middle East, where 36.1 percent (12.2 + 23.9) of all insertions were contributed over the last six months. Lower figures apply to Africa and Europe, with 19.5 and 19.1 respectively.

As is already obvious, Israel has at the present time very dynamic studies. Becoming aware of this at the end of September, we began a revitalization action for all Israeli studies. A cut-off date was assigned, lost-to-follow-up lists sent out (Appendix 23) and a tentative plan to proceed with the computation of rates this Spring conceived.

4. Finally, let us look at the inflow of admission records from the five world areas during the period encompassed by 1966 and 1967 with studies beginning during the first eighteen months of that period. Comparing the cumulative insertion total for those studies in mid-1967 to their absolute increase during the next six months, the following regional pattern emerges:

<u>SPAN IN MONTHS</u>	FREQUENCY		RATIO	
	18	6	18	6
Latin America	803	1,711	1	2.1
Africa	510	641	1	1.3
Europe	1,731	833	1	0.5
Middle East	741	635	1	0.9
Far East and Oceania	469	1,335	1	2.9
	4,254	5,155	1	1.2

Studies from Latin America showed a remarkable increase in new admissions over the last six months (2.1 times), while Europe's corollary studies demonstrate an impressive shrinking trend (0.5 times). Unfortunately, the ratio for the Far East is deceiving, as delays in arrival due to sea mail transportation from the Philippines shift the ratio in favor of the last six months. For Europe only is a clear-cut interpretation offered: France, having begun some 100 IUD projects, had a very sparse follow-up, some notable exceptions withstanding.

## PROJECTIONS INTO THE FUTURE

### FURTHER INCREASE OF DIALOGUE

During the two weeks that the inventory was conducted and figures were tabulated, some 100 letters, not counting the completed batches of questionnaires, arrived at our headquarters. It seems of paramount importance to nurture that international dialogue because the better the mutual understanding of our common and crucial subject matter, the higher the co-operator's motivation to accept technical directions. Although the correspondence load presently absorbs some twenty-four working hours, we feel very strongly that it would be erroneous to relegate the intercommunication to a second-priority category.

UNIFIED ANALYSIS OF PAST AND FUTURE STUDIES

Generally speaking, the data have not yet reached the coding stage, though many studies are now progressing in that direction. Scanning and checking for error and inconsistency is now continuing in our Processing Department.

Computation will be done according to the multi-decrement life table approach, furthermore taking into account all time segments during which the woman wears a device. In our revised sheet containing instructions for keeping records (Appendix 3), which had now reached some 500 doctors in perhaps seventy countries, the method was advertised as follows: "World-wide evaluation will be done in successive rounds, according to the Tietze-Potter life table approach (multiple segment-decrement), a landmark in use-effectiveness measurement."

A basic aim was to write the code in such a way that past and future information cores would be uniformly analyzable. It was thus created--in close cooperation with Christopher Tietze--a code to be singly used for the entire Pathfinder IUD operation. While allowing us to embark on the exploitation of the past operations, it also permits us to immediately link those of the future. The coding sheets have just reached a pre-final stage. One can obtain the full flavor by comparing those sheets (Appendices 24-27) to the segment strip of the new follow-up record (Appendix 7).

On December 13, 1967 Elton Kessel and I presented for discussion at the Harvard School of Public Health Seminar 2b our current developments. A condensed description of our thoughts with regard to the method of analysis was distributed and is given here for purposes of documentation (Appendix 28). It is quite apparent that the entire analysis machinery about to be put into action

is based essentially on the practical and theoretical considerations arrived at by C. Tietze and R. Potter over the last few years. In this respect, the reporter is rather a synchronizer, applying and combining the findings of two leading authorities on use-effectiveness measurement. It is indeed fortunate that we were able to elicit their consultation toward the future analysis of the Fund's expanding IUD Programme.

A temporary Ersatz for a future computer program allowing not only computation of event rates but also cross-tabulation by pre-insertion variables has been suggested by C. Tietze: use of a handy program for a desk-computer allowing the immediate calculation of event-rates. This would permit us to screen many a study for the value of its future analysis on a larger unit. The condensed learning period, which allowed use of the program just written for Tietze and arranged at Dr. Barron's office at Rockefeller University, terminated with the acquisition of an identical set by the Pathfinder Fund. I should like to express my gratitude to both for this essential step.

Even though pre-tabulation is quite elaborate, we are now able to embark on a new endeavour, namely, the calculation of rates on the Pathfinder premises. Dr. Behlilovic's study, a model in neatness and consistency of reporting, was chosen to open the series of studies to be analyzed.

Table 8 gives a computation log for the Yugoslavian series. Table 9 shows the proposed format to be used in conveying back to the contributor the results of computation. It is hoped that the material will serve as "solid basis for a pertinent local scientific publication," as stated in our instruction sheet (Appendix 3).

### RESULTS OF THE FIRST ANALYZED STUDY

Comparing the American with the Beograd experience in Table 10, one is struck by both:

1. The similarity in accidental pregnancy rates.
2. The contrast in removal rates for medical reasons. Allowing for re-insertions, twelve out of one-hundred American women had a definite removal for medical reasons, as opposed to two women in the Beograd experience.

As the Beograd study is of high-quality, the lost-to-follow-up being less than 3 percent and follow-up visits being dense and almost exactly to the scheduled day, the findings merit some attention. The first thought is that we were very fortunate to put our finger on this study. This very finding not only justifies but formally imposes analysis of the international material accumulating in Boston. It may point, however, to further considerations.

### NEED FOR UNDERSTANDING PRESENT IUD UNPOPULARITY

On the basis of my recent experience in IUD matters, I venture to advance the speculation that the reason for the presently-growing IUD unpopularity on an international scale may lie to a certain extent with the physician rather than with the uterus! This for at least two reasons:

1. Bleeding and pain are known to be most frequently encountered during the first months following insertion. There are now doctors who have soundly reacted to that fact and demonstrate justified hesitancy concerning premature removal. On the other side of the fence are those doctors to whom any bleeding and discomfort necessitate removal. We have no idea, at least not to my knowledge, about the proportionate parts doctors adhere to on either the one or the other extreme. We do, however, suspect that those two extremes may mean the difference between contributing an insignificant part or a major part to the discontinuation rate. For this reason it will be of interest to begin an inquiring dialogue with the Yugoslavian contributor, in order to obtain a plausible explanation of his very low removal rate for medical reasons.

Probing into the bleeding proper we come to the second point:

2. Although we are still on a fairly new territory concerning knowledge of the "mechanical" adaptation of the uterus to the IUD

shape (not to mention the chemical reactions!), it is thought that the very act of insertion must have a very broad quality range. Proper placing of a device may perhaps be more demanding than many physicians presently venture to concede. It may be that the "plugging-it-in" attitude is quite a general phenomenon. In many cases, skillful placement of the device must have decided on its staying in place well and on an insignificant bleeding pattern. Many partial expulsions (to say the least) are doubtlessly attributed to the same line of thought.

It seems to us that the time has come to pay strict attention to both points. We think it of importance not only to build into our dialogue an educational facet covering the first consideration, but also to strive for a better placement technique.

This raises the next practical question: do we have the perfect device? It is quite interesting to observe how little biomedical engineering is involved in the construction of the device, when one considers the million-fold use of IUDs the world over. It is our conviction that a radical change has to come about on that account. Research proper in IUD technology scarcely exists. The urgency for better-designed devices should now definitely motivate the biomedical engineers. There are engineers in the field of cardiology who have managed to solve far more demanding problems. It should be a real challenge for some of those specialists to look closer at the problem one floor below!

The Pathfinder Fund has adopted the following policy in IUD matters:

1. The spread and popularization of this method will continue unabatedly, via the combined functions of our Service and Research units.
2. Emphasis is placed on testing newer developments in IUD technology. A multi-area approach is favored whenever possible. It is hoped that the MD-IUD generation will have to make room for the ENG-IUD generation.

### PREPARATION FOR NEW FIELD TRIALS

A major facet of the Fund's present policy being the rapid scrutinization of new devices, comprehensive measures are now being taken to incorporate such a new operation, during the next few months, in the framework of the Pathfinder Fund's INTERNATIONAL IUD PROGRAMME. To that avail, some thirty doctors have already given their consent to join the new venture.

Presently, two spearhead field trials are being conducted in the U.A.R. and in Chile in order that the potential of the heart-shaped device might be known. A more-limited series for such device is being conducted presently by four other contributors. The "Lippes-D-Silicone" is being tested (Appendix 29) in Europe and some other models are presently on the priority list.

It is our opinion that the more rapidly a device can be eliminated from the race for optimal suitability, the better, as it will constitute one less item on the presently-stuffed list of fancy devices. Here then failure may mean success; it should not be that a device run five years before it is recognized as surpassable!

### HOW ARE THE RESULTS GOING TO BE UTILIZED?

Whatever the outcome of a trial, information on a particular device tested in a particular setting should be channeled in two directions:

1. To the physician who conducted the study, for his local publication.
2. To an Institute specializing in IUD design, to serve as a further clear-cut mosaic toward construction of the device.

In turn, that Institute should be able to speedily use the information as a guide to constructing an improved version, which should then be offered for trial on several continents. It is believed that such an intercommunication between engineer and trial-agency would speed up the construction of a superior

device, that is, one with extremely low expulsion and removal for medical reasons.

## CONCLUSIONS

Through the end of 1967, the Pathfinder Fund offered the chance to participate in its Field Studies to more than 1,000 doctors. Of those, 628 doctors in 82 countries established a records-dialogue, reporting back to the Boston headquarters 72,000 insertions.

The revitalized INTERNATIONAL IUD PROGRAMME is presently growing in size and quality.

Though the past operation has sustained a remarkable low on the analytical end, it is now apparent that many a study is on the way to statistical exploitability, judging from a presently low lost-to-follow-up rate in studies of some twenty doctors, the recent increase in density and quality of reporting and the most recently perceived further reduction in lost-to-follow-up in many studies. In time, this will allow us to cross-tabulate events by pre-insertion information, such as age at first insertion, parity and uterus parameters, to name a few.

Any doctor who asks for IUD supplies--the requests are increasing-- is offered the opportunity to serve as a link in the world-embracing chain of IUD testers (Appendix 30). Quality criteria on suitability for statistical exploitation are presently being set down.

An internal transfer mechanism providing for the shifting of any doctor from the research project to pure service and vice-versa, if his data should prove promising, is being established now. Handling the doctors in such a way is thought to serve some specific purposes:

1. Ramified professional focal spread of the IUD contraceptive method (Appendix 31).
2. World-wide random recruiting of potential candidates for the testing of new devices.
3. The project participants are thought to be particularly receptive to any new development in contraception and may prove instrumental in both the testing and rapid spread of innovation in birth control.

Certainly, these objectives must have nurtured the impetus for the prodigious drive of Clarence J. Gamble.

Boston, January 25, 1968

## TABLES

1. Four-week inflow of IUD records: Overview
2. " : 7 high-frequency countries
3. All recorded IUD insertions and contributors: By area  
Presently definite referrals
4. Continuing IUD studies: Overview
5. " : By area and study onset
6. " : Admissions  
By area and study onset
7. " : Recent trends of IUD insertions  
By area and study onset
  
8. Computation-log, Programma 101, illustrative series
9. Proposed format for data feed-back to the participants
10. Two IUD experiences: Comparison of results

Table 1

**INFLOW OF IUD RECORDS**  
**FOUR-WEEK INVENTORY**  
**(DECEMBER 11, 1967 - JANUARY 7, 1968)**

OVERVIEW

**FREQUENCY BY AREA**

<u>AREA</u>	<u>COUNTRIES</u>	<u>DOCTORS</u>	<u>MAILINGS</u>	<u>ADM.</u>	<u>FU</u>
Lat. America	13	19	36	531	1650
Africa	14	28	43	338	987
Europe	6	29	48	344	1051
Middle East	3	8	19	223	607
Far East and Oceania	7	12	17	164	435
<b>TOTALS</b>	<b>43</b>	<b>96</b>	<b>163</b>	<b>1600</b>	<b>4730</b>
<b>RATIO-1</b>	<b>1</b>	<b>: 2.3</b>			
	<b>RATIO-2</b>	<b>1</b>	<b>: 1.7</b>		
			<b>RATIO-3</b>	<b>1</b>	<b>: 3.0</b>

**PERCENT BY AREA**

<u>AREA</u>	<u>COUNTRIES</u>	<u>DOCTORS</u>	<u>MAILINGS</u>	<u>ADM.</u>	<u>FU</u>
Lat. America	30.2	19.8	22.1	33.2	34.9
Africa	32.6	29.2	26.4	21.1	20.9
Europe	13.9	30.2	29.4	21.5	22.2
Middle East	7.0	8.3	11.7	13.9	12.8
Far East and Oceania	16.3	12.5	10.4	10.2	9.2
<b>TOTALS</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

Table 2

INFLOW OF IUD RECORDS  
 FOUR-WEEK INVENTORY  
 (DECEMBER 11, 1967 - JANUARY 7, 1968)  
SEVEN COUNTRIES OUT OF FORTY-THREE  
WITH THE  
MOST DOCTORS, MAILINGS AND INSERTIONS

FREQUENCY

	<u>COUNTRY</u>	<u>DOCTORS</u>	<u>MAILINGS</u>	<u>ADM.</u>	<u>FU</u>
	Peru	3	6	98	205
	Guatemala	1	4	255	950
	Rhodesia	13	26	117	406
	England	8	15	82	448
	France	13	21	174	311
	Israel	6	17	214	604
	Philippines	4	6	144	197
TOTALS	7	48	95	1084	3121
ALL OTHERS	36	48	68	516	1609
GRAND TOTALS	43	96	163	1600	4730

PERCENT

	<u>COUNTRY</u>	<u>DOCTORS</u>	<u>MAILINGS</u>	<u>ADM.</u>	<u>FU</u>
	Peru	3.1	3.7	6.1	4.3
	Guatemala	1.0	2.4	15.9	20.1
	Rhodesia	13.5	15.9	7.3	8.6
	England	8.3	9.2	5.1	9.8
	France	13.5	12.9	10.9	6.7
	Israel	6.2	10.4	13.4	12.8
	Philippines	4.2	3.7	9.0	4.2
TOTALS	16.3	50.0	58.3	67.7	66.5
ALL OTHERS	83.7	50.0	41.7	32.3	33.5
GRAND TOTALS	100.0	100.0	100.0	100.0	100.0

ALL IUD INSERTIONS AND CONTRIBUTORS BY AREA  
 END 1967 INVENTORY  
PRESENTLY DEFINITE REFERRALS/BASELINE

FREQUENCY

AREA	UP TO END 1967						JULY - DECEMBER 1967			
	COUNTRIES	CONTRIBUTORS			INSERTIONS					
		REFERRED	ANALYZABLE*	TOTAL	REFERRED	ANALYZABLE+	TOTAL	REFERRED	ANALYZABLE	TOTAL
Lat. America	21	113	39	152	6,432	10,139	16,571	61	2,630	2,691
Africa	27	101	54	155	3,742	12,778	16,520	152	2,491	2,643
Europe	8	92	51	143	3,450	9,582	13,032	72	1,835	1,907
Middle East	6	27	15	42	1,456	2,674	4,130	21	966	987
Far East & Oc. (Canada)	19	92	39	131	10,687	10,323	21,010	321	2,343	2,664
	1	5	-	5	647	-	647	-	-	-
<b>GRAND TOTALS</b>	<b>82</b>	<b>430</b>	<b>198</b>	<b>628</b>	<b>26,414</b>	<b>45,496</b>	<b>71,910</b>	<b>627</b>	<b>10,265</b>	<b>10,892</b>

PERCENT/AREA

Lat. America	25.6	26.3	19.7	24.2	24.3	22.3	23.0	9.7	25.6	24.7
Africa	32.9	23.5	27.3	24.7	14.2	28.1	23.0	24.2	24.3	24.3
Europe	9.8	21.4	25.8	22.8	13.1	21.1	18.1	11.5	17.9	17.5
Middle East	7.3	6.3	7.6	6.7	5.5	5.9	5.7	3.3	9.4	9.1
Far East & Oc. (Canada)	23.2	21.4	19.7	20.9	40.5	22.7	29.2	51.2	22.8	24.5
	1.2	1.2	0.0	0.8	2.4	0.0	0.9	0.0	0.0	0.0
<b>GRAND TOTALS</b>	<b>100.0</b>	<b>100.1</b>	<b>100.1</b>	<b>100.1</b>	<b>100.0</b>	<b>100.1</b>	<b>99.9</b>	<b>99.9</b>	<b>100.0</b>	<b>100.0</b>

PERCENT/REFERRALS

Lat. America	-	74.3	25.7	100.0	38.8	61.2	100.0	2.3	97.7	100.0
Africa	-	65.2	34.8	100.0	22.6	77.4	100.0	5.7	94.3	100.0
Europe	-	64.4	35.6	100.0	26.5	73.5	100.0	3.8	96.2	100.0
Middle East	-	64.3	35.7	100.0	35.3	64.7	100.0	2.1	97.9	100.0
Far East & Oc. (Canada)	-	70.3	29.7	100.0	50.9	49.1	100.0	12.0	88.0	100.0
	-	100.0	0.0	100.0	100.0	0.0	100.0	0.0	0.0	0.0
<b>GRAND TOTALS</b>		<b>68.5</b>	<b>31.5</b>	<b>100.0</b>	<b>36.7</b>	<b>63.3</b>	<b>100.0</b>	<b>5.8</b>	<b>94.2</b>	<b>100.0</b>

\* Contributors whose studies are possibly analyzable  
 + Possibly analyzable

Table 4

CONTINUING IUD PROJECTS  
END 1967 INVENTORY

## OVERVIEW

## FREQUENCY BY AREA

AREA	COUNTRIES	DOCTORS	CUMULATIVE ADMISSIONS		INCREASE 6 MONTHS	OUTGOING LETTERS		
			6/67	12/67		3.QT.67	4.QT.67	
Latin America	16	39	7,509	10,139	2,630	35	117	
Africa	19	54	10,287	12,778	2,491	23	126	
Europe	7	51	7,747	9,582	1,835	36	177	
Middle East	4	15	1,708	2,674	966	10	68	
Far East and Oceania	11	39	7,980	10,323	2,343	16	67	
<b>TOTALS</b>	<b>57</b>	<b>198</b>	<b>35,231</b>	<b>45,496</b>	<b>10,265</b>	<b>120</b>	<b>555</b>	
	<b>RATIO-1</b> 1 :	<b>3.5</b>		<b>RATIO-5</b> 1 :	<b>1.29</b>		<b>RATIO-4</b> 1 :	<b>4.6</b>

## PERCENT BY AREA

Latin America	28.1	19.7	21.3	22.3	25.6	29.1	21.1
Africa	33.3	27.3	29.2	28.1	24.3	19.2	22.7
Europe	12.3	25.8	22.0	21.1	17.9	30.0	31.9
Middle East	7.0	7.6	4.8	5.9	9.4	8.3	12.2
Far East and Oceania	19.3	19.7	22.6	22.7	22.8	13.3	12.1
<b>TOTALS</b>	<b>100.0</b>	<b>100.1</b>	<b>99.9</b>	<b>100.1</b>	<b>100.0</b>	<b>99.9</b>	<b>100.0</b>

Table 5

## CONTINUING IUD STUDIES

END 1967 INVENTORY

BY AREA AND STUDY ONSET

## FREQUENCY

AREA	STUDIES WITH ONSET					TOTALS
	BEFORE 1966	1966		1967		
		1ST SEM.	2ND SEM.	1ST SEM.	2ND SEM.	
Lat. America	18	7	2	8	9	44
Africa	39	13	8	6	14	80
Europe	26	9	7	8	9	59
Middle East	6	4	1	3	1	15
Far East and Oceania	26	2	3	9	9	49
<b>TOTALS</b>	<b>115</b>	<b>35</b>	<b>21</b>	<b>34</b>	<b>42</b>	<b>247</b>

## PERCENT/AREA

Lat. America	15.7	20.0	9.5	23.5	21.4	17.8
Africa	33.9	37.1	38.1	17.6	33.3	32.4
Europe	22.6	25.7	33.3	23.5	21.4	23.9
Middle East	5.2	11.4	4.8	8.8	2.4	6.1
Far East and Oceania	22.6	5.7	14.3	26.5	21.4	19.8
<b>TOTALS</b>	<b>100.0</b>	<b>99.9</b>	<b>100.0</b>	<b>99.9</b>	<b>99.9</b>	<b>100.0</b>

## PERCENT/ONSET PERIOD

Lat. America	40.9	15.9	4.5	18.2	20.4	99.9
Africa	48.7	16.3	10.0	7.5	17.5	100.0
Europe	44.1	15.2	11.9	13.6	15.2	100.0
Middle East	40.0	26.7	6.7	20.0	6.7	100.1
Far East and Oceania	53.1	4.1	6.1	18.4	18.4	100.1
<b>TOTALS</b>	<b>46.6</b>	<b>14.2</b>	<b>8.5</b>	<b>13.8</b>	<b>17.0</b>	<b>100.1</b>

Table 6

## ADMISSIONS IN CONTINUING IUD PROJECTS

END 1967 INVENTORY

BY AREA AND STUDY ONSETFREQUENCY

AREA	STUDIES WITH ONSET					TOTALS
	BEFORE 1966	1966		1967		
		1ST SEM.	2ND SEM.	1ST SEM.	2ND SEM.	
Lat. America	7,506	1,460	473	581	119	10,139
Africa	10,926	705	220	226	701	12,778
Europe	6,806	1,378	535	651	212	9,582
Middle East	1,293	1,187	108	81	5	2,674
Far East and Oceania	8,359	240	122	1,442	160	10,323
TOTALS	34,890	4,970	1,458	2,981	1,197	45,496

PERCENT/AREA

Lat. America	21.5	29.4	32.4	19.5	9.9	22.3
Africa	31.3	14.2	15.1	7.6	58.6	28.1
Europe	19.5	27.7	36.7	21.8	17.7	21.1
Middle East	3.7	23.9	7.4	2.7	0.4	5.9
Far East and Oceania	24.0	4.8	8.4	48.4	13.4	22.7
TOTALS	100.0	100.0	100.0	100.0	100.0	100.0

PERCENT/ONSET PERIOD

Lat. America	74.0	14.4	4.7	5.7	1.2	100.0
Africa	85.5	5.5	1.7	1.8	5.5	100.0
Europe	71.0	14.4	5.6	6.8	2.2	100.0
Middle East	48.4	44.4	4.0	3.0	0.2	100.0
Far East and Oceania	81.0	2.3	1.2	14.0	1.5	100.0
TOTALS	76.7	10.9	3.2	6.6	2.6	100.0

Table 7

RECENT TRENDS OF IUD INSERTIONS AMONG CONTINUING STUDIES

END 1967 INVENTORY

BY AREA AND ONSET

	FREQUENCY					PERCENT						
	UP TO	1966		1967		TOTALS	UP TO	1966		1967		TOTALS
	DE/65	JA-JU	JU-DE	JA-JU	JU-DE		DE/65	JA-JU	JU-DE	JA-JU	JU-DE	
LAT. AMERICA	7,506				(800)	7,506	74.0				(7.9)	74.0
		→ 495	→ 965			1,460		→ 4.9	→ 9.5			14.4
		→ 78	→ 395			473		○ 0.8	○ 3.9			4.7
		○ 230	○ 351		581			○ 2.3	○ 3.5			5.7
			○ 119		119				○ 1.2			1.2
	7,506		803	1,830		10,139	74.0		7.9	18.1		100.0
AFRICA	10,926				(1,149)	10,926	85.5				(9.0)	85.5
		→ 368	→ 337			705		→ 2.9	→ 2.6			5.5
		→ 110	→ 110			220		○ 0.9	○ 0.9			1.7
		○ 32	○ 194		226			○ 0.3	○ 1.5			1.8
			○ 701		701				○ 5.5			5.5
	10,926		510	1,342		12,778	85.5		4.0	10.5		100.0
EUROPE	6,806				(790)	6,806	71.0				(8.2)	71.0
		→ 1,044	→ 334			1,378		→ 10.9	→ 3.5			14.4
		→ 379	→ 156			535		○ 4.0	○ 1.6			5.6
		○ 308	○ 343		651			○ 3.2	○ 3.6			6.8
			○ 212		212				○ 2.2			2.2
	6,806		1,731	1,045		9,582	71.0		18.1	10.9		100.0
MIDDLE EAST	1,293				(326)	1,293	48.4				(12.2)	48.4
		→ 641	→ 546			1,187		→ 24.0	→ 20.4			44.4
		→ 73	→ 35			108		○ 2.7	○ 1.3			4.0
		○ 27	○ 54		81			○ 1.0	○ 2.0			3.0
			○ 5		5				○ 0.2			0.2
	1,293		741	640		2,674	48.4		27.7	23.9		100.0
FAR EAST AND OCEANIA	8,359				(848)	8,359	81.0				(8.2)	81.0
		→ 232	→ 8			240		→ 2.2	→ 0.1			2.3
		→ 20	→ 102			122		○ 0.2	○ 1.0			1.2
		○ 217	○ 1,225		1,442			○ 2.1	○ 11.9			14.0
			○ 160		160				○ 1.5			1.5
	8,359		469	1,495		10,323	81.0		4.5	14.5		100.0
COMBINED	34,890				(3,913)	34,890	76.7				(8.6)	76.7
		→ 2,780	→ 2,190			4,970		→ 6.1	→ 4.8			10.9
		→ 660	→ 798			1,458		○ 1.4	○ 1.8			3.2
		○ 814	○ 2,167		2,981			○ 1.8	○ 4.8			6.6
			○ 1,197		1,197				○ 2.6			2.6
	34,890		4,254	6,352		45,496	76.7		9.3	14.0		100.0

○ Number of first insertions reported in studies initiated during that semester  
 ○ → Reported cumulative totals in that semester for studies begun earlier

ORD. MOS. post FIRST INSERTION  
 RE-INSERTIONS  
 TERM S E G M  
 CONT. G M E N I S  
 NEW TERM S  
 AGGREG. WOMEN MONTHS OF USE  
 RELE. CLOS. URES  
 ADJ. # WOMEN  
 CUM. CONT. RATE [1x]  
 INTERNATIONAL PROGRAMME - THE PATHFINDER FUND  
 START: 01/15/77  
 CUTOFF-1: 02/15/77  
 PERIOD: 2/11  
 STUDY: 3341001/Philovic  
 DEVICE: ILEJ-C  
 COMPUTER: E. Jukova/R. Sarna

SIFP 101	FIRST INSERTION			ORDINAL MONTH							NET CUMULATIVE EVENT RATES										O. M.					
	5C	5D	5F	5G	6B	6F	6L	7C	7E	7H	[per 100 women entering the first ordinal month]															
	1	2	3	3R	4	5	5R	6	6R <sub>1</sub>	6R <sub>2</sub>	3B	7a	7R <sub>a</sub>	3C	7b	7R <sub>b</sub>	3D	7c	7R <sub>c</sub>	3E		7d	7R <sub>d</sub>	3F	7e	7R <sub>e</sub>
1	9	-	-	9	2	12	274.5	9	279.0	0.96775	1	.00358	8	.02867	-	.00000	2	.00716	1	.00358	1					
2	1	-	-	1	3	7	262.5	4	264.5	0.95311	-	"	7	.05427	-	"	-	"	-	"	-	"	-	"	-	"
3	-	-	-	0	2	1	260.5	-	260.5	0.95311	-	"	1	.05792	-	"	-	"	-	"	-	"	-	"	-	"
4	12	-	-	12	-	3	253.5	3	255.0	0.94190	1	.00731	1	.06165	1	.00373	-	"	-	"	-	"	-	"	-	"
5	26	-	2	24	-	5	231.5	5	234.0	0.92178	1	.01133	1	.06567	1	.00775	-	"	-	"	2	.01162	-	"	-	"
6	29	1	1	29	1	5	200.5	3	202.0	0.90809	-	"	5	.08848	-	"	-	"	-	"	-	"	-	"	-	"
7	31	3	6	28	1	2	169.5	2	170.5	0.89743	-	"	-	"	-	"	1	.01248	1	.01694	-	"	-	"	-	"
8	37	2	7	32	-	2	138.0	2	139.0	0.88452	-	"	1	.09493	-	"	-	"	1	.01893	-	"	-	"	-	"
9	29	-	1	28	-	-	107.0	-	107.0	0.88452	-	"	-	"	-	"	-	"	-	"	-	"	-	"	-	"
10	21	-	3	18	-	-	84.0	-	84.0	0.88452	-	"	-	"	-	"	-	"	-	"	-	"	-	"	-	"
11	21	-	5	16	-	1	66.5	1	67.0	0.87132	1	.02452	-	"	-	"	-	"	-	"	-	"	-	"	-	"
12	11	-	2	9	-	-	53.5	-	53.5	0.87132	-	.02452	-	.09493	-	.00775	-	.01893	-	.01694	-		-		-	
13	15	1	3	13																						
14	-	-	-	0																						
15	1	-	-	1																						
16	8	-	-	8																						
17	9	-	1	8																						
18	12	1	3	10																						
19	7	1	2	6																						
20	1	-	-	1																						
21	4	-	2	2																						
22																										
23																										
24																										
total	284	9	38	255	9	38		29			29		24		2											

Computation log / Programma 101

Table 8

0.16307

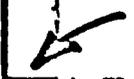


Table 9

## INTERNATIONAL IUD PROGRAMME - THE PATHFINDER FUND

COMPUTATION : December 1967  
 COMPUTER : Programma 101/rb  
 COMPUT.PLACE: The Pathfinder Fund

STUDY START : January 1966  
 CUTOFF-1 : September 1967  
 PERIOD : 21 MONTHS

Study: Prof. Br. Behlilovic  
 Device: Lippes Loop C  
 Study place: Beograd/YUG.

C U M U L A T I V E ** R A T E S							
per 100 women entering the first ordinal month							
		N E T				G R O S S	
		E V E N T		C L O S U R E		E V E N T	
		6	12	6	12	6	12
<u>Type of termination</u>							
PREGNANCY		1.13	2.45	1.13	2.45	1.18	2.65
EXPULSION							
First Expulsion		8.85	9.49	5.40	6.04	9.02	9.71
Later Expulsion		0.77	0.77	0.77	0.77	0.82	0.82
Total		9.62	10.26	6.17	6.81	(9.79)*	(10.47)*
REMOVAL							
Medical Reasons		0.72	1.89	0.72	1.89	0.72	2.02
Personal Reasons		1.16	1.69	1.16	1.69	1.22	1.80
Total		1.88	3.58	1.88	3.58	(1.94)*	(3.78)*
TOTAL TERMINATIONS		12.63	16.31	9.18	12.86	-	-

\*\*Tietze-Potter life table approach (multiple segment/decrement)

\*combined  
not added

Table 10

ONE-YEAR NET CUMULATIVE EVENT AND CLOSURE RATES  
PER 100 LIPPES LOOP "C" USERS

TYPE OF TERMINATION	AMERICAN EXPERIENCE*		BEOGRAD EXPERIENCE**	
	EVENT	CLOSURE	EVENT	CLOSURE
PREGNANCY	2.7	2.4	2.45	2.45
EXPULSION				
First	14.0	4.2	9.49	6.04
Later	4.8	1.8	0.77	0.77
Total	<u>18.8</u>	<u>6.0</u>	<u>10.26</u>	<u>6.81</u>
REMOVAL				
Medical Reasons	14.1	12.0	1.89	1.89
Personal Reasons	2.9	2.5	1.69	1.69
Total	<u>17.0</u>	<u>14.5</u>	<u>3.58</u>	<u>3.58</u>
<hr/>				
TOTAL TERMINATIONS	38.5		16.31	
DISCONTINUATIONS		22.9		12.86
CONTINUATIONS		77.1		87.14
WOMEN-MONTHS OF USE	30,397		2,101	

\*Ch. Tietze: "Cooperative Statistical Program for the Evaluation of Intra-Uterine Devices." Eighth Progress Report, July 1963 - June 1967. Extracted from Table 7, Col C.

\*\*Br. Behlilovic: In "International IUD Programme - The Pathfinder Fund." January 1966 - September 1967. Unpublished.