Study on the Acceptablity and Effectiveness of an Oral Contraceptive Among Iud Drop-outs in RuralKorea*

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Introduction

In Korea since 1964, the IUD has been recommended as the best contraceptive method, and more than one million Lippes' Loops have been inserted by Dec. 1967. However, the IUD cannot be effective enough to prevent all pregnancies and it is definitely imperfect as a high proportion of IUD wearers terminate use due to medical side effects and spontaneous expulsions. It is estimated that in Korea 38% of IUD acceptors terminated use by the end of he first year, and 56% by the end of the second year due to pregnancy, removal and expulsion. (1, 2, 3).

Following such termination, only about 40—45% of IUD drop-outs pra-ctice another contraceptive method. Eventually, within 12 months, 40% of IUD drop-outs conceived.(4) Therefore, it is highly important to provide an alternative method of family planning to IUD drop-outs so they may continue their practice of family planning.

To cope with this problem, Yonsei University College of Medicine, at the request of the gove-rnment, undertook a field study on the acceptability and effectiveness of an oral contraceptive among IUD drop-outs in Koyang County. The oral contraceptive was provided to IUD drop-outs at a price of 40 won(15 cents) per cycle.

The specific purposes of our study were:

1) To learn the current status of past IUD drop-outs and their attitude toward the oral contraceptive method.
2) To know how many of those who wanted to use the pill would be medically contraindicated against its use.
3) To know to what extent these medically eligible IUD drop-outs would actually accept and continue use of the pill.

*Note: This study was aided by a research grant from the Population Council New York.
The oral contraceptive used was "Ovulen" made by G.D. Searle & Co. Ltd. England which contains Ethynodiol diacetate Omg and Mestranol mg in each tablet.

4) To determine to what extent side reactions would occur among users of the pill.
5) To determine life table continuation rates and other data on regularity of use.
6) To determine the increase in field staff workload and the problem that might occur if the oral pill was added to the national FP. program.
7) To determine the possible effect on the IUD acceptance and continuation rates if the oral pill was offered as an alternate method for loop drop-outs.

The collection and reporting of information in the above areas was considered essential by Government FP Officials prior to adding the oral pill method for loop failure to the national problem.

Study Procedure and Method

1) Eligibility for entering thte oral pill study program:

During the first six months of the study period (Nov. '66—April '67) eligibility for oral pill use was limited to those who had terminated the IUD at least five months before. However as the acceptance rate was low, eligibility for the pill was liberalized to all IUD drop-outs regardless of their time of termination. This policy ran from May to August 1967. During this time it seemed that numerous unnecessary IUD removals were occuring, so eligibility was again limited to women who had terminated IUD-use two months or more before pill acceptance. This policy ran from September to December 1967

2) Screening process:

Based on the central file of clinical records from the various IUD clinics in Koyang county and on home visits by F.P. workers, all women who had terminated IUD use were reported to the project headquarters. Then, these women were contacted by the family planning field workers who asked them about their knowledge and attitude toward the use of oral pill (1) If they expressed a desire to use the pill, they were given a coupon for the physician's screening examination (2) and advised to visit the oral pill clinic in the health center on any Tuesday or Friday. Those women who visited the clinic were given a physical examination by the Ob.-Gyn. specialist. The findings were recorded in the clinical form.

3) Supply of pills:

Those who had no contraindications were given pills only for the first cycle. The pills for the second and third cycles were supplied at their monthly visits to the clinic. However, at the 4th visit, a 2-month-supply was given; afterward, a 3-month-supply was given at each visit(6th, 9th, 12th and so on).

During the early visits, thorough counseling was given to each women to counteract anxieties from unexpected side-effects. Also, leaflets with questions and answers about the pill were handed out. Also, the registration card with a calendar was given to tell how to take the pill and to be used as a daily record.

4) Follow-up procedure:

The tickler cards were kept according to the expected date of the next visit to detect women failing to make a return visit and to schedule follow up,

To those who failed to make return visits, postcard reminders were sent to remind them and to reduce the load of home visits by family planning field workers. Those women who did not respond to the postcard were home visited and asked why they did not do so. However, the field workers did not deliver pills to them at home,

The findings at each clinic session or follow-up visit were recorded in the clinical and follow-up record in which the relevent information concerning the client's socio-economic background and her physical conditions before and after

taking the pill(medical side-effects e.g. weight change, gastrointestinal trouble, abnormal bleeding, pregnancy, varicous vein etc.) were evaluated.

5) **Study period**:

The action program was conducted from November 1966 to December 1967. In this study period, an evaluation survey was conducted from 1 to 10 September 1967 to find out the status of those pill users not followed-up regularly and of those who had discontinued the use of the pills.

Results

Eligibility and Screening for Use of Oral Contraceptive

1) **Desire to use pill among IUD dropouts**

Based on the eligibility criteria mentioned above, it was planned to visit the 1,262 known drop-outs among the 3,349 IUD acceptors, to ask about their desire to use the oral pill in the study project. By December 1967, the family planning field workers were able to interview 911 women. Among them, 559 women or 61.4% of the 911 asked, expressed their desire to use the pill. This left 352 women(38.6%) who did not want to use it because of the following reasons(see table 1 and 2)

As shown in table 2, most of the reasons (70.4%)(Item 1, 3, 4)(currently practicing or want to use other methods or subfecundity). Only 23.6%(83 women) gave reasons related to the difficulty of taking pills(Item 2). Therefore, we can state that even in rural Korea most of the IUD drop-outs are in favor of trying the pill.

When we examine whether this desire to use the pill is related to the duration from IUD termination to availability of the pill, we see (table 3)that the proportion of women who want to use the pill is higher when IUD termination occurred more recently. (It was not possible to study the relation of this to actual pill acceptance, since the policy excluded prompt acceptance during much of the study period).

Table 1. IUD Insertions, Drop-outs and Approval Rate of Oral Pill

Total No. of women inserted IUD up to Octoder 1967	3,349
Total No. of IUD drop outs as of July-October 1967	1,262
Total No. of Interviewed at home by December 1967	911
No. of women wanted pill	559(61.4%)
No. of women not wanted pill	352(38.6%)

66 women had visited clinic before interview at home.

Table 2. Reasons for Disapproval of Oral Pill among IUD Drop-outs

1. Currently practicing or want to use other methods	98(27.8%)
a. IUD reinserted	35
b. Want IUD reinsertion	31
c. Prefer traditional method	32
2. Not want due to some problems	83(23.6%)
a. Economic problem	48
b. Lack of confidence about drugs	13
c. Too far to supply center and too busy	11
d. Troublesome to take	11
3. Temporary sterile or want more baby	90(25.6%)
a. Pregnancy or postpartum amenorrhea	64
b. Want more baby	26
4. Permanently sterile	60(17.0%)
a. Menopause	31
b. Surgery	16
c. Widowhood, divorced, separated, died	13
5. Others	21(6.0%)
a. Heart disease	1
b. Other disease	5
c. Unknown (did not answer)	15
Total	352(100.0%)

2) Number of clients who actually visited the clinic for the physical examination:

By December 1967, 401 women or 71,7% of 559 women who said they wanted to use the pill visited the Koyang Health Center for the physical examination including a pelvic examin-

Table 3. Approval Rate of Oral Pill by Duration from IUD Termination to Date of Interview

Duration from IUD Termination to Interview (months)	Total	Approved	
		Number	%
1	85	71	83.5
2	28	25	89.3
3	41	32	78.0
4—6	147	96	65.3
7—9	120	88	73.3
10—12	80	51	63.8
13—15	80	52	65.3
16—18	78	43	55.1
19 or more	141	97	68.8
Total	800	555	69.4

Note: 129 out of 929 interviewed up to October 1967 were excluded because of incomplete records.

ation. In addition, 66 women from among those not interviewed also came for this screening.

As a result of the physical examinations, 11 women or 2.4% of the 467 women were found to be contraindicated because of the reasons in table 4.

Table 4. Results of Physical Examination for Women Who wanted Pill

No. of women examined by ob. Gyn. specialist	467
No. of women contraindicated	11(2.4%)
1. Pregnancy	5
2. Marked cervical erosion	2
3. Heart disease	1
4. Breast mass	1
5. Uterine myoma	1
6. Persistent headache	1

As shown in table 4, contraindications other than early pregnancy were minor. Two cases of cervical erosion with suspicious cancer lesions and one case each of uterine myoma, breast mass, heart disease, and persistent headache were found.

3) Number of contraceptive users among women who received the first cycle of pills:

After the screening process mentioned above, the 456 women free of contraindication received the first cycle with detailed instructions on how to take the pills in relation to the date of their last menstruation.

As shown in table 5, the dates of the first visits varied, depending on each individual's menstrual cycle. Therefore, those who were in postpartum amenorrhea(15.8%) were asked to start the pill immediately, those who were between the first and fifth days from the onset of the menstruation(16.0%) were asked to start from the fifth day of that cycle. Those who were between the sixth to tenth days of that cycle (21.1%) were asked to start immediately, even though they missed one to four tablets. Because of the pregnancy risk invloved, this group was also asked to use another contraceptive method such as the condom through the end of that cycle. The rest of the women(47.1%), who came in after the tenth day of the cycle, were asked to begin from the next cycle (table 5).

Table 5. Oral pill Acceptors by the Interval from LMP to the Date of the First Visit for pill Examinations

Interval(days) from onset of menses	No.	%
Amenorrhea*	68	15.8
1—5 days*	69	16.0
6—10 days**	91	21.1
11 days or more***	203	47.1
Total	431	100.0

* Can start O. P. immediately.
** Can start O. P. immediately. with missing 1 to 4 tablets.
*** Must start from next cycle.

However after, receiving the first cycle of pills 25 out of 456 women(5.5%) did not take a pill at all by December 1967 because of the following reasons: 11 said they became pregnant while waiting for the next cycle, 4 changed their minds and decided to have more children, six

heard a bad rumor about the pill, one reinserted the IUD, one divorced, one felt she had experienced. menopause, and one became sick.

Therefore, 431 out of 456 women (94.5%) actually started and took one or more pills after receiving the first cycle.

4) Acceptance rate and characteristics of users.

Defining these 431 women as the actual acceptors(or users) among the known IUD drop-outs, we can calculate acceptance rates according to personal characteristics. In this calculation we assumed that the 911 IUD drop-outs who were offered the pill were representative of all 1,262 known drop-outs in the area.

As shown in table 6, the accptance rate was higher among those of advanced age, higher parity and higher education. This means that among IUD drop-outs the women over age 30 or with 4 or more children, or with a higher educational level are more likely to be recruited for the oral pill Apparently they regard it as superior to whatever other protection they had tried after losing the IUD. Especially, women who lost the IUD due to a medical reasons wanted and used the pill method.

Because of these factors, (table 7) most of the acceptors (80%) belong to the age group over 30, 62% of the users were women with 4 or more Living children, and 72% were graduates of primary school and above.

Accuracy and Regularity of Use:

Prior to adding the pill for loop drop-outs to the national program it was important to find out if acceptors could learn to take the pills correctly and would take them regularly in accordance with the instructions given at the clinics.

Table 6. Overall Acceptance Rate of Oral Pill among IUD Drop-outs by the Characteristics

	No. of IUD Drop-outs	No of Oral Pill Accptors	%
Age groups			
Below 24	102	7	6.9
25—29	336	80	23.8
30—34	402	162	40.3
35—39	286	122	42.7
40 and over	136	60	44.1
Total	1,262	431	34.1
No. of Living Children			
0—2	296	60	20.3
3	281	105	37.4
4	274	110	40.1
5 and over	411	156	38.0
Total	1,262	431	34.1
Educational Level			
Less than Primary school education	407	119	29.2
Primary school education	728	257	35.3
More than primary school epucation	107	55	43.3
Total	1,262	431	34.1
Reason for IUD Drop-outs			
Medical reason	775	321	41.4
Personal reason	113	7	6.2
Accidental pregnancy	115	40	34.8
Spontaneous expulsion	259	63	24.3
Total	1,262	431	34.1

1) Starting date for the first tablet of each cycle:

The clients were usually told to start taking the pill from the 5th day of the menstrual cycle. As shown in table 8, for the first three cycles, two thirds started taking the pill on the 5th day as directed. (First cycle is less because some were instructed to start on other days). The percentage rose sharply to about (80%) in later cycles.

Table 7. Characteristics of Oral pill Users

Total Number of Acceptors	431	100.0%
1. Wife's Age		
below 19	0	—
20—24	7	1.6
25—29	80	18.6
30—34	162	37.6
35—39	122	28.3
40 or more	60	13.9
2. Duration of marriage		
(Years)— 5	44	10.2
6—10	101	23.4
11—15	130	30.2
16—20	75	17.4
21 or more	81	18.8
3. Number of living children		
0	0	—
1	20	4.6
2	40	9.3
3	105	24.4
4	110	25.5
5	82	19.0
6 or more	74	17.2
4. Educational level:		
Less than primary school	119	27.6
Primary school	257	59.6
More than primary school	55	12.8

Tardiness in starting pill use in the first three cycles may be partly due to having to return to the clinic to get each new cycle. The percent of tardy starters fell as they became familiar with taking the pills and as they received two to three-month supplies at the 4th, 6th, 9th, and 12th cycles.(See table 8).

2) Number of pills missed in each cycle:

After starting pill taking, some women used them regularly without missing, some took pills irregularly forgetting to take a number of tablets, some dropped out in the midst of a cycle, and some dropped out between cycles.

In table 9, we examined missed tablets among those women who continued to complete the cycle involved. Those who dropped out are omitted from each cycle.

The table indicates that 69% of the users in the first cycle missed no tablets. After that, the proportion of regular users increased with later cycles, from 74% to 90%. Roughly half of the women who missed actually skipped one or two tablets. When we include those women who missed only one or two tablets as regular users, 79 to 90% were regular. This is based on verbal statements and personal records on pill taking.

Table 8. Days of Delayed Starting by Each Cycle

Days of Delayed Starting	Cycle																					
	1		2		3		4		5		6		7		8		9		10		12	
LMP 5	27263.1		212	46.4	194	67.1	209	80.4	189	79.8	133	79.2	141	84.9	124	80.5	84	78.5	81	85.3	38	92.7
6	33	7.7	34	10.3	38	13.1	24	9.2	20	8.4	15	8.9	10	6.0	15	9.7	14	13.1	6	6.3	2	4.9
7	14	3.2	6	1.8	13	4.5	4	1.5	1	0.4	7	4.2	3	1.8	2	1.3	2	1.9	1	1.1	0	
8	9	2.1	12	3.6	9	3.1	6	2.3	9	3.8	6	3.6	1	0.9	4	2.6	2	1.9	3	3.0	0	
9	6	1.4	7	2.1	7	2.4	1	0.4	4	1.7	2	1.2	4	2.4	0	0	2	1.9	1	1.1	0	
10	5	1.2	4	1.2	2	0.7	2	0.8	1	0.4	1	0.6	1	0.6	1	0.6	0		0		0	
11 or more	41	9.5	16	4.9	12	4.2	8	3.1	8	3.4	3	1.7	2	1.3	3	1.9	2	1.9	2	2.1	1	2.4
Incorrect User	51	11.8	38	11.7	14	4.9	6	2.3	5	2.1	1	0.6	4	2.4	5	3.4	1	0.8	1	1.1	0	
Total	100.0		100.0		100.0		100.0		100.0		100.0		100.0		100.0		100.0		100.0		100.0	
No. of Women	431		329		289		260		237		168		166		154		107		95		41	

Table 9. Number of Missed Tablet by Each Cycle(Only for women finishing the cycles involved)

No. of missed tablet	Cycle completed											
	1	2	3	4	5	6	7	8	9	10	11	12
0 (Regular user no tablet missing)	68.6	74.2	79.9	88.9	83.4	88.6	87.7	89.1	86.0	87.9	84.0	90.2
1	6.3	7.2	8.3	2.4	3.2	3.6	1.2	3.6	5.6	5.6	6.4	7.3
2	4.5	1.7	2.7	2.4	1.8	1.2	3.1	1.4	0.9	0.0	1.1	2.4
3	1.2	3.8	2.3	1.2	1.8	0.6	1.8	0	2.8	1.8	2.1	0
4	2.1	1.0	1.5	0.4	3.2	1.2	0.6	2.2	0	0	1.1	0
5	0.9	0.3	0.4	0.4	0.9	0.6	1.2	0	0	0	0	0
6 and more	9.3	4.1	2.7	3.2	2.8	2.4	2.4	2.9	3.7	2.7	3.2	0
Unknown	6.9	7.7	2.3	1.2	1.8	1.8	1.8	0.7	0.9	0.9	2.1	
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100 0	100.0	100.0	100.0
No. of comple ting cycle	331	291	264	253	217	166	163	138	107	107	84	41
No. of Women Drop-outs	100	38	25	7	23	2	2	16		1		

Table 10. Percent distribution of the Pill drop-outs, by the number of pill taken in the last cycle and by the reasons of drop-outs

Number of pill taken	Reasons for drop-outs									
	Medical reason		Unrelated disease		Personal reason		No need protection		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
1— 6	24	41.4	22	41.5	12	17.9	7	30.4	65	32.3
7—14	10	17.2	8	15.1	8	11.9	5	21.7	31	15.4
15—20	17	29.3	13	24.5	25	37.3	5	21.7	60	29.9
21	7	12.1	10	18.9	22	32.9	6	26.2	45	22.4
Total	58	100.0	53	100.0	67	100.0	23	100.0	201	100.0

Therefore, it seems fair to state that for those women who are basic continuer, the procedure of taking a pill daily is not a major problem.

As shown in table 10, drop-outs due to medical reasons were more likely to quit during the first week of the cycle, while among drop-outs due to personal reasons termination usually occured after taking 15 or more tablets.

Medical reactions:

1) **Improvement in pre-medication symptoms:**

More than 60% of women on the oral contraceptive feel well and, indeed, lose many of the discomforts of the so-called normal menstrual cycle. Especially, improvement in dysmenorrhea was noticable as shown in table 11.

Pre-existing leukorrehea also improved after pill use, perhaps partly due to the elimination of local irritation by the IUD following its removal.

2) **Side effects:**

Some of the women on pill medication occasionally exhibited troublesome symptoms which, in a number of instances, led them to discontinue, the tablets. Side effects which may be attributable to the pill compound are nausea, vomiting, indigestion, breast tenderness, decreased lactation, breathough bleeding etc. as shown in table 11.

The incidence of such side effects was higher in the first three cycles, becoming lower in the later cycles. The high incidence of "other medical diseases" reported during the first cycle may have been due to anxiety and anticipates

Table 11. Incidence of Medical Reactions by Dycle

Cycle No. of women	1 431(%)	2 331(%)	3 291(%)	1—3 %	4—5 264(%)	6—8 217(%)	9—11 138(%)	12—14 94(%)	15 Over 41(%)	4—15** over(%)	Total (%)
Weight gain (+5 lbs)	11.4	10.9	11.0	11.1	10.0	9.2	9.4	6.4	—	7.2	9.1
Weight loss (—5 lbs)	2.1	1.8	2.7	2.2	1.5	5.1	0.7	2.1	—	1.9	2.1
Nausea vomiting	35.7	5.7	3.4	14.9	3.8	0.9	0.7	1.1	—	1.3	8.1
G.I. upset	3.7	2.4	1.0	2.4	0.8	1.8	0.7	—	—	0.7	1.6
Lactation decrease	15.8	8.5	2.1	8.8	1.9	0.9	—	—	—	0.6	4.7
Matalgia	11.4	9.7	6.9	9.3	3.4	3.2	3.6	2.1	—	2.5	5.9
Bleeding	8.6	5.1	2.4	5.4	1.5	1.8	1.4	1.1	—	1.2	3.3
Other medical disease	9.5	6.9	3.8	6.7	3.8	2.8	5.1	3.2	—	3.0	4.9
Decreased menses	36.0	14.2	6.5	18.9	3.0	2.3	—	2.1	—	1.5	10.2
Dysmenorrhea											
Appeared	1.9	1.5	0.7	1.4	1.1	1.8	—	—	2.4	1.1	1.3
Agrevated	2.1	0.6	1.7	1.5	1.1	0.9	1.4	—	—	0.7	1.1
Disappeared	17.2	6.6	3.4	9.1	1.5	0.5	1.4	—	—	0.7	4.9
Leukorrhea											
Appeared	0.9	0.9	1.4	1.1	0.8	0.9	2.2	1.1	—	1.0	1.1
Aggravated	9.5	7.6	4.1	7.1	3.0	4.1	2.9	2.1	—	2.4	4.8
Disappeared	10.0	5.1	3.4	6.2	1.1	2.8	—	—	—	0.8	3.5

*Average incidence of Medical Reactions during lst to 3rd cycle.
**Average iucidence ofMedical Reacflons during 4th to 5th Cycle.

problems by the patient as well as by the interviewer or doctor. As the confidence and experience of the client and the workers grew and a women with more trouble were selected out the incidence of side effects for minor medical reasons quickly fell to a lower level.

Drop-out: Reasons and Rates

As of December 31, 1967, there were 219 patients continuing on medication, while 212 had, for various reasons, discontinued it. Table 12 shows drop-outs according to reason and cycle.

Of the 212 drop-outs, 100 occured during the first cycle, 38 during the 2nd cycle, 25 during the 3rd cycle and so on, at a gradually decreasing rate.

1) **Medical reasons**:

As shown in Table 12, nausea and/or vomiting caused 28 drop-outs, indigestion caused 14, during 12 cycles and were the most troublesome medical factor.

Breakthrough bleeding and decreased lactation caused 5 and 7 drop-outs respectively and thus were not so serious.

2) **Personal reasons**:

The oral pill is easy to start and easy to discontinue. Thus many women stopped for temporary reasons such as separation from husband. The difficulty to get pill supply was also a problem, for example, such reasons as too far or too busy were important in terms of continued. use. (34) The charge of ₩ 40 may have been the real factor benind some of these personal reasons. "Want another bady" is surprisingly high and may have hidden other reasons: thereeore, it comes under "personal reasons" rather than "protection not needed."

3) Accidental pregnancy:

One patient, listed as "pregnant during use", i.e. accidental pregnancy, was a case who missed two tablets at the beginning of the cycle (5th and 6 th days). Her record shows a

Table 12. Number of Drop-outs by Reasons and by Cycle of Pill Use

Reason for Drop-out	Cycle											
	1	2	3	4	5	6	7	8	9	10	11	Total
1. Reaction of drug												58(27.4)
a. Nausea & vomiting	22	1	1	2	1			1				28
b. G. I. upset	10		1	1	1					1		14
c. Bleeding	4		1									5
d. Milk secretion(—)	3	2	1	1								7
e. Varicosity								2				2
f. Facial pigmentation					2							2
2. Unrelated disease	23	11	10		3		1	5				53(25.0)
3. Persenal reason												67(31.6)
a. Too far & too busy	14	6	3	1	6							34
b. No Money	2	1			2							5
c. Want another baby	6	5	5	1	2	2	1	4				26
d. Prefer IUD	1		1									2
4. Accidental pregnancy	1											1 (0.5)
5. Protection not needed												23(10.8)
a. Near menopause	1	1										2
b. Separated from husband	2	4	1				1					8
c. Died & husband died or divorced	3	3	1	1								8
d. Surgery Lost to followup	2	2			1							
6. Lost to followup	6	2			2							10 (4.7)
Total	100	38	25	7	20	2	3	16		1		212(100.0)

menstrual cycle as short 22 as days. She started pill use on the 7th day from the date of her last period, and it is speculated that this women probably conceived on the 8th day, i.e. after taking only one tablet.

4) **Cumulative discontinuation rate:**

Table 13 shows, cumulative rates of discontinuation per 100 first admissions for all types of terminations, .(Life-table method)

Monthly discontinuation rates are relatively higher during the the first three months of pill use and thereafter decline to fairly low levels. This pattern of decline is similar to studies in Baltimore(4), Chicago(5) and North Carolina(10) However, over-all discontinuation rates are much higher than in the U.S.A. (4) (5) (10) (30% at the end of 4 months of use in Baltimore).

Table 13. Cumulative Discontinuation Rate by Reasons in each Cycle per 100 Women

Cycles	Cumulative Discontinuation Rate		
	Total	Reasons	
		Medical	Other Reasons
1	26.3	10.2	16.1
2	35.3	11.1	24.2
3	41.1	12.4	28.7
4	42.7	13.7	29.0
5	47.6	15.2	32.4
6	48.1	15.2	32.9
7	49.1	15.2	33.9
8	54.5	16.9	37.6
9	54.5	16.9	37.6
10	59.0	17.7	41.3
12	59.0	17.7	41.3

Table 14. Computation of Cumulative Continuation and Disconuation Rates(First Segment)

Cycle	A	B	C	D	E	F	G	H	I
1st	431	331	100	0	381	0.2625	0.7375	0.7375	0.2625
2nd	331	291	38	2	311	0.1222	0.8778	0.6474	0.3526
3rd	291	264	25	2	277	0.0903	0.9097	0.5889	0.4114
4th	264	253	7	4	258.5	0.0271	0.9729	0.5729	0.4271
5th	253	217	20	16	235	0.0851	0.9149	0.5241	0.4759
6th	217	166	2	49	191.5	0.0104	0.9896	0.9186	0.4814
7th	166	163	3	0	164.5	0.0182	0.9818	0.5092	0.4908
8th	163	138	16	9	150.5	0.1063	0.8937	0.4551	0.5449
9th	138	107	0	31	122.5	0	1	0.4551	0.5449
10th	107	94	1	12	100.5	0.0095	0.9005	0.4098	0.5902
12th	94	41	0	53	67.5	0	1	0.4098	0.5902

A: Total No. of received by cycle B: Total No. of comqleted by cycle C: Total No: of drop-out by cycle
D: Total No. of still using by cycle E: Adjusted woman-months of use(B+C/2+D/2)
F: Monthly rate of drop-out per woman entering current cylce(C/E)
G: Monthly rate of continuation per woman entering current cylce(1—F)
H: Cumulative rate of continuation to end of crrent cycle I: Discontinuation rate to end of current cycle(1—H)
Not:e Loss to follow-up was included into drop-out.
The months of use in the cases of drop-out. loss to follow-up and on cycle were estimated half cycle of use.
The women who discontinuated after completing a given cycle were catagorized as drop-outs on the next cycle.

The reasons for this are not clear. They may be due to(1) a different method of calculation particularly in the handling of lost-to-follow up cases, (2) a different characteristics of study populations, (3) a different brand used, and (4) a different transportation facilities which improve access to the clinics. Table 14 is illustrative of the method for calculation of cumualative rates.

5) Continuation rates by personal characte-reristics:

It was thought that the continuation rate might vary by personal characteristics of the users. To examine this, we classified the users in broad groups by age, number of living children, interval between IUD drop-out and pill use, duration of IUD use. and their body weight. As shown in table 15, it developed that over age 30 women had a higher conitnuation rate than those 20 to 29 years of age. Women having four or more children tend to continue better than women having less than 4 children. A longer interval from IUD termination to pill use seemed to help continuation in the early months but faded out later. Those who had persisted with the IUD at least a year tended to persist also with the pill.

When we see the continuation rates by body weight at the first visit, we note in table 15 that in the first cycle the continuation rate was higher among the heavier patients. However, in the later cycles there is no particular relationship between the rate and their initial body weight.

Follow-up of Drop-outs

1) Interim follow-up of the first termina tors(as of Sept. 1967)

Table 16 shows the follow-up of the first admisson terminations. As of September 1967, 140 women out of the 413 women who discontinued (terminated the first admission) were revisited to find out their contraceptive status after termination.

Of the 140, 35.7% were at risk of pregnancy without using any contraceptive method. Seven had become pregnant. It is also noted in table

Table 15. Cummulative Continuation Rate by the Characteristics

Characteristics	No. of Women	Cummulative Continuation Rate by Cycles(%)					
		1	2	3	6	9	12
Age							
20—29	87	76.9	62.2	54.1	43.9	34.7	34.7
30—34	162	75.8	67.6	64.6	57.2	52.3	52.3
35+40 over	182	72.5	66.5	59.3	52.8	50.7	49.7
Living Children							
less than 4	165	68.4	63.1	51.3	40.8	38.03	8.0
4	110	80.0	72.6	68.9	64.5	61.8	60.9
5 or more //	156	73.9	68.2	63.7	55.5	50.5	48.7
Interval between IUD Drop- uts and Pill Use							
1—3 months	168	65.0	58.7	52.3	46.7	45.1	45.1
4—15 //	157	75.7	69.3	63.6	52.1	49	47.8
16 or more //	94	77.5	72.3	61.2	53.8	45.4	44.4
Duration used IUD in the Past							
1—3 months	113	74.0	65.0	58.8	48.3	45.7	44.8
4—12 //	158	71.8	67.5	55.0	49.0	45.4	44.8
13 or more //	159	75.3	69.0	66.5	59.4	54.7	54.1
Body Weight							
below 100 Lbs	81	66.9	65.8	62.2	54.9	52.5	52.5
100—114 //	203	71.3	59.6	53.8	49.6	46.3	46.3
115 or More //	147	80.6	70.7	63.8	54.3	47.4	46.7

16, that 54 or 39% had utillized some type of contraception, as follows; 33 used traditional methods such as the condom, 5 had intra-uterine devices reinserted,and 16 restarted on the oral pill.

2) **Total retaking after first termination**(as of December 1967);

By the end of this study or as of December 1967, 35 women had re-started taking oral pills. 22 out of these 35 returned to the clinic after one month of nontaking, five women after two months and the rest(8 cases) beyond two months (Table 17).

Thus it seems that women who want to use pills again most of them started within two months after terminating the first segment.

When the retaking group was added to the first segment the continuation rate goes up to about 5% more than the first segment rate (See taale 18).

Table 16. Subsequent Status of Drop-outs of Oral Pill

Subseouent status	As of Sept. 1967	
	Number	%
a. Women become pregnant	7	5.0
b. No. at risk of pregnancy	50	35.7
c. No need protection	8	5.7
d. Reinsertion of IUD	5	3.6
e. Using traditional method	33	23.6
f. Retaking oral dill	16	11.4
g. Not contacted	21	15.0
Total	140	100.0

Table 17. Interval between Termination of Oral Pill and Retaking

Interval months	No. of Retaking	Per Cent
1	22	62.9
2	5	14.3
3	4	11.4
4	2	5.7
5	—	—
6	—	—
7	1	2.9
8	—	—
9 & over	1	2.9
Total	35	100.0

Table 18. Computation of Cumulative Rates of Continuation(All Segment)

Ordinal month	All Segment	First Segment Ooly
1lst	0.7890	0.7375
2nd	0.6918	0.6474
3rd	0.6578	0.5889
4th	0.6472	0.5729
5th	0.5730	0.5241
6th	0.5684	0.5189
7th	0.5475	0.5092
8th	0.5014	0.4551
9th	0.5914	0.4551
10th	0.5014	0.4098
11th	0.4668	0.4098
12th	0.4668	0.4098

*Note: Computation was based on Dr. Tietze's. "Recommended Procedures for the Computation of Net Cunulative Event and Closure Rates Based on All Segment." However those women who restarted the pills are considered to be continuous users since the first acceptance including any periods of non-use between segment. Final termination is at the end of final segment or at interview.

Summary

During a period of about one year(November '66 to December '67), the Yonsei University College of Medicine conducted a field trial of the oral contraceptive(Ovulen) in order to study its acceptability and use-effectiveness among IUD drop-outs in Koyang county. We can summarize the outstanding findings from this investigation as follows;

1. 61.4% of the IUD drop-outs interviewed (911 women) wanted to use the pill. Most of the reasons for not wanting to use it(352 women) pertained to either use of other contraceptive methods(98) or subfecundity(150) following IUD terminations. Only 83 out of 911 women gave reasons related to the difficulty of obtaining pills. Therefore, we can state that most IUD drop-outs if still in need of a contraceptive methods are in favor of trying the pill, and especially so if this method is conveniently available.

2. The 467 women or 37% of those who terminated IUD use actually visited the clinic for medical screening, and only 11 of them or 2.4% were rejected because of pregnancy and other medical reasons such as cervical erosion, myoma, breast mass, etc. 5.5% or 25 of the 456 women who received the first cycle did not take a single pill during the study period.

3. When we defined those 431 women who accepted and took one or more tablets we found that women over age 30, with 4 or more children, and/or with a higher educational level were the best prospects for recruitment.

4. In accuracy of use, about two thirds of the users started taking the pill on the 5 th day as directed for the first three cycles, but the percentages rose sharply to about 80% in later cycles. Tardiness in starting pill use in the first cycle may have occurred partly because they had to return to the clinic monthly to get each new cycle. Among acceptors who did not quit between cycles, 80 to 90% were regular users, missing two or less tablets in each cycle.

5) More than 60% of the users felt well and sometimes lost their pre-acceptance symptoms, especially dysmenorrhea. However, 27.4%(58 women) had side effects attributable to the pill compund as nausea, vomiting, indigestion, breast tenderness, decreased lactation or breakt-

hrough bleeding.

25.0%(53 women) also complained of medical diseases or symptoms not related to the pill, especially during the first three cycles. However, as the confidence and experience of the client and the field workers grew, the incidence of unrelated medical complaints quickly fell to a lower level in the later cycles.

6. As of the end of this study, on December 31, 1967, 49.2%(212 women) had discontinued the use of the pill for medical reasons as well as for the non medical reasons. Only one case terminated use due to a pregnancy after taking pills.

The cumulative continuation rates (by the life table method), were 58.9%, 51.9%, 41.0% at the end of 3 months, 6 months and one year, respectively. These rates are lower than in the U.S. studies. Even when we add the retaking group to the first segment, the continuation rate goes up only about 5% above the first segment rates mentioned above.

Possible explanations are different dosages, the newerness of the method and the use of only one point for pill distribution in the country together with a monthly return for cycle 1, 2, 3, and 4–6.

Action Implications

This study was undertaken not only to study the acceptability and effectiveness of the oral pill but also to gain experience that might be a useful reference in setting up the technical and administrative policies for adding the pill service to the national program. Based on this one-year study, we may present comments on the following questions:

a. What problems were encountered in client recruitment and in payment of fees?
b. What follow-up methods were used in the project, and what were the results?
c. What educative and informational methods and materials were used? How effective were they?
d. What forms and records were tested and what system of record-keeping and **reporting was** found **to** be best?
e. What was the effect on the "work load of" the staff and what administrative problems were encountered in this study?
f. What was the effect if any of the pill program on the loop program? For example, did women who were not eligible for the pill ask to try it? Did the pill increase the loop drop-out rate? Or reduce the acceptance rate?

a) Cost: Payment of 40 won or 15 U.S. cents per cycle is considered to be a reasonable fee for most of the clients. However, to obtain their monthly supply some clients often pay for the bus (about 40 won round trip) and or lunch (about 100 won) because of the distance invloved from the village to the clinic.

This meant that one cycle cost them about 180 to 200 won, which amount is about equivalent to the price for commercial pills. Therefore, it is re-commended that return visits be minimized. Following the first return visit(after taking the first cycle), which is mandatory to discuss difficulties met by the clients, a two or three months supply could be given. For the later cycles, supply depots might even be set up at the village level, and be main-tained by utilizing mothers' classes Leaders, village chiefs or local private practioners.

A policy of free supply to indigent clients means little to women of childbearing age, as the current Ministry of Health criterion for indigent refers to those who are more than 60 years old and have no guardian to provide their subsistence. Therefore, it is recommended that instead, the F.P. workers and or physicians might be given authority to use 10% to 20% of the pill supply for discretionary use, among wives known to be indigent or temporarily unable

to pay.

A mail delivery system may also be explored (as in Taiwan) to save the client's transportation cost, especially in semi-urbanized rural areas.

b) Follow-up method:

In this study project, mail and home visits were used to follow-up clients who failed to come in as scheduled. A mailing went to those woman who did not make a return visit one week or more after the scheduled day. If they responded to the mailing, it saved a home visit. 73% so responded.

We found that if women were unresponsive to the mailing, they were usually unresponsive to the home visit as well. Therefore, both mailing and home visit are not necessary unless the purpose of home visiting is to check their use status.

Reminding the women by mail seems to have improved the return rate by about 15 percentage points(total line, table 19).

In mailing a reminder card, however, it is important to ask the clients at the first visits whether they wish to receive reminder. A number of women were embarassed to receive such mail from the Health Center,particularly those who came without the consent of the mother-in-law.

In case of local village women are used as supply depots, simple follow-up or inventory sheets should be provided in order to record supply data, the scheduled dates of return visit date of drpo-out and reasons for drop-ou if known.

c) Educative and informational methods and materials:

In this study, the educational materials used were;

1. Instructions on how to take the pills
2. A leaflet on possible side effects in the early stage of pill-taking, with suggested treatment.
3. Record-keeping cards for recording daily pill use and date of menses

However, the verbal explanation by the field worker and physician is of the utmost importance for imparting confidence and preventing disillusionment due to unexpected side effects.

Repeating this sort of careful explanation is particularly effective after the women have had some experience with the pill.

d. Recerd forms:

Among the record forms found useful in this study were:

(1) Medical and follow-up record, (2) Tickler card for the next clinic visit, (3) Reminder card, and (4) Registration card. The space for the client to record daily pill use and menses in the registration card is optional as the clients are not accustomed to do this correctly and consistently.

e. work-load:

As clear from this study adding the oral contraceptive to the national problsm as an alternative method for wives who could not tolerate or retain a loop will increase the workload of all concerned. The field worker in particular will have to spend a considerable amount of her time in recruiting and providing follow-up services if she is to achieve her monthly target and a satisfactory continuation rate among acceptors. Obbiously, also, she will have the added problem of maintaining an adequate pill supply plus an increased burden of paper work. The plan to charge a service fee will further add to her administrative duties.

Fortunately, with foreign assistance, introduction of the pill will be accompanies by effort to reduce the workload on field workers serving in rural areas.

This effort by the government in cooperation with PPFK will consist of employing and training one person who will be stationed in each rural health center for the specific purposes of helping the workers administer the pill problem and

organize mhthers' classes. Mothers' classes, have proving most helpful to workers in promoting the small family concept and recruiting FP practices. Following termination of foreign assistance the government hopes to continue the above activities with funds from the service fee.

f) Effect of the pill program on the IUD program:

During one period, from May to August 1967 when the pill was offered to all IUD drop-outs regardless of the Interval since termination, recent drop-outs dominated among those coming to the clinic to obtain the pill. In table 19, we note that 75 out of 172 acceptors started pill use less than a month after IUD drop-out. It is interesting that more than half of those 75 women had used the IUD one year or more before terminating it. This suggests that some relatively long-term users shifted to the pill as it became available to them. Therefore, some women apparently did purposefully terminate the IUD when the pill is offered to all IUD drop-outs without regard to time since termination.

On the other hand, when the pills were given only to those women who had terminated the IUD at least 5 months before, some difficulty was experienced in recruiting clients. Furthermore the preblem was how to protect them from the risk of pregnancy during the waiting period. (Condoms and other methods are satisfactory only for some.)

Therefore, the limitation of the pill to certain sub-classes of IUD drop-outs should carefully be weighed, taking into account the advantages mentioned below:

As advantages of limiting eligility to those who dropped out at least 3 months before;

1. This may prevent an unnecessary removal or termination of the IUD.
2. This may give a chance to the administration programmer to estimate the number of women eligible for the pill, through knowing how many IUD users had terminated in the area.
3. A waiting period gives the couple a practice other methods such as the condom, so that they cancompare different methods through trial and error. This may, in turn give more confidence for the method finally chosen.

Disapvantages of a 3 months limitation would be;

1. Women are exposed to a high risk of pregnancy, in the first couple of months following IUD termination they are usually be highly fertile.
2. During such a waiting period, women may lose interest and may totally give up the practice of family planning as their motivation subsides.
3. A return visit for pill screening is necessary for the pelvic examination. It would not be necessary in removal cases if they could receive the pill at the same time.
4. To become eligible for the pill program, some unsatisfied IUD wearer will deliberately terminate the IUD anyway.

Taking all the above into account, it seems best to provide the pill on a priority basis as follows:

In the earler stage of the program:

1. First priority: those who had used the'loop more than 6 months, and terminated it more than 2 months before the pill program began. (We found that longer loop use was followed by longer pill use).
2. Next, those who had used the loop more than three months, and terminated it more than 2 months before the pill program began, who also have 4 or more children.
3. Those who terminatal pregnacy, as they may have lost their interest in IUD reinsertion.
4. Those with repeated expulsions of the loop.
5. Those who had removals due to sevre bleeding complications.
6. Those who had removals due to pain.

In the later stage of the program, when the population is more aware of the advantages as disadvantages of both IUD and pill, the pill could be provided without a waiting period to IUD drop-outs who had worn the loop more than 3 months.

Ultimately, the pill might eventually be offered to everyone as one metod in the usual cafeteria approach Such a transition would be determined subject to continous evlauation of the ab-going pill program and to the availability or enough pill supplies to meet such a need.

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