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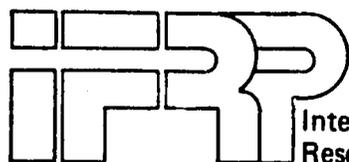
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**THE SRI LANKA
ORAL CONTRACEPTIVE AND VITAMIN STUDY**

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FINAL REPORT

June 1982



**International Fertility Research Program
Research Triangle Park, NC 27709 USA**

INTERNATIONAL FERTILITY RESEARCH PROGRAM

The Sri Lanka Oral Contraceptive and Vitamin Study

Final Report

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I. INTRODUCTION

A. Scope of the Study

The Sri Lanka Oral Contraceptives and Vitamin Study was designed to address three issues:

- (1) whether currently used oral contraceptives with estrogen doses of the order of 50 micrograms and progestagen doses of the order of 1 milligram, should be replaced in Sri Lanka and other developing countries by lower-dose preparations;
- (2) whether a multivitamin tablet taken daily in conjunction with the oral contraceptives will reduce side effects associated with the latter, and increase contraceptive continuation rates; and
- (3) whether a recruitment and delivery system involving use of young village women with moderate education and limited training, functioning from a clinic base as house-to-house motivators and suppliers, can be a successful and cost-effective mechanism for family planning service delivery.

The first two issues were addressed through three double blind clinical trials conducted in three different sites in Sri Lanka. These trials involved four treatment combinations: Norinyl, a "standard-dose" oral contraceptive, with a daily multivitamin

supplement; Norinyl with a placebo; Brevicon, a "low-dose" OC, with the vitamin supplement; and Brevicon with placebo. The third issue was addressed by setting up the proposed delivery system in two of the three clinical trial sites, and evaluating through a combination of service records and general population surveys.

These activities were carried out between 1978 and 1981 by the Family Planning Association (FPA) of Sri Lanka, a private non-profit organization. Administrative and technical monitoring was provided by the International Fertility Research Program (IFRP) under contract AID/pha-C-1191 with the United States Agency for International Development. The FPA, in turn, was funded through a subcontract with IFRP.

Three additional activities not specifically designed to address the three questions listed above were conducted during the contract period. These were: a study of the acceptability of the IUD in Sri Lanka; a test of young village women as field motivators in the context of a commercial retail sales program; and the production of a body of educational and promotional materials on population and family planning for use by the FPA in its programs.

The present report will cover all activities carried out under contract AID/pha-C-1191.

B. A Brief Historical Summary

The Sri Lanka OC/Vitamin Study had its origins in discussions between Dr. Gary Merritt of USAID and Mr. Daya Abeywickrema, Executive Director of the FPA/SL, in 1976. A brief outline of the proposed study by Dr. Merritt in July 1976 provided the basis for subsequent discussions. The basic features of the study were established early. There was to be a clinical trial in three sites, one urban and two rural, involving the four treatment combinations eventually used; for the two rural sites the clinical trials were to be established within a community distribution system which was to have research interest of its own as a mechanism to provide family planning services. Also at an early time, the IFRP was brought into the study as the direct contractor and monitor, to ensure proper implementation of the study and to analyze and disseminate results.

The study was to be started by October 1977, and the initial contract between USAID and IFRP was signed in August 1977, but a series of unforeseen difficulties served to delay implementation substantially. The most serious of these involved the procurement of the test supplies. The study design required the four treatments to be identical in appearance and packaging; this involved considerable time on the part of Syntex Laboratories, Inc., which provided the oral contraceptives, and Hoffman LaRoche, Inc., which provided the vitamin supplements. As a result of this and other difficulties, the study treatments did not arrive in Sri Lanka until November 1978. Meanwhile, the FPA

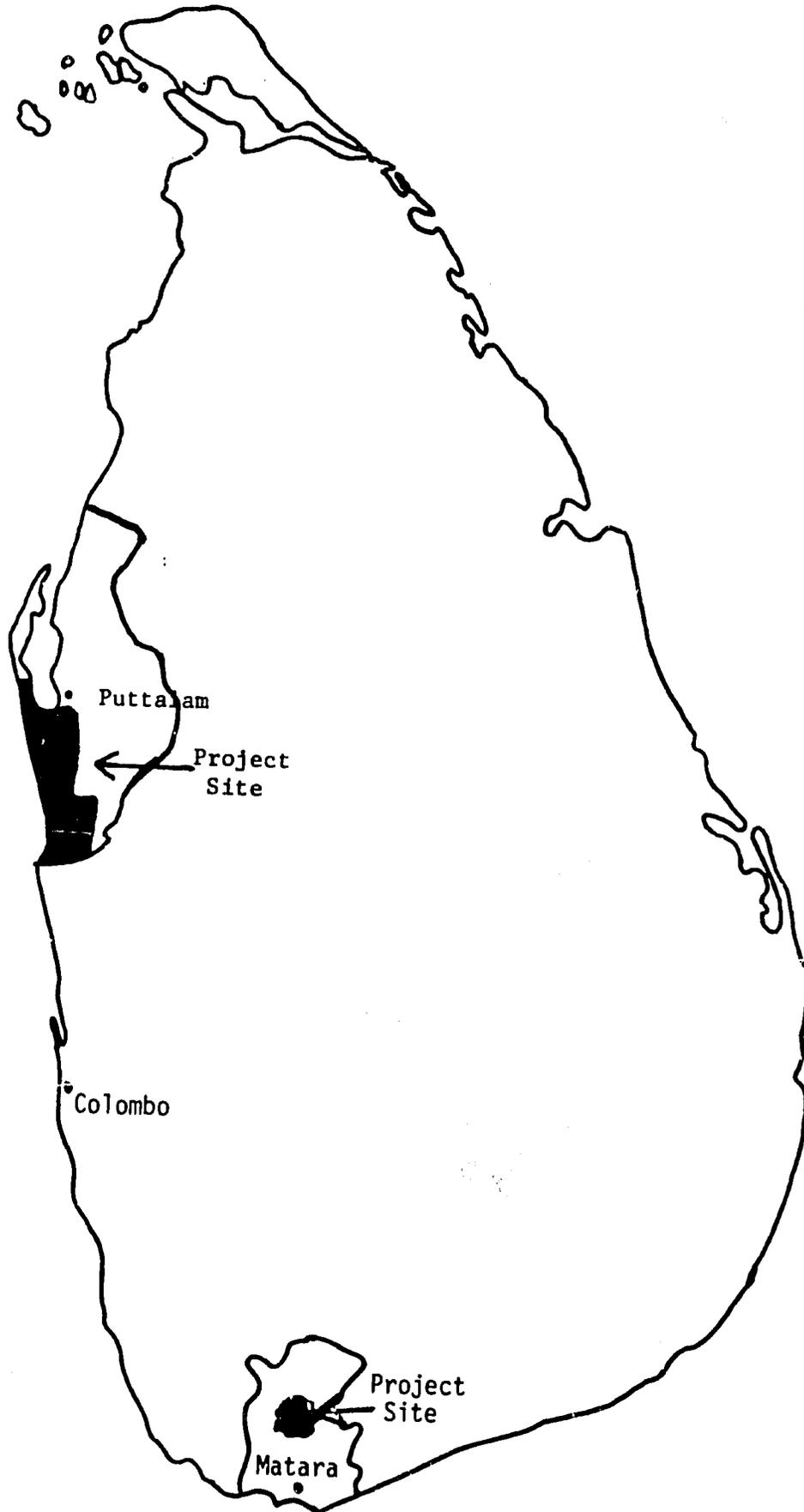
had chosen two rural areas in the districts of Matara in the South and Vavuniya in the North, as study areas. They were both underserved rural areas which differed substantially in ethnic and geographic character. However, ethnic disturbances in Vavuniya in 1978 made that area untenable as a research site, so part of another district, Puttalam, along the Northwest coast, was substituted, but activities there did not begin until eight months after they had started in Matara. Figure 1 locates the three study sites on a map of Sri Lanka.

More generally, it now appears that for a variety of reasons the original timetable was unrealistic. The requirement of coordination and cooperation with such a large number of different agencies--private and government, in the US and in Sri Lanka--made it impossible to implement the contract immediately after signature.

The delay in starting the study allowed time for developing and refining the work plan and other preparations for the study. Using standard IFRP clinical trial systems as a base, study forms were developed for both the urban and rural phases, and the precise designs of both the clinical trial and distribution system aspects of the project were elaborated. The Work Plan of January 1978 provided the foundation for implementation.

During the period between development of the original design and the start of project implementation, a number of decisions were made jointly by the FPA, IFRP and USAID which changed

Figure 1. Map of Sri Lanka, Showing Project Sites



substantially the nature of the clinic-based distribution system in the rural sites. These changes will be discussed in Section IV. Basically, they led to larger areas being covered with less input and a narrower range of services than the original design had envisioned. The design actually implemented, however, did not change substantially during the life of the project.

The three sites did not begin activities simultaneously. The first site to begin operations was Marowak Korale West, an Assistant Government Agent Division (sub-District) in the District of Matara, in October 1978. Since the Brevicon was not yet available, clients were offered standard Norinyl pills, with a vitamin/placebo supplement, in a special sub-area of the project area,* along with condoms and referrals for other methods. During the last quarter of 1978, 132 women accepted Norinyl in this area. In January 1979, the four-cell clinical trial began in the remainder of the Project Area, with the "Norinyl only" area continuing to be served as before.

The urban study also started in January 1979 with the availability of the Brevicon. In Puttalam, however, the late change of site from Vavuniya meant that the project did not begin

*The feature of the "Norinyl only" area was an attempt to determine the acceptability of vitamin supplements, as opposed to their pharmacological effect, in the rural areas. Various early versions of the project design had different approaches to testing this question; when it was known that the Brevicon shipments would be delayed, it was decided to start "norinyl only" clients in a separate area prior to initiation of the clinical trial. See Section III for more detailed elaboration of this design feature.

recruitment until June 1979, with the "Norinyl only" area starting simultaneously with the four-cell clinical trial area.

A target of 500 acceptors for the urban study had been established at an early date. The 500th acceptor was recruited in January 1979, and since follow-up was limited to one year in the urban study, it was clear that that study would end data collection about January 1980.

Meanwhile, two baseline population surveys were undertaken to determine the characteristics of the two rural sites and the knowledge, attitudes, and practices regarding contraception. The Matara survey was conducted in September 1978, one month prior to initiation of activities there; the Puttalam survey was done in March 1979, three months prior to the start of services.

With minor adjustments in personnel and procedures, the project proceeded as expected thereafter, with occasional monitoring visits conducted by IFRP and USAID personnel. However, the delays in initiating the study led to a request for a no-cost extension of the contract to allow sufficient time for completion of the trials and for data processing and analysis. Hence the termination date was extended from March 31, 1980, to June 30, 1981.

Meanwhile, a variety of changes were made in the personnel involved in the study. At IFRP, primary responsibility was shifted over the study period from Mr. Michael Thomas to Dr. Peter Donaldson to Mr. Peter Miller. At USAID, Dr. Merritt left the Washington office and was replaced as monitor by

Ms. Marnie Chen. These changes have led to shifts in emphasis and to some lack of continuity in the execution of the original design. At the FPA, however, the key personnel remained constant. Mr. Abeywickrema was Director; Dr. Sriani Basnayake, Medical Director, was responsible for the Colombo study; and Mr. Victor de Silva, Director of Evaluation and Research, was responsible for the rural study. As a result, procedures in the three study sites remained quite constant throughout the study.

During a visit by Donaldson and Miller to Sri Lanka shortly after approval of the first contract extension, it was decided to terminate the rural clinical trial data collection as of August 15, 1980, and to terminate the field work for the rural distribution system on December 31, 1980. At the same time, the post-project population surveys were scheduled in Matara and Puttalam for December 1980 and January 1981, respectively. These schedules were met.

Data for the various aspects of the project were sent to IFRP between September 1980 and April 1981. Since most of the forms were not directly compatible with existing IFRP processing systems, a variety of new loading and editing systems needed to be developed. This was done in late 1980 and early 1981. Preliminary analysis led to queries regarding the detailed implementation of the study, and modifications were necessary in some of the original plans. By June 1981, the data were prepared for analysis and basic tabulations had been completed. An additional no-cost extension was granted until February 28, 1982, to allow

for the completion of analysis and for the publication and dissemination of information.

Towards the end of the study, a number of ancillary activities were undertaken. As an extension of the distribution system experiment, a small-scale experiment involving the use of home visitors to help establish village-level demand for services was initiated in March 1981. A follow-up survey of rural clients reported to be still using oral contraceptives as of the end of 1980 was conducted in April 1981, to determine the effect of the loss of one source of supply on the women's contraceptive behavior. In July 1980, the Government of Sri Lanka asked the FPA to investigate the reasons for the national decline in acceptance of the IUD, in light of FPA experience in this area. As a result, ten different classes of providers and two categories of consumers answered over a thousand questionnaires in the Fall of 1980. The results were released by the FPA in March 1981, and published by the Government of Sri Lanka in April. Finally, the FPA is producing a series of educational and motivational materials on family planning for use in its programs, to be completed by September 30, 1981. Figure 2 summarizes the timing of all these activities.

In summary, contract AID/pha-C-1191 funded a complex, ambitious design involving a variety of agencies, study sites, designs, and areas of investigation. In spite of a variety of difficulties, the clinical trial aspect of the contract was implemented as

planned, and has yielded a large amount of high-quality data; the distribution system was successfully established and tested, although in somewhat altered form; and, as is common in such situations, there have been a variety of unanticipated benefits.

C. Summary of Results

1. Findings from the Clinical Trial

- a. Vitamin/Placebo Comparisons. The lack of effect of the vitamin supplements in all areas of investigation is consistent and striking. If there appears to be a slight tendency, overall, for vitamin supplements to be associated with fewer side effects, that tendency is neither substantial nor statistically significant, and is offset by the small, nonsignificant tendency for placebos to be associated with higher continuation rates. This conclusion is consistent across all three sites, and is highly unlikely to have been influenced by either provider or client bias. The quantity and quality of information is sufficient to justify a firm conclusion on this topic: in the population studied, the provision of a daily multi-vitamin supplement, taken in conjunction with either of two types of oral contraceptives, made no difference in either continuation or side effects associated with oral contraceptive use.
- b. Brevicon/Norinyl Comparisons. There are clear differences in side effects reported in the urban study

between Brevicon and Norinyl, and those differences are consistent with reasonable biological hypotheses and with other empirical data. Brevicon is associated with higher levels of breakthrough bleeding, and Norinyl is associated with higher levels of most other common side effects, with the notable exceptions of nausea and vomiting. Rural data were less conclusive as a result of the design of the study, but there did seem to be more complaints of menstrual side effects among Brevicon users in both Matara and Puttalam.

Final determination on comparative continuation rates cannot be made. There is a large, highly significant difference in the urban study in favor of Norinyl, but in terms of reported reasons for discontinuation this is entirely accounted for by differences in termination due to "personal reasons," "moved from area" and "lost to follow-up." It seems very unlikely that these results could have occurred by chance. In part, they are probably due to differences in the effectiveness of the two principal home visitors. The hypothesis that women actually discontinuing because of method dissatisfaction were reported to have terminated for "unrelated" reasons, and that this process occurred more frequently with Brevicon users, is unsubstantiated. Results from the rural sites show somewhat higher continuation for Norinyl at 12 months, but not necessarily earlier.

In sum, we are inclined to believe that most, if not all, of the observed difference in continuation rates between Norinyl and Brevicon in the urban study is due to a bias in field procedures, and that little or no difference can be ascribed to the pharmacology of the contraceptives.

- c. General Reactions to Oral Contraception. Levels of reported side effects were compared with a previous Sri Lanka study and with a US study, both of which used comparable methodology. Levels obtained in the previous Sri Lanka study were generally confirmed. Overall, the general levels of reports were somewhat lower than US data, and there were some striking differences for certain symptoms. Sri Lanka women reported more headache and far more dizziness; US women reported far greater levels of breakthrough bleeding, breast discomfort, abdominal bloating, change in acne, increased sexual desire, depression, rashes and vaginal itching.

For both Norinyl and Brevicon users, a cluster of four reported first-cycle side effects--nausea, vomiting, headache, and dizziness--tended to be highly correlated with each other, and to be strongly predictive of later discontinuation. Menstrual side effects were not highly correlated with other side effects, and were not as strongly predictive of discontinuation, for either drug.

These results would seem to have considerable clinical importance.

- d. Pharmacologic vs Programmatic Effects of Contraceptive Use. On the whole, differences in continuation rates among study treatments were far smaller than overall differences between study sites. In addition, in the rural areas differences between study treatments are far smaller than differences between the clinical trial areas and the "Norinyl only" areas, which appear to be due to some rather subtle differences in program execution. Finally, in the urban study, a major difference in continuation rates seems to be associated with the identity of the home visitor, even for women who were expected to return to the clinic for follow-up. The lesson is not new, but is nicely illustrated here: differences in procedures are likely to have far more effect on program effectiveness than minor differences in contraceptive method technology.

2. Findings Regarding the Distribution of Contraceptives

- a. The contraceptive distribution systems in Matara and Puttalam did not achieve sufficient coverage to have important impact on the population served. This was due to insufficient staff, which in turn was due to inadequate planning and failure to detect the problem early,

rather than to lack of effort or competence on the part of the field staff.

- b. Young village women with modest education and minimal medical training can serve effectively as home visitors for contraceptive distribution in Sri Lanka. They had no difficulty getting around or operating alone in strange villages. They were accepted in the community, and were able to induce a high proportion of the eligible women they visited to accept modern contraception.
- c. The distribution system was not particularly cost-effective, in spite of careful cost control on the part of the FPA. In part this was due to the research requirements of the study, and in part to the practical limitations on available methods. But to a considerable extent, the high costs per user reflect the considerable amounts of time required to travel each day to the site of the day's work, and to travel between houses.
- d. As in the national program, this study found an apparent discrepancy between the stated interest in small families and general approval of contraception on the one hand, and relatively low continuation and limited use on the other. This study found that acceptability of both the pill and the IUD are limited in Sri Lanka by strong reaction to and fear of side effects associated with these methods.

II. THE SETTING

A. The Urban Study

1. The Family Planning Association

The Family Planning Association of Sri Lanka (FPA/SL) is the oldest family planning organization in Sri Lanka (established 1953), and one of the world's oldest as well. It remains the largest in the private sector. It is an affiliate of the International Planned Parenthood Federation, and its core funding is through the IPPF, although it obtains funds from other sources as well. It is independent of the Government of Sri Lanka, although relations are good, and conscious efforts are made to avoid duplication of effort. The Executive Director of the FPA is on the Management Advisory Committee of the Family Health Bureau, the agency charged with implementing the government's family planning program. Most new FPA projects must be approved by the Ministry of Plan Implementation, whose Secretary is instrumental in providing direction to the national program. Hence FPA activities, while formally independent of the government, are planned to complement government activities.

The FPA headquarters is in Colombo, the capital city, in a largely residential area. The headquarters is also the site of the Colombo clinic of the FPA, its largest. The FPA provides a variety of services, emphasizing more effective

spacing methods such as pills (Norinyl), IUDs (Lippes Loop), and injectables (Depo-Provera), along with male and female sterilization. FPA acceptors are a small fraction of the government's program, but on an absolute basis, it remains a sizable program; total acceptors in 1980 came to 14,586 for all methods combined, or 9.5 percent of the national total. The Colombo clinic also provides infertility and sex counselling services on a regular basis.

Research is also a standard component of the FPA's programme. There is a full-time Director of Research and Evaluation, with staff, and the Medical services personnel also have a tradition of doing self-motivated research. For example, during 1981 the FPA produced research studies on the effect of incentives on the Government's vasectomy program, on the return to fertility after discontinuation of Depo-Provera, and on menstrual bleeding patterns associated with Depo-Provera use. Each of these was done solely on FPA funds and initiative, and each is being prepared for publication in international journals. Of particular relevance to this contract is the work done under what is known at the FPA as "The Goldzieher Study" (USAID contract PHA-C-73-32), a comparative trial of Norinyl, Ovral and the IUD undertaken to determine levels of biological and nutritional effects of pill usage. This project provided the FPA with valuable experience needed to carry out the current contract.

The Colombo clinic of the FPA serves the city of Colombo and its immediate suburbs. The clientele are generally in the lower to middle classes, depending partly on the nature of the service. For example, less than half of a recent sample of FPA vasectomy acceptors had been to school beyond the ninth grade, and more than half reported monthly incomes of less than \$US 32.50.

2. The Study Clientele

Part of the rationale for the clinical trial was that vitamin supplements, if useful, would be particularly so for women of poor nutritional status. Hence it was decided to concentrate client recruitment in Colombo on residents of slum areas. In Colombo, such areas are not clearly defined, nor are there one or two dominant slums with vast populations of the type that characterize some Asian capitals. This is partly because Colombo is rather small, both in absolute size (about 650,000) and as a proportion of the total national population. Colombo does not dominate Sri Lanka as, say, Bangkok dominates Thailand or Manila dominates the Philippines; both its economic power and its misery are on a somewhat smaller scale. No one can say exactly what proportion of the city lives in conditions which can be described as slums, but some FPA employees estimate it at about half. These are spread about town in small to medium-size pockets.

It was in these pockets that the FPA sought its clientele for this study. Aside from the medical criteria, it was not necessary that a specific acceptor be malnourished, or meet some specified requirements of poverty. As it turned out, women who entered the FPA study tended to be better off than most women in their neighborhoods, and at least in terms of education, better off than the 1975 WFS sample in Colombo. Our study population does not represent a middle class. Rather, it appears that many of our study acceptors were slum dwellers actively working to improve their condition, to whom family planning represented one part of that task. Nevertheless, it is not clear that their nutritional status was particularly poor, at least by Sri Lanka standards.

The study took place during a period of rapid economic change in Colombo. The 1977 election swept the United National Party (UNP), a pluralist, capitalist party, into overwhelming dominance, after nearly 20 years of increasingly nationalist and socialist policies. The UNP vigorously promoted private enterprise, both local and foreign, and the economy responded with unprecedented growth and high inflation. In addition, many Colombo folk, from household servants to skilled workers, found employment in the Middle East, which provided considerable incomes to relatives in Colombo and extra spaces in the local job market. The government also reduced sharply the extensive welfare structure, thus removing much of the cushion separating the poor from extreme deprivation. The

results, for the Colombo poor, were mixed. For some, the economic boom afforded an escape. For others, inflation coupled with reduced welfare benefits made life even harder.

3. Lives: Better and Worse

The IFRP Project Monitor spent a day in February 1981 visiting former project clients in the company of two project nurses. The variety of different directions clients' lives had taken was striking. For several, life was definitely looking up. Three had relatives in the Middle East, and were plump and prosperous, though still living in the same places. (Of the 500 urban study acceptors, at least 20 left the study when they or their husbands went to the Middle East.) One had just returned from the jungles near Trincomalee, where she had made a good deal of extra cash serving as an extra in the Bo Derek version of "Tarzan." That money was to go into expanding a small fruit stand she and her husband ran. Another woman's husband had recently, for the first time in many years, found steady work as a security guard. The extra money was just enough to send their only child, a 5-year-old boy, to Montessori school.

Others seemed to be making do, neither better nor worse off than before. But for three women, life hung on a rather precarious thread. One we did not see. Her husband had recently died--the nurses said he was dreadfully malnourished--and she had left with her five children to stay

with her father, a poor farmer across the island. The husband of another woman was in and out of jail; when out, as he now was, he earned little and spent much of what he earned on himself. She and her four living children (two others had died) lived in a nearly roofless shack on the outskirts of town, and survived largely on the charity of their neighbors. A third woman was pregnant with her third child--she was 21--and was seriously emaciated. She weighed 38 kilograms on admission to the study, but could not have weighed as much when we saw her. She was unable to converse effectively with the nurses--her sister, only slightly better off than herself, spoke for her. Her husband was said to be similarly incompetent. For these women, it seemed, there was little chance that things would get much better.

4. Alternative Sources of Contraceptives

Our discussions with the Colombo clients also confirmed that family planning has become an open topic of common conversation in this community. Most of our talks were held in gatherings of perhaps 5 to 20 people, including men and children as well as women, and there was no hesitation in speaking about personal contraceptive histories or the pros and cons of particular methods. Many women had used several methods, and had come to varying conclusions about which was best. This openness is a relatively new development in Sri Lanka, and is not so visible in the rural areas.

Part of the reason is the wide availability of choice. In addition to the FPA program, contraceptives (mostly condoms and pills) are sold in pharmacies, and more important, the City of Colombo has a vigorous distribution program through municipal midwives. In fact, a major problem in recruiting clients for our study was the competition from these municipal midwives, who were very effective in promoting oral contraceptives. In any case, the urban program operated in a context of wide availability of a variety of methods, and considerable public discussion and use.

B. Matara and Puttalam

The original study concept involved provision of contraceptives to two poor, underserved rural areas. It was understood that this should reflect, as far as possible, the geographic and ethnic diversity of the country. A natural start was to look for one "wet zone" Sinhalese area in the South, and one "dry zone" Tamil area in the North. The area around Morowaka, in the Southern district of Matara, seemed ideal. It is in many ways an archetypical wet zone area: lush, hilly country, a combination of individual rice farming and collective tea estates, a majority of Sinhalese Buddhists with a substantial minority of India Tamils. The second area was to be in Vavuniya District in the North, a dry, sparsely populated area with a rough balance between Sinhalese and Sri Lanka Tamils. However, communal disturbances in 1977 made it at least temporarily impossible to work in Tamil areas, and future prospects were uncertain. Hence the

decision was made to work instead near Puttalam town, in Puttalam District. While including a modest proportion of Sri Lanka Tamils, this area included two other important minorities-- Muslims and Roman Catholics, each of which comprises somewhat under ten percent of Sri Lanka's population.

While the absence of a major Sri Lanka Tamil population is a drawback, the areas in other respects represent rural Sri Lanka rather well. They are poor, rural, underserved, and present substantial difficulties of logistics and terrain. They present a fair sample of the problems of service delivery in difficult areas of Sri Lanka.

1. Matara

The site of the study was an A.G.A. (Assistant Government Agent) District known as Morowak Korale West, in the interior of the District about an hour's drive North of Matara, the District capital. The project area included all of the Division except the town of Morowaka, a total population estimated in 1978 at 82,500. The project area is about 120 square miles, so the density was around 700 persons per square mile. This population is rather evenly spread over a green, rugged terrain. The population is mainly agricultural; paddy rice is the primary crop, but there are numerous tea estates which dot the hillsides.

Prior to the beginning of service delivery activities, a sample survey was carried out among households in the

district in order to ascertain the level of contraceptive use and to provide some measure of fertility. A complete report of this survey has already been circulated by the Family Planning Association. Thus, it is necessary only to outline the key findings of that survey.

The survey provided ample evidence of the appropriateness of Matara as a study site for a project to investigate the distribution and impact of oral contraceptives on a poor, rural district in Sri Lanka. Rates of female labor force participation, widely regarded as a key determinant of contraceptive use and fertility behavior, were low. Only 4.5% of women worked outside the home.

Most of the men in the area are employed in the agricultural sector with only 8 professional, technical or kindred workers in the sample. This accurately reflects the labor force composition of the area which is heavily weighted toward the agricultural sector. The traditional character of the region is apparent by the fact that nearly 80% of those interviewed were born in the district. Over 85 percent were Buddhist and Sinhalese, but 11 percent were Hindu (ethnically, India Tamil) compared with only 3 percent in Matara District as a whole. The Tamils were primarily tea estate workers. 70% had less than 6 years of schooling. Thus, results of the sample survey confirm the findings of available government statistics that the district, although not selected on a

technically random basis, well reflects the rural Sinhalese Buddhist community typical of the wet zone of Sri Lanka.

The survey asked about fertility and contraceptive use. Predictably contraceptive use was low and fertility was high. Roughly 20% of the respondents reported currently using a contraceptive product, while an additional 4 percent reported themselves as previous users. Of current users, over half were sterilized (or their husbands vasectomized), and another quarter were using traditional methods, mainly "safe period," ie, calendar rhythm. Of the total sample, less than 2 percent were using oral contraceptives.

The mean number of children born to women aged 45 to 49, that is, those that have completed their reproductive life cycle, was 7. Younger women, of course, had fewer children. Marital fertility rates were high. Because of the small sample size, we are able to report rates only for those 15 to 29 and 30 to 39. In 1977, younger women had a marital fertility rate of 314.6 while older women had a marital fertility rate of 223.1.

In short, Matara is characterized by a traditional agricultural population, overwhelmingly Buddhist and Sinhalese, and women have very little education. As the project began, their fertility was fairly high, and their use of modern contraception low.

2. Puttalam

Puttalam District lies on the West coast of Sri Lanka, a 3 to 4 hour drive North of Colombo along the coast road. The project area included parts of three AGA Districts- Aratchikatuwa, Puttalam Pattu, and Kalpitiya. Project headquarters were located in Puttalam town, the district capital, but the town itself was not part of the project area. The "Norinyl only" area stretched up into a peninsula north of the town, while the rest of the project area ranged down to the southern border of the district. The land is flat and, compared with Matara, rather dry. Fishing, vegetable farming, and coconut culture represent the main sources of livelihood. Density is lower than in Matara, particularly away from the coast, and houses are widely scattered. The national highway and a couple of other stretches of paved road provide a better base for transportation than exists in Morowak Korale West, but away from the main roads the walking distances are generally greater.

Puttalam differs from Matara in that the ethnic and religious composition of the population is much more varied. In particular, roughly a third of the respondents (36%) were Buddhist while approximately half (47%) were Roman Catholic. The remainder were about equally divided between Muslims (10%) and Hindus (7%). The ethnic composition reflects the same range of diversity. Two thirds of the respondents said they were Sinhalese while approximately a quarter (23%) were Sri

Lanka Tamil. The remaining 10% reported being Sri Lanka Moor, the ethnic identification of Muslims who settled in Sri Lanka.

In spite of the ethnic diversity, the Puttalam district is in other ways similar to Matara. Residents are somewhat better off in that there are more skilled workers and professionals (12 percent) and in that women are a bit better educated (56 percent of respondents had less than 6 years of schooling). However, the district is still completely rural. Rates of labor force participation are very low; nearly 90% of the female respondents said they worked only as housewives. In rural agricultural communities, it is always dangerous to take data like this at face value. However, it is clear that work outside the home is not a significant influence on the fertility or contraceptive behavior of women in Puttalam.

The labor force, much like Matara, is largely composed of agricultural workers. Being a coastal area the Puttalam project area also included about 15 percent fishing families.

Fertility in Puttalam was at generally the same level as in Matara. (Due to a sampling error, fertility of women over 40 was not reliably measured.) As in Matara, 20 percent were current users of contraception, but there was much higher use of modern spacing methods--46 percent of current users were using the pill or the IUD. Along with 47 percent sterilized, this indicated that women who were current users were well

protected. Another 9 percent of the sample were past users. If perhaps Puttalam showed some greater degree of modern fertility behavior than Matara, the difference was slight. Both areas showed substantially less knowledge of and practice of contraception than the World Fertility Survey estimates for the population as a whole, three to four years earlier.

In short, very much like Matara, Puttalam represents a rural area composed primarily of people born in the district with little education and very little contact with outside urban influences. While the population in both places has benefited from Sri Lanka's expanded education and social welfare policies they are still, by the standards of the country, remote, rural and poor.

It should be clear that both areas satisfied the goal of the project to choose two areas, different in ethnic character and poorly served by contraceptive delivery systems, in which to conduct the experiment. These criteria were clearly met in Puttalam and Matara.

III. THE CLINICAL TRIAL

A. Design

1. Basic Structure

The clinical trial aspect of the OC/Vitamin study involves a four-cell comparative trial of two OC preparations with and without vitamin supplements. The four cells consist of the following treatments:

<u>Abbreviation</u>	<u>Treatment</u>
B/V	Brevicon® with multivitamin supplement
B/P	Brevicon® with placebo
N/V	Norinyl® with multivitamin supplement
N/P	Norinyl® with placebo

The individual substances in the treatments consisted of the following:

Norinyl : 21 oral contraceptive tablets containing 1 mg norethindrone and 0.05 mg mestranol, and 7 tablets containing 75 mg ferrous fumarate

Brevicon : 21 oral contraceptive tablets containing 0.5 mg norethindrone and 0.035 mg ethinyl estradiol, and 7 tablets containing 75 mg ferrous fumarate

Vitamins: 28 tablets containing 1.4 mg B₁, 1.7 mg B₂, 10.0 mg B₆, 4.0 mcg B₁₂, 0.8 mg folate, 60 mg C, and 16 mg Niacin

a. The Urban Study

The evaluation of the treatments differed, by design, in the urban as opposed to the rural study sites. In the urban site, a minimum of 400 clients were to be enrolled in the study, for a period of 12 menstrual cycles.

Recruitment was limited to low-income areas with reasonable access to the Colombo FPA clinic, and to physically healthy women 18 and 40 years of age. The following women were excluded from the study:

- 1) Women using oral contraceptives for therapeutic reasons.
- 2) Women who have used oral contraceptives during the previous six months.
- 3) Women whose medical histories indicate that oral contraception is an unsuitable method of contraception. Contraindications for systematic contraception were:
 - a) Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions.
 - b) Markedly impaired liver function.

- c) Known or suspected carcinoma of the breast.
 - d) Known or suspected estrogen-dependent neoplasia.
 - e) Undiagnosed abnormal genital bleeding
 - f) History of severe or frequent migraine headaches.
 - g) Significant hypertension (blood pressure greater than 140/100 mm Hg).
- 4) Women who are breast-feeding
- 5) Women who terminated their last pregnancy within the past three months.

All women must have had at least two normal menstrual periods since termination of their last pregnancy in order to participate in the study.

Recruitment for the urban study took place over a period of slightly more than one year, from January 10, 1979 to January 29, 1980. They were brought to the FPA Colombo clinic for a physical examination, and if willing and suitable for the study, assigned one of the four treatments on the basis of a prespecified random sequence supplied by IFRP. The treatment was provided in two packets, one for the contraceptives, the other for the vitamins/placebos. These packets were identical except for (1) the marking A, B, C, or no marking, to identify the treatment combinations, and (2) the contents of the oral contraceptive packets, ie, the pharmacologically active ingredients and their dosages. An admission form

was filled out at this visit (see Appendix A), and each acceptor signed an informed consent form.

Clients were scheduled for follow-up shortly after the expected ends of cycles 1, 3, 6, 9 and 12. At each of these clinic visits a follow-up form was administered, containing information on experience since the previous visit and on a list of 24 specific possible side effects during the previous 28 days. If a client did not appear for the scheduled visit, a letter was immediately posted and/or a home visitor went to the client's home to persuade her to come to the clinic. Clients were often visited at unscheduled times as well, to counsel, maintain contact, and check on maintenance of the study regime.

A group of clients selected at the admission visit for apparent reliability were asked to fill out symptom grids (see Appendix A) for cycles 1, 3, 6, 9 and 12. These involved noting on each day whether a pill was taken, whether vaginal bleeding (either "breakthrough" bleeding or "withdrawal" bleeding) occurred, and whether any of a list of six commonly reported side effects occurred. The client was visited at home during a cycle in which she was to be filling out a grid, to be sure she was remembering to use it and to discuss side effects with her, and the completed grid was discussed at the follow-up visit after the end of the cycle.

Women were urged to continue with the treatment as long as possible, but not in the face of an unreasonable level of discomfort. At the end of the 12th cycle, clients were terminated from the study, although many remained as FPA clients, either on orals or other contraceptives.

b. The Rural Study

In the two rural areas, the initial target called for enrollment of "as many as 2,000 acceptors of oral contraceptives". Each of the rural areas was divided into two subareas. In one subarea, the four treatment combinations used in the urban study were assigned on a sequential basis, after a random start, to acceptors on entry into the study. In the other (smaller) subarea, acceptors were provided with Norinyl tablets only, pharmacologically identical with the N/P group in the formal clinical trial. Since these women were recruited and served on a different basis than the acceptors of the study treatments, they form a comparison group whose differences in performance from the treatment groups could be expected to shed some light on the effect of service provision factors on the experience of the women involved, as compared with pharmacological factors.

Study acceptors were recruited by home visitors working in teams of two to four under nurse supervision. Upon discussion with a woman who indicated a desire to enroll

in the study, the supervising nurse would be called to visit the home, confirm eligibility, obtain acceptance information (Appendix A) and assign the study treatment. In the blind trial area, these treatments were identical to those in the urban area; in the "Norinyl only" area, the woman was simply handed a 3-month supply of Norinyl packets. All women signed informed consent forms.

Follow-up visits were conducted in the homes, by home visitors, rather than in the clinics. The first follow-up was scheduled for one month after admission; the second for two months after the first; and succeeding visits at two to three month intervals. Women were supplied with three treatment cycles at a time. At the following visits, women were asked about experience since the last visit, including adherence to the study regime and the "most disturbing side effect" since the last visit.

Acceptors were limited as to possible length of participation only by the termination of the study, which was August 15, 1980. In Matara, the study began in September 1978; in Puttalam, in June 1979. Since recruitment in the rural study continued throughout, the possible length of use for a woman who was continuing use at the cut-off date varied from 1 to 23 months.

Eligibility requirements for the rural study were the same as for the urban study, except that women up to age 49 and those currently breast-feeding were included. The inclusion of such women was due to an oversight in the preparation of instructions, and was not detected until the end of the study. Provision of the pill to breast-feeding women is therapeutically controversial, but it conforms with common practice in Sri Lanka and in Asia generally. The exclusion of women who had terminated their last pregnancy within the previous three months, along with the moderate to low dosage of estrogen in the study preparation, presumably served to minimize any possible effect on the breast milk. The error is regrettable, but it did provide an opportunity to compare currently breast-feeding and non-breast-feeding women.

c. Comparison of Rural and Urban Designs

Both the urban and rural studies involved use of the same treatment combinations, administered on an essentially double-blind random basis. However, there were some differences in circumstances and design which allow for interesting comparisons. The strategy for the urban study centered on self-reported clinical symptoms, in considerable depth and with great care, and made two important clinical measurements, weight and blood pressure. Emphasis was on comparing quantitative differences in reported symptoms associated with the regimes. The

rural study focused more on comparisons among treatments in use patterns in the rural areas and with distribution mechanisms more representative of Sri Lanka generally. Hence the period of use was not limited.

d. Value and Limitations of the Design

The value of a randomized blind trial is that, in controlling for all factors other than the pharmacological properties of the drug, it allows evaluation of those properties, apart from client or experimenter bias, psychological factors, or other possible noise. This is valuable information in deciding which drugs to use, but nevertheless the implications of results for programmatic use are not always straightforward. In the present study, they are in fact complex both for the contraceptives and for the vitamin supplements.

Regarding the oral contraceptives, it might first be noted that there is ordinarily a tradeoff involved in a higher vs lower dose comparison. For the higher dose, there are expected to be higher levels or most types of side effects, but also more complete cycle control, and hence less intermenstrual bleeding. Whether women prefer to put up with other side effects in order to avoid the bleeding or vice versa is primarily individually and culturally determined, with little objective basis for preference. The drug Norinyl is the standard oral

contraceptive in Sri Lanka; its side effects are known and widely tolerated. If Brevicon were associated with different side effect patterns, these might in a programmatic context be effectively dealt with in an educational campaign; or conversely, they might set off a chain of fears and rumors which could seriously hurt the program. A clinical trial can shed rather little light on this aspect. On general pharmacological principles, the lower dosage should be associated with lower levels of cardiovascular and other life-threatening disorders, but this has not been firmly established even for women in developed countries. Gathering convincing evidence on this topic is far beyond the capabilities of this study, so considerations on this important subject must be based on other evidence.

The vitamin/placebo comparison, in a programmatic context, involves determination of whether the vitamin supplements are effective in reducing side effects due to the pill; of the general value of vitamin supplements to the health of the women; of the costs and logistical problems involved in supplying the vitamin supplements; of the acceptability of the pills; and a variety of political questions. This clinical trial can deal only with the clinical effects of the vitamin supplements on pill side effects and continuation.

Hence, the proper use of the data from the clinical trial aspect of this study is as one of several types of inputs which need to go into programmatic decisions on what type of pill to use and whether or not to use vitamin supplements in Sri Lanka or elsewhere.

2. Implementation of Design

In its essential aspects, the clinical trial was implemented as designed. The double-blind, randomized nature of the trial was basically adhered to, sufficient numbers of clients were recruited in each site, and study procedures were followed so that nearly all the information envisaged was collected with the greatest degree of accuracy feasible. Nevertheless, there were a number of factors which, to some extent, led to modifications in the original design. Hence, the implementation will be reviewed in terms of particular design elements.

a. Recruitment of clients

The original design called for recruitment of "no fewer than 400" urban acceptors, and "as many as 2000" acceptors in each of the two rural areas. These targets were met or approached, except in Puttalam due to the shortened study period. The actual numbers of study acceptors by treatment and site are given in Table III-1.

Thus, acceptance in Colombo was somewhat greater than the minimum target, and acceptance in Matara and Puttalam was somewhat below maximum targets. In each site, numbers of recruited clients is sufficient to show any important differences in side effects or continuation.

b. Randomization

It is essential to the design that clients not be selected in such a way that comparisons between treatments might be effected. In the urban study, this was done through randomization of acceptors. The IFRP provided a random sequence of treatments to be assigned, and this was followed scrupulously. In the rural areas, allocation was sequential after a random start. In Puttalam, sequential allocation was adhered to within each of the three field groups, that is, each group was given a separate random start and assigned treatments sequentially thereafter. In Matara, separate random starts were given to each fieldworker. However, it was not made clear to the staff that each day the sequence should be picked up where it left off the proceeding day. Consequently each fieldworker gave the first new acceptor of each day the treatment prescribed in her random start. This accounts for the noticeable differences among acceptors by treatment.

It seemed clear to both IFRP and Senior FPA staff that the field staff had no strong consciousness of the differences in content of the study treatments, nor any noticeable personal preferences or impressions, even at the end of the study. Consequently, while selection biases in the rural area were theoretically possible, it is unlikely that the integrity of the study was actually affected by such biases.

In one study aspect, however, lack of randomization may have been important. In the urban study, home visiting chores were not randomly assigned. The two home visitors who remained throughout the trial were assigned to Sinhalese Norinyl clients and Sinhalese Brevicon clients, respectively. The third home visitor, who resigned during the study and was not replaced, was assigned to Tamil-speaking clients using both Norinyl and Brevicon. Home visitors were responsible for follow-up on missed visits, and for irregular home visiting between clinic visits. Hence, in this area there was a potential for selective bias in the Norinyl-Brevicon comparison, and as we shall see later, there is evidence that this bias may have been realized.

c. "Blind" treatment

In a pure double-blind study neither the provider nor the client is aware of which treatment is being provided to a

particular client, except by a code which is not broken until the end of the study. In the present study, this ideal was somewhat compromised in the design. As previously noted, the content of the oral contraceptives was printed on the packets. In all probability, few if any of the clients interpreted the significance of this, if they noticed it at all. On the other hand, it allowed the FPA providers to be aware of which pill was associated with which code. Regarding the vitamins/placebos, it was discovered early in the study that the vitamin packets (but not the placebo packets) had a tendency to spoil, if left at the clinic too long. There were, however, no reports of spoilage in the clients' homes, and it is likely that few if any clients were aware of which treatment they were receiving. On the other hand, the providers again had a source of information to differentiate between treatments. Assays performed on the "spoiled" vitamins indicated no pharmacological effect.

Whether this affected the study is questionable. It is highly unlikely that the clients were biased as a result of these factors. The providers might have been affected; but it appears that the staff directly involved in the provision of the services had little consciousness regarding which client was given which treatment, and little or no preconceived idea as to which treatment was preferable. Nevertheless, the possibility of provider

bias cannot be ruled out as a possibility in reviewing the results of this study.

d. Adherence to follow-up schedules

In the urban study, follow-up visits were scheduled after the first, third, sixth, ninth and twelfth cycles. It was understood that keeping to this schedule rigidly for all cases would not be feasible, nor is it necessary for valid analysis of results. Nonetheless, too drastic a departure could seriously affect the validity of analysis, and even modest departure complicates analysis.

According to the schedule, all visits theoretically should have taken place during cycles 2, 4, 7, 10 and 13. The actual distribution is given in Table III-2.

Roughly 80% of all visits took place during the scheduled cycle.

e. Field Personnel and Procedures

The division of the clinical trial into urban and rural components is reflected in study personnel from study directors to fieldworkers. The urban study was in the charge of Dr. Sriani Basnayake, Medical Director of the Family Planning Association of Sri Lanka. The day-to-day operation of the study was supervised by a senior nurse, Mrs. Helene Unambuwe. Another Nurse assisted at the clinic, while a third was the primary field

motivator. Three women with general education were charged with home follow-up visits for assisting with symptom grids, contacting acceptors who had missed follow-up visits, and making occasional unscheduled checks to determine whether women were adhering to the prescribed regimes. Hence although the scheduled visits took place at the FPA clinic, there was a very high level of home contact, and the home visitors often became quite close personally to the women in the study. This was especially useful because of the nature of the population. The urban study women were recruited from slum areas, and tended to be highly mobile, often irregular in their habits, pulled by a variety of day-to-day problems in coping, and confronted with substantial choices of preferred contraceptives. (This last issue also created difficulties in recruitment. Particularly popular alternatives were the injectable Depo-Provera, becoming widely used during the study period, and oral contraceptives supplied by government midwives, who supplied free baby formula with the contraceptives.)

All clinic visits were managed by Dr. Basnayake or one of the two nurses. A missed appointment was followed up with an immediate letter, and a home visit if necessary. For most symptom grids, a home visitor reviewed the grid with the client during the course of the cycle at least once, although the timing of the visit varied

substantially. Most clients also received one or more unscheduled home visits.

The rural trials were managed by Mr. S. Victor de Silva, Director of Evaluation and Research of the Family Planning Association. Each of the two clinics was run by a clinic coordinator: in Matara, Mr. V.G.A. Perera; in Puttalam, Mr. A.S. Thenuwara. Field work was done in each clinic by three nurses, in charge of eight home visitors. The nurses rotated field duty so that one nurse was always in the clinic during clinic hours. In addition, a backup physician was available for consultation and referral. The home visitors worked in pairs under nurse supervision, visiting a village together but then splitting up for individual recruitment and follow-up visits. The home visitor identified clients willing to enter the study, and handled follow-up visits and information gathering. The nurses started the clients on the study, were available for consultation, and supervised field activities.

An important aspect of study implementation involved the handling of reported side effects. It was the intention of the study designers that women who experienced common, short-term side effects should be reassured and encouraged to continue unless the side effects were too severe or unless they persisted over too long a period. The actual practice was quite variable. In Puttalam, one

group of four home visitors was sufficiently persistent and successful with this approach that they achieved substantially higher continuation rates for all treatments than was achieved elsewhere in the rural study. In Matara, on the other hand, the staff had the understanding throughout most of the study that women who complained of side effects should be immediately switched to another method. Hence continuation was very low, and side effects were reported for the most part only on the terminal visit. This practice was discovered only in April 1980, too late for changes in procedure to have a strong effect on the study.

During the second quarter of 1980, a check was made to the homes of clients reported to have been visited by home visitors to verify the report and to learn about public reaction to the program. These visits were done without the knowledge of the field personnel. A total of 316 homes were visited in Colombo, 265 in Matara, and 280 in Puttalam. The visits indicated overwhelming confirmation of the clinic records, and there was no indication of public hostility.

f. Summary of Implementation

The preceding discussion of necessity focuses on the shortcomings of design implementation. This should not be allowed to obscure the outstanding competence and

energy with which the FPA implemented the research design. That design, it should be remembered, was devised primarily at USAID and IFRP, and it was required that technical concepts in the minds of outside statisticians be translated into proper field procedures, by lay personnel not trained in research, in the slums of Colombo and in remote provincial villages. In addition, the design of the clinical trial was an inextricable part of a larger study, and the requirements of the clinical trial had to be fit in with those of a field distribution program, in addition to the broader concerns of the FPA. Nonetheless, the clinical trial was in all essential aspects carried out as planned. This is in itself an outstanding achievement by the Family Planning Association.

B. Results of the Clinical Trial

1. Data for Analysis

Of the original acceptors, not all remained appropriate for analysis. In the rural data, there were differences between the two sites in the handling of women who agreed to accept one of the study treatments (or the Norinyl only), but were subsequently determined never to have begun taking the treatment. In Matara, these were never included in the acceptor reports, and at this point there is no record of which women these were. In Puttalam, acceptor records were filled out

for such women, and they were included in the acceptor statistics. There were, in fact 277 such women. Thus, the number of "real" acceptors in Puttalam was 849 women. In the urban data, women were not in principle removed from analysis as a result of not actually starting use.

The removals at editing, as of this writing, and the remaining subjects included in this analysis, are given below.

	<u>Colombo</u>	<u>Matara</u>	<u>Puttalam</u>
Clients enrolled	500	1635	909
Removed at editing	3	65	60
Included in analysis	497	1570	849

2. Characteristics of Acceptors

Frequency distributions for a number of background variables of interest are provided in Table III-3 through Table III-11. Some general observations can be made. By and large, the Puttalam acceptors fall between the Colombo and Matara acceptors on most variables. The Colombo acceptors are younger than the Matara acceptors; are better educated (and married to better educated men); have fewer children; have had their children longer ago; want fewer additional children; and are more likely to have previously used contraception. On each of these variables Puttalam women occupy an intermediate place except for additional children wanted; they want even fewer children than Colombo acceptors. The three sites are quite different in their ethnic-religious

profiles. The Matara clientele is composed almost entirely of Sinhalese Buddhists and Tamil Hindus; Puttalam includes large minorities of Catholics and Muslims; and the Colombo clientele has some representation from each of the country's ethnic-religious combinations. Tamil Hindus are somewhat, but not drastically, underrepresented in the study in comparison with their concentration in the study areas, and somewhat more underrepresented in comparison with the national population.

In the rural areas, comparisons are possible with several characteristics of women in the catchment areas. In general, the study clientele were of the same educational, religious, and ethnic backgrounds as the general population, but were younger, more likely to have borne 1 or 2 children and to want 1 or 2 more (rather than none or more than 2), more likely to have borne their last child recently, more likely not have used contraception in the past, and more likely to be currently breast-feeding. That is, the general pattern is of a group of younger women interested in smaller families but not necessarily in terminating childbearing, and in social and economic characteristics representative of the general population--that is, the usual target clientele for the pill.

For those accepting the study treatment, the allocation of treatments by background variables was compared for nine variables in each of the three sites. Differences in treatment

allocations significant at the .10 level were found in five cases (husband's education and additional children wanted in Colombo; religious and ethnic group in Puttalam; age in Matara). This is not alarming. Significant differences would be expected in two or three cases even if tests were independent, and in this case the tests are not independent. The percentage differences are not striking, and background variables in general proved not to be strong predictors of continuation or side effects, regardless of treatment. Nonetheless, the effects of these anomalies in the randomization process should be generally kept in mind as possible explanations of observed differences in performance among treatments.

3. Rates of Continuation and Discontinuation of Study Treatments

a. Methodological considerations

The principal analytical tool used in this analysis is the multiple decrement life-table technique devised by Potter and Tietze, and for which relatively standard procedures have evolved for contraceptive evaluation. However, in this analysis those procedures have not always been followed, sometimes as a result of characteristics of the data and sometimes as a result of the nature of the analysis.

- 1) Standard procedures generally call for classifying clients who moved from the area or were otherwise

lost to follow-up in the category, "withdrawn from observation," that is, censored in the analysis rather than categorized as terminating. This is appropriate for programmatic research, where the levels of continuation and use effectiveness are of primary interest. In a clinical trial, however, it is the comparisons among treatments that are important; the absolute levels are of no particular significance. In this context, it is useful to analyze all terminations, regardless of reported cause; it is possible, for example, that loss to follow-up may in fact be a method-related phenomenon. Moreover, there is the philosophical observation that in terms of a clinical trial, a client in effect terminates as of the last point that information is available for her, regardless of whether or not she continues to use contraception. Hence, for most life-table analyses, "moved from area" and "lost to follow-up" are treated as separate reasons for termination rather than as withdrawals from observation.

- 2) In a similar vein, length of use for a continuing user is calculated to the point of the last clinic visit. For programmatic evaluation, continuing users and "incomplete observations" represent a complicated analytical hurdle. In a comparative trial of this

type, the comparison remains valid as long as the procedure is consistent among treatments.

- 3) In these analyses, clients who do not complete the first cycle are included in the analysis, on the grounds that termination during the first cycle may well be method-related. In the urban study, even clients never located after the admission visit are included; in the rural studies, the record of the treatment allocated is not available for such clients. In standard usage, clients for whom no data are available after acceptance are excluded from analysis, as are those not judged to be "bona fide" acceptors.

These are not statisticians' quibbles; they are of considerable importance to the present analysis, as we shall see, especially for the urban data. As it turns out, treatments in the urban data differ substantially by categories not usually considered in life-table computations, for reasons which probably will never be satisfactorily explained. In addition, however, each of the practices described above tends to reduce continuation rates in comparison with standard practice; as a whole, the effect is quite substantial. Consequently, for those wishing to compare these data with data from other studies, or who wish to infer program-type continuation rates, some

tabulations are provided according to more common procedures.

- 4) A final item affects the variability associated with these rates. Life-table computations require the classification of events according to the ordinal period (month) during which they occurred. In the rural study, dates are coded by month only, so that the ordinal month of termination cannot be precisely inferred. Hence we have estimated the month of termination by subtracting the acceptance month from the termination month, and alternately adding 1 or 0. The result leaves the rates unbiased, but subject to a small additional variance element not included in the variance estimates.

b. Overall Rates

Continuation rates for the four study treatments combined (in the rural areas, excluding "Norinyl only" patients) are shown in Tables III-12 to III-14. "Procedure A" follows the more standard life-table procedure of omitting from analysis those for whom no data are available after acceptance, and of classifying clients who moved away or could not be traced to the "withdrawn from observation" category. It is therefore appropriate for comparisons with life-table continuation data from most other studies. "Procedure B" analyzes all cases and

classifies "moved away" and "lost to follow-up" as terminations. These rates are therefore the overall rates to which rates for specific subgroups may be compared. The differences are very substantial, particularly in Table III-12.

Tables III-12 to III-14 also show marked differences in continuation by site, Colombo having far higher continuation than Matara, with Puttalam intermediate. These differences are not readily accounted for by differences in population characteristics (Table III-15). Where continuation rates differ by characteristic, they do so in ways that run counter to the observed trends. For example, older women tend to have higher continuation rates and the Colombo population is the youngest of the three and Matara the oldest. Thus the higher continuation rates in Colombo are in spite of rather than because of the age distribution. Similar observations hold for other relevant characteristics. Where background characteristics do influence continuation rates, differential dropout due to planned pregnancy is typically an important factor.

It seems probable that the differences in continuation rates by site are due to a combination of the levels of geographical and logistical difficulty in carrying out the trial, and the training and effectiveness of the study personnel. The urban study utilized highly trained

and well supervised personnel, and involved short travel distances with an efficient transportation system. Of the two rural areas, Matara involved more difficult terrain and a less developed transportation system, and the clinic personnel were considered, on the whole, less qualified and less motivated than the Puttalam staff. Another factor in the continuation rate difference between Puttalam and Matara was the procedural misunderstanding, alluded to above, that in Matara it was immediately suggested that a woman switch methods if she reported side effects from the pill.

Most of the difference in continuation rates between Colombo and the rural areas is in the second six months. In the urban study, continuation probabilities increased sharply during the latter part of the study, while in both rural areas, monthly probabilities of termination remain fairly high. Among several possible explanations for this is that in Colombo the study personnel, who had established a high level of personal contact with the clients, were able to persuade clients to remain in the study for the few more months until the end, whereas because of the open-ended nature of the rural study, this was not possible.

In general, differences between sites in overall continuation do not particularly complicate comparisons between treatments. These differences will be analyzed

separately by center, since design and execution differences make it inappropriate to pool them in any case. The magnitude of these differences, however, should serve as a reminder that differences in contraceptive technology are rarely the only factor, and are often not even a very important factor, in determining patterns of contraceptive use.

c. Comparisons among Treatments

Table III-16 shows six-month and twelve-month continuation rates, with standard errors, by site and treatment. Each of the four treatment combinations are shown separately, the Norinyl-Brevicon and vitamin-placebo comparisons are shown. Rates are computed using "Procedure B."

The vitamin-placebo comparison reveals no consistent or important differences. Twelve-month continuation rates are slightly higher for the placebo group, but the differences are minor and nonsignificant and are not paralleled by the six-month rates.

Norinyl-Brevicon differences, on the other hand, appear more convincing. Twelve-month rates are higher for Norinyl than for Brevicon in all three sites, for both vitamin and placebo clients. P values for the differences are $<.00001$ for Colombo, .13 for Matara and .08 for Puttalam. (The difficulty of accounting for the Colombo result by chance should be noted because, as we

shall see, it resists other explanations as well.) Six-month rates are less consistent, except that they are generally less favorable to Norinyl than the twelve-month rates. This is consistent with the hypothesis that the expected major difficulty with a lower dose pill, cycle control, may be less transient than the effects associated with a higher dose preparation.

d. Reasons for Termination

Tables III-17 to III-19 show gross terminations, by reason and treatment, for the three study sites. (Gross rates are preferable for comparisons between groups, since they take competing risks into account.)

Once again, comparisons between vitamin and placebo users show little of clinical or statistical significance. Neither examination by site nor by reason shows any consistent or convincing evidence that vitamin supplements make a difference in probabilities of continuation.

The results of the Brevicon-Norinyl comparison are rather surprising. For Colombo, there are no apparent differences by any measure in terminations for medical reasons. The difference in continuation rates between Norinyl and Brevicon is entirely accounted for by differences in terminations for personal reasons, moving from area and loss to follow-up, each of which is highly significant statistically. Theoretically there would

appear to be three possible explanations for this:

(1) chance; (2) bias due to differential treatment of Norinyl and Brevicon acceptors; or (3) method-related reasons for apparently non-method-related terminations. The p-value associated with the overall difference strongly suggests that we look beyond "chance" for answers. Regarding possible bias, the following observations may be made: (1) clients were assigned to treatments at random according to a sequence assigned by IFRP and accurately implemented by the FPA. (2) The two principal home visitors were assigned by treatments, one to Norinyl clients, the other to Brevicon clients, although they frequently worked together. The possibility thus exists that differences in discontinuation may have been due to differences in the diligence and skill of these home visitors. (3) FPA clinic staff interviewed clients as they arrived for appointments, irrespective of treatment group. (4) FPA daily staff showed little consciousness of OC treatment differences or preference for one or the other. If such a preference existed, it seems far more likely to have been felt through discontinuation for method-related than non-method-related reasons.

(5) While the contents of the oral contraceptives were printed on the study packets, and therefore could theoretically have provided clients with knowledge that might have affected continuation, it is extremely unlikely that many clients had the technical ability or interest to do

so, nor did any report to field personnel that they had done so. In any case, such knowledge should have affected reporting of side effects, but this does not appear to have happened. Hence, if important bias exists, it seems most likely to have been due to the assignment of home visitors by treatment.

A final hypothesis may be advanced. Perhaps clinic personnel, in trying to keep dropout rates as low as possible, persuaded women to agree to continue when they did not wish to do so. Hence when home visitors came around at the succeeding visit time, they found, for example, that the husband had developed an objection to the pill ("personal reason") or that the woman could not be found and neighbors said she had moved away, or they did not know where she was. If this were more common among Brevicon than Norinyl users, it could explain the data. Of particular interest would be breakthrough bleeding. Since it was expected to be (and in fact was) a common side effect, particularly for the lower dose, and since, as Table III-17 shows, almost no one was reported to have terminated for that reason, perhaps such terminations were disguised under other reasons.

For the following reasons, we have concluded that the difference in observed continuation was not due to method-related terminations being classified as not method-related.

- 1) If women were discontinuing use as a result of side effects but the discontinuations were being reported under non-method-related reasons, one would expect (a) that women discontinuing for non-method-related reasons would report higher levels of side effects on the visit preceding discontinuation than women who continue use after that visit; (b) that this would be particularly true among Brevicon users; (c) that these differences would be quite marked, to account for the magnitude of the observed differences in continuation; and (d) that they would be particularly manifested for menstrual symptoms. In fact, the data support none of these expectations.
- 2) Menstrual side effects reported on visit one were non-significant as predictors of later discontinuation. In general, the data give no evidence that menstrual side effects of pill use were particularly troublesome to women, in comparison with other side effects.
- 3) The rural data, like the Colombo data, show moderate levels of menstrual side effects compared with other major complaints, and these are more commonly reported among Brevicon users than Norinyl. Also, discontinuation reported as due to menstrual side effects is relatively rare. But continuation rate

differences in Puttalam and Matara are slight or non-existent.

- 4) Nearly the entire difference in continuation rates is accounted for by women who did not fill out symptom grids; the difference among grid users was non-significant, although in favor of Norinyl. This is not easily explained by the disguised dropout hypothesis. It is, however, consistent with differential fieldworker performance. Home visitors were to visit women not using grids only if they failed to make a scheduled visit; hence for most women, no regular contact was established. Symptom grid users, on the other hand, were to be visited during the cycle prior to each scheduled follow-up visit, as well as for follow-up on late appointments; hence there was a much greater level of routine contact. A difference between home visitors in locating clients and persuading them to come to the clinic would be likely to be more marked among the clients less frequently seen.

The data for some of these arguments will be presented later. Our conclusion is (with some remaining doubt) that there is no difference in continuation rates in the urban study between Norinyl and Brevicon.

Reason-specific termination rates for the rural areas (Tables III-18 and III-19) do not provide much support for large differences by method. While twelve-month termination rates are higher among Brevicon users for unplanned pregnancy, menstrual side effects and other medical reasons (the three most clearly method-related reasons), six-month rates and total numbers of terminations do not consistently favor either preparation. Once again, the vitamin-placebo comparison shows little difference of interest.

Comparison of reasons for termination within a group of acceptors is done most appropriately through use of net termination rates, since the sum of the reason-specific rates adds up to the aggregate termination rate.

Table III-20 shows such rates for each site, for the four trial treatments combined. The distributions are strikingly different for the three sites. Of particular note are: the low proportion of dropouts due to side effects, especially menstrual side effects, in Colombo; the dominance of "other medical reasons" as the main cause of discontinuation in the rural areas; and the high urban rates of loss due to personal reasons, moved from area, and loss to follow up. This latter pattern is consistent with the hypothesis that urban women may have disguised dropout resulting from side effects by "disappearing" or pleading personal reasons, but it is also consistent with

several other explanations. On the whole, however, it seems most likely that the striking difference in distribution in Table III-20 is due to differences in provider attitudes, resulting either in prejudiced recording of information or in modifications in client reporting.

4. Side Effects

a. Data and Methodological Considerations

Data on reported side effects represent a complicated body of information to analyze. Whether a given symptom is reported on a particular visit is related to physiology, culture and individual temperament, and may or may not be contraceptive related. Sorting out these various factors is a complicated business, but in a properly designed study, a good deal of valuable information can be obtained.

Side effect information was obtained from three different types of forms; in the urban study, both the follow-up form and the symptom grid form, and in the rural study, the follow-up form (See Appendix A). Table III-21 indicates the specific side effects elicited on each form.

The symptom grid contains, for a nonrandom subsample of urban study clients, information by cycle day on whether the woman took the pill that day (or more than one), incidence of spotting/breakthrough bleeding and

withdrawal bleeding, six common pill side effects, and "other" side effects. The sample for symptom grids was chosen at intake on the basis of the subjective impression of the intake person as to the woman's competence in filling out the grids and the willingness of the client to do so. Rather surprisingly, symptom grid users turned out to be very similar to women not asked to fill out grids in measured characteristics, except that they were somewhat better educated. Women kept the grid at home and filled it out each day and were visited once during the middle of the cycle and once at or after the end. The cycle starts with the first day of taking the active contraceptive. Grids are filled out for cycles 1, 3, 6, 9 and 12 of the study period. The grid thus provides information on the number of occurrences of a symptom during a given cycle, changes during the course of a cycle in symptom frequencies, length of episodes, and changes in symptom frequencies over several cycles. It is probably the most precise information available, but it is available only for a sample of acceptors, and for a few symptoms.

The symptom grids were incorporated into this study on the expectation that they would provide a rich store of information on the nature and timing of symptoms and interrelationships among symptoms. In theory, the possibilities of studying relationships through this mechanism

seem nearly limitless. In practice, the full realization of these possibilities was limited by three factors. First, the appropriate statistical models are very large, if analysis is not to be limited to study of row and column totals in the grids. For example, the set of pairwise comparisons of the 6 symptoms over 28 days involves some 11,760 individual comparisons. A reduced, parsimonious model is obviously called for. Second, the development of this parsimony is hindered by the lack of relevant theory and hypotheses. This study, for example, looks at simple correlations in monthly incidence between symptoms, a topic previously unreported in the literature. Developing important questions which require the detailed data from a symptom grid to answer has proven difficult. Finally, the nature of the Sri Lanka data further limit the usefulness of this analysis. Because of discontinuation, time analysis is of limited value. Moreover, the frequency of 7-day and 14-day episodes, along with the extremely low rates of reported symptoms in later months, lead us to have some question about the precision of the raw data. Hence, analysis of symptom grid data presented here is based on aggregating row and column totals for individual grids.

Urban follow-up forms contain information on the incidence (generally "yes" or "no") on 24 different specific side effects during "the last 28 days or since the last

visit, whichever is less." The follow-up visit was conducted after the end of the cycle for cycles 1, 3, 6, 9 and 12—that is, the same cycles as for the symptom grid. Ideally, the visit was within the first few days after the expected end of the cycle, but this was not always possible. Thus for clients who filled out symptom grids, the period of the grid generally overlapped partially, but not completely, with the period for which symptoms were detected on the follow-up form. The follow-up forms, then, contain information on a broad range of symptoms for all clients who had at least one follow-up visit, but the data are not as detailed as for the symptom grids and are presumably subject to greater recall error.

Uses of the data. To the extent that the randomized, double-blind nature of the study is successful, differences in reported side effects among the four treatment groups may be ascribed to the pharmacological properties of the treatments. Other types of interpretation are less rigid, but may still be useful. For one thing, reported side effects represent a kind of composite of how a woman perceives a variety of physiological, psychological and cultural factors, and as such are of interest in themselves. Comparisons with other reported data—particularly data collected in the same way—are important clues, even when they do not in themselves indicate the reasons for observed differences.

Similarly, rates of decrease in reported levels over time indicate how rapidly particular side effects cease to be salient to a woman, even where they are not very specific as to why they cease to be salient. In short, reported side effects, carefully analyzed, are important clues to a variety of questions, but in this study only differences in levels among study treatments, controlled for length of use, can be interpreted unequivocally.

b. General Levels

The proportions of women who had experienced particular side effects during a particular cycle are shown in Table III-22 from the urban follow-up data and Table III-23 from the symptom grids. These are for all treatments combined; differences among treatments do not greatly modify the overall impressions obtainable from these tables. Headache is the most commonly reported symptom, with a variety of other symptoms commonly reported but at a somewhat lower level. Breast discomfort is surprisingly rare. Depression is also rather uncommonly reported; this is doubtless due, at least in part, to lack of salience of the concept in Sinhalese culture--there is, in fact, no Sinhalese word for it.

The decline in reported symptoms over time is striking for nearly all symptoms. There are at least five factors

that may be operating here, probably all simultaneously.

(1) Clients are changing in the ability to metabolize the pill, thus reducing the physiological shocks which underlie the perceived symptoms. (2) Women become less nervous with experience, hence less tuned to minor bodily symptoms. (3) Women may be less diligent in monitoring and recording side effects in later stages. (4) At later stages, clients are increasingly selected by discontinuation for low rates of side effects. (5) Clients who remain in the study are presumably also selected for rapid reduction in side effect rates. With the exception of (4), these factors are inextricably confounded in these data. A separate analysis including only those who complete the study reduces the rate of decline in side effects, but only to a rather moderate degree. These data, like others, do suggest that for women who continue using the pill for several months, side effects become increasingly less obtrusive.

Table III-24 presents data from selected side effects in comparison with two particularly relevant comparison groups. A study of the clinical effects and metabolic alterations related to oral contraception and their relationship to nutritional status was conducted by the FPA, IFRP and the Southwest Foundation under USAID contract AID/pha-C-73-32. The study was managed primarily by Dr. Basnayake, used follow-up forms similar to those used

in the present study and included a group of 200 Norinyl users. This study, carried out in 1976-77, is colloquially known as the "Goldzieher Study" after its principal investigator, Dr. Joseph W. Goldzieher. Another relevant study, also funded by USAID and analyzed by IFRP, was conducted in Seattle, Washington, in 1973-75. It is the first and to date the only published data using the symptom grid to analyze OC side effects and included 149 Norinyl users. It is commonly known as the "Seattle Study." Table III-24 compares data from cycles 1 and 3, Norinyl users only, and includes our data from both follow-up forms and symptom grids, along with data from the Goldzieher and Seattle studies.

Given the ambiguous nature of reported side effects and the differing circumstances involved in these studies, the data seem generally rather comparable. Three differences stand out between the Seattle Study and the Sri Lanka data: the Seattle data show far higher levels of spotting/bleeding and, spectacularly, breast discomfort; and substantially lower levels of dizziness. These differences are consistent with (but not necessarily due to) reasonable pharmacological hypotheses. A given dose for smaller, less well-nourished Sri Lanka women might well lead to better cycle control but greater circulatory changes (hence more dizziness) than for larger, better nourished American women. The diminished

degree of breast discomfort may relate to smaller breast size, greater age and parity, and greater likelihood of past breast-feeding among Sri Lanka women. However, differences between American and Sri Lanka women on these or other symptoms may also well be cultural in origin, particularly to the degree that reported symptoms represent perceptions rather than discrete events. In other comparisons not shown, the Seattle women reported substantially higher levels of abdominal bloating, changes in acne, increased sexual desire, depression, rashes and vaginal itching, than clients in the present study.

It should be remembered that none of these data serve in any useful sense as a control for the others, and that the proportion of these symptoms which are actually related to contraceptive use is unknown in both populations.

Comparison between urban follow-up data and rural follow-up data are shown in Tables III-25 and III-26. The figures in Table III-25 represent proportions of forms on which none of the side effects listed on the rural form were reported. (Since only one side effect can be reported per visit on the rural forms, this is the most nearly valid comparison that can be made.) The far higher proportions of negative forms in the rural areas are probably explainable by the wording: the phrase "most disturbing side effect" can be interpreted to mean

that if no side effect was particularly disturbing, none should be reported.

Table III-26 shows the reports for the commonly reported side effects and their proportion of the total. None other than the four listed were reported at all commonly. While exact comparisons are not possible, it would appear that nausea and/or vomiting are taken especially seriously when they occur, that breakthrough bleeding, dizziness/headache, and abdominal pain are often troublesome, and that no other short-term side effect was a frequent cause for concern in the rural areas.

c. Treatment Comparisons

The present discussion is primarily a representation of the data rather than a detailed multivariate analysis. Where appropriate, some p-values have been computed based on simple random sampling, but formal hypothesis testing has not been undertaken. When looking at these tables, then, some caution is in order. For example, comparisons between two cycles primarily involved the same women; consequently, consistency of treatment differences is not as strong evidence as if the differences were independent. Also, differential dropout rates and their implications for side effects must be considered in evaluating treatment differences. Finally, consistency of treatment differences across symptoms must be viewed

in light of the fact that the reports are derived from the same women, and thus are presumably intercorrelated. Nonetheless, simple summaries will probably be sufficient to draw broad conclusions from the trial.

Tables III-27 and III-28 illustrate the numbers and proportions of clients reporting selected symptoms, all visits combined, by treatment. If it is hypothesized that Brevicon will be associated with higher breakthrough bleeding, but lower levels of all other side effects not related to cycle control, these data are broadly consistent with that hypothesis, but differences are not striking. Similarly, placebo clients have higher proportions for most side effects than vitamin users, but the differences are small. Only the higher levels of breakthrough bleeding among Brevicon users really stand out, although other differences may ultimately be statistically significant. No vitamin contraceptive interactions are apparent.

Tables III-29 and III-30 show proportions of positive symptom grids, by symptom and cycle, for the vitamin-placebo and Brevicon-Norinyl comparisons, respectively. Within cycles, a standard t-test is appropriate for comparison of treatment differences. Vitamin-placebo differences in general tend to be unimpressive and inconsistent, but vitamin users do seem to report higher levels of headache. From Table III-30, Brevicon users seem

to report higher levels of breakthrough bleeding and breast discomfort than Norinyl users, but lower levels of headache, fatigue, and vaginal discharge; no differences are apparent regarding nausea or vomiting. Norinyl-Brevicon comparisons from symptom grids are in general consistent with those from follow-up forms; vitamin-placebo comparisons are not particularly consistent.

Table III-31 shows the mean number of symptom-days per positive grid, for all grids combined, by treatment. For example, the mean number of days of headache reported on those grids on which at least one day was reported, is 4.67 for Brevicon and 5.33 for Norinyl. One interesting finding from this gross look at mean symptom-days is that for the Brevicon-Norinyl comparison, the preparation associated with higher mean symptom-days is also associated with higher proportions reporting the symptom, for every symptom. That is, if a type of oral contraceptive was associated with a higher probability of at least one symptom episode in a cycle, it was also associated with more days per cycle of that symptom for those grids on which the symptom was reported. No such consistency is observable in the vitamin-placebo comparison. Another rather striking fact is that for all symptoms, vitamin users have lower mean numbers of symptom-days than placebo users, given one or more symptom-days reported for the given cycle. This suggests the possibility that

vitamins may vitiate the severity of the symptoms, even though there is little evidence that they reduce the incidence. It should be kept in mind that this grand mean is a gross index influenced by a number of factors, and its variance has not been computed. Hence Table III-31 should be regarded as a set of clues.

Table III-32 shows the treatment comparisons for side effects reported in the rural study. These data are remarkable for their lack of treatment differences. Other than confirmation of higher breakthrough bleeding among Brevicon users than Norinyl, the rural study provides little evidence to support any particular treatment hypothesis. However, given the wording of the item on the form and the paucity of replies, this is perhaps not particularly informative.

d. Relationships among symptoms

It is of interest in studying symptoms of oral contraception to look at correlations between symptoms at the same time. One expects, for example, that reports of vomiting should generally accompany reports of nausea, but how commonly is either of these associated with headache, among pill users? What other symptoms may be associated with reports of breakthrough bleeding?

Table III-33 presents the association between pairs of symptoms reported on the first follow-up visit (from

follow-up forms), for the ten most commonly reported symptoms, for Norinyl and Brevicon separately. The measure of association used is Yule's Q, which like the standard correlation coefficient (r) ranges from -1 to $+1$. It has the advantage that it is insensitive to row and column totals; that is, it can take its full range -1 to $+1$ regardless of whether the two variables have the same incidence. For example, in our sample, headache is more commonly reported than spotting/bleeding, so cannot approach -1 or $+1$; hence the actual value of r depends both on the degree of association and the similarity in marginal totals. Yule's Q is insensitive to differences in marginal totals, so it is preferable for these data.

If a random sample were taken of people not using any drug, one would expect generally positive correlations among those symptoms. One reason is that some people are more likely, for whatever reason, to be aware of and to report symptoms. Another is that when you feel bad, you generally have more than one complaint.

The most striking finding of Table III-33 is that there is a clear grouping of four symptoms--nausea, vomiting, dizziness, and headache--which are all highly interrelated. The 12 pairs in this group include the 9 highest of the 90 values of Yule's Q, and all 12 are among the highest 15. If one takes the average of the values for Norinyl and Brevicon, the 6 resulting values in this

group would be the 6 highest of the 45 pairs. The other consistently high values of Yule's Q are between backache and abdominal pain and, surprisingly, between backache and hair loss. The other notable finding in this table is that spotting/bleeding is not particularly related to anything else (including symptoms not shown in this table), with the possible exception of abdominal pain.

This simple pattern of associations is in itself a useful finding. It becomes of particular value when these early symptoms are related to discontinuation, as will be shown in the next section.

5. Predicting Discontinuation

On the whole, background variables were not very powerful as predictors of discontinuation, nor were they consistent across sites. In Colombo, significant differences in continuation were found by age (higher continuation for older women), religion (higher for Buddhists than "other"), and, for Brevicon users only, whether the woman worked outside the home (higher if she did). In Matara, higher continuation rates were found for older, higher-parity women, because fewer moved from the area and fewer were planning another pregnancy; and for women who wanted no more children. In Puttalam, women with higher education were less likely to discontinue because of non-menstrual medical reasons.

Some analysis on the Colombo data indicate differences in continuation for other types of variables. For both Norinyl and Brevicon users, women who filled out symptom grids had considerably higher continuation rates than women who did not. This presumably reflects a combination of the process by which symptom grid users were selected and the extra attention they received during the trial.

Table III-34 indicated differences in 9-month continuation rates according to the presence of absence on visit 1 of the 10 symptoms listed in Table III-33. One useful way of looking at these data is to take the simple difference in the 9-month rates: for example, for Norinyl users, the presence of spotting/bleeding during the first month decreases the 9-month continuation rate by 22 percent. The p-values are based on a test which cumulates differences over the 9 months, and hence can be used to infer the extent to which a difference at 9 months is also observable in prior months. For example, among Brevicon users, the differences in continuation rates for spotting/bleeding and nausea are the same, but the p-value is much lower for nausea. This is because the difference in continuation for nausea is greater in previous months.

The consistent, substantial importance of nausea, vomiting, headache, and dizziness is clear; these variables are the ones whose interassociations stand out clearly in Table III-33. The early appearance of spotting/bleeding

makes some difference, especially for Norinyl users, and Brevicon users who report irritability during the first month are also likely to discontinue.

In addition to the univariate analysis just presented, life table regression methods were used to study for each treatment the association between the presence or absence of selected symptoms on the first follow-up visit (symptoms listed in Table III-34) and the time to discontinuation for any reason and for medical reasons exclusively. Among Brevicon users, the presence or absence of complaints of vomiting during the initial follow-up period was the most significant predictor of both the time to discontinuation for medical reasons alone and for any reason ($p \leq 0.005$).

Complaints of vomiting were also significantly associated with the time to medical discontinuation ($p = 0.018$). Among Norinyl users the strongest first follow-up predictor variable for the time to discontinuation for medical reasons was, as in the case of Brevicon, a complaint of vomiting ($p < 0.001$) with reports of headache also significant ($p = 0.006$). However, for time to discontinuation for any reason reports of dizziness and of headache during the first follow-up are the most significant explanatory variables, with dizziness being by far the most significant ($p < 0.001$ for dizziness and $p = 0.021$ for headache). In these analyses, no other variable was significant at the .10 level.

These multivariate analyses indicate the predictive effect of the given symptom controlling for the presence of other symptoms, and hence, in some sense, which symptoms are the "most important." However, given the high levels of interassociation, particularly among vomiting, nausea, dizziness, and headache, the results require careful interpretation. For example, the fact that vomiting alone stands out in the analysis of Brevicon users does not necessarily mean that nausea is unimportant, given the high correlation between the two. Moreover, in a clinical sense the univariate results shown in Table III-34 remain of interest regardless of the multivariate result, since they suggest the importance which may be attached to the reporting of a given symptom regardless of what others are reported. In all analyses, the importance of the four basic symptoms stands out.

6. Other Clinical Data

Some other data were measured over time in the Colombo study which bear on the comparisons among treatments. At each follow-up visit, weights and blood pressure readings were taken, and for symptom grid users, a record was kept showing each day during which menstrual bleeding occurred.

Table III-35 shows initial levels and changes in weight and blood pressure, for those who completed the study and for whom data are available on all items of interest. The initial weights and pressures are in line with other data from

Sri Lanka (eg, Southwest Foundation, 1978, and Bibile et al, 1949). Some initial differences in weights and blood pressures are apparent: vitamin users were slightly heavier, and the V/N group had slightly higher levels of systemic blood pressure. Changes did not differ substantially, and were not statistically significant, by treatment, except that the V/N group had an anomalous decline in systolic blood pressure. Both the higher initial mean systolic blood pressure for the V/N group and the subsequent decline are partly due to several women with initially high readings whose systolic pressure on the first follow-up visit was substantially reduced. Overall, clients on all treatments gained weight and dropped in diastolic blood pressure. These changes were statistically significant, but would not appear to be clinically important, and may or may not be related to the treatments.

Table III-36 gives selected statistics on the length and starting dates of withdrawal bleeding. Clients were divided into those for whom all five symptom grids were filled out (approximately, clients who completed the study) and those for whom 1-4 grids were available (approximately, dropouts after the first cycle). Dropouts had substantially higher proportions of grids with no reported withdrawal bleeding than those who completed the study. They also appeared to have lower mean length of menses and greater variability than study completers, but these differences disappear when analysis is limited to those who reported some withdrawal

bleeding. The day of onset of menses appears to be slightly more regular among study completers. These data could be interpreted to suggest either that clients tended to drop out because of menstrual irregularity, or that women who were irregular in pill use tended both to have menstrual irregularities and to discontinue use.

Separate analysis, not shown, indicates no appreciable difference in these findings by treatment.

7. The "Norinyl Only" Areas

Some of the strengths and limitations of the clinical trial approach to treatment comparisons are well illustrated by looking at the results from the "Norinyl only" areas. It will be recalled that each rural site included a sub-area within which all acceptors were given packets of Norinyl, with neither vitamin supplements nor placebos. They were told what drug they were receiving, and, of course, the providers knew. They were followed up by the same home visitors according to the same schedule as the treatment groups, and the same records were kept on them. In Matara, some were recruited prior to the beginning of the clinical trial, but period of use can be controlled in the analysis. The areas chosen were not chosen at random, and they were somewhat different in character. The "Norinyl only" area in Matara was in the Northwest corner of the project area, a bit more remote than the rest of the site. In Puttalam, the "Norinyl

only" area was in the Northwest peninsula along the coast. Here 90 percent of the acceptors were Muslim or Roman Catholic, as opposed to less than 40 percent in the rest of the area, and the women were somewhat less well-educated. In sum, the "Norinyl only" areas represent non-random selections, with neither acceptors nor providers "blind" as to treatment, but the basic field procedures were the same.

Table III-37 shows some comparisons between these acceptors and the study acceptors, particularly the Placebo/Norinyl acceptors, whose treatment was pharmacologically identical. In Matara, "Norinyl only" users had higher continuation and fewer side effects than study treatment acceptors in general or than N/P acceptors in particular; in Puttalam, they had lower continuation and more side effects. One measure of the degree to which performance in the "Norinyl only" area differed from the clinical trial area is in the overall chi-square test of aggregate continuation rates. Of the eight comparisons between "Norinyl only" users and users of individual treatment combinations in the two areas, all were significant at the .01 level; of the twelve internal tests of differences among study treatment acceptors, only one was significant at the .10 level, and that was due to differences in "non-relevant" terminations.

The reasons are extremely interesting from a methodological viewpoint. In Puttalam, one home visiting team, consisting of one nurse and four home visitors, recruited and followed

up over half the clients, but did not work in the "Norinyl only" area at all. The other two groups, each consisting of two home visitors and a nurse, recruited both clinical trial and "Norinyl only" acceptors. The home visiting team which did not work in the "Norinyl only" area was extremely diligent and persuasive in urging acceptors to continue with the study, and their clients had much higher continuation rates than the other two groups. For these other groups, continuation rates were the same for "Norinyl only" acceptors as for the study treatment group. Thus, the substantial difference in Puttalam is entirely explained as an artifact of the geographical assignment of providers.

In Matara, the differences in the opposite direction may never be explained with such certainty, but it appears to be primarily a function of the misunderstanding regarding handling of side effects alluded to in Section A.2.e. above. Throughout most of the study, home visitors in Matara encouraged study treatment acceptors to discontinue at the first report of side effects. They appear to have been far less nervous about the "Norinyl only" acceptors, since these women were receiving a known, familiar drug. There may also have been similar nervousness among clinical trial clients. In any case, the difference seems to be a function of the difference between a double-blind, clinical trial setting and a standard distribution program.

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There are perhaps two major lessons to be drawn from this. One is that, as every clinician knows, differences in the setting within which treatment is provided are often far more important in determining the success of the treatment than minor differences in chemical composition. This is clearly the case here. Second, apparently minor deviations in either design or execution from sound scientific study principles can profoundly affect results. In many studies, procedural differences as substantial as those between the "Norinyl only" and clinical trial areas have been ignored, and differences which may well have been due to confounding factors have been ascribed to study treatments. The importance of sound scientific design is reinforced by these results.

8. Effects of Breast-feeding Status at Admission on Treatment Use

In Section III.A.1.b, it was noted that currently breast-feeding women were by oversight eligible for admission into the rural studies. Unfortunately, we have not collected data on lactation or child health, so there is no useful information on the effect of the oral contraceptives on lactation in this study. We can, however, study the associations between breast-feeding status at admission and contraceptive use.

Table III-38 shows life-table continuation rates by initial breast-feeding status. In both sites, continuation rates

decrease from currently breast-feeding without supplements to currently breast-feeding with supplements to not breast-feeding. In Matara, this is primarily associated with termination for "planned pregnancy" and "menstrual side effects"; in Puttalam, with "other medical reasons" and "menstrual side effects." It is likely that these differences are related to strength of motivation to avoid pregnancy; since these women are primarily interested in spacing births, desire to avoid pregnancy is probably inversely proportionnal to time since last birth. These trends do not seem to differ by treatment.

C. CONCLUSIONS

1. Quality of Data

Before reaching even tentative substantive conclusions on the basis of this information, it might be wise to review what we know about the quality of the information presented. Some aspects of this were touched on in Section III.A.2 above, on implementation of the trial, and others are suggested in various parts of Section III.B. The following is a brief summary.

a. Adherence to randomized, double-blind procedures.

Randomization of clients to treatment was carried out precisely in the urban study, but home visits were allocated according to the OC received, which apparently affected rates of discontinuation for non-relevant reasons as described previously. In the rural sites, there

were minor deviations from complete randomization, but these were not of a nature or degree that would seem likely to affect the trial results. There were some limitations to the double-blind nature of the design. The problem of vitamin spoilage, particularly in Matara, could potentially have led to provider bias, as could the printing of the contents of the oral contraceptives on the package. There is no way to be certain that these biases were not present. It is reassuring in this regard that provider interest seems to have been on the vitamin supplement test rather than the OC dosage comparison, and the vitamin/placebo comparison yielded consistently negative results. In most ways, the spirit of a randomized, double-blind trial was carefully adhered to. The only apparent danger to the integrity of the treatment comparisons is in the allocation of home visitors to treatments.

- b. Adherence to protocol. The one major deviation from the original admission requirements was the inclusion of currently breast-feeding women in the rural study, as a result of miscommunication between IFRP and the FPA. Since information on breast-feeding at admission is available, treatment comparisons can be adjusted for this factor, and indeed it appears not to have been relevant for treatment comparisons. Unfortunately, there is no information available to assess the effect of pill

consumption on lactation or on the health of the children. Otherwise there were only a few scattered admissions not in conformance with protocol.

Adherence to the OC regime seems to have been quite good in the urban study, as indicated by symptom grid data, spot checks, and the overall twelve-month cumulative net failure rate of 2.6 percent. In the rural study, adherence seems to have been less regular, as indicated on follow-up forms and by 12-month cumulative net failure rates of 7.6 percent and 5.8 percent for Matara and Puttalam, respectively. Frequent unscheduled visits in both urban and rural areas, during which packets were routinely checked, indicated that vitamin supplements were consistently taken with the pills.

- c. Discontinuation. In spite of consistent and strong efforts at follow-up, rates of discontinuation were generally high, especially in Matara. In Colombo, a highly mobile slum population proved difficult to keep track of and sometimes hard to keep motivated despite strong efforts on the part of the staff. In both rural areas, client motivation to avoid pregnancy seemed low (in spite of professed desire for small family sizes), and in Matara this was compounded by the staff not understanding the need to urge continuation in spite of initial side effects. High discontinuation rates do not cause problems for treatment comparisons on continuation rates--

indeed, substantial dropout is necessary to have something to compare--but they do cause complications for the analysis of side effects, because continuing users are selected for low side effect rates and, presumably, rapid decrease in side effects.

- d. Side effect data. Data on reported side effects are inherently an amalgam of a variety of factors and, in principle, should never be directly interpreted as physiological events due to the drug in question. Good data on reported side effects cannot be more than the careful monitoring of perceived symptoms. Urban study data in this context seem quite good. There is some evidence that a substantial proportion of clients may have filled out their symptom grids retrospectively (ie, high frequencies of 7- and 14-day symptom durations). Also, the extreme reduction in side effects in the latter months of use probably reflects declining care in monitoring by the clients towards the end of their participation, among other factors. On the other hand, the fact that symptom levels reported on the follow-up forms on a one-cycle retrospective basis are comparable to the symptom grid data, and the general compatibility of the results with other relevant data both support the assertion that the urban side effect data are of reasonably good quality. The rural data were not designed to be comparable, but were expected to get indications of which

side effects were particularly bothersome to the clients. At this stage, there is no good way of evaluating the quality of these reports.

- e. Other data. In both urban and rural areas, background data were collected on all clients. As always, the quality of such data varies with the item in question. In general, the Sri Lanka population is highly educated and, even in the disadvantaged populations in this study, knowledge of basic socioeconomic concepts is quite good. The only clinical measurements in the urban study were weight and blood pressure, and there is no reason to doubt the accuracy of these measurements.

The quality of forms was consistently high for all sites, as reflected by the small percentage removed for editing (Section III.B.1.). The forms were filled out and checked with care, and the number of missing items and inconsistencies was minimal. In the rural study, there were some points of confusion in filling out follow-up forms, but these were generally found and corrected on site.

- f. Summary. The process of translating principles of complex statistical design from US-based statisticians to the homes of remote rural or poor urban women in Sri Lanka is an extremely difficult one, and it should be no surprise that in some instances there were errors in

execution. Nevertheless, in all three sites complex, large-scale clinical trials were executed with a high level of fidelity to sound research principles. The urban data in particular are of sufficiently good quality to be of international importance. The quality of these data is a high tribute to the competence and integrity of the Family Planning Association of Sri Lanka.

2. Preliminary Conclusions from the Clinical Trial

- a. Vitamin/Placebo Comparisons. The lack of effect of the vitamin supplements in all areas of investigation is consistent and striking. If there appears to be a slight tendency, overall, for vitamin supplements to be associated with fewer side effects, that tendency is neither substantial nor statistically significant, and is offset by the small, nonsignificant tendency for placebos to be associated with higher continuation rates. This conclusion is consistent across all three sites, and is highly unlikely to have been influenced by either provider or client bias. The quantity and quality of information is sufficient to justify a firm conclusion on this topic: in the populations studied, the provision of a daily multi-vitamin supplement taken in conjunction with either of two types of oral contraceptives made no difference in either continuation or side effects associated with oral contraceptive use.

b. Brevicon/Norinyl Comparisons. There are clear differences in side effects reported in the urban study between Brevicon and Norinyl, and those differences are consistent with reasonable biological hypotheses and with other empirical data. Brevicon is associated with higher levels of breakthrough bleeding, and Norinyl is associated with higher levels of most other common side effects with the notable exceptions of nausea and vomiting. Rural data were less conclusive as a result of the design of the study, but there did seem to be more complaints of menstrual side effects among Brevicon users in both Matara and Puttalam.

Final determination on comparative continuation rates cannot be made. There is a large, highly significant difference in the urban study in favor of Norinyl, but in terms of reported reason for discontinuation this is entirely accounted for by differences in termination due to "personal reasons," "moved from area" and "lost to follow-up." It seems highly unlikely that these results could have occurred by chance. In part, they are probably due to differences in the effectiveness of the two principal home visitors. The hypothesis that women actually discontinuing because of method dissatisfaction were reported to have terminated for "unrelated" reasons, and that this process occurred more frequently with Brevicon users, is unsubstantiated. Results from the rural sites

show somewhat higher continuation for Norinyl at 12 months, but not necessarily earlier.

In sum, we are inclined to believe that most, if not all, of the observed difference in continuation rates between Norinyl and Brevicon is due to a bias in field procedures, and that little or no difference can be ascribed to the pharmacology of the contraceptives.

- c. General Reactions to Oral Contraception. Levels of reported side effects were compared with a previous Sri Lanka study and with a US study, both of which used comparable methodology. Levels obtained in the previous Sri Lanka study were generally confirmed. Overall, the general levels of reports were somewhat lower than US data, and there were some striking differences for certain symptoms. Sri Lanka women reported more headache and far more dizziness; US women reported far greater levels of breakthrough bleeding, breast discomfort, abdominal bloating, change in acne, increased sexual desire, depression, rashes and vaginal itching.

For both Norinyl and Brevicon users, a cluster of fewer reported first-cycle side effects--nausea, vomiting, headache and dizziness--tended to be highly correlated with each other, and to be strongly predictive of later discontinuation. Menstrual side effects were not highly

correlated with other side effects, and were not as strongly predictive of discontinuation, for either drug.

- d. Pharmacologic vs Programmatic Effects on Contraceptive Use. Except for the still unexplained difference in continuation between Norinyl and Brevicon in Colombo, differences in continuation rates among study treatments were far smaller than overall differences between study sites. In addition, in the rural areas differences between study treatments are far smaller than differences between the clinical trial areas and the "Norinyl only" areas, which appear to be due to some rather subtle differences in program execution. Finally, in the urban study, a major difference in continuation rates seems to be associated with the identity of the home visitor, even for women who were expected to return to the clinic for follow-up. The lesson is not new, but is nicely illustrated here: differences in procedures are likely to have far more effect on program effectiveness than minor differences in contraceptive method technology.

Table III-1. Study Acceptors by Treatment and Site

<u>Site</u>	<u>Treatment*</u>					<u>All treatments</u>
	<u>B/V</u>	<u>B/P</u>	<u>N/V</u>	<u>N/P</u>	<u>N only</u>	
Colombo	125	125	125	125	---	500
Matara	309	339	370	352	265	1635
Puttalam	186	204	191	200	405	1186
All Areas	620	668	686	677	670	3321

*In Matara, these numbers do not include women who agreed to accept and were given supplies, but never actually began use. Such women were not reported, and their number is not available.

Table III-2. Distribution of Follow-up Visits by Cycle, Urban Study.

<u>Cycle</u>	<u>No. of Follow-up Visits</u>
1	37
2	394
3	75
4	286
5	48
6	50
7	214
8	35
9	44
10	181
11	24
12	7
13+	233

Table III-3. Age at Admission, by Site

<u>Age</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Under 20	55	11	36	2	57	7
20-24	182	36	368	23	307	36
25-29	161	32	493	31	274	32
30-34	68	14	345	22	129	15
35-39	29	6	253	16	60	7
40+	<u>2</u>	<u>0+</u>	<u>75</u>	<u>5</u>	<u>22</u>	<u>3</u>
All Ages	497	100	1570	100	849	100

Table III-4. Ethnic Group, by Site

<u>Ethnic Group</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Sinhalese	410	83	1360	87	632	74
Sri Lanka Moor	37	7	1	0+	150	18
Sri Lanka Tamil	31	6	141	9	67	8
Indian Tamil	6	1	68	4	0	-
Other	<u>13</u>	<u>3</u>	<u>0</u>	<u>-</u>	<u>0</u>	<u>-</u>
All categories	497	100	1570	100	849	100

Table III-5. Religion by Site

<u>Religion</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Buddhist	362	73	1367	87	389	46
Catholic	64	13	3	0+	287	34
Hindu	26	5	194	12	25	3
Muslim	37	8	3	0+	148	17
Other or none	<u>8</u>	<u>2</u>	<u>3</u>	<u>0+</u>	<u>0</u>	<u>0</u>
All Religions	497	100	1570	100	849	100

Table III-6. Clients' Education in Number of Completed School Year, by Site

<u>Year of School</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
0	6	1	408	26	87	10
1-5	78	16	715	45	393	46
6-9	208	42	278	18	264	31
10+	<u>205</u>	<u>41</u>	<u>169</u>	<u>11</u>	<u>105</u>	<u>12</u>
All categories	497	100	1570	100	849	100

Table III-7. Husband's Education in Number of Completed School Year, by Site

<u>Year of School</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
0	12	2	176	11	45	5
1-5	47	9	843	54	317	37
6-9	171	33	368	23	362	43
10+	266	54	183	12	125	15
Unknown	<u>1</u>	<u>0+</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
All categories	497	100	1570	100	849	100

Table III-8. Women by Number of Children Ever Borne, by Site

<u>Children</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
0	33	7	3	0+	5	1
1	148	30	300	19	156	18
2	169	34	392	25	249	29
3	95	19	282	18	165	19
4-6	46	9	463	30	217	26
7+	<u>6</u>	<u>1</u>	<u>130</u>	<u>8</u>	<u>57</u>	<u>7</u>
All numbers	497	100	1570	100	849	100

Table III-9. Age of Youngest Child, in Years, by Site

<u>Age (years)</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
<1	235	47	783	50	358	42
1	122	25	446	28	273	32
2	52	11	160	10	86	10
3	30	6	90	6	45	5
4	15	3	28	2	33	4
5+	<u>43</u>	<u>8</u>	<u>63</u>	<u>4</u>	<u>54</u>	<u>6</u>
Total children	497	100	1570	100	849	100

Table III-10. Number of Additional Children Wanted, by Site

<u>Number Wanted</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
0	246	50	832	53	531	63
1	207	42	437	28	199	23
2	37	7	265	17	111	13
3+	<u>7</u>	<u>1</u>	<u>36</u>	<u>2</u>	<u>8</u>	<u>1</u>
All numbers	497	100	1570	100	849	100

Table III-11. Contraceptive Method Mainly Used Previously, by Site

<u>Method</u>	Site					
	Colombo		Matara		Puttalam	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
None	265	53	1465	93	653	77
IUD	30	6	5	0+	25	3
Orals	82	16	48	3	164	19
Condoms	46	9	10	0+	5	0+
Withdrawal /rhythm	11	2	12	1	0	0
Injectables	63	13	1	0+	1	0+
Other	<u>0</u>	<u>0</u>	<u>29</u>	<u>2</u>	<u>1</u>	<u>0+</u>
All method	497	100	1570	100	849	100

Table III-12. Continuation Rates by Month and Computation Procedure,
All Treatments Combined, Colombo

Ordinal Month	N*2	Procedure A ¹			N*2	Procedure B ¹		
		Termi- nations	Cumulative Rate	Std Error		Termi- nations	Cumulative Rate	Std Error
1	478.0	56	.883	.015	497.0	94	.811	.018
2	395.0	25	.827	.018	403.0	41	.728	.020
3	353.0	21	.778	.020	362.0	39	.650	.021
4	320.5	12	.749	.021	323.0	17	.616	.022
5	301.0	18	.704	.022	306.0	28	.559	.022
6	275.5	8	.683	.022	278.0	13	.533	.022
7	262.5	8	.663	.023	265.0	13	.507	.022
8	250.0	3	.655	.023	252.0	7	.493	.022
9	241.0	0	.655	.023	245.0	8	.477	.022
10	235.5	1	.652	.023	236.0	2	.473	.022
11	157.0	2	.644	.024	161.5	10	.443	.023
12	43.0	2	.614	.031	44.5	3	.414	.027

¹ Procedure A assigns terminations due to "moved from area" and "lost to follow-up" to the "withdrawn from observation" category, and omits women with no follow-up information from analysis. Procedure B assigns separate termination categories for "moved from area" and "lost to follow-up," and includes women with no follow-up information in analysis.

² The estimated number of woman-months of risk during the month.

Table III-13. Continuation Rates for Randomized Treatments, by Month and Computation Procedure, Matara, First Twelve Months

Ordinal Month	N*2	Procedure A ¹			N*2	Procedure B ¹		
		Termi- nations ³	Cumulative Rate	Std Error		Termi- nations ³	Cumulative Rate	Std Error
1	1302.0	123	.905	.008	1305.0	129	.901	.008
2	1139.5	230	.723	.013	1147.0	245	.709	.013
3	845.0	135	.607	.014	854.5	154	.581	.014
4	648.0	97	.516	.015	655.0	111	.482	.014
5	510.5	60	.456	.015	516.0	71	.416	.014
6	421.5	44	.408	.015	423.5	48	.369	.014
7	345.5	38	.363	.015	348.5	44	.322	.014
8	267.5	21	.335	.015	271.0	28	.289	.014
9	199.5	17	.306	.015	202.5	23	.256	.014
10	142.5	20	.263	.016	143.0	21	.218	.014
11	97.0	13	.228	.017	98.5	16	.183	.014
12	66.0	9	.197	.017	67.0	11	.153	.015

¹For description of procedures, see Table III-12 and text, section III.B.3.

²The estimated number of woman-months of exposure during the period.

³Subject to random allocation error. See text, section III.B.3.iv.

Table III-14. Continuation Rates for Randomized Treatments, by Month and Computation Procedure, Puttalam, First Twelve Months

Ordinal Month	N*2	Procedure A ¹			N*2	Procedure B ¹		
		Terminations ³	Cumulative Rate	Std Error		Terminations ³	Cumulative Rate	Std Error
1	622.5	30	.952	.009	623.5	32	.949	.009
2	568.5	39	.886	.013	569.5	41	.880	.013
3	490.0	28	.836	.015	491.5	30	.827	.016
4	425.0	19	.798	.017	426.5	22	.784	.018
5	380.0	25	.746	.019	381.0	27	.728	.019
6	317.0	24	.689	.021	321.0	32	.656	.021
7	251.0	11	.659	.022	252.5	14	.619	.022
8	217.5	11	.626	.023	219.0	14	.580	.023
9	183.0	13	.581	.024	183.5	14	.536	.024
10	142.0	15	.520	.026	144.0	19	.465	.026
11	95.5	11	.460	.029	95.5	11	.411	.027
12	48.0	4	.422	.032	48.5	5	.369	.031

¹For description of procedures, see Table III-12 and text, section III.B.3.

²The estimated number of woman-months of exposure during the period.

³Subject to random allocation error. See text, section III.B.3.iv.

Table III-15. Six-Month and Twelve-Month Continuation Rates, by Selected Background Characteristic and Site

Background Characteristic	Colombo				Matara				Puttalam			
	6-Month Rate	S.E.	12-Month Rate	S.E.	6-Month Rate	S.E.	12-Month Rate	S.E.	6-month Rate	S.E.	12-Month Rate	S.E.
Age												
<25	.48	.03	.39	.03	.36	.02	.12	.02	.59	.03	.33	.04
25+	.58	.03	.46	.04	.42	.02	.19	.02	.60	.02	.33	.03
	$X^2 = 5.85, p = .015$				$X^2 = 11.00, p = .001$				$X^2 = 0.00, p = .992$			
Additional children desired												
0	.53	.03	.39	.04	.42	.02	.19	.02	.58	.02	.34	.03
1+	.54	.03	.46	.03	.38	.02	.14	.02	.63	.03	.31	.04
	$X^2 = .25, p = .617$				$X^2 = 3.58, p = .058$				$X^2 = 1.49, p = .222$			
Children ever born												
<3	.51	.03	.41	.03	.37	.02	.13	.02	.60	.03	.32	.04
3+	.58	.04	.46	.05	.42	.02	.19	.02	.59	.03	.34	.03
	$X^2 = 1.73, p = .188$				$X^2 = 9.99, p = .002$				$X^2 = 0.23, p = .63$			
Patient's education												
0-5	.49	.05	.33	.07	.40	.02	.17	.02	.55	.03	.31	.03
6+	.54	.02	.45	.03	.39	.02	.17	.02	.65	.03	.35	.04
	$X^2 = 0.85, p = .355$				$X^2 = 0.00, p = .991$				$X^2 = 2.98, p = .084$			

Table III-16. Six- and Twelve-Month Continuation Rates, by Site and Treatment

Treatment ¹	Colombo				Matara				Puttalam			
	6-Month Rate	S.E.	12-Month Rate	S.E.	6-Month Rate	S.E.	12-Month Rate	S.E.	6-month Rate	S.E.	12-Month Rate	S.E.
V/B	.47	.04	.25	.06	.34	.03	.12	.02	.73	.04	.34	.06
V/N	.60	.04	.55	.05	.37	.03	.14	.03	.62	.04	.41	.06
P/B	.46	.05	.37	.05	.40	.03	.15	.03	.63	.04	.30	.06
P/N	.60	.04	.50	.05	.36	.03	.22	.03	.60	.04	.45	.06
V	.53	.03	.39	.04	.35	.02	.14	.02	.71	.03	.33	.05
P	.53	.03	.43	.04	.37	.02	.18	.02	.62	.03	.37	.04
B	.47	.03	.30	.04	.37	.02	.13	.02	.70	.03	.32	.04
N	.60	.03	.52	.03	.37	.02	.18	.02	.61	.03	.43	.04
All	.53	.02	.41	.03	.37	.01	.15	.01	.66	.02	.37	.03

¹Treatment codes: V = vitamin supplement, P = placebo, B = Brevicon, N = Norinyl

Table III-17. Six-Month Gross Termination Rates and Total Terminations, by Reason and Treatment, Colombo

Reason for Discontinuation	Vitamins	Placebo	Brevicon	Norinyl
Unplanned pregnancy				
6-month rate (s.e.)	.028 (.013)	.020 (.011)	.032 (.012)	.017 (.01)
12-month rate (s.e.)	.075 (.047)	.020 (.011)	.086 (.054)	.017 (.01)
Total terminations	6	3	6	3
Menstrual side effects				
6-month rate (s.e.)	.000 (.000)	.012 (.009)	.005 (.005)	.007 (.007)
12-month rate (s.e.)	.000 (.000)	.012 (.009)	.005 (.005)	.007 (.007)
Total terminations	0	2	1	1
Other medical				
6-month rate (s.e.)	.083 (.019)	.102 (.021)	.087 (.020)	.098 (.020)
12-month rate (s.e.)	.083 (.019)	.109 (.022)	.095 (.021)	.098 (.020)
Total terminations	18	23	19	22
Planned pregnancy				
6-month rate (s.e.)	.023 (.012)	.024 (.012)	.028 (.014)	.020 (.010)
12-month rate (s.e.)	.047 (.018)	.063 (.023)	.047 (.019)	.061 (.021)
Total terminations	7	8	6	9
Personal reason				
6-month rate (s.e.)	.169 (.027)	.166 (.027)	.208 (.030)	.129 (.024)
12-month rate (s.e.)	.186 (.029)	.216 (.045)	.277 (.052)	.135 (.025)
Total terminations	35	38	45	28
Moved from area				
6-month rate (s.e.)	.099 (.021)	.085 (.021)	.124 (.025)	.064 (.017)
12-month rate (s.e.)	.178 (.033)	.122 (.027)	.222 (.037)	.090 (.023)
Total terminations	29	20	33	16
Program - specific				
6-month rate (s.e.)	.000 (.000)	.017 (.010)	.013 (.009)	.005 (.005)
12-month rate (s.e.)	.000 (.000)	.017 (.010)	.013 (.009)	.005 (.005)
Total terminations	0	3	2	1
Other reason				
6-month rate (s.e.)	.044 (.015)	.029 (.013)	.022 (.011)	.049 (.016)
12-month rate (s.e.)	.059 (.018)	.037 (.015)	.030 (.014)	.062 (.018)
Total terminations	10	6	5	11
Lost to follow-up				
6-month rate (s.e.)	.142 (.025)	.138 (.025)	.187 (.029)	.099 (.021)
12-month rate (s.e.)	.232 (.047)	.183 (.030)	.286 (.052)	.139 (.026)
Total terminations	36	34	43	27

Table III-17 (cont'd)

Reason for Discontinuation	Vitamins	Placebo	Brevicon	Norinyl
All terminations				
6-month rate (s.e.)	.466 (.032)	.468 (.032)	.534 (.032)	.400 (.031)
12-month rate (s.e.)	.609 (.040)	.570 (.037)	.699 (.040)	.477 (.032)
Total terminations	141	137	160	118

Table III-18. Six-Month and Twelve-Month Gross Termination Rates and Total Terminations, by Reason and Treatment, Matara

Reason for discontinuation	Vitamins	Placebo	Brevicon	Norinyl
Unplanned Pregnancy				
6-month rate (s.e.)	.064 (.014)	.073 (.014)	.051 (.013)	.086 (.015)
12-month rate (s.e.)	.253 (.048)	.168 (.040)	.229 (.049)	.177 (.034)
Total terminations	38	38	33	43
Menstrual Side Effects				
6-month rate (s.e.)	.058 (.013)	.037 (.009)	.064 (.014)	.038 (.010)
12-month rate (s.e.)	.070 (.015)	.091 (.030)	.107 (.028)	.052 (.014)
Total terminations	24	22	28	18
Other Medical				
6-month rate (s.e.)	.455 (.024)	.447 (.022)	.442 (.024)	.454 (.022)
12-month rate (s.e.)	.601 (.032)	.566 (.035)	.588 (.034)	.578 (.033)
Total terminations	255	265	245	275
Planned Pregnancy				
6-month rate (s.e.)	.002 (.002)	.014 (.007)	.010 (.005)	.006 (.005)
12-month rate (s.e.)	.062 (.036)	.056 (.025)	.091 (.042)	.061 (.037)
Total terminations	5	8	8	5
Personal Reason				
6-month rate (s.e.)	.029 (.009)	.017 (.007)	.019 (.007)	.019 (.007)
12-month rate (s.e.)	.029 (.009)	.023 (.009)	.033 (.012)	.019 (.007)
Total terminations	11	7	10	8
Moved from Area				
6-month rate (s.e.)	.089 (.017)	.074 (.015)	.064 (.014)	.083 (.015)
12-month rate (s.e.)	.218 (.042)	.161 (.033)	.238 (.048)	.152 (.030)
Total terminations	42	37	40	39
Program-Specific				
6-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
12-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
Total terminations	0	0	0	0
Other Reason				
6-month rate (s.e.)	.153 (.021)	.132 (.018)	.155 (.021)	.123 (.017)
12-month rate (s.e.)	.287 (.039)	.279 (.042)	.277 (.037)	.282 (.043)
Total terminations	72	68	70	70

Table III-18. (Cont'd)

Reason for discontinuation	Vitamins	Placebo	Brevicon	Norinyl
Lost to Follow-up				
6-month rate (s.e.)	.017 (.007)	.030 (.009)	.022 (.008)	.023 (.008)
12-month rate (s.e.)	.023 (.010)	.039 (.013)	.022 (.008)	.035 (.012)
Total terminations	7	12	8	11
All Terminations				
6-month rate (s.e.)	.647 (.021)	.627 (.020)	.629 (.021)	.633 (.020)
12-month rate (s.e.)	.863 (.019)	.824 (.022)	.866 (.019)	.822 (.021)
Total terminations	454	457	422	469

Table III-19. Six-Month and Twelve-Month Gross Termination Rates and Total Terminations, by Reason and Treatment, Puttalam

Reason for discontinuation	Vitamins	Placebo	Brevicon	Norinyl
Unplanned Pregnancy				
6-month rate (s.e.)	.030 (.012)	.018 (.010)	.021 (.011)	.033 (.013)
12-month rate (s.e.)	.119 (.046)	.117 (.050)	.175 (.056)	.033 (.013)
Total terminations	12	8	13	7
Menstrual Side Effects				
6-month rate (s.e.)	.059 (.017)	.073 (.018)	.045 (.014)	.066 (.016)
12-month rate (s.e.)	.219 (.063)	.120 (.029)	.165 (.040)	.126 (.040)
Total terminations	20	21	21	20
Other Medical				
6-month rate (s.e.)	.130 (.021)	.194 (.026)	.154 (.023)	.181 (.026)
12-month rate (s.e.)	.263 (.038)	.259 (.034)	.274 (.040)	.253 (.034)
Total terminations	50	54	52	52
Planned Pregnancy				
6-month rate (s.e.)	.005 (.005)	.019 (.009)	.017 (.009)	.012 (.008)
12-month rate (s.e.)	.081 (.045)	.109 (.053)	.130 (.054)	.050 (.038)
Total terminations	5	7	9	3
Personal Reason				
6-month rate (s.e.)	.068 (.017)	.077 (.019)	.044 (.013)	.104 (.022)
12-month rate (s.e.)	.223 (.054)	.127 (.034)	.147 (.038)	.173 (.032)
Total terminations	28	21	19	20
Moved from Area				
6-month rate (s.e.)	.029 (.012)	.055 (.017)	.042 (.014)	.057 (.018)
12-month rate (s.e.)	.074 (.023)	.142 (.034)	.115 (.031)	.129 (.042)
Total terminations	12	19	16	15
Program-Specific				
6-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
12-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
Total terminations	0	0	0	0
Other Reason				
6-month rate (s.e.)	.005 (.005)	.022 (.011)	.014 (.008)	.012 (.009)
12-month rate (s.e.)	.005 (.005)	.031 (.014)	.022 (.011)	.012 (.009)
Total terminations	1	5	4	2

Table III-19. (Cont'd)

Reason for discontinuation	Vitamins	Placebo	Brevicon	Norinyl
Lost to Follow-up				
6-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
12-month rate (s.e.)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
Total terminations	0	0	0	0
All Terminations				
6-month rate (s.e.)	.289 (.028)	.385 (.031)	.298 (.028)	.390 (.031)
12-month rate (s.e.)	.667 (.047)	.628 (.043)	.679 (.042)	.574 (.043)
Total terminations	128	135	134	129

Table III-20. Net 6-Month and 12-Month Termination Rates by Reason and Site, all Treatments (Standard errors in parentheses)

Reason	Colombo		Matara		Puttalam	
	6-Month	12-Month	6-Month	12-Month	6-Month	12-Month
Unplanned pregnancy	.016 (.006)	.026 (.011)	.041 (.005)	.076 (.008)	.027 (.006)	.058 (.011)
Menstrual side effects	.004 (.003)	.004 (.003)	.046 (.006)	.057 (.006)	.039 (.007)	.075 (.012)
Other medical	.081 (.012)	.083 (.012)	.363 (.013)	.441 (.015)	.195 (.015)	.277 (.019)
Planned pregnancy	.016 (.006)	.032 (.008)	.006 (.002)	.019 (.005)	.011 (.004)	.038 (.011)
Personal reasons	.133 (.015)	.152 (.019)	.011 (.003)	.013 (.003)	.079 (.010)	.125 (.014)
Moved from area	.072 (.012)	.104 (.014)	.042 (.005)	.084 (.009)	.043 (.008)	.083 (.012)
Program Specific	.006 (.004)	.006 (.004)	.000 (.000)	.000 (.000)	.000 (.000)	.000 (.000)
Other reasons	.026 (.007)	.032 (.008)	.080 (.007)	.128 (.010)	.010 (.004)	.014 (.005)
Lost to follow up	.113 (.014)	.148 (.018)	.012 (.003)	.014 (.003)	.000 (.000)	.000 (.000)
All terminations	.467 (.023)	.586 (.028)	.602 (.014)	.832 (.014)	.403 (.019)	.670 (.024)

TABLE III-21. Availability of Side Effect Data, by Source

Side Effect	Rural Follow-up	Urban Follow-up	Symptom Grid (Urban only)
Spotting/Breakthrough bleeding	●	●	●
Amenorrhea	●		
Nausea	●	●	●
Vomiting		●	●
Dizziness	●	●	
Headache		●	●
Hair loss		●	
Backache		●	
Diarrhea		●	
Constipation		●	
Abdominal pain	●	●	
Edema	●	●	
Leg pains/cramps	●	●	
Fatigue	●	●	●
Irritability	●	●	
Depression		●	
Breast discomfort/tenderness	●	●	●
Change of appetite	●	●	
Acne/oily skin	●	●	
Rashes		●	
Chloasma		●	
Change in sexual desire		●	
Vaginal itching		●	
Vaginal discharge		●	●
Weight change*	●	●	

*In the rural data, weight change was asked of the respondent.
 In the urban study, the respondent was weighed at each follow-up visit.

Table III-22. Numbers and Proportions of Symptom Reports, by Cycle of Visit¹ and Symptom, All Treatments, Urban Follow-up Data

Symptom	Cycle Nos.									
	1-2 (N=387)		3-5 (N=347)		6-8 (N=271)		9-11 (N=226)		12-13 (N=208)	
	No.	%	No.	%	No.	%	No.	%	No.	%
Spotting/ bleeding	82	.21	38	.11	20	.07	16	.07	2	.01
Nausea	111	.29	37	.11	14	.05	4	.02	0	.00
Vomiting	65	.17	16	.05	4	.01	2	.01	0	.00
Dizziness	104	.27	42	.12	9	.03	5	.02	2	.01
Headache	185	.48	129	.37	81	.30	78	.35	38	.18
Hair loss	63	.16	36	.10	20	.07	9	.04	2	.01
Backache	67	.17	50	.14	26	.10	11	.05	10	.05
Abdominal pain	66	.17	55	.16	27	.10	14	.06	2	.01
Irrita- bility	104	.27	79	.23	49	.18	34	.15	12	.06
Leg pains	53	.14	45	.13	26	.10	20	.09	6	.03
Tiredness	90	.23	80	.23	47	.17	42	.19	15	.07
Breast discomfort/ tenderness	16	.04	10	.03	8	.03	2	.01	1	.00+
Incr. vaginal discharge	31	.08	23	.07	21	.08	11	.05	3	.01
Decr. vaginal discharge	20	.05	8	.02	6	.02	4	.02	2	.01
Diarrhea	8	.02	1	.00+	1	.00+	0	.00	0	.00
Constipation	30	.08	15	.04	11	.04	7	.03	0	.00
Abdominal bloating	15	.04	11	.03	6	.02	4	.02	1	.00+
Edema	0	.00	1	.00+	0	.00	0	.00	0	.00
Depression	22	.06	26	.07	14	.05	14	.06	4	.02

Table III-22 (Cont'd)

Symptom	Cycle Nos.									
	1-2 (N=387)		3-5 (N=347)		6-8 (N=271)		9-11 (N=226)		12-13 (N=208)	
	No.	%	No.	%	No.	%	No.	%	No.	%
Increased appetite	43	.11	33	.10	25	.09	11	.05	2	.01
Decreased appetite	60	.16	34	.10	10	.04	12	.05	2	.01
Incr. acne / oily skin	9	.02	2	.01	0	.00	0	.00	0	.00
Decr. acne / oily skin	12	.03	1	.00+	0	.00	0	.00	0	.00
Rashes	8	.02	3	.01	1	.00+	0	.00	0	.00
Chloasma	2	.01	2	.01	2	.01	2	.01	1	.00+
Incr. sexual desire	11	.03	5	.01	6	.02	3	.01	4	.02
Decr. sexual desire	60	.16	41	.12	14	.05	8	.04	2	.01
Vaginal itching	9	.02	6	.02	0	.00	5	.01	0	.00

¹ Reference period is 28 days prior to visit, so symptom cycle is typically composed partly of cycle of visit and partly of previous cycle. Categories correspond roughly to scheduled visit cycles.

Table III-23. Numbers and Proportions of Positive Symptom Grids,¹ by Cycle² and Symptoms, All Treatments

Symptom	Cycle Nos.									
	1 (N=177)		3 (N=151)		6 (N=129)		9 (N=120)		12 (N=115)	
	No.	%	No.	%	No.	%	No.	%	No.	%
Spotting/ bleeding	36	.20	13	.09	8	.06	4	.03	1	.01
Nausea	51	.29	9	.06	2	.02	0	.00	0	.00
Vomiting	29	.16	5	.03	1	.01	0	.00	1	.01
Headache	79	.45	39	.26	24	.19	25	.21	15	.13
Fatigue (tiredness)	50	.28	25	.17	13	.10	6	.05	5	.04
Breast tenderness/ swelling	8	.05	5	.03	2	.02	1	.01	0	.00
Vaginal discharge	49	.28	24	.16	18	.14	11	.09	7	.06

¹ A "positive symptom grid" is one for which the given symptom was reported on at least one day of the cycle.

² Scheduled cycle. Generally, but not always, coincides with actual cycle.

Table III-24. Proportions of Positive Cycles for Selected Side Effects, Cycles 1 and 3,¹ Comparative Data for Norinyl Users

Symptom	Cycle	Sri Lanka Goldzieher Follow-up	Sri Lanka OC/Vit. Follow-up	Sri Lanka OC/Vit. Grids	USA Seattle Grids
Spotting/bleeding	1	.05	.14	.19	.50
	3	.06	.08	.09	.20
Nausea	1	.24	.30	.29	.36
	3	.12	.09	.04	.20
Vomiting	1	.07	.15	.14	.07
	3	.04	.04	.02	.09
Headache	1	.45	.50	.48	.33
	3	.29	.40	.27	.11
Dizziness	1	.40	.32	n.a.	.09
	3	.25	.11	n.a.	.04
Fatigue	1	n.a.	.27	.34	.30
	3	n.a.	.25	.17	.20
Breast discomfort	1	n.a.	.03	.01	.57
	3	n.a.	.02	.01	.42
Vaginal discharge	1	.50 ²	.54 ²	.37	.26
	3	.54 ²	.49 ²	.18	.19

¹ For the OC/vitamin data, cycle numbers are approximations, as in Table III-22 and III-23

² Computed as one minus the proportion reporting no discharge. Hence probably biased upward in comparison with symptom grid data.

Table III-25. Proportions Reporting No Side Effects, by Visit, Rural and Urban Follow-up Data

<u>Visit</u>	<u>Proportion Reporting No Side Effects</u>		
	<u>Colombo¹</u>	<u>Matara</u>	<u>Puttalam</u>
1	.14	.77	.68
2	.22	.69	.83
3	.35	.82	.88
4	.32	.84	.91
5	.68	.76	.88

¹Proportion reporting none of the side effects specifically listed on the rural follow-up form.

Table III-26. Numbers and Proportions of Reported Side Effects, Visits 1-5, by Site

<u>Side Effect</u>	<u>Matara</u>		<u>Puttalam</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Bleeding/spotting	60	7	71	21
Nausea/vomiting	250	28	129	39
Dizziness/headache	230	26	81	24
Abdominal pain	86	10	18	5
All other	<u>267</u>	<u>30</u>	<u>35</u>	<u>10</u>
All	893	100	334	100

Table III-27. Total Numbers of Side Effect Reports, by Treatment for Selected Side Effects, All Visits Combined, Urban Follow-up Data

Side Effect	Treatment							
	V/B	V/N	P/B	P/N	V	P	B	N
Spotting/bleeding	57	28	42	31	85	73	99	59
Nausea	28	36	36	42	64	78	64	78
Vomiting	12	23	29	19	35	48	41	42
Dizziness	24	41	35	38	65	73	59	79
Headache	65	83	68	80	148	148	133	163
Hair loss	20	31	18	25	51	43	38	56
Backache	26	33	25	31	59	56	51	64
Abdominal pain	22	39	28	35	61	63	50	74
Irritability	40	50	39	57	90	96	79	107
Leg pains/cramps	15	43	32	31	58	63	47	74
Tiredness	36	57	44	58	93	102	80	115
Breast discomfort	4	7	10	7	11	17	14	14
Vaginal discharge	9	24	15	29	33	44	24	53
Number of client-visits	304	415	327	393	719	720	631	808

Table III-28. Proportions of Visits on Which Side Effects Were Reported, by Treatment for Selected Side Effects, All Visits Combined, Urban Follow-Up Data

Symptom	Treatment								All
	V/B	V/N	P/B	P/N	V	P	B	N	
Spotting/bleeding	.19	.07	.13	.08	.12	.10	.16	.07	.11
Nausea	.11	.09	.13	.13	.10	.13	.12	.11	.12
Vomiting	.04	.06	.10	.05	.05	.07	.07	.05	.06
Dizziness	.09	.12	.12	.12	.11	.12	.10	.12	.11
Headache	.33	.37	.31	.39	.35	.36	.32	.38	.36
Hair loss	.09	.11	.07	.09	.10	.08	.08	.10	.09
Backache	.11	.12	.10	.12	.12	.11	.10	.12	.11
Abdominal pain	.11	.11	.11	.13	.11	.13	.11	.12	.12
Irritability	.18	.20	.18	.22	.19	.20	.18	.21	.19
Leg pains/cramps	.06	.14	.11	.09	.11	.10	.09	.12	.10
Tiredness	.14	.21	.19	.21	.18	.20	.16	.21	.19
Breast discomfort	.03	.02	.04	.03	.02	.03	.03	.02	.03
Vaginal discharge	.03	.07	.05	.09	.05	.07	.04	.08	.06
Number of client-visits	304	415	327	393	719	720	631	808	1439

Table III-29. Proportions of Positive Grids, by Cycle and Side Effect, Vitamins vs. Placebo

Side Effect	Cycle and Treatment (N)									
	1		3		6		9		12	
	V (94)	P (84)	V (82)	P (68)	V (72)	P (58)	V (65)	P (55)	V (62)	P (52)
Bleeding/ spotting	.17	.24	.06	.12	.08	.03	.05	.02	.02	.00
Nausea	.26	.32	.05	.06	.03	.00	.00	.00	.00	.00
Vomiting	.15	.17	.04	.03	.00	.02	.00	.00	.00	.00
Headache	.49	.39	.28	.24	.19	.17	.31***	.09	.15	.12
Fatigue	.30	.26	.17	.16	.13	.07	.08	.02	.03	.04
Breast discomfort	.05	.04	.06**	.00	.01	.02	.00	.02	.00	.00
Vaginal discharge	.31	.24	.16	.16	.13	.16	.08	.11	.03	.08

**p-value of the difference < .05

***p-value of the difference < .01

Table III-30. Proportions of Positive Grids, by Cycle and Side Effect, Brevicon vs. Norinyl

Side Effect	Cycle and Treatment (N)									
	1		3		6		9		12	
	B (83)	N (94)	B (68)	N (83)	B (59)	N (70)	B (51)	N (69)	B (48)	N (66)
Bleeding/ spotting	.22	.19	.09	.09	.10*	.03	.06	.01	.02	.00
Nausea	.28	.29	.07	.04	.02	.01	.00	.00	.00	.00
Vomiting	.18	.14	.04	.02	.00	.01	.00	.00	.00	.00
Headache	.40	.48	.25	.27	.19	.18	.18	.23	.13	.14
Fatigue	.22	.34*	.16	.17	.06	.13	.04	.06	.00	.06
Breast discomfort	.08	.01**	.06	.01	.03	.00	.02	.00	.00	.00
Vaginal discharge	.17	.37***	.13	.18	.10	.17	.04	.13*	.04	.06

*p-value of the difference < .10
 **p-value of the difference < .05
 ***p-value of the difference < .01

Table III-31. Mean Symptom-Days per Cycle, Given One or More Symptom-Days of that Symptom Reported for that Cycle, by Symptom and Treatment

Symptom	Treatment			
	V	P	B	N
Bleeding/spotting	3.16	4.35*	4.06*	3.39
Nausea	5.13	6.19*	5.72*	5.63
Vomiting	4.71	5.00*	5.22*	4.44
Headache	5.00*	5.14	4.67	5.33*
Fatigue	5.79*	7.65	5.60	7.08*
Breast discomfort	5.91*	6.40	6.14*	5.50
Vaginal discharge	8.95	9.98*	8.64	8.76*

*Associated with higher proportions of positive grids than comparison group (Tables III-29 and III-30).

Table III-32. Proportions of Follow-Up Visits on Which Side Effects Were Reported, by Treatment and Site for Selected Side Effects, Visits 1-5, Rural Data

Symptom	Site and Treatment								
	V	Matara			N	Puttalam			N
		P	B			V	P	B	
Bleeding/spotting	.02	.02	.02	.01	.05	.05	.05	.03	
Nausea/vomiting	.07	.07	.07	.07	.08	.08	.08	.08	
Dizziness/headache	.06	.06	.05	.07	.05	.05	.05	.05	
Abdominal pain	.03	.02	.03	.02	.01	.01	.01	.01	
All other	.07	.08	.07	.07	.02	.02	.02	.02	
Number of forms	1795	1929	1790	1934	857	764	831	790	

Table III-33. Association Among Selected Reported Symptoms at first Follow-Up, Measured by Yule's Q, Colombo

BREVICON

SYMPTOM	Spotting	Nausea	Vomiting	Dizziness	Headache	Hair loss	Backache	Abdominal Pain	Tiredness	Irritability
Spotting/Bleeding		.233	.030	.170	.346	-.127	.359	.330	.461	.388
Nausea	.468		.906	.675	.628	.403	.487	.317	.519	.507
Vomiting	.257	.926		.551	.658	-.015	.388	.365	.494	.503
Dizziness	.297	.784	.625		.619	-.023	.248	.017	.275	.406
Headache	.333	.649	.790	.567		.341	.403	.214	.546	.459
Hair loss	.018	-.037	-.180	.242	.246		.497	.387	.056	.078
Backache	.247	.244	-.199	.348	.524	.627		.583	.230	.298
Abdominal Pain	.550	.540	.122	.269	.419	.010	.590		.302	.490
Tiredness	.064	.345	.106	.263	.380	-.113	.126	.003		.367
Irritability	.020	.341	.390	.207	.345	.257	.486	.351	.307	

NORINYL

Table III-34. 9-Month Continuation Rates by Treatment and by Presence or Absence of Selected Symptoms on the First Follow-Up Visit, Colombo

<u>Symptom</u>	<u>Present on V1?</u>	<u>Norinyl</u>		<u>Brevicon</u>	
		<u>Continuation Rate</u> ¹	<u>P-Value</u> ²	<u>Continuation Rate</u>	<u>P-Value</u>
Spotting/Bleeding	No	.68	.051	.50	.371
	Yes	.46		.43	
Nausea	No	.70	.006	.50	.056
	Yes	.53		.43	
Vomiting	No	.67	.026	.51	.010
	Yes	.57		.36	
Dizziness	No	.76	.000	.50	.017
	Yes	.42		.40	
Headache	No	.75	.001	.53	.015
	Yes	.55		.42	
Hair Loss	No	.65	.644	.48	.866
	Yes	.66		.50	
Backache	No	.64	.529	.48	.889
	Yes	.72		.47	
Abdominal Pain	No	.67	.475	.49	.682
	Yes	.59		.45	
Tiredness	No	.68	.149	.50	.216
	Yes	.57		.42	
Irritability	No	.67	.613	.52	.042
	Yes	.61		.38	

1: Continuation rates were estimated by the product-limit approach of Kaplan and Meier. Unlike actuarial life tables, this approach uses individual times of discontinuation rather than times grouped in intervals.

2: Continuation curves are compared by using a modification proposed by Breslow of the Wilcoxon nonparametric rank statistic.

Table III-35. Changes in Mean Weight and Blood Pressure, by Treatment, Study Completers Only, Urban Follow-up Data

Treatment and Variable	Weight (kg.)		Systolic B.P.		Diastolic B.P.	
	Mean	s.e.	Mean	s.e.	Mean	s.e.
V/B (N = 36)						
Admission level	42.56	1.28	99.31	1.65	62.50	1.12
Change over 12 cycles	+0.78	0.33	+2.36	1.75	-1.39	1.24
V/N (N = 67)						
Admission level	43.02	1.12	105.30	1.26	63.36	0.77
Change over 12 cycles	+1.49	0.36	-3.66	1.56	-1.79	0.91
P/B (N = 44)						
Admission level	41.50	1.15	102.27	1.43	63.18	0.91
Change over 12 cycles	+0.50	0.35	+1.70	1.50	-1.93	1.04
P/N (N = 60)						
Admission level	39.88	0.64	102.00	1.28	61.92	0.87
Change over 12 cycles	+0.93	0.39	+0.17	1.40	-1.17	0.92
All treatments (N = 207)						
Admission level	41.71	0.53	102.66	0.70	62.75	0.45
Change over 12 cycles	+1.00	0.19	-0.36	0.78	-1.57	0.50

Table III-36. Selected Data on Length and Starting Day of Menses, Dropouts vs Completers, Symptom Grid Data

A. Length of Menses (no. of days)

<u>Statistic</u>	No. of Grids Per Client	
	<u>1-4</u>	<u>5</u>
Number of Grids	122	570
Percent Amenorrhoeic	19	5
Percent exactly 3 days	43	53
Mean number of days	2.25	2.59
- given one or more days	2.77	2.73
Standard deviation	1.29	0.97
- given one or more days	0.78	0.77

B. Cycle Day of Beginning of Menses

<u>Statistic</u>	No. of Grids Per Client	
	<u>1-4</u>	<u>5</u>
Number of Grids	122	570
Percent Amenorrhoeic	19	6
Number with menses	99	534
*Median	24	24
*Mean	24.33	24.21
*Percent 23rd-25th day	60	75
*Standard deviation	1.62	1.31

*Includes only clients with starting date given on grid.

Table III-37. Selected Comparisons between "Norinyl Only" Users, Norinyl/Placebo Users, and All Users Combined, By Site.

Statistic	Site and Treatment ¹					
	N	Matara			Puttalam	
		N/P	All	N	N/P	All
6-month Aggregate Continuation	.54	.36	.40	.44	.60	.60
12-month Aggregate Continuation	.23	.22	.17	.23	.45	.33
12-month Net Termination rates						
-- Unplanned pregnancy	.06	.05	.08	.06	.00	.06
-- Menstrual side effects	.13	.18	.06	.02	.06	.08
-- Other medical	.35	.46	.44	.41	.27	.28
-- All other	.23	.09	.25	.28	.12	.25
Side Effect Proportions, ² Visits 1-5						
-- Bleeding/spotting	.03	.01	.02	.05	.03	.05
-- Nausea/vomiting	.03	.07	.06	.07	.09	.08
-- Dizziness/headache	.03	.07	.05	.08	.06	.06
-- Abdominal pain	.01	.02	.02	.03	.01	.02
-- All side effects	.15	.25	.22	.27	.21	.22

¹ Codes: N = Norinyl only, N/P = Norinyl with Placebo, All = All treatments combined, including "Norinyl only"

² Numbers of forms on which symptom reported as "most disturbing side effect," divided by total number of forms for follow-up visits 1-5

Table III-38. Six-Month and Twelve-Month Continuation Rates by Site and Breast-feeding Status at Admission

Site and Statistic	Breast-feeding Status at Admission		
	Currently breast-feeding Without supplements	Currently Breast-feeding With supplements	Not Currently Breast-feeding
Matara			
No. of clients	547	674	349
6-month continuation (s.e.)	.42 (.02)	.40 (.02)	.36 (.03)
12-month continuation (s.e.)	.21 (.02)	.18 (.02)	.11 (.02)
Puttalam			
No. of clients	225	351	273
6-month continuation (s.e.)	.66 (.03)	.60 (.03)	.54 (.03)
12-month continuation (s.e.)	.43 (.05)	.29 (.04)	.30 (.04)

IV. THE CLINIC-BASED HOME DISTRIBUTION EXPERIMENT

A. Background and Development

In its original concept, the Sri Lanka project was to investigate the effectiveness of combining certain strengths of the standard clinic-based model of contraceptive distribution with features of a community-oriented, home-distribution outreach program. In particular, the original design proposed by Merritt in 1976 involved:

- Two rural service areas of 12,000 to 15,000 households each.
- A mobile van in each area, staffed by a physician and about six fieldworkers.
- Complete household canvassing in each area.
- A broad spectrum of contraceptives, including pills, IUDs, condoms, Depo-Provera, vaginal barrier contraceptives and vasectomy by the van and a clearly developed referral system for female sterilizations.
- Distribution of selected home medicaments in addition to the contraceptives.
- A comparative oral contraceptive trial as an incidental part of the household distribution system.

This initial concept, prior to detailed planning, was inevitably subject to change. It indicates, however, a concept of service

delivery that was never really abandoned, even though at each later step in planning, this concept was compromised. What eventually emerged was a home delivery system which functioned as a carrying vehicle for the OC/vitamin study, and which also yielded useful information on rural contraceptive distribution in Sri Lanka. It will be useful to relate how the rural design, as actually implemented, evolved.

The concept of the mobile van as the base of service delivery was dropped due to difficulty of acquisition at an early date. At the time the last draft of the project proposal was submitted in August 1977, the design called for:

- Two sites of 10,000 households each, in Matara and Vavuniya districts.
- Complete household canvassing, with a cafeteria of methods offered, and a number of basic household medications.
- A central clinic in each area staffed by a physician, two nurses, two attendants, and an unspecified number of community distributors.
- The comparative OC/vitamin clinical trial, in approximately the form described in Section III of this report.

The proposal was the basis of the governing contract, AID/pha-C-1191, signed later that month. By January 1978, a detailed Work Plan had been provided by IFRP, and approved by USAID. In this document, choice of sites was the same, and the

details of the clinical trial plan were elaborated. Some other plans, however, had been modified. Rather than an initial complete household canvass, the Household Registers kept to maintain the rice ration were to be used for baseline information and for the identification of eligible couples. Methods to be offered in the homes were reduced to pills, condoms, and injectables, and the use of home medicaments was no longer certain. Each clinic staff was to include a physician, two nurses, and four home visitors. In addition to providing home services, the home visitors were to motivate couples to come to the clinic for IUDs and sterilizations, treatment of side effects, counselling, and so on.

To implement this work plan, additional changes had to be made. First, recruitment of physicians to serve in such remote areas proved impossible, so it was agreed that the project should proceed with the part-time service of local government physicians. Second, a very explosive and dangerous level of ethnic tensions developed in Vavuniya, making it impossible to develop the site there as planned, so an alternative site in Puttalam District was chosen, on rather short notice. (The size of the two areas, however, was somewhat larger than originally planned: about 13,000 households in Matara, 18,000 in Puttalam). Third, without sufficient medical supervision it was considered unwise to provide injectable contraception on a house-to-house basis. Fourth, as a result of a change in national policy the rice ration system was drastically modified, making the Household Registers no longer useful as a basis for population information. Finally, it

was determined early that two nurses and four home visitors per site were inadequate, so the number was increased to three or four nurses and eight home visitors in each area.

Hence, by a long series of individual steps, each a considered response to practical constraints, the original concept of complete saturation with a combined clinic and household delivery system gradually became a more limited household distribution scheme with some medical support. Meanwhile, the clinical trial aspect of the study retained its original design, and in the context of the limited resources ultimately available, became the central focus of the rural study. In this context, we can now review the rural household distribution scheme as it was actually implemented, and consider what can be learned from such a project.

B. Project Description

1. Matara. The Matara Project site has been described in Section II. Having been chosen early, the clinic location was leased and renovated, and personnel hired, substantially in advance of actual operations. Service delivery was delayed by the late arrival of supplies and the problem in developing the second clinic site. Once the decision to proceed without a full-time physician was made, the local Medical Officer, Dr. Weeraman, was contacted to serve at the clinic on a per session basis. Initially the clinic was open on Monday, which was market day in Morawaka. This drew

little response, so clinics were held Thursdays, Fridays and Saturdays at 4:30-6:00 pm. Because these hours presented difficulties for women living in the more distant parts of the site, the Saturday clinic hours were finally changed to 1:00-3:00 pm. In practice, Dr. Weeraman was on constant call.

The difficulty of hiring and keeping nurses was more difficult to solve. Most nurses were recruited from private nursing homes, and did not have government training or certification. Furthermore, due to the difficulties of adjusting to life in a remote rural area (particularly problems with living accommodations), turnover was high. On the other hand, a suitable group of home visitors was recruited easily and remained throughout the project. These eight women ranged from 20 to 30 years of age, were all unmarried Sinhalese Buddhists, had generally middle school education, and had little previous employment or familiarity with family planning. Both nurses and home visitors were given a 3-day training course by the FPA near Colombo.

Project headquarters consisted of two rooms in a building in the town of Morowaka, which served as office and clinic space. The Project Coordinator, Mr. V.G.A. Perera, stayed at headquarters full-time. One nurse also stayed at headquarters on a daily rotating basis, so that the clinic always had a nurse and the Coordinator present, and a physician on call.

The nurse at headquarters provided injectables (Depo

Provera), and IUDs were inserted by the Medical Officer. Sterilizations, however, were referred to the Government Hospital in Matara Town, about two hours' drive to the south. Hence, contraceptive services were made available in the following ways: oral contraceptives and condoms through home delivery; injectables and IUDs at the clinic; and sterilizations only by referral at some distance. IFRP provided only the oral contraceptives; other contraceptive methods were supplied by the FPA.

Once the full complement of home visitors was available, they worked in pairs, each supervised by a nurse. The home visitor identified potential clients, and either provided condoms, referred to the clinic or hospital, or, if a pill acceptor, notified the supervisory nurse. The nurse determined the client's eligibility and, if suitable, entered her into the study. A project vehicle was available to take the field personnel out in the morning and bring them back each day, but road conditions were such that the vehicle often left the workers with a long walk, typically over very hilly terrain, to their day's destination. Moreover, village homes were typically very scattered, so substantial time was also required to get from house to house within a single village. Finally, in many homes no eligible woman or man was at home during the day. In all, it was frequently not possible to make contact with more than three or four potential clients in a day.

An educational campaign was undertaken in the project area prior to initiation of the study. This involved meetings in each of the 26 Gramma Sevaka Divisions led by a senior official of the FPA to explain the project, and distribution of promotional pamphlets throughout the area.

A log of each visit was kept by the home visitors and nurses in a notebook. At the end of each day, basic information was transferred from this notebook to a register kept in the clinic. For pill acceptors and current users, information on each visit was also transferred to the Project Couple Registration Record and the Acceptance and Follow-up Record (Appendix A).

Service delivery began in September 1978, and the clinic was officially opened by the local Member of Parliament on October 1. For the remainder of 1978, only the "Norinyl only" area was visited. Distribution of the clinical trial treatments started in January 1979. With the minor modifications in procedures and staffing described above, operations continued in this form until August 15, 1980. It was decided in early July 1980 to discontinue the rural clinical trial as of that date, and to cease recruitment of new clients immediately. During the remainder of 1980, clients were notified of the discontinuation of services and referred for alternative sources, arrangements were made to dispose of property, consolidate records, etc., and project staff for the most part sought new employment.

In addition to service records and financial data, evaluation of the delivery system was based on two general population surveys ("before", conducted in September 1978, and "after", conducted in December 1980) and a follow-up survey of women reported to be current users as of December 1980, conducted in April 1981.

2. Puttalam. For the most part, activities in Puttalam were carried out according to the same design as in Matara, with a few differences.

As in Matara, a full-time physician could not be recruited. The solution in Puttalam was that the Medical Officer, Dr. Vijayarathnam, held a family planning clinic at the Maternal and Child Welfare Centre three afternoons per week. As in Matara, she was also on call at other times.

Other personnel recruitment problems were not as difficult in Puttalam as they had been in Matara. The Project Coordinator, Mr. A.S. Thenuwara, was hired at once. Three nurses were recruited quickly, all with government qualifications, and stayed for the life of the project. The availability of living accommodations in the project headquarters and the slightly less remote nature of the town encouraged lower turnover. Eight home visitors were also recruited, and seven stayed with the project (the other was replaced). They were somewhat more heterogeneous than their Matara counterparts: ages ranged from 20-36, two were

married, two were Tamil (the other six were Sinhalese), five were Roman Catholic (the other three were Buddhist), and they had varied knowledge of contraception and some history of use. Training was similar to the training for Matara.

A headquarters building was rented in Puttalam Town (which, like Morowaka, was not included in the project area). Renovations were undertaken to provide suitable clinic, office and living space. As in Matara, nurses rotated for clinic duty. The local Government Medical Officer, Dr. Vijayaratnam, was on call at all times. Contraceptive services differed slightly from Matara; Depo Provera was not available, but both male and female sterilization could be provided at the Government hospital in Puttalam town.

In Puttalam, the project area was divided geographically among the three teams. One team, consisting of a nurse and four home visitors, worked in the Kalpitiya sub-district, part of which was set aside as the "Norinyl only" area and part for the four-cell trial. The other two teams, each consisting of a nurse and two home visitors, worked in defined areas further south. Work procedures for the nurses and home visitors were the same as in Matara. However, no project vehicle was available in Puttalam, so public transportation was used. Distances from headquarters were sometimes considerable--up to about 30 miles--and were only partly accessible to public transport.

Moreover, while the terrain was flatter in Puttalam than in Matara, houses in the rural areas were extremely scattered. Hence, staff relied on a combination of public transport, walking and resourcefulness, and a great deal of time was spent in slow and uncertain local travel.

Approval for changing the site from Vavuniya to Puttalam came in January 1979. The baseline survey was done in March, and field work began in June. During June, all field work was done in the "Norinly only" area, after which the general pattern of coverage began and was maintained until the end of the project. As in Matara, new recruitment ended in July 1980, and the clinical trial was terminated on August 15. Thus the Puttalam trial lasted slightly over one year.

As with Matara, an "after" survey of the general population was conducted in January 1981, and a follow-up survey of women reported to be current users as of December 1980, was conducted in April 1981.

C. Results

1. Recruitment. As a fully functioning distribution system, the programs in Matara and Puttalam ended with the termination of clinical trial recruiting in early July 1980. As of June 30, 1980, a total of 9,122 home visits had been made in Matara, and 8,212 in Puttalam, according to service records. With eight home visitors in each site, and with 22 months of operation in Matara and 13 in Puttalam, and allowing for leave,

holidays, etc, home visits averaged about 3-4 home visits per day in Matara, 5 in Puttalam. Given the nature of the terrain and transportation facilities available, this represents a substantial level of effort.

That effort is more impressive since it involves visits to all parts of each area; nearly all villages were covered in the program. Hence, the home visitors' efforts represented a great deal of travel time simply reaching the areas where they were to work for the day. In Matara, the project vehicle would leave a field worker with several kilometers' walk over hilly terrain, crossing gullies on rope bridges and walking difficult paths. In Puttalam, the terrain was easier, but the distances were often greater, and use of public transportation meant longer times reaching the nearest points available by vehicle.

The potential of this system can be suggested by looking at the amount of effort needed to maintain oral contraceptive users. If each user is visited every 3 months--the minimum, according to study protocol--then the number of continuing users who can be maintained in such a system is 3 times the number of monthly visits. In Matara, each home visitor averaged around 52 visits per month, sufficient to maintain a maximum of 156 users; 8 home visitors could thus maintain, 1,248 OC clients. This, of course, does not allow time for new recruitment, or home visiting for any other purpose.

Using the population figures from Table IV-1, this represents

about 11 percent of all married women of reproductive age, and about 17% of all "eligible couples". In Puttalam, comparable calculations indicate the potential of maintaining 1,896 clients, which represented about 20% of MWRA, and 35% of "eligible couples."

In fact, this capacity was approached, though not reached. In both Matara and Puttalam, revisits averaged about 30 to 50 per home visitor per month after the first few months of activity. This is supported by the clinical trial data, which indicated that revisits were generally done on a regular basis as scheduled. It is also reflected in acceptance data; in both locations, new acceptors declined after an early peak. This clearly represents the burden of high levels of effort spent in maintaining current users.

Largely as a consequence of these factors, the proportion of the total estimated number of "eligible couples" who were visited was less than half in both areas (see Table IV-1). Hence, the goal of covering the entire project area was not met, for reasons that represent inadequate planning rather than poor effort or supervision in the field.

2. Acceptance. Perhaps the most striking feature of acceptance is shown in Table IV-1: in both areas, well over half of all eligible couples visited accepted contraception. Particularly in light of the low level of current use of modern contraception at the beginning of the project, this has to be

viewed as extremely encouraging. As part of a complex and puzzling picture of demand in Sri Lanka, it will be discussed later.

Table IV-2 shows acceptance by method and by calendar quarter. The dominance of oral contraceptives is apparent, and due to two factors; first, that orals were one of only two methods available directly from the home visitors, and second, that recruitment of orals was stressed in order to provide adequate numbers for the clinical trial. The poor performance of the condom undoubtedly resulted from its being a male method in a program of women distributing primarily to women.

The "referrals" category involves IUDs and male and female sterilization in both sites, and injections in Matara only. The numbers are referrals recorded by the home visitors; records did not allow determination of how many of the referred clients actually accepted the method, nor how many of those who used clinic services were from the project area.

The distribution of method referrals was as follows:

	Matara	Puttalam
IUDs	151	63
Female sterilization	46	107
Male sterilization	53	26
Injection	167	-
Total	417	196

3. Continuation. Continuation rates are available only for oral contraceptives and these were discussed in some detail in Section III. Briefly, life-table continuation rates for Matara were .41 at 6 months and .20 at 12 months; for Puttalam, .60 at 6 months and .42 at 12 months. (These are the "Procedure A" rates, which are more comparable to continuation rates as calculated in other programmatic settings.) By nearly any standard, these rates are low in Matara, and even in Puttalam they are disappointing given the high level of home visitor support. One reason may be in the fact that the distribution systems were essentially supporting a clinical trial. Certainly in Matara, the home visitors were made more nervous as a result of not knowing exactly which treatment was being prescribed. The fact that, in Puttalam, one of the teams was able to achieve substantially higher continuation rates than the others indicates that continuation rates are to a substantial extent a function of provider attitudes.

Also, however, the low continuation is probably an indication of the lack of strength of motivation on the part of women in these settings, and of the strong fears of side effects associated with modern contraception. Whatever the reasons, the difficulties of maintaining continuing use in these settings was illustrated by a survey in April 1981, about 7 months after the end of the clinical trial and 3 to 4 months after the closing of the clinics in Matara and Puttalam. Of the

513 continuing users in Matara at the end of the clinic trial, only 49 were still using orals the following April. Of the 439 continuing users in Puttalam as of August 15, 1980, 122 were still using in April 1982. Absence of service was doubtless a major factor, but it also appears that Sri Lanka women are reluctant to continue using orals over substantial time periods.

4. The Public's View of the Project. In November-December 1980, surveys were undertaken with probability samples in Matara and Puttalam. One set of questions was designed to indicate the knowledge and experience of the clients with the project.

The correspondence between the proportions of eligible couples visited according to service statistics and the proportion of MWRA visited according to the survey is reasonably good. Table IV-1 shows 39.2 percent of eligible couples visited in Matara; 37.6% of survey respondents reported having been visited by a project worker. In Puttalam, 46.3% of eligible couples were visited, according to service statistics; 34.0% according to the survey. Since the definitions are not comparable, one cannot say exactly what these comparisons imply; but the relevant conclusions would seem to be that the service statistics were a fairly accurate reflection of project activity, and that respondents recognized the FPA visitors. By contrast, only 8.3% recalled having been visited by a government midwife in Matara, and 13.0% in Puttalam. Moreover, 81 percent of respondents in Matara and

63 percent in Puttalam reported having heard of the FPA program. It is clear that the project substantially increased the practical availability of oral contraceptives in the project areas.

Despite this level of public visibility, the projects seem not to have caused any major public stir. No public complaints were recorded regarding the project and, despite initial fears, government midwives did not indicate any resentment over what might have been regarded as competition. On the other hand, the home visiting did not seem to generate any major demand for clinic services, and the termination of the project was not viewed as the withdrawal of a crucial service.

5. Changes in Knowledge, Attitudes, and Practices in the Project Areas. It has been mentioned that during the project period, before-after population surveys were carried out in both Matara and Puttalam. The "before" surveys were carried out just prior to initiation of services (September 1978 in Matara; March 1979 in Puttalam), and the "after" surveys were carried out just before the clinics closed (November 1980 in Matara; December 1980 in Puttalam). They each involved stratified, systematic probability samples of currently married women 15-49, with sample sizes ranging from 782 to 886 interviews. The reports of the "before" surveys were written up previously, and were sent to USAID.

Table IV-3 indicates the comparability in samples between the "before" and "after" surveys. While there is general similarity, a few differences stand out. The higher proportion of women 45-49 in Puttalam in 1980 is at least partly due to errors in the preparation of the sampling lists in 1979. Differences in husband's occupation are apparently due to variations among interviewers in classification technique. In Puttalam, the 1980 distribution by religion (which corresponds with the ethnic distribution), probably corresponds more nearly with the religious composition of the project area than the 1979 distribution.

Of greater interest, perhaps, are the data in Table IV-4, showing changes in contraceptive use.

In both areas, both past use and current use increased for contraception generally. Current use of oral contraception increased noticeably in Matara, but declined slightly in Puttalam. Sterilization use in both areas increased substantially; considering the short time period, the change is considerable. On the whole, use of the most effective methods (pills, IUDs, Depo Provera, Female Sterilization, vasectomy) increased from 13 percent to 23 percent in two years in Matara, and from 19 percent to 21 percent in a somewhat shorter time in Puttalam.

Similar changes can be found in contraceptive knowledge and, to a lesser extent, in the desire for additional children.

The proportion of women who were able to name at least one method of contraception rose in Matara from 60 percent to 85 percent, and in Puttalam from 62 percent to 92 percent. The stated desire to avoid future childbearing increased, but much less: in Matara, the proportion wanting no more children rose from 64 percent to 67 percent; in Puttalam, from 73 percent to 77 percent.

Questions on contraceptive knowledge were not identical in the two sets of surveys. In the "after" survey, knowledge was elicited before and after probing. First, respondents were asked to name the methods they knew; then they were asked about specific methods not already named. Table IV-5 shows the results. Clearly, knowledge is greater for all methods in Puttalam, consistent with the somewhat more modern character of the place. (The interviewers as well as the questions were the same, so response biases should be comparable.) Also striking is the degree to which the most effective modern methods are better known than the barrier and traditional methods. Even condoms, which are marketed and advertised throughout the country, are not particularly well-known in these rural areas.

In the "after" surveys, respondents were asked whether they had accepted the pill from the FPA worker. In Matara, 9.7 percent said they had done so, compared with an estimate of 14.1 percent derived from service statistics. In Puttalam, 10.0 percent reported acceptance of the pill, compared with

an estimate of 12.7 percent from service statistics. A considerable variety of factors may have gone into these discrepancies; considering the circumstances, the degree of similarity in the two estimates is not disquieting.

The "after" survey also addressed the question of why women who stated that they wanted no further children, yet were apparently exposed to the risk of pregnancy, were not contracepting. The absence of questions relating to availability and convenience, which were prominent in the "other" category, limits the usefulness of this item. Nevertheless, the prominence of fears of side effects and health damage is notable, along with the absence of objection in principle to contraception. Table IV-6 summarizes these results.

In light of the impact of the program on contraceptive use, as well as the methodological intractability of linking program efforts to fertility decline, attempts to analyze the effect of the program on fertility were not attempted.

6. Costs and Cost Effectiveness. Table IV-7 shows the service delivery costs, as nearly as they can be extracted, of the rural project, in \$US. The intent is to remove the costs of technical assistance and research, and with some exceptions where costs are inextricably intertwined--such as the salary of the Director of Evaluation and Research, who served as project director, and the costs of filling out and processing research data--this has been effectively done.

This is basically a list of local, variable costs. About 80 percent of these expenses were incurred in Matara and Puttalam, the remainder from the central office in Colombo, indicating a relatively low cost of management and supervision. The total fixed costs depend on classifications, but represent in any estimate less than 20 percent of the total. Hence estimates of costs per unit of service or output calculated from these data are reasonable approximations of true unit costs, independent of the length of the project.

Some measures of cost effectiveness are given in Table IV-8. Costs per acceptor may be compared with costs computed from data given in the 10th edition of the Population Council Fact Book (Nortman and Hofstatter, 1980) for national family planning programs in nine countries over various years between 1975 and 1978. Service costs per acceptor varied in these data from \$2.64 to \$28.98, with a median at \$17.08.

Because continuation data were available for all pill acceptors, it was possible to compute couple years of protection directly, and hence to obtain cost effectiveness estimates based on this measure, although limited to pill acceptors only.

7. Discussion. In summary, a program designed originally to reach every eligible family in each of two areas with a variety of choices of contraceptives did not have substantial impact on contraceptive practices in the area for several

reasons. First, the original design was modified to the point where the program was too limited in scope and manpower to cover its target area effectively. Second, the emphasis of the program changed from one of service delivery to one of support for an oral contraceptive clinical trial. Third, although acceptance was high as a proportion of eligible couples contacted, continuation was poor in spite of strong home follow up support.

There remains an important and puzzling question of considerable relevance to the national program in Sri Lanka: Why is family planning use not higher? Our surveys corroborate evidence from the 1975 World Fertility Survey that desired family size is low, that many women want no more children, and that family planning is widely known and accepted in principle. Furthermore, the relatively high average age at marriage, and the considerable rise over the last generation in age at marriage, suggest that Sri Lankans are willing to take responsibility for ultimate family size through effective planning. Yet in this project, as nationally, effective response to the availability of a variety of contraceptive methods is relatively weak. Strikingly, 41 percent of all married women of reproductive age in Matara, and 51 percent in Puttalam, were in the situation of believing themselves at immediate risk of pregnancy, of not wanting more children, and yet not using an effective method.

In this situation the FPA made oral contraceptives and condoms freely available through home delivery, returned regularly for resupply and support, and offered medical backup. Women accepted readily, but were unwilling to continue use; within 6 months after acceptance, 60 percent had dropped out in Matara, 40 percent in Puttalam. Moreover, when program support was discontinued, use became almost non-existent, even though the pill was available, albeit with some effort.

We have no definitive answer. However, the difficulties caused by side effects seem to stand out. Most discontinuations in both Matara and Puttalam were the result of side effects, and side effects were prominent among reasons why women chose not to use contraception. Moreover, the study on the flagging performance of the IUD which was done as part of this contract also identified fears of side effects and health issues as the central issue for that method (see Section V). Why this should be particularly so in the Sri Lanka population, and what programmatically might be done, cannot be answered in this study.

8. Conclusions.

- a. The contraceptive distribution systems in Matara and Puttalam did not achieve sufficient coverage to have important impact on the population served. This was due to insufficient staff, which in turn was due to inadequate planning and failure to detect the problem early,

rather than to lack of effort or competence on the part of the field staff.

- b. Young village women with modest education and minimal medical training can serve effectively as home visitors for contraceptive distribution in Sri Lanka. They had no difficulty getting around or operating alone in strange villages. They were accepted in the community, and were able to induce a high proportion of the eligible women they visited to accept modern contraception.
- c. The distribution system was not particularly cost-effective, in spite of careful cost control on the part of the FPA. In part this was due to the research requirements of the study, and in part to the practical limitations on available methods. But to a considerable extent, the high costs per user reflect the considerable amounts of time required to travel each day to the site of the day's work, and to travel between houses.
- d. As in the national program, this study found an apparent discrepancy between the stated interest in small families and general approval of contraception on the one hand, and relatively low continuation and limited use on the other. This study found that acceptability of both the pill and the IUD are limited in Sri Lanka by strong reaction to and fear of side effects associated with these methods.

Table IV-1: Target Populations, Clinic Activities and Contraceptive Acceptors through June 30, 1980: Matara and Puttalam FPA Clinics

	Clinics and Dates	
	Matara (9.78-6.80)	Puttalam (6.79-6.80)
Total Population	82,550	66,459
Estimated MWRA ¹	11,565	9,311
Estimated no. of eligible couples ²	7,199	5,443
No. of eligible couples visited	2,822	2,521
Percent eligible couples visited	(39.2%)	(46.3%)
No. acceptors, all methods ³	2,090	1,421
Percent contacted eligible couples accepting	(74.1%)	(56.4%)
Percent all eligible couples accepting	(29.0%)	(26.1%)
Total number of home visits	9,122	8,212

¹Estimated from 1971 census data pertaining to the rural population of Sri Lanka.

²"Eligible couple" is defined as currently married, wife 15-49 years of age, husband present, wife not currently pregnant, believed fecund and not currently using a modern contraceptive method.

³Includes a small proportion of referrals for which method acceptance is not verified.

Table IV-2 New Acceptors and Referrals for Contraception by Method, Quarter and Site

Quarter Year	Matara			All Methods	Puttalam			All Methods
	Orals	Condom	Referrals		Orals	Condoms	Referrals	
Oct-Dec 1978	132	5	35	172	-	-	-	-
Jan-Mar 1978	182	5	37	224	-	-	-	-
Apr-Jun 1979	395	8	61	464	217*	5*	17*	239*
July-Sept 1979	289	3	34	326	570	12	70	652
Oct-Dec 1979	354	7	95	456	168	7	41	216
Jan-Mar 1980	113	6	93	212	178	4	56	238
Apr-Jun 1980	170	4	62	236	51	13	12	76
Totals	1635	38	417	2090	1184	41	196	1421

*Includes only June 6-30, 1979

Table IV-3: Comparisons between Samples of Percentage Distributions of Age, Education, Husband's Occupation and Religion by Site

	Matara		Puttalam	
	(1978) (N = 886)	(1980) (N = 872)	(1979) (N = 782)	(1980) (N = 882)
<u>Age</u>				
15-24	15.2	14.7	27.9	21.1
25-29	24.9	22.5	29.8	25.6
30-34	24.5	24.0	21.1	21.2
35-39	19.5	19.8	15.2	15.8
40+	15.8	19.0	6.0	16.3
<u>Education</u>				
No schooling	31.2	30.7	10.1	10.5
< Grade 5	40.3	38.6	45.7	44.5
Grades 6-9	15.8	16.5	34.0	32.6
> Grade 10	12.8	14.1	10.2	12.4
<u>Husband's Occupation</u>				
None	8.0	5.9	-	2.6
Professional, technical, etc.	0.9	4.5	1.8	2.3
Skilled worker	7.9	7.8	10.1	8.7
Service provider	4.2	6.4	8.6	8.5
Cultivator	10.3	23.3	19.6	23.7
Agricultural laborer	50.3	36.6	20.6	11.2
Fisherman	0.0	0.0	14.5	11.7
Unskilled worker	6.1	7.4	21.9	17.3
Other	12.3	8.1	0.3	14.0
<u>Religion</u>				
None	0.2	2.8	-	0.2
Buddhist	87.5	81.7	36.2	43.1
Hindu	11.3	13.4	6.6	9.1
Christian	1.0	2.2	47.2	30.7
Muslim		0.0	0.0	16.9

Table IV-4: Changes in Percentages of Contraceptive Use by Method and Site

	Matara		Puttalam	
	(1978) (N = 886)	(1980) (N = 872)	(1979) (N = 782)	(1980) (N = 882)
<u>Contraceptive History</u>				
Never used	77.0	61.5	70.7	61.2
Past user	3.8	9.6	9.1	13.8
Current user	19.2	28.9	20.2	25.0
<u>Method of Current Use</u>				
Orals	1.6	5.4	4.7	3.9
IUD	0.9	2.8	4.6	1.7
Condom	1.5	1.7	0.6	1.1
Rhythm ("safe period")	2.8	2.7	0.6	1.7
Abstinence	1.8	0.7	0.0	1.4
Withdrawal	0.2	0.7	0.0	0.1
Depo Provera	0.0	0.2	0.0	0.3
Female sterilization	9.4	10.6	9.3	13.8
Male sterilization	1.0	4.0	0.2	0.9

Table IV-5: Percentage of Respondents Naming Contraceptive Methods Before and After Probing, "After" Survey by Site

Method	Matara (N = 872)			Puttalam (N = 882)		
	Before Probing	After Probing	Total	Before Probing	After Probing	Total
Orals	69	18	87	85	11	96
IUD	43	29	71	74	16	90
Condom	25	29	54	42	36	77
Rhythm ("safe period")	20	26	46	22	41	63
Abstinence	19	22	41	17	41	58
Withdrawal	16	12	28	13	32	45
Foam	11	11	21	13	20	33
Diaphragm	6	7	13	7	19	26
Depo Provera	25	32	58	52	28	90
Female Sterilization	56	31	87	69	29	98
Male Sterilization	39	34	73	50	36	86

Table IV-6: Reasons for Non-Use by Respondents at Risk but Wanting No Further Children by Site

Reason	Matara (N = 457)	Puttalam (N = 548)
Believes herself sterile (but not sterilized)	21.7	17.0
Does not approve of contraception	3.7	4.2
Religious objection	0.4	4.4
Fear of side effects	15.8	19.3
Fear of damage of health	3.9	5.5
Practicing traditional method	6.3	3.3
Having sex without risk of pregnancy	2.8	2.0
Abstaining from sex	4.6	4.0
Other	40.5	40.3
All reasons	99.6	100.0

Table IV-7: Service Costs of the Rural Project by Line Item and Site (in \$ US)

Item	Matara	Puttalam
Salaries	19,149.17	14,562.05
Consultants (local physicians)	801.93	680.00
Travel and per diem	6,740.85	5,515.65
Field expenses (promotion, field supplies)	6,606.60	7,127.39
Vehicles	3,383.21	3,072.00
Office supplies	409.21	503.21
Rent	280.00	133.33
Pre-project costs	419.75	419.75
Other direct expenses (building renovation, medical supplies, communications, etc.)	<u>1,950.27</u>	<u>962.27</u>
Total	39,741.09	32,975.75

Table IV-8: Unit Service Costs of the Project by Type and Site (\$ US)

Type of Unit Cost	Matara	Puttalam
Cost per acceptor (referrals included)	19.01	23.21
Cost per acceptor (referrals excluded)	23.75	26.92
Cost per pill acceptor	24.31	27.85
Cost per couple year of pill protection	62.65	83.03

V. OTHER CONTRACT ACTIVITIES

A. The Intrauterine Device: Provider and Consumer Attitudes in Sri Lanka

At a meeting of the Advisory Committee of the Family Health Bureau of the Government of Sri Lanka in July 1980, the declining acceptance of the IUD nationally was discussed. Dr. Wickrema Weerasooria, Secretary to the Ministry of Plan Implementation, asked the Family Planning Association to investigate the reason for this and to recommend steps to remedy the situation.

With USAID concurrence, IFRP supported a multifaceted study of provider and consumer experience and attitudes. That study was conducted during the fall of 1980. The report was published in April 1981, by the Ministry of Plan Implementation, with an introduction by Dr. Weerasooria. This report has been submitted to USAID. The following is the summary of results from that report.

Summary of Findings

The Family Planning Association polled 305 service providers and 700 consumers from several areas in Sri Lanka in an effort to determine reasons for the unsatisfactory performance of the IUD. That this performance is unsatisfactory there can be little argument in absolute terms. The IUD had barely half the number of acceptors in 1980 as in 1975, and the proportion of all new acceptors who are IUD acceptors was about three times greater in

1975 than 1980. This decline is national in scope. Not a single S.H.S. Division had more loop acceptors in 1980 than in 1975.

The most striking result of this study was the degree to which consumer fears about the IUD, both rational and irrational, dominate responses about the method. When consumers had negative comments about the IUD, they overwhelmingly involved side effects, both actual and mythical. When providers were asked why the method was not more popular, they responded in terms of fears and side effects. Most consumers expressed various fears about the IUD and nearly all providers had heard these fears expressed to them by clients. As a result, providers of all categories overwhelmingly favored public education and motivation campaigns among their suggestions for reviving the IUD. Providers and consumers were in general agreement on these points and there were only slight differences among the various categories of providers.

Most allopathic physicians, both government and private, reported having been trained in IUD insertion, and most government physicians (but not private ones) reported that the IUD was available where they worked. Nevertheless, a substantial number of providers mentioned lack of service availability as a factor. The training of paramedics in IUD insertion was a common suggestion of providers for popularizing the IUD. However, complaints about services were conspicuously absent from consumer reports.

Providers of all kinds generally reported themselves to be more favorably disposed towards the IUD than consumers and reported substantial levels of effort to encourage it. Moreover, 72% of providers believe that the IUD ought to be popularized. In addition, to suggesting public education and motivation, increased services and paramedic training in insertion, the only other provider suggestions for popularizing the IUD involved incentive schemes, mostly for providers.

The inescapable finding from this study is that most women do not accept the IUD not because they cannot get it or do not want contraceptive protection but that they are afraid of the IUD. They are afraid of the real side effects caused by the IUD and they are afraid of side effects which are imaginary and are not caused by the IUD.

There is no evidence of a lack of enthusiasm or a lack of motivation on the part of the providers for IUD. The major recommendation of the providers for popularizing the IUD--education and motivation campaigns particularly geared to explain the real side effects and remove fears about mythical side effects--shows an appreciation on the part of the providers for the real reason for the lack of popularity of the IUD. Another recommendation made by service providers is that the midwives and other paramedical personnel should be trained to insert the IUD and their services

be made available to the community. This would also provide support within easy reach for acceptors with complaints. This recommendation too indicates an appreciation of the cause for its unpopularity.

The IUD does cause some real side effects. What these recommendations amount to is that the consumers must be told of the real side effects and they must be rid of the fears of side effects that are not caused by the IUD; and that in view of the real side effects the consumer needs support which would be more easily available if paramedical personnel and particularly midwives are trained and will provide the service.

B. Use of Village Workers to Develop Village-Level Demand

One of the lessons from the rural distribution system was that young women without medical training can be effective motivators for family planning, even though in the setting of the OC/vitamin study they were not cost-effective. Hence, the FPA decided to test the utility of these workers in another capacity. The FPA operates a nationwide social marketing program. In some areas, that program suffers from weak village-level demand. The FPA decided to send 11 pairs of home visitors to selected rural areas with nearby family planning marketing outlets to see if, by convincing women to accept family planning, they could stimulate local demand. After three months in an area, they would move on.

The experiment was done in April-June 1981. The workers were again able to demonstrate reasonable acceptance rates (27% of

eligible couples visited), though not as high as in Matara and Puttalam. However, supervision and logistics were difficult, reports were unreliable and the effect was not sufficient to justify the effort. The attempt was therefore discontinued.

C. Production of Information, Education and Communication (IEC) Materials

One limitation of the FPA's program recently is the lack of audiovisual materials suitable for reaching general audiences. With USAID concurrence, IFRP supported the production and acquisition by the FPA of a substantial set of IEC materials. These were timed to be available for the Association's major 2001 Exhibition in Colombo in September 1981. However, they were designed in such a way as to be easily useable for smaller scale presentations around the country. The FPA provided a report on the results of that effort of which the summary is presented here.

Production of IEC Materials

The Family Planning Association of Sri Lanka with the support of the IFRP recently produced a collection of valuable IEC materials which were exhibited at the 2001 Exhibition in Colombo from September 25-29, 1981.

The productions could be classified into three main areas:

1. Medical Information Material

One of the main problems in the Family Planning Programs in Sri Lanka is that, even though the awareness of Family Planning among the population is high, the practice level of contraceptive methods have been generally low. This is mainly due to the low levels of knowledge as well as the wrong beliefs regarding modern contraceptive methods. In order to counteract this situation, the Association produced the following IEC materials under this project.

- a. A series of charts on modern contraceptive methods explaining how methods are used their possible side effects, who should use the method and where services are conveniently available in different parts of the country. The charts were prepared by the Medical Division, carefully analyzing the type of information that should be given and was produced on large boards so that they could be taken from place to place for display purposes. The methods covered under this were condoms, orals, injectables, vaginal contraceptives, diaphragms, natural methods of family planning and male and female sterilizations.
- b. In order to support the above charts, three short films were produced on a video cassette. These films described the simplicity of vasectomy, showing an actual vasectomy

operation, how the IUD is inserted and how to use vaginal contraceptives.

- c. Special material on subfertility with a series of charts explaining in full the causes of subfertility, the type of treatment that could be taken and where treatment could be taken were produced for display. Also, a series of questions giving possible answers were all put out in chart form.
- d. Since the Association in its Clinical Program has a number of people who come with sexual problems, a special section on Human Sexuality was also put up on chart form. These dealt with such common areas as masturbation, impotency, premature ejaculation and husband-wife relationship.
- e. A chart on safe period method was produced with full explanation as to how to determine the safe period.

2. Population Education

In order to extend Population Education Programs throughout the country, the Association produced some valuable material for this section.

- a. Population Map--An electrically operated population map giving the total population of Sri Lanka, the breakdown of district population, the daily birth rate, death rate, land area and the projected population of the country of

the year 2001 were displayed on this map by means of moving electric lights. The whole map has been produced in such a way that it could be taken from place to place and displayed with the least amount of inconvenience.

- b. Charts--A series of charts explaining the country's population situation with information on employment, housing, food production, population density, per capita land availability and expenditure for education, health, subsidies, etc, were drawn in various colors and put onto boards which could again be taken from place to place very conveniently.
- c. Population Pyramid--A population pyramid which could be understood by the layman was produced in order to explain the current population situation and to indicate that if the present population growth rate were to continue, how the dependency rate would increase to a situation beyond control.
- d. Population Data--A population data chart was produced which could be distributed for school children and gave all basic information on demography.

3. Family Planning Program

Since there is still opposition for the extension of family planning activities on the basis of ethnic disruptions, a display of where family planning is currently carried out by

the government and the Association were produced once again in chart form so that it could be taken from place to place for exhibition and educational programs.

4. Beyond Family Planning

A section that dealt with what the future holds to nations like Sri Lanka if family planning was not encouraged was shown in this area. The production highlighted the compulsion programs that were made in India, the types of literature available in China and Singapore for small families and how the voluntary nature of family planning could change if family planning was not made available to the people.

5. Women's Development

Since family planning is closely linked with the development of women, a section dealing with Women's Development Programs and how they could assist in the development of the nation was also produced.

2001 Exhibition

The first place where the above productions were displayed to the public was the 2001 Exhibition. Approximately 50,000 people came for exhibition during the five days it was opened to the public. A large percentage was school children. The Exhibition was held at the Bandaranayake Memorial International Conference Hall and was declared open by the Hon. Minister for Lands and Mahaweli Development, Mr. Gamini Dissanayake. On this occasion, the first

ever Family Planning Stamp issued in Sri Lanka was also issued by the Hon. Minister for Posts and Telecommunication, Mr. D. B. Wijetunge. In addition, to these two Ministers, the Hon. Minister for Colombo Group of Hospitals and Family Health and the District Minister for Matara also participated at the opening ceremony. Well over 5,000 people waited outside on the opening day to get into the Exhibition Hall as it was opened.

In order to determine the real value of the Exhibition and the types of productions that were displayed, a special evaluation was conducted throughout the Exhibition period. (A detailed report of that was provided to IFRP.)

It is our opinion that IEC productions made from the IFRP Grant have proved to be extremely valuable and could assist us considerably in our future FP activities.

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Appendix A: Data Collection Forms for the Clinical Trial

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
SYSTEMIC CONTRACEPTIVE STUDY - ADMISSION RECORD**

Please Circle Appropriate Numbers and Fill In Appropriate Boxes and Blanks

No. _____

PATIENT IDENTIFICATION:

1. Your Hospital or Clinic No. _____ 2. Admission Date _____
Day Month Year

3. Patient's Name _____ 4. Husband's Name _____
Family First Maiden

5. Address _____ Telephone _____

6. Relative/Friend's Name _____

7. Address _____ Telephone _____

STUDY IDENTIFICATION

8. Center Name _____ and Number _____
 9. Study Name _____ and Number _____
 10. Patient Order in Study _____

PATIENT CHARACTERISTICS

11. Residence 1) urban 2) rural _____
 12. Age (years completed) _____
 13. Gainfully Employed 0) no 1) yes _____
 14. Race 1) Caucasoid 2) Mongoloid 3) Negroid
 8) other _____
 15. Religion 0) none 1) Buddhist 2) Catholic 3) Hindu,
 caste _____ 4) Jewish 5) Muslim 6) Orthodox
 7) Protestant 8) other _____
 16. Marital Status 1) never married 2) currently married
 3) formerly married 8) other _____
 17. Patient's Education (school year completed) _____
 18. Husband's Education (school year completed) _____
 19. Total Live Births _____
 20. Children Now Living _____ number of males
(If no living children, SKIP TO ITEM 22) _____ number of females
 21. Age of Youngest Child (completed years 8 or more = 8) _____
 22. Number of Additional Children Wanted _____
 23. Total Number of Abortions _____
 24. Number of Spontaneous Abortions (8 or more = 8) _____
 25. Total Stillbirths (8 or more = 8) _____
 26. Contraceptive Method Mainly Used Before This Prescription
 0) none 1) IUD 2) oral 3) tubectomy 4) vasectomy
 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/
 jelly 8) other _____

ADDITIONAL ITEMS (To Be Filled in Upon Request)

27. _____
 28. _____
 29. _____
 30. _____

PREGNANCY AND MENSES

31. Ever Pregnant (0) no 1) yes _____
 32. Date Last Pregnancy Ended _____
Day Month Year
 33. Last Pregnancy's Outcome 1) live birth 2) stillbirth
 3) induced abort on 12 weeks or less 4) induced
 abortion over 12 weeks 5) spontaneous abortion
 6) septic abortion 8) other _____
 34. Breastfeeding Now 0) no 1) yes _____
 35. Menses Since Last Pregnancy
 (0) no → SKIP TO ITEM 37 1) yes _____
 36. Date Last Menses Onset _____
Day Month Year

OVER LAST THREE PERIODS

37. Average Length of Cycle: (in days) 88) irregular _____ 62-63
 38. Average Duration of Flow: (in days; 8 or more = 8) _____ 64
 39. Average Amount of Flow: 1) scanty 2) less than normal
 3) normal 4) more than normal 5) excessive _____ 65
 40. Dysmenorrhea 0) none 1) mild 2) moderate 3) severe _____ 66
 41. Intermenstrual Bleeding 0) none 1) staining/spotting
 2) moderate 3) severe _____ 67
 42. Intermenstrual Pain: 0) none 1) mild 2) moderate
 3) severe _____ 68
 Interviewer's Name _____ 69
MEDICAL DATA
 43. Hematocrit 99) not done _____ 80
 44. Hemoglobin in Grams 99) not done _____ 11-12
 45. Blood Pressure: Systolic _____ 13-14
 Diastolic 999) not done _____ 15-17
 46. Weight in kg (98 and over = 98) _____ 18-20
 47. Height in cm _____ 21-22
 48. Primary Pre-Existing Medical Condition _____ 23-25
 _____ 26-27
 _____ 28

PRESCRIPTION

49. Contraceptive Prescribed Today 1) daily combined oral
 2) daily sequential oral 3) daily minipill 4) monthly
 oral 5) injectables 6) vaginal ring 7) implants
 8) other _____ 29
 50. Identification by Name or Code _____ 30-33
 51. Number of Cycles Given This Visit _____ 34-35
 52. How Will Patient Receive Next Supply 1) at follow-up
 visit 2) clinic depot 3) community depot 4) pharmacy
 5) mobile unit 6) home delivery 7) mail
 8) other _____ 36
 53. Today's Date _____ 38-40
Day Month Year
 54. Date of Starting Contraceptive _____ 44-46
Day Month Year
 55. Who Prescribed the Contraceptive 1) doctor
 2) nurse 3) midwife 8) other _____ 50
 56. Date Set for First Follow-Up Visit _____ 51-54
Day Month Year
 Prescriber's Name _____

Note: FOR SELF STARTING CONTRACEPTIONS
 Retain this form until the first Follow Up Contact
 confirming the initiation of contraception - but not
 longer than 90 days (See Manual for instructions)

No. _____ 58-60

IF RP 5YST 1/75

2 80

COMMENTS:

FAMILY PLANNING ASSOCIATION OF SRI LANKA

SYSTEMIC CONTRACEPTIVE STUDY—FOLLOW-UP RECORD

Please write appropriate numbers and fill in appropriate boxes and blanks

PATIENT IDENTIFICATION

1 Your hospital or clinic no _____ 2 Follow-up date _____ day month year

3 Patient's name _____ family first maiden Telephone _____

4 Address _____

STUDY IDENTIFICATION

5 Center name _____ and number

7	0	0
---	---	---

 1-3

6 Study name _____ and number

8	2	4
---	---	---

 4-6

7 Patient order in study _____ 7-10

8 IFRP admission form number _____ 11-16

9 Follow-up visit number _____ 17-18

10 Number of contraceptive cycles completed _____ 19-20

CONTACT DATA

11 Type of contact 1) clinic visit 2) home visit 3) moved 4) unable to locate 5) died. cause _____ 8) other _____ 21

12 Reason for this contact 1) scheduled 8) other _____ 22

13 Date this contact _____ 23-28

14 Date last contact _____ 29-34

MEDICAL DATA

15 Blood pressure systolic _____ diastolic _____ 999) not done _____ 53-55

16 Weight in kg (98 and over = 98) _____ 56-60

CONTINUATION DATA

17 Contraceptive identification by name or code 1) A/C package 2) A blank package 3) B/C package 4) B blank package

1	0	0	
1	0	0	0

 66-71

3

 72-76

18 Patient discontinued use 0) no 1) yes _____ 27-31

19 Date of last use _____ 30-35

20 Decision to discontinue made by 1) patient 2) doctor 8) other _____ 36

21 Primary reason for discontinuation 1) unplanned pregnancy 2) menstrual side effects, including pain 3) other medical reasons or side effects 4) planned pregnancy 5) personal reason 6) moved from area 7) program specific reason (lack of supplies, cost, service problems) 8) other reason, specify _____ 9) lost to follow-up _____ 39

22 Other method of fertility control accepted or planned by patient 00) none 01) orals 02) IUD 03) condom 04) foam jelly 05) diaphragm 06) safe period 07) abstinence 08) withdrawal 09) injectable 10) female sterilization 11) male sterilization 99) unknown _____ 40-41

23 Primary reason for irregular use 0) not irregular 1) discontinued 2) forgetfulness 3) side effects 4) clinic supply not available 5) temporarily not needed 6) supply misplaced 8) other _____ 42

24 How did patient receive last supply 1) at follow-up visit 2) clinic depot 3) community depot 4) pharmacy 5) mobile unit 6) home delivery 7) mail 8) other _____ 43

25. Date set for next follow-up visit _____ 46-51

day month year

4

 80

SIGNS AND SYMPTOMS (Complete Items 26-54 at every follow-up visit. Record for last 28 days or since last visit, whichever is less.)

26 Day within present cycle: _____ 21-22

27 Date of this contact. (repeat information recorded in Item 13) _____ 23-28

day month year

28 Occurrence of spotting/breakthrough bleeding: 0) none 1) yes, early cycle 2) yes, midcycle 3) yes, late cycle 4) yes, more than one phase _____ 29

29. Estimated number of days of spotting/breakthrough bleeding: 00) none _____ 30-31

30. Nausea: 0) no 1) yes _____ 32

31. Vomiting: 0) no 1) yes _____ 33

32. Dizziness: 0) no 1) yes _____ 34

33. Headache: 0) no 1) yes _____ 35

34. Hair loss: 0) no 1) yes _____ 36

35. Backache: 0) no 1) yes _____ 37

36. Diarrhea: 0) no 1) yes _____ 38

37. Constipation: 0) no 1) yes _____ 39

38. Abdominal pain: 0) no 1) yes _____ 40

39. Abdominal bloating: 0) no 1) yes _____ 41

40. Swelling (edema): 0) no 1) yes _____ 42

41. Leg pains or cramps: 0) no 1) yes _____ 43

42. Tiredness (fatigue): 0) no 1) yes _____ 44

43. Irritability: 0) no 1) yes _____ 45

44. Depression: 0) no 1) yes _____ 46

45. Breast discomfort/tenderness: 0) no 1) yes _____ 47

46. Change of appetite: 0) none 1) increased 2) decreased _____ 48

47. Acne and/or oily skin: 0) none 1) increased 2) decreased _____ 49

48. Rashes: 0) no 1) yes _____ 50

49. Facial pigmentation (chloasma): 0) no 1) yes _____ 51

50. Sexual desire: 1) unchanged 2) increased 3) decreased _____ 52

51. Vaginal itching: 0) no 1) yes _____ 53

52. Vaginal discharge: 0) none 1) unchanged 2) increased 3) decreased _____ 54

53 Other _____ 55-58

54 Pertinent physical findings related to above symptoms and treatment 0) none 1) yes specify _____ 57-59

INTERNATIONAL FERTILITY RESEARCH PROGRAM SYSTEMIC CONTRACEPTIVE ABBREVIATED DAILY SYMPTOM GRID

PATIENT IDENTIFICATION:

1. Hospital or Clinic Number _____ 2. Date completed _____
day month year

3. Patient's Name _____ Telephone _____
family first maiden

Address _____

5. Center number:

0	7	0	0
---	---	---	---

 1-4

6. Study number:

0	8	2	4
---	---	---	---

 5-8

7. Patient order number: _____ 9-13

8. IFRP admission form number: _____ 14-19

9. Cycle number: _____ 20-21

10. Symptom grid number within cycle:

1

 22

11. Date of first contraceptive cycle day in this cycle:

--	--

 day

--	--

 month

--	--

 year 23-28

12. Contraceptive: 1) A/C package 2) A/blank package 3) B/C package 4) B/blank package

0	0	0	
---	---	---	--

 29-32

13. Frequency of contact: 1) once a month 2) twice a month 3) once a cycle 8) other

--

 33

14. Contraceptive cycle days when contacts for this grid were made: 8R) not applicable First

--	--

 34-35
 Second

--	--

 36-37

15. Interview: 1) self 2) telephone 3) home visit 4) clinic visit 5) home and clinic visits 8) other

--

 38

DAILY SYMPTOM GRID – CONTRACEPTIVE CYCLE DAY

CONDITIONS (code 1 on days when condition occurred.)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32			
16. Contraceptive pill 0) pill missed 1) pill taken 2) 2 pills taken																																			0
	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	80		
17. Breakthrough bleeding/spotting. 1) condition occurred 2) withdrawal bleeding/menses																																			1
18. Vaginal discharge:																																			2
19. Nausea																																			3
20. Vomiting																																			4
21. Headache																																			5
22. Fatigue																																			6
23. Breast tenderness/swelling																																			7
24. _____																																			8
25. _____																																			9

RETURN TO: International Fertility Research Program, Research Triangle Park, North Carolina 27709 USA

**FAMILY PLANNING ASSOCIATION OF SRI LANKA
COUPLE REGISTRATION RECORD**

COUPLE IDENTIFICATION: 1. Wife's name _____ 2. Husband's name _____
3. Address _____

STUDY IDENTIFICATION

4. Center number:

 1-4
5. Couple serial number:

 5-8
6. A.G.A. division: 1) Morawak Korale West 2) other Matara 3) Vavuniya South (Tamil) 4) Vavuniya South (Sinhala) 5) Cheddi Kulam 6) other Vavuniya 8) other 9
7. Residence: 1) urban 2) rural 3) estate 4) traditional village 5) newly developed village 8) other 10
8. Date of enumeration:

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 day

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 month

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 year 11-19

COUPLE CHARACTERISTICS

9. Wife's current age: (years completed)

 17-19
10. Wife's age at first marriage: (years completed)

 10-20
11. Husband's current age: (years completed)

 21-23
12. Wife's occupation: 0) none/housewife: does not work outside the home or do anything at home to earn money, but may help husband with cultivation, etc. 1) works outside the home 2) earns money by work done at home 8) other

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 23 0

0	0
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 24-25
13. Husband's occupation: 0) none 1) professional, technical, administrative, managerial, related occupations 2) skilled worker (eg. mason, electrician, carpenter, driver, related occupations) 3) service provider (eg. clerk, supervisor, postmaster, related occupations) 4) cultivator 5) agricultural labourer in plantation or peasant sector 6) fisherman 7) unskilled worker (eg. bus conductor, postal peon, hospital attendant, related occupations) 8) other 26
14. Wife's education: (grade completed) 0) no schooling 1) grade 5 or less 2) grade 6 to 9 3) grade 10 or higher 27
15. Husband's education: (grade completed) 0) no schooling 1) grade 5 or less 2) grade 6 to 9 3) grade 10 or higher 28
16. Religion: 0) none 1) Buddhist 2) Hindu 3) Muslim 4) Roman Catholic 5) other Christian 8) other 29
17. Ethnic group: 1) Sinhalese 2) Sri Lanka Tamil 3) Indian Tamil 4) Sri Lanka Moor 8) other 30

18. Total live births:

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 31-32
19. Children now living:

 number of sons (8 or more = 8) number of daughters 33 34
20. Age of youngest living child in months completed: (less than one month = 0; 5 years and older = 60; no living children = 98)

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 35-36
21. Currently breastfeeding: 0) no 1) yes, without supplements 2) yes, with supplements 37
22. Live births in 1977: 38
23. Live births in 1978: 39
24. Is wife currently pregnant: 0) no 1) not certain 2) yes } Do NOT give pills 40
25. Duration of pregnancy in months: 0) not pregnant (8 or more = 8) 41
26. Number of additional children wanted: (8 or more = 8) 42
27. Contraceptive knowledge: (family planning methods known) 0) none 1) only one modern method 2) more than one modern method 3) only traditional methods 43
28. Contraceptive history: 0) never used 1) used previously, not using now 2) now using 44
29. Reason for not using contraception: 0) never heard of it 1) opposed to family planning 2) spouse opposed to family planning 3) desire to become pregnant 4) currently pregnant 5) breastfeeding 6) fear of side effects 7) services/methods not available 8) other, specify _____ 45
30. Contraceptive method most recently used: 00) none 01) orals 02) IUD 03) condom 04) foam/jelly 05) diaphragm 06) safe period 07) abstinence 08) withdrawal 09) injectable 10) female sterilization 11) vasectomy

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 46-47
31. Source of method most recently used: 0) never used 1) no supply needed 2) hospital/clinic 3) estate 4) midwife 5) private physician 6) shop 8) other, specify _____ 48

**FAMILY PLANNING ASSOCIATION OF SRI LANKA
ACCEPTANCE AND FOLLOW UP RECORD**

Center number: 1-4 Couple serial number: 5-8

STUDY PARTICIPATION

This section is to be completed ONLY if an acceptor chooses to participate in the study of oral contraceptives with supplements

Date last menses began: 9-11
day month year

Study regimen accepted:
 1) A package 2) A blank package
 3) B C package 4) B blank package

Date study regimen started: 12-15
day month year

This section is to be completed ONLY if the acceptor discontinues the study regimen

Date study regimen discontinued: 11-14
day month year

Number of cycles completed at the time of discontinuation: 15-17

Reason for discontinuation (use codes below): 18

REGISTER OF VISITS

Use codes below to complete this register

Visit number	Date day/month/year	Method accepted this visit	Number of pill cycles supplied	Method continued this visit	Side effect	Referral	Date of discontinuation day/month/year	Reason for discontinuation	Date next visit day/month/year
01	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
02	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
03	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
04	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
05	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
06	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
07	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
08	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
09	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
11	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
12	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
13	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
14	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
16	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
17	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
18	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
19	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
20	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

CODES

Method accepted/continued this visit: 00) none 01) study regimen 02) other orals 03) IUD 04) condom 05) foam/jelly 06) diaphragm 07) safe period 08) abstinence 09) withdrawal 10) injectable 11) female sterilization 12) vasectomy 09) unknown

Side effect (most disturbing side effect since last visit): 00) none 01) spotting/breakthrough bleeding 02) amenorrhoea 03) nausea/vomiting 04) dizziness/headache 05) abdominal pain 06) swelling of feet 07) leg pains/cramps 08) tiredness/fatigue 09) irritability/depression 10) discomfort/tenderness 11) change of appetite 12) rashes/acne/oily skin 13) weight change 88) other

Referral: 0) none 1) contraceptive side effects 2) IUD insertion 3) female sterilization 4) vasectomy 5) injectable 6) menstrual regulation 7) pregnancy 8) other

Reason for discontinuation: 1) unplanned pregnancy 2) menstrual side effects including pain 3) other medical reason or side effect 4) planned pregnancy 5) personal reason 6) moved from area 7) program-specific reason (lack of supplies cost, service problems) 8) other reason 9) lost to follow-up

Home visitor number: _____