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PROGRESS REPORT

COOPERATIVE AGREEMENT NO. A.I.D./DPE-3050-A-00-8059-00

MARCH 1, 1989 TO FEBRUARY 28, 1990

Submitted by

**THE POPULATION COUNCIL
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NEW YORK, NEW YORK 10017**

JUNE 1990

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INTRODUCTION AND SUMMARY

This is the second progress report on activities supported under Cooperative Agreement No. A.I.D./DPE-3050-A-00-8059-00. The agreement provides support for a program in family planning services for the period July 17, 1988 through August 25, 1993. Programmatic areas supported under the agreement are contraceptive development, contraceptive introduction and management, and family planning program research, support, and technical assistance. This report includes narrative progress reports and financial information for each in-house activity and subcontract supported under the agreement during the period March 1, 1989 through February 28, 1990. The progress reports and the summary of activities are presented by programmatic areas.

Contraceptive Development

Support was continued for contraceptive development projects involving subdermal implants, contraceptive rings, levonorgestrel releasing IUDs, LHRH analogs and high potency androgens, inhibin, gonadotropin surge inhibiting factor, and simple male sterilization. Another project being supported is ST 1435 toxicology. This work was carried out in-house and under subawards and subcontracts to other institutions.

Major emphasis was put on the progesterone ring study in nursing women, which evaluates safety for mother and child, and effectiveness and continuation rates in comparison to the Copper T 380A IUD. The dose finding studies for the progestin/estrogen combination rings were continued. The cartridge-loaded vasocclude device for a simple vasectomy technique was improved further and successfully tested in dogs. A new radioimmunoassay core laboratory was established in Finland and toxicology studies on ST 1435 in rats and rabbits were completed.

Contraceptive Introduction and Management

Support was continued for the contraceptive introduction program to facilitate the widest possible availability and the most appropriate use of the contraceptive technologies developed by the Population Council, consistent with the goals of the Council's User Perspective and Quality of Care in Family Planning programs. Current activities focus on two highly effective, long-acting, reversible contraceptives: The NORPLANT^R Contraceptive Subdermal Implant and the Copper T 380A Intrauterine Device.

Regulatory approval for marketing or programmatic use of NORPLANT^R has been gained in fifteen countries. Filings have been made to regulatory authorities in several additional countries. A New Drug Application to the United States Food and Drug

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Administration (USFDA) was submitted in October 1988. Pre-introduction trials have been conducted or are ongoing in 44 countries. Council staff and consultants currently monitor twelve of these trials directly, providing medical backstopping and technical assistance. In addition, they provide technical assistance to the primary monitors of trials in six other countries.

Emphasis has continued to shift from initial training of providers in insertion and removal techniques and evaluation of effectiveness and safety in different settings, to study of user- and programmatic needs for widespread use. Prototypical training and informational materials for program managers, clinicians, counselors, and users have been written. A draft training curriculum developed in collaboration with the Program for Appropriate Technology in Health (PATH), Family Health International (FHI), and the Association for Voluntary Surgical Contraception (AVSC) has been revised. The curriculum was field tested in Nigeria, and will be further tested in two other sites during 1990, probably in Bangladesh and Kenya.

The Guide to Effective Counselling has been translated into French and Spanish. A Clinician's Manual has been completed, as well as a Scientific Monograph summarizing all pertinent data on the method. A management study of NORPLANT^R and programmatic guidelines have been produced. These materials will be published during the next reporting period.

Following approval of the method in Kenya, the Council assisted in the development of a national introduction strategy. A comprehensive introduction project is being designed to facilitate the organizational upgrading needed to enable program staff and directors to manage this method.

The Copper T 380A IUD is broadly available. USFDA approval was gained in 1984. More than eight million Copper T 380A IUDs from a number of Council-licensed manufacturers have been distributed in over 70 countries.

The Council and PATH collaborated to prepare a package of prototypical materials for clinicians and field workers. This package includes guidelines for informed choice, a wall chart describing the method, and examples of culturally adapted materials.

PATH provided technical assistance to programs in Bangladesh, Brazil, Colombia, Tunisia, and Egypt in the development of country-specific and culturally-appropriate informational materials for decision makers, clinicians, field workers, and new and potential acceptors. Specific materials include two brochures on the Copper T 380A IUD in Colombia, one for users and one for potential users.

A factsheet, COPPER T 380A Intrauterine Device UPDATE on modes of action was published during this reporting period and was distributed widely throughout the field.

A monograph summarizing clinical and introduction data on the Copper T 380A IUD has been prepared and will be distributed during the next reporting period.

The draft training curriculum, initially prepared by the Council and PATH for the Family Welfare Visitors in Bangladesh on all aspect of Copper T 380A IUD use continued to be field tested where appropriate and made available for adaptation to regional or country needs.

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Family Planning Program Research, Support, and Technical Assistance

Support was continued for ongoing work in Bangladesh, Zaire, Kenya, Peru and Mexico. A program of family planning services was initiated during this period in Nepal. A delegation of Algerian officials also visited the United States for orientation on A.I.D. activities.

In Bangladesh, the Council continued its long-term collaboration with ICDDR,B on the MCH-FP Extension Project. Technical support was provided to the Extension Project to continue to field test and evaluate interventions within the government program in project field sites. Efforts focused on the consolidation of existing interventions, with priority given to incorporating promising research findings into national policy. Another area of emphasis during this period has been the microcomputer-based health and family planning management information system based in Matlab. This system is anticipated to have wide applicability for service delivery projects in other developing country settings.

In Zaire, the purpose of the Kananga Project was to measure how much the demand for contraception in the Kasai Region of Zaire could increase under optimal supply conditions. The Project team conducted focus group studies on the acceptability of contraception, especially Depo-Provera, in comparison with NORPLANT[®]. Results from these studies will be used to modify the existing program in an effort to provide the most appropriate and desirable methods.

In Kenya, the Population Council has been collaborating with the Population Studies and Research Institute (PSRI) at the University of Nairobi to strengthen its institutional capacity to implement a population research and information dissemination program. The purpose of the research program is to provide information on policies related to the implementation of the national family planning program to the Government of Kenya and the National Council for Population and Development (NCPD). PSRI is currently the main institution in the country charged with providing trained manpower for conducting population policy and program relevant research, and will become the training and research arm of NCPD. PSRI has well established a two year M.A./M.Sc. program in population studies and a diploma program for civil servants, but looks for a greater capability for population and policy relevant research. The Population Council is working with PSRI to build its capacity to conduct this type of research.

In Nepal, a Coordination Committee meeting was held in February 1990 to introduce the implementation plan for the systems development program in the districts, and to solicit inputs on this plan from committee members. The meeting was a success inviting suggestions regarding training and counseling, quality assurance systems, logistics systems, competitive reward systems, management information systems, and IEC approaches. Over the next four months, the activities stated in the project's scope of work will be completed, and additional documentation will be prepared for the project's extension.

At the request of A.I.D., the Population Council sponsored a study mission for a delegation of three Algerian officials. The purpose was to introduce them to a variety of innovative population and family planning activities being carried out by the A.I.D., S&T POP, cooperating agencies, and international donors. It was envisioned that this trip would open new dialogue between the U.S. and Algerian institutions

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involved in family planning. After the delegation returned, follow-up with the Algerian government was anticipated, however, there was a change in personnel in the ministries, and the delegates who participated in the mission are no longer in power.

The Council has undertaken numerous projects to foster breastfeeding for child health and birth spacing. Currently, it is involved in two projects which may help to promote early exclusive breastfeeding and to revise traditional postpartum family planning services.

The Council continues to support and provide assistance in the education of health professionals in lactation management. The Lima project, conducted through the Universidad Peruana Cayetano Heredia, aims to demonstrate how the effect of education for both the health professional and mother will increase the duration of exclusive breastfeeding.

The Mexico project, conducted in collaboration with Mexico City General Hospital and La Liga de la Leche de Mexico, studied the impact of intensive training in lactation management on hospital practices and breastfeeding patterns.

The Council has already developed special booklets on breastfeeding for both mother and health care providers. A Mother's Guide to Breastfeeding was produced in both English and Spanish and has been widely utilized. (It is now New York State's official breastfeeding information for mothers and has been translated into Haitian French and Lao for the local immigrant populations). A companion, Breastfeeding: A Nurse's Guide has also been widely used and has been translated into Spanish (in Peru) and Portuguese to better assist health care providers in meeting contraceptive needs of lactating women.

**II. PROGRESS REPORTS ON IN-HOUSE ACTIVITIES,
AWARDS, AND SUBCONTRACTS ACTIVE DURING
REPORTING PERIOD**

1. CONTRACEPTIVE DEVELOPMENT PROGRAM

POPULATION COUNCIL IN-HOUSE PROJECTCONTRACEPTIVE DEVELOPMENT PROGRAM - 1988/1989/1990

Period: July 17, 1988 to February 28, 1990

Amount: \$ 1,315,287
1,958,000^aApproved by A.I.D.: February 28, 1989
^aJuly 19, 1989

Status: Current

Purpose: To support contraceptive development activities pertaining to subdermal implants, contraceptive rings, the levonorgestrel IUD, LHRH analogs and high potency androgen, inhibin, gonadotropin surge inhibiting factor, barrier methods, simple male sterilization, and ST 1435 toxicology.

Subproject: Subdermal Implants (\$720,906)

After the manufacturer withdrew the elastomer comprising the core of the two-rod NORPLANT^R-2, the Council decided to file an NDA on the six-capsule NORPLANT^R system, which uses a different elastomer. The filing was submitted in August 1988. The Advisory Committee to the U.S. FDA for Fertility and Maternal Health Drugs has unanimously recommended approval of the NDA. Approval is expected in the near future. To date, NORPLANT^R has been approved for distribution in fourteen countries.

Implants manufactured with the softer grade of Silastic^R tubing were found to be more effective in preventing pregnancy. In order to obtain FDA approval for this softer, more effective grade of Silastic^R tubing for manufacturing NORPLANT^R implants, in vitro studies were carried out during the reporting period. Several batches of softer tubing were used to prepare progestin-filled capsules, comparable to those made with the previously used harder grade of Silastic^R tubing. A suitable replacement was identified, and our licensee is now manufacturing implants from this softer tubing in preparation for clinical studies to support New Drug Applications in many countries, including the United States.

NORPLANT^R-2 has been reformulated successfully, using a slightly different ingredient in the core to replace the elastomer that is no longer available. Reformulation of the implants has not altered their release rates in vitro and appears to have greatly facilitated manufacturing procedures. Clinical trials were started to determine blood levels and the effectiveness of the reformulated device.

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POPULATION COUNCIL IN-HOUSE PROJECTCONTRACEPTIVE DEVELOPMENT PROGRAM - 1988/1989/1990

Exploratory studies have been conducted on a single implant system that releases ST 1435. It is expected to provide advantages over both NORPLANT^R dosage forms and to fill special niches in contraceptive practice. Because of the chemical properties of ST 1435, the design of this implant^R differs significantly from that of either NORPLANT^R or NORPLANT^R-2.

The second-generation implant project will focus on ST 1435. Prototype devices are undergoing clinical trials in one clinic. Initial results are very promising: no ovulations have occurred in any of the women using the implant. Pharmacokinetic studies are in progress. Data from these and other studies are being assembled and will be used to obtain an Investigational New Drug (IND) exemption from the FDA. This will allow the Council and other organizations to use ST 1435 for a number of contraceptives, including implants.

Subcontracts:

CB89.02A/ICCR	University of Uppsala (\$10,000)
CB89.27A/ICCR	Professional Staff Association of the LAC/USC Medical Center (\$67,775)
CB89.29A/ICCR	Robert Wood Johnson Medical School (\$44,563)
CB89.32A/ICCR	The Regents of the University of California, San Francisco General Hospital (\$44,387)

Subproject: Contraceptive Ring (\$462,906)

After the progesterone-releasing ring was reformulated, Phase III clinical trials in lactating women were initiated at the end of 1989. These studies are being conducted at twelve sites, including one in the United States. Two of these trials are currently funded by the Agency for International Development. During 1989, ring development proceeded with

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POPULATION COUNCIL IN-HOUSE PROJECTCONTRACEPTIVE DEVELOPMENT PROGRAM - 1988/1989/1990

two progestins capable of inhibiting ovulation and giving good bleeding control, without adverse effects on lipoprotein patterns: norethindrone acetate (in combination with ethynylestradiol) and ST 1435 (with or without ethynylestradiol). These two progestins were chosen for continued development, and Phase II clinical trials with rings releasing norethindrone acetate in combination with various doses of ethynylestradiol are continuing. Small-scale trials with the ST 1435/ethynylestradiol ring have been completed in two clinics with favorable results. In a subsequent study, the levels of ethynylestradiol were reduced to identify the lowest dose of this steroid capable of maintaining excellent bleeding control, ovulation inhibition, and minimal effects on serum lipoprotein levels. Additional rings releasing ST 1435 with and without ethynylestradiol have been manufactured in a collaborating laboratory.

Subcontracts:

CB89.11A/ICCR National University of Singapore
(\$12,303)

CB89.18A/ICCR Hopital de Bicetre
(\$120,966)

CB89.28A/ICCR Professional Staff Association of the LAC/USC
Medical Center
(\$118,727)

CB89.31A/ICCR Professional Staff Association of the LAC/USC
Medical Center
(\$70,169)

Subproject: Levonorgestrel-Releasing IUD (\$145,139)

Phase III clinical trials in which the levonorgestrel IUD is being compared with the Copper T Model 380Ag have continued into their seventh and last year. The analysis of data over a seven-year span indicates that the levonorgestrel-releasing device is perhaps the most effective long-acting reversible method devised. In addition, it does not cause the increased bleeding often associated with other IUDs. Similar to NORPLANT^R-2, the levonorgestrel IUD was successfully reformulated in 1989.

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POPULATION COUNCIL IN-HOUSE PROJECT

CONTRACEPTIVE DEVELOPMENT PROGRAM - 1988/1989/1990

Subcontracts:

CB88.47A/ICCR National University of Singapore
(\$46,211)

CB89.26A/ICCR Professional Staff Association of LAC/USC
Medical Center (\$46,211)

CB90.01A/ICCR University of Helsinki
(\$65,040)

Subproject: LHRH Analogs and High Potency Androgen (\$278,545).

Phase I studies with the antagonistic and agonistic analogs of LHRH, LHRH-34, and LHRH-13 are continuing in men. A 90-day toxicity study in rats and rabbits was completed in order to extend clinical trials with LHRH-34. The results indicated no adverse effects. A final report has been submitted to the FDA which will allow the initiations of extended Phase II clinical studies. Preliminary studies with LHRH-40 (Antide), another antagonist, showed that, unlike other antagonists, LHRH-40 does not produce peripheral edema in rats when given in large doses. The duration of action is somewhat longer than that of LHRH-34.

The major emphasis of this project was directed toward developing a long-acting delivery system for LHRH analogs. Several prototype implants were tested in animals and in vitro. They will be used to inhibit spermatogenesis in men. A high potency androgen for use in supplementing the action of LHRH analogs in suppression of spermatogenesis is also under investigation. Acute toxicology and pharmacokinetic studies have been carried out.

Subproject: Inhibin (\$24,220).

Funding for these studies was discontinued and a final progress report was submitted on May 9, 1989.

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POPULATION COUNCIL IN-HOUSE PROJECTCONTRACEPTIVE DEVELOPMENT PROGRAM - 1988/1989/1990Subproject: Gonadotropin Surge Inhibiting Factor (GnSIF) (\$42,414)

This was a collaborative project between the Population Council and CONRAD. A strategy for the isolation of GnSIF from porcine follicular fluid and its separation from inhibin was developed. The purification method was adapted to the preparative level. Fractions from intermediate purification steps were assayed in Dr. G. Hodgen's laboratory for GnSIF and inhibin bioactivities. Funding for this project has been discontinued, and a final progress report was submitted on May 9, 1989.

Subproject: Simple Male Sterilization (\$171,423)

Following the decision to develop a "nonsurgical" or "no-scalpel" method of vasectomy, the Council entered into an agreement with a third party to design jointly a device capable of placing occluding clips on the vas deferens. Several prototype devices are being tested in dogs to optimize the design. At present, eighteen dogs have the clips in place. Azoospermia was achieved within one week. A progress report was submitted in May, 1990.

Subcontract:
CB89.42A/ICCR White Eagle Laboratories
(\$66,000)

Subproject: ST 1435 Toxicology (\$112,377)

Acute and 90-day toxicology studies in rats and rabbits have been completed. Pharmacokinetic studies in monkeys and in women are in progress.

POPULATION COUNCIL SUBCONTRACT NO. CB89.02A/ICCR

**To: University of Uppsala
Uppsala, Sweden**

Period: December 1, 1988 to November 30, 1989

Amount: \$ 10,000

Approved by A.I.D.: March 31, 1989

Status: Expired

Purpose: To continue the work in support of the project entitled, "Radioimmunoassay of Steroids as a Service Function to the ICCR," begun under Subcontract No. CB87.35A/ICCR funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00.

This contract has been terminated and all work has ceased. The function has been transferred to Finland.

During the last year, assays on serum samples from various clinics of women using NORPLANT^R, NORPLANT^R-2, and the levonorgestrel IUD were carried out to measure blood levels of levonorgestrel. Also, transfer of the RIA techniques was made to the laboratory in Finland so that uninterrupted RIA assay services could be continued.

POPULATION COUNCIL SUBCONTRACT NO. CB89.27A/ICCR

To: Professional Staff Association of LAC/USC Medical Center
Los Angeles, California, U.S.A.

Period: July 1, 1989 to June 30, 1990

Amount: \$ 67,775

Approved by A.I.D.: August 9, 1989

Status: Current

Purpose: To continue the work in support of the project entitled, "Comparative Use-Effectiveness of NORPLANT^R and NORPLANT^R-2 Contraceptive Subdermal Implants," begun under Subcontract No. CB87.20A funded under Cooperative Agreement A.I.D./DPE-3005-A-00-3003-00 and continued under Subcontract No. CB88.21A funded under Cooperative Agreement No. A.I.D./DPE-3050-A-00-8059-00.

This report includes activities undertaken under Subcontract No. CB88.21A.

This contract supported monitoring of a comparative study of 583 women using NORPLANT^R-2 and NORPLANT^R implants. Data from the trial were submitted to the US Food and Drug Administration as part of an NDA for the NORPLANT^R capsules.

As of April, 1990, all but 24 of the implants had been removed from continuing users. Twenty-eight women are considered lost to follow-up.

POPULATION COUNCIL SUBCONTRACT NO. CB89.29A/ICCR

To: University of Medicine and Dentistry of New Jersey - Robert Wood Johnson Medical School
New Jersey, U.S.A.

Period: May 16, 1989 to December 31, 1989

Amount: \$ 44,563

Approved by A.I.D.: August 9, 1989

Status: Expired

Purpose: To continue the project entitled, "Comparative Use-Effectiveness of NORPLANT^R and NORPLANT^R-2 Contraceptive Subdermal Implants" conducted under Population Council Subcontract No. CB88.02A funded under A.I.D./DPE-3005-A-00-3003-00.

This contract supported monitoring of a comparative study of 250 women using NORPLANT^R and NORPLANT^R-2 implants. Data from the trial were submitted to the U.S. Food and Drug Administration as part of an NDA for the NORPLANT^R capsules.

As of April 1990, all but eight of the implants had been removed from continuing users. Twenty-seven women were overdue for follow-up. Most of them are believed to retain the implants.

POPULATION COUNCIL SUBCONTRACT NO. CB89.32A/ICCR

To: The Regent of the University of California
San Francisco General Hospital
San Francisco, California, U.S.A.

Period: July 1, 1989 to December 31, 1989

Amount: \$ 44,387

Approved by A.I.D.: August 15, 1989

Status: Expired

Purpose: To continue the project entitled, "Comparative Use-Effectiveness of NORPLANT^R and NORPLANT^R-2 Contraceptive Subdermal Implants" conducted under Population Council Subcontract No. CB88.02A funded by A.I.D./DPE-3005-A-00-3003-00.

This contract supported monitoring of a comparative study of 250 women using NORPLANT^R and NORPLANT^R-2 implants. The data were submitted to the U.S. Food and Drug Administration as part of an NDA for the NORPLANT^R capsules.

As of April 1990, all but eight sets of implants had been removed from continuing users. Another eight women are considered lost to follow-up.

POPULATION COUNCIL SUBCONTRACT NO. CB89.11A/ICCR

To: National University Hospital
National University of Singapore
Singapore, Singapore

Period: May 1, 1989 to April 30, 1990

Amount: \$ 12,303

Approved by A.I.D.: August 7, 1989

Status: Current

Purpose: To conduct a clinical study on a progesterone releasing vaginal ring and TCu 380Ag IUDs for use by lactating women.

Recruitment to the study began in August 1989. Through the end of 1989, recruitment averaged two women per month per method, or four subjects per month. Apart from the slow recruitment, no problems have manifested themselves with either method.

POPULATION COUNCIL SUBCONTRACT NO. CB89.18A/ICCR

To: Hopital de Bicetre
Paris, France

Period: January 1, 1989 to December 31, 1989

Amount: \$ 120,966

Approved by A.I.D.: August 16, 1989

Status: Expired

Purpose: To support the project entitled, "Research on Contraceptive Vaginal Rings of ST 1435 and Ethynylestradiol Formulations."

Dr. Bouchard worked with rings delivering 100 µg of ST 1435 and either 5, 15, or 30 µg of ethynylestradiol (EE) per day in a total of 22 subjects. In women using the 5 µg EE ring, 5 out of 20 cycles were ovulatory; in women using the 15 µg ring only 3 out of 46 cycles were ovulatory. Out of three women using a 30 µg ring for a total of ten cycles, one ovulated twice during ring usage.

Bleeding patterns were somewhat irregular. Subjects in all three groups reported frequent spotting, particularly subjects in the 15 µg group. Two subjects in the 15 µg study group experienced amenorrhea, one for three cycles, starting in her third cycle in the study, the other during her second and fourth cycles.

Dr. Bouchard plans future studies with two different ST 1435/EE combinations: 100/30 and 150/15. Earlier preliminary studies with the 100/30 ring were encouraging, so this group will be expanded. Since some ovulation was seen with the 100/15 ring, it was felt that increasing the ST 1435 dose would solve this problem, while keeping the estrogen at this lower value.

POPULATION COUNCIL SUBCONTRACT NO. CB89.28A/ICCR

To: Professional Staff Association of LAC/USC Medical Center
Los Angeles, California, U.S.A.

Period: July 1, 1989 to June 30, 1990

Amount: \$ 118,727

Approved by A.I.D.: August 9, 1989
March 4, 1990^a

Status: Current

^aModified budget line items.

Purpose: To continue the project entitled, "Evaluation of Candidate Vaginal Ring Formulations" begun under Population Council Subcontract No. CB88.22A/ICCR.

This report includes activities being conducted under Population Council Subcontract No. CB88.22A. The subcontract period is August 1, 1988 to September 30, 1990.

Dr. Daniel R. Mishell, Jr., of the University of Southern California, conducted a study with 60 subjects using contraceptive rings containing norethindrone acetate (NETAC) and ethynylestradiol (EE). The subjects were divided evenly into two groups receiving NETAC (650 µg/day) and either 20 µg/day of EE or 30 µg/day of EE. The two different rings were randomized and distributed in a double blind fashion.

Side effects were relatively minor, with break-through bleeding being the most common. It occurred in half the subjects receiving the lower dose estrogen; only four of the women on the higher dose experienced this condition. Markedly better bleeding patterns occurred with the 30 µg ring.

Blood levels of norethindrone (NET) and EE were measured in ten subjects with each ring over four cycles. In addition, some subjects were sampled frequently over the first two days of ring usage to measure both of these steroids, and in a second group of women using oral contraceptives EE levels were measured over a 24-hour period.

Serum progesterone was measured in 20 women using either the 20 or 30 µg EE ring. No ovulation was seen in 40 cycles with the 30 µg ring, but four definite and three other possible ovulations were seen in 40 cycles of 20 µg ring usage. When urine samples were collected every other day for pregnanediol analysis, 2 definite and an additional 7 possible ovulations were seen with the 20 µg ring. No definite ovulations and only two possible ovulations were noted with the 30 µg ring.

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POPULATION COUNCIL SUBCONTRACT NO. CB89.28A/ICCR

To: Professional Staff Association of LAC/USC Medical Center
Los Angeles, California, U.S.A.

Lipid analyses were performed on all subjects. HDL cholesterol values increased favorably, and LDL-cholesterol values remained unchanged. Triglyceride levels increased, but were well within the normal range. Cholesterol increased only about 10%.

Due to the encouraging results obtained and an absence of major side effects, we plan an expanded study with the ring releasing 650 µg of NETAC and 30 µg of EE per day. We plan to study two other rings: one releasing 650 µg of NETAC and 25 µg of EE and another releasing 1,000 µg of NETAC and 20 µg of EE in order to see if we can decrease the dose of estrogen and still maintain ovulation suppression and good bleeding control. Studies will be conducted in Dr. Mishell's clinic and in two other clinics.

POPULATION COUNCIL SUBCONTRACT NO. CB89.31A/ICCR

To: Professional Staff Association of LAC/USC Medical Center
Los Angeles, California, U.S.A.

Period: September 1, 1989 to August 31, 1990

Amount: \$ 70,169

Approved by A.I.D.: August 5, 1989

Status: Current

Purpose: To conduct a clinical study on a progesterone releasing vaginal ring and TCu 380Ag IUDs for use by lactating women.

The study is aimed at investigating the safety, for mother and child, of progesterone rings and IUDs used as contraceptives initiated during the second postpartum month. Comparing the efficiency and acceptability of the two methods is another principal objective.

The project has been initiated at the clinic. Recruitment has proven somewhat slower than anticipated, with an average of one subject and her infant recruited per method per month.

POPULATION COUNCIL SUBCONTRACT NO. CB88.47A/ICCR

To: National University of Singapore
Singapore, Singapore

Period: January 1, 1989 to December 31, 1989

Amount: \$ 10,120

Approved by A.I.D.: October 23, 1989

Status: Terminated

Purpose: To support the project entitled, "A Metabolic Study of Levonorgestrel IUD Users."

This study was a controlled laboratory study in which lipid metabolism and coagulation factors were studied in thirty users of the levonorgestrel-releasing IUD at the conclusion of five years of use, and in Copper T 380A IUD users at five years. Values of these parameters were again measured six months later after removal of the levonorgestrel IUD, but with continuation of the use of the Copper T 380A IUD. Analysis of results is currently underway and will be presented at the International Symposium on Contraception in Heidelberg in June 1990.

POPULATION COUNCIL SUBCONTRACT NO. CB89.26A/ICCR

To: Professional Staff Association of LAC/USC Medical Center
Los Angeles, California, U.S.A.

Period: July 1, 1989 to June 30, 1990

Amount: \$ 46,211

Approved by A.I.D.: August 9, 1989

Status: Current

Purpose: To continue the project entitled, "Comparative Use-Effectiveness and Safety of Levonorgestrel and TCU 380Ag IUD," conducted under Population Council Subcontract No. CB88.20A.

This report includes activities undertaken under Population Council Subcontract No. CB89.20A during the period August 1, 1988 through June 30, 1989.

Initiated in January 1984, this comparative study recruited 263 women to measure safety and efficacy of the two IUDs. In April 1990, there have been three pregnancies among users of each device. There were 35 continuing users of the two devices and 47 women who may be considered LFU (lost to follow-up), as they were overdue for visits.

POPULATION COUNCIL SUBCONTRACT NO. CB90.01A/ICCR

To: University of Helsinki
Helsinki, Finland

Period: January 1, 1990 to December 31, 1990

Amount: \$ 65,040

Approved by A.I.D.: January 24, 1990

Status: Current

Purpose: To continue the activities in support of the project entitled, "Radioimmunoassay Core Laboratory for ICCR Research Centers" begun under Population Council Subcontract No. CB89.03A.

This report includes activities undertaken under Population Council Subcontract No. CB89.03A during the period January 1 through December 31, 1989.

During the first contract year 1989 the radioimmunoassay core laboratory was established in the Department of Medical Chemistry, University of Helsinki, Helsinki, Finland. A technician was hired and trained. Radioimmunoassays were set up for the synthetic progestins, levonorgestrel and ST 1435. The levonorgestrel assay involves a tritiated tracer, whereas ST 1435 radioimmunoassay utilizes a [¹²⁵I] iodinated derivative of ST 1435.

A total of 1,100 serum samples collected in research protocols of the Population Council have been assayed in duplicate for ST 1435.

The levonorgestrel assay was set up according to the protocol used in the laboratory in Uppsala, Sweden. Together with the evaluation samples, 40 samples were assayed that were also assayed in the Uppsala laboratory to confirm the identical performance of the assays. A total of 92 serum samples collected as part of the Population Council clinical research protocols were assayed in duplicate.

Fluoroimmunoassay methods were set up for measuring LH and hCG. A total of 200 serum samples for LH and 168 samples for hCG, respectively, have been assayed in accordance with the Population Council research protocols.

POPULATION COUNCIL SUBCONTRACT NO. CB89.42A/ICCR

To: White Eagle Laboratories
Doylestown, Pennsylvania, U.S.A.

Period: December 1, 1989 to June 30, 1990

Amount: \$ 66,000

Approved by A.I.D.: December 8, 1989

Status: Current

Purpose: To support the project entitled, "Laboratory Study on Dogs Vasectomized by the Vasocclude^R Technique."

A working model of a cartridge-loaded vasocclude device has been developed. Testing on plastic tubing reveals that this device consistently applies metal clips that are effective in occlusion of the lumen. Initial dog studies have revealed that two-clip in continuity occlusion of the vas deferens is effective in occluding 35 out of 36 vasa. A working model of the vasocclude device will now be employed to apply clips to 36 more vasa in 18 dogs. It is expected that the greatest consistency of clip pressure and application with the vasocclude device will reduce or eliminate failures. If failures still occur when the vasocclude device is employed to apply clips, the clips will then be modified to increase their strength and rigidity or to actually lock around the vas.

Further device development will be pursued simultaneously with animal studies and include development of a more ergonomic handle design and simplified trigger mechanism enabling application of the clips with fewer handle movements on the part of the vasectomist. Any further design modifications await completion of the ongoing dog studies.

POPULATION COUNCIL IN-HOUSE PROJECTSUBCHRONIC TOXICITY STUDY OF ST 1435 IN FEMALE RABBITS

Period: March 1, 1989 - February 28, 1990

Amount: \$ 88,168

Approved by A.I.D.: August 27, 1989

Status: Terminated

Purpose: To conduct toxicology studies in preparation for the filing of an IND with the regulatory authorities in Finland and the U.S. Food and Drug Administration.

In order to initiate Phase II clinical studies of ST 1435, a 90-day toxicity study was undertaken in female rabbits. ST 1435 was administered via subdermal Silastic implants to groups of 12 female rabbits. The implants releasing approximately 0, 25, 130, or 550 $\mu\text{g}/\text{day}$ were inserted subdermally.

All doses of ST 1435 were well tolerated and there were no apparent systemic toxic effects or adverse deviations in hematological and serum chemistry values.

ST 1435 depressed uterine weights and increased liver weights at all dose levels. In addition, rabbits receiving the high dose level of ST 1435 had lower adrenal and thyroid weights. Microscopic examination of 36 organs revealed no treatment-related toxicological effects. A progestational effect on the uterus was seen in all treated rabbits. The ovaries and thymus had occasional treatment-related effects in high dose rabbits. The primary treatment associated changes were observed in liver and adrenal glands in the high dose group. These changes included adrenocortical hypoplasia and increased glycogen content of hepatocytes. However, these effects were not seen at the lower doses.

From the results of this study it is concluded that ST 1435 did not produce systemic toxicological effects in female rabbits. The histological changes observed in liver and adrenal glands of the high dose group are attributed to a slight glucocorticoid-like activity of ST 1435.

POPULATION COUNCIL IN-HOUSE PROJECT

TWELVE-MONTH TOXICITY STUDY OF ST 1435 IN FEMALE RATS

Period: March 1, 1989 - February 28, 1990

Amount: \$ 150,419

Approved by A.I.D.: September 28, 1989

Status: Terminated

Purpose: To conduct toxicology studies in preparation for the filing of an IND with the regulatory authorities in Finland and the U.S. Food and Drug Administration.

A twelve-month toxicity study of ST1435 was initiated in female rats in September 1989 using the following study design:

<u>Group No.</u>	<u>Group Identification</u>	<u>Treatment Level</u>	<u>Rat Nos.</u>
1	Control (untreated)	(0)	1-24
2	Control (placebo)	(0)	25-72
3	Low Dose	3-5 µg/rat/day	73-96
4	Intermediate Dose	15-20 µg/rat/day	97-120
5	High Dose	60-70 µg/rat/day	121-144
6	Satellite Control (placebo)	(0)	145-156
7	Satellite High Dose	60-70 µg/rat/day	157-168

The rats in the satellite groups received ST 1435 for 3 months and fertility of those rats evaluated after about 12 weeks of recovery period. Fertility in the ST 1435 treated female rats was found to be normal suggesting that ST 1435 induced infertility is reversible.

ST 1435 treatment in principal groups would be terminated in September 1990 and complete evaluation of systemic toxicology undertaken.

2. CONTRACEPTIVE INTRODUCTION AND MANAGEMENT

- **PRE-INTRODUCTION EVALUATION OF NORPLANT^R CONTRACEPTIVE SUBDERMAL IMPLANTS**
- **INTRODUCTION OF THE COPPER-T 380A INTRAUTERINE DEVICE**

POPULATION COUNCIL IN-HOUSE PROJECT
PRE-INTRODUCTION EVALUATION OF NORPLANT
CONTRACEPTIVE SUBDERMAL IMPLANTS

Period: January 1, 1989 to December 31, 1990

Amount: \$691,642

Approved by A.I.D.: January 24, 1990

Status: Current

Purpose: To continue activities undertaken under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00 to facilitate the widespread availability and use of NORPLANT^R contraceptive subdermal implants in family planning programs throughout the world.

NORPLANT^R, the six capsule contraceptive implant method, has received regulatory approval for commercial or programmatic distribution in 15 countries: Chile, China, Colombia, Czechoslovakia, the Dominican Republic, Ecuador, Finland, Haiti, Indonesia, Kenya, Peru, Sri Lanka, Sweden, Thailand and Venezuela. In several additional countries, submissions to regulatory authorities are in preparation or under review. The New Drug Application to the U.S. Food and Drug Administration was submitted in 1988. In collaboration with Family Health International (FHI), Leiras Pharmaceuticals and World Health Organization (WHO), pre-introduction studies of the NORPLANT^R method have been completed or are ongoing in over 44 countries. Council staff and consultants of the Contraceptive Introduction Program currently monitor 12 of these trials directly, providing medical backstopping and technical assistance. In addition, they provide technical assistance to the primary monitors of trials in six other countries.

As NORPLANT^R becomes more widely known, a key activity of the Council's Contraceptive Introduction Program staff, both centrally and regionally, has been the management of negotiations for the commencement of new or expanded in-country pre-introduction trials. Such trials serve to evaluate the effectiveness, safety, and overall acceptability to users and providers of the method in specific country settings; serve to inform governmental authorities about the method; and form a basis for later assessment of user and programmatic management needs in different cultural and socioeconomic situations. Proposals are currently in hand to begin three more projects in 1990.

Monitoring of the clinical data on pre-introduction trial clients by Council staff and consultants in collaboration with FHI continues to be an important function. A unified database of the international clinical experience facilitates the preparation of status reports of significant events (pregnancies, serious and/or unanticipated adverse experiences) that have occurred in these trials, required by the U.S. Food and Drug Administration and regulatory agencies in other countries.

In addition to the monitoring of trials from a clinical perspective, Council staff and consultants conduct research on the determinants of user satisfaction and the evolution of programmatic needs for incorporation of the method in family planning programs.

A draft training curriculum developed in collaboration with PATH, FHI, and the Association for Voluntary Surgical Contraception (AVSC) has been revised. The curriculum has been field tested in Nigeria and will be further tested in two other sites in 1990, in Bangladesh and Kenya.

MORE...

POPULATION COUNCIL IN-HOUSE PROJECT
PRE-INTRODUCTION EVALUATION OF NORPLANT
CONTRACEPTIVE SUBDERMAL IMPLANTS

Following approval of the method in Kenya, the Council assisted in the development of a national introduction strategy. A comprehensive introduction project is being designed to facilitate the organizational upgrading needed to enable program staff to manage this new method. Since it is likely to be the first undertaking of its kind in the region, Kenya's experience is expected to provide a "case study" for other African countries seeking to introduce NORPLANT[®].

Support to Instituto Chileno de Medicina Reproductiva (ICMER) in Chile, and the Corporacion Centro Regional de Poblacion (CCRP) in Colombia terminated during this reporting period. Support to the Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP) in Brazil, Instituto Nacional de la Nutricion Salvador Zubiran (INNSZ) in Mexico, Siriraj Family Planning Research Center in Thailand, Universidad Cayetano Heredia in Peru, and Kenyatta National Hospital in Kenya for continued follow-up of pre-introduction trial clients and data collection for clinical studies is ongoing.

Work continues on the development and introduction of training and informational materials for program managers, clinicians and clients. The Guide to Effective Counselling has been translated into French and Spanish. A Clinician's Manual has been completed, as well as a scientific monograph summarizing all pertinent data on the method. In addition, a management study of NORPLANT[®], and programmatic guidelines have been produced. These materials will be published during the next reporting period.

POPULATION COUNCIL AWARD NO. I89.01A

To: Kenyatta National Hospital
University of Nairobi
Nairobi, Kenya

Period: January 1, 1989 to December 31, 1990

Amount: \$ 53,770

Approved by A.I.D.: March 21, 1989

Status: Current

Purpose: To continue the work on the pre-introduction evaluation of NORPLANT^R contraceptive subdermal implants in Kenya extending the study from a rural to an urban environment based at Kenyatta National Hospital. Previous study was conducted under Population Council Award No. I85.25A funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00.

This project is the second phase of the pre-introductory clinical trial for NORPLANT^R in Kenya. The initial phase involved 250 clients recruited between April and December 1986, and is being undertaken at two study sites, the original study area in the Machakos district, and in Kenyatta National Hospital (KNH).

Activities for the Machakos site includes: 1) follow up of clients recruited in phase 1 of the study, 2) further recruitment of new clients, and 3) training of physicians.

During this reporting period, over 85 new clients have been recruited into the study, for a total of 443 women using the method. There have been a total of 107 removals since the project began in 1986, 50 of which were done within the reporting period.

The new clients and the clients who have recently undergone removals participated in a training session held during this reporting period in which three residents in obstetrics and gynecology were trained.

The study at KNH began in October 1989. The startup of the project was delayed due to administrative changes. Only two residents in the Department of Obstetrics/Gynecology were trained and only 15 insertions were performed during the reporting period. No further delays are anticipated.

At KNH, activities include: 1) Preparation of clinic facilities including purchasing instruments, 2) Training of nurses which included a one-week course on the mechanisms of action, side effects and counseling for clients, and the practical demonstration of insertion and removal. During this reporting period, 12 nurse training sessions were held.

Follow-up of clients recruited at KNH and in Machakos continues with all data included in the world-wide database.

POPULATION COUNCIL AWARD NO. I89.02A

To: Instituto Chileno de Medicina Reproductiva (ICMER)
Santiago, Chile

Period: January 1, 1989 to December 31, 1989

Amount: \$ 10,534

Approved by A.I.D.: January 25, 1989

Status: Terminated

Purpose: To continue the work on pre-introduction evaluation of NORPLANT^R contraceptive subdermal implants in Chile begun under Population Council Award No. I85.20A to the Corporacion Privada Nacional de Desarrollo Social and continued under Population Council Awards No. I86.10A and No. I88.09A to ICMER funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00.

The specific objectives of the project are to: (1) develop an experience base for training medical personnel in insertion and removal procedures and in counseling of acceptors; (2) evaluate acceptability, training and service delivery requirements under local conditions; (3) disseminate information about the method to government officials, clinicians, family planning leaders, and potential users; (4) provide the government with information required to approve NORPLANT^R implants for distribution.

By June 1989, a total of 1,989 clients were using the method and 245 continuing users of NORPLANT^R-2 were being followed up. In the NORPLANT^R group, the continuation rate is 79 percent. Menstrual irregularities account for 28 percent of the removals. Thirty five percent of the women are in the 25-29 age group, 31 percent under 24, 24 percent between 30-34, and 10 percent between 35 and 40. Forty four percent have two children, while 31 percent have three children or more.

Supplementary funds provided in 1989 enabled the six collaborating clinics to continue to provide NORPLANT^R services. Following the method's approval in Chile in 1988, it had been hoped the APROFA, the IPPF affiliate, would be able to participate in the diffusion of the method to public health programs in 1989. APROFA was unable to allocate any of its existing funds for the purchase of NORPLANT^R, however, and could not secure additional funding. The investigators' objective, therefore, of moving this method to a broader institutional level was not possible in the period under review.

POPULATION COUNCIL AWARD NO. I89.08A

To: Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP)
Sao Paulo, Brazil

Period: March 1, 1989 to February 28, 1990

Amount: \$ 9,990

Approved by A.I.D.: March 21, 1989

Status: Terminated

Purpose: To continue coordinating the data collection and monitoring activities of the pre-introduction evaluation of NORPLANT^R contraceptive subdermal implants project in Brazil. Project was supported under Population Council Awards No. I85.02A, No. I86.22A and I87.52A funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00.

This project, originally funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00, was initiated in October 1985 with the objective of contributing to the establishment of a global data base to monitor the world wide experience with NORPLANT^R, and to give assistance to participating clinics in good clinical research practices, data management procedures and analysis and publication of results.

The database was established at CEMICAMP, at the University of Campinas, Brazil, and is fully operational for the LAC region, incorporating data from seven countries Brazil, Chile, Colombia, the Dominican Republic, Ecuador, Mexico and Peru.

CEMICAMP has given assistance to projects in the preparation of reports and papers for publication and several papers have been presented at various conferences, based on analysis of data performed by CEMICAMP. Data from the LAC database is routinely incorporated into the worldwide NORPLANT^R database and was invaluable to the Population Council in preparing the New Drug Application for the U.S. Food and Drug Administration. Several monitoring visits were made to all participating countries to ensure not only the formal correctness of data but also to ensure uniformity and a high quality standard of clinical procedures.

Local investigators will continue to have access to the database at the end of the project. CEMICAMP will also continue to provide technical assistance for further data analysis and publications.

The project has greatly contributed to the NORPLANT^R introduction process by maintaining quality through monitoring, encouraging communication between investigators of different countries, and providing investigators access to the various experiences and studies.

POPULATION COUNCIL AWARD NO. 190.11A

To: Program for Appropriate Technology in Health (PATH)
Seattle, Washington, U.S.A.

Period: January 1, 1990 to December 31, 1990 Amount: \$ 80,000

Approved by A.I.D.: February 16, 1990 Status: Current

Purpose: To continue the project on the appropriateness and effectiveness of the NORPLANT^R training curriculum begun under Population Council Award No. I88.13A funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00.

The goal of this project was to field test the appropriateness and effectiveness of a prototypical NORPLANT^R training curriculum in three sites in the developing world.

The prototype of the NORPLANT^R training curriculum was revised by PATH in 1988. This revision was based on inputs from an interagency working group comprised of staff from the Association for Voluntary Surgical Contraception (AVSC), Family Health International (FHI), and the Population Council.

In 1989 the first field evaluation of the training curriculum was held in Nigeria. This evaluation was conducted by the staff of the University College Hospital of the University of Ibadan. A three-day orientation session conducted by PATH and AVSC was held prior to the five-day training workshop to review the curriculum. Participants at the training workshop included twenty physicians and nurse-counselors from four university teaching hospitals and one Ministry of Health facility.

The training curriculum was well received. By the end of the course, the participants demonstrated a more accurate understanding of the method, even though 14 of 17 of them had said in the pre-test that they already knew about NORPLANT^R. Also, participants were more aware of the importance of counseling and explaining the procedure and side effects to potential clients. Suggestions for further revision of the training curriculum were made and taken into account in preparing for the second and third field tests.

Due to administrative delays beyond the control of the Population Council or PATH, the second and third field tests of the curriculum (Bangladesh and Kenya) had to be rescheduled for February and May 1990, respectively.

POPULATION COUNCIL IN-HOUSE PROJECT

INTRODUCTION OF THE COPPER T380A INTRAUTERINE DEVICE

Period: January 1, 1989 to December 31, 1990

Amount: \$483,358

Approved by A.I.D.: January 24, 1990

Status: Current

Purpose: To continue activities undertaken under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00 to facilitate better utilization of Copper T 380A IUD in family planning programs.

The goals of the Copper T 380A IUD Introduction program are to facilitate the widest possible availability and consistent user satisfaction. This can be accomplished by an improved service delivery system which recognizes that a woman's attitude towards the method is conditioned not only by her experience with the contraceptive itself, but also by the package of service provision, logistics and information related to the method. Council Contraceptive Introduction staff based in New York, Bangkok, Campinas, and Nairobi continued to work on the development of new initiatives and to provide technical assistance to on-going programs toward this end. In addition, Council staff collaborated with other international and local agencies on all aspects of service delivery for the Copper T 380A IUD.

The Council and PATH hosted an inter-agency meeting in September 1989 to explore collaborative activities directed toward better Copper T 380A IUD service delivery, focusing on improving training and expertise at the clinic level. Materials presented during the meeting were a direct result of decisions made at the 1988 inter-agency meeting, including: PATH's new version of the Copper T 380A IUD information package (partly funded by a subaward from the Population Council); a presentation of new packaging to assist in loading the IUD while maintaining aseptic conditions; a video on Copper T 380A IUD insertion training produced by IPPF (available in English, French, and Spanish); and a presentation on prototypical materials adapted for in-country training of clinicians, fieldworkers and potential users in Tunisia. At this meeting, two task forces were formed to consider technical and service delivery issues including training and logistics.

A factsheet entitled, COPPER T Intrauterine Device UPDATE on modes of action was published this year and distributed widely throughout the field. A monograph summarizing clinical and introduction data on the Copper T 380A IUD, has been finalized and will be distributed during the next reporting period.

A continued emphasis was placed on increased training of service providers, including those previously trained in inserting other IUDs such as the Lippes Loop. Client selection was also emphasized. The training of Brazilian physicians, begun in Sao Paulo in 1988, continued with additional funding through the end of 1989. The outcome of these training sessions will result in a final version of the training curriculum and educational materials.

Support to Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP) in Brazil for continuation of the project entitled, "Introduction of the Copper T 380A IUD in the State of Sao Paulo: Implementation of a Training Program and Evaluation of its Performance Compared with that of the Copper T 200B," and support to PATH for "Activities to Enhance the Introduction of the Copper T 380A IUD" is ongoing. In January 1990, the Council provided a subaward to the University of Nairobi to support an "Update Workshop on Intrauterine Devices." The findings will be reported during the next reporting period.

POPULATION COUNCIL AWARD NO. I89.15A

To: Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP)
Sao Paulo, Brazil

Period: October 1, 1989 to December 31, 1989

Amount: \$ 3,000

Approved by A.I.D.: July 19, 1989

Status: Expired

Purpose: To provide additional funds for the project entitled, "Introduction of the T-Cu 380A in the State of Sao Paulo: Implementation of a Training Program and Evaluation of its Performance Compared with that of the T-Cu 200B" being conducted under Population Council Award No. I88.18A funded under Cooperative Agreement No. AID/DPE-3005-A-00-3003-00.

The initiation of the project was delayed, due to administrative problems in obtaining the IUDs. The first activity was the preparation of the training curriculum and instructional materials, with collaboration from PATH.

A pilot training course for physicians and counselors from the region of Campinas was undertaken to test the curriculum and materials.

During the reporting period, over 72 physicians and health workers were trained at clinics in Santo Andre, Ribeirao Preto and Campinas. The Maternidade Vila Nova Cachoeirinha trained more than 60 physicians, counselors and educators.

All the centers continue to include the COPPER T 380A as one of the available methods of choice. Due to the practical training for insertions and the effective counselling, there has been a steady increase in the method's prevalence. To date, more than 700 COPPER T 380A's have been inserted with only 58 requests for removals.

The only significant obstacle to future expansion of the COPPER T 380A in Brazil is that availability will be restricted, despite the increased number of trained health workers, until the method is approved.

Beyond the expiration of the grant, physicians participating in clinical studies will be encouraged to publish their results in Brazilian journals in order to expedite MOH approval.

The clinics will continue offering training beyond the expiration of the grant.

POPULATION COUNCIL AWARD NO. I89.23A

To: Program for Appropriate Technology in Health / Program for the Introduction and Adaptation of Contraceptive Technology (PATH/PIACT)
Seattle, Washington, U.S.A.

Period: May 1, 1989 to December 31, 1989

Amount: \$ 17,740

Approved by A.I.D.: July 19, 1989

Status: Expired

Purpose: To provide additional funds for the project entitled "Activities to Enhance the Introduction of the Copper T 380A IUD" begun under Population Council Award No. I86.36A and continuing under Population Council Award No. I88.20A funded under Cooperative Agreement No. AID/DPE-3005-A-00-3003-00.

This is a supplementary award to Population Council Subaward No. 188.20A, funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00. The specific objective of this award was to provide additional funds for the publication costs of the Copper T 380A IUD Information Packet. The Information Packet includes a wallchart describing the loading and insertion techniques required for the Copper T 380A IUD, various prototypical information materials and guidelines for adapting these materials, a field workers' guide, and a clinician's manual. The Packet has been distributed among the coordinating agencies and has been disseminated widely in the field.

POPULATION COUNCIL AWARD NO. 190.02A

To: University of Nairobi
Nairobi, Kenya

Period: January 1, 1990 to May 31, 1990

Amount: \$ 4,397

Approved by A.I.D.: February 20, 1990

Status: Current

Purpose: To support an update workshop on intrauterine contraceptive devices.

The objective of this award was to improve the acceptance and continuation of use of IUDs among women wishing to practice family planning in Kenya. Specific goals included: 1) updating health providers' knowledge on the current status and appropriate use of IUDs in general with an emphasis on the Copper T 380A; 2) identifying, defining, and discussing problems related to IUDs with an emphasis on the Copper T 380A from the providers' point of view; and 3) improving the providers' attitudes towards IUDs as a means of contraception.

A workshop of 55 participants was held on February 21, 1990 consisting of health providers involved in family planning in the Nairobi area. Participants represented the Ministry of Health, City Commission health services, private sector health services, and other non-governmental organizations.

Final results will be available during the next reporting period.

**3. FAMILY PLANNING PROGRAM RESEARCH,
SUPPORT, AND TECHNICAL ASSISTANCE**

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POPULATION COUNCIL IN-HOUSE PROJECT
COUNCIL-ADMINISTERED COMPONENT OF EXTENSION
PROJECT, ICDDR, BANGLADESH

Period: January 1, 1989 to September 30, 1989
Extended to June 30, 1990^a

Amount: \$ 227,188
336,415^a

Approved by A.I.D.: April 9, 1989
^aOctober 24, 1989

Status: Current

Purpose: To continue the work begun under Cooperative Agreement No. DPE-3005-A-00-3003-00 in improving the efficiency and acceptability of family planning programs in Bangladesh through research aimed at fostering utilization of Matlab research findings in the national program.

During this period, technical support was provided by the Population Council to the MCH-FP Extension Project at ICDDR,B to assist the Government of Bangladesh to improve the health and family service delivery system. This support consisted of Dr. Michael Koenig, a Council Associate, partial support for Dr. James Phillips of the Council New York office; and for technical support through Council consultants with expertise in the areas of computer programming and operations research. Technical support to the Extension Project during this period included the following activities.

1) Operations Research and Field Testing of Interventions

Technical support was provided to the Extension Project to continue to field test and evaluate interventions within the Government Program in Project field sites. These included interventions to improve outreach coverage by female fieldworkers, decentralize paramedical care for MCH and clinical contraceptive services, broaden the range of contraceptives offered, improve the quality of family planning service delivery, and strengthen field management of the program. Efforts during the year focused upon the consolidation of existing interventions, with priority given to incorporating promising research findings into national policy.

2) Research on the Matlab Program

Efforts continued during this period in evaluating the demographic impact of maternal and child health/family planning interventions in Matlab. Research examined trends in contraceptive use effectiveness in Matlab, and found that while contraceptive prevalence has continued to increase over time, contraceptive failure rates have also tended to increase, suggesting the need to reconsider contraceptive prevalence-fertility projections for the national program. Current work is focusing on the health benefits to both mothers and children resulting from family planning programs.

A particular area of emphasis directed by Dr. Koenig during the last year has been the development of a microcomputer-based health and family planning management information system

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POPULATION COUNCIL IN-HOUSE PROJECT
COUNCIL-ADMINISTERED COMPONENT OF EXTENSION
PROJECT, ICDDR, BANGLADESH

based in Matlab. This innovative system provides routine service data on a monthly basis for over 15,000 reproductive aged women and 18,000 under five children, and is used for both service as well as evaluative research. It is anticipated that this system, when finalized as a complete package, will have wide applicability for service delivery projects in other developing settings.

3) Technical Assistance to the MOHFP

Efforts continued during the past year in assisting the Government of Bangladesh to translate key Project recommendations into broader national policy. This included the provision of continued technical assistance to the government planning, implementation, and evaluation to the recruitment of the 10,000 additional female fieldworkers. To date, almost 8,000 new workers have been recruited, with recruitment scheduled for completion by the end of 1990. Pilot testing of this initiative in Extension Project field sites indicates that these new staffing ratios are likely to lead to significant improvements in the quality and accessibility of family planning services. The Project has also provided technical assistance to the Government in the development of a national fieldworker recordkeeping system, based upon the prototype developed in the Extension areas. Current assistance includes evaluation of the impact of the introduction of this recordkeeping system upon service delivery in four pilot upazilas, and technical assistance in the planning, training, and implementation of this system nationally.

4) Dissemination Activities

During the past year, efforts to disseminate key Extension Project findings were intensified under the direction of Dr. Koenig. This included the continued production of summaries of major research findings in the form of focused briefing papers to a mailing list of over 1200 researchers and policy makers both within Bangladesh and internationally. A second area of dissemination was the organization of in-country workshops on specific operational issues; during the year, the Project successfully organized a national workshop on the issue of delivery of injectable contraception. The meeting led to plans for phased expansion of domiciliary of injectables nationally. Finally, the Project has worked closely with the Government and key donors -- through briefings, field trips, and the preparation of position papers -- to incorporate specific Project recommendations into the Fourth Population and Health Plan, in such areas as further improving coverage by female fieldworkers, improving the accessibility and quality of family planning services, and further strengthening field supervision and management.

POPULATION COUNCIL AWARD NO. I89.07A

To: University of Michigan
Ann Arbor, Michigan, U.S.A.

Period. January 1, 1989 to September 30, 1989
Extended to June 30, 1990^a

Amount: \$ 93,645
81,355^a

Approved by A.I.D.: April 2, 1989
^aDecember 26, 1989

Status: Current

Purpose: To support the assignment of Professor Rushikesh Maru as the operations research scientist to the International Center for Diarrhoeal Disease Research, Bangladesh (ICDDR/B) under the MCH-FP Extension Project, and of his relocation from the University of Michigan to Dhaka.

This report briefly reviews Rushikesh Maru's contributions to the Extension Project. He did not arrive in Dhaka until September 11, 1989 due to unavoidable delay in processing visa application by the Government of Bangladesh.

I. Activities undertaken during the reporting period:

1. Completed field investigation on the impact of method-specific targets on worker motivation and quality of care.
2. Initiated an action research project to strengthen performance planning and monitoring processes at the upazila and district level in project areas. Initial data collection for diagnosis of barriers to performance improvement has been completed. The next phase is to train supervisors and managers in micro planning problem-solving methodologies.
3. Supervised and guided the process of technical assistance to the MOH-FP for recruitment of field workers.
4. Developed a proposal for national implementation of MIS for the Directorate of Population Control. Currently guiding the ICDDR,B staff involved in designing training for MIS implementation.
5. Supervision and administration of staff involved in qualitative operations research, management interventions, and FWA Recruitment Unit.
6. Participated in the MOH-FP Committee to Draft National Health and Population Policy in October through December 1989. Also, provided assistance to the MOH-FP Fourth Plan Task Force on Organization, Management, and Supervision.

MORE...

POPULATION COUNCIL AWARD NO. I89.07A

To: University of Michigan
Ann Arbor, Michigan, U.S.A.

II. Plans for the next 12 months

- * Briefing paper on implications of targets.
- * Implement performance planning and monitoring process in one project Upazila and one non-project Upazila.
- * A study of the decentralization to the Upazila Parishad.
- * Research report on FWA recruitment process.
- * Technical assistance to the MOH-FP for national implementation of the MIS.

POPULATION COUNCIL IN-HOUSE PROJECT
THE KANANGA RESEARCH PROJECT, ZAIRE

Period: March 1, 1989 to February 28, 1990
Extended to December 31, 1990^a

Amount: \$ 27,885
30,692^a

Approved by A.I.D.: June 23, 1989
^aMarch 16, 1990

Status: Current

Purpose: To cover in-house costs in connection with Population Council Supplementary Award No. 189.10A and Population Council Award No. 190.19A to the Institut Medical Chretien du Kasai (IMCK), Kananga, Zaire, for Year 3 of the Kananga Research Project.

This report summarizes the activities carried out between 1 March 1989 and 28 February 1990 for the project entitled, "The Kananga Research Project, Zaire." The purpose of the project is to measure how much the demand for contraception in the Kasai region of Zaire can increase under optimal supply conditions. Two additional studies were also conducted: one to incorporate AIDS information into family planning information, communication, and education; and another to test the possibility of using the weight of the last born child as an indication for spacing births. The work has been carried out by the Population Council and the Institut Medical Chretien du Kasai (IMCK).

Years 1 and 2 were supported under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00. During the reporting period, the Population Council was able to support the costs of a consultant, Dr. Judith Brown, to the Kananga Research Project and the costs of providing technical assistance to research activities and project design by Council staff based in New York. Funding has also covered the costs of communication between the Council and the Institut Medical Chretien du Kasai.

The consultant visited the Council's New York office once during the year to give a seminar on the Kananga Project and discuss issues of quality of care and contraceptive accessibility as well as program efforts in AIDS prevention information, education, and communication. This seminar came at a time when Council staff were beginning discussions on how to operationalize quality of care. The Kananga project exemplified how to increase access to family planning methods by making contraceptives available through a social marketing program and enabling a wide variety of sources to distribute contraceptives.

During 1990, the consultant and New York based staff will continue to provide technical assistance to project activities and see that the data analysis and proposed contraceptive prevalence survey are carried out. The consultant will devote two days per month to the project.

POPULATION COUNCIL AWARD NO. I90.19A

To: Institut Medical Chretien du Kasai
Kinshasa, Zaire

Period: March 1, 1989 to February 28, 1990
Extended to December 31, 1990^a

Amount: \$ 46,625
47,775^a

Approved by A.I.D.: June 23, 1989
^aMarch 16, 1990

Status: Current

Purpose: To support Year 3 of the Kananga Project for an expanded family planning program begun under Population Council Award No. I87.82A funded under Cooperative Agreement No. A.I.D./DPE-3005-A-00-3003-00 and Population Council Supplementary Award No. I89.10A funded under Cooperative Agreement No. A.I.D./DPE-3050-A-00-8059-00.

This report summarizes the activities carried out between 1 March 1989 and 28 February 1990 for the project entitled, "The Kananga Research Project, Zaire." The purpose of the project is to measure how much the demand for contraception in the Kasai region of Zaire can increase under optimal supply conditions. Two additional studies were also conducted: one to incorporate AIDS information into family planning information, communication, and education; and another to test the possibility of using the weight of the last born child as an indication for spacing births. The work has been carried out by the Population Council and the Institut Medical Chretien du Kasai (IMCK).

CONTRACEPTIVE ACCESSIBILITY

In November 1987, before the project began, 4.2% of Kananga women used modern methods of contraception, and with the inception of the project, the contraceptive prevalence rate reached 8.2% by May 1988. To achieve a rate of 15% by the end of 1990 project staff work with urban and rural health centers to provide contraceptive services. Between March and December the number of clinics offering these services increased from 13 to 16. The social marketing program also increased contraceptive accessibility. Supplies are available from 36 drugstores, four medical centers, and three retailers. Several project team members acted as retailers in their neighborhoods and a part-time salesman has been hired to facilitate the marketing.

The project team conducted focus group studies on the acceptability of contraceptives, especially Depo-Provera to compare it with NORPLANT^R. Early findings suggest that monthly menstrual periods are very important to Kananga women and they are reluctant to use contraceptive methods that may cause amenorrhea. Results from these studies will be used to modify the existing program in an effort to provide the most appropriate and desirable methods.

AIDS INFORMATION DISSEMINATION

Project staff used a variety of methods to provide information on AIDS prevention and family planning. One was to give each month of the year different themes. The themes for March were NORPLANT^R, methods of AIDS transmission, and female anatomy; April was the month for tubal

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POPULATION COUNCIL AWARD NO. 190.19A

To: Institut Medical Chretien du Kasai
Kinshasa, Zaire

ligation and methods of AIDS prevention; May was devoted to spermicides, marital faithfulness, and counselling for AIDS patients. This was done to avoid monotony and maintain clients' interest in the information and activities.

The radio programs on family planning and AIDS prevention continued on a regular basis. The weekly radio program, "Baledi Dimudayi," ("Attention Parents") was broadcasted 18 times during this period. The number of clients interested in AIDS prevention and family planning coming to the health centers has increased as a result of these programs.

Project team members participated in the city fair to distribute information and sell books, brochures, condoms, and contraceptive foam. The team attracted clients through the use of advertising items (visors and plastic bags) supplied by the national social marketing program, a nightly lottery, and videos and films on family planning.

The project staff conducted focus groups with women with multiple partners to see if they recognized that they belonged to a high risk group and if this has caused them to change their behavior. Sessions revealed that women understood their situation but cannot readily change their behavior because their partners did not understand their fears of HIV transmission.

STUDY OF BIRTH SPACING

The study is now entering the critical period when children are approaching the weight, height, or age criterion of their group. The message about weight had the most impact, followed by the message about age. Motivators continue to give messages in Under Fives clinics and to make home visits.

The project team is well known throughout the city for information on AIDS prevention and family planning. Team members have modified the existing program with information study results to identify target groups, emphasize certain messages, and improve clinic services. Contraceptive prevalence has increased, but efforts must be strengthened if the project team is to reach its goal of 15% prevalence rate by the end of 1990. A strategy to achieve this is planned in the activities for 1990.

In the final year of the project, there will be one additional nurse to help with supervision and training to strengthen clinic services. New AIDS prevention media activities include production of videos, films, and written materials in Tshiluba, the regional language. Staff will participate in conferences and training sessions and attend an international meeting on AIDS prevention in Africa. Data analyses of small qualitative studies on contraceptive acceptability and larger quantitative studies (statistical evaluations of project activities by couple months of protection, a contraceptive prevalence survey and some cost analyses will be conducted.

POPULATION COUNCIL IN-HOUSE PROJECT
FURTHER STRENGTHENING OF THE POPULATION STUDIES AND RESEARCH
INSTITUTE, THE UNIVERSITY OF NAIROBI

At PSRI, Dr. Robinson is heavily involved with teaching and advising students and working with faculty to develop curriculum. He has also served on masters degree committees and supervised graduate papers. Additionally, he has developed a research implementation plan for PSRI to use the many research grants available to it from various donors.

Dr. Robinson has taken the leading role in developing and implementing a study on contraceptive prevalence differentials in six Kenyan districts, a two year project conducted with a research grant from the Danish International Development Agency. The purpose of the study is to enable Kenyan family planning program officials to better understand the role of "supply" factors such as quality and accessibility of family planning services in giving rise to observed contraceptive prevalence differentials among districts of Kenya. The study has three phases: (I) project development, secondary data analysis on socio-economic factors and population policy initiatives, and selection of districts; (II) in-depth study of selected districts, data analysis, and interpretation; and (III) dissemination of results and policy review.

The research is a collaborative effort between the Population Studies and Research Institute (PSRI) at the University of Nairobi, and the Population Council.

This study is designed to collect more data about the factors affecting contraceptive use and to examine the underlying causes of the contraceptive prevalence and fertility differentials. Information from this study will help identify why the national family planning program has been more successful in some areas compared to others, and will enable family planning researchers, managers, and policy makers to develop programs appropriate to specific population groups or districts.

The teaching and research activities are underway to allow Dr. Robinson more time for policy advising and networking among population institutions in the region. He has already made contacts with institutions in Botswana, Tanzania, and Zimbabwe. These tasks will take on a more important role as the population work at PSRI matures and can become incorporated into regional policy making activities.

POPULATION COUNCIL IN-HOUSE PROJECT
A SYSTEMS DEVELOPMENT PROGRAM FOR THE INSTITUTIONALIZATION
OF FAMILY PLANNING PROGRAM SERVICES IN NEPAL
and POPULATION COUNCIL SUBCONTRACT NO. CI90.06A
with NEW ERA, KATHMANDU, NEPAL

Period: January 1, 1990 to June 30, 1990

Amount: \$ 175,619

Approved by A.I.D.: February 20, 1990

Status: Current

Purpose: To develop selected modification of service delivery strategies in sample experimental districts in order to evaluate efforts to extend delivery systems for family planning program services in Nepal.

The Coordination Committee responsible for maintaining local commitment support, coordination, and cooperation among organizations and individuals engaged in family planning activities in the institutionalizing districts was established. The first meeting of the committee was held on February 6-7, 1990. The objective of the meeting was to introduce the implementation plan for the systems development program in the districts, and to solicit inputs on this plan from committee members. By all accounts, the meeting was a success with constructive suggestions made regarding training and counseling, quality assurance systems, logistics systems, competitive reward systems, management information systems, and IEC approaches.

A baseline survey was initiated in four districts to obtain estimates of contraceptive prevalence prior to selected systems interventions. The survey is expected to be completed in May 1990.

Monthly reporting forms to be used by Village Health Workers (VHWs), Health Post Workers (HPWs), and District Public Health Officers (DPHOs) for the modified management information system were prepared. Guidelines for the preparation of the forms were finalized.

Monthly reporting forms for the modified logistics system were prepared, and guidelines for their use by HPWs, DPHOs, and staff at regional warehouses were finalized.

Information on new FP acceptors recruited during the fiscal year 1989-90 in all 75 districts are being entered into microcomputers at the New Era office. Data on acceptors received from about 1,600 FP service outlets are also being entered on a regular basis. New Era will design, produce, and distribute acceptor status reports based on this information for districts and development regions.

Over the next four months, the activities stated in the project's scope of work will be completed, and additional documentation prepared for the projects extension.

POPULATION COUNCIL IN-HOUSE PROJECT

ALGERIAN DELEGATION

Period: March 25, 1989 to June 30, 1989

Amount: \$ 6,400

Approved by A.I.D.: March 21, 1989

Status: Terminated

Purpose: To support a study mission to the United States of a delegation of Algerian population officials to orient them to the activities of A.I.D. ST/POP, and to meet with other cooperating agencies and international donors.

At the request of A.I.D., the Population Council was asked to sponsor a trip for a delegation of three high level Algerian officials from March 26 to April 7, 1989. The fact-finding mission paid on-site visits to A.I.D., the cooperating agencies, and international donors. The purpose of the trip was to introduce the Algerian officials to a variety of innovative population and family planning activities being carried out by A.I.D. S&T/POP cooperating agencies and international donors. The mission was composed of the following officials:

- (1) Professor Belgacem Ait-Ouyahia, Director General of the National Institute of Public Health and Head of the Ob/Gyn Department of Mustafa Pasha University Hospital.
- (2) Dr. Al Abdel Medjid Barkat, Head of the Ob/Gyn Department of the University Hospital in Constantine.
- (3) Mme. Tamani Safir, of the Ministry of Social Affairs and Labor.

It was envisioned that the delegation's observational travel to the U.S. would open new dialogue between U.S. and Algerian institutions involved in population and family planning while providing an opportunity to discuss possibilities for expanded information exchange, technical assistance, and collaboration.

During the two week visit, the Council arranged meetings for the Algerian delegation with representatives of A.I.D., the State Department, and various S&T/POP cooperating agencies. These agencies included SOMARC/The Futures Group, JSI, JHPIEGO, PRB, AVSC, FHI, Columbia University, RONCO, and Pathfinder. The international donors visited were the World Bank and UNFPA.

Follow-up with the Algerian government was anticipated, however there was a change of personnel in the ministries and the delegates who participated in the mission are no longer in power. By the end of 1989 there was no further follow-up activities under the cooperative agreement.

POPULATION COUNCIL IN-HOUSE PROJECT
A CONTROLLED TRIAL TO EXTEND THE DURATION OF EXCLUSIVE
BREASTFEEDING IN LOW-INCOME MOTHERS IN LIMA, PERU

- * Conduct of a seminar on Human Lactation for OB/GYN residents at Cayetano Heredia Hospital (during three consecutive noon-hour seminars).
- * Conduct of four two-day courses on Exclusive Breastfeeding for non-medical personnel (nurses, midwives and auxiliaries) at both Dos de Mayo and Cayetano Heredia Hospitals.
- * Conduct of six one day sessions of a Practical Course in Exclusive Breastfeeding for auxiliary personnel at both Dos de Mayo and Cayetano Heredia Hospitals.
- * Conduct of an 8-hour lecture series for twenty pediatric residents.

EDUCATIONAL MATERIALS DEVELOPMENT

- * Completion of final editing and printing of 3000 copies of guide for health personnel on clinical management of lactation: Lactancia Materna. Guia Para Personal de Salud (translated and adapted from the Population Council's produce pamphlet Breastfeeding: A Nurse's Guide).
- * Completion of final artwork on 10 drawings for teaching cards for mothers, working with AED - contracted artist from Peru-Mujer.
- * Contract for, supervision, and completion of color silk screening of 30 sets of teaching cards for mothers and the printing of 7,500 copies of a take-home educational poster/calendar for postpartum mothers (companion to the teaching cards).
- * Distribution of poster/calendars to two intervention hospitals for distribution to each mother delivering in those hospitals during six to seven month study period.
- * Contract for, supervision, and completion of flipcharts of 30 sets of 10 teaching cards for mothers.
- * Distribution of guides for health personnel and plasticized flipcharts to the neonatology, pediatric and obstetric services of the two intervention hospitals.

PHASE III ACTIVITIES COMPLETED DURING THIS PERIOD:

Prospective Study:

- * Modification of questionnaire from baseline study for interview of mothers on postpartum wards.
- * Design and development of
 - 1) Selection methodology format
 - 2) Consent form
 - 3) Home Visit Questionnaire I
 - 4) Home Visit Questionnaire II
 - 5) 24-hour dietary recall
 - 6) Daily diary for baby
 - 7) System for scheduling and tracking home visits

MORE...

POPULATION COUNCIL IN-HOUSE PROJECT
A CONTROLLED TRIAL TO EXTEND THE DURATION OF EXCLUSIVE
BREASTFEEDING IN LOW-INCOME MOTHERS IN LIMA, PERU

- * Completion of pretesting and modification of research instruments
- * Hiring and training of six full-time field interviewers and three part-time supervisors. Training included theory, field practice, using research instruments with hospital and home visits, and practice with weighing and measuring infants. Twenty-one days of training were given in total.
- * Field work began on September 18, 1989. Home visits began on October 2, 1989. Completions dates for home visits are:

Cayetano Heredia Hospital	March 21, 1990
Arzobispo Loayza Hospital	April 19, 1990
Dos de Mayo Hospital	April 20, 1990
- * Completion of post-intervention KAP surveys of hospital personnel in Cayetano Heredia Hospital and Arzobispo Loayza Hospital
- * Coding of questionnaires and data collection formats was started.

Several problems were encountered in the execution of certain aspects of Phase II.

- * Delays in publication of the educational materials.
- * A physician strike and strike of administrative and technical personnel (i.e. auxiliary nurses) altered training schedules and normal hospital routines.

WORK TO BE COMPLETED AFTER REPORTING PERIOD

- * Post-intervention KAP survey of personnel at Dos de Mayo Hospital (scheduled for the last week in April, 1990)
- * Conduct one or two additional practical course(s) in Exclusive Breastfeeding for Auxiliary Personnel at Cayetano Heredia Hospital (scheduled for April 28, 1990)
- * Complete remaining home visits
- * Complete coding of all questionnaires and data collection formats.
- * Complete data entry and cleaning
- * Complete data analysis

POPULATION COUNCIL SUPPLEMENTARY AWARD NO. I89.13A

To: La Liga de la Leche de Mexico
Mexico City, Mexico

Period: March 1, 1989 to December 31, 1989

Amount: \$ 10,000

Approved by A.I.D.: June 21, 1989

Status: Terminated

Purpose: To provide additional funds for the project on the evaluation of professional training in lactation management and its effect on hospital practices and breastfeeding in Mexico City being conducted under Population Council Award No. I88.48A funded under Cooperative Agreement No. AID/DPE-3005-A-00-3003-00.

The objectives of the project were:

1. Design and carry out a lactation management program with three components:
 - a) Lactation management training for hospital personnel
 - b) Changes in hospital practices
 - c) Educational program for women who seek obstetric care in Mexico City General Hospital.
2. Evaluate the effect of these program activities on hospital practice in the infant feeding behavior of the obstetric population.

This project has been implemented largely by La Liga de La Leche de Mexico in collaboration with physicians and nurses from Mexico City General Hospital. The Population Council provided technical assistance through Dr. Beverly Winikoff and Dr. Maria de Carmen Elu de Lenero.

The Project consisted of five phases:

- 1) Selection and training of multi-disciplinary team from Mexico City General Hospital at Wellstart/San Diego Lactation Program.
- 2) Baseline data collection.
- 3) Development and implementation of educational programs for physicians and nurses to promote changes in existing hospital procedure. Implementation of recommended changes in hospital routines.
- 4) Development of educational programs on breastfeeding management for women who seek obstetric care at Mexico City General Hospital.
- 5) Evaluation management education.

MORE...

POPULATION COUNCIL SUPPLEMENTARY AWARD NO. I89.13A

To: La Liga de la Leche de Mexico
Mexico City, Mexico

Phase I was completed during the last reporting period. A total of five health professionals (nurses, pediatricians and obstetricians) from the General Hospital of Mexico City participated in Wellstart Lactation Management Education Course from August 29 through September 2, 1988.

PHASE II

Baseline Data Collection

The baseline data collection phase of the study is finished. Postpartum survey of the intervention group was carried out from April 26 to June 15, 1989 (180 mothers included).

PHASE III

Staff Education and Changes in Hospital Practices

During this reporting period, the following activities took place:

- * Pediatric residents and social workers participated in a twelve hour lactation management course in June and July 1989.
- * New hospital perinatal procedures were initiated in late April 1989 and carried out throughout the study period.

PHASE IV

Educational Program for Mothers

A prenatal breastfeeding orientation session was conducted for intervention group Primiparas. A postpartum final session on breastfeeding techniques was held with mothers prior to leaving the hospital with the newborns. Documentation about educational sessions was carried out.

PHASE V

Evaluation Activities

- * Follow-up studies of infant feeding behaviors in the control groups for months postpartum were completed. First month follow-up of primipara intervention group was begun on June 1, 1989. Fourth month follow-up on this group was postponed for September and October 1989.
- * Evaluation of new hospital procedures, prenatal and postnatal education sessions were carried out in August 1989.
- * Post intervention evaluation of professional lactation management courses was carried out at the end of July 1989 when residents and social worker courses ended.
- * Observations on post intervention procedures in the rooming-in area were carried out from June 2 - July 15, 1989 (18 observation hours included).

POPULATION COUNCIL IN-HOUSE PROJECT
TRANSLATION AND ADAPTATION OF MATERIALS ON CONTRACEPTION
DURING BREASTFEEDING FOR CLINICIANS

Period: November 1, 1989 to October 31, 1992

Amount: \$ 41,457

Approved by A.I.D.: March 23, 1990

Status: Current

Purpose: To produce a French and Arabic translation and adaptation of the publication Contraception During Breastfeeding: A Clinician's Sourcebook.

The objective of this project is to adapt and translate the publication Contraception During Breastfeeding: A Clinicians Sourcebook into French and Arabic.

This report covers activities from November 1, 1989 to April 30, 1990. From November - December 1989, the countries which would be participating in the project were identified. The French translation will be undertaken in Senegal and the Arabic translation in Egypt.

During January and February 1990, initial contact was made with Program for Appropriate Technology in Health (PATH). The Population Council will work in collaboration with PATH. PATH will undertake selected responsibilities depending upon the available resources of cooperating institutions. A preliminary budget has been submitted by PATH and is being reviewed by both Population Council and PATH offices.

From March - April 1990, local institutions and researchers were identified to handle the project in each country. A site visit was made in Senegal in March by Dr. Winikoff, Project Director. Discussions were begun with Mamadou Seck in Senegal, who will be supervising the project there. A local translator was identified.

Plans for the immediate future include:

1. Discussions to be held in early May with Population Council staff associate who will be managing the project in Egypt.
2. Development of subcontract with PATH.
3. Preparation of budgets for Senegal and Egypt.
4. Further identification of on-site personnel, as needed.

POPULATION COUNCIL IN-HOUSE PROJECT
INVESTIGATORS NETWORK FOR REVISION
OF POSTPARTUM CARE

Period: November 1, 1989 to June 30, 1990

Amount: \$ 97,495

Approved by A.I.D.: Pending

Status: Current

Purpose: To provide technical assistance to collaborating institutions and colleagues in developing proposals to study new models of postpartum service delivery; to plan and execute international meetings; and to develop projects which could be implemented through the operations research program.

This project, to form a network of collaborating scientists, service delivery institutions, and women's health advocates, is an effort to reformulate many of the traditional postpartum family planning programs which have often failed to adequately address women's needs. This network will reexamine contraceptive needs in the postpartum period and assess the effectiveness of new models of postpartum care, specifically with regard to including breastfeeding as a method of birth spacing.

A seminar on lactational infertility was a first step in developing this network; another international meeting is tentatively scheduled for later in 1990 and will be co-sponsored by the World Health Organization. This first seminar, "The Mechanisms of Lactational Infertility," was held in January 1990, co-sponsored by the Council's International Committee for Contraception Research (ICCR). Approximately 25 specialists from all regions attended. The seminar was designed to launch a series of activities whose end result could include better contraceptive advice to breastfeeding women and the development of contraceptives which reinforce lactational infertility without negative effects on the mother of breastfed child.

As a second component of this project a Council consultant was sent on a technical assistance visit to West Africa. The purpose of this initial visit was to assess the feasibility of a postpartum project site in Cameroon to test the inclusion of breastfeeding as an option for birth spacing postpartum. Currently another colleague is visiting two potential study sites in northeast Brazil. In addition, we have been pursuing collaboration on the establishment of a lactation training center at the Faculty of Medicine at Siriraj Hospital at Mahidol University in Bangkok.

**III. INFORMATION ON EXPIRED AWARDS
AND SUBCONTRACTS**

EXPIRED AWARDS AND SUBCONTRACTS

Award/ Subcontract No.	Administering Institution/ Subcontractor	Date of Progress Report Containing Final Substantive Report	Up-Dated Information
CB88.20A/ICCR	Professional Staff Association of the IAC/USC Medical Center	June 1989	Audit to be assigned.
CB88.21A/ICCR	Professional Staff Association of the IAC/USC Medical Center	June 1989	Audit to be assigned.

IV. FINANCIAL INFORMATION:

SUMMARY STATEMENTS OF EXPENDITURES

- * January 1, 1989 - March 31, 1989
- * April 1, 1989 - June 30, 1989
- * July 1, 1989 - September 30, 1989
- * October 1, 1989 - December 31, 1989
to be sent as soon as available
- * January 1, 1990 - March 31, 1990
to be sent as soon as available

The Population Council Fiscal Report
 Cooperative Agreement No. AID/ DPE-3050-A-00-8059-00 #2
 All Project Summary
 Statement of Expenditures
 For the Period January 1, 1989 through March 31, 1989
 Statement of Expenditures

	6/28/90	Cummulative	Current Period
Center for Biomedical Resea	\$1,924,635.81	\$1,281,830.47	\$298,530.06
International Programs	61,578.37	38,448.34	18,624.34
Total All Divisions	\$1,986,214.18	\$1,320,278.81	\$317,154.40

The Population Council
Cooperative Agreement No. AID/DPE-3050-A-00-8059-0
All Project Summary

Fiscal Report
3

Statement of Expenditures
For the Period April 1, 1989 through June 30, 1989

	Budget	Cummulative	Current Period
<i>Center For Biomed. Rsch</i>	\$4,880,017.87	\$1,612,064.37	\$330,233.91
<i>International Programs</i>	559,741.37	85,086.14	46,637.79
Total All Divisions	<u>\$5,439,759.24</u>	<u>\$1,697,150.51</u>	<u>\$376,871.70</u>

The Population Council Fiscal Report
 Cooperative Agreement No. AID/DPE-3050-A-00-8059-0 #4
 All Project Summary

Statement of Expenditures
 For the Period July 1, 1989 through September 30, 1989

	Budget	Cumulative	Current Period
<i>Center For Biomed. Rsch</i>	\$5,154,029.52	\$2,845,950.14	\$1,233,885.77
<i>International Programs</i>	1,374,596.67	361,703.62	276,617.48
Total All Divisions	\$6,528,626.19	\$3,207,653.76	\$1,510,503.25