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PROJECT AWARD NO. 188.20A, AMENDMENT NO. 1
ACTIVITIES TO ENHANCE THE INTRODUCTION OF THE COPPER T 380A IUD
SUBSTANTIVE REPORT NO. 2

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I. GOALS AND OBJECTIVES

The overall goal of this project, "Activities to Enhance the Introduction of the Copper T 380A IUD," is to make possible the smooth introduction and transition to widespread use of the Copper T 380A intrauterine device (IUD) in public- and private-sector family planning (FP) service delivery programs in various developing countries.

In order to accomplish this goal, the Program for Appropriate Technology in Health (PATH, formerly PIACT) has formulated the following objectives:

- A. To share information between and among other cooperating agencies (CAs) and organizations involved in introducing the Copper T 380A IUD in FP programs.
- B. To provide decision makers and program managers in developing countries with updated information to assist them in making policy and program decisions.
- C. To adapt for use in country-specific situations a variety of Copper T 380A materials prepared previously in cooperation with the Population Council.
- D. To focus increased attention on the informational and counseling needs of Copper T 380A acceptors and potential acceptors.
- E. To develop materials that can contribute to improved, more effective training for the various levels of service providers, each of which has specific informational requirements, depending upon job responsibilities.

II. GLOBAL ACTIVITIES

A. Information Sharing with the United States Agency For International Development (USAID), USAID Missions, USAID CAs, and other Organizations Involved in Copper T 380A IUD Activities

During the past six months, PATH has continued its work to improve coordination between the institutions involved in Copper T 380A IUD introduction by responding to requests for information from the Missions and other CAs. In addition, PATH takes a pro-active role in informing other organizations about the importance of providing standardized information concerning Copper T 380A IUD loading and insertion instructions. As more and more agencies are revising their education and training materials, PATH staff is working to ensure that the information provided is consistent with the new instructions developed and agreed upon by representatives from the Population Council, PATH, USAID, and Finishing Enterprises Inc. (FEI). For example, The Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO) is currently in the process of preparing an English text to accompany an IUD training film developed by their affiliate in Thailand. JHPIEGO staff is altering the film and the text to make it conform to the language used in the new PATH/Population Council prototype manual for clinicians.

1. PATH representatives participated in a second meeting with field staff of John Snow, Inc.'s (JSI) Family Planning Logistics Management project (FPLM) and USAID staff. The purpose of the meeting was to finalize the messages and language FPLM will use on a new one-page flyer comparing the Copper T 380A and the Copper T 200B. FPLM staff plans to distribute this flyer worldwide, along with supplies of Copper T 380A IUDs.

2. Responses to the global cable USAID sent to the Missions in late 1988 (see previous substantive report for details) continued to arrive. Three of these cables (from Egypt, Jamaica, and Peru) requested PATH

technical assistance (TA) in addition to copies of prototype materials. PATH was able to assist Egypt, as costs could be absorbed under the buy-in to another CA (Johns Hopkins University/Population Communication Services [JHU/PCS]) with whom PATH collaborates. However, there are not sufficient funds in project award No. 188.20A to begin a sustained program of TA to help Jamaica and Peru to introduce the Copper T 380A IUD properly. PATH asked the Population Council for additional money, but 1989/1990 funds for introductory activities have been severely reduced. PATH then wrote to the Population Officers at both the Missions and suggested that, if they have any local monies for TA, they discuss with the Population Council the possibility of providing a buy-in to the Population Council's centrally-funded project.

PATH also contacted other CAs who have worked in Jamaica and Peru, (such as JHPIEGO), to find out more about the IUD insertion and follow-up capabilities of these countries' clinicians so as to have a more accurate idea as to their training needs.

3. PATH staff has also tried to pursue alternative funding sources in order to meet these additional requests for assistance. Since the "rumor" that whole cadres of clinicians are inserting the Copper T 380A by the push-in rather than the "withdrawal" technique is now being substantiated during site visits in many countries, PATH believes the need for improved training and accurate information is vital if the Copper T 380A is to remain an acceptable contraceptive choice for Third World women. PATH prepared a letter proposal to the Population Crisis Committee (PCC) requesting that they consider programming some of their Special Projects funds to enable PATH to carry out important training activities in Peru. While they were sympathetic to our need, Peru is not one of PCC's priority countries, even though the unmet demand for contraceptives in Peru is among the highest in the world.

PATH has also met with, and collaborated with, staff of the Population Council to prepare a Copper T 380A concept paper that can be used to seek funds from other donors.

4. Although the prototype packet of materials on the Copper T 380A has not yet been printed, PATH continues to receive interim requests for copies of the photocopied version of the *Manual for Clinicians*. This is because CAs are reporting medical problems and feel the need for some good instructional material. These photocopied materials are currently being used as a stop-gap measure in Kenya and Nepal.

5. PATH continues to receive requests for a Spanish version of the *Copper T 380A: Guidelines for Informed Use* brochure. While PATH does not have the resources to prepare and print these guidelines in other languages, we can and do refer interested CAs, such as Management Sciences for Health (MSH) and Development Associates, to Asociación Sociedad Médico Farmacéutica (SOMEFA), a Colombian organization which prepared a brochure for physicians based on the Centers for Disease Control (CDC) guidelines. Similarly, for those CAs that can use a Portuguese version of the Guidelines, PATH staff refers them to the Center for Research and Control of Maternal and Child Diseases of Campinas (CEMICAMP), another organization with which PATH worked under this Population Council grant. CEMICAMP has printed a Portuguese version of the Guidelines.

6. When PATH staff hears about private- or public-sector institutions interested in introducing the Copper T 380A but that have no suppliers, such as ATBEF (the local International Planned Parenthood Federation [IPPF] affiliate in Togo), PATH passes this information along to FPLM so that they can follow up.

7. PATH has begun planning for the two-day Interagency Meeting on new contraceptive technologies (NORPLANT^R and the Copper T 380A), similar to the one held at the Population Council in March 1988. The agreed-upon dates for this meeting are September 14-15, 1989. Because of the recent staff changes at the Population Council, PATH was asked to host this year's meeting on behalf of the Population Council. Arrangements have been made to hold the meeting at a hotel convenient to the PATH office and a favorable rate was negotiated for people requiring hotel

accommodations. A letter of invitation was mailed in May to representatives from 30 organizations.

PATH will host a planning meeting next month, at which time representatives from the Association for Voluntary Surgical Contraception (AVSC), Family Health International (FHI), the Population Council, and PATH will prepare an agenda for this Interagency Meeting.

B. Assistance to Introduction Activities

1. The IPPF's training video on the Copper T 380A IUD has been completed. It is ready for use in Anglophone countries and for adaptation into other languages. This Population Council grant enabled PATH to play an important "behind the scenes" role in its development. PATH staff reviewed and commented on three versions of the video script. The final product is much different than it would have been without input from PATH and the Population Council. Such input ensured that the instructions for loading, insertion, and client counseling were consistent with instructions and language already approved by the Population Council, USAID, FEI, and the United States Food and Drug Administration (USFDA).

As the video was being filmed, PATH learned from discussions with IPPF medical staff that there were no plans to pretest it before preparing a final version. PATH convinced IPPF staff that this was a very important component, since they really needed input from representatives of those for whom the film is intended, i.e. clinicians working in Third World countries. PATH staff arranged to pretest a "rough cut" of the video in Sierra Leone and Zimbabwe. Results and recommended changes were sent to IPPF in London. Clinicians in these countries suggested that there was no need to spend time discussing all IUDs, but rather only those in widespread use in their respective countries. They also felt that not enough attention was given to the possibility of bleeding

irregularities. IPPF took these and many other suggestions into account when finalizing the visuals and narrative for this training video.

2. As mentioned above, JHPIEGO staff in Baltimore are currently adapting the Copper T 380A training film produced at Chulalongkorn University in Bangkok. PATH, in its role as a coordinator of Copper T 380A information, education, and communication (IEC) and training activities, has informed other CAs of the imminent availability of both of these training videos. PATH staff would like to work with other CAs on a mechanism to ensure the availability of the training videos in Third World training programs, such as the one in Bangladesh, where they are desperately needed.

3. During this reporting period, PATH continued its efforts to identify pelvic models that can be used to train clinicians and also to show potential acceptors of this method where the IUD is positioned. Based on an evaluation by its Procurement Department, PATH purchased the Gaumard Model Sima 36 for \$189.75 for use in Tunisia. When PATH staff tried to use the model to demonstrate insertion techniques, they found that the Copper T 380A could be inserted into the uterus of the model. However, because of the copper sleeves on the horizontal bar of the T, the IUD could not be removed without taking the model apart. Clearly this would not meet the needs of Third World trainers. PATH contacted the Vice President of Gaumard Scientific Company, Daphne Eggert, and explained the problem to her. Gaumard's pelvic models had been prepared with the Copper T 200B IUD in mind. Indeed, removal is quite simple with that device. Eggert encouraged her staff to design an improved uterus with an opening to the "vagina" that would allow trainees to practice withdrawal of the Copper T 380A IUD and would be consistent with actual clinical procedures. Gaumard has now replaced the previous uterus with a new one that is appropriate for in-country training situations.

PATH staff also recently heard that Gaumard has developed a \$9.00 hand-held model for use in the Philippines. While it does not seem feasible

that this model could properly simulate the "feel" of an actual insertion, PATH staff is investigating further before making additional recommendations to our colleagues in the developing world.

When viewing the IPPF training film for the first time, PATH noticed that one of the clinicians used a small hand-held model to demonstrate placement of the IUD in the uterus. PATH staff learned that these models were produced by Cilog Pharmaceuticals, Ltd. as promotional material for Family Planning Association clinics in the United Kingdom. Cilog will send PATH a few free samples to share with our colleagues in those countries where PATH is helping with country-specific introduction activities. While a few samples can be donated, large orders would have to be purchased from Cilog.

C. Revised Packet of Copper T 380A Materials

PATH sent a letter to each of the CAs whose programs are involved with the Copper T 380A, either in training, IEC, distribution and/or service delivery. The letter described each of the items in the Copper T 380A prototype packet and enclosed an order form so that CAs could purchase the entire packet of materials or, in some instances, individual items such as the *Manual for Clinicians* and the *Guide for Health Workers*, or the instructional wall chart on loading and insertion. It took much longer than anticipated for CAs to determine their needs and to place their orders. Therefore, PATH had to delay its request for bids from several printers. PATH recently signed a contract with a Seattle printer. The Copper T 380A materials should be ready for distribution in August. Five thousand copies of the entire packet will be printed. However, due to a greater demand for the wall chart and the *Manual for Clinicians*, 10,000 copies of these two items are being printed for use by a variety of CAs in their respective worldwide programs.

III. COUNTRY ACTIVITIES

A. Bangladesh

PATH staff visited Bangladesh for one month in January and February to follow up on Copper T 380A manual distribution activities and to work with non-governmental organizations (NGOs) to further promote their use of additional manuals. Over 15 major NGOs were visited, need for the manuals was determined, and additional orders were taken. Several of the NGOs were using the manual on a regular basis in their training programs; others had distributed the manuals to the clinic and health worker staff located at their field sites throughout the country.

In several situations, the availability of the manuals was beneficial to local programs. While reviewing the official government training manual on IUD insertion, PATH staff discovered that the wrong instructions were printed for the insertion procedure of the Copper T 380A. As a result, it was agreed that the Copper T 380A Reference Manual for Clinicians, prepared by the Information, Education, and Motivation (IEM) Unit of the Family Planning Directorate and PIACT/Bangladesh, would be used as a supplement to the government training manual until it could be revised. In a different situation, an NGO, AVSC, used illustrations from the Clinicians' manual to develop a slide show to use in training clinic staff in the IUD insertion procedure. The manual was also used as a critical component of this NGO's training curriculum. In a meeting with the National Institute for Population Research and Training (NIPORT) to discuss the orientation of staff to the manuals, the head of Family Welfare Visitor (FWV) training suggested incorporating the Copper T 380A Clinician and Motivator manuals into their standard training curriculum.

Due to changes in the government approval process, the collaborative effort between Concerned Women for Family Planning (CWFP) and NIPORT was not finalized. A different NGO, the Bangladesh Association for Voluntary Sterilization (BAVS), is interested in replacing CWFP in this

project; recently major changes in the administration of NIPORT and the Family Planning Directorate has further delayed these negotiations.

PATH staff visited the NGO (PIACT/Bangladesh) conducting the postal distribution of the manuals to the Upazila Family Planning Officers (UFPOs). This unique system, described in a recent report, concluded that the system worked so well that it is recommended for future materials distribution projects of this kind.

The client booklets are being distributed through the government distribution channels. Due to weather conditions and contract difficulties with the Bangladesh Rural Advancement Committee (BRAC), the study and evaluation of the client booklets has been delayed.

B. Colombia

PATH provided TA to the Ministry of Health's Division of Maternal and Child Health (MOH/MCH) to develop Copper T 380A educational materials. Thirty-two MOH/MCH nurses from 23 departments (states) participated in an IEC workshop. The participants were trained in materials development methodology, thereby providing MOH staff nationwide with the training they need to design materials for any audience on a variety of topics. Each workshop participant was made responsible for carrying out Copper T 380A materials development activities and training other MCH staff members in their department.

Focus Group Discussions (FGDs) were conducted by representatives from all 23 departments. Results of FGDs conducted with 238 IUD users and 238 nonusers indicated that few women knew what the Copper T 380A looked like, where it was placed in the body, and how it prevented pregnancy. Side effects, such as cramping, heavy periods, abdominal pain, discharge, and pregnancy, were frequently cited as reasons for not choosing to use or discontinuing use of the IUD. Rumors about the Copper T 380A--that it causes cancer, pelvic inflammation, weight loss or gain, birth defects, and abortions--were widespread.

Based on the FGD results, draft messages and line drawings were developed for two brochures: one for Copper T 380A users and one for nonusers. The messages in both brochures include a general description of the Copper T 380A, how it functions, and the advantages and disadvantages of the method. Side effects and common rumors are also addressed. The brochure for nonusers includes a description of FP and briefly describes other FP methods available in Colombia. The draft brochures were sent to departmental representatives for pretesting.

C. Brazil

PATH completed its TA to (CEMICAMP) to facilitate the introduction of the Copper T 380A into São Paulo state health and FP services. The new São Paulo state FP program will expand FP options, provide oral contraceptives, condoms, and the diaphragm, and introduce the Copper T 380A IUD. Until government support for FP was gained, available contraceptive methods were virtually limited to two: oral contraceptives (usually purchased over the counter, with neither medical screening for contraindications nor appropriate education on proper use) and female sterilization (which, studies show, was frequently thought by women to be a temporary method). Less than one percent of contracepting women used the IUD. This project has focused on improving provider competence and counseling skills.

During January and February 1989, a series of materials to support Copper T 380A introduction, which were described in PATH's January 1989 substantive report to the Population Council, were printed. The training curricula for physicians and counselors were finalized. In February 1989, the training curriculum for physicians was introduced in a four-day training-of-trainers workshop for 13 physician trainers from six medical schools in the state of São Paulo. PATH staff co-facilitated the workshop along with CEMICAMP and Population Council staff. The physicians practiced insertion and removal of the Copper T 380A and client counseling skills, including the use of the newly-prepared support materials. These physicians are now training at

least six physicians from the São Paulo state services monthly. During a three-day workshop in April, 20 FP counselors from the six medical schools were trained to use the counseling curriculum and support materials to train others.

Although evaluation of the trainings has not yet begun, there is evidence of the impact of this project's activities. CEMICAMP staff has gained skills and recognition for its capabilities in materials development, curriculum design, and FP training. CEMICAMP has received requests for assistance in training from other states. In addition, several of the physicians trained at the training-of-trainers workshop indicated that they plan to utilize the curriculum, or parts of it, in trainings that they conduct in states other than São Paulo. The São Paulo state Secretariat of Health contracted CEMICAMP to design and conduct a training program for the staff of two university teaching hospitals that have not previously been involved in FP. The curriculum for this program draws heavily upon the curriculum developed with PATH assistance. CEMICAMP staff is enthusiastic about the trainees' reactions to the curriculum and reports that it is very satisfying to have the opportunity to give providers the elements necessary for such a good start in FP service delivery. Berlimed, the Schering, A.G. subsidiary in Brazil, has expressed interest in supporting the costs of developing and printing additional user-oriented materials on the oral contraceptive. CEMICAMP is also using its new curriculum design skills in a Ministry of Education pilot project to train junior high school teachers to provide sexuality and AIDS education in public schools.

D. Tunisia

A PATH team visited Tunisia in January 1989 to work with the Tunisian Office Nationale de la Famille et de la Population (ONFP). The purpose of the visit was to determine specific ways in which PATH might provide TA to ONFP to further enhance its ongoing Copper T 380A IUD activities, including training, materials development, and/or improving overall quality of care. Staff members conducted a small needs assessment which

enabled them to visit several clinics and speak to clients as well as to all levels of clinic and FP program personnel. Although most staff in these facilities seemed knowledgeable, dedicated, and caring, PATH discovered that most of the women who had IUDs inserted had not been given adequate, uniform information regarding side effects, follow-up, effectiveness, return to fertility, or advantages, nor were they told when the IUD should be removed. The team observed that in most cases the problem was caused not by a lack of knowledge on the part of clinic staff, but rather a lack of uniformity during pre-insertion and post-insertion counseling.

After reporting our findings from field site visits and various meetings to ONFP staff, PATH staff worked with ONFP to plan an overall strategy and to help them prepare a plan of action for future activities.

In the spring, ONFP presented a proposal to PATH and requested funding for IUD-related activities. The Population Council and PATH have subsequently approved this project whose overall objective is to improve the quality of IUD service delivery and care offered by ONFP to Tunisian women. As part of this project, ONFP plans to train 23 supervisory Sage-Femmes (midwives), 23 Sage-Femmes who work in the FP clinics, 23 Sage-Femmes who operate the "mobile units," and 23 Animatrices (social workers). Once trained, this staff will form teams of four, one for each region, and will be responsible for training other Sage-Femmes and Animatrices within their respective regions.

With the assistance of PATH, ONFP will prepare two curricula. The curriculum for Sage-Femmes will cover all medical, educational, and counseling aspects of Copper T 380A service delivery, and will be one week in length. A three-day curriculum for Animatrices will focus on improving education and counseling techniques. This will provide them with uniform information to give to all clients. ONFP will adapt some prototype materials prepared by PATH to use as support material for training and use in the clinics. These include the following:

1. *Guide for Informed Use*: ONFP has already translated this pamphlet into French for use in training Sage-Femmes and for distribution to all medical personnel. A simplified version will be translated into Arabic for use by Animatrices.

2. *Manual for Clinicians*: This manual will be translated into French, photocopied, and used as a handout to reinforce the medical training given to the Sage-Femmes.

3. IUD flip chart: Portions of the information contained in the prototype *Guide for Health Workers* will be adapted for use in a new IUD flip chart to be used by all ONFP Sage-Femmes and Animatrices. It will be divided into three sections and will remind clinic staff what to tell clients before they receive an IUD, after they have the IUD inserted but before they leave the clinic, and when they return for their follow-up visit.

Included in this program is a proposal to prepare an audio cassette for clinic waiting rooms. At present, waiting rooms are usually crowded but they are not often used to provide information to the clients. Based on the success of the tape used in the Sfax's Maternity 40th Day Postpartum Program, ONFP will prepare an entertaining, educational cassette.

Interspersed with popular song, messages will point out advantages of the Copper T 380A, describe women who make good IUD candidates, and acquaint them with some of the side effects of this method so that they can think about whether it is an appropriate method for them to use.

ONFP has requested TA from PATH to help them develop the two curricula, counseling modules, and various handouts to be used during the trainings.

E. Egypt

In late 1988, as a result of the cable that USAID/Washington sent to its Missions, PATH was asked to provide TA to an Egyptian organization who

would adapt some of the materials in the Copper T 380A prototype packet. PATH proposed working with the Egyptian Fertility Care Society (EFCS), as PATH had already trained some EFCS staff members in the materials development process when working with them to develop new materials on NORPLANT^R. A PATH staff person visited Egypt in June 1989 and worked with EFCS staff to pretest an Arabic version of the *Guide for Health Workers*. Pretesting was conducted at El Galal teaching hospital. Further pretests of this manual plus a translation of the *Manual for Clinicians* will be conducted in urban and rural areas of upper and lower Egypt.

Since there was no money in Population Council Award No. 188.20A, PATH staff put together a packet of "creative financing." PATH's TA was covered by a Mission buy-in to JHU/PCS, as PATH is a subcontractor on that project. Funds for EFCS to do the translations, adaptations, two rounds of pretests, and then to prepare camera-ready copy, were provided by PATH to EFCS from private foundation monies. Eventually, all printing costs will be provided by the Mission through augmenting an existing FHI grant to EFCS.

IV. Future Activities

A. Bangladesh

Further activities in this country are dependent upon additional funding. If PATH had sufficient funds, its staff would continue to promote the use of the clinician and motivator manuals by the NGOs; follow-up with them is critical to ensure continued use. Staff would also meet with government representatives to determine the extent of distribution of the client manuals and evaluate their use in the field.

In the interim, via correspondence or possible staff visits for other projects, PATH will continue its efforts to develop a contract between NIPORT and an NGO to ensure the distribution of and orientation to the manuals in the government training centers.

B. Colombia

Two draft materials on the Copper T 380A, one for users of this contraceptive method and one for nonusers, will be pretested nationwide. Representatives from 23 departments (states) will pretest both draft brochures until complete comprehension and acceptability are achieved. The draft brochures will be revised according to the pretest results then printed and distributed to all departments. Training sessions on the use of the materials will be conducted by each department representative. Three months after their distribution the materials will be evaluated for their acceptability and effectiveness. Development of the Copper T 380A brochures coincides with the training of MOH physicians in insertion and removal of this contraceptive method, which is expected to help facilitate the introduction of the Copper T 380A in Colombia.

C. Brazil

The project has been completed; no future activities are planned.

D. Tunisia

In July 1989, a PATH staff member will spend three weeks in Tunisia working with counterparts from ONFP. At the request of ONFP, she will help its staff develop two Copper T 380A IUD training curricula (described in Section III). She will also help ONFP produce appropriate training support materials and assist them in translating some of the prototype Copper T 380A IUD materials into French and in preparing for pretesting.

E. Egypt

EFCS should have Arabic versions of the two prototype IUD manuals (one for clinicians and one for health workers) fully tested, revised, and ready for printing by the end of this year. Once they are printed, the

USAID Mission in Cairo plans to distribute them to all Egyptian FP service delivery organizations. This includes the MOH, the Egyptian Family Planning Association, Clinical Services Improvement project, Health Insurance Organization, the Cairo Health Organization, and Family of the Future. They will be used during trainings and given to clinicians and para-professionals as reference materials.