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# CHILE

Family Health International

Summary of Activities

(1972-1997)

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- Appendix 2: FHI AIDS Control and Prevention Activities
- Appendix 3: List of Publications

## LIST OF ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
CChPS	Corporación Chilena de Prevención del SIDA
COPRECOS	Civil-military program in Peru
CONRAD	Contraceptive Research and Development Program
Cu-I	Copper I IUD
Cu-7	Copper 7 IUD
Cu-T	Copper T IUD
D&C	Dilation and Cutterage
FHI	Family Health International
FEMCAP	Vaginal Barrier Contraceptive
FEMCEPT	Balloon tipped cannula designed to deliver a measured amount of the adhesive to each tube
FEMTEST	An uterotubal gas insufflator that determines tubal patency
HSG	Hysterosalpingogram
HIV	Human Immune Deficiency Virus
ICMER	Instituto Chileno de Medicina
ILGA	International Lesbian and Gay Alliance
IPCS-52	Intrauterine Progestasert Contraceptive Device
IUD	Intrauterine Device
IUM	Intrauterine Membrane Modified Wishbone
LACCASO	Latin American and Caribbean Council of AIDS Service Organizations
LLD	Lippes Loop D IUD
MCA	Methylcyanoacrylate
N-9	Nonoxynol 9
OC	Oral Contraceptives
PID	Pelvic Inflammatory Disease
PPT	Postpartum T IUD
STD	Sexually Transmitted Disease
USAID	United States Agency for International Development

## OVERVIEW

Chile has a total population of approximately 14.5 million, with a crude birth rate of 21/1000, a crude death rate of 6/1000 and a 1.6% annual rate of natural population increase. The life expectancy at birth is 69 for males and 76 for females. The infant mortality rate is 13/1000 and the total fertility rate is 2.5.

The majority of the population has access to modern family planning services: 90% of the total population have access to IUDs and condoms, 85% have access to oral contraceptives and 25% have access to injectables. Female sterilization is available to 60% of the population, but male sterilization, at only 1%, is almost non-existent.

The Chilean government views the current population growth as satisfactory and supports public access to family planning services through its national family planning program. There are no legal obstacles or major limits on access to contraception; abortion is illegal.

The first case of AIDS in Chile was diagnosed in 1984. UNAIDS reports indicate that in 1994 there were 1,060 cases reported throughout the country, of which 92.8% of people with AIDS were male. Of these cases, 82% were reported to be the result of unprotected sexual intercourse, and of these 66.8% were males who identified themselves as homosexual or bisexual. Heterosexual transmission has increased steadily; the ratio of homosexual/bisexual transmission to heterosexual transmission has declined from 7.2:1 for the years 1984 - 1989 to 3.9:1 for the period of 1990-1994. Seven percent of the AIDS cases were due to the exchange of blood: 60% were among IV drug users, 20% from blood transfusions and 16% in hemophiliacs.

Of the numerous activities conducted by FHI in Chile, those most notable are the studies that initiated non-surgical sterilization of women by using quinacrine and the pioneering research on the evaluation and acceptability of Copper-T IUDs. Both of these methods were initiated by Chilean researchers and have greatly influenced contraceptives now available and those currently under investigation.

This Annotated Bibliography describes the activities conducted by Family Health International (FHI) over the past twenty-five years. The first section is a narrative of projects divided by subtopic. The second part of the document consists of three appendices. Appendix One is a matrix of FHI population activities that lists the collaborating agencies, funding sources, project objectives and other relevant information. Appendix Two presents the same type of information for AIDS control and prevention activities also in matrix format. Appendix Three is a list of publications stemming from FHI's work in Chile.

## POPULATION ACTIVITIES

### *Evaluation, Acceptability and Introduction of Contraceptive Methods*

- Intrauterine Devices (IUDs)

#### **A Comparative Trial of String Versus Stringless IUDs: IUDs and PID (1980-1987)**

A multi-centered clinical trial was designed to determine the possible role of IUD marker strings in the etiology of pelvic inflammatory disease (PID). Admissions to the trial were conducted from September 1980 through July 1986 at five medical institutes in Chile, Dominican Republic, France, Guatemala and Yugoslavia. A total of 1,265 women were admitted and randomly allocated to receive either a standard Cu T200 IUD or a Cu T200 IUD without marker strings. In Chile, 68 women participated in the study; 30 were randomly assigned to the Cu T without strings and 38 women to the Cu T with strings. All study volunteers were followed-up for one year postinsertion.

In Chile, 23 devices were inserted by an obstetrician/gynecologist; forty-three devices were inserted by a qualified midwife. At insertion there was one laceration (3.3%) in the stringless group and four (10.5%) in the with-strings group, none of which required treatment. All lacerations were caused by the tenaculum.

Twenty-eight women (3.3%) in the stringless group and all of the women in the with-strings group returned for at least one follow-up visit. One woman in the with-strings group was hospitalized for 16 days with a cholecystectomy. Adnexitis was diagnosed in one without strings user (3.3%) and in one with-strings user (2.6%). Overall, two women (6.7%) in the stringless group and two women (5.3%) in the with-strings group were diagnosed with some type of inflammation/infection.

The termination and removal rates were similar for both groups. Two uterine pregnancies occurred in the stringless group, yielding a 12-month pregnancy rate of 7.4. During the first month of the study, two expulsions occurred in the without strings group, yielding a 12-month expulsion rate of 6.8. In the with-strings group, five expulsions occurred yielding a two-month expulsion rate of 13.3. The 12-month continuation rate for the stringless group was 82.6 and for the with-strings group, 84.1.

In Chile, as in the other sites, no statistically significant differences were found between the two groups of IUD users with respect to the incidence of infection or inflammation. The study results indicate that the IUD string does not play an important role in the etiology of PID associated with the use of IUDs.

Study results were reported in *Advances in Contraception* 1991; 7:231-240 and *Infectious and Medical Disease Letters for Obstetrics and Gynaecology* 1990 Jan-March; 12(1):3-6.

## Evaluation of the Copper T200 and the Progestasert IUDs Inserted Postpartum by Hand or Inserter Techniques (1978-1983)

The purpose of this study was to compare the Intrauterine Progestasert Contraceptive Device (IPCS-52) with the Copper T 200 (Cu T 200) when inserted ten minutes postplacenta by either hand or inserter method.

The IPCS-52 mg is a 'T'-shaped configuration made of ethylene/vinyl acetate. The model used in this study contained 52 mg of progesterone that was released over a 3-year period. The IPCS-52 mg was a modification of an earlier IPCS containing only 38 mg of progesterone. The increase in the amount of progesterone extended its theoretical life span from one to three years. The IPCS-52 mg was designed to improve effectiveness of the IUD by means of its active ingredient. The Copper T 200 is also a "T"-shaped device. It is constructed of polyethylene and has 200 mm<sup>2</sup> of copper wire around the vertical stem. Copper had been shown to improve contraceptive effectiveness.

The IUDs were inserted in 400 women at the Hospital Barros Luco in Santiago from November 1978 through April 1980, 100 each in: IPCS/Hand, IPCS/Inserter, Cu T/Hand and Cu T/Inserter.

Over 90 percent of the women in this study returned for at least one follow-up visit. The incidence of complications/complaints for all groups was low; one perforation of the cervix was diagnosed at the six-month follow-up in a woman in the Cu T/Hand group. Several complications resulted in hospitalization. In all, one woman each in the Cu T/Hand and the IPCS/Hand groups, and three in the IPCS/Inserter group were rehospitalized for IUD-related problems such as ectopic pregnancy, spontaneous abortion, pelvic inflammatory disease (PID) and infection. Other rehospitalizations were due to unrelated illnesses or surgery.

The follow-up rate at 36-months was 55.8 for Cu T/Hand users, 58.4 for Cu T/Inserter users, 61.5 for IPCS/Hand users and 45.1 for IPCS/Inserter users. Differences among the four groups' continuation rates were significant throughout the study: 67.6, 69.2, 38.8 and 42.5, respectively.

There were six pregnancies in the study, two in each group except the IPCS/Hand group, which had none. At 36-months the pregnancy rates were 4.7 for the Cu T/Hand group, 7.6 for the Cu T/Inserter group, and 14.3 for the for the IPCS/Inserter group.

The most common termination reason was expulsion. At 36 months, cumulative expulsion rates were higher for the IPCS groups: 42.4 IPCS/Hand and 40.0 IPCS/Inserter compared with 10.7 for the Cu T/Hand group and 14.2 for the Cu T/Inserter group. When the data were pooled into hand and inserter groups and expulsion rates were analyzed separately for women with either the Cu T or the IPCS, no significant differences were found. There were no differences in the expulsion rates for the following comparisons: IPCS/Hand versus IPCS/Inserter and the Cu T/Hand

and the Cu T/Inserter, which is indicative that the differences between the expulsion rates for all four groups reflect primarily differences in the device.

The results of this study were published in *Contraceptive Delivery Systems* 1983; 4:143-147 and they were pooled with data from other trials and published in Long Acting Contraceptive Delivery Systems, 1984.

### **A Comparative Study of the Delta T and the Copper T 220 in Postpartum Women (1980 - 1983)**

A study comparing the safety and effectiveness of the Delta Copper T (Delta T) to the Copper T 220 (Cu-T) IUD in postpartum women was conducted at the Hospital Barros Luco in Santiago. Insertions were performed between May 1980 and December 1982. Devices were inserted by hand within ten minutes of delivery in 609 women. The Delta T was placed in 302 women, and the Cu-T was placed in 307 women. Devices were randomly assigned.

The Delta Copper T IUD consisted of a standard Cu-T 220C with the addition of two biodegradable suture projections tied to the crossbar copper sleeves. The suture projections were approximately 0.5 cm in length. The sutures were added to lower expulsion rates among postpartum women by holding the device in place during uterine involution.

One perforation of the cervix was diagnosed in a CU-T acceptor at the three-month follow-up; her device was removed. Three women in the Delta T group were hospitalized, Two were treated for perineal dehiscence; one of those cases was complicated by endometritis. The third woman was hospitalized for a retained placenta. Among the Cu-T users, five women were hospitalized. One woman was treated for a kidney infection. Two women were treated for perineal dehiscence, one of whose condition was compounded by endometritis. One woman was hospitalized for a sterilization procedure and another was given treatment for invasive cancer of the cervix and uterus.

Ten cases (3.3%) of endometritis were reported in the Delta T group as compared to eight cases (2.6%) in the Cu-T group. Adnexitis was reported by four women (1.3%) in the Delta group and by one woman in the Cu-T group (0.3%). There was one case of parametritis in each group.

PID and loss of appetite were the reasons given for the two removals in the Delta T group for "other medical" reasons. The six month removal rate was 0.8. Among Cu-T users "other medical" reasons included one perforation and five cases of PID; the 6-month removal rate was 2.4.

At 1-month, the rate for expulsions/displacements was 5.3 in the Delta T group and 9.4 in the Cu-T group, compared to 6-month rates of 9.7 and 13.3 respectively. The

continuation rate was 86.0 for the Delta T users and 81.9 for the Cu-T users at six months.

### **Evaluation of Copper I IUD (1979-1981)**

The increased effectiveness of IUDs due to the addition of copper has allowed a reduction in the size of the copper-bearing IUDs. The development of the Copper I IUD (Cu-I) was an attempt to decrease the incidence of unpleasant side effects (primarily pain and bleeding) associated with IUD use. This was to be accomplished by reducing the size of the vector carrying the copper. This acceptability and efficacy study was conducted in 1979 with 98 interval women recruited from the Hospital Barros Luco in Santiago.

The Cu-I used in this study was made of a high density polyethylene stem that was 20 percent barium sulfate (for radio-opacity). The cross arms were designed to anchor the IUD in place and were composed of elastomeric ethylene vinyl acetate to make them pliable. The crossarms formed an "X" configuration of projections 0.5 cm long with the intention to become anchored into opposing, anterior-posterior, endometrial surfaces. The copper addition to the device consisted of 5 copper collars, 0.5 cm long, spaced evenly along the stem.

Eighty-eight women (90%) returned for at least one follow-up examination. There were four women (4.5%) with PID confined to the uterus and two women (2.3%) with PID confined to the adnexa. One woman with adnexitis and one woman with endometritis had their IUDs removed at the time of diagnosis.

The follow-up rate at 12 months was 55.3. The 12-month pregnancy rate was 9.0. The expulsion rate was also high (15.8). The overall continuation rate at 12 months was 73.

The high expulsion rate of the Cu-I indicated that the anchoring of the Copper-T against the lateral edges of the uterus was more effective than anchoring against the anterior-posterior surfaces of the uterus. Even though the Cu-I had an "X" configuration to assure anchoring contact and was sloped to allow motion in the fundal direction while resisting motion in the cervical dissection, anchoring was not adequate.

The results of this study were published in *Advances in Contraceptive Delivery Systems*. Monograph 1, 1985; pp 104-106.

### **Comparative Study of the Delta LLD and Lippes Loop D IUDs (1979-1981)**

The purpose of this study was to compare the rates of expulsion rates of these two IUDs in post-partum women. The Delta Lippes Loop D (Delta) is a Lippes Loop D (LLD) IUD, but is retained in the endometrium by three sutures for the purpose of reducing expulsions during involution of the uterus.

From April 1979 through October 1980, 136 women received the Delta and 123 women received the LLD IUD at the Hospital de Juan Noè in Arica. The incidence of dysmenorrhea and spotting was similar for both groups. Three women (2.2%) in the Delta group were diagnosed with endometriosis. One woman (0.7%) was hospitalized with adnexitis and had the IUD removed. In the LLD group, five women (4.1%) had endometritis and one resulted in hospitalization.

At the three-month follow-up visit, the expulsion rate of the Delta at 15.3 was significantly lower than that of the LLD at 28.3. In both groups, the expulsions were more frequent in the first month than any time thereafter. The groups were similar in other reasons for termination. Continuation rates at three months for the Delta were significantly higher (81.6) than that of the LLD (68.1).

Results of this study were published in the *Revista Colombiana de Obstetrica y Ginecologia* 1985; 36(1):43-47.

### **Evaluation of the Post Cesarean-Section Insertions of Copper T 200 (1976-1981)**

From August 1976 through May 1980, Copper T 200 IUDs (Cu-T) were inserted in 691 postpartum women who had delivered by cesarean section within the past eight days. The study was conducted at the Hospital Barros Luco in Santiago to examine retention rates. Eighty-one of these women expelled their IUDs (11.7%) at some point and had a new IUD inserted. Most of these reinsertions were done a month or more after the first insertion. First insertions were analyzed as one group and reinsertions were analyzed as a separate group. Data were recorded retrospectively.

Six hundred sixty-three women (95.9%) in this group returned for at least one follow-up. At a 12-month follow-up visit, one posterior cervical perforation was found. The IUD was removed at this time. A total of 470 women (68.0%) had one or more complications or complaints at follow-up. Adnexitis was diagnosed in 34 women (4.9%) and endometritis was diagnosed in 16 women (2.3%). A total of 192 women (27.9%) had some inflammation or infection at follow-up.

Twenty women (2.9%) were rehospitalized after insertion. Four women were hospitalized for spontaneous abortion, two for pelvic inflammatory disease (PID), two for metrorraghia, three for postpartum-related problems and one for conization. The remaining hospitalizations were not IUD related.

In the reinsertion group, all but one woman returned for at least one follow-up. Eight were (9.9%) were diagnosed with adnexitis and one woman (1.2%) was diagnosed with endometritis. One woman (1.2%) was rehospitalized for treatment of an inflamed vulvovagina; gland (Bartholinitis).

The 12-month follow-up rate for the first insertion group was 86.4 and for the reinsertion group, 58.3. In the first reinsertion group, the pregnancy rate at the end of

the study was 1.3, the expulsion rate was 12.8, removal rate for pain/bleeding was 1.8 and the removal rate for other medical reasons was 1.9. At the end of one year, the overall continuation rate was 80.7 for the first insertion group. At six months, the continuation rate was 92.3 for the reinsertion group.

### **Evaluation of the Copper T and Sutured Copper T (1978-1980)**

From January through August 1978, a study of the Sutured Copper T and the standard Copper T IUD was conducted at the Hospital Juan Noe in Arica. The sutured Copper T had two biodegradable suture projections approximately 0.5 cm in length. The purpose of the addition of the sutures was to lower the high expulsion rate associated with immediate postpartum insertion.

The Sutured Copper T was inserted in 146 women immediately after delivery. The standard Copper T was inserted in 130 women during the period of 48 hours to six weeks after delivery. The women were followed-up for a period of one year.

Forty-four women receiving the Sutured Copper T reported inflammation/infection at one or more follow-ups, with a total of 63 cases. Thirty-five women receiving the Copper T reported inflammation/infection at one or more follow-ups, with a total of 44 cases.

The rate of expulsion or displacement was 4.9 at three months for the Sutured Copper T; the comparable rate for the Copper T was 16.7. The 12-month continuation rates were 87.3 for the Sutured Copper T and 67.9 for the Copper T. The follow-up rate for the sutured device was 76.9 at the end of the year, compared to 56.3 for the Copper T. The differences in expulsion rates may be due to differences in timing of insertion for the two devices.

### **The IUD and Anemia: A Study of Hematocrit (1978-1980)**

Increased menstrual and intermenstrual blood loss are the most frequently cited negative side effects of IUD use because they may increase the likelihood of anemia. This study was designed to test the relationship between IUD use and anemia and to test the effect of daily iron supplements on hematocrit levels in conjunction with IUD use. This study conducted at the Hospital Barros Luco in Santiago is an evaluation of the events related to IUD use and hematocrit for 400 women wearing either Lippes Loop D (LLD) or a Copper T-200 (Cu-T).

LLD or Cu-T devices were randomly assigned to 400 women, none of whom had been recently pregnant. Daily iron supplements were randomly assigned to 200 women in the group, and all women with hematocrit values of 30 or less received iron supplementation regardless of the allocation formula. Hematocrit readings were performed at admission and at each subsequent follow-up. Twenty-one women in the

non-iron group received iron supplementation because of low hematocrit levels at study admission.

Mean admission hematocrit values were compared with mean hematocrit values for each follow-up visit by iron group and device type. No statistically significant differences were found between the admission and follow-up hematocrit values for the women taking iron supplements with either device. However, for both the Cu-T and LLD users not taking iron supplements, there were statistically significant declines in the mean hematocrit values at three months and at six months, when compared to the admission values, but the mean hematocrit values at 12 months increased to admission levels.

The differences in mean hematocrit values between women using the Cu-T and the LLD at each follow-up by iron group were evaluated. Although the mean hematocrit values for volunteers in the Cu-T group were consistently higher than those in the LLD group, the difference was statistically significant only for the women taking iron supplements at twelve months, where the values were 40.3 and 38.1, respectively.

Cases were then divided into groups by device to determine differences between mean hematocrit values for the two iron groups. For both iron groups, regardless of the device used, there was a tendency for mean hematocrit values to decline from admission at 3 and 6 months and to increase again at one year.

No statistically significant differences were found between any of the pertinent event rates for the two iron groups. The single significant influence on hematocrit for this study population was the use of daily iron supplements.

The results of this study were published in *Contraceptive Delivery Systems* 1980; 1:49-53.

#### **A Four-way Comparative Postpartum IUD Study: Intrauterine Membrane, Lippes Loop D, Copper T, and Postpartum T (1977-1979)**

From May through December 1977, four different IUDs were inserted in 840 women for a study conducted at Hospital Barros Luco in Santiago to compare acceptability of the devices. The devices, Intrauterine Membrane Modified Wishbone (IUM), Lippes Loop D (LLD), Copper T (Cu-T), and Postpartum T (PPT), were randomly allocated to study volunteers. The insertions were performed from 2 to 36 hours following a normal vaginal delivery.

The groups were similar with respect to age and education, but the LLD acceptors had a significantly lower number of live births (2.0) than women in the other three groups. The IUM and LLD groups had 210 acceptors each, the Cu-T group had 209, and the PPT group had 211 acceptors. The follow-up visits were scheduled at three and six months.

One cervical laceration was caused by the tenaculum in a woman receiving the PPT. Seven other inserter-related problems were reported for that group; most of those involved difficulty in releasing the device from the inserter. At follow-up, three cervical perforations were found in the PPT group. The most serious infections reported were adnexitis and endometritis; fewer of these were reported for the PPT (8 cases) than for the IUM group (15 cases), LLD group (13 cases), or the Cu-T group (14 cases).

Menstrual-related problems occurred with about the same frequency for each of the four groups. However, there was a tendency for more problems with the IUM and fewer with the PPT.

The rates of expulsion after 6 months were significantly higher for the LLD (46.7) and the PPT (41.0) than for the IUM (22.0) and the Cu-T (29.7). At six months, the pertinent termination rates due to pregnancy, expulsion, or other medical reasons were also statistically significant: 49.9 for the LLD, 42.9 for the PPT, 23.0 for the IUM and 32.2 for the Cu-T. The six-month continuation rates were 49.7 for the LLD, 57.1 for the PPT, 76.0 for the IUM, and 66.6 for the Cu-T. Follow-up rates were good for all devices at six months, ranging from 78.3 with the LLD to 89.7 with the IUM.

#### **Postpartum Cu-T 200 Study (1976-1979)**

From August 1976 through June 1978, 1142 insertions of the Copper-T 200 were made at the Hospital Barros Luco in Santiago. The devices were inserted in postpartum women, the majority of whom (96.1%) received their devices within 72 hours of giving birth.

There were no complications or complaints reported by the women at insertion. Nine hundred forty-five (82.7%) of the study volunteers returned for one or more follow-up visits. Cervical perforation was found at follow-up in two (0.2%) women. Nine (0.7%) were hospitalized during the study period; two were hospitalized because of retained placentas, two because of a perineotomy infection, four because of endometritis and one for the spontaneous abortion of a pregnancy conceived with the IUD in situ. One hundred fifty-eight (13.8%) of the study volunteers were diagnosed as having one or more incidents of inflammation/infection. Included among these were 19 (1.7%) cases of adnexitis and 20 (1.8%) cases of endometritis. Dysmenorrhea was reported by 23.7 percent of the women. Intermenstrual bleeding/pain was reported by 297 (20%) of the women, and 113 (9.9%) reported intermenstrual spotting. The continuation rate after one year was 55.5. The three-month termination rates were 0.3 for accidental pregnancy, 32.1 for expulsion/displacement, 0.2 for bleeding/pain and 1.3 for other medical reasons. Most (25.9) expulsions occurred within the first month post-insertion.

Three hundred seventy-two (32.6%) women who received Cu-T 200 IUDs in this study expelled their devices, and 370 of them received a replacement IUD. Of these, 349 women received a second Cu-T 200. The expulsion IUD rate for reinsertions, done

primarily after the postpartum period, was much lower (7.7 at 12 months). The overall continuation rate for these reinsertions was 86.4.

On all other indices of performance, the Cu-T 200 inserted in postpartum women did much better. Reports of bleeding and spotting in the first insertion group were few. Removal rates for bleeding/pain at 12 months were low. This may be indicative of the validity to the assumption that lochia helps to mask the bleeding associated with early IUD use, and removals for this reason are low in the postpartum period.

Results of this study were published in the *IPPF Medical Bulletin* 1977 Aug; 11(4):2-3 and the *International Federation of Gynaecology & Obstetrics* 1983; 21:71-75.

### Comparison of Lippes Loop D and Ypsilon (1976-1978)

From May through September 1976, a comparative study of the Lippes Loop D (LLD) and the Ypsilon IUD was conducted at the Hospital Sotero del Rio in Santiago to determine acceptability and efficacy. The Ypsilon had a Y-shaped stainless steel frame, with a silicone rubber membrane stretched between the arms of the device and a silicone rubber tail. The large surface area of the silicone membrane was to minimize pregnancy; the membrane's compliancy was to reduce rates of removal for bleeding and pain; the lateral pressure of the Y-shaped frame was to reduce expulsions. The standard Lippes Loop D was used as a control device.

The two devices were randomly assigned to 133 women. Fourteen women were excluded from the analysis because they were postabortion or postpartum patients at the time of the insertion. Thus, the analysis was based on 63 women who received the LLD and 56 women who received the Ypsilon. Difficulty at insertion was reported in four instances among LLD recipients, with two resulting in failed insertions. There were five instances of difficulty at insertion reported among Ypsilon recipients, of which three resulted in failed insertions.

At the 12-month follow-up visit, one case of parametritis and two cases of endometritis were reported in the LLD group, and two cases of parametritis and one case of adnexitis were reported in the Ypsilon group. Dysmenorrhea, the most common menstrual-related problem, was reported in 14 LLD patients (23.0%) and in 25 Ypsilon patients (47.2%).

The total number of cases was too small to provide statistically comparable rates. However, there were two (3.3%) pregnancies in the LLD group and five (9.4%) in the Ypsilon group. Four devices (6.6%) were expelled in the LLD group and six devices (11.3%) in the Ypsilon group. Total terminations were 16.5 percent for the LLD group and 35.8 percent for the Ypsilon group.

### **Acceptability Study of the Copper T and the Lippes Loop D (1976-1977)**

This study evaluated the acceptability of the Copper T (Cu-T) and the Lippes Loop D (LLD) IUDs with regard to pregnancy, expulsions and removal for bleeding/pain.

During a six-month period, 400 women were enrolled in the study and followed-up for one year. Half of the group was randomly assigned to receive the Cu-T and the other half the LLD. The characteristics of the women in the Cu-T and LLD groups were similar in age and parity, 25.56 versus 25.19 and 1.94 versus 1.88 respectively. At the end of 12 months, there were no significant differences between the two groups in the rates for pregnancy, expulsions and removal for bleeding/pain.

However, when the data was pooled according to parity (more than three and less than three), the difference in removal rates (for all reasons) was statistically significant. In the parity group of more than three, the LLD had a much lower removal rate at 2.2 than the Cu-T at 13.6. These results, though not definite, suggest that higher parity women do better with the LLD.

Even though both devices seem to be adequate for the family planning programs in Chile, the parity factor was the more important characteristic when determining which IUD to provide.

The results of this study were published in *Revista Colombiana de Obstetricia y Ginecologia* 1978; 29(5):230-234.

### **Retrospective Evaluation of the Timing of IUD Insertion (1975-1977)**

At the time of this study, it was recognized that an IUD may be inserted at any time during the menstrual cycle, but it was thought that there might be a relationship between the timing of the IUD insertion and the continuation and termination rates. This study was conducted to determine the relationship between these factors.

From October 1969 to April 1971, 510 insertions of the Cu-7 and 762 insertions of the Cu-T 200 IUDs were performed at the University of Chile School of Medicine in Santiago. The IUDs were not randomly assigned to the women. The type of IUD inserted depended on the woman's preference and the availability of IUDs. For 429 women who had the Cu-T 200 IUD inserted and 438 women who had the Cu-7 inserted, the timing of the insertion in relation to the phase of the menstrual cycle could be determined from the clinic records. All women had regular menstrual cycles of 24 to 40 days.

Data from insertions performed during the proliferative, midcycle and secretory phases of the menstrual cycle were combined and compared to data from insertions performed during menstruation. For the Cu-T 200 group, the 12-month pregnancy rate was 2.1 among those who received IUDs during menstruation and 3.6 during the proliferative

phase. In the Cu-7 group, the 12-month pregnancy rate was 4.6 among those who received their IUD during menstruation and 3.3 among those who received their IUD during the proliferative phase.

This study showed that the Cu-T 200 and the Cu-7 IUDs can be inserted at any time during the menstrual cycle without any increased risk of subsequent pregnancy during the first 12 months postinsertion.

The results of this study were published in *Contraception* 1979 May; 19(5):449-454.

### **Post-Abortion Insertion of the Pleated Membrane IUD (1974-1977)**

This study evaluated 154 insertions of pleated membrane intrauterine devices in patients treated for spontaneous or incomplete induced abortions at the Hospital Barros Luco between May 1974 and March 1976. The study volunteers were all inserted with an intrauterine membrane (IUM) before discharge from the hospital and within three days of undergoing dilation and curettage (D&C) for an incomplete or inevitable abortion.

The IUM was made from Alathon-20 polythene, with a relatively large surface area of 2,350mm<sup>2</sup>. Its ability to fit different sized and shaped uteri and to adjust to uterine motility resulted from its corrugated structure, its thinness (0.0005mm) and the flexibility of Alathan-20 polythene. A barium-sulfate injection molding strengthened the base of the device.

At the end of one year of study, the cumulative continuation rate was 77.7 per 100 users; less than 10 percent were lost to follow-up. Study results indicate low 1-year net cumulative event rates for pregnancy (1.7 per 100 users), expulsion (7.2 per 100 users) and removal for bleeding or pain (3.9 per 100 users). At the end of one year, there were 5.5 removals per 100 users for all other medical reasons. These rates were similar to those reported in a study of interval insertions of the IUM. Moreover, these results compared favorably with corresponding rates of post-abortion insertions reported in five postabortion insertion studies: Lippes D (2.8 per 100 users), two Lippes Loop studies (17.2 and 16.5 per 100 users), and two Cu-T studies (13.0 and 0.0 per 100 users).

The results of this study were published in *International Journal of Gynaecology & Obstetrics* 1977; 15:275-178.

### **IUD Insertions by Midwives (1974-1977)**

Since 1968, certified nurse-midwives have routinely performed IUD insertions in Chile. These personnel have inserted the three most commonly used IUDs: the Lippes Loop D (LLD), the Copper-7 (Cu-7), and the Copper-T (Cu-T). This study compared the experiences of nurse-midwives and physicians in inserting these devices at the same hospital.

A total of 96 LLD, 174 Cu-7 and 363 Cu-T devices were inserted by midwives. Correspondingly, physicians inserted 399 LLD, 340 Cu-7 and 470 Cu-T devices. All insertions were performed at the Hospital Sotero del Rio in Puente Alto. Study volunteers were not randomly assigned to either the nurse-midwife or physician's groups. On days when a physician was in attendance at the hospital or clinic, the IUD insertions were performed by a physician, otherwise insertions were performed by the nurse-midwives. For each device and for either service provider, age and parity distributions of the study volunteers were similar, with the exception of the age distributions of the LLD acceptors, which were higher for midwives (28 years versus 25 years).

For all three devices, continuation rates among women whose IUDs were inserted by nurse-midwives were approximately 83 per 100 women at the end of one year. The continuation rates among women whose IUDs were inserted by physicians ranged from 79 to 89 per 100 women at the end of one year.

The one-year pregnancy rates for the LLD groups were significantly different, 9.3 per 100 for the nurse-midwife group and 2.2 for the physician group. Ten (91%) of the 11 pregnancies were accounted for by one nurse-midwife who performed 79 insertions. Pregnancy rates with the copper devices were similar regardless of the service providers: 3.2 versus 3.1 for the Cu-7 and 2.3 versus 2.2 for the Cu-T.

Expulsion rates for the nurse-midwife group were significantly lower than the rates for the physician group for LLD insertions (7.0 versus 12.4), but significantly higher for the Cu-7 insertions (8.1 versus 2.5). For the Cu-T, the expulsion rate was higher among patients whose IUDs were inserted by the nurse-midwives but not significantly so (4.3 versus 2.7). One year expulsion rates for the nurse-midwife group ranged from 4.3 to 8.1 per 100 acceptors. For the physician group, the rates ranged from 2.5 to 12.4. Removals for bleeding and/or pain for the two groups of service providers were not significantly different.

Results of this analysis indicate that nurse-midwives can participate safely and effectively in an IUD insertion program but that continued monitoring of paramedical staff is needed to identify those who are in need of additional training.

Results of this study were published in *International Journal of Gynaecology & Obstetrics* 1977; 15:84-87.

### **Evaluation of the Finland Copper-T and the Copper T-220C (1972-1976)**

From November 1972 through October 1973, a study of the Copper T 220C (Cu-T 220C) was conducted at the Hospital Sotero del Rio in Santiago. From September 1975 through August 1976, a study of the Finland Copper T (Cu-T) was conducted at the same center. This study report looked at the data from both studies to compare continuation rates. Menstruating women who had not been pregnant within the past 30

days were included in the analysis, which was based on 259 women who received the Finland Cu-T and 237 women who received the Cu-T 220C.

The Cu-T 220C is a polyethylene T-shaped device that supports five solid copper sleeves on the vertical arm and two sleeves on the horizontal arm, for a total surface area of 220mm<sup>2</sup>. The Finland Cu-T differs from the standard Cu-T 200C in four ways: 1) bulbous protrusions at the end of the horizontal arm that should prevent embedding; 2) a loop at the end of the vertical arm that should prevent perforation; 3) thicker copper wire that should be less likely to break; and 4) the copper surface is 200 sq. mm.

No insertion complications or complaints were reported for either group. The Finland Cu-T group had a higher proportion of infection problems than the Cu-T 220C group: 22.4 percent of the former reported PID compared with 9.7 percent in the latter group. Dysmenorrhea was the most common menstrual-related problem for both groups: 54.8 percent in the Cu-T group and 24.9 percent in the Cu-T 220C group.

The six-month follow-up rate was 85.4 for the Cu-T and 82.8 for the Cu-T 220C. The 12-month follow-up rate was 57.7 for the Cu-T and 80.0 for the Cu-T 220C.

The six-month pregnancy rate for the Cu-T was 0.4 and for the Cu-T 220C the pregnancy rate was 0.0; at 12-months the rates were 2.3 and 1.7, respectively.

Termination rates due to expulsion or displacement were identical at the end of six months for the Cu-T and Cu-T 220C groups: 4.5 and 4.6, respectively. The rate also was the same (5.1) for both devices at the end of 12 months. After six months, the rate of removal for bleeding and pain was 1.8 for the Cu-T and 0.5 for the Cu-T 220C. The rate of removal for bleeding and pain was significantly higher for the Cu-T (7.2) when compared to the Cu-T 220C (1.6) after 12 months.

The difference between the Cu-T and the Cu-T 220C was statistically significant at the 12-month visit for removal due to bleeding and pain, 7.2 versus 1.6, respectively.

The six-month continuation rates were similar: 90.1 for the Cu-T and 92.6 for the Cu-T 220C. The 12-month continuation rates were significantly different: 75.9 for the Cu-T and 88.5 for the Cu-T 220C.

- **Non-surgical Female Sterilization**

### **Cohort Study of Chilean Women Who Received Insertions of Quinacrine as a Transcervical Method of Sterilization (1992-1996)**

During the two decades preceding this study, research was being conducted in Chile on the transcervical installation of quinacrine hydrochloride for effecting permanent sterilization. Studies indicated that quinacrine selectively produced significant structural changes in the reproductive tract and caused permanent tubal fibrosis. The original

means of sterilization via quinacrine was with the schedule of three installations of a solution of 1.5 gm of quinacrine powder suspended in 5 ml of two percent xylocaine into the uterine cavity. This regimen was unsatisfactory because of the unacceptably high pregnancy rates and the production of an occasional transient toxic psychosis. The solution also created intrauterine pressure and involved the preparation of the solution immediately prior to insertion.

Quinacrine hydrochloride pellets were developed to produce a delivery system that would bring the chemical into prolonged contact with the tubal ostia through delayed uterine retention and thus increase the probability of successful occlusion. Because the quinacrine pellet dissolves relatively slowly within the uterine cavity, the risk of rapid intravascular absorption present in the solution may be reduced.

Each quinacrine hydrochloride pellet has a cylindrical shape with a diameter of less than 4 mm. The pellets are compacted to contain about 10 mg of quinacrine per mm of length. Insertion is accomplished by placing the pellets in a plastic tube with a push rod positioned behind them; the procedure is essentially the same as inserting an IUD. The tube is then passed through the cervical canal until the fundus is reached. Dilation is not necessary.

The objective of this retrospective long-term follow-up study was to determine whether a cluster of eight cancers identified during the long-term follow-up of 572 women who had received transcervical quinacrine hydrochloride was a random occurrence or evidence of an increased risk of cancer. This study built on information obtained in the recently completed retrospective cohort study and involved the long-term follow-up of women who received transcervical insertions of quinacrine pellets for nonsurgical female sterilization at the Hospital Sotero del Rio in Santiago and the Escuela de Medicina in Valdivia.

Information was sought on 1,492 women who received insertions of quinacrine between 1977 and 1989. During the study period, 802 women of the original 1,492 (54.6%) were located and interviewed. Of the 151 women from Valdivia, 138 of them (91.4%) were interviewed, whereas only 664 of the 1,341 women from Santiago (49.5%) were interviewed. Clinic records ranging from one to 14 years were available on an additional 600 of the non-interviewed women. A comparison between the information gained during the 664 interviews from study volunteers in Santiago and from the charts of the 677 who were not interviewed was also conducted.

The preliminary results of this study confirmed the occurrence of the unusual cluster, but no evidence was found of excess cancer risk associated with quinacrine pellet sterilization. All interviews have been completed, and data entry and data cleaning activities are in progress.

Discussions of this study were published in *Fertility and Sterility* March 1996, 65(3):680-681; *Fertility and Sterility* August 1995 64(2):325-334 and the *International Journal of Gynecology & Obstetrics* 1995, 51 (Suppl. 1):S57-S69.

## **Sterilization Cohort Study of Chilean Women Who Received Insertions of Quinacrine as a Transcervical Method of Sterilization (1991-1993)**

Since the mid-1970's women in Chile had access to transcervical insertions of quinacrine pellets for non-surgical sterilization. The purpose of this study was to determine whether women who have undergone the quinacrine method of sterilization were at increased risk of cervical carcinoma.

This retrospective study was designed to compare incidence of high grade lesions among quinacrine acceptors with a comparison population. Investigators reviewed all cytologic records of women sterilized with intrauterine quinacrine in the Hospital Soltero del Rio in Santiago between March 1977 and October 1990, as well as the results of the histopathologic studies obtained from the archives of the hospital pathology system.

The available cytologic records include a group of 1,061 women. In this group, there were 19 patients in whom an in situ carcinoma, or cervical cancer, was found at the time of the first quinacrine pellet insertion (prevalence of 1.8%). Comparison data were taken from a previous report on the incidence of preclinical cervical pathology in metropolitan Santiago. The control group included data from 36,520 women who had a Pap smear in 1981 or 1982 and had at least one Pap smear in the subsequent five years.

The results of this study showed that the age-adjusted incidence rate of an in situ cervical carcinoma in patients treated with quinacrine (2.62 per 1,000 woman-years) was not significantly higher than the incidence rate in the comparison group. The investigators conceded that the groups were from different parts of Santiago, that the data were not comparable on risk factors such as age at first intercourse, and the difference in length and intensity of follow-up.

Discussions of this study were published in *Fertility and Sterility* August 1995, 64(2):325-334 and *Network* 1991,12(2):26-27.

## **Evaluation of Two Applications of Methylcyanoacrylate (1983-1985)**

Methylcyanoacrylate (MCA) is a tissue adhesive that has the potential for use in occluding the Fallopian tubes. MCA produces tubal occlusion by causing tissue necrosis, inflammation and fibrosis of the tubal lumen; the adhesive biodegrades at twelve weeks. The MCA is delivered transcervically to the oviducts by means of the FEMCEPT<sup>®</sup> device, a balloon-tipped cannula designed to deliver a measured amount of the adhesive to each tube. Initial human trials showed a bilateral occlusion rate of greater than 70 percent for one application of MCA as demonstrated by hysterosalpingogram (HSG).

This study was to determine whether two applications of MCA delivered at intervals of two months, three months or four months apart was the optimal interval to occlude the tubes.

From February 1983 to June 1983, 61 women at the outpatient clinic of the Universidad Austral de Chile in Valdivia volunteered for this study. One-third of the women were to receive two MCA applications at two months apart, one-third at three months apart and one-third at four months apart.

Procedures were scheduled for four to seven days following onset of menses to rule out pregnancy. Premedication with 0.5mg atropine, 10mg diazepam and 50 mg demerol was given intravenously 10 to 15 minutes prior to the MCA application. Women were instructed to use oral or barrier contraception until the results from the HSG, scheduled for four months after the second application, indicated bilateral tubal closure. Clinical follow-up was scheduled for one month after each procedure and four months after the second procedure. Women who did not show patency on HSG at the four-month visit were declared sterile and scheduled for follow-up at six-month intervals for two years.

Of the women entering the three groups, six did not return on schedule. For analysis purposes, these women became part of the other protocol schedule, depending on when they did return for the second procedure. All women returned for the second procedure.

Difficulties with the insertion and functioning of the FEMCEPT<sup>®</sup> device occurred for 10-18 percent of the procedures. None of the difficulties prevented the procedure from being completed.

All of the women returned for one or more follow-up visits. Changes in menstrual flow and dysmenorrhea were the most frequently reported events.

HSGs were performed for all the women. Bilateral closure ranged from 86 percent for women with an interval of four months between procedures to 100 percent for women with a two-month interval between applications. Seventy-five percent of the women were followed-up for six months and sixty percent for 12 months after they were declared sterile. One pregnancy was reported; it occurred three months after the woman was declared sterile.

The two applications of MCA were found to be safe; no serious morbidity was reported, and complaints were minor and temporary. The premedication regimen used appeared to be successful in controlling pain. No significant difference was found in the bilateral closure rates obtained in the three groups of women.

Results of this study were published in *Advances in Contraception* 1986; 2:91-95.

### **Safety and Efficacy of Two Insertions of 100-Minute Releasing Quinacrine Hydrochloride Pellets for Non-Surgical Female Sterilization (1982-1985)**

By the early 1980's extensive research had been undertaken to develop a simple method of non-surgical female sterilization. Early studies with pellets that dissolved over a 10-

minute period showed that three insertions were required to obtain an acceptable 12-month pregnancy rate of less than five per 100 women. This study was designed to examine the safety and efficacy of pellets that dissolve over a 100-minute period, which was thought to produce a higher rate of tubal closure and thus reduce the number of insertions required.

One hundred twelve study volunteers were recruited at the Hospital Sotero del Rio in Santiago from July 1982 through July 1984. Each woman received transcervical insertions of 250 mg of 100-minute releasing quinacrine pellets at admission and again at one month following admission. Insertions were performed during the proliferative phase of the menstrual cycle in women who had not recently been pregnant. Clinical follow-up was scheduled at 6, 12 and 24 months after the second insertion and at any time when complications or complaints occurred. The end point of the study was pregnancy and not tubal patency as demonstrated by hysterosalpingogram.

Only 5.4 percent of study volunteers did not receive the two scheduled insertions. One was due to pregnancy, two for pelvic inflammatory disease, and three did not come in to the clinic as scheduled. The pregnancy was non-ectopic.

The gross cumulative life table pregnancy rate per 100 women at 12 months after completed treatment was 2.0. In the first year, 15 women (14.6%) reported amenorrhea of variable length.

Three women had hematometra. One woman was hospitalized and cervical dilatation performed under anesthesia; approximately 15 ml of blood were removed. Simple hysterectomy resolved the problem for the other two women. None of the women had repeat occurrence of hematometra. Only 27 percent of study volunteers returned for the 24 month follow-up visit.

This study suggested that two insertions of 100-minute releasing pellets may be as effective as three insertions of 10-minute releasing pellets.

Results of this study were published in *Advances in Contraception* 1987; 3:255-261.

### **Efficacy of Three Insertions of 10-Minute Releasing Quinacrine Hydrochloride Pellets for Non-Surgical Female Sterilization (1978-1984)**

One hundred forty three patients were recruited at the Hospital Sotero del Rio in Santiago between December 1978 and October 1982 to participate in a study to determine the efficacy of three transcervical insertions of quinacrine to produce tubal occlusion.

Seven pellets containing a total of 250 mg of 10-minute releasing quinacrine hydrochloride were inserted at admission and again one month and two months after admission. Insertions were performed during the proliferative phase of the menstrual

cycle in women who had not recently been pregnant. No additional contraceptives were used. Clinical follow-up was scheduled at 6, 12 and 24 months after the third insertion and at any time when complications or complaints occurred. The end point of the study was pregnancy and not tubal patency as demonstrated by HSG.

Nine women did not receive a second insertion. At twelve months, four women had become pregnant but two of them were thought to have been pregnant at the time of enrollment in the study. One woman had a cervical synechia, and three women failed to return to the clinic.

Eleven women did not receive their third insertion. Two had become pregnant, one experienced a possible perforation of the uterus (and was successfully treated with penicillin), one had a cystic mass, one experienced metrorrhagia, one experienced intense vaginitis, and five failed to return to the clinic.

In total, 14 percent of the study volunteers did not complete the scheduled three insertions of quinacrine. The gross cumulative life table pregnancy rate per 100 women at 12 months was 3.3 and at 24-months was 6.7. Twenty women (16.5%) reported amenorrhea of varying duration.

Approximately 90 percent of the women returned for a 36-month follow-up. Most complications and complaints reported in the second and third years were minor and transitory, although two were serious. One woman had a hysterectomy for carcinoma of the cervix eighteen months after receiving her third insertion. A Pap smear was not completed at admission so that the finding of dysplasia at the six-month follow-up visit did not necessarily represent the beginning of a new disease. A second woman underwent a hysterectomy for an intra-epithelial metaplasia 28 months after her third insertion; she had had two negative Pap smears at the study site.

Results of this study were published in *Advances in Contraception* 1987; 3:255-261.

### **Efficacy of Three Insertions of Quinacrine Hydrochloride Pellets (1979-1983)**

From March through December 1979, 151 women at an outpatient clinic at the Universidad Austral de Chile in Valdivia entered the study to determine the efficacy of three insertions of quinacrine to produce tubal occlusion.

Seven pellets containing a total of 250 mg quinacrine hydrochloride were to be inserted at admission, again at one month and two months after admission. Insertions were performed during the proliferative phase of the menstrual cycle in women who had not been pregnant within the previous forty-two days. No additional contraceptives were used. Clinical follow-up was scheduled at 6, 12, 24 and 36 months after the third insertion and at any time when complications or complaints occurred.

Only two women did not complete the scheduled three insertions of quinacrine pellets. One woman had chronic pelvic inflammatory disease, and the second contracted a viral infectious hepatitis after the insertion. Only seven minor complications and complaints (similar to those associated with IUD insertions) were reported at insertion or between insertions. In most cases, the complications or complaints were of a temporary nature, disappearing within a few hours or a few days after the procedure.

More than 80 percent (81.1%) of the women returned for the 36-month follow-up. There were seven pregnancies in this study. Four were terminated by an induced abortion procedure, one ended in a spontaneous abortion, and two were carried to term. The term pregnancies occurred 18 and 24 months after the third insertion; the infants were born without any problems. The cumulative gross life-table pregnancy rate was 4.3 per 100 women at 36 months.

Follow-up problems were reported by 27.5 percent in the 36 months after the third insertion. Although most were minor and transitory, surgery was required for seven women, including four conizations of the cervix in women with dysplasia, one appendectomy and one removal of an ovarian cyst. The seventh woman had exploratory surgery because of intermittent and chronic pelvic pain. The genital tract was normal. Both tubes were excised and histological examination showed bilateral closure.

The results of this study were published in *Clinical Report: Quinacrine-Fused Pellets*. Reprinted from Female Transcervical Sterilization: Proceedings of an International Workshop on Non-Surgical Methods for Female Occlusion, *Advances in Contraceptive Delivery Systems*, Monograph 1, 1985:146-149 and *Contraceptive Delivery Systems* 1984 5:131-135.

### **Efficacy of Quinacrine Hydrochloride Pellets (1977-1980)**

From January 1977 through June 1978, 139 women giving informed consent at an outpatient clinic in Santiago received three transvaginal insertions of 250mg of quinacrine pellets preceded by a single pellet of 20 mg of sodium thiopental as their only means of contraception. The purpose of the study was to determine the efficacy of three insertions of quinacrine combined with sodium thiopental to produce tubal occlusion. Sodium thiopental, a hydroscopic agent, was used to increase the viscosity of the uterine fluid in an attempt to improve the intrauterine retention of the quinacrine.

Insertions were performed during the proliferative phase of three consecutive menstrual cycles. Clinical follow-up was scheduled at six and 12 months after the third insertion and at any time when complications or complaints occurred.

The results obtained from this study indicate that the pellet method of quinacrine insertion is more effective than the quinacrine solution method. The unacceptably high

pregnancy rate associated with the quinacrine solution installation procedure that occurred in the month between the first and second installation (9.1 at one year) was reduced to 3.1 in the pellet study. In addition, the pellet method appeared to reduce the risk of transient toxic psychosis. No such event was reported for the pellet patients, compared with two percent of quinacrine solution patients.

Results of this study were reported in *International Journal of Gynaecology and Obstetrics* 1980; 18:275-279. Results of this study were merged with results from two other clinical trials and presented at the International Workshop on Nonsurgical Methods for Female Occlusion; 1982 June 22-24; Chicago, IL.

- **Oral Contraceptives**

### **A Comparative Study of Triquilar Versus Lo-Femenal (1986-1988)**

A comparative study of two low-dose combined oral contraceptives (OC) was conducted at the Universidad Austral de Chile in Valdivia. This study was designed to determine if there were differences in the discontinuation rates between Triquilar and Lo-Femenal, as well as the frequency of selected symptoms contributing to method discontinuation.

Triquilar is a triphasic OC patterned after the hormonal profile of a normal female menstrual cycle, which provides a high degree of pregnancy protection at a lower monthly steroid dosage than conventional constant-dose preparations. Therefore, Triquilar may be associated with a lower incidence of reported side effects than the conventional OCs. The studied OCs were selected so that a comparison could be made between pills with a low-dose monophasic regimen and a triphasic regimen.

Women were admitted to the study from January 1986 through January 1987. A total of 300 women were recruited and randomly allocated to receive either Triquilar or Lo-Femenal. Due to a randomization error, 151 women were given Triquilar and 149 were given Lo-Femenal. Follow-up visits were scheduled at one, four, eight and twelve months. Two women in the Triquilar group and one from the Lo-Femenal group were excluded from analysis because they had no menses at the time of admission. Another woman in the Lo-Femenal group was excluded from analysis because she was under age. Of the 296 women included in the analysis, all were interval patients.

Serious complications were reported by two women in the Triquilar group during the study period. One reported severe abdominal pain and discontinued OC use because of gastric pain. The other woman reported severe headaches, and Triquilar was discontinued for this reason. Other complications, such as weight gain, nervousness, and abdominal discomfort were reported by 34 women (22.3%) in the Triquilar group and 32 (21.8%) in the Lo-Femenal group.

Approximately 30 percent of the women in both groups reported at least one menstrual complaint; there was an increase of scanty menses and menorrhagia, and a decrease of dysmenorrhea in both groups. Likewise, there was not a significant difference between the two groups in the number of women who reported at least one pill-related problem or complaint.

There were, however, significant changes in the percentages of women reporting complaints at admission and at the one-month follow-up visit in each group. In the Triquilar group, there were significant decreases in intermenstrual bleeding and other menstrual complaints (7.4 to 2.7 and 23.4 to 8.9 respectively), but a significant increase (8.1 to 18.5) in reports of nausea. In the Lo-Femenal group, there was a significant decrease (23.8 to 5.5) for other menstrual complaints and a significant increase (11.6 to 21.4) in reports of nausea.

A total of 34 women (22.8%) in the Triquilar group and 37 women (25.2%) in the Lo-Femenal group discontinued during the study period. Side-effects were the primary reason given for discontinuation in both groups. There was one accidental pregnancy in the Triquilar group during the study period, which was due to user failure. The lost-to-follow-up rates for both groups were not significantly different: 1.3 for the Triquilar and 3.4 for the Lo-Femenal group.

Results of this study were pooled with data from four other centers and published in *Contraception* 1993; 47:515-525.

- **Barrier Methods**

#### **Safety and Efficacy Study of FEMCAP<sup>®</sup> Used with Spermicide vs the Ortho All-Flex<sup>®</sup> Diaphragm Used with Spermicide (1994-1997)**

The purpose of this study is to evaluate and compare the safety and contraceptive efficacy of Femcap<sup>®</sup> used with two percent nonoxynol-9 (N-9) and Ortho All-Flex<sup>®</sup> contraceptive diaphragm used with two percent N-9 and to follow colposcopic changes, if any, occurring in the two groups and to describe the differences.

Femcap<sup>®</sup> is a vaginal barrier device designed as an alternative to currently available vaginal barrier contraceptives. This contraceptive efficacy study in Chile involves 80 participants who are randomly allocated to either Femcap<sup>®</sup> or an Ortho All-Flex<sup>®</sup> diaphragm and followed-up for six months. This study is being implemented in the Instituto Chileno de Medicina Reproductiva (ICMER) in Santiago. The Contraceptive Research and Development Program (CONRAD) is conducting the study in conjunction with a US study involving 800 women, in collaboration with FHI.

The outcome of the study is expected to lead to the approval of a new barrier method and increase our knowledge of contraceptive effectiveness and user dynamics of these two female barrier contraceptives. Data collected from a questionnaire given to male

partners of participants will enhance the available understanding of the influence of male attitudes and male supportive behavior on the use of these methods.

Recruitment is ongoing.

### Vaginal Spermicides (1981-1983)

A total of 198 sexually active, parous, non-lactating women were recruited from the family planning clinic of the Hospital Sotero del Rio in Santiago to study the efficacy of propranolol as a spermicide.

Each evening from the last day of menstruation until the first day of the next menstrual period, study volunteers inserted a commercially available 80 mg tablet of propranolol into the vagina. Insertion of the tablet was routine whether intercourse took place in the evening or morning. No other method of contraception was used during the eleven-month study period.

The volunteers were followed-up after the first month of treatment and then at three monthly intervals. The pattern of menstruation, symptomatic side effects and reasons for discontinuation were investigated and method failures documented. In a sub-group of thirty women, an ovulation test was performed at days twelve and fourteen of the menstrual cycle, and post-coital tests were performed on the first day that the cervical mucus was penetrable. These women were asked to insert the propranolol tablet at 9pm and have intercourse at about 7am on the morning of the post-coital test. The spermatozoa in the cervix were sampled and examined about three hours after intercourse.

There were no noticeable effects on menstruation, and no systemic adverse reactions were noted among the study volunteers. Among the 198 study volunteers, five became pregnant and 73 discontinued, 33 for itching or pain, 10 for personal reasons and 30 were lost to follow-up. Discontinuations because of local itching or discomfort occurred mainly in the first three months of treatment, and any such complaint was rated as mild. The calculated lifetable pregnancy rate at one year was three to four per 100 women.

The five women who became pregnant were not among those in whom post-coital testing was performed. All of those who became pregnant chose to terminate their pregnancy by abortion; no abnormalities were noted in the fetuses. Post-coital testing did not show any motile spermatozoa in the endocervical samples.

Results of this study were published in *Contraceptive Delivery Systems* 1984; 5:303-309 and *The British Medical Journal* 1983 29 October; 287:1245-1246.

## *Other Population Projects*

### **Analysis of Impact of Breastfeeding Duration (1989-1992)**

The purpose of this study was to analyze the variables that influenced the duration of lactation in healthy mothers and to describe the growth patterns of fully breast-fed infants during the first 12 months of life. All infants (n=1,217) were healthy singletons born at the public hospital for the central area of Santiago, Hospital San Borja-Arriarán. Their mothers were 18-35 years old; had a parity of 1-3; had a normal pregnancy and a vaginal, term delivery; and had no chronic disease or condition requiring continuous drug therapy. All infants were fully breast-fed at 30 days postpartum and 63 percent and 24 percent were still fully breast-fed at six and twelve months postpartum, respectively.

The probability of remaining fully breast-fed for 12 months was significantly higher in infants with higher birth weight and with higher maternal weight. The main variables that affect the duration of breast-feeding were found to be nutrition status and suckling frequency, both of which are susceptible to interventions by health services. The comparison of the monthly weight of the infant and the number of months of being breast-fed with WHO/National Center for Health Statistics reference data showed that when mothers and infants are healthy, breast milk was sufficient to support adequate infant growth and health during the first months of life.

The results of this study reinforced the need for maternal nutrition during pregnancy in order to provide women the nutritional support they need to sustain a high suckling frequency.

The results of this study were published in *American Journal of Clinical Nutrition* 1995; 62:371-376.

### **Evaluation of the FEMTEST Device Pre- and Post-Sterilization (1985-1987)**

The FEMTEST uterotubal gas insufflator was developed to determine tubal patency by tubal insufflation with carbon dioxide gas (CO<sub>2</sub>). The device was designed to be inserted into the uterus until the tip of the device touched the fundus. Upon manual activation of a plunger, a small balloon (1-2 cm) inflated inside the uterus. The physician would then withdraw the device so as to seal the internal os with the outer surface of the balloon. Carbon dioxide was then released into the uterine cavity, and if the indicator stabilized and showed no movement, blockage was assumed.

A study was conducted at the University of Valdivia in Valdivia to evaluate the safety, ease of use, and effectiveness of the FEMTEST device. Tubal patency rates determined by the FEMTEST were compared with tubal patency rates determined by the hysterosalpingogram (HSG) for women pre-and post-sterilization.

A total of 122 interval women were admitted into the study between February 1985 and August 1986. Thirteen women who had used an intrauterine device within thirty days of the FEMTEST procedure were excluded from this analysis.

The FEMTEST and HSG procedures were performed within three weeks pre-sterilization. The person interpreting the results of the HSG was not the same person performing the FEMTEST procedure, nor did the person know the sterilization status of the women. Women were scheduled for follow-up FEMTEST and HSG procedures no sooner than three months post-sterilization.

Forty-two women underwent sterilization using methylcyanoacrylate (MCA), and 67 underwent surgical sterilization procedures. Information regarding the approaches and techniques of the surgical sterilization procedure was not provided to FHI. One woman who was sterilized surgically did not return for FEMTEST or HSG after sterilization.

There was one case (0.9%) of difficulty encountered during a FEMTEST procedure performed pre-sterilization. In this case, three cannulae were required due to failure of the balloon. No difficulties were encountered during HSG procedures. Complications during the HSG procedure conducted pre-sterilization were reported in three cases; one incidence of hydrosalpinx in both tubes, one case of lymphatic passage of the dye, and one report of an IUD found in the abdominal cavity of the patient.

FEMTEST and HSG findings were in agreement for 97.2 percent of the pre-sterilization women and 100.0 percent of the women post-sterilization. Of the 11 women having patent tubes after sterilization, ten had been sterilized using MCA.

## AIDS CONTROL AND PREVENTION ACTIVITIES

### *AIDS and High Risk Groups*

#### **Study of HIV-positive Individuals and Their Partners in Santiago (1991-1994)**

The conceptual framework underpinning this project was derived from research suggesting that behavior change is most likely to occur where the need for change is most notable to the individual. The HIV epidemic in Santiago appeared to be mostly concentrated in an identifiable risk groups, namely homosexual and bi-sexual men. This study, a collaborative effort between the University of Pennsylvania and the Catholic University of Chile, used a behavioral intervention model focusing on HIV-positive individuals and their sex partners.

The objectives of this project were:

- to conduct behavioral research to identify acceptable strategies for AIDS prevention programs in Chile;
- to develop a screening instrument for assessing HIV risk in clinic patients; and
- to design and implement interventions for use with 600 sample patients.

Interviews with all 44 known HIV-positive individuals in the area to assess potential for contact tracing and partner notification. Results showed:

- 89 percent were still sexually active
- over 80 percent believed their stable and casual partners should be informed about their potential exposure to HIV
- the majority of respondents could locate all stable sex partners but none of their casual partners over the past two years.

An assessment of the efficacy of existing counseling and blood bank screening programs in Santiago was made. Results showed that a substantial amount of blood testing already occurred in the Chilean health system and constituted a fairly good de facto surveillance system. In addition, there was a high level of blood testing for HIV infection with adequate coverage of high risk groups, although there was a need for HIV counseling.

### *Information Dissemination*

#### **LAC Regional HIV/STD Conference (1995)**

FHI, through the Corporación Chilena de Prevención del SIDA (CChPS), provided funds to support the participation of representatives from NGOs to the Tenth Latin American Congress on STDs/Fourth Panamerican Conference on AIDS in Santiago in November 1995 and for three satellite meetings organized in conjunction with the Congress. Thirty-eight of the 40 delegates from 12 Latin American countries were supported with funds from FHI, along with 19 representatives from Chilean NGOs

based outside of Santiago. FHI also provided support to 17 commercial sex workers to attend a Conference satellite meeting on sex work.

The three satellite meetings supported by FHI facilitated the Latin American and Caribbean Council of AIDS Service Organizations (LACCASO) to evaluate its medium-term plan and the AIDS Working Group of the International Gay and Lesbian Alliance (ILGA) to discuss regional strategies. The support also allowed the Diego Portales University in Santiago to convene a post-Congress seminar on Sexuality, Research and HIV/AIDS.

### **Media Orientation Seminar (1995)**

FHI collaborated with CChPS and The Panos Institute of Washington to support a seminar for representatives of the media who would be reporting on the Tenth Latin American Congress on STDs/Fourth Panamerican Conference on AIDS in Santiago. During the week immediately preceding the Conference, a six-hour orientation seminar for 30 journalists from Spanish-speaking countries was held. The purpose of the orientation was to thoroughly brief the journalists on key issues likely to be raised during the meeting. In addition, journalists were put in contact with individuals who were instrumental in the organization of the Conference.

### **Pre-Alliance Workshop (1995)**

FHI provided support to The Civil-Military Alliance to Combat HIV and AIDS which enabled them to conduct two civil-military workshops on AIDS in conjunction with the Tenth Latin American Congress on STDs/Fourth Panamerican Conference on AIDS in Santiago in November of 1995. The first workshop "HIV and AIDS: Military and Civil-Military Responses" provided a forum for the Alliance to present their global efforts, disseminate information on regional models on civil-military collaboration and distribute materials. Argentina, Bolivia, Brazil, Chile, Honduras and Peru participated in this meeting. The second workshop "Planning Session for Latin America and the Caribbean: Military and Civil-Military Possibilities" provided a forum for senior international representatives from military and civil institutions to develop a strategy and develop a work agenda for the region. The first workshop focused on epidemiological, national and regional perspectives on HIV/AIDS. The second workshop clarified the relationship between ongoing civil-military efforts such as COPRECOS in Peru and the Alliance, created an advisory council with senior representatives from five countries, and prepared a workplan. The outcome of these workshops was a comprehensive briefing book on technical issues and civil-military responses to HIV/AIDS and a report in Spanish and English that summarized the recommendations and workplans.

## APPENDIX ONE

<b>FHI POPULATION ACTIVITIES IN CHILE</b>							
Project Name	Effective Dates	Collaborating Agencies	Funding Source	Total Funding	FCO	Project Status	Project Objective
<i>Evaluation, Acceptability and Introduction of Contraceptive Methods</i>							
• <b>INTRAUTERINE DEVICES (IUD)</b>							
A Comparative Trial of String Versus Stringless IUDs: IUDs and PID	1980-88	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To determine the possible role of IUD marker strings in the etiology of PID, through an international multi-centered clinical trial.
Evaluation of the Copper T 200 and the IPCS-52 MG Intrauterine Devices Inserted Postpartum by Hand or Inserter Techniques	1978-85	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To compare the effectiveness of the IPCS-52 IUD with the Cu-T 200.
A Comparative Study of the Delta T and the Copper T200 in Postpartum Women	1980-83	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To compare the Delta T and the Cu-T 200 IUDs in postpartum women.
Evaluation of Copper I IUD	1979-81	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To study the acceptability and efficacy of the new Cu-I IUD.
Comparative Study of the Delta and Lippes Loop D IUDs	1979-81	Hospital de Juan Noe in Arica	USAID	Not Available	Not Available	Completed	To compare the rates of expulsion rates of Delta and Lippes Loop D IUDs in post-partum women
Evaluation of the Post Cesarean-Section Insertions of Copper T 200	1976-81	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To evaluate the complications associated with post cesarean-section insertion of the Cu-T 200 IUD.
Evaluation of the Copper T and Sutured Copper T	1978-80	Hospital Juan Noe	USAID	Not Available	Not Available	Completed	To determine if there was a lower expulsion rate for the Sutured Cu-T IUDs than for the standard Cu-T.
The IUD and Anemia: A Study of Hematocrit	1978-80	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To test the relationship between IUD use and anemia and to test the effect of daily iron supplements on hematocrit levels in conjunction with IUD use.
A Four-way Comparative Postpartum IUD Study: Intrauterine Membrane, Lippes Loop D, Copper T, and Postpartum T	1977-79	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To compare the complication and continuation rates of four different IUDs.
Postpartum Cu-T 200 Study	1976-79	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To evaluate the effectiveness and potential side-effects of the Cu-T 200 IUD among postpartum women.

### FHI POPULATION ACTIVITIES IN CHILE

Project Name	Effective Dates	Collaborating Agencies	Funding Source	Total Funding	FCO	Project Status	Project Objective
Comparison of Lippes Loop D and Ypsilon	1976-78	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To compare the effectiveness of the Lippes Loop D and the Ypsilon IUDs.
Acceptability Study of the Copper T and the Lippes Loop D	1976-77	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To evaluate the acceptability of the Cu-T and the Lippes Loop D IUDs in regards to pregnancy, expulsions or removal for bleeding/pain
Retrospective Evaluation of the Timing of IUD Insertion	1975-77	University of Chile School of Medicine	USAID	Not Available	Not Available	Completed	To determine the relationship, if any, between the timing of IUD insertion and the continuation and termination rates.
Post-Abortion Insertion of the Pleated Membrane IUD	1974-77	Hospital Barros Luco	USAID	Not Available	Not Available	Completed	To evaluate the effectiveness of the pleated membrane IUD in women undergoing treatment for inevitable or incomplete abortion.
IUD Insertions by Midwives	1974-77	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To compare the experiences of nurse-midwives and physicians in inserting IUDs.
Evaluation of the Finland Copper T and the Copper T 220C	1972-76	Hospital Sotero del Rio	USAID	Not Available	Sotero Not Available	Completed	To examine and compare data from two separate studies of the Cu-T 220C and the Cu-T IUDs.
• <b><u>FEMALE STERILIZATION</u></b>							
Cohort Study of Chilean Women Who Received Insertions of Quinacrine as a Transcervical Method of Sterilization	1992-96	Hospital del Rio/ Escuela de Medicina	USAID	\$178,041	2219	Completed	To determine whether a cluster of cancers identified during long-term follow-up of women who had received transcervical quinacrine hydrochloride was a random occurrence or evidence of an increased risk of cancer.
Sterilization Cohort Study of Chikan Women Who Received Insertions of Quinacrine as a Transcervical Method of Sterilization	1991-93	Hospital Sotero del Rio	Mellon	\$444,660	1680	Completed	To determine whether the incidence of cancer among women who have undergone the quinacrine method of sterilization were at increased risk of cervical carcinoma.
Evaluation of Two Applications of Methylcyanoacrylate	1983-85	Universidad Austral de Chile	USAID	Not Available	Not Available	Completed	To evaluate the use of methylcyanoacrylate to occlude the Fallopian tubes.
Safety and Efficacy of Two Insertions of 100-minute Releasing Quinacrine Hydrochloride Pellets for Non-surgical Female Sterilization	1982-85	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To examine the safety and efficacy of quinacrine hydrochloride pellets that dissolve over a 100-minute period

### FHI POPULATION ACTIVITIES IN CHILE

Project Name	Effective Dates	Collaborating Agencies	Funding Source	Total Funding	FCO	Project Status	Project Objective
Efficacy of Three Insertions of 10-minute Releasing Quinacrine Hydrochloride Pellets for Non-surgical Female Sterilization	1978-85	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To determine the safety and efficacy of quinacrine hydrochloride pellets that dissolve over a 10-minute period
Efficacy of Three Insertions of Quinacrine Hydrochloride Pellets	1979-83	Universidad Austral de Chile	USAID	Not Available	Not Available	Completed	To determine the safety and efficacy of three insertions of seven quinacrine pellets.
Efficacy of Quinacrine Hydrochloride Pellets	1977-80	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To evaluate the safety and efficacy of quinacrine hydrochloride pellets compared to the quinacrine solution method.
• <u>ORAL CONTRACEPTIVES</u>							
A Comparative Study of Triquilar Versus Lo-Femenal	1986-88	Universidad Austral de Chile	USAID	\$117,850*	3138	Completed	To conduct a comparative study of two low-dose combined oral contraceptives and assess differences in discontinuation rates and the frequency of certain side effects.
• <u>BARRIER METHODS</u>							
Safety and Efficacy Study of FEMCAP Used with Spermicide vs the Ortho All-Flex Diaphragm Used with Spermicide	1994-97	Instituto Chileno de Medicina (ICMER)	USAID	\$353,632	2218	Ongoing	To evaluate and compare the safety and efficacy of FEMCAP used with 2% N-9 and Ortho All-Flex contraceptive diaphragm used with 2% N-9.
Vaginal Spermicides	1981-83	Hospital Sotero del Rio	USAID	Not Available	Not Available	Completed	To study the efficacy of propranoiol as a spermicide.
<i>Other Population Projects</i>							
Analysis of Impact of Breastfeeding Duration	1989-92	Hospital San Borja-Arriaran	USAID	\$10,271	6385	Completed	To analyze the variables that influenced the duration of lactation in healthy mothers and to describe the growth patterns of fully breast-fed infants during the first 12 months of life.
Evaluation of the FEMTEST Devise Pre- and Post-Sterilization	1985-87	University of Valdivia	USAID	\$43,589	3162	Completed	To evaluate the safety, ease of use and effectiveness of the FEMTEST uterotubal gas insufflator.

<sup>1</sup> Indicates total funding available or multi-contry project

## APPENDIX TWO

<b>FHI AIDS CONTROL AND PREVENTION ACTIVITIES IN CHILE</b>							
Project Name	Effective Dates	Collaborating Agencies	Funding Source	Total Funding	FCO	Project Status	Project Objectives
<i>AIDS and High-risk Groups</i>							
Study of HIV-positive Individuals and Their Partners in Santiago	1991-94		USAID	\$81,000	23053	Completed	To conduct behavioral research to identify strategies for AIDS prevention programs in Chile, to develop a screening instrument for assessing HIV risk in clinic patients and to design and implement interventions for use with patients
<i>Information Dissemination</i>							
LAC Regional HIV/STD Conference	1995	Corporación Chilena de Prevención del SIDA (CChPS)	USAID	\$13,758	56345	Completed	To support the participation of representatives from NGOs in the Tenth Latin American Congress on STDs / Fourth Panamerican Conference on AIDS in Santiago and for three satellite meetings organized in conjunction with the Congress.
Media Orientation Seminar	1995	CChPS; PANOS Institute	USAID	\$25,026	55348	Completed	To support a seminar for representatives of the media who would be reporting on the pre-conference media seminar of the Tenth Latin American Congress on STDs / Fourth Panamerican Conference on AIDS held in Santiago.
Pre-Alliance Workshop	1995	The Civil-Military Alliance to Combat HIV and AIDS	USAID	\$18,500	56346	Completed	To conduct two civil-military workshops on AIDS in conjunctions with the Tenth Latin American Congress on STDs / Fourth Panamerican Conference on AIDS.

## Appendix 3

### List of Publications

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