A RETROSPECTIVE STUDY OF QUINACRINE STERILIZATION IN VIETNAM

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INTRODUCTION

Quinacrine has been used on a limited basis as a method of nonsurgical female sterilization since the 1970s. In a number of developing countries quinacrine represents an effective, simple and inexpensive way to provide sterilization services to large segments of the population.

Quinacrine has been used in 13 countries by an estimated 80,000 women (Contraceptive Technology Update, 1994). In the 1970s and 1980s, clinical trials with quinacrine were conducted in several countries including Chile (Zipper et al., 1980), Egypt (El Kady et al., 1993), India (Bhatt & Waszak, 1985), Pakistan (Bashir, 1993), Malaysia (Arshat et al., 1987) and Indonesia (Agoestina & Kusuma, 1992). In 1989, the Ministry of Health in Vietnam conducted two preliminary clinical trials of quinacrine on 200 women in two provinces. With promising results in these two sites, quinacrine services were expanded to include 24 provinces, though only those providers who agreed to client follow-up to monitor method failure and complications were allowed to participate in this introduction. By the end of 1992 nearly 32,000 Vietnamese women had undergone a quinacrine sterilization. A paper describing the clinical experience of these women was published in ***The Lancet*** in 1993 (Hieu et al., 1993).

Most previous research on quinacrine users has involved relatively small data sets and has focused on issues of safety and efficacy. No published studies have described the acceptability of quinacrine to women or their satisfaction with the method and service delivery. The large number of participants in the Vietnam program presented an opportunity to gather information from a sizeable number of users and to fully examine women's perspectives on the method. With funding provided by the U.S.-based Buffett Foundation, Family Health International conducted a retrospective survey of quinacrine users in conjunction with the Vietnamese Ministry of Health.

Family Planning in Vietnam

The results of the 1988 National Demographic and Health Survey (DHS) suggested that Vietnamese women's contraceptive needs were not being met. At that time, nearly 60% of the women of reproductive age indicated that they did not want any more children. There are no published statistics on the numbers of women who do not want children and who are not using contraception. However, in the DHS report it was estimated that for the five years preceding the survey the total wanted fertility rate for women between the ages of 15 and 44 was 2.5 children while the actual total fertility rate of this group was 4.5 (National Committee for Population and Family Planning (NCPFP), 1990).

Contraceptive prevalence in 1988 was estimated at 53% (39% modem methods), and the IUD was found to be the method most commonly used and most widely available. However, reports suggest that there is dissatisfaction with the IUD and that failure rates are high (Allman et al., 1991). In addition, other reports indicate a reluctance on the part of providers to distribute pills because of a lack of confidence in women's ability to take them properly and a preference

for IUDs (UNFPA, 1993). Almost 45% of contraceptive users were supplied at the commune health centers and 37% at a district hospital. WhileIUDs are usually inserted at the commune health centers, pills and condoms are generally not available at the commune level and must be obtained from the district hospital (NCPFP, 1990) making access to resupply of these methods more difficult than for the IUD. Abortions and menstrual regulations(MRs) are very common, and apparently many women perceive pregnancy termination as a means of fertility control (Hieu et al., 1994). The government however, does not recognize abortion and MR as methods of family planning, but rather as a means of addressing method failures.

At the time the quinacrine trials were initiated in Vietnam, quinacrine sterilization was viewed as a possible way to fill the gap in demand for permanent contraceptive services. According to the quinacrine program's administrator, the demandfrom women themselves for this permanent method of contraception motivated a number of providers to request training and supplies so that the method could be introduced within their own district's family planning programs. Unfortunately, the demand outweighed the resources available; officials acknowledge that the training for insertors was done in an informal way and often was inadequate. Furthermore, supervision of insertors was minimal.

Policy required that women who received quinacrine were to be at least 30 years old and have at least two children; the youngest of these should have been at least three years old (though a third child could be younger than three years) prior to insertion. Variations in this policy allowed younger women with a greater number of children to be eligible for quinacrine sterilization. There were no incentives for quinacrine sterilization from the central level of the Ministry of Health, but a number of officials at the district and commune level did provide women undergoing quinacrine sterilization with food or money. This was viewed by officials as a means of compensating time or lost wages rather than as incentives. This kind of compensation was not limited to quinacrine sterilization and was given for other methods as well, such as the IUD and surgical sterilization.

History of Quinacrine Sterilization[1]

The use of quinacrine as a method of nonsurgical sterilization was first proposed by Dr. Jaime Zipper in Chile (Zipper et al., 1968). Different methods of administration were tried, but the procedure most commonly used now involves the transcervical insertion of seven pellets of quinacrine into the uterus using a modified IUD inserter. The pellets dissolve within about 30 minutes. Most commonly, two insertions given one month apart are performed during the proliferative phase of the menstrual cycle (days five to 12). As the pellets dissolve they produce necrosis of the endometrial lining of the uterus and inflammation of the intramural portion of the fallopian tubes. Although the endometrium regenerates itself, the fallopian tubes are permanently fibrosed and closed in a high percentage of women.

In the 1970's, quinacrine suspensions or slurries were studied; however, these studies were discontinued due to concerns about toxicity, cases of serious central nervous system (CNS)

'For a more complete review of the history of quinacrine sterilization, see Sokal, et al., in press.

excitation and three deaths which were reported to the U.S. Food and Drug Administration (USFDA). There have been no reports of similar severe complications following the use of quinacrine pellets and, in fact, major complications from the use of quinacrine pellets are rare (Sokal et al., in press). In *The Lance?* paper on the clinical experience of over 30,000 women in Vietnam, eight cases of major complications were reported (Hieu et al., 1993). This is a rate of 0.03% or one in 4000 women. There were no cases of uterine perforation reported in Vietnam although three cases in other trials have been reported (Zipper et al., 1983; El Kady et al., 1993). No investigators have reported a case of acute CNS excitation with the use of quinacrine pellets, and no deaths have been reported immediately following quinacrine pellet insertions. However, following multiple (but not single) insertions of quinacrine pellets, abnormal endometrial lesions may occur (El Sahwi, 1992; Merchant et al., 1986). Also, occasional cases of uterine synechia (adhesions within the uterus), including one in Vietnam, and hematometra (an accumulation of blood in the uterus) have been reported (Zipper, 1987 & Hieu, 1993).

Although few major complications have been associated with quinacrine pellets, minor side effects or complaints have been documented in the various clinical trials. From 9 to 25% of women who have participated in various trials of this method have reported cramping or lower abdominal pain following the insertion, similar to that often experienced during an IUD insertion. Other transient complaints include backache, bleeding, headaches and dizziness. The leakage of quinacrine into the vagina causes vaginal pruritus (itching) in some women. Amenorrhea and irregular menstruation of several months' duration have been reported in 1 to 20% of women undergoing this procedure and may be more frequent in women who have had multiple insertions (Sokal, in press).

Currently available human data on the possible risk of cancer from the intrauterine use of quinacrine are not sufficient to draw any firm conclusions. A cluster of eight cancers of different types, including a uterine leiomyosarcoma, was detected during long-term follow-up of 572 women in Chile, but the results of a retrospective cohort study suggest that the cluster was probably a random occurrence, not causally related to quinacrine. This cohort is being followed up for at least an additional five years, through 1996 (Sokal et al., in press).

Despite the many trials that have been conducted, there is still no standard regimen for administering quinacrine, and studies have varied in terms of number of doses, insertion technique and the use of adjuvants (a supplemental drug given to increase effectiveness). In Vietnam, the standard protocol required two insertions, though at least one provider implemented a one-insertion protocol for older women. In some districts, treatment included the use of an intrauterine insertion of ampicillin as an adjuvant. The use of different adjuvants has been studied by Dr. Zipper, who found a low failure rate after three years (one pregnancy in 114 women), using a combination of quinacrine, betamethasone and copper sulfate (Zipper et al., 1993).

Because of the differences in these studies and the lack of controlled clinical trials, it is difficult to estimate the efficacy of quinacrine, although pregnancy rates are higher than those seen after surgical sterilization. Examples of pregnancy rates found in studies without the use of adjuvants include: 5% at one year after one insertion (Hieu et al., 1993), 3.7% at four years after three insertions (Bhatt & Waszak, 1985) and 8% at 10 years after three insertions (Mullick, manuscript in preparation). A recent study which used adjuvants and supplementary

contraception for the first few months after quinacrine insertion, however, found a pregnancy rate of 0.7% at 18 months following one insertion (Mullick, manuscript in preparation).

The available data suggest that the risk of ectopic pregnancies after quinacrine sterilization is less than among noncontraceptors. Data from women in Vietnam indicate that in the short term, the risk of ectopic pregnancy is similar to the risk in IUD users. More recent data from Chile show that ectopic pregnancies can occur up to 10 years after quinacrine sterilization (Sokal et al., manuscript in preparation).

The Quinacrine **Controversy**

The introduction of quinacrine in Vietnam on such a large scale has sparked a debate among the world's reproductive health providers, researchers, donors and women's health advocates. Quinacrine has been studied since the 1970s, and its short-term safety has been documented. In approximately 80,000 quinacrine sterilizations, no deaths have been reported immediately following quinacrine pellet insertion yet three to eight deaths would be expected based on the same number of surgical sterilizations in the developing world (Khairullah et al., 1992). This method is inexpensive and easy to administer, which means that health workers who are not physicians can be trained to perform the insertions. Overall, it has the potential to greatly increase access to sterilization services at a price (about US $1.00/insertion that is affordable to most family planning programs.

However, many fear that not enough is known about the safety and efficacy of the method. Quinacrine has not been approved by the USFDA for intrauterine use. Questions have been raised about toxicity and the possibility of a link to cancer. Furthermore, quinacrine has not been proven to be as effective at preventing pregnancy as surgical sterilization, and method failure has led to concerns about an increased risk of ectopic pregnancies. The possibility of coercion is an issue that has also been raised. In response to these concerns, the government of Vietnam suspended the quinacrine program in December 1993, pending additional information on the method. There were also concerns that women would worry about their quinacrine sterilizations when, as a result of the suspension and reports coming from international meetings on quinacrine, articles were published in Vietnamese newspapers and magazines, which claimed that quinacrine was unsafe and could cause cancer.

The Retrospective Study

The retrospective study described in this report was developed prior to the suspension of Vietnam's quinacrine program, but the results may answer some of the questions defining the controversy. The study was designed to evaluate the strengths and wealmesses of the quinacrine sterilization program from the users' perspectives, and thus, provides information about how the method has been experienced by the women themselves. Of primary interest are women's perspectives on how they made the decision to use the method, the method itself, the care received, the impact method use has made on their health and personal lives, and their satisfaction with quinacrine. In order to place the results of the survey of quinacrine users into the overall context of family planning in Vietnam, interviews were also conducted with a comparison group of IUD users. IUDs are the most widely used method of contraception in

Vietnam and would have been the most likely alternative used if quinacrine were not available. Surgical sterilization was relatively unavailable during the same time period; though it seems logical to compare quinacrine with another permanent method, not enough acceptors of surgical sterilization were available to permit comparison.

This study addresses many of the issues of interest to the medical community, such as side effects and complications, pregnancy, and informed consent as reported by users. When this study was being developed, it also had been hoped that some additional analyses could explore factors related to method failure using the logbook data on the original 30,000 women; unfortunately, the logbooks often lacked data on last menstrual period and previous contraceptive use, and this plan had to be changed.

Questions about toxicity, teratogenicity, potential carcinogenicity, and the best insertion technique for quinacrine sterilization are beyond the scope of this project, however, and cannot be answered in this report. These issues will only be resolved with further research, such as pre-clinical toxicology studies and additional well-controlled clinical trials (Phase I/II) to better assess the most effective regimen of quinacrine. Favorable results from the Phase I/II trials could be the basis for initiation of larger Phase III clinical studies (Sokal, personal correspondence 10/15/94).

METHODOLOGY

Objectives

The purpose of this study was to evaluate the quinacrine sterilization program from the users' perspectives. The specific objectives were to answer the following research questions, which were asked in the context of the family planning program in Vietnam at the time of the initiation of the quinacrine program:

1. What factors influenced acceptance of quinacrine sterilization?
2. What were women's experiences with quinacrine sterilization services?
3. What were women's experiences with the method itself in terms of side effects, complications and illness, method failure and its effects on their daily lives?
4. What were the levels of satisfaction and regret among quinacrine acceptors?

Study Design

The study was designed to retrospectively obtain information from women who had undergone the quinacrine sterilization procedure during its introduction in Vietnam from 1989 through 1993. A sample of IUD users was also interviewed to get comparative data on the outcomes of interest. The sample populations were drawn from three provinces: Nam Ha, Thai Binh and Hai Hung (Figure 1). These provinces are located near Hanoi and were selected because they were the first provinces in which quinacrine sterilization was provided and had the greatest numbers of quinacrine insertions from 1989 through 1993. The four districts in each of

these provinces with the greatest number of quinacrine acceptors were chosen for the study. The comparison sample of IUD users was drawn from the same 12 districts.

Selection of participants. The sampling frame was developed by using logbooks which recorded data on quinacrine insertions at all service delivery sites within the chosen districts. A database was created which included the logbook information on all 6535 quinacrine insertions in these districts between April 1989 and December 1993. A random sample of women to be interviewed was drawn from this database using a SAS program, which stratified the population according to province, district, and five-year age intervals. The probability of being selected was equal across strata.

The sample of IUD acceptors. in these districts was drawn from a sampling frame constructed using logbooks kept at the district hospitals. The logbooks listed women who had IUDs inserted at the hospital itself and at commune health facilities visited by mobile team personnel from the district hospitals. A total of 6446 IUD insertions, performed from January 1989 to December 1993 in the same 12 districts, comprised the sampling frame for randomly choosing IUD acceptors to be interviewed. The IUD sample was frequency matched to the quinacrine sample on the same three stratification variables in the quinacrine sample: province, district and age. As a result, these factors are not expected to be confounders in comparisons of characteristics at insertion, complications experienced, satisfaction or other variables between IUD and quinacrine acceptors.

Sample size. The sample size chosen for the quinacrine users was 1815. Assuming 25% non-response, a planned sample of 1800 subjects per group would yield sufficient power (greater than 80%) to detect a 5% difference in any dichotomous outcome variable. For outcomes that occur in less than 10% of the population, the sample size would allow sufficient power to detect absolute differences of 3% or less. A total of 1679 of 1815 quinacrine users selected and 1511 of 1685 IUDs users selected were interviewed. The IUD sample was smaller because some strata had fewer IUD users available in the sampling frame. The number responding in each group was greater than the number needed (1350 per group) to achieve the planned power.

The **Questionnaires**

Two questionnaires were developed for this study: one for the quinacrine acceptors and one for the IUD acceptors (Appendix A). The two questionnaires were similar, and both were designed to provide information on sociodemographic characteristics; contraceptive knowledge, attitudes and practices; the decision to accept a particular method; service delivery characteristics, such as care and counseling received; complications and side effects associated with the method, including pregnancies; other clinical and non-clinical outcomes associated with the method; and user satisfaction. In addition, for quinacrine acceptors, questions on regret were included. The questionnaires contained both pre-coded and open-ended questions.

The questionnaires were originally developed in English and were translated into Vietnamese by research staff at the Hanoi Medical College in Hanoi. Independent translators in the U.S. backtranslated the questionnaires to English. Questionnaires were pretested prior to and

during the interviewer training. Revisions after the backtranslations were made on the basis of these pretests.

Data Collection

Interviews for the quinacrine acceptors took place between March and April 1994 and for IUD acceptors between July and August 1994. The implementation of the survey was coordinated by the Hanoi Medical College. The study coordinator and interviewer supervisors were staff members at the College. They were responsible for managing logistics related to implementation as well as the verification of questionnaires. Personnel from the Maternal and Child Health/Family Planning Centers (MCH/FP) in each of the study provinces also facilitated the interviews and verified the addresses of the respondents.

Primary and secondary school teachers from each study district were recruited and trained to serve as interviewers. One supervisor was responsible for the interviewers in each district. Local teachers were chosen over health workers to reduce participants' reluctance to be critical about the method or the services they received and to increase their comfort during the interview.

Potential respondents were informed of their right not to participate in the study. Every respondent who agreed to participate signed an informed consent form, which explained her rights to terminate the interview at any time or to refuse to respond to any particular question she did not want to answer. Respondents were paid the equivalent of $1 .OO (US) to compensate for the time spent answering questions.

The interviewers were able to locate and interview 1679 women (93%) of the quinacrine sample and 15 11 women (90%) of the IUD sample. The reasons interviews were not conducted with the remainder of the samples are given in Appendix B. The data presented in Table 1 show that the groups of respondents for each method had similar geographic distributions. All quinacrine users who reported a pregnancy were reinterviewed by health workers from the provincial MCH/FP centers with a second questionnaire to verify the pregnancy and its outcome.

Data Processing **and** Analysis

Data were entered into a personal computer by the staff of the Hanoi Medical College and the Ministry of Health in Hanoi using the Epi Info data entry program (Dean et al., 1990). The Ministry of Health was responsible for coding open-ended questions. The data were cleaned in Hanoi with the assistance of an FHI staff member and were jointly analyzed by the MOH and FHI in Hanoi and North Carolina using Epi Info (Dean, A. et al., 1990), SPSS-PC (Norusis, 1990) and SUDAAN (Shah, B. et al., 1991).

Results presented in this report are descriptive comparisons of answers to interview questions given by quinacrine and IUD acceptors. Weights were calculated to account for both non-response among quinacrine and IUD acceptors selected and insufficient numbers of IUD users in the sampling frame for some strata. The Ns reported in the tables are the unweighted Ns, but the percentages, means and standard deviations reported in the text and tables are the weighted results. Likelihood chi square and t-tests of significance were performed to compare most outcomes as they were related to the two methods. SUDAAN was used to conduct these

comparisons. SUDAAN incorporates the correlation within a stratum (province-district-age) and the increased variability due to the weights when calculating error terms for these statistics.

Age at insertion and insertion dates were obtained from logbook data. There was no way to identify women who were supposed to get only one insertion from those who did not return for an intended second insertion. The number of quinacrine insertions were &fined as the number of insertions prior to a method failure if there was one. A few women obtained two or three insertions but may have had the last insertion after a method failure. For example, a woman who got pregnant after one insertion, but then had two more insertions after the pregnancy was terminated was counted in the one insertion group. Method failures were confirmed for the women in the quinacrine group on the basis of a second interview, conducted with the women who indicated during the first interview that they had gotten pregnant after the quinacrine insertion.

To calculate failure rates for quinacrine users and to examine the relationship between method failure for quinacrine users and several other factors, lifetable analyses were conducted using the SPSSPC "survival" program. Failure rates were compared on the following variables: age at insertion (< 35 years vs. 35 or more years); number of insertions (one insertion vs. more than one insertion (before pregnancy diagnosed)); age by number of insertions; prior IUD use (women who had been using an IUD immediately prior to quinacrine insertion vs. those who had not); prior IUD use by age; and district (as a proxy for service delivery differences). These subgroups were compared using Cox's proportional hazards regression procedure in SUDAAN. Failure rates for the IUD acceptors could not be calculated because the question about the date of the pregnancy was inadvertently omitted from the IUD questionnaire.

Although questions posed to IUD acceptors regarding IUD failures, results of the pregnancy, menstrual patterns, etc., were intended to refer to the reference IUD (i.e., the IUD inserted on the date given in the IUD logbooks), this was not always the case. For a few women, the reference IUD was removed and another was later reinserted. In these cases, answers given refer to the most recent IUD, not the reference IUD.

The analyses presented in this paper were designed to address the questions set forth in the objectives. Subsequent papers will address additional questions and hypotheses generated by the results presented in this report. Secondary data analysis appropriate for addressing any follow-up questions will be performed at that time. All data analyses were verified by FHI's Division of Biostatistics.

Human Subjects Review

Prior to implementation of the study, the protocol and questionnaires were reviewed and approved by Vietnam's Ministry of Health and FHI's Protection of Human Subjects Committee, an institutional review board conforming to U.S. Public Health Service Regulations.

RESULTS AND DISCUSSION

1. What factors influenced women's decisions to obtain a quinacrine sterilization?

Contraceptive decisions are made based on knowledge, experience, individual and family needs, personal preferences and availability. Specifically, factors which may influence a woman's decision to accept a contraceptive method include sociodemographic characteristics (age and parity); contraceptive history; information about the method; social influences; and perceptions of availability and advantages of a method. Concerns have been raised about the possibility of coercive measures taken to pressure women to accept quinacrine in Vietnam and its role was investigated.

So&demographic characteristics. At the time of insertion, the quinacrine respondents were on average 34.9 years old and the IUD users were 34.3 years old (Table 2) indicating that the frequency matching and weighting led to quinacrine and IUD samples which were quite comparable on age, as desired.

The quinacrine respondents had a mean of 3.6 children while the IUD group had 2.9 children ($p<.001$). These results are consistent with the expectation that controlling for age, women with more children would be more inclined to accept apermanent method.

Most women met the age and parity criteria for receiving quinacrine sterilization services, though the results indicate that some respondents were younger or had fewer or younger children than stated policy. Ten percent of the women were under age 30 at the time of insertion, and all had at least two children. Only six women had one child, and all of these women except one were over 30 years old.

Contraceptive history. The majority of women in both groups had experience with contraceptive methods before their quinacrine or IUD insertion (Table 3). Not surprisingly, the IUD was the predominant method used. Other modem methods, such as condoms, oral contraceptives and injectables, had been used by a much smaller percentage of women (less than 15% for any of these methods).

Over 40% of the quinacrine users and 15% of the IUD users had experienced at least one method failure ($p<.001$), and the IUD was the method which had failed for the majority of these respondents. The average number of abortions and MRs was greater for quinacrine users as compared to IUD acceptors ($p<.001$).

Sources **of information. The** first source of information for the majority of women in both groups were service providers (Table 4). A larger percentage of IUD acceptors than quinacrine acceptors knew someone who had used the method (88% vs. 60%, respectively; $p<.001$) —not surprising since quinacrine was a new method at the time many of them underwent the procedure.

Social influences. The data indicate that women felt themselves to be in control of the decision to obtain their chosen method of contraception though it is clear that women also discussed their methods with people within their personal realm —husbands, neighbors and

relatives. An overwhelming majority of women in each group identified themselves as the person who most influenced their decision to get the method (Table 4). The percentage of IUD users who discussed the method with their husbands was slightly higher than that of quinacrine acceptors. A higher percentage of quinacrine users (17%) than IUD users (8%) did not discuss the method with anyone else ($p<.001$). A higher percentage of IUD users (91%) compared to quinacrine users (77%) reported that their husbands approved of their method before insertion; 20% of the quinacrine acceptors compared to 8% of the IUD acceptors did not tell their husbands they had gotten the method ($p<.001$) (Table 5).

Most quinacrine users were offered food or money as compensation for time lost or transportation costs or even as an incentive to accept the method (Table 6). This practice is not unique to the quinacrine program in Vietnam and has been used for IUD and surgical sterilization services (Hieu et al., in press). Eighty percent of the quinacrine acceptors and 54% of the IUD acceptors said that they received something when they obtained their method. Over 50% of the quinacrine acceptors received food (usually rice) compared to 16% of the IUD acceptors. Thirty-four percent of the IUD acceptors said they received medicine (usually ampicillin). Close to 100% of the women in both groups said that they felt no pressure to accept the method that they chose (Table 7).

Ninety-seven percent of the quinacrine acceptors said that they signed a consent form before obtaining the method, and 84% said that the risks and benefits were explained to them prior to getting the method (Table 8). Since no consent form is required for IUD use in Vietnam, these two questions were not asked of IUD users.

Perceptions. To provide insight into their perceptions of the advantages of the method chosen, respondents were asked to identify reasons why they preferred the method they had chosen over other methods (Table 9). The most commonly given reason for women using both methods was that their chosen method was "more convenient;" 65% of the quinacrine users and 73% of the IUD users responded in this way. "Convenience" as the primary reason for method choice is expected for methods that are not user- or coitus-dependent. Quinacrine users were more likely than IUD users to say they chose the method because it was reliable or because it did not require surgery; reliability as a motivating factor makes sense in light of the high percentage of quinacrine users who had experienced a method failure prior to their quinacrine insertion. A higher percentage of quinacrine users than IUD users citing "no surgery required" perhaps indicates that they had been considering quinacrine as an alternative to surgical sterilization. No one spontaneously cited incentives as one of the reasons for undergoing the sterilization.

In order to further understand reasons for their contraceptive choices, women were asked which method they would have chosen if their current method were not available (Figure **2).** Over half the quinacrine acceptors answered "IUDs," and 17% answered "tubectomy." Four percent of the quinacrine users said "no method" while in contrast, 29% of the IUD acceptors responded that they would be using no method if IUDs were not available ($p<.001$). Over 20% said they would be using a permanent method such as tubectomy or quinacrine, and 40% said they would be using user-dependent methods: condoms, abstinence or withdrawal. Although some quinacrine and IUD users indicated that they would have had a tubectomy, this may not

have been a realistic alternative since surgical sterilization services were not readily available at this time.

Women in Vietnam had little variety in contraceptive choice during this time period. IUDs were the most widely available method, yet many of the quinacrine users had already experienced an IUD failure, which would probably motivate them to try another method. Furthermore, the results as a whole provide no evidence of coercion and indicate that women who obtained a quinacrine sterilization were highly motivated to seek a permanent method of fertility control.

2. **What were women's experiences with quinacrine sterilization services?**

The results of this study indicate that service delivery for quinacrine sterilization in Vietnam was comparable to that received by IUD acceptors of comparable ages. Generally, access to these two services was good and waiting time, with a few exceptions, was reasonable. However, certain weaknesses were identified, primarily with respect to client counseling, provider training and supervision, and client follow-up. While quinacrine respondents were asked about their experiences at each insertion visit, only the experience at the first visit is reported since there was a high level of correlation in responses between the first and second insertions.

Access and waiting time. According to the respondents in this survey, access to quinacrine services was not more or less convenient than access to IUD services (Table 10). The majority of quinactine and IUD acceptors received their services at a commune health center (74% and 69%, respectively). For the remainder, quinacrine users were more likely to get their insertion at a district maternity hospital while the IUD users went to a district hospital or polyclinic.

About90% of both groups received services at a site which was three kilometers or less from their home. Service sites were reached by walking or by riding bicycles, the most common methods of transportation in Vietnam. Nearly all the women in both groups reported that it took one hour or less to reach the clinic. The total time spent at the clinic was two hours or less for about 90% of the women with a range of less than one hour to six hours; 6% of the quinacrine users and 3% of the IUD users felt that they had waited too long.

Counseling. Counseling was evaluated in terms of important information which should have been explained to the client about their chosen method, primarily with regard to side effects. A slightly higher percentage of quinacrine acceptors (88% vs. 82%; p=.014) reported that they receive family planning counseling before receiving their method although the IUD acceptors were more likely to have received written materials with information about their method (27% vs. **10%;** p<.001). As reported by respondents, two-thirds of the IUD counseling and over three-fourths of the quinacrine counseling was done by physicians with the remainder by nurses or midwives. For nearly three-fourths of women in both groups, the person who provided counseling was the same person who performed the insertion (Table 11).

Quinacrine users were asked if they had been told about common side effects associated with quinacrine insertions such as lower abdominal pain, mild fever, headache, menstrual irregularity, and yellow vaginal discharge. While over two-thirds of the quinacrine users were

told about the possibility of yellow discharge, less than half were told about possible abdominal pain and one-third about bleeding. Only 18% of the respondents reported that they were told about the possibility of menstrual irregularities.

IUD users were asked whether they had been counseled about the primary side effects related to IUD use: irregular or excessive menstrual bleeding, discharge due to infection and pain. Two-thirds of the respondents reported that they were told about the possibility of excessive bleeding and over one-half were told about pain. Only one-fourth mentioned menstrual irregularity and one-third mentioned discharge.

Women were asked if there was any important information which they wish they had been told before receiving their method. Only six percent of the quinacrine acceptors said "yes;" most of these women wished they had more information on side effects, the effectiveness of quinacrine and the effect it could have on their health. There were seven women (.004%) who reported that they had not understood that quinacrine sterilization was a permanent method. The IUD acceptors who wanted more information (4%) had similar questions; most wanted more details on side effects, and information on the effect of the IUD on their health and on its effectiveness.

The majority of quinacrine users were not aware of the most common side effects associated with its use. While the IUD counseling was somewhat better, there was still a large percent of women who did not receive sufficient information. Since the persons who counseled the women were often the same ones who performed the procedures, it is likely that they did not have enough time to do adequate counseling. Yet, good counseling is crucial to providing quality services, and this is one area of service delivery which can be strengthened.

The procedure. While most women were supposed to receive two insertions of quinacrine, some women never returned for the second insertion. Furthermore, one investigator in Nam Ha implemented a one-insertion protocol. Nearly three-fourths of the respondents received two insertions one month apart, nearly one-fourth received only one insertion and a few received three insertions (Table 12). According to investigators, third insertions were sometimes performed in women who had a method failure or who requested a third insertion after hearing about the method failure of a friend or neighbor. For the purposes of this analysis, however, only those women who received three insertions without an intervening method failure were counted as having three insertions. According to the respondents, most of the health care providers inserting the quinacrine and theIUDs were physicians.

3. What **were women's experiences with quinacrine sterilization as a method of family planning?**

Method use affects more than just fertility outcomes and can have an impact on day-to-day experience. It is important to understand what beneficial and negative physical effects are associated with the method and how these effects relate to other activities and relationships. Physical aspects that were evaluated included side effects, illnesses, hospitalizations, other health outcomes, pregnancies and menstrual pattern changes. The "clinical" results reported here were based solely on women's reports. While women may have interpreted certain outcomes, such as illnesses and hospitalization, as being caused by method use, these are not clinical judgments.

These reports are important because they can affect women's evaluations of satisfaction and acceptability of the method.

Side effects. The side effects reported by quinacrine and IUD users were similar to those reported in other studies (El Kady et al., 1993; Agoestina et al., 1992; Arshat et al., 1987). While most quinacrine acceptors reported some type of complaints associated with their method, most of these complaints were for minor problems. Table 13 shows that 67% of quinacrine users said they experienced at least one side effect after their insertion(s). The most common complaints among the respondents were yellow discharge (42%) and pain (22%). Nineteen percent of the quinacrine acceptors went to a health facility because of a problem. Yellow discharge and pain were the main reasons for returning. Although fewer women experienced itching, menstrual irregularities and headache, the ones who did were more likely to return (45%, 41% and 34%, respectively; not shown in table) than women who reported other side effects.

Fewer IUD users (44%) reported side effects, and only 11% returned to a clinic because of a problem. The most common complaints were bleeding and pain although they occurred in only about 15% of the respondents. Bleeding and pain were also the most common reasons for returning to a health facility, although the women who complained of cervicitis or backache and abdominal pain had the highest percentages returning to the clinic (55% and 30%, respectively; not shown in table).

Overall, there was a significant difference between the percentages of quinacrine users and IUD users returning to a health facility because of complaints ($p<.001$). Furthermore, within individual categories of side effects, the quinacrine users were always more likely to return for pain or irregular menses (Figure 3). This might signify that the problems experienced were more severe, or it could indicate women's awareness of quinacrine's more experimental status. It may also reflect the need for more adequate counseling because they may not have not that they were experiencing common side effects.

Illnesses since insertion. Respondents were asked to report any illnesses they had since their insertion (Table 14). Fifty-seven percent of quinacrine users and 43% of IUD users reported having an illness, and the types of illnesses varied. The primary complaint among the quinacrine users who had an illness was fever (64%) and, to a much lesser extent, gynecological problems (11%). While fever was also the most common illness among IUD acceptors, it was only experienced by 32% of the group; an additional 25% reported problems due to arthritic disease.

Hospitalizations. The percentages of hospitalizations were roughly similar for both groups, and fewer than half of these were gynecological in nature. Less than 10% of women interviewed reported that they had been hospitalized (either on an inpatient or outpatient basis) since their insertion (9% of quinacrine acceptors and 6% of IUD acceptors; $p=.015$) (Table 14). Though this difference is statistically significant, the absolute difference is small and can perhaps be explained by the greater number of quinacrine users who were hospitalized as a result of a method failure. Of the women hospitalized, approximately 40% in each group reported a hospitalization that was due to a gynecological or obstetrical problem. In the quinacrine group, half of these hospitalizations were pregnancy-related reasons: MR or abortion, a tubal ligation and, in six cases, an ectopic pregnancy. Most of the remainder were hospitalized for menstrual

difficulties, such as menorrhagia and dysmenorrhea. The majority of the IUD hospitalizations in this category were menstrual-related or due to endometritis. Three women using an IUD reported they were hospitalized because of an ectopic pregnancy. The second most frequently cited reason for hospitalization in both groups was a fever or infectious disease.

One percent of respondents in each group reported that they had been diagnosed with a cervical or uterine tumor. The period of time from insertion to interviews did not permit any determination of either method's possible association with malignancy. Most of the quinacrine users had less than five years experience with the method and studies attempting to establish a causal relationship with cancer frequently discount the first four to five years of follow-up data. Assessing the risk of carcinogenesis in humans requires longer follow-up, usually on the or&r of 10-20 years.

Other health outcomes. Women were asked to describe other changes in their health since their quinacrine or IUD insertions (Table 15). Among the quinacrine users, the five most frequently cited changes included: lightheadedness (24%); weight loss (19%); weakness (16%); weight gain (14%); and headaches (10%). Among IUD users, the greatest percentages of women said they had experienced lightheadedness (20%); weight loss (16%) and headaches (14%).

Pregnancy among quinacrine users. Two-hundred and twenty-two quinacrine acceptors (13%) reported a pregnancy or a suspected pregnancy after one or more quinacrine insertions (Table 16). Among these, 78% had a menstrual regulation or an abortion. Since no pregnancy tests were done and no pathology reports were available, it is not possible to know with complete accuracy how many of the women who had MRs were truly pregnant. The percentages and rates estimated here are thus the upper bounds of the true pregnancy rates.

Pregnancies resulted in live births for 11% of the women reporting pregnancies. Nearly 3% of these women were still pregnant at the time of the interview. Ectopic pregnancies were reported by six women who had experienced method failures or 0.34% of the total sample.

Pregnancy rates were calculated using the lifetable method and compared on factors thought to be related to failure rates: number of insertions; age at insertion; district as a proxy or indicator variable for variations in service delivery characteristics; and IUD use immediately prior to quinacrine insertion. Because of the large difference between the pregnancy rates for one- vs. two or more insertions ($p<.001$), all rates were disaggregated by number of insertions. The one-year pregnancy rate for women with two insertions was .05 compared to .17 for women with only one insertion. At three years these rates were .11 for women with two or more insertions and .28 for women with one (Table 17).

When the rates were further disaggregated by age categories (< 35 years vs. 35 or older), it was found that there also was a significant main effect for age. Women in the older categories had lower failure rates than those in the younger categories for each insertion group ($p<.001$) (Table 18). Among all the women receiving two or more insertions, those under 35 had a 12-month pregnancy rate of .06 compared to .04 for those in the over 35 group. Among those in the one insertion group, the 12-month pregnancy rate was .25 for the younger women and .11 for the older ones (Table 18).

Noticeable differences were seen in the pregnancy rates calculated by district for women receiving two or more insertions but not for those receiving one insertion because of the low

numbers in many of the individual districts (Table 19). One year rates ranged from .01 in the Nghia Hung and Nam Thanh districts to .07 in Quynh Phu and Ly Nhan. Thi xa TB was dropped from this analysis because of the small number of women in this district.

The variability in effectiveness rates in different districts may indicate differences in the skills of the insertors. Hieu and his colleagues have acknowledged the difficulty of providing adequate training in insertion techniques and the need for a standardized technique emphasizing high fundal placement of the quinacrine pellets, taught under close supervision of skilled clinicians. Hieu reported that by the end of 1992, 1307 physicians and midwives were performing quinacrine insertions (Hieu et al., 1993). The fact that so many physicians and midwives began participating in the quinacrine services program made quality control difficult and may have lead to higher rates of method failure than was found in small scale clinical trials in other countries.

Parallels are found in the research literature on postpartum IUD insertion. In areas where the method was widely introduced to a large number of providers without adequate supervision of training the results showed very high expulsion rates (Chi, 1994). This situation has been reversed, however. Newer studies of postpartum IUD insertion demonstrate very low expulsion rates where training and insertor competence are emphasized (Mate et al., 1994).

Although only providers who agreed to client follow-up were supposed to be trained for the introductory trial, the majority of women who had only one insertion were supposed to have two insertions. In view of the much higher pregnancy rates for one as compared to two insertions, mechanisms to ensure follow-up for those who do not return for the second insertion need to be established. During counseling women need to be aware of the higher risk of failure associated with one insertion. Also, better counseling on side effects could minimize the number who fail to return after one insertion because of problems they experienced.

A further analysis was conducted to determine if IUD use prior to quinacrine insertion might increase a woman's risk of method failure (Table 20). Researchers questioned whether the possibility of blood in the uterus after IUD removal might interfere with the action of quinacrine. When pregnancy rates were compared for women who did and did not have an IUD removed prior to quinacrine insertion, no difference was found. When rates were calculated for age and prior IUD use, no interaction was found. A main effect for age continued (higher rates for younger women), but no effect for IUD use occurred within either of the two age categories (not shown in tables).

A complicating factor in determining pregnancy rates in this survey is that the calculations were based solely on women's reports of pregnancy. In a majority of these cases, however, the "pregnancy" ended in an MR but was never confirmed. Pregnancy tests are not done routinely (pregnancy test kits are not generally available in Vietnam). Furthermore, a woman in Vietnam will typically have an MR even if she is only a few days late with her period (Gorbach, 1994). While one cannot actually estimate the "true" pregnancy rate from these data, one small survey done by the Thai Binh MCH/FP Center found that up to one-third of the MRs performed in their study were unnecessary (Ministry of Health, Vietnam, unpublished report). Therefore, it is likely that the pregnancy rates estimated from these data are higher than the true pregnancy rates.

Ectopic pregnancies. There were six ectopic pregnancies, four in women with two insertions and two in women with one insertion. Both one-insertion ectopic

pregnancies were among women over 35 years old; two-insertion ectopic pregnancies occurred in three women less than 35 and one woman over 35. Two ectopic pregnancies occurred in the first year of quinacrine use; two occurred in the second and two occurred in the third year. The rates per 1000 woman years are 1.33 for women with two insertions and 2.83 for women with one insertion. The rate after one insertion is higher, but the difference is not statistically significant, p=0.3. Women with only one insertion might be at higher risk for ectopic pregnancy, but this study is too small to address that issue.

The overall rate of ectopic pregnancies per 1000 person years is 1.62. This rate is difficult to interpret for several reasons: (1) the study was not designed to look at rates of ectopic pregnancy; (2) the number of ectopic pregnancies is small, only 6 cases; and (3) the rates of ectopic pregnancy per 1000 women years in other populations of Vietnamese women, such as non-contracepting women, women using IUD's, or women who have been surgically sterilized, are not available for comparison.

Comparisons with data from other populations is difficult because of different standards of diagnosis, and because of the wide temporal, ethnic and geographic variations in rates of ectopic pregnancy. For example, the rate of ectopic pregnancy in the US has been steadily increasing over the past 20 years. In the US, rates of ectopic pregnancy are generally higher in non-white women and in older women.

Sivin (199 1) estimated that among cohabitating, non-contracepting women in the US during the period 1970-78, that the rate of ectopic pregnancy per 1000 women of all races was about 4 to 5 per 1000 woman years among women aged 25 to 44. In the same report, Sivin gives the following ectopic pregnancy rates per 1000 person years among women that were observed during studies of the two USFDA-approved IUDs currently available in the US: for the TCu380A, a rate of 0.2 per 1000 women years; and for the Progestasert, a rate of 5.4 to 7.5 per 1000 woman years. (The relatively high proportion of ectopic pregnancies seen with some types of IUDs probably are not caused by the IUD, but rather result because the IUD is very effective in preventing intrauterine pregnancies but not tubal pregnancies.) The rate of ectopic pregnancy observed in this study following one or two insertions of quinacrine pellets, therefore, is within the range seen with the use of FDA approved IUDs.

Pregnancy among IUD acceptors. Eighteen percent of IUD acceptors reported a failure of their most recent IUD use (Table 21). Over half of the most recent method failures terminated in abortions or menstrual regulations. Over one-third of them ended in live births. Most women who reported having an IUD method failure for their most recent IUD, were using a method of contraception at the time of the interview, and most of these women were using an IUD. After the IUD, tubectomy and quinacrine were the methods most often used, though by a much lower percentage. Pregnancy rates were not calculated for IUD acceptors because the date of pregnancy was not collected.

IUD removals. Seventy-six percent of the IUD acceptors had an IUD at the time of the interview (Table 22). IUDs had been removed in nearly a quarter of the sample due to method failures, medical reasons and personal reasons. Medical reasons for termination included: expulsion (19%); bleeding and pain (22%); method failure with no reinsertion (10%); and infection (7%). Nearly one-fourth of those who had a removal said they wanted another method, primarily sterilization, and 6% had their IUDs removed for a planned pregnancy.

Menstrual **pattern changes.** Women were asked questions about their menstrual and intermenstrual bleeding and pain. During the three months prior to the interview, current users in the IUD group reported heavier menstrual flow compared to the women in the quinacrine group (Figure 4). Consistent with this, when asked to compare menstrual flow before and after method insertion, quinacrine acceptors were more likely to say that flow was lighter afterwards, and current IUD users were more likely to say that it was heavier than before they received the method (Figure 5). This is also consistent with the results concerning the number of bleeding days. Quinacrine users were more likely to report a shorter than average number of days of bleeding compared to IUD users (3.9 for IUD users and 3.0 for quinacrine users) (Figure 6). Intermenstrual bleeding was reported in equally small percentages (<6%) for both quinacrine and IUD users (not shown). Dysmenorrhea (painful menstruation) was more likely to be experienced by IUD users than by quinacrine acceptors during the three months prior to the survey (Figure 7), though equal percentages of women in each group reported dysmenorrhea prior to quinacrine or IUD insertion (not shown).

The data are consistent with previous studies of both methods. Quinacrine acceptors reported less menstrual and intermenstrual bleeding and pain associated with their method use than did the IUD acceptors. The increase in bleeding and pain associated with IUD use is thoroughly documented (Rybo & Andersson, 1994). Clinical trials of quinacrine sterilization also have demonstrated a decrease in menstrual bleeding and pain (El Kady et al., 1993; Arshat et al., 1987). The comparison of menstrual pain and bleeding between quinacrine and IUD users may seem somewhat biased due to the increased pain and bleeding usually associated with IUDs. However, quinacrine's effect on the endometrium is probably similar to an endometrial curettage, which is often used to treat dysfunctional uterine bleeding in older women in developed countries (Mattingly & Thompson, 1985). Thus the perceived decrease in menstrual bleeding and pain is probably real. Prospective studies where baseline and follow-up data can be collected will be needed to further consider this matter.

Daily life experiences. The use of contraceptive methods has varying effects on the daily lives of their users. These effects result from both the physical experience of method use (side effects, menstrual pattern changes, complications, and method failures) and the social experience (support of partner, family and friends for limiting fertility and/or using a method and the ability to fulfill important roles despite physical side effects). The effects of certain methods on these daily life experiences have received little attention in the research literature until recently, and much needs to be learned about what the effects are and how to measure them. They are of extreme importance in the ways in which women make decisions about whether and which method they use. The questions asked in this survey have no precedent and should be considered a first step in thinking about what to ask. Resource constraints limited our ability to do more

qualitative work prior to questionnaire development, though the need for further work of this type is suggested by the current findings. Because questions like this are so infrequently asked of women in this context, the range of possible responses could not always be anticipated; thus, a mixture of open-ended questions and pre-coded multiple choice questions was used. The response categories used in the multiple choice questions were based on answers to pretest questions before the study was initiated.

Forty percent of women in both samples responded that they did feel differently about themselves after the use of their method. The wide variety of responses is listed in Table 23. Most of these answers were related to their physical well-being and included: health was worse or better, fatigue, headaches, backaches, dizziness, or weight gain or loss.

It is clear that some women felt that method use was related to feelings about themselves, their relationships with others and their ability to carry out various roles and duties. There were also apparent differences between the groups of women. Twenty-three percent of IUD users said that it had affected their ability to do farm work compared to 18% of quinacrine users (p=.004). Twice the percentage of IUD users (15%) than quinacrine users (7%) reported that it affected their ability to do housework. Though we have no way to know for sure, this is likely to be related to increased menstrual bleeding and pain.

Women were also asked whether their contraceptive method use affected various aspects of their lives such as their family relationships or their ability to carry out specific roles (Table 24). Only very small percentages of women in each group said that method use had affected their relationships with their husbands, other family members or ability to care for children. When women were asked how method use had affected these aspects of their lives, most of the small percentage of women described the negative ways it had done so: It had made it harder to do work or caused fatigue. Among quinacrine users, these explanatory answers, however, were from less than half of those who cited some effect.

In order to examine one further indication of the effect of method use on their lives, women were asked whether their sex lives were better, worse or the same as before the insertion (Table 25). More of the IUD acceptors reported "no change" as compare with quinacrine acceptors (93% vs. 83%, respectively), with more quinacrine users than IUD users reporting less satisfaction with their sex life (15% vs 7%; p<.001). This finding is supported by other responses in Tables 23 and 24.

At least one study of the relationship between surgical sterilization and sexuality has shown a decrease in excitement in sexual life, though a review of the literature in the same paper indicates that most other research has found improved or unchanged libido, coital frequency or sexual satisfaction (Kjer, 1990) However, focus group discussions conducted for another study in Vietnam found that fears of surgical sterilization were partly due to expectations of a decrease in sex drive (Hieu et al., 1994). Therefore, the reports of a worse sex life could be a consequence of the expectation of lower sex drive after any type of sterilization. This issue deserves further analysis and study.

4. **What were the levels of satisfaction or regret among quinacrine sterilization acceptors?**

Answers to global questions about satisfaction (e.g., "How satisfied were you with...?") usually are unsatisfactory to researchers because respondents tend to provide favorable answers,

and there is little variance in the responses to these questions despite variations in other aspects of experience with the method. In an attempt to avoid this, a number of questions were asked to tap several dimensions of satisfaction, such as whether the method was a good choice, fears about pregnancy, and the best and worst things about the method. Satisfaction was also evaluated in terms of support or disapproval of family member and friends.

Satisfaction. Eighty-six percent of the quinacrine acceptors and 80% of the IUD acceptors interviewed felt their method was a good choice of contraception for them (Table 26). Nine percent of the quinacrine acceptors and 5% of the IUD acceptors, however, felt that it was not a good method because they had gotten pregnant. Three percent of the respondents in the quinacrine group cited health problems as the reason it was not a good method compared to 6% in the IUD group. Less than one percent (0.02%) said they had wanted more children.

Since the purpose of contraception is to prevent pregnancy, it was expected that method use would alleviate fear of pregnancy. In response to questions about fear of pregnancy, 61% of the quinacrine group and 57% in the IUD group said they never felt worried about getting pregnant, while lower percentages of women in the two groups (8% and 7%, respectively) worried frequently about this (Table 27). Though this was more than half the women in each group, the percentage who say they never worry about pregnancy was far less than expected.

To see how having a method failure affected the responses to questions about fear of pregnancy and whether or not the method was a good choice, results to these questions were examined separately for women with and without method failure (Table 28). Women in both method groups were much more likely to say that the method had been a good choice for them if they had not had a failure than if they had ($p < .001$ for each method group comparison). Women who were using either method and who experienced a failure were more likely to sometimes or frequently worry about a pregnancy than were women who had never had a failure ($p < .001$ for each method group comparison).

Women were asked in open-ended questions to identify the best and worst things about the method (Table 29). The most common responses from quinacrine users with regard to the best thing was that it "prevents pregnancy/reduces the need for abortion" **(23%);** it is a "permanent method" (23%); it is "safe" (14%); it "improves health" (11%); and it is "convenient" (9%).

A larger percentage of IUD acceptors said that the best thing was that it "prevents pregnancy" (59%), while the next most common responses were "convenience" (12%) and "improves health" (8%). The majority of both the quinacrine and IUD acceptors either said that they could not think of anything bad about the method or gave no response to the question on the worst thing about their method. Among those who could identify the worst thing, the responses from the two groups were similar, with respondents most often citing worsening health, method failures and side effects.

Quinacrine and IUD acceptors reported support from friends and family for their method use. Eighty-eight percent of quinacrine users and 93% of IUD users had been told by friends or family of their approval for their method use. Seventy-six percent of quinacrine users and 93% of IUD users had heard no disapproval spoken by friends or family members (Table 30). The higher percentage of disapproval expressed to quinacrine users compared to IUD users can

perhaps be attributed to less familiarity with quinacrine because of its more recent introduction as a contraceptive method in Vietnam.

Women in the study were asked whether they had ever recommended the method to anyone else. Eighty-eight percent of the quinacrine and IUD acceptors had recommended it to someone else (Table 31). Those who had not done so and who responded to the question of why they had not said that they either wanted to keep their use a secret or had not had an occasion to do so. Only 1% of the IUD group cited dissatisfaction (side effects) as a reason for not recommending the method.

Regret

Regret is a concern related to methods that cannot be reversed.' High levels of regret may indicate inappropriate pressure or inadequate counseling and screening of clients. Regret was measured in this study by asking if and why quinacrine users felt regret and whether they wished they could change their mind about their sterilization. Conversely, lack of regret was measured by asking if a woman wishes she could have had the procedure earlier. Published studies on surgical sterilization have reported rates of regret from 1% to 25%. Regret cannot be completely eliminated because it often is a response to changes in women's lives, though it can be reduced through effective counseling and screening of sterilization candidates. (Bartfai and Kaali, 1989; Bertrand, et al., 1991; Islam and Rahman, 1993; Kjer, 1990a; Grubb et al., 1985; Hapugalle, Janowitz et al., 1989; McGonigle and Huggins, 1990; Pitaktepsombati and Janowitz, 1991; and Wilcox, et al., 1991).

Only 2% of quinacrine users said that they regretted having done something that would prevent them from having more children (Table 32). However, further examination of their reasons for regret showed that less than half of these women specifically said that they wanted more children. The most common other reason stated was "method failure," which should be considered a measure of dissatisfaction rather than of regret. The low percentage of women reporting regret because they want more children can be interpreted as providing evidence that women were appropriately informed about the permanent nature of this procedure and not pressured or coerced. This is consistent with other findings which were already presented. None of the seven women who reported that they did not understand that quinacrine was a permanent method before acceptance expressed regret when this question was asked (not shown). **As expected,** when this measure of regret was stratified by method failure, there was little relationship between failure and regret (Table 32).

When women were asked if they could change their minds about getting the method, however, a greater percentage -- 11 — said "yes." The reason most women gave was method failure (Table 32). Forty-one percent of those who had a method failure compared to 5% of those who had not said that they wished they could change their minds($p<.001$).

Sixty-two percent of the quinacrine acceptors said that they wished they had the procedure done earlier indicating a need felt by women for greater availability of permanent methods ($p<.001$) (Table 32). Consistent with the above results, the percentage of women wishing they had had the procedure earlier was nearly twice as high (66%) for those with no failure as for those with a method failure (35%).

Nearly 6% of the women said that their husbands had expressed regret over the sterilization; on the other hand, 70% of the women, said that their husbands had told them they

were glad about the sterilization (Table 33). Of the women who reported regret, 45% had husbands who had expressed regret about the quinacrine sterilization (not shown).

Fear of cancer

When respondents were asked if they had heard anything in the news about quinacrine, 87% said they had not, 8% said they had heard that the method was effective and 1% had heard that it had no side effects (Table 34). Only 1% had heard that it caused cancer and an additional 1% heard it was unsafe. A fear of cancer or a more generalized concern for safety was found by a similarly small percentage of women in responses to open-ended questions such as "reasons why the method was not a good choice" and "worst things about the method." For the first question, 1% said they felt the method was not safe, and less than 1% mentioned a fear of cancer specifically (Table 26). To the second question, 3% answered that fear of disease was the worst thing, and another 1% answered that feeling that the method was not safe was the worst thing (Table 29).

5. Data limitations

A limitation to any retrospective survey is that the quality of the data collected is dependent on the respondents' memories. In this study, women were interviewed who had their insertions up to five years before the survey. Conversely, there were also women interviewed who had less than six months experience with their method, which may not be enough time to adequately assess satisfaction and regret. However, the outcomes of interest are perceptions related to use and these are necessarily influenced by the passage of time. While they may not represent "objective" truth, these perceptions are the truth that women use to make judgments about future use and the information that they pass along to other women. The possibility exists that the user of a newer method of contraception might remember the negative aspects of the method because of its more "experimental" status; on the other hand, quinacrine users may have dismissed some of the side effects to justify their use of a permanent method.

Another concern is a "courtesy bias" influencing respondents to give more favorable responses that they think the interviewer wants to hear. This bias may have been especially strong because respondents were interviewed in their homes, which often are crowded. While this bias may be stronger in Asia than in other parts of the world, it is found within all research. Also, we do not expect that this demand bias would affect the responses of the quinacrine group differently than those of the IUD group. Also, investigators were concerned that perceptions of quinacrine users might be negatively biased by the media coverage of the quinacrine controversy just months prior to the survey, but there is no evidence that this occurred.

Unfortunately, due to logistical issues, the surveys of quinacrine and IUD acceptors were conducted sequentially rather than simultaneously. This could have led to some differences in the ways the questions were posed by the interviewers, as well as different responses concerning recent events. For example, the high level of reported fevers among the quinacrine acceptors might reflect the occurrence of an epidemic of infectious disease (e.g. influenza) in the months immediately preceding the quinacrine interviews.

Another possible limitation of the data results from the use of the district hospital logbooks for the IUD sampling frame. In Hai Hung province, most of the names of the women

in these logbooks actually had their IUDs inserted in the hospital, whereas in the other two provinces, these logbooks contained the names of women who had IUDs inserted by teams of doctors in mobile units who went to the commune health centers to deliver services. It also was necessary to drop 10% of the women from the sampling frame due to insufficient addresses. It is possible that women with difficult to find addresses may differ from other women in some way.

CONCLUSIONS AND RECOMMENDATIONS

A The results demonstrate that, overall, the respondents in this study were satisfied with their use of quinacrine and did not regret their decision to get sterilized. Furthermore, the decision to use quinacrine was typically made by the woman herself, usually in consultation with her husband. The results do not provide any evidence of undue pressure or coercion. However, the findings do point to certain weaknesses in the service delivery structure, which affected the quality of care the women received. Finally, questions remain about the optimal means of administering quinacrine. While this uncertainty is not specific to Vietnam, it is an issue which, nonetheless, must be resolved.

The issues related to quinacrine services are both clinical and programmatic. From a clinical standpoint, this study validates other research findings, which have found quinacrine to be a safe method of contraception in the short-term. It does not appear to be as effective as surgical sterilization, but effectiveness can be improved by (1) requiring a two-insertion procedure and (2) limiting use to women 35 years or older.

Controlled clinical trials need to be conducted in order to determine the most effective means of quinacrine administration. While the data from Vietnam demonstrated clinically significantly lower pregnancy rates with two insertions, other data have suggested that one or two insertions, with the use of an adjuvant such as ibuprofen, can result in low pregnancy rates. Also, particular insertion techniques may improve effectiveness.

The evaluation of long-term safety and effectiveness was not within the scope of this study and can only be assessed through longitudinal data collection. Family Health International plans to continue to follow this cohort of women to provide the information necessary to address concerns such as ectopic pregnancy, cancers, and hospitalizations and illnesses that may have been related to quinacrine.

Programmatically, several elements of service delivery need to be improved for both quinacrine and IUD services to improve quality of care: counseling (information to users), provider training and supervision (technical competence), and client follow-up (continuity of care). While most quinacrine users received family planning counseling, the majority were not aware of the most common side effects associated with quinacrine. Improved counseling and information about expected side effects could improve levels of satisfaction with the method and may also decrease the number of women who fail to return for their second insertion. Counseling would also alleviate fears that may result from rumors or misconceptions. Counselor training workshops should be conducted to give providers comprehensive family planning information and improve their communication skills.

The clinical training for quinacrine service providers was often inadequate, and follow-up and supervision of providers was minimal. These results emphasize that future training would have to be more rigorous and providers would have to be monitored to ensure they are using the proper techniques. The lack of adequate training may have resulted in higher pregnancy rates and subsequently led to dissatisfaction in those women who experienced a method failure. Follow-up of clients to ensure that they return for their second insertion also needs to be an integral part of quinacrine services. This is especially important in view of the higher pregnancy rates seen with one insertion. Also, women should be monitored more closely because quinacrine is a relatively new method of contraception.

The retrospective survey is a first step in a developing area of research: the effect of family planning on women's lives. Further multivariate analyses will be done to determine the relationships between satisfaction and regret regarding women's experiences with the method and their personal characteristics. Method acceptance and satisfaction among those who wish to limit their fertility might be improved by additional qualitative research on the use of quinacrine. This could provide information relevant to how women make decisions about method use and could describe more clearly how the use of this method affects their day-today lives. Research on women's perspectives also can provide insights into how quality of care could be improved.

Should the quinacrine sterilization program be restarted in Vietnam? To answer this question, it is important to consider the place of quinacrine within the context of a changing family planning program. While the introduction of quinacrine was a logical response to existing conditions in Vietnam at that time, current circumstances necessitate a rethinking of the program.

As the presence of international donors increases in **Vietnam,** more funding has become available, which should assist in the training of family planning providers as well as in the provision of other family planning methods. In practical terms, this means that method choice is expanding as oral contraceptives, injectables and surgical sterilization become more widely available. Also, **clinical traingin** and newer IUDs can make this method a more attractive choice. Furthermore, the TCu380 IUDs are now recommended for up to 10 years of use and may be a reasonable alternative, especially for many women who are under 35 years of age. Women who experience unacceptable pain and bleeding associated with the IUD, however, may want to have the option of quinacrine sterilization available. Further research into the acceptability of IUD use, especially with newer longer lasting IUDs, should be conducted to make this determination.

While quinacrine seems promising as a contraceptive choice, this paper has noted many issues which still remain, including efficacy, safety and appropriate service delivery mechanisms.

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TABLES

Table 1. Province and district of respondents

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Province/ District		
Nam Ha	51	51
Binh Luc	10	10
Ly Nhan	10	10
Hai Hau	24	24
Nghia Hung	6	6
Hai Hung	26	26
My Van	10	10
Cam Binh	7	7
Nam **Thanh**	5	5
Chau Giang	4	4
Thai Binh	23	23
Dong Hung	10	10
Quynh Phu	7	7
Kien Xuong	4	4
Thi xa TB	2	2

*Totals may not equal 100% due to rounding

NOTE: For all tables, **N** = unweighted sample size

Table 2. Sociodemographic characteristics

	Quinacrine acceptors (N= 1679) %*	IUD acceptors (N-1511) %*
Age at insertion		
25-29	10	10
30-34	35	35
35-39	39	39
40-44	15	15
45-49	**<1**	0
Age		
-mean	**34.9 years**	34.3 years
-standard error	0.692	0.720
Currently married	**99.5**	**98.5**
Living children (at interview)		
o-1	**<1**	7
2-3	53	67
4-9	47	26
Missing	**<1**	
Number of living children**		
-mean	3.6	**2.9**
-standard deviation	0.074	0.078
Age youngest **child** (at interview)		
O-3	15	28
4-10	65	56
11 or older	19	16
Missing	**<1**	**<1**

*Totals may not equal 100% due to rounding
**p<.001

Table 3. Contraceptive history

	Quinacrine acceptors (N= 1679) %*	IUD acceptors (N=1511) %*
Previous use of birth control**		
None	6	2
IUD	88	70
Pill	12	4
Condom	10	13
Injectable	8	1
Withdrawal	12	12
Abstinence	9	10
Quinacrine	--	2
Tubal ligation	<1	1
Other	--	1
Method failure+		
No	57	85
Yes, once	26	12
Yes, more than once	17	4
Missing	<1	
Specified **failures*****	(N=950)	(N=245)
IUD	85	59
Withdrawal	8	14
Abstinence	4	6
Condoms	1	12
Pills	1	4
Quinacrine	<1	5
Abortions/MRs+		
0	39	63
1	21	22
2 or more	32	15
Missing	7	
Mean number abortions/MRs	1.3	0.6

*Totals may not equal 100% due to rounding
**More than one response is possible
***Denominators reflect the number of failures. Up to two failures per woman are possible; 711 quinacrine users reported 950 failures and 230 IUD users reported 245 failures.
+p<.001

Table 4. Sources of information and influence about method

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Where first heard about the method		
Health care provider	60	51
Friend/neighbor/relative	25	18
Women's Union	12	24
Mass communication	1	<1
Youth Union	<1	<1
Communal leader	<1	1
Can't remember	1	5
Other	<1	<1
Knew anyone **who used method before insertion****	60	88
With whom discussed method before insertion*		
Husband	76	87
No one**	17	8
Friends	15	21
Relatives	12	16
Health care provider	5	6
Women's Union	<1	--
Other	<1	<1
Greatest influence to woman to get method?		
Herself	91	90
Husband	4	7
Health care provider	3	2
Women's Union	1	<1
Friend	<1	<1
Relative	<1	<1
Other, unspecified	<1	<1

* Multiple responses possible for each woman.
**p<.001

Table 5. Husband's approval

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Husband approved before insertion		
No	3	1
Yes	77	91
Didn't discuss*	20	8
Not applicable	<1	<1

*p<.001

Table 6. Compensation/incentives

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
What woman received when accepting method		
Nothing	20	46
Food	53	16
Money	17	1
Both	4	<1
Medicine	5	34
Other	<1	<1
Doesn't remember	<1	1

Table 7. Pressure to accept method

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Who pressured woman to get method?		
No one	99	99
Health care provider	<1	0
Family planning worker	<1	0
Husband	0	<1
Other, unspecified	<1	0

Table 8. Informed consent*

	Quinacrine acceptors (N= 1679) %
Were risks and benefits of method explained before insertion?	
No	16
Yes	84
Don't know	**<1**
Did you sign a consent form before insertion?	
No	**3**
Yes	**97**
Don't know	**<1**

* Informed consent is not required of IUD acceptors.

Table 9. Reasons for method choice*

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Reasons for getting method		
Convenience	60	64
Reliability	56	32
Long-term protection	30	12
Fewer side effects	16	11
Other methods difficult to get	5	15
Don't have to remember anything	1	6
Don't know	1	3
Not permanent	NA**	9
Reasons preferred to other methods		
More convenient	65	73
More reliable	63	42
No surgery required	24	10
More available	6	22
Better incentive	0	<1
Don't know	2	7

* More than one response may be given by each woman.
** NA=Not applicable

Table 10. Access to services and waiting time

	Quinacrine acceptors (N= 1679) %*	IUD acceptors (N=1511) %*
Insertion performed at		
Communal health center	74	69
District maternity	18	<1
District hospital	7	10
Polyclinic	<1	20
Other	<1	<1
Number kilometers from home		
3 km or less	89	92
4-10 km	10	8
More than 10km	<1	<1
Time to get to clinic		
1 hour or less	98	99
2-3 hours	2	1
Transport to clinic		
Walk	54	49
Bicycle	46	50
Other	1	1
Total time at clinic		
2 hours or less	89	94
3+ hours	11	6
Waiting time too long	6	3

*Totals may not equal 100% due to rounding

Table 11. Counseling

	Quinacrine acceptors (N-1679) %	IUD acceptors (N=1511) %
Received counseling before procedure*	**88**	**82**
Received written materials**	10	**27**
Who counseled	**(N=1468)**	**(N=1235)**
Nurse	10	6
Midwife	11	25
Physician	77	66
Don't remember	2	2
Missing	**<1**	
Same **person as insertor**		
Same	**74**	**77**
Different	**24**	**22**
Don't know	1	1
Missing	**<1**	
Told about possible problems***		
No/no answer	**17**	**10**
Pain	**44**	**53**
Bleeding	**33**	**68**
Discharge	**70**	**34**
Pelvic heaviness	11	
Menstrual irregularity	18	**24**
Headache	1	**3**
Fever	3	**<1**
Itching	8	--
Other	2	1
Don't remember	2	--
Told where to get help	**83**	**90**
Important information wish you had **been told**	**6**	**4**
What information		
Side effects	**(N=107)**	(N-56)
Can get pregnant again	**63**	76
Method is permanent	**20**	6
Bad influence to health	**7**	--
other	**5**	15
	5	2

*p=.014
**p<.001
***More than one answer possible.

Table 12. Insertion procedure

	Quinacrine acceptors (N= 1679) %*	IUD acceptors (N=1511) %*
Number of insertions		
One	24	100
Two	74	NA**
Three	2	
Who inserted		
Nurse	1	2
Midwife	7	17
Physician	89	79
Don't know	3	3
Missing	<1	

*Totals may not equal 100% due to rounding.
**NA=Not applicable.

Table 13. Side effects

	Quinacrine acceptors (N= 1679) %*	IUD acceptors (N=1511) %*
Experienced problems		
None	34	56
1	32	26
2 or more	35	18
What problems**		
Pain	22	14
Bleeding	12	15
Discharge	42	9
Pelvic heaviness	11	7
Menstrual irregularity	9	11
Headache	12	6
Itching	4	
Other	6	4
Return to clinic because of problems***	19	11

*Totals may not equal 100% due to rounding.
**More than one answer possible.
***p<.001

Table 14. Illnesses and hospitalizations since insertion

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Illnesses since insertion	57	43
what **illness***	**(N=1111)**	**(N=747)**
Fever/infectious disease	64	32
Ob/gyn	11	8
Digestive system	8	9
Nervous system & sense organs	7	15
Arthritic disease	4	25
Urology	2	3
Circulatory/pulmonary	2	5
Other	2	3
Missing	**<1**	16
Hospitalized**	**9**	**6**
For specified reasons	9	6
For non-specified reasons	**<1**	**<1**
Specified reasons	(N= 147)	**(N=84)**
Ob/gyn	39	38
Fever/Infectious disease	18	14
Nervous system & sense organs	13	7
Digestive system	18	13
Circulatory/pulmonary	4	9
Other***	8	18
Uterine or cervical cancer	1	1

*Denominator reflects number of illnesses. A woman may report up to three illnesses; 954 quinacrine users reported 1113 illnesses and 645 IUD users reported 78 1 illnesses.

****p=.015**

***No individual reason more than 6%.

Table 15. Changes in health noticed since insertion

	Quinacrine acceptors (N= 1679) %	IUD acceptors (N=1511) %
Changes in health since insertion*		
Lightheadedness	24	20
Weight loss	19	16
Weakness	16	8
Weight gain	14	2
Headaches	10	14
Pelvic heaviness	7	3
Mood changes	6	1
Backache, abdominal pain	5	5
Pelvic tenderness	3	2
Infection	3	2
Health improved	2	<1
Vaginal discharge	1	<1
Health worse	1	<1
Fever	1	
Amenorrhea	1	<1
Itching	<1	
Hemorrhage	<1	<1
Loss of libido	<1	<1

* More than one response possible per woman.

Table 16. Method failures for quinacrine acceptors

	Quinacrine acceptors (N= 1679) %
Percentage of quinacrine acceptors reporting pregnancy	13
Results of pregnancy	(N-222)
Live births	11
Stillbirths	1
Miscarriage	4
Abortion/MR	78
Ectopic	2
Still pregnant	3
Missing	1
Method of contraception used after quinacrine failure	**(N=222)**
None or still pregnant	26
IUD	21
Tubectomy	14
Quinacrine	4
Pills	4
Condoms	5
Abstinence	11
Withdrawal	9
Vasectomy	1
Injectable	1

FIGURES

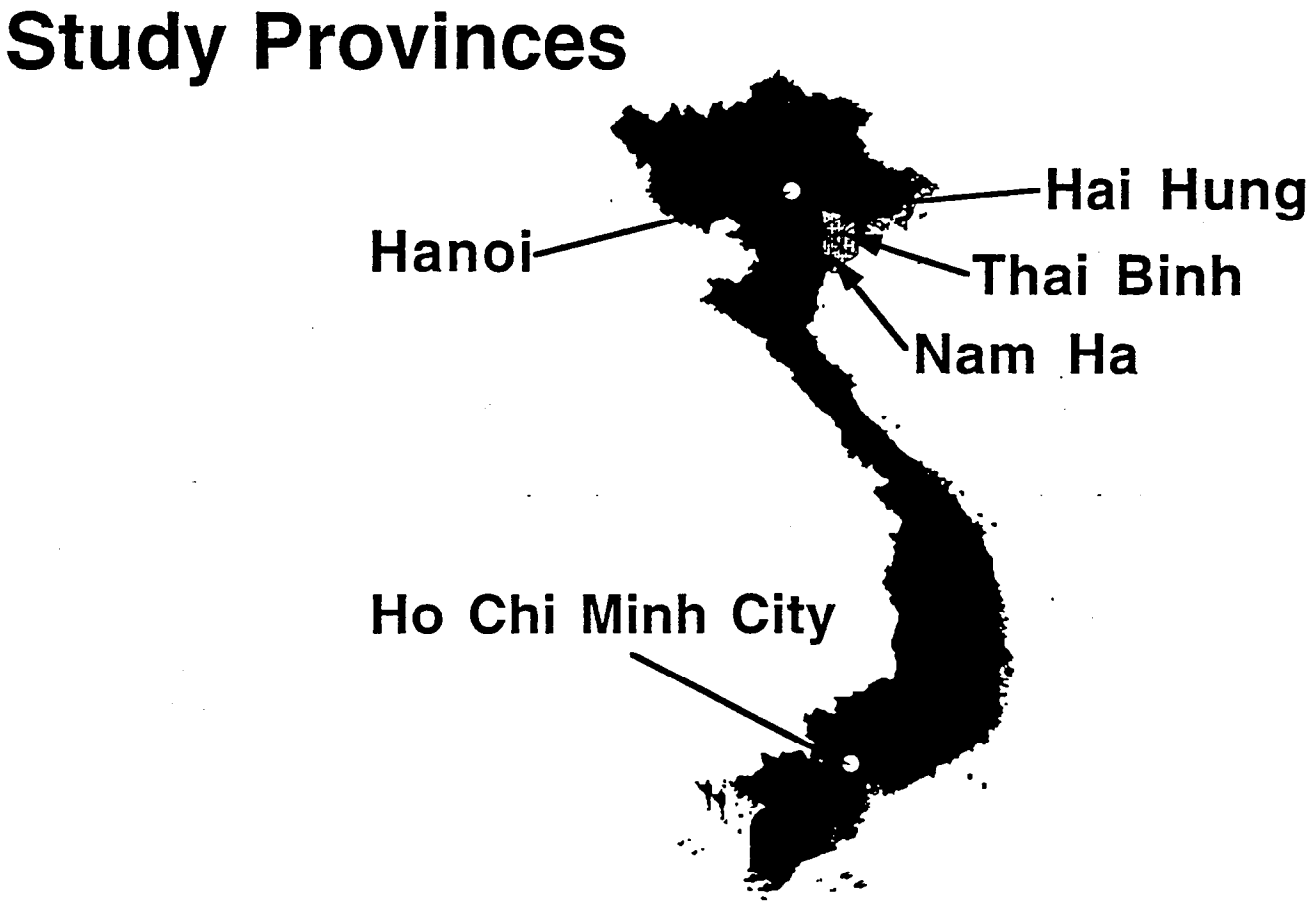
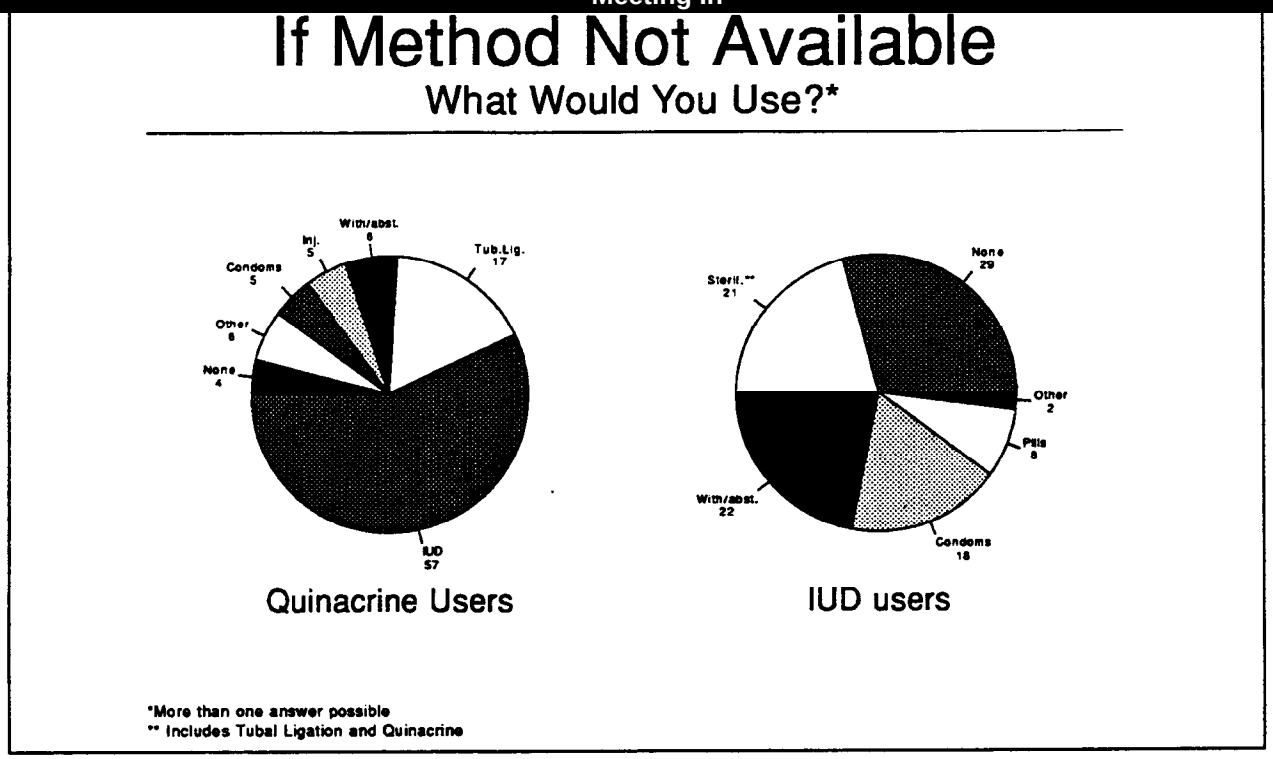


Figure 1



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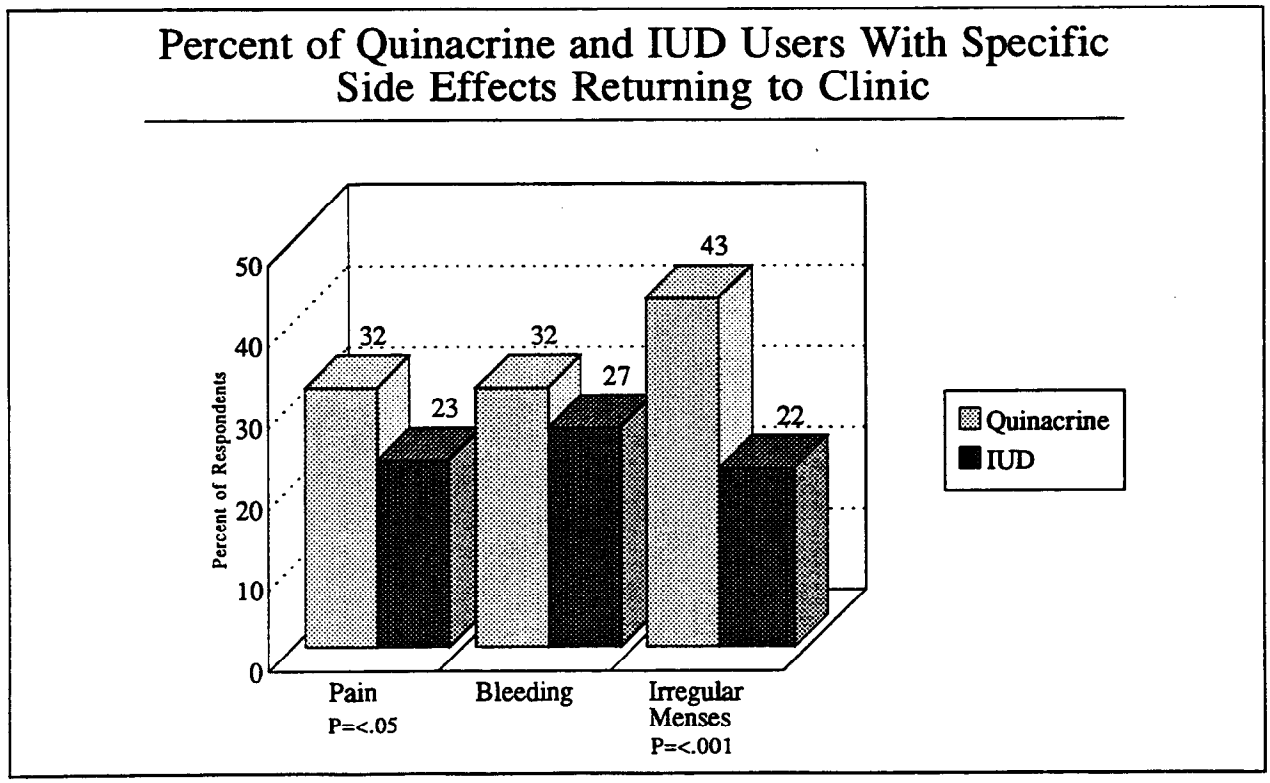
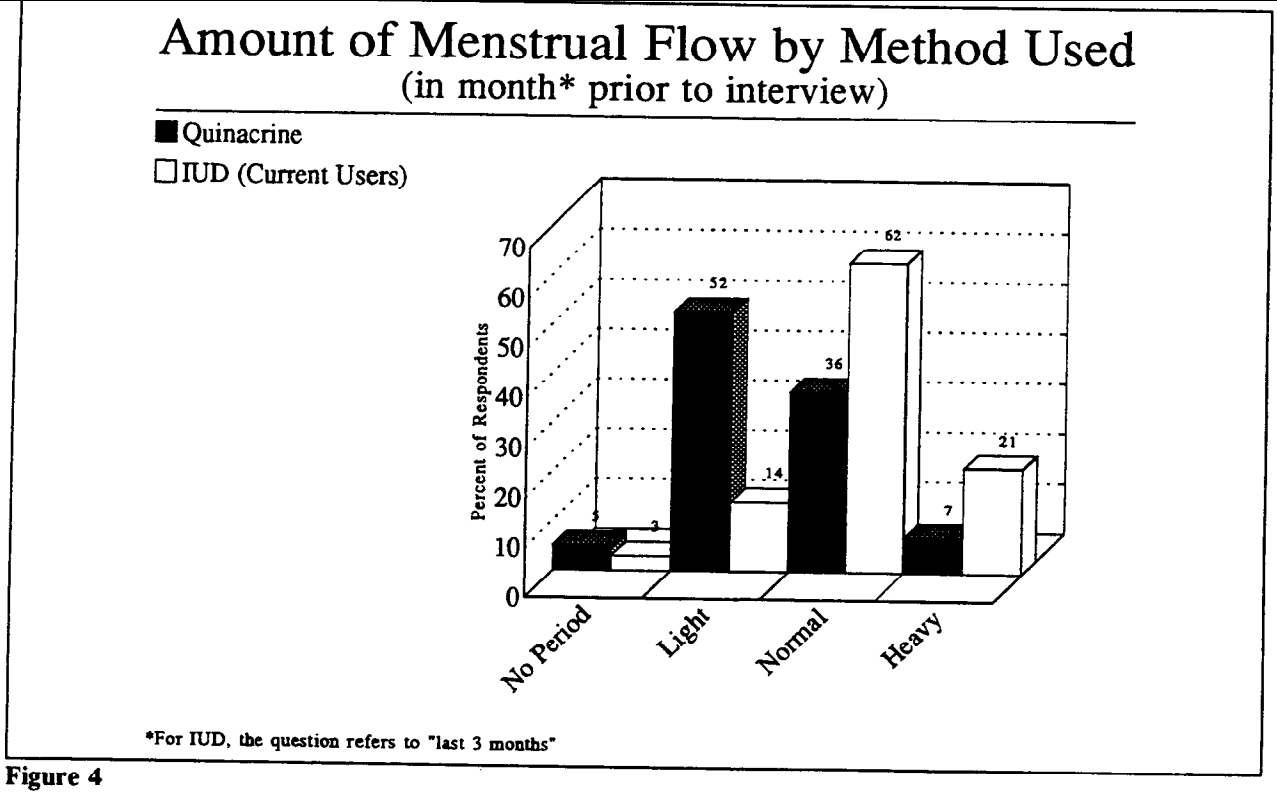


Figure 3



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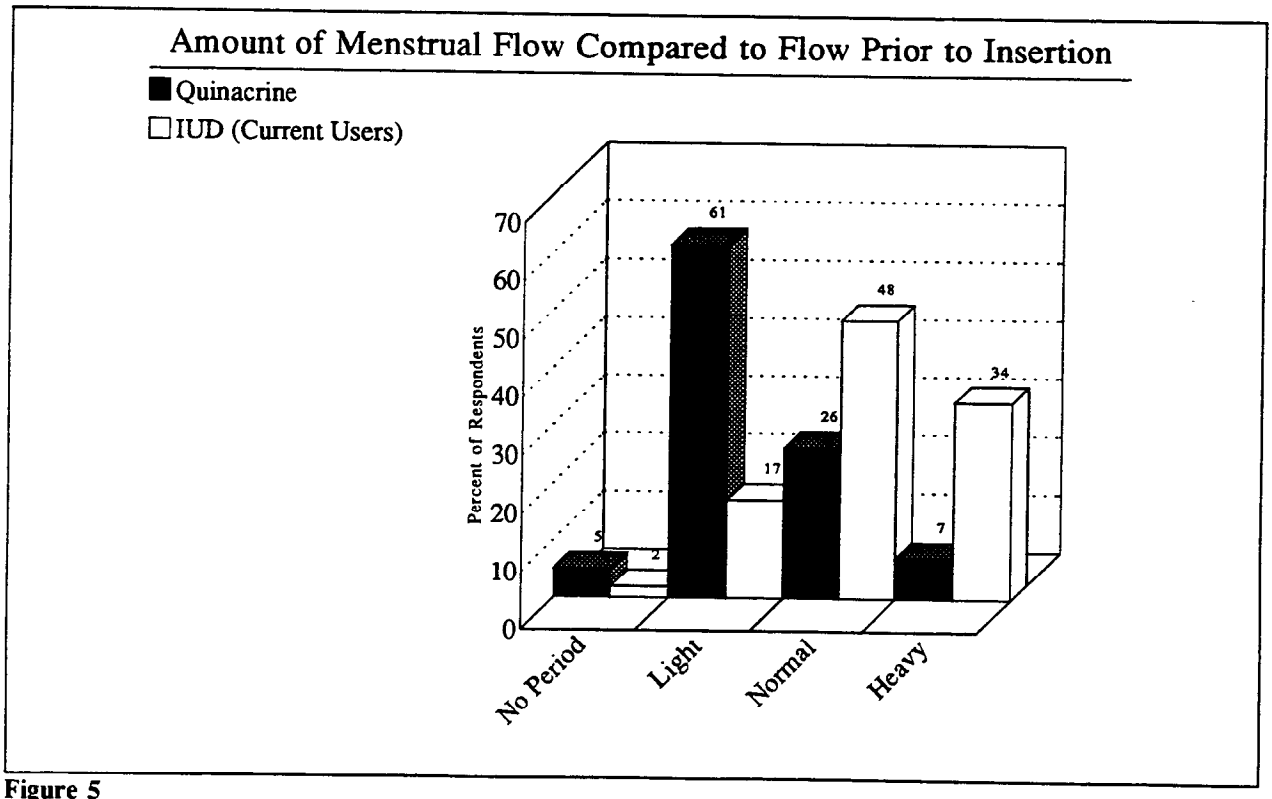

Figure 5

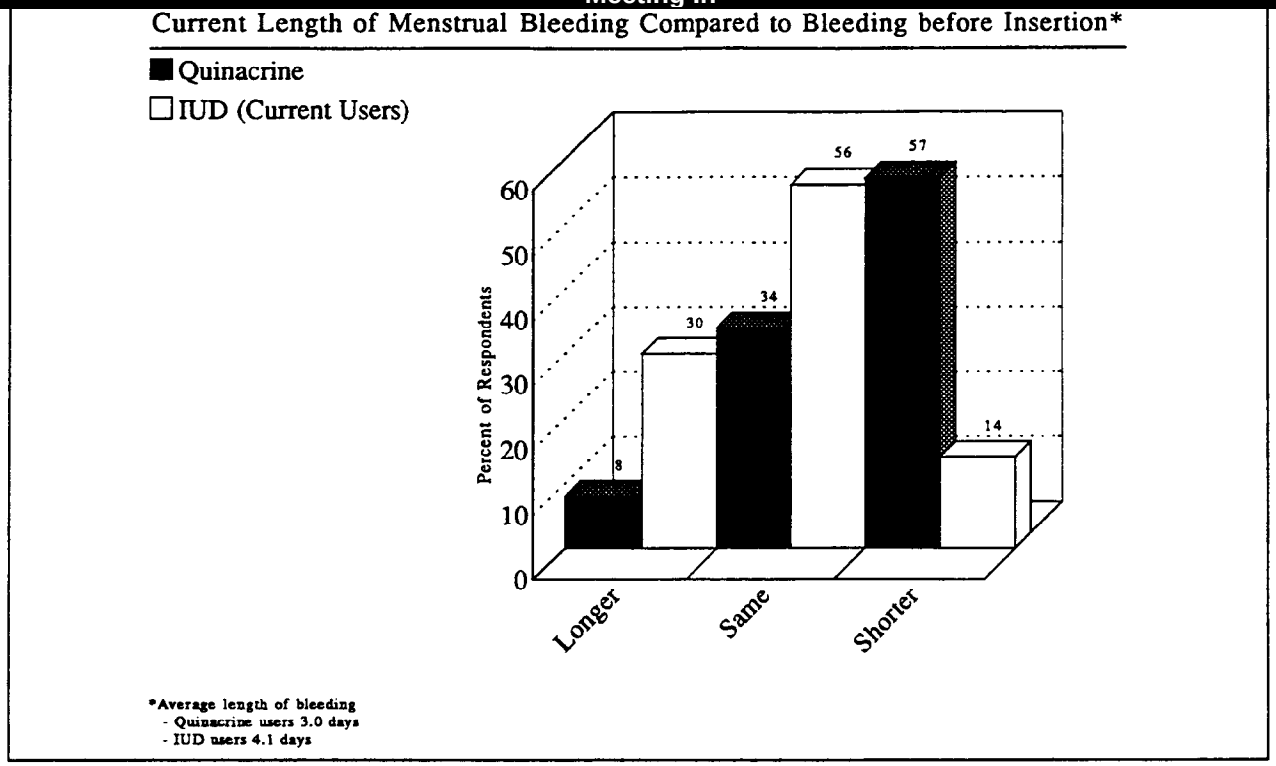

Figure 6

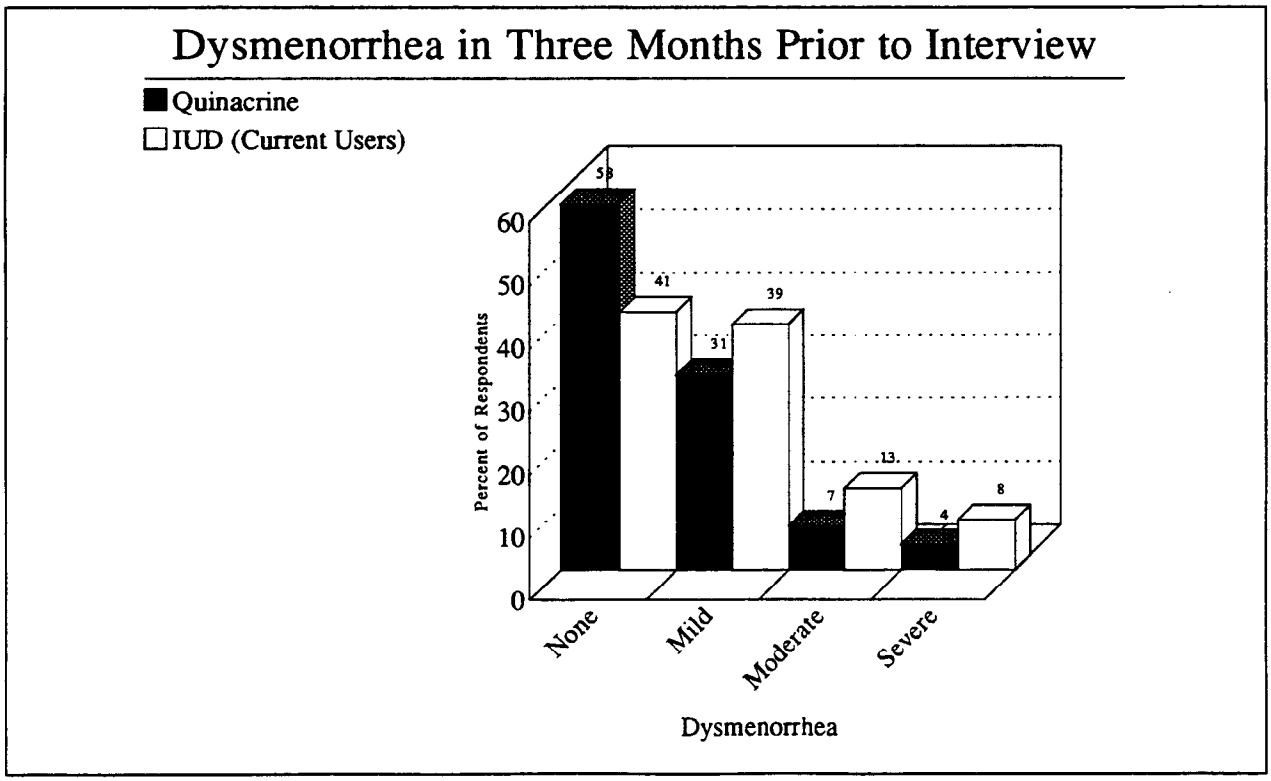

Figure 7