

**Memorandum**

Date **April 19, 1982**

From **Christine Zahniser, MPH, Nurse Educator, Family Planning Evaluation Division (FPED), Center for Health Promotion and Education (CHPE)**  
**George L. Rubin, MD, Medical Epidemiologist, Epidemiologic Studies Branch (ESB), FPED, CHPE**

Subject **Foreign Trip Report, (AID/RSSA): Bangkok, Thailand, February 14-28, 1982**  
**Training Course in the Epidemiologic Approach to Contraceptive Studies**

To **William H. Foege, M.D.**  
**Director, Centers for Disease Control**  
**Through: Horace G. Ogden**  
**Director, CHPE**

- I. SUMMARY
- II. DATES AND PLACES
- III. PURPOSE
- IV. CHIEF CONTACTS
- V. ACCOMPLISHMENTS
- VI. RECOMMENDATIONS

**I. SUMMARY**

From February 22 through February 27, 1982, we conducted a course on the Epidemiologic Approach to Contraceptive Studies in Bangkok, Thailand. Preparation and training for the course was a joint effort by CDC and the Population Council, Southeast Asia Office. There were 14 course participants from 4 countries: 2 from Bangladesh, 4 from Indonesia, 4 from the Philippines, and 4 from Thailand.

Two of the three objectives of the course were met by the completion of the course: 1) The course participants demonstrated a measured increase in knowledge of epidemiologic principles by the end of the course; and 2) five research proposals for contraceptive safety research studies were presented. The third objective of the course, the implementation of a research project in any participating country, remains to be observed at this date. This is the second of four workshops planned for the Southeast Asia region. The next workshop has been tentatively planned for September 1982.

**II. DATES AND PLACES**

Bangkok, Thailand - February 14-28, 1982.

**III. PURPOSE**

The development and implementation of a training course in the Epidemiologic Approach to Contraceptive Studies was initially undertaken to improve the knowledge and skills of personnel in Southeast Asia with which to conduct contraceptive safety research. This workshop was the

second of four planned collaboratively by the Centers for Disease Control, the Population Council, and The Ford Foundation. (See trip report of January 6, 1981, by Rubin and Zahniser.)

#### IV. CHIEF CONTACTS

##### Population Council

Barnett Baron, Ph.D., Senior Representative, South and East Asia  
Andrew Fisher, Ph.D., Regional Advisor, Family Planning Research  
Jean Baker, M.P.H., Research Assistant

##### World Health Organization

David Brandling-Bennett, M.D., D.T.P.H., Director, Field Epidemiology  
Training Program

##### United States Agency for International Development (USAID)

David Oot, M.P.H., Population Officer

##### Family Health Division, Ministry of Public Health, Bangkok, Thailand

Tony Bennett, M.S., Visiting Staff, Columbia University, Center for  
Population and Family Health

##### Chulalonghorn University Medical School

Sumana Chompootaweep, M.D., M.P.H., Clinical Researcher, Institute of  
Health Research

Termri Chumnijarakij, M.D., D.T.P.H., Department of Preventive and  
Social Medicine

Dr. Nikorn Dusitsin, Department of Obstetrics and Gynecology

##### University of Singapore, Kandang Kerbau Hospital

Mark Cheng, M.D., Associate Professor in Obstetrics and Gynecology

##### International Project of the Association for Voluntary Sterilization (IPAVS)

Russell Vogel, Director of Asia Office

Stephen Smith, Associate Director of Asia Office

#### V. ACCOMPLISHMENTS

In January and February 1982 we revised the materials that were used in the September 1981 Contraceptive Safety Workshop. Based on the recommendations and evaluation following the September course, we made the following changes:

- 1) Minimized the material dealing with basic principles of epidemiology.

- 2) Omitted the section on problem solving.
- 3) Included information on selection of sample size.
- 4) Increased information on data analysis and tabulation.
- 5) Incorporated epidemiologic studies conducted in Southeast Asia in the workbook as examples of descriptive and analytic epidemiologic studies.
- 6) Revised the pre- and post-test instrument to better measure the level of understanding of epidemiologic principles.

Invitations for nomination of participants were sent by the Population Council, Southeast Asia to: Bangladesh, Indonesia, Philippines, Sri Lanka, and Thailand. The selection criteria for the participants was the same as required for the September workshop (see trip report January 6, 1982). In all cases, persons nominated by their government were accepted. Sri Lanka did not send anyone to this workshop.

From February 16-19, 1982, we further developed the teaching materials in Bangkok, Thailand, and made logistical arrangements. This included:

- 1) Reorganization of the agenda for the training course;
- 2) Revision and incorporation of material developed by the Population Council representative into the course manual;
- 3) Printing of course manual;
- 4) Set up course facility.

The course was conducted from Monday, February 22, through Saturday, February 27. A combination of didactic and small group participatory sessions were used for teaching purposes. The resource personnel included: George Rubin, Christine Zahniser, David Brandling-Bennett, Andy Fisher, and Mark Cheng. Mark Cheng, a clinician and researcher from Singapore, greatly contributed to discussions with his knowledge of current research in Southeast Asia.

A list of the names and affiliations of the course participants and resource personnel is attached in Appendix A. An outline of the course schedule is attached in Appendix B. The manual used in conjunction with the other course material is available on request.

Approximately half of the sessions were didactic, where we presented a simplified approach to epidemiologic methods. During the remaining half of the sessions, the participants developed a group research project. Groups were first established by country, and within each country, participants were advised to work on a research proposal in groups of two to three. The group from the Philippines (4), Bangladesh (2) and Thailand (4) preferred to work on one proposal, while the group from Indonesia (4) worked on two proposals.

During the September course, each group was required to complete one descriptive and one analytic study. Comments following that course indicated that 5 1/2 days was not sufficient for the adequate development of two proposals; thus, we only required each group to develop either a descriptive or analytic study during this workshop.

Five proposals\* were developed by the participants of the four countries represented. These included:

1) Bangladesh

A comparative study of complication rates of tubal sterilization procedures performed in camps versus clinics.

2) Philippines

An analytic study to determine the immediate and long-term complications associated with postpartum and interval sterilization procedures.

3) Thailand

A study of the complication rates associated with the Multiload versus the Lippes Loop IUD.

4) Indonesia

a) A study of the side effects and acceptability associated with 30 mcg versus 50 mcg estrogen content oral contraceptive pills used by Indonesian women.

b) A study of the effect of vasectomy on sexual behavior.

On Friday afternoon participants presented their proposals to a group of outside persons with an interest in contraceptive safety research in the region. This permitted an opportunity for the participants to receive constructive feedback concerning research design, relevance of the topic, and feasibility of funding the study. Members of the panel included:

1) Barnett Baron, Senior Representative, Population Council

2) David Oot, Population Officer, USAID

3) Tony Bennett, Visiting Staff, Columbia University, Center for Population and Family Health, Bangkok, Thailand

4) Dr. Termuri Chumnijarakij, Department of Preventive and Social Medicine, Chulalongkorn University

\*See Appendix C

Course participants were eager to learn more of epidemiologic methods and group discussions flowed well. Approximately half of the participants had some trouble communicating in English. Fewer persons at this workshop, compared with the workshop held in September 1981, had previous training in epidemiology (29% versus 100% in September). Thus, there was a marked difference in the understanding of basic epidemiologic principles between those participants with advanced training versus those without the training.

The pre-test was administered on day 1, prior to presentation of didactic material. Participant scores ranged from 20% to 93%. The mean score was 54% (median 50%). The pre-test is attached as Appendix D. At the end of the training course, the same test was administered as a post-test. Scores ranged from 53% to 100%. The mean score was 83% (median 90%). The distribution of scores and questions missed is attached as Appendix E.

We administered a course evaluation questionnaire at the end of the training course. A summary of all course evaluation comments are included in Appendix F.

Suggestions for future training courses included:

- 1) Spend more time writing the proposal.
- 2) Use the afternoon for discussion of examples of research proposals and/or previously conducted studies, rather than lectures.
- 3) Spend more time discussing contraceptive issues relevant to their particular situation.
- 4) Incorporate more problems for group work and allow groups to compute answers themselves.
- 5) Extend the time period for this training course.
- 6) Give advance notice to the participants to bring background information concerning a contraceptive safety problem of special interest to them.

In conclusion, a successful training course in the epidemiologic approach to contraceptive safety studies was held in Bangkok, Thailand, from February 22-27, 1982.

## VI. RECOMMENDATIONS

1. The Population Council should continue to facilitate the process of identifying funds for proposals and obtaining technical assistance, when necessary. The Population Council should also follow up the participants to determine the status of proposals developed in September 1981.

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2. Dr. Mark Cheng should be invited as a resource person for 1-2 days, to present a lecture on Contraceptive Safety Research in Southeast Asia, and to provide feedback to course participants regarding their study topic, methodology, plans for implementation, etc.
3. Revise the course materials as follows:
  - a. Include written course objectives.
  - b. Revise section on problem statement and definition to include more appropriate research objectives.
  - c. Develop some examples of descriptive studies for participants to work through.
  - d. Insert the section on Cohort Studies before Case-Control Studies, and rearrange order of examples.
  - e. Consider including:
    - 1) How to review epidemiologic studies reported in the literature
    - 2) How to write for publication
4. Consider the feasibility of conducting small group tutorials for participants with advanced training/experience in epidemiology.
5. Prepare for the next course to be held in Bangkok in September 1982.

Christine Zahniser, M.P.H.

George L. Rubin, M.D.

6 Attachments

## APPENDIX A

### List of Participants and Resource Personnel

#### Contraceptive Safety Workshop

February 22-27, 1982

#### Participants

##### Bangladesh

1. Mrs. Najma Ahmed  
Research Coordinator  
Bangladesh Fertility Research Programme  
G.P.O. Box 279  
Dacca-7, Bangladesh
2. Mrs. Rownak Mowla  
Assistant Research Coordinator  
Bangladesh Fertility Research Programme  
G.P.O. Box 279  
Dacca-7, Bangladesh

##### Indonesia

1. Dr. Hakim Sorimuda Pohan  
Staff Member of Dept. OBGYN  
Medical Faculty  
Sriwijaya University/General Hospital  
Jalan Jenderal Sudirman  
Palembang, Indonesia
2. Dr. Muchlis Hasan  
Staff Member of Dept. OBGYN  
Medical Faculty  
Andalas University  
Padang, West Sumatra  
Indonesia
3. Dr. Nukman Moeloek  
Lecturer in Biology & Andrology  
Faculty of Medicine  
University of Indonesia  
Jl. Salemba 6, Jakarta Pusat  
Indonesia
4. Dr. Prijono Hadiluwih  
Lecturer in Biology & Andrology  
Faculty of Medicine  
Diponegoro University  
Jl. Dr. Sutomo No. 18  
Semarano, Semarang  
Indonesia

Philippines

1. Dr. Martin De La Rosa  
UP Institute of Public Health  
625 Pedro Gil Street  
Ermita, Manila  
Philippines
2. Dr. Rebecca Ramos  
Family Planning Center  
Jose Fabella Memorial Hospital  
Lope de Vega Street  
Sta. Cruz, Manila  
Philippines
3. Dr. Caridad Ancheta  
UP Institute of Public Health  
625 Pedro Gil Street  
Ermita, Manila  
Philippines
4. Ms. Norma Paraiso  
Population Center Foundation  
P.O. Box 2065, MCC  
Makati, Metro Manila  
Philippines

Thailand

1. Miss Yupa Thararoop  
Research and Evaluation Unit  
Family Health Division  
Ministry of Public Health  
Bangkok, Thailand
2. Dr. Mongkol Na Songkhla  
Provincial Health Office  
Chiang Mai
3. Dr. Suwath Singhakovin  
Maternal and Child Health Centre  
Chiang Mai
4. Dr. Samrerng Yanggratoke  
Sung Noen District Hospital  
Sung Noen District  
Nakornrajasima

Resource Personnel

1. Dr. Mark C.E. Cheng  
Dept. of OBGYN  
National University of Singapore  
Kandang Kerbau Hospital for Women  
Hampshire Road  
Singapore 0821
  
2. Dr. George Rubin  
Medical Epidemiologist  
Epidemiologic Studies Branch  
Family Planning Evaluation Division  
Centers for Disease Control  
Atlanta, GA 30333  
U.S.A.
  
3. Ms. Christine Zahniser  
Training Coordinator  
Family Planning Evaluation Division  
Centers for Disease Control  
Atlanta, GA 30333  
U.S.A.
  
4. Dr. David Brandling-Bennett  
Field Epidemiology Training Programme  
World Health Organization  
Ministry of Public Health  
Bangkok, Thailand
  
5. Dr. Andrew Fisher  
Regional Advisor  
Family Planning Research  
The Population Council  
P.O. Box 11-1213  
Bangkok 11, Thailand

## APPENDIX B

### WORKSHOP SCHEDULE:

#### THE EPIDEMIOLOGIC APPROACH TO CONTRACEPTIVE STUDIES

##### Monday -- Feb. 22

08:30 Introduction of participants and staff

09:30 Workshop objectives

10:00 TEA BREAK

10:15 Discussion of individual country family planning programs and problems related to contraceptive safety issues

11:15 Workshop pretest

11:45 Problem statements

12:15 Administrative arrangements: hotel, flights, per diem

12:30 LUNCH

01:30 Problem definition

01:45 Justification of proposed research

02:00 Issues in contraceptive safety

03:00 Small group assignment:  
a) select a research topic  
b) define the problem  
c) justify proposed research

05:00 SOCIAL HOUR

##### Tuesday -- Feb. 23

08:15 Small group reports with discussion: problem selection, definition and justification

09:15 Writing research objectives

09:45 TEA BREAK

10:00 Small group assignment: write research objectives  
11:00 Small group reports and discussion on research objectives  
12:00 Outline for writing a research proposal  
12:15 LUNCH  
01:15 Overview of epidemiologic studies  
Descriptive studies  
Analytic studies

Wednesday -- Feb. 24

08:15 Analytic studies continued  
10:15 TEA BREAK  
10:30 Small group assignment:  
a) Design Study  
b) Select study area and population  
c) Define terms and variables  
d) Specify data collection procedures  
12:15 LUNCH  
01:15 Review of small group progress on developing a research proposal  
02:15 Continuation of small group development of research proposals  
06:30 DINNER AT TRAINING CENTER

Thursday -- Feb. 25

08:15 Further issues on epidemiologic studies  
09:30 Small group assignment: Continue developing research proposal  
12:15 LUNCH

- 01:15 Data tabulation and analysis
- 01:45 Small group assignment: Specify data tabulation and analysis plans
- 03:30 Further issues on epidemiologic studies

Friday -- Feb. 26

- 08:15 Small group reports on progress developing a research proposal
- 09:30 Further issues: Research proposals
- 10:15 Small group assignment: Continue developing a research proposal
- 12:15 LUNCH
- 01:15 Small group assignment: Continue developing a research proposal
- 03:00 PRESENTATION OF FINAL PROPOSALS TO SPECIAL PANEL

Saturday -- Feb. 27

- 08:15 Final revisions of research proposals
- 09:30 Ask, tell or explain: Epidemiologic methods and/or contraceptive safety issues
- 10:30 Posttest and course evaluation
- 11:00 Closing ceremony and presentation of workshop certificates
- 12:00 LUNCH

APPENDIX C

PHILIPPINES

TOPIC : A Comparative Study of Patient Satisfaction with Postpartum and Interval Sterilization.

I. ABSTRACT

This study aims to compare the psychological and surgical complications between postpartum and interval sterilized women, using a cohort study design. The sample will consist of 800 postpartum and 400 interval patients of a government hospital in Metro Manila recruited within a one-year period. Follow-up will be done through structured interviews and examination of medical records will be conducted within 24 hours prior to the procedure, 4-6 weeks, 6 months, and 12 months after sterilization. Operators, pre and post operation procedures, techniques of operation, and type of anesthesia will be standardized. Relative risks of bleeding, infection, and psychological sequelae will be calculated.

II. PROJECT IDENTIFICATION AND DEFINITION

Sterilization is one of the more effective methods promoted by the Philippine Population Program. It was introduced as a program method only in the mid 70's. Sterilization acceptors have steadily increased since then.

Seventy per cent of sterilization cases are performed in the postpartum state, due to the following reasons :

1. Patients are easily persuaded to accept the method

because of the recency of experience of childbirth;

2. It is convenient and economical for the patient since she needs not be readmitted to the hospital; it is also convenient for the doctor because the procedure is easier to perform at this time, because of enlarged uterus, lax abdomen, etc.

Interval acceptors, on the other hand constitute thirty per cent of sterilization cases.

Much concern has been expressed about the possible psychological effect of postpartum sterilization. It has, in particular, been contended that performing sterilization after delivery does not give patients sufficient time to arrive at well-thought out decisions before undergoing an irreversible procedure. They further maintain that because of this, women subsequently develop anxiety, tension and guilt feelings about having made such a rush and drastic decision.

### III. IMPORTANCE OF THE PROBLEM

The Population Program is likely to suffer a setback if too many women continue to complain about being "forced" to accept the method. Very few studies have been done to confirm the validity of these contentions.

#### IV. OBJECTIVES OF THE STUDY

Postpartum and interval sterilization patients in government hospitals in Metro Manila, Philippines will be followed-up during a one-year period to determine.

1. The relationship between time interval of sterilization and the development of psychological sequelae.
2. The psychological sequelae observed in the two groups of sterilized women.
3. The incidence rates of infection and bleeding associated with postpartum and interval sterilization.

#### V. STUDY DESIGN

A cohort design will be used to compare the rates of complication and psychological sequelae between women who underwent interval sterilization and postpartum sterilization. The study will be completed within two and a half-year period: one year for recruitment, another year for follow-up, and half a year for preparation and completion of reports.

##### Definition of Study Population

The sample of the study will be drawn from a government hospital in Metropolitan Manila, inhouse patients are by and large similar in terms of parity, age, and marital and socioeconomic status.

Postpartum acceptors considered in this study as the exposed group, are those who decide to undergo sterilization before or during hospitalization. The procedure is performed anytime within 72 hours after an uncomplicated abortion or normal delivery.

Interval acceptors considered in the study as the unexposed group, are those who come on their own for sterilization or are recruited from the field. They should not have undergone delivery or abortion at least 6 weeks prior to recruitment.

Both types of acceptors should be: within 25-40 years of age, permanent residents of Metro Manila, and with at least 2 children.

Women who had been hospitalized or had received therapy for the following diseases will not be included in the study: 1) psychological disorders; 2) gynecological disorders such as infection; 3) tumors and menstrual disorders; 4) urinary tract infection; 5) cardiovascular diseases such as heart diseases and hypertension; 6) malignancy; 7) diagnosed anemia; and 8) those suspected to have endometriosis or retained placenta.

Eight hundred postpartum patients and 400 interval patients who satisfy the aforementioned criteria will be recruited to the study, to satisfy 85% confidence level.

#### Definition of Outcome

Major complications :

1. Bleeding - one that requires blood transfusion.
2. Infection - fever of 38.0° and above, occurring at least within a 12-hour interval, excluding the first 24 hours after the procedure; or tenderness of pelvic organs with foul vaginal discharge, and hypogastric pains.
3. Perforation of a hollow viscus.
4. Cardiopulmonary crisis.
5. Death.

**Minor complications :**

1. Wound bleeding - oozing to actual hematoma.
2. Wound infection - pus coming from the wound with or without dehiscence.
3. Psychological sequelae - tests to diagnose the outcome will be formulated by a psychiatrist consultant.

**Data Collection :**

The study will make use of a structured interview questionnaire and review of medical records. The study population will be inter-

viewed four times. The first interview will be conducted within 24 hours before sterilization, the second, 4-6 weeks after sterilization, the third, 6 months, and the fourth one year after sterilization.

The study population will be advised to come back to the hospital during the interview specified or anytime during the follow-up period, to report complaints or observed abnormalities. Those who are not able to come back will be followed up in their homes.

Demographic variables to be collected for possible correlation with the findings of the study are: sex, age, number of children, occupation, educational attainment and socio-economic status.

The following will be standardized as to operators, pre and post operative procedures, technique of operation and type of anesthesia.

Confidentiality will be observed by assigning members to each of the study population.

Ten percent (10%) of randomly selected women from both groups will be reinterviewed to check for quality control.

## VI. ANALYSIS OF DATA

The data will be analyzed by determining the relative risks of each complication, adjusting for possible compounding factors and applying tests of statistical significance.

Copy of the following tables :

Table I : Selected Characteristics of Patients by Timing of Tubal Sterilization Procedure, Hospital X, Manila, 1982-1983.

Table II : Distribution of Complication Between Postpartum and Interval Sterilization, Hospital X, Manila, 1982-1983.

Table III : Complication Rates Between Postpartum and Interval Sterilization, Hospital X, Manila, 1982-1983.

Table IV : Distribution of Subjects by Complications and Age Group, Hospital X, Manila, 1982-1983.

Table V : Distribution of Subjects by Psychological Sequelae, Number and Sex of Children, Hospital X, Manila, 1982-1983.

## VII. RESOURCES AND FACILITIES REQUIRED BY THE STUDY

A hospital with facilities and staff needed in performing postpartum and interval sterilization and in screening and follow-up of patients will be used in the study. A computer center in a university in Metro Manila will be employed for data processing.

VIII. REPORTING OF RESEARCH FINDINGS

Semi annual progress reports will be submitted to the funding agency. Final reports to be completed by the thirtieth month of the study will be submitted to the Commission on Population for dissemination to, and possible utilization of specific audiences and to policymakers, managers of service delivery programs and medical professionals in general. Efforts will be made to publish the findings in an international journal.



TABLE II.

Distribution of Completion between  
Postpartum and Interval Sterilization  
in Hospital X, M.M. 1982-1983

COMPLETION	Postpartum Sterilization		Interval Sterilization	
	No.	%	No.	%
Hemorrhage				
Infection				
Psychological				
a)				
b)				
c)				
Total				

TABLE III.

Complication Rates Between Postpartum  
and Interval Sterilization in Hospital X,  
M.M. 1982-1983

COMPLICATION	Postpartum Sterilization		Interval Sterilization		Relative Risk	
	No Complication	With Complictn.	No Complictn.	With Complictn.	P.P.S.	I.S.
Hemorrhage						
Infection						
Psychological						
a)						
b)						
c)						
Total						

TABLE IV.

Distribution of Subjects by  
Complications and Age Group

AGE	Hemorrhage		Infections		Psychological	
	P.P.S.	I.N.T.	P.P.S.	I.N.T.	P.P.S.	I.N.T.
25 - 29						
30 - 34						
35 - 40						

TABLE V.

**Distribution of Subjects by Psychological  
Sequelae and Number and Sex of Children  
Hospital X, Manila, 1982-1983**

Sex of Children \ Number of Children	Postpartum		Interval	
	2 - 4	4+	2 - 4	4+
With boys and girls				
All boys				
All girls				
Total				

STUDY BUDGET

<u>Personnel</u>	<u>Per Month</u>	<u>30 Months</u>
1 Principal investigator	P 3,000	P 90,000
2 Associate investigators	2,000	60,000
1 Research assistant	900	27,000
1 Clerk typist	600 for 6 mos.	3,600
1 Consultant (Statistician)	by contract	5,000
5 Interviewers	P 600	<u>90,000</u>
		P 275,000
 <u>Administrative Costs</u>		
Honorarium for participating hospital	P 1,000 for 1 yr.	P 12,000
Transportation		20,000
Communication		5,000
Office supplies		<u>5,000</u>
		P 42,000
 <u>Production</u>		
Printing of Questionnaire		P 10,000
Data Processing		P <u>15,000</u>
		P 25,000
		P 352,600
	10% inflation =	<u>35,260</u>
		P 377,860
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		P 43,983

## SCHEDULE OF ACTIVITIES

1.	Planning Phase	2 months
	1) Preparation, Pretesting & Revision of Questionnaire	2 months
	2) Training of Interviewers	1 week
	3) Orientation of Staff	1 day
2.	Data Collection	2 years
3.	Data Processing	2 months
4.	Data Analysis	1 month
5.	Writing of Report	2 months

BANGLADESH

RESEARCH PROPOSAL

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r

1. Title : A comparative study on complication rate of female sterilization in camp vs clinic.
  
2. Principal Investigators : Najma Ahmad  
Rownak Mowla
  
3. Starting Date : July 1982
  
4. Completion Date : June 1983

## Introduction :

A comparative study will be conducted to find the complication rate of sterilization performed in different camps and clinics in rural Bangladesh.

## Problem Identification and Definition :

We do not have enough data from where we can find the difference in complication rate of female sterilization performed in clinics and camps. It is essential to know whether the complication rate varies in different settings (camps and clinics) where the sterilization is done even by same doctors.

## Justification of Proposed Research :

Female sterilization is a major component of the National Family Planning programme in Bangladesh. The government has worked out a plan to increase the number of acceptors of female sterilization in Bangladesh. But the available clinical facilities are not sufficient to enforce the national policy. Camp is required where a mobile team of trained doctors will be sent to perform sterilization and the government is directing efforts to improve the surgical facilities to make the procedure safer in different settings.

It is very difficult to say how far government will be successful in the massive campaign of female sterilization as no complication rate has been compile in a comparative manner to assess the safety of performing sterilization in different settings. Only one study was conducted in 1975-76 to compare the sterilization procedure performed in camp and clinic.

In this study it has been shown that comparative rate was very high (45.8%) in camp in comparison to clinic (4%). But this study report did not mention whether the sterilization was done by the same doctors in both places.

The findings of proposed study therefore may help the government to assess the safety of performing female sterilization in both the settings and to take a bold step for implementing its policy of sterilization.

Objective :

The main objective is to determine the complication ratio and patients' satisfaction in regard to the services offered by the management during pre and post operative period. Patients will be followed up at 7 days and at 28 days after procedure.

Its ultimate goal is to help the government to take necessary action in time against any problem identified through this study.

Study Design :

It is a prospective cohort study to measure the complication rate of sterilized women of both camps and clinical situation.

Exposed group will be the women sterilized in camp.

Unexposed group will consist the women sterilized at clinic.

Research Methodology :

Study sites : The study will be conducted in 4 thanes of different districts of 4 divisions of Bangladesh. In each thane one clinic and one camp will be selected for conducting the study. The clinic has a permanent place for operation where trained personnel and other facilities like operation table, autoclave, laboratory for hemoglobin and urine test, oxygen electricity and water supply are available. But the camp has no permanent settings. Sometimes public buildings like school, union board office or any other suitable places are used as camp in rural areas. All measures are tried to maintain the same standard of clinic.

Patient Selection :

Women living around the clinic will be sterilized in clinics whereas women living around the camp will be sterilized in the camp. The patient's socio demographic characteristics are expected to be similar in nature as the condition of rural areas are almost same. A group of healthy

women without any chronic disease and of 20-45 years of age will be included in the study.

Operative Procedure :

The operative procedure will be only pomeroy via minilaparatomy and only local anesthesia will be used both in clinics and camps. Same doctors will perform the procedure in both the places.

Sample Size :

Total sample size will be 800 cases altogether from 4 study areas i.e. 200 cases for each area (100 cases from clinic and 100 cases from camp).

Duration of Study :

The study will be conducted for one year. Admission period for sterilization patients will be for six months and one month for following up the patients after procedure. Rest of the study period will include planning, training data processing and analyzing and reporting.

Data Collection :

Information on female sterilization will be recorded on two phases -- in first phase information will be collected at the time of hospitalization of the following matter :

- a) Patient identification.
- b) Socio-demographic characteristics: age parity, number of living children, education, husband's education, outcome of last pregnancy, contraceptive used before procedure.
- c) Medical data:
  - i. Abnormal bleeding during operation.
  - ii. Bleathing or cardio-vascular arrest due to anesthesia.
  - iii. Injury of bladder or bowl.
  - iv. Any wound disruption before the discharge.
  - v. Number of nights hospitalized.
- d) Facilities available in camps or clinics: oxygen, autoclave, etc.

Another phase of data collection will be done twice at the time of follow up. All follow-up will be done at home for both the groups i.e. clinic and camp patients.

Follow-up :

First follow-up will at the 7 days after the procedure i.e. at the time of stitch removal and second follow-up will be at 28 days after the procedure. Followings will be recorded during the follow-up time :

- 1) Death if any from sterilization related problem.
- 2) Pain in the abdomen and pus in the wound.
- 3) Fever required treatment.
- 4) Any ultra complication required treatment or hospitalization.
- 5) How long it took her to return to her normal duties.

All these information will be recorded on a pre-coded questionnaire by the trained paramedics. And the follow-up of the patients will be tried for cent percent (100%).

Data will be processed in computer and data tabulation will be done on complication rate of both the group related to the procedure and socio-demographic characteristics like age, parity, etc.

Analysis of the tables on the complications will be made to measure the relative risks and attributable risks and to identify the problems which are to be reported in the form of publication to the Bangladesh government and funding agency.

BUDGET

1. Personnel services.
2. Travel and transportation of persons.
3. Transport of materials.
4. Rent, communication and utilities.
5. Printing and publication.
6. Other contractual services.
7. Supplies and materials.
8. Equipments.
9. Transport.
10. Miscellaneous.

THAILAND

## Does the Multi-Load IUD Have Less Complications Than Lippes-Loop?

### Problem Definition

The multi-load and Lippes-loop IUD have been used in Thailand for many years. Lippes-loop IUD has been studied but studies of complications with use of multi-load have never been done. In 1976 multi-load IUDs were introduced in Thailand in some private clinics and private hospitals but they have never been used in public health units before. Now the Ministry of Public Health is considering the introduction of multi-load IUDs to be used for family planning services throughout the country. Lippes-loop IUDs cost Bht. 2.50 in comparison with Bht. 1.50 each for the multi-load IUDs. So complications of both methods should be compared for help consideration.

### Review Literature

Lippes-loops in Thailand

Multi-loads in Thailand if available

Multi-loads outside Thailand

### Objectives

1. To compare complication rate among new acceptors of multi-load and lippes-loop IUDs.

2. To randomly assign two groups of acceptors for lippes-loop and multi-load IUDs using the double blind technique.
3. To perform this study at the MCH Centre Khon Khen Province in January 1st, 1982.

#### Assumptions

The results of this research will provide policy makers with information concerning the more cost-beneficial IUD type for use in Thailand.

#### Identify Demographic Needed Data

1. Information on acceptors in the two comparison groups.
2. Number of complications occurring in each group during determined by a follow-up questionnaire.

#### Definition of Complication

1. Pain is pain lasting longer than 1 hour requiring use of anagesics.
2. Abnormal bleeding means menstrual function change before and after.

3. PID means clinical diagnosis (fever, lower abdominal pain, abnormal vaginal discharge, pain on uterine movement)
4. Discontinuation means removal of IUD.

The definition of complication in this research means at least one of four complications.

### Selection of Method

#### Cohort Study

Exposed group is the group of women using multi-load IUD.

Unexposed group is the group of women using lippes-loop IUD.

Outcome is one or more complication defined above.

Women seeking IUD contraception for the first time at the MCH Centre Khon Khen province will be randomly divided into two groups. Insertion of both kind of loop selected by the double blind method. The tail of the loops will be cut to avoid ascertainment bias during follow-up examination. The physician who performs IUD insertion, the interviewer, the researcher (investigator) will be different for each subject to avoid bias.

Exclusions

Previous history of PID, previous abnormal bleeding tendency, chronic illness, previous IUD use, new acceptors with no husband, women with irregular menstruation.

Equipment Testing

Secretary, recorder, interviewer, physician who provided IUD insertion, interviewing forms should be tested before use.

Data Collection

Subjects collect in the MCH Centre Khon Khen Province for 1 year. Total sample size is 1200. These new IUD acceptors will be randomly allocated to 2 groups. Double blind method will be used for IUD type. Insertion will be provided by the same well trained physician for both groups. The investigator will not know who uses which kind of loop and history taking will be before giving insertion. Cases are followed up after insertion at periods of 1 month, 6 month and 1 year using a standard questionnaire. This questionnaire will determine information on

- a. complication
  - pain
  - abnormal bleeding
  - PID
- b. discontinuation
- c. reasons for discontinuation

Data Analysis

We will compare the risk for

r

- a) discontinuation
- b) complications

for the multi-load IUD group relative to the Lippes-Loop group and determine 95% confidence interval around these relative risk.

Data Tabulation

Table 1

Characteristics of Women in the Multi-load and Lippes-loop Group

	<u>Multi-load</u>	<u>Lippes-loop</u>
Mean age	_____	_____
Mean parity marital	_____	_____
% with irregular menstrual bleeding	_____	_____
% with menstrual bleeding lasting 76 days	_____	_____
% with painful period	_____	_____

Table 2

Complication Occuring At 1 Month

	<u>Multi-load</u> (N=600)	<u>Lippes-loop</u> (N=600)	<u>RR(95%CI)</u>
Pain			
Abnormal bleeding			
PID			
Discontinuation			
One or more complication			
Total complications			

Table 3

Pain Occuring at 1 Month in Each Age Group

<u>Age</u>		<u>Multi-load</u>	<u>Lippes-loop</u>	<u>RR (95% C.I.)</u>
-24	Pain	$a_1$	$b_1$	$RR_1 = \frac{a_1 M_1}{b_1 N_1}$
	Total Subj.	$N_1$	$M_1$	
25-34	Pain	$a_2$	$b_2$	$RR_2 = \frac{a_2 M_2}{b_2 N_2}$
	Total Subj.	$N_2$	$M_2$	
35+	Pain	$a_3$	$b_3$	$RR_3 = \frac{a_3 M_3}{b_3 N_3}$
	Total Subj.	$N_3$	$M_3$	
Total	Pain	$a_{123}$	$b_{123}$	$RR_{123} = \frac{a_{123} M_{123}}{b_{123} N_{123}}$
	Total Subj.	$N_{123}$	$M_{123}$	

Table 4 Abnormal bleeding occuring at 1 month in each age group.

Table 5 PID occuring at 1 month in each age group.

Table 6 Discontinuation occuring at 1 month in each age group.

Table 7 One or more complication occuring at 1 month in each age group.

The data tabulation at 6 months and 1 year repeat the same table at 1 month.

### Interpretation and Report

By comparison incidence rate, relative risk of the two methods from analytic data. And the result of analysis will be described to point out what method is the safest one. At the end of this report the benefit cost ratio will be presented to allow rational decision making concerning the type of IUD that should be used in Thailand.

### Limitation of the Research

1. This research performed in the MCH Centre. Khonkhaen Province Northeast of Thailand may not be representative of the whole country.
2. This research will be conducted within 1 year, this may not be enough to determine discontinuation rate and certain complication rates. The comparison of complications and discontinuation rate between the 2 methods beyond 1 year may be different from the 1 year period.

Course of Research Performing

Ministry of Public Health

<u>Budget</u>	<u>Baht</u>	
Past time cost for personnel	300,000	
Interviewing cost	54,000	
Training cost	1,885	
Professional and technical consulting cost	60,000	
Stationery	20,000	
Miscellaneous	10,000	
Multi-load	90,000	
Lippes-loop	<u>1,500</u>	
Total	<u>537,385</u>	= \$ 23,884
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INTERVIEWING FORM BEFORE I.U.D. INSERTION

Name of interviewer : \_\_\_\_\_

Name of interviewee : \_\_\_\_\_

Address of acceptor : \_\_\_\_\_

Date of I.U.D. insertion: day \_\_\_\_\_ month \_\_\_\_\_ year 1982.

1. How old are you?

- 24 years

25-34 years

34-44 years

2. How many children?

- 2

2 - 4

+ 4

3. How long your last delivery?

-  $\frac{1}{2}$  year

6/12 - 1 year

+ 1 year

4. How long your minstrual cycle?

- 28 days

28-30 days

+ 30 days

5. How long your bleeding period?

- 3 days

3 - 5 days

+ 5 days

6. Is it regular?

yes

no

7. Amount of blood?

same

increase

decrease

8. If increase, how much?

slightly

much

9. If decrease, how much?

slightly

much

10. Have you ever had abnormal discharge?

yes

no

11. Have you ever had lower abdominal pain?

yes

no

12. If yes, how often?

very often

scarcely

INTERVIEWING FORM AFTER I.U.D. INSERTION

Name of interviewer : \_\_\_\_\_

Name of interviewee (I.U.D. acceptor): \_\_\_\_\_

Address of interviewee : \_\_\_\_\_

Date of insertion : day \_\_\_\_\_ month \_\_\_\_\_ year \_\_\_\_\_

Date of interviewing : day \_\_\_\_\_ month \_\_\_\_\_ year \_\_\_\_\_

Time of interviewing : \_\_\_\_\_ minutes

----- o0o -----

Answer the questions :

1. Did you pain after previous interview?

yes

no

2. If pain, how long?

- 1 hour

1 - 6 hours

more than 6 hours

3. Did you need anagesics?

yes

no

4. Did you have to see the doctor?

yes

no

5. Did you get fever and lower abdominal pain after previous interview?

yes

no

6. Have you any abnormal discharge after I.U.D. insertion?

yes

no

7. When you got abnormal discharge after I.U.D. insertion, how did you do?

bought medicine from drug store

see a doctor     others \_\_\_\_\_

did nothing

8. Had you any abnormal bleeding after I.U.D. insertion?

yes

no

9. What kinds of abnormal bleeding did you have after I.U.D. insertion?

Hypermmorrhra     regulation changing

spotted bleeding     amount changing

others

10. If hypermmorrhra, how many days?

within 5 days

within 7 days

more than 7 days

11. Did you remove I.U.D.?

yes

no

12. If yes, why?

bleeding

want more child

pain

pregnancy

others

**INDONESIA**

## THE EFFECT OF VASECTOMY ON SEXUAL BEHAVIOR

### Problem Statement

We don't know whether there is any effect of vasectomy on sexual behavior. We should know how vasectomy influences sexual behavior.

### Define of the Problem

Results from a study done in Indonesia in 1980-1981 indicated that young vasectomised men under age 40 had significant increase of their libido. Older vasectomised men over 40 had no significant increase of their libido.

It was also found that the effect of vasectomy on sexual behavior is more significant for young vasectomised men than for older vasectomised men.

### Justification of the Problem

The acceptance of male contraception in Indonesia is much less than the acceptance of female contraception.

Indonesian government has a specific demographic target of a 50% reduction in the 1971 fertility rate by the year 1990.

To achieve the target, the male contraception must be intensively developed to control the fertility.

There are 7,000 men vasectomised each year in the Middle of Java. Unfortunately we don't have data on vasectomised men in the rest of Indonesia.

Vasectomy is permanent contraception for men. If we know acceptability and we can motivate those men for vasectomised maybe it can reduce fertility more in Indonesia.

One of the most important problems related to acceptance of vasectomy is that men fear that vasectomy can effect the sexual behavior or libido.

Therefore, we should know how is the effect of vasectomy on the sexual behavior.

### Objective

In two year period between 1982-1984 the investigation associated with University of Indonesia, the Andrology Dept. will conduct the cohort study at 200 male selected from 5 Family Planning centers for purpose of examining the effect of vasectomy on sexual behavior.

Study Design : cohort study

- Exposed group : vasectomised men

- Unexposed group : men without vasectomy, which their wife is tubectomised.
- Outcome: identified sexual problem.

### Define Terms and Data Collection

The define of the sexual problem is to have average intercourse less than once or more than three times a week, have complain of erection and have complain the time between penetration and ejaculation.

The study group is collected from the patients which come to family planning clinics.

The study were consists of 400 men (200 vasectomised & 200 non vasectomised men) in selected Indonesia areas will be studied

The exposed group are 200 men which received vasectomy services in 5 areas in Indonesia, and for each area we collected the first 40 vasectomised men.

The age of vasectomised men are between 30-50 years, and these exposed group must have :

- at least 2 children.
- average intercourse between once to three times a week.

- have no complain of erection.
- have no complain time between penetration and ejaculation.

The unexposed group are 200 men whose wife received the tubectomy services in 5 areas in Indonesia, and for each area we collect the first 40 partners whose wife received the tubectomy. This unexposed group also must have minimal 2 children and they must be selected according to the same criteria as exposure above.

These unexposed and exposed groups must be living with their wife at least one year.

To collect the data a trained male social worker will be used to interview the vasectomised men and a trained female social worker will interview their wife. Follow up will be done by the trained social worker to look for the acceptor if they don't come back.

Data Tabulation

<u>6 month</u>	<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>	<u>(95 C.L.)</u>
	The pregnancy of inter- course	The pregnancy of intercourse	-	
<b>Sexual Problem</b>	Erection	Erection	-	
	Ejaculation	Ejaculation	-	
<b>Total</b>	200	200		

Crude RR = ..... (C.L. : )

Adjusted RR M-H = ..... (C.L. : )

<u>12 month</u>	<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>	<u>C.L.</u>
	The pregnancy of inter- course	The pregnancy of intercourse	-	
<b>Sexual Problem</b>	Erection	Erection	-	
	Ejaculation	Ejaculation	-	
<b>Total</b>	200	200		

Crude RR = ..... (C.L. : )

Adjusted RR M-H = ..... (C.L. : )

Distribution of Vasectomised Men by Age in having a Sexual Problem

<u>Age (Year)</u>		<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>	<u>C.L.</u>
+ 40	Sexual problem	a <sub>1</sub>	b <sub>1</sub>	$\frac{a_1}{N_1} / \frac{b_1}{No.1}$	
	Total	N <sub>1</sub>	No.1		
- 40	Sexual problem	a <sub>2</sub>	b <sub>2</sub>	$\frac{a_2}{N_2} / \frac{b_2}{No.2}$	
	Total	N <sub>2</sub>	No.2		
Total	Sexual problem	a	b	$\frac{a}{b}$	
	Total	200	200		

Adjusted RR M-H = ..... (C.L.: )

Distribution of Vasectomised Men by Age in having Pregnancy of Intercourse  
Chances

<u>Age (Year)</u>		<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>	<u>C.L.</u>
+ 40	Preg. Inter- course chances	a' <sub>1</sub>	b' <sub>1</sub>	$\frac{a'_1}{N'_1}$	$\frac{b'_1}{No.1'}$
	Total	N' <sub>1</sub>	No.1'		
- 70	Preg. inter- course chances	a' <sub>2</sub>	b' <sub>2</sub>	$\frac{a'_2}{N'_2}$	$\frac{b'_2}{No.2'}$
	Total	N' <sub>2</sub>	No.2'		
Total	Preg. inter- course chances	a'	b'	$\frac{a'}{200}$	$\frac{b'}{200}$
	Total	200	200		

Adjusted RR M-H : ..... (C.L.)

Distribution of Vasectomised Men by Age in having of Erection Strength

Chances

<u>Age (Year)</u>	<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>
+ 40	Erec. strength chances	$a''_1$	$\frac{a''_1}{N''_1} / \frac{b''_1}{No.1''}$
	Total	$N''_1$	
- 40	Erec. strength chances	$a''_2$	$\frac{a''_2}{N''_2} / \frac{b''_2}{No.2''}$
	Total	$N''_2$	
Total	Erec. strength chances	$a''$	$\frac{a''}{b''}$
	Total	200	

Adjusted RR M-H : ..... (C.L.)

Distribution of Vasectomised Men by Age in having of Ejaculation Period

Chances

<u>Age (Year)</u>		<u>Vasectomised</u>	<u>Non Vasectomised</u>	<u>R.R.</u>		<u>C.L</u>
+ 40	Ejac. period chances	$a_1'''$	$b_1'''$	$\frac{a_1'''}{N_1'''} =$	$\frac{b_1'''}{No.1'''} =$	
	Total	$N_1'''$	$No.1'''$			
- 40	Ejac. period chances	$a_2'''$	$b_2'''$	$\frac{a_2'''}{N_2'''} =$	$\frac{b_2'''}{No.2'''} =$	
	Total	$N_2'''$	$No.2'''$			
Total	Ejac. period chances	$a'''$	$b'''$	$\frac{a'''}{N'''} =$	$\frac{b'''}{No.'''} =$	
	Total	200	200			

Adjusted RR M-H : ..... (C.L. )

BUDGET

A. Personnel

1 Project leader \$75/month, 24 months	\$ 1,800.-
1 Vice project leader \$60/month, 24 months	1,440.-
2 Consultants \$75/month, 8 months (1 Psychologist & 1 Statistician)	1,200.-
2 Interviewers \$50/month, 18 months	1,800.-
1 Type writer \$40/month, 4 months	<u>160.-</u>

Total \$ 6,900.-

B. Administration

\$ 200.-

C. Computer costs

\$ 1,500.-

1 area \$ 8,100.-

5 areas \$ 36,500.-

D. Travels

Medan - Jakarta v.v.	\$ 400.-
Sumarang - Jakarta v.v.	130.-
Bali - Jakarta v.v.	280.-
Manado - Jakarta v.v.	\$ <u>500.-</u>

\$ 1,310.-

E. Hotel : \$600/day/personnel  
5 personnels, 2 days in Jakarta

\$ 6,000.-

F. Perdiem : \$45/day/personnel  
5 personnels, 2 days in Jakarta

\$ 450.-

Total

\$ 44,260.-  
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## INDONESIA

### PROBLEM STATEMENT :

We don't know which contraceptive pill has more side effects or is more suitable in Indonesia between the oral contraceptive pill of 30 M.Gr. or 50 M.Gr. Estrogen concentration.

We should know which has more side effects or is more suitable.

Comparison of two types of oral contraceptive, 30 and 50 M.Gr. Estrogen among the Indonesian women.

I. OBJECTIVE

I.A. General Objective

This study will compare the side effect, efficacy and acceptability of two types of oral contraceptive, contain 30 and 50 M.Gr. Estrogen among 1,600 Indonesian women, done in 8 family planning clinics in four provinces for a 2 years follow up.

I.B. Specific Objective

1. The side effect of oral contraceptive on the two groups of acceptors that will be observed, are

1.1 Spotting

1.2 Break through bleeding

1.3 Amenorrhoe

1.4 Weight gain

1.5 Another subjective complain:

Anorexia, vomiting, dizziness.

2. The efficacy is stated by pregnancy per 100 women per year.

3. The discontinuation from the two groups of acceptors observed are, the time when they stop the pill and the reason of not taking pill.
4. From this study, evaluation will be made, what factors influence or correlate with the side effect, efficacy and which pill is more suitable for the Indonesian women.

## II. JUSTIFICATION

1. Pill is one of the contraceptive method introduced by the national family planning coordination board in Indonesia.
2. Most of the acceptors (65%) in Indonesia choose pill for their contraceptive method. By 1981, for a 10 years program, 5 million women are current users.
3. Studies in other countries show that the lower Estrogen content in the pill, the lower complication as well as less side effect. In Indonesia side effects of 50 M.Gr. pill as spotting, break through bleeding and amenorrhoe occurred about 5%. A multi centre study between 50 and 30 M.Gr. pill in Indonesia has not been done yet.

4. Indonesian women as all women from the other developing countries are differ from the women of the industrialized nations in diet, habit, life style, genetic heritage and environment.
5. Most of the Indonesian women are Moslem; spotting and break through bleeding will disturb their rite in their religion.
6. About two-third of the Indonesian women go to married before the age of 20; some of them have two or three children when they are 20 or 22 years old. Before they change their contraceptive method into permanent method, they use the oral contraceptive for a longer period.

They need a contraception with less side effect.

7. Discontinuation rate among the acceptors of oral contraceptive is very high, about 50%, study for the reason stopping the pill has not been done
8. If we find the more suitable pill with less side effect but low failure rate, it will increase acceptors and achieve the target by 1990. Reduce the fertility rate to 50% in 1971.

**III. STUDY DESIGN**

- 1. Problem** : Are there any differences between two types of oral contraceptive (50 & 30 M.Gr.) including side effect, efficacy and acceptability.
- 2. Study Design** : Analysis cohort prospective study.
- 3. Expose Group** : Women taking 30 M.Gr. pill.
- 4. Unexpose Group** : Women taking 50 M.Gr. pill.
- 5. Outcome** :
  - 5.1** Side effect, spotting, break through bleeding, amenorrhoe, weight gain, anorexia. vomittine. dizziness.
  - 5.2** Preenancy per 100 women per year.
  - 5.3** Discontinuation
    - 5.3.1** When the acceptors stop their pill.
    - 5.3.2** The reasons of stopping pill.
    - 5.3.3** Correlation of stopping the pill due to

5.3.3.1 Side effect.

5.3.3.2 Additional children  
desired.

5.3.3.3 Living children.

6. **Data Collection :** Data are collected from the family planning clinics at first visit, 1 month, 3 months and the next every 3 months until 2 years. Time for recruitment of patients 3 months.

7. **Data Analysis :** Data from family planning clinics at first month, 3 months and the next 3 months until 2 years of follow up are analyzed in each group for :

7.1 Side effect and discontinuation rate per 100 women.

Relative risk is calculated from two by two tables.

The result are tested for statistical significance.

7.2 Pregnancy per 100 women per year is calculated for the first and second year by using the peer index.

The table is shown below.

7.3 Side effect then analyzed adjusted to age, parity, age for the first marriage classification of body weight.

7.4 Discontinuation then analyzed adjusted to age, parity, additional children desired, living children, education and side effect

Conclusion of the discontinuation classified into 3 criteria, due to

- Complication
- Change with other method
- Want to pregnant again.

**CORRELATION OF SIDE EFFECT OF PILL  
WITH TYPE OF PILL BASED ON FOLLOW UP INTERVAL**

FOLLOW UP INTERVAL	SIDE EFFECT	50 Ug.	30 Ug.	R.R.	CONFIDENCE LIMIT
1 MONTH	BLEEDING TOTAL RATE				
3 MONTH	BLEEDING TOTAL RATE				
6 MONTH	BLEEDING TOTAL RATE				
9 MONTH	BLEEDING TOTAL RATE				
12 MONTH	BLEEDING TOTAL RATE				
24 MONTH	BLEEDING TOTAL RATE				

TOTAL R.R.

(C.L. 95% )

ADJUSTED R.R. M.H.

**NEXT → DEVELOP WITH OTHER COMPLICATION AS WEIGHT GAIN, AMENORRHEA, SUBJECTIVE COMPLAINS, ETC.**

**CORRELATION BETWEEN DISCONTINUATION  
WITH ADDITIONAL CHILD ON EACH GROUP PILL**

1	ADDITIONAL CHILD	OUTCOME	50 Ug.	30 Ug.	R.R.	CONFIDENCE LIMIT
1		DISCONTINUATION TOTAL RATE				
2		DISCONTINUATION TOTAL RATE				
3		DISCONTINUATION TOTAL RATE				
4		DISCONTINUATION TOTAL RATE				

**TOTAL R.R. (C.L. )**  
**ADJUSTED R.R. M.H.**

**NEXT → DEVELOP WITH OTHER OUTCOME AS EDUCATION,  
 PARITY, AGE, ETC.**

DISCONTINUATION ASSOCIATED WITH OTHER FACTORS

REASON	30 Ugro (Rate)	50 Ugro (Rate)	RR	CL
- Bleeding	- (X)	- (Y)	$\frac{X}{Y}$	
- Subj. Compl.	-	-		
- Family Size	-	-		
- Living Child	-	-		
- Change Method	-	-		
- Other	-	-		
<b>TOTAL</b>	<hr style="width: 50%; margin: 0 auto;"/> $N_1$ $R.R. \frac{N_1}{800}$ $R.R. M.H.$	<hr style="width: 50%; margin: 0 auto;"/> $N_0$ $R.R. \frac{N_0}{800}$		

TOTAL 750

DISCONTINUATION DUE TO TIME

PERIOD	30 Ugro	50 Ugro	RR	CL 95%
1 MONTH	DISC. -	-		
	TOTAL -	-		
	RATE -	-		
3 MONTH				
6 MONTH				
9 MONTH				
⋮				
24 MONTH				

**8. Selection of Study Area and Population:**

This study will be conducted in 4 provinces in Indonesia and randomize 2 family planning clinics for research for total number of sample 800 for each group.

- Criteria of samples :
- 8.1 New acceptors, have never use O.C.
  - 8.2 Ever use OC not prior to the last three months.
  - 8.3 Non lactating women but have regular menstruation at least 2 cycles.

The sample above also never have injectable contraceptive and not treated with corticosteroid for the last 3 months.

- 9. Contra Indication :**
- 9.1 High blood pressure.  
Systolic more than 140 mm HG.  
Diastolic more than 95 mm HG.
  - 9.2 Varices.  
Enlargement of venous blood vessels of the leg.
  - 9.3 History of liver disease, blood disease, diabetes mellitus, heart disease.

10. Age : Age between 15-35 years old.

11. Data Collection Procedures

11.1 All parous women who come to family planning clinics request for oral contraception are selected by midwife and assignment of group are systematic in sequence until 100 for each group

11.2 Acceptors have their first pill at the first visit.

11.3 The next 2 weeks, the field worker visit the patients for attention of patients taking pill and record any complications.

11.4 Follow up is made by midwife in clinic at 1 month, 3 month and every 3 months until 2 years, to find any side effect and complain. Every complications must consult to the physician.

11.5 Every patients receive a sheet of paper, called menstrual chart or bleeding diary. This paper collect by field worker and send it to clin

11.6 For patients who stop take their pill, field worker or midwife ask the reason. Technique of the question is "Open Question" and than specify the answer.

IV. BUDGET ABOUT US \$54,000 =



TERMS

- Spotting is bleeding occurs beside the normal cycle but not as much as menstrual blood.
- Withdrawal bleeding is bleeding occurs after the normal menstruation but the amount is likely the menstruation.
- Menorrhagia is flow of menstrual blood more than 7 days or more profuse.
- Amenorrhea is lost of menstruation after taking pill for two months regularly.
- Underweight is the body weight less than 10% below the ideal weight.
- Ideal weight is calculated from  $[(\text{height (CM)} - 100) - 10\%]$  kg.
- Over weight is the body weight 10% above the ideal weight.

APPENDIX D  
EPIDEMIOLOGY WORKSHOP  
EVALUATION

1. Which statement below most clearly identifies a problem? (Choose one)
  - (1) Two women have died following a sterilization.
  - (2) There were 10 ectopic pregnancies diagnosed in Hospital B last year.
  - (3) Unmarried females aged 10-14 years in Community A do not become pregnant; however, last year 5 unmarried girls (aged 10-14 years) delivered babies in Community A.
  
2. Objectives will keep people focused on the desired achievement of a project. Which statement below most clearly identifies the intended outcome of a prenatal care program? (Choose one)
  - (1) To reduce the rate of low birth weight infants by providing more prenatal services.
  - (2) To provide nutrition counseling to malnourished prenatal patients.
  - (3) By January 1983, to deliver prenatal care to at least 80 percent of pregnant women in the community during the first trimester of pregnancy.
  - (4) To deliver increased prenatal care to pregnant women in the community.
  
3. The difference between analytic epidemiologic studies and descriptive epidemiologic studies is: (Choose one)
  - (1) Descriptive studies allow calculation of relative risks.
  - (2) Analytic studies have a comparison group which allows study of associations between cause and effect.
  - (3) Descriptive studies allow us to make statements of causal associations.
  - (4) Analytic studies permit the monitoring of disease in communities.

4. What is a cohort? (Choose one)

- (1) A group of people selected for a special purpose or study.
- (2) A diseased person having specific characteristics.
- (3) A form of epidemiologic analysis.
- (4) A nondiseased person.
- (5) A comparison group used to evaluate the effect of exposure.

5. A district contains 100,000 people (45,000 males and 55,000 females), and 1,000 people die each year (600 males and 400 females). Last year there were 2,000 births; 10 women died during childbirth.

Compute:

(a) Crude death rate (per 1,000):

\_\_\_\_\_

(answer)

(b) Crude birth rate (per 1,000):

\_\_\_\_\_

(answer)

(c) Maternal mortality rate (per 100,000 live births):

\_\_\_\_\_

(answer)

6. Which of the following study designs are Descriptive and which are Analytic?

(a) Case-control (retrospective) study. (Choose one)

(1) Descriptive

(2) Analytic

(3) Unknown

(b) Surveillance (Choose one)

(1) Descriptive

(2) Analytic

(3) Unknown

(c) Cohort (prospective) study (Choose one)

(1) Descriptive

(2) Analytic

(3) Unknown

7. Surveillance studies may: (Choose one)

(1) Prove cause and effect relationships.

(2) Generate hypotheses to be tested by analytic studies.

(3) Provide estimates of relative risks.

(4) be more likely than other study designs to contain ascertainment bias.

8. The relative risk of developing PID for women using oral contraceptives, compared to women using no contraceptive method, is 0.5. Another way of saying this is: (Choose one)

- (1) 5 women using oral contraceptives developed PID.
- (2) Women using oral contraceptives have a greater risk of developing PID than women using no contraceptive method.
- (3) Women using oral contraceptives have half the risk of developing PID compared with women using no contraceptive method.
- (4) Non oral contraceptive use is more likely to cause PID than oral contraceptive use.
- (5) Oral contraceptive use is not associated with PID.

9. Six of 10 women wearing an IUD for 1 year develop PID. Two of 20 women using oral contraceptives for 1 year develop PID. Compute the relative risk of PID for women using an IUD compared to women using oral contraceptives.

RR = \_\_\_\_\_

(answer)

10. A prospective (cohort) study is done to examine the association between depo-medroxyprogesterone acetate (DMPA) use and abnormal vaginal bleeding.
- (a) The exposed group consists of: (Choose one)
- (1) Women not using DMPA
  - (2) Women with abnormal vaginal bleeding
  - (3) Women not using IUDs
  - (4) Women without abnormal vaginal bleeding
  - (5) Women using DMPA
  - (6) Women using IUDs
- (b) The non-exposed group consists of: (Choose one)
- (1) Women not using DMPA
  - (2) Women with abnormal bleeding
  - (3) Women not using IUDs
  - (4) Women without abnormal bleeding
  - (5) Women using DMPA
  - (6) Women using IUDs
11. If your "Cases" of a certain disease are persons diagnosed in the community (i.e., in the hospitals and in all other health facilities, including private physician's offices), what would be the best "Control" group? (Choose one)
- (1) A sample of patients in the hospitals who do not have the disease being studied.
  - (2) A sample of the community population with a similar disease.
  - (3) A sample of the community population without the disease.
  - (4) A sample of persons without the disease in a nearby community.
  - (5) Other, specify \_\_\_\_\_

12. In a case-control (retrospective) study, which of the following is LEAST likely to lead to "bias"? (Choose one)
- (1) Cases are selected from hospital A and controls from hospital B.
  - (2) Exposure data are collected from cases by interview and from controls by medical record review.
  - (3) Cases and controls are selected from the same health facility.
  - (4) Cases are selected from the health department, and controls are selected from a registry.

13. Which items below belong in a research proposal?

- (a) Justification of research
- (b) Abstract of proposal
- (c) Study methodology
- (d) Budget
- (e) Statement of research objectives

Circle the correct answer. (Choose one)

- (1) a, b, d, e
- (2) a, c, e
- (3) c, d, e
- (4) a, c
- (5) All of the above.

14. The possibility of confounding can be examined in a study by which of the following techniques: (Choose one)

- (1) calculation of the standard deviation
- (2) stratification and standardization of data
- (3) aggregation of data
- (4) estimation of study size needed

15. Match the following words to their correct definition.

(Definition)

- |                              |  |
|------------------------------|--|
| _____ 1. Incidence Rate      | (a) Bias introduced through collection of information in a way that is different for cases and controls.                                 |
| _____ 2. Sensitivity         | (b) Study of the amount and distribution of health problems in a population.   |
| _____ 3. Retrospective Study | (c) The number of people in a population who have a health problem at a specified time.  |
| _____ 4. Ascertainment Bias  | (d) A ratio of the incidence of a condition in a group exposed to a risk factor to the incidence of that condition in those not exposed. |
| _____ 5. Confounding         | (e) The ability to correctly identify those without the condition of interest.   |
| _____ 6. Prevalence Rate     | (f) Study moving from cause (exposure) to effect (disease).  |

- \_\_\_\_\_ 7. Specificity (g) Rate at which people without a health problem develop the problem during a specified period of time.
- \_\_\_\_\_ 8. Descriptive Study (h) The ability to correctly identify those with the condition of interest.
- \_\_\_\_\_ 9. Relative Risk (i) Study moving from effect (disease) to cause (exposure).
- \_\_\_\_\_ 10. Prospective Study (j) The absolute amount of risk that is due to a particular exposure.
- \_\_\_\_\_ 11. Attributable Risk (k) Bias introduced because cases and controls differ in some characteristic which is associated with both the condition and the exposure being studied.

16. Have you ever designed a research proposal to study a contraceptive safety problem?

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APPENDIX E

PRETEST SCORES FOR WORKSHOP PARTICIPANTS  
FEBRUARY 22-27, 1982

<u>Number of Incorrect Answers</u>	<u>Number of Persons</u>		<u>Score</u>
2	1		93%
5	1		83%
9	2		70%
11	1		63%
12	1		60%
14	1		53%
16	2		47%
18	2		40%
19	2		37%
24	1		20%
<u>Overall</u>	<u>14</u>	Mean Score =	<u>54%</u>

POST TEST SCORES FOR WORKSHOP PARTICIPANTS

<u>Number of Incorrect Answers</u>	<u>Number of Persons</u>		<u>Score</u>
0	3		100%
2	2		93%
3	2		90%
5	1		83%
8	1		73%
9	3		70%
14	1		53%
<u>Overall</u>	<u>13</u>	Mean Score =	<u>83%</u>

**FREQUENCY OF PRETEST AND POST TEST QUESTIONS MISSED**

**BANGKOK WORKSHOP**

<u>Frequency of Misses</u>	<u>Question Number/Pretest</u>	<u>Question Number/Posttest</u>
0	-	3, 5a, 5b, 6a, 6c, 10a, 13, 15(4)
1-4	3, 5a, 5b, 6a, 6c, 10a, 12, 15(3), 15(10)	1, 2, 6b, 7, 8, 9, 10b, 12, 14, 15(2), 15(3), 15(5), 15(7), 15(8), 15(9), 15(10), 15(11)
5-9	1, 4, 7, 8, 9, 10b, 11, 13, 14, 15(1), 15(4), 15(6), 15(8), 15(9), 15(11)	4, 5c, 11, 15(1), 15(6)
10-14	2, 5c, 15(2), 15(5), 15(7)	-
15		-

APPENDIX F

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SUMMARY  
Training Evaluation Form  
Bangkok, Thailand  
February 22-27, 1982  
Epidemiology and Contraceptive  
Safety Workshop

- 1) Did the course meet your expectations? If no, what was different than you expected?

Yes - 12

"More than what I had expected."

- 2) Were the objectives clear to you from the beginning of the workshop? If not, please make suggestions for improvements.

Yes - 9            No - 3

- a. It would have been better if these were written in the red book.
- b. Objectives were not stated as specifically as possible. So, it's difficult to determine the extent to which the workshop objectives were achieved.
- c. The objectives were not clear to me at first. I don't know whether you were to teach me how to write a proposal or have me give a proposal for funding.
- d. It would be better if they were written down and distributed to each participant.

- 3) Will this workshop help you do better family planning epidemiologic research?

If not, describe why not

Yes - 11            No - 1

"I don't believe it can actually do the research, but maybe design and critique epidemiologic studies."

4) How was the course content practical, in terms of the work you do?

Yes - 3

- a. Discussion of proposal design
- b. Writing proposals; planning for health surveillance
- c. The course content is very useful, but the time is too short.
- d. The theoretical aspects were clarified and correlated with practical aspects.
- e. It was practical only to a limited extent - specifically in examining bias, generalizability, association vs. cause and effect.
- f. I think it's good to give the participants practice; if all we know is theory and knowledge we can't do a proposal.
- g. It helped me to learn how to make a protocol for a study, and how to be sure that the necessary bias would be reduced.

5) Were the handouts and other teaching aids helpful and adequate? If not, please make suggestions for improving the handouts and other teaching aids:

Yes - 11

- a. The microphone is not sensitive enough.
- b. Especially the red book. More self assessment questionnaires which the participant can do outside the classroom.
- c. Red manual - Yes. I am not sure how the trainee should use the book authored by Morton et al - we were not told how.
- d. The red book was great (2).

6) For which subjects (if any) did you feel that the course materials were confusing?

No - 5

- a. Interpreting the results
- b. Biostatistics

- c. The use of adjusted RR because we only received the formula without training on how to use the formula.
  - d. Surveillance. You didn't give the explanation about it. Is it a descriptive or analytic study.
  - e. Examples of objectives which are more particularly "program objectives" should be distinguished from "research objectives."
  - f. Sequence of topics discussed and sequence they appeared in red manual not explained. We were told rotely just to turn to certain pages for case analysis.
  - g. Subjects were clear, but I confuse the English.
  - h. When it came to the derivation of formulas.
- 7) Did you get satisfactory chances to contribute your ideas? If not, please make suggestions for improvements:
- Yes - 10            No - 1
- 8) Did you get satisfactory answers to your questions?
- Yes - 10            No - 1
- a. I think the resource persons are very knowledgeable.
  - b. Not so good, but the best I could get.
- 9) Did you feel that the trainers respected your feelings and point of view? If not, please make suggestions for improvements:
- Yes - 12
- a. There were some occasions when the trainers treated some participants like child learners instead of adult learners.
- 10) What aspect of the trainers' presentations were particularly well done?
- a. Contraceptive issues was well discussed and well presented.
  - b. Making conclusions and interpretation of relative risk and statistical significance. (2)

- c. All (2)
- d. Analytic studies
- e. Explaining the terms.
- f. Different types of research design and interpretation of confidence level.
- g. Distinction between analytic studies and descriptive studies with exercises; computation of relative risk.
- h. Sometimes examples were given that were confusing.
- i. The presentations of Dr. Rubin and Dr. David Bennett.

11) What suggestions for improvement in the presentations would you make?

- a. No specific improvement is required.
- b. Prepare the presentation before.
- c. None (3)
- d. More training for more complicated examples.
- e. Instead of repeating what's in the red book, its contents should be reinforced more.
- f. Problem statement. More case problems from actual (more complex) studies which are not in manual.
- g. Best to use practical examples to make points clear.

12) Did you like the way the course was run?

Yes - 12

A suggestion would be to give an afternoon off.

13) What aspects of the workshop were particularly well done?

- a. Writing of the project proposal

- 
- b. To improve the ability to make a good/reliable proposal study. (2)
  - c. All (place, time, light, sound, materials, schedule, etc.) (2)
  - d. Analytic studies
  - e. What considerations should a person take before preparing a most feasible project proposal?
  - f. The faculty (for being very patient!)
  - g. 1) Knowledge  
2) Practice

14) What suggestions for improvement would you make?

- a. More time should be given for writing the proposal.
- b. None (3)
- c. Afternoon sessions should not contain any lectures. It should be the the practice of the exercise.
- d. It is better when meals are served near the session hall.
- e. Give an afternoon off.

15) Did you like the format of the workshop? If no, specify what you did not like and make suggestions for improvement:

Yes - 9

- a. There is no time for Muslims to perform prayers at Mosque on Friday.
- b. I think we would have benefitted if there were other research proposals which we could have discussed, especially to illustrate certain issues like selection bias, etc. More time to discuss among participants contraceptive issues of relevance to their particular situation and probable types of studies that could be done.
- c. Group work for more complex case problems for analysis, computation, etc.

16) Was the length of the course appropriate? If no, specify why not and make suggestions for improvement:

Yes - 9

No - 3

- a. Time was not enough to go through and discuss the problems which needed more; another week to have the thorough knowledge.
- b. I think the answer is "yes" for some people, but for me at least 6 months would possibly be enough (it is not a very easy subject!).
- c. For people who have no prior research experience, maybe a week more would be helpful.

17) What type of followup would help you to implement the skills you have learned when you get home?

- a. Whether we have developed any other project proposal and have implemented the proposal which we have developed here and conducted the study as per proposal.
- b. Make the research by case-control study.
- c. Discuss problem statement.
- d. Regular information about what is going on in the research field.
- e. Communication between trainees and trainers.
- f. Send another study proposal to Pop Council and correction will be made by Pop Council.
- g. Need to be informed about recent developments of contraceptive technology and studies done on contraceptive safety.
- h. Technical assistance to improve or make proposals
- i. Some trainers in Thailand can advise me. That will be good enough
- j. By sending us proposals of study.
- k. You can send the proposals discussed in the previous workshop.

- 
- 18) How can future workshops of this kind be improved? In your opinion, what new material should be added?
- Extend the time period.
  - Publications of previous research
  - Tell the participants beforehand to bring enough background information to justify the proposal.
- 19) What material should be deleted?
- None - 4
- Computation as to the derivation of formulas.
- 20) What material should be most emphasized?
- All - 1
- Statistics
  - To bring a very sensitive issue regarding contraceptive safety.
- 21) Other comments:
- Workshop is very fruitful and well organized. Thanks to the organizers and trainers.
  - We want to know how to collect the number of samples we need on the population for a good/valid study.
  - Air conditioner was too cold.
  - It is a workshop, so why does certificate say training course? It was not explained how to determine normal and abnormal curve. It was not explained how to measure the number of the sample size needed.
  - Good individual care was taken. I am very pleased to have attended the workshop.
  - It may be helpful if these courses could be conducted in other areas where previous participants come from. It will be some form of follow

up for them and also affords a better chance for trainers to have a grasp of country situations and therefore guide and redirect trainees as to the feasibility of research topics and design.

- g. Accommodations are very comfortable and conveniently located from center. Very considerate for the Council to pay for lodging in addition to our per diem and for cost of coming to airport.