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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date January 26, 1982

From Medical Epidemiologist, Epidemiologic Studies Branch, Family Planning Evaluation Division (FPED), Center for Health Promotion (CHPE)

Subject Foreign Trip Report (AID/RSSA): Thailand, September 13-27; Indonesia, September 28-29; India, October 1-2; Switzerland, October 2-4; England, October 5-6; New York City, October 7, 1982

To William H. Foege, M.D.
Director, Centers for Disease Control
Through: Horace W. Ogden
Director, CHPE
Roger Rochat
Director, FPED

I. PLACES, DATES AND PURPOSE OF TRAVEL
II. PRINCIPAL CONTACTS
III. ACCOMPLISHMENTS
IV. RECOMMENDATIONS

SUMMARY

From September 13-26 I, participated in designing and teaching a course in epidemiologic methods applied to contraception safety research (see trip report Rubin, Zahniser, Bangkok, Thailand September 11-26, 1981. I subsequently met with persons from agencies involved in contraception safety research: 1)the World Federation of Health Agencies for the Advancement of Surgical Contraception (WFHA-AVSC), 2) the Human Reproduction Unit, World Health Organization (WHO), and 3) International Planned Parenthood Federation (IPPF).

My activities included 1) the design and teaching of an epidemiologic methods course in Bangkok, Thailand, 2) participation in a committee to develop a document of standard terminology and definitions to be used for sterilization studies by the WFHA-AVSC, 3) discussion of current research in sterilization safety carried out by IPPF and the Indian Medical Research Council, and discussion of current projects in contraception safety conducted by WHO.

I. PLACES, DATES AND PURPOSE OF TRAVEL

Bangkok, Thailand, September 13-27
Jakarta, Indonesia, September 28-29
New Delhi, India, October 1-2
Geneva, Switzerland, October 2-4
London, England, October 5-6
New York City, October 7

For details on the Bangkok training course on epidemiologic methods, see trip report Rubin, Zahniser, Bangkok, Thailand September 11-26, 1981. I was requested by the Secretariat of WFHA-AVSC to attend a meeting of the statistics committee of that organization to develop a document of standard terminology definitions to be used by WFHA-AVSC for sterilization. The document was to be prepared for presentation to the general assembly of the WFHA-AVSC by November 3, 1981. I next set out to become familiar with current contraceptive safety research undertaken by The Indian Council of Medical Research, WHO, and IPPF.

II. PRINCIPAL CONTACTS

Bangkok, Thailand - see trip report Rubin, Zahniser, Bangkok, Thailand, September 11-26, 1981.

Jakarta, Indonesia

Does Sampoerno, MD, MPH
Dean, School of Public Health
University of Indonesia
Jakarta, Indonesia and
Chairman Statistics Committee WFHA-AVSC

Boonlert Leoprapiai
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Badri N. Saxena, MD
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Human Reproduction Unit, WHO

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Maternal and Child Health Unit, WHO

London, England

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Medical Director, IPPF.

New York City, New York

Oscar Harkavy, PhD
Program Officer in Charge
International Division
Ford Foundation

III. ACCOMPLISHMENTS

A. Training course in the use of epidemiologic methods in contraception safety research. (See Trip Report Rubin, Zahniser. Bangkok, September 11-26, 1981)

B. In Jakarta I participated in a meeting of the Statistics Committee of WFHA/AVSC to develop a document of standard terminology and definitions for use in sterilization studies in countries participating in WFHA-AVSC. (See attachment A.) The definitions and mortality surveillance model developed by CDC were accepted with little modification. Wide dissemination of the document will assist FPED/CDC in its efforts to 1) set up an international sterilization mortality registry and 2) standardize definitions used in international sterilization morbidity studies.

C. I met with Dr. Susan Holck to discuss current studies on the health effects of DMPA supervised by WHO, and Dr. Earle Wilson to discuss WHO's current tubal sterilization research. The latter include the study of the psychological sequelae of tubal sterilization, menstrual blood loss after tubal sterilization, and the incidence of breast cancer in women who have had a tubal sterilization procedure.

D. I attempted to obtain data on deaths occuring after sterilization procedure in India from Dr. Badri Saxena. However, the Indian government is reluctant to share data from epidemiologic studies with other countries prior to publication of the data. We did discuss current studies of the health effects of tubal sterilization and vasectomy being undertaken currently in India. These studies include a multi-center study of complications occuring within the first three months after tubal sterilization, and cardiovascular complications occuring after vasectomies.

E. At IPPF I discussed progress to date of the worldwide survey of IPPF physicans for sterilization associated deaths. This project is being conducted jointly by IPPF and CDC. I learned of the logistics of the mailing process and met with IPPF personnel responsible for the questionnaire mailing and data collection.

F. In New York City I met with Dr. Oscar Harkavy to discuss the progress and results of the training course in epidemiologic methods held in Bangkok.

IV. RECOMMENDATIONS

A. FPED/CDC should assist development of epidemiologic expertise in the South and East Asia region by participating in further seminars on the use of epidemiologic methods in contraceptive safety research.

B. FPED/CDC should maintain its cooperative relationship with the WFHA/AVSC and offer technical assistance to those countries wishing to carry out sterilization morbidity studies.

C. FPED/CDC should, through WFHA/AVSC publicize its efforts to set up an international registry of sterilization deaths.

D. With respect to sterilization studies FPED/CDC should maintain a collaborative relationship with WHO, IPPF, and the Indian Council of Medical Research.

George Rubin

George L. Rubin, MB BS

RECOMMENDATIONS OF THE STATISTICS COMMITTEE FOR PRESENTATION AT THE WFHA-AVSC GENERAL ASSEMBLY TO BE HELD IN BANGKOK, THAILAND NOVEMBER 3-5, 1981

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I.

Standardization of Terminology for the Collection of Data on Voluntary Surgical Contraception

Voluntary Surgical Contraception Statistics Committee
World Federation of Health Agencies for the Advancement
of Voluntary Surgical Contraception

October, 1981

The performance and health consequences of voluntary surgical contraception (VSC) are of worldwide concern. To allow international data comparisons, standardized definitions and terms should be used. The Voluntary Surgical Contraception Statistics Committee of the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception (WFHA-AVSC) recommends that the following terminology be used in the compilation of voluntary surgical contraception statistics.

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A. Definitions of Types of Surgical Operations and Techniques Used in Voluntary Surgical Contraception (VSC)

1. Female Surgical Contraception

1.1 Timing

1.1.1 Post-Partum - performed during the first week after vaginal delivery.

1.1.2 Concurrent with Cesarean Section - Performed in conjunction with cesarean section delivery.

1.1.3 Concurrent with Abortion - Performed in conjunction with induced abortion.

1.1.4 Post-Abortion - Performed within one week after induced or spontaneous abortion.

1.1.5 Interval - Performed at any time other than within one week following the termination of a pregnancy.

1.2 Surgical Approaches

1.2.1 Laparotomy - An abdominal approach to the peritoneal cavity using either a subumbilical midline or low transverse incision more than 5 cm length.

1.2.2 Mini-Laparotomy - An abdominal approach with an incision 5 cm or less, generally transverse suprapubic for interval and post abortion sterilization, and transverse or midline subumbilical for post-partum sterilization.

1.2.3 Colpotomy - A transvaginal incision through the cul-de-sac to approach the peritoneal cavity and expose the fallopian tubes.

1.2.4 Laparoscopy - An abdominal approach to the peritoneal cavity using a laparoscope (electrically lighted fiberoptic instrument for examining the peritoneal cavity). Instruments for tubal occlusion can be introduced either through a second incision, or together with the laparoscope (operating laparoscope).

1.2.5 Culdoscopy - A vaginal approach to the pelvic cavity using an endoscope that is introduced through the posterior vaginal formix. Instruments for tubal occlusion are introduced by the same route.

1.2.6 Hysteroscopy - (experimental) - A trans-cervical approach to the uterine cavity using a fiberoptic instrument (hysteroscope). The tubes may then be occluded either by coagulation , silastic plugs, or sclerosing agents.

1.3 Surgical Techniques

1.3.1 Pomeroy Technique - Use of an absorbable suture to ligate and excise the tubes and the loop of the tube (distal and proximal ends draw apart when the suture material dissolves)

1.3.2 Madlener Technique - Crushing and ligation of tubes with a non-absorbable ligature.

1.3.3 Irving Technique - Division and ligation of tubes with burial of the proximal end in the uterine muscle.

1.3.4 Cooke Technique - Burial of the proximal end of a previously sectioned tube into the round ligament.

1.3.5 Uchida Technique - Burial of the proximal end of a previously sectioned tube into the folds of the broad ligament which have been previously separated by injecting a physiologic saline; the distal end of tube projects into the abdominal cavity.

1.3.6 Fimbriectomy - Ligation and excision of the distal segment of the tubes and fimbriae.

1.3.7 Salpingectomy - Excision of the entire tube; partial salpingectomy denotes removal of either a proximal, medial, or distal segment (fimbriectomy).

1.3.8 Band - Falope Ring™ (Yoon band) - a silicone rubber band applied by laparoscope/laprocator on a loop of the fallopian tube, thereby occluding it.

1.3.9 Clip - Various types of clips can be used to occlude the tubes. These include

1.2.9.1 Tantalum clips (Filshie)
1.2.9.2 Spring-loaded clips (Hulka, Rocket)
1.2.9.3 Plastic clip - (Bleier)

1.3.10 Electrocoagulation - Tubal occlusion using simple electrocoagulation under laparoscopic control (operating laparoscope is a telescope with a channel for an ancillary instrument); currents are unipolar or bipolar.

1.3.11 Thermocoagulation - Tubal occlusion using heat generated between blades of scissors or forceps by an electric current. No electric current passes through the tubal tissue.

1.3.12 Ovariopexy (experimental) - The ovaries are suspended and sutured to the supporting ligaments after covering them with a silastic pouch to prevent the escape of mature ova into the peritoneal cavity.

2. Male Surgical Contraception

3.1 Vasectomy - Bilateral occlusion of the vas deferens through incision(s) through the skin and thin muscle layer of the scrotum.

B. INFORMED CONSENT

1. Informed consent is broadly defined in terms of 'understanding the nature and consequences of the procedure to be performed,' that is, the voluntary, knowing assent from an individual, after he or she has been advised on a variety of specific matters, to proceed with VSC.

2. Informed consent is comprised of three elements:

- The person must not be mentally incompetent or have impaired capacity to consent.
- The consent must be voluntary.
- The person must be given sufficient information to weigh the alternatives and to make the decision.

2.1 Mental Incompetence and Impaired Capacity - A person of 'impaired capacity' is one who has not been formally declared incompetent, but who:

- On the basis of professional assessment is found to be sufficently mentally impaired so as to be unlikely to make a reasoned and informed judgment about an issue as grave as sterilization (that is, he or she is considered incapable of understanding the nature and consequences of the procedure).
- While possessing the mental capacity to make an informed judgment, is under some form of confinement or duress which limits his or her freedom to exercise such judgment.

2.2 Voluntary Consent - Voluntary consent is given by an individual based upon the exercise of free choice and is not obtained by any special inducement or element of force, fraud, deceit, duress or other forms of coercion or misrepresentation.

2.3 Suggested Informational Content

2.3.1 o Temporary contraceptive methods are available to the individual and his/her partner;

2.3.2 o Sterilization is a surgical procedure;

2.3.3 o Certain discomforts and risks attend the procedure (these must be explained by the physician);

2.3.4 o Sterility is not guaranteed;

2.3.5 o Complications and side effects which may ensue from the procedure;

2.3.6 o If successful, the operation will prevent the patient from having any more children;

2.3.7 o The operation is irreversible; and

2.3.8 o The individual may decide against the procedure at any time before the operation and no services or benefits will be withheld from him as a result.

C. INCENTIVES/DISINCENTIVES

The legal Committee of the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception has noted that the issue of free consent to surgical contraception is tied to questions of incentives and disincentives. The Committee states that:

> "this issue brings about the inherent conflict between the right of an individual to a free choice and the possible need of a state to conduct an effective population policy. The problem is how to draw a boundary between unobjectionable privileges (such as some positive incentives) and threats of deprivation from basic amenities (such as access of children to desirable schools). Incentives or disincentives should not exploit a weakness in the position of an individual."

It is recommended that incentives/disincentives include economic and/or social rewards offered to or denied the population of potential acceptors of surgical contraception.

D. STERILIZATION FAILURE

Sterilization failure means the occurrence of conception after a sterilization procedure.

For females, this excludes pregnancies resulting from the implantation of an already fertilized ovum (luteal phase pregnancy). After vasectomy, this excludes conceptions occurring before the development of azospermia.

E. STERILIZATION ASSOCIATED MORBIDITY

1. Sterilization Associated Morbidity - Complications occurring during or within 42 days following a male or female sterilization procedure. The complication may be directly related to the surgical procedure and/or anesthesia.

   1.1 The complication may be classified as minor or major.

   1.1.1 Minor - The complication does not require an unintended surgery* , unexpected hospitalization** , blood transfusion or treatment of life-threatening cardiac and/or pulmonary events.

   1.1.2 Major - The complication requires unintended surgery*, unexpected hospitalization**, blood transfusion or treatment of life-threatening cardiac and/or pulmonary events, or results in death.

   *Any additional surgery at the time of the sterilization or subsequent operation (a)

   **An extension of the planned time of hospitalization, rehospitalization or admission to a hospital from outpatient facilities

F. STERILIZATION ASSOCIATED MORTALITY

1. A Sterilization - associated death is death of a VSC acceptor from any cause within 42 days of tubectomy or vasectomy. Although death might have occurred after 42 days, the onset of the fatal complication must have occurred before the end of the 42 day period. A Sterilization - associated death may be subclassified as:

   1.1 A sterilization-attributable death - A death resulting from complications of the operation itself, or from the chain of events initiated by the operation which lead to death, or from aggravation of an unrelated condition by the physiologic or pharmacologic effects of the operation which subsequently caused the death.

   1.2 A non-attributable sterilization death - A death occurring during or after the operation which is not causally associated with the operation, its complications, or their management.

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II. Recommendations for minimum data collection on VSC procedures for program planning and management.

1. Type of health facility
2. Acceptor name
3. Home address
4. Sterilization procedure
5. Age of acceptor
6. Age of spouse
7. Number of living children
8. Contraceptive methods used in the past

Suggested additional items

1. Profession of operator
2. Acceptor religion
3. Acceptor education
4. Spouse education
5. Acceptor occupation
6. Spouse occupation
7. Duration of marriage

See appendix A for an example data collection form.

III. Health effects of VSC

Background and justification

The incidence, characteristics, and risk factors for the development of complications following all surgical procedures should be known. Voluntary surgical contraception (VSC) is performed frequently and under many different conditions; the gathering of information on complications is thus of particular concern.

Important reasons for clearly defining the risks of VSC include the following:

1. Use of VSC is common; thus complications, even if rare, are important public health concerns.
2. The safety of VSC performed under different conditions in different countries is not well established. Aggregation of information on complications collected on a world-wide scale is an important first step in an effort to improve the safety of VSC.
3. VSC is an elective procedure performed predominantly on healthy people.
4. VSC usually requires anesthesia.
5. VSC is one of the few surgical procedures performed in rural settings.
6. VSC may be performed by paramedics.
7. No specific agency has been designated to be responsible for collection of information on VSC complications on a world-wide basis.
8. VSC may be a socially or politically sensitive issue.

a. VSC related mortality

Proposal for surveillance of VSC-related deaths.

A small number of unnecessary deaths has the potential of severely impairing the effectiveness of a contraceptive program. Careful monitoring of deaths occurring after VSC is essential to ensure rapid identification of problems so that corrective action may be taken to avoid further preventable deaths occurring.

As a first step in monitoring the safety of VSC on a world-wide basis, WFHA-AVSC proposes that VSC mortality surveillance be instituted in participating countries. The following is a suggested outline for simple standard system for monitoring deaths occurring after VSC.

1. Definitions We suggest that definitions outlined in Section I (Standardization of terminology for the collection of data) be used.

2. Persons responsible for data collection One person in each country should have the responsibility for collecting relevant information from different institutions performing VSC and forwarding this information on a regular basis to a central agency, for example, WFHA-AVSC.

APPENDIX A

WFHA-AVSC Monthly/Quarterly Report of Sterilization (Male & Female) Procedures Performed

Name and Address of Medical Facility: _____

Type of facility:

___ Hospital

___ Non-hospital clinic

___ Doctor's office

___ Other, specify _____

Does this facility have: Emergency ventilation equipment ___Yes ___No

Blood transfusion facilities ___Yes ___No

Facilities for surgical management of operative complications ___Yes ___No

Date Day/Mth/Yr	Acceptor Name and Address	Acceptor Age Years	Spouse Age Years	No. of Living Children	Clinical Information (Use Codes from back) A	B	C	D	E	F	G	Comments (more space on back)
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/ /												
/ /												
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Directions:

1) Include all cases of surgical sterilization, male or female (interval, post partum and post abortion).
2) Information on cases should be recorded horizontally on a separate line for each case.
3) For columns in the section "Clinical Information", please use the appropriate numbered codes (see below), for vasectomy enter 8 in columns B-D.
4) For any additional information, use the "Comments" column. This may include both information requested to be specified in the Clinical Information Codes and any other information you consider valuable. If you need more room, you may continue on the additional space at the bottom of this page.

CODES FOR CLINICAL INFORMATION

A. Previous Method(s) of Contraception Ever Used
- 1 none
- 2 oral contraceptives
- 3 IUD
- 4 barrier methods (condoms, diaphragm)
- 5 spermicides (foam, cream jelly, etc.)
- 6 injection
- 7 other (specify in comments collumn)
- 8 more than one (specify in comments column)
- 9 unknown

B. Timing of the Sterilization
- 1 post partum (within 1 wk)
- 2 with cesarean section
- 3 post abortion (within 1 wk)
- 4 interval (not preg-assoc)
- 8 N/A (vasectomy)
- 9 unknown

C. Approach
- 1 laparotomy
- 2 minilaparotomy (incision 5 cm. or less, interval or post-pregnancy)
- 3 laparoscopy
- 4 vaginal (colpotomy or culdoscopy)
- 5 other (specify in comments)
- 8 N/A (vasectomy)
- 9 unknown

D. Method of Tubal Sterilization
- 1 electrocoagulation (specify unipolar, bipolar in comments)
- 2 Fallope ring
- 3 clip
- 4 Pomeroy, fimbriectomy, salpingectomy, or other surgical tubal occlusion
- 5 other (specify in comments)
- 9 unknown

E. Anesthesia
- 1 general
- 2 regional (spinal, epidural caudal)
- 3 local
- 9 unknown

F. Surgical Accident
- 1 none
- 2 uterine perforation
- 3 intestinal perforation/burn
- 4 major vessels perforation
- 5 bladder perforation/burn
- 6 anesthetic complication
- 7 more than 1 (specify in comments)
- 8 other (specify in comments)
- 9 unknown

G. Who Did Procedure?
- 1 M.D. - OB/GYN or surgeon
- 2 M.D. - other
- 3 medical student
- 4 nurse
- 5 other - specify in comments

Appendix B

INTERNATIONAL STERILIZATION MORTALITY REGISTRY - CENTERS FOR DISEASE CONTROL, ATLANTA, GEORGIA

Age at death (Yrs.)	Date of Death Day/Mo/Yr.	Name and Address of Institution(s) Where Sterilization Was Performed and/or Where Complications Were Treated	Clinical Information (Use codes from below) A	B	C	D	E	F	G	H	Comments
26	/11/80	~~Women's Memorial~~ Hospital, No., Street, City, County	1	2	4	1	1	1	3	2	No intubation-Example
	/ /										
	/ /										
	/ /										
	/ /										
	/ /										
	/ /										
	/ /										
	/ /										
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CODES FOR CLINICAL INFORMATION

A Timing of the Sterilization
1 post partum (within 1 wk)
2 with cesarean section
3 post abortion (within 1 wk)
4 interval (not preg-assoc)
8 N/A (vasectomy)
9 unknown

B Approach
1 laparotomy
2 minilaparotomy (incision 5 cm. or less, interval or post-pregnancy)
3 laparoscopy
4 vaginal (colpotomy or culdoscopy
5 other (specify in comments
8 N/A (vasectomy)
9 unknown

N/A = not applicable

C Method of Tubal Sterilization
1 electrocoagulation (specify unipolar/bipolar in comments)
2 Falope ring
3 clip
4 Pomeroy, fimbriectomy, salpingectomy, or other surgical tubal occlusion
5 other
8 NA (vasectomy)
9 unknown

D Anesthesia
1 general
2 regional (spinal, epidural caudal)
3 local
9 unknown

E Surgical Accident
1 none
2 uterine perforation/
3 intestinal perforation/ laceration
4 major vessel perforation
5 bowel burn
6 bladder transection/ perforation
7 more than 1 (specify in comments
8 other (specify in comments)
9 unknown

F Interval sterilization-to-death
1 less than 1 hour
2 1-24 days
3 1-7 days
4 8-42 days
5 more than 42 days
9 unknown

G Main Cause of Death
1 hemorrhage
2 infection
3 anesthetic complication
4 pulmonary embolism
5 other (specify in comments)
9 unknown

H Who did procedure?
1 M.D. - Ob/GYN or surgeon
2 M.D. - other
3 medical student
4 nurse
5 other - specify in comments

STERILIZATION-ASSOCIATED DEATHS*

DIRECTIONS:

1) Information on deaths should be recorded horizontally on a separate line for each death.

2) For columns in the section "Clinical Information", please use the appropriate numbered codes from the footnotes. (For vasectomy enter 8 in columns A-C).

3) For any additional information use the "Comments" column. (This may include both information requested to be specified in the Clinical Information codes and any other information you consider valuable.)

4) If there is not enough room on the following page, you may continue on additional pages.

Example: A 26-year old woman died in November 1980, ten minutes after a tubal sterilization, performed by a resident of the "Women's Hospital, City, Country", the day after delivering a baby. Using general anesthesia (without intubation) a small subumbilical incision was made to perform a bilateral fimbriectomy. While the incision was being closed, the woman presented hypoventilation problems followed by cardiac arrest. Resuscitation efforts were unsuccessful and she died. Anesthetic complication was the cause of death. Using the Codes for Clinical Information on the next page, this information is as follows:
A) Timing = 1; B) Approach = 2; C) Method = 4; D) Anesthesia = 1;
E) Surgical Accident = 1; F) Interval = 1 ; G) Cause of Death = 3;
H) Performer = 2.

The information about this example is entered in the first line.

---

*Include deaths attributable to anesthesia associated with sterilization procedure.

Each participating country may designate a responsible person for data collection at a district, regional, or state level. Persons responsible for data collection should report their findings on a regular basis and receive feedback from the national and international levels on a regular basis.

3. Data to be collected It should be emphasized that all data collected is to be used for statistical purposes only and that no identification data is required after the initial investigation is completed at the local level. No patient who died or physician should be identified at the national or international level.

   1. Number of VSC procedures performed. See suggested data collection form Appendix A.
   2. Number of sterilization-related deaths occurring by cause of death, sterilization procedure, surgery-death interval, demographic characteristics of the victims, profession of the operators, type of health facility and region of the country.

   It is recommended that some special effort be made to insure completeness of ascertainment of VSC related deaths. See Appendix B for suggested mortality surveillance data collection form.

b. Morbidity

Sterilization morbidity surveillance requires special study. A suggested study mechanism is currently being developed. However, at this stage, it is suggested that programs interested in performing VSC associated morbidity studies consult with the secretariat.