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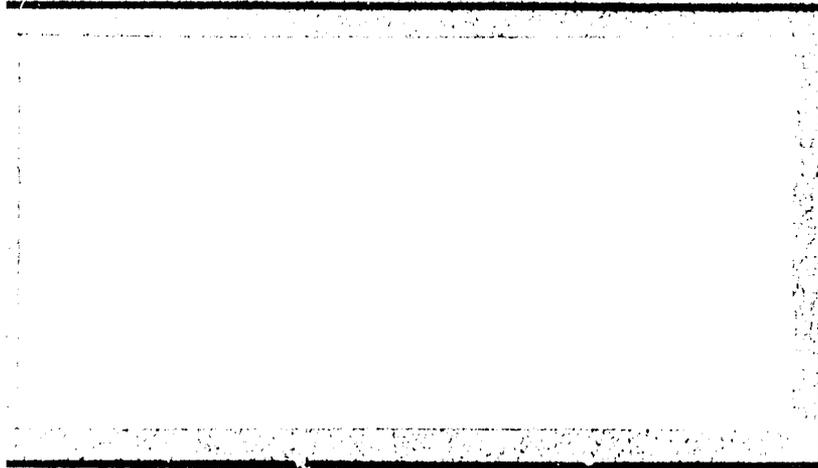
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BANGLADESH ASSOCIATION FOR
VOLUNTARY STERILIZATION

A Report Prepared By:
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This report was prepared by John I. Fishburne, Jr., M.D., Professor of Obstetrics and Gynecology, Associate Professor of Anesthesiology, and Chief, Maternal and Fetal Medicine, Bowman Gray School of Medicine, Winston-Salem, North Carolina.

The author wishes to acknowledge the excellent assistance of Mr. Terrence Jezowski, Mr. Russ Vogel, and Dr. Carol Carpenter-Yaman. In addition, the author gratefully acknowledges the kind assistance of Dr. Azizur Rahman and Dr. Salahuddin Ahmed without whose cooperation this mission would have been wholly unsuccessful.

EXECUTIVE SUMMARY

Although the Bangladesh sterilization program once had an enviable record of safety, recent epidemiological investigations revealed that 28 deaths had occurred over a 15-month period. Twenty-nine percent of these deaths were attributed to respiratory arrest following administration of anesthesia.

The author first visited Bangladesh in July 1980 to evaluate anesthesia practices for sterilization operations. Tubectomy operations carried out under the auspices of the Bangladesh Association for Voluntary Sterilization (BAVS) and the Bangladesh government were observed. In the author's opinion, most patients were receiving excessive systemic sedation and analgesia--primarily, large doses of intravenous diazepam. In fact, the author observed that virtually all patients were experiencing transient general anesthesia in lieu of analgesia to supplement a local anesthetic field block. He suggested changes in the anesthetic regimen, recognizing that the recommended method must be tailored to conditions in rural Bangladesh. It was apparent that a local field block technique had to be used and that that technique should be augmented by systemic analgesia. Because diazepam (Valium), meperidine (Pethidine), promethazine (Phenergan), and Atropine were readily available, the author recommended that they continue to be used, but in reduced dosage, with an altered sequence of administration. The final recommendation was for diazepam premedication followed by operative analgesia consisting of intravenous Pethidine, Phenergan, and Atropine.

Following the author's departure, a study was initiated at the BAVS clinic in Dacca to evaluate the recommended anesthetic technique. The details of that study are included in this report.

The purpose of the author's second visit was: (1) to evaluate the results of this study; (2) to assist the BAVS in developing a training curriculum; (3) to train several BAVS trainers in the recommended anesthetic technique and in cardiopulmonary resuscitation (CPR); and (4) to help BAVS personnel prepare a manual for emergency procedures. These tasks were accomplished during the visit.

The consultant reviewed the results of the BAVS study, noting that although surgeons' satisfaction improved with the new regimen, patients were less satisfied because they did not go to sleep during the procedure and therefore remembered some intraoperative discomfort. It seemed likely that patients were receiving inadequate local anesthetic blocks. Also, because they were anticipating general anesthesia and amnesia, the patients were disappointed to find themselves awake.

During his visit, the author assisted with, or observed, 34 tubectomy procedures performed at the BAVS clinic in Dacca. Various modifications of the recommended technique were tried, but it became apparent that the

critical factor was the performance of a satisfactory local block. When this was accomplished, patients' satisfaction improved significantly. Surgeons' satisfaction similarly improved when patients became more cooperative. The consultant observed that it was no longer necessary for four assistants to hold a patient on the table during surgery. Generally, the conscious, sedated patient who experienced little discomfort remained quite still during the operation. Three BAVS surgeons developed significant expertise with the recommended technique and demonstrated the ability to perform a successful local anesthetic field block.

The author also assisted the BAVS medical staff in developing a training curriculum, and he made contributions to the emergency procedures manual which was being prepared at the time of his visit.

Training in cardiopulmonary resuscitation was given. Approximately nine hours were devoted to CPR training. During this time, movies on endotracheal intubation and methods of cardiopulmonary resuscitation were shown. These were followed by a one-hour didactic session on basic CPR. With the arrival of the recording Resusci-Anne, practical training was provided. Three BAVS surgeons became proficient in the techniques of one- and two-person CPR. A two-hour lecture was given on advanced life support using the American Heart Association (AHA) slide series. All CPR teaching materials were left with the BAVS medical staff for use in future training activities.

While in Dacca, the author was asked to present a paper on anesthetic practices for sterilization procedures in Bangladesh at the Fifth Annual Contributors Conference of the Bangladesh Fertility Research Program. A manuscript was prepared and distributed to those who attended the presentation.

The author recommended that his anesthetic technique be adopted throughout Bangladesh. He emphasized that systemic analgesia should be used in conjunction with an effective local anesthetic field block and extremely gentle surgical technique. He also recommended that pelvic examinations be given immediately before surgery and that an instrument to elevate the uterus be introduced into the uterus at this time.

The author emphasized that the success of the recommended anesthetic technique would depend entirely on the efficacy of a training program for operating surgeons.

Finally, the consultant attended a meeting of the government Technical Committee. It was proposed at this meeting that the author's recommended anesthetic technique be formally adopted nationwide. This proposal received the unanimous support of the committee. In addition to formally mandating a change in the anesthetic regimen, the Technical Committee decided to initiate anesthesia training with a two-day course to orient trainers. This course was scheduled to begin before the end of December 1980.

ABBREVIATIONS.

AHA	American Heart Association
AID	Agency for International Development
APHA	American Public Health Association
BAVS	Bangladesh Association for Voluntary Sterilization
BFRP	Bangladesh Fertility Research Program
BP	Blood Pressure
CDC	Centers for Disease Control
CPR	Cardiopulmonary Resuscitation
HR	Heart Rate
IM	Intramuscular
IPAVS	International Project of the Association for Voluntary Sterilization
IUD	Intrauterine Device
IV	Intravenous
JAMA	Journal of the American Medical Association
MR	Menstrual Regulation
NIPORT	National Institute of Population Research and Training
OR	Operating Room
OT	Oral Temperature
R	Respiration
RR	Recovery Room
RSSR	Resources Support Services Report
VS	Vital Signs
VSC	Voluntary Surgical Contraception

I. INTRODUCTION AND BACKGROUND

I. INTRODUCTION AND BACKGROUND

The author was first invited to visit Bangladesh in July 1980 to evaluate anesthesia practices for sterilization operations. Earlier epidemiological investigations conducted under the auspices of the Centers for Disease Control (CDC) revealed that 28 deaths had occurred in the sterilization program over a 15-month period. Of these, 29 percent were ascertained to be secondary to respiratory arrest presumably related to the method of anesthesia employed.^(1,2)

During his July consultancy, the author studied the anesthesia techniques used in various government and BAVS sterilization centers and observed 11 operations. In his report⁽³⁾ he described the prevailing technique as follows: Pethidine (meperidine), 50-100 mg. IM, and Atropine, 0.5-0.6 mg. IM, as premedication 20-45 minutes before surgery. Surgical analgesia consisted of intravenous Seduxen (diazepam), 10-20 mg., and Phenergan (promethazine), 50 mg. It was noted that, after receiving these systemic medications, all 11 patients experienced general anesthesia. Little attention was paid to the local infiltration block, which was accomplished with a single subcutaneous injection of 1 percent lidocaine or procaine. Almost all the tubectomy patients aroused from their general anesthesia near the midpoint of the surgical procedure. At that time, they generally became vocal and began to struggle. Two to four people were needed to hold the patient so that surgery could proceed. Postoperative questioning revealed that virtually all patients had complete amnesia for the event.

Pre-, intra-, and postoperative monitoring were practically nonexistent. In addition, the author found that resuscitation equipment was either absent or inadequate, and that surgeons appeared to lack the necessary resuscitation skills.

In his recommendations, the author noted that "ideal surgical anesthesia" was beyond the capabilities of those rural centers where most tubectomy procedures are performed. He recognized that in order to improve the risks to the patient, smaller doses of systemic drugs would have to be administered. In addition, greater attention would have to be given to the achievement of an effective local anesthetic block. The solution, therefore, appeared to be threefold: (1) to decrease the quantity of systemic drugs employed; (2) to readjust the time sequence and route of administration; and (3) to launch a training program to teach the effective use of local anesthesia and techniques of cardiopulmonary resuscitation. To that end, the following recommendations were made:

Medications

A. Premedication

1. Diazepam: Usual dose: 10 mg. p.o., one hour before surgery. (Reduced to 5 mg. if weight is less than 75 pounds.) This drug is given to allay anxiety and to provide mild amnesia.
2. Meperidine (Pethidine): This drug is not used for premedication. (See section B.)
3. Atropine: This drug is not used for premedication. (See section B.)
4. Promethazine (Phenergan): This drug is not used for premedication. (See section B.)

B. Operative Analgesia

1. Meperidine (Pethidine): Usual dose: 50 mg., administered intravenously. (Reduced to 25 mg. if weight is less than 75 pounds or if patient has any concomitant debilitating illness.) One-half of the dosage is administered, two to three minutes are allowed to elapse, and then the remaining dose, if indicated (i.e., if response to painful stimulus is excessive) is administered. This drug will provide analgesia for the operation. When given intravenously, it is effective within two minutes. A dangerous side effect is respiratory depression.
2. Atropine: Usual dose: 0.6 mg. (1/100 grain), administered intravenously. (Reduced to 0.4 mg. if weight is less than 75 pounds.) This drug is used to block vagal stimulation arising from traction on the uterus and tubes.
3. Promethazine (Phenergan): Usual dose: 25 mg., administered intravenously. This drug is given to potentiate the narcotic and to reduce the emetic effect of intravenous Pethidine. Subcutaneous and intra-arterial injection should be avoided.

C. Local Anesthesia

1. Lidocaine (Xylocaine, Lignocaine), 1 percent solution. The maximum dosage should be 5 mg/kg. (A 40 kg. woman should have no more than 200 mg., or 20 cc., of a 1 percent solution.) Adrenalin added to the anesthetic solution offers little real advantage and contributes its own toxicity.

In administering the drug, the subcutaneous tissues, fascia, subfascia, and peritoneum are infiltrated first and three to five minutes are allowed to elapse before the operation is begun. Local anesthetic solution may also be flowed onto the tubes and uterus to provide topical anesthesia. Five ml. should be used for this purpose. Lidocaine 0.5 percent may be used. This affords an extra margin of safety. Two-chloroprocaine (Nesacaine) has reduced toxicity but may be more allergenic.

Purpose of Assignment

Following the author's initial visit in July 1980, the medical director of the BAVS agreed to initiate a study to evaluate prevailing anesthetic regimens and compare them with the regimen recommended by the author. Accordingly, in the two weeks between November 24 and December 6, 1980, 137 patients who were visiting the BAVS Family Planning Hospital and Training Center for Sterilization in Dacca were assigned to one or the other anesthetic regimen.

The purpose of the author's second visit was: (1) to review the results of the BAVS study; (2) to help BAVS staff develop a training curriculum; (3) to train four or five BAVS trainers in the recommended anesthetic technique and in basic and advanced cardiopulmonary resuscitation; and (4) to help BAVS personnel prepare a manual for emergency procedures.

Itinerary

The author arrived in Dacca, Bangladesh, at 12:00 noon on Sunday, December 7, 1980. That afternoon he met Dr. Carol Carpenter-Yaman, Mr. Terrence Jezowski, Dr. Azizur Rahman, and Russ Vogel. Together, they planned the activities for the week-long consultancy. The author was given a copy of the tentative schedule for his visit (see Appendix B) and a draft

of the plan of action for studying, demonstrating, and implementing safer anesthesia practices in BAVS clinics (see Appendix C).

On Monday morning, December 8, the consultant visited the model BAVS clinic in Dacca to discuss the results of the study on the BAVS anesthetic regimen. At the meeting were Dr. Mizanur Rahman, Dr. Salahuddin Ahmed, Dr. A. J. Faisal, Dr. Azizur Rahman, Dr. Carol Carpenter-Yaman, and Mr. Terrence Jezowski. (A draft copy of the report on the study, entitled "Safe Anesthesia Regimen for Female Sterilization Procedures," is attached as Appendix D.)

Two different anesthetic regimens were used. The first, coded 117, consisted of diazepam, 10 mg. IM, one hour before surgery. This was followed by Pethidine, 25-50 mg., in combination with Atropine, 0.6 mg., and Phenergan, 25 mg. intravenously at the beginning of surgery. (It subsequently became apparent that Atropine had been mistakenly administered in a 1 mg. dose rather than the prescribed 0.6 mg.) The local anesthesia consisted of 20 cc. of 1 percent Lidocaine solution infiltrated into the operative site and flowed onto the fallopian tubes and uterus after the peritoneum was opened. This method was compared to the regimen coded 044, which consisted of intramuscular Pethidine, 50 mg., Atropine, 0.6 mg., and Phenergan, 50 mg., administered approximately one hour before surgery. Operative medication consisted of diazepam, 10 mg. intravenously. Local anesthesia was administered exactly as it had been administered in the 117 technique.

Of the 137 patients studied, 97 were assigned to Code Group 117 and 40 to Code Group 044. Data were collected according to the protocol attached as Appendix E. The results of this study are described in Chapter II.

After discussing the protocol for the study, the author went into the operating theater to observe tubectomy procedures in which both Code 117 and Code 044 anesthetic regimens were used. Seven surgical procedures were observed. Four procedures were performed using the Code 117 technique and three were performed using the Code 044 technique. One additional patient received operative analgesia according to the 117 regimen and developed palpitations and tachycardia. Her blood pressure rose to 130/100 and the surgery was canceled. This phenomenon, it was later discovered, occurred because the patient received 1 mg. of Atropine intravenously but was thought to have received only 0.5 mg. Of those patients experiencing Code 117 anesthesia, only one lost her lid reflex. Even then, this patient was easily aroused and responded to questions. All patients in this category complained to some degree on elevation of the peritoneum and fallopian tubes. Although an inadequate local anesthetic technique was used, it still appeared to be better than the technique observed by the author on his previous visit in July 1980. In all cases, intraperitoneal flushing with anesthetic solution was carried out before the fallopian tubes were

elevated. In all four Code 117 cases, the surgeon deemed the anesthesia to be satisfactory. The patients remained cooperative throughout the procedure and forceful restraining was not required.

Of the three patients to whom Code 044 anesthesia was administered, only one had satisfactory anesthesia, according to the surgeon's evaluation. This patient experienced pain on skin incision and on elevation of the fallopian tubes. She appeared to be moderately sedated throughout but maintained a normal lid reflex. The other two patients in this category also reacted to the pain of skin incision, peritoneal entry, and elevation of the fallopian tubes. In one, the lid reflex was lost after injection of intravenous diazepam. This patient also experienced slow respirations, with some airway obstruction. During the procedure she became combative and cried out loudly when the fallopian tubes were elevated.

Following the day in the operating theater, the author met Dr. B. B. Barua of the Bangladesh Fertility Research Program (BFRP). Dr. Barua stated that time had been made available at the Fifth Annual Contributors Conference of the BFRP, which was held on December 13, 1980, for a presentation by the author. He requested that a manuscript be prepared in advance for distribution at the meeting.

Tuesday, December 9, 1980, was spent in the operating theater. The author scrubbed on seven procedures and assisted the operating surgeon, Dr. Mizanur Rahman, in performing the local anesthetic block. Four operations were performed using Code 117 anesthesia; the remaining three operations involved Code 044 anesthesia. On this day, an effort was made to have patients get up and walk from the operating theater to the recovery room after the surgical procedure was completed. Three of the patients to whom Code 117 anesthesia had been administered walked, as did all patients who received Code 044 anesthesia.

Dr. Rahman proved to be an excellent and highly experienced surgeon, having personally accomplished 11,000 tubectomy procedures. He quickly learned the local anesthetic field block, and both he and the author noted an immediate, though subjective, improvement in the patients' responses to surgery. Although patients who received Code 044 anesthesia generally appeared to be more sedated, when good local block technique was used, there appeared to be little difference in the patients' responses to the two techniques. By using careful and adequate local infiltration, the procedures were rendered painless, with the exception of elevation of the fallopian tubes.

After the morning's operating schedule was completed, the anesthesia equipment was inspected. Attached to the anesthesia machine was one cylinder each of nitrous oxide and oxygen. Both cylinders appeared to be full. The flow meters worked well, and the fail-safe system, which prevents administration of 100 percent nitrous oxide, seemed to function normally.

Hoses and masks were present; however, one hose was slightly too large for its connector, resulting in a loose connection subject to leakage. The re-breathing bag was intact, and positive pressure could be obtained in the system when the bag was compressed.

Next, the author attended a meeting to discuss the BAVS emergency manual, a preliminary draft of which was attached to the earlier report as Appendix E. The meeting was attended by the author; Dr. A. K. Azad Khan, Associate Professor of Medicine, Institute of Postgraduate Medicine and Research, Dacca; Dr. Atiqur Rahman Khan, a member of the planning commission; Dr. Salahuddin Ahmed; Dr. Azizur Rahman; Dr. A. J. Faisal; Mr. Russ Vogel; and Mr. Terrence Jezowski. The participants agreed that major rewriting of the proposed manual was needed, and they divided up the various portions for individual attention. The author agreed to outline the sections on preoperative and operative medications and monitoring of the operative patient. (These outlines are attached as Appendix F.) The author also suggested that the sections on cardiopulmonary resuscitation and emergency drugs be adapted from the supplement to the Journal of the American Medical Association (JAMA), Vol. 227, No. 7, February 18, 1974.(4) Pertinent sections from this supplement were copied and distributed to those participating in the meeting. A follow-up meeting was scheduled for Friday, December 12, 1980.

Following the meeting, the consultant returned to the operating theater to observe 10 additional tubectomy procedures. All patients received Valium, 10 mg. p.o., for premedication. This was followed by operative medication consisting of Stadol, 1 mg., and Atropine, 0.5 mg. intravenously. Because the systemic analgesia appeared to be insufficient in the first six patients, the last four patients received Phenergan, 25 mg. intravenously, in addition to Stadol and Atropine. Nine of the 10 patients walked from the operating theater to the recovery room at the conclusion of surgery. Two patients were considered by their surgeons to have had unsatisfactory anesthesia. One of the two cried throughout the entire procedure, independently of surgical stimulation. When questioned the next day, this patient remembered all of her operation, particularly the pain. Although she experienced discomfort, she stated that she would still recommend the procedure. The other patient who had unsatisfactory anesthesia appeared to be very apprehensive upon transfer to the operating room. She complained of pain when her medications were injected and cried intermittently throughout the procedure. She was given an additional 1 mg. of Stadol without significant benefit. When questioned the next day, this patient stated that she had wanted general anesthesia, but did not remember having felt pain at the time of surgery. She, too, she said, would recommend the procedure to her friends. The other patients all had satisfactory anesthesia, although most had some discomfort upon elevation of the fallopian tubes. The consultant concluded at the end of the day that the surgeons were technically quite expert and operated quickly, but that, in many instances, speed was achieved at the expense of gentleness.

On Wednesday, December 10, the author and Dr. Salahuddin Ahmed visited the BAVS dormitory where patients who had undergone surgery the previous day were quartered. It appeared that the dormitory was once a converted single-family dwelling that had been adapted to accommodate as many as 100 persons for short-term convalescence.

With Dr. Ahmed as interpreter, the author conversed with a field motivator who said that during her years of service she had recruited approximately 1,600 patients for the sterilization program. She said she was very happy with the new anesthetic regimen that had been in use during the previous two weeks. She thought that patients were much less sedated post-operatively and better able to care for themselves. They could be discharged earlier and were less subject to fainting spells. She also stated that she now informs patients that they will be awake during the procedure but will not experience pain. She emphasizes the positive aspects of the operation, including the improved safety of the procedure under lessened systemic sedation.

Sixteen of the 17 patients who underwent surgery on Tuesday, December 9, were interviewed. It is likely that the patients felt threatened during this interview. Although all readily agreed that they would recommend the procedure, the validity of the information they provided during their interview is questionable. Even though lower doses of systemic drugs were administered, most patients could recollect little of the surgical procedure itself.

The author and Dr. Ahmed returned to the BAVS clinic in Dacca for a day of CPR instruction. The Resusci-Anne training model had not yet cleared customs, so didactic sessions and a demonstration of the resuscitation equipment were held. Time was also devoted to intubation training using the intubation model. Among the physicians who attended the CPR training session were Dr. A. J. Faisal, Dr. Mizanur Rahman, Dr. Monowara Begum, Dr. Jenna Banu, Dr. Jakia Banu, Dr. Badrunnesa Raja, and Dr. Suraiya Begum. The intubation movie, which had been mailed earlier to the BAVS, was viewed and intubation techniques were practiced using the teaching model. The CPR film, which the author had hand-carried to Bangladesh, was also viewed at this time. Following this, the author lectured on techniques of cardiopulmonary resuscitation, using the CIBA Foundation's collection of slides to illustrate his talk.

The resuscitation equipment at the BAVS clinic was then examined and its use demonstrated on the intubation model. With the exception of the foot-operated vacuum pump, the tubes of which were reversed, thus preventing suction, the equipment was found to be operative. The vacuum pump was repaired by the consultant. It was noted that there were no Magill adaptors for the endotracheal tubes, thus, no tube could be connected to a positive pressure resuscitation bag. These adaptors will have to be ordered and supplied by the BAVS.

The afternoon session was devoted to a lecture on advanced life support. Slides and written lecture materials produced by the American Heart Association (AHA) were used. Special attention was devoted to the section on resuscitation drugs and airway maintenance. The AHA teaching materials and the CIBA collection of CPR slides were left with Dr. Ahmed for use in future teaching efforts. The consultant recommended that copies of Cardio-pulmonary Resuscitation (CPR) be purchased for distribution to future CPR trainees.

On Thursday, December 11, 1980, the author met with Mr. Terrence Jezowski to discuss the need for training in intubation techniques and the dissemination of equipment to more remote sterilization centers. Mr. Jezowski gave the author a copy of "Minimum Medical Service Standards for Female Voluntary Surgical Contraception Programs" (see Appendix G) in which is described the stated policy of the International Project of the Association for Voluntary Sterilization (IPAVS): that all clinics have readily available a laryngoscope and endotracheal tubes. The author suggested that this requirement be eliminated.

Mr. Jezowski pointed out that Dr. Faisal and Dr. Satterthwaite were writing a training curriculum for the BAVS. The author suggested that the curriculum include sections on anesthesia and resuscitation. The section on anesthesia could be obtained from the author's July 1980 report; the resuscitation portion could be taken from the JAMA Supplement, Vol. 227, No. 7, February 1974.

Following this meeting, the author returned to the operating room, where another six tubectomy procedures were observed. All of the patients received Valium, 10 mg. p.o., 45-60 minutes before the operation, then Atropine, 0.5 mg., Pethidine, 50 mg., and Phenergan, 25 mg. intravenously, immediately before surgery was begun. All patients experienced satisfactory anesthesia, from the surgeon's viewpoint, and all walked from the operating table to the recovery room. All maintained lid reflexes and, when somnolent, were easily arousable. Again, the only painful part of the procedure seemed to be the elevation of the fallopian tubes. In all instances, the local anesthetic block appeared to have been well done.

Following the morning's surgery, the author attended a meeting to discuss the implications of the new anesthetic regimen. Attending the meeting were Mr. Charles Gurney, Dr. Carol Carpenter-Yaman, Dr. Shafiqur Rahman of the National Institute of Population Research and Training (NIPORT), Dr. Azizur Rahman, Dr. Salahuddin Ahmed, Dr. Penny Satterthwaite of NIPORT, Dr. Nargis Akhter, Dr. Shafiqur Rasul, Dr. A. J. Faisal, Dr. Qader (an anesthesiologist from the Dacca Medical College), Colonel M. Hashmat Ali, and Mr. Terrence Jezowski. The meeting began with a presentation by the consultant of the reasons for recommending a new anesthetic regimen. The results of the clinical trial and the first three days of experience at the BAVS clinic in Dacca were presented. The author

carefully pointed out that the recommended anesthetic technique was not an ideal technique but represented a compromise suited to Bangladesh. The regimen, he said, represented an attempt to achieve maximum patient satisfaction while simultaneously enhancing patient safety. It was pointed out that an ideal anesthetic technique would require the services of a trained anesthesiologist with sophisticated equipment at his disposal, conditions not now present in rural Bangladesh. Dr. Nargis Akhter said that she was convinced that the proposed anesthetic regimen was appropriate for use in Bangladesh, and she was prepared to recommend its adoption to the Technical Committee.

It was pointed out that motivators and patients will need to be educated about the different approach (i.e., analgesia in lieu of anesthesia). Furthermore, the operating surgeons must be reeducated to perform better local anesthesia and more gently handle tissues.

Dr. Shafiqur Rahman indicated that he thought a new study should be set up in the Thana health centers to determine the impact of the altered anesthesia regimen in a rural setting.

Physician training was addressed next. Mr. Charles Gurney indicated that the availability of AID funds would be tied to the accomplishment of early retraining.

The meeting ended with a decision to convene the Technical Committee for a meeting on Sunday morning, December 14, 1980. The author was invited to present the rationale for his recommended anesthetic regimen.

Following the meeting, the author conducted a third CPR training session. By this time, the recording Resusci-Anne training model had cleared customs and was available for use. The CPR movie was shown again and BAVS trainers practiced techniques of CPR under the author's guidance and instruction.

On Thursday evening, December 11, the author attended a dinner at the Dacca Club at the invitation of Dr. Azizur Rahman and two BAVS board members, Mr. Aziz Ahmed and Mr. Hussein. Dr. Carol Carpenter-Yaman, Mr. Terrence Jezowski, Mr. Russ Vogel, and Dr. Joseph Speidel also attended the dinner.

The next morning, Friday, December 12, the author conducted a second practical CPR training session using the recording Resusci-Anne. Dr. Suraiya Begum, Dr. Mizanur Rahman, and Dr. A. J. Faisal practiced one- and two-man resuscitation techniques. The practice continued until each of these persons achieved acceptable recordings. The cleaning and maintenance routine for the Resusci-Anne CPR training model was then demonstrated to encourage adequate future maintenance. The author spent the remainder of the morning working on the BAVS emergency procedures manual.

At 2:00 p.m. on Friday afternoon, December 12, 1980, the author attended a meeting of the BAVS emergency manual committee, consisting of Dr. Azizur Rahman, Dr. Azad Khan, Dr. Atiqur Rahman Khan, Dr. Salahuddin Ahmed, Dr. A. J. Faisal, and Mr. Terrence Jezowski. The introduction to the manual was mapped out, and it was decided that the general style should be professional but understandable to the layman. A table of contents was formulated to include descriptions of (1) cardiopulmonary resuscitation; (2) resuscitation equipment; (3) preoperative and intraoperative medications; (4) monitoring techniques; (5) resuscitation drugs; (6) preoperative medical screening; (7) patient follow-up procedures; and (8) common emergencies and their treatment. The author suggested that Penfield's monograph on female sterilization⁽⁵⁾ be used as a model for constructing the manual. The various topics were then divided among Dr. Azizur Rahman, Dr. Azad Khan, and Dr. Atiqur Rahman Khan for formulation before the next meeting, which was scheduled for 9:00 a.m., December 16, 1980. The meeting was then adjourned.

The author returned to the operating theater to observe four surgical procedures, which, again, were carried out under p.o. Valium premedication, with Pethidine, Atropine, and Phenergan operative sedation. All patients walked to the recovery room following completion of surgery. The surgeon deemed three of the four anesthetics to be satisfactory. The fourth patient complained of pain at the end of her operation and moved excessively during the procedure, although she did not seem to experience significant discomfort. The other three patients appeared to be calm and were quiet and cooperative throughout the procedure. The same four procedures were observed by Dr. Joseph Speidel, who felt that the anesthetic technique was fully acceptable.

On Saturday, December 13, 1980, the author attended the Fifth Annual Contributors Conference of the Bangladesh Fertility Research Program at NIPORT, Azimpur, Dacca. (The program appears in Appendix I.) The author presented a paper entitled "Anesthesia for Sterilization Operations in Bangladesh." (See Appendix J.)

On Sunday, December 14, the author attended the Technical Committee meeting at NIPORT, Azimpur, Dacca. The meeting was chaired by Dr. Hashmat Ali and was attended by Dr. Nargis Akhter, Dr. Azizur Rahman, Professor A. Rashid, Dr. Rafiqul Islam, Professor A. Hye, Professor A. Rahman Chowdhury, Dr. Altafunnessa Begum, Mr. Rafiqul Islam, Dr. Shafiqur Rahman, Professor S. N. Samad Chowdhury, Dr. Shafiqur Rasul, Brigadier Sirai Jinnat, Mr. Russ Vogel, Mr. Terrence Jezowski, Dr. Carol Carpenter-Yaman, Dr. Tony Measham, and Dr. Michael Rosenberg. The author was asked to begin the meeting with a discussion of the anesthesia practices for sterilization operations in Bangladesh and to present his recommendations for improving anesthetic techniques.

Dr. Rashid discussed the importance of the pre-anesthetic evaluation. Dr. Samad Chowdhury discussed the problem of drug interactions and the need for expert monitoring during operative procedures. Although Dr. Chowdhury would prefer that an anesthesiologist monitor all surgical patients, he agreed in principle that a suitably trained nurse would suffice. Dr. Shafiqur Rasul discussed the different possible anesthetic techniques and stressed the importance of the availability of suitable narcotic antagonists. Dr. Rasul also suggested the possibility of Entonox and Trialene inhalation analgesia. He endorsed the author's regimen, however, believing it to be a suitable starting point until the level of anesthetic expertise increases throughout the country. Dr. Chowdhury suggested using ketamine, but he also agreed in principle to the author's recommendations. Dr. Margis Akhter formally proposed that the author's recommended technique be adopted. The committee discussed the advisability of using IV Pethidine. The general consensus was that Pethidine must be used intravenously to provide sufficient analgesia and sedation for the operation to proceed.

The Technical Committee accepted the author's recommendations in full and stated that in the future the training of surgeons and ancillary medical personnel in anesthetic techniques, patient screening, and appropriate use of resuscitation equipment should be emphasized.

The committee next took up the question of infection control. At this time, there are approximately 400 sterilization centers in Bangladesh. At each of these centers, one to three sets of surgical instruments are available. This leads to problems in instrument sterilization if more than one to three cases are treated each day. The committee agreed that emphasis should be placed on infection control. They recommended increased participation in the tetanus immunization program and increased attention to aseptic technique and the sterilization of instruments.

The committee discussed the use of antibiotic prophylaxis. There appeared to be a consensus that tetracycline should be retained as the standard drug, but that its effectiveness should be evaluated. In addition, the Technical Committee recommended standardization of the patient prep to iodine and alcohol.

Finally, the subject of training was raised. A handout entitled "Training Plan on Surgical Sterilization for THAs and MOs in the National Family Planning Program" was passed out to those at the meeting. (See Appendix K.) The committee agreed that early training that includes instruction in proper local anesthetic technique and cardiopulmonary resuscitation is needed.

The author pointed out the importance of an adequate local anesthetic field block in the performance of anesthesia for sterilization. This must be taught to all physicians who perform sterilization operations so that maximum patient comfort may be obtained. The author indicated that, if

the reduced systemic analgesia regimen is initiated without benefit of an adequate local anesthetic block, patient acceptance would be low. He was concerned that this might jeopardize the entire sterilization program.

The Technical Committee decided to initiate training with a two-day course to orient trainers. The course would begin within two weeks and would be supported with funds from the IPAVS. Ultimately, 10-12 training centers would be established and multiple courses would be offered to gain access to all physicians now performing sterilization operations in Bangladesh.

II. OBSERVATIONS

II. OBSERVATIONS

Results of the BAVS Comparative Study

The BAVS study was conceived in such a way that the author's recommended anesthetic technique (Code 117) was compared not with the usual anesthetic regimen used in Bangladesh, but with a modified technique of lower drug dosage (Code 044). As indicated in the earlier report released in July 1980, patients undergoing tubectomy in government facilities received, in general, Pethidine, 100 mg., and Atropine, 0.6 mg., approximately 45 minutes before surgery. In the BAVS facilities, patients received 50-100 mg. of Pethidine, 0.6 mg. of Atropine, and 50 mg. of Phenergan intramuscularly as premedication, then 20 mg. of Valium intravenously at the time of surgery. The 044 technique consisted of 50 mg. of Pethidine, 0.6 mg. of Atropine, and 50 mg. of Phenergan administered intramuscularly as premedication; these drugs were followed by Valium, 10 mg., administered intravenously at the time of surgery. This represents a substantially reduced dosage compared to the dosage usually administered. Efforts were made to flow local anesthetic solution over the tubes and uterus upon opening of the peritoneum. No attempt to do this had been made previously.

In the Code 117 regimen, diazepam was administered intramuscularly one hour before surgery in lieu of the oral medication prescribed in the recommended technique. It is well known that oral diazepam is better absorbed than the same quantity of drug given intramuscularly.

Another criticism of the study is that no effort appeared to have been made to randomize patients for one study group or another. Ninety-seven patients were assigned to the 117 group, but only 40 were assigned to the 044 group. In addition, no blinding was used in the evaluation of results. Although efforts were made to maintain impartiality, it was inevitable that bias would creep into such a study.

No effort was made to subject the results to statistical analysis. The study parameters and results are described below.

1. Monitoring of consciousness 45 minutes after premedication: Sensory stimulation with pinprick was used and drowsiness was assessed subjectively. There appeared to be no difference between the two groups.
2. Monitoring of consciousness five minutes after operative medication: Sedation appeared to be less in the Code 117 group. Also, reflexes appeared to be better preserved in this group.

3. Consciousness was monitored at five-minute intervals after local infiltration. Reflexes again seemed to be better preserved in the 117 group. Incisional pain was noted by most of the patients in both groups. Almost all patients complained of pain when the peritoneum was opened and the fallopian tubes were manipulated. In the author's view, these incidences of pain reflect unsatisfactory local anesthetic block.
4. Blood pressure variations were measured. It was noted that patients in the Code 117 group experienced significantly greater hypertension than those in the 044 group. This was subsequently found to be due to the fact that all of these patients inadvertently received excessive (1.0 mg.) doses of intravenous Atropine at the time of the operation.
5. One patient in Group 117 experienced respiratory depression after being administered 25 mg. of Pethidine intravenously. She was treated with Narcan and oxygen and recovered uneventfully.
6. Surgeons evaluated patient cooperation during surgery. Forty-four and four-tenths percent of the patients in the 117 group failed to cooperate, and 52.5 percent of those in the 044 group failed to cooperate. Surgeons were satisfied 56.7 percent of the time in the Code 117 group and 45 percent of the time in the Code 044 group.
7. Virtually all the patients in the Code 117 group walked from the operating room to the recovery room; only 67.5 percent of the patients in the 044 group were able to walk to the recovery room.
8. Patient awareness following surgery was evaluated. Eighty-five and six-tenths percent of the patients in Group 117 and 87.5 percent of the patients in Group 044 reported being aware during the procedure. Presumably, these persons sensed the skin incision, the opening of the peritoneum, and lifting of the fallopian tubes, but they did not necessarily interpret this sensation as pain. Again, this must be considered a result of failure to provide an adequate local anesthetic field block.
9. Patient satisfaction appeared to be greater in the Code 044 group than among those patients assigned to the 117 group. One-third of the patients in the latter group experienced pain and fear, listing both as the major cause of their dissatisfaction. All patients in the 044 group and 80 percent of the patients in the 117 group said they would recommend the procedure to others. The author believes that greater attention to the local field block, gentler handling of tissues, and a more concerned and gentle

approach to the patient will reduce the level of dissatisfaction. Also, patients must be counseled that they will not be asleep and that they may remember events that occurred in the operating room. It would seem obvious that, if the patient came to surgery expecting to be asleep and later found herself to be awake, her level of dissatisfaction would be heightened.

Postoperative Department of Patients

It was the author's impression that patients subjected to the recommended pre-anesthetic regimen (Valium, 10 mg. p.o.) were generally drowsy when they arrived in the operating room and appeared to be somnolent on the operating table. They reacted minimally to intravenous injection of the drugs and to infiltration of the skin. In general, they remained quiet during the procedure, but tended to arouse and grimace during elevation of the fallopian tubes. The author noted that often considerable tugging and rough manipulation were needed to elevate the fallopian tubes into the small abdominal wall incision. It would seem obvious that use of a uterine elevator to position the cornual area of the uterus just below the incision would facilitate atraumatic elevation of the fallopian tubes. This technique was never observed by the author during his stay in Bangladesh.

Almost all patients who received the recommended anesthetic technique were able to walk from the operating room to the recovery room following surgery, and they always were arousable when they were stimulated gently during the immediate postoperative period. This is in contrast to the author's experience in July 1980, when patients appeared to be considerably more deeply sedated, both intraoperatively and postoperatively.

Recovery from the Effects of Anesthesia

Patients observed 24 hours after surgery appeared to be quite alert and were able to ambulate easily without assistance. According to one female patient-motivator, clients are much less subject to syncopal episodes when the recommended anesthetic technique is used.

Acceptability

When diazepam was administered orally one hour before surgery and when adequate local anesthetic field blocks were employed, patients seemed to tolerate the operation readily. Among such patients the level of

acceptability was high. The author believes that when surgeons become skilled in the anesthetic block technique and learn to more gently handle tissues, patient acceptability will become almost universal.

Cardiopulmonary Resuscitation Training

Cardiopulmonary resuscitation training was given to three BAVS surgeons with the expectation that these persons would then train other surgeons performing sterilization operations in Bangladesh. Movies depicting CPR and intubation techniques were shown. In addition, lectures were given using the CIBA collection of basic CPR slides and advanced life support slides produced by the American Heart Association. These teaching materials were left with Dr. Salahuddin Ahmed to aid him in training other physicians. The Resusci-Anne CPR teaching model arrived during the author's stay in Bangladesh and was used extensively to provide practical training for the three BAVS trainers. All three easily mastered the technique and will be able to train other physicians in the basic methods of CPR.

III. RECOMMENDATIONS

III. RECOMMENDATIONS

Anesthetic Regimen

After observing or participating directly in 34 tubectomy procedures at the BAVS clinic in Dacca, the author believes that the recommended technique, which he described fully in his first report, remains the most practical technique for Bangladesh.

Stadol (butorphanol) was evaluated as a possible substitute for Pethidine (meperidine). Initially in the comparison, butorphanol was administered only with Atropine, the Phenergan (promethazine) being omitted. Patients to whom this drug regimen was administered seemed to have less sedation and analgesia than those who had been treated with intravenous Pethidine, Phenergan, and Atropine. When Phenergan (promethazine) 25 mg. was added to the regimen and administered intravenously immediately before surgery, satisfactory sedation and analgesia resulted.

Butorphanol in a 1 mg. dose therefore seems to be a reasonable alternative to intravenous Pethidine. The advantage of butorphanol is that it offers less respiratory depression in intravenous doses in excess of 2 mg.

Although the author feels that butorphanol would be the preferred drug for future use, he recommends continued usage of Pethidine at this time. Pethidine is produced locally and costs less than butorphanol. When patients who are given IV Pethidine are carefully monitored and when minimal, effective intravenous doses are administered, respiratory depression is not a likely consequence.

Local Anesthetic Technique*

The author recommends use of the following local anesthetic technique.

1. Because lidocaine 1 percent appears to be universally available in Bangladesh, it should continue to be used. An individual patient should never receive more than 20 cc. of a 1 percent solution (e.g., a 40 kg. patient should never receive more than 200 mg. of the drug).
2. The skin should be infiltrated in the midline, with the needle burrowed intradermally and subcutaneously to left and right, cephalad and caudad. Note that the needle should not be advanced through the subcutaneous fat but rather in and just beneath the skin itself. Five to eight cc. of 1 percent lidocaine solution

* See Appendix L.

should be injected at this site. The surgeon should then wait 2-3 minutes before beginning the operation.

3. After the skin has been incised, the anterior rectus fascia should be infiltrated with 2-4 cc. of lidocaine. One should then wait an additional 1-2 minutes before proceeding.
4. Once the anterior fascia has been opened, the posterior fascia and peritoneum should be infiltrated through the rectus muscle. Two to four cc. of lidocaine solution should be administered. One should wait an additional 1-2 minutes before proceeding.
5. After the peritoneum and posterior fascia have been elevated, one should again infiltrate with 1-2 cc. of drug.
6. The peritoneum should then be opened. Two to five cc. of 1 percent lidocaine solution should be injected into the peritoneal cavity in the region of the fallopian tubes. To accomplish this, the needle should be removed from the syringe and the barrel of the syringe should be introduced through the peritoneal incision. After two minutes have elapsed, elevation of the fallopian tubes may be accomplished.
7. If the patient has pain after elevation of the fallopian tubes, one may infiltrate the mesosalpinx and tube with a small volume of local anesthetic solution. Experience suggests that this is seldom needed if the peritoneal surfaces have been adequately covered (Step 6).

Diazepam

The author recommends that diazepam be administered orally rather than intramuscularly as the premedication agent. Oral administration results in more predictable absorption. Sedation following oral administration is more profound than sedation following a like dose administered intramuscularly.

Intravenous diazepam has been known to produce general anesthesia and respiratory depression.⁽⁶⁾ Its use in tubectomy procedures should, therefore, be discouraged.

Pain of Tubal Elevation

The author encourages the use of a uterine elevator. The instrument should be gently inserted into the uterus during the pelvic examination on

the operating table and after intravenous analgesia has been administered. By using a uterine elevator, the surgical assistant can displace the uterus anteriorly, thus making access to the fallopian tubes easier for the surgeon and reducing the patient's discomfort. In addition, if the surgeon performs a pelvic examination immediately before the operation, he will be able to avoid unpleasant surprises during the procedure.

Operative Technique

While witnessing the 34 tubectomy procedures, the author was impressed with the surgeons' speed and dexterity. He believes, however, that some speed could be sacrificed to enhance the local anesthetic blockade and to encourage gentler handling of tissues to minimize patient discomfort. The surgeons' emphasis must shift from speed to gentleness.

Intubation of the Trachea

The IPAVS manual, "Minimum Medical Service Standards for Female Voluntary Surgical Contraception Programs," recommends that laryngoscopes and endotracheal tubes be deployed to all centers where sterilization operations are performed. The author believes that this recommendation is inappropriate for Bangladesh because the majority of procedures are performed in small clinics where the expertise needed to accomplish tracheal intubation is not likely to be found. Respiratory arrest is better handled by mouth-to-mouth, oral airway, or mask positive pressure ventilation rather than by tracheal intubation, unless the operator has considerable experience and skill in performing the latter procedure. Improper technique may readily cause trauma to the patient's airway. Misplacement of the tube may result in ventilation of the esophagus and stomach. It is the author's conviction that in the major clinics laryngoscopes and endotracheal tubes should be available for use and that all operators should be trained to use them, but the equipment should not be deployed universally.

Training

A successful training program is essential if patient satisfaction with the sterilization procedure is to be maintained. The author is deeply concerned that his recommended anesthetic technique will be inaugurated by governmental decree without adequate supportive training in the local anesthetic technique. Surgeons who use reduced analgesia and sedation in addition to inadequate local anesthesia will have unhappy patients. It

is, therefore, mandatory that all surgeons who adopt the author's recommended analgesia be simultaneously trained to perform a satisfactory local anesthetic block.

Not an Ideal Procedure

The author recognizes that his recommended anesthetic technique is not an ideal procedure. If complete patient and surgeon satisfaction with minimal anesthetic risk was the only goal, an entirely different anesthetic approach would be used. However, given current conditions in Bangladesh, it is not possible for every patient undergoing tubectomy to be attended by an anesthesiologist. Nor are sophisticated drugs and equipment available in most localities. Therefore, one must use the safest and most comfortable technique possible, given the limitations of the environment.

NOTES

- ¹ Rosenberg, M. Resources Support Services Report (RSSR/AID). London, England, April 29 and May 15, 1980; Dacca, Bangladesh, May 2-13, 1980; Boston, Massachusetts, May 16, 1980. Department of Health and Human Services, Public Health Service, Center for Disease Control.
- ² Grimes, D.A. and B.B. Peterson. Sterilization Deaths in Bangladesh. July 3, 1980.
- ³ Fishburne, J.I. Anesthesia Practices for Sterilization Operations in Bangladesh. July 21-29, 1980.
- ⁴ "Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care." Supplement to JAMA. 227(7):833-868. February 18, 1974.
- ⁵ Penfield, A. Jefferson. Female Sterilization by Mini Laparotomy or Open Laparoscopy. Urban Schwarzenberg, 1980.
- ⁶ Forster, A., et al. "Respiratory depression by midazolam and diazepam." Anesthesiology. 53:494, 1980.

APPENDICES

Appendix A
LIST OF PERSONS CONTACTED

Appendix A
LIST OF PERSONS CONTACTED

Mr. Aziz Ahmed, General Manager, Janata Bank

Dr. Salahuddin Ahmed, Director, BAVS Model Clinic, Dacca

Dr. Nargis Akhter, Director, MCH/Family Planning Services,
Bangladesh Government

Colonel M. Hashmat Ali, Director-General, NIPORT

Dr. Jakia Banu, Surgeon, BAVS Model Clinic, Dacca

Dr. Jenna Banu, Surgeon, BAVS Model Clinic, Dacca

Dr. B. B. Barua, BFRP, Dacca

Dr. Altafunnessa Begum, Obstetrician-Gynecologist, Medical Consultant,
Bangladesh Family Planning Association

Dr. Monowara Begum, Surgeon, BAVS Model Clinic, Dacca

Dr. Sultana Begum, National Medical Director, BAVS

Dr. Suraiya Begum, Surgeon, BAVS Model Clinic, Dacca

Dr. Carol Carpenter-Yaman, Population, Health, and Women's Division,
USAID/Bangladesh, Dacca

A. Rahman Chowdhury, Professor of Pharmacology, Institute of Postgraduate
Medicine, Dacca

S. N. Samad Chowdhury, Professor of Anesthesiology, Chittagong Medical
College

Dr. A. J. Faisal, Surgeon, BAVS Model Clinic, Dacca

Charles Gurney, Head, Population, Health, and Women's Division,
USAID/Bangladesh, Dacca

A. Hye, Professor of Pathology, Dacca Medical College

Dr. Rafiqul Islam, PCFP

Terrence Jezowski, Head, IPAVS, Dacca

Brigadier Sirai Jinnat, Consultant Surgeon, Bangladesh Army Medical Corps

Atiqur Rahman Khan, Chief, Population Division, Planning Commission,
Bangladesh Government

Dr. A. K. Azad Khan, Associate Professor of Medicine, Institute of
Postgraduate Medicine and Research, Dacca

Dr. Qader, Anesthesiologist, Dacca Medical College

Dr. Azizur Rahman, President, BAVS

Dr. Mizanur Rahman, Surgeon, BAVS Model Clinic, Dacca

Dr. Shafiqur Rahman, Director of Biomedicine, NIPORT

Dr. Badrunnesa Raja, Surgeon, BAVS Model Clinic, Dacca

A. Rashid, Professor of Anesthesiology, Institute of Postgraduate Medicine,
Dacca

Dr. Shafiqur Rasul, Associate Professor of Anesthesia, Sir Sallimullah
Medical College, Dacca

Dr. Penny Satterthwaite, UNFPA Consultant, MCH/Family Planning Services,
Bangladesh Government

Dr. Joseph Speidel, Acting Director, Office of Population, USAID/Washington

Russ Vogel, IPAVS, Dacca

Appendix B

TENTATIVE SCHEDULE FOR VISIT OF
DR. JOHN I. FISHBURNE

Appendix B

TENTATIVE SCHEDULE FOR VISIT OF
DR. JOHN I. FISHBURNE*

Sunday 7 December	3:45 p.m.	Arrival in Dacca via BG494 (check in at American Club Guesthouse).
	7:00 p.m.**	Dinner and informal briefing with: Dr. Azizur Rahman, BAVS; Dr. Carol Carpenter-Yaman, USAID; Mr. Terrence W. Jezowski, IPAVS.
Monday 8 December	9:00 a.m. - 4:30 p.m.	Observation and review of modified anesthesia regimen at BAVS Dacca clinic.
Tuesday 9 December	9:00 a.m. - 4:00 p.m.	Further observation and discussion of modified regimen.
	1:00 p.m. - 3:00 p.m.	Luncheon meeting to review and discuss BAVS's draft Emergency Manual.
	3:00 p.m. - 4:30 p.m.	Develop plans for training sessions on Wednesday (CPR).
Wednesday 10 December	9:00 a.m. - 4:30 p.m.	Training: Work with three or four BAVS trainers (CPR).
Thursday 11 December	9:00 a.m. - 11:00 a.m.	Training (CPR).
	11:00 a.m. - 12:30 p.m.	Meeting with officials of NIPORT (National Institute of Population Research and Training) to discuss implications for introducing modified regimens countrywide.
	1:00 p.m. - 2:00 p.m.	Lunch.
	2:00 p.m. - 4:30 p.m.	Training (CPR).

* All sessions will be at the BAVS Clinic in Dacca unless noted otherwise.

** Approximated.

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Friday 12 December	9:00 a.m. - 1:00 p.m.	Training (CPR).
	2:00 p.m. - 3:00 p.m.	Luncheon meeting to continue discussion on BAVS's draft Emergency Manual.
	3:00 p.m. - 4:30 p.m.	Training (CPR).
	3:15 p.m.	Joe Speidel to see procedures.
Saturday 13 December	9:00 a.m. - 1:00 p.m.	BFRP Contributors Conference.
	Afternoon	Wrap up discussions; discuss future training curriculum.
Sunday 14 December	9:00 a.m.	Technical Committee meeting. Departure.

Names of BAVS Trainers who will work with Dr. Fishburne

Dr. Mizanur Rahman

Dr. Abu Jamil Faisal

Dr. Suraiya Begum

Dr. Selina Sultana

Dr. Biaquat Ali

Ad-Hoc Committee for BAVS Emergency Manual
(Tuesday Luncheon)

Dr. Atiqur Rahman Khan

Dr. A. K. Azad (Internist)

Dr. Sultana Begum

Dr. Azizur Rahman

NIPORT Officials
(Thursday, 11:00 a.m.)

Dr. Shafiqur Rahman

Dr. M. I. Rasul (Anesthetist)

Dr. A. P. Satterthwaite

Professor S. Sabeen

Appendix C

PLAN OF ACTION FOR STUDYING, DEMONSTRATING, AND
IMPLEMENTING SAFER ANESTHESIA PRACTICES
IN BAVS CLINICS (Draft)

Appendix C

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PLAN OF ACTION FOR STUDYING, DEMONSTRATING, AND
IMPLEMENTING SAFER ANESTHESIA PRACTICES
IN BAVS CLINICS

<u>Timeframe</u>	<u>Activity</u>
28-31 October 1980	Finalize protocol for conducting a comparative study of current and new recommended anesthesia regimens. Work with Dr. Carpenter-Yaman and others to finalize protocol.
1-30 November 1980	<ul style="list-style-type: none"> a. Conduct pilot study of alternative anesthesia regimens in BAVS Dacca clinic as per protocol. b. Revise and re-draft BAVS VSC Emergency Manual (Dr. Atiqur Rahman Khan and an anesthesiologist). c. Prepare for technical assistance visit of Dr. Fishbourne in December. d. Identify and obtain suitable training films and materials on emergency techniques (IPAVS/Asia Office). e. Explore with PCFPD, its Technical Committee, and others the potential for a national VSC conference on anesthesia and other practical matters in safe VSC service delivery. f. BAVS Medical Committee and regional medical supervisors meeting (November 7-8). g. Attend BFRP Contributors Conference (November 14).
1-8 December 1980	<ul style="list-style-type: none"> a. Compile, analyze, and write report on anesthesia pilot study. b. Finalize preparations for Dr. Fishbourne's visit.
8-15 December 1980	Technical assistance visit by Dr. Fishbourne, who will undertake with BAVS the following:

<u>Timeframe</u>	<u>Activity</u>
	<ul style="list-style-type: none"> a. Review results of anesthesia pilot study. b. Finalize BAVS anesthesia policies. c. Develop a curriculum (practical and didactic) for training VSC surgeons in revised anesthesia regimens. d. Train trainers in revised anesthesia practices and training methods. e. Review BAVS draft Emergency Manual.
15-31 December 1980	Implement revised anesthesia practices in BAVS clinic in Dacca and a few selected satellite clinics.
Early January 1981	Conduct BAVS Annual Medical Workshop for all BAVS medical staff and selected observers from government and allied organizations (theme: "Avoiding Complications and New Anesthesia Practices").
Mid-January- February 1981	Regional training of all BAVS medical and clinical staff in revised anesthesia regimens and emergency treatment techniques (potential format and process: (a) four regional training sessions; (b) first two days to involve didactic sessions and emergency training for staff of all clinics at one site; (c) following didactic training, visit by trainer to each clinic in his assigned region and three to four days of intensive on-site practical training).

* * * * *

In implementing the above actions, every attempt will be made by the BAVS to involve PCFPD staff in planning and implementation. Once the BAVS training is completed, the BAVS will explore and work with the PCFPD and others to develop training programs for government medical and clinical staff.

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Appendix D

SAFE ANESTHESIA REGIMEN FOR FEMALE
STERILIZATION PROCEDURE

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SAFE ANESTHESIA REGIMEN FOR FEMALE
STERILIZATION PROCEDURE:

A STUDY OF THE
BANGLADESH ASSOCIATION FOR VOLUNTARY STERILIZATION
DACCA, BANGLADESH

INTRODUCTION

In Bangladesh, female sterilization as a method of contraception is quite popular. As a routine practice, female sterilization is being performed using local anesthesia with sedation. This, of course, implies that patients are awake, but relaxed and tranquil. The patients actually are unconscious during the operation because of heavy sedation.

There has been a recent cluster of deaths during the tubectomy procedure. M. Rosenberg, M.D., MPH; David A. Grime, M.D.; and Best B. Paterson, M.D., have made two important studies on these deaths. The investigations revealed that the major cause of death is anesthesia overdose leading to respiratory failure. This contributed to 29 percent of the total number of deaths.

Reduction of complication and of risk of death because of present anesthetic practice is most desirable and ethical. A safer anesthesia regimen should be evolved and practiced in order to minimize the risk factor. At the recommendation of Dr. I. Fishburne, a new anesthesia regimen has been developed. While using this regimen, a study was carried out at the BAVS clinic in Dacca.

METHODOLOGY

The study was carried out at the BAVS clinic in Dacca. It included all the components of sterilization procedure, from counseling and client selection to follow-up. A detailed pro forma check list is attached as Appendix B.

The subjects were 137 females who visited the Family Planning Hospital and Training Centre for Sterilization between November 24, 1980 and December 6, 1980 (14 days).

This comparative study was done using the new, safer anesthesia regimen developed by Dr. I. Fishburne and the modified BAVS anesthesia practice. Code 044 for the modified BAVS method and Code 117 for the newer regimen of Dr. I. Fishburne were used. To record the patients' identities and other related aspects, as well as physical examination, operation note, etc., the usual admission form was used (see Appendix A). In addition, the other checklist was used to compare the results of patients' consciousness level, sensory stimuli, reflexes, condition of vital signs, and patients' and surgeons' satisfaction.

For the new anesthesia regimen, the following medication was used:

CODE 117

A. Preoperative Medication

1. Diazepam, 10 mg., IM or orally, one hour before surgery.

B. Operative Medication

1. Meperidine (Pethedine): The usual dose is 50 mg. intravenously, reduced to 25 mg. if weight is less than 75 pounds or if the patient has any concomitant debilitating illness. The drug is administered slowly.
2. Atropine: The usual dose is 0.6 mg. intravenously, reduced to 0.4 mg. if weight is less than 75 pounds.
3. Promethazine (Phenergan): The usual dose is 25 mg., administered intravenously.

C. Local Anesthesia

1. Lidocaine (Xylocaine, Lignocaine): 20 cc. of a 1 percent solution are infiltrated into the operation area and also flowed onto the tubes and uterus.

Under the modified BAVS anesthesia practice, the following medication was used:

CODE 044

A. Preoperative Medication

1. Meperidine (Pethedine): The dose ranged from 50 mg. to 100 mg., according to the weight, blood pressure, and anemia condition. The drug is administered intramuscularly.
2. Atropine: The usual dose is 0.6 mg. intramuscularly.
3. Promethazine (Phenergan): The usual dose is 50 mg. intramuscularly.

B. Operative Medication

1. Diazepam: 10 mg. of the drug administered intravenously.

C. Local Anesthesia

1. Lidocaine (Xylocaine, Lignocaine): 10 cc. - 20 cc. infiltrated in the operation area, as well as flowed onto tubes and uterus.

RESULTS

Of 137 cases, 97 cases were of Code 117; the remaining 40 cases were of Code 044.

A. Age Group

Most of the subjects of the study were 21-30 years old.

B. Weight of the Subjects

The 137 study subjects weighed between 70 pounds and 110 pounds. Only two patients weighed less than 70 pounds.

C. Monitoring of Consciousness After Premedication

The patients' sensory stimuli, drowsiness, and responses to questions were observed and recorded. The patients' responses using the two anesthetic methods are shown in Table 1. In both types, the responses seem to be the same.

Table 1

		<u>CODE 117</u>	<u>CODE 044</u>
Sensory Stimuli	Present	97 = 100%	40 = 100%
	Absent	x	x
Drowsiness	None	52 = 53.6%	24 = 60%
	Mild	45 = 46.4%	16 = 40%
	Excessive	0	0
Response to Question	None	24 = 24.7%	1 = 2.5%
	Yes	73 = 72.3%	39 = 97.5%

D. Monitoring of Consciousness After Operative Medication

At this state, the patients' sensory stimuli, and responses to questions and drowsiness were recorded. Drowsiness was less marked in anesthesia regimen 117. Drowsiness was so marked in 044 that the patients could not even respond to questions. In 30 percent of the cases of Code 044, corneal reflexes were lost, a condition not marked in those of Code 117.

Table 2

		<u>CODE 117</u>	<u>CODE 044</u>
Sensory Stimuli	Present	97 = 100%	40 = 100%
	Absent	x	x
Drowsiness	None	17 = 17.5%	02 = 5%
	Mild	80 = 82.5%	30 = 75%
	Excessive	x	08 = 20%
Response to Question	None	x	10 = 25%
	Yes	97 = 100%	30 = 75%
Reflexes			
Lid Reflexes	Present	96 = 98.9%	34 = 85%
	Absent	01 = 1.1%	06 = 15%
Corneal Reflexes	Present	95 = 97.9%	28 = 70%
	Absent	02 = 2.1%	12 = 30%
Laryngeal Reflex	Present	97 = 100%	39 = 97.5%
	Absent	x	01 = 2.5%

E. Monitoring of Consciousness During Operation

During the operation the lid, corneal, and laryngeal reflexes were marked. All the reflexes were unaltered in Code 117, but in Code 044, 20 percent of the cases lost lid reflexes and 30 percent lost corneal reflexes. Thus, the patient had a dummy sensation during incision, opening of peritoneum, and lifting of tubes in Code 117.

Cases having no sensation at all were more marked in Code 117 than in Code 044.

Table 3

Intraoperative Reflexes

		<u>CODE 117</u>	<u>CODE 044</u>
Lid Reflexes	Present	96 = 98.9%	32 = 80%
	Absent	01 = 1.1%	08 = 20%
Corneal Reflexes	Present	95 = 97.9%	28 = 70%
	Absent	02 = 2.1%	12 = 30%
Laryngeal Reflexes	Present	97 = 100%	39 = 97.5%
	Absent	x	01 = 2.5%
Incision Pain	None	31 = 32%	09 = 22.5%
	Yes	66 = 68%	31 = 77.5%
Pain at Opening of Peritoneum	None	10 = 10.3%	02 = 5%
	Yes	87 = 89.7%	38 = 95%
Pain at Lifting of Tubes	None	07 = 7.2%	02 = 5%
	Yes	90 = 92.8%	38 = 95%

F. Pulse

The pulse rate in both code cases increased more during the operative stage than in the preoperative stage, and again settled down in the postoperative stage.

G. Variation of Blood Pressure

Blood pressure recordings were taken before, during, and after operative procedures. In Code 117 there was a rise of blood pressure, both systolic and diastolic. But in Code 044 cases, 55 percent had a fall of systolic blood pressure and 35 percent had a fall of diastolic blood pressure.

H. Respiratory Rate

The respiratory rate variation was relative to the pulse rate. One patient of Code 117 had respiratory depression and, in that case, the operation was abandoned.

I. Temperature

One patient of Code 044 had a rise in temperature to 101° F. after her operation. The remaining patients of both codes had a temperature variation of 0.5° F. - 1° F. after preoperative medication.

J. Cooperation During Surgery

Fifty-five and six-tenths percent of the study cases of Code 117 cooperated well during the operation and 44.4 percent did not cooperate. The percentage of non-cooperation was much more in 044 (52.5 percent).

K. Surgeon Satisfaction

Surgeons were satisfied in 56.7 percent and 45 percent in Code 117 and Code 044 cases, respectively.

L. Process of Patients' Transfer from Operating Room to Recovery Room

Patients of Code 117 were almost ambulatory, and they could walk out easily from the OR to the RR after the operation. On the other

hand, 32.5 percent of the cases of Code 044 could not walk and were transported on a trolley to the RR.

M. Follow-up Record

All the study cases were counseled during discharge, and the findings were noted in the follow-up record. The main question was whether they had any sensation during the operative procedure: 85.6 percent of the Code 117 cases and 87.5 percent of Code 044 cases could remember everything about the operation (i.e., they could sense the skin incision, opening of the peritoneum, lifting and cutting of tubes, and closure of abdomen).

Table 4

		<u>CODE 117</u>	<u>CODE 044</u>
Sense During Surgery	No	14 = 14.4%	05 = 12.5%
	Yes	83 = 85.6%	35 = 87.5%
Pain During Surgery	None	20 = 24%	30 = 85.7%
	Mild	15 = 18%	x
	Mode Rate	27 = 32.5%	04 = 11.4%
	Severe	21 = 25.5%	01 = 2.9%
Remember Stages of Surgery			
Skin Incision	None	30 = 36.1%	31 = 88.5%
	Yes	53 = 63.9%	04 = 11.5%
Lifting of Tube	None	22 = 26.5%	30 = 85.7%
	Yes	61 = 73.5%	05 = 14.3%
Closure of Abdomen	None	39 = 47%	31 = 88.5%
	Yes	44 = 53%	04 = 11.5%

N. Satisfaction of Patients

Level of satisfaction was more in Code 044 (95 percent) than in Code 117 cases (67 percent). The 33 percent of unsatisfied cases of Code 117 cited pain and fear as the major factors of dissatisfaction. Those who were satisfied said that they would recommend this procedure to others.

Table 5

		<u>CODE 117</u>	<u>CODE 044</u>
Patient's Satisfaction	Yes	65 = 67%	38 = 95%
	No	32 = 33%	02 = 5%
Reason for Dissatisfaction	Pain	18 = 56.2%	02 = 100%
	Pain and Fear	10 = 31.3%	x
	No Cause	04 = 12.5%	x
Recommendation to Others	Yes	52 = 80%	38 = 100%
	No	13 = 20%	x

O. Additional Medication Used

In Code 117 cases, only 4.1 percent violently resisted during operative procedure; thus, extra medicine was used. In these cases, Meperidine (Pethidine), 25 mg., was used intravenously. Of Code 044 cases, 12.5 percent were given extra medicine. They were given Diazepam, 10 mg., intravenously.

Appendix E

BAVS PROTOCOL FOR CLINICAL TRIAL
OF ALTERNATE ANESTHESIA REGIMENS (Draft)

IPAVS - ASIA

Orig. W. Gall/ST
cc. L. Mes - SM
cc. P. J. S. A.
cc. Fishburne (Dec 4 visit)
STATUS REPORT

Kharullah - review please

TO: Dr. Marilyn E. Schima
FROM: Terrence W. Jezowski
SUBJECT: Draft BAVS Protocol for Clinical Trial of Alternate Anesthesia Regimens
DATE: 06 November 1980

The attached draft protocol is further to BAVS efforts to introduce modified anesthesia. The protocol will be finalized by the end of the week and the series completed by the end of November prior to Fishburne's expected visit in early December.

BAVS received able assistance from Dr. Carol Carpenter-Yaman of USAID/Dacca and others in developing the protocol.

cc. Russ Vogel

Attachment:

TWJ:scs

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① Gall prepare copy for Fishburne visit Dec. 4th.

DRAFT

REPORT OF THE INTERIM INVESTIGATION IN
THE NATIONAL STERILIZATION PROGRAM (NSP) IN
BANGLADESH

RECEIVED
 NOV - 6 1980
 IPAVS - ASIA

INTRODUCTION :

There has been several recent severe complications and related deaths of acceptors undergoing Tubectomy in the National Sterilization Program. The IPAVS has carried out detail post-death investigations to determine the cause of the deaths.

There also has been two important studies on sterilization deaths undertaken by experts from USA.

These studies are by :

- (1) Dr. H. Rosenberg, M.D. Mph. who visited Bangladesh in May 2 - 12, 1980 and studied 1,556 Tubectomy and 206 Vasectomy in 41 Sterilization Centres and detected 3 Tubectomy deaths ; all of those 3 deaths were apparently due to respiratory complications.

Bangladesh government during this period recorded 13 Tubectomy and 5 Vasectomy deaths of which 5 deaths were attributed to respiratory failure.

- (2) To further the study of this problem ; a second investigation was undertaken by two CDC investigators — Dr. David A. Grime MD and Bert B. Peterson MD. They visited Bangladesh in June '80. They made an extensive epidemiological study of all deaths that occurred in National Sterilization Programs in two divisions (Dacca and Rajshahi) between January 1, 1979 and March 31, 1980. The investigators examined the circumstances of a total of 28 deaths (21 Tubectomy and 7 Vasectomy) and identified causes of deaths as follows :

a. Anesthesia overdose	... 29%
b. Tetanus	... 21%
c. Haemorrhage	... 14%

The rest of the deaths were due to various reasons such as Pulmonary Embolism, anaphylactic reaction, malignant hyperthermia, small bowel obstruction etc.

Several very important observations were made from these studies by the investigators like :

- (1) With respect to present practice of systemic analgesia, Dr. Rosenberg observed that "The current combination of drugs seems to lead to a marked respiratory depression in addition to powerful sedation".

(More)

- (2) Dr. Jahan and Dr. Patterson reported that all surgeons interviewed claimed to be using "Local Anesthesia with Sedation" which means that patients should be awake but relaxed and tranquil. The investigators observed the procedure and indicated that the patients were unconscious and heavily sedated. In fact all the cases observed by the investigators were with an anesthetic stage II or stage III or under general anesthesia.

Both the investigators noted that there was lack of minimum emergency equipment present and the surgeon and staff had little or no training in treating medical emergency.

Investigation Result:

When these investigation results were made available to Government and USAID, they became anxious to explore the possibilities for further investigation leading to development of a Safe Anesthesia Regimen to reduce the anesthesia related complications and deaths. Dr. John J. Nicholburne an O.R.N.I. and a qualified anesthesiologist from Bowen Gray Medical Centre, was invited to come to Bangladesh to continue assessment of anesthesia practice and surgical facilities in Bangladesh.

Dr. Nicholburne visited Bangladesh in July for 7 days. He visited several upcountry sterilization facilities and some centres in Dacca city. He worked extensively with me and we decided to take up a pilot study at DAVS Dacca clinic for a new and safer anaesthesia regimen where the acceptor will not be awake during the procedure but relaxed and will not feel the discomfort of the surgery.

Present practice of Anesthesia in Tubectomy:

Pre-op Preparation

There is wide variation in the patient preparation. We in DAVS practice extensive counselling, pelvic and general examination, cleansing — shower and mandatory blood and urine examination. In other clinics very superficial examinations are carried out and no efforts are made to bathe the patient or change the clothes. Very little attention is directed to see that patient arrives for surgery in fasting state. In DAVS all patient for surgery must fast atleast for 6 hours.

Pre-medication:

Almost all clinics use pre-medication which consists of Injection Pethedine 50 - 100 mg and Inj. Atropine 0.6 mg, administered before surgery.

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General Medication:

In general operative medication consists of Inj. Diazepam 10 mg and Inj. Phentoperon 50 mg, both given I.V. before starting tubectomy. In all cases after this medication the patient loses consciousness and do not move spontaneously.

Local Anesthesia:

About 10-12 cc of Glylocaine 1% or 2% plainocaine is used for local anaesthesia in and around the site of incision.

Observation:

Using the above described anaesthesia regime, the surgeons believe that they are using "Local Anesthesia" but in fact this is not local anaesthesia because all patients lose consciousness, they become motionless, and do not move spontaneously. The respiration become slow and shallow, they lose lid reflexes and corneal reflexes and some of them even have apnea. Without having the advantage of the patient under intubation and controlled respiration the situation becomes very dangerous and at times many surgeons wonder whether his patient is breathing at all or not.

In fact all tubectomy patients with this regime go in transient general anaesthesia varying from stage I to stage III of anaesthetic stage. Moreover as the anaesthesia is transient, sometime the acceptors move during the procedure due to pain, which sometime become difficult for the surgeon and on many occasion patient has to be restrained by two people holding the legs and arms.

Another very important observation can be drawn from the practice, that almost all operating surgeons rely on the intravenous anaesthesia and do not use field block judiciously. They do not infiltrate all layers of the anterior abdominal wall as should be done and patient experiences pain during opening up of the peritonium and during pulling and tying of the tubes.

With the impression of using local anaesthesia which is in fact wrong, nobody monitors the patient during the procedure, and in fact atleast on one occasion the surgeon was operating upon a dead patient.

(more)

What can be done?

11-1-73

Reduction of complication and possible danger due to present Anaesthesia practices — is most desirable and ethical. The proposal is an Operation research to find out whether a safe anaesthesia regime can be developed to minimize the risk factor that are associated with present practice.

During Dr. Richardson's visit to our clinic, we developed a new Anaesthesia regime, which, if practiced, will definitely reduce anaesthesia-related complications. We proposed to study this new regime to find out its suitability, acceptability both from cultural and surgical point and views.

Study protocol

This study will investigate all aspect i.e. the cultural acceptability attitude of referer, acceptors, surgeons and clinical staff attitude, attainment of proper local anaesthesia response of patient, easiness of operation and any other relevant point that might be important. So the trial will encompass motivational activity with the referer, counselling of client, motivation of service delivery personnel and post-operative evaluation of acceptors.

A detail proposal has been developed and is enclosed herewith. A qualified and reputed Gynaecologist and Anaesthetist will be needed who will work as Consultant and will monitor both aspect i.e. anaesthesia, its level, change in patient vital sign etc.

The consultant will be available in the operating room during the whole period of trial study. Study protocol is described in detail alongwith the budget and justification.

Recommendation :

The following recommendations are intended to enhance the operative experience for the patient while at the same time reduce risk. Because Pethidine can produce profound respiratory depression, it is urged that this drug not be administered intravenously unless appropriate resuscitator equipment is available and the operating surgeon is experienced in the use of resuscitation devices. If these conditions cannot be satisfied, the author recommends that only oral and intramuscular medications be given, and then in reduce dosage, and that the primary emphasis be on an adequate local anesthetic block. Under optimal conditions, intravenous administration is to be preferred, and is recommended below.

Medications

a. Preanesthesia

1. Dil. opam : Usual dose : 10 mg. P.O., one hour before surgery. (Reduced to 5 mg. if weight is less than 75 pounds). This drug is given to allay anxiety and to provide mild analgesia.

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(more)

2. Meperidine (Pethidine) : This drug is not used for premedication (See below).
3. Atropine : This drug is not used for premedication. (See below).
4. Promethazine (Phenergan) : This drug is not used for premedication. (See below).

B. Operative Analgesia

1. Meperidine(Pethidine): Usual dose : 50 mg., administered intravenously. (Reduced to 25 mg. if weight is less than 75 pounds and/or if patient has any concomitant debilitating illness). One-half of the dosage is administered, two to three minutes are allowed to elapse, and then the remaining dose, if indicated (i.e., if response to painful stimulus is excessive) is administered. This drug will provide analgesia for the operation. When given intravenously it is effective within two minutes. A dangerous side effect is respiratory depression.
2. Atropine : Usual dose : 0.6 mg. (1/100 grain), administered intravenously. (Reduced to 0.4 mg. if weight is less than 75 pounds). This drug is used to block vagal stimulation arising from traction on the uterus and tubes.
3. Promethazine(Phenergan): Usual dose : 25 mg., administered intravenously. This drug is given to potentiate the narcotic and to reduce the emetic effect of intravenous Pethidine. Subcutaneous and intra-arterial injection should be avoided.

C. Local Anesthesia

1. Lidocaine(Xylocaine, Lignocaine), 1 percent solution: The maximum dose should be 5 mg/kg. (A 40 kg. woman should have no more than 200 mg., or 20 cc., of a 1 percent solution). Adrenalin added to the anesthetic solution offers little real advantage and contributes its own toxicity.

In administering the drug, the subcutaneous tissues, fascia, subfascia and peritoneum are infiltrated first and three to five minutes are allowed to elapse before the operation is begun. Local anesthetic solution may also be flowed onto the tubes and uterus to provide topical anesthesia. Five ml. should be used for this purpose. Lidocaine 0.5 percent may be used. This affords an extra margin of safety. Tetracaine (Nesacaine) has reduced toxicity but may be more allergenic.

Counselling and Information:

The Field Level officers shall be instructed to explain the effects of the new and old sterilization regimen and all patients, prior to undergo the new procedure must be counselled and explained the advantage and disadvantage of the new regimen by the appropriate persons. (see counselling case file no. 117)

Data Collection:

Data will be collected on prescribed Forms (Form-B see appendix) by trained data collectors keeping in view that no item goes untouched or unrecorded.

Study Protocol Detail:

This comparative study will be done on 150 new and 150 old procedure. The MVS Female Sterilization admission records may be used to gather information on patient characteristics, obstetric and other history along with Form-B. The admission record of the particular patient under study shall be given a special identity mark with rubber stamp (see appendix) before attaching with Form-B. Then a selection card (enclosed appendix) shall be drawn from a sealed envelope to determine the procedure.

The code 011 for old and 117 for the newer regimen have been selected. Each envelope will contain two cards of the same number to ensure the confidentiality of this comparative study.

Attention:

The envelope shall be opened using counselling session for determining the procedure as well as selection of the patient.

Form-B

The Form-B consists of queries about patient's consciousness level, amnesia, sensation, reflexes etc. shall be filled up by the data collector as monitored by the investigator during premedication, intra operative and post operative medications. The Form-B, after completion of data collection, shall be stapled with the admission records. The admission record marked earlier shall then be given the code number of performed procedure as indicated in selection card.

Data Process :

The data will be tabulated, analyzed and processed by the concerned persons for presentation of final report after the completion of study.

Work Outline: Time Schedule and Budget:A. Time Schedule:

The final study will begin in November 1980 on the basis of protest : was done in the last week of October, 1980. The final report will be revised in December

State Protocol D-11:

Safe Anesthesia Record

Form 1

Admission serial number : Date _____

Patient order number : Code No. _____

1. Age of the patient _____ years 2. Weight _____ lbs.

3. Time when the patient arrived at the pre-operative room

4. Drugs Administered:

Drug Name (generic name)	Dose	Time

Drugs given by : _____

5. Preanesthesia Monitoring

A. Consciousness

1) Sensory stimuli : Absent Present

Drowsiness : None Mild Excess

Response to question None Yes

B. Amnesia : None Yes

(more)

C. Vital signs - Post medication (Every 15 minutes)

Times	Pulse	Res.	B.P.	Temp

C. Operative Analgesia

Drug used	Dose	Time

Drugs administered by : _____

7. Operative Monitoring

- A. Consciousness : i) Responded to question Yes No
 ii) Sensory stimuli Present Absent
 iii) Drowsiness None Mild Excessive

B. Amnesia None Yes

C. Vital signs (Every five minutes)

Time	Pulse	Res.	B.P.	Temp

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- D. Reflexes : i) Lid : Absent Present
 ii) Corneal: Absent Present
 iii) Laryngeal: Absent Present

8. Local Anesthetics: (Specify generic name and dosage of drugs)

9. Operative Monitoring :

- A. Consciousness : i) Responded to question : None Yes
 ii) Sensory stimuli : Present Absent
 iii) Drowsiness : None Mild Excessive

- B. Sensation : Responded incision Responded peritoneum opening
 Tube lifting

C. Reflexes :

- i) Lid Absent Present
 ii) Corneal Absent Present
 iii) Laryngeal Absent Present

10. Operating time (Incision to closure) : _____ Minutes.

Name of the Operating Surgeon : _____

Date : _____

12. Vital signs (Every 15 minutes for one hour post operative)

	Pulse	Resp.	Temp.	B.P.

13. Any other complication relating surgery : No Yes

If yes, please _____

13. Treatment administered and their results (in detail)

14. Vital signs (Every four hours from post operative monitoring until discharged).

Time	Pulse	Resp	Temp	B.P.

15. Name of the Data Collector _____

(more)

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— 1" —

SAFER ANESTHESIA REGIMEN
 CODE : 011

2"

— 1/4" —

SAFER ANESTHESIA REGIMEN
 CODE : 117

2"

2"

RUBBER STAMP

SAFER ANESTHESIA REGIMEN
 CODE :

1 1/2"

3"

ANESTHESIA - PREOPERATIVE COUNSELLING(Counselling Checklist)Admission Serial No. Patient order No. Code :

Note : The counsellor will select the patient during the session by drawing the selecting card from sealed envelope. The following points should be discussed and explained in addition to usual counselling aspects.

This checklist shall be used for the patients selected for newer regimen (Code No. 117)

1. Introduction: Discussed Not discussed

(Consciousness - The patient will have full sense during surgery. There will be no pain or irritation except dumb awareness of the procedure)

2. Advantages/Disadvantages: Explained Not explain

(Advantages : Less chance of respiratory failure, quick recovery from sleepiness, drowsiness and quick return in physical movement/ household activities).

(Disadvantages: Prolonged pain or painful sensation would take place if surgical procedure is resisted by the patient).

Name of Counsellor : _____

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ANESTHESIOLOGICAL REGION

(FOLLOW-UP RECORD)

Note : The post-operative follow-up of the patients under study shall be done at Ambulatory before the patients leave for home.

Questionnaire:

1. Did you have full sense during operation : Yes

a. if yes, have you experienced any pain during surgery ?

None Mild Moderate Severe

b. can you remember stages of surgery as stated below:

i) Skin incision : None Yes.

ii) Lifting of any inside organs : None Yes

iii) Closure of abdomen : None Yes

2. Are you satisfied with this type of procedure ?

Yes Not

a. If no specify reason : _____

b. If yes, will you recommend this type of procedure to anyb

Yes No

Name of the person filling up this form : _____

Personnel :

Principal Investigator	:		
Project Co-ordinator	:	Tk. ...	3,000/-
Surgeon In-Charge (1)	:	Tk. 100 x 1 x 30 =	3,000/-
Assistant Surgeons(4)	:	Tk. 50 x 4 x 30 =	6,000/-
Paramedics (3)	:	Tk. 20 x 3 x 30 =	1,800/-

16,800/-

Data Coordinator	:	Tk.	2,500/-
Consultant: Anesthetist	:	Tk. 300 x 25 =	7,500/-
Gynecologist	:	Tk. 300 x 25 =	7,500/-
Stationeries & Printing	:	Tk.	1,000/-
Data coding, punching, Editing and Reporting	:	Taka	3,000/-
Additional Investigation	:	Taka	3,000/-
Contingency and overhead	:	Taka	1,000/-

12,300/-

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Appendix F
PREOPERATIVE AND OPERATIVE MEDICATIONS

Appendix F

PREOPERATIVE AND OPERATIVE MEDICATIONS

I. OBJECT

The object is to relieve anxiety and to induce light somnolence during the preoperative period. Intraoperatively, medication should enhance somnolence without removing protective reflexes, while at the same time providing good systemic analgesia.

II. PREOPERATIVE MEDICATION

See pharmacology of these drugs in Fishburne's earlier report.

1. Diazepam provides sedation, inducing tranquillization and somnolence. It does not provide analgesia, although a slight degree of amnesia may be noted subsequently.
2. Meperidine provides moderate sedation and analgesia. Some nausea and respiratory depression may occur. No amnesia occurs.
3. Atropine produces tachycardia and drying of secretions. It may thus induce discomfort. Overdose leads to CNS excitation, palpitations, and hypertension.
4. Promethazine is a minor tranquillizer and antiemetic. It has a weak alpha adrenergic blocking activity. It has no amnesic effect.

Note: Of these various drugs, diazepam by itself seems most rational. This drug enjoys rapid and complete absorption when given orally. Only 60 percent of the drug is absorbed when it is administered intramuscularly.

III. CHOICE OF OPERATIVE MEDICATION

1. Desired Effect
 - a. Analgesia
 - b. Sedation
 - c. Partial vagal blockade

- d. Drying of secretions (not indicated unless general anesthesia is used).

2. Preferred Drugs

- a. Meperidine provides analgesia and sedation. Given intravenously, its effect is prompt (2-3 minutes).
- b. Butorphanol provides analgesia and sedation. Given IV, the effect is prompt (2-3 minutes). The peak effect occurs in less than 30 minutes. The advantage of this drug is that reduced respiratory depression is associated with larger doses as compared to meperidine.
- c. Atropine reduces partial vagal blockage, which is necessary to avoid bradycardia, which occurs during peritoneal and tubal traction.
- d. Promethazine may potentiate action of the narcotic drugs. Its antiemetic action minimizes the risk of vomiting induced by narcotics.

IV. DOSSAGE SCHEMA (Protocol for Administration?)

1. Preoperative Medication

- a. Diazepam: 10 mg., p.o. 45-60 minutes preoperative.

2. Operative Medications

- a. Meperidine: 25-50 mg. IV, 3-5 minutes before surgery.
- b. Atropine: 0.4-0.6 mg. IV, 3-5 minutes before surgery.
- c. Promethazine: 25 mg. IV, 3-5 minutes before surgery.

Note: Mix all three together. Give one-half of total volume, then observe patient for 2-3 minutes for signs of adverse reactions. If none occur, give remaining drug intravenously.

MONITORING

It is only through careful and repetitive monitoring of vital signs that the more subtle complications of analgesia and anesthesia and surgery may be recognized. It is therefore mandatory that the medicated, operative, and postoperative patient be closely observed. The following regimen is suggested as a model.

I. Preoperative Medication

The vital signs (VS) should include blood pressure (BP), heart rate (HR), and respiratory rate (R). The signs should be checked before preoperative medication is administered, and then every 15 minutes until the patient is transferred to the OR. Oral temperature (OT) should also be taken before administration of the drug, but this task need not be repeated.

II. Operation

Baseline VS should be taken on arrival of the patient to the OR. Once the operative medication has been given, HR and BP should be monitored every 5 minutes by a nurse, FWV, or MD. Respiration should be monitored continuously by observation of chest and abdomen, and also by feeling the patient's breath blowing on the hand, which is held near the patient's nose and mouth.

Respiratory arrest may occur unobserved if it is not carefully looked for.

III. Postoperative

BP, HR, and R should be obtained every 5 minutes for the first 15-30 minutes, then advanced to every 15 minutes, then every hour, and then every 2 to 4 to 6 hours, depending on the patient's condition. Temperature should be checked on arrival in the recovery unit, then every 2 to 4 hours.

IV. Psychomotor Testing

It may be deemed advisable to perform psychomotor testing to evaluate the patient's recovery before discharge from the clinic. A simple test, such as the Romberg finger-to-nose test, will generally suffice

Appendix G

MINIMUM MEDICAL SERVICE STANDARDS FOR FEMALE
VOLUNTARY SURGICAL CONTRACEPTION PROGRAMS

MINIMUM MEDICAL SERVICE
STANDARDS FOR FEMALE
VOLUNTARY SURGICAL
CONTRACEPTION PROGRAMS

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MINIMUM MEDICAL SERVICE STANDARDS FOR FEMALE VOLUNTARY SURGICAL CONTRACEPTION PROGRAMS

Marilyn E. Schima, R.N., Ed.D., M.P.H.
Director of International Programs



**INTERNATIONAL PROJECT OF THE ASSOCIATION
FOR VOLUNTARY STERILIZATION, INC.**

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FIRST EDITION

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Introduction

The International Project of the Association for Voluntary Sterilization (IPAVS) is a program of the Association for Voluntary Sterilization (AVS), a private, non-profit agency based in the United States. The primary purpose of IPAVS is to advance the acceptance and availability of high quality voluntary surgical contraception services as a basic component of health programs throughout the world. IPAVS provides assistance to voluntary, non-profit, and public health and medical organizations as well as governmental agencies for the development and implementation of voluntary surgical contraception service programs in developing nations.

The Minimum Medical Service Standards for Female Voluntary Surgical Contraception Programs* were written specifically for IPAVS by the medical and program staffs of IPAVS together with the Biomedical and International Committees of the Association for Voluntary Sterilization (AVS) under the direction of the Director of International Programs, IPAVS. Therefore the purpose of developing these standards is solely for the implementation of IPAVS-AVS policies and programs.

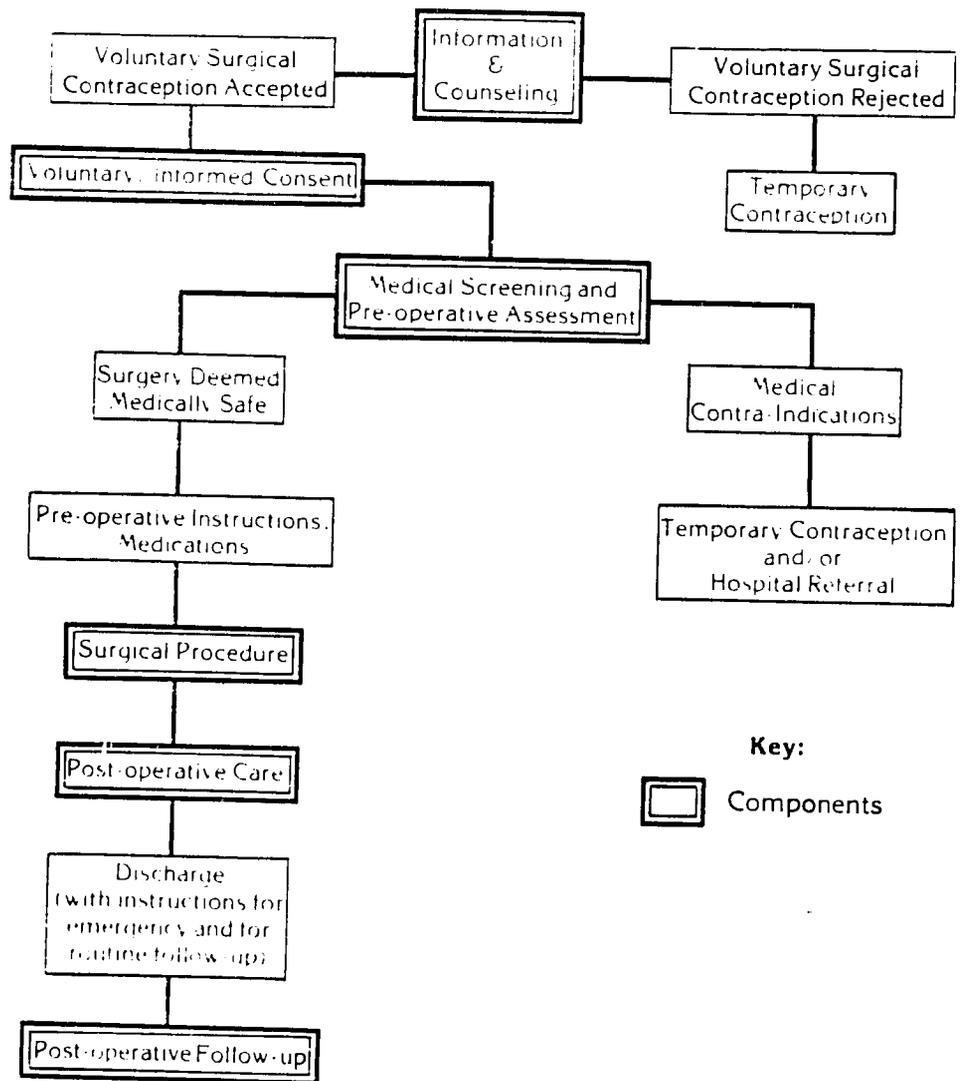
The Standards underwent many revisions and refinements in order to clearly set forth requirements that are not only consistent with the principles of sound medical practice but are also considered to be achievable by hospitals and multi-purpose and single purpose clinics throughout the world.

The unintentional or inadvertent omission of any significant basic requirement for responsible surgery should not be construed to imply that that requirement may be safely overlooked. Rather, the need for its inclusion in these standards should be brought immediately to the attention of the Director, IPAVS.

* Hereinafter referred to as the Standards. (Male minimum medical service standards also are available.)

Purpose

- 1.1 The purpose of the Standards is to establish minimum requirements for a comprehensive delivery system of high quality voluntary surgical contraception services. This delivery system includes voluntary surgical contraception techniques and all of the other supportive program elements which, when combined, are necessary to ensure the safe delivery of services, and which must be an integral part of any whole and comprehensive program of voluntary surgical contraception.
- 1.2 IPAVS delivery systems include the following recommended sequence of steps once the client enters the service delivery system.



**Scope**

- 1.3 These standards were developed for and apply to all projects or programs which receive funding in whole or in part from IPAVS.

Objective

- 1.4 To assure that each person availing herself of permanent voluntary surgical contraception provided under the support of IPAVS is clearly aware of the significance of her voluntary decision. No pertinent, useful or valuable information should be overlooked or omitted during counseling. Surgical procedures, when performed, should be provided under the best possible conditions in any given circumstance.

Policy

- 1.5 The Project Director is responsible for implementation of and compliance with these standards. He is also responsible for having this document translated in its entirety into the language of the country, when it is appropriate.

Users

- 1.6 The Project Director of an IPAVS subgrant and each member of the professional staff are intended to be the primary users of this document.

Compliance

- 1.7 In order to be eligible for IPAVS funding and to maintain IPAVS support, each project providing voluntary surgical contraception services must, as a bare minimum, fulfill the requirements set forth in these standards. Failure to meet these requirements in currently funded programs will result in suspension and possible termination of IPAVS support.

- 1.8 Compliance with the Standards will be reviewed by IPAVS staff during regular site visits. (See Appendix D.)

Exceptions

- 1.9 In the event that a project seeks an exception to any of the requirements as described in the Standards, a written request for exception, with justifications and alternative proposals, should be submitted to IPAVS. No surgery should be initiated until the minimum standards are met or the exception is formally approved.

Recommendations and Changes

- 1.10 From time to time, recommendations may be incorporated into the Standards by the International Office. When these or other changes occur, they will be sent to each Project Director so that immediate posting of the changes can take place.

Definition of Terms

1.11 Since these standards are intended for use in diverse areas of the world with differing systems for the delivery of medical services, and with varying interpretations of medical terminology, the meanings of the key terms as used throughout this document are defined here.

HOSPITAL:	Generally, a health facility whose primary function is to provide comprehensive diagnostic and therapeutic medical and surgical services on an inpatient basis.
MULTI-PURPOSE CLINIC:	Similar to a hospital in that it provides diagnostic and therapeutic services to inpatients in various medical and surgical services; it differs from a hospital in that it generally has fewer beds and is often non-governmental.
SINGLE PURPOSE/ FREE-STANDING CLINIC:	A facility, or part of another health facility, offering diagnostic and therapeutic services to outpatients. It may be devoted specifically to the delivery of voluntary surgical contraception services.
INPATIENT:	Generally, an individual who has been admitted at least overnight to a health facility for the purpose of receiving diagnostic or therapeutic medical or surgical services.
OUTPATIENT:	Generally, an individual who receives ambulatory care at any health facility.
SURGICAL CONTRACEPTION:	Also called "sterilization." It means the interruption of the reproductive capability of the female for the purposes of fertility termination. Surgical contraception techniques do not affect the normal functioning of the ovary with the exception of the reproductive function.(1)
VOLUNTARY:	Means the procedure is performed at the request and with the informed consent of the person who has elected sterilization for the purpose of terminating her fertility.(2)

(1) Cf. Article III of the Bylaws of the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception, para. 1.

(2) *Ibid.*, para. 2.



Program Components

General Policy

- 2.1 A comprehensive voluntary surgical contraception service program must have the following components:
- **Information and Counseling**
 - **Informed Consent**
 - **Medical Screening and Pre-operative Assessment**
 - **Surgical Procedure**
 - **Post-operative Care**
 - **Post-operative Follow-up**

Information and Counseling

Policies

- 2.2 A prospective client for voluntary surgical contraception must be provided with all of the information necessary to make a reasoned, non-coerced decision to terminate her fertility. The information must be provided in the language and terminology she best understands.
- 2.3 In view of the critical and sensitive nature of this decision, it is essential that information and counseling be provided by a doctor, nurse, educator, trained paramedic or other health professional, such as a social worker, who is trained for this task. Although more than one staff member may counsel a client, one individual must be assigned the responsibility for this service component by the Project Director.

- 2.4 Temporary methods of contraception must be made available to:
- a. Those individuals who decide not to proceed with the voluntary surgical contraception;
 - b. Those who are judged by local policies to be ineligible for other reasons, such as age, number of children, and
 - c. Those with physical or other complications as determined by a qualified physician.

- 2.5 If a client requests additional information on any contraceptive method or if she asks for referral information for any method not available at the service site, it should be given.

Minimum Requirements

- 2.6 The initial information and counseling sessions prior to surgery must provide the following:
- a. Description and discussion of both temporary and permanent methods of contraception, including what the benefits and risks of the available techniques are, with special attention to their failure rates, types of possible complications, and specific side effects.
 - b. Special attention to the intended permanency of all voluntary surgical contraception procedures.
 - c. Discussion of the various voluntary surgical contraception procedures and types of anesthesia available, including specific information as to what the possible operative and post-operative complications and side effects may be, as well as the possibility of failure with subsequent intra- or extra-uterine pregnancy.
 - d. Assurance that withholding or withdrawing consent at any time prior to the voluntary surgical contraception procedure will not prejudice future care, and will not result in the loss of other program benefits to which the client might otherwise be entitled.
- 2.7 The client should have the option of being accompanied by a person of her choice who is also free to ask questions.
- 2.8 Counseling sessions before the voluntary surgical contraception procedure should be an occasion for assessing the emotional fitness of the person to undergo voluntary surgical contraception, for listening to her carefully, understanding and recording her feelings and realistic fears and expectations. To ascertain that the counseling is successful and that the client understands fully the implications of voluntary surgical contraception, the Informed Consent Form must be presented to the client, and carefully explained to her before she signs the form. (Suggested Model Informed Consent Forms for literate and illiterate clients are attached as Appendices A and B.)



Informed Consent

Policy

- 2.9 An Informed Consent Form in the specific language of each country or area must be documented for each client.

Minimum Requirements

- 2.10 Voluntary, informed consent is considered to be achieved when:
- a. The individual presents herself at the treatment center after choosing freely to do so, having been offered no undue inducement or incentive, nor having been subjected to any force, fraud, duress, or other form of constraint.
 - b. The individual is capable of understanding, and, in fact, does understand the nature and effects of the voluntary surgical contraception she is requesting. Specifically, she must be apprised of all the elements contained in the Informed Consent Form (Appendices A and B) and discussed during counseling.

Medical Screening and Pre-operative Assessment

Policies

- 2.11 The prospective clients for voluntary surgical contraception must be assessed to determine their physical and emotional fitness for surgery in general, and for surgical contraception in particular.
- 2.12 No voluntary surgical contraception procedures should be performed when a client has any medical condition indicating that surgery may involve above normal risk. Such clients should be provided with temporary methods of contraception, if appropriate, and/or referred to a hospital for further medical assessment. No surgery should be performed on a medically high risk client.

Minimum Requirements

- 2.13 Obtain and record on the client's record the following information:
- a. Medical History
 1. Age
 2. Family health history
 3. Past illness and other medical conditions. Include any convulsive disorders, asthma or use of anti-asthmatic drugs, heart disease or cardiac surgery, mental conditions, anemia, obesity, bladder, pelvic/abdominal surgery, retroverted uterus, pelvic inflammatory disease, endometriosis, adnexal pathology, hypertension, diabetes
 4. Allergies
 5. Obstetrical history (pregnancy, abortion, deliveries)
 6. Menstrual pattern and last menstrual period
 7. Present state of health
 8. Previous use of contraceptive methods
 - b. Physical Examination by a Physician
 1. Weight
 2. Pulse and blood pressure
 3. Evaluation and nutritional status
 4. Auscultation of heart and lungs
 5. Abdominal palpation
 6. Breast examination
 7. Pelvic examination (including estimation of size and mobility of uterus and adnexa to rule out pregnancy and gynecological abnormalities)
 8. Other examinations based on client's medical history
 - c. Laboratory Examination
 1. Hemoglobin and/or hematocrit
 2. Urinalysis for glycosuria and proteinuria determinations
- 2.14 If the results of the physician's examination so indicate, a pregnancy test and/or Pap smear should be performed.
- 2.15 For individuals who are to undergo the voluntary surgical contraception procedure, pre-operative instructions should include special information, such as the necessity of fasting after midnight of the day preceding surgery, bathing before surgery, or any other instructions that might be appropriate. The client should be informed that she can bring along a companion to assist her. Clients must also be alerted to the importance of seeking immediate medical attention if pain or other problems occur post-operatively.



Surgical Procedures

Policies

- 2.16 Surgical procedures will be performed on clients qualified by the screening process.
- 2.17 While IPAVS recommends the use of systemic sedation and local anesthesia, the use of other methods (such as general or regional anesthesia) will be left to the discretion of the Medical Director of the facility who will base the decision on the availability and experience of health personnel and on client characteristics.
- 2.18 Each Medical Director is required to establish mandatory procedures for the sterilization of surgical equipment, drapes, and other items used during surgery, and to ensure that aseptic conditions are met. Guidelines must be developed to clearly specify the procedure to be followed, the persons responsible, the methods to be used, the kinds of solutions to be used, skin preparation, and the requirement that sterile gloves be used for all procedures.

Minimum Requirements

- 2.19 While female surgical procedures may be performed on an inpatient or outpatient basis, the following operating conditions must be met:
- a. The surgery must be performed in an adequately equipped operating room under aseptic conditions with appropriate surgical instruments and sterile gloves, and accessory emergency backup equipment. (For an elaboration of requirements, see Chapters 3 and 4.)
 - b. The procedure must be performed by a licensed physician who is competent in the particular procedure. He must also have the necessary expertise to deal with any immediate complications that may arise during the performance of the procedure.
 - c. A trained nurse or paramedic is required to assist the operating physician during the performance of each procedure and to care for and monitor the client throughout the surgical procedure.
 - d. Vital signs such as blood pressure, pulse and respiration must be monitored and recorded by trained health personnel during the operation, regardless of which surgical procedure is performed.

Post-operative Care

Policies

- 2.20 Written and verbal instructions for follow-up and where to go for emergency care should be given to the client before discharge.

- 2.21 Accommodations for overnight stay at the service site, if necessary, must be available.

Minimum Requirements

- 2.22 Immediately following surgery, the client should be transferred to the recovery room/ward area where:
- a. She must be observed by a nurse or trained paramedic and must have her vital signs monitored intermittently for at least two hours, or until she has fully recovered from the anesthetic. Vital sign values must be entered in her record.
 - b. She must not leave the facility until she is fully stable and is discharged by qualified staff.
 - c. She must receive oral and written post-operative instructions on problems that may arise after discharge; she must also be told how to care for the incision and whom to contact in case of emergency.

Post-operative Follow-up

Policy

- 2.23 There must be a minimum of one follow-up examination for a client who has undergone the voluntary surgical contraception procedure.

Minimum Requirements

- 2.24
- a. The follow-up examination should be scheduled approximately one week after surgery and the results must be recorded.
 - b. The examination may be performed by health personnel other than a physician, but a physician must be available as a backup.
 - c. During the visit, the client must again be informed of the possibility of failure (i.e., subsequent intra- or extra-uterine pregnancy), with stress on the need for immediate follow-up if amenorrhea, pain or abnormal bleeding should occur.
- 2.25 It is preferable that post-operative follow-up be done at the facility where the voluntary surgical contraception procedure was performed. However, clients may be referred to other health centers or to public health personnel provided that previous formal administrative arrangements have been made.



Minimum Space and Equipment Requirements

General Policy

- 3.1 Space must be provided for all program component activities as discussed throughout the Standards.

Minimum Requirements

- 3.2 As a general minimum requirement, the facility must have available running water, electricity, and toilet facilities. Auxiliary spaces are not discussed here inasmuch as the identification and organization of these space requirements are more flexible and are left to the discretion of administrators.
- 3.3 Following are lists of minimum equipment requirements, by area. However, certain items, such as office and examining room furniture as well as incidental surgical and non-surgical supplies, are intentionally omitted, although it is recognized that they may be necessary to the operations of most service facilities.

Examining Room

Minimum Requirements

- 3.4 The following equipment must be available in the examining room or area:
- a. Examining table
 - b. Adult weight scale
 - c. Adequate lighting
 - d. Sphygmomanometer
 - e. Stethoscope
 - f. Thermometer
 - g. Instruments for basic pelvic examination: speculum, tenaculum, sponge, forceps, straight clamp, uterine sound, and any other standard equipment the physician may require.

Operating Room

Minimum Requirements

- 3.5 The surgical space allocated to voluntary surgical contraception must be located in a separate area, building, or floor that is isolated from non-surgical client services. The area should be easy to enter and leave in case of emergency. Sterile equipment and supplies should be easily accessible for surgery and for management of immediate complications. Single purpose clinics require additional emergency backup. (See Chapter 4.)
- 3.6 The following items are mandatory:
- a. Operating table adjustable to the Trendelenburg position. It must have a drop end and be fitted with lithotomy leg supports
 - b. Instrument tray
 - c. Surgical supplies or kits or endoscopy equipment
 - d. Adequate lighting, approved by the surgeon and designed to minimize the danger of explosion
 - e. Emergency light (battery operated) to be used in case of power failure
 - f. Sphygmomanometer and stethoscope
 - g. Emergency equipment (See Chapter 4)
 - h. Hand washing facilities in or adjacent to the operating room
 - i. Window screening

Recovery Room or Ward Area

Minimum Requirements

- 3.7 The post-operative recovery room or ward area must have good lighting and ventilation. The number of beds will be determined by the available space and the expected number of clients. Thermometers and at least one sphygmomanometer and one stethoscope should be readily available.

**4****Minimum Emergency Care Requirements**

General Policy**4.1**

All facilities must:

- have basic emergency equipment
- be able to perform emergency surgical procedures, including emergency laparotomy
- be staffed adequately to perform these emergency procedures
- have an anesthesiologist or competent anesthesia technician available for emergencies

Minimum Emergency Care Equipment**Minimum Requirements****4.2**

The following emergency care equipment must be readily available and in good working order within all facilities in which female voluntary surgical contraception procedures are performed:

- a. Airway
- b. Ambubag
- c. Laryngoscope and endotracheal tubes
- d. Suction apparatus
- e. Oxygen unit
- f. Intravenous administration sets with large caliber needles
- g. Intravenous fluids
- h. Emergency drugs and antidotes for treating narcotic overdose or adverse reaction to anesthesia or other drugs
- i. Standard laparotomy tray
- j. Anesthesia machine (required only in facilities where laparoscopy is performed)



- 4.3 This emergency care equipment and a tray containing the emergency drugs must be kept in an accessible place. The Medical Director is responsible for maintaining emergency care equipment in good working order and for making sure that all staff is familiar with its location and proper use.

Additional Emergency Backup Requirements for Single Purpose Clinics

Minimum Requirements

- 4.4 Since single purpose clinics generally are limited in their capability to perform major surgery and often do not have inpatient facilities, the following emergency backup must be provided:
- a. All single purpose clinics must have an established arrangement with a fully equipped hospital that would permit the transfer, hospitalization and treatment of clients in the event of major complications.
 - b. The location of the hospital must be no further than a 10-minute drive from the clinic.
 - c. Adequate means of motor vehicle transportation must be standing by at all single purpose clinics during surgery and until all post-operative patients have been discharged.
 - d. No laparoscopy procedures may be performed in facilities that are not adequately staffed and equipped to perform an emergency laparotomy within five minutes.
 - e. An anesthesiologist or competent anesthesia technician must be immediately available while a laparoscopy is being performed. General anesthesia, when used, must be administered by an anesthesiologist or a physician who is competent in the specialty.



Requirements for Specific Surgical Procedures

General Policy

5.1 IPAVS supports voluntary surgical contraceptive procedures which include:

- **Minilaparotomy**
- **Colpotomy**
- **Culdoscopy**
- **Laparoscopy**

IPAVS does not support services in which hysterectomy is routinely used for voluntary sterilization.

Whether the procedure is done on an outpatient or an inpatient basis, the operative conditions described below have to be met. Final client selection should be made by the attending physician in conjunction with the Medical Director of the facility.

Minilaparotomy

Minimum Requirements

- 5.2
- A. **Facility:** The procedure must be performed in an operating room of a hospital, multi-purpose clinic, or single purpose clinic.
 - B. **Equipment:** Standard sterile surgical equipment with the recommended addition of a uterine manipulator/elevator, small retractors and a tubal hook for the delivery of the tubes.
 - C. **Staff:** The procedure must be performed by physicians with knowledge and experience in performing simple abdominal surgery who have special training in this technique.



Colpotomy

Minimum Requirements

- 5.3**
- A. Facility: The procedure must be performed in an operating room of a hospital, multi-purpose clinic, or single purpose clinic.
 - B. Equipment: Standard sterile gynecological equipment including a heavyweight speculum, tenaculum, vaginal retractors and some form of forceps to grasp the Fallopian tubes are required. The operating table must have a drop end and be fitted with lithotomy leg supports.
 - C. Staff: The procedure must be performed by gynecologists or surgeons experienced in standard gynecological surgery who have special training in this technique.

Culdoscopy

Minimum Requirements

- 5.4**
- A. Facility: The procedure must be performed in an operating room of a hospital, multi-purpose clinic, or single purpose clinic.
 - B. Equipment: The requirements are the same as for colpotomy, with the addition of a culdoscope, a trocar or cannula, a light source and the instruments designed for tubal occlusion.
 - C. Staff: The procedure must be performed by gynecologists or surgeons experienced in standard gynecological surgery who have special training in this technique.



Laparoscopy

Minimum Requirements

- 5.5
- A. Facility: The procedure must be performed in an operating room with the equipment necessary to perform an emergency laparotomy within five minutes should any complications occur that require major surgical intervention. This means that laparoscopy must be performed only in a fully equipped operating room in a hospital or multi-purpose clinic.
 - B. Equipment: The basic items include a trocar and needle for insufflation, the insufflation apparatus, a light source, the laparoscope and the instrument for tubal occlusion. Other special equipment used for this procedure will depend on factors such as the type of laparoscope, or method of tubal occlusion.
 - C. Staff: Laparoscopy requires efficient team work. The procedure must be performed by a gynecologist or surgeon who has received special training in the technique. In addition to nursing support for operating assistance and client monitoring, an individual responsible for equipment maintenance during surgery must also be provided. An anesthesiologist or adequately trained anesthesia technician must also be immediately available when laparoscopy is being performed. When used, general anesthesia must be administered by an anesthesiologist or a physician who is competent in the specialty.

Hysterectomy

- 5.6 IPAVS does not support hysterectomy as a surgical contraceptive procedure.
- 5.7 All of the foregoing requirements are summarized in Appendix C.

Medical Record Requirements

General Policy

- 6.1 A complete medical record must be written and maintained for each client who undergoes a voluntary surgical contraception procedure.

Medical Record

Minimum Requirements

- 6.2 The Medical Record should contain:
- a. Pre-operative assessment (medical history, physical examination and laboratory test results)
 - b. Signed Informed Consent Form for each client
 - c. Surgical procedure notes
 - d. Post-operative data
 - e. Complications and outcome notes (Use IPAVS Complication Report and/or IPAVS Female Voluntary Sterilization-Related Death Report; see Appendices E and F)
 - f. Follow-up data

Storage

Minimum Requirements

- 6.3 Records must be kept for three (3) years after discharge of the client. Adequate filing cabinets, binders, and other items must be available for this storage.

Requirements for Reporting Complications and Deaths

General Policy

- 7.1 All deaths must be reported immediately. All complications occurring during or after surgery which necessitate surgical intervention, hospitalization, or medical treatment that is above and beyond that normally provided in conjunction with a voluntary surgical contraception procedure must be reported to IPAVS.

Complications

Minimum Requirements

- 7.2 When a complication occurs, the IPAVS Complication Report (Form C-1) should be completed and forwarded to IPAVS with the required quarterly reports. (See Appendix E.)

Deaths

Minimum Requirements

- 7.3 When a voluntary surgical contraception-related death occurs, report such death to IPAVS by telephone or by cable within 24 hours, then complete and forward to IPAVS within seven days the Female Voluntary Sterilization-Related Death Report. (See Appendix F.)

MODEL INFORMED CONSENT FORM FOR LITERATE ACCEPTORS

(This form is a model, prepared by IPA VS to assist sub-grantees in implementing an informed consent program. The form is designed to be used by clients who can read. A form of this kind should be in the local language(s) and designed to best fit your needs while conforming to the underlying informed consent concept.)

I, the undersigned, wish to be sterilized by the following procedure: _____
(specify sterilization procedure to be performed). I understand the following:

1. There are temporary methods of contraception I can use instead of sterilization for planning my family.
2. The sterilization is a surgical procedure, the details of which my physician has explained to me.
3. The sterilization operation involves risks, which my physician has explained to me.
4. If the operation is successful, I will be unable to have any more children.
5. The sterilization operation is permanent.
6. I have applied for a sterilization procedure of my own free will without coercion or inducement and know I can change my mind at any time and decide against the sterilization procedure.

Date

Signature of client

Date

Signature of physician or other authorized person
attesting to the client's understanding of the above
statement.

MODEL INFORMED CONSENT FORM FOR ILLITERATE ACCEPTORS

(This form is a model, prepared by IPAVS to assist sub-grantees in implementing an informed consent program. The form is designed to be used for clients who cannot read. A form of this kind should be in the local language(s) and designed to best fit your needs while conforming to the underlying informed consent concept.)

I, _____, certify that _____
(name of attending physician or authorized assistant) (name of client)

has presented himself/herself freely to undergo a _____
(specify sterilization procedure to be performed.) I have explained to the client and he/she understands the following:

1. Temporary contraception techniques are available which the client and his/her partner can use to plan their family.
2. The contraceptive procedure is a surgical one.
3. The contraception operation involves some risks, which have been fully explained.
4. While sterility is not guaranteed, if the operation is successful, the client will be unable to have more children.
5. The contraception operation is permanent.
6. The client has applied for a surgical contraceptive procedure of his/her free will without coercion or inducement and can change his/her mind at any time and decide against the procedure.

I certify that the client's mark or signature is made with the understanding that such mark attests to the fact that I have explained the above to the client and that he/she understands it fully.

Date

Signature of attending physician or other authorized person

Date

Signature or mark of client

Date

Signature of witness of client's choosing

SUMMARY TABLE REQUIREMENTS FOR SPECIFIC SURGICAL PROCEDURES

TYPE OF PROCEDURE	TYPE OF SETTING	SPECIAL EQUIPMENT	TRAINING OF PHYSICIAN AND OTHER STAFF REQUIREMENTS
Minilaparotomy (p. 15)	Operating room of hospital, multi purpose clinic, or single purpose clinic	Uterine manipulator/elevator Small retractors Tubal hook	Knowledge and experience in simple abdominal surgery Certified in minilaparotomy
Colpotomy (p. 16)	Operating room of hospital, multi purpose clinic, or single purpose clinic	Operating table with drop end fitted with lithotomy leg supports Heavyweight speculum Tenaculum Vaginal retractors Forceps to grasp Fallopian tubes	Gynecologist or surgeon with experience in standard gynecological surgery Certified in colpotomy
Culdoscopy (p. 16)	Operating room of hospital, multi purpose clinic, or single purpose clinic	SAME as for colpotomy PLUS Culdoscope Troc at or cannula Light source Tubal occlusion instrument	Gynecologist or surgeon with experience in standard gynecological surgery Certified in culdoscopy
Laparoscopy (p. 17)	Operating room of hospital or multi purpose clinic equipped to perform emergency laparotomy within 5 minutes (generally, a single purpose clinic will not meet requirements.)	Depends on type of laparoscope, method of tubal occlusion, etc. Troc at Needle for insufflation Insufflation apparatus Light source Instrument for tubal occlusion Anesthesia machine	Gynecologist or surgeon with minimum of 3 years experience in abdomino-pelvic surgery Certified in laparoscopy Anesthesiologist or trained anesthesia technician
Conventional Laparotomy	Operating room of hospital or multi-purpose clinic	Standard surgical equipment	Knowledge and experience in conventional laparotomy Certified in conventional laparotomy

IPAVS MINIMUM MEDICAL SERVICE STANDARDS SITE VISITOR COMPLIANCE REPORT

INSTRUCTIONS:

IPAVS site visitors will use this form only when checking on the compliance of an IPAVS sub-grantee with the provisions of the IPAVS Minimum Medical Service Standards for Male and Female Voluntary Surgical Contraception Programs. All items should be completed to indicate that all aspects of the program were

checked. Fill in the blanks, check the boxes, and use descriptive narrative when appropriate. Mark portions which are not applicable with "NA" and, when you do not have the required information, mark "don't know." When space is inadequate, attach continuation sheet(s).

To: Director, International Project of the Association for Voluntary Sterilization (IPAVS), 708 Third Avenue, New York, NY 10017

From: _____
(Name of site visitor) (Title of site visitor)

(Address of site visitor)

(Date) (Signature of site visitor)

PART 1

1. _____
(Name of facility)
2. _____
(IPAVS sub-grant number)
3. _____
(Date of site visit)
4. Type of visit:
 - Initial
 - Program Assessment
 - Medical Site
 - Other (Specify) _____

APPENDIX D

PART 2

5. Services Available:

- Temporary contraceptive methods (Specify types)

- Male voluntary surgical contraception
- Female voluntary surgical contraception
- Infertility
- Post-operative follow-up
- Short term follow-up (one visit)
- Other (specify)

PART 3

6. Voluntary Surgical Contraception Procedures provided at this clinic:

Type	Average No. Performed	Type of Anesthetic Used	Comments
<input type="checkbox"/> Minilaparotomy			
Pomerov			
Ring			
Other			
<input type="checkbox"/> Laparoscopy			
Ring			
Coagulation			
Clip			
<input type="checkbox"/> Colpotomy			
Pomerov			
Other			
<input type="checkbox"/> Culdoscopy			
Pomerov			
Other			
<input type="checkbox"/> Postpartum tubal ligation			
<input type="checkbox"/> Interval Laparotomy			
<input type="checkbox"/> Vasectomy			

(continued)

PART 3 (Continued)

7. On what basis are the voluntary surgical contraceptions done?
 Inpatient Outpatient Both

8. Scheduling of voluntary surgical contraception services:
Number of clinic sessions per week _____
Number of hours per clinic session _____

9. Is there a waiting list?
 Yes No If yes, for how long? _____

PART 4

10. Information and Counseling:

Counseling is routinely provided by a
 Doctor Counselor Nurse Paramedic
Other (specify) _____

Is one individual appointed to be responsible for counseling? Yes No

Is there pre-operative counseling? Yes No

Is there post-operative counseling? Yes No

PART 5

11. Informed Consent:

Are informed consent forms on file? Yes No

Compliance with IPAVS guidelines:
Has it been explained to the client, in the language of the country or area which the client understands, that:

There are temporary methods of contraception available? Yes No

Voluntary sterilization is a surgical procedure? Yes No

Sterility is not guaranteed? Yes No

There may be discomfort, risk, and side effects? Yes No

The operation is intended to be permanent? Yes No

Voluntary surgical contraception will permanently prevent future pregnancies?
 Yes No

If the client elects not to be sterilized, other services will still be provided?
 Yes No

APPENDIX D

PART 6

12. Medical Screening and Pre-operative Assessment:

Where is the medical screening accomplished?

- At facility
- Elsewhere (specify) _____

When is pre-operative assessment made?

- Day of scheduled surgery
- Other (specify) _____

Are written pre-operative instructions provided? Yes No

What laboratory tests are performed?

- None
- Hematocrit
- Urine analysis
- Hemoglobin
- Other (specify) _____

PART 7

13. Post-operative Observation and Monitoring:

How long on the average do clients stay at the facility post-operatively? _____

Are written post-operative instructions provided? Yes No

PART 8

14. Post-operative Follow-up:

How long after surgery is follow-up visit scheduled?

- Less than 7 days
- 7-14 days
- More than 14 days

Where does follow-up visit take place?

- At facility
- Elsewhere

If elsewhere, what arrangements are made for records transfer?

PART 9

15. Facilities:

Location of facility: Urban Semi-urban Rural

Type of facility: Hospital Hospital clinic
 Single purpose clinic Multi-purpose clinic

Does the functional space have:

	Yes	No	Comments
Running water			
Electricity			
Toilet			
Registration/reception area			
Waiting room area			
Private space for client interviews			
Examining room(s)			
Laboratory test space			
Operating room (or isolated surgical area)			
Recovery room/ward area			
Sterilization room			
Scrub facilities			
Storage area			
Dressing room(s)			

16. Does the Examining Room have:

	Yes	No	Comments
Examining table			
Adult weight scale			
Adequate lighting			
Sphygmomanometer			
Stethoscope			
Thermometer			
Pelvic exam instruments			

17. The Operating Room is dedicated to:

Voluntary surgical contraception use only Multi-purpose use

Asceptic conditions are: Adequate Inadequate

(continued)

APPENDIX D

PART 9 (Continued)

Does the Operating Room have:

	Yes	No	Comments
Operating table			
Instrument tray			
Instrument table			
Operating Room lights			
Emergency light			
Sphygmomanometer			
Stethoscope			
Anesthesia machine			
Screened windows (if applicable)			
Handwashing facilities (in or adjacent)			
Other (specify)			

18. Does the facility have the following voluntary surgical contraception instruments on the premises:

	Yes	No	Comments
Laparoscope			
Laproscator			
Culdoscope			
Minilap Kit			
Colpotomy Kit			
Vasectomy Kit			
Other (specify)			

19. Is the following emergency equipment on the premises:

	Yes	No	Comments
Airway			
Ambubag			
Laryngoscope			
Endotracheal tubes			
Suction apparatus			
Oxygen unit			
I.V. set with large caliber needles			
I.V. fluids			
Emergency drugs and antidotes			
Standard laparotomy tray			
Anesthesia machine			

(continued)

PART 9 (Continued)

20. Based on client flow, is the equipment adequate? Yes No

21. Is the cleanliness and general appearance of the facilities adequate?
 Yes No

Comments: _____

22. Is an emergency backup hospital: Applicable Not applicable
 Available Not available

If available, give the following information:
 Distance: _____ Time: _____

Is an emergency vehicle available? Yes No

23. Is there an alternate system? Yes No

PART 10

Recordkeeping:

Are records maintained for all voluntary sterilization clients? Yes No

Did you audit any records? Yes No If yes, how many? _____

Are the records complete? (Minimum requirements include voluntary consent forms, past medical history, physical examination, operative procedure, post-operative period and follow-up) Yes No

PART 11

25. Personnel:

Indicate the number and type of clinical staff involved in voluntary surgical contraception service activities:

Type	Total	Part-time	Full-time	Comments
Physicians				
Anesthesiologist or Anesthesia Technician				
Nurses				
Paramedics				
Counselors or Social Workers				
Others (specify)				

APPENDIX D

PART 12

26. Have there been any voluntary sterilization-related deaths at this facility?

Yes No If yes, how many? _____

Was Female Voluntary Sterilization-Related Death Report(s) forwarded in compliance with IPAVS policy? Yes No

If a death was not reported, explain: _____

Comment: _____

PART 13

27. Preparedness:

Based on your observations, are the facility and personnel adequate to handle an emergency or major complication resulting from the voluntary surgical contraception procedure? Yes No

Based on your observations, interviews, and review of data, would you say this service program is being conducted according to acceptable medical standards?

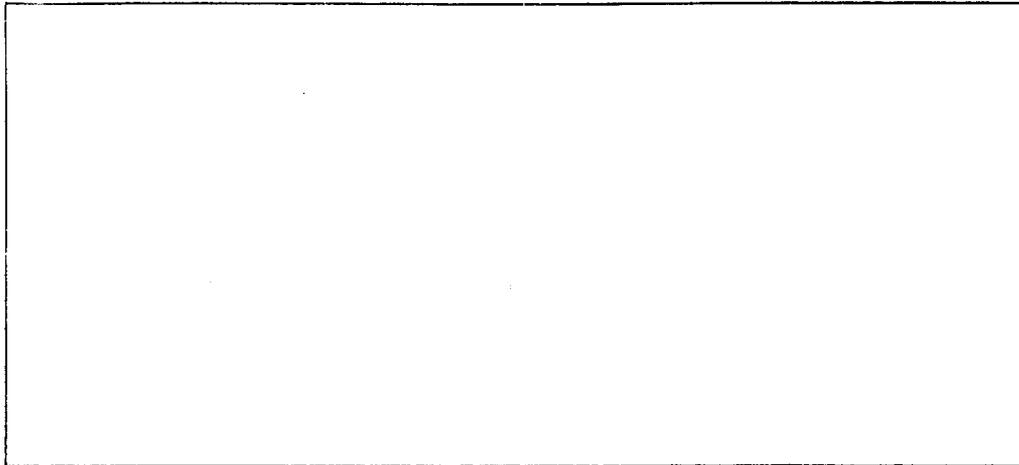
Yes No

Additional comments and observations: _____

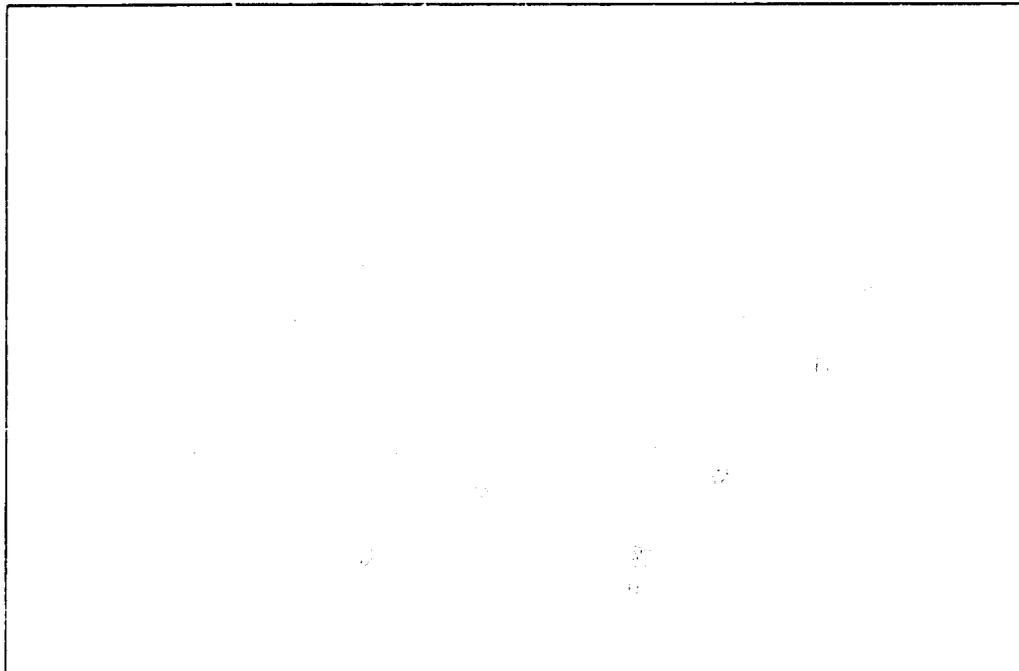
PART 14

28. Personal Contact(s):

List names and title(s) of persons interviewed/contacted.



29. Continuation Sheet (specify continued item by number).



(continued)

PART 14 (Continued)

Continuation Sheet (Specify continued item by number)

A large, empty rectangular box with a double-line border, occupying most of the page. It is intended for a continuation sheet where the user would specify continued items by number.

Date _____

Sub-Grant No. _____

COMPLICATION REPORT

Major Complications of Voluntary Sterilization Procedures

A major complication is defined as any problem occurring during or after surgery necessitating surgical intervention, hospitalization, or medical treatment that is above and beyond that normally provided

in conjunction with a voluntary sterilization procedure. Pregnancies following voluntary surgical sterilization are also considered major complications. This form should be completed by the Project Director.

- | | |
|---|--|
| <p>1. Date of voluntary sterilization _____</p> <p>2. Date when complication occurred _____</p> <p>3. Date of complete recovery _____</p> <p>4. Age of client _____</p> <p>5. Sex of client _____</p> | <p>6. Number of living children _____</p> <p>7. (For women only)</p> <p>Total number of pregnancies _____</p> <p>Total number of abortions _____</p> <p>Number of children ever born _____</p> |
|---|--|

Please indicate your answer by checking (✓) the appropriate response

8a. By whom was the voluntary sterilization performed?

- Staff Physician Trainee

8b. What was the qualification of the person performing the voluntary sterilization procedure?

- General Practitioner Ob/Gyn Surgeon
- Other: (Specify) _____

9. Please specify with a check mark (✓) the type of procedure performed.

- | | |
|--|-------------------------------------|
| <input type="checkbox"/> Laparoscopy | <input type="checkbox"/> Culdoscopy |
| <input type="checkbox"/> Mini-Laparotomy—interval | <input type="checkbox"/> Colpotomy |
| <input type="checkbox"/> Mini-Laparotomy—post-partum | <input type="checkbox"/> Vasectomy |
| <input type="checkbox"/> Laparotomy—interval | |

10. What type of anesthesia did you use?

- Local Regional General

APPENDIX E

11. What type of complications did you have? (Please check all relevant answers).

a. Complications related to Anesthesia

- Respiratory arrest/depression
 Cardiac arrest
 Convulsions
 Other: (specify) _____

b. Unintended Trauma

- Injury to bladder
 Injury to bowel
 Uterine perforation
 Electrocoagulation of any organ other than the Fallopian tubes
 Other: (specify) _____

c. (1) Hemorrhage

- Epigastric vessels
 Fallopian tubes
 Hematoma (requiring hospitalization)
 Other: (specify) _____

c. (2) Did the client receive blood transfusion?

- Yes No

d. Infection

- Wound abscess
 Wound disruption
 Epididymitis or epididymo-orchitis requiring hospitalization
 Other: (specify) _____

e. Pregnancy

- Intrauterine Ectopic

f. Other complications not mentioned above (specify) _____

12. Was the client hospitalized? No Yes If yes, for how long? _____

13. Please describe the type of treatment administered. _____

14. What was the final outcome of the complication?

- Client completely recovered with no permanent physiological damage.
 Client recovered but with permanent physiological damage.
 Client died. (Please provide a detailed report of exactly what happened, in addition to this form.)

FEMALE VOLUNTARY STERILIZATION-RELATED DEATH REPORT

1. INSTRUCTIONS

Voluntary sterilization-related deaths must be reported to IPAVS by telephone or cable within 24 hours. This report must be completed within 7 days, together with the curricula vitae of the involved physicians, pertinent medical records, and findings of the post-mortem, if one was conducted, forwarded to the Director, International Project of the Association for Voluntary Sterilization, Inc. (IPAVS), 708 Third Avenue, N.Y., N.Y. 10017

Complete all parts of this form by checking the appropriate boxes and filling in the blanks where indicated. When a response is unknown, mark "Unk." In areas where there is not enough space for complete explanation, attach continuation sheet(s). The report must be signed by either the Project Director, Medical Director, or Operating Surgeon. The person who actually prepares the report must also sign it.

2.

<p>To: DIRECTOR, IPAVS 708 Third Avenue, 4th Floor New York, N.Y. 10017 Attn: Field Clinician</p>	<p>From: (Name of Project Director) _____ (Name of Project) _____ (Address of Project) _____ (Sub Grant Number) _____</p>
--	--

3. DATE OF

Report _____ Sterilization Procedure _____ Death _____

4. CLIENT CHARACTERISTICS

Initials _____ Age _____ Height _____ Weight _____
 Total number of pregnancies _____ Number of live births _____
 Number of abortions _____ Number of living children _____
 Age of youngest living child _____
 Relevant past medical history _____

 Pre-operative physical findings _____

5. CONTRACEPTIVE METHOD USED BEFORE SURGERY

None _____ IUD _____ Orally _____ Condom _____ Withdrawal/Rhythm _____
 Foam-Diaphragm _____ Other: Specify _____

6. FACILITY

Hospital _____ Hospital Clinic _____ Multi-purpose Clinic _____ Single Purpose Clinic _____

7. EQUIPMENT AVAILABLE IN FACILITY

<p><input type="checkbox"/> Oropharyngeal airway <input type="checkbox"/> Ambu bag (Manual resuscitation bag) <input type="checkbox"/> Laryngoscope <input type="checkbox"/> Endotracheal tubes <input type="checkbox"/> Suction apparatus <input type="checkbox"/> Oxygen Unit</p>	<p><input type="checkbox"/> Standard laparotomy tray <input type="checkbox"/> Intravenous fluids and/or plasma volume expanders <input type="checkbox"/> Antidotes for treating narcotic overdose or adverse reactions to anesthesia or other drugs <input type="checkbox"/> Anesthesia machine</p>
--	--

APPENDIX F

8. STERILIZATION PROCEDURE

Type of procedure: Inpatient Outpatient

Anesthesia: Local General Regional Other Specify _____

Technique: Minilaparotomy Laparoscopy Colpotomy Culdoscopy

Pomeroy Ring Other Pomeroy Ring Other

Other Describe _____

9. STERILIZATION TIMING

Interval Postpartum Post-abortal

Other Describe _____

10. COMPLICATIONS AND TREATMENT ADMINISTERED (Describe in detail)

Complications encountered before or during surgical procedure _____

Post-operative complications (if indicated) _____

Treatment administered _____

11. CAUSE OF DEATH

Presumptive Definitive

12. POST-MORTEM

Was a post-mortem examination performed? No Yes

If yes, describe findings _____

In the opinion of the Medical Director of this Facility, was this death preventable? No Yes

If yes, what measures are being taken to prevent a recurring situation? Be specific _____

13. SIGNATURE

 (Name & Title of person completing this form)

SIGNATURE _____

(Of Project Director, Medical Director, or Operating Surgeon)

Attachments:

Appendix H

COMPREHENSIVE TRAINING IN
FERTILITY MANAGEMENT, BAVS

Appendix H

COMPREHENSIVE TRAINING IN FERTILITY MANAGEMENT, BAVS

A training program from the perspective of a national population program is especially important. The need for such a program is formidable. To man the rapidly increasing service facilities and to ensure safe service delivery, a person with the highest professional capabilities should be assigned. This can only guarantee quality service in all aspects.

The BAVS, working in the field of voluntary surgical sterilization, is one of the main institutions of service delivery in the country. It recognized the need for personnel trained in voluntary sterilization. Besides providing institutional support, the BAVS provides training facilities. It introduced an organized training program in April 1975.

OBJECTIVES

1. To improve physicians' skills, efficiency, and capability in all aspects of voluntary sterilization service.
2. To increase understanding about management function and its relation to the implementation and supervision of a sterilization program.

TRAINING CENTER

The training course will be conducted in the Family Planning Hospital and Training Centre, BAVS, House No. 161, Road No. 13/2 (Old), Dhanmondi Residential Area, Dacca.

TRAINEE SELECTION CRITERIA

The candidate must be a medical graduate who has finished in-service training. Preference will be given to persons who are particularly interested and involved in family planning service delivery. The intending physician must submit the required application form, which is available at the training center, and he must agree to abide by the rules and regulations for the training course.

TRAINING DURATION

The training will last three weeks. The trainees will attend the training center as per schedule circulated to them.

THE DIDACTIC CURRICULA OF THE TRAINING

The training will comprise theoretical lectures, demonstrations, and practical work. The subjects to be covered in the course are detailed below.

- A. Registration and Orientation
- B. Theoretical (27 hrs.)

FUNDAMENTAL INSTRUCTIONS

1. Demography and Population Policy
(demographic objectives, population policy, world population trends, and FP program in Bangladesh) - 2 hr
2. Anatomy and Physiology of Male Reproductive System - 1 hr
3. Anatomy and Physiology of Female Reproductive System - 1 hr
4. Pharmacology of Drugs Used in FP Practice
(analgesic drugs, narcotics, local anesthetic drugs, and drugs used in resuscitation) - 2 hr
5. Different Contraceptive Methods (temporary) - 1 hr
6. Asepsis and Sterilization - 1 hr
7. Psychological Aspects in Voluntary Sterilization Procedure - 1 hr
8. Medical Team Work - 1 hr

ADVANCE INSTRUCTIONS

1. Client Recruitment and Counseling - 1 hr
2. Preoperative Management in Voluntary Sterilization Procedure (history-taking, physical examination, rejection, and lab work-up) - 2 hr
3. Steps of Tubectomy Operations - 1 hr
4. Steps of Vasectomy Operations - 1 hr
5. Client Handling and Monitoring During Operation - 1 hr
6. Postoperative Client Management and Client Monitoring - 1 hr
7. Emergency Equipment and Drugs - 1 hr
8. Common Complications During SS Procedure and How to Handle Them - 2 hr
9. Anesthesia Practice in SS - 1 hr
10. Follow-up and Other Related Matters - 1 hr
11. Common Gynecological Problems During Contraceptive Practice - 1 hr
12. Clinic and Hospital Management, Overall Supervision, Reporting, etc. - 1 hr
13. Laparoscopy and Other, Newer Techniques of Female Sterilization - 1 hr
14. Recanalization Surgery of Vas and Fallopian Tubes - 1 hr
15. Management of Infertility - 1 hr

C. Practical (110 hrs.)

The practical part of the training will include observing, assisting, and performing by themselves each and every aspect concerned. Every trainee will observe 5 tubectomy and 5 vasectomy operations, assist 10 tubectomies and 5 vasectomies, and perform 15 tubectomy and 10 vasectomy procedures.

1. Client Reception and Counseling
2. Physical Check-up (including pelvic examination)
3. Preoperative Preparation of Patient
4. Preoperative OT and Clinic Preparation
5. Technique of Operation (tubectomy and vasectomy)
6. Patient Monitoring during Operation
7. Postoperative Management
8. Follow-up
9. Emergency Handling Maneuvers (including use and maintenance of emergency equipment and drugs)
10. Recordkeeping

D. Audiovisual Session (5 hrs.)

1. Film Show
2. Slide Demonstration

E. Evaluation (10 hrs.)

1. Pre-training Evaluation
2. Self-Evaluation Sessions to Identify and Rectify Self-Loopholes through Group Discussion by Trainees
3. Post-training Evaluation and Assessment (theoretical and practical)

CERTIFICATE-GIVING CEREMONY

Upon successful completion of training, trainees will receive a certificate.

RESOURCE PERSONNEL (List)

TRAINEE FOLLOW-UP

Whom to follow up? All trainees to be followed up, especially those who are actively participating in sterilization program.

When to follow up? There may be a short- and long-term follow-up.

How to follow up? The follow-up can be done by the trainers or anyone connected with the training program.

Process of follow up:

- a. A pre-set questionnaire will be mailed to the trainees to ascertain whether trainees are performing sterilization and how well they are performing.
- b. After trainees submit completed pre-follow-up questionnaire, a schedule of on-spot follow-ups will be prepared.
- c. For the on-spot follow-up, a checklist will be used.
- d. The checklists will be evaluated during a discussion about the trainers.

Appendix I

BANGLADESH FERTILITY RESEARCH PROGRAM

Appendix I

BANGLADESH FERTILITY RESEARCH PROGRAM
3/7 Asad Avenue (1st floor)
Mohammadpur, Dacca-7

Venue: NIPORT
Azimpur, Dacca

Date: 13 December 1980

Time: 8:15 a.m. to 5:00 p.m.

PROGRAM

FIFTH ANNUAL CONTRIBUTORS CONFERENCE

INAUGURAL SESSION
(8:15 a.m. to 9:30 a.m.)

Chief Guest

Professor M. A. Matin, The Honorable Minister
for Health and Population Control

Chairman

Mr. A. M. Hyder Hussain
Secretary, Health and Population Control
Chairman, Executive Council,
Bangladesh Fertility Research Program

8:35 a.m.	Twlawate Quran	
8:40 a.m.	Address of Welcome	Colonel M. Hashmat Ali, Vice Chairman, BFRP
8:50 a.m.	Inaugural Speech	Professor M. A. Matin, The Honorable Minister for Health and Population Control
9:00 a.m.	Address by Chairman	Mr. A. M. Hyder Hussain
9:15 a.m.	Vote of Thanks	Dr. Shafiqur Rahman, Director, Bangladesh Fertility Research Program

TEA BREAK

SESSION I: MATERNAL AND CHILD HEALTH CARE

(10:00 a.m. to 1:00 p.m.)

<u>Sl. No.</u>	<u>Name of Paper</u>	<u>Presenter</u>
1.	Obstetric Problems of Semi-Urban Areas in Bangladesh	Professor S. Firoza Begum
2.	A Study of the Abortion-Related Admission in Three Hospitals of Bangladesh	Professor Nurjahan Bhuiyan
3.	Maternity Care Services in Hospitals and Clinics in Bangladesh (Preliminary Report)	Dr. Sufia Begum
4.	Characteristics of Maternity Cases in Chittagong Medical College Hospital, Bangladesh	Professor Nurjahan Bhuiyan
5.	Maternity Cases at Rangpur Medical College Hospital	Dr. Shafiqur Rahman
6.	Characteristics of Maternal Patients of Sylhet Medical College Hospital	Dr. A. Barua
	Discussion	

SESSION II: MISCELLANEOUS

7.	Profile of 350 Couples Attending the Infertility Clinic at P.G. Hospital	Dr. Sadequa Tahera Khanam
8.	Menstrual Patterns of the Parous Women Prior to and After Sterilization (A Study of 2,171 Mothers)	Dr. M. A. Quader
9.	Organized Efforts Correlates of Contraceptive Usage and Continuation in Rural Bangladesh	Mr. M. Obaidullah
10.	Anesthesia for Sterilization Operations in Bangladesh	Dr. John I. Fishburne

<u>Sl. No.</u>	<u>Name of Paper</u>	<u>Presenter</u>
11.	Indigenous Contraception in Bangladesh: A Preliminary Survey	Md. Abu Yusuf Choudhury
12.	Morbidity and Mortality in Voluntary Service Program	Dr. Azizur Rahman
13.	A Preliminary Report on Bangladesh Family Planning Program as Compared with that of China	Colonel M. Hashmat Ali

LUNCH BREAK

SESSION III: METHODS ON FERTILITY REGULATION

(2:00 p.m. to 4:30 p.m.)

14.	Profile of Menstrual Regulation Clients of Mohammadpur Model Clinic	Dr. Shafiqur Rahman
15.	Tubectomy in Bangladesh: Correlates of Acceptance and Demographic Impact, 1980	Dr. Anthony R. Measham
16.	Complications, Side Effects, and Continuation Rate of Postpartum Photoreduced Tapered Loop in Sir Salimullah Medical College Hospital, Dacca, Bangladesh	Mrs. Hasina Banu
17.	Vasectomy Follow-up of 500 Cases at BAVS Clinic Tongi, Dacca	Dr. Nazimuddin Ahmed
18.	Female Sterilization: Service Facilities and Complications	Mr. Jalaluddin Akbar
19.	Preliminary Experience with Use of Multiload Copper 250 IUD in Bangladesh	Dr. Atiqur Rahman Khan
20.	An Experience with Use of the Delta LLD, Dacca Medical College Hospital, Dacca, Bangladesh	Dr. Kamrun Nahar

<u>Sl. No.</u>	<u>Name of Paper</u>	<u>Presenter</u>
21.	MR Comparative Study at Mohammadpur Model Clinic	Dr. Husn Ara Ali
22.	IUD Follow-up Study	Mr. M. Nawab Ali

TEA

Appendix J

ANESTHESIA FOR STERILIZATION
OPERATIONS IN BANGLADESH

ANESTHESIA FOR STERILIZATION
OPERATIONS IN BANGLADESH

Prepared For

BFRP CONTRIBUTORS CONFERENCE
Dacca, Bangladesh
December 13, 1980

John I. Fishburne, Jr., M.D.
Professor of Obstetrics and Gynecology
Associate Professor of Anesthesiology
Chief of Maternal and Fetal Medicine
Bowman Gray School of Medicine
Winston-Salem, North Carolina

During July, 1980, anesthesia practices for tubectomy operations were studied in Bangladesh. It appeared from this study that the primary method of anesthesia employed for tubectomy consisted of systemic analgesia and sedation coupled with local infiltration anesthesia. Systemic medications included intramuscular and/or intravenous meperidine (Pethidine), 50 to 100 mg.; promethazine (Phenergan) 50 mg. intramuscularly or intravenously, and diazepam (Seduxen) 10 mg. to 20 mg. intravenously at the time of operation. Local anesthesia was obtained with 1% lidocaine or procaine solution injected subcutaneously.

In addition, it was recognized that resuscitation equipment was in scarce supply in Bangladesh.

It was apparent to the author from observation of tubectomy procedures that the anesthesia was not merely local anesthesia plus sedation, as it was believed to be by those performing the operations, but was in fact general anesthesia induced by Pethidine, promethazine and diazepam. Because these drugs seem to be poorly understood, it is deemed appropriate to review the pharmacology of these various agents.

Pethidine (meperidine) was first described in 1939 as a compound derived from atropine-like spasmolytic compounds having morphine-like analgesic activity. Like most synthetic narcotic drugs, it was introduced as a non-addicting compound, but was later found to produce analgesia, sedation, euphoria and respiratory depression in addition to having addicting qualities. (1)

The mean "fast" or "distribution" half-life of Pethidine is 7.6 minutes, indicating that the drug is distributed extensively into the tissues. Metabolism occurs primarily in the liver, with only 3.8% of an administered dose being excreted unchanged. Approximately 80% of a 100 mg. dose of Pethidine injected intramuscularly is absorbed over six hours, with the mean time to maximum Pethidine plasma concentration being 24 minutes. There is marked variation in the plasma concentration obtained in individual subjects. Stambaugh et al.⁽²⁾ in 1976 reported that peak serum concentrations occurred an hour following intramuscular injection. Sixty-four percent of the intravascular drug is bound to plasma proteins.⁽³⁾

The major metabolites of Pethidine are the N-demethylated product norpethidine and the hydrolysis product pethidinic acid and its congeners. Of these metabolites, norpethidine is the most potent, being half as active an analgesic as the parent compound, but twice as active a convulsive agent.

Patients with liver disease have been studied and it has been noted that clearance of Pethidine from the blood is substantially reduced in the presence of cirrhosis.

There is considerable variability in the dose of Pethidine required to produce analgesia in different subjects. The degree of analgesia corresponds to the blood concentration. Control of severe pain requires blood concentrations of at least 0.6 - 0.7 mg. per liter.

Respiratory depression is the most significant side effect. Significant respiratory depression occurs at doses required to produce analgesia. The onset

of depression of minute volume and tidal volume is apparent as early as 10 minutes after intramuscular injection. Following intravenous administration, initially high Pethidine plasma concentrations, averaging 0.8 mg. per liter occur, and are associated with respiratory depression and depression of regulatory response to carbon dioxide (Fung, et al., 1975).⁽⁴⁾ When the plasma concentration falls to approximately 0.4 mg. per liter, the regulatory response returns to normal.

Nausea may occur in up to 40% of patients receiving Pethidine and is seen primarily while plasma levels are rising rapidly, occurring at plasma concentrations between 0.15 and 0.3 mg. per liter.

Abnormal responses due to altered Pethidine disposition following a single dose are of short duration. However, when multiple doses are employed these differences may be more pronounced and long lasting.

When Pethidine is administered intravenously in a bolus injection of 50 mg., a rapidly achieved plasma level of 1 mg. per liter occurs. This level falls quickly such that by the end of 15 minutes the plasma level has fallen to 0.4 mg. per liter. With the intramuscular injection of 100 mg. of Pethidine, the peak effect occurs at approximately 1 hour, with the blood level slightly in excess of 0.5 mg. per liter. This gradually falls to below 0.2 mg. per liter by the end of 4 hours.

In the performance of tubectomy, a surgical procedure which seldom takes longer than 10 minutes, one would be most interested in having adequate analgesia, i.e. plasma levels of 0.6 to 0.8 mg. per liter during the time of surgery, with subsequent rapid fall off in the plasma level to

minimize post operative depression. Large intramuscular doses of Pethidine are associated with prolonged analgesia, but also prolonged respiratory depression. It would therefore appear that if Pethidine could be administered safely intravenously, and if resuscitation measures could be instituted promptly in the event of a respiratory complication, then low dose intravenous Pethidine at the time of surgery would be preferable to high-dose intramuscular Pethidine administered at an undetermined time, varying between 20 minutes to 60 minutes prior to surgery.

Diazepam is a benzodiazepine whose pharmacological characteristics have been extensively investigated.⁽⁵⁾ It is metabolized both by demethylation and hydroxylation, reactions which take place primarily in the liver. It is of interest that no correlation has been shown between plasma levels of the drug and therapeutic effect. Absorption following oral administration of diazepam is rapid and complete with peak plasma levels being reached within 30-90 minutes. The absorption peak occurs earlier in younger individuals, and may be delayed in the elderly. In the presence of chronic alcoholic cirrhosis, a lower but not delayed absorption peak has been observed.

Therapeutic effects of diazepam first appear within 60 minutes after oral administration. Poor and irregular absorption is noted following intramuscular administration and plasma levels are only 60% of those attained following an equivalent oral dose. Bolus intravenous administration of 10 mg. results in plasma concentrations of approximately 400 nanograms per milliliter, 15 minutes following administration. All subjects appear relaxed and drowsy with slurred speech by 10 minutes following administration.

Sleep will generally persist for 2 hours but can be broken at any time.

Diazepam is highly bound to plasma proteins (96-99%), but accumulates rapidly in the brain and other lipid-rich tissues. The terminal half-life of elimination is 24-48 hours. With increasing age, this half-life is prolonged. Detoxification of diazepam is accelerated by hepatic enzyme induction, which may occur through previous use of the drug or by exposure to other enzyme-inducing agents. Patients with liver disease show delay in the appearance of active metabolites of diazepam, but this effect is probably negligible with one time usage.

Diazepam has been used as an induction agent for producing general anesthesia. It is particularly useful in patients in whom myocardial disease is present, and for whom sodium pentothal might be contraindicated.

Promethazine (Phenergan) is a phenothiazine derivative with antihistaminic, sedative, antiemetic and anticholinergic effects. The duration of action of a single dose is generally 4-6 hours, the major side effect being sedation. Its use in association with a narcotic such as Pethidine is primarily to provide antiemetic activity to counteract nausea, which may be produced by the injection of this drug. It has also been alleged to potentiate the analgesic effects of Pethidine but this has not been conclusively demonstrated. The most dangerous side effect associated with the use of this drug is gangrene of an extremity following inadvertent intra-arterial injection. Arterial spasms may also occur when Promethazine is extravasated around an artery. This may result in gangrene requiring subsequent digital amputation. Intra-arterial local anesthetic solution, sympathetic block and heparinization have all been

used to treat this serious complication.⁽⁶⁾ Promethazine is also a weak alpha adrenergic blocker, the use of which has been reported to produce hypotension.

Lidocaine (Xylocaine) is an amide-type of local anesthetic drug with a pKa of 7.9.⁽⁷⁾ Its protein binding in the human is approximately 64%. Central nervous system toxicity becomes manifest at plasma drug concentrations of approximately 5 micrograms per ml. The convulsion producing dose for the monkey is 14-22 mg. per kilogram. Adverse reactions are rare, but when they occur, are usually due to rapid inadvertent intravenous injection of normal extravascular doses administered into highly vascular areas. Central nervous system toxicity can occasionally occur with very small doses and should not be confused with the infrequent allergic response which happens with ester-type local anesthetic agents. Allergic reactions to amide drugs, such as lidocaine, are almost unheard of. Central nervous system toxicity is manifested by apprehension, restlessness, and tremor which may progress to convulsions. The plasma concentrations accompanying convulsions are two- to three-fold those related to the earliest signs of central nervous system toxicity.

Cardiovascular toxicity includes both vasodilatation and vasoconstriction, myocardial stimulation and depression. Severe overdose may lead to hypotension and cardiac arrest.

The disappearance half-life of lidocaine is approximately one and a half hours. Average plasma clearance ranges from .54 to 1.44 liters per minute.

Lidocaine is metabolized by means of aromatic hydroxylation, N-dealkylation, and amide hydrolysis. The major metabolites include monoethylglycinexylodide, glycine xylodide and 4-hydroxyproduct formed from lidocaine. Only the first, monoethylglycinexylodide, contributes to the effects of the parent drug.

Although intravascular injection is associated with a rapid rise in blood levels, intraperitoneal infusion of large doses of lidocaine during tubal ligation procedures is accompanied by relatively low maximum plasma drug concentrations. This is explained by the theory that absorption into the portal circulation leads to extensive hepatic extraction during the first passage of the circulation.

In summary, Pethidine has been shown to produce severe respiratory depression and apnea. In addition, cardiovascular collapse and coma may occur with severe overdosage. Diazepam has been reported to cause respiratory arrest primarily in elderly individuals. Promethazine produces central nervous system depression and in overdosage may also lead to unconsciousness and circulatory collapse. Intra-arterial injection is the most commonly encountered serious complication associated with the use of this drug.

During his observations of tubectomy procedures in Bangladesh, the author has noted that in almost every instance general anesthesia was induced, in some instances transiently and in others for a more prolonged period of time. In no case were proper precautions taken to administer

and monitor a general anesthetic. In all instances, the surgeons felt that they were operating under local anesthesia, but one might surmise that even without local infiltration, the surgery in many instances could have been performed without complaint from the patient.

General anesthesia may be associated with many hazards, not the least of which include aspiration of vomitus, respiratory failure, airway obstruction from the tongue or other soft tissues, and marked hypotension. In an unmonitored patient, these problems might easily lead to death before they were recognized and proper treatment instituted.

The aim of sedation and analgesia accompanying local anesthesia is to reduce psychic and emotional trauma, while the local block eliminates pain. At the same time, one must be able to accomplish this with safety. In order to do this, one must obtain maximal analgesia from the local injection of anesthetic solution and utilize the systemic drug to control anxiety and minor operative discomfort not blocked by the local anesthetic agent. As previously indicated, intravenous diazepam often produces general anesthesia, while low-dose intravenous Pethidine will produce analgesia of short duration. Intramuscular Pethidine is apt to produce poor analgesia at a time that would coincide with the surgical procedure. If the analgesia is sufficient for surgery, then it is apt to be quite prolonged and associated with marked respiratory depression. Intramuscular diazepam, on the other hand, results in poor absorption and diminished activity.

Local anesthetic drugs also produce toxicity. In general, the maximum

safe dose of lidocaine (Xylocaine) is 5 mg. per kilogram. Dosages in excess of this may substantially increase the risk of central nervous system excitation with convulsions, coma and cardiovascular collapse. Some measure of safety is afforded by the concomitant use of diazepam, which will increase the seizure threshold for the local anesthetic drug.

Another method to reduce local anesthetic drug toxicity is to reduce the concentration of the injected agent. Lidocaine 0.5% may be used quite successfully for infiltration analgesia. The disadvantages of this technique are that more time is required for an adequate block to occur, and the duration of the block may be shortened.

The question arises as to why certain individuals administered a "standard" dose of sedative and narcotic would experience respiratory arrest, while most exhibit a predictable response.

The most likely explanation for this is biological variation. With numerous procedures being done, it would seem reasonable to expect to find significant numbers of individuals at each end of the dose response spectrum. Consequently, although the majority of individuals would respond to a given dose with a predictable level of sedation, certain individuals might prove resistant to the effects of the drug, whereas others might prove particularly sensitive. Since a standard dose is employed and generally administered independent of body weight, it is conceivable that in unusually sensitive individuals this "usual dose" could produce fatal respiratory depression.

The following recommendations are offered with the view to enhancing the operative experience for the patient while at the same time reducing risk. However, since Pethidine can produce profound respiratory depression, it is urged that this drug not be administered intravenously unless appropriate resuscitation equipment is available and the operating surgeon be experienced in the use of the resuscitation devices. If this is not the case, the author recommends that only oral and intramuscular medications be given and then in reduced dosage, with the primary emphasis being placed on an adequate local anesthetic block. Under optimal conditions, however, IV administration is to be preferred and is therefore recommended below.

1. Medications

A. Premedication

1. Diazepam: Usual dose 10 mg. p.o. one hour prior to surgery. (Reduce to 5 mg. if weight is less than 75 lbs.)
This drug is given to allay anxiety and to provide mild amnesia.
2. Meperidine (Pethidine): None for premedication.
(See below.)
3. Atropine: None for premedication. (See below.)
4. Promethazine (Phenergan): None for premedication.
(See below.)

B. Operative analgesia

1. Meperidine (Pethidine): Usual dose 50 mg. IV. Reduce to 25 mg. if weight is less than 75 lbs. and/or if patient has any concomitant debilitating illness. Give one-half of dose, then wait 2-3 minutes and give rest if indicated; i.e., excessive response to painful stimulus. This drug will provide analgesia for the operation. When given IV it is effective within 2 minutes. Dangerous side effect is respiratory depression.
2. Atropine: Usual dose 0.4 mg. IV. Reduce to 0.3 mg. if weight is less than 75 lbs. This drug is used to block vagal stimulation arising from traction on the uterus and tubes.
3. Promethazine (Phenergan): Usual dose 25 mg. IV. This drug is given to potentiate the narcotic and to reduce the emetic effect of IV Pethidine. Avoid subcutaneous and intra-arterial injection.

C. Local anesthesia

1. Lidocaine (Xyllocaine, Lignocaine): 1% solution. Maximum dosage should be 5 mg/kg. (40 kg. woman should have no more than 200 mg. or 20 cc. of a 1% solution). Adrenalin added to the anesthetic solution offers little real advantage and contributes its own toxicity.

Infiltrate subcutaneous tissues, fascia, subfascia and peritoneum. Wait 3-5 minutes before proceeding with operation. Local anesthetic solution may also be flowed onto the tubes and uterus to provide topical anesthesia. Five ml. should be used for this purpose. Lidocaine 0.5% may be used and affords an extra margin of safety.

D. Narcotic reversal

1. Naloxone (Narcan): Usual dose 0.4 mg. IV. Onset of action is prompt, but duration of action may be exceeded by that of the narcotic. The patient should therefore be re-evaluated frequently for signs of re-narcotization. In this event, additional Naloxone should be administered. Naloxone has virtually no toxicity or narcotic agonist effect of its own.

E. Resuscitation drugs - emergency tray should contain:

1. Naloxone (Narcan): See above.
2. Epinephrine (Adrenaline): 1 cc. ampule of 1:1000 solution. Useful in treatment of acute CV collapse, anaphylactic shock, acute asthma, hypotension, etc.
3. Solu-cortef: 100 mg. ampule. For IV use in event of severe shock, in large doses (30 mg/kg) for acute aspiration of gastric contents.
4. NaHCO₃ (Sodium bicarbonate solution): 50 ml. ampule

contains 44.6 milliequivalents NaHCO_3 . Used to treat the metabolic and respiratory acidosis which occur in association with tissue hypoxia from shock or apnea.

5. Physostigmine (Antilirium): 2 ml. ampule with 1 mg/ml. Usual dose is 0.5 - 1.0 mg. IV to antagonize CNS effects of atropine and diazepam.
6. Calcium chloride: 1 ampule. Used for its positive inotropic effects and for ventricular fibrillation.

II. Monitoring

- A. Pre-operative: Monitor BP, P & R every 15 minutes from time of administration of premedication until start of surgery. Record on suitable form.
- B. Intra-operative: Monitor and record BP, P & R and level of anesthesia (Stage I, II or III) every 5 minutes during surgery. Record with drugs, dosages and times of administration on suitable form.
- C. Post-operative: Monitor and record BP, P & R every 15 minutes for one hour post-op, then every four hours until discharge and record on suitable form.

III. Intravenous Fluids

- A. Proper intravenous solutions and solution administration sets should be available in the CR for use in the event of an emergency.

IV. Resuscitation

A. Equipment

1. Anesthesia mask and self-inflating bag with O₂ nipple.
2. O₂ tank with reducing valve, flow meter, tubing, and mask.
3. Suction machine with (2) traps and tubing.
4. Nasal airways (2 sizes).
5. Oral airways (2 sizes).
6. IV fluids - as above.

- B. Instruction: Time should be provided in the family practice and/or family planning training curriculum for teaching basic techniques of resuscitation. This should include airway management, external cardiac massage and use of resuscitation drugs.

V. Training in Anesthesia for Family Planning Doctors

- A. An anesthesiology curriculum should be prepared and taught during the training period. Subjects to be taught include:

1. Pharmacology of local anesthetic drugs, narcotics and their antagonists, tranquilizers, atropine, and drugs used in resuscitation.
2. Clinical use of above drugs. Dangers should be emphasized.
3. Monitoring of anesthesia and airway maintenance.
4. Resuscitation, including use of bag and mask for ventilation, airway maintenance, external cardiac massage and use of resuscitation drugs.

3. Practical training using models for learning resuscitation.

VI. Monitoring of the Sterilization Program

On site monitoring of the anesthetic techniques used in the sterilization program should be initiated. Trained anesthesia personnel should visit periodically all facilities in which tubectomies and vasectomies are performed. The anesthetic practices should be observed and inventory taken of supplies and resuscitation equipment.

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Appendix K

TRAINING PLAN ON SURGICAL STERILIZATION FOR
THAs AND MOs IN THE NATIONAL
FAMILY PLANNING PROGRAM

Appendix K

MINIMAL VARIATION: ESTIMATION FOR IAS AND LOS IN THE NATIONAL FAMILY PLANNING PROGRAMME

FREE AVAILABLE DOCUMENT

Introduction and Background

1. Male and female contraceptive sterilization is an important component of the National Family Planning Programme. For the first year of the SFYP the target is set at 100,000 operations, representing 20% of all contraceptive acceptors. With the successful unfolding of the Third Revolution this target may be doubled.

Expected Contraceptive Prevalence Ratio during 1980-85 (Per cent)

Method	1979-80 (Base yr.)	1980-81 %	1981-82 %	1982-83 %	1983-84 %	1984-85 %
Sterilization	19	25	30	33	39	43
Oral pills	40	40	30	25	25	22
Condoms	34	25	25	25	21	19
IUD	6	6	8	8	8	9
Others*	1	4	7	7	7	7

* Pill, Rhythm, M.R., Injectables, Emko, Foaming tablets.

Source: The Second Five Year Plan 1980-85. Planning Commission. Dacca, May 1980

Targets for New Family Planning Acceptors by Methods 1980-85 (000's)

	1980-81	1981-82	1982-83	1983-84	1984-85
Sterilization	407	552	666	804	968
Oral Pills	828	614	670	917	837
Condoms	409	648	779	665	742
IUD	101	206	192	222	328
Others	119	208	168	194	222

Source: Family Planning Main Scheme

Contraceptive Sterilizations 1974-1980

Year	Vasectomies	Tubectomies	Total
1974-75	14,469	4,707	19,176
1975-76	37,839	11,076	48,915
1976-77	75,066	41,246	116,312
1977-78	32,643	44,722	77,365
1978-79	24,705	81,719	106,424
1979-80	27,534	171,248	198,782

Source: MIS, PCFP Division

2. An epidemiologic study of the reported sterilization procedures done in Rajshahi and Dacca Division for the period 1 January 1979 to 31 March 1980 was as follows:

Death-To-Case Ratio for Tubectomy and Vasectomy
Dacca and Rajshahi Division, Bangladesh
Jan. 1, 1979 to March 31, 1980

Type of Procedure	No. of Deaths	No. of Procedures	Rate	95% CI
Tubectomy	21	108,875	19.3	14.1-24.5
Vasectomy	7	22,526	31.1	18.1-44.1
Total	28	131,401	21.3	16.1-26.5

¹Deaths per 100,000 procedures (with 95% confidence interval in parentheses) (Dacca)

²Based on an index rate for tubectomy of 19.5 per 100,000 procedures

Source: Grimes, D.A. and Peterson, H.H.: Investigation of Sterilization-Related Deaths: Bangladesh, June 11 to July 4, 1980

This study indicated that all seven of the vasectomy deaths and 21 out of 21 tubectomy deaths were due to infection in spite of the use of broad-spectrum antibiotics. The other major cause of death among tubectomy cases was overdose of analgesic agents in 29% (6 cases). Because of this latter finding a second consultant, an anaesthesiologist visited Bangladesh in July 11-19, 1980 and made recommendations for improved training in the pharmacology of analgesic narcotic and resuscitation measures.

3. In line with the recommendations from these two reports, modifications are being proposed in the present training courses for certification of physicians. Much more emphasis must be given to O.T. management and sterile techniques; and a revised schedule for analgesia should be introduced along with presentation of pharmacology and drug actions; and training in emergency resuscitation techniques. More careful screening of patients for operation and closer monitoring during and after operation are imperative.

4. Not only will the training curriculum require revision but the National Technical Committee must be energized to review the above-mentioned reports and set the norms for training of surgeons and for the certification and monitoring of the sterilization centres. Decentralization of supervision will shift the ultimate responsibility to District level Technical Committees to be chaired by the Civil Surgeon who monitors all health related activities in his district. The District Civil Surgeon who does not himself perform sterilization operations will be in a position to supervise the centres performing operations and training operations. Quality is not sacrificed for quantity. The Civil Surgeon will be the ultimate authority to the Deputy Civil Surgeon.

5. Training is especially important since the Family Welfare Centre staff of the Health and Family Welfare Programme in the Districts are not all trained in sterilization. Many of the staff may have been trained in sterilization. In order to institutionalize the sterilization programme, it is proposed that 100 FWCs will each perform 6 cases per year for the first 5 years. If this target was reached then the original target of 600,000 sterilizations would be achieved. With the addition of staff to be in a position to handle the three pre-natal institutional facilities, the number of staff would be doubled. It should be possible to achieve targets for 50% of the original sterilization target. (This would require doubling the number of staff, equipment and supplies required).

6. Training Objectives

- A. To improve training of doctors in surgical sterilization with special reference to:
 - 1) the surgical techniques of minilap tubectomy and vasectomy;
 - 2) management of anaesthesia and local anesthetic agents;
 - 3) emergency measures for resuscitation;
 - 4) O.R. asepsis in preparation of the patients, the surgical team and the sterile instruments and supplies.
- B. To increase understanding about professional functions of FWCs and relation to the administration and supervision of the sterilization programme, including responsibility for counselling, termination of cases and follow-up.
- C. Improvement in understanding of Maternal and Child Health services provided by the FWCs and FHCs and the ancillary approach through the teamwork of all field staff in the units. This will include periodic (at least fortnightly) visits to the FWCs for consultation and supervision.

7. Training Plan

It is proposed to establish 40 permanent training centres throughout the country. These will be located at the eight medical college hospitals, the Mohammedpur Model Clinic and BAVS clinic in Dacca and Dhaka and a clinic in the District Hospital, Comilla with the assistance of ICMC and the Civil Surgeon and others. Two doctors (FHCs/ICCs) will be assigned to each training centre for a course duration of three weeks. Between the courses there will be an interval of one week. Each centre will train at least 10 doctors per year for a total of 200 doctors per year. The course will consist of 120 hours of lecture and demonstration each day presented in the form of a lecture-discussion. There will be six hours of practical experience in the I.C.M. and the Out-patient clinic. Each trainee will be required to perform 5 cases, assist in 5 cases and perform 10 cases independently with a minimum 75% attendance.

7. **Subjects** - topics covered in the course include the following:

- A. Introduction:
 - 1) Population policy, National Health Service, etc.
 - 2) Organization of Health and NEH Divisions, etc.
 - 3) Roles and responsibilities of field level staff, etc.
- B. Screening of the patients for operation:
 - 1) Review of contraceptive technology with special reference to IUD, injectables, M.R.
 - 2) Counselling of clients to assist in selecting appropriate method. Explaining informed consent; explaining the operation and the analgesic and local anesthesia.
 - 3) History and Physical examination and laboratory work-up. Temperature, Weight, B.P. Hgb. Urine for albumin and glucose. Heart and Lungs, Pelvic examination.
- C. Preparation for the Sterilization Procedure.
 - 1) Preparation of patient
 - 2) Preparation of the surgical team; the O.T.
 - 3) Preparation of instruments, linen supplies, etc. Training of supporting staff in carrying out these procedures.
- D. Analgesia, and local anesthesia.
 - 1) Analgesic agents; including pharmacology of local anesthetics, narcotics and their antagonists, tranquilizers, barbiturates, and drugs used in resuscitation.
 - 2) Clinical use of these drugs and dangers to be avoided.
 - 3) Procedures with local anesthesia. Taking time for patient; gentle handling of tissues.
 - 4) Emergency drugs. Methods of resuscitation, maintaining the airway. Practice with models. Preparation of all equipment in the O.T.
 - 5) Monitoring the patient during operation and post-operatively.
- E. Operative procedures.
 - 1) Anatomy of the male - procedure for vasectomy
 - 2) Anatomy of the female reproductive system - procedure for tubectomy
- F. Post-operative Management and Follow-up.
 - 1) Treatment of complications for vasectomy
 - 2) Management of post-operative complications of tubectomy
- G. Management of the Sterilization Programme
 - 1) Financial aspects
 - 2) Indents for supplies and equipment
 - 3) Reports and returns
 - 4) Principles of Supervision. Workplan for the Centre.

... Health services ...
... and the field through auxiliary ...
... at various ...
... .

- 4) Concerning high - risk pregnancies.
 - Grand multiparity, severe toxemia; history of abortion
 - Abortions, toxemia, eclampsia
- 5) Instruction for washer and infant-boost ...

- 6) ...
- 7) ...
- 8) ... and control of common disease. Instruction
 ... for prevention of neo-natal tetanus and
- 9) ... training

8. Phase I of the Training will include bringing the directors of the ...
designated training centres to NIFORT, Dacca for a work-shop to discuss the
recommendations of the consultants in epidemiology and anaesthesia and to plan the
curriculum for the three week training programme.

9. Particular emphasis must be placed ^{on} practical demonstration of the proper method
of sterile technique in the rural areas where there is no electricity. The workers must
get experience in training supporting staff in carrying out all functions of preparation
of patients, the O.T. equipment and supplies. Enough sets of instruments must be
available to permit adequate boiling of instruments for sterilisation.

10. The workshop may be followed by a meeting of the National Technical
Committee to agree on the norms of anaesthetic, local anaesthetic, respiratory equipment,
resuscitation measures and asepsis to be introduced in the certification of sterilisation
centres. (Members of the National Technical Committee are listed in the annex.)

11. The National Technical Committee should agree on the composition of the
District Technical Committee; and the responsibilities of the district committees for
certification, for monitoring and supervision of the sterilisation programme.

12. Management of the Training Programme

The training programme will be conducted by the chief executive officer of the selected
training centre. The trainers will be selected by the Local Director of Health Services
Director, GEP from among the medical officers of the district. Each training
centre will be responsible for training doctors from adjacent districts. The salary
of the trainers will be paid out of regular budget where they draw their salary.

INVESTIGATION OF STERILIZATION-RELATED DEATHS:
BANGLADESH, JUNE 11 - JULY 4, 1980

by

David A. Grimes, M.D.
Herbert B. Peterson, M.D.

SUMMARY

From January 1, 1979, to March 31, 1980, 28 sterilization-related deaths were identified in Dacca and Rajshahi Divisions, Bangladesh. We investigated these deaths at the theme or facility level. Two temporal clusters of deaths were identified, 1 cluster of 3 deaths from vasectomy and the other of 5 deaths from tubectomy. Both of these clusters occurred in the summer of 1979. The leading cause of death from tubectomy was anesthesia overdose and from vasectomy, scrotal infection. Overall, the sterilization-related death-to-case rate was 27 deaths per 100,000 procedures, with the risk of death associated with vasectomy 1.6 times higher than that with tubectomy (p .05).

Adherence to sterile technique for vasectomy should reduce the number of deaths due to infection. More appropriate use of analgesic agents, closer supervision of patients, and increasing capabilities for resuscitation should reduce the number of deaths due to complications of anesthesia for tubectomy. We estimate that approximately 1000 maternal deaths are averted for every 100,000 tubectomies performed. Thus, the net health impact of voluntary sterilization is strongly favourable.

RECOMMENDATIONS

- A. Recommendations concerning management of anesthesia for tubectomy will be referred to Dr. John Fishburne.
- B. All instruments used for vasectomy and tubectomy should be sterile. The patient's skin should be disinfected, and the surgeon should wear sterile gloves after thorough handwashing with an antiseptic soap. Masks should cover both nose and mouth. Gowns should be sterile.
- C. Vital signs should be monitored frequently after tubectomy. A protocol might include observing the patient and recording vital signs in this manner on a standardized form:

<u>Place</u>	<u>Observation</u>	<u>Frequency</u>
Recovery room	Color, tone, respiratory excursion and rate, pulse, blood pressure	Every 5-15 minutes until stable
Ward	Symptoms, color, pulse, respirations, blood pressure	Every hour (twice) Every 2 hours until Then if stable, every 4 hours until dis-
Ward	Patient temperature	Every 4 hours

- C. Abnormality should be called to the attention of the surgeon immediately.
- D. If prophylactic antibiotics are used, the first dose should probably be given prior to operation. Prophylactic antibiotics should not be considered substitutes for strict sterile technique.
- E. Strict sterile technique and avoidance of crushing tissue offer the most practical means of reducing the risk of tetanus after operation. Definitive prophylaxis by means of active immunization should also reduce the risk of tetanus.
- F. A maximum acceptable ambient temperature and humidity for allowing elective operations should be determined. Until acceptable temperature and humidity limits have been determined we suggest that operating conditions for patients and staff are suboptimal when temperature in the operating theatre exceeds 38°C (100.4°F). Elective sterilization could be delayed until more favourable conditions exist.
- G. An active surveillance system to identify, investigate, and classify sterilization deaths should be established in Bangladesh. Because of limited written documentation of complications and their management, prompt on-site investigation appears important to gain needed information.

BEST AVAILABLE DOCUMENT

ANESTHESIA PRACTICES
FOR STERILIZATION OPERATIONS
IN BANGLADESH

A Report Prepared By:
John I. Fishburne, Jr., M.D.

IV. RECOMMENDATIONS

The following recommendations are intended to enhance the operative experience for the patient while at the same time reduce risk. Because Pethidine can produce profound respiratory depression, it is urged that this drug not be administered intravenously unless appropriate resuscitation equipment is available and the operating surgeon is experienced in the use of resuscitation devices. If these conditions cannot be satisfied, the author recommends that only oral and intramuscular medications be given, and then in reduced dosage, and that the primary emphasis be on an adequate local anesthetic block. Under optimal conditions, intravenous administration is to be preferred and is recommended below.

Medications

A. Premedication

1. Diazepam: Usual dose: 10 mg. p.o., one hour before surgery. (Reduced to 5 mg. if weight is less than 75 pounds.) This drug is given to allay anxiety and to provide mild amnesia.
2. Meperidine (Pethidine): This drug is not used for premedication. (See below.)
3. Atropine: This drug is not used for premedication. (See below.)
4. Promethazine (Phenergan): This drug is not used for premedication. (See below.)

B. Operative Analgesia

1. Meperidine (Pethidine): Usual dose: 50 mg., administered intravenously. (Reduced to 25 mg. if weight is less than 75 pounds and/or if patient has any concomitant debilitating illness.) One-half of the dosage is administered, two to three minutes are allowed to elapse, and then the remaining dose, if indicated (i.e., if response to painful stimulus is excessive) is administered. This drug will provide analgesia for the operation. When given intravenously it is effective within two minutes. A dangerous side effect is respiratory depression.
2. Atropine: Usual dose: 0.6 mg. (1/100 grain), administered intravenously. (Reduced to 0.4 mg. if weight is less than 75 pounds.) This drug is used to block vagal stimulation arising from traction on the uterus and tubes.

BEST AVAILABLE DOCUMENT

3. Promethazine (Phenergan): Usual dose:25 mg., administered intravenously. This drug is given to potentiate the narcotic and to reduce the emetic effect of intravenous Pethidine. Subcutaneous and intra-arterial injection should be avoided.

C. Local Anesthesia

1. Lidocaine (Xylocaine, Lignocaine), 1 percent solution: The maximum dosage should be 5 mg/kg. (A 40 kg. woman should have no more than 200 mg., or 20 cc., of a 1 percent solution.) Adrenalin added to the anesthetic solution offers little real advantage and contributes its own toxicity.

In administering the drug, the subcutaneous tissues, fascia, subfascia, and peritoneum are infiltrated first and three to five minutes are allowed to elapse before the operation is begun. Local anesthetic solution may also be flowed onto the tubes and uterus to provide topical anesthesia. Five ml. should be used for this purpose. Lidocaine 0.5 percent may be used. This affords an extra margin of safety. Two-chloroptocaine (Nesacaine) has reduced toxicity but may be more allergenic.

D. Narcotic Reversal

1. Naloxone (Narcan): Usual dose:0.4 mg., administered intravenously. Onset of action is prompt, but duration of action may be exceeded by that of the narcotic. The patient should be reevaluated frequently for signs of re-narcotization. If re-narcotization occurs, additional Naloxone should be administered, Naloxone has virtually no toxicity or narcotic agonist effect of its own.

E. Resuscitation Drugs

The emergency tray should contain:

1. Naloxone (Narcan): See above.
2. Epinephrine (Adrenaline): 1 cc. ampule of 1:1000 solution. This drug is useful in treating acute CV collapse, anaphylactic shock, acute asthma, hypo-tension, etc.
3. Ephedrine: 50 mg. (1 cc.) ampule. A 12.5 mg. to 25 mg. IV is administered to treat hypotension while starting IV fluids.
4. Solucortef: 100 mg. ampule. For IV use in event of severe shock, this drug is given in large doses (30 mg/kg) for acute aspiration of gastric contents.

5. NaHCO_3 (Sodium bicarbonate solution): 50 ml. ampule containing 4.6 milliequivalents NaHCO_3 . This drug is used to treat metabolic and respiratory acidosis which occur in association with tissue hypoxia from shock or apnea.
6. Aminophyllin: 10 ml. ampule of 500 mg. This drug is used to treat acute asthmatic attack. The drug is diluted in 500 cc. D5/NS and titrated to the desired endpoint.
7. Physostigmine (Antilirium): 2 ml. ampule with 1 mg/ml. The usual dose is 0.5 mg. to 1.0 mg., administered intravenously to antagonize CNS effects of atropine and Diazepam.

F. Optional Drugs

1. Ketamine (Ketaject, Ketalar): 10 ml/mg. in 10 ml. vial. This drug may be used to supplement Pethidine analgesia when the latter proves inadequate. The dosage should not exceed 0.4 mg. to 0.5 mg/kg₁₀ IV (maximum dose is 25 mg. IV) and should not be repeated.

Monitoring

A. Pre-operative

The patient's blood pressure, pulse, and respiration should be monitored every 15 minutes from the time premedication is administered until surgery begins. The results should be recorded on a suitable form.

B. Intraoperative

The patient's blood pressure, pulse, and respiration, and the level of anesthesia (Stage I, II or III) should be monitored and recorded every five minutes during surgery. These conditions, and the drugs, dosages, and times of administration should be recorded on a suitable form.

C. Postoperative

The blood pressure, pulse, and respiration should be monitored and recorded every 15 minutes for one hour post-op, then every four hours until discharge. These conditions should be recorded on a suitable form.

Intravenous Fluids

IV fluids (D5/NS or other fluids) should be prepared, and the administration set and needle attached, before the first case each day. Another set should be prepared and kept on hand for subsequent cases.

Resuscitation

A. Equipment

The following resuscitation equipment should be on hand:

1. Anesthesia mask and self-inflating bag with O₂ nipple
2. O₂ tank with reducing valve, flow meter, tubing, and mask
3. Suction machine with (two) traps and tubing
4. Nasal airways (two sizes)
5. Oral airways (two sizes)
6. IV fluids (see above)

B. Instruction

Time should be provided in the family practice and/or family planning training curriculum for teaching basic techniques of resuscitation, including airway management, external cardiac massage, and use of resuscitation drugs.

Pre-anesthetic Screening*

All patients with intercurrent illness or systemic disease should be rejected, pending resolution of the condition. (Further evaluation may lead to subsequent acceptance, as with the diabetic, asthmatic, or hypertensive patient.)

Hemoglobin of less than 8 grams percent should be grounds for delaying an operation, pending appropriate evaluation and treatment of anemia.

Training in Anesthesia for Family Planning Doctors

An anesthesiology curriculum should be prepared and taught during the training period. The following subjects should be taught:

1. Pharmacology of local anesthetic drugs, narcotics and their antagonists, tranquilizers, atropine, and drugs used in resuscitation
2. Clinical use of above drugs. Dangers should be emphasized
3. Monitoring of anesthesia and airway maintenance
4. Resuscitation, including use of bag and mask for ventilation, airway maintenance, external cardiac massage and use of resuscitation drugs.

Practical training using models for learning resuscitation should be emphasized.

Monitoring of the Sterilization Program

On-site monitoring of the sterilization program should be initiated. Trained anesthesia personnel should visit periodically all facilities which tubectomies and vasectomies are performed. The anesthetic practice should be observed and an inventory taken of supplies and resuscitation equipment.

* See page 8 of Draft Manual for Sterilization Operations, Appendix H

Appendix L

LOCAL ANESTHESIA TECHNIQUE FOR TUBECTOMY

LOCAL ANESTHESIA TECHNIQUE FOR TUBECTOMY

As Presented At The
Third Emergency Meeting
Of The National Technical Committee
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LOCAL ANESTHESIA TECHNIQUE FOR TUBECTOMY

1. Never use more than 20 cc. of 1 percent lidocaine for any patient. (The maximum dose should be 200 mg.)
2. Infiltrate the skin in the midline, moving to the left and right and up and down. This should be in the skin, not in the subcutaneous fat. Use 5-8 cc. of 1 percent lidocaine. Wait 2-3 minutes before making incision.
3. After skin has been incised, infiltrate the anterior rectus fascia with 2-4 cc. of drug. Wait 1-2 minutes.
4. Once fascia is open, infiltrate the posterior rectus sheath and peritoneum through the rectus muscle. Use 2-4 cc. of drug and wait another 1-2 minutes.
5. After peritoneum and posterior sheath have been elevated, infiltrate with 1-2 cc. of drug.
6. Open peritoneum. Flow 2-5 cc. of drug into peritoneal cavity in region of tubes, without using needle on syringe (i.e., merely flow the solution over the pelvic organs). Wait 2 minutes and proceed with elevation of tubes.
7. One may also infiltrate the mesosalpinx and tube with a small volume of drug. Experience indicates that this is seldom necessary if the peritoneal surfaces have been adequately covered in Step 6.