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MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : William H. Foege, M.D.
Director, Center for Disease Control (CDC)
Through: Philip S. Brachman, M.D.
Director, Bureau of Epidemiology (BE) ____

DATE: 16 SEP 1980

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

SUBJECT: Investigation of Sterilization-Related Deaths: Bangladesh, June 11 - July 4, 1980

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

A. Description of Clusters of Deaths
B. Death-to-Case Rates for Vasectomy and Tubectomy
C. Causes of Death

VI. RECOMMENDATIONS

I. 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 thana 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 21 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 favorable.

II. DATES AND PLACES

Dacca and Rajshahi Divisions, Bangladesh, June 13 - July 4, 1980.

III. PURPOSE

We were requested by USAID/Bangladesh and the Population Control and Family Planning Division of the Government of Bangladesh to assist in

investigating sterilization-related deaths in Bangladesh since 1978. Our goal was to confirm that these deaths had occurred and were related to the sterilization operation, and to make recommendations as to how similar deaths might be averted in the future.

IV. CHIEF CONTACTS

USAID/Bangladesh
Mr. Charles Gurney, Population Officer
Mr. John Dumm, Population Officer

Ford Foundation
Dr. Anthony Measham, Population Consultant

Population Control and Family Planning Division
Dr. Atiqur Rahman Khan, Director
Dr. Rafiqul Islam, Assistant Director

International Center for Diarrheal Diseases Research Lab/Bangladesh
Dr. Roger Glass
Dr. Barbara Stoll

Population Crisis Committee
Ms. Merle Goldberg, Consultant

Bangladesh Association for Voluntary Sterilization
Dr. Azizur Rahman, President
Mr. Morshed Chowdhury

Bangladesh Medical Association
Dr. Firoza Begum, President

International Projects/Association for Voluntary Sterilization
Mr. Terry Jezowski, Population Officer
Mr. Farouk Chowdhury, Population Officer

Sir Sallimullah Medical College
Dr. Suraiya Jabeen, Director, Department of Ob/Gyn
Dr. M. Razul, Chairman, Department of Anesthesiology

V. ACCOMPLISHMENTS

Introduction

Female and male contraceptive sterilization is an important component of the family planning program in Bangladesh. Over 130,000 such operations were reported to the Government of Bangladesh in 1979 (1). Although the morbidity rates associated with these procedures are low (2,3), the risk of death from sterilization operations in Bangladesh is unknown.

The government of Bangladesh supports the voluntary sterilization program in several ways. First, the operation is free to acceptors. Second, the

Government reimburses acceptors for transportation and food costs, and it provides a new garment to be worn as surgical apparel. Third, in case of death resulting from the operation, the Government offers a financial compensation up to Tk. 5000 (approximately U.S. $345) to the family of the deceased. The first full year that this system of death benefit payment was in effect was 1979; 18 deaths were reported. Thus, a system was established which provided the first nationwide surveillance of sterilization deaths in Bangladesh. In response to an apparent increase in the number of sterilization deaths in early 1980 and because of reported clusters of death from tetanus and complications of anesthesia, we investigated these cases to identify potentially preventable causes of death.

Methods

We identified deaths from January 1, 1979, to March 31, 1980, primarily through Government records of compensation to families of deceased sterilization patients. This list was augmented by deaths 1) reported from clinics of the Bangladesh Association for Voluntary Sterilization, 2) detected through a prospective study of sterilization in Bangladesh conducted under the auspices of the Bangladesh Fertility Research Program and the Center for Disease Control, and 3) identified by intensive case-finding efforts conducted throughout Dacca and Rajshahi Divisions (2 of 4 geographic divisions in Bangladesh). We obtained information on the number of tubectomies and vasectomies performed by month and by District (5 districts are in each division) from the Government of Bangladesh.

Detailed clinical and demographic information was lacking for most reported deaths. Hence, we investigated in the field all deaths reported within Dacca and Rajshahi Divisions. These 2 geographic regions were selected on the basis of 3 considerations: 1) 77% of sterilizations in Bangladesh during the study period were performed in these 2 Divisions; 2) the reported clusters of tetanus and anesthesia overdosage deaths occurred in these Divisions; 3) these Divisions were more accessible by road than the other 2 during the monsoon season.

We obtained information about deaths from several sources. We interviewed Deputy Directors of Population Control and Family Planning in the Districts within the 2 Divisions, and we reviewed their records. We likewise interviewed Thana (county) medical officers, family planning officers, nurses, family welfare visitors, and family welfare assistants and reviewed their records. We also spoke with the local physicians involved in the care of these patients. In several cases, we visited villages to gather information from spouses and neighbors. In the course of our investigation, we assessed the equipment and personnel used for sterilization operations, and we observed operations whenever possible.

Definitions

We defined a sterilization death as the death of a patient from any cause occurring within 42 days of tubectomy or vasectomy. This interval was chosen to be consistent with definitions of maternal mortality (4) and abortion mortality (5) Although death might have occurred after 42 days, the complication must have begun

within this interval. The onset of all fatal complications reported to the Government occurred within 42 days of operation. We subdivided sterilization deaths into those related and those not related to the operation. A sterilization-related death is a death resulting from complications of the operation itself, from the chain of events initiated by the operation which led to death, or from aggravation of an unrelated condition by the physiologic or pharmacologic effects of the operation which subsequently caused the death. A non-related sterilization death is a death occurring during or after the operation which is not causally associated with the operation, its complications, or their management.

We developed case definitions for 3 causes of death.

1) Tetanus: An illness developing 2 or more days after operation and characterized by muscular rigidity with or without reflex spasms, fever, and hyperhidrosis.

2) Anesthesia overdosage: Respiratory and/or cardiac arrest within 4 hours of administration of analgesics or tranquilizers, and without alternative explanations for the death.

3) Intraperitoneal hemorrhage: Death within 3 days of operation following any of these symptoms: progressive weakness, orthostatic hypotension, excessive thirst, or abdominal pain.

We calculated death-to-case rates for vasectomy and tubectomy for each month with 95% confidence intervals based on the Poisson distribution. Since the overall death-to-case rate was approximately 20 deaths per 100,000 procedures, we defined a temporal cluster of deaths as a number of deaths from either vasectomy or tubectomy within any month resulting in a death-to-case rate whose lower confidence limit exceeded 20.

Results

We identified 31 sterilization deaths between January 1, 1979, and March 31, 1980. Twenty-eight of these were sterilization-related, and 3 were not. Of these 3 women, 1 died of status asthmaticus before operation and without administration of preoperative medication, 1 suffocated on roundworms in her oropharynx after operation, and 1 died 3 weeks after operation of an undetermined cause. Only the 28 deaths determined to be sterilization-related will be presented.

All tubectomies used the Pomeroy technique with a small abdominal incision. No sterilization was performed within 6 weeks of a pregnancy, and no patients were reported to have serious pre-existing conditions. All vasectomies were performed on men without reported pre-existing conditions.

Two Clusters of Sterilization-Related Deaths

Two temporal clusters of sterilization-related deaths occurred during the study (Figure 1). The first was a cluster of 5 deaths from tubectomy performed in June, 1979. Three of these operations took place on June 5, 1979, but in widely separated facilities throughout the 2 Divisions. One factor common to each of these operations, however, was the unusually hot weather.

June of 1979 was the hottest June at Rajshahi station since 1972, with a mean maximum temperature of 36°C (96.8°F) and a mean minimum of 26°C (78.8°F). The mean relative humidity at 0900 hours was 69% during the month of June. During the first week of June 1979, the maximum temperature in Rajshahi was ≥ 41°C (105.8°F) daily, with a maximum of 43°C (109.4°F) recorded on June 5 (6). Although daily relative humidity data are unavailable for Rajshahi station, during the first week of June, the relative humidity at 0900 hours at Dacca station ranged from 67% to 81%. None of the facilities with deaths had air-conditioned operating theatres or wards, although some had electric ceiling fans.

One death was heat-related, the patient having died from malignant hyperthermia or heat stroke. Another died later from complications of a bowel laceration sustained during operation; extreme heat or humidity may have contributed to this operative error by the surgeon. The relationship between the weather and death of the third woman from presumed pulmonary embolism is unclear.

The second temporal cluster consisted of 3 deaths after vasectomy in July 1979. This also represented a geographic cluster, since 2 men from the same village died from scrotal infections after vasectomy on July 19, 1979, by the same surgeon at a single clinic (Figure 2). Another death occurred from scrotal infection earlier the same month. The surgeon and clinic associated with the deaths after operation on July 19 had another death from scrotal infection in January 1980. Three vasectomy deaths related to 1 surgeon in a single remote facility strongly suggests a breach of sterile technique. This could not be confirmed since this clinic does not have a physician at present.

Death-to-Case Rates

The death-to-case rate for all procedures combined was 21.4 deaths per 100,000 procedures, with the rate for vasectomy 1.6 times higher than that for tubectomy (Table 1). This difference was not statistically significant ($p>.05$). Death-to-case rates were similar in Dacca (16.8 per 100,000 procedures) and Rajshahi Divisions (25.0).

Death-to-case rates by month for tubectomy ranged from 0 to a maximum of 86.2 deaths per 100,000 tubectomies in June 1979 (95% confidence interval 27.9-201.2). Corresponding rates for vasectomy ranged from 0 to a maximum of 137.4 deaths per 100,000 vasectomies in July 1979 (95% confidence interval 28.4-401.7).

Probable Causes of Death

Anesthesia overdosage was the leading cause of death from tubectomy (29%) while scrotal infection accounted for all deaths from vasectomy (Table 2). Tetanus (24%) and intraperitoneal hemorrhage (14%) were other important causes of death from tubectomy. Post-mortem examination was done on only 1 patient, and this report was unobtainable.

Laboratory Analysis of Drugs

Several physicians expressed the opinion that drugs used in Bangladesh for sedation and pain relief were less potent than labeled. Hence, some physicians might be administering larger than usual doses to patients to "compensate" for supposedly less potent drugs. To test this hypothesis, we submitted samples of drugs used for sterilization in Bangladesh (Appendix A) to the U.S. Food and Drug Administration for analysis. All products tested contained a mean of $\geq$ 95% of labeled potency and met labeled identity, except Seduxen (diazepam) by Richter of Hungary, which contained a mean of 3.2 mg. of lidocaine per 2 cc vial. Thus, the concern about drug potency was not substantiated.

Clinical Observations

Deaths from Tetanus and Other Infection

Sterile instruments were not assured at most facilities where infection deaths occurred. The method of cleaning instruments was determined for 12 of 13 of these facilities. Only 2 (17%) routinely autoclaved instruments; the remainder boiled them.

Some facilities boiled caps, masks, gowns, and gloves. In others, however, these supplies were reused without boiling or else not used at all. One surgeon operated wearing only a mask, undershirt, long pants, and sterile gloves. He wore no cap or gown. Another surgeon performed a vasectomy with bare hands, which is reportedly common practice. Some of the surgeons interviewed felt that such lapses in sterile technique were less important if prophylactic antibiotics were administered.

Deaths from Anesthesia Overdosage

All surgeons interviewed claimed to be using "local anesthesia with sedation," which implies that patients are relaxed but conscious. The apparent intent of most surgeons, however, is to have patients unconscious during the operation. To accomplish this, patients are heavily sedated. Patients with a mean weight of 40 kg (7) receive as much as meperidine 100 mg, promethazine 50 mg, and diazepam 20 mg, all administered intravenously.

We examined 5 patients during tubectomies performed in 5 different facilities; none was conscious. Although developed to describe levels of anesthesia with inhalation of ether in a patient without premedication, Guedel's System* may be

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*Stage I - Amnesia (loss of recall) and Analgesia (reduction or alteration of pain perception). This lasts from the beginning of anesthesia to the loss of consciousness.

Stage II - Delirium. This lasts from the loss of consciousness until respiration becomes regular and the lid reflex disappears (the normal attempt of the eyelid to close when passively opened).

Stage III- Surgical Anesthesia (general anesthesia). This lasts from the onset of regular respiration and loss of lid reflex to the cessation of spontaneous breathing.

Stage IV - This precedes death and lasts from the cessation of respiration to the failure of circulation.

helpful in assessing the depths of anesthesia in these patients (8). Of the 5 patients, none was in Stage I, 2 were in Stage II, and 3 were in Stage III (or general) anesthesia. Equipment and skills required for resuscitation were, with a few exceptions, inadequate to manage complications of anesthesia. Most surgeons interviewed described respiratory depression resulting in death as "anaphylactic shock due to local anesthesia" or as an "unpredictable response" to local anesthesia. In general, they appeared unaware that when the dosages they were using are administered parenterally, it can be predicted that some patients will develop respiratory depression and die if not adequately treated.

Although these depressant drugs are used in large dosages, few facilities had personnel assigned to monitor the patient's status before, during, and after the operation. Consequently, the surgeons were not aware of complications related to anesthesia. In at least 3 tubectomy cases, the surgeon unknowingly operated on a patient who had already sustained cardiac arrest or had died, evidenced by the absence of bleeding during operation.

Deaths from Inability to Resuscitate

Resuscitation capabilities were limited in most facilities. In some cases complications were not recognized early enough for effective intervention. In other instances, once the complications were recognized, appropriate equipment and medications were not available. For example, few facilities had airways, Ambu bags, oxygen cylinders, sodium bicarbonate, or narcotic antagonists. Finally, even when equipment and medications were available, personnel frequently lacked the expertise to know when and how to use them.

Discussion

The first temporal cluster of deaths occurred in June 1979, one of the hottest months in Bangladesh in recent years. We speculate that extreme heat in facilities without air-conditioning may contribute to surgical mishaps; profuse perspiration by patients and operating teams may make sterile technique more difficult to maintain (2). To confirm whether this cluster of deaths is seasonal will require continued surveillance.

The increased number of deaths in the first quarter of 1980 (Figure 1) may be accounted for in part by the dramatic increase in the number of sterilizations done over the study period. The death-to-case rate for January-March 1980, was only slightly higher than that for the entire 15 months (25 versus 21 deaths per 100,000). There was no apparent change in practices during the study period to account for changes in the incidence of deaths.

The completeness of our ascertainment of cases of death is unknown. The Government policy of compensation in case of death is reported to be widely known throughout Bangladesh, and the cash benefit approximates a year's income for a family of 4. Hence, there is strong motivation for families to report deaths to the Government even though the patient may not have had medical followup. Moreover, our field investigations identified only 4 additional deaths not known to us at the outset; 1 death on the Government list was found not to be a

sterilization death. Thus, our casefinding provided a net of 3 additional sterilization-related deaths, or 11% of the total. We found no evidence of systematic underreporting of deaths for either tubectomy or vasectomy.

Infection

A number of procedures may be used to minimize the risk of infections after operations; we will briefly discuss handwashing, skin disinfection, gloves, masks, housekeeping in the operating theatre, sterilization of instruments, and prophylactic antibiotics. We will also discuss prevention of a specific infection, tetanus.

Thorough washing of the surgeon's hands and forearms for 5-10 minutes should precede vasectomy or tubectomy to reduce the bacterial contamination of the surgeon's skin. In settings where rubber gloves are reused, gloves may be more likely to crack or tear during operation. Careful handwashing can minimize the amount of contamination resulting from holes in gloves. Handwashing should be done with a stiff-bristled brush; antiseptic soap, i.e., containing an antimicrobial agent, is advisable (10).

Careful preparation of the patient's skin prior to operation is also important. Thorough washing of the operative site and application of disinfectants will eliminate transient bacteria and reduce the number of the more superficial resident bacteria. Three steps should be carried out: First, the skin should be scrubbed with soap, preferably with a brush for 7 minutes. Second, a preparation of iodine and alcohol should be applied with gauze, keeping the skin wet for 5 minutes. Finally, the iodine should be removed by brisk rubbing with gauze moistened with either ethanol or isopropanol (11).

Sterile gloves should be worn for all operations. The failure to use gloves for vasectomy may be based in part on a published description of a "no-touch" vasectomy technique (12). Even after handwashing, the deep resident bacteria (*S. epidermis* and *Corynebacterium acnes*) remain largely intact (11). Direct inoculation of bacteria into the anaerobic environment of the scrotum seems highly probable during a vasectomy performed without gloves if the wound, vas, or suture material is touched.

Clean surgical masks can diminish the amount of aerosolized bacteria above the operative site. To be effective the mask must be worn over both nose and mouth, a procedure not followed in all facilities we visited. Masks should be changed between cases.

The cleanliness of operating theatres appears to vary widely throughout Bangladesh. However, there is very little documentation of the relationship between general surface contamination (e.g., of floors) in hospitals and spread of infection (10). Although windows frequently must be open because of excessive heat in operating theatres, window screening should reduce entrance of flying insects. Disinfectant-detergent products are recommended for surface cleaning (10).

Microbial contamination most frequently serves as a source of transmission of postoperative infection when contaminated instruments (or hands) directly introduce pathogenic bacteria into a wound (10). In general, the die is cast by the time the last suture is placed (13). Thus, it is critical that all surgical instruments be sterile.

Sterility of instruments is not assured in many facilities we visited. Boiling is not reliable for sterilization because the temperature achieved is inadequate to kill spores of bacteria, notably tetanus. The most effective means of sterilizing instruments is to subject them to saturated steam under pressure, i.e., 10-15 minutes at 121°C, obtainable in an autoclave. Cutting instruments, however, are dulled by steam. Hence, glass syringes and cutting instruments should be sterilized by dry heat, i.e., 1-3 hours at 160°C, obtainable in specially-designed electric ovens (11). Alternatively, disposable instruments can be substituted for those which require the more lengthy dry heat sterilization. Other means of sterilizing instruments, such as immersion in glutaraldehyde, are probably impractical for most facilities in Bangladesh.

Prophylactic antibiotics are commonly given perioperatively. The usual regimen is oral tetracycline 250 mg 3 or 4 times per day for 5 to 7 days, starting after operation. Some facilities also administer intramuscular penicillin before operation. Nevertheless, documentation of the efficacy of prophylactic antibiotics for these 2 operations is lacking. Although tetracycline is relatively inexpensive and safe, we are unaware of documentation of its efficacy in averting infection after vasectomy or tubectomy. Tetracycline is not the drug of choice for Staph. aureus, Strep. pyogenes, or enteric bacteria, the usual pathogens in wound infections (13). In randomized clinical trials, a single dose of prophylactic antibiotic before vaginal hysterectomy has been found to be of comparable benefit as multiple doses before and after operation (14). If prophylactic antibiotics are used, the first dose should probably be given prior to operation with a sip of water; thus, concentrations of antibiotics will be present in tissue at the time of operation. We are concerned that some facilities may rely on oral tetracycline to compensate for fundamental violations of sterile technique. Antibiotics cannot substitute for asepsis.

Social and economic conditions in Bangladesh make tetanus an important potential complication of operations (15). Prophylaxis against tetanus has 3 components: treatment of local lesions, active immunization, and passive immunization. Care of the surgical wound is of primary importance; infection and associated anaerobiosis are to be avoided. "Meticulous aseptic technique in performance of gynecologic and obstetric procedures is effective in prevention of post-operative tetanus" (15). The role of prophylactic antibiotics is unclear except in the case of a severe old wound (15, 16).

Active immunization is an effective and practical method of protecting against tetanus. The optimal time for immunization is in infancy; a series of 4 intramuscular injections of diphtheria-pertusis-tetanus (DPT) antigen provides durable immunity. For children 6 weeks through 6 years of age, the manufacturer's dose of DPT should be given at 4-8 week intervals for 3 doses, with the fourth dose about 1 year after the third (17). Another strategy would

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be to immunize pregnant women, which would protect against tetanus in the woman as well as neonatal tetanus. Two to 3 injections of depot tetanus toxoid at 4-6 week intervals during the second or third trimesters are recommended, with the last injection given about 4 weeks prior to anticipated delivery (15).

Passive immunization against tetanus with heterologus antitoxin or homologous human tetanus immune globulin appears impractical for tubectomy and vasectomy; its use should be restricted to large or dirty wounds (17). The risks associated with heterologus antitoxin probably outweigh the potential benefits; serum sickness occurs in 5-10% of patients, and acute anaphylcatic death in 0.5 per 100,000 (15). Indeed, 1 woman died of anaphylactic shock after administration of anti-tetanus (horse) serum prior to tubectomy.

Medical staff with whom we spoke commonly cited the limited hygiene of patients and their homes as important risk factors in post-operative wound infection. Existing epidemiologic literature does not support this contention. Most species of microorganisms in air and on inanimate objects rarely cause infections. Most surgical incisions develop scabs promptly, and objects that do not contact patients are rarely involved in spreading disease (10). We believe that strict aseptic technique during operations is an important determinant of the likelihood of wound infection; a dirt floor in the patient's home probably is not. With only rare exceptions, the innoculations of wounds occurs in the operating theatre while the wound is open (13).

Anesthesia

A number of potentially lethal complications of intravenous anesthesia can occur. Intravenous meperidine depresses respiration and may cause breathing to stop; alternatively, convulsions, cardiovascular collapse, and coma may occur. Intravenous diazepam has also been reported to cause respiratory arrest. Promethazine overdose results in central nervous system depression, which can lead to unconsciousness and circulatory collapse (18). Moreover, combining these drugs may potentiate their individual depressant effects.

In addition to respiratory failure, other fatal complications can occur. The patient's tongue may fall backwards in the pharynx and obstruct the airway. With abolition of the patient's protective reflexes, vomitus may be aspirated into the lungs. Hypotension may develop unnoticed.

Several approaches may minimize deaths from anesthesia. First, patients who are conscious are unlikely to sustain life-threatening complications. Smaller doses of analgesics and tranquilizers, tailored to body weight will provide relaxation and amnesia without depressing respiration or obtunding reflexes. Diazepam may be administered orally before operation with a sip of water. A disadvantage of using intravenous diazepam to produce unconsciousness is the prolonged time for awakening after operation. Facilities using a combination of meperedine, phenergan and diazepam report that patients sleep an average of 3-6 hours after operation.

Careful attention to dosage should apply to the local anesthetic as well. The smallest volume of the lowest concentration of local anesthetic that is

adequate should be used. Some physicians use 10-15 ml of 1-2% lidocaine for tubectomy; this could constitute as much as 300 mg. Although prior administration of diazepam will raise the seizure threshold for lidocaine and other local anesthetics (19) (i.e., higher blood levels of anesthetic are tolerated before convulsions occur), this may represent an overdose for most Bangladeshi women. The maximum amount of lidocaine without vasoconstrictor that should be used is 4.5 mg/kg, which converts to 180 mg for a 40 kg patient. Use of 0.5% lidocaine allows larger volumes to be used for infiltration while offering a wider margin of safety, as does use of procaine. Several minutes should be allowed for the anesthetic to become effective before operating. Careful infiltration not only of the skin but also of the full thickness of the abdominal wall is necessary. Topical anesthetic sprayed or dripped into the tubes by syringe is rapidly effective in case of discomfort from tubal manipulation.

Second, if patients are rendered unconscious, scrupulous management of anesthesia is needed to insure safety. Even brief periods of respiratory failure can cause irreversible brain damage or death. A patent airway must be assured at all times by extending the neck and elevating the mandible. The frequency and adequacy of respiration must be monitored without interruption. The pulse should likewise be monitored continuously; palpation of the radial or temporal artery is a convenient means. The blood pressure should be determined frequently, such as at 5 minute intervals during operation. Since peak blood levels of intramuscular medications may occur after operation, continued close monitoring of vital signs is necessary in the recovery room. Adequate numbers of skilled nurses should be available to monitor patients after operation.

Finally, if complications of anesthesia occur, the operating team should have the equipment, drugs, and expertise to deal with such problems (20). Basic resuscitation supplies such as intravenous solutions, sodium bicarbonate, and vasopressors are lacking in many facilities. Many facilities still rely on suboptimal measures for resuscitation, with nikethamide and steroids frequently used as primary or sole therapy. A narcotic antagonist, preferably naloxone, should be present in the room wherever narcotics, such as meperidine, are used.

Intraperitoneal Hemorrhage

Intraperitoneal bleeding, although an infrequent complication of tubectomy, is potentially fatal. Ligatures around the fallopian tube, a highly vascular structure, may slip off. Alternatively, tears of the mesosalpinx may occur unnoticed. Unlike vasectomy, where bleeding into the scrotum manifests itself as a hematoma, bleeding into the abdomen may be less obvious.

Three factors can minimize deaths from intraperitoneal hemorrhage after tubectomy. First, the surgeons should be gentle and meticulous. The incision should be wide enough to allow easy mobilization and visualization of the tubes. Ligatures must be secure and hemostasis complete.

Second, patients must be monitored post-operatively for signs of concealed bleeding. Common practice at facilities we visited is for vital signs (pulse,

respiration, and blood pressure) to be determined only once after operation. More frequent patient observation and monitoring of vital signs, particularly in the first hours after operation, may provide earlier warning of bleeding. An increase in pulse and decrease in blood pressure, especially when the patient is vertical, can prompt intervention before the woman is moribund.

Third, facilities performing tubectomy should have staff and equipment to perform a simple laparotomy. Administration of intravenous fluids and control of bleeding vessels are life-saving in this situation. Reliance on transfer of patients to other facilities for management of post-operative bleeding does not appear practical for rural Bangladesh.

Comparative Safety

The risk of death from tubectomy in Dacca and Rajshahi Divisions of Bangladesh (19 deaths per 100,000 procedures) is approximately twice that in the United States (21). The surgical settings and clientele are, however, vastly different. We believe this low mortality rate is an impressive accomplishment for Bangladesh.

The risk of death from fertility control measures should be viewed in the context of other reproductive alternatives for women. The Government of Bangladesh estimated that female sterilization averts an average of 1.78 births over the remaining reproductive career of the woman (9). Assuming a mean age at sterilization of 30 (7) and a mean age at menopause of 45 in Bangladesh, the mean reproductive span remaining after sterilization is approximately 15 years. For a cohort of 100,000 women sterilized in a year, about 178,000 births would be averted over the next 15 years. Assuming a stable maternal mortality rate of 570 deaths per 100,000 live births (22), a total of 1,015 women (or 68 per year) from this cohort would be expected to die from pregnancy complications over these 15 years. Thus, the cost in lives of tubectomy (19 deaths) would be offset by 68 lives saved in the first year alone. This cohort would then enjoy the health and social benefits of fertility control during subsequent years. Thus, the impact of tubectomy on Bangladeshi women is strongly favorable.

The risk of death from vasectomy in this study (31 deaths per 100,000 procedures appears to be the highest in the world's literature. Potts and associates (23) have estimated the risk of death from sterilization in less advanced developing countries as being 50-100 deaths per 100,000 tubectomies and 0.1 death per 100,000 vasectomies. We observed the converse to be true in Bangladesh. The vasectomy death-to-case rate in Bangladesh during the study period was nearly 4 times higher than that reported from the 1971 Family Welfare Festival in India (8.1 deaths per 100,000 vasectomies) (24).

V. 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:

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

Any 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 a substitute 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 favorable 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.

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

Type of Procedure	No. of Deaths	No. of Procedures	Rate[1]	Relative Risk[2]
Tubectomy	21	108,875	19.3 (11.9-29.5)	1.0
Vasectomy	7	22,526	31.1 (12.4-64.0)	1.6
TOTAL	28	131,401	21.3 (14.2-30.8)	

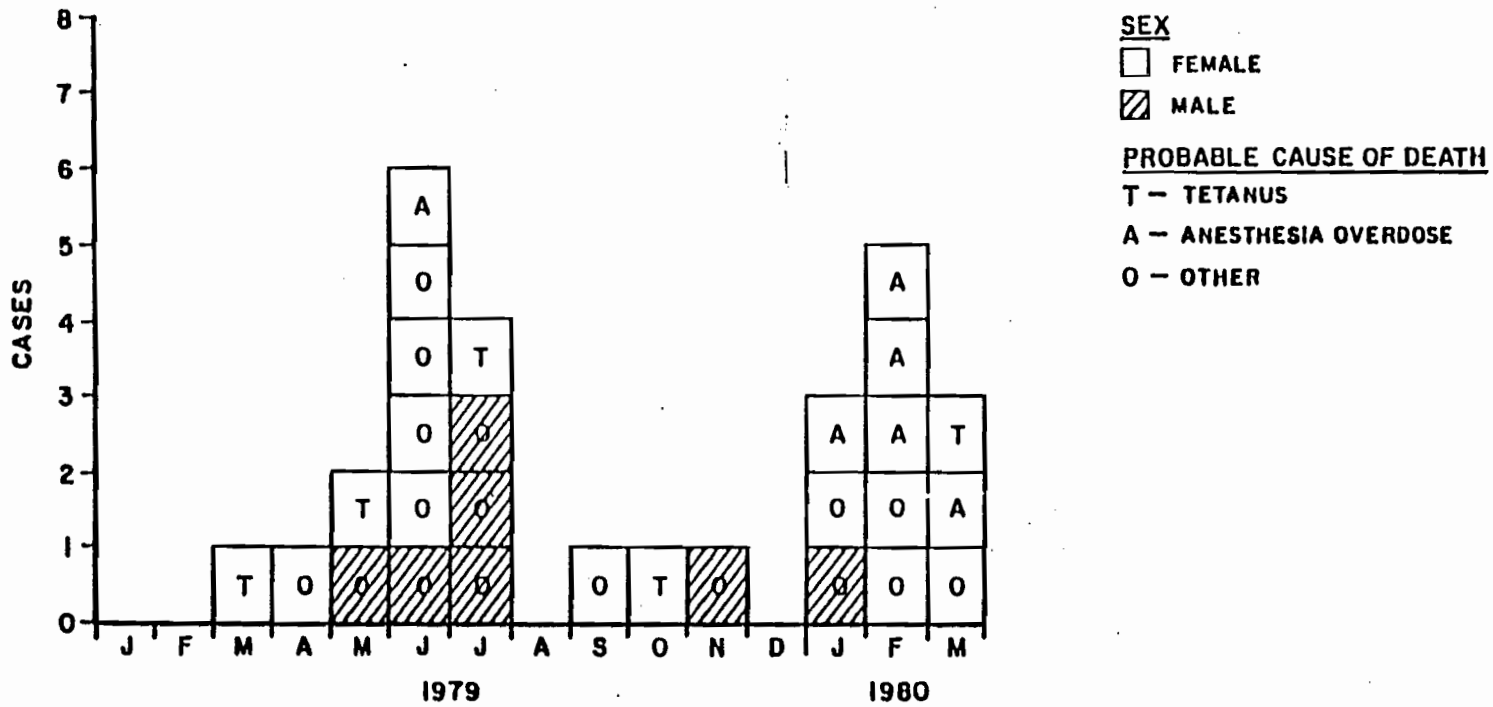
[1]Deaths per 100,000 procedures (with 95% confidence interval by Poisson distribution)
[2]Based on an index rate for tubectomy of 19.3 per 100,000 procedures

Table 2
Probable Causes of Sterilization-Related Deaths, by Type of Procedure, Dacca and Rajshahi Divisions, Bangladesh, Jan. 1, 1979 to March 31, 1980

Probable Causes of Death	Type of Procedure			
	Tubectomy		Vasectomy	
	No.	(%)	No.	(%)
Anesthesia Overdose	6	(29%)		
Tetanus	5	(24%)		
Intraperitoneal Hemorrhage	3	(14%)		
Infection Other Than Tetanus	1	(5%)	7	(100%)
Other[1]	6	(29%)		
TOTAL	21	(100%)	7	(100%)

[1]Includes pulmonary embolism (2), anaphylaxis from heterologous anti-tetanus serum, malignant hyperthermia/heat stroke, small bowel obstruction, and aspiration of vomitus.

Fig. 1 STERILIZATION-RELATED DEATHS BY SEX, PROBABLE CAUSE OF DEATH, AND MONTH OF OPERATION, DACCA AND RAJSHAHI DIVISIONS, BANGLADESH, JANUARY 1, 1979 – MARCH 31, 1980



Appendix A
Results of Bangladesh
CDC Sample Analyses

Drug					
Brand Name	Generic Name	Manufacturer	Identification & Exp. date	Labeled Concentration	% Labeled Concentrat found
Phenergan	Promethazine	Bangladesh Pharmaceutical Industry Ltd.	lot 198	50 mg/2 ml	100.4%
Phenergan	Promethazine	Bangladesh Pharmaceutical Industry Ltd.	lot 214	50 mg/2 ml	100.2%
Atropine	Atropine	KDH Lab Ltd. Dacca	Batch No. 19	.01 gr/ml	104%
Atropine	Atropine	KDH Lab Ltd. Dacca	Batch No. 23	.01 gr/ml	102%
Pethidine HCl	Meperidine HCl	Amino Ltd.	7/3	50 mg/1 ml	101.0%
Pethidine HCl	Meperidine HCl	Jayson Pharmaceuticals Ltd. Dacca	Batch No. 219	100 mg/2cc	104.5%
Pethidine HCl	Meperidine HCl	Jayson Pharmaceuticals Ltd. Dacca	Batch No. 237	100 mg/2cc	98.7%
Pethidine HCl	Meperidine HCl	B.P. 63	Batch No. 6C07	100 mg/2 ml	98.6%
Pethidine HCl	Meperidine HCl	Vifor Geneve		100 mg/2 ml	103.6%
Pethidine HCl	Meperidine HCl		DMI No. 20	100 mg/2 ml	105.7%
Pethidine *	Meperidine HCl *		Unmarked *	----	102.8 mg/2ml
Valium	Diazepam	Hoffmann-La Roche	B391S Exp. 6/80	10 mg/2 ml	100%
Seduxen ***	Diazepam Lidocaine	Richter	77621.1075	10 mg/2 ml ----	100% 3.5 mg/2 ml

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Appendix A
Results of Bangladesh
CDC Sample Analysis

Drug Brand Name	Generic Name	Manufacturer	Identification & Exp. date	Labeled Concentration	% Labeled concentratio found
Seduxen ***	Diazepam Lidocaine	Richter	42879.1173	10 mg/2 ml ----	90% 2.9 mg/2 ml
Seduxen ***	Diazepam Lidocaine	Richter	38704.0178	10 mg/2 ml	94% 3.1 mg/2 ml

* unmarked (reported to be pethidine)
** reported as mg/2 ml since no labeled concentration
*** reported to be diazepam (Hugarian)

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APPENDIX B

EGISTRY OF STERILIZATION-RELATED DEATHS, BY SEX AND PROCEDURE-TO-DEATH INTERVAL, DACCA AND RAJSH DIVISIONS, BANGLADESH, 1 JANUARY 1979 - 31 MARCH 1980

FEMALES

Date of Procedure	Date of Death	Interval	Age	Parity	Type Anesthesia	Probable Cause of Death
19/4/79	19/4/79	Prior to operation	30	3	None	Anaphylaxis from anti-tetanus serum
24/1/80	24/1/80	Prior to operation	35	3	Parenteral[123]/ local	Anesthesia overdose
26/2/80	26/2/80	Prior to operation	26	5	Parenteral[123]/ local	Anesthesia overdose
10/3/80	10/3/80	Prior to operation	28	2	Parenteral[123]/ local	Anesthesia overdose
27/6/79	27/6/79	During operation	36	7	Parenteral[123]/ local	Anesthesia overdose
25/2/80	25/2/80	During operation	32	6	Parenteral [13]/ local	Anesthesia overdose
24/3/80	24/3/80	During operation	29	7	Parenteral[123]/ local	Aspiration of vomitus
5/6/79	5/6/79	<4 hr	33	3	Parenteral[123]/ local	Hyperthermia
17/2/80	17/2/80	<6 hr	35	8	Parenteral[123]/ local	Anesthesia overdose
5/6/79	5/6/79	<10 hr	32	5	Parenteral[123]/ local	Pulmonary embolism
14/6/79	15/6/79	1d	30	6	Parenteral[123]/ local	Intraperitoneal hemorrhage
16/2/80	18/2/80	2d	35	3	Parenteral[123]/ local	Intraperitoneal hemorrhage

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te of ocedure	Date of Death	Interval	Age	Parity	Type Anesthesia	Probable Cause of Death
/1/80	21/1/80	4d	22	3	Parenteral[123]/ local	Intraperitoneal hemorrhage
2/80	13/2/80	4d	35	4	Parenteral[123]/ local	Peritonitis
/9/79	4/10/79	8d	30	7	Parenteral[123]/ local	Pulmonary embolism
/10/79	26/10/79	9d	30	5	Parenteral[123]/ local	Tetanus
3/3/79	30/3/79	11d	28	5	Parenteral/ local	Tetanus
/7/79	14/7/79	11d	29	6	Parenteral[23]/ local	Tetanus
6/5/79	31/5/79	15d	27	3	Parenteral[123]/ local	Tetanus
9/3/80	18/4/80	20d	25	4	Parenteral[123]/ local	Tetanus
/6/79	17/7/79	42d	36	5	Parenteral[123]/ local	Small bowel obstruction

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MALES

ate of rocedure	Date of Death	Interval	Age	Type Anesthesia	Probable Cause of Death
12/11/79	19/11/79	7d	35	Local	Scrotal infection
23/6/79	4/7/79	11d	32	Local	Scrotal infection
28/5/79	9/6/79	12d	42	Local	Scrotal infection
2/7/79	16/7/79	14d	35	Local	Scrotal infection
24/1/80	8/2/80	15d	35	Local	Scrotal infection
19/7/79	31/8/79	43d	40	Local	Scrotal infection
19/7/79	4/9/79	47d	40	Local	Scrotal infection

[1]Meperidine [2]Promethazine [3]Diazepam