PD-AAL-207

ISN 0312

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date June 18, 1981

From David A. Grimes, M.D.

Subject Foreign Trip Report: Investigation of Sterilization-Attributable Deaths, Bangladesh, May 8-22, 1981

To William H. Foege, M.D.
Director, Centers for Disease Control (CDC)
Through: Horace G. Odgen
Director, Center for Health Promotion and Education

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D. Voluntary Sterilization Centre Site Visit Checklist

I. SUMMARY

Nineteen sterilization-attributable deaths were identified in Bangladesh after operations performed from September 16, 1980, to April 15, 1981. These deaths were investigated at the facility, thana, or District level. One common-source epidemic of tetanus was identified. Overall, the death-to-case rate was 12.4 deaths per 100,000 operations, with no deaths from vasectomy reported during this 7-month study interval. This death-to-case rate was lower than that (21.3) calculated for sterilization procedures in Dacca and Rajshahi Divisions from January 1, 1979, through March 31, 1980.

The leading cause of death continues to be anesthesia overdose. More appropriate use of analgesia, better monitoring of patients, and increasing capabilities for resuscitation should help prevent such deaths. Better means of sterilizing instruments and attention to aseptic technique should minimize deaths from tetanus and other infections. Overall, the health impact of contraceptive sterilization on the people of Bangladesh remains strongly favorable. For every 100,000 tubectomies performed, over 1,000 maternal deaths are averted.

II. PLACES, DATES, AND PURPOSE OF TRAVEL

Dacca and Barisal Districts, Bangladesh, May 8-22, 1981.

I was requested to assist with the investigation of sterilization-attributable deaths in Bangladesh during 1981. I was to confirm that these deaths were attributable to sterilization, estimate the risk of death, identify probable causes of death, and recommend measures to prevent such deaths. I was also to attend a national conference on surgical sterilization in Dacca on May 17 and 18.

III. PRINCIPAL CONTACTS

USAID/Dacca
Mr. Charles Gurney, Chief, Division for Population, Health, and Women's Affairs (DPHWA)
Dr. Carol Carpenter-Yaman (DPHWA)

Government of Bangladesh
Dr. Nargis Akhter, Deputy Director, MCH/FP Division
Dr. Rafiqul Islam, MCH/FP Division
Dr. Shafiqur Rahman, Biomedical Division, NIPORT

United Nations Fund for Population Activities
Dr. Penny Satterthwaite

Bangladesh Association for Voluntary Sterilization
Dr. Azizur Rahman

International Projects, Association for Voluntary Sterilization
Mr. Russell Vogel, Director, Asia Office
Mr. Steve Smith, Assistant Director, Asia Office

Pathfinder Fund
Dr. Robert Holtrop

Ford Foundation
Dr. Anthony Measham

IV. ACCOMPLISHMENTS

An investigation (Grimes and Peterson Trip Report, 1980) of sterilization-attributable deaths in 2 divisions of Bangladesh from January 1, 1979 through March 31, 1980 identified an overall death-to-case rate of 21.3 deaths per 100,000 operations. Infection was the only cause of death from vasectomy, and anesthesia overdose was the leading cause of death from tubectomy. Because of reports of deaths during the early months of 1981, a reappraisal of sterilization-attributable deaths in Bangladesh was requested.

Methods

The list of death payments made by the Government of Bangladesh served as the principal source for identifying deaths. To identify other deaths not known to the MCH/FP Division, we interviewed Civil Surgeons and/or Deputy Directors for Population Control and Family Planning in 15 or 20 Districts of Bangladesh. A study interval of September 16, 1980 to April 15, 1981, was chosen to correspond to monthly reports of procedures done and to include the most recent month for which denominator data were available. Deaths from April 1-September 15, 1980, which were reported to the MCH/FP Division were not studied and are not included in this report. The majority of case investigations were performed at the thana or facility level by Dr. Penny Satterthwaite, UNFPA, with the assistance of Dr. M. Begum, of PCFP Division. I joined in the ongoing investigation. Definitions for attributable deaths and causes of death were the same as in the earlier report.

A. Description of Cluster of Tetanus Deaths

One common-source epidemic of tetanus occurred at the Nawabganj Thana Health Complex, Rajshahi District, on March 9, 1981. Seven women underwent tubectomies performed by the same surgeon that day. Patient 1 had an uneventful recovery; the other 6 all developed tetanus. Cases 3, 4, and 6 died; the other 3 recovered.

Within 2 weeks after these operations, the Government of Bangladesh sent a technical committee to investigate the circumstances surrounding this cluster. Operations performed on the days immediately before and after May 9 had no reported complications. No differences in sterility of the instruments or operative technique on March 9 were found. The committee was unable to identify the course of the epidemic, but the committee noted poor sanitation in the operating facility. The committee also felt that suboptimal management of patients 3, 4, and 6 at the local infectious disease hospital (viz, inadequate doses of penicillin and anti-tetanus serum, combined with inadequate supportive care) contributed to these deaths, since the other 3 patients, who were not treated at the infectious disease hospital, all survived. The incubation periods of the 6 cases of tetanus, however, suggest that the patients who died may have hd more serious illness, manifested by earlier onset of disease. The mean incubation period (operation to onset of symptoms) for the patients who died was 6.7 days, whereas that for those who survived was 8.3 days ($p>.05$ by Student's t test). The occurrence of tetanus in 6 successive patients undergoing operation strongly suggests a large inoculation of tetanus organisms during operation. None of these women had been pregnant recently or had a known alternative source of infection. Potential vectors include scalpel blades or gloves. The technical committee ordered the operating theater in the facility to be closed, and the epidemic stopped.

B. Death-to-Case Rates

Nineteen women died after tubectomies performed during this 7-month period (Table 1, Figure 1). One patient who died of an anesthesia overdose was 11

days post partum, and 1 patient who died from hemorrhage had a combined abortion-sterilization procedure. No other patient had been pregnant within 6 weeks of operation. There were no vasectomy attributable deaths. These deaths occurred among 153,032 operations, for a death-to-case rate of 13.7 for tubectomy and 12.4 for all sterilization operations combined (Table 2).

Deaths occurred in all geographic Divisions of Bangladesh (Table 3). Sterilizations performed in Khulna Division had the highest death-to-case rate (18.9), while the Division with the tetanus cluster (Rajshahi) had the lowest (6.0).

As shown in Table 4, the death-to-case rate was highest for the month February 16-March 15 (25.5). This interval included the 3 deaths from tetanus cited earlier (Figure 1). The variation in rates from month to month represents the small numbers of deaths and procedures performed.

C. Causes of Death

As shown in Table 5, the principal causes of death were anesthesia overdose (8 cases), tetanus (5 cases), hemorrhage (2 cases), and infection other than tetanus. The mean intervals from operation to death for these causes were 0.3 $\pm$ 0.7 days for anesthesia, 11.6 $\pm$ 4.6 days for tetanus, 1.0 $\pm$ 0.0 days for hemorrhage, and 27 days for infection other than tetanus. All patients who died from anesthesia overdose had received parenteral pethidine, promethazine, and diazepam in various regimens. Naloxone was unavailable at each of these facilities where anesthesia deaths occurred. One patient, unattended and apparently still groggy from medication, fell out a window at 3:00 a.m. on the morning after operation and died within an hour from trauma sustained during the fall. One patient died suddenly at home on the day after operation. One death lacked sufficient information to identify the probable cause.

One patient who died from hemorrhage had had a "menstrual regulation" abortion just prior to sterilization. No uterine trauma was noted at tubectomy. The patient bled heavily from the vagina and abdominal wound prior to death; the possible contribution of the abortion to this death is unknown. Neither this patient nor the other who bled to death underwent laparotomy to control bleeding.

Failure to reoperate also contributed to the death of 1 patient from infection other than tetanus. In this case, the surgeon inadvertently entered a large pelvic abscess while attempting tubectomy. He aspirated approximately 200 cc of pus, closed the incision, and transferred the patient to a medical college hospital. There, failure to perform a total abdominal hysterectomy and bilateral salpingo-oophorectomy resulted in death.

Discussion and Recommendations

Detailed recommendations for preventing deaths from sterilization were made in a previous trip report (Grimes and Peterson, Op. Cit.) and in that of Dr. John Fishburne. The Sterilization Conference and Manual for Sterilization Operations should further reduce the number of preventable deaths.

The Manual for Sterilization Operations (attachment B), however, contains some technical misinformation that may contribute to the continuing problem with tetanus. On page 14, the Manual recommends immersion in Savlon solution for 30 minutes as a means of sterilizing instruments. Neither this technique nor boiling should be relied on to kill tetanus spores. Temperatures in excess of 100°C are needed to kill these spores. Likewise, Savlon (chlorhexidine gluconate 0.3% w/v and cetrimide B.P. 3.0% w/v) may provide a high level of disinfection, but tetanus spores on scissors and scalpel blades may survive this treatment. The most common means of chemical sterilization in the United States is immersion in 2% glutaraldehyde (Cidex) for at least 3 hours. I suggest that this regimen replace the Savlon immersion when chemical sterilization is undertaken.

In conclusion, this investigation corroborates the earlier report; surgical sterilization is a safe procedure in Bangladesh. The absence of vasectomy deaths may be in part attributable to better sterile technique, as was recommended previously. The health benefits of surgical sterilization in Bangladesh remain strongly favorable. For each 100,000 women who undergo tubectomy, over 1,000 maternal deaths are averted.

D. Sterilization Conference

On May 17-18, 1981 a national conference on surgical sterilization was held in Dacca (attachment A). The meeting was jointly sponsored by the PCFP Division, Government of Bangladesh, and the Bangladesh Association for Voluntary Sterilization. Over 800 delegates, most of whom are surgeons who perform sterilizations, attended. The first day consisted of a series of motivational and educational presentations. Speakers from the United States included Dr. Ira Lubell and Dr. Donald Minkler. The second day consisted of a series of concurrent workshop sessions to discuss components of the newly published Manual for Sterilization Operations (attachment B).

V. ATTACHMENTS

A. Program, Sterilization Conference
B. Manual for Sterilization Operations
C. Bangladesh Voluntary Sterilization Surveillance System
D. Voluntary Sterilization Centre Site Visit Checklist

Table 1
Sterilization-Attributable Deaths, Bangladesh,
September 16, 1980-April 15, 1981

Age	Parity	Division	Date of Operation	Date of Death	Operation-to-Death Interval (days)	Probable Cause of Death
30	5	Khulna	Oct. 6	Oct. 6	0	Anesthesia Overdose
20	UNK	Khulna	Oct. 28	Oct. 30	2	Anesthesia Overdose
35	UNK	Dacca	Dec. 19	Dec. 19	0	Anesthesia Overdose
28	5	Khulna	Jan. 24	Jan. 24	0	Anesthesia Overdose
40	11	Dacca	Mar. 25	Mar. 25	0	Anesthesia Overdose
35	5	Khulna	Mar. 27	Mar. 27	0	Anesthesia Overdose
30	3	Dacca	Mar. 30	Mar. 30	0	Anesthesia Overdose
35	2	Dacca	Apr. 4	Apr. 4	0	Anesthesia Overdose
UNK	UNK	Chittagong	Oct. 30	Nov. 7	8	Tetanus
UNK	UNK	Chittagong	Feb. 22	Mar. 13	19	Tetanus
35	7	Rajshahi	Mar. 9	Mar. 22	13	Tetanus
30	4	Rajshahi	Mar. 9	Mar. 17	8	Tetanus
30	8	Rajshahi	Mar. 9	Mar. 19	10	Tetanus
20	2	Khulna	Sep. 23	Sep. 24	1	Hemorrhage
28	1	Dacca	Feb. 25	Feb. 26	1	Hemorrhage
35	9	Dacca	Mar. 12	Apr. 8	27	Infection Other Than Tetanus
UNK	UNK	Dacca	Sep. 20	Sep. 21	1	Trauma
30	10	Dacca	Feb. 18	Feb. 20	2	Pulmonary Embolism
35	5	Khulna	Jan. 23	Jan. 24	1	Unknown

Table 2
Death-to-Case Rates for Sterilization-Attributable Deaths by Type of Operation, Bangladesh, September 16, 1980 - April 15, 1981

Type of Operation	No. of Deaths	No. of Operations	Rate[1]
Tubectomy	19	138,745	13.7
Vasectomy	0	14,287	0.0
TOTAL	19	153,032	12.4

[1]Rate per 100,000 operations

Table 3
Death-to-Case Rates for Sterilization-Attributable
Deaths by Division, Bangladesh,
September 16, 1980 - April 15, 1981

Division	No. of Deaths	No. of Operations	Rate[2]
Dacca	8	49,294	16.2
Chittagong	2	17,171	11.6
Khulna	6	31,760	18.9
Rajshahi	3	50,240	6.0
TOTAL	19	148,465	12.8

[1]Excludes 4,567 operations in voluntary agencies
[2]Rate per 100,000 operations

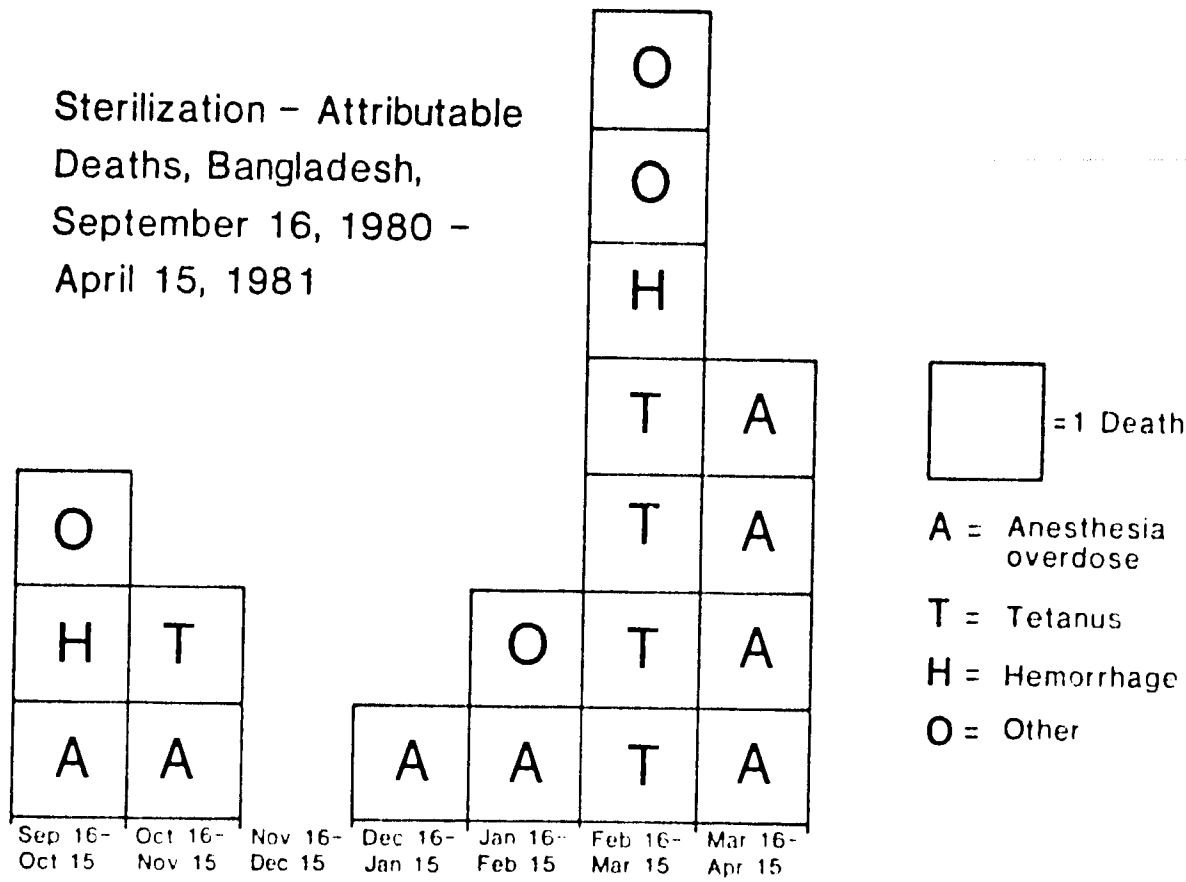
Table 4
Death-to-Case Rates for Sterilization-Attributable
Deaths by Month, Bangladesh,
September 16, 1980 - April 15, 1981

Month	No. of Deaths	No. of Operations	Rate
Sep. 16 - Oct. 15	3	27,489	10.9
Oct. 16 - Nov. 15	2	23,654	8.5
Nov. 16 - Dec. 15	0	16,102	0.0
Dec. 16 - Jan. 15	1	15,308	6.5
Jan. 16 - Feb. 15	2	22,282	9.0
Feb. 16 - Mar. 15	7	27,454	25.5
Mar. 16 - Apr. 15	4	20,743	19.3
TOTAL	19	153,032	12.4

Table 5
Probable Causes of Sterilization-Attributable Deaths, Bangladesh, September 16, 1980 - April 15, 1981

Probable Cause of Death	No. of Deaths
Anesthesia overdose	8
Tetanus	5
Hemorrhage	2
Infection other than tetanus	1
Trauma	1
Pulmonary embolism	1
Unknown	1
TOTAL	19

Figure 1


Sterilization - Attributable Deaths, Bangladesh, September 16, 1980 - April 15, 1981
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Sep 16- Oct 15
Oct 16- Nov 15
Nov 16- Dec 15
Dec 16- Jan 15
Jan 16- Feb 15
Feb 16- Mar 15
Mar 16- Apr 15
=1 Death
A = Anesthesia overdose
T = Tetanus
H = Hemorrhage
O = Other