PNAAT 263
40928

Prepared for:
The Government of Sri Lanka
and the
Office of Population
Bureau for Science and Technology
Agency for International Development
Washington, D.C.
Under Contract No. DPE-3024-C-00-4063-00
Project No. 936-3024

OBSERVATIONS AND RECOMMENDATIONS ON VOLUNTARISM AND MEDICAL QUALITY IN SRI LANKA'S SURGICAL CONTRACEPTION PROGRAM

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March 21-31, 1985

Edited and Produced by:

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Report No.: 85-26-014
Published July 1, 1985

TABLE OF CONTENTS

Page

LIST OF ABBREVIATIONS ii

EXECUTIVE SUMMARY iii

I. INTRODUCTION 1

I.1 Purpose of Assignment 1
I.2 Methodology 1

II. VOLUNTARISM 3

II.1 Summary 3
II.2 Level of Contraception--Current and Future 3
II.3 Provider Incentives and Acceptor Payments 3
II.4 Guarantees of Voluntary Acceptance 4
II.5 Factors Inhibiting Access to Sterilization 5
II.6 Improvement of Temporary Methods Program 5
II.7 Conclusions and Recommendations 7

III. AVAILABILITY AND QUALITY OF STERILIZATION SERVICES 8

III.1 Availability and Quality of Sterilization Services 8
III.2 Equipment 9
III.3 Training 10
III.4 Surveillance 12
III.5 Conclusions and Recommendations 17

TABLES AND SUMMARY DESCRIPTION

Table 1 — Selected Data on Morbidity Risk Attributed to Female Surgical Contraception
Table 2 — Selected Data on Morbidity Risk Attributed to Male Surgical Contraception
Table 3 — Selected Data on Mortality Risk Attributed to Female Surgical Contraception
Table 4 — Selected Data on Failure Rates Following Female Sterilization by Approach, Method of Occlusion, and Timing
Summary Description — Selected International Data on Complications Following Vasectomy

APPENDICES:

Appendix A — Itinerary
Appendix B — National Family Health Programme - Declaration of Consent for Sterilization
Appendix C — Complication Report
Appendix D — Female Voluntary Sterilization-Related Death Report

LIST OF ABBREVIATIONS

AVS	Association for Voluntary Sterilization
CPR	Cardio-pulmonary Resuscitation
CPS	Contraceptive Prevalence Survey
CDS	Community Development Services
FHB	Family Health Bureau
FHW	Family Health Worker
FPASL	Family Planning Association of Sri Lanka
GSL	Government of Sri Lanka
MOH	Ministry of Health
MOOH	Medical Officers of Health
MOPI	Ministry of Plan Implementation
PHM	Public Health Midwife
SLAVSC	Sri Lankan Association for Voluntary Surgical Contraception
UNFPA	United Nations Fund for Population Activities
VSC	Voluntary Surgical Contraception
WFVSC	World Federation of Voluntary Surgical Contraception

EXECUTIVE SUMMARY

1. Scope of Work

This report was requested by the Government of Sri Lanka as a followup of an earlier report by the same consultant on the Sri Lankan program for surgical contraception with particular reference to voluntarism. The consultant had found originally that the program of paying financial incentives to service providers and out-of-pocket expenses to acceptors did not constitute "undue influence." This followup report was to explore further the issue of voluntarism and to examine the medical quality of the surgical contraception program.

2. Voluntarism

2.1 Conclusions

The major conclusions regarding voluntarism flow from the observation that Sri Lankans are well-informed about sterilization and hold favorable attitudes toward the procedure. The current surgical contraception program is designed to prevent involuntary acceptance, and there is no evidence that the program has been compromised by the current pattern of provider incentives and out-of-pocket payments to acceptors. Screening and consent forms provide protection to potential acceptors from undergoing the procedure without adequate consideration of its consequences.

On the other hand, the report provides evidence that voluntarism is being compromised from another standpoint. Instances of ethnic zeal, and the application by some physicians of arbitrary age-parity criteria that are inconsistent with minimum Government requirements, have made it difficult, or even impossible, for some individuals to get the sterilizations they wish. In short, the pressures endangering the voluntary acceptance of sterilization are less likely to arise from its promotion than from political perceptions or other factors that impede service delivery. In this situation, voluntarism would be strengthened by the presence of a more vigorous temporary methods program operating alongside the surgical contraception program. With improved counseling, such a program would provide the individual or families which wished to limit family size a viable choice among alternative methods.

2.2 Recommendations

The report includes recommendations to provide even stronger guarantees for voluntarism, with the proviso that, because they would require considerable staff time, they might not be entirely practical to implement.

1. To further guarantee voluntary acceptance, screening procedures should be tightened in some institutions and the use of the consent form extended to all hospitals. The burden on staff would need to be considered in executing these recommendations.

2. To improve counseling on all methods, support and supervision should be provided to family health workers to assist them to become more active counselors of all contraceptive methods; and

3. Written materials on contraceptive methods could be prepared for distribution in clinics and hospitals.

3. Availability and Quality of Sterilization Services

3.1 Conclusions

The medical quality of the Sri Lankan surgical contraception program appears very good. Doctors are technically well trained and hospitals which offer services are well equipped. Doctors, nurses, midwives, and other health workers may need better training in areas not directly related to the surgical procedure (counseling and cardio-pulmonary resuscitation [CPR]). One equally important issue, however, in regards both to medical staff and equipment is availability, not quality. Some doctors, though trained, will not perform the procedure and a substantial number of smaller hospitals cannot offer the service because they do not, or do not feel, they have the necessary equipment.

As the availability of sterilization services becomes greater, however, especially in the smaller hospitals, the need will grow to verify independently the quality of the services, and assumptions of excellence based on the level of training and equipment should be substantiated. Currently, in the absence of a uniform, active surveillance system and periodic followup surveys, no systematic verification is possible. Anecdotes are the main source of information and, although often suspect, can also be unsettling. While some few efforts have been made formally to collect data, available reports are limited in coverage.

3.2 Recommendations

The report includes recommendations pertaining to equipment and training for the sterilization program and a design scheme for surveillance of major and minor complications as well as of failure of surgical contraception. It also suggests that a long-term followup survey might be undertaken to assess satisfaction and the developmental impact of sterilization on the family.

3.2.1 Equipment

Recommendations regarding equipment recognize that small hospitals are providing an increasing number of sterilizations and therefore that there is a clear need to determine the availability of equipment in all hospitals throughout Sri Lanka and to decide the level of sophistication which would be practical in the smaller institutions. It is therefore recommended that:

1. As planned, the Sri Lankan Association for Voluntary Surgical Contraception (SLAVSC), in cooperation with the Family Health Bureau (FHB), quarterly, through very short questionnaires and/or by telephone, should assess the status of necessary equipment and drugs at the 107 institutions providing sterilization, and consideration should be given to computerizing the information gathered.

2. A group of doctors should reconsider the the minimum list of equipment in the SLAVSC booklet "Minimum Medical Standards for Voluntary Surgical Contraception," keeping both safety and benefit in mind.

3.2.2. Training

While basic technical training is good, certain areas need additional emphasis. It is recommended that the following areas be improved:

3. Vasectomy training should be provided both to doctors in training and to those in practice who have not yet learned this skill.

4. CPR should be a required part of all basic medical training and retraining and posters should be available near every surgical theater.

5. Training must take more account of screening, counseling, and risk/benefit issues.

Doctors willing and trained to perform surgical sterilization are not always available. The following recommendations might improve the situation.

6. Senior and perhaps retired consultants should be available more regularly to support and supervise junior physicians at smaller hospitals.

7. A mandatory retraining policy may be necessary for some junior medical officers who have been inactive after their basic training.

8. A revised system may be desirable to anticipate the posting of an untrained officer, or, after arrival, to release him/her for early training.

3.2.3. Surveillance

Because the Government has no formal means to follow up complications resulting from surgical contraception, a variety of procedures should be instituted, depending on the type of problem. It is recommended that:

9. For the rare case of death or serious morbidity, a hospital-based reporting system be instituted, with encouragement for reporting. An independent Investigative Committee should be established to conduct a special confidential inquiry to assess the relationship of the reported event to the surgical procedure, and, if related, its preventability.

10. For the much more numerous minor complications not requiring hospital admissions, short-term followup surveys are recommended, biased toward acceptors in the smaller hospitals where problems are more likely to occur. The study design should be organized to encourage acceptor participation and to yield quick feedback to program planners.

11. For failure, again a rare occurrence, delivery personnel should be encouraged to report all post-sterilization pregnancies. Information could be reviewed by the Investigative Committee (Recommendation 9) or the evaluation unit in FHB.

I. INTRODUCTION

I.1 Purpose of Assignment

Eighteen months ago, the Association for Voluntary Sterilization (AVS) requested this consultant to comment on the Sri Lankan program for surgical contraception, with particular reference to voluntarism. The major focus of this report was the Government of Sri Lanka's (GSL) continuing program of paying financial incentives to service providers and out-of-pocket costs to male and female surgical contraceptive acceptors. The conclusion was that the acceptor payments did not constitute "undue influence." The consultant found the climate "informed and open" and concluded that the payments reflected GSL's commitment to eliminating "any economic impediment to accceptance of what they consider to be their most successful method for achieving a more desirable rate of population growth."[1]

As a follow-up, the Ministry of Plan Implementation (MOPI) requested a second review of voluntarism, together with an examination of the medical quality of the surgical contraception program.

The consultant drafted a scope of work which was designed to be responsive to the needs identified by MOPI. It included the following:

1. Review through interviews and field visits (to key urban and rural medical centers/clinics) the issue of voluntarism and medical quality of the Voluntary Surgical Contraception (VSC) program.

2. Draft formal procedures for continuing, active surveillance (quality control) to identify, and when necessary investigate, important medical complications among VSC acceptors that may be related to their surgery.

3. Suggest a priority list of practical research/evaluation projects to help answer prevailing and anticipated questions about the operation and impact of the VSC program.

4. Conduct a seminar in Sri Lanka on the findings and suggestions.

5. Prepare a short report based on these findings and suggestions.

In the following report, the voluntarism issue is treated in Chapter II and surveillance is discussed in Chapter III in the wider context of the quality and availability of training of medical staff and equipment. Suggestions for practical research and evaluation of the impact of the VSC program are provided only in summary, in consideration of the more pressing needs of a surveillance program.

I.2 Methodology

The consultant spent 10 days in Sri Lanka, and, in the course of discussions in Colombo and during a short but intense field trip, benefited from the

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1/ Wright, N.H., "Report on the Sri Lankan Incentive Program for Voluntary Sterilization," A.V.S., 26 October 1983.

views of many knowledgeable individuals, both medical and non-medical. These discussions included individuals from the Government's Family Health Bureau (FHB), Ministry of Health (MOH), MOPI, and three active non-governmental organizations: Family Planning Association of Sri Lanka (FPASL), Community Development Services (CDS), and the Sri Lankan Association for Voluntary Surgical Contraception (SLAVSC). Information was provided freely and conversations were refreshingly open. Access to hospitals and health centers was similarly open. While my visits could not be representative of all institutions, hospital staff were cordial and interactive, and contributed significantly to my understanding of their work and the constraints they face. A list of contacts/visits appears as Appendix A.

II. VOLUNTARISM

II.1 Summary

Sri Lankans are well-informed about sterilization and hold favorable attitudes toward the procedure. The current surgical contraception program is designed to prevent involuntary acceptance. There is no evidence that the program has been compromised by the current pattern of provider incentives and out-of-pocket payments to acceptors. Screening and consent forms, meanwhile, provide protection to potential acceptors from undergoing the procedure without adequate consideration of its consequences. On the other hand, voluntarism is being compromised from another standpoint. Instances of ethnic zeal, and the application by some physicians of arbitrary age-parity criteria that are inconsistent with minimum Government requirements, have made it difficult, or even impossible, for some individuals to get the sterilization they wish. In short, the pressures endangering the voluntary acceptance of sterilization in Sri Lanka arise mainly from factors that limit access to service.

In this situation, voluntarism would be strengthened by the presence of a more vigorous temporary methods program. With improved counseling, such a program would provide the individual or families which wished to limit family size a larger choice of methods.

II.2 Level of Contraception - Current and Future

According to the 1982 Contraceptive Prevalence Survey (CPS), 20.7 percent of currently married Sri Lankan women reported that they (17.0) or their husbands (3.7) had been sterilized.[1] The Family Health Impact Survey, done about the same time, reported a comparable 23.1 percent (20.0 for wives and 3.1 for husbands).[2] Since the beginning of 1982, and up to the end of 1984, approximately 270,000 additional sterilizing operations have been reported. Based on the estimated number of married couples at risk, assuming no major husband/wife duplication, and allowing for aging (wives becoming older than 49 over the period), the conclusion is that the proportion of couples in Sri Lanka protected by sterilization must be very close to 30 percent, if not greater. Given such a high prevalence (both in Asia and the world), acceptability and confidence in the procedure must also be high.

II.3 Provider Incentives and Acceptor Payments

In no instance did the consultant perceive counseling in the hospitals visited to be high pressure or coercive. At the current level of acceptance of

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1/ "Sri Lanka Contraceptive Prevalence Survey Report," Department of Census and Statistics (DSC) and Westinghouse Health Systems, Colombo, Sri Lanka, 1983.

2/ Family Health Impact Survey, Sri Lanka, 1981-1982. Evaulation Unit, FHB, MOH, May 1984.

surgical contraception in the population, there is simply no need for salesmanship. Clearly, hospital staff are not promoting surgical contraception to increase the extra-work payment available to them.[1] The out-of-pocket payment to the acceptor has remained at Rs. 500 since June 1983 and is now worth significantly less because of inflation.[2] The number of sterilization acceptors, which increased 70 percent in 1983, declined somewhat in 1984, perhaps because out-of-pocket costs are now less likely to be completely met, but possibly also because of demographic reasons. Acceptance rates, however, remain high, as is current prevalence.

Unless family size desire declines, and the Sri Lankan medical profession is willing to accommodate such a trend, acceptance of sterilization may slow. The birth cohorts of 1950-1965 were comparatively large and are reaching marriageable age (or have married - the crude birth rates rose from the mid-1970s). Many in the age group now have small families, but their ultimate wishes are unknown.

II.4 Guarantees of Voluntary Acceptance

The current surgical contraception program is well-designed to prevent involuntary acceptance. The Government has instituted a policy that families must have a minimum of two living children, and, if only two, the youngest should be at least a year old, before sterilization is permitted. It has also developed a comprehensive consent form for all prospective sterilzation clients. The screening for present family size is a protection, both to the client and the Government, against later requests for reversals. The consent form gives the acceptor a final opportunity to affirm his or her decision before the sterilization takes place.

Screening for the age and parity criteria varies in its thoroughness. Some well-staffed, model clinics require full documentation, including birth certificates, and reject up to 15 percent of first applications for surgical contraception. The more general pattern seems to be acceptance of the information as volunteered by the interested man or woman. Given current family size preferences in Sri Lanka and the critical staff shortages in Government hospitals, this practice seems reasonable and practical. The perceived low risk of misrepresentation is thought to be potentially greater for vasectomy applicants than for postpartum, or even interval, tubal ligation applicants. Women, and their reporductive histories, are likely to be known by nurses and midwives at their local hospital. Reversal requests have been very, very few, prompted by divorce and remarriage, or increasingly rare cases of infant and/or child death.

The comprehensive consent form developed by SLAVSC, and approved by the MOH, is in widespread use in both large and small hospitals (Appendix B). In a few of the institutions visited, however, signatures of the couple were recorded only on the hospital record. Severe shortage of medical and paramedical staff dictated a less cumbersome procedure in these places. An in-

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1/ The total extra payment to the operating team, Rs. 65 per tubectomy and Rs. 35 per vasectomy, has remained constant since mid-1979.

2/ I argued in my 1983 report that the distribution of out-of-pocket costs resisted accurate measurement, but clearly were distributed around Rs. 500.

ventory of the use of the consent form, now planned by SLAVSC, should yield more reliable information on the extent of use of the full consent form in Sri Lanka. It might be more desirable in some institutions to reinforce screening procedures further, including promoting use of the consent from by all institutions. The desirability of such moves, however, would need to be balanced against the resulting increased work demands on already overburdened staff.

II.5 Factors Inhibiting Access to Sterilization

While the Government's major concern appears to be that its sterilization program is perceived as voluntary, other forces are at work which are making it difficult for some families to get the sterilization they want. These include a difficult ethnic situation, in which, for demographic reasons, one group fears it will be numerically bypassed if the birth rate in its members is reduced, and cautious doctors who sometimes refuse to provide sterilization if they feel a couple has too few children.

The continuing ethnic problem is threatening voluntarism. Anonymous letters have been sent to doctors in several districts, resulting in the surgical contraception program being deliberately slowed. Fortunately, these reactions seem to be temporary in the affected districts. The national figures show a slight downturn in August 1983, after the late July disturbances, but then increase. It is encouraging to note that, despite the sporadic civil unrest, some of the most troubled districts, especially in the East, show very high rates of surgical contraception acceptance in 1983. In view of the current political situation, however, it is not clear how this threat to voluntarism can be resolved in the near future.

There is abundant evidence that doctors in Sri Lanka are not reluctant in counseling couples, especially women, with regard to the minimum number of children they should think of having. Despite the GSL policy requiring a minimum of two living children, many consultant obstetrician-gynecologists and medical officers require three or even more. The risk of infant and child death often seems perceived as higher than reported, and the right of the couple, knowing the facts, to make their own decisions often is limited. The decision, however, is sociocultural, and it is true that the risk of infant and child mortality does vary significantly from district to district. While the doctor's caution may strengthen voluntarism, it may also thwart an increasing number of younger, better educated couples, who feel capable of assessing the risk of child death themselves. If alternative surgical contraceptive services are not easily available, and the local temporary methods program lacks strength, they will be at high risk of an unwanted pregnancy, or two. While GSL has no acceptor or demographic targets, it is evident that this practice of refusing to provide sterilization, if widespread, would have clear demographic implications. This issue is beyond the scope of this report, but deserves mention nonetheless.

II.6 Improvement of Temporary Methods Program

Probably the best guarantee that acceptors are choosing sterilization voluntarily would be if they had selected it from a wide array of alternative methods. In fact, this is not the case. The temporary methods service program at

the hospitals and in the field is relatively weak, often critically so at the hospitals. There are various reasons for this situation. Foremost, perhaps, is the current shortage of medical and paramedical personnel. Secondly, the surgical contraception program, where available, is often perceived as being of higher priority by hospital personnel. It also fits the "curative mode" of these institutions. While some smaller hospitals had very active temporary method programs, others, large and small, saw these methods more the province of the Medical Officers of Health (MOOH), the preventive side of the MOH. While tubal ligation might be done in the hospital three or four days a week, the temporary methods clinic there might function only once a week, if that frequently. The most practical time for most women to receive contraceptive counseling and assistance is after delivery; many, however, are not accommodated by the present program. If they do not want surgical contraception, but cannot get a modern temporary method before discharge from the hospital, then fail to return for a six-week postpartum check (the vast majority), and are not contacted promptly by family health workers/public health midwives (FHW/PHM) under the MOOH in the field, they are likely to become pregnant again after a brief period of protection during breastfeeding. With a stronger temporary methods postpartum program in the hospitals before discharge, including thorough counseling, voluntarism in Sri Lanka would be better protected.[1]

In addition to the need for better access to non-permanent methods, women also would profit from more thorough counseling in their use. While most postpartum women interviewed knew about one or two temporary methods, their knowledge was not complete and tended to be dominated by an unreasonably magnified fear of complications and no strong perception of benefit.[2] Efforts are under way to improve counseling for sterilization, particularly through development of the source book "Counseling on Voluntary Surgical Contraception" by SLAVSC; the draft is promising, but might be strengthened by including more information on temporary methods, especially for the increasing number of lower-parity women who are not eligible, or not interested, in surgical contraception, but would like to space their next pregnancy. A printed counseling sheet with balanced infor-

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1/ Some doctors seem to believe that most couples prefer not to use modern temporary methods, but, instead, having reached their desired family size, opt for surgical contraception. Because survey data document that use of inefficient, traditional methods is highly prevalent, it seems unlikely to this observer that couples would not accept one of the more efficient, modern, temporary methods, if it were more easily available. Other evidence on this point is unclear, i.e., that modern methods <u>are</u> more available than can be perceived by the casual observer, and that Sri Lankan couples, for their own reasons, perhaps because of exaggerated fear of risks, are disinterested. One test of this question is a more vigorous modern temporary methods program, including thorough counseling. In my view, such a program will require less direct medical control over access to these methods.

2/ See the data developed in a Gallop Poll commissioned by the American College of Obstetricians and Gynecologists suggesting that (American) women are "grossly misinformed" about contraceptive safety, especially the pill, as reported in "The Nation's Health," April 1985.

III. AVAILABILITY AND QUALITY OF STERILIZATION SERVICES

mation on all methods was available to sterilization acceptors at the FHB. Since literacy is high in Sri Lanka and hospital staff time very limited, this minimal approach might usefully be extended to all MOH hospitals. It should not substitute, however, for person-to-person counseling when that is feasible.

Counseling might take place either in the villages or in the hospitals. Special counselors are currently being trained at the SLAVSC Model Clinic, and they can be expected to contribute to the new guidelines being developed by SLAVSC. It should be kept in mind, however, that most individuals responsible for counseling at Government institutions will not have equivalent educational backgrounds. Currently providing a good share of the counseling are young FHWs with midwifery training. Some are stationed in villages where, under the direction of the MOOH, they counsel and assist village women in regards to family planning. Others either are based at hospitals or may visit hospitals to assist in the clinic or to follow an acceptor after discharge. FHWs observed during hospital visits were alert and well-trained, but they are junior and some are unmarried. Without strong supervision and encouragement, many FHWs appear to have adopted the traditional practice of waiting for a request for advice or help.

On the other hand, with better support and supervision, the FHW could potentially provide an important link in the counseling chain, for both temporary methods and sterilization.

II.7 Conclusions and Recommendations

In summary, the general climate is open, and Sri Lankans are literate, informed, and hold favorable attitudes toward surgical contraception. While one cannot exclude an occasional case of manipulation to gain a share of the out-of-pocket expense payment, the system is well-protected against abuse. It might be desirable to reinforce screening procedures, including promoting use of the consent form by all institutions. Further strengthening of the modern, temporary methods program is, however, more urgent.

Because the situation regarding voluntarism was by-and-large favorable, the consultant had few recommendations for improvements. The suggestions below are offered with the realization that, because of staff shortages, it may be difficult to execute any or all of them. With this proviso, it is recommended that:

1. To further guarantee voluntary acceptance, screening procedures should be tightened in some institutions and the use of the consent form extended to all hospitals. The burden on staff would need to be considered in executing these recommendations.

2. To improve counseling on all methods:
Support and supervision should be provided to FHWs to assist them to become more active counselors of all contraceptive methods.

3. Written materials on contraceptive methods could be prepared for distribution in clinics and hospitals.

III. AVAILABILITY AND QUALITY OF STERILIZATION SERVICES

III.1 Availability and Quality of Sterilization Services

III.1.1 Assumptions Based on Training and Equipment

There is good reason to believe that the medical quality of the Sri Lankan surgical contraception program is high. Doctors are technically well-trained and hospitals which offer services are well-equipped. Doctors may need better training in areas not directly related to the surgical procedure (counseling and cardio-pulmonary resuscitation [CPR]). One equally important issue, however, in regards both to medical staff and equipment is availability, not quality. Some doctors, though trained, will not perform the procedure, and a number of smaller hospitals cannot offer the service because they do not have the equipment. The sections below offer recommendations as to how the Government might deal with the lack of equipment and with gaps in training.

III.1.2 Anecdotal Information

As the availability of sterilization services becomes greater, however, the need will grow to verify independently the quality of the services. Assumptions of excellence based on the level of training and equipment and on universal use (since the 1970s) of local anesthesia should be substantiated. Currently, in the absence of a uniform, active surveillance system and periodic followup surveys, no verification is possible. Anecdotes are the main source of intelligence and, although sometimes suspect, can also be unsettling. The consultant heard several stories about severe complications, some causing death, albeit often at institutions other than the one where surgery was performed. Medical opinion (unpublished and not unanimous) holds that a number of major complications were more common in the late 1980-early 1981 surge of acceptance when facilities were severely strained.[1] Small epidemics of minor complications were also discussed, usually wound infections, which were "cured" locally.

III.1.3 Studies

Some few efforts have been made formally to collect data. For minor complications, a number of short-term surveys have been conducted by individual Sri Lankan physicians.[2] Currently, FPASL is conducting a survey of its tubectomy cases, using small incentives and a lottery to achieve high followup rates.

1/ Compared to the base period January-September 1980, the number of monthly tubectomy and vasectomy acceptors from October through February 1981 increased by two- and eleven-fold, respectively.

2/ For a review, see papers in "Voluntary Surgical Contraception," Proceedings of the Second National Conference, eds. Drs. P.T. Jayawickramarajah and S.M.X. Corea, SLAVSC, 1982.

Community Development Services (CDS) reported information on major and minor complications in urban areas for 1984. These reports are limited in scope, however, and high followup rates would need to be achieved to make both studies and routine reporting reliable. Beyond these small formal studies, informal local investigations of individual cases are the rule.

III.2 Equipment

III.2.1 According to the FHB, 107 hospitals in Sri Lanka, the majority of them small, are reported to be providing surgical contraception. A major thrust of the past few years has been to provide these smaller hospitals with equipment to provide these services. Assistance has come through the FHB, the United Nations Fund for Population Activities (UNFPA) and, indirectly, AID. Since most observers agree that it is in these smaller hospitals that the risk of medical complications is greatest, there is considerable interest in reaching agreement on appropriate equipment standards for these institutions.

III.2.2 SLAVSC has prepared a useful booklet, entitled "Minimum Medical Standards for Voluntary Surgical Contraception,"[1] which contains a comprehensive list of equipment and drug requirements. Using an informal list provided by SLAVSC, the consultant, where possible, checked on availability of recommended drugs and equipment in smaller hospitals. He found that non-functioning equipment and periodic absence of certain drugs were problems. While some hospitals had abandoned the effort to provide surgical contraception, others were continuing to do so, despite unavailability of certain equipment and drugs. The smaller hospitals are said to have an ambulance on call the day of surgery, so that an emergency case can be taken quickly to a larger hospital for attention by appropriate senior doctors. In several instances, these vehicles were standing ready.

III.2.3 SLAVSC has proposed, in cooperation with FHB, to undertake an inventory of equipment and drugs in all 107 hospitals said to be providing surgical contraception. This will be a very useful activity, particularly if it is put on a longitudinal basis with, perhaps, quarterly reports based on telephone interviews and/or short, mailed questionnaires. If computerized, current reports would be available quickly to all concerned, providing rapid feedback so that deficiencies could be remedied quickly.

The issue of appropriate standards, however, also needs to be addressed. The consultant agrees with a number of doctors that the list in "Minimum Medical Standards . . ." may be impractical for small hospitals and may need to be for emergencies at peripheral hospitals. Nor are these hospitals being supplied with anesthetic machines or laryngoscopes and endotracheal tubes. It is not clear to the consultant that the absence of these items seriously compromises safety, particularly in view of the benefits of surgical contraception. Reconsideration of this list, with both safety and benefit in mind, by a group of Sri Lankan doctors with both small and large hospital experience is suggested.

1/ Belingaswatle, A.M.L., ed., 1983

III.3 Training

III.3.1 Basic Training

With a medical school for over 100 years and a well-established pattern of specialty training, Sri Lanka has a long and distinguished medical tradition. A National Health Service, unique in Asia, has been in place since the late 1940s. In addition, a number of useful training documents and training programs have been developed by FHB, FPASL, SLAVSC, and others, many of which may merit early extension to all Government hospitals. Certainly "Minimum Medical Standards..." is one of these. Although this consultant did not see it outside Colombo and Kandy, he believes it warrants wider distribution.

Consultant surgical and obstetrical/gynecological specialists are the key persons in training, certification, and supervision of young doctors. These experts are very well-trained, but consultant surgeons are currently in short supply. They supervise all surgical sterilization training, both during internship and later during specialization. The training may take place either at major hospitals or in clinics run by non-governmental hospitals. The consultant specialists are also responsible for certification of competence in surgical contraception. When the consultant feels a trainee is competent, a letter is sent to the FHB. A certificate is then sent to the consultant for final verification, after which the Director General, Health Services, MOH, issues the certificate to the trainee. There are separate certificates for competence in vasectomy and tubal ligation techniques, and a doctor must have one to be eligible for the small provider payment (see II.3). It is felt that, given the many learning and other variables involved, a minimum set of training requirements would be impractical. While it is acknowledged that not all consultants may be equal in training ability, since nothing in medical education explicitly prepares a doctor to be a teacher, the consensus in Sri Lanka feels this to be a minor issue. The computerized reports suggested for equipment (see II.2.3) could be used to track the training status of institutional medical officers. Such record-keeping would assist the MOH to staff Government health facilities.

III.3.2 Areas Needing Enrichment

III.3.2.1 Low Priority to Vasectomy While tubal ligation has long been part of standard obstetrical-gynecological training, instruction in vasectomy appears to be more limited, and there are a number of districts in Sri Lanka where vasectomy acceptance rates are low, quite possibly reflecting the lack of doctors competent to perform this operation. A training program in this skill is now being offered at the SLAVSC Model Center in Kandy, and will supplement the existing programs of FPASL and the MOH. Government doctors from districts with low vasectomy rates might be given priority for additional training at the SLAVSC Center. A problem may be whether they could be released from their current responsibilities. The recent decision to extend the internship period from one to two years should increase the exposure of young doctors to both tubal ligation and vasectomy techniques.

III.3.2.2 Cardio-pulmonary (CPR) Resuscitation The consultant noticed only one poster outlining a standard method of CPR, this in a smaller institution. He did not see this poster again and established in several other hospitals that neither the paramedical staff nor (in one case) the doctor, knew what CPR was. The implications of this knowledge gap are, of course, considerably more far-reaching than for surgical sterilization where, in fact, may have relevance only rarely. If this knowledge gap is a general problem, however, it needs to be remedied on an urgent basis. Posters should be available near every surgical theater, and CPR should be part of basic training and retraining of all health professionals.

III.3.2.3 Counseling Skills Training should take account of the screening and counseling responsibilities of doctors and thus should cover such issues as eligibility, medical indications, and risk-benefit as they relate to permanent contraception. A host of questions come to mind. For example, how many Caesarian sections must a women undergo before a doctor suggests permanent contraception? When do other maternal conditions and risk factors, including advanced maternal age, e.g., over 40, demand a more activist approach? When should a high-risk case be referred to a specialist for surgical contraception? Should social and medical criteria be separated? Is there a medical reason for suggesting that a tubal ligation acceptor be at least 30? The age-parity minimum product of 60 seems highly arbitrary (and inconsistent with GSL criteria). How is a physician to judge the patient's socio-economic condition?

The useful SLAVSC booklet "Minimum Medical Standards . . ." deals with many of these issues. A second edition, however, might be strengthened by more detailed attention to such questions. More examples, more precision, and perhaps some recognition that the couple may have a stronger claim than the doctor to decide, after suitable counseling, what is in their best interest - all seem needed in a new edition, and will be helpful in guiding training/retraining programs.

A new edition might also provide data on both risks and benefits to give the doctor some perspective on risks as compared with expected benefits. Risk and benefit information could be drawn from currently available international sources, to which, later perhaps, could be added Sri Lankan minor and major complication rates (see III.4). Information on benefits could even now be applied to the Sri Lankan situation. For example, if a tubal ligation were found to prevent at least one subsequent birth, the 62,000 procedures in 1984 would have prevented at least 50 maternal deaths over the next year,[1] not to speak of major and minor obstetrical morbidity requiring expensive hospital treatment. Such comparative information should help a trainee to develop a balanced view.

III.3.3 Availability

III.3.3.1 Supervision and Retraining A number of doctors who have been

1/ The overall Sri Lankan maternal mortality rate in 1979 was 0.8 per 1,000 live births. It is somewhat higher for older women who are more likely to accept surgical contraception.

trained to perform surgical contraception may be reluctant to do so, either due to inexperience or to the feeling that they need retraining to refresh or update their skills. Measures both for supervision of junior doctors and retraining should be available on a widespread basis. It is likely that more than a few junior doctors, already trained and with the necessary equipment, have as yet provided no surgical contraception services in their small institutions. The problem in part may be one of confidence, and also the anxiety of possibly making an error in a setting where backstopping is limited. If the doctor feels the sterilizing procedure to be an optional one in an otherwise healthy individual, the overriding motivation to do no harm may be very strongly felt. To help these doctors gain confidence, senior consultants based at major hospitals are sometimes sent to smaller hospitals to assist and teach at a few operating sessions. Some District Superintendants of Health Services and/or Medical Superintendants of major hospitals make a practice of ensuring that senior consultants are available for this important work. Staff shortages, however, restrict the practice. If it could be expanded, it is likely that the availability of doctors willing to perform surgical contraception would also grow. If incentives are needed, they should be considered. Using retired consultants to provide part-time on-the-job training at smaller hospitals should also be explored.

While retraining sessions are available at FHB, FPASL, and the SLAVSC Model Center for all doctors who feel the need, consideration might be given to making retraining mandatory for all doctors who had not done any sterilizations in the first two or three years after completion of training.

III.3.3.2 Assignment of Doctors Because of frequent transfers, doctors trained to provide surgical contraception services are sometimes replaced with untrained ones and surgical contraception services are thus interrupted.
The FHB system now in place to handle this problem may need periodic review to ensure early anticipation of such transfers and maximization of continuity of services.

III.4 Surveillance

III.4.1 Need for and Design of Surveillance Program

Although good training and equipment, medical screening, and use of local anesthesia have combined to provide what appears to be a very safe environment for surgical contraception in Sri Lanka, obviously any serious complication or death must be of concern. As stated above (see III.1.3), no system is currently in place systematically and uniformly to investigate these relatively rare events and to assess their relationship to surgery and, if related, their preventability. Anecdotal information and local, non-uniform investigation do not provide an adequate picture. An October 1984 circular from FHB asks all institutions to keep a record of complications available on request. Because this request has

met with no response, additional steps will need to be taken.

This consultant therefore proposes that the Government initiate an active surveillance program to provide quality control. The program would differ according to the seriousness of the complication, as follows:

- Major complications, death, or a problem that "requires intervention and management, including unintended surgery, unexpected hospitalization, blood transfusion, or treatment of life-threatening events, and that does not result in death,"[1] require promotion of reporting and creation of a special Investigative Committee.

- Minor complications, defined as a problem that "requires intervention and management but not unintended surgery, unexpected hospitalization, blood transfusion, or treatment of life-threatening events and that does not result in death,"[1] would be traced through periodic followup surveys.

- Failures, particularly because they might result in life-threatening ectopic pregnancies, might also be referred to the special Investigative Committee or other formal body.

While all programs of voluntary surgical contraception have experienced major and minor complications attributed to the procedure, it is often difficult to know how to assess this experience. The information provided in Tables 1-4 and Summary Document may provide a helpful guide in evaluating data from a Sri Lankan surveillance program. In reviewing the data, however, the reader should keep in mind that it is difficult to separate out the myriad factors that bear on safety, e.g., skill of surgeon, timing, surgical approach, selection of cases, anesthesia, etc. Because these factors differ from place to place, the country information should not be compared rigorously. The information is provided only to give a general idea of the range of complication rates that might be expected in Sri Lanka if a surveillance program were initiated.

III.4.2 Major Complications and Death

III.4.2.1 Reporting Because major complications and, to a large extent, deaths are very likely to be referred to and seen at the large hospitals, an active hospital-based reporting system is recommended. To investigate the cases, an independent medical Investigative Committee should be established. Its field of inquiry should include assessment of the relationship of the event to the surgical procedure and, if related, its preventability.

An October 1984 circular from FHB asks all institutions to keep a record of complications available on request. The response of institutions is still unclear, but it seems very likely to this consultant that additional, more active steps will need to be taken. Multiple reporting mechanisms are are desirable and could include formal reporting by the hospital staff or through the death certificate and informal reports by the client and/or his/her family. Hospital staffs would be encouraged to cooperate in reporting such incidents, with involvement by the medical superintendent, admitting officers,

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1/ Definition taken from the World Federation of Voluntary Surgical Contraception (WFVSC), 1983.

and all the medical personnel on the surgical and obstetrical/gynecological wards. Any one of them could initiate the report, perhaps on a standard post-card giving name, address, date of event, date of operation, type of complication, and institution. It might be expedient to provide substantial incentives for reporting both major complications and death. The incentive should be provided within two months after the tubectomy or vasectomy to ensure timely reporting.

In addition, since it may prove that deaths will be harder to detect than major hospitalized complications, particularly if the death occurs late, well after discharge following sterilization, it might prove expedient for the GSL to provide a death benefit, as is done in Bangladesh, to help promote complete reporting. A mechanism to review all death certificates signed out as due to tetanus may be useful to assess their relevance to the Sri Lankan program.

If more assurance is required, a sample of death certificates[1] among men and women 25-49 might be drawn. Excluding causes of death clearly unrelated to sterilization, e.g., accidents, suicide, etc., one could focus on related deaths that were missed by the formal active surveillance program. Ideally, the identity card number should appear routinely on both the acceptor record and death certificate. If this could be achieved at some future time, and then computerized, problems with surveillance of rare cases of death following sterilization would be eased greatly.

III.4.2.2 Investigative Committee An independent Investigative Committee should be established under the auspices of the College of Obstetrics and Gynecology and Surgery, the Sri Lankan Medical Association, or SLAVSC to investigate all reports. It should be primarily medical in its membership. The Committee would require a budget for its investigative work.

The Committee secretary, a medical officer, would receive reports and conduct a confidential inquiry. Using a standard form, e.g., see "Minimum Medical Standards..." (Appendices C and D), the secretary would gather the required information on selected cases from the reporting institution, the institution where the sterilization was performed, and the patient, or family, of the deceased. This information would then be evaluated by the Committee, which would decide whether the misadventure was related to the sterilizing operation, and, if so, whether it was preventable. Risk factors (including certain chronic diseases, previous abdominal or pelvic surgery, and obesity) are well-known, and would be considered, as would operative (including anesthesia), training status, and other factors. Feedback could be used to improve the system. The types of major complications to be reviewed might include severe wound infection or pelvic abscess, uterine perforation, drug reactions, hemorrhage, tetanus, and bladder and bowel injury. Serious risks are higher for female sterilization than for male(see Tables 1 and 3).

It should be pointed out that no system of surveillance is ever 100 percent complete, but that is not an absolute requirement to evaluate epidemiologically complication rates and preventable factors. Multiple reporting mechanisms are desirable to help ensure more complete ascertainment. Constant stimulation of the relatively few major hospitals, the use of reporting incentives, perhaps death benefits, and feedback of the results of the confidential

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1/ Reporting of deaths in Sri Lanka has been shown to be virtually complete.

inquiry are very likely to improve the system further and win the trust of the medical profession.

III.4.3 Minor Complications

Minor complications likely to be reported following female sterilization are wound infection and small hematomas (see Table 1). For vasectomy, minor complications would include wound infection and small hematomas, epididymitis, small abscesses, granulomas, and sinuses (see Summary Description). The range of minor complication rates following both interventions would reflect surgical skill, operative procedure, sanitation in the general environment, personal hygiene, level of followup, and other hard-to-measure factors that would vary considerably by institution, community, and country setting.

Because these side effects are far more numerous (see Table 1) than major complications, detailed individual reporting would not be practical on a program-wide basis. Some Governmental institutions and the better-staffed non-governmental organizations maintain high followup rates at one week following sterilization and are able to monitor accurately short-term complications. While high followup is desirable, this simply would not be feasible at the majority of Government institutions. It must also be recognized that clients may tend to take their minor problems elsewhere. A system of record linkage would be useful, but it would not be feasible in the near future.

While individual institutions and the non-governmental organizations will continue their informal and formal efforts to monitor minor complications and correct any problems that are detected, what seems needed now are periodic followup surveys based on national samples of sterilization acceptors. Because medical problems seem more likely to arise at the smaller Government hospitals, it is suggested that the acceptor sample be biased toward these institutions. A sample size of approximately 2-3,000 male and female sterilization acceptors should be adequate.

The study design should be organized to encourage acceptor participation, to yield quick feedback to program planners, and to be low cost. Use of a postcard, which should be returned two weeks after the sterilization, would satisfy criteria both of timely response and low cost. For a fixed period of time, all acceptors in the sampled institutions would be given a prepaid postcard to return to the organization doing the research. They would be provided an incentive to return the card; one idea, originated by FPASL, would be a lottery with prizes to be awarded based on a random selection of returned cards. Acceptors who reported that they were healthy, happy, and had not returned to the medical officer for treatment would not need home followup. The minority reporting complications, or a sample of them, would require home followup. The general scheme could be pre-tested for practicability. If promising, it would save money, encourage acceptor participation, and yield quick results. What is desired above all is a speedy, one-time survey with rapid feedback to those concerned with quality and safety so that corrective action, if indicated, can be taken.

Such periodic, practical surveys might consider including questions on client satisfaction with the sterilization procedure, including counseling and

voluntarism. They also should ask for information on educational level and contraception used before surgery. These items are not completely recorded in FHB's routine service statistics and are needed to assess the effects of the out-of-pocket reimbursement scheme and its cost-benefit to the GSL.

In addition to the short-term, rapid followup studies, an argument should be made for a longer, more detailed longitudinal followup of sterilization acceptors. Such a study would involve a panel of acceptors, identified either prospectively or retrospectively from past records. The panel would then be followed at periodic intervals over time. The sample size here might approach 1-2,000 male, and a similar number of female acceptors. The focus of interest would be long-term satisfaction and developmental impact of permanent contraception on the family, as well as short-term complications. Failure rates (see III.4.4.) could also be monitored in this group. Costs will be higher than the short-term studies proposed, and good followup critical to success.

III.4.4 Failure

Pregnancy rates following female sterilization are summarized in Table 4. This is not a frequent event, but the risk continues longer than the risk of medical complications. Failures in Sri Lanka will be minimized by the current widespread use of minilaparotomy with the Pomeroy ligation technique. However, no systematically collected information on failure is available. Since a significant proportion of pregnancies after female sterilization will be tubal (ectopic), which carry increased maternal risk, it may be important to develop such information.

Since delivery in Sri Lanka is highly institutionalized, it should be possible to encourage reporting through a surveillance system using incentives. Delivery personnel will know of cases of failure and should be asked to report each one to a central registry, perhaps maintained by FHB, or another suitable organization. The client's name and address, institution and date of sterilization procedure, and date of last menstural period (if known) or date of pregnancy termination and outcome (live birth, still birth, ectopic, etc.) should be given. The hospital discharge status of the woman should also be recorded.

Ectopic pregnancies will be more difficult to enumerate, but, because of the risk factor, a special effort should be made. It might prove feasible to examine hospital data on ectopics to identify failures, and certainly all maternal deaths certified as due to ectopic pregnancy should be individually reviewed to assess whether the patient had a tubal ligation earlier.

Failure rates should be calculated by standard life table procedures and may be analyzed by institution, surgeon, type of procedure, characteristics of the woman, and other relevant variables. Careful attention to timing will rule out cases where sterilization was done without detecting early pregnancy. This information should be reviewed by the Investigative Committee (see III.4.2.2), or the Evaluation Unit of FHB, to identify any institutional, technical, or other relevant associations.

It is suggested that pregnancies following vasectomy be followed up, if at all, with great care and tact. Pregnancies in the first three months after

vasectomy may be due to residual sperm and failure to use a recommended temporary method. Recanalization may also occur, early and, less commonly, later.[1] Later pregnancies may raise difficult, social problems, particularly if the man is found on examination to be without viable sperm.

III.5 Conclusions and Recommendations

III.5.1 Equipment

As small hospitals provide an increasing number of sterilizations, there is a clear need to determine the availability of equipment in all hospitals throughout Sri Lanka and to decide the level of sophistication which would be practical in the smaller institutions. It is therefore recommended that:

1. SLAVSC, in cooperation with FHB, quarterly, through very short questionnaires and/or by telephone, assess the status of necessary equipment and drugs at the 107 institutions providing sterilization and that considertion be given to computerizing the information gathered.

2. The minimum list of equipment in the SLAVSC booklet "Minimum Medical Standard..." be reconsidered with both safety and benefit in mind by a group of doctors with small- and large-hospital experience.

III.5.2 Training

III.5.2.1. While basic technical training is good, certain areas need additional emphasis. It is recommended that the following areas be improved:

3. Vasectomy training should be provided both to doctors in training and those in practice who have not yet learned this skill.

4. CPR should be a required part of all basic medical training and retraining and posters should be available near every surgical theater.

5. Training must take more account of screening, counseling, and risk/benefit issues.

III.5.2.2 Doctors willing and equipped to perform surgical sterilization are not always available. The following recommendations might improve the situation.

6. Senior and perhaps retired consultants should be available to support and supervise junior physicians at smaller hospitals.

7. A mandatory retraining policy may be necessary for some junior medical officers who have been inactive after their basic training.

8. A revised system may be desirable to anticipate the posting of an untrained officer, or, after arrival, to release him/her for early training.

1/ "Late Failure of Vasectomy, "Editorial, Lancet, pps 794-5, April 6.

III.5.3. Surveillence

Because the Government has no formal means to follow up complications resulting from surgical contraception, a variety of procedures should be instituted, depending on the type of problem. It is recommended that:

9. For the rare case of death or serious morbidity a hospital-based reporting system be instituted, with encouragement for reporting. An independant Investigative Committee should be established to conduct a special confidential inquiry to assess the relationship of the event to the surgical procedure and, if related, its preventability.

10. For the much more numerous minor complications not requiring hospital admissions, short-term followup surveys are recommended biased toward smaller hospitals where problems seem more likely to occur. The study design should be organized to encourage acceptor participation and to yield quick feedback to program planners.

11. For failure, again a rare occurrence, delivery personnel should be encouraged to report all post-sterilization pregnancies. Information could be reviewed by the Investigative Committee (recommendation 9) or the Evaluation Unit in in FHB.

12. More formal, long-term longitudinal studies may be desirable to assess satisfaction and the developmental impact of sterilization on the family.

TABLES AND SUMMARY DESCRIPTION

Table 1: Selected Data on Morbidity Risk Attributed to Female Surgical Contraception[a]

Study/ Country	Total Cases	Complications[b] Major Number	Major Rate/1,000	Minor (and complaints) Number	Minor Rate/1,000
1. Multinational Study, Postpartum mini-incision	1,026	3	3	43	42
2. WHO, Geneva					
a. Minilaparotomy	196	0	0	7	36
b. Culdoscopy	199	6	30	3	15
3. India					
a. Minilaparotomy					
1. postpartum	14,072	26	3	-	-
2. interval	2,824	12	4	-	-
b. Laparoscopy					
1. postpartum	222	5	23	-	-
2. interval	1,391	16	12	-	-

Source: Draft edition, "Sterilization Factbook", Chapter 8, IPAVS, 1984

Note:

(a) The studies listed tend to be small and the complication rates have wide 95 percent confidence limits.

(b) Complications after sterilization undertaken in connection with another surgical procedure, e.g. Caesarian Section, are excluded from this table.

Table 2: Selected Data on Mortality Risk Attributed to Male Surgical Contraception

Study/ Country	Number of Procedures	Number of Deaths	Deaths per[d] 100,000 Procedures
1. Bangladesh			
1/79 - 3/80[a]	22,526	7	31
9/80 - 4/81[b]	14,287	0	0
9/81 - 7/83[c]	170,000	5	3
2. Association for Voluntary Sterilization International Programs 1973-1983	144,844	0	0

Source: Draft edition, "Sterilization Factbook", Chapter 7, IPAVS, 1984

Notes:

(a) Scrotal infection other than tetanus were associated with all deaths. During this time gloves were not usually worn.

(b) This time period followed adoption of recommended aseptic technique, including use of sterile gloves.

(c) This data represents nationally reported complications. Although a death benefit was paid, the completeness of reporting is uncertain.

(d) The 95 percent confidence limits are not given, but will vary widely around the rate estimates, especially when denominators are smal

Table 3: Selected Data on Mortality Risk Attributed to Female Surgical Contraception

Study/ Country	Number of Procedures	Number of Deaths	Deaths per(h) 100,000 Procedures
1. Bangladesh			
1/79-3/80(a)	108,875	21	19
7/79-6/80(b)	5,042	5	99
9/80-4/81(c)	138,745	19	14
12/80-6/83(d)	100,000	2	2
2. U.K.			
4/76-3/77(e)	29,661	3	10
3. India			
9/76-6/78(f)			
a. Minilap, postpartum	14,076	1	7
b. Minilap, interval	2,840	0	0
c. Laparoscopy	2,290	0	0
4. United States			
1977-78(g)	414,513	15	3.6
5. Association for Voluntary Sterilization-International Programs 1973-1983			
a. Minilap	340,024	23	6.8
b. Laparoscopy	266,526	14	5.3

Source: Draft Edition, "Sterilization Factbook", Chapter 7, IPAVS, 1984.

Notes:

(a) This information is from a review of sterilization attributable deaths in 2 of the 4 divisions of Bangladesh.

(b) This data is from a prospective study in 41 Government and private centers. Four deaths were due to over sedation. One was due to aspiration pneumonia.

(c) From a review of all sterilization-attributable deaths reported in Bangladesh. The main causes were anesthesia overdose and tetanus.

(d) Review of deaths in 25 clinics in the Bangladesh AVS system. One death due to anesthesia, the other due to tetanus.

(e) One year prospective survey of laparascopic procedures.

(f) This data is from a prospective study in 13 teaching hospitals sponsored by the Indian Council of Medical Research.

(g) This study stimated deaths occurring only during hospitalization for female sterilization. The fifteen deaths are based on 9 reviewed deaths attributable to surgical contraception and 6 unreviewed deaths assumed to be attributable.

(h) The 95 percent confidence limits are not given, but will vary widely around the rate estimates, especially when denominators are small.

22

Table 4: Selected Data on Failure Rates Following Female Sterilization by Approach, Method of Occlusion, and Timing

Study/ Country	Number of Women	Number of Pregnancies	Crude failure rate per 100 procedures	Life Table failure rate per 100 women[a] 12 mo	24 mo
1. Singapore					
a. Minilap	7,989	-	-	0.2	0.3
b. Laparascopy	221	-	-	3.6	4.5
2. Family Health International-Multinational Study I					
a. Laparascopy(ring)					
1. Interval	3,091	14	-	0.5	-
2. Postpartum	295	3	-	1.5	-
b. Minilap(Pomeroy)					
1. Interval	1,682	5	-	0.4	-
2. Postpartum	182	0	-	0.0	-
3. India					
a. Minilap	10,141	11	0.1	-	-
b. Laparoscopy	850	5	0.6	-	-

Source: Draft Edition, "Sterilization Factbook", Chapter 8, IPAVS, 1984

Note:

(a) The Life table method is preferred over crude failure rates, but not all studies use it.

Summary Description

Selected International Data on Complications Following Vasectomy[a]

Hematoma - less than 10 per thousand procedures in most series, but as high as 40 in others (1 to 4 percent).

Wound infection - less than 20 per thousand procedures in some reports but as high as 60 in other series (2 to 6 percent).

Epididymitis - less than 10 per thousand procedures to 15 in other series using controls (non-vasectomized men for comparison). (1 to 1-1/2 percent)

Granulomas - from less than 10 to 30 per thousand procedures. (1 to 3 percent).

(a) Source: Draft edition, "Sterilization Factbook", Chapter 8, AVS, 1984, and Population Reports, Series D, Number 4, November-December 1983. Johns Hopkins University.

APPENDICES

APPENDIX A

ITINERARY

3/20/85 - Arrival; Discussions with Population Division, MOPI; Briefing at USAID, Colombo.

3/21/85 - Further discussions with MOPI, including representatives of the FHB, USAID, SLAVSC, and other non-Governmental agencies. Meet with Secretary, MOPI.

3/22/85 - (1) Meeting at FHB, MOH

(2) Meeting at SLFPA

3/23/85 - Meeting at CDS

3/24/85 - Departure to Kandy. Discussions on arrival with SLAVSC staff and an evening meeting later to review preliminary findings and share opinions.

3/25/85 - (1) Visit Kandy General Hospital

(2) Visit SLAVSC Training Center

(3) Departure to Matale. En route, visit Akurana D.H.

(4) Briefing with G.A., Matale, and visit Matale B.H.

3/26/85 - (1) Visit Kerkirawa D.H.

(2) Briefing with A.G.A., Anaradhapura, and visit Anaradhapura B.H.

(3) Visit Galnewa D.H.

(4) Visit Galawewa P.u.

3/27/85 - (1) Visit Maho D.H.

(2) Briefing with Integrated Rural Development Project and G.A., Puttalam.

(3) Visit Puttalam D.H.

(4) Return to Colombo

3/28/85 - (1) Visit Colombo Municipal Clinic at Bandaranaike Maternity Home.

(2) Discussion with Dr. Navaratne, Prof. of Surgery, Faculty

of Medicine, Colombo.

(3) Briefing at USAID

(4) Discussion at FHB, MOH

3/29/85 - (1) Briefing with Senior Advisor, UNFPA

(2) Seminar/Discussion at Population Division, MOPI

(3) Meeting with Secretary, MOPI

3/30/85 - Report drafting

3/31/85 - (1) Report drafting

(2) Meeting with Director (MCH), FHB, MOH

(3) Departure to US, (4/1)

Appendix 'B'

NATIONAL FAMILY HEALTH PROGRAMME - DECLARATION OF CONSENT FOR STERILIZATION

I, the undersigned .....

aged ..... years and residing at .....

request that a Vasectomy/Tubectomy be performed on me.

I certify that I understand the following:

(a) Sterilization is a permanent method of contraception and after a successful operation I will not be able to have any more children.

(b) Sterilization is a surgical procedure, and the details of the procedure, attended discomforts, possible risks, and the benefits to be expected have been explained to me by Health Personnel.

(c) Sterilization operation is irreversible.

(d) There are temporary methods of contraception I can use instead of sterilization for planning my family.

I have ..... living children and the age of my youngest child is ..... years ..... months.

I have applied for sterilization on my own free will without any coercion or inducement. I can change my mind at any time and decide against the sterilization procedure.

Date: Signature of Accepotr

I understand the above and hereby declare my consent.

Date: Signature of Spouse

I certify that the contents were explained and the client understands them fully. Signed before me on .....

Place: Signature, Name & Designation of Authorised Officer

Date:

Authorised Officers to attest the signature of the couple:

Medical Officer, Registered Medical Practitioner, Assistant Medical Practitioner, Public Health Nursing Sister, Public Health Inspector, Health Education Officer, Public Health Midwife, Registered Ayurvedic Practitioner, Assistant Government Agent, Development Officer, Vishesha Seva Niladari, Grama Seva Niladhari, Employee of Government, State Corporation or Local Authority drawing a salary not less than Rs. 1,000/- per month, Attorney at-Law or Justice of Peace, Member of Municipal/Urban Council, District/Divisional Development Council, Superintendent, Assistant Superintendent, EMA or Registered Midwife of an Estate, Executive of a recognised Commercial, Industrial or Voluntary Organization.

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.

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

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.

☐ Laparoscopy ☐ Culdoscopy
☐ Mini-Laparotomy—interval ☐ Colpotomy
☐ Mini-Laparotomy—post-partum ☐ Vasectomy
☐ Laparotomy—interval

10. What type of anesthesia did you use?

☐ Local ☐ Regional ☐ General

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 abcess
   ☐ 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.)

_____
(Signature of Project Director)

Appendix C

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.

To:

DIRECTOR, IPAVS
708 Third Avenue 19th Floor
New York, N.Y. 10017
Attn: Med. Division

From:

(Name of Project Director) _____
(Name of Project) _____
(Address of Project) _____
(Sub Grant Number) _____

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 ☐ I U D ☐ Orals ☐ Condom ☐ Withdrawal/Rhythm
☐ Foam/Diaphragm ☐ Other Specify: _____

6. FACILITY

☐ Hospital ☐ Hospital Clinic ☐ Multi purpose Clinic ☐ Single Purpose Clinic

7. EQUIPMENT AVAILABLE IN FACILITY

☐ Oropharyngeal airway
☐ Ambubag (Manual resuscitation bag)
☐ Laryngoscope
☐ Endotracheal tubes
☐ Suction apparatus
☐ Oxygen tank
☐ Standard laparotomy tray
☐ Intravenous fluids and/or plasma volume expanders
☐ Antidotes for treating narcotic overdose or adverse reactions to anesthesia or other drugs
☐ Anesthesia machine

8. STERILIZATION PROCEDURE

Type of procedure: ☐ Inpatient ☐ Outpatient

Anesthesia: ☐ Local ☐ General ☐ Regional ☐ Other Specify: _____

Technique:

☐ Mini-laparotomy	☐ Laparoscopy	☐ Colpotomy	☐ Culdoscopy
☐ Pomeroy	☐ Ring	☐ Pomeroy	☐ Pomeroy
☐ Ring	☐ Coagulation	☐ Ring	☐ Ring
☐ Other	☐ Clip	☐ Other	☐ 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)