

**Safety of
Voluntary
Surgical
Contraception**

**Report of an
Expert Committee
Manila
May 9-12, 1983**



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

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Introduction

Voluntary surgical contraception (VSC) is a medical and family planning service that is steadily gaining in popularity, both in the developed and the developing world, including rural areas where other forms of surgery are rare. Fortunately, the procedure is one of the safest contraceptive methods available. Nevertheless, because surgical contraception is an elective procedure and because its acceptance depends upon quality medical services, program leaders must take every possible measure to ensure high standards of care and safety.

In Asia, where national family planning programs are well established, service providers have had many years of experience safely delivering voluntary surgical contraception. To take advantage of this wide expertise, the Asian Regional Association for Voluntary Sterilization and the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception convened an expert committee meeting on the safety of voluntary surgical contraception.

The purpose of the meeting was to examine the experience of a number of Asian countries in providing safe male and female VSC services and to develop recommendations for quality assurance that would be useful for other Asian countries as well as other regions of the world.

The Expert Committee met from May 9-12, 1983, in Manila. The meeting was hosted by the Philippines Association for the Study of Sterilization. Thirty-three experts participated, representing 11 Asian countries, several international health and family planning organizations, and three additional countries – Egypt, Mexico, and the United States. Background materials for the meeting included a bibliography of more than 90 scientific and technical articles and 14 country reports.

Dr. C. S. Dawn of India and Dr. Azizur Rahman of Bangladesh served as committee co-chairpersons.

Several specific issues of concern were addressed in four different task forces, which met separately for two full days. The four task forces were:

1. Preoperative Medical Evaluation, Postoperative Follow-Up, and Variations in Vasectomy Techniques
2. Safety Issues of Specific Female Surgical Procedures
3. Anesthesia, Asepsis, and Emergency Procedures
4. Program Monitoring and Supervision

This report presents the recommendations of the committee's four task forces. Throughout the meeting, the emphasis was on the safety of female VSC techniques, although vasectomy techniques were discussed briefly. The

reader who is interested solely in vasectomy may omit Chapters 2 and 4 which deal exclusively with female procedures.

The Committee has attempted to formulate practical guidelines that can be widely used in voluntary surgical contraception programs in both urban and rural settings. While the Committee prefers to establish standards that represent the best and safest that modern medicine has to offer, it recognizes that the personnel, equipment, resources, and infrastructure to support this ideal are not always available. The standards recommended in this book are those which, the Committee believes, will safely serve the largest number of clients under the conditions that typically prevail in the developing world.

Programs may need to adapt these guidelines according to the circumstances in which services are provided. The Committee affirms that all persons involved in the delivery of VSC services must always aspire and attempt to achieve the best possible conditions and standards. In every instance, the safety of the client should be the primary consideration.

The work of the Expert Committee on Safety and the contents of this report were approved by the World Federation's international membership at its Eighth General Assembly on December 8, 1983, in the Dominican Republic.

Highlights of the Recommendations

The Expert Committee on the Safety of Voluntary Surgical Contraception established these guidelines and recommendations for health and family planning program administrators, government officials and policymakers, hospital administrators, administrators of medical schools and other training institutions for health professionals, private practitioners, and international donor organizations.

Preoperative Medical Evaluation

Service providers should conduct a preoperative medical evaluation to determine each client's fitness for voluntary surgical contraception (VSC) and to ensure that he or she does not have a condition that unduly increases the risk of contraceptive surgery. The evaluation should include a medical history, physical examination, and appropriate laboratory investigations. The more remote the facility, the more rigorous the evaluation should be.

A number of conditions may indicate VSC for health reasons. VSC should be considered when all other contraceptive methods are contraindicated and when other obstetrical or medical conditions pose serious risks for a woman if she were to become pregnant. Although such conditions may themselves increase the risks of VSC, the operator needs to weigh the relative risks of pregnancy and surgery. In all such

cases, the procedure should be performed by skilled surgeons and in fully equipped facilities with complete emergency equipment and back-up services.

Preoperative Instructions

To enhance the safety of surgery and to reassure the client, every VSC client should receive preoperative instructions. These instructions should be given in a language that the client easily understands and should include the following:

How to prepare for surgery

How to care for the wound and to use any medications prescribed after surgery

Common postoperative complications, including any pain or discomfort the client may experience

What to do and where to go if an emergency arises

Male clients should be told that they must use temporary contraception after surgery for at least 15 ejaculations.

Surgical Techniques

Vasectomy is the safest voluntary surgical contraception procedure. Every effort should be made to stimulate the development and implementation of national programs offering vasectomy.

Minilaparotomy is considered the safest female VSC technique in the context of prevailing conditions in developing countries. Most complications from the procedure are minor (see page 20) and usually can be managed if the client has been properly screened and the operator and surgical team have been adequately trained. Given its safety, simplicity, effectiveness, and general lack of major complications, minilaparotomy is an appropriate technique for national VSC programs in both urban and rural areas.

Laparoscopy is a safe interval procedure. However, rare complications can be life threatening. Therefore, the procedure should be performed by well-trained and skilled surgeons who are fully aware of the specific risks inherent in the procedure, the precautions necessary to avoid problems, and the actions to take if complications arise. In addition, laparoscopy should be performed in facilities well equipped for life-threatening emergencies.

Postpartum VSC should be included in permanent contraception service delivery. Because of the anatomical and physiological changes of the postpartum woman, the procedure should be performed

within one week of a vaginal delivery, preferably between the first 12-48 hours. Minilaparotomy is considered the most appropriate approach.

Training in Techniques for Surgical Contraception

Training institutions for VSC techniques should meet accepted medical standards, should be fully equipped to immediately handle surgical and anesthesia-related complications, and should have sufficient case loads to ensure that trainees have the opportunity to perform an adequate number of procedures in a relatively short period of time.

The trainer should be qualified and competent in the VSC technique that he or she is teaching and should have extensive experience in both that procedure and in all aspects of VSC service delivery.

Trainees should be selected according to established criteria (see page 27). Wherever possible, laparoscopy training should be complemented by training in minilaparotomy.

Certificates should be issued to all candidates who successfully complete training and who have been judged competent in the specific surgical technique and in all aspects of VSC service delivery.

Anesthesia

Serious problems more often occur with general and regional anesthesia than with properly administered local anesthesia. Therefore, national VSC programs that have different grades of skilled personnel and surgical facilities should adopt a local anesthesia regimen as the norm to minimize complications. The Committee has developed guidelines for local anesthesia techniques and dosages for minilaparotomy, laparoscopy, and vasectomy; they are outlined on pages 31-32.

It is imperative that VSC personnel be fully trained and equipped to identify and manage anesthesia-related complications, including respiratory and cardiovascular problems. Surgical personnel should routinely monitor the client for anesthesia-related complications before, during, and after surgery.

Resuscitation and Emergency Equipment

For all female VSC procedures, the following equipment should be available for managing complications:

Anesthesia mask and self-inflating bag with oxygen nipple

Oxygen tank with reducing valve, flow meter, tubing, and mask

Suction machine with tubing and two traps

Nasal airways (two sizes)

Oral airways (two sizes)

Intravenous fluids and drugs

Abdominal surgery kit

All equipment should be complete, sterilized, and in good functioning order.

Wherever trained personnel are available, a laryngoscope and a set of different-sized endotracheal tubes should be at hand for every female VSC procedure. However, if personnel have not been trained in intubation, oral airways and manual respirators with face masks are the preferred resuscitation equipment.

Asepsis

Meticulous aseptic techniques and standards are mandatory for all voluntary surgical contraception programs. Asepsis is essential for the client, service personnel, and the facility before, during, and after surgery. VSC training, program monitoring, and supervision should stress aseptic techniques and standards.

Nonlaparoscopic equipment and linen should be sterilized in an autoclave. The Committee recommends methods for sterilizing and disinfecting which are outlined in Table 7.1.

Postoperative Care and Follow-Up

The medical team should monitor vital signs for female clients at least one hour after surgery. The same applies to male clients if sedation has been used; otherwise, men who have undergone vasectomy may leave the clinic after half an hour.

Before the female or male client is discharged, and after the effects of sedation have worn off, trained staff should repeat all preoperative instructions related to postoperative concerns and care, and should schedule a follow-up examination, if necessary.

The woman should return for a follow-up examination within seven to fourteen days after surgery.

The medical team should offer male clients at least one routine follow-up examination. Seminal analysis should be available for all men who request it.

Program Monitoring and Supervision

To assure and improve quality of services, countries with VSC programs should establish national monitoring and supervision systems. The essential elements of an effective monitoring system are simple and easy-to-complete data collection instruments; efficient analysis of data; rapid feedback of analyzed data to health care workers and training programs; supervision of facilities and supplies; and rapid correction of problems, including the identification of personnel who need further training.

The cost of the monitoring and supervision system should be part of the total cost of the VSC program and should be included in routine budgetary calculations.

At the national level, associations for voluntary sterilization, whether they provide services or not, should encourage and support the development of national monitoring and supervision systems aimed at ensuring safety and improving quality services. The World Federation is encouraged to assist them in this task.

At the international level, the World Federation should initiate and encourage the development of uniform data collection instruments to allow collation and comparison of worldwide data.

**Expert
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the Safety of
Voluntary
Surgical
Contraception
May 9-12, 1983**

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The World Federation and the Asian Regional Association for Voluntary Sterilization wish to thank these individuals for their active participation in this project.

The World Federation is a consortium of leadership organizations that share a dedication to the inclusion of voluntary surgical contraception as a basic component of health services. The Asian Regional Association for Voluntary Sterilization is a regional member of the Federation. As one of its major program priorities, the World Federation works to establish standards and guidelines. We look forward to publishing other documents similar to this report in the future.

Beth S. Atkins
Executive Secretary
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Advancement of Voluntary Surgical Contraception

Preoperative Medical Evaluation

Preoperative evaluation is an opportunity to do an overall health screening, a factor of considerable importance in countries where many people rarely visit health facilities. Thus, the Committee has attempted to be thorough. However, lengthy questioning and examination of the client are often impractical and can even alarm the client if not handled properly.

All recommendations regarding preoperative medical evaluation and postoperative follow-up assume the following general conditions:

The client has provided informed, voluntary consent.

The more removed the facility is from established medical centers, the more rigorous the evaluation process should be. Because remote facilities usually do not have a full range of emergency equipment and services, it is essential to identify, during the evaluation process at these sites, those clients who have conditions that may increase the risk of surgery. The medical team must determine if such clients can safely undergo surgery in the remote facility, or if they require the complete emergency systems provided by an established medical center.

The decision to operate must be based on the client's total profile, including medical, social, and cultural factors.

The overall objectives of the preoperative medical evaluation are to determine the client's fitness for voluntary surgical contraception and to identify any conditions that may increase the risk of VSC.

It is desirable that a physician conduct all preoperative medical evaluation. However, under some circumstances a trained paramedic may carry out preliminary screening (in particular, the medical history), using a checklist prepared by a physician. The paramedic must be trained to detect any abnormalities or contraindications and to report them to a physician. The final decision to offer voluntary surgical contraception to the client is the responsibility of the physician. After reviewing the client's history, the physical findings, and the client's suitability, the operator conducts a final assessment, immediately before surgery.¹

The final evaluation should take place where the procedure is to be performed. Preliminary screening can be done in other places, such as the client's home or at a local health center.

¹The World Federation Policy Statement on the use of paramedics in VSC specifies that the physician may delegate the responsibility for

Medical History

The Committee recognizes that the medical history may be taken at different times and by individuals with different levels of training and expertise. If trained paramedics record the history, they should use a checklist, designed by one or more physicians, to elicit some of the information described below. Such a checklist can be written in simple language that describes physical symptoms indicating serious medical conditions. The completed checklist should be evaluated by a physician who should, if necessary, question the client further, examine him or her, and then determine if VSC is appropriate. (See note on page 13.)

For both sexes, the medical history should contain such general information as age, occupation,² education,³ number of children, age of last child, and family health history.

For female requestors, the medical history should also record incidence of any of the following: heart disease, hypertension, anemia, diabetes, pelvic or abdominal surgery, pelvic inflammatory disease, vaginal discharge, bladder disorders, convulsive disorders, psychiatric conditions, active tuberculosis, bleeding disorders, drug addiction, and allergies to medications. The history should document the obstetrical record (e.g., pregnancies, miscarriages, deliveries), menstrual pattern and date of last menstrual period, previous and current use of contraceptive methods, obesity, and the drugs the client is presently taking.

For vasectomy requestors, the medical history should also record the incidence of conditions such as bleeding disorders, scrotal or inguinal surgery, scrotal abnormalities, asthma, convulsive disorders, fainting spells, psychiatric conditions, and allergies to medications.

deciding to perform VSC and for performing the procedure to a paramedic if a number of conditions are fulfilled:

The paramedic should be qualified and trainable.

The paramedic should not perform endoscopic procedures.

Good training is a prerequisite.

Under all circumstances, paramedics should work only in suitable settings, and qualified physicians should always be available when needed.

²Occupation may indicate the type of physical activities that are routinely performed by the client (a factor affecting postoperative instructions). Such information may also be useful when analyzing client data and when determining trends on local, regional, or national levels.

³Education frequently indicates level of literacy (a factor in counseling and instructing the client).

Physical Examination

For both sexes, the examination should include the following: blood pressure, pulse, auscultation of heart and lungs, examination of the local operative area, evaluation of the client's nutritional status, and other examinations as indicated by the medical history.

For female requestors, the examination should also include weight, abdominal palpation, pelvic examination (the size and position of the uterus), and breast examination. If the woman and her partner have not been using contraception or if the medical team believes there is a chance of pregnancy, standard pregnancy tests should be conducted.

In the event of positive findings during the examination, the physician may need to consult a specialist before deciding to operate. If the client is judged unsuitable for surgery for medical reasons, he or she should be referred for a complete evaluation of the condition identified in the examination. In such cases alternative contraceptive methods should be recommended and, if possible, provided.

Health Considerations in the Preoperative Screening Process

Female Procedures

Pelvic infection is an absolute temporary contraindication to VSC. If infection is the only problem, the woman should be treated for the infection and provided with a temporary contraceptive method. After the infection has been controlled, surgery may be performed in either a stationary or mobile clinic.

The following conditions may increase the risks of voluntary surgical contraception:

- Heart disease
- Irregular pulse
- Hypertension (should be controlled before surgery)
- Mass in the pelvic area
- Uncontrolled diabetes
- Bleeding disorders
- Pregnancy
- Severe nutritional deficiencies
- Severe anemia
- Uncertainty of the client regarding surgery

Some additional screening considerations apply to postpartum clients. If surgery immediately after delivery will increase the risk of complications, VSC should be deferred to the interval period. Some considerations for the postpartum woman are:

- Puerperal fever
- Prolonged rupture of membranes
- Hypertensive states
- Eclampsia
- Antepartum or postpartum hemorrhage
- Trauma to the genital tract
- History of previous postpartum psychoses

If the woman has a condition that may increase the likelihood of complications, the physician needs to determine if the risk of pregnancy is greater than the risk of surgery. He or she should weigh all of the factors involved, such as the woman's circumstances and the availability of specialists and equipped facilities. In all cases with increased risk, the procedure should be performed in a fully equipped facility with complete emergency equipment and back-up services. If surgery is postponed, temporary contraception should, of course, be provided.

VSC may also be considered when all other contraceptive methods are contraindicated. In some cases, depending on the particular circumstances, a couple may be advised to consider vasectomy instead of female VSC.

Male Procedures

For vasectomy, the following are temporary or relative contraindications:

- Infection in the operative area
- Large hydrocele
- Elephantiasis
- Local pathological conditions
- Severe anemia
- Bleeding disorders

In some cases vasectomy may be impractical or unsafe, depending upon the circumstances. The physician and the client must weigh the risks of the procedure against its benefits.

The Committee stresses that the man be told voluntary surgical contraception does not affect potency or normal sexual functioning. He should also understand the possibility and consequences of failure (i.e., pregnancy) and the importance of using temporary contraception until azoospermia is attained.

In addition, during counseling, staff members must be able to identify men who are indecisive, doubtful about

undergoing surgery, or concerned about reversal. Such clients should be advised to reconsider. It may be necessary to obtain additional professional evaluation for such men.

Nonmedical Contraindications

Both male and female clients should be told to consider the operation permanent. VSC should be postponed or discouraged if the client is uncertain or has unresolved concerns regarding acceptance of the procedure. Temporary methods should be made available to these clients.

Youth itself is not a contraindication to VSC as long as the client is of legal age. The operator should be aware, however, that young clients (both male and female) are more likely to be uncertain about the procedure. In some countries it is advisable that the woman have at least two children, the youngest being no younger than six months of age.

Laboratory Investigations

For all VSC procedures, laboratory tests for anemia and diabetes (hemoglobin, urinalysis for sugar) should be routine. Any other appropriate investigations should be conducted if indicated by the medical history or physical examination.

In postpartum cases, standard laboratory investigations should be conducted as a routine part of pregnancy, labor, and delivery care.

In interval cases, depending upon specific indications, the physician should conduct other appropriate investigations (e.g., pregnancy test if pregnancy is considered a possibility, chest x-ray in cases of suspected tuberculosis).

Western standards for hemoglobin levels (e.g., 10 grams) are usually inappropriate in developing countries. Practitioners should set their own standards based upon the hemoglobin levels and nutritional profiles of their clients. The Committee notes that some programs in Asian countries have set a level of seven grams as the minimum safe level required before surgery can be performed.

Positive laboratory findings should be considered when determining whether the surgery is to be performed, who performs the surgery, and where it should be performed.

Consent

In the interest of marital harmony, it is advisable to counsel both partners and to receive written consent from both of them, in person, after counseling. If this is not possible or practical, the client should be encouraged to discuss the decision with the spouse, before surgery.

**Timing of
the Procedure**

For the healthy male or nonpostpartum female client with no contraindications, surgery should be offered as soon as convenient for the client. Because of transportation and other problems, in many countries it is impractical to require a waiting period between counseling, evaluation, and surgery. In postpartum cases, surgery may be performed immediately after delivery, provided there are no complications.

**Preoperative
Instructions to the
Client**

Preoperative instructions are important to ensure the safety of VSC and to inform and reassure the client. Staff members should provide all information in language the client can easily understand. In postpartum cases, instructions should be given before delivery whenever possible. The following points are essential for all clients:

The steps of the operation

Instructions for wound care

Where to go if complications arise

How to use any medication prescribed after surgery

To prepare for the operation, all clients should bathe and preferably shave the pubic area. The woman may be shaved at the facility. In any case, shaving should be done less than six hours before surgery. If possible, clients should bring someone with them to accompany them home after the operation.

The female client should be told to fast after midnight before surgery. She should know the common likely postoperative complications and what to do in each case. The health-care worker should tell the woman what pain and discomfort she might experience and when she can return to work and resume sexual relations.

The male client should be asked to bring clean scrotal support, if none is provided. He may resume sexual relations as soon as he feels comfortable. The physician or counselor should describe how the surgery becomes effective, emphasizing that some sperm remain for a period of time after the operation. Some form of contraception, either male or female, is required for at least 15 ejaculations (Freund and Davis, 1969; Marshall and Lyon, 1972; Brownlee and Tibbels, 1983). The health-care worker should provide condoms and, if necessary, explain how to use them.

If appropriate, the counselor or physician may tell the client that reversibility is possible but that success cannot be guaranteed.

Specific Techniques for Female Voluntary Surgical Contraception

To ensure the safety of all women undergoing contraceptive surgery, it is of utmost importance that:

The surgeons and staff are well trained and skilled in the techniques they are using, in emergency abdominal surgery, and in the management of other emergencies.

The facility is well equipped with drugs and equipment to handle life-threatening situations and other emergencies.

All instruments and equipment are in optimum working order and are checked before the start of the surgical procedure.

Strict asepsis is maintained (see Chapter 7).

Clients are carefully screened and selected in order to identify any conditions that may increase the risk of the procedure (see Chapter 1).

There is an adequate volume of procedures so that the operator and the surgical team can maintain their skills. (However, a single operator should perform no more than 10-15 procedures in one session.)

In addition, when laparoscopy is performed, proper endoscopic equipment must be well maintained, and a trained anesthetist must be available.

Minilaparotomy

Minilaparotomy (minilap) is a modified and simplified version of conventional laparotomy. The approach was developed so that VSC services could be safely provided on a large scale and at minimal cost. Minilaparotomy is both safe and effective and may be used for interval and postpartum surgical contraception. It can be performed on an outpatient basis under local anesthesia and requires little surgical time.

Based on the experience of the participating experts, the Committee considers minilaparotomy the safest female VSC approach. Considering the prevailing conditions in a region like Asia, and given the safety, simplicity, and effectiveness of this approach, the Committee recommends minilaparotomy as appropriate for national VSC programs, particularly for rural areas. The most relevant advantages of the approach are as follows:

Minilaparotomy has a low complication rate; most importantly, it has a low rate of serious complications.

The equipment is simple and inexpensive and can be maintained easily.

Physicians who are not highly specialized can learn the approach in a short period of time and can perform it effectively.

Sophisticated facilities are not required.

Variations in the minilaparotomy approach make little difference for client safety if the operator is properly trained:

The incision of approximately 2.5 cm can be either transverse or longitudinal.

Depending on the preference and skill of the operator, the procedure can be performed with or without the uterine elevator or abdominal retractor.

Skin closure may be performed with absorbable sutures if no follow-up is anticipated. However, if the woman is likely to return after a week, nonabsorbable sutures should be used.

The operator should not manage associated pathology at the time of the procedure unless doing so is in the best interest of the woman's health.

Complications of Minilaparotomy

In general, serious complications are rare and the mortality rate of minilaparotomy is low. When complications do occur, they are usually minor¹ and can be readily managed, if the operator and the surgical team are adequately trained and if the client has been screened properly. The complications of minilaparotomy can be compared to those associated with similar surgical procedures; they are mainly of the following nature:

Bleeding from an abdominal wound or from the mesosalpinx

Visceral injuries: uterine or bladder perforations, intestinal injuries

Infections of the incisional wound or pelvic cavity

¹The World Federation has defined a minor complication 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. See *Standard Terms for Voluntary Surgical Contraception*, published by the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception, New York, 1983.

Postpartum Female Voluntary Surgical Contraception

The Committee recommends that postpartum surgical contraception be included in VSC programs. The period after the birth of a child may be the most convenient time to perform the procedure for both the client and the service providers. However, the decision for postpartum VSC should, to the extent possible, be made before the onset of labor. The Committee recommends that information about postpartum surgical contraception be included as part of routine antenatal counseling and that existing community health workers and facilities be used to provide that information. The postpartum procedure should be performed at the facility where delivery takes place.

Bearing in mind the anatomical and physiological changes of postpartum women, the Committee makes the following recommendations to ensure the safety and success of the surgery:

The procedure should be performed within one week of vaginal delivery, preferably between the first 12-48 hours. At this time, the fundus is at, or a little above, the umbilicus, permitting an easier subumbilical incision. Also, an unnecessary long hospital stay is prevented, and early ambulation is achieved.

The approach should be minilaparotomy using a small incision (approximately 2.5 cm), either longitudinal or transverse subumbilical at the level of the fundus (World Health Organization, November 1982). The operator should open the fascia and peritoneum carefully because of the proximity of the bowel.

The equipment used to pick up the fallopian tubes should be appropriately sized and atraumatic. Retractors, a proctoscope, or the index finger can be used with manipulation of the incision. The operator should handle the tubes gently to prevent bleeding. To maintain exposure of the tube, the operator may place external pressure on the abdominal wall to manipulate the uterus.

The method of tubal occlusion should be tubal ligation and resection (commonly known as Pomeroy: ligation of a loop of the mid-third of the tube with absorbable catgut and resection of the top of the loop). Adequate hemostasis is essential before returning the tube to the abdomen.

The procedure should be performed under local anesthesia with light sedation.

Laparoscopy

Laparoscopy² is generally considered a safe approach for voluntary surgical contraception and is available to any gynecologist-obstetrician, general surgeon, or physician willing to undergo additional training. It is effective and can be performed safely as an interval procedure or after an uncomplicated first trimester abortion.

Like minilaparotomy, laparoscopy requires little surgical time and can be performed on an outpatient basis under local anesthesia. Laparoscopy is acceptable to requestors because it causes minimal discomfort to the client and leaves no visible scar. The equipment necessary for performing laparoscopy can also be used for endoscopic diagnosis.

Compared to minilaparotomy, laparoscopy is a more complex art which requires much skill and versatility in the use of optics, light sources, electric current, gas insufflation, and an array of rapidly changing and improving instruments. As new instrumentation and more complex procedures evolve, the list of reported serious complications increases. Laparoscopy is not for every physician.

Laparoscopy has several disadvantages that should be considered, particularly in developing countries. The risk of mortality is greater than with minilaparotomy because complications may be life threatening. Therefore, a standby anesthetist is required at all times, and the surgeon must have an aptitude for endoscopy as well as extensive training and experience in abdominal surgery. Finally, the equipment used for laparoscopy is expensive, requires maintenance, and needs a continuous supply of spare parts.

Complications of Laparoscopy

Complications can occur during any part of the procedure or become manifest after surgery; they can range from inconvenience to death of the client. Contributing factors can be associated with anesthesia, instruments and equipment, characteristics of the client, and the level of skill possessed by the surgeon and the surgical team (Chaturachinda, 1983). The most serious complications are discussed below, along with measures that can be taken to prevent them.

²Since open laparoscopy is not practiced extensively in Asia, the Committee did not discuss this technique. Editor's Note: "Open laparoscopy . . . is essentially a combination of minilaparotomy and laparoscopy. The abdomen is entered surgically either through or slightly below the umbilicus, and the laparoscope is inserted through this small defect" (Grimes, 1981, p. 375). This technique is particularly suitable for free-standing facilities and local anesthesia. For more information see the forthcoming *Biomedical Bulletin* published by the Association for Voluntary Sterilization, 122 East 42nd Street, New York, NY, USA.

Safe Practice of Laparoscopy

Trendelenburg Position: To avoid hypotension and possible cardiac arrest resulting from the creation of pneumoperitoneum, the client should be in the Trendelenburg position (not exceeding 15 degrees) before pneumoperitoneum is induced.

Pneumoperitoneum: To avoid, or reduce, the risk of bowel perforation, pneumoperitoneum should be sufficient to separate the anterior abdominal wall and bowel. The operator should introduce the least possible amount of gas (less than one liter), under minimal pressure (not exceeding 20 mm of mercury) through a gas meter. Gas should never be given directly from the cylinder.

Embolism does not occur unless gas is introduced directly into the vascular system. To avoid gas embolism, the instrument used to introduce the gas should be a sharp outer needle with a blunt obturator, such as the Veress needle. The operator should take care not to insert the tip of the needle into a vessel.

The Committee does not recommend nitrous oxide for laparoscopy because of its cost, its limited availability, and the increased chance of combustion (Gunatilake, 1978). Either carbon dioxide or room air are appropriate for establishing pneumoperitoneum (Laufe and Atwood, 1980).

Introduction of Trocar: To avoid injury to large vessels, equipment should be in good functioning condition; specifically, the trocar should be sharp. The skin incision should be large enough to let the trocar sleeve pass through without difficulty, but small enough to prevent leakage of gas. The operator should introduce the trocar at the appropriate angle in the midline position, directed toward the hollow of the sacrum. Particular care is needed with thin clients. The operator should lift the abdominal wall away from the gut manually or by appropriate instrument.

Tubal Occlusion Methods: In view of the complications associated with electrical methods (e.g., visceral burns), the Committee recommends mechanical tubal occlusion.

If tubal rings are used, three precautions will help prevent tubal or mesosalpingeal hemorrhage.

1. At all times, the operator should move slowly and smoothly to draw the tube into the sleeve (cylinder) of the laparoscope.
2. The operator should avoid pulling up and back on the scope or applicator; these motions cause the tube and mesosalpinx to be unduly pulled and lifted, and hemorrhage can result. Rather, the

operator should move the instrument slowly and smoothly toward the tube. The scope should approach the tube; the operator should not make the tube approach the scope.

3. If the tubes are thick or fixed, the operator should not use tubal rings for occlusion.

If electrical methods are used, available data suggest that bipolar equipment is safer (Riedel and Semm, 1982). While electrocoagulating, the operator should be particularly careful to avoid inadvertently touching the bowels or other visceral organs. Furthermore, the Committee recommends that the tube not be divided (i.e., the surgeon should use a "burn only" procedure).

Gas explosion is a rare complication. Because the reason for explosion is unknown, no specific prevention is possible. However, if electrical methods are not used, there will be no explosion. A flammable gas mixture should never be used. Local anesthesia does not produce an explosive mixture of gases. However, to reduce the chance of contamination by flammable agents, gas for pneumoperitoneum should not be introduced through the anesthesia machine.

Equipment for Laparoscopy

A properly maintained laparoscope is essential to the client's safety. The Committee advises the following:

Sufficient spare parts should be available in-country.

Repair and maintenance capabilities should be available in-country.

Programs should have operational and effective systems both for routine maintenance and for emergency service when equipment problems arise.

Personnel should be trained how to properly handle and maintain laparoscopic equipment.

Appropriate cold solutions (such as Cidex, Savlon, or quarternary ammonium compounds) should be available to disinfect the laparoscope (see Table 7.1).

Adequate time should be allowed between procedures to disinfect the laparoscope (see Table 7.1).

Failure of Female VSC Procedures

After a VSC procedure, service providers must be aware that ectopic or intrauterine pregnancy is possible; they must be prepared to identify such conditions early. Symptoms such as lower abdominal pain, amenorrhea, or

abnormal uterine bleeding are prominent features of an ectopic pregnancy. If pregnancy, particularly ectopic, is suspected, the woman should be referred immediately to a physician for diagnosis and treatment.

Recent data indicate that mechanical occlusion methods have a slightly greater risk of failure (i.e., pregnancy) than electrical methods (Bhiwandiwalla, Mumford, and Feldblum, 1982; Loffer and Pent, 1980; Chi, Mumford, and Gardner, 1981). However, pregnancies after electrocoagulation are more likely to be ectopic; pregnancies after mechanical occlusion are more likely to be intrauterine.

A luteal phase pregnancy is not the result of a failed VSC procedure. Nevertheless, health personnel need to know that the noncontracepting client who undergoes a procedure late in the menstrual cycle has a greater risk of luteal phase pregnancy (Chi and Feldblum, 1981). In such cases, service providers should inform the woman of this possibility.

The failure rates of female VSC procedures recommended by this committee range from 1-10 failures per 1,000 procedures (Bhiwandiwalla, Mumford, and Feldblum, 1982; Chi et al., 1980; Chi, Mumford, and Gardner, 1981).

3 Variations in Vasectomy Technique

The ideal technique for vasectomy should provide the maximum likelihood of success as well as the maximum possibility of reversal. Because no method at this time satisfies both of these criteria (they may, in fact, be inversely related), success of the procedure must be the prime consideration. At present, the most satisfactory method of vasal occlusion appears to be thermocoagulation with fascial interposition of the divided vas (as described by Schmidt, 1974).¹

In the current Asian context, however, the necessary funding, equipment, facilities, and training are not available for the widespread use of this method. Therefore, the Committee recommends the following as the most practical technique for the moment.

The vas should be divided, a small section (usually 1-2 cm) should be removed, and both ends should be ligated with nonabsorbable sutures. If possible, fascial interposition is desirable. The Committee recommends bilateral incisions, particularly for the inexperienced surgeon.

The Committee makes these recommendations with the understanding that the final decision should be based on the individual surgeon's practice and the particular case.

Vasectomy is the safest of all voluntary surgical contraception procedures.

¹For a more extensive discussion of vasectomy, see *Studies in Family Planning*, special issue on vasectomy, Volume 14, Number 3, March 1983.

4 Training in Surgical Techniques for Female Surgical Contraception

One of the most important factors affecting the safety of VSC is the physician's ability to perform the surgical procedure competently. Thus, training is of utmost importance.

Requirements for Training Institutions

The Committee recommends that training institutions for VSC techniques meet acceptable medical standards, be fully equipped to handle immediate operative complications, and have sufficient case loads to ensure an adequate number of procedures in a relatively short period of time.

Qualifications of the Trainers

The Committee recommends that the trainer of VSC techniques be a qualified obstetrician-gynecologist, general surgeon, or physician; be competent in the VSC technique to be taught; and have extensive experience in performing that procedure (preferably a minimum of three years of continuous experience with at least 10 cases per month).

The trainer should be well versed in the physiology of the reproductive system, the principles of surgery, the management of surgical complications, the phases of the VSC service-delivery system (client recruitment, counseling and informed consent, preoperative evaluation, and client follow-up), and appropriate anesthesia and its pharmacology.

The trainer should be able to manage all complications, with ready access to all necessary facilities. He or she should know how to communicate effectively and how to impart theoretical and practical knowledge; the trainer should have had experience using these skills.

Qualifications of the Trainees

The candidate for training in minilaparotomy should be a qualified physician. For training in laparoscopy, the trainee should be either an obstetrician-gynecologist, general surgeon, or physician who has competence and continuous experience in abdominal surgery or minilaparotomy. Training or experience in minilaparotomy is desirable for the laparoscopy trainee. The Committee recommends that any physician trained in laparoscopy be trained in minilaparotomy as well.

The candidate should wish to receive training in VSC on his or her own volition, rather than being required or persuaded to seek instruction. The trainee should be planning to practice VSC regularly and continuously. No barriers (such as lack of equipment, inadequate space, or organizational opposition) should prevent the trainee from using the newly acquired skills when he or she returns to the home institution.

Certification of Competency

A certificate of competency should be issued to each trainee who has completed didactic and practical training, and who has been judged by the trainer to have adequate knowledge and skills in the surgical technique and in all aspects of the service-delivery system.

To ensure competency and skill, the trainee should complete a minimum number of observations and supervised solo procedures before being certified in each specific VSC technique. The trainer or training institution should set the minimum requirements. The Committee recommends that the graduate be observed and evaluated within six months after instruction.

5 Anesthesia

Guiding Principles

The goals of anesthesia for voluntary surgical contraception (VSC) are (1) to minimize psychological and emotional distress and trauma to the client and (2) to free him or her from pain and discomfort. While there are innumerable anesthesia regimens that may be adopted for VSC, and while different regimens may be used safely in particular countries, *the Committee nevertheless recommends that every country with a national VSC program adopt and implement a standard anesthesia regimen in order to better ensure quality control in the program.*

In choosing a standard anesthesia regimen, program managers and decision makers should be mindful of the following principles:

Manpower capability. The regimen must be within the technical capabilities of the vast majority of surgeons and other personnel who administer anesthesia in the program.

Appropriate drugs. Drugs chosen for the standard regimen should be safe, affordable, readily available and procurable, and in constant supply. Because of the short duration of the VSC procedure itself, drugs chosen for anesthesia and sedation must have a duration of effect that is compatible with the surgical procedure, i.e., the effects of the anesthesia should not extend significantly beyond the surgical procedure itself.

Client satisfaction. The standard regimen must be safe and comfortable for the client.

Ease of complications management. The frequency of complications associated with the regimen and the type of complications that may occur must be successfully manageable in the vast majority of cases.

Because the skills of surgeons and the quality of facilities may vary widely within a national VSC program, each program should adopt an anesthesia regimen that can be safely administered by nonspecialist surgeons in the most basic surgical setting found in the program.

Types of Anesthesia

Three broad categories of anesthesia have been commonly used in national VSC programs:

General. The desired effects of satisfactory general anesthesia are analgesia, amnesia, and relaxation so that the surgeon can operate on a quiet and relaxed client. Additional highly trained personnel and spe-

cial equipment are required for proper administration.

Local. The desired effects of satisfactory local anesthesia are a local field block augmented in most cases with mild systemic analgesia so that the client is awake, responsive, and cooperative. Additional trained personnel and special equipment are not needed.

Regional. The desired effect of satisfactory regional anesthesia is complete relief of discomfort while maintaining normal body functions and consciousness. This requires additional highly trained personnel. The goals of regional anesthesia are similar to those of local anesthesia, but they are accomplished at significantly greater risk to the client.

Safety of the Various Types of Anesthesia

General and regional anesthesia offer more opportunities for serious problems than properly administered local anesthesia. The Committee recommends that *national VSC programs, with different grades of skilled personnel and surgical facilities, adopt a local anesthesia regimen as the norm to minimize complications.*

However, when the client is unalterably opposed to, or psychologically unsuited for, local anesthesia, the surgeon may, at his or her discretion, choose another anesthesia regimen, if trained personnel, adequate facilities, and proper equipment are available.

Prerequisites for Successful Local Anesthesia¹

Because the client is fully conscious during properly administered local anesthesia, certain prerequisites must be observed.

Counseling. Preoperative counseling is extremely important to ensure the cooperation of the client during the procedure and to minimize his or her fears.

Good communication. Because a conscious client is an excellent monitor of analgesia effects, the surgeon or operating staff should frequently talk with the client during the procedure.

Timing and patience. It is essential that the surgeon wait for analgesia and anesthesia to take effect.

If in spite of the above precautions, the client continues to experience unallayed discomfort, the operator

¹Because local anesthesia is considered the method of choice in all but a very few cases, the Committee did not address specific aspects of general or regional anesthesia.

should consider abandoning the procedure rather than increasing systemic analgesia or exceeding the recommended doses of local anesthesia.

Techniques for Local Anesthesia²

The recommended local anesthesia techniques and doses for minilaparotomy, laparoscopy, and vasectomy are outlined below.

Minilaparotomy

Thirty to sixty minutes before the operation, sedate the patient with diazepam 10 mg, given orally with a sip of water. If the client weighs less than 35 kg (75 lb.), reduce the dose to 5 mg.

Before surgery, with the patient on the operating table, give the following drugs, in combination or sequentially, for operative systemic analgesia. Give half the dose intravenously over a period of 10-30 seconds, and note any untoward effects. If there are no untoward effects, give the remaining dose over a period of 10-30 seconds.

Inject atropine 0.6 mg. Reduce the dose to 0.4 mg if the client weighs less than 35 kg (75 lb.).

Inject meperidine 50 mg. If the patient weighs less than 35 kg (75 lb.) and becomes excessively drowsy after the first half of the dose, do not inject the second half of the dose.

Inject promethazine 25 mg.

Locally infiltrate 1% lidocaine 3-5 cc (without epinephrine) into the skin and subcutaneous tissues through a single puncture at the operative site; after waiting 1-3 minutes, incise the skin. Then inject 1% lidocaine 3-5 cc into the fascia; after waiting an additional 1-3 minutes, incise the fascia. Inject 1% lidocaine 3-5 cc into the peritoneum and preperitoneal fascia. Then open the peritoneal cavity. Apply 1% lidocaine 5 cc onto both tubes and the uterus.

The maximum safe dose of lidocaine is 5 mg (without epinephrine) per kg body weight. For a woman weighing 40 kg, this is equivalent to 280 mg or 28 cc of 1% lidocaine.

²Synonyms and proprietary names for generic terms used in this section are given below. Proprietary names are in brackets.

diazepam	=	[Valium]	
epinephrine	=	adrenaline	
lidocaine	=	lignocaine	= [Xylocaine]
meperidine	=	pethidine	= [Demerol]
promethazine	=	[Phenergan]	

There are no indications that epinephrine should be used with local anesthesia; indeed, there are significant contraindications (Fishburne, 1983).

Laparoscopy

Begin by using the preoperative sedation and analgesia regimen described for minilaparotomy.

Through a single puncture at the planned site of the laparoscopic insertion, subcutaneously inject 1% lidocaine 3-5 cc (without epinephrine). Advance the needle through the rectus sheath and its contents down to the peritoneal layer. Infiltrate above and below the peritoneal layer in a diamond-shaped pattern until a local field block is established, not exceeding a maximum dose of 1% lidocaine 15 cc. To achieve local analgesia, apply 1% lidocaine 3-5 cc onto both tubes and the uterus through the laparoscope. (Fishburne and Keith, 1974)

Vasectomy

If the client appears to need sedation, give diazepam 10 mg orally with a sip of water, thirty to sixty minutes before the operation.³

Before surgery, locally infiltrate 1% lidocaine 1-2 cc (without epinephrine) into the skin; after waiting 2-3 minutes, incise the skin. Then inject 1% lidocaine 1-2 cc into the sheath of the vas, advancing proximally (Wortman and Piotrow, 1973).

For additional safety and comfort, administer atropine 0.6 mg intravenously to prevent vasovagal effects.

³On June 6, 1983, the Association for Voluntary Sterilization held a special seminar on vasectomy in New York. At that meeting twelve experts from the United States agreed that the anesthesia of choice for vasectomy is local anesthesia without premedication.

6 Complications of Voluntary Surgical Contraception: Prevention and Management

Complications of Anesthesia

Because the incidence of serious complications associated with vasectomy is quite low, most of this chapter addresses morbidity related to female voluntary surgical contraception.

Tables 6.1 and 6.2 describe the major complications that may occur with general and local anesthesia for both minilaparotomy and laparoscopy (Fishburne, 1983). Serious complications are likely to occur as a result of overdose, improper administration of anesthesia, or inadequate monitoring. Because the doses of drugs used for local anesthesia are much lower with vasectomy than with female VSC procedures, the related major complications are virtually nonexistent.

Table 6.1

Complications of General Anesthesia for Laparoscopy and Minilaparotomy

A. Respiratory Complications

1. Hypoxia
2. Hypercarbia (more common with laparoscopy)
3. Pneumothorax (more common with laparoscopy)

B. Cardiovascular Complications

1. Hypotension
2. Hypertension (more common with tracheal intubation)
3. Gas embolism (laparoscopy)
4. Cardiac arrhythmias
5. Cardiac arrest

C. Gastrointestinal Complications

1. Regurgitation of gastric contents followed by pulmonary aspiration
2. Gastric dilation due to active ventilation by face mask

D. Complications Related to Positioning of Patient

Table 6.2

Complications of Local Anesthesia and Systemic Sedation for Laparoscopy and Minilaparotomy

1. Excessive drug-induced sedation and narcosis, which may produce hypoventilation and respiratory arrest
2. Toxicity due to overdosage of local anesthetic drugs
3. Allergic reactions, particularly to para-aminobenzoic acid (PABA) ester drugs, such as chlorprocaine used for paracervical blocks

Managing Anesthesia-Related Complications¹

There are three principles to observe in managing acute complications related to anesthesia:

1. Identify the problem immediately.
2. Take immediate, prompt action based upon the nature of the problem.
3. Do not delay, stall, or temporize.

Two broad categories of complications associated with anesthesia are discussed here along with general procedures for managing the episodes.

Respiratory Complications

In cases of respiratory depression, the committee recommends the ABC procedure, supplemented with naloxone:

1. Keep the Airway open.
2. **B**reathe; oxygenate the patient using mouth-to-mouth resuscitation or resuscitation equipment.
3. Check the **C**irculation; monitor pulse, blood pressure, and respiration.
4. Administer naloxone 0.4 mg intravenously.

¹Synonyms and proprietary names for generic terms used in this section are given below. Proprietary names are in brackets.

diazepam	=	[Valium]
epinephrine	=	adrenaline
hydrocortisone		
sodium succinate	=	[Solu-Cortef]
naloxone	=	[Narcan]
physostigmine	=	[Antilirium]

Naloxone acts promptly, has no toxicity, and is quickly metabolized. The surgical team must monitor the client closely because the effect of the narcotic causing the depression may outlast the effect of naloxone; repeated administrations of this antagonist may be required. Several doses of naloxone may be administered without untoward effects. If respiratory depression is not immediately reversed after the first dose of naloxone, the surgical team should discontinue its use. The operator must then consider other causes of respiratory depression, such as overdose of diazepam or atropine.

In the case of atropine overdose, the surgical team should administer 0.5 to 1.0 mg physostigmine intravenously.

Naloxone should routinely be the drug of first choice for respiratory depression.

Cardiovascular Complications

To prevent cardiovascular complications, the operator should not administer a sudden bolus injection of sedative. The sedative should be given slowly, with close clinical monitoring of the client's vital signs. Furthermore, the dose must be adjusted according to the client's body weight and general health condition.

If a cardiovascular complication does occur, the Committee recommends the following procedure:

1. Begin external cardiac massage.
2. Oxygenate the client using mouth-to-mouth resuscitation or resuscitation equipment.
3. Establish an intravenous line and administer resuscitative drugs as appropriate and as indicated:

Naloxone

Epinephrine

Lidocaine

Hydrocortisone sodium succinate

Sodium bicarbonate solution

Physostigmine

Calcium chloride

Hemorrhage at the Operative Site

For female procedures, the surgical team should manage a hemorrhage at the operative site in the following manner:

1. Establish an intravenous line, preferably with a large needle so that fluid or blood can be rapidly administered.

2. Introduce plasma expanders and blood, or intravenous fluids.
3. Perform emergency abdominal surgery if necessary. (NB: A sterile emergency laparotomy kit must always be available for female VSC procedures.)

Intubation

National VSC programs should make every effort to train physicians in intubation and the use of the laryngoscope. Wherever trained personnel are available, a laryngoscope and a set of different-sized endotracheal tubes should be at hand for every female VSC procedure. However, if personnel have not been trained in intubation, using endotracheal tubes and a laryngoscope may prove more hazardous than the complication the client is experiencing. In these instances, oral airways and manual respirators with face masks are the preferred resuscitation equipment.

Anesthesia Monitoring

Client monitoring must be thoroughly ingrained as part of the routine practices of VSC personnel. All staff should receive training in how to monitor the client during surgery.

For female procedures, monitoring must take place before, during, and after the operation.

Preoperative. Blood pressure, pulse, and respiration should be checked before and after the preoperative dose of diazepam is given. This provides the baseline data for the client.

Intraoperative. During surgery the medical team must monitor blood pressure, pulse, and respiration frequently. To assess the status of analgesia, staff members should talk to the client continually.

Postoperative. Blood pressure, pulse, and respiration must be monitored and recorded at least every 15 minutes until the client is stable. Under no circumstances should the client be left alone. The client must be observed constantly during the postoperative period. (Fishburne, 1981).

Blood pressure, pulse, and respiration must always be recorded on the original client form.

Resuscitation and Emergency Equipment: Female Procedures

For all female VSC procedures, the following equipment should be available for the management of complications:

Anesthesia mask and self-inflating bag with oxygen nipple

Oxygen tank with reducing valve, flow meter, tubing, and mask

Suction machine with tubing and two traps

Nasal airways (two sizes)

Oral airways (two sizes)²

Intravenous fluids and drugs³

Abdominal surgery kit

All emergency equipment must be readily available, complete, sterilized, prepared for use, and in good functioning condition. Staff must check all items immediately before each operating session.

Emergency Requirements for Vasectomy

The Committee did not specifically address managing emergencies for vasectomy. However, in light of the procedure's limited nature and the Committee's recommendations on anesthesia, the following equipment should be available:

Oropharyngeal airways

Intravenous fluids and administration sets with large caliber needles

Emergency drugs for managing adverse reactions to anesthetic agents and other medications

²See also "Intubation," p. 36.

³See "Cardiovascular Complications," p. 35.

Asepsis

Meticulous aseptic technique is mandatory in all VSC programs; it must be stressed in training, program monitoring, and supervision. Asepsis is required at all times, without compromise, before, during, and after surgery.

Asepsis before Surgery

Client: Both male and female clients should bathe or shower, preferably before coming to the clinic, or in the clinic before surgery. If the client cannot bathe or shower, the operative site should be carefully and thoroughly cleaned with soap and water. The medical staff should inspect every client for infected foci; if the client has a focal infection, the operation should be postponed and a form of temporary contraception provided. The client should change from street clothes into surgical apparel, including a head cover. Shaving of the operative site is optional. All removable jewelry should be removed. The medical staff should determine and evaluate the client's history of cuts and wounds for the month preceding surgery.

Surgical Personnel: Street shoes must not be worn or taken into the changing room. All personnel must change into operating theatre clothes, including gowns, caps and masks. Personnel who have any infection should not be allowed in the operating theatre.

Facility: In stationary clinics the operating theatre (OT) should have a tiled or concrete floor that can be cleaned thoroughly. The OT should be fly-proof, have adequate lighting, and be well isolated from the part of the clinic that is open to the public. The operating theatre should be locked when not in use; it should not serve as a storeroom. Similarly, camps and itinerant or mobile units must use facilities that enable the operating team to maintain strict asepsis.

Ideally, no operations involving dirty or infected cases should be performed in the same theatre as VSC procedures. If the same operating room must be used, it should be fumigated with 40% formaldehyde after surgery on infected cases. The OT should be fumigated at least once a week on nonworking days. If possible, regular bacteriological examinations should be conducted. Windows should be six feet above the floor or high enough to prevent cross-ventilation in the operative field.

Asepsis during and after Surgery

Client: The operative site should be prepared with an antiseptic solution such as iodine and spirit, povidone-iodine (Betadine), or chlorhexidine. After the procedure, an ordinary sterile dry dressing should be used. Every client should receive clear, simple instructions for post-operative care until stitches are removed. While removing stitches, staff should observe aseptic precautions and conditions.

Surgical Personnel: All personnel must scrub thoroughly with soap and water. A brush may be used. The surgical mask must be kept over the bridge of the nose at all times. Sterilized and holeless gloves are mandatory. Movements in or out of the OT must be minimized. The surgeon and his or her assistants must scrub thoroughly between procedures.

Sterilization and Disinfection of Equipment

Nonlaparoscopic equipment and linen are to be sterilized in an autoclave. If an autoclave is not available, these instruments may be sterilized by boiling. Recommended methods are outlined in Table 7.1.

The best disinfectant for laparoscopes and laproscators is 2% glutaraldehyde (Cidex) for 10 minutes. Ultraviolet disinfection is not recommended for laparoscopes and laproscators.

The recommended procedure for sterilizing both laparoscopes and laproscators is well outlined in two publications: *Advanced Laparoscopic Systems* (1980) and *Laproscator: Preventive Care and Maintenance* (1980), published by the Johns Hopkins Program for International Education in Gynecology and Obstetrics, Baltimore, Maryland, U.S.A.

Preventing Tetanus

To prevent tetanus, programs must strictly adhere to aseptic procedures and standards. The Committee emphasizes the following specific points:

All procedures outlined in this chapter must be followed.

Staff must perform standard autoclave testing.

Personnel who are responsible for disinfecting, sterilizing, and using the autoclave must be supervised routinely.

Active immunization programs should be extended to the most susceptible groups, i.e., mothers and children.

Using tetanus toxoid, hyperimmune serum, and prophylactic antibiotics at the time of surgery does not guarantee the prevention of tetanus (Khairullah, 1981).

Strict asepsis combined with proper disinfection and sterilization of equipment are the most appropriate methods for preventing tetanus.

Table 7.1
**Methods of Sterilization and
 Disinfection for Materials**

Materials	Methods of Sterilization/Disinfection	
Linens (drapes, sponges, scrub suits, operating packs, etc.)	Autoclave:	120°C (250°F) 10 kg (20 lb.) pressure 30 minutes
Rubber goods (gloves, catheters, and rubber tubing)	Autoclave:	120°C (250°F) 10 kg (20 lb.) pressure 20 minutes
	Immersing in disfectant solution:	<i>Sporicidin</i> <i>Cidex</i>
	<i>Sterilization time</i>	6¾ hours 10 hours
	<i>Disinfection time</i>	10 minutes 10 minutes
	<i>Dilution</i>	1 in 16 No dilution
Surgical instruments	Autoclave:	120°C (250°F) 10 kg (20 lb.) pressure 30 minutes
	Dry heat sterilizer:	150°C (300°F) 60 minutes
	Immersing in disfectant solution:	<i>Sporicidin</i> <i>Cidex</i>
	<i>Sterilization time</i>	6¾ hours 10 hours
	<i>Disinfection time</i>	10 minutes 10 minutes
	<i>Dilution</i>	1 in 16 No dilution

Source: Khairullah, 1981.

8 Postoperative Care and Follow-Up

For female clients, medical staff should monitor the woman's vital signs for at least one hour immediately after surgery. The same applies to male clients if sedation has been used; otherwise, men who have undergone vasectomy may leave the clinic after resting 30 minutes.

Before the male or female client is discharged, and after sedation has worn off, a trained staff member should repeat all preoperative instructions related to postoperative concerns and care. For example, the client should know how to care for the wound, how to use any postoperative medications that are given, what complications to look for and what to do about each of them, when to resume normal activities, and when to return for a follow-up visit. For literate clients, it is helpful to provide written instructions in language the client easily understands.

The Follow-Up Examination

It is desirable that the operator conduct the follow-up examination. However, it may be more practical for another member of the medical team to examine the client, or for the client to visit the nearest health center. A trained, qualified health professional who is not a physician can conduct the examination, unless there are major complications.

For female clients, the follow-up visit should take place within seven days of surgery or, if this is not possible, within two weeks of surgery. A three-month follow-up to confirm success of the procedure is desirable only if the woman has stopped menstruating.

The follow-up visit should include an examination of the operative site, a pelvic examination, suture removal (if nonabsorbable sutures were used), and any other relevant examination depending upon the requirements of the case.

The use of nonabsorbable sutures increases the likelihood that the client will return for the follow-up visit. Operators must realize, however, that nonabsorbable sutures also increase the chance of infection if they are not removed.

After vasectomy, at least one routine follow-up examination should be offered to the client. The visit should include an examination of the scrotal area and any other relevant examination depending upon the requirements of the case.

Analysis of the seminal fluid is desirable where it is practical and for men who specifically request it. If the facility is not equipped to do semen analyses, the man should be told where to go for this service. If analysis reveals that azoospermia has not been achieved, the physician must reevaluate the case and take appropriate steps.

**Transfer of Client
Records**

If surgery has been performed in an established facility and if the client returns to that facility for follow-up, all records should be maintained at that site. If the follow-up is done at another facility far removed, record transfer may be too difficult; transferral is recommended only in cases with major complications.

Rest after Surgery

Depending upon the anesthesia used and the individual woman's characteristics, the healthy interval client needs to rest no more than seven days after surgery. For healthy women who undergo VSC after delivery of a child, surgical contraception does not extend the normal rest period advised for these procedures.

Male clients should, as a rule, rest for three days after surgery. A longer period may be required, depending upon the type of work the man does or the travel he must undertake.

9 **Program Monitoring and Supervision**

The Committee recognizes the importance of systematically recording, reporting, and analyzing information about the delivery of all contraceptive services, so that policymakers and planners can accurately assess the magnitude and quality of programs.

The following recommendations provide a framework for a quality control system that includes medical reporting, feedback of data, and related administrative actions. The system can be used by programs in which voluntary surgical contraception is offered. The Committee believes that such a system will provide essential feedback so that the quality, safety, and accessibility of services will be improved.

VSC data should be carefully collected and analyzed for the following reasons:

Voluntary surgical contraception is one of the safest contraceptive methods, but the safety and quality of VSC, when it is performed under different conditions in different countries, are not currently well established. Collecting information about the number of procedures performed and the number of clients experiencing complications is an important first step in assuring quality services.

Voluntary surgical contraception is rapidly becoming widespread, even in rural areas where other forms of surgery are rare. In some places, VSC is performed by paramedics. In such unique circumstances, complications, even if they are rare, constitute an important public health concern.

VSC usually requires anesthesia, a process that necessitates particular attention to client safety.

In most countries no single agency is responsible for collecting or analyzing VSC morbidity and mortality data.

In countries where VSC is a socially or politically sensitive issue, particular care must be given to ensure the quality of surgery and the improvement of services, when it is called for.

A small number of deaths can severely impair the social acceptability of a contraception program. By monitoring deaths carefully, program managers can rapidly identify problems and make the changes needed to prevent deaths.

Components of a Monitoring and Supervision Program

The objective of a monitoring and supervision system is to continually improve the quality of services and the ability to deliver those services. The essential components of such a system are:

Simple and easy-to-complete data collection instruments

Efficient analysis of collected data

Rapid feedback of analyzed data to health-care workers and training programs

Supervision of personnel, facilities, and supplies

Rapid correction of problems, including the identification of personnel who need retraining

**Simple and
Easy-to-Complete
Data Collection
Instruments¹**

The Committee stresses the following points regarding data collection:

Programs should periodically check the completeness and validity of morbidity and mortality reporting.

Programs should review morbidity and mortality data with a view toward improving the quality of health-care delivery for voluntary surgical contraception. The reporting system should be presented to health personnel in a nonthreatening way — as a means of ensuring client safety, not as a way to censure physicians or other staff members.

Programs should devise and test innovative measures, such as monetary compensation, to improve reporting of VSC-related deaths.

Form A: A form containing the following information should be completed on each client:

Identification: client's name, address, etc.

Demographics: sex, age, marital status, etc.

Clinical: sufficient medical data so that Form A can be the official record of the procedure

Morbidity: pre-discharge and post-discharge information about complications, covering the first seven days after surgery²

Special needs: space to record special local information or data from local studies

¹The forms discussed here may be used for both male and female procedures with minor adjustments.

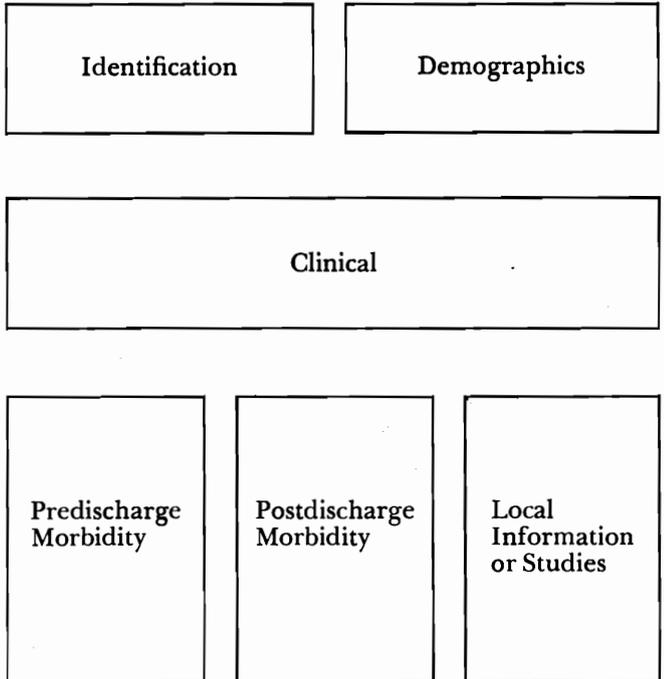
²One to two weeks after the operation the female client should return to the health facility for a follow-up visit, or an outreach worker from the health facility should visit her.

Data collected on morbidity should include tetanus, wound infection, unintended surgery, hemorrhage requiring transfusion or other replacement therapy, febrile illness requiring antibiotic treatment, anesthesia or sedation complications requiring cardiac or respiratory resuscitation, hematoma or dehiscence requiring surgical management, rehospitalization for VSC-related reasons, and death.

Form A should be simple and no longer than one page. It should contain a minimum amount of data, consistent with program management needs and standardized morbidity reporting. It should also be comparable with forms from other countries to facilitate international comparisons.

Figure 9.1

Form A



Form B: Selected information reported about individual clients on Form A should be transferred to Form B. For example, local programs would record the number of procedures of type X, the number of clients experiencing particular complications, and the number of deaths. They would then forward Form B to a regional or national monitoring agency. Occurrence rates of particular procedures as well as morbidity and death rates associated with or attributed to VSC could then be calculated on local, regional, and national levels.

Form C: This form should be used to collect data on any deaths associated with or attributed to voluntary surgical contraception. To complete this form, programs must investigate each reported death.

VSC-associated deaths are deaths occurring within 42 days of surgery, or deaths resulting from complications occurring before the end of the 42-day postoperative period. VSC-associated deaths may be classified further:

Attributable Deaths: Deaths resulting from complication(s) of the operation and/or anesthesia, from the chain of events initiated by the operation and/or anesthesia, or from aggravation of an unrelated condition by the physiologic or pharmacologic effects of the operation and/or anesthesia.

Nonattributable Deaths: Deaths occurring within the 42-day postoperative period that are not causally associated with the operation and/or anesthesia, their complications, or their management.

A trained medical person should investigate every death associated with VSC to determine the immediate and underlying causes of death, whether the death was attributable to VSC, and if any of the factors related to the death (e.g., client factors, physician or health-worker factors, community factors) could have been anticipated and prevented.

Form C should include the client's identification; demographic, medical, and social information; and a detailed account of the VSC procedure and subsequent events. Copies of medical charts should be attached whenever possible. The report should be submitted to responsible persons at the regional and national levels.

A medical team should review every death as reported on Form C. This group, including at least one physician, may be organized at the local, regional, or national level. The team should decide if the form and the charts provide adequate information and should seek additional data, if necessary.

After the medical team reviews a death, three types of information should be recorded: whether the death was

attributable to VSC, the cause of the death, and preventable factors that were identified.

Death reports should be collated regularly (every six months or once a year). Data from these reports can be used to determine the major causes of VSC-attributable death and the preventive measures that need to be taken.

Form D: This form should be used to collect information about pregnancies occurring after VSC procedures. To complete Form D, programs must determine if the pregnancy resulted from a VSC failure, how much time elapsed between surgery and pregnancy, and whether the pregnancy is ectopic or luteal phase. This information can be used to determine efficacy rates for voluntary surgical contraception.

Efficient Analysis of Collected Data

If suitable data collection instruments are used, analysis can take place at clinic, regional, or national levels, and perhaps at all three, depending on needs and resources. Wherever analysis is done, it should be performed rapidly so that program managers can have access to relevant and up-to-date information.

Rapid Feedback of Analyzed Data

Once analyzed data are available, they must be put into a form suitable for dissemination to health-care workers. While recognizing that this form may be different in different settings, the Committee strongly emphasizes that dissemination is an essential component of any scheme. Rapid feedback of information boosts the morale of health-care workers and is essential to identify and correct problems.

To remedy problems, programs may need to modify their training activities; for this reason trainers as well as clinic personnel must receive and review reports of analyzed data to initiate any needed changes.

Supervision of Personnel, Facilities, and Supplies; Rapid Correction of Problems

In any monitoring system collecting, analyzing, and disseminating data are not enough. To minimize complications and to prevent mortality, personnel, facilities, and supply lines must be properly supervised.

Responsible staff members representing different levels within the monitoring system must regularly visit all facilities providing VSC services. Such visits serve several purposes:

Providing personal feedback about analyzed data

Validating information sent from the facility by randomly checking data collection forms against primary records

Inspecting the site and equipment

Evaluating the number and skills of the facility's personnel

Identifying supply problems

Assuring that informed consent is correctly obtained

Providing on-the-job training

Supervisors should use standard checklists during these visits. When data analysis has revealed problems, responsible persons need to visit facilities having the difficulties and begin working with staff to make appropriate changes. The visitor must convey to personnel at the facility that the purpose of supervision is to improve the quality of care, not to apportion blame.

Resources for Monitoring and Supervision

Establishing and maintaining a monitoring and supervision system are the responsibility of the organizations, agencies, or governments that provide services. A greater measure of impartiality may be achieved if persons and organizations unaffiliated with the service providers conduct monitoring and supervision activities; however, this model is probably impractical in most settings.

A monitoring and supervision system requires both human and material resources. It is not possible to specify all the precise requirements without examining each individual setting. Nevertheless, the Committee has identified some broad categories of resources that are needed by all programs:

Facilities and staff to handle and process data

Staff to produce easily read information based on the data analyses

Staff to make site visits

Appropriate transport for site visits, or financing for such transport

A permanent medical review panel or panels that can be convened at short notice to investigate reports of deaths and to make recommendations for improvements

The cost of monitoring and supervising VSC services should be considered part of the total cost of any such service; it should always be included in the calculations for budgetary requirements.

The Role of Nongovernmental Organizations

National associations for voluntary surgical contraception have a special responsibility regarding monitoring and supervision. Whether they provide services or not, they should encourage and support the development of na-

tional monitoring and supervision systems aimed at assuring and improving quality services. If the associations provide services, their programs should be exemplary and should include monitoring and supervision components, to provide models for other service providers in the country.

The World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception should initiate and encourage the development of uniform data collection instruments. Such instruments would make it possible to collate and compare international data and to monitor the worldwide status of voluntary surgical contraception. The VSC Statistics Committee should be responsible for developing simple, efficient model instruments that can be used by all countries. The World Federation should convene an international policy group on VSC data collection to make final recommendations. This group should be small (approximately 15 members). It should include representatives from the data collection and evaluation departments of national family planning programs with large VSC components and from international organizations involved in VSC, such as the World Health Organization and the International Planned Parenthood Federation.

The World Federation should also encourage prospective multicenter studies on the physiological and psychosexual changes after voluntary surgical contraception such as menstrual function and changes in libido.

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