MINILAPAROTOMY UNDER LOCAL ANAESTHESIA MANUAL *for* UTTAR PRADESH

JUNE 1997

State Innovations in Family Planning Services Agency, Lucknow

Department of Health and Family Welfare, Government of Uttar Pradesh

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INTRODUCTION

BACKGROUND

Worldwide, voluntary sterilization (VS) is the most popular and most effective method of contraception. Currently female voluntary sterilization is three times more common than male sterilization (Ross 1992). In addition to being permanent, VS is safe and relatively free of side effects. The most important aspect of the procedure, however, relates to its permanence. Clients must understand that sterilization is permanent contraception and counsellors must be able to communicate this concept effectively.

Over the years, programs have evolved to the point that services are provided safely, efficiently and in a manner convenient to clients. The mortality rates for female voluntary sterilization fell from 7.1 per 100,000 procedures for the period 1973–1981 to 3.7 per 100,000 for those done between 1982–1988, largely because of improved anaesthesia and infection prevention (Khairullah, Huber and Gonzales 1992). Furthermore, procedures as they are performed today are truly minor operations, with small incisions and involving only a short stay at a surgical facility (i.e., only a few hours).

In India, acceptance of voluntary sterilization has grown rapidly over the past decade. As many as 5 to 6 million VS procedures are now done annually in India. To insure the quality of these services, the Ministry of Health and Family Welfare has established regional training centers and revised the VS standards. The standards address issues of informed consent, counselling, the surgical procedure, pre- and postoperative activities, followup and treatment of side effects and complications.

Potential Clients

The following criteria for female VS acceptors are required in the Government of India Guidelines (Ministry of Health and Family Welfare, Government of India 1996):

- Appropriate for clients who have completed their childbearing.
- The client must be married, and her spouse must be living with her.
- The client preferably should be below age 45 and above age 22.
- The number of children must not be a criterion for determining the eligibility for sterilization acceptors; however, the client should have at least one living child of at least one year of age.
- The client or spouse must not have undergone previous sterilization. (This condition may be waived in case of failure of the previous operation.)
- The client must be in the proper state of mind to understand fully the implications of the sterilization surgery and must be counselled about the permanence of the procedure.

- Appropriate screening of clients is required to assure that those who are at high risk of complications are referred to an appropriately equipped facility with personnel trained to deal with their medical or surgical problems.
- A couple should be counselled that the simplest sterilization procedure, with the lowest morbidity, is vasectomy.
- The client must sign an informed consent form indicating her agreement to undergo the procedure.

DESCRIPTION

Female voluntary sterilization (VS) is called **tubal occlusion**; one method of tubal occlusion is minilaparotomy under local anaesthesia. This is a simplified version of a conventional laparotomy using a small (3 cm) suprapubic (interval cases) or infra-umbilical (postpartum) incision. The approach was developed so that female VS could be provided on a large scale and at minimal cost using doctors with limited surgical training and experience. Minilaparotomy under local anaesthesia is both safe and effective.

Tubal occlusion can be performed in the immediate postpartum period provided there are no complications during labour and delivery, postabortion or in the "interval" period (6 or more weeks after delivery or any time when the woman is not pregnant).

Major advantages of minilaparotomy under local anaesthesia are:

- The equipment and instruments are simple, inexpensive and easily maintained.
- Doctors who have little surgical training can learn to perform the procedure competently in a short time.
- It is particularly well-suited for rural areas where support staff, equipment and supplies are limited and the volume of procedures is low.
- It can be performed on an outpatient basis with a stay of a few hours.
- It may be used for both interval and postpartum tubal occlusion.

MECHANISM OF ACTION

In the female reproductive system, an egg (ovum) is produced in the ovary every month from menarche until menopause. The fallopian tubes provide a passage from the ovary to the womb (uterus). The egg travels from the ovary through the fallopian tube where it meets the sperm from the male partner. During a minilaparotomy procedure, both fallopian tubes are occluded, generally by cutting and tying. After the procedure, the egg cannot travel beyond the occluded area and so cannot be fertilized by the sperm. After a tubal occlusion, the woman will still menstruate just as before the operation.

SURGICAL APPROACH

Minilaparotomy under local anaesthesia can be performed on an outpatient basis and requires simple, inexpensive and easily maintained equipment. For both interval and postoperative procedures, the incision can be either transverse or longitudinal; for postpartum procedures, a curved incision is made just below the umbilicus. Once the abdomen is opened, the fallopian tubes are identified and occluded by tying each off with suture material and then cutting out a small piece of tube. The modified Pomeroy technique is the most widely used method of tubal ligation. With this technique, a segment of the tube is tied in a loop and the top portion of the loop is cut and removed. The resected segment should be in the isthmic portion of the tube where the diameter of each stump will be the same. Following this, the abdomen is closed, a dry, sterile dressing applied and the client usually can be discharged within two to four hours after the procedure, provided there are no problems.

TIMING OF PROCEDURE

Minilaparotomy can be performed in the immediate postpartum period provided there are no complications during labour and delivery, postabortion or in the "interval" period (6 weeks after delivery or any time when the woman is not pregnant). For **interval** procedures, minilaparotomy may be performed at any time in the menstrual cycle, although it is preferable to do it at the end of the menstrual period or shortly thereafter to ensure that the client is not pregnant.

Immediate **postabortion** or **postpartum** procedures should be performed within 48 hours if there are no complications. Within 48 hours after delivery, the fundus is near the umbilicus; permitting a small subumbilical incision and ready access to the fallopian tubes. In some situations, a delay of 12 hours may be justified to permit a more accurate assessment of the baby's chances for survival. The likelihood of postpartum haemorrhage is much reduced after 12 to 24 hours as well.

After 48 hours, a lower and larger incision may be needed, and the tubes are not easily accessible. Bacteria are present more often in the tubes and endometrial cavity at this time.

After 7 days postpartum, the uterus descends into the hollow of the pelvis, further increasing surgical difficulty; therefore, the procedure generally should be delayed for 6 weeks (42 days) or later when the uterus is fully involuted. For clients who will not have tubal occlusion within the immediate postpartum period and are not breastfeeding, temporary contraception should be stressed.

In many countries, immediate postpartum (within 48 hours of delivery) tubal occlusion services are an integral part of maternity services. The major medical advantages of postpartum VS include:

- A woman generally has been admitted to the facility and her current health status usually can be established from delivery and prenatal records.

- The uterus is high in the abdomen and a small incision (1.5–3.0 cm) just below the umbilicus is usually sufficient to complete the procedure.

- The fallopian tubes are easier to reach with the uterus in this position.

- Several often uncomfortable steps necessary in interval sterilization are not required. These include the bimanual exam, the lithotomy position, application of the cervical tenaculum, and insertion of the uterine manipulator.

- Local anaesthesia with light sedation/analgesia is usually sufficient.

- Hospital stay beyond that of a normal delivery (often 24 hours or less) is not required.

At the same time, special steps must be taken to ensure the safety of immediate postpartum VS. These include:

- Postpartum women should be carefully screened. Special problems include postpartum haemorrhage or any condition that would lead to increased risk of infection.

- Entry into the abdominal cavity must be cautious to avoid injuring the intestine.

- Special care must be taken when exposing the tubes since the engorged postpartum vessels can bleed vigorously if injured.

- The provider must ensure that ligatures on the tubes are secure to prevent slipping and haemorrhage after the procedure is completed.

- The procedure should be performed within 48 hours of delivery before involution progresses to reduce the potential for infection.

FACILITIES AND PERSONNEL

Minilaparotomy under local anaesthesia can be performed in any hospital, including community health centre, primary health centre and maternity hospital, and temporary or mobile facilities with access to referral care. There are certain minimum requirements, including running or potable water; electricity or other light source; toilet facilities; separate reception, counselling, examination and postoperative areas; and a clean surgical area, isolated from the other facilities. In addition, certain equipment, instruments and drugs should be available for use in the operating theatre and recovery areas and staff should be trained in its use (see **Appendix A** for more information on emergency preparedness).

The minilaparotomy procedure may be performed by doctors with basic surgical ability and skills.

PERMANENCY

Minilaparotomy should be considered permanent. In India, where a few microsurgical facilities are available, it is possible in some cases to reverse the procedure, that is, rejoin the ligated fallopian tubes. Even when such services are available, however, the client may not be able to afford it, may not be a proper surgical candidate (this is a major surgical procedure) or a reversal attempt may not be successful. Therefore, couples who are considering minilaparotomy should be certain that they do not wish to have any more children.

Because minilaparotomy should be considered a permanent procedure, women requesting it should be well counselled and have plenty of time to think about their decision. Some requests will come from highly motivated clients (e.g., from women with multiple pregnancies, those with medical problems, those who are older, those who have had repeated caesarean sections). Generally, these self-motivated clients need little more than a review of the information and verification that the decision was made after careful thought. Other requests may come from younger women, those with lower parity or women who have been advised not to have any more pregnancies because of medical problems. In these situations, great care should be taken with counselling, including exploring the client's feelings which may not be clear at first. All clients should give their informed consent only after careful exploration of the matter so that no person makes the decision for voluntary sterilization without fully understanding that it is permanent.

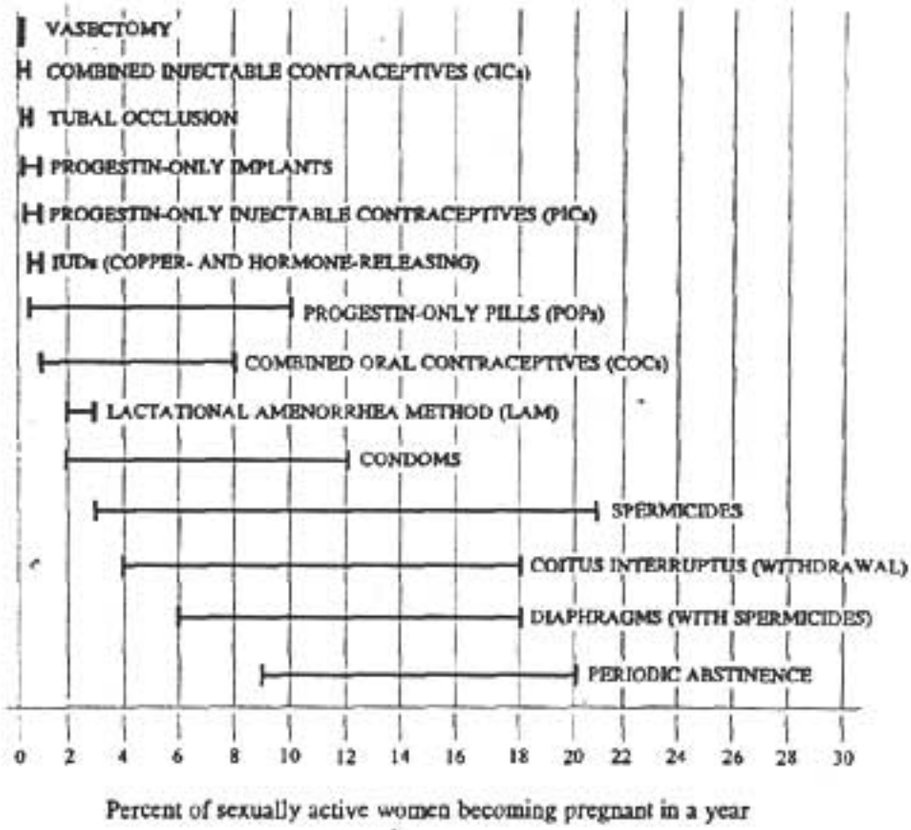
Remember: People are less likely to change their minds after minilaparotomy when the decision has been made after much thought over a period of time.

EFFECTIVENESS

The effectiveness of a contraceptive method usually is the most important factor, both for the individual (or couple) trying to choose a method and for the service provider. For valid comparisons of effectiveness to be made among the most commonly used methods, failure rates must be presented not only for individuals using the method **consistently** and **correctly**, but also for **typical users**. Data presented in this way, showing the range of failures rates for the first year of use for most contraceptive methods, are illustrated in **Figure 1-1**.

Tubal occlusion is one of the most effective methods of contraception. It is more effective than combined oral contraceptives (COCs), IUCDs or injectables. The failure rate is usually 0.1–0.5% in the first year of use.

Figure 1-1. Range of Theoretical and Typical Use Pregnancy Rates per 100 Women During First Year of Use



Adapted from: Labbok, Cooney and Coly 1994; Population Action International 1991; Trussell et al 1990; WHO 1993.

SAFETY

Minilaparotomy under local anaesthesia in the hands of a well-trained clinician is a safe, highly effective approach for performing tubal occlusion. "In many countries the mortality risk associated with an unwanted pregnancy is 50 to 80 times the risk of death for female voluntary sterilization" (Khairullah, Huber and Gonzales 1992). Fewer than 1 percent of women suffer major complications as result of female voluntary sterilization and less than 5 percent have even minor complications (Church and Geller 1990).

Client assessment before the procedure also reduces the likelihood of complications. Factors that may complicate minilaparotomy include obesity, previous pelvic or abdominal surgery and previous pelvic or abdominal infection.

FAILURE

Although failure rates for minilaparotomy are very low, failure can occur. Causes of failure include abnormalities of the fallopian tubes, procedural errors and opening of the tube (recanalization) during the healing process (Soderstrom 1986). The presence of early, undetected pregnancy at the time of the procedure may be perceived as a failure and must be avoided. Most cases of failure occur within 2 years of the procedure (Pollack 1993).

Minilaparotomy does not increase the frequency of ectopic pregnancy. If a woman does become pregnant after minilaparotomy, however, she is more likely to have an ectopic pregnancy. Among women who become pregnant after voluntary sterilization, more than one half of all pregnancies are ectopic (Pollack 1993). Therefore, all women who have had a minilaparotomy and present with symptoms of pregnancy should be carefully evaluated.

SIDE EFFECTS

Adverse Effects

There also are few side effects associated with minilaparotomy. Initial pain or discomfort associated with the surgery generally ends within a few days. While it has been suggested that "post-tubal sterilization syndrome" (e.g., increased menstrual bleeding, dysmenorrhoea) may occur, studies have not led to conclusive evidence. Some studies suggest that menstrual bleeding changes may instead be caused by switching from another method to VS, by the normal aging process or by gynaecological abnormalities (Pollack 1993; "Post-tubal sterilization syndrome": Does it exist? 1993).

Beneficial Effects

A beneficial effect of minilaparotomy may be a reduction in the risk for ovarian cancer. Some studies suggest that the risk may be as much as 70 percent lower in women who have been sterilized (Edwards 1994; Hankinson et al 1993). Another theory is that blockage of the fallopian tubes prevents contamination of the ovaries with possible carcinogens (e.g., talcum powder). Further studies of the mechanism of action need to be conducted (Pollack 1993).

SATISFACTION AND DISSATISFACTION AFTER MINILAPAROTOMY

Most clients choosing minilaparotomy are happy with their decision. As with any major life choice, however, some individuals will later have a change of mind about the decision to end their fertility. In general, age at the time of sterilization has proven to be the best predictor of regret; in one study 4.3 percent of women between the ages of 20–24 regretted the surgery while only 2.4 percent of those aged 30–34 had similar regret (Very few women found to regret sterilization 1992).

When this happens, it is often the result of their having experienced an unanticipated change of circumstances, such as a new spouse or loss of a child, which may lead them to want more children. It is not possible to prevent all dissatisfaction, but if programs take measures to assure voluntary, informed choice and if they assist clients before surgery to consider the implications of ending fertility, postoperative dissatisfaction and regret will be kept to a minimum. For those clients who do adjust poorly after minilaparotomy the program should offer counselling to help them come to terms with the effect of their decisions. Finally, if reversal services are available and realistic for the individual client, they should be presented as an option.

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TWO

COUNSELLING

BACKGROUND

Counselling is of particular importance in programs providing voluntary sterilization services because the method involves surgery and is intended to be permanent. Voluntary sterilization involves consequences, risks and fears that need to be discussed with each client. Providers have an obligation to ensure that the client understands the benefits, risks, implications of and alternatives to voluntary sterilization, and that those who choose it do so voluntarily. The service provider should discuss each client's feelings about ending fertility and assess the client's psychological readiness for the procedure and its consequences.

Remember: Counselling is a critical checkpoint between the client's intention to seek voluntary sterilization and the steps that follow, leading to surgery.

Service providers should listen to clients carefully to determine if there are signs of doubt, conflict, misunderstanding or unrealistic expectations about the procedure. In view of the critical and sensitive nature of this decision, it is essential that the counsellor collect information from the client about her personal circumstances and feelings about voluntary sterilization (World Federation 1988).

One of the principal aims of counselling is to identify clients who are likely to adjust poorly or change their minds after undergoing a procedure. If proper counselling is provided, regret is uncommon among clients. Regret is often triggered by major changes in circumstance, such as the loss of child or partner, or remarriage. It is sometimes strong enough to lead clients to seek reversal. Because reversal is usually not a realistic option, it is important to help clients avoid regret.

A few characteristics have been identified which, if not addressed during counselling, may increase the likelihood of regret following surgery (**Table 2-1**). These factors should **not** be used as arbitrary ground for denying sterilization to a client. Rather, they are signals to the service provider to devote special time and care to ensuring the client carefully weighs the choice of voluntary sterilization and its alternatives. In such cases, it may be appropriate to encourage these individuals to take more time to consider their request for voluntary sterilization and to accept a temporary method in the interim.

In addition, counselling helps clients who are good candidates for sterilization by preparing them psychologically, both for what it will mean not to be able to have any more children and for the experience of surgery. By guiding clients to consider the implications of their choice and helping them address whatever doubts or anxieties they may have before surgery, service providers enhance the chances that those who choose voluntary sterilization will be satisfied with their decision. In general, **clients are likely to adjust well and be satisfied with their decision after surgery if service providers have told them what to expect and if they take responsibility for the decision to end their fertility.**

Finally, counselling is an ongoing process that is integrated into all aspects of family planning service provision, enabling clients to make a voluntary, informed choice. Every person working in a family planning service centre contributes to this process. Therefore, it is important that all of them are oriented to family planning counselling in order to provide quality service. Even though only a few staff may be involved in providing family planning counselling, other staff probably will be curious about contraception. If they also are given information about available methods, they will be able to talk knowledgeably about family planning in the clinic and the community.

If more people have accurate information about family planning methods, the less likely it is that incorrect rumours will develop and spread. Good counselling of potential clients helps to ensure that clients will be satisfied and also reduces unnecessary returns to the clinic or discontinuation due to misunderstanding of the method.

Table 2-1. Some Warning Signs, Which If Not Addressed During Counselling, Could Increase Regret After Voluntary Sterilization

- Young age
- Children are few in number or of the same sex or in poor health
- Pressure from someone else
- Marital instability
- Partner not in agreement
- Temporary stress
- Lack of access to other methods of contraception
- Unresolved doubt
- Economic inducement
- Incomplete or incorrect information about voluntary sterilization
- Sterilization is medically indicated
- Excessive interest in reversal
- History of psychological problems, including sexual problems

Adapted from: Neamatalla and Harper 1990.

PERMANENCY[1]

Voluntary sterilization procedures should be considered permanent. During counselling it is important to identify clients who are indecisive about undergoing surgery or concerned about reversal, and to help such clients to consider their decision further. In India, reversal of ligation is available at limited clinical sites where microsurgical facilities are present. The counsellor should explain, however, the following points:

[1] *Adapted from*: Pile JM. 1996. Personal communication, 15 February.

- Reversal involves complicated and difficult surgery, requiring great skill.

- Some individuals who request reversal may be inappropriate because of age, fertility impairments or insufficient length of tube for reversal.

- Even for clients who are suitable candidates for reversal, and even when a highly skilled doctor using the most advanced surgical techniques performs the reversal procedure, functional success (term pregnancy) cannot be assured.

- Reversal procedures are costly, and the requestor is usually responsible for the expense.

Women who are advised to undergo sterilization because pregnancy poses a serious health risk for them are at high risk for regret. These women may not have chosen to end their fertility under other circumstances; thus, they need help to understand and accept why an end to childbearing is recommended. They must understand the dangers that pregnancy poses to them. Barring medical contraindications, effective, long-acting contraceptives (e.g., IUCDs, vasectomy) should be presented as alternatives to women who do not want to undergo sterilization.

CLIENT RIGHTS[2]

There are various reasons why individuals and couples decide to start, continue or stop practicing family planning. Some people may wish to delay the birth of their first child. Others may want to space the births of their children and some may want to ensure that only a desired number of children is born. There is another group of people who may wish to use family planning services not so much for protection from unplanned or unwanted pregnancy, but for other reasons, including achieving pregnancy or for the protection of their reproductive and sexual health.

Any member of the community who is of reproductive age should be considered a potential client of family planning services. Moreover, all individuals in the community have a right to information about family planning for themselves and their families, regardless of their ethnic origin, socioeconomic status, religion, marital status or political beliefs. Finally, **all persons have a right to decide freely whether or not to practice family planning.**

Family planning programs should assist people in the practice of informed, free choice by providing unbiased information, education and counselling, as well as a range of contraceptive methods. Clients should be able to obtain the method they have decided to use.

Clients also have the right to discuss their concerns in an environment in which they feel confident. The client should be aware that her/his conversation with the service provider will not be listened to by other people.

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[2] *Adapted from*: Huezo and Briggs 1987.

When a client is undergoing a physical examination or surgical procedure it should be carried out in an environment in which her right to bodily privacy is respected. The client's right to privacy also includes the following aspects related to quality of services:

- When receiving counselling or undergoing a physical examination, the client should be informed about the role of each person in the room (e.g., service providers, individuals undergoing training, supervisors, instructors, researchers, etc.).

A client should feel comfortable when receiving family planning services. To a certain extent this is related to the adequacy of service delivery facilities (e.g., proper ventilation, lighting, seating and toilet facilities). **During the minilaparotomy procedure, however, comfort is directly related to the provision of gentle, supportive care.** Moreover, the time the client spends at the premises to receive requested services should be reasonable.

The services provided to a client should not be discontinued unless a decision to do so is made jointly between the provider and the client. In particular, a client's access to other services should not depend on the continuation or refusal of contraceptive services. Additionally, referral and followup are two important aspects of a client's right to continuity of services.

Finally, the client has a right to express her views about the service she receives. Her opinions about the quality of services, either thanks or complaint, together with her suggestions for changes in service provision, should be viewed positively in a program's ongoing effort to monitor, evaluate and improve its services.

BENEFITS OF COUNSELLING

For the woman

- Counselling results in the woman arriving at a free, informed and informed decision. She feels in control of her choice of minilaparotomy and does not feel she has been pressured into accepting a method of contraception with which she does not feel happy.

- The woman knows exactly what to expect with minilaparotomy. She understands all the benefits it will offer and will also be prepared for any side effects that may develop.

- She knows whom to ask for advice if she feels concerned about anything at any time.

- She knows that the surgery is permanent.

For the clinician

- Although counselling may appear to be time-consuming, it is cost-effective and saves time in the long run. **Satisfied clients spread positive messages regarding the contraceptive method they are happy with. They may also influence their friends and people from their family circle to accept the same method. They will not talk against the method.**

COUNSELLING PROCESS

Good counselling focuses on the individual woman's needs and situation, and good service providers are willing to listen to the woman's questions and concerns. Counselling must be based on trust and respect between the client and the service provider. Staff must provide a prospective minilaparotomy client with all the information necessary to make a reasoned, non-coerced decision to terminate her fertility. The information must be in the language and terminology that the woman best understands.

Remember: All information exchanged in the counselling session should be treated confidentially.

Family planning counselling should enable a client to:

- consider her reproductive goals;
- make free, informed and voluntary decisions about fertility and contraception; and
- understand how to use her method of choice safely and effectively.

The elements of the counselling process have been organized into a system called **GATHER** (Gallen, Lettenmaier and Green 1987; Lettenmaier and Gallen 1987). This acronym is designed to help service providers remember important points in an effective counselling session. **GATHER is one approach to counselling; in practice, counselling should be tailored to the individual circumstances and may follow a different sequence or technique.**

GATHER means:

G—Greet
A—Ask
T—Tell
H—Help
E—Explain
R—Return visit/Refer

Steps in Counselling Clients for Minilaparotomy

The counselling process for clients considering minilaparotomy goes through three stages with the second stage having several steps.

Stage I. General Counselling

This is the first stage and is carried out during the initial contact with the family planning client. During this session, family planning needs are discussed; information on various contraceptive options is provided; client concerns, myths, questions are addressed; and decision making and method choice begin.

Stage II. Method-Specific Counselling

This is the second stage. In this stage, decision making and method choice occur; more specific information on the chosen method is provided; the screening process and procedures are explained; instruction regarding use is given; verification is done, by having the client repeat back key instructions; what to do if problems arise is discussed; and when to return is discussed.

In the case of clients opting for voluntary sterilization, the following steps are carried out:

Step 1

- method characteristics (benefits and limitations) and side effects are explained;
- how the method prevents pregnancy is explained;
- the client is told that sterilization is permanent;
- how the procedure is performed, how long it takes and what discomfort, if any, to expect are explained;
- the client is made aware that sterilization does not affect normal sexual functioning, physical or mental health;
- the consequence of failure is explained;
- warning signs or regret are addressed **(Table 2-1)** and the service provider is confident that the client's decision is informed, voluntary and well considered; and
- the client is screened (history and physical examination by a doctor) to ensure that she has no contraindications for the surgical procedure.

Step 2 (Preprocedure counselling)

Though the client has been made to understand how the procedure is performed and how long it will take in the previous step, the client may still have last minute doubts that must be addressed:

- Any questions that the woman may have regarding the procedure and what she can expect (e.g., how long it will last, recovery period, pain at the incision site for a few days, etc.) should be answered.
- The request form is reviewed with the client to ensure that she has indeed given an informed voluntary consent for the permanent surgical method of contraception.
- The woman is given clear instructions on how to prepare for surgery.

Step 3 (Postprocedure counselling)

This is usually given immediately after surgery. Some elements of this type of counselling, however, should be given earlier and reinforced at this time (e.g., pain at the incision site for a few days). Postprocedure counselling should focus on those warning signs (e.g., fever, persistent abdominal pain, bleeding or pus at the incision site) which indicate the need for a quick return to the clinic. In addition, she should be:

- told whom to contact if she develops any problems or has any concerns, and
- given written information telling her the date of her followup visit.

Stage III. Followup Counselling

Information given postprocedure is reinforced. Service providers need to listen attentively and be prepared to answer questions about any problems the client has had. Answering questions helps a client cope with any problems or side effects. At each followup visit the following should be addressed gently and patiently:

- any problems encountered since the last visit, and
- concerns about side effects and/or any problems.

The key points and steps in providing counselling for minilaparotomy are summarized in **Figure 2-1**.

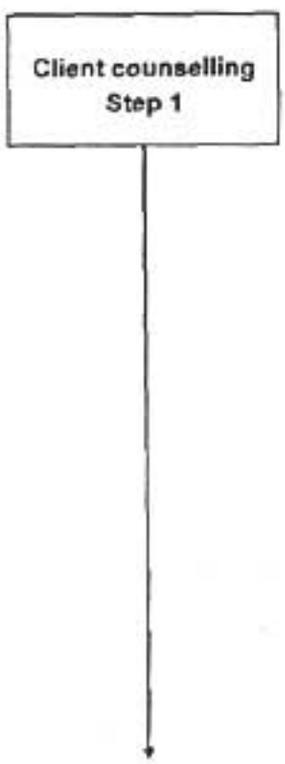
Figure 2-1. The Counselling Process for Minilaparotomy

Stage I. General Counselling

- Greet the client by introducing yourself and warmly welcoming her to the clinic.
- Ask the client why she has come to see you. For information? For a method? Because of a problem with a method?
- Explain the purpose of the counselling session.

- Gather information from the client:
  - Personal data (age, number and sex of children, marital status).
  - Previous contraceptive experience, if any.
  - Health status.
- Assess what the client knows about the following:
  - Human reproductive system.
  - Benefits, risks, side effects of temporary and permanent methods.
- Provide information to the client.
  - Tailor information depending upon client's knowledge about family planning goals.
  - Provide accurate, unbiased information.
  - Correct misunderstanding and fill gaps in knowledge.
- Help the client choose a method that suits her health and reproductive needs.

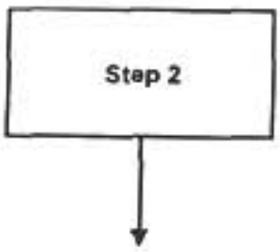
Stage II. Method-Specific Counselling (If she chooses minilaparotomy)



- Explain in detail the following:
  - How the method prevents pregnancy (use an anatomic diagram or model to explain).
  - How the procedure is performed, how long it takes and what discomfort, if any, to expect (use an anatomic diagram or model to explain).
  - Sterilization does not affect normal sexual functioning, or physical or mental health.
  - Method characteristics (benefits and limitations) and side effects.
  - Consequence of failure.
  - Minilaparotomy does not protect the woman from GTIs and other STDs, including HIV/AIDS.
- Ensure that the client understands that the method involves surgery and is intended to be permanent. Explain that reversal involves complicated and difficult surgery, requiring great skill, and even then functional success (term pregnancy) cannot be assured.
- Assess the client's decision and feeling:
  - Why does the client want to end fertility (completed family size, economic reasons, health reasons, etc.)?
  - How long has the client been considering sterilization?
  - What does the partner think?
  - How would the client feel if circumstances changed after the sterilization (death of child or partner, divorce, remarriage)?

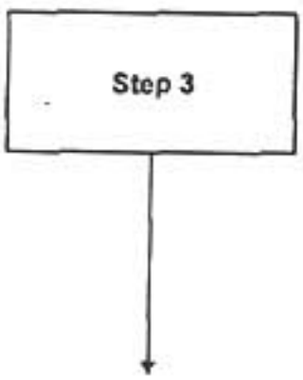
- Ask yourself: Is the client making a well-considered decision? (See **Table 2-1** for warning signs).
- Carry out a physical examination of the client to rule out contraindications for the surgical procedure.
- If there are no contraindications for minilaparotomy, ask her to sign the consent form.

Preprocedure Counselling



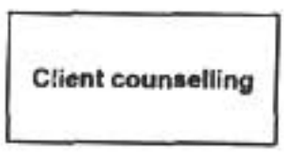
- Review the consent form with the client to ensure that she has indeed given an informed, voluntary consent to have a permanent method of contraception—minilaparotomy.
- As the woman if she has any questions regarding the procedure.
- Explain to her what she can expect (e.g., how long it will last, recovery period, pain the incision site, etc.).
- Give her clear instructions on how to prepare for surgery.

Postprocedure Counselling



- After sedation has worn off, give postoperative instructions, orally and in writing if appropriate, including how she should care for the surgical site and what to do if she experiences any problems or side effects.
- Provide information on warning signs for medical problems and the need to return to the clinic immediately should any occur.
- Schedule a return visit within 7 days.
- Discuss arrangements for discharge.
- Assure the client she can return to the same clinic at any time to receive advice and medical attention.
- Answer any remaining client questions.
- Complete the client record.

Stage III. Followup Counselling



- Inquire about problems and respond to concerns about side effects or any problems.

COUNSELLING FOR POSTPARTUM VOLUNTARY STERILIZATION

Counselling pregnant women requires special care. Although postpartum sterilization is easier for doctors to perform than interval procedures, and while the immediate postpartum period may be the most convenient time for women to have the procedure done, it is a poor time for clients to decide whether or not they want to end their fertility. This decision should have been reached during the pregnancy or earlier, because pain, stress, sedatives or other factors associated with delivery may lead to a decision the women otherwise might not have made. A candidate for postpartum sterilization should be helped to consider the survival, health and gender of the newborn, and the number and sex of living children, when deciding about postpartum sterilization.

It is important to separate the desire to end childbearing from the choice of a permanent or long-term contraceptive method. The service provider should ask the woman when she decided

she wanted no more children. If the decision was reached a considerable time before delivery (i.e., several weeks or months), the client may be a suitable candidate for postpartum sterilization. This is especially true if she states that she has reached the decision jointly with her partner. The service provider's task is then to help the client select the best contraceptive option available to her. Voluntary sterilization should be discussed as one of several different possibilities, even if the woman did not decide before delivery on surgical contraception. If, on the other hand, the woman decided not to have any more children very shortly before or immediately after delivery, she may not be a good candidate for immediate postpartum sterilization. In this situation, it may be best for the client to be given a temporary method if required during the postpartum period. Doing this allows the client (couple) the opportunity of reaching a well-considered decision about future fertility and choice of method. This cautious approach avoids the risk of making a hasty, permanent decision under the stress related to childbirth.

COUNSELLING POSTABORTION CLIENTS

Precautions must be taken with respect to the timing of counselling for sterilization after abortion to assure that the stress of termination or related complications does not influence the client's decision. The possibility of the postabortion client making a hasty decision she may come to regret is very high.

Clients may be informed about their contraceptive options at any time before or after the abortion, but the decision to undergo sterilization and the documentation of the informed consent must not take place until the client is free from stress of the abortion and her judgement is unimpaired.

Acceptance of contraception must not be a prerequisite for abortion services or treatment of abortion complications. Depending on the receptivity of the woman, counselling about family planning can be offered to the client before the abortion, while she is in the health facility after abortion or at the followup visit.

Remember: When considerable time has passed between signing the form and the delivery or abortion, the provider must **confirm the client's decision** to undergo sterilization and remind her that she has the right to change her mind.

RUMOURS AND FACTS

Correcting false rumours and misinformation is an important job of family planning providers. When talking to the client about rumours and misinformation, do not just say that what they have heard is not true. Always explain politely or show why it is not true, and **explain what is true**. Be careful not to embarrass the client because s/he has a mistaken idea or belief.

The following are some of the more common mistaken ideas:

False Rumour: After a minilaparotomy, a woman becomes weak and sickly and can no longer do heavy work.

Response: Explain that minilaparotomy has no long-term effect on a woman's ability to work, on her strength or energy. A woman can resume her normal activities after the minilaparotomy procedure (after a short period of rest to recover from the surgery). If the woman knows of someone who had health problems after a minilaparotomy, these were most probably due to the woman's poor health prior to the surgery.

False Rumour: Minilaparotomy can lead to premature menopause.

Response: Explain that the procedure does not alter in any way a woman's menstrual cycle. She will have regular periods just as before the procedure. Minilaparotomy is not a hysterectomy—her uterus and ovaries are intact and she will continue to produce eggs and menstruate.

False Rumour: Minilaparotomy lessens a woman's satisfaction during sexual intercourse.

Response: Explain that a woman's sexual desire and physical response to sexual stimulation do not change after minilaparotomy. Indeed, sexual satisfaction is often enhanced because she and her husband will not have to worry about pregnancy.

To help the client better understand and remember the most important facts about voluntary sterilization, be sure to explain them to her clearly and simply, and repeat them several times. Important facts about minilaparotomy are summarized in **Table 2-2**.

Table 2-2. Important Facts About Minilaparotomy

Who can have a minilaparotomy?	
Minilaparotomy is appropriate for women who:	***Minilaparotomy is not appropriate for women who:***
• Want a convenient, reliable and permanent method of contraception • Are certain they want no more children • Might have a high-risk pregnancy due to their age or health problems	• Are considering having more children • Are at high risk for surgical complications
Benefits and limitations of minilaparotomy	
Benefits:	***Limitations:***
• Reliable, permanent method of protection • Does not interfere with sexual intercourse • Very effective • No daily action required • Easy to use and requires no further action other than followup visit; does not interfere with normal daily activities • Comfortable—once the incision site has fully healed (about 1 week) • Few side effects	• Minilaparotomy is a surgical procedure and therefore may be associated with infection, bleeding or bruising. • The woman cannot discontinue the method (counselling should make her understand that the method is permanent): • Minilaparotomy does not protect the woman from GTIs and other STDs, including HIV/AIDS.

TIPS ON GOOD COUNSELLING

- Listen attentively.
- Answer questions objectively.
- Reinforce important information on side effects, warning signs, etc.

Remember: Counselling should be part of every interaction with the client.

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THREE

INFORMED CONSENT[1]

BACKGROUND

The process that leads to informed consent is important to clients because it ensures that they receive the information they need to make informed, well-considered decisions regarding their fertility. In addition, the process lessens the possibility of regret after minilaparotomy, which is more likely to occur when clients are not fully informed or when they do not request the procedure voluntarily. Furthermore, the act of signing an informed consent document in the presence of a witness may impress upon clients that they are making an important and, in most cases, irrevocable decision.

Properly administered informed consent procedures are important to service providers for three reasons:

- They help to assure that minilaparotomy clients are satisfied and well informed, a goal of all family planning programs.
- They are likely to reduce the incidence of regret, thus enhancing the program's acceptability.
- The signed consent document serves as evidence of the client's request and can provide protection against charges of performing a sterilization procedure against the client's wishes.

INFORMED CONSENT FOR MINILAPAROTOMY: WHAT IT IS

Informed consent is a client's agreement to undergo a minilaparotomy voluntarily, in full possession and understanding of the relevant facts. Consent is voluntary when the client gives it of her own free will and not because of any special inducement (e.g., a cash payment), force, fraud, deceit, duress, bias or other form of coercion or misrepresentation.

Before a client can make an informed choice regarding minilaparotomy, a staff member must explain to her, and she must understand, the following facts:

- Temporary methods of contraception are available to her and her husband.
- Minilaparotomy under local anaesthesia is a surgical procedure.
- The effect of this procedure is permanent.
- If successful, the operation will prevent her from having any more children.

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[1] *Adapted from*: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia.* Family Planning Service, Department of Health: Manila, The Philippines.

- Certain risks and benefits are associated with the procedure.
- There is a very small chance of failure (0.1-0.5% in the first year of use).
- She can decide against the procedure without sacrificing the right to other services.
- The simplest sterilization procedure, with the lowest risk of ailment, is vasectomy.

INFORMED CONSENT: WHAT IT IS NOT

Documenting informed consent is not a guarantee of voluntarism. A client who signs an informed consent form under duress or without fully understanding the nature of the procedure and its effects has not given informed consent. The fact that the client signs the form does not necessarily mean that she requests the operation willingly or in full knowledge of the facts and options available.

Informed consent is not counselling. Counselling is the process by which the clinic staff helps to ensure that clients make free, informed and well-considered decisions about their fertility (see **Chapter 2** for more detailed information about counselling). Through counselling, the staff:

- Provides any information the client needs to make a fully informed decision about fertility, including information about minilaparotomy, other sterilization or anaesthesia techniques and other contraceptive methods.
- Determines whether the client understands the consequences of, and is comfortable with, her decision.
- Determines whether the client's choice is voluntary. Counselling is a process—an informed decision is the intended outcome of counselling. Informed consent for minilaparotomy is one of several informed decisions the client may make.
- Explores the client's feelings about ending fertility and the reasons for adopting minilaparotomy, in order to reduce the likelihood of regret later.

Documenting informed consent is one component of the counselling process designed to safeguard the client's right to make a voluntary, informed choice. It also satisfies legal requirements, and safeguards the service provider against possible lawsuits. Documentation takes place after counselling, once the client has made a firm decision to undergo surgery.

DOCUMENTATION OF INFORMED CONSENT

In India, the client's signature on an informed consent form is the legal authorization for the minilaparotomy to be performed.

The client must always sign or mark the informed consent form (see **Appendix B** for a sample consent form used in India). Since voluntarism is ultimately the responsibility of the operating

doctor (see below), the doctor or his authorized representative may be the individual with primary responsibility for counselling the client.

Illiterate clients should mark the informed consent form with a thumbprint. A witness chosen by the client must also sign or mark the form. Because voluntary sterilization involves sensitive personal issues related to sexuality, it is preferable that the witness be someone with whom the client is comfortable discussing such issues.

Consent for minilaparotomy should not be obtained when physical or emotional factors may compromise a client's ability to make a carefully considered decision about contraception. Special care needs to be taken when a woman is pregnant; specifically, consent should not be obtained when a woman is in labour, when a woman is sedated or when a woman is experiencing stress before, during or after a pregnancy-related event.

All women requesting minilaparotomy must be informed about other methods available, and their advantages and side effects in comparison to minilaparotomy.

Spousal Consent

There is no requirement for spousal consent, but because minilaparotomy is a permanent procedure, a joint decision usually will mean more satisfied clients and fewer complaints to health workers following the surgery. It may be advisable to find out how the spouse feels about adopting the method. If the spouse is not in favour of it, the provider should caution the client about going ahead with the procedure.

Informed Consent for Postpartum Minilaparotomy

Counselling pregnant women requires special care. When considerable time has passed between signing the informed consent form and the delivery or spontaneous abortion, the provider must confirm the client's decision to undergo minilaparotomy and remind her that she has the right to change her mind.

It is often not possible to counsel clients and obtain and document informed consent long before delivery or spontaneous abortion, especially when women do not come to the health facility for prenatal care. Informed consent should not be obtained when a woman is sedated; in labour; or experiencing stress before, during or after a pregnancy-related event or procedure.

Documenting Denial of Minilaparotomy

When a client is evaluated to be unsuitable for minilaparotomy for either medical or non-medical reasons, the client record should specify the reasons (e.g., the client has a condition that precludes surgery, client is uncertain about her choice, etc.). The action taken by the provider should be described (e.g., referral, treatment, etc.). These records should be kept at the service facility where the client was judged unsuitable for minilaparotomy.

RESPONSIBILITY OF THE OPERATING DOCTOR

By the time the client meets the doctor who will perform the surgery (if she was counselled by a counsellor who was not a doctor), she should have:

- been counselled about her contraceptive options,
- made an informed decision to undergo minilaparotomy, and
- signed a consent form.

It is the responsibility of the operating doctor to verify informed consent by talking with the client before the procedure. Before starting any part of the surgery, including administration of sedative drugs, the doctor must assure that the client has made a free, informed and well-considered decision in order to minimize the possibility of regret in the future.

The doctor may use a card printed with guidelines for assessing a client's decision to undergo minilaparotomy as shown in **Figure 3-1**.

Figure 3-1. Operating Doctor's Guidelines for Assessing Client's Decision for Minilaparotomy

How to Assess a Client's Decision for Minilaparotomy under Local Anaesthesia: A Doctor's Guide for Final Assessment

Has the client signed an informed-consent form? YES NO

If the answer is yes, ask the client these questions:	STOP Should not have surgery now ▲	CAUTION Needs more counselling ▲	GO Signs of a sound decision ▲
WHO made the decision for sterilization?	Someone else	Client decided, but partner objects	Client and partner (or client, if single)
WHEN did the client decide to have no more children?	Now	Recently	Some time ago
WHY did the client choose minilaparotomy under local anaesthesia?	Pressure from someone else	Has heard procedure can be reversed	Wants no more children
HOW did the client decide?	While upset or under stress	Without enough consideration or information	After consideration and with full information
WHAT does the client know about: • Minilaparotomy under local anaesthesia	Does not know that: • The method is permanent • The method involves surgery • She will be awake during the procedure • If the surgery is successful, she will not be able to have any more children	Has some understanding about the method	Understands that: • The method is permanent • The method involves surgery • She will be awake during the procedure • If the surgery is successful, she will not be able to have any more children
• Other contraceptive methods	Would prefer other method if available	Has little knowledge of other methods or their availability	Knows of other methods, but prefers permanent contraception

Source: Association for Voluntary Surgical Contraception 1989.

The doctor should ask the client the questions listed in the left-hand column, rephrasing them as necessary to be sure the client understands.

- If any of the woman's responses fall under the STOP category, the doctor should resolve the problem or cancel surgery and offer the woman an alternative contraceptive method.

- If any of the woman's answers fall into the CAUTION column, she needs further counselling. The doctor or another clinic staff member should correct any misunderstandings the client has, provide her with any additional information she needs, explore her reason for choosing permanent contraception and determine if she is still

interested in having the surgery. If the woman needs more time to think over the decision, the surgery should be postponed.

- If all of the woman's answers fall in the GO column, she probably is an appropriate candidate for permanent contraception, unless the doctor finds other evidence to the contrary.

Using such a guide does not substitute for client counselling which should occur much earlier. Furthermore, this guide should not serve as an inflexible screening instrument. The doctor must exercise good judgement when using this or any other guide and interpreting the results. For example, if all of a woman's answers fall into the GO category, but she is unduly nervous and her agitation does not appear to be related to the fear of surgery, the doctor or other staff member should take time to determine what is causing her anxiety. If only one of the woman's responses falls into the CAUTION column, the doctor should take some time to counsel the woman and examine her reason for requesting minilaparotomy, rather than canceling surgery solely on the basis of that response. After counselling, the doctor may conclude that the woman is well informed and has made a voluntary, carefully considered choice. The surgery may then proceed as planned.

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FOUR

INDICATIONS AND PRECAUTIONS

BACKGROUND

A contraindication is a condition or a disease that makes a drug or treatment unsafe or inadvisable for a client. In the past, to protect clients from contraceptive complications, lists of contraindications have been developed for each contraceptive method. Although such lists are produced with the best interest of the client in mind, potentially serious, but often rare, complications are overemphasized. As a consequence, clients sometimes are prevented from choosing their preferred contraceptive method rather than guided in their decision-making.

Another disadvantage is that while contraindications change over time, the lists tend to become permanent. (The same is true to a certain extent for lists of indications.) Moreover, what may be an appropriate contraindication in one country, when applied to another setting with different reproductive health characteristics, may not be appropriate. Finally, in many countries, new information is slow in arriving and the contraindication list remains the standard for many years.

A partial solution to this problem is to require that every list of indications and contraindications be dated, and state clearly the country or setting for which the list was intended. Beyond this, one could consider alternatives to the use of the word contraindication, which carries such dire implications.

In this manual, we have chosen to replace **contraindications with precautions**. Making this change, however, does not solve the problem entirely. Therefore, in addition to listing the indications and those conditions requiring precautions, a brief statement is included explaining the rationale for categorizing the condition as such.

WHO CLASSIFICATION SYSTEM

There is no medical condition that would make a client ineligible for voluntary sterilization (VS). There are, however, conditions or circumstances which require precaution either for the timing of the procedure or selecting the facility where the procedure should be performed. At the World Health Organization (WHO) meeting in 1995, a separate system was developed for assessing **how, when** and **where** VS procedures should be performed. While some conditions (e.g., severe haemorrhage following delivery) may necessitate delaying the VS procedure, others which are listed in the WHO document do not require any action.

This chapter describes a number of conditions for which there are precautions. As in the WHO guidelines, where delay is recommended, the VS procedure should not be performed until the condition is evaluated and/or corrected. In addition, those conditions that preclude performing the procedure in the ambulatory setting are listed. **For these conditions, referral to an appropriate facility where full backup and/or a more experienced doctor is available may be necessary.**

CONTRACEPTIVE CHOICE AND WOMEN'S REPRODUCTIVE HEALTH CARE

When a woman selects a contraceptive method, she and the health care worker should consider the degree to which the client values her future fertility as well as the degree to which she is willing to risk a potential health problem (e.g., use of a progestin-only contraceptive with active liver disease).

Under most circumstances, a woman's risk of dying from pregnancy is many times greater than her risk of dying from minilaparotomy or any other modern contraceptive method. In fact, the higher a country's maternal mortality rate, the more important it is to offer women the widest choice of effective methods.

As a consequence, protocols that list the indications and precautions for minilaparotomy should be flexible in order to maximize the client's access to quality family planning services. To achieve this objective, they should be designed to help the service provider consider not only the woman's individual history and living conditions but also the local medical morbidity and mortality.

INDICATIONS FOR USE

Minilaparotomy is an appropriate method for a woman:

CONDITION	RATIONALE
Who is certain that she wants no more children	Tubal ligation should be considered permanent. Even where microsurgical facilities for a reversal procedure are available, the client may not be able to afford it, may not be a proper surgical candidate or a reversal attempt may not be successful. Therefore, couples who are considering minilaparotomy should be certain they do not wish to have any more children.
Whose age or health problems might cause high-risk pregnancy	The risk of dying from minilaparotomy is less than that for pregnancy complicated by age or health problems.
Who understands and voluntarily gives informed consent for the procedure	A client who understands and voluntarily gives informed consent for the procedure is less likely to regret the decision and will be more satisfied after the procedure.
Who prefers a method which does not require taking contraceptive action daily or before sexual intercourse	After the procedure, only a followup visit is required. Contraceptive effect is immediate and permanent.

PRECAUTIONS FOR USE

The rationales for the precautions listed in this section are based on the most recent epidemiologic and clinical data regarding medical criteria for minilaparotomy. For women with any of the following conditions, health care workers need to assess the appropriateness of minilaparotomy for **each client**, not only in terms of her special needs but also in relation to the available local health facilities.

CONDITIONS REQUIRING PRECAUTIONS

CONDITION	PRECAUTION	RATIONALE
Pregnancy	If pregnancy is suspected, it should be ruled out before performing a VS procedure. If the client is pregnant, counsel regarding options and risks.	Procedure performed early in pregnancy may be confused with failure. Also, use of uterine elevator may cause disruption of pregnancy and possible miscarriage (spontaneous abortion).
Postpartum		
7 to 42 days (6 weeks)	Delay procedure until after 6 weeks.	Increased risk of complications when not done during first few days postpartum or before uterus has fully returned to prepregnancy size.
Preeclampsia (severe)	Delay procedure until recovered (>6 weeks).	Increased risk of anaesthesia-related problems if general anaesthesia used.
Prolonged-rupture membranes (>24 hours)	Delay procedure until > 6 weeks.	Increased risk of serious postoperative infection.
Intrapartum or *postpartum sepsis*	Delay procedure until infection is treated (>6 weeks).	Increased risk of serious postoperative infection.
Severe haemorrhage (>500 ml)	Delay procedure until anaemia improved (>6 weeks).	Client may have been anaemic before delivery and may be unable to tolerate risk of further blood loss.
Trauma to genital tract (cervical or vaginal tears)	Delay procedure until recovered (> 6 weeks).	Because client may have been anaemic before delivery, she may not be able to tolerate the risk of further blood loss and is at increased risk of infection.
Uterine rupture or perforation	Delay procedure until recovered (> 6 weeks).	May have significant blood loss or other intra-abdominal trauma. If emergency surgery (laparoscopy or laparotomy) is required, tubal occlusion may be performed only if there is no additional risk.
Home delivery tetanus immunization status not known	Provide tetanus toxoid and delay procedure for 6 weeks	Home delivery may result in unintentional exposure to tetanus. If client is incubating this organism and develops tetanus postoperatively, the operative procedure may be blamed, affecting the reputation of the voluntary sterilization program.

CONDITIONS REQUIRING PRECAUTIONS

CONDITION	PRECAUTION	RATIONALE
Unexplained vaginal bleeding	Delay procedure only if serious problem is suspected.	If serious problem suspected, evaluate (and treat) before surgery.
Active pelvic infection (PID including purulent cervicitis)	Delay procedure until infection treated and resolved. Provide client with a temporary method.	If procedure is performed in presence of uterine, tubal or peritoneal infection, abscess formation or increased severity of infection may result.
Acute systemic infection (e.g., cold, flu, gastroenteritis, viral hepatitis)	Delay procedure until infection treated and resolved. Provide client with a temporary method.	Although tubal occlusion is a minor surgical procedure, it should not be performed when the client is sick.
Anaemia (Hb <8 g/dl)	Delay procedure until anaemia improved.	Client may be unable to tolerate stress of surgery or further blood loss.
Abdominal skin infection	Delay procedure until treated.	Increased risk of postoperative infection.
Cancer of the genital tract (cervix, endometrium or ovaries)	Do not perform.	In general, treatment for these cancers results in sterility. Refer client for treatment.
Deep veins thrombosis/pulmonary embolism (current)	Delay procedure until fully recovered.	Increased risk of recurrence or embolism.
Tuberculosis	Delay procedure until appropriate Anti TB received.	Procedure could cause flare-up or spread of disease. The coughing associated with tuberculosis may cause herniation at the site of the incision.
Asthma (acute)	Delay procedure until acute asthma attack resolved.	Client with compromised respiratory functions may not tolerate the sedation and/or a Trendelenburg position. In addition, higher expiratory pressure will cause abdominal straining and complicate procedure.
Postabortion		
Puerperal sepsis or fever ($>38°C$)	Delay procedure until infection resolved.	Determine cause and treat before performing VS.
Severe haemorrhage ($>$ 500 ml)	Delay procedure until anaemia improved.	Client may have been anaemic before procedure and may not be able to tolerate further blood loss.

CONDITIONS REQUIRING PRECAUTIONS

CONDITION	PRECAUTION	RATIONALE
Trauma to genital tract (cervical or vaginal)	Delay procedure until anaemia improved and injury healed.	Because client may have been anaemic before abortion, she may not be able to tolerate further blood loss and is at increased risk of infection.
Uterine perforation	Delay procedure until recovered.	May have significant blood loss or intra-abdominal trauma. If emergency surgery (laparoscopy or laparotomy) is required, tubal occlusion may be performed only if there is no additional risk.
Acute haematometra (postabortion syndrome)	Delay procedure until recovered.	Evacuate uterus (vacuum aspiration) and assess anaemia before performing tubal occlusion.

Women with the following conditions may require additional counselling or special surgical and followup management:

PROBLEMS REQUIRING ACTION

PROBLEM	ACTION	RATIONALE
Client has: • Diabetes • Symptomatic heart disease • High BP (>160/100) or with vascular disease • Coagulation (clotting) disorders (rare) • Is overweight (over 75 kg/165 lb if not normal Ht/Wt ratio) • Abdominal or umbilical hernia • Multiple lower abdominal incisions/scars	Should only be performed by experienced clinician in a facility with full backup. Note: Diabetes should be under control before surgery.	Clients with significant medical problems may need special surgical and followup management (e.g., general anaesthesia) for voluntary sterilization. Only those clients who meet the acceptable criteria should have their surgery in ambulatory facilities. Attempting to perform the procedure in women who do not meet these criteria (e.g., overweight women or those with extensive pelvic adhesions) invariably necessitates: • more sedation/analgesia for client comfort, • larger incision, • longer operating time, and • prolonged recovery. As a consequence, there is an increased risk of complications, especially infections, in this high-risk group.
Desire for more children	Further assess concerns and, if appropriate, help client choose another method.	Tubal occlusion is permanent. Help couples considering more children choose another method.
Excessive interest in reversal	Further assess concerns and, if appropriate, help client choose another method.	Tubal occlusion is permanent. Help couples who might be interested in more children choose another method.

PROBLEMS REQUIRING ACTION

PROBLEM	ACTION	RATIONALE
Disagrees with or does not want to sign informed consent form	Determine if concerns represent misunderstanding about method (e.g., rumour, myth). If so, provide additional counselling. If client still does not wish to sign, help her choose another method.	Clients often have misconceptions about a procedure, even after counselling. Informed consent must be obtained before performing surgical procedures.
Pressure from someone else	Further assess concerns and, if appropriate, help client choose another method.	Voluntary sterilization regret is higher when the decision was made as a result of undue pressure.
Depression	Further assess concerns and, if appropriate, help client choose another method.	Tubal occlusion is permanent. If emotional instability is present, the decision should be postponed.
Marital problems	Further assess concerns and, if appropriate, help client choose another method.	Because tubal occlusion is permanent, the decision to have the procedure should be delayed until marital problems are resolved.
Client states religious beliefs would be violated	Help client choose another method.	The likelihood of regret is reduced and satisfaction is increased if the client is emotionally comfortable with the method.

PROBLEMS REQUIRING ACTION (POSTPARTUM)

PROBLEM	ACTION	RATIONALE
Umbilical hernia	Defer procedure for interval.	Incision is usually made in area of hernia.
Intrapartum or postpartum fever	If client is afebrile for 24 hours prior to procedure, surgery may be performed.	Surgery could spread infection and lead to septicaemia.
Antepartum or postpartum haemorrhage	If haemoglobin and cardiovascular status are stable, procedure may be performed.	Low haemoglobin (< 8 g/dl) may increase risk; premedication relaxes the uterus, increases bleeding.

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FIVE

CLIENT ASSESSMENT

BACKGROUND

Minilaparotomy under local anaesthesia is intended for use on healthy women, and can be performed in surgical facilities with limited resources and equipment. This surgical approach has proven to be an extremely safe, low-risk procedure.

Selecting clients who are acceptable (low-risk) for having minilaparotomy performed in an ambulatory (outpatient) setting is a key factor in minimizing the risk of complications—both technical and infectious. Guidelines for selecting acceptable (low-risk) clients are presented in Table 5-1.

Table 5-1. Sample Guidelines for Screening Clients for Minilaparotomy in Ambulatory Health Care Facilities

	SELECTION CRITERIA	
CATEGORY	Acceptable	Not Acceptable
General health (assessed by history and limited physical examination)	Negative history and no current symptomatic heart, lung or kidney disease	Uncontrolled diabetes or history of bleeding disorder; current symptomatic heart, lung or kidney disease
Emotional state	Calm, stable	Unresolved fear and anxiety
Blood pressure	< 160/100 mm/Hg	≥ 160/100 mm/Hg
Weight	Maximum weight: 75 kg (165 lbs) Minimum weight: 35 kg (77 lbs)	>75 kg <35 kg
Previous abdominal/pelvic surgery	C-sections—only if mobile abdominal scar and normal pelvic examination	Other abdominal surgery, fixed scar or abnormal pelvic examination
Previous pelvic disease (PID, ectopic pregnancy) or ruptured appendix	No history and normal abdominal and pelvic examination	Abnormal abdominal/pelvic examination
Anaemia	Hg ≥ 8 g/dl	Hg < 8 g/dl

Only those clients who meet the acceptable criteria should have their surgery in outpatient or mobile outreach facilities. Attempting to perform minilaparotomy in women who do not meet these criteria (e.g., obese women or those with extensive pelvic adhesions) invariably requires:

- larger incisions,
- longer operating time,
- increased risk of complications, and
- prolonged recovery.

Women who have conditions that make these operations difficult or increase the risks should have their surgery in a well-equipped facility, where the availability of deeper levels of anaesthesia and other special requirements are available.

MEDICAL ASSESSMENT

Medical assessment of potential minilaparotomy clients should include demographic information, a brief medical history, limited physical examination and a complete pelvic examination. When evaluating women in a rural or mobile outreach service, the preoperative assessment must be rigorous. At these sites, it is essential to identify clients who have conditions that may increase the risks associated with surgery, as described above.

A doctor must conduct or supervise all pre-operative medical evaluation. A paramedic may carry out preliminary screening (in particular, the medical history) using a checklist prepared by a doctor. The paramedic must be able to detect any abnormalities or conditions requiring precautions and report them to a doctor for evaluation and assessment. **The final decision to offer minilaparotomy to the client is the responsibility of the operating doctor.**

Demographic Information

This basic identifying information should include the client's name, address, age, marital status and husband's name and occupation.

Medical History

Specific information which should be obtained as part of the medical history includes:

- Number of pregnancies, living children and age of youngest child
- Date of last menstrual period (LMP)
- Current/last contraceptive method used
- PID or ectopic pregnancies
- Past severe illnesses and other medical conditions, including symptomatic or chronic respiratory problems, heart or kidney disease, diabetes, anaemia, bleeding disorders (haemophilia), active tuberculosis, sexually transmitted diseases (especially GTIs), psychiatric conditions
- Previous abdominal or pelvic surgery
- Allergies (especially to local anaesthetics and pain medications)
- Current medications (e.g., those taken chronically for blood pressure control or diabetes, etc.)

- High blood pressure
- Convulsions
- Vaginal discharge
- Urinary tract infections

Physical Examination

General examination: Check

- General condition and nutritional status

  If severe anaemia (Hgb <8 g/dl or Hct <24) is suspected and haemoglobin (Hgb) or haematocrit (Hct) are not available, check for:

  - pallor of skin or eyes (conjunctiva)
  - rapid pulse (>100)
  - heart murmurs (auscultation)

- Weight
- Pulse and blood pressure
- Auscultation of heart and lungs

Abdominal examination: Check for

- suprapubic or pelvic tenderness
- masses or gross abnormalities
- surgical scars

Pelvic examination (make sure the client has voided before performing the exam)

- External genitalia
  - inspect external genitalia for abnormalities and lesions (enlarged groin nodes)
- Speculum examination
  - check for vaginal discharge
  - check cervix for purulent cervicitis
  - if indicated by history and physical findings, and if microscope is available, obtain specimens of vaginal and cervical discharge for diagnostic studies

- Bimanual
    - check for cervical motion tenderness
    - determine size, shape, position and mobility of uterus
    - check for enlargement or tenderness of the adnexa, active PID, etc.
    - check for pregnancy signs
    - check for uterine abnormalities

- Rectovaginal (perform only if findings on bimanual examination are suspicious; for example, if mass in cul de sac is suspected)
    - check for pouch of Douglas mass or tenderness

Pregnancy testing is usually not necessary except in cases where it is difficult to confirm pregnancy by pelvic exam (i.e., 6 weeks or less from the LMP) or the results of the pelvic examination are equivocal (e.g., the size and consistency of the uterus are difficult to determine because the client is overweight or has a retroverted uterus). In these situations, a highly sensitive pregnancy test (positive within 10 days after conception) may be helpful, if readily available and not expensive. If **pregnancy testing** is not available, counsel the client to use a barrier method until her menses occur or the possibility of pregnancy is confirmed.

How To Be Reasonably Sure the Client Is Not Pregnant

You can be reasonably sure a client is not pregnant if she has no signs or symptoms of pregnancy (e.g., breast tenderness or nausea) and:

- has not had intercourse since her last menses; or
- has been correctly and consistently using a reliable contraceptive method; or
- is within the first 7 days after the start of her menses (days 1–7); or
- is within 4 weeks postpartum (for women who are not breastfeeding); or
- is within the first 7 days postabortion; or
- is fully breastfeeding, is less than 6 months postpartum and has had no menstrual bleeding (see below).

Source: Technical Guidance Working Group 1994.

Relying on the Lactational Amenorrhoea Method (LAM)

The lactational amenorrhoea method (LAM) is highly effective (98% protection during the first 6 months postpartum) (Labbok, Cooney and Coly 1994). A service provider can be reasonably sure that a fully or nearly fully breastfeeding woman is not pregnant if she is still within the first 6 months postpartum and has remained amenorrhoeic. When a woman is more than 6

months postpartum, you still can be reasonably sure that she is not pregnant if she has kept her breastfeeding frequency high, she is still amenorrhoeic and has no clinical signs or symptoms of pregnancy (Labbok, Cooney and Coly 1994; TGWG 1994).

Laboratory Investigations

Extensive, routine laboratory investigations are unnecessary as long as the staff performs a careful clinical assessment of the client. For procedures using local anaesthesia, it is not necessary to conduct laboratory tests to screen for anaemia, diabetes and renal disease unless the medical history or physical examination indicates otherwise. Other appropriate investigations may be conducted as necessary (e.g., a pregnancy test). In postpartum cases, the women should have had standard laboratory investigations as a routine part of pregnancy, labor and delivery care. If the postpartum client has had excessive bleeding during or immediately after delivery, reassessment of haemoglobin is necessary.

SCREENING FOR CONDITIONS THAT MIGHT INCREASE RISK

If the medical examination reveals conditions that are likely to increase the risks associated with surgery, the doctor may need to consider a more advanced facility or consult with another practitioner before deciding to operate. If the clinic staff judges the client unsuitable for surgery for medical reasons, she should be referred for a complete evaluation of the condition identified in the examination. She should also be offered alternative contraceptive methods. If staff judges a client unsuitable for the type of tubal occlusion service available at that clinic, she should be referred to a facility capable of providing appropriate services.

Medically high-risk clients, after being informed of the risks and benefits of the procedure, should receive services from providers with the highest level of medical expertise and at the most fully equipped medical facility available.

FINAL MEDICAL ASSESSMENT

After reviewing the client's history, the physical findings and the client's suitability for minilaparotomy, **the operating doctor should conduct a final medical assessment immediately before surgery.**

The pelvic examination done for a preoperative assessment does not remove the need for the doctor to conduct a pelvic examination on the day of surgery to ensure the absence of other gynaecologic disorders, including infection, and to determine the position, flexion, mobility, size, shape and condition of the uterus.

This final evaluation should take place at the facility where the procedure is to be performed. (Staff may conduct preliminary screening in other places, such as the client's home or a local health centre.)

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SIX

INFECTION PREVENTION[1]

BACKGROUND

Thousands of minilaparotomy under local anaesthesia procedures are performed safely throughout the world each year without serious complications due to infection. Occasionally, however, life-threatening infections, including tetanus, gangrene and abdominal sepsis, are associated with this surgical procedure. Other more common, but less serious, infectious complications include minor surgical wound infections. In order to prevent problems caused by infection, aseptic technique, including good surgical technique, must be followed during each procedure.

Another concern is the increasing danger of transmission of hepatitis B or AIDS to clients, health care providers or clinic staff.[2] **Using disposable items to reduce this risk often is unnecessary.** Most of these disposables are expensive, difficult to dispose of safely and create environmental pollution problems. Furthermore, adequate supplies of disposable items, such as surgical gloves, often are not available in many countries.

To reduce the risk of infection as well as allow safe reuse of instruments and other items, contaminated waste must be properly disposed of and instruments and other items should be decontaminated, cleaned and sterilized or high-level disinfected after completing each procedure. Because tetanus and gangrene are caused by spore-forming bacteria, equipment should be **sterilized** whenever possible. Sterilization is the only method that reliably destroys bacterial endospores. When sterilization facilities are not available, **high-level disinfection** (HLD) is the only acceptable alternative. (See **Appendix C** for information on processing surgical instruments and other items.) The emphasis on this chapter is on the use of infection prevention practices that are practical and feasible in any country and setting.

Remember: Regardless of whether sterilization or high-level disinfection is used, thorough cleaning to remove soil and organic material is the most effective way to reduce the risk of tetanus and gangrene from instruments and other items.

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[1] *Adapted from*: Tietjen L, W Cronin and N McIntosh. 1992. *Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual.* Essential Medical Information Systems, Inc.: Durant, Oklahoma.

[2] Throughout this manual, when hepatitis B virus (HBV) is mentioned, hepatitis C virus (HCV) and Delta hepatitis virus (HDV) also are referred to because their occurrence is worldwide and their modes of transmission/prevention are similar.

DEFINITIONS

Microorganisms are the causative agents of infection. They include bacteria, viruses, fungi and parasites. For infection prevention purposes, bacteria can be further divided into three categories: vegetative (staphylococcus), mycobacteria (tuberculosis) and endospores (tetanus), which are the most difficult to kill.

Infection prevention often relies on placing barriers between the host and microorganisms. **Protective barriers** are physical, mechanical or chemical processes which help prevent the spread of infectious microorganisms from client to client, clinic staff to client and client to staff.

The terms **asepsis, antisepsis, decontamination, cleaning, disinfection** and **sterilization** often are confusing. For the purposes of these guidelines, the following definitions will be used:

- **Asepsis and aseptic technique** are general terms used to describe the combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of asepsis is to **reduce to a safe level, or eliminate**, the number of microorganisms on both animate (living) surfaces (skin and tissue) and inanimate objects (surgical instruments and other items).

- **Antisepsis** is the prevention of infection by killing or inhibiting the growth of microorganisms on skin and other body tissues by using a chemical agent (antiseptic).

- **Decontamination** is the process that makes objects **safer** to be handled by staff **before** cleaning (i.e., reduces, but does not eliminate, the number of microorganisms on instruments and other items). Objects to be decontaminated include large surfaces (e.g., pelvic examination or operating tables) and surgical instruments, gloves and other items contaminated with blood or body fluids.

- **Cleaning** is the process that physically removes **all** visible blood, body fluids or any other foreign material such as dust or dirt from skin or inanimate objects.

- **Disinfection** is the process that eliminates most, but not all, disease-causing microorganisms from inanimate objects.

- **High-level disinfection** (HLD) by boiling, steaming or the use of chemicals, eliminates **all** microorganisms except **some** bacterial endospores from inanimate objects.

- **Sterilization** is the process that eliminates **all** microorganisms (bacteria, viruses, fungi and parasites) **including** bacterial endospores from inanimate objects.

WHICH PROCESS TO USE

As summarized in **Figure 6-1, decontamination** is the first step in processing soiled (contaminated) surgical instruments, gloves and other items. For example, soaking contaminated items briefly in 0.5% chlorine solution rapidly kills HBV and HIV, thereby making instruments and other items safer to be handled during cleaning (American Association of Operating Room Nurses 1990). Larger surfaces such as examination and operating tables, laboratory bench tops and other equipment which may have come in contact with blood or other body fluids also should be decontaminated. Wiping them down with a suitable disinfectant (e.g., 0.5% chlorine or 1-2% phenol) is a practical, inexpensive way to decontaminate these items.

After instruments and other items have been decontaminated, they need to be cleaned and then finally processed by either sterilization or HLD (Tietjen and McIntosh 1989). As outlined in **Table 6-1**, which method is used for final processing (i.e., sterilization or HLD) depends on whether the instruments will touch only intact (unbroken) skin, intact mucous membranes or broken skin, or tissue beneath the skin which normally is sterile (Spaulding et al 1968).

Table 6-1. Final Processing (High-Level Disinfection and Sterilization) for Surgical Instruments, Gloves and Other Items

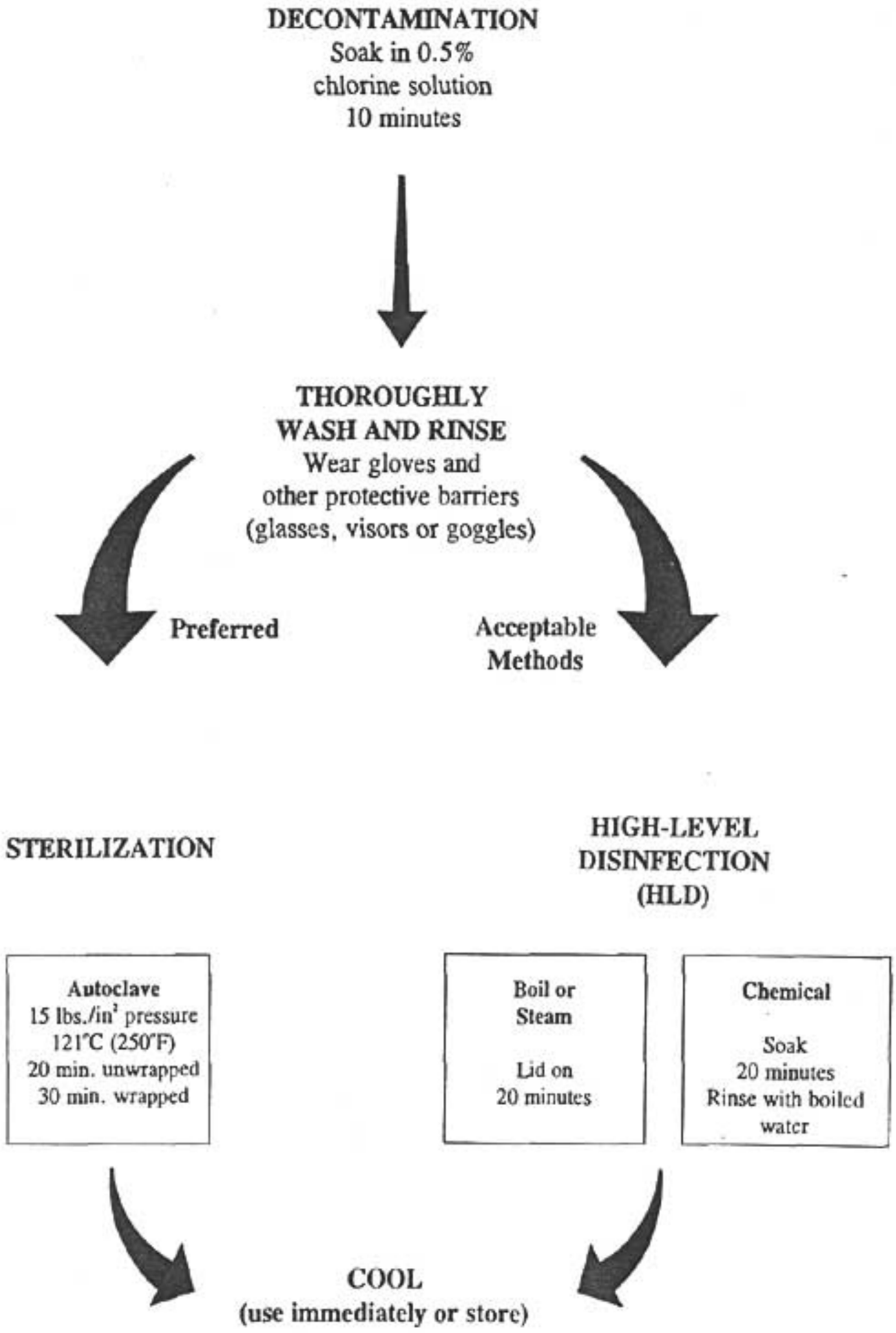
Tissue	Final Processing	Examples
Intact mucous membranes or broken skin	**High-level disinfection (HLD)** destroys all microorganisms except some endospores.[a] HLD should be preceded by decontamination and cleaning.	Uterine sounds and vaginal specula
Tissue beneath the skin which normally is sterile	**Sterilization** destroys all microorganisms, including endospores. Sterilization should be preceded by decontamination and cleaning.[b]	Surgical instruments such as needles and syringes, scalpels and trocars for insertion/removal of implants and surgical gloves

[a] Bacterial endospores are forms of bacteria which are very difficult to kill because of their coating; types of bacteria which can produce endospores include the bacteria causing tetanus (*Clostridia tetani*) and gangrene (*Clostridia sp.*). Bacterial endospores can be killed reliably only by sterilization.

[b] If sterilization is not available, HLD is the **only acceptable** alternative (see **Figure 6-1**).

Adapted from: Spaulding et al 1968.

Figure 6-1. Processing Surgical Instruments, Gloves and Other Items



Source: WHO 1990.

When is sterilization absolutely essential? When is HLD an acceptable alternative?

Most authorities recommend that the final step in processing instruments and other items used for surgical contraceptive procedures, such as voluntary sterilization, should be sterilization. While sterilization, when correctly performed, clearly is the safest and most effective method for processing instruments, if it is neither available nor suitable (e.g., for laparoscopes), then HLD is the **only acceptable** alternative (see **Table 6-1**).

Remember: For either sterilization or HLD to be effective, decontamination and cleaning of instruments and other items must be done first.

PROTECTIVE BARRIERS

Placing a physical, mechanical or chemical "**barrier**" between microorganisms and an individual, whether a client or health worker, is an effective means of preventing the spread of disease (i.e., the barrier serves to break the disease transmission cycle). The following actions create protective barriers for infection prevention:

- handwashing;
- wearing gloves (both hands), either for surgery or when handling contaminated waste materials or soiled instruments;
- using antiseptic solutions for preparing the skin, cervix and vagina prior to surgery;
- using drapes during surgical procedures;
- wearing appropriate attire (e.g., goggles, mask or apron) when contact with blood or body fluids is possible (e.g., cleaning instruments and other items); and
- decontaminating, cleaning and either sterilizing or high-level disinfecting surgical instruments, gloves and other items after use.

HANDWASHING, SURGICAL SCRUB AND GLOVES

Thorough handwashing coupled with the use of protective gloves, when performing minilaparotomy or handling contaminated waste materials, are key components in minimizing the spread of disease and maintaining an infection-free environment (Garner and Favero 1986). In addition, understanding when sterile or high- level disinfected gloves are required and, equally important, **when they are not**, can reduce costs while maintaining safety for both clients and staff.

Handwashing may be the single most important procedure in preventing infection. The vigorous rubbing together of all surfaces of lathered hands mechanically removes and often

inactivates most organisms. To encourage handwashing, program managers should make every effort to provide soap and a continuous supply of fresh water, either from a tap or bucket.

For most activities, a brief handwashing with plain soap (an antiseptic is not necessary) for about 15 to 30 seconds followed by rinsing in a stream of water is sufficient.

Handwashing is indicated **before**:

- examining (direct contact with) a client, and
- putting on **sterile** or **high-level disinfected** surgical gloves.

Handwashing is indicated **after**:

- any situation in which hands may be contaminated, such as:
  - handling soiled instruments and other items, or
  - touching mucous membranes, blood or other body fluids (secretions or excretions), and
- removing gloves.

Remember: Wash hands after removing gloves because they may have invisible holes or tears (Bagg, Jenkins and Barker 1990; Martin et al 1988).

Microorganisms grow and multiply in moisture and in standing water. Therefore:

- If bar soap is used, provide small bars and soap racks which drain.
- Avoid dipping hands repeatedly into basins containing standing water. Even with the addition of an antiseptic agent, such as Dettol® or Savlon®, microorganisms can survive and multiply in these solutions.
- Choose from several options when running water is not available:
  - Use a bucket with a tap which can be turned off to lather hands and turned on again for rinsing, or a bucket and pitcher.
  - Use an alcoholic handrub which does not require water.

Note: A nonirritating alcohol solution can be made by adding either glycerine, propylene glycol or Sorbitol® to the alcohol (2 ml in 100 ml 60–90% alcohol solution) (Garner and Favero 1986). Use 3 to 5 ml for each application and rub the solution over the hands for about 2 minutes, using a total of 6 to 10 ml per scrub (Larson et al 1990; Rotter, Koller and Wewalka 1980).

- Dry hands with a clean towel or air dry; shared towels quickly become contaminated. (Carrying one's own small towel or handkerchief is a good way to avoid using dirty towels.)

- Collect used water in a basin and discard in a latrine if a drain is not available.

Surgical Handscrub

The surgical team (doctor and OT nursing assistant/attendant) should perform a **3 to 5 minute surgical handscrub** prior to performing minilaparotomy using Betadine®, Savlon or other locally available antiseptic (see **Appendix D**). Alternatively, when only soap and water are used for the surgical handscrub, rub with a 60 to 90 percent alcohol solution is recommended. Additional information on how to prepare and use antiseptics is presented in **Appendix E.**

The surgical handscrub is performed before gowning (if used) and putting on sterile or high-level disinfected gloves. Ideally, the operating doctor and assistant should scrub thoroughly between each procedure. In high-volume settings, this may not be feasible because the skin cannot tolerate the irritation caused by frequent scrubbings. **In such settings, surgical staff should do a 3-minute scrub every hour or after every four or five cases (whichever comes first), to minimize recolonization of the skin by microorganisms.** They also should scrub if they leave the operating theatre for any reason, and after every case where glove(s) are torn.

When to Wear Gloves

Gloves should be worn by all staff prior to contact with blood and body fluids from any client. **A separate pair of gloves must be used for each client to avoid cross contamination.** Using **disposable gloves** is preferable; however, surgical gloves can be decontaminated, washed, dried and either sterilized by autoclaving or high-level disinfected by boiling or steaming before reuse.

Which Gloves to Use

- **Clinicians: Sterile** surgical gloves should be worn when performing the minilaparotomy. **High-level disinfected** gloves may be used for the placement of the uterine elevator (or uterine manipulator), if used. When sterilization equipment is not available, surgical gloves can be **high-level disinfected** by steaming or boiling.

- **Clinic Staff: Clean utility gloves** should be worn when processing instruments, equipment and linens; for handling contaminated wastes and when cleaning contaminated surfaces.

Do not use gloves which are cracked, peeling or have detectable holes or tears.

Instructions are provided in **Appendix F** for how to process surgical gloves, by sterilization and HLD, and store them safely.

ANTISEPSIS

Infection following surgical procedures, such as minilaparotomy, may be caused by microorganisms from the skin of the client or from the hands of the health care worker (Larson et al 1990). Washing hands before and after each case and cleaning the client's skin, cervix and vagina with antiseptic solution help prevent infection at the operative site.

Selection of Antiseptics

Antiseptics do not have the same killing power as the chemicals used for HLD. Thus, antiseptic solutions **never** should be used to high-level disinfect objects such as instruments or surgical gloves.

Many chemicals qualify as safe antiseptics. The following antiseptics are commonly available in India:

- Alcohols (60–90% ethyl, isopropyl or "methylated spirit")
- Chlorhexidine gluconate (4%) (e.g., Hibiclens®, Hibiscrub®, Hibitane®)
- Chlorhexidine gluconate and cetrimide, various concentrations (e.g., Savlon)
- Iodine (1–3%); aqueous iodine and alcohol-containing (tincture of iodine) products
- Iodophors, various concentrations (e.g., Betadine)
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol)

PROCESSING INSTRUMENTS, GLOVES AND OTHER ITEMS

In working to create an infection-free environment, it is important that the rationale for each of the recommended infection prevention processes (and their limitations) be clearly understood by clinic staff at all levels—from service providers to cleaning and maintenance staff.

For minilaparotomy, the infection prevention processes which should be used to reduce disease transmission from contaminated instruments, gloves and other items are:

- waste disposal and decontamination,
- cleaning and rinsing, and
- sterilization, or
- high-level disinfection (HLD).

The sequence and details for performing each of these processes are summarized in **Tables 6-2** and **6-3**.

After completing surgery, and while still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a leak-proof container or plastic bag. **Following this**, surgical instruments, reusable needles and syringes, and gloves which were in contact with blood or body fluids should be **decontaminated** by soaking for 10 minutes in a disinfectant (0.5% chlorine solution). The surface of operating tables, instrument stands and lamps should be decontaminated before reuse by wiping with a cloth soaked in a disinfectant cleaning solution. Next, instruments and reusable items such as surgical gloves should be thoroughly **cleaned** with liquid soap or detergent and water and completely rinsed before further treatment. **Finally**, instruments, gloves and surgical drapes should be **sterilized**. If sterilization is not possible, **HLD** is the only acceptable alternative (see **Appendix C** or details on processing surgical instruments and other items).

Table 6-2. **Infection Prevention Guidelines for Minilaparotomy**

WASTE DISPOSAL AND DECONTAMINATION

STEP 1: After completing the minilaparotomy, and while still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a properly marked leak-proof container (with a tight- fitting lid) or plastic bag.

STEP 2: Fully immerse all metal instruments in a plastic container filled with a 0.5% chlorine solution for 10 minutes before allowing staff and cleaning personnel to handle or clean them. Before immersing assembled needles and syringes, fill with chlorine solution. (This step is necessary to help prevent transmission of HBV and HIV/AIDS to clinic staff.)

STEP 3: If using disposable needles and syringes, remove from decontamination solution and place in puncture-proof container. If reprocessing syringe only (the recommended practice) or both needle and syringe, flush 0.5% chlorine solution from syringe. Carefully remove needle from syringe and either place the needle in a puncture-proof container for disposal or clean as described below.

STEP 4: All surfaces (such as the OT table, instrument stands and OT lamps) that could have been contaminated by blood and mucus also should be decontaminated by wiping down with chlorine solution.

STEP 5: Briefly immerse both gloved hands in the bucket containing the chlorine solution and then carefully remove by turning them inside out. If disposing of gloves, place in the leak-proof container. If the gloves are reusable, deposit the gloves in the chlorine solution and soak for 10 minutes.

CLEANING AND RINSING

STEP 6: After decontamination, thoroughly clean instruments with water, liquid soap or detergent and a soft brush, taking care to clean all teeth, joints and surfaces. Rinse well after cleaning to remove all soap or detergent (some detergent can render chemical disinfectants inert). Dry instruments before further processing. Surgical drapes should be washed with liquid soap or detergent and water and air or machine dried.

STEP 7: Wash syringe (and needle) in soapy water and rinse (x3) with clean water. (If processing needle, be sure to clean hub area of needle. Put syringe and needle back together and rinse by flushing [x3] with clean water. Detach needle from syringe and examine for damage. Dispose of damaged needles in puncture-proof container.)

Table 6-2. Infection Prevention Guidelines for Minilaparotomy (*continued*)

STERILIZATION

Instruments, surgical gloves, syringes (and needles if reused) and surgical drapes should be sterilized by autoclaving. If necessary, metal instruments and glass syringes also can be sterilized by dry heat.

Steam sterilization: 121°C (250°F) at 106 kPa (15 lbs/in^2) pressure for 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry thoroughly before removing.

Storage: Unwrapped instruments must be used immediately or stored in dry sterile containers (1 week only). Wrapped instruments, gloves and drapes can be stored for up to 1 week if the package remains dry and intact, and up to 1 month if sealed in a plastic bag.

HIGH-LEVEL DISINFECTION

High-level disinfection by boiling, steaming or the use of chemicals is recommended if sterilization is not possible. Surgical (metal) instruments, surgical gloves, syringes (and needles if reused), and surgical drapes should be steamed or boiled for 20 minutes and allowed to dry. Alternatively, surgical instruments can be soaked for 20 minutes in a glutaraldehyde, 8% formaldehyde solution, or 0.1% chlorine solution prepared with boiled water, thoroughly rinsed with boiled water and air dried. Use immediately or store for up to 3 days in a clean, dry high-level disinfected container with a tight-fitting lid.

Table 6-3. Steps in Processing Surgical Instruments, Gloves and Other Items

Process	Decontamination is the first step in handling used items; reduces risk of HBV or HIV/AIDS.	Cleaning removes all visible blood, body fluids and dirt.	Sterilization destroys all microorganisms, including endospores.	High-Level Disinfection destroys all viruses, bacteria, parasites, fungi and some endospores.
Instruments/Items	**Decontamination**	**Cleaning**	**Sterilization[a]**	**High-Level Disinfection**
Operating table top, or other large surface areas	Wipe off with 0.5% chlorine solution.	Wash with liquid soap or detergent and water if organic material remains after decontamination.	Not necessary	Not necessary
Surgical drapes	Not necessary (Laundry staff should wear protective gowns, gloves and eyewear when handling soiled linens.)	Wash with liquid soap or detergent and water. Rinse with clean water; air or machine dry.	Autoclave at 121°C (250°F) and 106 kPa (15 lb/in^2) for 30 minutes.	Not practical
Surgical gloves	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.[b]	Wash with liquid soap or detergent and water. Rinse with clean water and check for holes. If they will be sterilized, dry inside and out (air or towel dry) and package (see Appendix F).	**Preferable:** Autoclave at 121°C (250°F) and 106 kPa (15 lb/in^2) for 30 minutes. Do not use for 24 to 48 hours.	**Acceptable:** Steam for 20 minutes and allow to air dry in steamer for 4 to 6 hours (see Appendix F). Boil in water for 20 minutes. (After cooling, gloves should be worn "wet" as drying and storing without contaminating them is difficult.)
Surgical instruments including trocars for implants insertion	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.[b]	Using a brush, wash with liquid soap or detergent, and water. Rinse with clean water. If they will be sterilized, air or towel dry.	**Preferable:** Autoclave at 121°C (250°F) and 106 kPa (15 lb/in^2) for 20 minutes if unwrapped, 30 minutes if wrapped.	**Acceptable:** Boil for 20 minutes and air dry before use or storage. Chemically high-level disinfect by soaking for 20 minutes. Rinse well with boiled water and air dry before use or storage (see Appendix C).

Table 6-3. Steps in Processing Surgical Instruments, Gloves and Other Items *(continued)*

Instruments/Items	Decontamination	Cleaning	Sterilization[a]	High-Level Disinfection
Hypodermic needles and syringes	Fill assembled needle and syringe with 0.5% chlorine solution. Flush (x3) and either dispose of syringe, or, soak for 10 minutes prior to cleaning. Rinse by flushing (x3) with clean water.	Disassemble, and wash with liquid soap or detergent, and water. Rinse with clean water, air or towel dry syringes (only air dry needles).	**Preferable:** Autoclave at 121°C (250°F) and 106 kPa (15 lb/in^2) for 20 minutes if unwrapped, 30 minutes if wrapped.	**Acceptable:** Boil or steam as for surgical gloves. (Chemical HLD is not recommended because chemical residues may remain even after repeated rinsing with boiled water. These residues may interfere with the action of drugs being injected.)
Storage containers for instruments	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.[b]	Wash with liquid soap or detergent and water. Rinse with clean water, air or towel dry.	Autoclave at 121°C (250°F) and 106 kPa (15 lb/in^2) for 20 minutes if unwrapped, 30 minutes if wrapped. Sterilize when empty or contaminated, or weekly.	Boil container and lid (see Appendix C). If container is too large: Fill container with 0.5% chlorine solution and soak for 20 minutes. Rinse with water which has been boiled for 20 minutes and air dry before use. High-level disinfect when empty or contaminated, or weekly.

[a] If unwrapped, use immediately; if wrapped, may be stored up to 1 week prior to use.
[b] Avoid prolonged exposure (> 20 minutes) to chlorine solution to minimize discoloration and corrosion of instruments and deterioration of rubber or cloth products.
[c] Instruments with cutting edges and needles should not be sterilized at temperatures above 160°C to avoid dulling them.

Adapted from: Perkins 1983.

OPERATING THEATRE

The OT should be an enclosed area with doors that can be locked and should be located away from heavily used areas of the clinic or hospital. The OT should:

- have adequate lighting,
- have tile or concrete floors to facilitate cleaning,
- be kept free of dust and insects, and
- be adequately ventilated. (If windows need to be open for ventilation, they should have tight fitting screens.)

There should be adequate handwashing facilities including a supply of clean water (i.e., clear, not cloudy with sediment) nearby and a clothes changing room for staff. This area should be positioned so that staff can enter directly into the OT area without passing through high-traffic areas (e.g., client waiting area) or high-risk (contaminated) areas such as hospital wards or treatment rooms. Suitable containers, with tight-fitting lids or plastic bags for disposal of waste items also should be available.

TRAFFIC FLOW

The number of microorganisms in a designated area tends to be related to the number of people present and their activity. To help reduce the level of microbial contamination in the OT:

- Keep the number of people and movement to a minimum during surgery.
- Keep doors closed to discourage entrance of unauthorized persons and to reduce movement and air flow.
- Separate clean and soiled items.
- Finally, clients should enter the OT and go to the OT table without crossing through areas where sterile or high-level disinfected instruments are set up and stored.

PREPARATION OF CLIENTS

Although skin cannot be sterilized, pre-operative washing of the surgical site and antiseptic preparation minimizes the number of microorganisms on the client's skin. Both are important in reducing the risk of surgical wound infection following minilaparotomy.

- Clients selected for surgery should bathe prior to surgery. (If this is not possible, staff should thoroughly clean the operative site with soap and water before entering the OT.)

- Pubic and abdominal hair should not be shaved. (If the hair must be cut, trim it close to the skin surface immediately before the procedure.)

- Liberally apply a locally available antiseptic, such as an iodophor (PVI), to the operative site.

- Allow the antiseptic enough time to be effective before beginning the procedure. For example, when iodophors are used, allow 1 to 2 minutes before proceeding.

For a listing of antiseptic solutions, their use and relative advantages and disadvantages, **Appendix E**.

SURGICAL ATTIRE FOR CLIENTS AND OPERATING THEATRE STAFF

The OT is designated as a clean area; therefore, clients and OT staff should be attired appropriately:

- Clients should change into a clean gown before the procedure. (A clean cloth wrap can be used if gowns are not available.)

- OT staff (including cleaning staff) should change into clean scrub suits or gowns, caps and masks **prior to entering the OT**.

- Masks should **fully cover the nose, lower face, jaw and facial hair** and should be replaced when damp.

- Caps should cover all hair.

- Street shoes should be covered or changed to shoes or boots that are worn only in the OT.

Are Face Masks Necessary for Observers in the OT?

It is always necessary for all staff who are actively involved in the procedure to wear face masks in the OT. It is not always feasible, however, for observers who are present in a training situation to wear masks. The following information is presented to offer guidance in this situation.

According to the results of a study reported in a recent article in the *Journal of Hospital Infection* (Mitchell 1991), oral microbial flora dispersed by unmasked volunteers standing 1 metre from the OT table failed to contaminate exposed bacterial dishes (settle plates) placed on the table. According to the article, the numbers of air-borne bacteria expelled from the nose and mouth are insignificant compared with the substantial amount of bacteria shed from the skin. This study confirms earlier findings that during quiet breathing few, if any, nasal bacteria are expelled into the air, despite heavy colonization of the nose.

The article concludes that surgical masks are costly and not necessary for all OT personnel in all cases, but it states that masks should be worn by the operating doctor and all personnel who are scrubbed.

USE OF MULTI-USE VIALS

The following guidelines are important to follow when using multi-use vials of lignocaine:

- After using a needle for the client's injection, never introduce it again into the vial.
- After using a syringe for an injection, never use it again to withdraw more solution from the vial. Injecting air into the vial with a used syringe, in order to facilitate withdrawal of the liquid, causes the contents of the vial to become contaminated.
- Do not leave a needle in the vial between withdrawals of solution because it will contaminate the contents.
- Ideally, there will be enough sterile syringes and needles so that each is used only once.
- Alternatively, the required amount of lignocaine can be withdrawn from the vial in two equal doses. Each dose is injected into a sterile stainless steel bowl on the surgical stand. The necessary amount of lignocaine can then be withdrawn from the supply in the bowl.

SURGICAL TECHNIQUE

Good surgical technique that minimizes tissue trauma and adequately controls bleeding (haemostasis) will reduce the risk of infection. For both interval and postpartum minilaparotomy, the technical aspects of performing each procedure should be standardized to reduce the potential for intra-operative and postoperative problems.

INFECTION PREVENTION TIPS

To minimize the client's risk of infection after minilaparotomy, OT staff should strive to maintain an infection-free environment. To do this the clinician should:

Before Procedure

- Operating theatre (OT) staff and any other personnel entering the OT who are ill (e.g., have a cold or the flu), infectious or have draining lesions or cuts on exposed areas (face, arms or hands) should be excused or assigned other duties out of the OT area until they are well.
- Select clients who are low-risk for infection and pelvic adhesions, and who are not grossly malnourished or obese.

- Where possible, have client bathe and thoroughly wash her genital and abdominal areas before entering the OT.

- Surgically scrub hands with antiseptic solution and water.

- After gloving and while looking at the cervix, liberally apply antiseptic solution several (at least two) times to the cervix and vagina before applying the uterine elevator (or manipulator). (If iodophors such as Betadine are used, give them time to work, 1 to 2 minutes to allow for release of free iodine and contact time to kill the microorganisms.)

- Wash/scrub abdomen and liberally apply antiseptic solution to the operative site, starting at the center and moving towards the sides of the abdomen. (Give special attention to the navel as appropriate.)

During Procedure

- Keep number of people and movement in the OT to a minimum.

- Wear appropriate surgical attire.

- Use **sterilized** or **high-level disinfected** instruments, gloves and surgical drapes.

- Use good surgical technique that minimizes tissue trauma and controls bleeding (haemostasis).

After Procedure

- While still wearing gloves properly dispose of contaminated wastes (gauze, cotton and gloves) in a leak-proof container or plastic bag.

- Decontaminate instruments and reusable items immediately after use (while they are still in the OT) or before cleaning.

- Decontaminate operating table, instrument stands, lamps and other surfaces contaminated during surgery after each case.

- Follow guidelines for cleaning and processing soiled instruments, gloves, linens and needles and syringes (**See Appendices F and G**).

- Wash hands after removing gloves.

"Hands-free" Technique for Passing Surgical Instruments

A safer method of passing sharp instruments (needles, scissors and scalpels) during surgery has been developed recently. Called the "hands-free" technique of instrument transfer, this technique is inexpensive and simple to use and ensures that the operating doctor, assistant and/attendant **never** touch the same instrument at the same time (Bessinger 1988).

Instruments passed with the hands-free technique include anything sharp enough to puncture a glove (e.g., scalpels, mosquito forceps, loaded needle holders). Using the hands-free technique, the nursing assistant/attendant places a sterile or high-level disinfected kidney basin or other suitable small container on the sterile field between her/himself and the operating doctor. The container is designated as the neutral zone on which the assistant places sharp instruments. The assistant alerts the doctor that a sharp instrument has been placed in the neutral zone by saying "scalpel," or "suture ligature," while placing it there. The doctor then picks up the instrument and returns it to the container after use.

Another way to do this is to have the assistant place the instrument into a container such as a kidney basin and pass it to the operating doctor. The doctor lifts the instrument out of the container which is left on the field until the doctor returns the instrument to it. The assistant then picks up the container and returns it to the Mayo stand.

> Note: If the operating doctor complains that the scalpel blades are dulled because the cutting edge touches the metal container, a plastic container may be used.

MAINTENANCE OF A SAFE ENVIRONMENT

Maintaining a safe, infection-free environment is an on-going process which requires frequent retraining and close supervision of clinic staff. With diligent application of recommended practices, infections following surgery and transmission of diseases such as hepatitis B and AIDS can be avoided. The practices described in this chapter, however, must be conscientiously applied before, during and after each procedure. Laxity at any point in the routine can have disastrous results for the safety of the procedure.

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SEVEN

ANAESTHESIA

BACKGROUND

The goals of anaesthesia for minilaparotomy procedures are to:

- Prevent pain and discomfort
- Minimize stress and anxiety

Local anaesthesia, when properly administered and managed by the operating doctor and his assistant, meets both of these goals and is recommended for minilaparotomy. The key to having a successful minilaparotomy program, however, depends on doctors being adequately trained to operate on awake (or lightly sedated) clients (i.e., are specially trained to handle tissues gently and use "verbal" anaesthesia ["verbacaine"]).

Because minilaparotomy often is performed in ambulatory facilities, it is important that each program determine the pain control method most suited to their facility. They should consider the technical abilities of the clinicians providing pain control medication, the availability of drugs and their ability to manage complications of chosen regimens.

GOAL OF PAIN MANAGEMENT

The purpose of pain management for minilaparotomy is to ensure that the client experiences a minimum of anxiety and discomfort as well as the least risk to her health. Appropriate use of various agents combined with gentle technique and verbal support from the provider and nursing staff allows the client to be awake, responsive and in minimal fear and discomfort. Achieving the balance of maximum comfort and minimum risk requires the accurate assessment of each client's pre-operative condition (general physical assessment and vital signs—temperature, pulse and blood pressure) as well as her individual needs (body size, history of chronic disease, level of anxiety and drug allergies).

PAIN MANAGEMENT TECHNIQUES

The keys to pain management and client comfort with minilaparotomy under local anaesthesia are:

- A client who is emotionally ready to have surgery while awake; this is achieved by supportive attention from staff before, during and after the procedure (helps reduce anxiety and lessen pain)
- A provider who is comfortable working with clients who are awake and is trained to handle instruments and tissues gently
- The selection of an appropriate level of pain medication

Use of "verbacaine" by the provider can make the procedure much easier for the client. "Verbacaine" involves being able to:

- Quickly establish a positive relationship with the client
- Comfortably and openly talk with the client throughout the procedure

Tips for working with clients who are awake and not, or only lightly, medicated include:

- Mention each step of the procedure prior to performing it.
- Wait a few seconds after performing each step or task (e.g., placing the tenaculum) to allow the client to prepare for the next one.
- Move slowly, without jerky or quick motions.
- Use instruments with confidence.
- Avoid saying things like "This won't hurt" when, in fact, it will hurt; or "I'm almost done" when you're not.
- Talk with the client **throughout** the procedure.
- Be sensitive to what you are saying and doing.

PREOPERATIVE MEDICATION

Generally, pre-operative medication for minilaparotomy clients is not needed and should be discouraged. If the client appears to need sedation, the first step is to identify why she is unduly anxious or nervous and provide appropriate counselling. In most cases this is sufficient; if it is not, then she may be given diazepam 5–10 mg orally 30 to 45 minutes before the procedure. If premedication is given, it should be given an appropriate time before the procedure (30 to 60 minutes for oral medications) so that maximum relief will be provided during the procedure. Premedication with a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen 800 mg) also may be used to reduce uterine cramping.

If sedatives, tranquilizers or analgesics are needed during the procedure, give them intravenously so that the effect is immediate.

ANAESTHESIA

The dangers of general anaesthesia, particularly in settings that lack skilled staff (anaesthetist) and facilities for close monitoring of the client during the procedure and recovery, have been well documented. Therefore, it is important to use alternative approaches for the safe, effective management of pain. Local anaesthesia with or without sedation (so-called "modified local") is safer than either general or regional (spinal/epidural) anaesthesia, especially when

procedures are being performed in an outpatient setting (see **Table 7-1**). In addition, use of general anaesthesia subjects clients to increased risk of serious complications (e.g., aspiration of gastric contents or cardiac arrest) as a result of overdose, improper administration of general anaesthesia (e.g., failure to intubate the client) or inadequate monitoring.

Local anaesthesia, most commonly provided by a local field block with lignocaine, is widely used to ease the pain associated with minilaparotomy. Local anaesthesia causes minimal physiologic disturbance, allowing the client to recover rapidly.

Because clients remain alert and awake during the procedure, it is especially important to ensure:

- Counselling to increase the client's cooperation and to minimize her fears
- Good provider-client communication throughout the procedure (see above)
- Time and patience as local anaesthetics are not effective immediately

The following are conditions for the safe use of local anaesthesia:

- All members of the operating team must be knowledgeable and experienced in the use of local anaesthetics (lignocaine or bupivacaine).
- Emergency drugs and equipment (suction and resuscitation apparatus) should be readily available, in usable condition and all members of the operating team trained in their use.
- Whenever possible, it is advisable to have an anaesthetist available.

Lignocaine is the anaesthetic most commonly used for minilaparotomy. **Lignocaine** is the world standard for local anaesthesia. It is inexpensive, safe, effective and has rapid onset of action. Furthermore, there is a low risk of allergic reaction associated with the use of lignocaine. Lignocaine is the preferred anaesthetic for minilaparotomy. See **Appendix H** for more information on the pharmacology of drugs commonly used for local anaesthesia.

Table 7-1. Advantages, Disadvantages, Indications and Precautions for Local, General and Spinal/Epidural Anaesthesia for Minilaparotomy

	Local	General	Spinal/Epidural
Advantages	Avoid risks of general and spinal/epidural anaesthesia Low cost Rapid recovery when light or no sedation used Rapid induction Client awake and able to give early warning of some complications Decreased postoperative nausea and vomiting Presence of anaesthetist not required	Stationary operative field Complete analgesia Amnesia present Anxiety eliminated	Client awake and able to give early warning of some complications Stationary operative field Reduced need for sedation Decreased postoperative nausea and vomiting
Disadvantages	Requires precise and gentle surgical technique Mild to moderate client discomfort Toxicity of local anaesthetic agents	More costly; requires special equipment, personnel and environment Longer recovery May cause greater postoperative discomfort Postoperative sore throat may result form intubation Nausea and vomiting common Toxicity of anaesthetic agents	Not easy to administer; requires specialized training Takes relatively long time to administer (10-30 minutes for epidural) Recovery slower than with local anaesthesia Toxicity of anaesthetic agents
Indications	All clients without contraindications for local Setting other than operating theatre Client's fear of general anaesthesia Pulmonary disease Cardiac disease	Anxious client Less experienced operating doctor Client with presumed pelvic pathology Extremely obese client	Client's fear of general anaesthesia Pulmonary disease

Table 7-1. Advantages, Disadvantages, Indications and Precautions for Local, General and Spinal/Epidural Anaesthesia for Minilaparotomy *(continued)*

Precautions	Anxious client Less experienced doctor Conditions increasing operating time and abdominal manipulation of organs (e.g., obesity, pelvic pathology) Sensitivity to intended medications	Severe cardiac or pulmonary disease Client's fear of general anaesthesia Lack of appropriate equipment Sensitivity to intended medication	Seldom justified for short VSC procedure Pre-existing back disorder (relative contraindication) Sensitivity to intended medications History of neurological disease Coagulopathy Inexperienced anaesthetist Anxious client Cutaneous infection at incision site

Source: World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception 1988.

A sample local anaesthesia regimen which conforms to these guidelines is presented in **Table 7-2.**

Table 7-2. Local Anaesthesia Regimen

DRUGS	REGIMEN	
	USUAL DOSE	MAXIMUM DOSE (unit/kg)
Premedication[a]:		
Atropine	0.6 mg	
Phenergan	50 mg	
Alternatives:		
Diazepam (Valium)	5.0 mg	.15 mg/kg
Pentazocine (Fortwin)	30 mg	
If client comfort requires additional medication, use Pentazocine (Fortwin)	30 mg	
Local Anaesthesia[b]	Lignocaine (Xylocaine®, Lignocaine®) 1%, Bupivacaine (Marcaine®) 0.5%	5.0 mg/kg
Fallopian tubal analgesia[c] (supplemental)	5 ml 1% lignocaine (Xylocaine, Lignocaine) on each tube	

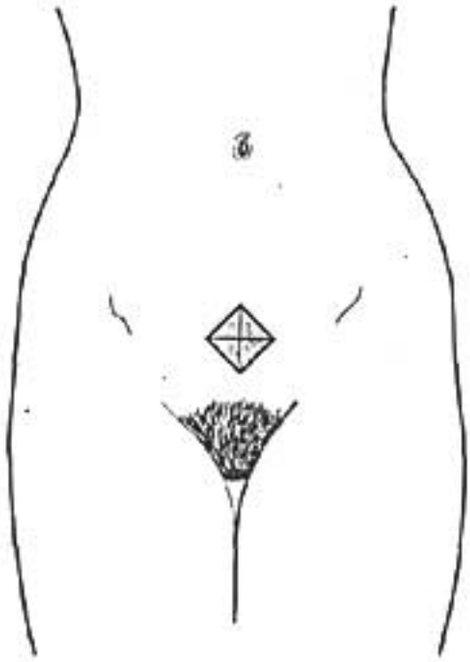
[a] These drugs can be given intramuscularly (IM) or intravenously (IV).
[b] Field block anaesthesia
[c] Topical anaesthesia

Administration of Local Anaesthesia

Local anaesthesia often is augmented with a mild systemic analgesic. Before surgery, give analgesic drugs in combination or sequentially. They can be given intramuscularly 25 to 30 minutes before the procedure or, for rapid onset of action, intravenously 2 to 3 minutes before the minilaparotomy. If intravenous, inject the dose over a period of 10 to 30 seconds, and note any untoward effects.

The goal of local anaesthesia is to achieve an anaesthetic block that infiltrates all layers of tissue from the skin to the peritoneum (see **Figure 7-1**). It is not necessary to infiltrate every layer in four directions. The anaesthetic spreads both above and below the line of infiltration in the subcutaneous space. To achieve maximum effect of the local anaesthesia into the fascial layers, it is important to infiltrate with a needle at a 45 degree angle so that the point of the needle reaches the fascia. The infiltration of the peritoneal layer does not require more than one needle thrust at a 90-degree angle to the skin.

Figure 7-1. Local Anaesthetic Block for Interval Minilaparotomy



Anaesthesia may be augmented if necessary as the fascial and peritoneal layers are exposed. For additional anaesthesia, lignocaine may be dripped on each fallopian tube.

The maximum safe dose of 1% lignocaine (without epinephrine) is 5 mg per kg body weight (e.g., 20 ml for 40 kg body weight). If lignocaine is supplied in 2% strength, it should be diluted to 1% with normal saline or sterile water because achieving an adequate block with 2% frequently requires more than 5 mg per kg body weight. The 1% strength results in better volume for more effective infiltration.

Complications of Local Anaesthesia

Major complications from local anaesthesia are extremely rare. Convulsions and deaths have, however, been reported in cases where excessive doses were used or injections into a vein occurred. To minimize the risk of major complications, local anaesthetics should be used in the smallest effective doses with careful attention to proper technique. **In most cases, 10 ml of 1% lignocaine is adequate. In no cases should the total dose exceed 5 mg per kg body weight of the client (i.e., about 20 ml).** Aspiration (pulling back on the plunger of the syringe) prior to injection reduces the risk of intravenous injection. When recommended dosages are followed, and the plunger is withdrawn before each injection, toxic levels of local anaesthetic agents rarely occur. Nonetheless, it is important to recognize the signs and symptoms of toxicity so that no further injections are made and medical treatment is begun.

Remember: The keys to safe use of a local anaesthetic are to be sure that it is not injected directly into a vein and to use the lowest effective dose.

The following sequence indicates increasingly toxic levels of local anaesthetic:

Mild effects
- Numbness of lips and tongue
- Metallic taste in mouth
- Dizziness and light-headedness
- Ringing in ears
- Difficulty in focusing eyes

Severe effects
- Sleepiness
- Disorientation
- Muscle twitching and shivering
- Slurred speech
- Tonic-clonic convulsions (generalized seizures)
- Respiratory depression or arrest

For mild effects, wait a few minutes to see if symptoms subside, talk to the client and then continue the procedure. Immediate treatment is needed for severe effects: keep the airway clear and give oxygen by mask or ventilation (Ambu) bag. Should convulsions occur or persist despite respiratory support, small increments (1–5 mg) of diazepam may be given intravenously.

> Note: The clinician should be aware that the use of diazepam to treat convulsions may cause respiratory depression.

MONITORING VITAL SIGNS

Client monitoring must be a routine practice in performing minilaparotomy. All staff members should be trained in how and how often to monitor the client while she is under the effects of sedation and local anaesthetic. Local anaesthetic and analgesic agents and sedatives may cause respiratory depression, cardiovascular depression, hypersensitivity reactions and central nervous system toxicity. Knowledge of the etiology and symptomatology of these reactions enables intervention that may prevent further complications. Staff members should be able to recognize the following:

- normal and abnormal reactions to drugs used during the procedure
- normal physiological baseline for the client
- changes in the client's condition

The staff must monitor and record blood pressure, pulse and respiratory rate before, during and after the procedure until the client is fully recovered.

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EIGHT

THE SURGICAL PROCEDURE

BACKGROUND

Minilaparotomy under local anaesthesia is a safe and simple procedure. To minimize problems, programs should be guided by the following principles:

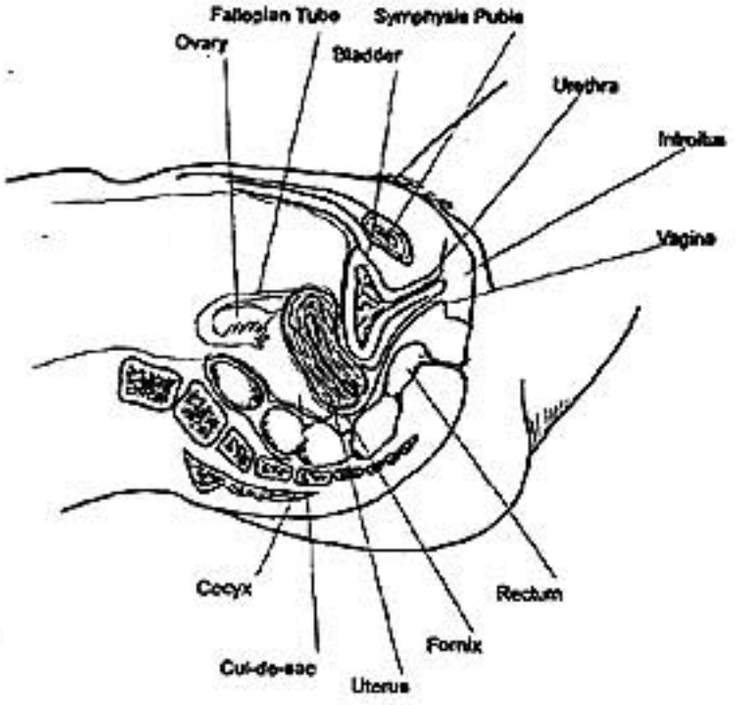
- Doctors and staff should be trained and skilled in the minilaparotomy technique, use of appropriate anaesthesia, proper use of uterine elevator and abdominal retractor, emergency abdominal surgery and other procedures for managing emergencies.
- The facility must be equipped with drugs to handle emergencies.
- All instruments and equipment must be in optimum working order before beginning the surgical procedure.
- The service staff must maintain strict infection prevention practices.
- Clients must be carefully screened and selected.

The material presented in this chapter is intended to reinforce practical training and to serve as a ready reference for questions. It cannot substitute for actual practice which is absolutely necessary for the clinician to become proficient in minilaparotomy.

Female Pelvic Anatomy

The female reproductive tract (**Figure 8-1**) consists of the vagina, uterus, fallopian tubes and ovaries. The vagina lies at an angle of approximately 45 degrees with the vertical plane of the body. It ends in a blind vault into which the uterine cervix projects. The walls of the pocket surrounding the cervix are very thin and the internal pelvic organs can be palpated through them. The uterus sits in the pelvic cavity between the bladder and the rectum and opens into the vagina via the external cervical os. The nonpregnant uterus measures about 5.5–8.0 cm in length, about 3.5–5.0 cm in width at its upper portion and about 2.0–2.5 cm thick. The fallopian tubes join the top of the uterus (fundus) and extend laterally to the ovaries. The ends of the fallopian tubes which reach into the pelvic cavity are fimbriated. The ovaries are approximately 3 cm long, 2 cm wide and 1 cm thick in an adult woman during her reproductive years (Hughes 1972).

Figure 8-1. Female Pelvic Anatomy



CLIENT ASSESSMENT

Only those clients who meet the acceptable criteria should have their surgery in ambulatory facilities (see **Chapter 5**). The final decision to offer minilaparotomy to the client is the responsibility of the operating doctor who should conduct a final medical assessment immediately before surgery. The pelvic examination done for a preoperative assessment does not eliminate the need for the operating doctor to conduct a pelvic examination before surgery.

TIMING OF PROCEDURE

Minilaparotomy can be performed at any time during the "interval" period (6 or more weeks after delivery or any time when it is reasonably certain that the client is not pregnant), immediately postpartum or postabortion, provided there are no complications. For interval procedures, tubal occlusion may be performed at any time in the menstrual cycle although it is preferable to do it at the end of the menstrual period or shortly thereafter to ensure that the client is not pregnant. Immediate postpartum procedures should be performed within 48 hours of vaginal delivery.

PREPARATION

The minilaparotomy kit (see **Appendix I**) contains all the instruments needed to perform minilaparotomy. It is important that the instruments be in excellent condition (e.g., the scalpel must be sharp). In addition, check that all instruments and other items have been sterilized or high-level disinfected (see **Chapter 5** and **Appendices C–G**).

The following instruments and other items are recommended for each minilaparotomy procedure:

- operating table with capability for Trendelenburg position
- soap for washing abdomen and perineal area
- sterile surgical drape
- examination and sterile (or high-level disinfected) surgical gloves
- antiseptic solution
- local anaesthetic (1% lignocaine)
- bivalve vaginal speculum
- vulsellum forceps (optional)
- uterine elevator
- scalpel with blade (#22)
- haemostats
- Babcock clamps
- needle holder and needles
- surgical dissecting scissors (Metzenbaum)
- suture cutting scissors
- tissue forceps
- sponge or ring forceps
- half circle cutting needle
- narrow ribbon retractors
- Richardson retractors, small
- 10 cc Luer lock syringe
- tubal hook (Ramathobodi)
- sterile gauze with surgical tape
- stainless steel bowls (2)
- kidney tray
- absorbable suture material, chromic

Resuscitation and emergency equipment and drugs which should be available are listed in **Appendix A**.

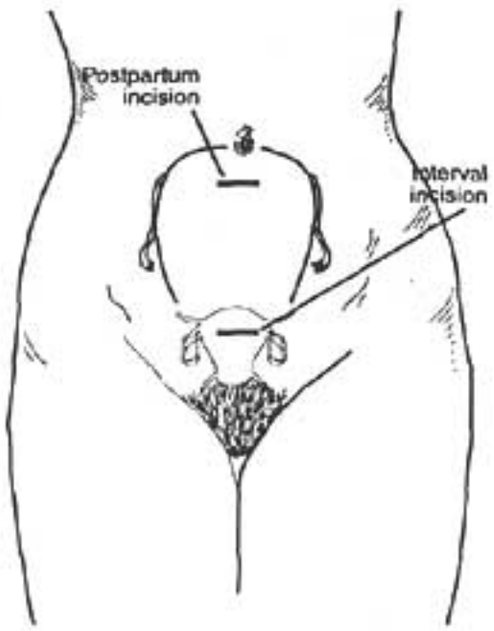
GENERAL PROCEDURE

Minilaparotomy requires only a small transverse incision, no more than 5 cm long and usually much smaller, made just above the pubic hairline (interval minilaparotomy). Using a uterine elevator inserted through the cervix, the doctor moves the uterus to bring each fallopian tube into the abdominal incision. Part of the tube is gently brought out of the abdominal incision with a Babcock forceps or tubal hook, where it is ligated and then replaced in the abdomen. The incision is closed with either absorbable or nonabsorbable sutures. The operation takes an average of 10 to 20 minutes. Women usually can leave the clinic or hospital 2 to 3 hours after surgery.

For postpartum procedures, when the uterus and tubes are high in the abdomen, a slightly different procedure is used. A curved incision no more than 3 cm is made just below the umbilicus. The

doctor can move the uterus easily with a finger to bring the tubes to the incision. The tubes are blocked by ligation and excision.

Figure 8-2. Incision Site: Postpartum and Interval Minilaparotomy



STEP-BY-STEP PROCEDURE FOR MINILAPAROTOMY

Before starting the procedure, again check to be sure whether the client has:

- given informed, voluntary consent for the procedure (a signed consent form does not assure that consent has been given freely and with full information),
- emptied her bladder (voided),
- been given the test for local anaesthesia, only if the history was positive for previous allergic reaction

Talk to the client:

- Explain to her that her skin will be anaesthetized but she will feel a little pain. Tell her that she may feel pressure, pulling or cramping during some of the steps of the operation.
- Tell her that if she feels any discomfort at any time, she should inform a member of the surgical team so that a team member can do something to relieve her discomfort.

Getting Ready

STEP 1: Operating doctor changes into surgical apparel (scrub suit or dress, cap and mask).

STEP 2: Review client history and physical examination; check haemoglobin and urine reports. Check that informed consent was obtained and verify client's identity.

STEP 3: If the client did not bathe at home, have her wash her abdominal and pelvic area with soap and water and rinse thoroughly being sure to remove all traces of soap (residual soap decreases the effectiveness of some antiseptics).

STEP 4: Check that client has emptied her bladder (voided).

STEP 5: If IM premedication is to be used, give it 25 to 30 minutes before the procedure.

Preoperative Tasks

STEP 1: Have the client undress and help position her flat on her back on the operating table.

STEP 2: Determine that sterile or high-level disinfected instruments and emergency tray are present.

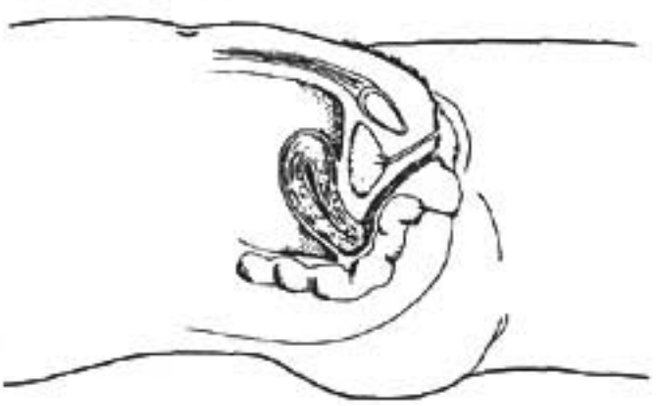
STEP 3: Wash hands thoroughly with soap and water and air dry or dry them with a clean cloth.

STEP 4: Ensure that client is in a "frog leg" position.

STEP 5: Put new examination or high-level disinfected surgical gloves on both hands.

STEP 6: Perform a gentle bimanual examination to assess uterine size, determine position, mobility and shape of the uterus and whether there is any pelvic abnormality. **Figure 8-3** shows a normal anteverted uterus.

Figure 8-3. Normal Anteverted Uterus



STEP 7: Insert vaginal speculum to see cervix. Thoroughly apply an antiseptic solution (povidone iodine) two times to the cervix (especially the os) and vagina. This step greatly reduces the load of contaminating microorganisms normally present.

Instructions for Performing Cervical and Vaginal Preparation

Ask the client about allergic reactions (e.g., to iodine) before selecting an antiseptic.

After inserting the speculum, thoroughly apply antiseptic solution two or more times to the cervix (especially the os) and then the vagina using a sponge forceps and gauze or cotton.

If iodophors are used, allow up to 2 minutes before proceeding. (Iodophors require time to release free iodine, the active substance.)

STEP 8: Insert uterine elevator without touching the tip to vaginal walls. Use vulsellum forceps to visualize cervix if necessary. **Figure 8-4** shows the elevator inserted in a normal anteverted uterus. **Figure 8-5** shows the elevator inserted in a retroverted uterus. To avoid contamination of the elevator, do not touch the elevator above the guard. Pass the elevator only once through the cervical canal. (This minimizes contamination of the uterine cavity with microorganisms introduced during insertion of the elevator.)

Figure 8-4. Normal Anteverted Uterus with Elevator Inserted

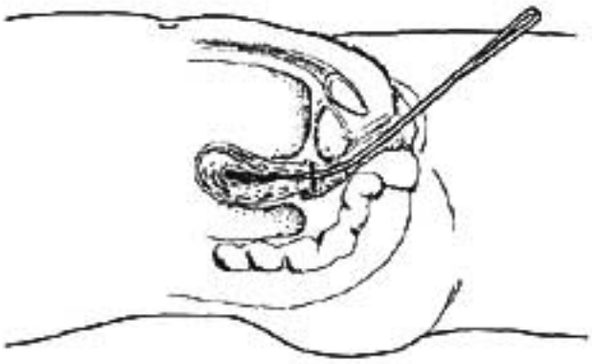
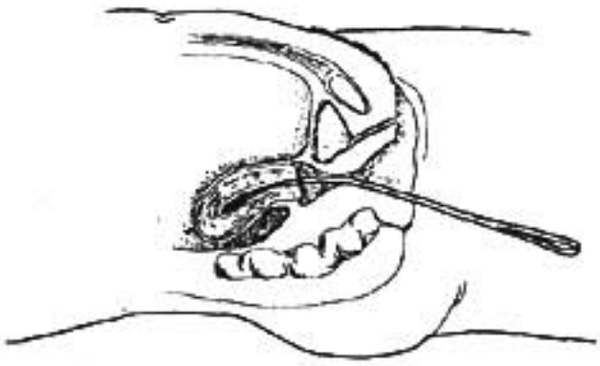


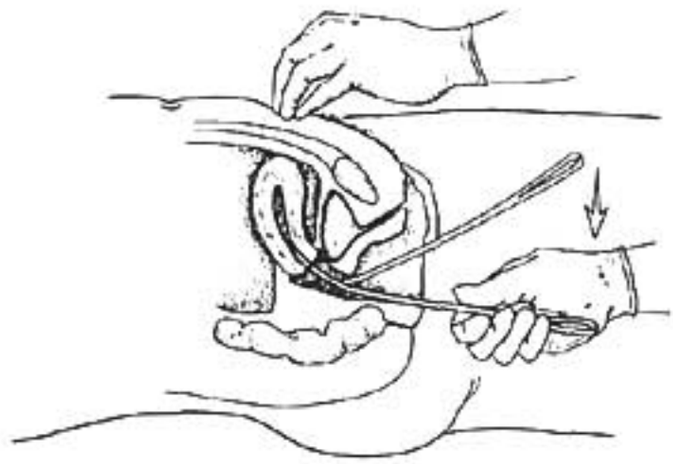
Figure 8-5. Retroverted Uterus with Uterine Elevator Inserted



STEP 9: Remove the vaginal speculum and vulsellum without dislodging the uterine elevator and place in 0.5% chlorine solution for decontamination.

STEP 10: Determine fundal height by gently pushing down on exposed end of uterine elevator and palpating abdominally (**Figure 8-6**). Do not use undue force to displace the uterus. A bulge indicates the height of the fundus—usually 2 to 3 cm above the pubic symphysis. Identify the site of the incision. The incision is made 1 to 2 cm below the height of the palpated fundus (**Figure 8-2**). Do not remove the elevator.

Figure 8-6. Lowering the Handle of the Uterine Elevator to Raise the Fundus Against the Abdominal Wall



STEP 11: Select incision site about 1 cm inferior to uterine fundus or 3 cm above pubic symphysis if fundus could not be palpated.

STEP 12: Position client's legs flat on the operating table with the handle of the elevator between her thighs and place soft belt just above her knees to keep her legs from moving.

STEP 13: If disposing of gloves, immerse both gloved hands briefly in chlorine solution and then carefully remove gloves by turning inside out and place in the waste container.

STEP 14: If reusing gloves, immerse both hands briefly in chlorine solution to decontaminate the outside. Remove by turning inside out. To ensure that both surfaces of the gloves are decontaminated, place them in the chlorine solution and soak for 10 minutes.

STEP 15: Perform surgical scrub and put on surgical gown and sterile gloves on both hands.

STEP 16: Apply antiseptic solution two times to the incision area. Use a sterile or high-level disinfected sponge forceps to hold a cotton or gauze swab soaked with antiseptic. (If preparation is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepared skin.) Begin by wiping at the incision site and move outward in a circular motion for 10 to 15 cm (4 to 6 inches) (or as for any abdominal procedure) and allow to air dry (about 2 minutes) before proceeding.

Pubic hair should not be shaved. (If the hair must be cut, trim it close to the skin surface with a scissors immediately before the procedure.)

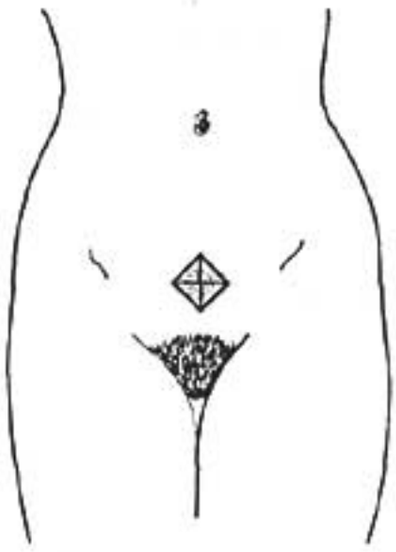
STEP 17: Drape the client with a sterile or high-level disinfected surgical cloth.

Talk to the client throughout these preparatory steps, explaining what is being done.

LOCAL ANAESTHESIA

The technique described below results in a diamond-shaped anaesthesia block (see **Figure 8-7**). The needle enters the skin in the **midline** and is inserted in both lateral directions along the incision line. Through the same puncture site, the needle is inserted at a 45° angle to the fascia in four directions, thus creating the diamond shape. A 90° infiltration of the peritoneum completes the procedure.

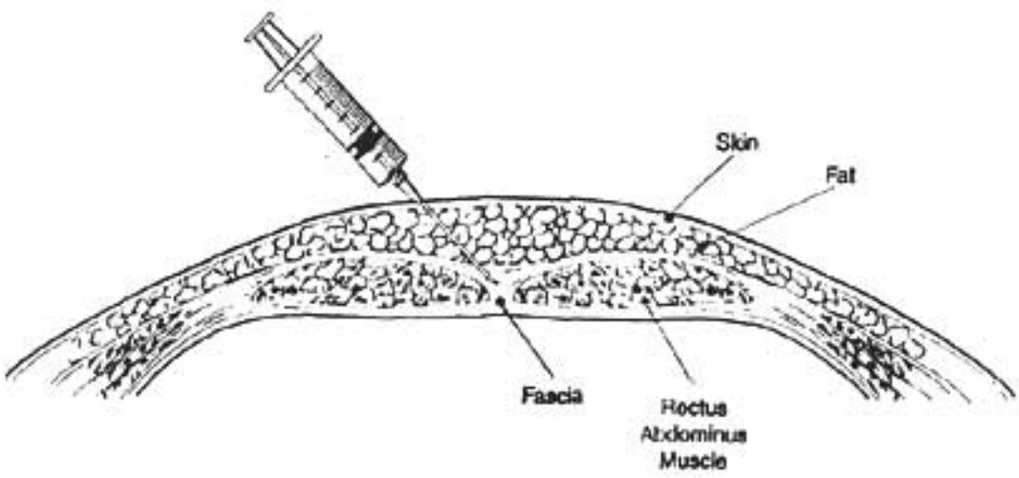
Figure 8-7. Local Anaesthetic Block for Interval Minilaparotomy



STEP 1: Raise a small skin wheal at center of incision site using 1% local anaesthetic (e.g., lignocaine) in a 10 or 20 ml sterile or high-level disinfected syringe (dose 5 mg/kg). Starting at the center of the planned incision, administer local anaesthetic (about 3 to 5 ml) just under the skin along both sides of the incision line.

STEP 2: Again starting at the center of the incision line, insert needle into the fascia at a 45° angle with the needle directed slightly above the incision line. Aspirate to ensure the needle is not in a blood vessel; then withdraw the needle slowly while injecting 3 to 5 ml of lignocaine. (Repeat on other side of incision line.)

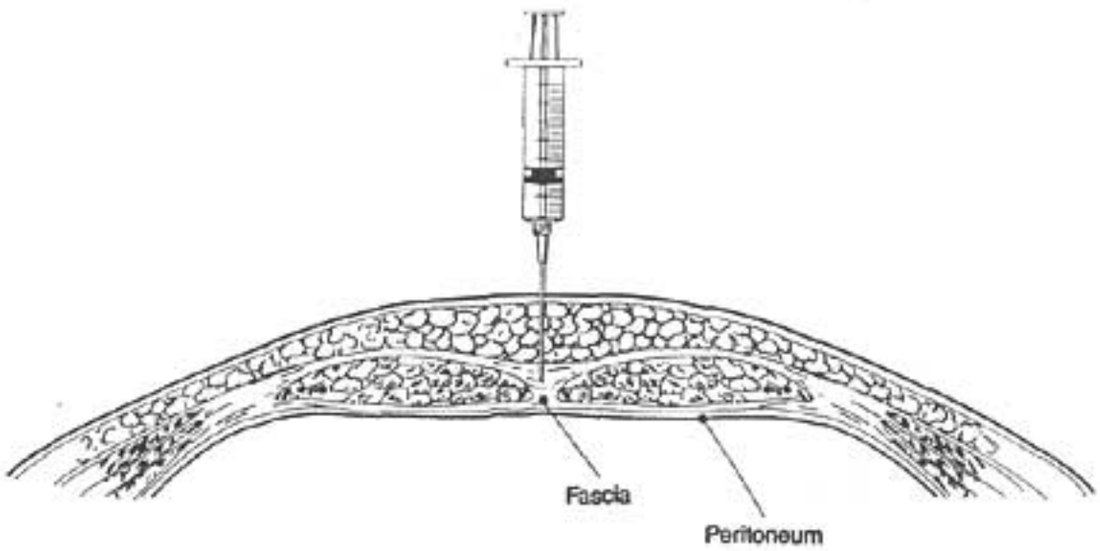
Figure 8-8. Infiltrating the Fascia (Needle at 45° Angle)



STEP 3: Insert the needle straight down through the rectus sheath to the peritoneum (Figure 8-9). Aspirate to be sure the needle is not in a blood vessel. Inject 1 to 2 ml of anaesthetic into the peritoneal layer.

STEP 4: Withdraw the needle and place on sterile or high-level disinfected tray in safe place to prevent accidental needle sticks. (Reserve a small amount of lignocaine in the syringe for supplemental use on the fascia, peritoneum and tubes as needed.)

Figure 8-9. Infiltrating the Peritoneum (Needle at 90° Angle)



STEP 5: Massage the skin gently to spread the anaesthetic into the tissues. Wait 2 to 3 minutes for the anaesthetic to take effect.

STEP 6: Test the incision site for adequate anaesthesia using tissue forceps. If client can feel a pinch, wait 2 to 3 minutes more and retest the incision site.

ABDOMINAL ENTRY

Members of the surgical team should stay alert for signs of client discomfort. Watching the woman's facial expression can be more helpful than asking her how she feels.

Use of the Trendelenburg position is optional. It can facilitate the bowel falling away from the incision site. If the head of the table is lowered, it should be done after the peritoneum has been opened and remain lowered only until the tubes have been occluded. The tilt of the table should not exceed 20° to avoid compromising the woman's breathing.

> Talk to the client throughout the procedure, explaining each step prior to performing it. Wait after each step to prepare the woman for the next step. Move slowly, without jerky or quick motions.

STEP 1: Make a 3 cm transverse incision in the skin about 3 cm above the pubic symphysis (usually about 1 cm below the height of the fundus). Do not incise the subcutaneous tissues. Control bleeders, if any.

STEP 2: To minimize bleeding, **bluntly dissect subcutaneous tissues** with scissor tips. Insert retractors into the incision, holding horizontally with hands on top of the retractors.

STEP 3: Identify and grasp fascia at two places with a pair of Allis forceps and cut transversely with scissors.

STEP 4: Separate rectus muscles in the midline (longitudinally) using blunt dissection with haemostat and clean off preperitoneal tissue if necessary.

STEP 5: Insert retractors to further separate the rectus muscles and expose the extraperitoneal fat. Strip fat away, if necessary, to expose the peritoneum, and grasp it with forceps. (Using only the syringe, sprinkle a small amount of lignocaine on the peritoneum if the woman feels pain.)

STEP 6: Confirm identification of peritoneum by using the tip of the scissors to check for transparency of the tissue. Move bowel or other abdominal tissue away from planned entry site. While elevating the peritoneum with forceps, make a small incision in the peritoneum with scissors.

STEP 7: Enlarge opening with scissors, place haemostat on upper and lower (superior and inferior) cut edges of peritoneum and reposition retractors (longitudinally) within abdominal cavity. Use retractors to move abdominal contents away from operative site. Retraction must be gentle. The retractors should be held in a horizontal plane. If they are held at a 45°, the blade ends within the abdomen can traumatize the underlying tissue.

LOCATING THE FALLOPIAN TUBES

STEP 1: Gently push down on handle of uterine elevator to bring uterine fundus upward toward the incision and closer to the abdominal wall. (The client may be placed in the head-down, Trendelenburg, position if needed).

> **Note:** When moving the elevator handle, the movement should be a gentle "pressing down" on the handle, not a "pushing in," which will displace the uterus and could result in an incision site that is too high.

If the uterus cannot be brought up or manipulated, check to see if the uterine elevator is in place—it may have to be reinserted. If the tip of the uterine elevator can be palpated through the abdominal wall, it may have perforated the uterus.

STEP 2: Visually confirm presence of fundus underneath the incision site. (The fundus of the uterus should be visible through the incision site before attempting to retrieve the tube. Blind poking can cause trauma and spasms, complicating the procedure.)

STEP 3: Rotate the uterine elevator around its long axis to bring the right or left cornu and fallopian tube under the incision site. Move the elevator handle to the right of the client to visualize the right tube and to the left to visualize the left tube.

> Note: The fimbria may not be visible if the tube is fixed due to adhesions. If this is the case, pay special attention to other structures and determine their relationship to the tube (e.g., position of the ovary, round ligament etc.).

STEP 4: Visually confirm presence of cornual portion of tube at the incision site.

GRASPING THE FALLOPIAN TUBES: FORCEPS METHOD

STEP 1: Insert a Babcock forceps and locate fallopian tube.

STEP 2: Identify midportion of tube and gently grasp it with the Babcock forceps. **Do not lock forceps.**

STEP 3: Gently bring the tube through the incision. Avoid grasping the cornu.

STEP 4: Identify the fimbriated end of the tube by "walking" the forceps laterally.

GRASPING THE FALLOPIAN TUBES: TUBAL HOOK METHOD

STEP 1: Maintain downward pressure to ensure that a fundus remains under the incision site.

STEP 2: Insert the tubal hook behind the uterus. Move one end of the hook laterally until it is positioned behind the mesosalpinx. (The hook should slide behind the fundus and be swept outward toward the fimbriated end of the tube. When the hook is swept toward the fimbria, the handle of the hook should lie across the incision.)

STEP 3: Press the handle of the hook against the abdominal wall until parallel with it (flat). (Trying to capture the tube between the hook and the side wall of the uterus can cause undue tension on the cornua and isthmic portions and because the hook cannot lie across the incision, the tube usually slides off the hook.)

STEP 4: Visualize the midportion of the tube held by the hook and bring it up to the incision. The hook will not hold the tube on the small ring end if the handle is vertical. In order for the tube to stay on the hook, the handle must be at least 45° to the horizontal. Once the tube has

been "hooked," the handle of the hook can be gently withdrawn from the incision, bringing the tube with it.

STEP 5: Insert a Babcock forceps and gently grasp the tube.

STEP 6: Use Babcock forceps to grasp the midportion of the tube gently and bring it through the incision. Do not lock forceps. (Avoid grasping the cornu.)

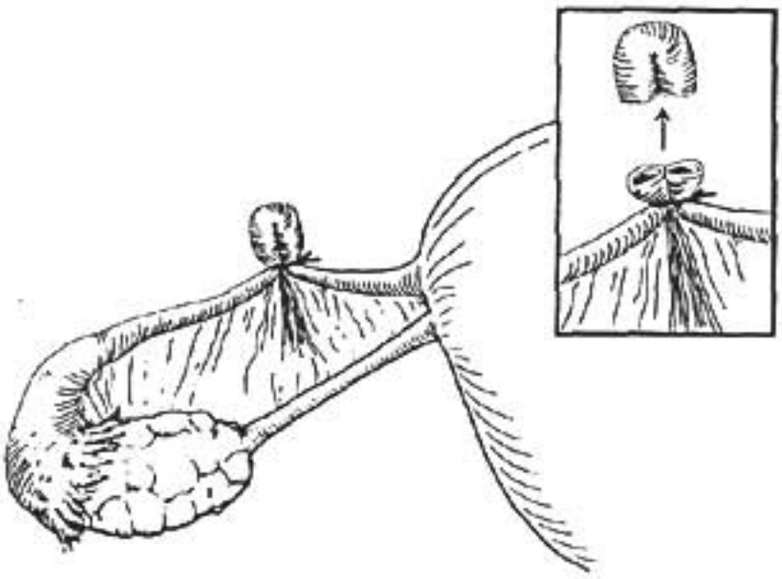
STEP 7: Identify the fimbriated end of the tube by "walking" the forceps laterally.

TUBAL OCCLUSION

The simple Pomeroy technique is the most widely used method of ligation in minilaparotomy. The resected loop or segment should be in the midportion of the tube, where the diameter of each stump will be the same. Fimbriectomy, or excision of the fimbrial end of the fallopian tube, is not recommended since it increases the risk of failure.

In the simple Pomeroy technique, a loop of tube is ligated and the knuckle of the tube above the ligature is excised (**Figure 8-10**). Because the blood vessels of the mesosalpinx are caught in the ligature, haemostasis must be assured before releasing the tube into the abdominal cavity.

Figure 8-10. Pomeroy Technique of Tubal Occlusion



STEP 1: While grasping the midportion of the tube, place single free tie (absorbable suture) around a 1 to 2 cm loop of tube (about 3 cm from cornu) and tie square knot.

STEP 2: Cut out a loop of tube with scissors and while still holding ligature, inspect the stump for haemostasis.

STEP 3: Cut ligature 1 cm from stump and release the tube, allowing it to return to the abdomen.

STEP 4: Repeat the procedure on the opposite side for the second tube.

> **Note:** After occlusion of the tubes, adjust the table so that it is once again parallel to the floor.

CLOSURE

When haemostasis is assured, close the wound in layers. The peritoneum need not be closed.

STEP 1: Secure rectus sheath edges with two interrupted sutures.

STEP 2: Close skin with absorbable suture material. Dress the wound.

PROCEDURE TO FOLLOW AFTER COMPLETION OF MINILAPAROTOMY

Client Care

- Remove the uterine elevator and check for bleeding from the uterus.
- Help the client from the operating table and assist to the recovery area. Handle the client gently when moving her..
- Make the client as comfortable as possible.
- Monitor vital signs until stable.

(See **Chapter 9** for detailed information on postoperative recovery and discharge.)

Waste Disposal and Decontamination

- Dispose of excised tubes in proper receptacle for biologic hazard materials.
- Before removing gloves, place instruments into a container filled with 0.5% chlorine solution for decontamination (see **Appendix C** for how to make a solution from household bleach). Before immersing the needle and syringe, fill with chlorine solution. (Do not disassemble.) Soak for 10 minutes. Rinse immediately with clean water to avoid discoloration or corrosion of metal items.
- The surgical drape must be washed before reuse. Place in a dry covered container and remove to the designated washing area.

- While still wearing gloves, place all contaminated objects (gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid or in a plastic bag.

- If disposing of gloves, immerse both gloved hands briefly in chlorine solution and then carefully remove gloves by turning inside out and place in the waste container.

- If reusing gloves, immerse both hands briefly in the chlorine solution to decontaminate the outside. Remove by turning inside out. To ensure that both surfaces of the gloves are decontaminated, place them in the chlorine solution and soak for 10 minutes.

- Wash hands thoroughly with soap and water.

- All waste material should be disposed of by burning or burying.

CLIENT INSTRUCTIONS FOR WOUND CARE AT HOME

- Rest and keep the operative site dry for 2 days, gradually resuming normal activities as she feels able. (She should be able to return to normal activities within 7 days after surgery.)

- Do **not** have sexual intercourse for 1 week, and stop if it is uncomfortable.

- Avoid heavy lifting or putting tension on the incision for 1 week.

- For pain take one or two analgesic tablets, such as ibuprofen, every 4 to 6 hours. (Do not use aspirin as it may increase bleeding.)

- Return to have wound inspected after 7 days.

- See a health care provider if signs of pregnancy develop. While pregnancy after tubal occlusion is rare, if it does occur there is an increased chance that it will be in the fallopian tube (ectopic pregnancy), which is a life-threatening situation.

- If signs of infection occur, such as fever with inflammation (redness plus heat) at the site, or if there is persistent abdominal pain for several days, return to the clinic.

TIPS FOR SUCCESSFUL PROCEDURES

To minimize complications in **both interval and postpartum** procedures, the operating doctor should remember to:

- Examine a fold of the peritoneum before incising, to ensure that bowel is not adherent. Expose the fimbrial end of the tube for absolute identification.

- Perform the surgery gently to prevent bleeding and tearing of the fallopian tubes and mesosalpinx.
- Apply sutures and ligatures carefully and correctly.
- Use a non-toothed instrument, such as a Babcock or a straight artery forceps (Kelly or Pean) to grasp intra-abdominal tissue.
- Inspect the tissues thoroughly before closing the incision to make sure there is no bleeding.

To minimize complications in **interval procedures** the operating doctor should remember to:

- Avoid incising the bladder (have the client empty her bladder just before surgery).
- Insert and manipulate the uterine elevator properly and gently to avoid perforating the uterus.

To minimize complications in postpartum procedures, the operating doctor should remember:

- Do not use a uterine elevator.
- Perform surgery within 48 hours of delivery.
- Rule out any condition that would increase the risk of infection or complications of anaesthesia. Infection is an indication for postponement after vaginal delivery; other such indications are intrapartum or postpartum haemorrhage resulting in severe anaemia and pulmonary or cardiac problems.
- Use caution in making the incision in the thin abdominal wall near the umbilicus so as not to cut the intestine.
- Be careful to avoid trauma to the uterine cornu during the procedure.

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NINE

POSTPARTUM MINILAPAROTOMY[1]

BACKGROUND

Postpartum tubal occlusion should be included in every voluntary surgical contraception program. The period after the birth of a child may be the most convenient time for the procedure both for the client and the service provider. The decision for postpartum tubal occlusion, however, should be made before the onset of labor whenever possible. Information about postpartum tubal occlusion should be included as part of routine prenatal counselling.

The postpartum procedure is best performed at the health care facility where the delivery takes place. It should not be performed, however, at the site of a home delivery or in a maternity center that does not have staff trained to perform the procedure.

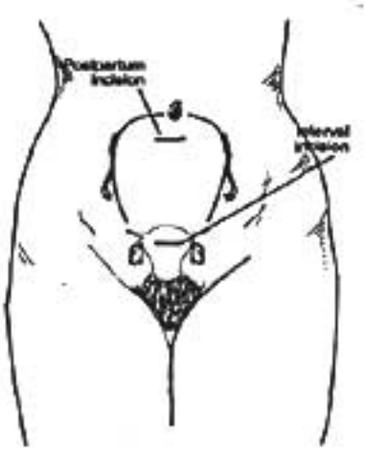
Minilaparotomy is the preferred approach during the immediate postpartum period. The incision for postpartum minilaparotomy is often smaller than that needed for interval procedures.

DIFFERENCES BETWEEN POSTPARTUM AND INTERVAL PROCEDURES

The size and position of the uterus differ in postpartum and interval clients and the procedures differ accordingly.

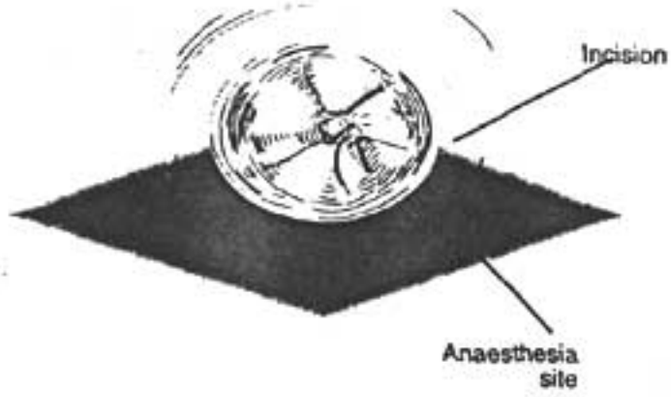
- After delivery the uterus is high in the abdomen. The fallopian tubes are therefore easily accessible through a small subumbilical incision (**Figure 9-1**). **Figure 9-2** shows a closeup of the incision.

Figure 9-1. Incision Sites for Postpartum and Interval Minilaparotomy



[1] *Adapted from*: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia.* Family Planning Service, Department of Health: Manila, The Philippines.

Figure 9-2. Closeup of Postpartum Minilaparotomy Incision



- For postpartum procedures, it is not necessary to use the uterine elevator because the tubes are readily accessible.

- The fallopian tubes are generally bigger, often oedematous and more friable; therefore, greater care is needed in handling them.

TIMING OF POSTPARTUM PROCEDURES

The recommended time for performing a postpartum minilaparotomy is within 48 hours of vaginal delivery. During that time, the fundus is near the umbilicus so that a small subumbilical incision affords ready access to the tubes. In addition, an unnecessarily long hospital stay is prevented.

It is preferable to wait at least 12 hours after delivery. This allows time to assess the condition of the baby and to identify postpartum complications such as haemorrhage. An exception to this is when general or regional anaesthesia will be used for delivery.

Clients presenting for a postpartum procedure after a home delivery must be asked whether they have been immunized against tetanus. If not, tetanus toxoid should be given and the client told to return in 6 weeks. At that time, the second tetanus toxoid dose should be given and the procedure can be performed. If the client states that she has been immunized against tetanus, the procedure can be performed under antibiotic cover.

If minilaparotomy is done after 48 hours and the uterus has started to involute, the incision may be done vertically about 2 cm below the fundus. A suprapubic incision also can be done if the fundus is more than halfway below the umbilicus.

If possible, minilaparotomy should not be performed from 7 days postpartum up to the end of the puerperium (6 weeks after delivery) for two reasons:

- During this period, the uterus can no longer be reached through an incision near the umbilicus. For the first 48 hours, the uterus lies just beneath the skin and fascia, below the umbilicus. After that time, as it descends it lies beneath an area with additional layers of

fat and muscle, making entry into the peritoneal cavity more difficult and possibly requiring a larger incision.

- The postpartum uterus is soft and enlarged, prohibiting the use of a uterine elevator.

If the procedure is postponed for 28 or more days after delivery, the risk of becoming pregnant begins to increase for women who are not fully breastfeeding. Appropriate methods of contraception are needed in this situation.

HOSPITAL STAY

In most cases, the postpartum procedure and its recovery period do not add to the usual hospital stay required for normal delivery. In some instances, the surgical schedule at the facility may make it necessary for the woman to stay longer than if she had not had the procedure.

THE SURGICAL PROCEDURE

Vertical Incision: Local Anaesthesia

STEP 1: Raise a small skin wheal at the center of the incision site using 1% local anaesthetic (without epinephrine) in a 10 or 20 ml sterile (or high-level disinfected) syringe. The maximum dose should not exceed 200 mg.

STEP 2: Starting at the center of the planned incision line, administer about 3 to 5 ml of local anaesthetic just under the skin, along both sides of the incision line.

STEP 3: Starting again at the center of the incision line, insert needle into the fascia at a 45° angle with the needle directed along the upper half of the incision line.

STEP 4: Aspirate to ensure that the needle is not in a blood vessel. Withdraw the needle slowly while injecting 3 to 5 ml of lignocaine. Repeat on the lower half of the incision line.

Subumbilical Incision: Local Anaesthesia

STEP 1: Raise a small skin wheal at the center of the incision site using 1% local anaesthetic (without lignocaine) in a 10 or 20 ml sterile (or high-level disinfected) syringe. The maximum dose should not exceed 200 mg.

STEP 2: Starting at the center of the planned transverse incision line, administer about 3 to 5 ml of local anaesthetic just under the skin, along both sides of the incision line.

STEP 3: Starting again at the center of the incision line, insert needle into the fascia with the needle directed towards the transverse half of the incision line.

STEP 4: Aspirate to ensure that the needle is not in a blood vessel. Withdraw the needle slowly while injecting 3 to 5 ml of lignocaine. Repeat on the other half of the incision line.

Abdominal Entry: Vertical Incision

- Make a vertical skin incision, approximately 3 cm long, about 1 cm inferior to the uterine fundus.

Abdominal Entry: Subumbilical Incision

- Make a transverse skin incision, approximately 3 cm long, about 1 cm inferior to the uterine fundus. Because the peritoneum lies just below the umbilicus, be careful not to incise the bowel while opening the thin layers.

Delivery of the Fallopian Tubes

- The uterine elevator is not used to manipulate the uterus in a postpartum minilaparotomy procedure. Instead, with the help of the nurse/assistant, reposition the retractors to move the incision site in the loose abdominal wall over each tube. Or, move the tube to the incision site by pressing a hand against the side of the abdomen and pushing the uterus to the side.

- A separate minilaparotomy kit is not needed for the postpartum procedure. Never use toothed instruments to grasp intraperitoneal tissue. Great caution must be used in identifying and grasping the tubes because tubal edema may lead the operating doctor to think the tube is the intestine or vice versa.

- Avoid grasping the cornual portion of the tube because it is easily traumatized.

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TEN

POSTOPERATIVE RECOVERY, DISCHARGE AND FOLLOWUP[1]

BACKGROUND

Monitoring the client after surgery is a very important function because it is during this period that any effects of surgical trauma or other postoperative complications become apparent. Although nurses or other staff members will carry out the tasks related to postoperative recovery and discharge, the operating doctor is ultimately responsible for the quality of recovery room care.

Before discharge, a staff member should give the client postoperative instructions, orally and in writing. The client should be asked to repeat these instructions to ensure that she has understood them and be given a followup appointment. The operating doctor or medical officer assesses that she is ready for discharge.

The client should expect a visit by a health worker within 48 hours of discharge. The followup clinic visit should occur within 7 days of surgery so that the sutures (if nonabsorbable sutures were used) can be removed at the optimum time and look for signs of infection. The visit should include an examination of the operative site and any other relevant examination required by the specifics of the case and symptoms or complaints of the client. If the client has a problem that cannot be resolved, another visit should be scheduled.

POSTOPERATIVE MONITORING

In the postoperative period, staff must observe the client constantly. The person assigned this duty has the following responsibilities:

- Receive the client from the operating theatre; review the client record.
- Make the client as comfortable as possible (handle the woman gently when moving her).
- Make sure that a semiconscious client is never left unattended.
- Monitor the client's vital signs:
  - Check blood pressure, respiration and pulse every 15 minutes until they are stabilized at pre-operative levels
  - Thereafter, check vital signs every 30 minutes until the client has fully recovered from the effects of the anaesthesia.
  - Record vital signs in the client record each time they are checked.

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[1] *Adapted from*: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia.* Family Planning Service, Department of Health: Manila, The Philippines.

- For interval cases, check for vaginal bleeding other than menstruation. If the client is bleeding, the doctor should check for possible injury to the cervix that may have been caused by the uterine elevator.
- Check the surgical dressing for oozing or bleeding.
- Observe the general condition of the client (including changes in skin color, postoperative pain, level of consciousness and orientation to time and space).
- Administer drugs or treatment for symptoms according to the doctor's orders.
- Provide liquid and carbohydrates (e.g., hard candy, clear fruit juices, tea, coffee, Sikanji) in order to raise blood sugar and carbohydrate levels.
- Complete the client record form.

SIGNS OF POSTOPERATIVE COMPLICATIONS

The staff should be able to recognize and respond to the following signs of distress:

- Excessive somnolence
- Respiratory rate of less than 10 per minute
- Hyperventilation
- Systolic blood pressure of less than 90 mm mercury
- Rapid pulse rate (over 90 per minute) or weak pulse
- Pallor or cyanosis

The following may be signs of an intra-operative complication:

- Inability to retain fluids (vomiting)
- Inability to urinate
- Inability to ambulate (client is unsteady when standing)
- Signs of hypovolemia (client feels faint upon rising, has rapid heart rate)
- Severe abdominal distention

POSTOPERATIVE INSTRUCTIONS

After the sedation has worn off and before the client is discharged, the client should be told the following postoperative instructions:

- She should rest and keep the operative site dry for 2 days. She can gradually resume normal activities as she feels able. (She should be able to return to normal activities within 7 days after surgery.)

- She should **not** have sexual intercourse for 1 week, and should stop if it is uncomfortable.

- She should avoid heavy lifting or putting tension on the incision for 1 week.

- She should return to the clinic or contact the clinic or doctor immediately if she develops any of the following:
  - Fever (greater than 38°C or 100.4°F)
  - Dizziness with fainting
  - Persistent or increasing abdominal pain
  - Bleeding or fluid coming from the incision
  - Signs or symptoms of pregnancy

- For pain she may take one or two analgesic tablets, such as ibuprofen, every 4 to 6 hours. (Do not use aspirin as it may increase bleeding.)

- She should see her health care provider if she ever has signs of pregnancy. While pregnancy after tubal occlusion is rare, if it does occur there is an increased chance that it will be in the fallopian tube (ectopic pregnancy), a life-threatening situation.

- She should expect a visit by a health worker within 48 hours.

- She should return for a **followup visit** within 7 days of surgery, or at the latest within 2 weeks.

Written instructions summarizing the above also should be provided to the client or her spouse.

How to Give Postoperative Instructions

- Give the client a copy of the postoperative instructions written in a language she understands.

- If the client is illiterate, ask her to name a literate friend or relative near her home who can read the instructions to her at a later date.

- Explain the instructions to the client in a language that she understands.

- Explain what the client can expect to feel on the days following surgery. Common symptoms include:

  - uterine cramps
  - incision discomfort
  - abdominal discomfort
  - light vaginal bleeding

- Explain the warning signs of complications and where she should go if they occur:
  - abdominal pain that is persistent, severe or increasing
  - bleeding or pus or swelling at the incision site
  - fever within a month of the minilaparotomy

- Check whether the client understands the instructions by asking her to repeat them.

- If the followup visit is to take place at another facility, make sure that the client knows where the clinic is and how to get there.

- Encourage the client to ask questions.

DETERMINING WHEN THE CLIENT IS READY FOR DISCHARGE

Occasionally a client may require overnight observation. The following are indications that a client is **not ready** for discharge:

- She is unable to retain fluids (vomiting).

- She is unable to ambulate (unsteady when standing).

- She shows signs of possible abdominal bleeding.

- She shows signs of hypovolemia. She is unable to void or is dizzy or has an increase in pulse rate when moving from lying down to a sitting up or standing position. (An increase in pulse rate when moving from a lying to sitting position with legs dangling is a more sensitive indicator of hypovolemia than is low blood pressure.)

- She shows incomplete recovery from anaesthesia by the time she should leave the facility to start for home at a reasonable hour.

- A responsible adult is not available to accompany or transport her home.

The client is recovered sufficiently to be discharged when she meets the following conditions:

- She is taking and retaining fluids and light nourishment.

- She can pass the Romberg test (stand upright with eyes closed and feet together, without dizziness).

- She can walk upright with minimal support.

- Her vital signs are at pre-anaesthetic levels.
- She has no bleeding or seepage from the wound.
- She has no unusual complaints.

Before discharging the client, the staff should assure the following:

- She understands the signs of potential problems (warning signs).
- She understands that she should return to the clinic immediately or seek emergency care if a problem develops.
- She has heard and repeated the postoperative instructions.
- She has received any medications ordered.
- She has received a followup appointment.
- She has a responsible adult to accompany her home.

TRANSFER OF CLIENT RECORDS

All client records should be maintained at the service site where the procedure took place. If the followup visit will take place at another facility, the client should be given a card to give to the followup provider. The card should state the date of the procedure, the type of procedure and any special instructions. If it is necessary to transfer a copy of the client's records, the original should be kept at the facility where the surgery took place.

FOLLOWUP

Although it is preferable that the operating doctor conduct the followup examination, a trained nurse or midwife can perform the examination and manage minor complications. If the client goes to another health center for followup, it is important that the staff at that facility be trained to do a careful followup examination and report any observed complication to the facility where the minilaparotomy took place.

When to Return to the Clinic

The first **followup visit** should occur within 7 days of surgery (or at the latest within 2 weeks) and should include an examination of the operative site, suture removal (if nonabsorbable sutures were used) and any other relevant examination called for by the specifics of the case and symptoms or complaints of the client.

Subsequent Followup

A subsequent followup visit should be made after either 1 month or the next menstrual period, whichever is earlier. During this visit the staff assesses the client to determine if she has any side effects or complications related to the surgery. In addition to medical problems, a staff member should look for signs that the client may be experiencing dissatisfaction or regret related to the procedure.

The followup visit should include the following tasks:

- Check the medical record or referral form, if available, for background information on the client and the surgical procedure.

- Ask the client if she has experienced any problems or had any complaints since the surgery. Specifically, ask if the woman has experienced any of the following:
  - vaginal discharge or bleeding
  - wound discharge or bleeding
  - urinary difficulties
  - fever
  - pain or other distress

- Examine the operative site to assess healing and the absence of infection.

- Clean the operative site.

- Remove nonabsorbable sutures, if used.

- Treat or refer for any complications indicated by the examination.

- Remind the client to return to the clinic if she misses a menstrual period or shows other signs of pregnancy.

- Document the followup visit in the client's medical record, including complaints, diagnosis and treatment.

Emergency Followup

Clients making an emergency followup visit should receive immediate attention. Staff should be alert to the possibility of internal bleeding, bowel injury or infection.

If the woman had surgery at another health facility, the medical records may not be available. The staff member conducting the interview should obtain chronological information covering all events since the day of surgery. Complications and treatment should be reported to the facility where the minilaparotomy was performed.

The emergency visit should include the following tasks:

- Examine the client immediately. Check all areas related to her complaint.
- Read the medical record, if available.
- Obtain chronological information from the client. Include any problems during the surgery or in the recovery period; development of problems or increase in discomfort and any medications taken or treatments obtained.
- Decide on the treatment for problems that can be handled on an outpatient basis.
- Arrange for a higher level of treatment for potentially serious complications.
- Note on the client record all problems and actions taken.
- Inform the facility where the minilaparotomy was performed about the emergency followup visit (if applicable).

FAILURE OF TUBAL OCCLUSION

Tubal occlusion is one of the most effective methods of contraception. Ectopic or intrauterine pregnancy is, however, possible after a tubal occlusion procedure. Service providers must be prepared to identify such conditions early. Symptoms of an ectopic pregnancy include lower abdominal pain, amenorrhoea and abnormal uterine bleeding. If pregnancy, particularly ectopic, is suspected, the woman should be referred immediately to an appropriate medical facility for diagnosis and treatment.

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ELEVEN

MANAGEMENT OF COMPLICATIONS[1]

BACKGROUND

Complications are abnormal conditions caused by the procedure that require intervention or management beyond routine postoperative care. For example, a wound infection noted on the fifth day after surgery that requires opening the wound is a **complication**, while abdominal cramping on the day after the procedure is a **side effect**.

Serious complications are rare and the mortality rate for minilaparotomy is low if complications are immediately and accurately diagnosed and effectively treated. Complications of minilaparotomy generally are the same as those associated with similar abdominal surgery:

- Anaesthesia-related complications
- Vasovagal reactions
- Bleeding from the incision site or mesosalpinx
- Abdominal injuries: uterine perforations, bladder or bowel injuries
- Infections of the wound or pelvic cavity

Overall, minilaparotomy is a safe procedure and few women experience complications. Major complications occur in less than 2% of all cases. Anaesthesia-related complications are summarized in **Table 11-1**; management of surgical complications is summarized in **Table 11-2**.

In addition to the specific interventions described in this chapter, the following steps should be taken when a complication arises during the procedure:

- Abandon surgery while emergency treatment is underway.
- Return the table to the parallel position.
- Complete the surgery only if the client's condition has stabilized.
- Consider hospitalizing the client for observation.
- Record the complication and the treatment in the client record.

ANAESTHESIA-RELATED COMPLICATIONS

Serious anaesthesia-related complications are likely to occur as a result of overdose, improper administration of the anaesthesia or inadequate monitoring. To manage acute complications related to anaesthesia:

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[1] *Adapted from*: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia*. Family Planning Service, Department of Health: Manila, The Philippines.

- Identify the problem immediately.
- Take prompt action based on the nature of the problem.
- Do not delay in taking action.

Cases of **respiratory depression** should be managed as follows:

- Keep the airway open.
- Ventilate the client using Ambu bag; attach O_2 tube, if possible.
- Check the client's circulation; monitor pulse, blood pressure and respiration.

Table 11-1. Anaesthesia-Related Complications

Complication
Respiratory depression or arrest
Cardiovascular changes, including arrhythmia, hypotension or hypertension
Cardiac arrest
Convulsions
Aspiration of vomitus
Signs
Decreased breathing rate
Short, shallow, quick breathing
Dyspnea, gasping, laryngeal stridor
Circumoral cyanosis (blueness around the mouth)
Cyanotic nail beds (bluish fingernail beds)
Irregular or rapid pulse
Central nervous system changes (restlessness, anxiety, disorientation)
Convulsions or loss of consciousness
Absence of pulse, heart sounds, respiration, reflexes and muscle tone
Hypotension
Possible Cause
Overdose of sedative or tranquilizer
Combined effect of drugs
Delayed effect of drugs
IV injection of lignocaine
Overdose of lignocaine
Pre-existing cardiac disease
Severe blood loss with intravascular volume depletion

- Administer naloxone 0.4–0.8 mg intravenously if a narcotic agent has been used. This dose may be repeated within 2 to 3 minutes if the desired improvement in respiratory function is not obtained.

  Naloxone should routinely be the drug of first choice for respiratory depression when narcotics have been used. It acts promptly, has little toxicity and is quickly metabolized. The client must be monitored closely because the effect of the narcotic causing the depression may outlast the effect of naloxone; repeated administrations may be required.

Several doses of naloxone may be administered over a short period without untoward effects.

If there is no response after naloxone 2 to 4 mg, other causes of respiratory depression should be considered.

- For pulmonary aspiration of gastric contents, suction the trachea immediately and administer hydrocortisone sodium succinate 1 to 1.5 g intravenously. Begin broad-spectrum antibiotics.

- For convulsion, give small increments (1 to 5 mg diazepam) to control seizures. (Be aware that diazepam may aggravate respiratory depression.)

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

If a cardiovascular complication does occur, the surgical team should be prepared to provide basic cardiopulmonary resuscitation.

- If a cardiac arrest is confirmed, given an immediate precordial thump and begin external cardiac massage.

- In case of respiratory arrest, give oxygen through resuscitation equipment (or begin mouth-to-mouth resuscitation).

- Cannulate a vein and administer resuscitative drugs as appropriate and indicated.

Table 11-2. Management of Complications Associated with Minilaparotomy

COMPLICATION	POSSIBLE CAUSE	ASSESSMENT	MANAGEMENT
Wound infection	Failure to observe appropriate IP practices Failure to instruct client in proper care of wound	Confirm presence of infection or abscess.	If skin infection is present, treat with antibiotics. If abscess is present, drain and treat as indicated.
Postoperative fever	Infection	Determine source of infection.	Treat infection based on findings.
Bladder injuries (rare)	Failure to ensure bladder was emptied before surgery Inappropriate location of incision	**Intraoperatively** Clear fluid welling up into the incision or operative site Sight of the rugal folds of bladder mucosa **Postoperatively** Presence of haematuria Suprapubic pain Fever	**Intraoperatively** Insert a Foley catheter. Instill sterile solution into bladder through catheter. Repair injury in two layers using continuous suture of fine catgut with atraumatic needle. Continue minilaparotomy if injury is minor. Begin course of antibiotics. Hospitalize if injury is extensive. **Postoperatively** Refer to appropriate centre as necessary.

COMPLICATION	POSSIBLE CAUSE	ASSESSMENT	MANAGEMENT
Bowel injury	Failure to feel the grasped tissue of the fold to ensure bowel is not adherent before opening	**Intraoperatively** Visualization of bowel serosa or muscularis	**Intraoperatively** Repair in multiple layers using fine silk suture (or chromic catgut if available) with atraumatic needle.
	Failure to look for translucence of the tissue fold before opening	Visualization and smell of bowel contents	If injury is superficial (serosal layer only), allow client to rest an extra hour. Discharge with instructions to return immediately if pain or fever begins. Follow up to monitor any change in condition over next 48 hours.
	Quick and deep entry through the thin abdominal wall at the umbilicus during postpartum procedures	Abdominal pain	If injury is through to bowel lumen, initiate IV antibiotics.
		Postoperatively Abdominal pain that increases in severity Vomiting Failure to pass flatus Acute illness Fever with rapid pulse (early) Return of temperature to normal or subnormal (later) Abdominal distension Abdominal tenderness	Hospitalize for observation following repair. If faecal matter is expelled into the abdomen, lavage the peritoneal cavity with sterile solution. Complete minilaparotomy after repairing bowel. **Note: If the health centre does not have the facilities and staff to treat bowel injuries, the client should be referred to the nearest district hospital.**
Haematoma (subcutaneous)	Unrecognized injury to blood vessels, bleeding beneath skin surface	Confirm presence of infection or abscess.	Apply warm, moist packs to site. Observe; it usually will resolve over time but may require drainage if extensive. If infected, treat as indicated (antibiotics).
Unusually severe pain at incision site	Subcutaneous collection of pus, serum or blood	Determine presence of infection or abscess. Check for fluctuance, expression of pus or serum, severe induration.	Treat based on findings (e.g., moist heat, analgesics, antibiotics).

COMPLICATION	POSSIBLE CAUSE	ASSESSMENT	MANAGEMENT
Immediate pregnancy, ectopic	Conception occurred prior to tubal ligation with embryo trapped in distal portion of tube	Sudden intense pain, persistent pain or cramping in the lower abdomen, usually localized to one side Irregular bleeding or spotting with abdominal pain after a missed or abnormally light menstrual period Fainting or dizziness associated with either of the above conditions, that persists for more than a few seconds (could indicate internal bleeding)	Manage based on findings.
Remote pregnancy, ectopic	Failed tubal ligation or recanalization of ligated portion of tube	Sudden intense pain, persistent pain or cramping in the lower abdomen, usually localized to one side Irregular bleeding or spotting with abdominal pain after a missed or abnormally light menstrual period Fainting or dizziness associated with either of the above conditions, that persists for more than a few seconds (could indicate internal bleeding)	Manage based on findings.
Pregnancy, intrauterine	Undetected pregnancy at time of minilaparotomy Incomplete occlusion of tube or procedure performed on structure other than the tube Spontaneous recanalization Formation of fistulas at occluded end of tube	Pelvic evaluation Pregnancy test	Manage according to GOI guidelines.

COMPLICATION	POSSIBLE CAUSE	ASSESSMENT	MANAGEMENT
Superficial bleeding (skin edges or subcutaneously)	Failure to maintain haemostasis during surgery	Determine presence of infection, abscess or haematoma.	**Postoperatively** Place secure pressure dressing on wound. If bleeding persists, reopen wound under local anaesthesia and clamp and ligate the bleeding points.
Abdominal/Pelvic adhesions	Pelvic inflammatory disease, endometriosis, septic abortion, previous abdominal surgery	Adhesions noted upon entering the abdomen or attempting to locate and identify tube	If adhesions can be lysed safely and gently, tubal ligation can proceed. If adhesions are dense, however, and tube cannot be identified/grasped without risking injury to internal organs or without causing significant pain, general anaesthesia and larger incision may be required to complete the procedure. If this can be provided at the time of the attempted minilaparotomy, tubal ligation can be completed. If not, abdomen should be closed, and the client should be informed of a failed procedure and referred to a centre where general anaesthesia is available.
Uterine perforation	Improper insertion of uterine elevator Rough manipulation of uterine elevator Postpartum uterus still soft	Tip of elevator protruding through uterus Inability to elevate the uterus against the abdominal wall Superficial palpation of the tip through the abdominal wall Metallic sound of the tip against the abdominal retractors Bleeding	If uterus is anteverted, elevator may be left in place while minilaparotomy completed. Caution required if uterus is manipulated. If uterus is retroverted, reposition elevator, rotating the uterus to anteverted position, then complete minilaparotomy. After minilaparotomy completed, remove elevator and examine perforation site for bleeding. If fresh bleeding occurs, control with mattress suture using chromic catgut. If bleeding controlled, close the abdomen and observe the client for extra 1 to 2 hours. Initiate course of antibiotics. Consider hospitalization if continuous bleeding is suspected or if posterior perforation with vessel injury occurred.

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TWELVE

PROVIDING QUALITY SERVICES

BACKGROUND

Successful family planning service programs are characterized by:

- emphasis on quality and client satisfaction,
- provision of services in a manner acceptable to the client,
- a good followup care and referral system,
- efficient and effective management and monitoring systems,
- realistic goals setting, and
- efficient logistics.

The previous chapters focused on the technical competence and skills required to provide voluntary sterilization services. The objective of this chapter is to provide clinicians and clinic managers with information on **how to improve and maintain quality services.**

Quality of care refers to the way in which individuals and couples are treated by the health care system providing services. The quality of care process involves three steps:

- setting standards of care which describe how services will be provided and what the expected results (indicators) will be,
- assessing quality of care by gathering information (data) on whether the standards of care are being met, and
- ensuring (or improving) quality of care by taking corrective action when standards are not being met.

Remember: A high quality program is client-oriented and helps individuals achieve their desired reproductive goals.

SETTING QUALITY OF CARE STANDARDS IN VS SERVICES

The first task for clinicians and program managers concerned with improving client satisfaction is to define the quality of care (standards) they would like to provide within their specific service delivery program. These **standards of care** will form the basis for subsequent **quality assessment** and **quality assurance** (improvement) activities (Jain, Bruce and Mensch 1992).

A quality of care standard is a specific and clear statement of expectation which is:

- measurable;
- attainable;
- relevant; and
- frequency-bound (i.e., how often will it occur, as, for example, "for all clients").

There are several key aspects of service delivery which contribute to client satisfaction. Setting standards of care in these areas helps clinicians and managers assess and improve the quality of services being offered. Bruce (1990) has defined these as follows:

- **Choice of contraceptives** refers to the variety of contraceptive methods available to an individual/couple. Clinicians should have the knowledge and skills required to offer several family planning methods in order to provide the one most appropriate for each client's needs.

- **Information given to clients** refers to information that enables clients to choose and use a contraceptive method with satisfaction and provides a good understanding of the method. This information should be part of the counselling process (see **Chapter 2**) and includes how the methods work, precautions for use, benefits and limitations, how to use the method selected and any potential side effects and complications. When this task is performed appropriately, clients should be able, for instance, to correctly explain and use the method chosen.

- **Client-provider interaction** refers to the provider's skill in establishing a positive atmosphere and two-way communication to assist clients in discussing any fears, misgivings or biases that they may have about a specific contraceptive method or family planning in general (see **Chapter 3**).

- **Technical competence** refers to the level of the clinical skills of providers, their observance of protocols (written descriptions of steps to be followed during service provision) and use of recommended infection prevention practices in delivering family planning services. Clinical tasks required for the provision of minilaparotomy services are described in **Chapters 2 through 11**.

- **Continuity of care** refers to the mechanisms by which clients can have any side effects treated, switch their method if desired and receive supplies easily.

- **Appropriateness and acceptability of services** refers to providing accessible and acceptable health care which supports the reproductive health needs of clients (i.e., integrated as opposed to vertical health care programs).

ASSESSING QUALITY OF SERVICES

The **second step** in the quality of care process is assessing whether clients are receiving care at the level described in the clinic standards. **Quality assessment** involves gathering data to determine the level of achievement of standards set by the clinic (Donabedian 1988; Kumar, Jain and Bruce 1989). For example, this assessment process can identify deficiencies in service provision, which in turn will determine the steps required to improve the overall quality of services.

The assessment process includes:

- determining quality of service issues,
- specifying indicators of quality care,
- specifying the data that should be collected to measure the indicators, and
- identifying strategies for collecting and processing the data.

There are many sources from which data for monitoring quality can be obtained. The most common sources include:

- observation of clinic services (e.g., IUCD insertion);
- review of client records;
- data retrieved from clinic records which show patterns of use, contraceptive method mix or quantities of service provided (e.g., VS acceptors);
- client interviews; and
- self-assessment by clinic staff.

Once the data have been analyzed, a judgement can be made to determine whether quality is good or bad, satisfactory or unsatisfactory.

Remember: High-quality service does **not** necessarily involve use of technically sophisticated equipment in expensive clinic facilities. Each clinic must make a judgement according to its own situation and available resources.

Clinic staff and managers should regularly review their efforts to improve the quality of care provided to the client. These efforts should involve periodic assessments of various elements of quality. For voluntary sterilization, this process should involve the entire service delivery team and be an ongoing activity.

Examples of "how to" assess each of the key quality of care indicators are listed below.

Assessing Choice of Contraceptive Method

- Provider discusses all methods appropriate to reproductive goals of the client.
- Provider refers client for methods unavailable at service delivery site.
- Client receives her method of choice, appropriate to her reproductive goals.
- All contraceptive methods supplied at the clinic are stored according to established guidelines.
- Established logistic guidelines are followed in the distribution of contraceptive commodities.

Assessing Information Given to Clients

- Provider gives overview of all methods.
- Provider gives in-depth information on method chosen:
  - how it works,
  - how it is used,
  - known health benefits,
  - side effects and other health problems and their management,
  - potential complications,
  - followup requirements, and
  - how to obtain resupply (e.g., oral contraceptives, condoms, etc.).
- Client correctly explains method chosen:
  - how it is used,
  - possible side effects and what to do if side effects occur,
  - when to return, and
  - where to return.
- Method-specific informational materials are available (brochures, samples, etc.).
- Acceptable privacy is provided for:
  - counselling, and
  - examination (when necessary).
- Consent form is available and signed by client.

Assessing Client-Provider Interaction

- Provider establishes good rapport with client in order to assess her personal situation (e.g., family circumstances, nature of sexual relationships, etc.). Client feels:

- welcomed by staff,
- at ease and comfortable asking questions, and
- that staff and providers treat her with respect.

Assessing Technical Competence of Provider[1]

- Provider can explain contraceptive methods available:
  - benefits and limitations,
  - mechanism(s) of action,
  - indications and precautions for use,
  - how they are used, and
  - side effects and other health problems and their management.
- Provider is proficient in clinical procedures (according to guidelines).
- Provider uses recommended infection prevention practices.
- Client receives a contraceptive method which is:
  - appropriate based on her health status (is safe for her to use), and
  - appropriate for her sexual lifestyle (including risk of GTIs and other STDs).
- Provider is capable of managing GTIs and other STDs (this is especially important for IUCD services).
- Basic items (equipment and supplies) needed to deliver available methods are in stock.
- Supervision is adequate.

Assessing Mechanisms to Ensure Continuity of Care

- Resupply for continuing users (e.g., oral contraceptives, injectables or condoms) is available.
- Provider informs and encourages client to return as needed.
- Followup/return schedule is appropriate for method.

Assessing Organization of Services

- Clients perceive that:
  - privacy for counselling is acceptable;
  - privacy for examination is acceptable;
  - waiting time is acceptable;
  - time with provider is acceptable;

---

[1] Requires existence of written family planning guidelines and up-to-date job descriptions for each clinic position.

  - hours/days are convenient; and
  - staff is appropriate in terms of gender, ethnic group and age.

- Clients perceive that the health care facility has adequate:
  - waiting room,
  - examination room,
  - cleanliness/hygiene,
  - water, and
  - toilet facilities.

Assessing Outcomes

Data are collected for:

- number of new acceptors,
- complication rate for specific methods,
- continuation rate (of any method),
- new clients recommended by other users, and
- clients achieving reproductive goals.

ENSURING QUALITY OF SERVICES

The third and final step in the quality of care process involves quality assurance activities. Quality assurance (QA) is an ongoing process to objectively and systematically assess and monitor client care based, in part, on the pre-established service standards and on the client's feedback and needs. Traditionally, the QA process has involved service providers and managers reviewing data obtained during the assessment in order to identify the problems and explore possible solutions (reactive process).

Recently, the purpose of quality assurance has been expanded to ensure that gradual and continuous improvements are made in all clinic functions, not just problem areas (proactive process). The latter is part of the continuous quality improvement approach (Leebov and Ersoz 1991). Continuous quality improvement (CQI) is a methodological approach used to achieve stated or implied standards. It is based on the belief that staff members at any level can make valuable suggestions about ways to improve services; recognizes that many problems result from poorly designed or implemented systems and processes, rather than individuals; and assumes that any aspect of family planning service delivery, not just problem areas, can benefit from some improvement. The differences between the traditional QA system and the CQI approach are listed in Table 12-1.

Table 12-1. Traditional Quality Assurance (QA) Versus Continuous Quality Improvement (CQI) Approach

Aspects	QA	CQI
Quality standards	Quality is based on pre-determined program objectives and is monitored periodically.	Quality is based on clients' feedback and needs. Quality is monitored continuously and is built into the work process.
Problem solving	Problem solving and decision making are done by senior managers and specialists.	Problem solving and decision making are done in collaboration with staff and based on hard data.
Improvement process	Short-term improvements are made, often at point of crisis (reactive).	Gradual, continuous improvements are made in all functions (proactive).
Program clients	Clients are not usually consulted for their opinions.	Clients are partners and are regularly consulted.
Work environment	Staff work individually.	Staff work in teams.
Performance recognition	Authority is rewarded.	Capabilities are rewarded.
Source of problems	Problems come from people.	Problems come from complex processes and systems.
Style of supervision	Control and direct staff.	Encourage staff to take initiatives.
Financial perspective	Quality costs money.	Quality saves money.

Adapted from: Llewelyn Leach 1992; Mayer 1992.

The principles of CQI were presented in a recent issue of *The Family Planning Manager* (Wolff et al 1993). This report also provides a detailed discussion of what a clinic manager or service provider needs to do in order to prepare for CQI, how to initiate it and the steps involved in implementing the CQI approach.

Improving the Quality of Care

In working to improve the quality of care provided, it is important for the clinic staff to first state the problems they would like to address and then identify the steps to be followed to solve them. To achieve this objective, some (or all) of the following questions need to be answered by clinic staff:

- **Is the clinic adequately prepared and organized to offer a given standard of care?** *Example*: Review existing resources (supplies and equipment), client flow, staff training and allocation of responsibilities.

- **What is the process involved in providing a given standard of care?** *Example*: Review steps required and used to provide a specific service (e.g., minilaparotomy) including sequence of events.

- **Which part(s) of the service delivery process is not being satisfactorily performed?** *Example*: Identify step(s) which is not properly performed (e.g., infection prevention practices for minilaparotomy).

- **What are the causes of the problem?** *Example*: Identify causes which may explain the problem identified.

- **What can be done to improve the process?** *Example*: Suggest solutions which can be implemented at clinic and managerial levels (e.g., provision of recommended infection prevention supplies).

- **Who should be involved in planning and implementing the solution?** *Example*: Assign responsibilities for monitoring improvements (e.g., role of each staff member in improving recommended infection prevention practices).

- **What indicators of success can be used to assess performance?** *Example*: Use indicators already defined in the statement of standard to monitor progress (e.g., reduction in the number of infections following minilaparotomy.

Table 12-2 provides an illustrative example of how quality assurance could be applied to the infection prevention standards in a clinic-based program providing minilaparotomy services.

Remember: The best programs are never perfect and new ways to improve the quality of services are always evolving.

In summary, providing quality services is an ongoing activity. The quality of care process described in this chapter is designed to monitor and evaluate client care objectively and systematically, based on pre-determined standards. Its purpose is to assist clinic staff and managers in eliminating or correcting identified problems and to assure that client care is the best it can be, given the resources available.

Table 12-2. Steps in Family Planning Quality Assurance Process

STEPS	EXAMPLE
STEP 1: Establish a standard for the clinic based on what is valued or important in client care. The standard is a statement of: • what will be done, • by which staff, and • to achieve what results.	**Standard**: Recommended infection prevention (IP) practices will be followed by providers during minilaparotomy to minimize risks to clients and clinic personnel.
Assess whether the clinic is achieving the stated standard.	Observe minilaparotomy service provision using a checklist. Assess competency of clinicians and support staff in following recommended IP practices.
Review whether the clinic is adequately prepared to meet the standard.	Staff trained in IP practices? Adequate space and equipment to process instruments? Selection and use of gloves? Antiseptics? Client and staff traffic flow reduce risk of infection? IP supplies and equipment available?
STEP 2: Review the process involved in meeting the standard.	**Process**: Decontamination, cleaning, sterilization or HLD **Findings**: Standard is not met because cleaning is not performed satisfactorily.
STEP 3: Identify causes of problem(s) and suggest solution(s).	**Possible Causes**: Lack of knowledge of how to do cleaning and lack of consumable supplies (e.g., disinfectants or gloves) **Corrective Measures**: Staff should be given on-the-job training and provided with necessary supplies.

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THIRTEEN

MOBILE OUTREACH SERVICES

BACKGROUND

In India, reproductive health services are often not accessible in rural areas. In order to make voluntary surgical contraception services available to all people, in the 1970s "camps" were introduced in the service delivery system. There are two types of camps used for provision of VS services in India. In the first, a trained surgical team from outside the district provides services at a district hospital where VS services usually are not provided. In the second, a team from the District Hospital travels to Community Health Centres (CHC) and Primary Health Centres (PHC) within the district on a fixed day of the week. Other settings (e.g., schools and community centres) are not being used for providing sterilization services in camp settings.

An estimated 80 percent of sterilization in Uttar Pradesh occurs in camps organized by the Ministry of Health and Family Welfare (MOHFW) (Kumar 1988). A camp is any grouping of clients to receive a specific service. It does not refer to the location of the site or the quality of services offered there. Even when services are provided at a health facility, such as a PHC or Postpartum Centre (PPC), the event is labelled as a camp when either personnel (e.g., doctors, anaesthetists) or materials (e.g., medicines, equipment) are supplied externally (Townsend, Khan and Gupta 1995).

Although the provision of VS services in camp settings has been widely accepted in India and is generally believed to be of high quality, it is important that such service provision remain of high quality. The quality standards applied to camps should be the same as those for fixed sites. In some cases, the requirements for camps may be greater than those for fixed sites. For example, the clinicians who work at camps must be experienced not only in the provision of VS services but also in diagnosis and treatment of problems, because the emergency backup at camps is less than that available at fixed sites. The provision of services in camps requires some special considerations.

It was not until 1991 that official standards for care were provided by the MOHFW. Previously there had been guidelines, but much reliance was placed on the personal skills of the doctor and camp organizers. The standards for mobile services should be reviewed with all team members and used as the basis for training and supervision.

STAFF

Staff who work on mobile teams should be the most highly trained, skilled and experienced personnel available. In the camp setting, the emergency backup system is likely to be less accessible than when services are delivered at fixed sites. Providers must, therefore, be able to recognize problems promptly and to manage them appropriately. Training is not allowed in mobile settings. Nurses who work as members of mobile teams should have OT experience and should be able to handle surgical instruments correctly. It is important that the skills of providers be up-to-date. If providers do not perform procedures on a regular basis, they may need to have their skills updated before working at a camp. Coordination with and utilization

of staff from the area is desirable in camp settings. No training of service providers shall be conducted in mobile sterilization camps.

It is important that an adequate number of doctors and support staff (nurses, etc.) and equipment be available in the camp setting to meet the demands of the anticipated client load. This is to assure that clients are adequately counselled, that instruments and other items are properly processed and that staff do not become fatigued, leading to inadequate client care.

COUNSELLING

Counselling and client education often are performed by local health workers before the camp is opened. This allows for a more efficient flow of clients during the camp, as those clients who come will already have chosen VS.

All family planning clients should receive the same degree of counselling, regardless of the service delivery site. Counselling provides an opportunity for clients to learn about all methods of family planning so that they are better able to make an informed choice of an appropriate method. Because VS is permanent, it is of particular importance that clients make an informed choice. Although clients must sign an informed consent form prior to the procedure, this form does not ensure that the client has been counselled adequately. The final assessment of clients in terms of being certain they area eligible and have made an informed choice for sterilization is the responsibility of the mobile team. (See Counselling chapter for more information on the counselling process.)

CLIENT ASSESSMENT

Client assessment for mobile VS services may begin before the site is ready to receive clients. For example, local health care workers trained to perform client assessment for VS may be able to determine if VS is appropriate for a client before the client is referred to the camp. When this is done, clients must be given temporary methods of family planning to ensure that they are not pregnant when they arrive at the camp.

> Note: Postpartum clients who have delivered at home are not eligible for sterilization in the camp setting.

Client assessment at mobile sites should be the same as at fixed sites. It is extremely important to assess clients to ensure that high-risk clients do not have VS procedures in mobile settings. Assessment should include a medical assessment by a trained health care provider as well as haemoglobin and urinalysis testing. In addition, client assessment should include questions to ensure that the client has made an informed choice of VS. If on assessment VS is found to be not suitable for a client, she should be referred for further counselling and provided with another family planning method.

INFECTION PREVENTION

Standard infection prevention procedures should be followed at mobile sites. Handwashing supplies should be provided, including running water or a bucket and pitcher. If neither of these is available, an alcohol rub must be provided. Standard OT gowns, masks and caps must be worn. Surgical gloves must be provided and they must be processed (sterilized or high-level disinfected) between cases. All instruments used for the procedure must also be processed between cases. Finally, waste must be disposed of according to the MOHFW/GOI *Standards for Male and Female Sterilization.*

Clients must change into clean OT clothing prior to surgery and preparation of their skin should be emphasized.

ANAESTHESIA

According to the MOHFW/GOI *Standards for Male and Female Sterilization,* only local anaesthesia must be used for minilaparotomy in camps. It is preferable that an anaesthetist be available at camps.

EMERGENCY BACKUP

Emergency backup is required for all sites offering VS services. When such services are provided in mobile sites, the need for backup is even more important. Mobile teams must be supplied with all the supplies and equipment needed to manage surgical emergencies.

In particular, every site must have:

- a functioning oxygen cylinder,
- tubing and masks,
- medicine to manage emergencies, and
- an Ambu bag.

The mobile team must be trained in the management of emergencies, including use of all emergency equipment and drugs.

The team must have formal relationships with district or primary health care centres in the area. The local backup facilities must have supplies, equipment and trained staff required to handle complications following VS. These facilities should be prepared to receive clients from the camps if additional emergency backup is needed. Relationships with local facilities also will ensure that clients who need continued medical treatment after emergencies will have a way to receive it.

FOLLOWUP CARE

Clients who undergo VS procedures in mobile settings require the same followup care as those who receive services at fixed sites. At some sites, members of the mobile team may remain at the site until all clients have returned for their followup visits or they may return on the day on which followup visits are scheduled. If this is not possible, clients can return for followup visits with local health care providers. In any case, local providers should be trained to provide followup care in case problems develop or questions arise. Referral centres should be identified for followup of complicated cases and local providers should be made aware of where clients should be referred. The client should be given the name of a local doctor at the time of discharge from the mobile centre.

PLANNING

Providing VS services in mobile settings requires coordination at both the central and district levels. Planning should address the promotion and implementation of mobile sites and should include budgets, schedules, manpower and administration.

LOGISTICS

In order to ensure quality of care at mobile sites, logistics should be monitored at all times. The services should be monitored from the perspective of both the clients and the service providers. As with fixed sites, managers should ensure that clients are not waiting too long for services. They should ask clients to assess the services they received. In addition, they should ask providers if they have encountered any problems and help them to solve them. Each day the manager should check the supplies and arrange to replenish any supplies that are low. The manager should also monitor infection prevention practices.

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APPENDIX A

EMERGENCY PREPAREDNESS[1]

Staff must take certain precautions and make preparations prior to sterilization procedures to effectively manage emergencies. Staff must be skilled in administration of intravenous fluids and drugs. They must understand which drugs may be used, how to administer them and their expected actions. They must be familiar with the use of all emergency equipment and must check all such equipment before each operating session. Members of the staff must be trained to handle specific complications. The person monitoring the client in the operating room and in the recovery room must be aware of early signs of complications, and be able to take initial emergency action. At least one member of the surgical team must know how to administer cardiopulmonary resuscitation. The emergency care supplies and drugs must be kept in an accessible place, known to the staff members.

The equipment listed below must be available for emergency use in the operating room and recovery area. All emergency equipment must be immediately available, prepared for use and in good functioning condition. A laryngoscope and endotracheal tube are appropriate only when trained and experienced personnel are available to use them. A battery-operated light source should be available for backup or focused illumination of the operative site.

EMERGENCY EQUIPMENT AND SUPPLIES

- Stethoscope
- B.P. instruments
- Oral airways (two sizes)
- Nasal airways (two sizes)
- Suction machine with tubing and two traps
- Ambu bag
- Anaesthesia face mask and tubing and oxygen nipple
- Oxygen cylinder with reducing valve and flow meter
- Blanket
- Gauze pieces
- Kidney tray
- Torch (flashlight)
- Syringes and needles, including butterfly sets

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[1] *Adapted from*: Department of Family Welfare, Ministry of Health and Family Welfare, Government of India. 1996. *Standards for Male and Female Sterilization.* Ministry of Health and Family Welfare: New Delhi.

- Intravenous infusion sets and fluids
- Adhesive strapping
- Sterile laparotomy instruments

EMERGENCY DRUGS

The drugs listed below should be readily available in the operating theatre and recovery area. Staff need to be well informed about the drugs—their use, doses, strength, route of administration, toxicity and treatment of overdose.

Emergency Drugs (All Injectables Only)

- Adrenaline
- Atropine sulphate
- Corticosteroids (Dexamethazone or Hydrocortisone)
- Physostigmine
- Aminophylline
- Antihistamine (Phenergan, Avil)
- Diazepam
- Pethidine
- Pentazocine
- Sodium Bicarbonate (7.5%)
- Calcium Gluconate (10%)
- Frusemidine
- Dopamine
- Dextrose 5% in water
- Dextrose 5% in normal saline
- Glucose 25%
- Ringer's Lactate solution

Hospital Backup

If the sterilization operation is provided in a clinic with limited capability for handling emergencies, such as a mobile service facility, special planning is necessary. Mobile service teams must have all supplies and equipment needed to handle the immediate surgical emergency. In addition, they should have relationships with established backup medical facilities in the area so that clients who need continued medical treatment during and after

emergencies can receive reliable care. The local backup facilities must have the supplies, equipment and trained staff required to handle complications following sterilization operations.

REFERENCE

Department of Family Welfare, Ministry of Health and Family Welfare, Government of India. 1996. *Standards for Male and Female Sterilization.* Ministry of Health and Family Welfare: New Delhi.

APPENDIX B

STERILIZATION CONSENT FORM[1]

Name	Shri/Smt._____
Spouse's name and address	Shri_____
Father's name and address	_____
Operating centre	_____

Dear Sir/Madam:

Please arrange to have me sterilized. My age is_____ and my spouse's age is_____. We are married and my spouse is alive. We have_____ male and_____ female living children. The age of the youngest child is _____ years.

- The decision to undergo the sterilization operation has been taken independently by me without any outside pressure, inducement or force.
- I am aware that other methods of contraception are available to me which have been properly explained.
- The eligibility criteria for the operation have been explained to me, and I affirm that I am eligible to undergo the operation according to the criteria.
- I know that for all practical purpose this operation is permanent and that after the operation I will be unable to have any more children.
- I also know that there are some chances of failure of the operation, for which the hospital/institution and operating doctor will not be held responsible by me or my relatives or any other person whomsoever. I will report to the centre/doctor if there is any missed menstrual cycle of mine/my spouse within two weeks.
- My spouse has not been sterilized previously.
- I am also aware that I am undergoing an operation which carries an element of risk.
- I agree to come for followup to the centre/doctor as instructed, failing which I shall be responsible for consequences, if any.
- I agree to undergo the operation under any type of anaesthesia which the doctors think suitable for me and to be given other medicines as considered appropriate by the doctors concerned.

The above information has been read/read out and explained to me.

_____ _____

Signature, Name and Address of Witness* Signature of acceptor

* Witness can be any person not associated with the Service Centre.
Applicable to the cases where the client cannot read and the above information is read out.

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[1]*Source*: Department of Family Welfare, Ministry of Health and Family Welfare, Government of India. 1996. *Standards for Male and Female Sterilization*. Ministry of Health and Family Welfare: New Delhi.

1. I know Shri/Smt._____.To the best of my knowledge the information given by him/her is correct.

_____
Signature of Motivator
Name and Full Address

2. The client has been fully counselled about the above method.

_____
Signature of Counsellor**
Name and Full Address

3. I certify that I have satisfied myself that Shri/Smt._____ is within the eligible age-group and is mentally and medically fit for a sterilization operation. (There is no evidence that he/she has undergone a sterilization operation previously.) I have explained to the acceptor that this form has the authority of a legal document.

_____
Signature of Operating Doctor
(Name and Address)

_____
Signature of Medical Officer
(Name and Address)

DENIAL OF STERILIZATION

I certify that Shri/Smt._____ is not a suitable case for sterilization for the following reasons:

1.

2.

He/she has been provided the following alternative method of contraception.

_____

_____
Signature of Counsellor** or
Doctor Making Decision
(Name and Address)

** Counsellor can be any health personnel including doctor.

REFERENCE

Department of Family Welfare, Ministry of Health and Family Welfare, Government of India. 1996. *Standards for Male and Female Sterilization.* Ministry of Health and Family Welfare: New Delhi.

APPENDIX C

INFECTION PREVENTION PROCESSES FOR SURGICAL INSTRUMENTS AND OTHER ITEMS[1]

The three basic steps for processing instruments, gloves and other items used for minilaparotomy are:

- decontamination,
- cleaning, and
- sterilization or high-level disinfection (HLD).

Details for the safe reuse of instruments, gloves and other items are provided in this appendix. (See **Appendix F** for information on processing surgical gloves and **Appendix G** for information on processing needles and syringes and linens.)

DECONTAMINATION

Decontamination is the first step in handling soiled surgical instruments and other items. It is important to decontaminate instruments and items that may have been in contact with blood or body fluids.

Immediately after use, place instruments and other items in a 0.5% chlorine solution for 10 minutes. This step rapidly inactivates HBV and HIV and makes items safer to handle by personnel who clean them.

Making Dilute Chlorine Solutions

The World Health Organization recommends **0.5% chlorine solution** for decontaminating instruments before cleaning or when potable water is not available for making the solution (WHO 1989). For HLD, a 0.1% solution is satisfactory provided boiled water is used for dilution.

Table C-1 describes how to make 0.5% and 0.1% chlorine solutions using commercially available liquid bleach products. The general formula for making a dilute solution from a commercial preparation of any concentration is shown in **Figure C-1.**

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[1] *Adapted from*: Tietjen L, W Cronin and N McIntosh. 1992. *Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual.* Essential Medical Information Systems, Inc.: Durant, Oklahoma.

Table C-1. Preparing Dilute Chlorine Solution from Liquid Bleach (Sodium Hypochlorite Solution) for Decontamination and HLD

Type or Brand of Bleach (Country)	Chlorine % Available	Ratio of Bleach to Water[a] 0.5%	0.1%[b]
JIK (Kenya), Robin Bleach (Nepal)	3.5%	1 : 6	1 : 34
Household bleach (USA, Indonesia), ACE (Turkey), Eau de Javal (France) (15° chlorum[c])	5%	1 : 9	1 : 49
Blanquedor, Cloro (Mexico)	6%	1 : 11	1 : 59
Lavandina (Bolivia)	8%	1 : 15	1 : 79
Chloros (UK), Lejía (Peru)	10%	1 : 19	1 : 99
Chloros (UK), Extrait de Javel (France) (48° chlorum[c])	15%	1 : 29	1 : 149

[a] For the ratio of bleach to water, read as one part concentrated bleach to x parts water (e.g., JIK - 1 part bleach to 6 parts water for a total of 7 parts).

[b] Use boiled water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter which inactivates chlorine.

[c] In some countries the concentration of sodium hypochlorite is expressed in chlorometric degrees (°chlorum); 1°chlorum is approximately equivalent to 0.3% available chlorine.

Figure C-1. Formula for Making Dilute Chlorine Solution from Concentrated Solution

$$\textit{Total Parts (TP) water} = \left[\frac{\%\ \textit{Concentrate}}{\%\ \textit{Dilute}}\right] - 1$$

Example: Make a dilute solution (0.5%) from 5% concentrated solution.

1. Calculate TP water: $\left[\frac{5.0\%}{0.5\%}\right] - 1 = 10 - 1 = 9$

2. Add 1 part concentrated solution to 9 parts water.

The approximate amounts (grams) needed to make 0.5% and 0.1% chlorine-releasing solutions from several commercially available compounds (dry powders) are listed in Table C-2. The formula for making a dilute solution from a powder of any percent available chlorine is listed in Figure C-2.

Table C-2. Preparing Dilute Chlorine Solution from Dry Powder

Available Chlorine Required	Grams per Litre of Water	
	0.5%	0.1%*
Calcium hypochlorite (70% available chlorine)	7.1	1.4
Calcium hypochlorite (35% available chlorine)	14.2	2.8
NaDCC (60% available chlorine)	8.3	1.5
Chloramine (25% available chlorine)	20	4
NaDCD-based tablets (1.5 g of available chlorine per tablet)	4 tablets/litre	1 tablets/litre

* Use boiled water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter which inactivates chlorine.

Adapted from: World Health Organization 1989.

Figure C-2. Formula for Making Dilute Chlorine Solution from Dry Powder

$$Grams/Litre = \left[\frac{\%\ Dilute}{\%\ Concentrate}\right] x\ 1000$$

Example: Make a dilute chlorine solution (0.5%) from a dry powder (35%).

1. Calculate grams/litre: $\left[\frac{0.5\%}{35\%}\right] x\ 1000 = 14.2\ g/l$

2. Add 14.2 grams (3 level teaspoons) to 1 litre of water.

If items cannot be washed immediately after decontamination, rinse with cool water to prevent discoloration and corrosion (rusting) and to remove visible organic material before cleaning thoroughly. Personnel should wear gloves while handling soiled instruments. Inexpensive utility gloves work well for this.

Surfaces (especially procedure tables) that may have come in contact with body fluids also should be decontaminated. Wiping with a suitable disinfectant such as a 0.5% chlorine solution before reuse, when visibly contaminated or at least daily, is an easy-to-do, inexpensive way to decontaminate large surfaces.

CLEANING

Cleaning is a crucial step in providing safe, infection-free equipment and instruments. A thorough cleaning with water and liquid soap or detergent physically removes organic material such as blood and body fluids. Dried organic material can trap microorganisms in a residue that protects them against sterilization or HLD. Organic matter also can partially inactivate disinfectants, rendering them less effective (Porter 1987).

Utility gloves should be worn while cleaning instruments and equipment. Discard gloves if torn or damaged; otherwise, clean and leave to dry at the end of the day for use the following day. In addition to wearing gloves, extreme care must be taken to prevent needle sticks or cuts.

If available, glasses, plastic visors or goggles should be worn while cleaning instruments and other items. This protects staff from splashing contaminated water into their eyes.

Clean instruments with a brush (old toothbrushes work well) and soapy water. Give special attention to instruments with teeth, joints or screws where organic material can collect. After cleaning, rinse items thoroughly with water to remove detergent residue which can interfere with chemical disinfection.

If either hypodermic syringes (or needles and syringes) are being reused, disassemble only after decontaminating and then cleaning with soapy water, paying special attention to the hub area. Rinse at least three times with clean water, expelling the water through the needle into another container so as not to contaminate the rinse water, and dry.

See **Appendix G** for detailed information on decontaminating and cleaning instruments, needles and syringes and linens and **Appendix F** for steps in processing surgical gloves.

STERILIZATION

Instruments and other items such as needles or scalpels that come into direct contact with tissues beneath the skin which are normally sterile, should be sterilized after first being decontaminated and thoroughly cleaned, rinsed and dried. **The sterilization process destroys all microorganisms, including bacterial endospores.** Bacterial endospores are particularly difficult to kill because of their tough coating. (Bacteria that form endospores include *clostridia tetani*, which causes tetanus.) Sterilization can be achieved by autoclaving (high-pressure steam), dry heat or by using chemicals ("cold sterilization").

Heat Sterilization

High-pressure saturated steam (autoclaving) or dry heat (by hot air oven) are the most readily available methods used for sterilization. Steam sterilization generally is the method of choice for instruments and other items used in family planning and health care facilities. Where electricity is a problem, instruments can be sterilized in a nonelectric steam autoclave using kerosene as a heat source. The standard conditions for sterilization by steam or dry heat are shown in the following box.

Remember: When instruments and equipment are steam sterilized, it is essential that steam reach all surfaces; autoclaving closed containers will sterilize only the outside of the containers!

Standard Conditions for Heat Sterilization

Steam sterilization: Temperature should be 121°C (250°F); pressure should be 106 kPa (15 lb/in^2); 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry before removing.

Note: Pressure settings (kPa or lbs/in^2) may vary slightly depending on sterilizer used. Whenever possible follow manufacturer's recommendations.

Sterile instruments should be used immediately unless they:

- have been wrapped in a double layer of muslin, paper or other appropriate material prior to steam sterilization; or
- can be stored in a dry sterile container with a tight-fitting lid.

The material used for wrapping instruments must be porous enough to let steam through but tightly woven enough to protect against dust particles and microorganisms.

Wrapped sterile instruments have a shelf life of up to 1 week, **but only if kept dry and intact** (Perkins 1983). Placing a wrapped pack in a sealed plastic bag will increase its shelf life to 1 month. All packs and sterile containers should be labeled with an expiration date.

Chemical Sterilization

An alternative to steam or dry-heat sterilization is chemical sterilization by soaking for 8 to 10 hours in a glutaraldehyde or at least 24 hours in an 8% formaldehyde solution. Glutaraldehydes, such as Cidex®, often are in short supply and expensive, but they and formaldehyde are the only practical liquid sterilants usable for instruments, such as laparoscopes, which cannot be heated. Because glutaraldehydes and formaldehyde require special handling and leave a residue on treated instruments, rinsing with sterile water (which can be prepared only by autoclaving) is preferable. (Because boiling does not inactivate some endospores reliably, using boiled water can contaminate sterile instruments.)

Although formaldehyde is less expensive than glutaraldehyde, it is more irritating to the skin, eyes and respiratory tract (**Table C-3**). When using either formaldehyde or glutaraldehyde, gloves should be worn, eyes should be protected, exposure time limited and both chemicals used only in a well-ventilated area.

Note: Chemical sterilization of needles and syringes is **not** recommended because chemical residues may remain even with repeated rinsing with sterile water. These residues may interfere with the actions of the drug being injected.

HIGH-LEVEL DISINFECTION

When sterilization equipment is either not available or not suitable, HLD is the only acceptable alternative. High-level disinfection destroys all microorganisms, including viruses causing hepatitis B and AIDS, but **does not reliably kill all bacterial endospores.** High-level disinfection can be achieved by boiling in water, steaming or soaking in chemical disinfectants such as 0.1% chlorine, 2–4% glutaraldehyde or 8% formaldehyde.

Because boiling and steaming require only inexpensive equipment, which usually is readily available, they are the preferred methods for small clinics or those located in remote areas. Regardless of the method selected, however, HLD is effective **only** when instruments and other items first are decontaminated and then thoroughly cleaned and rinsed **before** HLD.

Moist heat at 80°C kills essentially all bacteria, viruses, parasites and fungi in 20 minutes. Therefore, unless the altitude of the health facility is over 5,500 meters (18,000 feet) it is not necessary to increase the steaming or boiling time (Favero 1985).

High-Level Disinfection by Boiling

Open or take apart all instruments and other items. Submerge in water and cover pan. Boil for 20 minutes. Timing should begin when the water is at a rolling (bubbling) boil and all items should be totally under the water. Nothing should be added to the container after the water begins to boil. After boiling for 20 minutes, remove boiled items using high-level disinfected forceps, place in a high-level disinfected container and allow to cool and air dry.

Use instruments and other items immediately or leave in a covered, **dry** high-level disinfected container. (The container used for drying the instruments can be used for storage only if there is no water in the bottom of the container.) Store for up to 1 week.

Boiling Tips

- Always steam or boil for 20 minutes using a pot with a lid.
- Start timing when the water begins to boil.
- Items should be covered completely[2] with water.
- Do not add anything to the pot after the water begins to boil.

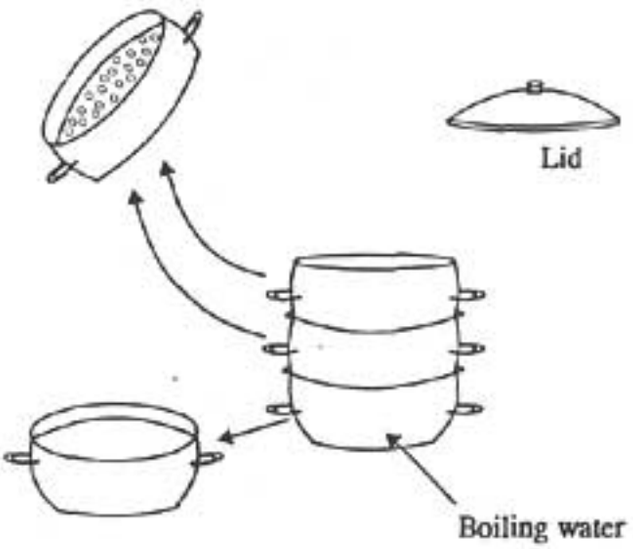
High-Level Disinfection by Steaming

Recently, a new process for high-level disinfecting surgical gloves by steaming (low-pressure moist heat) has been reported (McIntosh et al 1994). Steaming surgical gloves, which have been washed and thoroughly rinsed, in a one-to-three tiered steamer has been used as the final step in processing gloves for many years in Indonesia and other parts of South East Asia. Until now, however, the effectiveness of this process for HLD was never tested.

In the study reported, the steamer (**Figure C-3**) used consisted of:

- a bottom pan (approximately 31 cm in diameter) for boiling water,
- one to three circular pans with multiple, 0.5 cm (diameter) holes in their bottoms to permit the passage of steam up through them and water back down to the bottom pan, and
- a lid which fits on the top pan.

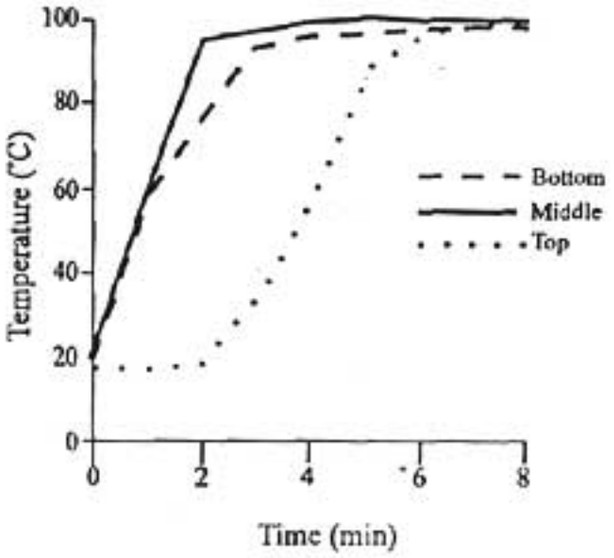
Figure C-3. Three-Tiered Steamer Used for HLD



Two types of tests were conducted to determine whether surgical gloves could be high-level disinfected by this process.

In the first set of experiments, a thermocouple was placed inside a glove in each of the three pans, respectively, and the rate and extent of the temperature change recorded. As shown in Figure C-4, when from 5 to 15 pairs of surgical gloves were placed in each of the three pans, the temperature reached 96–98°C in less than 4 minutes in the bottom and middle pans and within 6 minutes in the upper pan. Thereafter, the temperature remained constant throughout the remaining 20 minutes.

Figure C-4. Temperature Rise in Gloves as a Function of Tray Position



In the second set of experiments, batches of new surgical gloves were contaminated with *Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa* and *Candida albicans* as well as *Bacillus subtilis* (heat-sensitive) and *Bacillus stearothermophilus* (heat-resistant) endospores. Next the gloves were placed in one of the three pans and steamed for 20 minutes. After this, they were removed from the pans and incubated for 24 hours in sterile media and then plated on blood agar. In all cases (6, 15 and 30 gloves per pan), there was no growth of any microorganisms or *B. subtilis* endospores at 24 hours and, as expected, only a reduction in the number of *B. stearothermophilus* endospores.

Based on the results of these experiments, it would appear that steaming is effective in high-level disinfecting surgical gloves.

Use of Steaming for HLD: Advantages and Disadvantages

At the present time **steaming has several distinct advantages over boiling** for the final processing of surgical gloves. Although boiling and steaming gloves are equally easy to do, to date no practical solution for drying boiled gloves has been discovered (i.e., it is difficult to prevent contamination while they are air-drying which takes up to 24 hours). As a result, health facilities lacking an autoclave either had to use new disposable sterile gloves for every surgical procedure or wear boiled (high-level disinfected) gloves "wet." With steaming, the gloves dry in less time (about 4 hours) and they are not contaminated while drying. Additional advantages are that steaming is less destructive and more cost-effective because it uses much less fuel than does boiling.

The major disadvantage of steaming is that if the steamers available locally are small, it is only practical to use them for small items (e.g., surgical gloves, MVA cannulae and syringes). Large boiling pots are easier to use with metal instruments and require less attention to be sure that the boiling process is being done correctly (Salle 1973; Spaulding 1939). (A boiling pot is easier to watch than one that is steaming.)

High-Level Disinfection by Soaking in a Chemical Solution

At present, only four chemicals are approved worldwide for use as high-level disinfectants:

- chlorine,
- glutaraldehyde,
- formaldehyde (formalin), and
- hydrogen peroxide.

Although **alcohols** and **iodophors** are inexpensive and readily available, they are no longer classified as high-level disinfectants (Rutala 1993). Alcohols do not kill some viruses, and *Pseudomonas species* have been known to multiply in iodophors. These chemicals should be used for disinfection only when the high-level disinfectants listed above are not available or appropriate.

Table C-3 provides guidelines for preparing and using these chemical disinfectants.

> **Note**: Chemical HLD of needles and syringes is not recommended because chemical residues may remain even after repeated rinsing with sterile water. These residues may interfere with the actions of the medication being injected.

The major **advantages** and **disadvantages** of each disinfectant are described below.

- **Chlorine solutions** are fast acting, very effective against HBV and HIV, inexpensive and readily available.

  A major disadvantage is that concentrated chlorine solutions (≥ 0.5%) can discolor and corrode metals. Stainless steel instruments, however, can be soaked safely in a 0.1% chlorine solution (using a plastic container) for up to 20 minutes. Discoloration is only a problem where calcium (not sodium) hypochlorite powders are used. (Wiping instruments with vinegar, which is weakly acidic, will quickly remove the discoloration.) Also, corrosion will not be a problem if items are rinsed with boiled water and dried promptly.

  Because chlorine solutions break down rapidly and can lose their effectiveness, fresh solutions should be made at least daily or more often if the solution is visibly cloudy.

- **Formaldehyde** (8%) can be used as a chemical sterilant and also is an effective high-level disinfectant, but the vapors are very irritating. Care must be taken to protect both staff and clients from the fumes when mixing and using formaldehyde solutions. (Wear gloves, protect eyes from splashes, limit exposure time and use only in well-ventilated areas.) **Do not dilute with chlorinated water as a dangerous gas (bis-chloromethyl-ether) can be produced.**

- **Glutaraldehydes**, which can be used for chemical sterilization, are effective high- level disinfectants as well. Although less irritating than formaldehyde, they too should be used in well-ventilated areas following recommended precautions.

Remember: Both glutaraldehyde and formaldehyde solutions leave a residue; therefore, instruments must be rinsed thoroughly with boiled water after HLD to remove any residue and prevent skin irritation.

- **Hydrogen Peroxide**, (H_2O_2), which must be diluted to a 6% solution, often is available locally and is less expensive than other chemical disinfectants. (The 3% H_2O_2 solutions used as antiseptics should not be used as disinfectants.) The major disadvantage of H_2O_2 is that it is highly corrosive. It should not be used to disinfect copper, aluminum, zinc or brass. Because hydrogen peroxide loses potency rapidly when exposed to heat and light, it must be stored carefully.

  WHO does **not** recommend using H_2O_2 in hot (tropical) climates because of its instability in the presence of heat and light.

Table C-3. Preparing and Using Chemical Disinfectants

Disinfectant(common solution or brand)	Effective Concentration	How to Dilute	Skin Irritant	Eye Irritant	Respiratory Irritant	Corrosive	Leaves Residue	Time Needed for HLD	Time Needed for Sterilization	Activated Shelf Life[a,b]
Chemicals for Sterilization or High-Level Disinfection										
Chlorine	0.1%	Dilution procedures vary[c]	Yes (with prolonged contact)	Yes	Yes	Yes[d]	Yes	20 minutes	Do not use	Change daily; sooner if cloudy
Formaldehyde (35–40%)	8%	1 part 35–40% solution to 4 parts boiled water	Yes	Yes	Yes	No	Yes	20 minutes	24 hours	Change every 14 days; sooner if cloudy
Glutaraldehyde (Cidex)	Varies (2–4%)	Varies: read instructions on container	Yes	Yes vapors	Yes	No	Yes	20 minutes at 25°C[e]	10 hours for Cidex	Change every 14 days; sooner if cloudy
Hydrogen Peroxide (30%)	6%	1 part 30% solution to 4 parts boiled water	Yes	Yes	No	Yes	No	30 minutes	Do not use	Change daily; sooner if cloudy
Chemicals for Disinfection (alcohols and iodophors are not high-level disinfectants)										
Alcohol (ethyl or isopropyl)	60–90%	Use full strength	Yes (can dry skin)	Yes	No	No	No	Do not use	Do not use	Change weekly; daily if heavily used; sooner if cloudy
Iodophors (10% povidone iodine/PVI)	Approximately 2.5%	1 part 10% PVI to 3 parts water	No	Yes	No	Yes	Yes	Do not use	Do not use	Change daily

All chemical disinfectants are heat and light sensitive and must be stored appropriately.
Always check manufacturer's instructions for when to discard.
See Tables D-1 and D-2 for instructions on preparing chlorine solutions.
Corrosive with prolonged (> 20 minutes) contact and/or concentrations ≥ 0.5% if not immediately rinsed with boiled water.
Different commercial preparations of Cidex and other glutaraldehydes are effective at lower temperatures (20°C) and for a longer activated shelf life.

dapted from: Rutala 1993.

Key Steps in Chemical High-Level Disinfection

- Decontaminate instruments that have been in contact with tissue beneath the skin which normally is sterile. Thoroughly clean and dry all instruments.
- Cover all items completely with correct dilution of high-level disinfectant which has been properly stored.
- Soak for 20 minutes.
- Remove using high-level disinfected forceps or wearing high-level disinfected gloves.
- Rinse well with boiled water and air dry.
- Use promptly or store for up to 1 week in a high-level disinfected, covered container.

  To prepare a high-level disinfected container, boil if small or (if large) fill a plastic container with 0.5% chlorine solution and soak for 20 minutes. (The chlorine solution can be transferred to a plastic container and reused.) Rinse the inside thoroughly with boiled water. Air dry before use.

Storage of Disinfectants

- Disinfectants should be stored in a cool, dark area.
- Never store chemicals in direct sunlight or in excessive heat (e.g., upper shelves in a tin-roofed building).

Processing Used Chemical Containers

Glass containers may be washed with soap and water, rinsed, dried and reused. Alternatively, thoroughly rinse the container (at least two times) with water and dispose of by burying.

Plastic containers used for toxic substances such as glutaraldehydes or formaldehyde should be rinsed (at least two times) with water and disposed of by burning or burial.[2]

Note: Do not reuse plastic containers which originally held these chemicals.

Products That Should Not Be Used as Disinfectants

Many antiseptic solutions are used incorrectly as disinfectants. While antiseptics (sometimes called "skin disinfectants") are adequate for cleaning skin before an injection or surgical procedure, they are not appropriate for disinfecting surgical instruments. **They do not destroy bacteria, viruses or endospores reliably.** For example, Savlon (chlorhexidine gluconate with

[2] To further prevent plastic containers from being reused, put a hole in each container before disposal so that it cannot be used to carry water or other liquids.

or without cetrimide), which is readily available worldwide, is a good antiseptic but is often mistakenly used as a disinfectant.

Antiseptics that should not be used as disinfectants are:

- Acridine derivatives (e.g., gentian or crystal violet)
- Cetrimide (e.g., Cetavlon®)
- Chlorhexidine gluconate (e.g., Hibiscrub, Hibitane)
- Chlorhexidine gluconate and cetrimide in various concentrations (e.g., Savlon)
- Chlorinated lime and boric acid (e.g., Eusol®)
- Chloroxylenol (e.g., Dettol)
- Hexachlorophene (e.g., pHisoHex®) is not recommended for use as a disinfectant or antiseptic because it is readily absorbed through the skin and is neurotoxic.
- Mercury solutions (such as mercury laurel) cause birth defects and are too toxic to use as either disinfectants or antiseptics (Block 1991).

Other products frequently used to disinfect equipment are 1-2% phenol (e.g., Phenol®), 5% carbolic acid (e.g., Lysol®) and benzalkonium chloride, a quaternary ammonium compound (e.g., Zephiran®). These are low-level disinfectants and should be used only to decontaminate environmental surfaces (e.g., examination tables) when chlorine compounds are not available.

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APPENDIX D

SURGICAL HANDSCRUB

SUPPLIES

- Soap (plain) or antiseptic, which is preferred, as provided by the facility (Larson 1988)
- Running water
- Stick or brush for cleaning the fingernails (these items must be cleaned and preferably high-level disinfected, after each use)
- Soft brush or sponge for cleaning the skin (these items must cleaned and preferably high-level disinfected, after each use)
- Towels (sterile towels should be provided in the operating theatre)

PREPARATION

The operating doctor, scrub nurse or technician should wear a short-sleeved shirt or scrubsuit to perform this procedure because it involves scrubbing to the elbows (Sorensen and Luckman 1979).

Procedure	Rationale
1. Remove all jewelry.	1. Jewelry harbors microorganisms and is difficult to clean.
2. Adjust water to comfortable temperature.	2. Comfort of operating doctor, scrub nurse or technician. Also, excessively hot water opens pores to bacteria. Warm water enhances action of the soap.
3. Holding hands above the level of the elbow, wet hands thoroughly. Apply soap and clean under each fingernail using the brush.	3. Water should flow from area of least contamination to most contamination. Soap can kill some microorganisms.
4. Beginning at the fingertips, lather and wash with a soft brush or sponge, using a circular motion. Wash between all fingers. Move from fingertips to the elbow of one arm and repeat for the second arm.	4. Friction and lather raise microorganisms. Wash from area of least contamination to area of most contamination.
5. Wash using a soft brush or sponge for three-to-five minutes (when using alcohol, pour or rub for two minutes).	5. Adequate time is required to inhibit or kill as many microorganisms as possible.
6. Rinse each arm separately, fingertips first, holding hands above the level of elbows.	6. Do not let rinse water flow over clean area. Water should flow from area of least contamination to area of most contamination.

Procedure	Rationale
7. Using a separate towel for each hand, wipe from the fingertips to the elbow, and then discard the towel.	7. Do not contaminate clean hand by using soiled towel. During drying move from area of least contamination to area of most contamination.
8. Before putting on sterile gloves (and gown): hold hands above the level of the waist and do not touch anything.	8. Contact with contaminated object renders clean object contaminated. Area below the level of the waist is considered contaminated.
9. If scrubbed hands touch any "dirty" object during the procedure, steps 3 through 8 must be repeated.	9. See #8.

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APPENDIX E

ANTISEPTICS

Many chemicals qualify as safe antiseptics. Table E-1 lists several recommended antiseptic solutions, their killing actions, advantages and disadvantages. Information on how to prepare and use antiseptics is presented in this appendix.

Many chemicals qualify as antiseptics. The following products are available in different countries in the world:

- Alcohols (60 to 90%), ethyl, isopropyl or "methylated spirit"
- Cetrimide and chlorhexidine gluconate, various concentrations (e.g., Savlon)
- Chlorhexidine gluconate (4%) (e.g., Hibiclens, Hibiscrub, Hibitane)
- Hexachlorophene (3%) (e.g., pHisoHex)
- Iodines (1 to 3%), tincture and aqueous (e.g., Lugol's®)
- Iodophors, various concentrations (e.g., Betadine)
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol)

ALCOHOL SOLUTIONS (ETHYL OR ISOPROPYL)

Ethyl and isopropyl alcohol (60–90%) are excellent antiseptics, commonly available and inexpensive. Their rapid killing action makes them very effective in reducing numbers of microorganisms on skin, even under gloves. Alcohols are effective against HBV and HIV. They should not be used on mucous membranes (vaginal preparation). (Alcohols dry and irritate mucous membranes which, in turn, promotes the growth of microorganisms.)

Alcohols are among the safest known antiseptics. A 60–70% solution of ethyl or isopropyl alcohol is effective, is less drying to the skin and is less expensive than higher strengths. Because isopropyl alcohol tends to be a more efficient fat solvent than ethyl alcohol, it causes dry skin when used repeatedly; therefore, ethyl alcohol may be more gentle for frequent use on skin (Larson 1988).

Note: In many countries, alcohols are available as "industrial methylated spirit", or ethyl alcohol denatured with a small amount of wood (methyl) alcohol (Harpin and Rutter, 1982). Because methyl alcohol is the least effective of the alcohols it should not be used alone as an antiseptic or disinfectant. Be sure the ethyl alcohol is of adequate strength (60–90%) in locally available "spirit."

Table E-1. Antiseptic Solutions

Group	Activity Against Bacteria							Potential Uses			
	Gram Positive	Most Gram Negative	TB	Viruses	Fungi	Endo-spores	Relative Speed of Action	Affected by Organic Matter	Surgical Scrub	Skin Preparation	Comments
Alcohols (60-90% ethyl or isopropyl)	Very good	Very good	Good	Good	Good	None	Fast	Data varies	Yes	Yes	Not for use on mucous membranes
Chlorhexidine* (4%) (Hibitane, Hibiscrub)	Very good	Good	Poor	Fair	Fair	None	Slow	Slight	Yes	Yes	Has good persistent effect
Hexachlorophene (3%) (pHisoHex)	Good	Poor	None	Fair	Poor	None	Slow	Slight	Yes	No	Rebound growth of bacteria may occur
Iodine preparations (3%) Iodine and alcohol (tincture of iodine)	Very good	Very good	Good	Good	Good	Poor	Interme-diate	Slight	No	Yes	Not for use on mucous membranes
Iodophors (1:2,500) (Betadine)	Very good	Good	Good	Good	Good	None	Slow	Yes	Yes	Yes	Can be used on mucous membranes

* Note: Savlon, which contains chlorhexidine, is not listed because the concentration of chlorhexidine varies from country to country from as little as 1% to 4%.

Adapted from: World Federation of Health Agencies for Advancement of Voluntary Surgical Contraception 1988; Larson 1988.

Advantages

- Rapidly kill all fungi and bacteria including mycobacteria; isopropyl alcohol kills most viruses, including HBV and HIV, and ethyl alcohol kills all viruses.
- Although alcohols have no persistent killing effect, the rapid reduction of microorganisms on skin protects against regrowth of organisms, even under gloves, for several hours.
- Can be used for occasional soaking of rubber (latex) items (e.g., diaphragms or fitting rings).
- Are relatively inexpensive and are widely available throughout the world.
- Both are not corrosive to metals.

Disadvantages

- Evaporate rapidly, and cause drying of skin. (Ethyl alcohol may be less drying than isopropyl.)
- Expensive if imported.
- Easily inactivated by organic materials.
- Flammable, requiring storage in cool, well-ventilated areas.
- Will damage rubber (latex) over time.

CHLORHEXIDINE

Chlorhexidine gluconate (CHG) is an excellent antiseptic. It remains active against microorganisms on skin many hours after use, and is safe even for use on newborn infants. Because CHG is inactivated by soap, its antimicrobial activity is dependent upon the concentration used. Chlorhexidine (4%) commonly is available and is the recommended concentration. Clorhexidine (0.5%) in 60–90% alcohol also is effective.

Advantages

- Has persistent action on skin.
- Chemical protection (the number of microorganisms inhibited) increases with repeated use.
- Minimally affected by organic material.

Disadvantages

- Expensive and not always available.
- Action reduced or neutralized by natural soaps and by substances present in hard tap water.
- Must be used repeatedly for maximum effectiveness and residual activity.
- Patient ototoxicity.

HEXACHLOROPHENE

Hexachlorophene (3%) is active against gram-positive cocci such as staphylococcus, but has little or no activity against Gram-negative bacteria, viruses, *Mycobacterium tuberculosis* and fungi. It is not fast acting, and one wash with hexachlorophine does reduce skin flora. Hexachlorophene has neurotoxic side effects which make it risky to use on newborn infants. Use on broken skin or mucous membranes and for routine bathing is not recommended. When used intermittently, bacteria may grow back in large numbers (rebound growth) between uses.

Advantages

- Residual activity excellent when used regularly.

Disadvantages

- Rapidly inactivated by iodine and alcohol.
- May lead to serious neurotoxic side effects.
- Rebound growth of bacteria when use is discontinued or intermittent.

IODINE AND IODOPHOR SOLUTIONS

Iodines are very effective antiseptics. 1–3% iodines are available as both aqueous (Lugol) and tincture (iodine in 70% alcohol) solutions. Iodophors are solutions of iodine mixed with a carrier which releases small amounts of iodine and usually are available locally. (Povidone iodine is the most common iodophor.) The iodophors kill vegetative bacteria, mycobacterium viruses and fungi; however, they **require up to two minutes of contact time to release free iodine** (Larson 1988). Once released, however, the iodine has rapid killing action. It is not usually necessary to dilute commercially available iodophors manufactured for antisepsis (e.g., Betadine or Wescodyne). Iodophors are generally non-toxic and non-irritating to skin and mucous membranes.

> **Note:** Iodophors manufactured for use as antiseptics are **not** effective for disinfecting inorganic objects and surfaces. Antiseptic solutions have significantly less iodine (Rutala 1990).

Advantages

- Inexpensive, effective and widely available.
- Iodophors are non-irritating (unless the person is iodine allergic) on skin or mucous membranes, making them ideal for vaginal preparation before IUCD insertion.
- Do not stain skin at 1:2,500 concentration.

Disadvantages

- Iodophors have little residual effect.
- Like alcohols, iodine and iodophors are inactivated by organic materials.
- Iodine (tincture or aqueous) may cause skin irritation and must be removed from skin after drying. (Use alcohol to remove iodine.) **Iodine (aqueous or tincture) must never be used on mucous membranes.**
- Skin absorption (and through mucous membranes) of free iodine may cause hypothyroidism in newborn infants (Newman 1989).

SOLUTIONS TO AVOID

Zephiran® (benzalkonium chloride)

Zephiran is commonly used in many parts of the world as an antiseptic, however, it has several distinct disadvantages:

- Solutions of benzalkonium chloride have repeatedly been shown to become contaminated by *Pseudomonas* species and other common bacteria (Block 1983).
- Solutions of benzalkonium chloride are easily inactivated by cotton gauze and other organic material and are incompatible with soap (Block 1983).
- Zephiran takes at least 10 minutes to kill HIV, the virus causing AIDS (INTRAH 1992). (By contrast, 0.5% chlorine solution kills HIV in less than a minute.)

Mercury Laurel or other Mercury-Containing Compounds

Although frequently sold for antisepsis, mercury-containing chemicals should be avoided due to their high toxicity (Block 1983).

- Skin exposure to low levels of mercury causes blister formation and contact dermatitis.
- Inhalation or ingestion of low levels of mercury causes central nervous system effects (numbness, speech impairment, deafness), and higher levels (200 mg) are fatal.

- Skin contact alone can result in absorption of measurable amounts of mercury.

- Pregnant women exposed to small doses may not show toxic effects themselves. Their fetus, however, may be harmed because mercury is a potent teratogen (causes birth defects, including cleft palate, cerebral palsy and other central nervous system abnormalities).

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APPENDIX F

PROCESSING SURGICAL GLOVES[1]

The risk in reusing surgical gloves is that processed gloves contain more invisible tears than new ones and therefore provide less protection to the wearer. Sterilization (autoclaving) and HLD (steaming or boiling) of gloves, when correctly performed, can provide a high quality product. In addition, **double-gloving** for high-risk procedures can be done. Therefore, processing surgical gloves constitutes an **appropriate reuse of disposable items.**

HOW TO DECONTAMINATE AND CLEAN SURGICAL GLOVES BEFORE STERILIZATION OR HIGH-LEVEL DISINFECTION (HLD)

STEP 1: Before removing soiled gloves, immerse hands briefly in a container filled with 0.5% chlorine solution (or other locally available disinfectant).

STEP 2: Remove gloves by turning inside out and soak in the chlorine solution for 10 minutes.

(Performing **Steps 1 and 2** insures that both surfaces of the gloves are decontaminated.)

STEP 3: Wash gloves in soapy water, cleaning inside and out.

STEP 4: Rinse gloves in clean water until no soap or detergent remains. (Residual soap or detergent can interfere with subsequent sterilization or HLD.)

STEP 5: Test gloves for holes by inflating them by hand and holding them under water. (Air bubbles will appear if there are holes.)

STEP 6: Gently dry gloves inside and out before proceeding with sterilization or HLD. (Gloves which remain wet for long periods of time will absorb water and become tacky.)

> **Note**: Gloves should be discarded after processing three times because invisible tears may occur with additional processing (Bagg, Jenkins and Barker 1990; Martin et al 1988).

HOW TO STERILIZE SURGICAL GLOVES

After decontamination, cleaning and drying, gloves must be packaged prior to sterilizing by autoclaving. First, fold the cuffs of the gloves out towards the palm so that they can be put on easily and without contamination after sterilization. Next, put gauze or paper inside each glove and under the fold of the cuff and wrap the gloves as shown in **Figure F-1**. (Do not tie tightly

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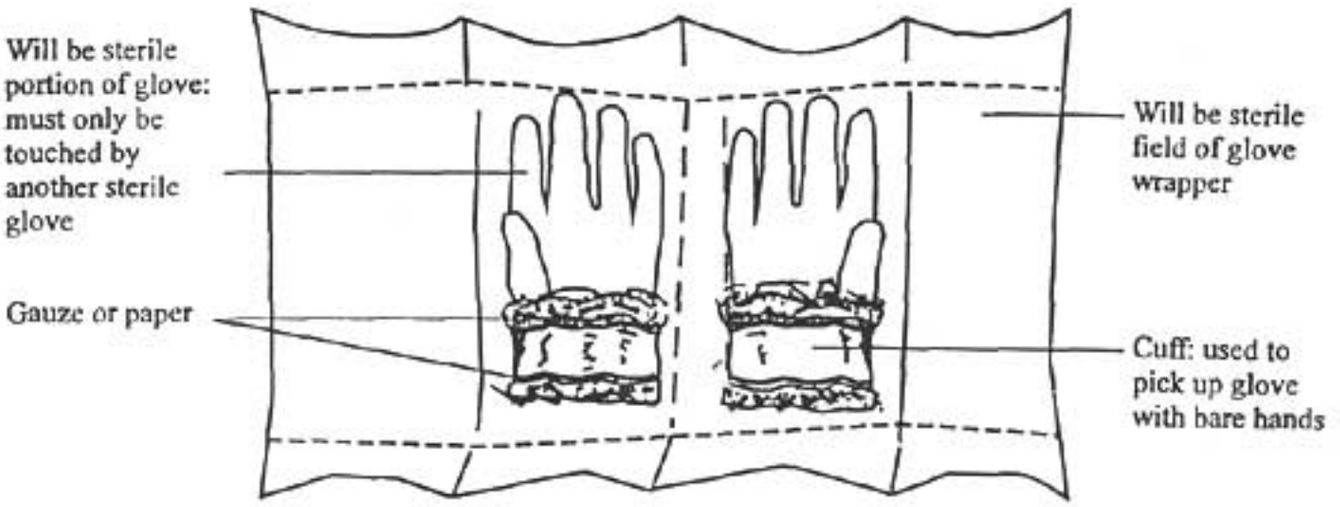
[1] *Adapted from*: Tietjen L, W Cronin and N McIntosh. 1992. *Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual*. Essential Medical Information Systems, Inc.: Durant, Oklahoma.

or wrap glove packs with rubber bands.) Finally, place them in a wire basket on their sides to allow optimum steam penetration. (If gloves are stacked in piles, penetration of steam under the cuffs may be poor.) Autoclave at 121°C (250°F) for 30 minutes and at a pressure of 106 kPa (15 lb/in^2).

Figure F-1. Preparing Gloves for Autoclaving (steam sterilization)



Source: South East Asia Office/ World Health Organization 1988.

Remember: Higher temperatures and pressures are destructive to gloves.

Immediately after autoclaving, gloves are extremely friable and tear easily. Gloves should **not** be used for 24 to 48 hours to allow the elasticity to be restored and to prevent tackiness (stickiness). (Table F-1)

HOW TO HIGH-LEVEL DISINFECT SURGICAL GLOVES BY STEAMING

After gloves have been decontaminated and thoroughly washed, they are ready for HLD by steaming (McIntosh et al 1994). (See **Appendix C** for more information on steaming.)

STEP 1: Fold up the cuffs of the gloves so that they can be put on easily and without contamination after HLD.

Table F-1. Tips to Help Avoid Glove Problems

Probable Cause	Recommended Solution
PROBLEM: TACKY OR STICKY GLOVES	
Residual liquid soap or detergent	Reduce amount of liquid soap or detergent used when washing gloves. Rinse gloves at least three times in clean water.
Heated to high temperature for too long	Use 30 minutes sterilizing time at 121°C (250°F) and remove gloves from sterilizer as soon as cycle is completed.
Gloves sterilized with other goods	Sterilize gloves separately.
Gloves not allowed to dry completely after steaming	Wear "wet" within 30 minutes or allow to dry for 4 to 6 hours before using.
Poor powdering	Use absorbable glove powder and follow manufacturer's instructions to insure a film of powder on all surfaces.
Surfaces of gloves touching each other	Gauze or paper wicks should be inserted between the palm and back of hand of each glove and between the hand of the glove and the turned-back cuff. This allows steam to contact all surfaces during sterilization and prevents surfaces from adhering to each other.
Breakdown (deterioration) of rubber (latex) (Rubber gloves deteriorate while stored even though they have not been used. They become soft, sticky and unusable.)	Store in a dry, cool area. Do not store in direct sunlight.
PROBLEM: EXCESSIVE TEARING OR RUPTURING	
Gloves used too soon following sterilization	Do not use gloves for 24 to 48 hours after sterilization. This allows gloves to regain their elasticity before use.

Source: Tomlinson 1991.

STEP 2: Place gloves into one of the steamer pans with holes in its bottom. To make removal from the pan easier, the cuffs should be facing outward toward the edge of the pan (Figure F-2). Five to fifteen pairs can be put in each pan depending on the size (diameter) of the pans.

Figure F-2. Gloves in Steamer Pan

STEP 3: Repeat this process until up to three steamer pans have been filled with gloves. Stack the filled steamer pans on top of a bottom pan containing water for boiling. A second (empty) pan without holes should be placed on the counter next to the heat source (see **Step 9**).

STEP 4: Place lid on top pan and bring water to a full rolling boil. (When water only simmers, very little steam is formed and the temperature may not get high enough to kill microorganisms.)

STEP 5: Reduce heat so that water continues to boil at a rolling boil. (When water boils too violently, it evaporates quickly and wastes fuel.)

Remember: Be sure there is sufficient water in the bottom pan for the **entire** 20 minutes of steaming.

STEP 6: When steam begins to come out between pans, start timer or note time on clock and record time in the HLD log.

STEP 7: Steam gloves for 20 minutes.

STEP 8: Remove top steamer pan and place cover on top pan remaining on the stack. Gently shake excess water from the gloves in the pan just removed.

STEP 9: Place pan containing gloves on the second (empty) pan (see **Step 3**). Repeat until all pans containing gloves are restacked on this empty pan. (This step allows the gloves to cool and dry without becoming contaminated.)

Remember: Do **not** place pans containing gloves down on a table top, counter or other surface as gloves will be contaminated.

STEP 10: Allow gloves to air dry in the steamer pans (4 to 6 hours) before using.[2]

STEP 11: Using a high-level disinfected forceps, transfer the dry gloves to a dry, high-level disinfected container[3] with a tight-fitting lid. Store for up to 1 week. (Gloves also can be stored in the stacked and covered steamer pans.)

HOW TO HIGH-LEVEL DISINFECT SURGICAL GLOVES BY BOILING

Although boiling effectively high-level disinfects gloves, it is difficult to dry them without contaminating them. Therefore, boiling surgical gloves should be done **only** if the gloves are to be used immediately (i.e., worn "wet" after they have been allowed to cool).

After surgical gloves have been decontaminated and thoroughly washed they are ready for HLD.

STEP 1: Place gloves in a bag made of plastic or nylon netting.

STEP 2: Place a weight in the bag so that all gloves and the bag will be at least 2.5 cm (1 inch) below the surface of the water.

STEP 3: Close lid over pan and bring water to a full, **rolling** boil. (When water only simmers, very little steam is formed and the temperature at the water's surface may never get high enough to kill microorganisms.)

Remember: Be sure there is **sufficient** water in the pan to cover items for the **entire** 20 minutes of boiling.

STEP 4: Reduce heat so that water continues to boil at a rolling boil. (When water boils too violently, it evaporates quickly and wastes fuel.)

STEP 5: When rolling boil begins, start timer or note time on clock and record in HLD log. **(No objects or water should be added after timing starts.)**

STEP 6: Boil gloves for **20 minutes.**

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[2] Alternatively, allow gloves to cool for 5 to 10 minutes before wearing "wet." Gloves should be used within 30 minutes, if possible. After this time, the fingers of the gloves stick together and the gloves are hard to put on despite being damp. Gloves which have been removed from the steamer pan(s) to be worn "wet" but were not used during the clinic session should be reprocessed before using.

[3] To prepare a high-level disinfected container, boil (if small) or fill a plastic container with 0.5% chlorine solution and soak for 20 minutes. (The chlorine solution can then be transferred to another container and reused.) Rinse the inside thoroughly.

STEP 7: After boiling for 20 minutes, remove bag of gloves with **high-level disinfected**, dry forceps. (Never leave boiled objects in water which has stopped boiling. As the water cools and steam condenses, air and dust particles are drawn down into the container and may contaminate the gloves [Perkins 1983].)

STEP 8: Allow excess water to drip off gloves (shake the bag gently). Place the bag in a high-level disinfected container, cover and allow to cool (about 5 to 10 minutes) before using.

STEP 9: Wear high-level disinfected gloves to untie the bag. Remove gloves from the container using a high-level disinfected forceps. Gloves which are worn "wet" may be weakened and less stretchy (elastic). Therefore, put on "wet" gloves very carefully.

STEP 10: Gloves remaining in the bag at the end of the clinic session should be reprocessed. (They will not dry completely inside and outside.)

> **Note**: After boiling, gloves should be used within 30 minutes, if possible. After this time, the fingers of the gloves stick together and the gloves are hard to put on despite being damp.

ACCIDENTAL CONTAMINATION OF STERILE OR HIGH-LEVEL DISINFECTED GLOVES

There are several ways to contaminate sterile or high-level disinfected surgical gloves:

- tearing or puncturing the glove,
- touching any nonsterile object with the glove, or
- touching the outside of a glove with an ungloved hand.

Service providers wearing sterile or high- level disinfected gloves should be careful not to contaminate gloved hands inadvertently by touching nonsterile objects, unprepped skin or mucous membranes.

REGLOVING AFTER CONTAMINATION

To reglove after contaminating a glove during a procedure:

- Remove contaminated glove by the cuff, and place in chlorine solution for decontamination, if reusing, or in waste container.

Sterile Glove:

- Have circulating nurse or technician open sterile glove pack, laying the glove package on a clean surface.

- Put on replacement glove in the usual manner.

Alternatively:

- Have circulating nurse or technician open the sterile glove package, remove a sterile glove and hold the glove open by the cuff. Put hand into the glove without touching the outside of the glove.

- Adjust the glove after the nurse or technician lets go of the cuff (Sorensen and Luckman 1979).

High-Level Disinfected Glove:

- Have circulating nurse or technician pick up replacement glove with high-level disinfected forceps.

- Grasp replacement glove by turned-down cuff and put on glove in the usual manner.

Alternatively:

- Have circulating nurse or technician remove a replacement glove from the high-level disinfected container with forceps and hold the glove open by the cuff. Put hand into the glove without touching the outside of the glove.

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APPENDIX G

DECONTAMINATING AND CLEANING INSTRUMENTS, HYPODERMIC NEEDLES AND SYRINGES AND LINENS[1]

HOW TO DECONTAMINATE AND CLEAN SURGICAL (METAL) INSTRUMENTS

Decontamination

STEP 1: After use, immerse all soiled instruments in a plastic container filled with 0.5% chlorine solution or other locally available disinfectant for at least 10 minutes. (This step is necessary to help prevent transmission of HBV or HIV/AIDS to clinic staff.)

STEP 2: If the instruments and other items cannot be washed immediately, rinse the objects with water and towel dry to minimize possible corrosion (rusting) due to chlorine.

Cleaning

Remember: If available, wear utility gloves, eyewear and mask. Do not use hot water because it coagulates protein, making blood and body fluids hard to remove.

STEP 3: Scrub instruments under water to prevent splashing of infectious materials. Use a soft brush and liquid soap or detergent and water (be sure to clean the teeth, joints and screws—an old toothbrush works well).

STEP 4: Rinse again with clean water until no soap or detergent remains. (Soap or detergent can interfere with the action of some chemical disinfectants.)

STEP 5: Dry by air or with a clean towel. (Water from wet instruments will dilute chemicals used for HLD, making them ineffective.) Drying is not necessary for instruments which are to be boiled.

STEP 6: Proceed with sterilization (if available) or HLD by steaming, boiling or soaking in a chemical disinfectant (see **Appendix C**)

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[1] *Adapted from*: Tietjen L, W Cronin and N McIntosh. 1992. *Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual*. Essential Medical Information Systems, Inc.: Durant, Oklahoma.

HOW TO DECONTAMINATE, CLEAN AND DISPOSE OF NEEDLES AND SYRINGES

The use, and especially the disposal of both needles and syringes, however, creates logistical and infection prevention problems. For example, a clinic or health care facility using disposable needles and syringes must ensure that adequate supplies are available at all times. Without a continuous supply of needles and syringes, services for Norplant implants and other surgical contraceptive methods, as well as other activities, will be disrupted.

An even larger problem is how to safely dispose of used needles and syringes if they cannot be burned or buried. In many countries, boxes of used disposable needles can be found lying discarded outside health care facilities and hospitals. These used needles and syringes constitute an increasing health risk, especially to children and adults seeking items to play with, sell or use.

An alternative to disposing of both needles and syringes would be to reprocess **only** syringes but **not** needles. The rationale for this is the following:

- It is primarily contaminated needles that are responsible for injuries and the potential risk of acquiring a life-threatening disease.
- Needles are difficult to decontaminate, clean and either sterilize or high-level disinfect; syringes are not.
- Plastic syringes, many of which are made of polyvinyl chloride (PVC), contribute heavily to environmental pollution when incinerated at high temperatures.

Although processing used needles represents an **inappropriate reuse of disposables** and is responsible for numerous infections (Phillips et al 1971), in some circumstances it is the only available option.

Instructions

When available and affordable, **disposable** (plastic) sterile syringes and needles are recommended for all client care and surgical procedures. If disposables are being used, it is important to:

- Maintain adequate supplies.
- Decontaminate needles and syringes and discard them in a puncture-proof container immediately after use.
- Dispose of these containers after they are filled by burning or burying them.

As mentioned above, if disposable needles and syringes will be reused, the safest approach is to process **only** syringes but **not** needles.

For those situations where **both needles and syringes** must be reused, care must be taken to avoid accidental needle sticks to cleaning staff during processing.

Instructions for processing needles (and for their disposal) and syringes for each of these options are given below.

Disposal of Needle and Syringe

STEP 1: Do not recap needle or disassemble needle or syringe.

STEP 2: Immediately after use, decontaminate needle and syringe:

- hold the needle under the surface of a 0.5% chlorine solution, fill with solution and push out (flush) three times, **or**
- draw a small amount of 0.5% chlorine solution into the syringe through the needle and soak in chlorine solution for 10 minutes.

STEP 3: Place assembled needle and syringe into a puncture-proof container such as a heavy cardboard box, plastic bottle or tin can with lid. (Old intravenous fluid bottles also may be used, but they may break.)

Remember: Do not recap needles prior to disposal.

Place the container close to the area where it will be used so that health care staff do not have to carry sharp items a long distance.

STEP 4: When the container is three quarters full, seal and destroy by burning (incineration) or burying.

Disposal of Needle but Syringe Reused

STEP 1: Do not recap needle or disassemble needle and syringe.

STEP 2: Immediately after use draw a small amount of 0.5% chlorine solution into the syringe through the needle.

STEP 3: Decontaminate assembled needle and syringe by placing in a 0.5% chlorine solution for 10 minutes.

STEP 4: Wearing utility gloves, remove from decontamination solution, push out (flush) solution from assembled needle and syringe and **remove the needle** from the syringe.

STEP 5: **Dispose of needle** in puncture-proof container. When the container is three quarters full, seal and either burn or bury.

STEP 6: Wash syringe in soapy water and rinse at least three times with clean water.

STEP 7: Sterilize or high-level disinfect syringe by steaming or boiling for 20 minutes (see **Appendix C**).

Reuse of Both Needle and Syringe

STEP 1: Do not recap needle or disassemble needle or syringe.

STEP 2: Immediately after use, draw a small amount of 0.5% chlorine solution into the syringe through the needle.

STEP 3: Decontaminate assembled needle and syringe by placing in a 0.5% chlorine solution for 10 minutes.

STEP 4: Wearing utility gloves, remove from decontamination solution and push out (flush) solution from assembled needle and syringe.

STEP 5: Take needle and syringe apart and clean with soapy water. (Be sure to clean hub area of the needle.) Insert stylet or needle wire through hub of needle to be sure it is not blocked.

STEP 6: Put syringe and needle back together. Rinse at least three times by filling with clean water and pushing out (flushing) water into another container so as not to contaminate the rinse water.

STEP 7: Detach needle from syringe.

STEP 8: Examine needle and syringe for:

- bent needle tip or other damage,
- needle hub fit to syringe, and
- readable syringe markers (lines indicating volume, cc or ml).

STEP 9: Dispose of damaged needles in a puncture-proof container. When container is three quarters full, seal and either burn or bury.

STEP 10: Sterilize or high-level disinfect by steaming or boiling for 20 minutes.

Recapping Needles

If needles must be recapped, use the "one-handed" recap method:

- First, place cap on a hard, flat surface, then remove hand.
- Next, with one hand, hold syringe and use needle to "scoop up" cap.

- Finally, when cap covers needle completely, hold cap at base with other hand and secure cap on needle hub.

HOW TO CLEAN LINENS AND SURGICAL DRAPES

All linen items used in the direct care of a client must be thoroughly washed in water with liquid soap or detergent before reuse. Decontamination prior to washing is **not necessary**.

STEP 1: At the end of the insertion or removal procedure, and while still wearing gloves, lift and remove the surgical drape and carefully place in a container or plastic bag.

STEP 2: Wash the **entire item** in water with liquid soap or detergent to remove all contamination, even if invisible.

Remember: Never just wash bloody or wet areas of linen.

STEP 3: Rinse with clean water.

STEP 4: Completely air or machine dry before further processing. (Air dry in direct sunlight, if possible, keeping the fabric off the ground, away from dust and moisture.)

STEP 5: After linens are totally dry, they should be checked for holes and very threadbare areas. If these are present, the item must be discarded or repaired before reuse. (If there are any holes or many repaired areas, the item should not be used as a drape. It can be cut into pieces to be used as cleaning rags.)

> Note: If surgical drapes or surgical gowns are to be sterilized, do not iron. (Ironing dries out the material making autoclaving more difficult.)

If a **clean drape** is acceptable, the air-dried drape can be ironed before placing it on a shelf or in a container for storage. A clean drape should be used for procedures when sterile drapes are not available or necessary (e.g., Norplant implants insertion and removal).

Clean gowns and drapes should be stored in a clean, dry space which is mold-, dust- and insect-free, preferably in a closed cabinet and not near areas that are frequently mopped or near sinks. (Air should circulate between the items in the storage area and the supply should be rotated.)

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APPENDIX H

PHARMACOLOGY OF DRUGS RELEVANT TO LOCAL ANAESTHESIA[1]

DRUGS AVAILABLE IN ALL CENTERS

Lidocaine Hydrochloride

Other names: Xylocaine, lignocaine

Action: Local anaesthetics act by preventing generation and transmission of impulses along nerve fibers and at nerve endings. Although toxicity occasionally occurs as a result of overdose with local anaesthesia, allergic reactions to the amide-linkage drugs, such as lignocaine and bupivacaine, are exceedingly rare. In fact, it is questionable whether true anaphylaxis to lignocaine given **without epinephrine** has ever been shown.

Dosage: The usual dose for local infiltration of a minilaparotomy incision site is 20 ml of 1% lignocaine. The maximum safe dose of 1% lignocaine without epinephrine is 5 mg per kg body weight. For a woman weighing 40 kg (88 lb), this is equivalent to 200 mg, or 20 ml, of 1% lignocaine (or 10 ml of 2% lignocaine).

Regimen: Through a single incision site, the doctor should locally infiltrate 1% lignocaine without epinephrine, about 15 ml, into the skin, fascia, and peritoneum. After waiting 2–3 minutes for the local field block to take effect, the doctor should incise. The remaining 5 ml of the lignocaine can be used to augment the anaesthesia block as needed.

One may elect to use 0.5% lignocaine and inject a greater volume. However, 2% solutions should routinely be diluted with normal saline to make a 1% strength, because the more concentrated 2% solution (with a maximum dose of 5 mg/kg) will not allow enough volume to provide adequate infiltration of all tissue layers.

Warnings: Adverse effects may occur as a result of the addition of a vasoconstrictor (epinephrine).

Adverse effects of lignocaine on the central nervous system are seen after accidental intravenous injection. The client usually first complains of numbness of the tongue and mouth, lightheadedness, tinnitus, visual disturbances, and slurring of speech. The client may lose consciousness and have convulsions. If the injection is stopped, the drug passes rapidly, and the convulsions will stop within 2 minutes. Coma can occur if the intravenous dose is very high.

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[1] *Adapted from*: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia*. Family Planning Service, Department of Health: Manila, The Philippines.

The doctor should pull back the plunger of the syringe when injecting each tissue layer to ensure that the solution is not being injected into a vessel; all injections should be given slowly.

Pentazocine

Other Name: Fortwin

Action: Pentazocine, a member of the benzazocine series (also known as the benzomorphan series) is a synthetic narcotic with a potent analgesic effect. It weakly antagonizes the analgesic effects of morphine and meperidine. It has about 1/50 the antagonistic activity of nalorphine. It also has a sedative effect. When given intravenously, its onset of action is within 2 to 3 minutes and lasts up to 4 hours. When given intramuscularly, its onset of action is within 15 to 20 minutes.

Dosage: The usual adult dose is 30 mg, which is usually as effective as morphine 10 mg or meperidene 75–100 mg. Doses of more than 30 mg IV per single injection or a total daily dose of more than 360 mg are not recommended.

Regimen: Pentazocine can be administered intramuscularly or intravenously.

Warnings: Special care should be exercised in prescribing for emotionally unstable patients and for those with a history of drug misuse. Since sedation, dizziness and occasional euphoria have been noted, ambulatory patients should be warned not to operate machinery, drive cars or unnecessarily expose themselves to hazards. Concomitant use of CNS depressants with parenteral pentazocine may produced additive CNS depression. Adequate equipment and facilities should be available to identify and treat systemic emergencies as they occur.

Treatment of Overdose: Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. For respiratory depression due to overdose or unusual sensitivity, parenteral naloxone is a specific and effective antagonist.

Diazepam

Other names: Valium, Calmpose

Action: Diazepam is a benzodiazepine with anticonvulsant, anxiolytic, sedative, muscle-relaxant, and amnestic properties. Diazepam is a useful premedication for clients who will undergo minilaparotomy under local anaesthesia, to induce a calming effect and to diminish the client's recall of the procedure.

Dosage: For clients over 35 kg (75 lb), the dose is 10 mg. If a client weighs less than 35 kg, the dose should be reduced to 5 mg. The staff should use a lower dose (usually 2–5 mg) for debilitated clients.

Regimen: Diazepam can be given by mouth, 30–60 minutes before the procedure, with a sip of water.

Diazepam may be given intravenously at the start of a procedure but the staff member should take the following steps:

- Inject the solution slowly, taking at least one minute for each 5 mg (1 ml) given.
- Do not use small veins, such as those on the back of the hand or the inside of the wrist.
- Take extreme care to avoid intra-arterial administration or extravasation.
- Do not mix or dilute diazepam with other solutions or drugs in the syringe. If diazepam cannot be administered directly intravenously, it may be injected slowly through the infusion tubing as close as possible to the needle insertion site.
- Avoid intramuscular administration for premedication usage, as the time of maximum effect is not dependable.

When diazepam is used with a narcotic analgesic, such as meperidine, as the preoperative medication for minilaparotomy under local anaesthesia, the staff should reduce the narcotic dosage by at least one-third and administer it in small increments. In some cases, the use of a narcotic may not be necessary.

Warnings: When diazepam is combined with the use of a narcotic (such as meperidine) or other sedative, respiratory depression is increased. Therefore, oxygen and resuscitative equipment should be readily available.

Side effects most commonly reported are drowsiness, fatigue, and ataxia. Other side effects include bradycardia, cardiovascular collapse, and hypotension.

Manifestations of diazepam overdose include somnolence and confusion.

Diazepam and ketamine, being chemically incompatible because of precipitate formation, should not be injected in the same syringe.

Treatment of overdose: The staff should administer an antidote, such as physostigmine 0.5–1.0 mg intravenously, or flumazenil 0.2 mg intravenously, given over 30 seconds, with subsequent doses of 0.3 mg and then 0.5 mg given at one-minute intervals up to a total dose of 3 mg.

Naloxone will not reduce the sedation caused by diazepam.

Promethazine Hydrochloride

Other name: Phenergan

Action: Phenergan is a phenothiazine tranquilizer. It has antihistaminic, sedative, antiemetic, and anticholinergic effects. Phenergan can be used in minilaparotomy under local anaesthesia

for preoperative sedation, for prevention and control of nausea and vomiting, and as an adjunct to analgesics for control of postoperative pain.

Dosage: For preoperative and postoperative medication, the usual adult dose is 25 mg or 50 mg.

Regimen: For anaesthesia premedication, Phenergan is administered intramuscularly.

Warnings: Phenergan adds to the sedative effect of narcotics. If it is given with meperidine before a minilaparotomy, the dose of meperidine should be reduced by one quarter to one half.

Administration of Phenergan should not be subcutaneous, which may result in tissue necrosis.

Atropine Sulphate

Other name: Atropine

Action: Atropine has an antispasmodic action on smooth muscle, and it reduces secretions.

The primary use of atropine in minilaparotomy under local anaesthesia is to decrease the possibility of vasovagal syncope that might occur with the insertion and manipulation of the uterine elevator.

Dosage: The usual adult dose is 0.4–0.6 mg (or 1/150 g). If the client weighs less than 35 kg (75 lb), the staff should give only 0.4 mg.

Regimen: The staff can administer atropine either intramuscularly 30 minutes before the surgery, or intravenously when the client is on the operating table.

When the staff gives the drug intravenously, she should administer half of the dose over a period of 10–30 seconds while the client is monitored for signs of adverse effects. If there are none, the staff should give the remaining dose over another period of 10–30 seconds.

Warnings: Common side effects include thirst and dryness of the mouth, with difficulty in swallowing and talking. Atropine may cause a rapid pulse.

Naloxone Hydrochloride

Other names: Narcan, naloxone, lethindrone

Action: Naloxone is indicated for the reversal of respiratory depression caused by narcotics, including pethidine (meperidine, Demerol), nalbuphine (Nubain), butorphanol (Stadol), fentanyl (Sublimaze), and pentazocine (Talwin). Naloxone has no toxicity.

Dosage: The initial dose is 0.4 mg given intravenously. The staff may give repeat doses intravenously at intervals of 2–3 minutes until the desired degree of reversal (adequate

ventilation and alertness) is achieved. Several doses of naloxone, even over a short period, may be given without untoward effects.

Regimen: Administration of naloxone is intravenous for a rapid onset of action, which is generally apparent within two minutes.

The requirement for repeat doses of naloxone will depend on the amount, type, and route of administration of the narcotic being antagonized.

Intravenous administration is recommended in an emergency situation because it achieves the most rapid onset of action.

Warnings: If the surgical team observes no response after a total dose of 2–4 mg, it should consider other causes of respiratory depression, such as overdose of diazepam or hypoxia due to internal hemorrhage.

The surgical team must monitor the client closely because the effect of the narcotic causing the depression may outlast the effect of naloxone.

Naloxone is not effective against respiratory depression due to nonnarcotic drugs, such as diazepam and midazolam.

In addition to naloxone, resuscitative measures such as maintenance of a free airway, artificial ventilation, cardiac massage, and vasopressor agents should be available and employed when necessary to counteract acute narcotic oversedation.

Naloxone ampules and vials show an expiration date. Because this drug is not used frequently, the supply may not be fresh. Injections repeated at shorter intervals, or increased doses, may be needed for effectiveness if the expiration date has passed.

ADDITIONAL DRUGS AVAILABLE IN SOME CENTERS

Ketamine Hydrochloride

Other names: Ketalar, ketamine

Action: Ketamine is a rapid-acting, nonbarbiturate, nonnarcotic drug producing either profound analgesia or rapid anaesthesia, depending on the dose. It produces a trancelike state in which the client rapidly becomes dissociated from the environment.

Ketamine allows for normal pharyngeal-laryngeal reflexes and normal muscle tone, so the risk of respiratory depression is minimal.

Blood pressure begins to rise shortly after injection, reaches a maximum within a few minutes, and usually returns to preinjection values within 15 minutes after injection.

Dosage: For analgesia, the dose is 0.2–0.5 mg/kg (8–20 mg for a client weighing 40 kg [88 lb]), given intravenously. (The total adult dose must be titrated for client's weight and condition.) This provides a duration of 10–15 minutes of analgesia.

For general anaesthesia, the dose is 2 mg/kg intravenously.

Regimen: To minimize the psychotropic effect of ketamine, the client should take diazepam by mouth one hour before surgery. Intramuscular or intravenous administration of atropine in a separate injection, before the ketamine, will minimize vasovagal reactions related to uterine manipulation. The staff should administer the ketamine intravenously, slowly, and over a period of 60 seconds. Given the short duration of ketamine's effect, the staff may give supplemental doses about one-third less than the initial analgesic dose at 10-minute intervals as needed. However, supplemental doses will prolong the recovery period and increase the chance of psychotropic reactions.

Warnings: Ketamine should be used by or under the direction of physicians experienced in administering general anaesthesia, maintaining an airway, and assisting respiration.

The staff must continually monitor cardiac function during the procedure in clients with hypertension or cardiac decompensation.

Barbiturates and ketamine, being chemically incompatible because of precipitate formation, should not be injected in the same syringe.

Prolonged recovery time may occur if barbiturates or narcotics are used concurrently with ketamine.

If respiratory depression occurs because of overdose or a too-rapid rate of administration, respiration must be supported mechanically.

Precautions: To reduce psychotropic reactions, such as frightening dreams, hallucinations, or delirium, the staff should minimize stimulation (verbal, tactile and visual) during the recovery period.

REFERENCE

Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia*. Family Planning Service, Department of Health: Manila, The Philippines.

APPENDIX I

MINILAPAROTOMY KIT

ITEM	QUANTITY
Instrument tray with cover, SS	1
Stainless steel bowl	2
Toothed thumb forceps	1
Forceps, artery straight, SS, 6"	2
Forceps, artery curved, SS, 6"	2
Forceps, Allis, straight, SS, 6"	2
Forceps, mosquito, artery, curved, SS, 4"	4
Forceps, small, Babcock, SS, 6"	2
Forceps, uterine vulsellum, curved, SS, 10"	1
Forceps, sponge, straight, SS, 10"	2
Forceps, (clamp) towel, SS, 5"	2
Holder, needle, SS, 7"	1
Retractor, double ended (Czerney), SS	1 set
Scissors, operating, standard pattern, straight, SH/BL, SS 6"	1
Scissors, fine, curved, SS, 7"	1
Syringe, hypodermic, 10 cc, luer lock, glass	2
Needle, hypodermic, 22 gauge x 1½", SS, 6/package	2 packages
Needle, eye, ½ circle, taper point, size 3, SS, 6/package	2 packages
Needle, eye, ½ circle, cutting edge, size 3, SS, 6/package	1 package
Handle, surgical knife, size 3, SS	1
Blade, surgical, size 15	2 dozen
Elevator, uterine, SS	1
Speculum, vaginal, either Sims or bivalve, medium, SS, double-bladed	1
Suture, absorbable, plain catgut 0 gauge	1
Tray, kidney, SS	1

BACKUP TRAY (1 per institution)

Retractor, Richardson (set of 2), SS	1
Catheter, urethral, female, #14, French, SS	2
Hook, tubal, Ramathibodi, SS	2
Retractor, vaginal, anterior wall, SS	1