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Maternal and Child
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Minilaparotomy under Local Anesthesia

Reference Manual

The Maternal and Child Survival Program (MCSP) is a global U.S. Agency for International Development (USAID) cooperative agreement to introduce and support high-impact health interventions in 24 priority countries with the ultimate goal of ending preventable child and maternal deaths (EPCMD) within a generation. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment. MCSP will tackle these issues through approaches that also focus on health systems strengthening, household and community mobilization, gender integration and eHealth, among others. Visit www.mcsprogram.org to learn more.

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Abbreviations

BCS	Balanced Counseling Strategy
BP	blood pressure
CHG	chlorhexidine gluconate
CIC	combined injectable contraceptive
COC	combined oral contraceptive
CREST	Collaborative Review of Sterilization
H ₂ O ₂	hydrogen peroxide
HBV	hepatitis B virus
HLD	high-level disinfection/disinfected
IPC	infection prevention and control
LAM	lactational amenorrhea method
LMP	last menstrual period
ML/LA	minilaparotomy under local anesthesia
NSAID	non-steroidal anti-inflammatory drug
OR	operating room
PID	pelvic inflammatory disease
PM	permanent methods
POI	progestogen-only injectable
POP	progestogen-only pill
SAE	severe adverse event
STI	sexually transmitted infection
VS	voluntary sterilization
WHO	World Health Organization

One. Introduction

Background

Worldwide, permanent methods (PM) of contraception are the most popular and most effective contraceptive methods. Female sterilization, in fact, is the most popular contraceptive method in the world, used by about 20% of women between the ages of 15 and 49 who are married or in a union (Knowledge for Health Project). It is a safe, effective, and reliable method, with a failure rate under 2% over the first 10 years (Marie Stopes International et al. 2014).

The most important aspect to emphasize about female sterilization is its permanence. Through counseling, the client must understand that the procedure is meant to result in permanent voluntary infertility.

Over the years, PM services have become increasingly safe, efficient, and convenient. Procedures as they are performed today are relatively minor operations requiring small incisions and involving only a short stay at a surgical facility (i.e., usually just a few hours).

Developments in PM for women since they were first recognized as effective and efficient surgical contraceptives have focused on two areas: surgical techniques for accessing the fallopian tubes and methods for blocking them (see Mechanisms of Action, below).

History¹

Early sterilization surgery was done through a laparotomy incision, frequently in association with cesarean section and often to prevent pregnancies in women facing specific health risks. It required general or regional anesthesia and a postoperative hospital stay of several days.

Beginning in the late 1950s, surgical developments made it possible to approach the tubes through a much smaller incision. Surgical sterilization became much more common in the 1960s and 1970s. The surgical techniques adopted then were laparoscopy and minilaparotomy and they are still the most common procedures used today. A large-scale study of both techniques in the mid-1970s showed them to be similar in safety and effectiveness (World Health Organization [WHO] Task Force 1981). Minilaparotomy, however, clearly offers other advantages. Laparoscopic sterilization is more costly and requires specialized surgical training and equipment. In contrast, minilaparotomy requires only basic surgical training and instruments, making it better suited for widespread use in settings with limited medical resources.

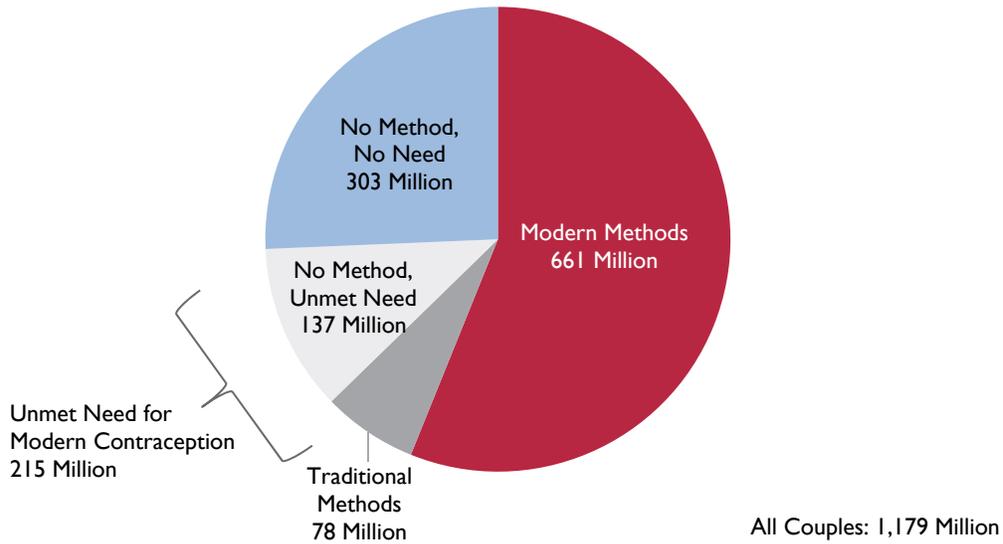
Advances in anesthesia have also played a major role in promoting surgical sterilization. Both minilaparotomy and laparoscopy can be performed under local, rather than general or regional anesthesia, which greatly reduces surgical risks and recovery time.

Current Need

There is still a large, unmet need for modern contraception—an estimated 215 million people worldwide who would like to use contraception are using either no method or a traditional method (see **Figure 1-1**).

¹ Adapted from: Wilson 1995.

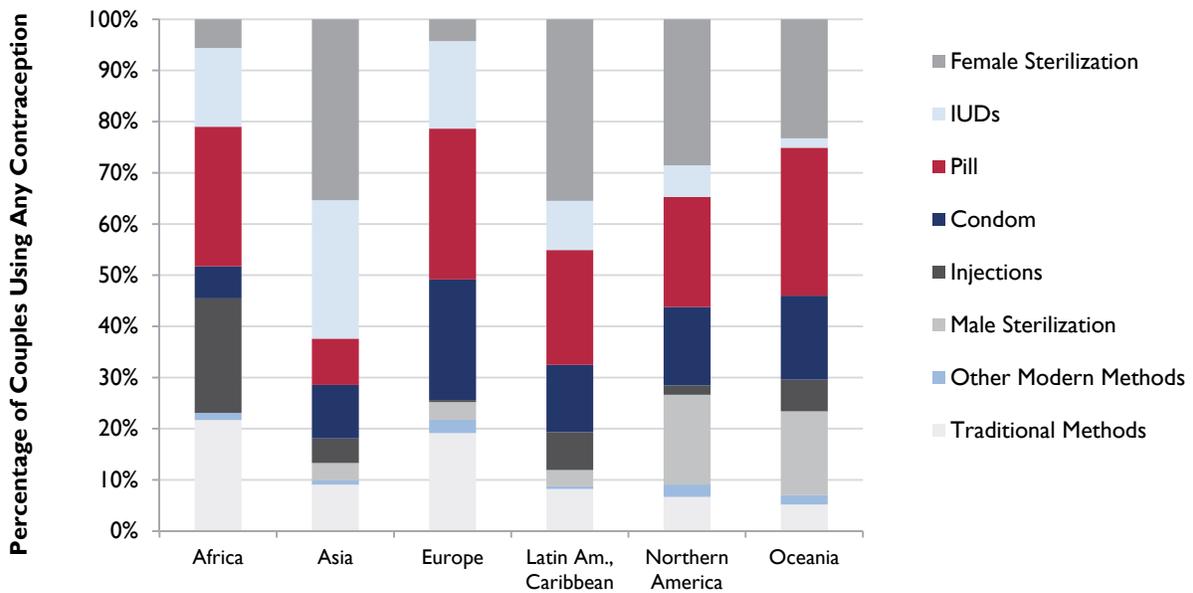
Figure I-1. World Contraceptive Use and Unmet Need, 2009



Source: Reading BF. 2012. Data Highlights: Growth in World Contraceptive Use Stalling; 215 Million Women's Needs Still Unmet, citing Earth Policy Institute, United Nations, Guttmacher Institute. http://www.earth-policy.org/data_highlights/2012/highlights26.

Worldwide, 34% of couples who are using a modern method choose female sterilization, which is more common than male sterilization, especially in America and Asia (Reading 2012). **Figure 1-2** shows the variations in contraceptive prevalence, by region, among couples using any method of contraception.

Figure I-2. Contraceptive Method Prevalence by Region, Latest Year



Source: Compiled by Earth Policy Institute from U.N. Population Division, World Contraceptive Use 2011, wall chart, February 2011.

Regionally, women have different types of unmet need for family planning—some may want to space births and others may want to limit births. At the couple level, needs are greatly influenced by social and economic factors. At the country or regional level, unmet need for limiting is very high. In sub-Saharan Africa, for example, nearly 8 million women have demand for limiting future births (Van Lithet al. 2013).

Unmet need is a dynamic concept, as the need for spacing may change to the need for limiting among couples and populations. Unmet need should not be considered an indication of the failure of family planning programs. There are many reasons why women do not use family planning, including demand-side reasons such as cultural or religious objections, lack of knowledge, or fear of side effects (Mills et al. 2010). As women's needs change, they must be matched by changes in family planning services. For these changes and improvements in services to happen, significant investment in family planning programs must be made.

Mechanism of Action

The fallopian tubes at each lateral side of the uterus provide a passage way for the mature ovum (egg) to travel from the ovary to the uterus (womb). The ovum released from the ovary travels through the fallopian tube, where it is fertilized by the ascending spermatozoa. In a sterilization procedure, the fallopian tubes are blocked (cut and ligated), effectively preventing the meeting of the sperm and egg. After tubal occlusion, the woman still releases eggs from the ovaries (ovulation) and has her regular menstruation just as before the operation.

Minilaparotomy under Local Anesthesia

This manual focuses on one of the most common approaches to female sterilization: minilaparotomy under local anesthesia (ML/LA). The approach was developed so that female sterilization could be provided on a large scale and at minimal cost by non-specialist doctors with specific surgical training in minilaparotomy. In this manual, the term “surgeon” is used to describe the person performing the procedure—it could be a specialist in surgery, a general practitioner, or other clinician (such as clinical officers in Kenya and Malawi) who has been trained in the procedure. ML/LA is safe and effective and can be performed on an outpatient basis, requiring simple, inexpensive, and easily maintained instruments, equipment, and supplies.

Minilaparotomy uses a small incision of about 3–5 cm either at the suprapubic (for interval cases) or infra-umbilical (for postpartum cases) incision. Although the incision is smaller, the operation should not be considered simpler than traditional laparotomy.

Minilaparotomy is safest and most efficient when performed under local anesthesia. A client can return home within hours after the procedure with a short period of rest and observation. The use of local anesthesia eliminates the problems and possible complications associated with general anesthesia (Lipscomb and Ling 1995; Ruminjo and Lynam 1997).

Clients may have apprehension if minilaparotomy is performed under local anesthesia that they may experience pain or discomfort. This fear can be alleviated when the provider reassures the client through continuous verbal feedback to explain the procedure as it is being done (Lipscomb and Ling 1995; Ruminjo and Lynam 1997). This technique of ongoing verbal contact has been termed “verbacaine” and is an important component of administering local anesthesia that minimizes discomfort to the client.

Once the abdomen is opened, the fallopian tubes are identified, exposed, and occluded by tying each with absorbable sutures and then cutting out a small piece of tube. The abdomen is closed by layers, and a dry, sterile dressing applied on the surgical wound. The client usually can be discharged within 2–4 hours after the procedure, provided there are no problems.

Methods of Tubal Occlusion

There are several methods of tubal occlusion using the minilaparotomy technique under local anesthesia that are currently used:

- Tubal ligation, in which the fallopian tubes are ligated or tied. This is the preferred method of tubal occlusion because it is the most effective and does not require special equipment or mechanical devices (Moss and AVSC 1991). The 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.
- Application of mechanical devices (e.g., spring clips, silastic bands) using a special applicator such as the Laprocator™.
- Electrocoagulation, in which electrical current is used to burn and occlude the tubes.

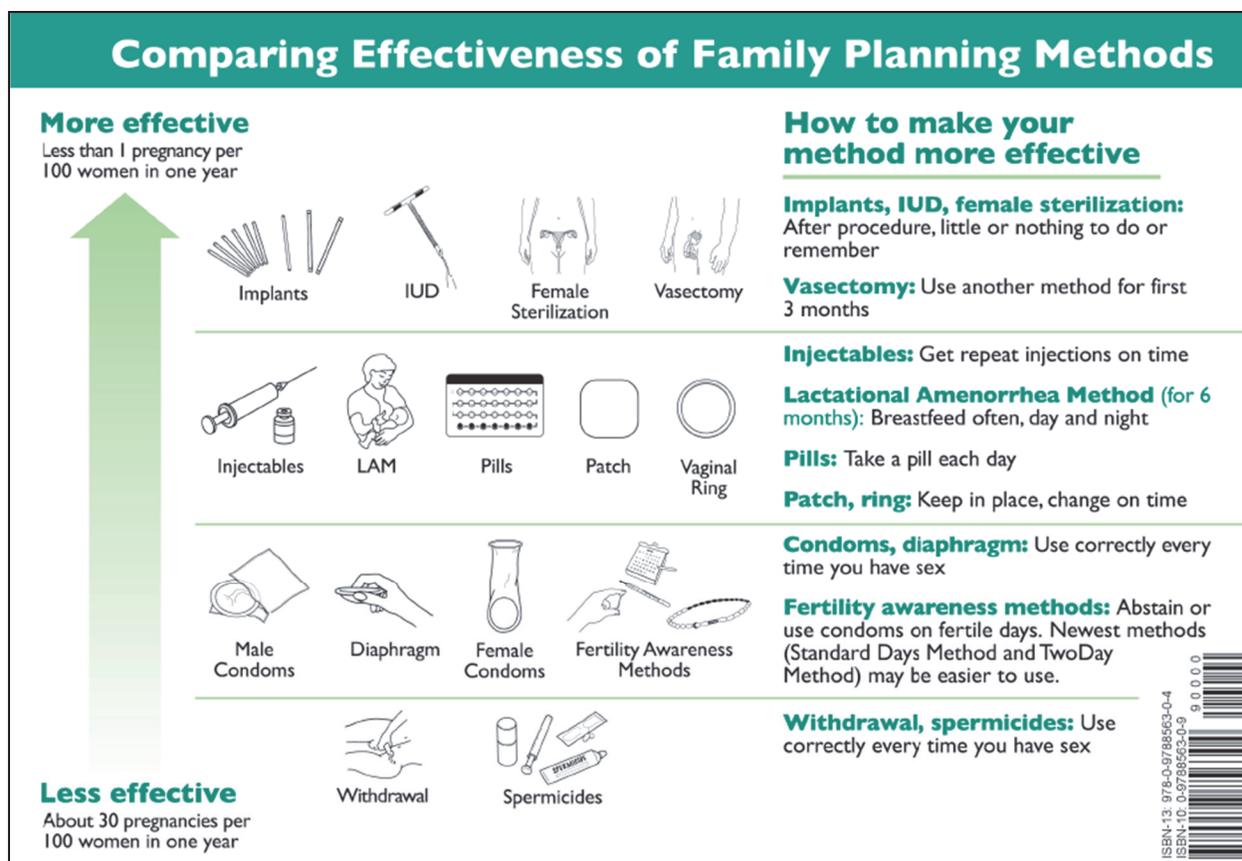
Timing of the Procedure

Minilaparotomy can be performed in the interval period (6 weeks after delivery or any time when the woman is not pregnant), or in the immediate postpartum or postabortal periods. For interval procedures, minilaparotomy may be performed at any time in the menstrual cycle as long as the woman is not pregnant, 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. For postpartum or postabortal procedures, minilaparotomy can be performed within 7 days after delivery or abortion, provided there are no complications.

Effectiveness

Female sterilization is one of the most effective contraceptive methods, together with the other methods shown at the top of **Figure 1-3**. In the first year after having a sterilization procedure, less than 1 woman in 100 will become pregnant (5 per 1,000). Effectiveness varies slightly depending on how the tubes are blocked, but pregnancy rates are still very low. One of the most effective techniques is cutting and tying the cut ends of the fallopian tubes after childbirth (postpartum tubal ligation).

Figure I-3. Comparing Effectiveness of FP Methods



Source: World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP) INFO Project. 2011. *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva, Switzerland: CCP and WHO.

Safety

Female sterilization by ML/LA is a safe method of contraception. Complications arising from the procedure are uncommon. The WHO definition for complication following female sterilization is: “problems directly related to the surgery or the anesthesia that occur within 42 days and that require intervention and management beyond what would normally be provided.” Examples include infection, bleeding, unintended injury to internal organs, and depressed respiration or blood pressure (BP) due to anesthesia (WHO 1992). Minilaparotomy under local anesthesia in the hands of a trained surgeon is a safe, highly effective approach for performing tubal occlusion. Serious complication is very rare and occurs in less than 1% of women.

Complication Rates

Complication rates vary by the quality of care provided at the service site, the expertise of the surgeon, the approach and occlusion technique used for sterilization, the type of anesthesia, the timing of the procedure, and the characteristics of the client (e.g., obese clients or those with history of pelvic infection). Client assessment before the procedure reduces the likelihood of complications. Factors that may complicate minilaparotomy include obesity, previous pelvic or abdominal surgery, and previous pelvic or abdominal infection. For more information about client assessment, see **Chapter 4**.

Complications can be kept to a minimum if clients are preoperatively assessed correctly, appropriate techniques are used, and the procedure is performed in a high-quality, standard setting.

Female Sterilization as a Permanent Method

Female sterilization should be considered permanent. It may be possible in some cases to reverse the procedure by surgical reanastomosis of the ligated fallopian tubes. But even when such services are available, this is difficult and return to fertility is not assured. The client may not be able to afford the reversal procedure, or she may not be a good surgical candidate as this is a major surgical procedure, or a reversal attempt may not be successful. Clients and couples who are considering minilaparotomy should receive effective counseling about the procedure and the impact a permanent method will have on their reproductive future.

Failure Rate

Failure rates for female sterilization are very low. A small risk of pregnancy remains beyond the first year of use and until the woman reaches menopause. Reports of failure rates following tubal ligation ranged from 0.2%–0.9% at 1–2 years of post-sterilization follow-up. Causes of failure included abnormalities of the fallopian tubes, procedural errors, and opening of the tube (recanalization) during the healing process (Soderstrom 1986).

Failure rates for different methods of occlusions are not the same. The 5-year failure rates are: 0.75% for tubal ligation and division, 3.7% for application of mechanical devices, and 2.5% for electrocoagulation (Peterson et al. 1997). Failure rates are often due to improper technique or improper placement of a mechanical device, and are not solely the result of a particular method not working as well as another method.

The U.S. Collaborative Review of Sterilization (CREST) study found an overall cumulative failure rate of 1.9%, more than double the failure rate accepted previously (Peterson et al. 1996; Update on female sterilization 1996). The study showed that the risk of failure is greatest within the first year after the procedure and then virtually disappears (Trussell et al. 1995; Vessey et al. 1983). Data from the CREST study, however, which followed subjects for 10 years, showed that failures do not occur exclusively or primarily during the first 2 years after the procedure. Rather, the cumulative risk increases over time and may continue even beyond 10 years after the procedure (Update on female sterilization 1996), when two pregnancies per 100 women (18–19 per 1,000 women) may occur.

Advantages of Female Sterilization

Major advantages of ML/LA are that it:

- Is highly effective and does not require additional client action
- Is effective immediately
- Is permanent with no need to worry about getting pregnant again
- Does not affect breastfeeding
- Does not interfere with intercourse
- Is good for clients for whom pregnancy would pose a serious health risk
- Does not cause changes in sexual function
- Involves instruments and supplies that are simple, inexpensive, and easily maintained
- Can be performed by doctors who have basic surgical training

- Is particularly well-suited for rural areas where support staff, equipment, and supplies are limited and the volume of procedures and resources are low
- Can be performed on an outpatient basis with a stay of a few hours
- Can be used for interval, postabortion, and postpartum tubal occlusion
- Decreases risk of ovarian cancer

Reduced Risk of Ovarian Cancer

An important beneficial effect of female sterilization by minilaparotomy appears to be a reduction in the risk for ovarian cancer (Cibula et al 2011; Edwards 1994; Green et al. 1997; Hankinson et al. 1993; Irwin et al. 1991; Kjaer et al.; Madsen et al. 2014 Sieh et al.; Whittemore et al. 1992). A prospective study by Hankinson et al. (1993) of more than 120,000 female nurses found that women who elected to undergo sterilization were much less likely to develop ovarian cancer. This protective effect persisted even when adjustments for age, parity, use of oral contraceptives, and other risk factors were made and were present in the first 15 years of sterilization. This study suggested that the risk for ovarian cancer may be prevented by as much as 70% in women who have been sterilized. A meta-analysis of relevant studies by Cibula et al. (2011) also yielded consistent data on a significant reduction of ovarian cancer risk in women who had undergone tubal ligation. And a Danish population-based study by Kjaer et al. (2004) found that women who had undergone tubal sterilization had a decreased risk of subsequent development of ovarian cancer, and the protective effect did not decrease with years of follow-up.

Limitations of Female Sterilization

ML/LA has the following limitations:

- It must be considered permanent.
- The client might have regrets later if not properly counseled.
- There is a small risk of complications (wound infection or abscess).
- The client may experience some short-term discomfort after the operation.
- It requires a trained doctor to do the surgery.
- It does not protect the clients against sexually transmitted infections (STIs), including AIDS.

Side Effects

There are no long-term side effects associated with tubal ligation using ML/LA. 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, dysmenorrhea) may result from the procedure, studies have not found conclusive evidence. It was once postulated that blocking the fallopian tube altered blood supply to the ovary, leading to changes in ovarian function after sterilization (DeStefano et al. 1985; Gentile et al. 1997). But there is no convincing evidence that such changes occur (Post-tubal sterilization syndrome 1993). Some studies suggest that menstrual bleeding changes may instead be caused by switching from another method to voluntary sterilization (VS), by the normal aging process, or by other gynecological abnormalities (Gentile et al. 1997; Pollack 1993; Post-tubal sterilization syndrome 1993).

The most recent literature concludes that if post-tubal sterilization syndrome exists at all, it affects a very small minority of women (Post-tubal sterilization syndrome 1993). Abnormal menstrual cycles (sometimes developing more than 2 years after the procedure) may be more common among women who have undergone sterilization by specific methods, notably electrocoagulation or clip techniques that were used in the 1970s (DeStefano et al. 1985). Other studies have found slightly higher reports of menstrual changes (positive as well as negative) among women who had been sterilized before the age of 30, and especially among those who had abnormal menstrual patterns before the surgery (Gentile et al. 1997).

If a client reports menstrual changes after tubal sterilization, the health care provider should consider all possible causes, and must be able to explain them to the client. These changes are likely to be unrelated to tubal sterilization and may indicate other conditions or problems.

Ectopic Pregnancy

Female sterilization does not increase the frequency of ectopic pregnancy. If a woman does become pregnant after tubal ligation, however, she is more likely to have an ectopic pregnancy (Mol et al. 1995; Peterson et al. 1997). Among women who become pregnant after voluntary sterilization, more than one half of all pregnancies are ectopic (Pollack 1993). These ectopic pregnancies occur when the tube is only partially occluded, allowing the sperm to enter but preventing the fertilized ovum from reaching the uterus. Therefore, women undergoing the procedure should be counseled about this risk, and all women who have had a minilaparotomy and present with symptoms of pregnancy should be carefully evaluated.

Delivery of Services

Voluntary and Informed Choice

Because of its permanence, women who choose sterilization for contraception must do so voluntarily, without coercion, inducements (such as cash payments), or perceived pressures from partners, counselors, or others. Before she can make an informed decision, the client must receive accurate information about the advantages and disadvantages of PM as well as the availability of other contraceptive methods. She should receive client-specific counseling to help her choose the contraceptive method that is best suited to her own circumstances and reproductive goals. Information should be fully discussed, including the procedure, its benefits and advantages as well as risks, in ways the client can clearly understand. She must also be made aware that she can decide against PM without giving up the right to receive other medical services.

Quality of Care

Because sterilization is a widely performed procedure, maintaining a high quality of care must be an ongoing concern. Service providers should understand that they may be the only contact a client will have with a doctor. For this reason, the quality of service they provide must be high.

One parameter of quality service is ensuring that clients' rights are protected and upheld during the provision of services. Since family planning is considered to be one of the rights of clients, it is the responsibility of the service provider to uphold it. This concept is ensured during the counseling process, in which the counselor uses her or his knowledge and skills in providing accurate, adequate, and appropriate information to help clients make well-informed decisions.

Another important aspect of quality services is the ability of the service provider to deliver and provide these services. As such, the delivery of quality services is influenced by a number of factors to which service

providers are exposed, including the quality of their work environment, the information and training they receive, and the equipment and supplies available to them.

Ensuring quality of care should be foremost in providing VS. Providers, especially non-specialists, should receive competency-based training in the standardized technique of tubal ligation including the proper use/handling of instruments and the administration of local anesthetic. Appropriate and sufficient training in counseling should be emphasized so that clients requesting the procedure understand their contraceptive options, and future regret at the decision to undergo voluntary sterilization can be minimized (Advances in female sterilization research 1995).

Facilities and Personnel

ML/LA can be performed in any health center, including community health centers, primary health centers, and maternity hospitals, and temporary or mobile facilities that can provide referral care as long as the requirements for safely and effectively delivering ML/LA are in place and practiced. Several studies have found that both safety and high quality of care can be achieved at these different types of locations (Mehta 1991; Nisanian 1990; Siswosudarmo 1991). For more information about mobile facilities, see **Chapter 11, Mobile Outreach Services**.

The minimum physical requirements for a facility providing ML/LA services are:

- Clean, running water
- Electricity or other light source
- Toilet facilities and washing facilities, preferably separate for clients and staff
- Separate reception/registration area and comfortable waiting area for clients, with nearby changing area
- Counseling area with privacy
- Examination room for preoperative and follow-up examination, and postoperative area for monitoring clients
- A clean surgical/operating room with nearby scrubbing area, isolated from the other facilities
- Facilities for cleaning, sterilizing, and autoclaving surgical instruments, equipment, linen, and dressing
- Space for storage of records, supplies and equipment

In addition, certain equipment, instruments, and drugs, including drugs that may be needed for emergency events, should be available for use in the operating room and recovery areas and staff should be trained in their use. (See **Appendix A** for more information on emergency preparedness.) The minilaparotomy procedure should be performed by a trained clinician with basic surgical skills.

The Needs of the Health Care Staff

Health care staff desire to perform their duties well. However, if they lack administrative support and critical resources, they will not be able to deliver the high-quality services to which clients are entitled.

Health care staff need:

- **Information, training, and development:** Health care staff need knowledge, skills, and ongoing training and professional development opportunities to remain up-to-date in their field and to continuously improve the quality of services they deliver.
- **Supplies, equipment, and infrastructure:** Health care staff need reliable, sufficient inventories of supplies, instruments, and working equipment, as well as the infrastructure necessary to ensure the uninterrupted delivery of high-quality services.

Client Counseling

Because minilaparotomy is considered to be a permanent procedure, women requesting it should be well-counseled and have sufficient time to think about their decision. All clients should give their informed consent only after careful exploration of the matter so that no woman makes the decision for voluntary sterilization without fully understanding that it is permanent.

Women considering a sterilization procedure should be carefully informed of all their contraceptive options, including long-term, reversible methods. They must be counseled about the risks involved in the procedure, including the risk of regret and the limited possibilities for a successful reversal procedure. Clients should understand that although sterilization is a very effective method of contraception, there is a possibility of failure. This risk continues until menopause. Ectopic pregnancy and its symptoms also should be explained (Update on female sterilization 1996).

Many minilaparotomies are conducted at mobile units set up specifically for this purpose. It is especially crucial that women served by mobile units receive thorough counseling because these clients may not have other access to health care providers.

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.

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.

Most of the published literature on regret has found regret correlated with young age (< 30 years), a change in life circumstances (new partner, death of child), or preoperative depression, but not with parity (Bail et al. 2003). However, in Zimbabwe, among 418 women who had an emergency cesarean section and who were successfully followed up (for a mean time since delivery of 3.8 months), 72% had been offered a tubal ligation and 80% accepted. This study found that 89% of these women were happy with the decision. Of the 117 (out of the 418) women not offered a tubal ligation, 64% regretted not having one (Verkuyl 2002).

Also in the Zimbabwe study, tubal ligations performed during emergency cesarean section had no higher regret rate (2.5%) than those performed during elective cesarean section (3.2%). Women who did **not** have a tubal ligation during an *emergency* cesarean regretted this (56.4%) significantly more often than women who did **not** have the procedure with an *elective* cesarean (35%) or after vaginal delivery (45%). Women were far more likely to regret declining a tubal ligation (40%) than regret accepting one (2.5%). The main ethical argument against offering a tubal ligation with an emergency cesarean section is that such an important

decision should not be taken on such short notice and during such a stressful situation. However, the authors of this study concluded that it is unethical *not* to offer such woman a tubal ligation. And some women are more likely to die from another pregnancy than to regret having the procedure (Verkuyl 2002).

It is not possible to prevent all dissatisfaction, but if programs take measures to assure voluntary, informed choice, and if before surgery they assist clients 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 counseling 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.

Fears, including fear of side effects, may keep women from using PM, and this factor must be addressed during counseling. Other reasons, including partner opposition, lack of access, high cost, etc. must also be addressed (see **Figure 1-4**).

Figure 1-4. Why Women Who Wish to Avoid Pregnancy Do Not Use Family Planning

REASONS	SSA (R/%)	SCA (R/%)	SEA (R/%)
HEALTH/SIDE EFFECTS	1/24%	4/18%	1/39%
INFREQUENT SEX	3/17%	2/22%	2/25%
POSTPARTUM/ BREASTFEEDING	3/17%	3/19%	3/11%
WOMAN/PARTNER OPPOSED	2/23%	1/32%	3/11%
NO ACCESS/HIGH COST	4/10%	5/06%	4/10%
UNAWARE OF METHODS	5/08%	6/02%	5/03%
PERCEIVED SUB-FECUND	6/01%	7/01%	6/01%

Source: Darroch JE, Sedgh G, Ball H. 2011. *Contraceptive Technologies: Responding to Women's Needs*. New York, NY: Guttmacher Institute. SSA=sub-Saharan Africa; SCA=South Central Asia; SEA= Southeast Asia

Summary

Female voluntary sterilization by tubal occlusion is a widely used, safe, and highly effective form of permanent contraception. ML/LA is a commonly used method that is particularly well-suited for large-scale use in low-resource settings. ML/LA can be performed on an outpatient basis by non-specialist doctors who are trained in the procedure, using relatively simple, inexpensive equipment and supplies. A high level of quality can be achieved in a variety of settings, including hospitals, clinics, and mobile facilities. Complication rates are very low, especially when clients are carefully assessed before the procedure. ML/LA can be performed during either the interval or postpartum/postabortal period, and there are few conditions that would make a woman ineligible. Because of its permanence, the client must receive careful counseling and make a well-informed choice before undergoing the procedure.

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Two. Counseling

Background

Counseling is of particular importance in programs providing PM services because the methods involve surgery and are intended to be permanent. PM involve consequences, risks, and fears that need to be discussed with each client. Providers are responsible for ensuring that the client understands the benefits, risks, implications of and alternatives to PM, and that those who choose them should do so voluntarily.

The decision to undergo a procedure to permanently end the ability to have more children is solely the woman's to make. However, it may be helpful for the counselor to discuss this option jointly with the woman and her partner. Nevertheless, it is vital for the client to have time alone with the counselor, so that she has the opportunity to express concerns or ask questions that she may not wish to raise in front of her partner (Haws et al. 1997; World Federation 1988).

The counselor should discuss each client's feelings about ending fertility and assess the client's psychological readiness for the procedure and its consequences. Counselors should listen to clients carefully to determine if there are signs of doubt, conflict, misunderstanding, or unrealistic expectations about the procedure (World Federation 1988). In such cases, it may be appropriate to encourage these individuals to take more time to consider their request for PM and to accept a temporary method in the interim. Ultimately, the counselor may help the client choose another contraceptive method that better suits her feelings or circumstances.

Counseling also helps clients who are good candidates for PM 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, counselors enhance the chances that those who choose PM will be satisfied with their decision. In general, clients are likely to adjust well and be satisfied after surgery with their decision if they have taken responsibility for their decision to end their fertility, and if service providers have told them what to expect.

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

Counseling about Permanency¹

Clients should be informed that voluntary sterilization is considered permanent. During counseling, it is important to identify clients who are indecisive about undergoing sterilization or concerned about reversal, and to advise such clients to consider their decision further. In some countries, reversal of ligation is available at limited clinical sites where microsurgical facilities are present. The counselor should explain, however, the following points:

- Reversal involves complicated and difficult surgery, requiring great skill.
- Some individuals who request reversal may be ineligible because of age, fertility impairments, partner's infertility, or insufficient length of tube for reversal.

¹ Adapted from: World Federation 1998.

- 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.

Signs of Regret

One of the principal aims of PM counseling is to identify clients who are likely to adjust poorly or change their minds after undergoing the procedure. If appropriate counseling is provided, regret is uncommon among PM clients.

Several studies show that women who undergo sterilization before age 30 are significantly more likely than older women to have regret later. For example, in a 5-year follow-up study of more than 7,000 women, the US Collaborative Review of Sterilization (CREST) found that women in the youngest age groups (under 30) were two to three times more likely to report regret than women 30–35 years of age. This age difference was independent of the number of living children a woman had or her marital status at time of sterilization (Wilcox et al. 1991).

Women who are advised to undergo sterilization because pregnancy poses a serious health risk for them also 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 conditions, effective, long-acting contraceptives (e.g., IUDs, injectables, vasectomy, contraceptive implants) should be presented as alternatives to women who do not want to undergo sterilization (AVSC 1993; Pile 1996).

Characteristics that, if not addressed during counseling, may increase the likelihood of regret following surgery are summarized in the box on the next page. These factors should **not** be used as arbitrary grounds for denying sterilization to a client. Rather, they are signals to the counselor to devote special time and care to the client, being sure she 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 a permanent method and to accept a temporary method in the interim.

Client Characteristics Associated with Regret following Voluntary Sterilization

- Client is young.
- Client has children who are all of the same sex.
- Client has a child, especially the youngest, who is in poor health.
- Client's marriage is unstable.
- Partner disagrees with the decision for a permanent method.
- Partner or someone else pressured client to undergo the procedure.
- Decision was made under unusual stress (for example, during labor or following an abortion).
- Decision was made quickly without time to reflect and reconsider.
- Client lacks access to other methods of contraception.
- Client has unresolved religious or other cultural conflicts.
- Decision was made under the influence of payments or other incentives.
- Client is incompletely or incorrectly informed about PM.
- Client is having VS because of medical indications.
- Client has unfulfilled maternal desires (an especially important factor if sterilization is medically indicated or where the country policy is to encourage smaller families).
- Client has unrealistic expectations about the procedure and its consequences.

- Client has history of psychological problems, including sexual problems.
- Client has unresolved feelings about the permanence of the method.
- Client has unresolved feelings about wanting more children if she were to remarry after the procedure.
- Client has unresolved feelings about wanting more children if an existing child were to die after the client had been sterilized.

Adapted from: AVSC 1993; Neamatalla and Harper 1990.

Client Rights²

The goal of health service delivery is quality of care. Since the practice of family planning has been recognized as the right of individuals and couples, delivery of quality services is protecting and upholding these rights. These so called “rights,” which are embodied in international covenants, are:

- **Information:** Clients have the right to accurate, appropriate, understandable, and clear information related to reproductive health and sexuality, and to health overall. Informational materials for clients need to be available in all parts of the health care facility. All individuals of reproductive age 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. Because sterilization is intended to be permanent, the client should receive complete information and careful counseling before choosing this option.
- **Access to services:** Clients have the right to services that are affordable, are available at convenient times and places, are fully accessible with no physical barriers, and have no inappropriate eligibility requirements or social barriers, including discrimination based on sex, age, marital status, fertility, nationality or ethnicity, social class, religion, and sexual orientation. A client should be able to obtain the method she or he has decided to use, provided the method is available and there are no reasons why the person should not use it (WHO 2015).
- **Informed choice:** All persons have a right to decide freely whether or not to practice family planning. It is the right of individuals or couples to make a voluntary, well-considered decision that is based on options, information, and understanding. Family planning programs should assist people in the practice of informed and voluntary choice by providing unbiased information, education, and counseling, as well as an adequate range of contraceptive methods. It is the responsibility of the service provider to confirm that a client has made an informed choice or to help the client reach an informed choice.
- **Safe services:** Clients have the right to safe services, which require skilled providers, attention to infection prevention, and appropriate and effective medical practices. Safe services also mean proper use of service delivery guidelines, quality assurance mechanisms within the facility, counseling and instructions for clients, and recognition and management of complications related to medical practice.
- **Privacy:** Clients have the right to a private environment during services and counseling. This means that a facility must have an area where clients cannot be seen or heard during counseling, physical examinations, and clinical procedures. This includes privacy and confidentiality during counseling, physical examinations, and clinical procedures, as well as in the staff’s handling of clients’ medical records and other personal information.

² *Adapted from: Huezo and Briggs 1992.*

- **Confidentiality:** Clients have the right to be assured that personal information will not be disclosed. This includes maintaining secrecy about clients' histories, results of examinations and counseling, and also in keeping clients' records. Clients have the right to discuss their concerns in an environment in which they feel confident. This includes being sure that conversations with the counselor or service providers will not be listened to by other people.
- **Dignity:** Clients have the right to be treated with courtesy, respect, and consideration. The service provider gives utmost attention to the client's need.
- **Comfort:** Clients have the right to be at ease and relaxed while in a health facility for services. Service providers need to ensure that clients are as comfortable as possible during procedures. Clients 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 ML/LA procedure, however, comfort is directly related to the provision of gentle, supportive care. In addition, the time clients spend receiving requested services should be reasonable.
- **Express opinion:** Clients have the right to express their views on the services being offered. Clients should be encouraged to express their views freely, even when their views differ from those of the service providers. Finally, clients have a right to express their views about the service received. Opinions about the quality of services, either thanks or complaint, together with suggestions for changes in service provision, should be viewed positively in a program's ongoing effort to monitor, evaluate, and improve its services.
- **Continuity of care:** All clients have the right to continuity of services, supplies, referrals, and follow-up necessary to maintain their health. Clients have the right to receive services and supplies for as long as they need them. This can either be through the service provider or by referral. 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.

Client Issues

- The client has the right to change her/his mind at any time prior to the procedure.
- No incentives should be given to clients to accept PM.
- The client should be counseled about the risks and benefits of VS, and about alternative contraceptive methods, so that she can make an informed choice.
- A standard consent form must be signed by the client before the PM procedure.
- Spousal/partner consent is not mandatory.
- In mobile outreach PM programs, the standards for counseling and follow-up should be the same as at fixed sites, and all recommended infection prevention practices should be followed.

Benefits of Counseling

For the Woman

- Counseling results in the woman having a free and informed decision. She feels in control of her choice of sterilization and does not feel she has been pressured into accepting a method of contraception with which she is not comfortable.
- The woman knows exactly what to expect with sterilization. She understands all the advantages it offers and will be prepared for any discomfort she may experience or side effects that may develop.
- She knows whom to ask for advice if she feels concerned about anything at any time.
- She understands that sterilization is permanent.

For the Clinician

- Although counseling may appear to be time-consuming, it is cost-effective and can save time and prevent problems in the long run. For example, surgeons report that their clients experience far less pain or discomfort during the procedure when they have been counseled on what to expect (Ruminjo and Lynam 1997).

Counseling Process

Good counseling focuses on the individual woman's needs and situation, and good counselors are willing to listen to the woman's questions and concerns. Counseling must be based on trust and respect between the client and the counselor. Staff must provide a prospective minilaparotomy client with all the information necessary for her 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 counseling session should be treated confidentially.

Family planning counseling should enable a client to:

- Consider her reproductive goals;
- Make informed and voluntary decisions about fertility and contraception; and
- Understand how to use her method of choice safely and effectively.

The Balanced Counseling Strategy Plus

The Balanced Counseling Strategy Plus (BCS+): A Toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings, was developed by the Population Council (Population Council 2012). It describes a client-friendly, interactive process for providing counseling on family planning and prevention and treatment of sexually transmitted infections, including HIV. The toolkit contains a trainer's guide, user's guide, algorithm for using the strategy, and a number of method-specific counseling "cue" cards and brochures, including ones on tubal ligation (see **Appendix B**). The tools are generic and can be adapted according to specific regional or country needs. People who are counseling clients on PM may find the BCS+ toolkit a useful guide to providing comprehensive, high-quality counseling.

Steps in Counseling

Education about all methods can be done effectively and efficiently in a group setting prior to individual counseling. It gives the client an opportunity to ask questions about specific family planning methods in which she is interested.

Individual counseling, which should take place in private, is important because it may be the first time the client has had the opportunity to discuss her contraceptive options fully. At this time, the client can:

- Discuss personal issues and needs;
- Be helped to choose a suitable method;
- Receive further explanation about how to use the method safely, effectively, and with satisfaction.

If a client expresses an interest in knowing more about sterilization, use an anatomic model or a visual aid to demonstrate how the procedure is performed.

Subsequent counseling about sterilization should cover the following points:

- Basic health information to ensure that there are no reasons (e.g., suspected pregnancy) why the woman should not have sterilization;
- How the method prevents pregnancy;
- Method characteristics (benefits and limitations) and side effects;
- Permanence of sterilization;
- That this is a surgical procedure that requires recovery time and involves potential risks related to anesthesia;
- How the procedure is performed, how long it takes, and what discomfort, if any, to expect;
- That sterilization does not affect normal sexual functioning, physical health, or mental health; and
- The possibility of failure (i.e., pregnancy).

The counselor should also ask about and assess the client's decision and feelings:

- 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 a child or partner, divorce, remarriage)?

If the counselor is confident that the client has made an informed, voluntary, and well-considered decision to have the procedure, the informed consent form is discussed with and signed by the client.

Pre-procedure counseling is given before the procedure is performed:

- Any questions the woman may have regarding the procedure and what she can expect (e.g., how long it will last, etc.) should be answered.
- The consent 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 should be given clear instructions on how to prepare for surgery.

Post-procedure counseling usually is given immediately after surgery. This is a good time to reinforce information given earlier (e.g., that there will be pain at the incision site for a few days). Post-procedure counseling should focus on those problems (e.g., fever, persistent abdominal pain, bleeding or pus at the incision site) that indicate the need for a quick return to the clinic. In addition, the client should be:

- Given instructions orally and in writing (if appropriate) about care of the surgical site and recovery from surgery,
- Told whom to contact if she develops any problems or has any concerns, and
- Given written information (if appropriate) telling her the date of her follow-up visit.

Follow-up counseling should reinforce information given before the procedure. Counselors need to listen attentively and be prepared to answer questions about any problems the client has experienced. At the follow-up visit, the woman should be asked if she has had any problems since the procedure. Answering these questions helps a client cope with any problems or side effects.

The key points and steps in providing counseling for minilaparotomy are summarized in the boxes on the following pages.

Steps in Counseling for Female Sterilization by Minilaparotomy in the Interval Period

1. Greet the client by introducing yourself and warmly welcoming her to the clinic.
2. Obtain basic information (name, address, age, etc.).
3. Use the Balanced Counseling Algorithm and Cue Cards.
4. Listen for the client's contraceptive needs.
5. Rule out pregnancy using the counseling card with six questions or a pregnancy checklist.
6. Ask her if she wants to space or limit births.
7. Help the client begin to choose an appropriate method.
8. If she chooses minilaparotomy:
 - Make sure there is no medical condition that would make the client a poor candidate for minilaparotomy under local anesthesia.
 - Clearly discuss the benefits of minilaparotomy, emphasizing the following points:
 - It is permanent (although there is a small chance of failure).
 - It is very effective.
 - It has no long-term side effects.
 - Explain the importance of the partner being involved in the decision process.
 - Explain that minilaparotomy does not provide protection against STIs, including HIV/AIDS. If the client is at risk for STIs, she should also use a barrier contraceptive.
 - Explain common side effects and be sure they are understood fully.
 - Describe the surgical procedure and what the woman should expect during and afterwards. Explain common complications of the procedure.
 - Assess the client's decision and feelings and decide if she is making an informed, well-considered decision.
 - Discuss scheduling the procedure and the possible need for contraception prior to minilaparotomy.
 - If the medical assessment has determined that there are no contraindications for minilaparotomy, ask her to sign the consent form.
 - Verify the client's identification and check that informed consent was obtained.
 - Review client assessment data to determine if the client is an appropriate candidate for minilaparotomy.
 - Ask the woman if she has any questions about the procedure.
 - Explain to the client what will happen next and what she should expect (e.g., how long the procedure will last, recovery period, etc.). Explain that she will feel a little pain during the procedure, and if she is troubled by this at any time, she should inform a member of the surgical team so that a team member can do something to relieve her discomfort.
 - After sedation has worn off and client is preparing for discharge, 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 that she can return to the same clinic at any time to receive advice and medical attention.
 - Have the client repeat all instructions back to you.
 - Answer any remaining client questions.
 - Complete the client record.
 - Inquire about problems and respond to concerns about side effects or any problems.

Steps in Counseling for Female Sterilization by Minilaparotomy in the Postpartum Period

1. During the focused antenatal care visit, greet the client by introducing yourself and warmly welcoming her to the clinic.
2. Review her basic information (name, address, age, etc.). Listen for the client's contraceptive needs.
3. Ask her if she wants to space or limit births.
4. Use the Balanced Counseling Algorithm and Cue Cards.
5. Help the client begin to choose an appropriate postpartum method.
6. If she chooses minilaparotomy tubal ligation:
 - Make sure there is no medical condition that would make the client a poor candidate for minilaparotomy under local anesthesia.
 - Clearly discuss the benefits of minilaparotomy, emphasizing the following points:
 - It is permanent (although there is a small chance of failure).
 - It is very effective.
 - It has no long-term side effects.
 - Explain the importance of the partner being involved in the decision process.
 - Explain that minilaparotomy does not provide protection against STIs, including HIV/AIDS. If the client is at risk for STIs, she should also use a barrier contraceptive.
 - Explain common side effects and be sure they are understood fully.
 - Describe the surgical procedure and what the woman should expect during and afterwards. Explain common complications of the procedure.
 - Assess the client's decision and feelings and decide if she is making an informed, well-considered decision.
 - Discuss when the procedure will be performed after delivery. Discuss also conditions at the time of delivery when the procedure may have to be delayed.
 - If the medical assessment has determined that there are no conditions affecting the provision of minilaparotomy, ask her to sign the consent form.
 - At the time of delivery, verify the client's identification and check that informed consent was obtained.
 - Verify that she is still intent on proceeding with the procedure.
 - Review client assessment data to determine if the client is an appropriate candidate for minilaparotomy.
 - Ask the woman if she has any questions about the procedure.
 - Explain to the client what will happen next and what she should expect (e.g., how long the procedure will last, recovery period, etc.). Explain that she will feel a little pain during the procedure, and if she is troubled by this at any time, she should inform a member of the surgical team so that a team member can do something to relieve her discomfort.
 - After sedation has worn off and client is preparing for discharge, 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 that she can return to the same clinic at any time to receive advice and medical attention.
 - Have the client repeat all instructions back to you.
 - Answer any remaining client questions.
 - Complete the client record.
 - Inquire about problems and respond to concerns about side effects or any problems.

To help the client better understand and remember the most important facts about PM, be sure to explain them to her clearly and simply, and repeat them several times. Important facts about minilaparotomy are summarized in **Table 2-1**.

Table 2-1. Important Facts about Minilaparotomy

Who Can Have a Minilaparotomy?	
Minilaparotomy is appropriate for women who: <ul style="list-style-type: none"> • 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 	Minilaparotomy is not appropriate for women who: <ul style="list-style-type: none"> • Are considering having more children • Are at high risk for surgical complications
Benefits and Limitations of Minilaparotomy	
Benefits: <ul style="list-style-type: none"> • Reliable, permanent method of protection • Not tied to sexual intercourse • Very effective • No daily action required • Easy to use and requires no further action other than follow-up visit; does not interfere with normal daily activities • Comfortable once the incision site has fully healed (about 1 week) • No long-term effects 	Limitations: <ul style="list-style-type: none"> • Minilaparotomy is a surgical procedure and therefore may be associated with infection, bleeding, or bruising. • The woman cannot discontinue the method (counseling should, however, prepare her for this). • Minilaparotomy does not protect the woman from STIs, including HIV/AIDS.

Counseling for Postpartum Voluntary Sterilization

Counseling pregnant women requires special care. Although postpartum sterilization is easier for surgeons to perform than interval procedures, and while the immediate postpartum period may be the most convenient time for women to have the procedure performed, it is a **poor time** for clients to decide whether or not they want to end their fertility.

If the woman states that she wants no more children, the service provider’s task is then to help the client select the best contraceptive option available to her. If she reached this decision 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 says that she has reached the decision jointly with her partner. The counselor should make sure, however, that she is not likely to regret the decision later based on the gender, poor health, or death of the newborn or other children.

On the other hand, if the woman’s decision not to have any more children was made very shortly before or immediately after delivery, pain, stress, sedatives, or other factors associated with delivery, the decision may be one she otherwise might not have made. In that case, she may not be a good candidate for immediate postpartum sterilization. Instead, it may be best for the client to use a temporary method during the postpartum period. This allows the client or couple the opportunity to carefully consider all contraceptive options and whether or not to end fertility.

In some programs, a woman may give consent months before the procedure is to take place. If she later opts not to have the procedure, there should not be any consequences for her as a result of her decision, and it should not affect the other care health services she receives.

Postabortion ML/LA

Because many abortions are related to unplanned pregnancy, postabortion family planning counseling is important, especially because of the possibility of return to fertility within 7 days. Postabortion clients should receive counseling on options for contraception from short-acting to long-acting to permanent methods. If the client's family size is complete and she intends to limit future conception, she should be counseled on tubal ligation for herself or vasectomy for her partner. Her eligibility for ML/LA prior to discharge will depend on her condition. When there are conditions necessitating delaying the procedure, for example, genital trauma or sepsis, provide an alternative method of contraception and schedule her for follow-up.

Rumors and Facts

Correcting false rumors and misinformation is an important job of health care workers. When talking to the client about rumors and misinformation, do not just say that what she has heard is not true. Always politely explain or show her why it is not true, and **explain what is true**. Be careful not to embarrass the client because she has a mistaken idea or belief.

The following are some of the more common mistaken ideas:

- **False Rumor:** 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 partner will not have to worry about pregnancy.
- **False Rumor:** 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 will remain intact, she will continue to produce eggs and menstruate, and her menstrual bleeding patterns will not change.
- **False Rumor:** 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 Rumor:** A woman becomes promiscuous after having a minilaparotomy.
Response: Explain that there is no physical connection between minilaparotomy and promiscuity. A responsible woman will exercise caution in her sexual activities regardless of whether she has had a minilaparotomy.

Tips on Good Counseling

- Listen attentively.
- Answer questions objectively.
- Reinforce important information on side effects, warning signs, etc.
- Let the client make her own decision.

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

Frequently Asked Questions that the provider may need to answer during pre-procedure counseling are presented below.

Counseling and Client Satisfaction

Service providers must put the best interests of the client before any other concerns. It is both ethically and programmatically important that providers pay close attention to the needs of clients. Over the long term, programs are more likely to attract and keep clients when they offer services that meet clients' needs (Gallen et al. 1987).

Answers to Frequently Asked Questions about ML/LA

Answering questions about voluntary sterilization by minilaparotomy, as well as telling clients what to do if certain problems occur, promotes the client's satisfaction with her decision to have this procedure. In particular, providers should know the answers to these common questions:

How effective is sterilization by tubal occlusion?

Female VS is one of the most effective contraceptive methods available, comparable to vasectomy and combined injectable contraceptives. Although failure rates for minilaparotomy are very low, pregnancies can occur. The risk is greater in younger women (especially under age 30) because women in that age group are more fertile in general. The risk of pregnancy continues until the woman reaches menopause, regardless of how many years have passed since she had the procedure.

How quickly does tubal occlusion become effective? How soon after the procedure can a couple resume sexual relations?

Tubal occlusion is effective immediately. The client should not have sexual intercourse for 1 week after the procedure, however, and should stop if it is uncomfortable. If the client continues to have discomfort, she should return to the clinic.

How long will this procedure be effective?

Tubal occlusion is a permanent method of contraception. After the procedure, the client does not need to take any further action to assure the continued effectiveness of VS.

Will tubal occlusion protect a woman from AIDS?

No. This method does not protect against STIs (e.g., hepatitis B virus [HBV], HIV/AIDS). If either the client or her partner has other sexual partners, they should use a barrier method (condom) to minimize the risk of getting an STI.

How widely has this procedure been used and tested?

Minilaparotomy under local anesthesia has been widely used around the world, beginning in the 1960s. Numerous research studies have shown it to be one of the safest and most effective types of contraception available.

Can a woman breastfeed after the procedure?

Yes. A woman's ability to breastfeed is not affected by this procedure.

What are the most common side effects?

Common side effects are uterine cramps, incision discomfort, abdominal discomfort, and light vaginal bleeding. Side effect will usually subside within a few days after surgery.

When should the client return to the clinic?

The client should return to the clinic within 7 days of surgery so that the sutures (if non-absorbable sutures were used) can be removed at the optimal time and staff can evaluate the healing process.

She should visit the clinic again after either 1 month or the next menstrual period, whichever is earlier, so that staff can again assess her and look for any medical problems.

Does tubal occlusion affect menstruation?

The procedure does not alter a woman's menstrual cycle. She will have regular periods just as before the procedure. Minilaparotomy is not a hysterectomy. Her uterus and ovaries remain intact and she will continue to produce eggs and menstruate. Some studies show that a small minority of women experience some change in duration or flow of their periods within a few years after VS, especially women who had the procedure before the age of 30. Such changes may be caused, however, not by VS, but by switching from another contraceptive method to VS, by the normal aging process, or by other gynecological abnormalities.

Should a woman be concerned if her menstrual period is delayed?

Yes, because this could be an indication 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. If the client has a delayed menstrual period, or other signs of pregnancy, she should see her healthcare provider.

What are the warning signs of problems?

The client should return to the clinic or contact the clinic or doctor immediately if she develops any of the following:

- Fever (greater than 38 degrees C or 100.4 degrees F)
- Dizziness with fainting
- Persistent or increasing abdominal pain
- Bleeding or fluid coming from the incision
- Signs or symptoms of pregnancy

Can the procedure be reversed, and fertility restored?

Voluntary sterilization procedures should be considered permanent. In some countries, reversal of tubal ligation is available at limited clinical sites where microsurgical facilities are present, but:

- Reversal involves complicated and difficult surgery, requiring great skill.
- Some individuals who request reversal may be ineligible because of age, fertility impairments, partner's infertility, 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 client is usually responsible for the expense.

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Three. Informed Choice

Background

Informed choice is a fundamental principle of quality service, recognized as a human right by the international community (WHO 2014), and is the foundation of all sterilization programs. This section of the manual describes the process for informed choice in a service delivery setting and defines the basic terms of informed choice, informed consent, and counseling.

Informed choice in health care is a client's well-considered, voluntary decision based on method options, information, and understanding. Informed choice from the client's perspective is an interplay of several factors to be considered in relation to making a decision. Examples of these are:

- His or her own personal circumstances, beliefs, and preferences
- The sociocultural and health and human rights context and community factors
- The availability and attributes of the different methods or the service modalities
- Service delivery factors that affect access to options and the individual's ability to make free and voluntary decisions (EngenderHealth 2002)

The key elements in informed choice are:

- It is voluntary, meaning that clients are not limited by coercion or barriers to access.
- Clients should be given sufficient accurate information about different contraceptive options, and about their relative effectiveness in preventing both pregnancy and STIs, their advantages and disadvantages, their contraindications, and their complications and side effects.
- Lastly, there should be available a wide range of options.

Informed choice requires full information about the risks and benefits of the methods available.

Informed choice involves effective access to information on reproductive choices and to the necessary counseling, services, and supplies that help individuals choose and use appropriate family planning methods.

Informed choice helps couples make various reproductive choices, including the possibility of choosing pregnancy.

Informed choice refers to making a decision regarding a particular method or procedure without coercion, undue influence, or fraud.

Five Major Components of Informed Choice

- Provision of information to couples and individuals on reproductive choices, including counseling concerning pregnancy, breastfeeding, and infertility.
- Provision of counseling to ensure comprehension of information and to assist with decision-making.
- Provision of appropriate information on a range of family planning methods, including their advantages, disadvantages, and how to access services and supplies.
- Provision of comprehensive information on the correct usage of the client's chosen method.

- Efforts to ensure that a range of methods is available to the user either through the service provider or through referral to another agency.

Informed choice increases client satisfaction in using a method, decreasing reservations or fears of possible side effects.

Counseling assures that each client is guided to make a well-informed and voluntary decision that is best suited to her (or his) individual needs. The best method for a client is what she chooses herself.

Voluntarism

Voluntarism is decision-making on the choice of a family planning method based on free choice and not obtained by any inducements or forms of coercion. The following explains the principle of informed choice and voluntary decision-making for better understanding and compliance.

Informed Consent

Informed consent is a client's agreement to receive the treatment or surgery as a result of having informed choice (EngenderHealth 2002). Informed consent for PM is important because it ensures that clients receive the facts they need to make informed, well-considered decisions about their fertility. Furthermore, the process lessens the possibility of regret after the sterilization procedure, which is more likely to occur when clients do not have complete information about the procedure or when they do not undergo the procedure voluntarily. In addition, signing the informed consent form in the presence of a witness demonstrates to clients that they are making a very important decision to have a procedure which, in most cases, cannot be reversed, although they can change their **decision** at any time before the procedure is done.

Informed consent is the written, voluntary decision of a client to accept a particular family planning method or to undergo a sterilization procedure. It is important that the service provider asks the client to sign the appropriate written informed consent form.

Importance of Informed Consent

The important points about informed consent among clients who have decided to undergo PM are that it:

- Ensures that the clients receive the information they need to make informed, well-considered decisions regarding fertility.
- Ensures that the clients make the decision of their own free will.
- Helps to assure satisfied and well-informed clients.
- Reduces the incidence of regrets, thus enhancing the program's acceptability and prestige.
- Diminishes regret after the surgical procedure.
- Impresses upon clients that they are making an important and irrevocable decision.
- Serves as evidence of the clients' requests and can protect against charges of induced or uninformed sterilization.

Informed Consent for Minilaparotomy: What It Is

Informed consent is a client's agreement to undergo ML/LA voluntarily, with full 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 ML/LA, a staff member must tell her, and she must understand, the following facts:

- Temporary methods of contraception are available to her and her partner.
- ML/LA is a surgical procedure.
- The effect of this procedure is permanent.
- If successful, the operation will prevent her from having any more children.
- Certain risks and benefits are associated with the procedure.
- She can decide against the procedure without giving up the right to other services.

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, without being fully aware of other contraceptive options or without fully understanding the nature of the procedure and its effects, has not given informed consent. 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 (WHO 1994).

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

- Provide relevant information the client needs to make a fully informed decision about fertility, including information about ML/LA as well as other sterilization techniques (e.g., no-scalpel vasectomy). They inform the client about other contraceptive methods available, and their advantages and side effects in comparison to minilaparotomy.
- Determine whether the client understands the consequences of, and is comfortable with, her decision.
- Determine whether the client's choice is voluntary. Counseling is a process and an informed decision is the intended outcome of counseling. Informed consent for ML/LA is one of several informed decisions the client may make.

Documenting informed consent is one component of the counseling process designed to safeguard the client's right to make a voluntary, informed choice. It also satisfies legal requirements, safeguarding service providers against possible lawsuits.

When to Obtain Informed Consent

Documentation takes place after counseling, once the client has made a firm decision to undergo surgery. The counselor should not introduce the consent form until she or he feels that the client clearly understands the information presented during counseling and is comfortable with her decision to have the procedure. Consent

for ML/LA should not be obtained when physical or emotional factors may compromise a client's ability to make a carefully considered decision about contraception.

A woman should sign the consent form before she is scheduled to have the procedure. She should be told that signing the consent form does not mean that she **must** go through with the procedure. She can change her mind at any point before surgery begins without giving up access to other services.

Informed Consent for Postpartum Minilaparotomy

Counseling pregnant women requires special care, because women who undergo sterilization during or soon after delivery are more likely to experience regret (Chi and Jones 1994).

It is often not possible to counsel clients and obtain 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 labor; or experiencing stress before, during, or after a pregnancy-related event or procedure.

It is good clinical practice for the surgical team always to verify consent for the procedure. This is true regardless of when the consent was provided.

Documentation of Informed Consent

The client's signature on an informed consent form is the legal authorization for the sterilization to be performed.

The client must always sign or mark the informed consent form. (See **Sample 3-1** at the end of this chapter for a sample consent form.) Since voluntarism is ultimately the responsibility of the surgeon (see below), the surgeon or her/his authorized representative may be the individual with primary responsibility for counseling the client.

Clients who cannot read should mark the informed consent form with a thumb print. A witness chosen by the client also must 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.

Spousal/Partner Consent

There is **no requirement** for spousal or partner consent but because sterilization is a permanent procedure, a joint decision usually will mean more satisfied clients and fewer complaints to health workers following the surgery.

It may not be possible, however, to obtain written partner consent in certain situations. An example of such a situation is a woman who has a serious medical problem (e.g., symptomatic heart disease). Pregnancy would be extremely dangerous for her, but the partner is not available to sign the consent form.

Note: If the partner does not sign the consent form, it is advisable to document the client's explanation of why spousal consent was not available. But this should not stop the woman from getting the surgery. If the woman's signature is on the Informed Consent Form, surgery can be performed.

Documenting Denial of Minilaparotomy

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

Responsibility of the Surgeon

By the time the client meets the doctor (if she was counseled by a non-medical counselor) who will perform the surgery, she should have:

- Been counseled about her contraceptive options,
- Made an informed decision to undergo ML/LA, and
- Signed a consent form.

It is the responsibility of the surgeon 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 surgeon must ensure that the client has made a free, informed, and well-considered decision and has not changed her mind or had second thoughts since making that decision. This will minimize the possibility of regret in the future.

Sample 3-1. Informed Consent Form¹

I, _____ (client's name), the undersigned, request that sterilization via _____ (specify the procedure) be performed on my person.

I make this request of my own free will, without having been forced or given any special inducement. I understand the following:

1. There are temporary methods of contraception available to me and my partner.
2. The procedure to be performed on me is a surgical procedure, the details of which have been explained to me.
3. This surgical procedure involves risks, discomfort, and complications in addition to benefits, both of which have been explained to me.
4. If the procedure is successful, I will be unable to have any more children.
5. The procedure is less than 100% effective.
6. The effect of the procedure is permanent.
7. I can decide against the procedure at any time before the operation is performed (and no medical, health, or other benefits or services will be withheld from me as a result).

Signature or mark of client

Date

Signature of attending doctor/counselor or designated assistant

Date

If the client cannot read, a witness of the client's choosing, of the same sex and speaking the same language, must sign the following declaration:

I, the undersigned, attest to the fact that the client has affixed his/her thumb print or mark in my presence.

Signature or mark of witness/guardian

Date

¹ Source: Nepal Ministry of Health. 1995. *National Medical Standard for Reproductive Health. Volume I: Contraceptive Services*. Kathmandu, Nepal: Ministry of Health, Family Health Division.

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Four. Eligibility, Precautions, and Client Assessment

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 the client from contraceptive complications, lists of contraindications had 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.

In addition, 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 may not be appropriate when applied to a setting that has different reproductive health characteristics. Finally, in many countries, new information is slow in arriving and the **contraindication** list remains the standard for many years, despite being outdated and inaccurate.

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

World Health Organization Classification System

There is no medical condition that would make a client ineligible for ML/LA. There are, however, conditions or circumstances that require precaution, either for the timing of the procedure or selection of the facility where the procedure should be performed. At the World Health Organization (WHO) scientific working group meeting in 1995, a system specific to PM procedures was developed for assessing **how**, **when**, and **where** they should be performed. While some conditions (e.g., severe hemorrhage following delivery) may necessitate delaying the PM procedure, others listed in the WHO guidelines 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 PM procedure should not be performed until the condition is evaluated and/or corrected. In addition, we have listed those conditions that preclude performing the procedure in the ambulatory setting. For these conditions, referral to an appropriate facility where full backup and/or a more experienced physician is available may be necessary. **Table 4-1** summarizes the categories for female sterilization in the WHO Medical Eligibility Criteria (WHO 2015).

Table 4-1. Categories for Female Sterilization

Accept (A)	There is no medical reason to deny the method to a person with this condition or in this circumstance.
Caution (C)	The method is normally provided in a routine setting, but with extra preparations and precautions.
Delay (D)	Use of this method should be delayed until the condition is evaluated and/or corrected. Alternative, temporary methods of contraception should be provided.
Special (S)	The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anesthesia, and other backup medical support. The capacity to decide on the most appropriate procedure and anesthesia support also is needed. Alternative, temporary methods of contraception should be provided in referral is required or there is otherwise any delay.

Source: World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for Health Project. 2011. *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva, Switzerland: CCP and WHO.

Because PM procedures are permanent, voluntary informed choice **must** be ensured. This chapter includes some circumstances that indicate the need for further counseling. Also, national law must be considered in the decision-making process. Finally, if the PM procedure must be delayed (either to wait for the condition to resolve or for referral), a temporary method of contraception should be provided. Furthermore, because ML/LA is elective, alternative methods of contraception may be more appropriate for a woman if safety with regard to facilities, medications, or surgical competence is questionable.

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 she values her future fertility as well as the degree to which she is willing to risk a potential health problem.

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 range of effective contraceptive methods. Thus, in order to maximize clients’ access to quality family planning services, protocols that list the indications and precautions for ML/LA should be flexible. They should be designed to help the service provider consider not only a woman’s individual history and living conditions but also the local maternal health situation.

Indications for Use

Minilaparotomy is an appropriate method for a woman:

Condition	Rationale
If she 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 sterilization should be certain they do not wish to have any more children.
If her age or health problems might cause high-risk pregnancy	The risk of dying from sterilization is less than that for pregnancy complicated by age or health problems.

Condition	Rationale
If she 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.
If she prefers a method that does not require taking contraceptive action daily or before sexual intercourse	After the procedure, only a follow-up visit is required. Contraceptive effect is immediate and permanent.

Conditions Requiring Precautions for Use

The precautions listed in this section are based on the most recent epidemiologic and clinical data regarding medical criteria for minilaparotomy (WHO 2015). For women with any of the following conditions, health care workers need to assess the appropriateness of sterilization for **each client**, not only in terms of her special needs but also in relation to the health care climate in which she lives.

Conditions Requiring Precautions		
Condition	Precaution	Rationale
Pregnancy	If the client is pregnant, delay until she has delivered and counsel regarding options in the immediate postpartum period, including postpartum tubal ligation.	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 <i>Up to 7 days</i>	If after 7 days, 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 pre-pregnancy size.
<i>Pre-eclampsia (severe)</i>	Delay procedure until recovered (> 6 weeks).	Tubal ligation is an elective procedure and can be delayed until pre-eclampsia is fully resolved.
<i>Prolonged rupture of membranes (> 24 hours)</i>	Delay procedure until > 6 weeks.	Increased risk of serious postoperative infection.
<i>Intrapartum or postpartum sepsis</i>	Delay procedure until infection is treated (> 6 weeks).	Increased risk of serious postoperative infection.
<i>Severe hemorrhage (> 500 ml)</i>	Delay procedure until anemia improved (> 6 weeks).	Client may have been anemic before delivery and may be unable to tolerate risk of further blood loss.
<i>Trauma to genital tract (cervical or vaginal tears)</i>	Delay procedure until recovered (> 6 weeks).	Because client may have been anemic before delivery, she may not be able to tolerate the risk of further blood loss.
<i>Uterine rupture or perforation</i>	Delay procedure until recovered (> 6 weeks).	If exploratory surgery or laparoscopy is done, repair of the problem and tubal sterilization can be performed concurrently if there is no additional risk involved.

Conditions Requiring Precautions		
Condition	Precaution	Rationale
Unexplained vaginal bleeding	Delay procedure only if serious problem is suspected.	Evaluate condition before performing procedure.
Acute pelvic infection (PID [pelvic inflammatory disease], including purulent cervicitis)	Delay procedure until resolved.	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 resolved.	Although tubal occlusion is a minor surgical procedure, it should not be performed when the client is sick.
Anemia (Hb < 7 g/dl)	Delay procedure until anemia 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)	Delay procedure.	In general, treatment for these cancers results in sterility.
Deep venous thrombosis/pulmonary embolism (current)	Delay procedure until fully recovered.	Increased risk of recurrence or embolism.
Postabortion Sepsis or fever (> 38°C)	Delay procedure until resolved.	Determine cause and treat before performing the procedure.
Severe hemorrhage (> 500 ml)	Delay procedure until anemia improved.	Client may have been anemic before procedure and may not be able to tolerate further blood loss.
Trauma to genital tract (cervical or vaginal)	Delay procedure until condition improved.	Because client may have been anemic before delivery, she may not be able to tolerate further blood loss.
Uterine perforation	Delay procedure until recovered.	May have significant blood loss or intra-abdominal trauma. If emergency surgery (laparotomy) is required, tubal occlusion may be performed only if there is no additional risk.
Acute hematometra (postabortion syndrome)	Delay procedure until recovered.	Evacuate uterus (vacuum aspiration) and assess anemia before performing tubal occlusion.

Women who have any of the following conditions may require additional counseling or special surgical and follow-up management:

Conditions Requiring Action		
Condition	Action	Rationale
<p>Client has:</p> <ul style="list-style-type: none"> • Diabetes • Symptomatic heart disease • High BP (> 160/100) or with vascular disease • Coagulation (clotting) disorders (rare) • Is overweight (over 80 kg/176 lb if height/weight ratio is not normal) • Abdominal or umbilical hernia • Multiple lower abdominal incisions/scars 	Should be performed only by experienced clinician in a facility with full backup.	<p>Clients with significant medical problems may need special surgical and follow-up management (e.g., general anesthesia) for voluntary sterilization. Only those clients who meet the acceptable criteria should have their surgery in ambulatory facilities.</p> <p>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:</p> <ul style="list-style-type: none"> • More sedation/analgesia for client comfort, • Larger incision, • Longer operating time, and • Prolonged recovery. <p>As a consequence, there is an increased risk of complications, especially infections, in this high-risk group.</p>
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.
Disagrees with or does not want to sign informed consent form	Determine if concerns represent misunderstanding about method (e.g., rumor, myth). If so, provide additional counseling. If client still does not wish to sign, help her choose another method.	Clients often have misconceptions about a procedure, even after counseling. Informed consent must be obtained before performing surgical procedures, especially voluntary sterilization.
Pressure from someone else	Further assess concerns and, if appropriate, help client choose another method.	Regret about voluntary sterilization 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 is best made with both partners in agreement.

Conditions Requiring Action		
Condition	Action	Rationale
Is single	Further assess situation and, if appropriate, help client choose another method.	Tubal occlusion is permanent. Regret and request for reversal are higher in single women, especially young, single women, than in older married women.
Has no children	Further assess situation and, if appropriate, help client choose another method.	Tubal occlusion is permanent. Regret and request for reversal are higher in nulliparous women, especially young, nulliparous women, than in older multiparous women.
Conditions Requiring Action (Postpartum)		
Condition	Action	Rationale
Umbilical hernia	Delay until interval procedure can be performed.	Incision is usually made in area of hernia. If possible, hernia repair should be performed concurrently with tubal sterilization.
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 septicemia.
Severe antepartum or postpartum hemorrhage	Delay until client's situation has stabilized or perform the procedure in the interval period.	Low hemoglobin (< 7 g/dl) may increase risk.

Client Assessment

Female sterilization by ML/LA is intended for women who voluntarily opt for it, after proper counseling and informed consent, 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. Although no medical condition or circumstance should prevent a woman from obtaining PM, in some women the procedure should be delayed until certain conditions have been treated and resolved, while in others, special arrangements are necessary for the procedure to be performed safely. Therefore, health care workers need to know how to assess potential ML/LA clients who:

- May need additional evaluation and management before undergoing the procedure;
- May require the procedure to be performed with caution, such as those with history of pelvic inflammatory disease since the previous pregnancy, previous pelvic surgery, or uterine fibroids; and
- Have medical conditions that require action, including special surgical and follow-up management, or additional counseling, prior to undergoing the procedure. The final decision to have the procedure should necessarily be influenced by the fact that the woman has the condition, because almost all women can undergo ML/LA after appropriate management of acute or chronic disease.

Selecting clients who are acceptable (low-risk) for having ML/LA performed in an ambulatory 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 4-2**.

Table 4-2. Sample Guidelines for Screening Clients for Minilaparotomy in Ambulatory Health Care Facilities

Category	Selection Criteria	
	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 mmHg	≥ 160/100 mmHg
Weight	Maximum weight: 80 kg (176 lb) Minimum weight: 35 kg (77 lb)	> 80 kg < 35 kg
Previous abdominal/pelvic surgery	Cesarean sections only if normal pelvic examination indicating no adhesions (uterus mobile)	Other abdominal surgery, fixed scar, or abnormal pelvic examination
Previous pelvic disease, ectopic pregnancy, or ruptured appendix	No history and normal abdominal and pelvic examination	Abnormal abdominal/pelvic examination
PID	No acute PID and normal abdominal and pelvic examination	Acute PID, abnormal abdominal/pelvic examination
Anemia ^a	Hg > 7g/dl	Hg < 7g/dl

^a WHO Eligibility Criteria recommend caution in performing voluntary sterilization if hemoglobin is < 7g/dl. (The procedure is normally conducted in a routine setting, but with extra preparation and precautions.)

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 anesthesia and other special requirements are available, consider an alternative, safer method of contraception.

Female Sterilization for Women Living with HIV and AIDS

- Women with HIV/AIDS (with or without antiretroviral therapy) should not be denied female sterilization. However, special arrangements are necessary for those who have AIDS or are HIV-positive.
- Tubal sterilization should be provided to all women, including those with HIV, without coercion or pressure.
- Women with HIV or at risk of acquiring HIV infection should use condoms (male or female) in addition to female sterilization to protect themselves and their partners from HIV and other STIs.

Basic Steps in Client Assessment

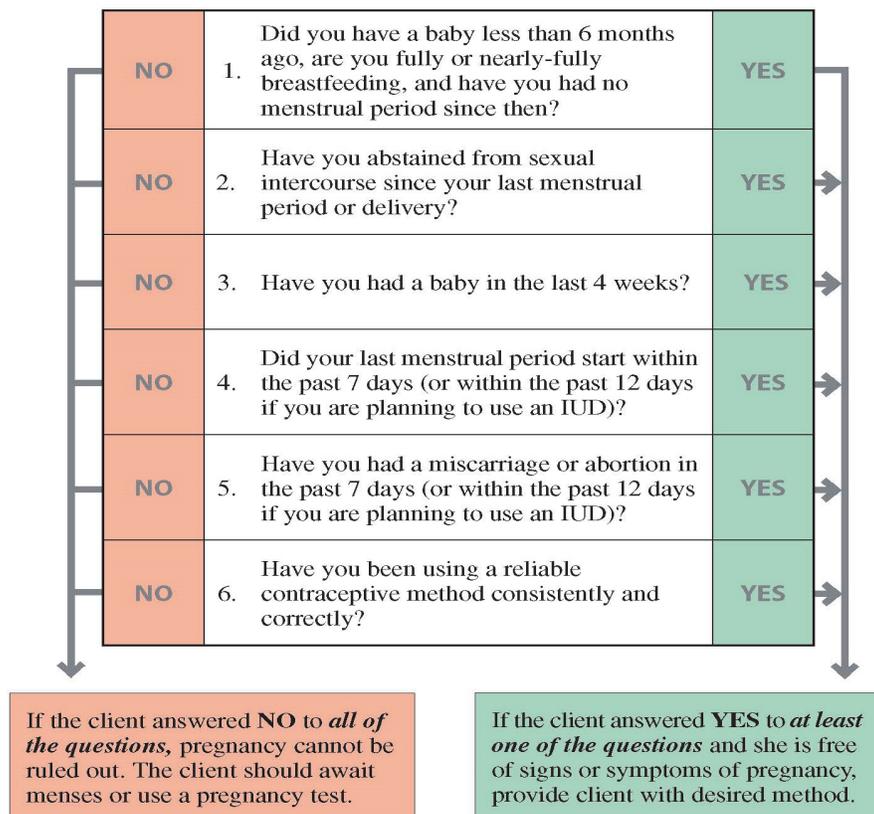
In assessing potential ML/LA clients, clinic staff should:

- Ask clients about their reproductive goals.
- Check clients for any condition that may be a precaution for ML/LA.
- Evaluate clients by medical history and examination.
- Make sure that potential clients have been counseled about ML/LA; its benefits, limitations, and side effects; as well as about other contraceptives, before making the decision to have the procedure.

Absence of a history of any of the conditions that may delay or contraindicate the procedure is sufficient to permit provision of ML/LA, **assuming there is no suspicion of pregnancy**. When conducting the client assessment, service providers may find it helpful to use a checklist so that no important information is left out (see **Figure 4-1**). A pregnancy checklist in particular is a useful tool for ruling out pregnancy.

Figure 4-1. How to Be Reasonably Sure a Client Is Not Pregnant

Ask the client questions 1–6. As soon as the client answers **YES** to *any question*, stop, and follow the instructions.



Source: Family Health International. 2008. How to Be Reasonably Sure a Client is Not Pregnant. <https://www.k4health.org/toolkits/implants/how-be-reasonably-sure-client-not-pregnant>.

If the provider is uncertain about whether conception has occurred, he/she may want to order a **pregnancy test**. Pregnancy testing is unnecessary 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 client is overweight, making sizing of the uterus difficult). In these situations, a sensitive urine pregnancy test may be helpful, if readily available and affordable. If **pregnancy testing is not available**, counsel the client to use a temporary contraceptive method or abstain from intercourse until her menses occurs or the possibility of pregnancy is confirmed.

Medical Assessment

Medical assessment of potential ML/LA 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 health care provider must do a rigorous preoperative assessment. At these sites, it is essential to identify clients who have conditions that may increase the risks associated with surgery, as described above.

Paramedical personnel who have been trained to recognize abnormalities or conditions requiring precautions can take a medical history or conduct preliminary screening. This screening can take place in the client's home or a local health center. Nevertheless, a clinician must re-evaluate the client before performing tubal sterilization. It is the surgeon's responsibility to decide whether or not the client is eligible for voluntary sterilization.

Demographic Information

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

Medical History

- Specific information that 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, anemia, bleeding disorders (hemophilia), active tuberculosis, STIs, and psychiatric conditions
- Previous abdominal or pelvic surgery
- Allergies (especially to local anesthetics and pain medications)
- Current medications (e.g., those taken chronically for blood pressure control or diabetes, etc.)
- Substance abuse
- High blood pressure
- Convulsions
- Vaginal discharge
- Urinary tract infections

Physical Examination

General examination: Check for:

- General condition and nutritional status
- Weight
- Pulse rate
- Blood pressure
- Pallor of skin or eyes (conjunctiva) (anemia)
- Heart murmurs (auscultation of heart) and lungs

If **severe** anemia (Hgb < 7 g/dl) is suspected and hemoglobin (Hb) or hematocrit (Hct) is not available, check for:

- Rapid pulse (> 100)
- Weight
- Pulse and blood pressure
- Auscultation of heart and lungs

Note: Severe anemia with hemoglobin less than 7 g/dl is a condition for delaying the tubal ligation until the condition is resolved. The provider should counsel the client about using another method while waiting for the PM procedure.

Abdominal examination: Check for:

- Suprapubic or pelvic tenderness
- Masses, organ enlargement, or gross abnormalities
- Surgical scars

Pelvic examination (make sure the client has voided to empty urinary bladder before performing the exam):

- 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 laboratory tests are available, obtain specimens of vaginal and cervical discharge for diagnostic studies
- Bimanual:
 - Check for pregnancy signs
 - 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 mass or tenderness

- Check for uterine abnormalities
- Rectovaginal (Perform only if findings on bimanual examination are suspicious; for example, if mass in cul de sac is suspected.)

Amenorrhea in the First 12 Months Postpartum

The lactational amenorrhea method (LAM) is a highly effective method of family planning. It has a failure rate of less than 2% during the first 6 months postpartum (Labbok et al. 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 amenorrheic.

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;
- Has still not had menstrual bleeding (amenorrheic); and
- Has no clinical signs or symptoms of pregnancy (Labbok et al. 1994; TGWG 1994); and
- Used an effective contraceptive method, including condoms.

Laboratory Tests

Most laboratory tests are not necessary as long as the staff carefully assess the client (see **Table 4-3**). For clients having ML/LA, tests for diabetes, anemia, and renal disease should not be performed unless their medical history or physical examination revealed signs of these diseases. Other appropriate tests (e.g., a pregnancy test) should be conducted as necessary. In postpartum cases, the clients should already have undergone routine laboratory tests as part of their care during pregnancy, labor, and delivery. If postpartum clients have excessive bleeding during or immediately after delivery, the staff should reassess their hemoglobin levels before judging them suitable for minilaparotomy.

Table 4-3. Applicability of Various Procedures or Tests for Contraceptives Methods

Specific Situation	COC	CIC	POP	POI	Implants	IUD	Condom	ML/LA	Vasectomy
Breast exam by provider	C	C	C	C	C	C	C	C	NA
Pelvic/genital exam	C	C	C	C	C	A	C	A	A
Cervical cancer screening	C	C	C	C	C	C	C	C	NA
Routine lab tests	C	C	C	C	C	C	C	C	C
Hemoglobin test	C	C	C	C	C	B	C	B	C
STI risk assessment: Medical history and physical exam	C	C	C	C	C	A*	C	C	C
STI/HIV screening: Lab tests	C	C	C	C	C	B*	C	C	C
BP screening	‡	‡	‡	‡	‡	C	C	A	C§

Adapted from: World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for Health Project. 2011. *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva, Switzerland: CCP and WHO.

COC = combined oral contraceptives; CIC = combined injective contraceptives; POP = progestogen-only pills; POI = progestogen-only injectables

Class A = Essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B = Contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context. The risk of not performing an examination or test should be balanced against the benefits of making the contraceptive methods available.

Class C = Does not contribute substantially to safe and effective use of the contraceptive method.

* If a woman has a very high individual likelihood of exposure to gonorrhea or chlamydia, she generally should not have an IUD inserted unless other methods are not available or not acceptable. If she has current purulent cervicitis, gonorrhea, or chlamydia, she should not have an IUD inserted until these conditions are resolved and she is otherwise medically eligible.

† Women at high risk of HIV infection or AIDS should not use spermicides. Using diaphragms and cervical caps with spermicide is not usually recommended for such women unless other more appropriate methods are not available or acceptable.

‡ Desirable, but in settings where the risks of pregnancy are high, and hormonal methods are among the few methods widely available, women should not be denied use of hormonal methods solely because their blood pressure cannot be measured.

§ For procedures performed using only local anesthesia.

NA=Not applicable

When Risk Factors Are Found

When the medical examination reveals conditions that are likely to increase complications resulting from the procedure, the client should be informed about these risks and how they weigh against the benefits of undergoing the operation. The doctor performing the examination should consult with a senior doctor before making the decision to perform the procedure. The doctor may also want to consider sending the client to a higher-level facility. High-risk clients should receive services at the highest level of medical care available.

If the client is found to be unsuitable for surgery for medical reasons, the procedure should be postponed and the client referred for a complete evaluation and management of the condition revealed in the examination. The staff should help her to choose another method of contraception. In cases where the type of tubal occlusion service available at the clinic is not appropriate for the client, she should be referred to another facility that offers the appropriate services.

Final Medical Evaluation

The pelvic examination performed as part of the preoperative assessment does not eliminate the need for another pelvic examination on the day of surgery. After reviewing the client's history and physical findings, the surgeon performing the operation should make a final medical assessment immediately before performing the procedure. This final evaluation should take place at the facility where the procedure is to be performed. At this time, the surgeon performing the operation will look for gynecologic disorders, including infection, and will determine the size, shape, position, flexion, mobility, and condition of the uterus.

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Five. Infection Prevention and Control¹

Background

The two primary objectives of infection prevention and control (IPC) in family planning facilities are:

- To prevent infections when providing surgical contraceptive methods such as sterilization by ML/LA
- To minimize the risk of transmitting serious infections such as hepatitis B² and HIV not only to clients but also to service providers and staff, including cleaning and housekeeping personnel

Thousands of ML/LA 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. To prevent problems caused by infection, good surgical technique, including aseptic technique, must be followed to prevent infections.

To reduce the risk of infection, contaminated waste must be properly disposed of and instruments and other items should be decontaminated, thoroughly cleaned, and sterilized by autoclaving (high-pressure steam) or heat. If sterilization is not possible, high-level disinfection (HLD) (by boiling or steaming) is the only acceptable alternative.

The IPC practices described in this chapter are intended for use in all types of medical and health care facilities from large urban hospitals to small rural clinics, and in mobile services as well. They are designed to minimize costs and the need for expensive and often fragile equipment while at the same time assuring a high degree of safety.

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.

The terms **asepsis**, **antisepsis**, **decontamination**, **cleaning**, **disinfection**, and **sterilization** often are confusing. For the purposes of this manual, 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 using a chemical agent (antiseptic).

¹ Adapted from: Tietjen L, Bossemeyer D, McIntosh N. 2003. *Infection Prevention Guidelines for Healthcare Facilities with Limited Resources*. Baltimore, MD: Jhpiego.

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.

- **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.

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;
- Wearing appropriate attire (e.g., goggles, mask, or apron) when contact with blood or body fluids is possible;
- Using antiseptic solutions to prepare the skin, cervix, and vagina prior to surgery;
- Using safe work practices such as **not** recapping or bending needles, safely handling surgical instruments, and properly disposing of waste materials;
- Processing surgical instruments and other items after use by decontamination, cleaning, and either sterilization or HLD; and
- Using drapes during surgical procedures.

Handwashing, Surgical Scrub, and Gloves

Thorough handwashing and use of protective gloves are key components in minimizing the spread of disease and maintaining an infection-free environment (Garner and Favero 1986). In addition, understanding when sterile 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 (see **Figure 5-1**). 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 continual supply of clean water, either from a tap or bucket, and single-use towels. Do not use shared towels to dry hands.

Experience has shown that the most effective way to increase handwashing is to have **doctors or other respected individuals** (role models) consistently wash their hands and encourage others to do the same.

When to Wash Hands

Handwashing is indicated **before**:

- Examining (direct contact with) a client, and
- Putting on **sterile** 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.

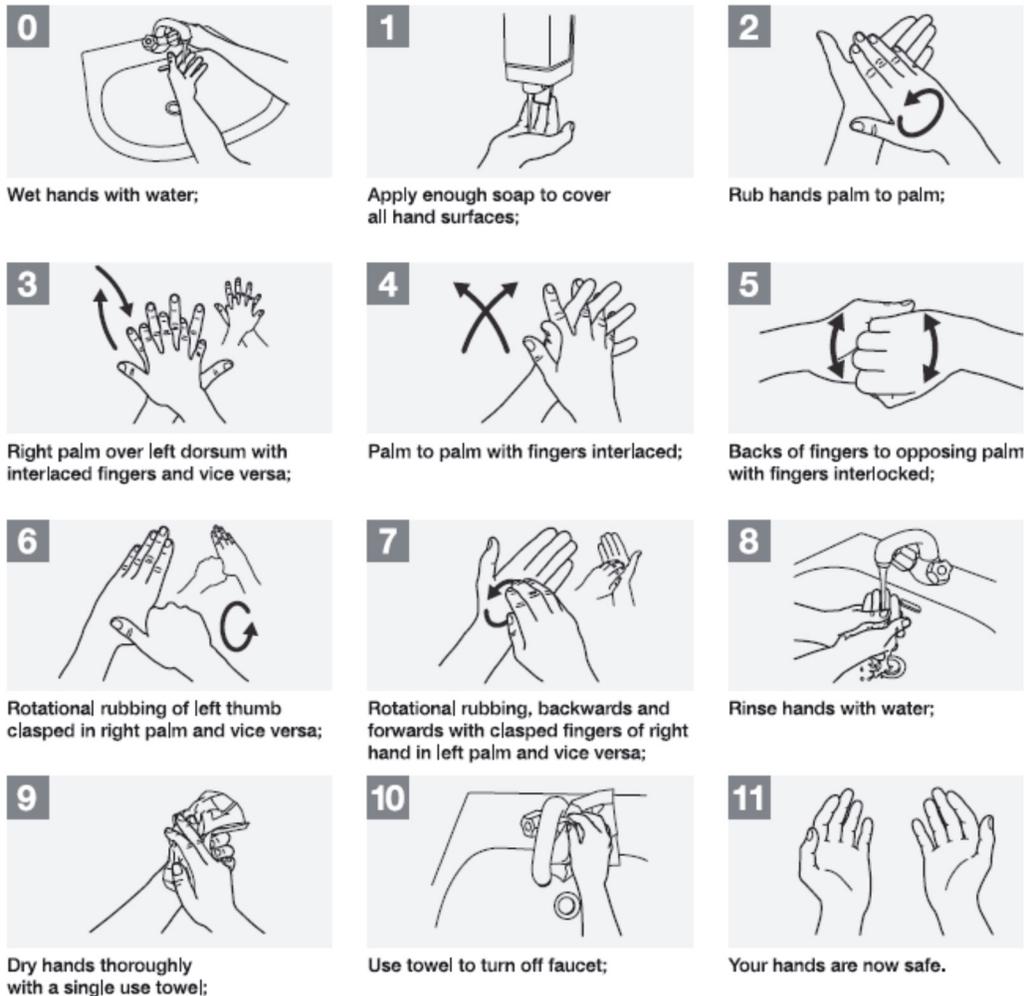
Microorganisms grow and multiply in moisture and in standing water. Therefore:

- If bar soap is used, provide small bars and soap racks that drain.
- Avoid dipping hands repeatedly into basins containing standing water. Even with the addition of antiseptic agents 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 that can be turned off to lather hands and turned on again for rinsing, or a bucket and pitcher.
 - Use an alcoholic handrub that 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 3–5 ml for each application and rub the solution over the hands for about 2 minutes, using a total of 6–10 ml per scrub (Larson et al. 1990; Rotter et al. 1980).

- Dry hands with a clean, dry 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 toilet or latrine if a drain is not available.

Figure 5-1. Steps for Handwashing Using Soap and Water



Based on: The How to Handwash. http://www.who.int/gpsc/5may/how_to_handwash_poster.pdf © World Health Organization 2009. All rights reserved.

Surgical Handscrub

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

The surgical handscrub is performed before gowning (if used) and putting on sterile or high-level disinfected gloves. Ideally, the surgeon 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 scrubbing. **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 OR 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. Wear gloves:

- When performing a procedure such as ML/LA;
- When handling soiled instruments, gloves and other items; and
- When disposing of contaminated waste items (cotton, gauze, or dressings).

A **separate** pair of gloves must be used for each client to avoid cross-contamination.

Which Gloves to Use

The glove requirements for providing minilaparotomy services are presented in **Table 5-1**.

Table 5-1. Glove Requirements for Minilaparotomy under Local Anesthesia

Task Or Activity	Are Gloves Needed?	Preferred Gloves	Acceptable Gloves
Pelvic examination	Yes	Exam ^a	Surgical ^b
Minilaparotomy procedure	Yes	Sterile surgical	Sterile surgical ^b
Handling and cleaning instruments	Yes	Utility	New exam or new surgical ^b
Handling contaminated waste	Yes	Utility	New exam or new surgical ^b
Cleaning blood or body fluid spills	Yes	Utility	New exam or new surgical ^b

^a This includes new, never used individual or bulk-packaged gloves (as long as boxes are stored correctly).

^b In the absence of the preferred gloves, it is acceptable to substitute these types of gloves temporarily, but the substitute gloves must be new.

Client and Staff Attire

The OR is designated as a clean area; therefore, clients and OR 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.)
- OR staff (including cleaning staff) should change into clean scrub suits or gowns, with plastic or rubber aprons under their scrub suits or gowns, and caps and masks, **prior to entering the OR**.
- Masks should fully cover the nose, lower face, jaw, and facial hair and should be replaced when damp.
- Staff should also wear face shields or goggles to protect themselves against splatters of blood and body fluids.
- Caps should cover all hair.
- Street shoes should be covered or changed to shoes or boots that are worn only in the OR.

Are Face Masks Necessary for Observers in the OR?

It is always necessary for all staff who are actively involved in the procedure to wear face masks in the OR. 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 an article in the *Journal of Hospital Infection* (Mitchell and Hunt 1991), oral microbial flora dispersed by unmasked volunteers standing 1 meter from the OR table failed to contaminate exposed bacterial dishes (settle plates) placed on the table. The numbers of airborne 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, even when there is heavy microbial colonization in the nose. The article concludes that surgical masks are costly and not necessary for all OR personnel in all cases, **but it states that masks should be worn by the surgeon and all personnel who are scrubbed** (i.e., those within 1 meter of the OR table).

Antisepsis

Although skin cannot be sterilized, pre-operative cleaning of the surgical site with soap and water followed by antiseptic preparation minimizes the number of microorganisms on the client's skin. Both steps are important in reducing the risk of infection following minilaparotomy.

Infection following surgical procedures such as ML/LA may be caused by microorganisms from the skin of the client or from the hands of the health care worker (Larson et al. 1990). Preparing the client's skin, cervix, and vagina with antiseptic solution helps 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 different parts of the world:

- 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)

Safe Work Practices

Avoiding Needle-Stick Injuries

Accidental needle sticks will occur:

- **Surgeons and assistants** are most often stuck by needles during procedures.
- **Cleaning staff** are most often stuck by needles when processing soiled instruments.
- **Housekeeping staff** are most often stuck by needles when disposing of waste material.

Safety Tips When Using Hypodermic Needles and Syringes

- Use each needle and syringe only once.
- Do **not** disassemble needle and syringe after use.

- Do **not** recap, bend, or break needles prior to disposal.
- Dispose of needle and syringe in a puncture-proof container.

How to Withdraw Medication from a Sterile, Multidose Bottle

- Wipe the top of the bottle with a cotton swab soaked in 60%–90% alcohol or other locally available disinfectant. Allow to dry.
- If using a new disposable needle and syringe, open the sterile pack.
- If using a sterile or high-level disinfected needle and syringe, remove from covered container using dry, sterile, or high-level disinfected forceps.

Never use a syringe for more than one injection. Studies have shown that changing **only** the needle, not the syringe, between clients can result in transmission of hepatitis B virus (HBV), and presumably HIV.

- Attach needle to syringe by holding the hub (base) of the needle and the barrel of the syringe.
- Turn the bottle containing the drug upside-down and draw the fluid into syringe using the **same** needle you will use for the injection.
- Withdraw needle from bottle.

Do **not** leave a needle inserted in the rubber stopper of a multiple dose bottle. This practice is **dangerous** because it provides a direct route for bacteria to enter the drug bottle and contaminate the fluid between each use.

Waste Disposal

Medical waste may be noncontaminated or contaminated. Noncontaminated waste (e.g., paper from offices, boxes) poses no infectious risk and can be disposed of according to local guidelines. Proper handling of contaminated waste (blood- or body fluid-contaminated items) is required to minimize the spread of infection to clinic personnel and to the local community. Proper handling means:

- Wearing utility gloves
- Transporting solid contaminated waste to the disposal site in covered containers
- Disposing of all sharp items in puncture-resistant containers
- Carefully pouring liquid waste down a utility drain or flushable toilet or latrine
- Burning or burying contaminated solid waste
- Washing hands, gloves, and containers after disposal of infectious waste

Operating Room

The OR should be an enclosed area with doors that can be locked. If possible, it should be located away from heavily used areas of the clinic or hospital. The OR should:

- Be well-lighted,
- Have tile or concrete floors to make cleaning easier and more thorough,

- Be kept free of dust and insects, and
- Be adequately ventilated or air-conditioned if possible; if floor fans are used, the air should be directed away from the surgical field. (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), and a toilet near the staff room where they change clothes. This area should be positioned so that staff can enter directly into the OR 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 OR:

- 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 OR and go to the OR table without crossing through areas where sterile or high-level disinfected instruments are set up and stored.

Infection Prevention Tips: Minilaparotomy

To minimize the client's risk of infection after ML/LA, OR staff should strive to maintain an infection-free environment by following the steps listed below.

Before Procedure

- OR staff and any other personnel entering the OR 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 OR area until they are well.
- Select clients who are **low-risk** for infection and pelvic adhesions, and who are not grossly malnourished or obese.
- Before entering the OR, have the client wash her genital and abdominal areas thoroughly with soap and water and rinse well to be sure all traces of soap have been removed. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.
- Surgically scrub hands with antiseptic solution and water.
- Put sterile surgical gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)
- Apply antiseptic solution at least two times to the cervix and vagina by holding the cotton or gauze swab with a sterile or high-level disinfected sponge forceps. (If the swab is held with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)
- Prep the operative site with an antiseptic solution, starting at the center and moving toward the sides of the abdomen. (Give special attention to the navel as appropriate.)

During Procedure

- Keep the number of people and movement in the OR to a minimum.
- Wear appropriate surgical attire.
- Use **sterilized or high-level disinfected** instruments and surgical drapes.
- Use good surgical technique that minimizes tissue trauma and controls bleeding (hemostasis).

After Procedure

- Before removing gloves, decontaminate instruments by placing them in a container with 0.5% chlorine solution for 10 minutes; then rinse **immediately** with clean water to avoid discoloration or corrosion of metal items.
- Decontaminate operating table, instrument stands, lamps, and other surfaces contaminated during surgery after each case.
- The surgical drape must be washed before reuse. After using, place in a dry, covered container and remove to the designated area for washing.
- While still wearing gloves, dispose of contaminated wastes (gauze, cotton, and other waste items) in an appropriately marked, leakproof container with a tight-fitting lid or a plastic bag. Needles and syringes should be disposed of in a puncture-proof container.
- Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out.
- Place in a leakproof container or plastic bag.
- After completing the procedure, wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.

Hands-Free Technique for Passing Surgical Instruments

A safer method of passing sharp instruments (needles, scissors, and scalpels) during surgery has been developed. Called the hands-free technique of instrument transfer, this technique is inexpensive and simple to use and ensures that the surgeon, 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 surgeon. The container is designated as the neutral zone on which the assistant places sharp instruments. The assistant alerts the surgeon that a sharp instrument has been placed in the neutral zone by saying “scalpel,” or “suture ligature,” while placing it there. The surgeon 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 surgeon. The surgeon performing the operation lifts the instrument out of the container, which is left on the field until she or he returns the instrument to it. The assistant then picks up the container and returns it to the instrument stand.

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

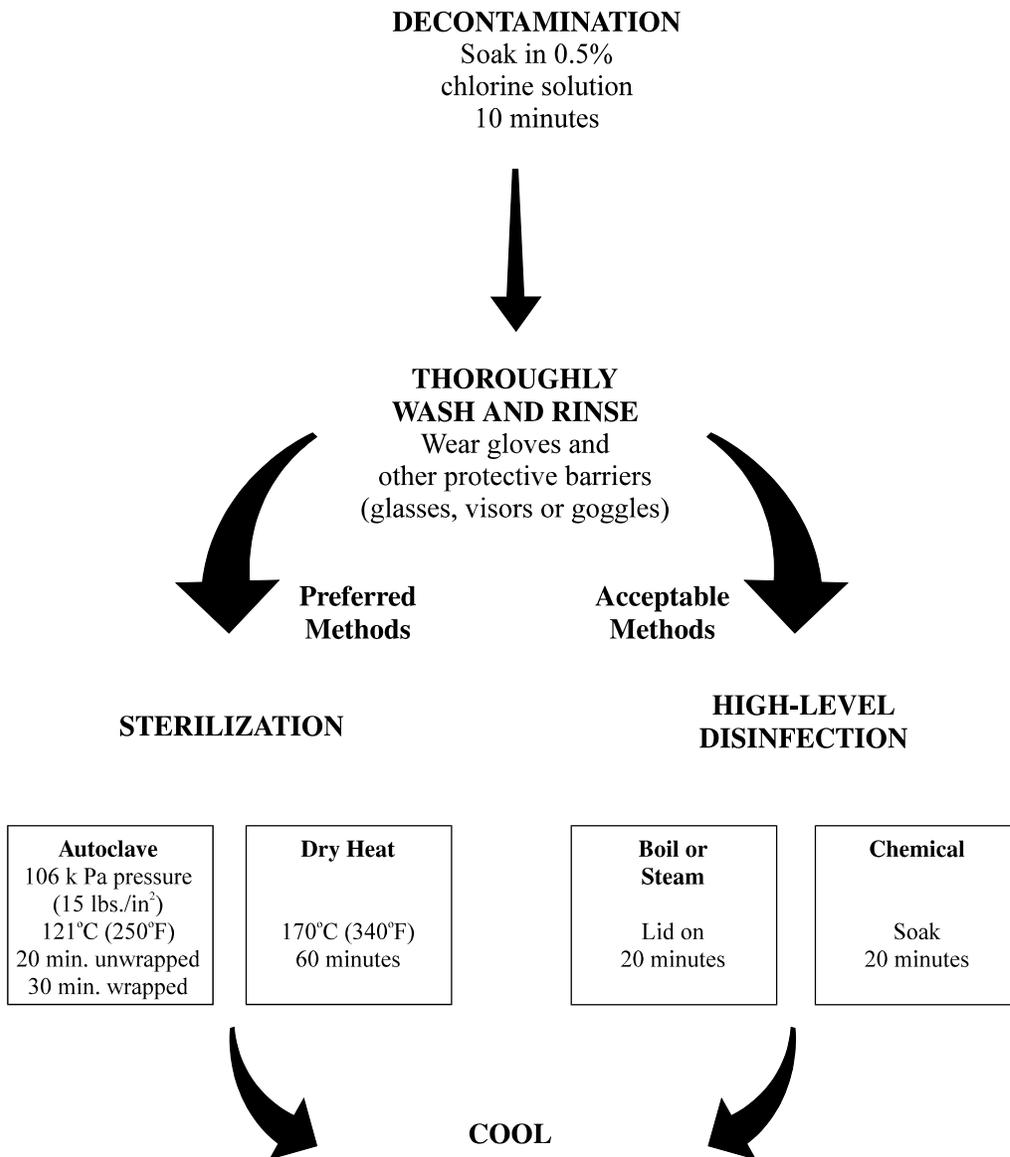
Processing Instruments and Other Items

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

After completing the ML/LA procedure, and while still wearing gloves, dispose of contaminated objects (gauze, cotton, and other waste items) in a leakproof container or plastic bag. (Do not allow waste items to touch the outside of the container or bag.)

As illustrated in **Figure 5-2, decontamination** is the first step in processing soiled surgical instruments 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 (AORN 1990). Larger surfaces such as examination and operating tables, laboratory bench tops, and other equipment that 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.

Figure 5-2. Key Steps in Processing Surgical Instruments and Other Items



After instruments and other items have been decontaminated, they need to be **cleaned** and then final processed by either **sterilization** or **HLD** (Tietjen and McIntosh 1989). The effectiveness of each of these processes for killing or removing microorganisms is listed in **Table 5-2**.

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

Table 5-2. Effectiveness of Methods for Processing Instruments

Method	Effectiveness (kill or remove microorganisms)	End Point
Decontamination	Kills HBV and HIV and most microorganisms	10 minute soak
Cleaning (water only)	Up to 50%	Until visibly clean
Cleaning (detergent and rinsing with water)	Up to 80%	Until visibly clean
Sterilization	100%	Autoclave, dry heat or chemical for recommended time
High-level disinfection	95% (does not inactivate some endospores)	Boiling, steaming, or chemical for 20 minutes

As outlined in **Table 5-3**, the method used for final processing (i.e., either sterilization or HLD) usually depends on whether the instrument and other items will touch only intact (unbroken) skin, intact mucous membranes or broken skin, or tissue beneath the skin, which normally is sterile.

Table 5-3. Final Processing (Sterilization and HLD) for Instruments 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, uterine elevators 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.)	Surgical instruments such as minilap instrument kits, including retractors, tubal hook, forceps, etc.

Adapted from: Spaulding et al. 1968.

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

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 ML/LA be sterilization. When correctly performed, sterilization is the safest and most effective method for processing these items. If sterilization equipment (autoclave or dry heat sterilizer) is neither available nor suitable, then HLD is the **only acceptable** alternative.

See **Appendices E and F** for detailed information on processing surgical instruments and other items.

Maintenance of a Safe Environment

Maintaining a safe, infection-free environment is an ongoing process that requires frequent retraining and close supervision of clinic staff. With diligent application of recommended IPC practices, infections following surgery and transmission of diseases such as HBV and AIDS can be avoided. The practices and processes 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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Six. Anesthesia

Background

The purpose of pain management for ML/LA is to ensure that the client experiences a minimum of anxiety and discomfort as well as the least risk to her well-being. Anesthesia is administered to the client undergoing minilaparotomy in order to:

- Prevent pain and discomfort
- Minimize stress and anxiety

Local anesthesia, when properly administered and managed by the surgeon and his assistant, meets both of these goals and is recommended for minilaparotomy. Local anesthesia is used in 75% of sterilizations worldwide and has been shown to safe and effective (Pati et al.1998).

A recent study of more than 1,000 clients confirmed the finding that pre-operative counseling, adequate assessment, and careful explanation of the procedure to the clients helped them to be psychologically prepared to undergo the procedure under local anesthesia with excellent results. The use of local anesthetic techniques has made surgical contraception faster, safer, simpler, and cheaper, thereby making more clients readily accept the procedures (Ujah and Mutahir 1998).

Because ML/LA often is performed in ambulatory facilities, it is important that each program's staff determine the pain control method most suited to their facility. They should consider the availability of drugs, the technical capabilities of the clinicians providing pain control medication, and their ability to manage complications of chosen regimens. Local anesthesia with verbal support, and with no or minimal sedation, will be the most appropriate method in most circumstances.

Pain Management Using Local Anesthesia

The key to having a successful ML/LA 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 anesthesia, or "verbacaine").

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 as relaxed and comfortable as possible. 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 ML/LA 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; and
- 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, and
- 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 before 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 finished” when you’re not.
- Talk with the client throughout the procedure.
- Be sensitive to what you are saying and doing.

Preoperative Medication

Generally, routine pre-operative medication is **not** needed and should be discouraged. A study compared ML/LA clients who did or did not receive sedative premedication (pethidine) before local anesthesia. The study found no significant difference in the clinical performance of the operation as evidenced by length of the incision, amount of local anesthesia required, or duration of the operation or perception of pain. In addition, among the pre-sedated clients there were higher complaint rates for dizziness, nausea, vomiting, headache, and faintness (Ruminjo et al. 1995).

If the client appears to need sedation, the first step is to identify why she is unduly anxious or nervous and provide appropriate counseling. In most cases, this counseling is sufficient. If it is not, then she can be given either diazepam or promethazine before the procedure. For dosage information and methods of administration of preoperative medications, see **Table 6-1**.

A systemic analgesic may be administered before the local anesthetic to augment its effects. Before surgery, the surgeon can give analgesic drugs in combination or sequentially with a sedative, either intramuscularly 15–30 minutes before the procedure or, for rapid onset of action, intravenously 2–3 minutes before the procedure. If intravenously, the doctor should inject the dose over a period of 10–30 seconds, and note any untoward effects. For dosage information and methods of administration, see **Table 6-1**.

If preoperative sedatives or analgesics are to be given, they should be given an appropriate time before the procedure (30–60 minutes for oral medication and 15–30 minutes for IM) so that maximum relief will be provided during the procedure.

The client may also be given a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen 800 mg) before the operation to reduce uterine cramping.

Table 6-1. Preoperative Medication (Usually Not Needed)

Drug	Other Names/ Trade Names	Route of Administration and Usual Dose	Maximum Mg per Kg	Maximum Dose for 60 Kg Adult (mg)	Precautions
Sedative: Diazepam OR	Valium	Orally: 2–10 mg IV: 2–20 mg IM: 2–20 mg	0.33 mg/kg	20 mg	Inject slowly Can cause respiratory depression
Promethazine	Phenergan	Deep IM: 25–50 mg IV: 25–50 mg	0.83 mg/kg	50 mg	Not to exceed 25 mg per minute Can increase effects of narcotics
Systemic analgesic: Pentazocine OR	Talwin	IM: 30 mg IV: 30 mg SC: 30 mg	1 mg/kg 0.5 mg/kg 1 mg/kg	IM: 60 mg IV: 30 mg SC: 60 mg	Can cause respiratory depression Can cause hallucinations
Meperidine	Demerol	IM: 50–100 mg SC: 50–100 mg IV: increments of 25 mg	0.83–1.67 mg/kg	100 mg	Inject slowly IV: decrease dosage and inject slowly, preferably using dilute solution Can cause respiratory depression Can interact with other central nervous system depressants
Mild analgesic (to lessen uterine cramping): An NSAID such as ibuprofen	Brufen Advil Motrin Nuprin	Oral: 800 mg	53.3 mg/kg	3,200 mg per day	Avoid use with those who have had an allergic reaction to aspirin

Local Anesthesia

The dangers of general anesthesia, particularly in settings that lack skilled staff (anesthetists) and facilities for close monitoring of the client during the procedure and recovery, have been well-documented. Use of general anesthesia 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 anesthesia (e.g., failure to intubate the client), or inadequate monitoring.

Therefore, it is important to use alternative approaches for the safe, effective management of pain. Local anesthesia, most commonly provided by a local field block with lidocaine, is widely used to ease the pain associated with minilaparotomy. Local anesthesia with or without sedation (so-called modified local) is safer than either general or regional (spinal/epidural) anesthesia, especially when procedures are being performed in

an outpatient setting (see **Table 6-2**). Local anesthesia causes minimal physiologic disturbance, allowing the client to recover rapidly.

Lidocaine is the world standard for local anesthesia and the preferred anesthetic for minilaparotomy. It is inexpensive, safe, effective, and has rapid onset of action (about 2 minutes after infiltration). Furthermore, there is low risk of allergic reaction associated with the use of lidocaine. See **Appendix G** for more information on the pharmacology of drugs commonly used for local anesthesia.

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

- Initial counseling to increase the client’s cooperation and to minimize her fears
- Good provider-client communication before, during, and after the procedure (see above)
- Time and patience, as local anesthetics are not effective immediately; wait at least 2 minutes between injection and operation

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

- All members of the operating team must be knowledgeable and experienced in the use of local anesthetics (lidocaine).
- 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 anesthetist available.

Table 6-2. Advantages, Disadvantages, Indications, and Precautions for Local, General, and Spinal/Epidural Anesthesia for Minilaparotomy

	Local	General	Spinal/Epidural
Advantages	Avoids risks of general and spinal/epidural anesthesia 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 anesthetist 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

	Local	General	Spinal/Epidural
Disadvantages	Requires precise and gentle surgical technique Mild to moderate client discomfort Toxicity of local anesthetic agents	More costly; requires special equipment, personnel, and environment Longer recovery May cause greater postoperative discomfort Postoperative sore throat may result from intubation Nausea and vomiting common Toxicity of anesthetic agents	Not easy to administer; requires specialized training Takes relatively long time to administer (10–30 minutes for epidural) Recovery slower than with local anesthesia Toxicity of anesthetic agents
Indications	All clients without contraindications for local Setting other than operating room Client's fear of general anesthesia Pulmonary disease Cardiac disease	Anxious client Less experienced surgeon Client with presumed pelvic pathology Extremely obese client	Client's fear of general anesthesia Pulmonary disease
Precautions	Anxious client Less experienced surgeon 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 anesthesia Lack of appropriate equipment Sensitivity to intended medication	Seldom justified for short PM procedure Pre-existing back disorder (relative contraindication) Sensitivity to intended medications History of neurological disease Coagulopathy Inexperienced anesthetist Anxious client Cutaneous infection at incision site

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

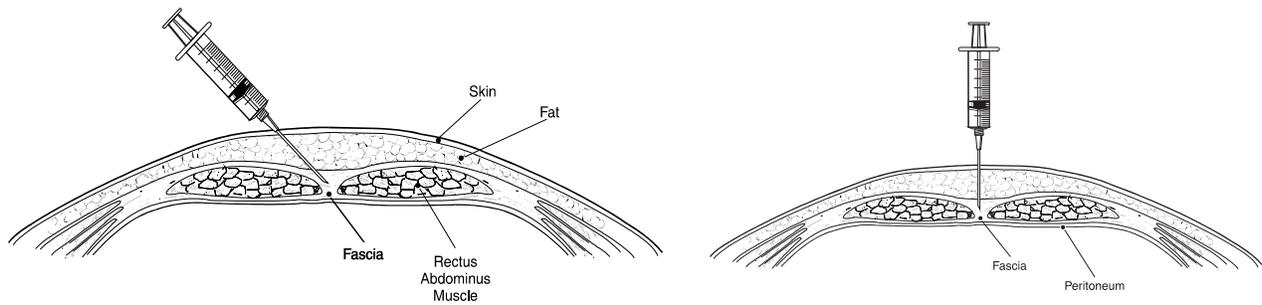
Pre-Testing Patients before Using Local Anesthesia

Allergic reactions to lidocaine are extremely rare. Therefore, it is not necessary to conduct allergy testing before administering local anesthetic. During her medical assessment (see **Chapter 4**), the client will be asked if she has had a reaction to local anesthetic or other medication in the past. If she answers “yes,” the provider should refer the client to a center that can investigate further and, if necessary, perform the procedure using an alternative method of pain management.

Administering Local Anesthesia

The purpose of local anesthesia is to achieve an anesthetic block that infiltrates all layers of tissue from the skin to the peritoneum (see **Figure 6-1**). In both interval and postpartum tubal ligation, the principles of local infiltration using 1% lidocaine are the same whether the incision is suprapubic or subumbilical.

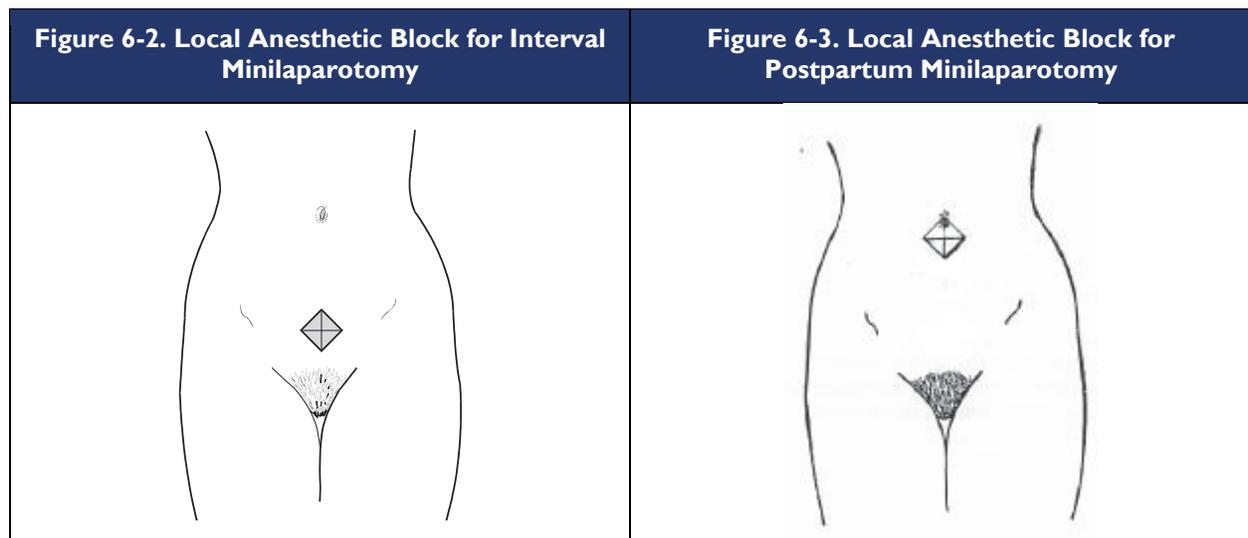
Figure 6-1. Infiltration of All Layers of Tissue from Skin to Peritoneum



To anesthetize the skin, the surgeon raises a small skin wheal at the center of the incision site. Starting at the center of the planned incision, the surgeon administers local anesthetic just under the skin along both sides of the incision site.

Without removing the needle from under the skin, the surgeon inserts the needle at a 45° angle so that the point of the needle reaches the fascia. This will create a field of anesthetized tissue in a diamond shape (see **Figure 6-2** for interval and **Figure 6-3** for postpartum). It is not necessary to infiltrate every layer in four directions. The anesthetic spreads both above and below the horizontal line of infiltration in the subcutaneous space. To infiltrate the peritoneal layer, the surgeon inserts one needle at a 90° angle to the skin.

Step-by-step instructions for administering local anesthetic are given in **Chapter 7**.



The maximum safe dose of lidocaine is 3.0 mg per kg of body weight (e.g., 12 ml of 1% lidocaine for 40 kg body weight). Using 1% lidocaine will provide a large enough volume of anesthetic to infiltrate all layers of the abdominal wall. If lidocaine is supplied in 2% strength, it should be diluted to 1% with normal saline or sterile water so that there will be enough volume of anesthetic to achieve an adequate block.

If necessary, anesthesia may be increased as the fascial and peritoneal layers are exposed. To block pain in the fallopian tubes, lidocaine may be dripped on each tube.

The surgeon should wait at least 2 minutes for the anesthetic to take effect before making the incision. To test the incision site for adequate anesthesia, pinch the skin with a tissue forceps. If the client can feel the pinch, wait 2–3 minutes more and retest the incision site.

Complications of Local Anesthesia

Major complications from local anesthesia are extremely rare. Convulsions and deaths, however, have been reported in cases in which excessive doses were used or injections into a vein occurred.

To minimize the risk of major complications:

- Use the smallest effective dose of local anesthetic. In most cases, 10 ml of 1% lidocaine is adequate. In no cases should the total dose exceed 3.0 mg per kg body weight of the client (i.e., about 12 ml for a 40-kg female).
- Use the plunger withdrawal technique. Pull back on the plunger of the syringe prior to injection to reduce the risk of intravenous injection.
- Use the moving needle technique. Keep the needle constantly in motion while injecting to let the anesthetic spread. This is the preferred method in tissue infiltration.

When recommended dosages are followed, and the plunger is withdrawn before each injection, toxic levels of local anesthetic agents rarely occur. Nonetheless, it is important to recognize the signs and symptoms of toxicity so that no further injections are given and medical treatment is begun.

Remember: The keys to safe use of a local anesthetic 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 anesthetic:

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, the service provider should 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.

For more information on managing complications of local anesthesia, see **Chapter 10**.

Supplementing Local Anesthesia during the Procedure

In some circumstances, the client may need additional sedatives or analgesics to supplement the local anesthetic during the minilaparotomy procedure. One reason would be if the client complains of pain.

Additional medication also may be needed if the procedure is taking longer than expected. Typically, this procedure can be performed in approximately 10–20 minutes. The local anesthetic regimen described above will start to wear off after about 30 minutes. Therefore, if the procedure is taking longer than usual because of complications, such as difficulty in locating the tubes, the surgeon may need to consider giving additional medication.

Supplemental medication should be given only when it is needed and only when there is no risk of danger to the client. The decision about whether or not to give supplemental medication will depend on:

- What has been given before, how much, and when; do not give additional medication too soon if there is a risk of possible overdose
- The client's vital signs
- What is available
- Anticipated length of the procedure
- The surgeon's best judgment of whether supplementary medication is really necessary

If sedatives, tranquilizers, or analgesics are needed during the procedure, they should be given intravenously so that they will have an immediate effect. For minor delays, a combination of diazepam or promethazine plus pentazocine or meperidine can be used. If the surgeon anticipates a longer procedure, he or she may elect to administer ketamine. For dosage information and methods of administration, see **Tables 6-3 and 6-4**.

Table 6-3. Pain Management Using Local Anesthesia

Drug	Other names/ trade names	Route of administration and usual dose	Maximum mg per kg	Maximum dose for 60 kg adult (mg)	Precautions
Field block anesthetic: Lidocaine	Lignocaine Xylocaine	10 ml of 1% (100 mg) lidocaine infiltrated into tissues	3.0 mg/kg	180 mg	Avoid accidental IV administration by pulling back on syringe before infiltration If using 2% lidocaine, dilute to 1% before administration (1:1 dilution) Maximum dose should never exceed 300 mg
Fallopian tube analgesic: Lidocaine	Lignocaine Xylocaine	Use approximately 1 cc of 1% lidocaine solution; drip directly on tube, OR Using 2% lidocaine gel, wipe on sufficient amount of gel to cover the loop of the tube			

Table 6-4. Supplemental Medications (If Needed during Procedure)

Drug	Other Names/ Trade Names	Route of Administration and Usual Dose	Maximum Mg per Kg	Maximum Dose for 60 Kg Adult (mg)	Precautions
For Minor Delays					
Sedative: Diazepam OR	Valium®	IV: 2–20 mg	0.33 mg/kg	20 mg	Inject slowly Can cause respiratory depression
Promethazine	Phenergan®	IV: 25–50 mg	0.83 mg/kg	50 mg	Not to exceed 25 mg per minute Can increase effects of narcotics
Systemic analgesic: Pentazocine OR	Talwin®	IV: 30 mg	0.5 mg/kg	IV: 30 mg	Can cause respiratory depression Can cause hallucinations

Drug	Other Names/ Trade Names	Route of Administration and Usual Dose	Maximum Mg per Kg	Maximum Dose for 60 Kg Adult (mg)	Precautions
Meperidine	Demerol®	IV: increments of 25 mg	0.83–1.67 mg/kg	100 mg	Inject slowly Can cause respiratory depression Can interact with other central nervous system depressants
For Major Delays					
General anesthetic: Ketamine	Ketalar®	IV: Slow infusion over 60 seconds, 10–45 mg/kg/min	0.2–0.5 mg/kg	12–30 mg	Can cause hallucinations Should be used by a doctor experienced in administering general anesthesia, maintaining an airway, and assisting respiration

Monitoring Vital Signs

Client monitoring must be a routine practice in performing ML/LA. 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 anesthetic. Local anesthetic and analgesic agents and sedatives may cause respiratory depression, cardiovascular depression, central nervous system toxicity, and hypersensitivity reactions. 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, and
- Changes in the client's condition.

Before the procedure, the staff must monitor and record blood pressure, pulse, and respiratory rate for a baseline measurement. During the procedure, as the surgeon and assistant talk to the client, they should also observe her carefully to make sure she is conscious and showing no abnormal physical reactions. After the procedure, the staff should measure and record her blood pressure, pulse and respiratory rate every 15 minutes until these rates return to the baseline measurements that were recorded before the procedure. The staff should continue to monitor and record vital signs every 30 minutes until the client has fully recovered from the effects of the anesthesia.

References

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Seven. The Surgical Procedure

Background

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

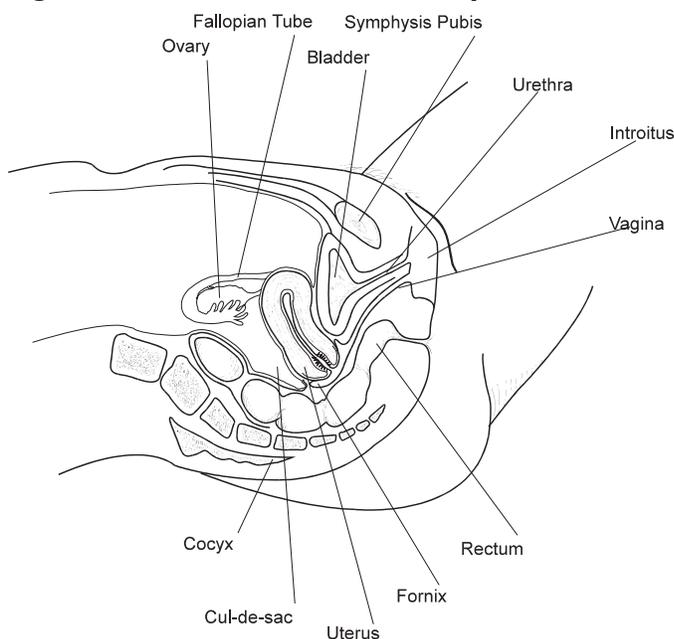
- The surgical team should be trained and skilled in the minilaparotomy technique, use of appropriate anesthesia, correct use of the uterine elevator and abdominal retractor, emergency abdominal surgery, and other procedures for managing emergencies.
- The facility must be equipped with drugs to handle emergencies.
- All instruments and equipment must be in optimum working order before the surgical procedure is begun.
- 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 ML/LA.

Client Assessment

Only those clients who meet the **acceptable** criteria should have their surgery in ambulatory facilities (see **Chapter 4**). The final decision to offer ML/LA to the client is the responsibility of the surgeon, who should conduct a final medical assessment immediately before surgery. The pelvic examination conducted for a preoperative assessment does not eliminate the need for the surgeon to do a pelvic examination before surgery. **Figure 7-1** shows a lateral view of the pelvic anatomy.

Figure 7-1. Female Pelvic Anatomy



Timing of Procedure

ML/LA can be performed at any time during the interval period (6 or more weeks after delivery or at 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 the first 7 days after vaginal delivery.

Preparation

The minilaparotomy kit (see below) contains all of the instruments needed to perform ML/LA. 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 E and F**).

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 anesthetic (1% lidocaine)
- Instrument pan and cover
- 2 iodine cups
- emesis pan
- Thumb forceps, toothed
- Forceps, nontoothed
- 2 Kelly forceps
- 4 mosquito forceps
- 2 Baby Babcock forceps
- Tenaculum
- 2 sponge forceps
- 4 (clamp) towel forceps
- Needle holder
- Round and cutting suturing needles
- 2 Richardson-Eastman retractors
- 2 double-ended, U.S. Army/Navy retractors
- Mayo scissors
- Metzenbaum scissors
- Hypodermic syringes (10 cc) and needles (gauge 23)

- Surgical scalpel handle (size 3) and blades (size 15)
- Urethral catheter, #14 French
- Uterine elevator, Ramathibodi
- Tubal hook
- Bivalve speculum
- Sterile gauze with surgical tape
- Chromic absorbable suture material

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

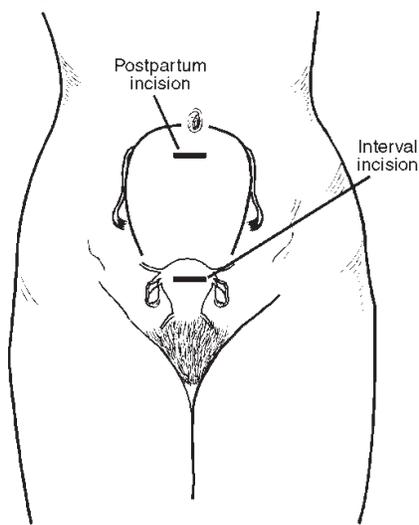
General Procedure

Minilaparotomy requires only a small transverse incision about 2.5–3 cm or larger, but no more than 5 cm long, made just above the pubic hairline (interval minilaparotomy) (See **Figure 7-2**). Using a uterine elevator inserted through the cervix, the surgeon 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 (chromic catgut, polyglactin, or Vicryl) sutures. The operation takes an average of 10–20 minutes. Women usually can leave the clinic or hospital 2–3 hours after surgery when fully awake and with stable vital signs.

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 (infra-umbilical). The surgeon can move the uterus easily with a finger to bring the tubes to the incision. The tubes are blocked by ligation and excision.

The following step-by-step procedure details the provision of interval tubal ligation using the minilaparotomy approach. The approach for performing tubal ligation in the postpartum period generally is similar, except for certain steps that are unique to the interval period. **Chapter 8** details the steps for postpartum tubal ligation.

Figure 7-2. 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), and
- Emptied her bladder (voided).

Talk to the client:

- Explain to her that her skin will be anesthetized 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 is troubled by 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: Surgeon changes into surgical apparel (scrub suit or dress, cap, and mask).

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

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/IV premedication is to be used, give it 25–30 minutes before the procedure.

Preoperative Tasks

STEP 1: Have the client undress and change into clean operating room attire.

STEP 2: Help position her flat on her back on the operating table.

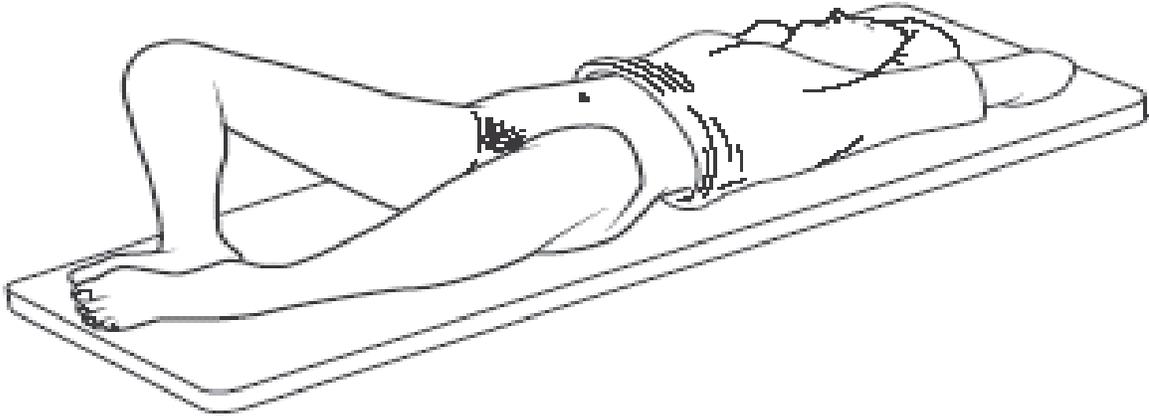
STEP 3: Determine that all sterile or high-level disinfected instruments and emergency tray are present.

STEP 4: Wash hands thoroughly with soap and water and air dry or dry them with a clean cloth.

STEP 5: Ensure that client is in a frog leg position, as shown in **Figure 7-3**.

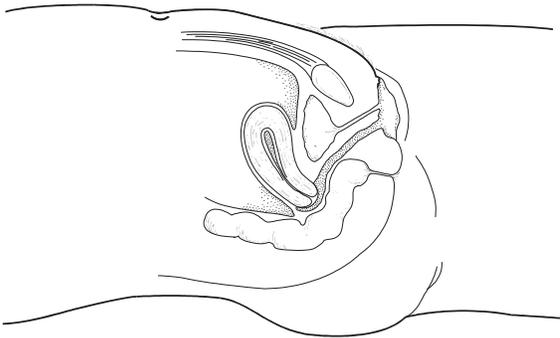
STEP 6: Put new examination or high-level disinfected surgical gloves on both hands.

Figure 7-3. Client in Frog Leg Position



STEP 7: 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 7-4** shows a normal anteverted uterus.

Figure 7-4. Normal Anteverted Uterus



STEP 8: 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 9: Insert the uterine elevator without touching the tip to the vaginal walls. Use a tenaculum to visualize the cervix if necessary. **Figure 7-5** shows the elevator inserted in a normal anteverted uterus. **Figure 7-6** 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 7-5. Normal Anteverted Uterus with Uterine Elevator Inserted

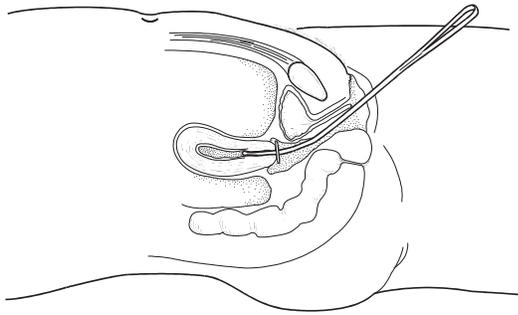
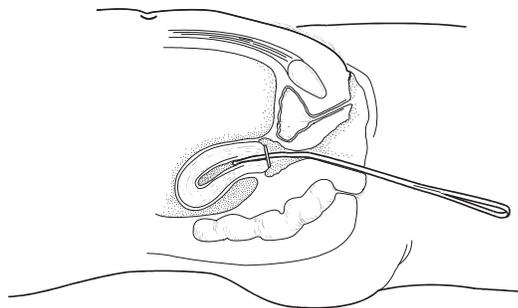


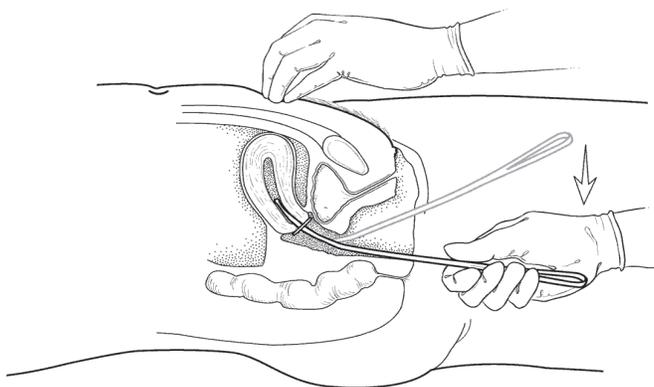
Figure 7-6. Retroverted Uterus with Uterine Elevator Inserted



STEP 10: Remove the vaginal speculum and tenaculum without dislodging the uterine elevator and place in 0.5% chlorine solution for decontamination.

STEP 11: Determine fundal height by gently pushing down on the exposed end of the uterine elevator and palpating abdominally (**Figure 7-7**). Do not use undue force to displace the uterus. A bulge indicates the height of the fundus usually 2–3 cm above the pubic symphysis. Identify the site of the incision. The incision is made 1–2 cm below the height of the palpated fundus (**Figure 7-2**). Do not remove the elevator.

Figure 7-7. Lowering the Handle of the Uterine Elevator to Raise the Fundus against the Abdominal Wall



STEP 12: Select the incision site about 1 cm inferior to the uterine fundus or 3 cm above the pubic symphysis if the fundus could not be palpated.

STEP 13: Position the client's legs flat on the operating table with the handle of the elevator between her thighs and place a soft belt just above her knees to keep her legs from moving.

STEP 14: To dispose of gloves, immerse both gloved hands briefly in 0.5% chlorine solution and then carefully remove the gloves by turning them inside out and place them in the waste container.

STEP 15: Perform surgical scrub and put on the surgical gown, cap, mask, 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 10–15 cm (4–6 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.)

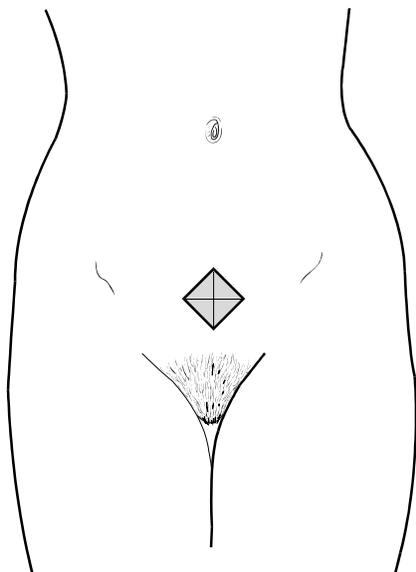
STEP 17: Drape the client with a sterile or high-level disinfected surgical cloth.

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

Local Anesthesia

The technique described below results in a diamond-shaped anesthesia block (see **Figure 7-8**). 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.

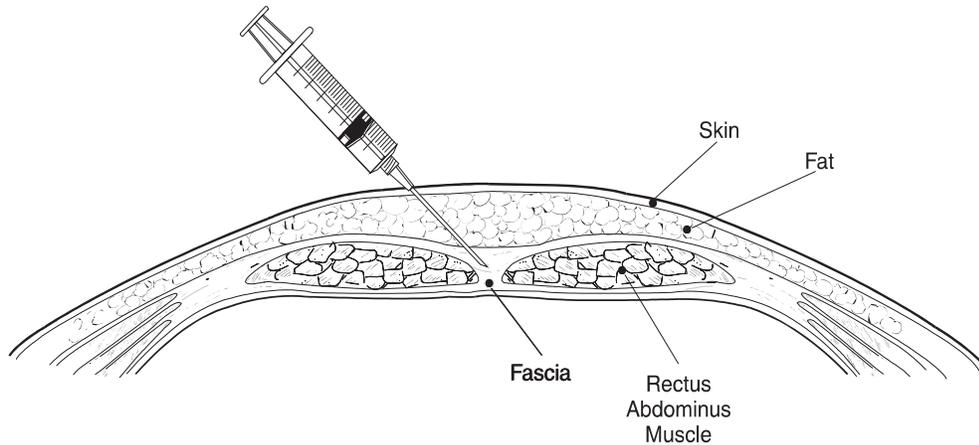
Figure 7-8. Local Anesthetic Block for Interval Minilaparotomy



STEP 1: Raise a small skin wheal at the center of the incision site using 1% local anesthetic (e.g., lidocaine) in a 10- or 20-ml sterile or high-level disinfected syringe (maximum dose of 3.0 mg/kg). Starting at the center of the planned incision, administer local anesthetic (about 3–5 ml) just under the skin along both sides of the incision line.

STEP 2: Again starting at the center of the incision line, and without withdrawing the needle, insert the needle into the fascia at a 45° angle, with the needle directed slightly above the incision line (see **Figure 7-9**). Aspirate to ensure that the needle is not in a blood vessel; then withdraw the needle slowly while injecting 3–5 ml of lidocaine. (Repeat on other side of incision line.)

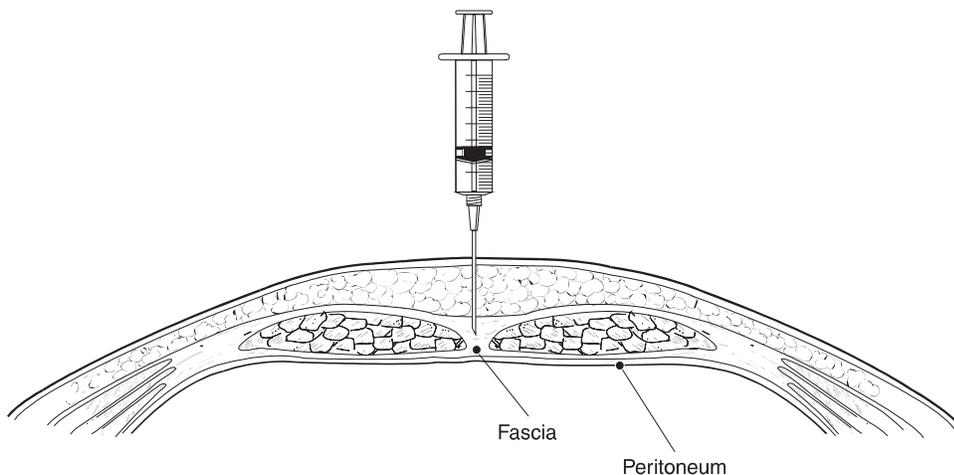
Figure 7-9. Infiltrating the Fascia (Needle at 45° Angle)



STEP 3: Insert the needle straight down through the rectus sheath to the peritoneum (**Figure 7-10**). Aspirate to be sure the needle is not in a blood vessel. Inject 1–2 ml of anesthetic into the peritoneal layer.

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

Figure 7-10. Infiltrating the Peritoneum (Needle at 90° Angle)



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

STEP 6: Test the incision site for adequate anesthesia using tissue forceps. If the client can feel a pinch, wait 2–3 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 should 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.

When passing the scalpel, have it placed in a sterile or high-level disinfected kidney basin. This is a safer method of passing sharp instruments.

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 the fascia at two places with a pair of Kelly forceps and cut transversely with scissors.

STEP 4: Separate rectus muscles in the midline (longitudinally) using blunt dissection with the hemostat 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 lidocaine on the peritoneum if the woman feels pain.)

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

STEP 7: Enlarge opening by placing a hemostat on the upper and lower (superior and inferior) cut edges of the peritoneum and repositioning retractors (longitudinally) within the abdominal cavity. Use retractors to move abdominal contents away from operative site. Another option is to place the table in a head down position of up to a 15° angle. Retraction must be gentle. The retractors should be held in a horizontal plane. If they are held at a 45° angle, 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 the 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, make sure that the movement is 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 the uterine fundus underneath the incision site. (The fundus of the uterus should be visible through the incision site before you attempt 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 the cornual portion of the tube at the incision site.

Grasping the Fallopian Tubes: Forceps Method

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

STEP 2: Identify the midportion of the 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.

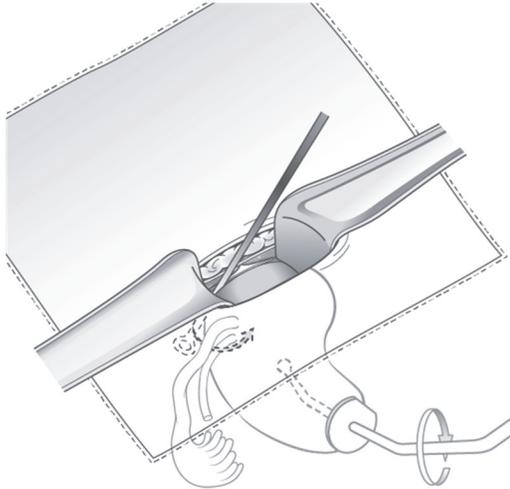
STEP 4: Identify the fimbriated end of the tube by walking the forceps laterally.

Grasping the Fallopian Tubes: Tubal Hook Method (Optional)

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

STEP 2: With the hand that is not holding the uterine elevator, gently 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 on one side of the uterus toward the anterior wall. When the hook is swept toward the anterior wall, the handle of the hook should lie across the incision.)

Figure 7-11. The Tubal Hook Is Inserted behind the Fundus and Is Swept around One Side of the Uterus



Source: EngenderHealth. 2003. *Minilaparotomy for Female Sterilization: An Illustrated Guide for Service Providers*. New York: EngenderHealth.

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. 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.)

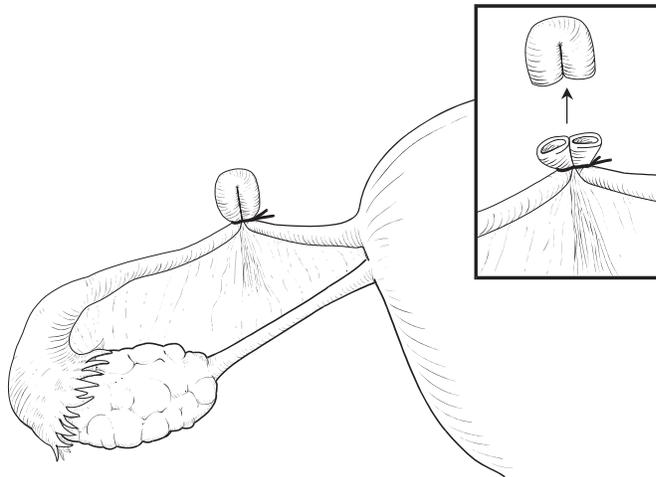
STEP 7: Identify the fimbriated end of the tube by walking the forceps laterally.

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 because 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 (see **Figure 7-12**). Because the blood vessels of the mesosalpinx are caught in the ligature, hemostasis must be assured before the tube is released into the abdominal cavity.

Figure 7-12. Pomeroy Technique of Tubal Occlusion



STEP 1: While grasping the midportion of the tube, place a single free tie (absorbable suture) around a 2 cm loop of tube (about 3 cm from the cornu) and tie a square knot. A 2 cm loop will assure an adequate tube to be excised and a longer stump, which will be unlikely to retract from the suture and cause hemorrhage.

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

STEP 3: Cut the ligature 1 cm from the 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 operating table so that it is once again parallel to the floor.

Closure

When hemostasis is assured, close the abdomen in layers. The peritoneum need not be closed.

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

STEP 2: Close the 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 her 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 a proper receptacle for biologic hazard materials.
- Before removing gloves, place instruments into a container filled with 0.5% chlorine solution for decontamination. (See **Appendix E** for how to make a solution from household bleach.) Before immersing the needle and syringe, fill them 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 it in a **dry**, covered container and remove it to the designated washing area.
- While still wearing gloves, place all contaminated objects (gauze, cotton, and other waste items) in a properly marked, leakproof container with a tight-fitting lid or in a plastic bag.
- To dispose of gloves, immerse both gloved hands briefly in chlorine solution and then carefully remove gloves by turning them inside out and place them in the waste container.
- Wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.
- All waste material should be disposed of by burning or burying.

Tips for Successful Procedures

To minimize complications in **both interval and postpartum** procedures, the surgeon 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), to grasp intra-abdominal tissue.
- Grasp the tube at the midpoint, and preserve the proximal tubal segments 1 to 2 cm in length. Using this technique will reduce the risk of reconnection. Research suggests that a short stump is more likely to hold a build-up of uterine fluid, which could either prevent complete closure of the tubal lumen during healing or cause a fistula to form after healing (Pati et al. 1998).
- Inspect the tissues thoroughly before closing the incision to make sure there is no bleeding.

To minimize complications in **interval procedures**, the surgeon should remember to:

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

To minimize complications in **postpartum procedures**, the surgeon should remember the following:

- Do not use a uterine elevator.
- Perform surgery ideally within 48 hours of delivery (although it can be performed up to 7 days after delivery).
- Rule out any condition that would increase the risk of infection or complications of anesthesia. Infection is an indication for postponement after vaginal delivery; other such indications are intrapartum or postpartum hemorrhage resulting in severe anemia 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.

References

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Pati S, Carignan C, Pollack AE. 1998. What's new with female sterilization: An update. *Contemporary OB/GYN*. (June):91–114.

Eight. Postpartum Minilaparotomy¹

Background

Postpartum tubal occlusion should be included in every voluntary surgical contraception program (Knowledge for Health Project; WHO/RHR/CCP 2011). The period after the birth of a child may be the most convenient time for the procedure for both the client and the service provider. The decision for postpartum tubal occlusion should be made **before** the onset of labor whenever possible. Information about postpartum tubal occlusion should be included as part of routine prenatal counseling.

Minilaparotomy is the preferred technique/approach to expose the tube for tubal occlusion through tubal ligation (Pomeroy method) during the immediate postpartum period. The incision for postpartum minilaparotomy is often smaller than that needed for interval procedures.

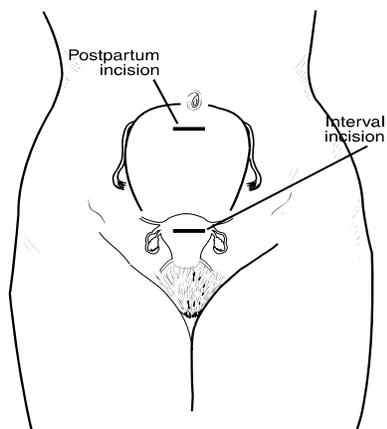
The postpartum procedure is best performed at the health care facility where the delivery takes place. It should not be performed at the site of a home delivery or in a maternity center that does not have staff trained to perform the procedure and complete ML/LA facilities.

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 8-1**). **Figures 8-2 and 8-3** show a close-up of the local anesthesia application and the incision.

Figure 8-1. Incision Sites for Postpartum and Interval Minilaparotomy



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

Figure 8-2. Close-Up of Postpartum Local Anesthesia Application

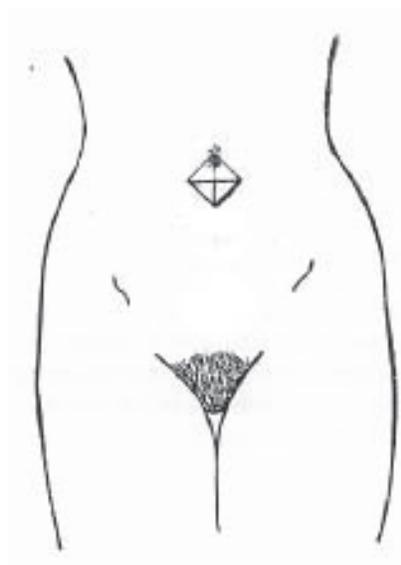
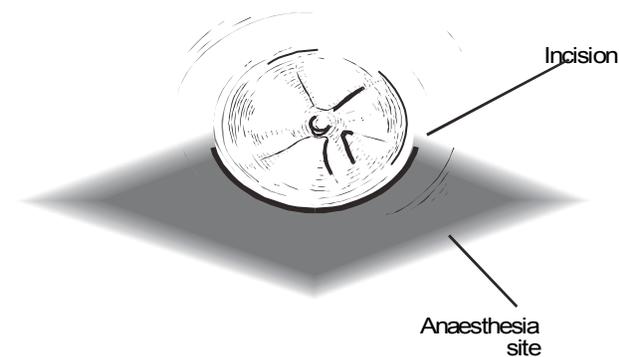


Figure 8-3. Close-Up of Postpartum Minilaparotomy Incision



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

After delivery, the fallopian tubes are generally bigger, often edematous, and more friable; therefore, greater care is needed in handling them.

Timing of Postpartum Procedures

The recommended time for performing a postpartum minilaparotomy is immediately or within 7 days after giving birth, if the woman has made voluntary, informed choice in advance. During that time, the fundus is near the umbilicus and a small subumbilical incision affords ready access to the tubes. In addition, an unnecessarily long hospital stay is prevented (WHO 2015).

If possible, postpartum minilaparotomy should not be performed after 7 days from delivery, and should not be performed until after the puerperium or until 6 weeks after delivery. The primary reasons for delaying are that during this period, the uterus can no longer be reached through an incision near the umbilicus, and the fundus may be more difficult to palpate through the abdominal wall.

When the procedure is postponed until after the puerperium and in women who are not using LAM, appropriate methods of contraception should be offered as fertility may return as early as 3 weeks after delivery.

Conditions Requiring Actions for Postpartum Procedure

Condition	Action	Rationale
7 to 42 days after delivery	Delay procedure until at 42 days or more after childbirth.	Increased risk of complications when not performed during first 7 days postpartum or before uterus has fully returned to pre-pregnancy size.
Severe pre-eclampsia and eclampsia	Delay procedure until full recovery.	Increased risk of anesthesia-related problems if general anesthesia used.
Prolonged rupture of membranes (> 24 hours)	Delay procedure until infection is treated and resolved.	Increased risk of serious postoperative infection.
Intrapartum or postpartum sepsis	Delay procedure until infection is treated and resolved.	Increased risk of serious postoperative infection.
Severe hemorrhage (> 500 ml)	Delay procedure until anemia has resolved. Continue delay and provide temporary contraception when severe anemia of Hb < 7 is present.	Client may have been anemic 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.	Because client may have been anemic before delivery, she may not be able to tolerate risk of further blood loss.
Uterine rupture or perforation	The decision to include tubal ligation as part of the surgical intervention should be undertaken in a setting where there are an experienced surgeon and support staff, equipment needed to undertake the primary intervention, access to appropriate anesthesia, and other backup medical support. When a decision to delay the procedure is made, an alternative, temporary method of contraception should be provided.	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.

For additional conditions requiring precautions for both postpartum and interval procedures, see **Chapter 4**.

Special Precautions after a Home Delivery

Clients who come to the clinic for tubal ligation after a home delivery should be accommodated unless there are complications or concerns. Following are the factors that the surgeon and staff should consider:

- Timing.** The procedure should be performed immediately or within 7 days after childbirth. If the procedure cannot be done within 7 days of delivery, it should be postponed until after 42 days following childbirth. The client should be provided with another method of contraception until the procedure can be performed.

- **Complications.** A woman is more likely to visit the clinic after a home delivery if she is suffering from some complication, such as bleeding or infection. Delay the procedure until the complication is resolved. If the procedure cannot be done within 7 days of delivery, it should be postponed until at least 42 days (6 weeks) after childbirth. The client should be provided with another appropriate method of contraception (such as LAM) until the procedure can be performed.
- **Concerns about tetanus.** Clients presenting for a postpartum procedure after giving birth at home must be asked whether they have been immunized against tetanus, and if so, when. If the client has been immunized against tetanus within a specified time period, the procedure can be performed under antibiotic cover.

If the client is not fully immunized, she will need a booster dose. If the client does not know if she has been immunized against tetanus, or cannot remember when she was immunized and no record is available, active (toxoid) immunization should be given as a precaution just before the procedure.

If the client is at high risk for tetanus, such as having childbirth under unsafe condition or attended by an untrained birth attendant, she should receive both active and passive immunization before the procedure, because passive immunization will provide protection immediately. Alternatively, tetanus toxoid may 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.

Hospital Stay

In most cases, the postpartum procedure and its recovery period do not add to the usual hospital stay required for normal delivery.

The Surgical Procedure

Subumbilical Incision: Local Anesthesia

STEP 1: Raise a small skin wheal at the center of the incision site using 1% local anesthetic (**without** epinephrine) in a 10- or 20-ml sterile syringe. The maximum dose should not exceed 150 mg for a woman who weighs 50 kg.

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

STEP 3: Starting again at the center of the incision line, insert the needle into the fascia with the needle directed toward 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 3–5 ml of lidocaine. Repeat on the other half of the incision line.

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 surgeon to think the tube is the intestine or vice versa. Identify the uterine tube by following it laterally to the fimbrial end.
- Avoid grasping the cornual portion of the tube because it is easily traumatized.

Tips for Successful Procedures

To minimize complications in **both interval and postpartum** procedures, the surgeon 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 forceps to grasp intra-abdominal tissue.
- Grasp the tube at the midpoint, and preserve proximal tubal segments 1–2 cm in length. This is likely to reduce the risk of reconnection. Research suggests that a short stump is more likely to hold a build-up of uterine fluid, which could either prevent complete closure of the tubal lumen during healing or cause a fistula to form after healing (Pati et al. 1998).
- Inspect the tissues thoroughly before closing the incision to make sure there is no bleeding.

To minimize complications specifically in **postpartum procedures**, the surgeon should remember the following points:

- Do not use a uterine elevator.
- Perform surgery immediately or within 7 days of childbirth.
- Rule out any condition that would require caution or delaying the procedure, or increase the risk of infection or complications of anesthesia. Infection is an indication for postponement of postpartum tubal ligation after vaginal delivery. Other such indications are intrapartum or postpartum hemorrhage resulting in severe anemia 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. Postoperative Recovery, Discharge, and Follow-Up¹

Background

Monitoring the client immediately following surgery is an essential component of postoperative care because it is during this critical period that acute effects of surgical injury, adverse anesthesia reaction, or other postoperative complications usually become apparent. Although nurses or other staff members will carry out the tasks related to postoperative recovery and discharge, the surgeon is ultimately responsible for the quality of recovery room care.

Clients are usually ready to be discharged within 2–3 hours after the procedure. Prior to discharge, clients must:

- Meet minimum discharge criteria; and
- Receive discharge instructions on what to expect, self-care, warning signs, and when to follow up.

Postoperative Monitoring

In the postoperative period, the recovery room nurse (or other staff member) must closely monitor the client. The staff person assigned this duty must be trained and designated to monitor clients in the recovery room, be able to respond and initiate emergency management if a complication arises, and be able to discharge clients. This staff person has the following responsibilities:

- Receive the client from the operating room and receive a report from the operating room team, as well as review the client record.
- Handle the woman gently when moving her and make her as comfortable as possible.
- Monitor the client and record the observations on a standardized postoperative monitoring form. The frequency of observations will depend upon the stage of recovery, the nature of the surgery, and clinical condition of the patient. Monitoring the client includes the following:
 - Observing and recording the client's general condition:
 - Level of consciousness; the semi-conscious client should never be left unattended
 - Patency of the airway and respiratory effort
 - Level of postoperative pain
 - Nausea and vomiting
 - Skin color

Note: Engaging the client in conversation is a form of monitoring and observation. The ability to talk and follow simple instructions shows that the client is recovering appropriately.

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

- Checking and recording the client’s vital signs: pulse, blood pressure, and respiratory rate:
 - Every 15 minutes for at least the first hour and until they are stabilized at pre-operative levels, then every 30 minutes until the client has fully recovered from the effects of sedation.
 - If the client is not awake, continue monitoring every 15 minutes until she is fully awake.
- Checking the surgical dressing for signs of bleeding and recording the findings.

Note: For interval cases, check for vaginal bleeding other than menstruation, as this may be a sign of injury to the cervix that may have been caused by the uterine elevator.

- Providing liquids and small amounts of bland, solid food to assess the client’s ability to tolerate oral fluids and food without nausea or emesis.
- Administering drugs or treatment for symptoms according to the doctor’s orders.

Immediate Postoperative Complications

Emergency management preparedness is an essential component of ML/LA services. Facilities that provide these services must be able to manage minor complications, recognize and manage/stabilize more serious complications, and transfer clients for management of more serious complications. This includes monitoring for, recognizing, and managing:

- Excessive somnolence
- Respiratory difficulty or respiratory stridor
- Respiratory depression
- Hyperventilation
- Chest pain
- Hypotension
- Tachycardia
- Excessive pain
- Pallor or cyanosis

In addition, the client should be monitored for these signs of a potential intra-operative complication:

- Signs of hypovolemia (tachycardia, hypotension, or orthostasis)
- Inability to retain fluids (nausea and vomiting)
- Inability to ambulate (client is unsteady when standing)
- Severe abdominal distention
- Excessive bleeding from surgical incision site
- Inability to urinate

The facility must also ensure the immediate availability of and access to functional equipment, adequate supplies, and appropriate drugs for monitoring and for management of complications—regardless of the type of anesthesia used.

Minimum Criteria for Discharge

- The client is fully conscious, alert, able to converse, and follow simple instructions.
- Vital signs are stable.
- Pain and postoperative nausea and vomiting are adequately controlled She is able to retain oral fluids.
- The client is able to ambulate without assistance and dress herself.
- The client is able to urinate.
- No excessive bleeding from the surgical incision site is noted.

Discharge usually occurs within 2 hours of an interval procedure; however, if a sedative has been used, this time frame will vary according to the type of sedative used and dosage given. In the case of postpartum sterilization, the woman will be discharged when the baby is ready to leave the hospital.

Postoperative Instructions

After sedation has worn off and before discharge, a trained staff member should repeat the postoperative instructions to the client or the designated person accompanying the client.

- Explain the instructions to the client in a language that she understands.
- Encourage the client to ask questions and to repeat back what she hears.
- Give the client a copy of the postoperative instructions written in a language she understands.
- If the client cannot read, ask the designated accompanying person to read them, or ask the client to name a friend or relative near her home who can read the instructions to her at a later date.

What the Client Should Expect

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

- Incisional discomfort. This is normal and is usually easily controlled with oral pain medications, which are often required for only the first few days following the procedure. Typically, the incisional discomfort improves quickly.
- A small amount of bleeding, or later, clear discharge, from the wound is not unusual.
- Abdominal discomfort. This tends to be related mostly to the incisional discomfort noted above.
- Mild uterine cramps and light vaginal bleeding. These symptoms may occur following an interval ML/LA and are due to the instrument used to elevate the uterus. Any uterine cramping or vaginal bleeding following postpartum tubal ligation is due to the delivery itself.

Self-Care for the Client

- Rest for approximately 2 days, though walking is encouraged. Gradually resume normal activities as you feel able. You should be able to resume most of your normal activities within 7 days.
- Do not lift anything heavy (more than 7 kg, or 15 lbs) or engage in strenuous activity (e.g., running) for at least 1 week. While the outside incision heals quickly and you may feel well, the deeper part of the incision requires more time to heal.

- Keep the incision site clean and dry. You can remove the dressing the next day and leave the incision uncovered. It is okay to loosely cover the site with clean gauze and tape, but it is not necessary. If the incision is covered for too long or too tightly, it can prevent proper healing.
- Wear loose, clean clothing that will not press on the surgical incision site.
- You can have sexual intercourse as soon as it is comfortable, which is usually after 1 week.
- Take any medications as prescribed.
- Make your follow-up visit in 7–14 days following the procedure.

Warning Signs

Any of the following warning signs require immediate evaluation, preferably by the doctor who performed the procedure or at the facility where the procedure was performed:

- Abdominal pain that is persistent, severe, or increasing
- Bleeding or pus or swelling at the incision site
- Fever
- Later (even years later): if the client misses her menses or thinks she may be pregnant

Note: Pregnancy is rare following minilaparotomy tubal ligation (< 1% at 10 years following the procedure), but ectopic/tubal pregnancy is increased if the woman does become pregnant. Therefore, any woman who becomes pregnant *at any time* following a tubal sterilization procedure must be evaluated for possible ectopic pregnancy.

Transfer of Client Records

All client records should be maintained at the service site where the procedure took place. If the follow-up visit will take place at another facility, the client should be given a card for the follow-up 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.

Failure of Tubal Occlusion

Tubal occlusion is one of the most effective methods of contraception, but failures do occur. Recent research suggests that failure rates from tubal occlusion in general may be higher than previously believed. The U.S. Collaborative Review of Sterilization (CREST) study found an overall cumulative failure rate of 1.9%, more than double the failure rate accepted previously. The risk of pregnancy continues until the woman reaches menopause, regardless of how many years have passed since she had the procedure. That means that the younger a woman was at the time of sterilization, the more likely she is to have a sterilization failure at some time in the future (Peterson et al. 1996; Update on female sterilization 1996).

When failures occur, there is about a one in three chance of an ectopic pregnancy. The risk of pregnancy, and of ectopic pregnancy, has been shown to continue for at least 10 years after the procedure (Peterson et al. 1997).

Because ectopic or intrauterine pregnancy is potentially life-threatening, service providers must be prepared to identify such conditions early. Symptoms of an ectopic pregnancy include lower abdominal pain, amenorrhea, 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.

The rates of failure, and of ectopic pregnancy, vary by method and timing of the procedure, as seen in **Table 9-1**. Women who were under 30 years of age at the time of sterilization were nearly twice as likely as older women to have a subsequent ectopic pregnancy, possibly because the greater fecundity of that age group leads to more failures in general (Peterson et al. 1997).

Table 9-1. Estimated Cumulative Probability of Pregnancies and Ectopic Pregnancies, Per 1,000 Clients, Up to 10 Years after Tubal Sterilization

Method	All Pregnancies	Ectopic Pregnancies
Coagulation ^a	7.5	1.8
Silicone rubber-band application	17.7	7.3
Interval partial salpingectomy ^b	20.1	7.5
Postpartum partial salpingectomy ^{b,c}	7.5	1.5
All methods	18.5	7.3

Adapted from: Peterson et al. 1996, 1997.

^a Unipolar, the most common method.

^b This includes the Pomeroy method.

^c After vaginal delivery or at the same time as a cesarean section.

Answers to Common Questions about Reversal and Fertility

Can the procedure be reversed, and fertility restored?

Voluntary sterilization procedures should be considered permanent (Knowledge for Health Project). In some countries, reversal of tubal ligation is available at limited clinical sites where microsurgical facilities are present, but:

- Reversal involves complicated and difficult surgery, requiring great skill.
- Some individuals who request reversal may be ineligible because of age, fertility impairments, partner's infertility, 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 client is usually responsible for the expense.

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Ten. Management of Complications¹

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 treatment 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:

- Anesthesia-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. Most cases of mortality or morbidity result from the use of anesthesia, particularly general anesthesia. Anesthesia-related complications are summarized in the following section; management of surgical complications is summarized below.

Steps to Take When Complications Arise during the Procedure

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

1. Abandon surgery while emergency treatment is under way.
2. Return the table to the parallel position.
3. Complete the surgery only if the client's condition has stabilized.
4. Consider hospitalizing the client for observation.
5. Record the complication and the treatment in the client record.

Anesthesia-Related Complications

Complications Caused by General Anesthesia and/or Sedatives

When general anesthesia and/or sedatives are used, serious anesthesia-related complications are likely to occur as a result of overdose, improper administration of the anesthesia, or inadequate monitoring. The most common complications are listed below.

Complications/Signs

- Respiratory depression or arrest:
 - Cyanosis

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

- Central nervous system changes (restlessness, anxiety, disorientation)
- Dyspnea or difficult breathing
- Cardiovascular changes, including arrhythmia, hypotension, or hypertension:
 - Irregular or rapid pulse
 - Central nervous system changes (restlessness, anxiety, disorientation)
- Cardiac arrest:
 - Absence of pulse, heart sounds, respiration, reflexes, and muscle tone
- Convulsions:
 - Tonic and clonic seizures followed by loss of consciousness
- Aspiration of vomitus:
 - Dyspnea, gasping, cyanosis
 - Presence of vomitus in the mouth cavity

Possible Causes

- Overdose of sedative
- Combined effect of drugs
- Delayed effect of drugs
- IV injection of lidocaine
- Overdose of lidocaine
- Pre-existing cardiac disease
- Severe blood loss with intravascular volume depletion
- Full stomach

To manage **acute complications** related to anesthesia:

- 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 O₂ tube, if possible.
- Check the client's circulation; monitor pulse, blood pressure, and respiration.

Administer naloxone 0.4–0.8 mg intravenously if a narcotic agent has been used. This dose may be repeated within 2–3 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 2–4 mg, other causes of respiratory depression should be considered:

- For pulmonary aspiration of gastric contents, suction the trachea immediately and administer hydrocortisone sodium succinate 1–1.5 g intravenously. Begin broad-spectrum antibiotics.
- For convulsion, give small increments (1–5 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, give 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.

Complications Caused by Local Anesthesia

Major complications from local anesthesia are extremely rare. (For more information on complications of local anesthesia, see **Chapter 6**.) Convulsions and deaths have, however, been reported in cases in which excessive doses were used or injections into a vessel occurred. It is important to recognize the signs and symptoms of toxicity so that no further injections are given and medical treatment is begun.

The following sequence indicates increasingly toxic levels of local anesthetic:

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, the service provider should 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: the airway must be kept clear and oxygen must be given 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.

Key Steps in Treating Cardiac Arrest

1. Stay with the client.
1. Call for additional help and note the time.
2. Send someone to get the emergency kit.
3. Move the client onto the ground if she is not already on a firm, low surface.
4. Examine:
 - Airway: Look, listen, and feel for air exchange.
 - Breathing: If not breathing, give two quick breaths.
 - Circulation: Check carotid pulse.
5. Begin cardiopulmonary resuscitation.
6. Have someone begin IV fluids.
7. Give oxygen at 10 liters/minute using Ambu bag.
8. If heartbeat is present:
 - Closely monitor vital signs and continue oxygen.
 - Consider cause of the arrest and address the problem.
 - Prepare client for transfer.
9. If no heartbeat is present:
 - Give cardiac massage.
 - Give atropine 3 mg IV followed by sodium bicarbonate 50 ml 8.4% IV slowly.
 - Ensure dose of adrenaline for IV administration is 1:10,000, then adrenaline 1:10,000, 0.5 mg.
 - Ensure sodium bicarbonate is administered slowly.
 - Repeat adrenaline 1:10,000, 0.5 mg IV after 5 minutes.
10. If heartbeat resumes, follow steps above for when heartbeat is present.
11. If heartbeat is still not present:
 - Continue cardiac massage and artificial ventilation until the heartbeat and respiratory effort return.
 - If no response, abandon resuscitation after 30 minutes.

Other Complications

Complications from minilaparotomy can range from mild (such as minor infections that can be easily treated with antibiotics) to severe (including bowel or bladder injuries that require surgical repairs). Most types of complications can be avoided if providers handle tissue gently, apply appropriate infection prevention practices, and use correct techniques.

When complications do occur, the surgeon must address them immediately. By diagnosing and treating problems early, providers can prevent more serious complications from developing. Depending on the skill of the surgeon and the resources of the health care facility, clients with complications may be treated on site or referred to another facility that offers a higher level of care.

Table 10-1 lists the most common complications of minilaparotomy and general principles for assessing and managing them.

Table 10-1. Management of Complications Associated with Minilaparotomy

Complication	Possible Cause	Assessment	Management
Wound infection	<p>Failure to observe appropriate IPC practices</p> <p>Failure to instruct client in proper care of wound</p>	<p>Confirm presence of infection or abscess</p>	<p>If skin infection is present, treat with antibiotics. If abscess is present, drain and treat with antibiotics as indicated.</p>
Postoperative fever	<p>Infection</p>	<p>Determine source of infection</p>	<p>Treat infection based on findings.</p>
Bladder injuries (rare)	<p>Failure to ensure bladder was emptied before surgery</p> <p>Inappropriate location of incision</p>	<p>Intraoperatively: Clear fluid welling up into the incision or operative site</p> <p>Sight of the rugal folds of bladder mucosa</p> <p>Postoperatively: Presence of hematuria Suprapubic pain Fever</p>	<p>Intraoperatively: Diagnose problem and manage appropriately. Insert a Foley catheter to keep the bladder empty for at least 1 week.</p> <p>Instill sterile solution into bladder through catheter.</p> <p>Repair injury in two layers using continuous suture of fine catgut with atraumatic needle.</p> <p>Continue minilaparotomy if injury is minor.</p> <p>Begin course of antibiotics.</p> <p>Hospitalize if injury is extensive.</p> <p>Postoperatively: Refer to appropriate center as necessary.</p>

Complication	Possible Cause	Assessment	Management
Bowel injury	<p>Failure to feel the grasped tissue of the fold to ensure bowel is not adherent before opening</p> <p>Failure to look for translucence of the tissue fold before opening</p> <p>Quick and deep entry through the thin abdominal wall at the umbilicus during postpartum procedures</p>	<p>Intraoperatively: Visualization of bowel serosa or muscularis</p> <p>Visualization and smell of bowel contents</p> <p>Abdominal pain</p> <p>Postoperatively: Abdominal pain that increases in severity</p> <p>Vomiting</p> <p>Failure to pass flatus</p> <p>Acute illness</p> <p>Fever with rapid pulse (early)</p> <p>Return of temperature to normal or subnormal (later)</p> <p>Abdominal distension</p> <p>Abdominal tenderness</p>	<p>Intraoperatively:</p> <p>Diagnose problem and manage appropriately.</p> <p>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.</p> <p>If injury is through to bowel lumen, repair in multiple layers using fine silk suture (or chromic catgut if available) with atraumatic needle. Initiate IV antibiotics.</p> <p>If fecal matter is expelled into the abdomen, lavage the peritoneal cavity with sterile solution.</p> <p>Hospitalize for observation following repair.</p> <p>Complete minilaparotomy after repairing bowel.</p> <p>Note: If the health center does not have the facilities and staff to treat bowel injuries, the client should be referred to the nearest district hospital.</p>
Hematoma (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	<p>Determine presence of infection or abscess</p> <p>Check for fluctuance, expression of pus or serum, severe induration</p>	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	<p>Sudden intense pain, persistent pain, or cramping in the lower abdomen, usually localized to one side</p> <p>Irregular bleeding or spotting with abdominal pain after a missed or abnormally light menstrual period</p> <p>Fainting or dizziness associated with either of the above conditions, which persists for more than a few seconds (could indicate internal bleeding)</p>	Manage based on findings.
Remote pregnancy, ectopic	Failed tubal ligation or recanalization of ligated portion of tube	<p>Sudden intense pain, persistent pain, or cramping in the lower abdomen, usually localized to one side</p> <p>Irregular bleeding or spotting with abdominal pain after a missed or abnormally light menstrual period</p> <p>Fainting or dizziness associated with either of the above conditions, which persists for more than a few seconds (could indicate internal bleeding)</p>	Manage based on findings.

Complication	Possible Cause	Assessment	Management
Pregnancy, intrauterine	<p>Undetected pregnancy at time of minilaparotomy</p> <p>Incomplete occlusion of tube or procedure performed on structure other than the tube</p> <p>Spontaneous recanalization</p> <p>Formation of fistulas at occluded end of tube</p>	<p>Pelvic evaluation</p> <p>Pregnancy test</p>	<p>Manage based on findings.</p>
Superficial bleeding (skin edges or subcutaneously)	<p>Failure to maintain hemostasis during surgery</p>	<p>Determine presence of infection, abscess or hematoma</p>	<p>Postoperatively: Place secure pressure dressing on wound to control bleeding.</p> <p>If bleeding persists, reopen wound under local anesthesia and clamp and ligate the bleeding points.</p>

Complication	Possible Cause	Assessment	Management
Uterine perforation	<p>Incorrect insertion of uterine elevator</p> <p>Rough manipulation of uterine elevator</p> <p>Postpartum uterus still soft</p>	<p>Tip of elevator protruding through uterus</p> <p>Inability to elevate the uterus against the abdominal wall</p> <p>Superficial palpation of the tip through the abdominal wall</p> <p>Metallic sound of the tip against the abdominal retractors</p> <p>Bleeding</p>	<p>If uterus is anteverted, elevator may be left in place while minilaparotomy is completed. Caution required if uterus is manipulated.</p> <p>If uterus is retroverted, reposition elevator, rotating the uterus to anteverted position, and then complete minilaparotomy.</p> <p>After minilaparotomy completed is, remove elevator and examine perforation site for bleeding.</p> <p>If fresh bleeding occurs, control with mattress suture using chromic catgut.</p> <p>If bleeding controlled, close the abdomen and observe the client for extra 1–2 hours.</p> <p>Initiate course of antibiotics.</p> <p>Consider hospitalization if continuous bleeding is suspected or if posterior perforation with vessel injury occurred.</p>

Tips for Working with Clients Who Have Abdominal/Pelvic Adhesions

Possible cause: Pelvic inflammatory disease, endometriosis, septic abortion, previous abdominal surgery.

Assessment: Adhesions noted upon entering the abdomen or attempting to locate and identify the tube.

Management:

1. If adhesions can be lysed safely and gently, tubal ligation can proceed under local anesthesia.
2. If adhesions are dense, and tube cannot be identified or grasped without risking injury to internal organs or without causing significant pain, general anesthesia and larger incision may be required to complete the procedure.
3. If general anesthesia can be provided at this time, tubal ligation can be completed.
4. If general anesthesia cannot be provided at this time, the abdomen should be closed. The client should be informed of a failed procedure and referred to a center where general anesthesia is available.

Tips for Working with Underweight and Overweight Clients

1. Screen clients carefully to ensure that women who weigh more than 80 kg (176 lbs) are not advised to have ML/LA.
2. If the client presenting for ML/LA weighs more than 80 kg (176 lbs) or less than 35 kg (77 lbs), explain the increased risks of voluntary sterilization.
3. Counsel her to consider another method of family planning.
4. Counsel her about proper nutrition so that she may understand the importance of and steps needed for attaining a healthier weight.

Key Steps in Repairing and Treating Bowel Injury

1. Gently apply two Babcock clamps to the loop of the bowel, and use a tetra or sponge to prevent stool from spilling into the peritoneum.
2. Use 3-0 chromic sutures to repair the injury. If injury is superficial, perform one-layer closure; if wound is deeper, close in two layers, taking care not to put stitches in too deep.
3. Make sure that there is no bleeding along the suture line and no damage to the bowel serosa.
4. If stool has spilled into the peritoneum, irrigate the peritoneal cavity with warm sterile water or saline.
5. Complete the tubal ligation if possible.
6. Admit the client, and give adequate analgesia postoperatively.
7. Continue with intravenous line at 2.5–3 liters/day for at least 24 hours and until bowel sounds return and she is passing flatus.
8. Consider broad spectrum antibiotics.
9. Discharge the client.
10. If tubal ligation was not completed, offer the client another method of family planning.
11. Counsel the client to be aware of signs of complications.

Key Steps in Treating and Repairing Bladder Injury

1. Gently place clamps on the outside of the bladder to help hold it securely in place.
2. Use nonabsorbable suture material, if available, to repair the injury.
3. Insert a Foley catheter and test to make sure the bladder is water-tight.
4. Complete the ML/LA procedure if possible.
5. With the catheter still in place, transfer her to a ward.
6. Check that bowel sounds are audible on auscultation.
7. Remove the catheter in 7 days.
8. Discharge the client as soon as she is able to pass urine spontaneously.
9. If tubal ligation was not completed, offer the client another method of family planning.
10. Counsel the client to be aware of signs of complications.

Reporting Complications²

After any complication occurs, it is important to explain to the client what has happened. In some circumstance a complication will lead to further clinical developments about which the client and other doctors will need to be aware. Any injury to the bowel, for example, may lead to later obstructions and adhesions. As soon as the client is well enough to accept and understand the information, the doctor should explain what happened and allow time to answer questions. Finally, the doctor should give the client a short, written summary to take home.

The doctor must clearly explain any precautions or treatment in a manner the client can understand and follow. Does the client know the warning signs of further problems? Does she have access to a competent medical opinion if there is some further development? It is a good practice to invite a friend or relative to participate in the discussion so that after the client has left the clinic she will be able to verify or check any information.

The clinical staff should review and discuss the circumstance leading to any complication. The staff can learn from the experience and possibly develop ways to reduce the likelihood of complications in the future.

After any complication, the clinic may be required to submit a medical report to the supervising health service, such as the provincial or district health office. This office may undertake further investigation and recommend additional action.

Reporting Accidental Death³

Although female sterilization is generally very safe, deaths can occur. In a 15-year study in 50 countries, 4.7 deaths were reported per 100,000 female sterilizations. The most common causes were anesthesia-related problems (especially respiratory depression due to heavy sedation with narcotics), surgical error (especially bowel injury), infection, and hemorrhage. Mortality rates have been declining significantly since the 1980s due to improvements in anesthesia, asepsis, and surgical training. Of course, the risk of death from unwanted pregnancy continues to be much greater than the risk from voluntary sterilization—as much as 50–80 times greater in some countries (Khairullah et al. 1992).

A voluntary sterilization death is one occurring within 42 days of surgery, or a death resulting from complications occurring before the end of the 42-day postoperative period. A voluntary sterilization death may be classified further as either:

- **An Attributable Death:** a death resulting from complication(s) of the operation and/or anesthesia, from the chain of events initiated by the operation and/or by the physiologic or pharmacologic effects of the operation and/or anesthesia; or
- **A Nonattributable Death:** a death occurring within the 42-day postoperative period that is not causally associated with the operation and/or anesthesia, their complications, or their management.

² Adapted from: *Management of Emergencies in Family Planning Services in Nepal*. 1999.

³ Adapted from: Jhpiego. 1988. VS Accidental Death Report. Jhpiego. The information in this document was developed in conjunction with AVSC International.

When a death occurs, the clinic's medical review team should conduct an investigation as soon as possible following the initial notification and formal report of death. The objectives of the mortality investigation are to:

- Determine the **cause of death**
- Identify **contributing factors**
- Ascertain whether the death was **attributable to the procedure or anesthesia**
- Determine whether the death was **preventable**
- Design a list of **recommendations** or **corrective measures** to prevent occurrence of similar events

As part of the investigation, the team should interview:

- The surgeon, anesthetist, operating room staff, and clinic director
- Medical and paramedical staff involved in screening and postoperative care
- Family members, field staff, and other doctors who may have seen the client (in cases where death occurred after discharge)

The team should also review:

- The client's admission record, medical history, physical examination notes, laboratory findings, surgical notes, record of anesthesia regimen, anesthesia notes, and record of the monitored vital signs
- Documentation of the onset (time) of the complication(s) and the outcome(s)
- Re-admission record with all relevant data (if client was re-admitted)
- Record from the referral hospital (if the client was treated in another facility)
- Findings from the second surgery (if one was performed)
- Postmortem findings (if available)

Any site-related aspects associated with the complication must receive special emphasis during this review. For example, if the cause of death is surgical error, the medical review team reviews surgical technique; if the cause is anesthesia-related, the team reviews the anesthesia regimen, practice, and monitoring. There must also be a review of any previous incidents of morbidity and mortality in which the service provider(s) or the service site have been involved.

After collecting the required information, the medical review team will prepare a narrative report that includes findings, an analysis of the findings, the conclusions about the factors that caused the death, and recommendations for corrective measures. The report should be forwarded to the supervising health service, such as the provincial or district health office, which may undertake further investigation and recommend additional action.

A form for reporting accidental death is presented in **Appendix H**.

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Eleven. Mobile Outreach Services¹

Background

Health services are often not readily available in rural areas. To make voluntary surgical contraception services available to as many people as possible, mobile outreach services or camps have been introduced in a number of countries. In some countries, mobile surgical teams are deployed to provide services on a periodic basis. Use of mobile teams allows a program to offer sterilization to address the unmet need for services in areas where clients live a great distance from fixed facilities. The use of outreach services is one of the high-impact practices that can be implemented for PM.

There may be several types of camps used for provision of VS services. A trained surgical team from outside the district may travel to a district hospital where these services usually are not provided, and offer PM procedures for a limited period of time. In another type of camp, a team from the district hospital may travel to community and primary health centers within the district to provide services on a fixed day of the week. In still a third type of camp, non-health care settings such as community centers and schools may be used temporarily as camp settings (World Federation 1988).

The provision of PM services in camp settings has been widely accepted in some countries and is generally believed to be of high quality. Studies have shown that mobile settings can achieve the same level of safety and quality of care as permanent facilities (Siswosudarmo 1991; Thapa and Friedman 1998).

It is important to institute procedures for ensuring that high quality is maintained. Quality standards applied to camps should be at least as strict as those for fixed sites, but 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 PM 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. The standards for mobile services should be reviewed with all team members and used as the basis for training and supervision (World Federation 1988).

Mobile outreach services should work in close cooperation with existing permanent services and local providers so that clients can be readily referred to them for emergency and routine follow-up care. Providers who will provide follow-up care of PM recipients must have received an orientation to their follow-up role. In addition, clients who come in for sterilization services may need to be referred to local providers and facilities to meet their other health care requirements (Bakamjian and Harper 1997).

Mobile services can be an important first step in bringing PM to new areas. But as demand in an area grows, the health care system should review the feasibility of establishing PM services at fixed sites. Ideally, the provision of mobile services should be temporary, and PM services should increasingly be offered at permanent health care facilities that are equipped and staffed to give clients more comprehensive care.

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

Planning and Coordinating Mobile Outreach Services

The team must have established coordination with the district or primary health care centers in the area. The local backup facilities must have the supplies, equipment, and trained and experienced staff necessary to handle any complications that occur. These facilities should be prepared to receive clients from the camps if additional emergency backup is needed. Coordination with local facilities also will make it possible for clients who need continued medical treatment after emergencies to receive that care (World Federation 1988).

The following actions will help in planning and coordinating services:

- Define roles and responsibilities of both the host and the mobile services team,
- Coordinate with the host site to allow for preparation to mobilize the community and generate demand,
- Prepare the facility and other stakeholders to support the outreach, and
- Conduct initial education and counseling of potential clients and schedule their participation in the outreach service.

Follow-Up Care

Clients who undergo PM procedures in mobile settings require the same follow-up 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 follow-up visits, or they may return on the day on which follow-up visits are scheduled. If this is not possible, clients can return for follow-up visits with local health care providers. In any case, local providers should be trained to give follow-up care if problems develop or questions arise. Referral centers should be identified for follow-up 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 center.

Staffing Mobile Facilities

Service providers who offer mobile outreach services should be the most skilled and experienced staff 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 (World Federation 1988). Nurses who work as members of mobile teams should have operating room 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 are desirable in camp settings. No training of service providers should be conducted in mobile sterilization camps.

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

Counseling

Counseling and client education often are performed by local health care workers before the camp is opened. Providing counseling before the camp opens allows for a more efficient flow of clients during the camp, as those clients who come will already have chosen PM.

All family planning clients should receive the same degree of counseling, regardless of the service delivery site. Counseling 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 counseled adequately. The final assessment of clients to make certain they are eligible and have made an informed choice for sterilization is the responsibility of the mobile team. (See **Chapter 2, Counseling**, for more information on the counseling process.)

Client Assessment

Client assessment for mobile PM 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 that 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.

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 screening by a trained health care provider as well as hemoglobin, urine, or other laboratory testing if indicated by the examination or the client's medical history. In addition, client assessment should include questions to ensure that the client has made an informed choice. If on assessment VS is found not to be suitable for a client, she should be referred for further counseling 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 pail and pitcher. If neither of these is available, an alcohol rub must be provided. Clients must change into clean operating room clothing prior to surgery and preparation of their skin should be emphasized. Staff must wear standard operating room gowns, masks, and caps. Sterile surgical gloves must be provided between cases. All instruments used for the procedure must also be processed between cases. Finally, waste must be disposed of according to infection prevention guidelines.

Anesthesia

Only local anesthesia must be used for minilaparotomy in camps. Light sedation may be an option and provided as needed. It is preferable that an anesthetist 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 crucial. Mobile teams must have all the supplies and equipment needed to manage surgical emergencies. In particular, every site must have:

- a functioning oxygen cylinder/tank,
- tubing and masks,
- drugs/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.

Planning

Providing PM 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

To ensure high quality of care at mobile sites, logistics should be monitored at all times. The services should be monitored from the perspectives 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 IPC practices.

References

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Appendix A. Emergency Preparedness¹

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 what their expected actions are. 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 area 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
- Blood pressure (BP) instruments
- Oral airways (two sizes)
- Nasal airways (two sizes)
- Suction machine with tubing and two traps
- Ambu bag
- Anesthesia 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
- Intravenous infusion sets and fluids
- Adhesive strapping
- Sterile laparotomy instruments

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

Emergency Drugs

The drugs listed below should be readily available in the operating room 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%)
- Furosemide
- 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*. New Delhi, India: Ministry of Health and Family Welfare.

Appendix B. Family Planning Counseling Guidelines

Section One: Framework for Family Planning Counseling

- Helping Clients Get the Most from Counseling
- Who Should Do Counseling
- Being a Good Counselor
- Counseling Process
- Steps in Family Planning Counseling
- Summary
- References

Section Two: How to Hold Group Discussions

Section Three: Balanced Counseling Strategy Plus (BCS+) Tubal Ligation Brochure and Counseling Cards

Section One. Framework for Family Planning Counseling

Helping Clients Get the Most from Counseling

Counseling is a vital, though often poorly performed, component of family planning services that helps clients arrive at an informed choice of reproductive options, including pregnancy and contraceptive use. If the client chooses to use a family planning method, counseling should also help the client (or couple) select a method she or he is satisfied with and prepare the client to use the method safely and effectively.

Because information about how to use a method may be new and sometimes difficult to understand, providers need to make it easy to remember. This can be a major challenge. Six key points in helping the client remember are:

- **Brevity**
Ask the client what she already knows about family planning and specific contraceptive methods. This assists the provider in determining the information the client needs and ensures that the most important matters are emphasized.
- **First things first**
Give the most important instructions first, that is, what the client has to do to use the method effectively.
- **Simplicity**
Use short sentences and simple words that clients understand. Avoid technical terms and scientific explanations.
- **Repetition**
Repeat the most important information and instructions. Ask the client to repeat the instructions. If available (and appropriate), give the client printed material and remind her of the instructions.

- **Organization**

Organize information into categories to make it easier to explain. Use memory aids such as acronyms to remind users of the important information they need to remember. For instance, the client using an IUD or after a minilap procedure needs to remember the warning signs of potentially serious problems for which she should return to the clinic as soon as possible.

- **Specificity**

Instructions should be specific and concrete rather than abstract and vague. For example, a vague instruction would be: “Dress the wound regularly.” The more helpful and specific instructions might be: “In the next 5–7 days, check daily that the dressing is dry. Change as needed when wet or soiled.”

Who Should Do Counseling?

Every health worker who talks to women (or couples) about contraception should understand why counseling is important and the role it plays in increasing the user’s satisfaction with a family planning method. The provider’s sensitivity to the needs of clients is important, especially for provider-dependent methods such as tubal ligation, vasectomy, the IUD, and contraceptive implants. Because provision of these methods requires medical personnel whose cultural backgrounds, social positions, and often gender may distinguish them from their clients, special efforts must be made to ensure that clients make informed, free choices.

Even though only a few staff may be involved in providing family planning counseling, 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.

Remember: The more people who have accurate information about family planning methods, the less likely it is that incorrect rumors will develop and spread.

Good counseling 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. By taking the time to train staff to counsel effectively now, the program will benefit in the future.

Being a Good Counselor

A good counselor knows that it will take a few minutes to put the client (or couple) at ease so that the client can talk about her beliefs and feelings about contraceptive methods. Taking time to do this will be cost-effective in the long run. For example, when counseling is done effectively, the client will be more satisfied with her choice and less likely to discontinue use after a short period of time.

A good counselor should provide information and reassurance to clients or couples so that they can make their own decisions about contraception and feel comfortable with their decisions. Sound knowledge and good communication skills are essential if the counselor is to discuss all available contraceptive methods adequately. These skills also help reduce method discontinuation due to ignorance or unnecessary anxiety.

The counselor must recognize the potential importance of the views of other members of a client’s family and should help the client deal with them. The counselor should also present the relevant information clearly and concisely. Overly technical information and academic language and jargon should be avoided. Questions, particularly about the negative aspects of the method, should be answered honestly.

A good family planning counselor:

- Encourages maximum participation and involvement by the client (or couple); helps the client to convince herself instead of trying to convince the client;
- Is an information giver, facilitator, and problem solver; suggests alternatives; helps the client to analyze and choose from known options; doesn't prescribe solutions; and helps a client understand that she is making her own choice or decision;
- Helps the client to reveal her personality and life situation rather than making assumptions; and
- Determines the client's fears, concerns, and other issues that could serve as barriers to effective learning.

General advice when counseling:

- Clients may become embarrassed discussing methods of family planning. Try to set the tone of the visit in a low-key, non-pressured manner. Assure the client (or couple) that the conversation is confidential.
- Encourage the woman to express her views by listening attentively and using nonverbal gestures, such as nodding, to encourage discussion.
- Be patient and never put pressure on the client to finish speaking.
- Use open-ended questions that require more than "yes" or "no" answer to increase the amount of information the woman gives to you.
- Be sensitive to any cultural and religious considerations and respect the woman's views.
- Repeat the most important information and instructions.
- Give the woman written information (if available and appropriate) to remind her of instructions.
- Finally, ask the client to repeat back to you the key points to assure her understanding.

Keys to Good Counseling

A good counselor:

- Understands and respects the client's rights
- Earns the client's trust
- Understands the benefits and limitations of all contraceptive methods
- Understands the cultural and emotional factors that affect a woman's (or a couple's) decision to use a particular family planning method
- Encourages the client to ask questions
- Uses a nonjudgmental approach that shows the client respect and kindness
- Presents information in an unbiased, client-sensitive manner
- Actively listens to the client's concerns
- Recognizes when she or he cannot sufficiently help a client and refers the client to someone who can
- Understands the effect of nonverbal communication

Counseling Process

Counseling is an ongoing process that should be included in all aspects of family planning services. The medical and technical information important to effective counseling should not be presented and discussed at just one point in the provision of services. Rather, good counseling techniques should be applied and appropriate technical information provided and discussed in an interactive and culturally appropriate manner throughout the client's visit.

Counseling enables the client to make a voluntary informed choice. Moreover, clients who have made an informed choice of method are more likely to be satisfied with it and, by talking about their positive experience, become the most effective means of promoting it (Gallen et al. 1987).

To counsel clients effectively, health workers must be properly informed about the contraceptive methods offered, and potential users must be able to make an informed choice from the methods available.

Information should be given to aid client choice, **not to persuade, press, or induce a person to use a particular method**. Furthermore, the decision to refuse a method offered, like the decision to accept it, must be based on adequate information. This implies an understanding not only of the effectiveness of that method, but also of its limitations and the alternative choices available. To achieve this objective, all health workers dealing with family planning clients should be trained in counseling techniques and develop good communication skills. In addition, appropriate educational materials must be produced for use by both **literate** and **non-literate** clients (Gallen et al. 1987).

In reviewing contraceptive alternatives with clients, health care workers should discuss all available methods in which the client is interested. Health care workers should be aware of a number of factors that may be important, depending on the method in question. These include:

- Reproductive goals of the woman (spacing or timing births);
- Subjective factors including the time, travel costs, pain, or discomfort likely to be experienced;
- Accessibility and availability of other products that may have to be procured to use the method;
- Benefits and limitations of the method;
- Reversibility;
- Long- or short-term side effects; and
- Need for protection against reproductive tract infections and other STIs including HIV/AIDS.

Steps in Family Planning Counseling

In a practical sense, the elements of counseling fit into the three major phases of providing family planning services, namely, initial counseling at reception; method-specific counseling prior to service provision; and follow-up counseling. Counseling should, however, be part of every interaction with the client. Because information and counseling preferably may come from more than one source, clinic staff need to work as a team. In addition, staffing patterns as well as client load may require shifting counseling activities to alternative staff or locations to meet varying needs.

Initial Counseling

At the time of client reception, initial counseling (or education) may be provided by any clinic staff trained in family planning counseling. It is intended to provide the client with general information on all methods and other services offered by the clinic. Such education can be effectively provided in a group setting. Initial counseling helps the client **identify** an appropriate method for herself or her partner. Counseling in waiting areas with individuals or groups provides:

- An explanation about what the client should expect during the clinic visit,
- Education about all available contraceptive methods and what method may be best for her,

- Education about the effectiveness of fully breastfeeding as a contraceptive method for clients up to 6 months postpartum, and
- Information that may help the client identify questions to ask the counselor on a one-to-one basis on the benefits of birth spacing or limiting.

Guidelines for conducting group sessions can be found in **Section Two** of this Appendix.

Method-Specific Counseling

Individual, method-specific counseling should take place in a private counseling area or an examination room in which counseling may be done. During this phase of counseling, the service provider should:

- Ask the client about her reproductive goals and assesses her need for protection against reproductive tract infections and other STIs including HIV/AIDS. This should help tailor the range of methods presented to her in more detail.
- Ask the client which method(s) interests her and what she knows about the method(s). This gives the service provider the opportunity to correct false rumors and misinformation, and to provide true information.
- Tell the client about and discuss in greater detail how the method(s) in which she is interested works, its effectiveness, benefits, and limitations.
- Help the client choose a method. Based on the client's needs and history, the service provider should advise the client on the suitability of any method in which the client expresses an interest. This process leads to selection of a contraceptive.
- Advise the client on the possible need for further medical assessment depending on the method selected.

Note: At this time, the service provider conducts any physical and laboratory investigations, if indicated, to confirm the suitability of the chosen contraceptive method.

After completing the client assessment, the selected contraceptive method is provided to the client if it is available or scheduled when necessary. If it is **not** possible to start the method at this time, the client should be given an alternative method or instructions on what to do so as not to become pregnant in the interim. If the method, in this case tubal ligation, can be provided at this time, the service provider should:

- Explain simply and clearly how the procedure will be performed and the next steps to prepare for the operation and possible problems.
- Provide the method.
- Prior to discharge, provide clear post-operative instructions, warning signs to return immediately, and the routine return visit a week after the operation.
- Ask the client to repeat all instructions to be sure she understands them.

In general, it is important for the service provider to recognize that clients are less likely to stop practicing family planning if they have access to providers with whom they can discuss issues and concerns regarding their chosen methods. When clients receive appropriate reassurance, expected symptoms and minor side effects do not lead to discontinuation.

Follow-Up Counseling

When providing follow-up counseling, providers and counselors need to listen carefully and be prepared to answer any questions. Doing this helps the client accept any side effects or other problems that may occur.

The specific objectives of follow-up counseling are:

- Review information provided previously.
- Find out whether the client is satisfied and is still using the method.
- Make sure that the client is using the method correctly and, if appropriate, repeat instructions for use.
- Provide supplies as appropriate.
- Answer the client's questions.
- Reassure and treat minor side effects (if possible).
- Check for any medical problems and refer for evaluation if necessary.
- Help the client change or stop a method if she desires.

Summary

Using these guidelines, clients can be adequately counseled. Health professionals, however, need to know what to do in each situation and how to adjust their counseling to each client. In particular, providers must be able to recognize the difference between serious problems that require referral and minor problems that are manageable.

Section Two. How to Hold Group Discussions

Hold group discussions to:

- Give information about family planning methods to more than one person per session, which saves time;
- Help people share their own experiences and support one another in their family planning decisions; and
- Give information that may provide answers to questions some people may be too shy to ask.

When to hold group discussions:

- While clients wait in clinics; or
- When community groups meet in schools, clubs, and other places.

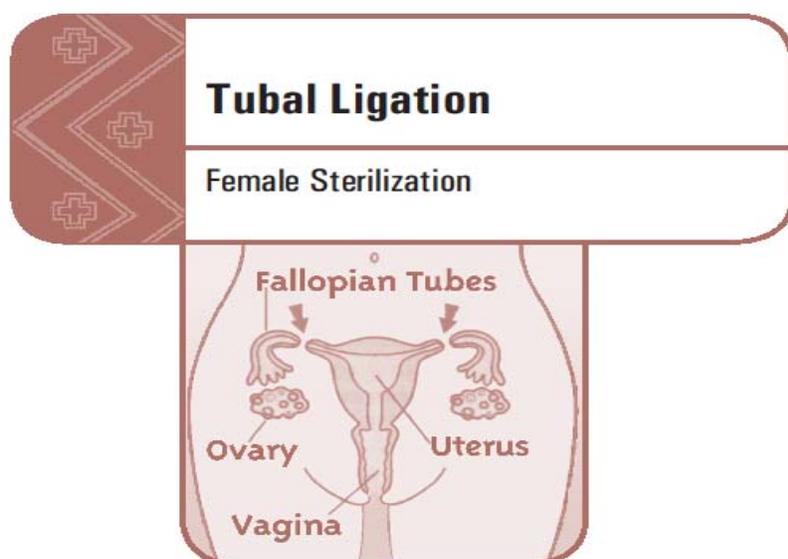
Suggestions for leading group discussions:

- Choose a quiet place with enough space. Avoid places where many people are coming and going.
- Limit groups to 10 people or fewer if possible. It is desirable that someone look after the children.
- Seat group members in a circle and sit with them.
- Introduce yourself and explain the subject of the discussion.
- Help group members feel at ease. This may be done by playing a short game or by asking group members to introduce themselves.
- Start the discussion by presenting clear information. For example, if the purpose of the discussion is to talk about family planning methods, begin by briefly describing the methods.

- Use words that all in the group can understand.
- Show samples of family planning supplies when you talk about them. Let group members hold them and look at them.
- Use flip charts, diagrams, or posters to help show important points.
- Ask many questions. Ask them in a gentle way. Encourage group members to talk with each other about the questions.
- Encourage group members to ask questions.
- Ask group members to tell about their own experiences with family planning.
- Summarize important points during the discussion and again at the end.

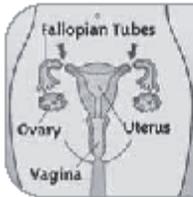
Section Three. The Balanced Counseling Strategy Plus¹

Tubal Ligation Brochure



Balanced Counseling Strategy Plus (2nd Ed.)

¹ Source: Population Council. 2012. *The Balanced Counseling Strategy Plus (BCS+): A Toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings*, 2nd ed. Washington, DC: Population Council.
<http://www.popcouncil.org/research/the-balanced-counseling-strategy-plus-a-toolkit-for-family-planning-service>.



Tubal Ligation

Female Sterilization

General information:

- Permanent method for women who do not want more children.
- Involves a surgical procedure. There are both benefits and certain risks in the procedure.
- Protects against pregnancy right away.
- Safe for a woman with HIV/AIDS, even if she takes antiretroviral (ARV) medicines.
- Does not protect against sexually transmitted infections (STIs), including HIV.

Effectiveness for pregnancy prevention: Pregnancy rate after the procedure is:

- In first year — Less than 1 pregnancy per 100 women (1%)
- Over 10 years — 2 pregnancies per 100 women (2%)

How method works:

- A trained provider makes a small incision on your abdomen. S/he then ties off (or cuts) the two fallopian tubes. These tubes normally carry eggs from the ovaries to the uterus.
- With the tubes blocked, the eggs cannot move down the tubes. They cannot meet with the man's sperm.
- The method is intended to be permanent.

Important facts:

- No need to worry about contraception again. The method is very effective.
- Easy to use, nothing to do or remember.
- Does not affect sexual desire.
- Complications of surgery and anesthesia are possible. But they are uncommon and extremely rare.
- Special arrangements are needed to perform a tubal ligation on a woman with AIDS.
- Always use male or female condoms to prevent HIV and other STIs.

Method not advised if you:

- Are pregnant.
- Are depressed.
- Have certain medical conditions that make it necessary to delay the procedure.

Side effects: None**Health Benefits:**

- Protects against risks of pregnancy and pelvic inflammatory infections (PID).
- May help protect against ovarian cancer.

Informed consent:

- Informed consent is required for this method.
- Before you give informed consent, you must understand the following points:
 - Temporary contraceptives are also available.
 - Tubal ligation is a surgical procedure.
 - There are certain risks of the procedure as well as benefits. (Both risks and benefits must be explained in a way that you understand them.)
 - If successful, the procedure will prevent you from ever having any more children.
 - The procedure is considered permanent and probably cannot be reversed.
 - You can decide against the procedure at any time before it takes place. You will not lose rights to other medical, health, or other services or benefits.
- Before the procedure you may need to sign a consent form. If you cannot read or write, someone will read the form to you and a witness can sign for you.

How to use:

- A trained provider gives you a pelvic exam.
- A trained provider performs the tubal ligation in a place that has the necessary supplies and equipment.
- The provider will give you light sedation to relax you.
- Usually, a local anesthetic is then injected in your abdomen. You stay awake during the procedure. This is the safest way to stop pain. Sometimes the provider uses general anesthesia. If so, you will be referred to a center that can provide it.
- You can usually leave in a few hours after the surgery.

Follow-up:

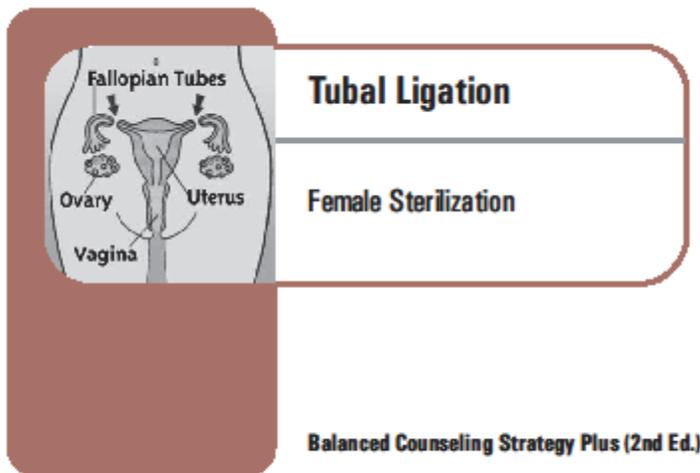
- After the procedure, rest for 2 days.
- Avoid vigorous work and heavy lifting for 1 week.
- Abdominal pain and swelling after the procedure is common. It usually goes away within a few days.
- Take paracetamol or ibuprofen in case of pain. Do not take aspirin. It slows healing. You rarely need a stronger pain reliever.
- Keep the incision clean and dry for 1 or 2 days. Avoid rubbing the incision for 1 week.
- Do not have sex for at least 1 week. If pain lasts more than 1 week, avoid sex until all pain is gone.
- If possible, after 7–14 days, return to the health care facility. The health care provider will check the incision site. S/he will look for signs of any infection and remove any stitches.

Return to the health care facility any time if:

- You have any questions or problems.
- You develop any health problems.
- You think you may be pregnant.



Balanced Counseling Strategy Counseling Cards



Tubal Ligation

Female Sterilization

Effectiveness for pregnancy prevention:

Pregnancy rate after the procedure is:

- In first year – less than 1 pregnancy per 100 women (1%)
- Over 10 years – 2 pregnancies per 100 women (2%)

- Permanent method for women who do not want more children.
- Involves a surgical procedure. There are both benefits and certain risks involved in the procedure.
- Protects against pregnancy right away.
- Safe for a woman with HIV/AIDS, even if she takes antiretroviral (ARV) medicines.
- Does not protect against sexually transmitted infections (STIs), including HIV.

1 – 2

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Appendix C. Surgical Handscrub

Supplies

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

Preparation

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

Table C-1. Procedure and Rationale for Using Surgical Handscrub

Procedure	Rationale
1. Remove all jewelry.	1. Jewelry harbors microorganisms and is difficult to clean.
2. Adjust water to comfortable temperature.	2. Comfort of surgeon, 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 soft 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 3–5 minutes (when using alcohol, pour or rub for 2 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.
7. Using different side of the towel for each arm, 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 D. Antiseptics

Many chemicals qualify as antiseptics. The following antiseptics are available in different parts of the world:

- Alcohols (60%–90% ethyl, isopropyl or “methylated spirit”)
- Chlorhexidine gluconate (4%) (e.g., Hibiclens, Hibiscrub, Hibitane)
- Cetrimide and chlorhexidine gluconate, various concentrations (e.g., Savlon)
- Iodines (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)

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 (e.g., 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, less drying to the skin, and less expensive than higher strengths. Because it is less drying to skin, ethyl alcohol may be more appropriate than isopropyl alcohol 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.”

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.
- Are relatively inexpensive and are widely available throughout the world.

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.
- Not good cleaning agents.

- Must be allowed to evaporate completely.

Chlorhexidine Gluconate

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 residual antimicrobial activity is dependent upon the concentration of CHG in the commercial product. As a result, 4% chlorhexidine is the recommended concentration. New 2% aqueous formulations and chlorhexidine (0.5%) in 60%–90% alcohol also are effective (Larson 1995).

Advantages

- Persistent action on skin (chemically active for 6 hours¹).
- 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.
- Not effective against tubercle bacillus, only fairly active against fungi.

Iodine and Iodophor Solutions

Iodine solutions are very effective antiseptics. Iodine solutions with 1%–3% 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 2 minutes of contact time to release free iodine**, which is the active chemical (Larson 1988). Once released, however, the iodine has rapid killing action. It is not usually necessary to dilute commercially available iodophors manufactured for antiseptics (e.g., Betadine or Wescodyne). Finally, iodophors are generally nontoxic and nonirritating to skin and mucous membranes.

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

Advantages

- Aqueous iodine preparations are inexpensive, effective, and widely available.
- Iodophors are nonirritating on skin or mucous membranes (unless the person is allergic to iodine), making them ideal for vaginal preparation before IUD insertion.
- They do not stain skin at 1%–3% concentration.

¹ For maximum effectiveness and residual activity, it must be used repeatedly.

Disadvantages

- Iodophors have little residual effect.
- Like alcohols, iodine and iodophors are inactivated by organic materials.
- Tincture or aqueous iodine 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.**
- Absorption of free iodine through skin and mucous membranes may cause hypothyroidism in newborn infants (Newman 1989).

Parachlorometaxylenol (PCMX or Chlorohexylenol)

Parachlorometaxylenol (PCMX) is a halogenated derivative of xyleneol that is widely available in concentration of 0.5%–4%. PCMX destroys microorganisms by breaking down the cell wall. It has low germicidal activity (Favero 1985) compared to alcohols, iodine, and iodophors and is less effective in decreasing skin flora than either CHG or iodophors (Sheena and Stiles 1982). Because it penetrates the skin, it may be toxic when applied to some areas of the body. Therefore, commercial products with PCMX concentrations above 4% should not be used. PCMX should not be used on newborn infants.

Note: In commercial preparations such as Dettol, which is expensive, the antiseptic and disinfectant activity is due primarily to the alcohol content, not the PCMX. A 60%–90% alcohol solution is equally effective and much less expensive.

Advantages

- Only minimally affected by organic chemicals.
- Residual effect persists for several hours.

Disadvantage

- Inactivated by soaps (nonionic surfactants) making it less useful for skin preparation.

Products That Should Not Be Used as Antiseptics

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 hexachlorophene does not reduce skin flora. Hexachlorophene has neurotoxic side effects and can penetrate the skin of newborn infants. It should never be used on broken skin or mucous membranes. Also, when used intermittently, bacteria may grow back in large numbers between uses (rebound growth).

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 (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 antiseptics, 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 fetuses, 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 E. Infection Prevention Processes for Handling Surgical Instruments and Other Items¹

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

- Decontamination,
- Cleaning, and either
- Sterilization or high-level disinfection (HLD).

Details on how to process instruments and other items are provided in this appendix.

The sequence for performing each of these processes is summarized in **Tables E-1** and **E-2**.

Table E-1. Infection Prevention Guidelines for Processing Instruments and Other Items

WASTE DISPOSAL AND DECONTAMINATION

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

STEP 2: Fully submerge 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. (This step is necessary to help prevent transmission of HBV and HIV/AIDS to clinic staff.)

STEP 3: Decontaminate all surfaces (such as the OR table, instrument stands, and OR lamps) that could have been contaminated by blood or other body fluids by wiping down with chlorine solution.

STEP 4: Immerse both gloved hands in the bucket containing 0.5% chlorine solution and then carefully remove gloves by turning them inside out. Place them in the leakproof container or plastic bag.

CLEANING AND RINSING

STEP 5: 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, rinsed with clean water, and dried by air or machine.

STERILIZATION

Instruments and surgical drapes should be sterilized by autoclaving. If necessary, metal instruments can be sterilized by dry heat.

Steam sterilization: 121°C (250°F) at 106 kPa (15 lbs/in²) pressure for 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry thoroughly before removing.

Dry heat:

170°C (340°F) for 60 minutes (total cycle time—placing instruments in oven, heating to 170°C, timing for 1 hour, and then cooling—is from 2–½ hours), or 160°C (320°F) for 2 hours (total cycle time is from 3–3½

¹ Adapted from: Tietjen L, Bossemeyer D, McIntosh N. 2003. *Infection Prevention Guidelines for Healthcare Facilities with Limited Resources*. Baltimore, MD: Jhpiego.

STERILIZATION (CONTINUED)

hours).

Note: Dry heat sterilization (170°C for 60 minutes) can be used only for metal or glass instruments.

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

HIGH-LEVEL DISINFECTION

High-level disinfection by boiling, steaming or using chemicals is recommended if sterilization is not possible. Surgical (metal) instruments should be steamed or boiled for 20 minutes and allowed to dry.

Alternatively, instruments can be soaked for 20 minutes in 2%–4% 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 1 week in a clean, dry high-level disinfected container with a tight-fitting lid or cover.

Table E-2. Steps in Processing Surgical Instruments and Other Items

Instruments/ Items	Process			
	Decontamination is the first step in handling used items; it reduces risk of HBV or HIV/AIDS.	Cleaning removes all visible blood, body fluids, and dirt.	Sterilization ^a destroys all microorganisms, including endospores.	High-Level Disinfection destroys all viruses, bacteria, parasites, fungi, and some endospores.
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 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: Dry heat for 1 hour after reaching 170°C (340°F), ^c or Autoclave at 121°C (250°F) and 106 kPa (15 lb/in ²) for 20 minutes if unwrapped, 30 minutes if wrapped. For sharp instruments: Dry heat for 2 hours after reaching 160°C (320°F). ^c	Acceptable: Steam or boil for 20 minute. Chemically high-level disinfect by soaking for 20 minutes. Rinse well with boiled water and air dry before use or storage.
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.	Preferable: Dry heat for 1 hour after reaching 170°C (340°F), ^c or 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.	Acceptable: Boil container and lid. If container is too large: fill container with 0.5% chlorine solution and soak for 20 minutes. Rinse with water that has been boiled for 20 minutes and air dry before use. High-level disinfect when empty or contaminated, or weekly.

Adapted from: Perkins 1983.

^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 (e.g., scalpels) should **not** be sterilized at temperatures above 160°C, to avoid dulling them.

Decontamination

Decontamination makes objects safer to be handled by staff **before** cleaning. It 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 (WHO) 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 E-3 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 E-1**.

Table E-3. Preparing Dilute Chlorine Solution from Liquid Bleach (Sodium Hypochlorite Solution) for Decontamination and HLD

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

^a Read as one part (e.g., cup or glass) concentrated bleach to x parts water (e.g., JIK (0.5% solution)—mix 1 cup bleach with 6 cups water for a total of 7 cups).

^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 E-1. Formula for Making Dilute Chlorine Solution from Concentrated Solution

- Check concentration (% concentrate) of the chlorine product you are using.
- Determine total parts water needed using the formula below.

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

- Mix 1 part concentrated bleach with the total parts water required.

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

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

Step 2: Take 1 part concentrated solution and add 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 E-4**. The formula for making a dilute solution from a powder of **any** percent available chlorine is listed in **Figure E-2**.

Table E-4. Preparing Dilute Chlorine Solution from Dry Powder

Available Chlorine Required	Grams per Liter of Water	
	0.5%	0.1% ^a
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
NaDCC-based tablets (1.5 g of available chlorine per tablet)	4 tablets/liter	1 tablets/liter

Adapted from: WHO 1989.

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

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

STEPS

Determine concentration (% concentrate) of the powder you are using.
Determine grams bleach needed (use formula below or **Table E-4**).

$$\text{Grams/Liter} = \left[\frac{\% \text{ Dilute}}{\% \text{ Concentrate}} \right] \times 1000$$

Mix measured amount of bleach powder with 1 liter water.

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

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

2. Add 14.2 grams (~14 g) to 1 liter 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. Personnel should wear gloves while handling soiled instruments, even after decontamination. Inexpensive utility gloves work well for this task.

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, 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, health workers must take extreme care 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 that can interfere with chemical disinfection.

Sterilization

Instruments and other items, such as 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 autoclave (high-pressure steam), dry heat, or 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 non-electric steam autoclave using kerosene as a heat source.

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 container!

Dry-heat sterilizers are good in humid climates but need a constant supply of electricity, making them impractical in many remote (rural) areas. Furthermore, dry-heat sterilization can be used only with glass or metal objects—other substances, such as plastic and rubber, will melt and could burn. (Other instruments with cutting edges should be dry-heat sterilized at temperatures not higher than 160°C/320°F; otherwise, the sharpness of the cutting edges will be destroyed.) The standard conditions for sterilization by steam or dry heat are shown in the following box.

Standard Conditions for Heat Sterilization

Steam sterilization: Temperature should be 121°C (250°F); pressure should be 106 kPa (15 lb/in²); 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry before removing.

Note: Pressure settings (kPa or lbs/in²) may vary slightly depending on the sterilizer used. Whenever possible, follow manufacturer's recommendations.

Dry heat: 170°C (340°F) for 1 hour (total cycle time—placing instruments in oven, heating to 170°C, timing for 1 hour, and then cooling—is from 2–2½ hours) or 160°C (320°F) for 2 hours (total cycle time is from 3–3½ hours).

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 8–10 hours in a 2%–4% 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, that cannot be heated. Because glutaraldehydes and formaldehyde leave a residue on treated instruments, they should be rinsed with **sterile** water (which can be prepared only by autoclaving). (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. When using either formaldehyde or glutaraldehyde, health workers should wear gloves, protect their eyes, limit exposure time, and use both chemicals only in a well-ventilated area.

High-Level Disinfection

When sterilization equipment is neither available nor 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^a

- 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 with water.
- Do not add anything to the pot after the water begins to boil.

^a An IPAS report documented that the interior temperature of a plastic cannula floating on the surface of boiling water reaches a temperature of 96–98°C in less than a minute (IPAS 1993). For items that float (e.g., MVA cannulae or rubber items), it is not absolutely necessary that they be fully covered by the water to achieve HLD.

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 E-5 provides guidelines for preparing and using these chemical disinfectants.

Table E-5. Preparing and Using Chemical Disinfectants

Chemicals for Sterilization or High-Level Disinfection										
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}
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

Adapted from: Rutala 1993.

^a All chemical disinfectants are heat- and light-sensitive and must be stored appropriately.

^b Always check manufacturer's instructions for when to discard.

^c See **Tables E-3** and **E-4** for instructions on preparing chlorine solutions.

^d Corrosive with prolonged (> 20 minutes) contact and/or concentrations > 0.5% if not immediately rinsed with boiled water.

^e Different commercial preparations of Cidex and other glutaraldehydes are effective at lower temperatures (20°C) and for a longer activated shelf life.

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

Chlorine solutions (0.1%) 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 lose their effectiveness with time, 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 (2%–4%), 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.

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 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 burying.²

Note: Do not reuse plastic containers that originally held glutaraldehydes or formaldehyde.

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 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)

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.

- 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 F. Decontaminating and Cleaning Instruments and Linens¹

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 a face 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 that are to be boiled or steamed.

STEP 6: Proceed with sterilization (if available) or HLD by steaming, boiling, or soaking in a chemical disinfectant (see **Appendix E**).

Disposal of Needle and Syringe

STEP 1: Do **not** recap needle or disassemble needle or syringe.

STEP 2: 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 can 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.

¹ Adapted from: Tietjen L, Bossemeyer D, McIntosh N. 2003. *Infection Prevention Guidelines for Healthcare Facilities with Limited Resources*. Baltimore, MD: Jhpiego.

STEP 3: When the container is three-quarters full, seal and either burn or bury.

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** because repeated soaking of linens in chlorine solution will cause the fabric to deteriorate more quickly.

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.²

STEP 2: Wash the **entire item** in water with liquid soap or detergent to remove all contamination, even if invisible.

Remember: Never wash only the bloody or wet areas of linen or drapes.

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.)

STEP 6: If sterile linens are required, sterilize wrapped packs as discussed in **Appendix E**.

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., contraceptive implants insertion and removal).

Sterile or clean linens should be stored in a clean, dry space that is free of mold, dust, and insects, preferably in a closed cabinet and not near sinks or areas that are frequently mopped. Air should circulate between the items in the storage area and the supply should be rotated (first-in/first-out).

Reference

Tietjen L, Bossemeyer D, McIntosh N. 2003. *Infection Prevention Guidelines for Healthcare Facilities with Limited Resources*. Baltimore, MD: Jhpiego.

² If there are blood- or mucus-stained areas on the linens, wet with a small amount of 0.5% chlorine solution prior to taking them for washing.

Appendix G. Pharmacology of Drugs Relevant to Local Anesthesia¹

Drugs Available in All Centers

Lidocaine Hydrochloride

Other names: Xylocaine®, Lignocaine

Action: Local anesthetics 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 anesthesia, allergic reactions to the amide-linkage drugs, such as lidocaine and bupivacaine, are exceedingly rare. In fact, it is questionable whether true anaphylaxis to lidocaine given without epinephrine has ever been shown.

Dosage: The usual dose for local infiltration of a minilaparotomy incision site is 20 ml of 1% lidocaine. The maximum safe dose of 1% lidocaine without epinephrine is 3 mg per kg of body weight. For a woman weighing 40 kg (88 lb), this is equivalent to 120 mg, or 12 ml, of 1% lidocaine (or 6 ml of 2% lidocaine).

Regimen: Through a single incision site, the doctor should locally infiltrate 1% lidocaine 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 lidocaine can be used to augment the anesthesia block as needed.

One may elect to use 0.5% lidocaine 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 3 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 lidocaine 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.

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.

Meperidine Hydrochloride

Other names: Pethidine, Demerol

Action: Meperidine is a narcotic analgesic similar to morphine, used for preoperative medication as an adjunct to local anesthesia and for the relief of pain that might result from the procedure.

¹ Adapted from: Philippine Family Planning Program. 1993. *Guidelines: Minilaparotomy with Local Anesthesia*. Manila, The Philippines: Family Planning Service, Department of Health; and Physicians' Desk Reference. <http://www.pdr.net/browse-by-drug-name>.

Dosage: The usual adult dose for analgesia as a preoperative medication for minilaparotomy under local anesthesia is 50 mg, given intravenously. If the client is experiencing pain during the procedure, the staff may administer an additional dose, up to 25 mg.

The initial dose of 50 mg should be reduced by one-half (down to 25 mg) for clients weighing less than 35 kg (75 lb).

Regimen: Before surgery, with the client on the operating table, the staff should give half of the drug intravenously over a period of 10–30 seconds, and note any negative effects. If there are none, the staff should give the remaining dose over another period of 10–30 seconds. If the client becomes excessively drowsy after the first half of the dose, the staff should not inject the second half.

Warnings: Respiratory depression, hypotension, and profound sedation or coma may result when meperidine is combined with a sedative, such as diazepam or midazolam, as is often the case for minilaparotomy under local anesthesia.

Only persons specifically trained in the use of intravenous medications, in monitoring anesthesia, and in the management of the respiratory depression that may result should administer intravenous meperidine.

Rapid intravenous injection of meperidine increases the incidence of adverse reactions.

Like other narcotics, meperidine may produce orthostatic hypotension in ambulatory patients. Clients may experience side effects when starting to ambulate.

The most frequently observed reactions include lightheadedness, dizziness, sedation, nausea, vomiting, and sweating. These adverse reactions may be alleviated if the patient lies down for a longer period.

When meperidine is used intravenously, naloxone, oxygen, and resuscitative equipment should be readily available.

Treatment of overdose: The staff should administer support oxygen, intravenous fluids, vasopressors, and other supportive measures as indicated. As a specific antidote, the staff should give an immediate intravenous dose of naloxone, 0.4 mg. It may be repeated every 2–3 minutes as needed. Therapy may need to be reassessed if no response is seen after a cumulative dose of 10 mg.

Pentazocine

Other name: Talwin

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 2–3 minutes and lasts up to 4 hours. When given intramuscularly, its onset of action is within 15–20 minutes.

Dosage: The usual adult dose is 30 mg, which is usually as effective as morphine 10 mg or meperidine 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 central nervous system (CNS) depressants with parenteral pentazocine may produce 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 anesthesia, 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 1 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 anesthesia, 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 1-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 anesthesia 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 anesthesia 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 anesthesia 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 giving the drug intravenously, the staff 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, Lethidrone

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 2 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 anesthesia, depending on the dose. It produces a trance-like 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 the client's weight and condition.) This provides a duration of 10–15 minutes of analgesia.

For general anesthesia, 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 doctors experienced in administering general anesthesia, 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.

References

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

Physicians' Desk Reference. <http://www.pdr.net/browse-by-drug-name>.

Appendix H. Reporting Severe Adverse Events and Accidental Death

Severe Adverse Events

All **severe adverse events** (SAE), including death, that occur during *training, service delivery, and other related medical or surgical activities* should be reported.

The mechanism, outlined here, is by design optimized to protect client confidentiality and privacy. It is recognized that reports might be required by in-country institutions such as Ministries of Health and donor organizations.

Below is the definition of a severe adverse event that must be reported.

Severe Adverse Event is defined as an injury related to clinical management (medical or surgical interventions), in contrast to complications of disease. Clinical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Severe adverse events may be preventable or non-preventable.

All programs, field offices, and health care facilities should promptly report severe adverse events, including death, which occur under training, service delivery, and other related medical activities they support.

Reportable severe adverse events are considered ones that require continuing care for an injury or side effect related to a clinical service provided during activities. Minor adverse events and common complications are not reportable.

In addition, if a patient expresses dissatisfaction about any treatment outcome, and remains dissatisfied or concerned about perceived or actual severe adverse outcomes following clinical consultation, then such an event and the patient dissatisfaction should also be reported.

Note: All complications or side effects of clinical care are NOT reportable, but good clinical care requires that when complications arise, extra care and vigilance are mandatory, and good records must be maintained.

A sample form for reporting a severe adverse event is included at the end of this appendix.

Accidental Death

Although accidental death from ML/LA is extremely rare, all clinics must have a system in place for investigating and reporting a death if it occurs.

By carefully reviewing the circumstances and contributing factors that led to the death, health care providers and the supervising health agency may be able to learn from the incident and take steps that can prevent deaths or serious complications in the future. In addition, they will be better able to inform and assist the surviving family members.

Each clinic must follow the official system of its locality for reporting any serious complications or deaths related to voluntary sterilization. The clinic must take responsible for finding out, in advance, which agency

to inform, how soon, and by what method the report should be submitted, and what information the report must contain. To report accidental death, the clinic may use a document such as the following.

Section One. Generic Voluntary Sterilization Death Report Form

INSTRUCTIONS: Complete all parts of this form (print or type). When a response is unknown, enter “Not Known.” If there is not enough space for complete explanations, attach continuation sheets. Forward this report, along with pertinent medical records, by express mail within 48–96 hours (2–4 days) after the death to:

Medical Director or Associate Medical Director

[Name of Sponsoring Organization]

[Street Address]

[City, State, Country]

Telephone: _____ Fax: _____ E-mail: _____

If a postmortem examination is performed, the findings also should be forwarded to the above address when they become available.

1. Client Characteristics

Name: _____ Sex: Male Female
Age: _____ Height: _____ Weight: _____

Female Only:

Total number of pregnancies: _____ Number of abortions: _____
Number of live births: _____ LMP: _____

2. Dates

3. Date of Death _____

(Date of VS procedure): _____

(Date report submitted): _____

(Date report received): _____

4. Site of VSS Procedure

Name of facility: _____

Location: Urban Rural

Type of facility: Hospital Free-standing surgical center/clinic

Other: _____

5. Background of Health Care Provider (e.g., surgeon, anesthetist)

Name: _____

Title: _____

Medical training: MD or MBBS Specialist (specify): _____

Other (specify): _____

6. Anesthesia

Local General, intubated

Regional (spinal, etc.) General, not intubated

If local or regional anesthesia was used, was analgesia and/or sedation used?

Yes No (If Yes, indicate dosage (in milligrams) of each drug used.)

Diazepam : _____ mg

IM

IV

Pethidine : _____ mg

IM

IV

Other (specify) : _____ mg

IM

IV _____

7. Relevant Past Medical History

8. Preoperative Physical Findings

Pulse: _____ Blood pressure: _____ Hemoglobin/Hematocrit: _____

9. Type of Procedure

Minilaparotomy: Occlusion Method
 Pomeroy
 Ring
 Other (specify): _____

Laparoscopy: Occlusion Method
 Ring
 Electrocoagulation
 Other (specify): _____

Vasectomy: Standard (one or two incisions)
 No-scalpel

10. Timing of voluntary sterilization procedure (female voluntary sterilization only)

- Interval (not pregnancy related)
- 0 to 48 hours postpartum
- 3 to 7 days postpartum
- 8 to 27 days postpartum
- 28 days or more postpartum (interval)
- With caesarean section
- Postabortal (within 1 week of spontaneous or induced)
- Other (specify) _____

11. Was procedure done in conjunction with a second procedure?

Yes No (If Yes, give name of second procedure): _____

12. Complications and Treatment Administered

Complications encountered: None
 Before surgery
 During surgery
 After surgery

If any complications, explain each:

Treatment administered: _____

I3. Emergency Equipment Available at Facility Where Voluntary Sterilization Performed

Equipment:

- Blood pressure equipment
- Oropharyngeal airways (two sizes)
- Nasal airways (two sizes)
- Ambu bag with mask
- Suction machine with tubing and two traps
- Anesthesia face mask, tubing, and oxygen nipple
- Oxygen tank with reducing valve and flow meter
- Syringes and needles
- Intravenous infusion sets, IV fluids, and expanders
- Sterile or high-level disinfected laparotomy tray
- Medications for treating allergic reactions and adverse effects of medication/anesthesia agents used at facility

Note: A laryngoscope and endotracheal tubes are appropriate only when trained and experienced personnel are available to use them. A battery-operated light source (flashlight) also should be available for backup in case of electricity failure.

I4. Any Equipment Available That Was Not in Working Condition

No Yes (Please list and describe problem, if possible)

I5. Describe in detail, circumstances surrounding the death including treatment(s) and other measure(s) instituted (attach continuation sheets if additional space needed).

I6. Cause of Death

Presumptive: _____

Definitive: _____

If postmortem examination was done, give results:

17. In the opinion of the director of the facility where the surgery was performed, was this death preventable?

Yes No

(If Yes, what measures are being taken or will be taken to prevent a similar situation from occurring?)

Be specific:

18. Persons Interviewed/Contacted

(Please type or print names.)

Name: _____ Title: _____

(Name of director or in-charge of facility)

(Director's signature)

(Name of surgeon)

(Surgeon's signature)

(Name of doctor investigating the death)

(Doctor's signature)

(Director/Coordinator of sponsored training)

(Director/Coordinator's signature)

Section Two. Guidelines for Investigating a Voluntary Sterilization Death

If a medical review is requested by the sponsoring organization, the medical review team should conduct the investigation as soon as possible following the initial notification and formal report of the death, and should include the following:

- The team should hold interviews with:
 - Surgeon, anesthetist, operating room staff, and clinic director
 - Medical and paramedical staff involved in screening and postoperative care
 - Family members, field staff, and other doctors who may have seen the client (in cases where death occurred after discharge)
- The team also should review:
 - Client's admission record, medical history, physical examination notes, laboratory findings, surgical notes, record of anesthesia regimen, anesthesia notes, and record of the monitored vital signs
 - Documentation of the onset (time) of the complication(s) and its outcome
 - Re-admission record with all relevant data (if re-admitted)
 - Record from the referral hospital (if the client was treated in another facility)
 - Findings from the second surgery (if one is performed)
 - Postmortem findings (if available)
- Any site-related aspects associated with the complication must receive special emphasis during this review. For example, if the cause of death is surgical error, the investigator reviews surgical technique; if the cause is anesthesia-related, the medical review team reviews anesthesia regimen, practice, and monitoring. There must also be a review of any previous incidents of morbidity and mortality in which the service provider(s) or the service site have been involved.
- After collecting the required information, the medical review team will prepare a narrative report that includes findings, an analysis of the findings, the conclusion about the factors that caused the death, and recommendations for corrective measures.

Date of Event: _____ Date of Report Completion: _____ Date of Submission: _____

1. Describe the Serious Adverse Event (SAE):

2. Gender of client who experienced SAE: Male _____ Female _____

3. Name of client and contact information:

Name: _____

Address: _____

E-mail: _____

Phone/Mobile: _____

4. Date of birth (day/month/year): _____ / _____ / _____

5. Emergency contact:

Name _____

Address _____

E-mail _____

Phone/Mobile _____

Relationship to client _____

6. Name and location of facility where SAE occurred:

7. Name and location of facility where SAE managed:

8. Name and addresses of individuals involved in patient care when the SAE occurred (provider, trainer, preceptor, etc.):

9. Individual and institutional name and addresses of individuals managing the clinical care of the patient with SAE:

Facility: _____

Clinician(s): _____

10. Describe the clinical management of the severe adverse event (medical and or surgical interventions, length of hospitalization, medications prescribed, etc.):

11. Current status/condition of the client (please state whether management/treatment is complete in addition to clinical outcome of the patient **OR** if the patient is still being managed for sequelae of the SAE):

12. Was the potential for the severe adverse event discussed with patient before the medical/ surgical service?

- Yes
- No

If no, please explain. _____

13. Is the signed consent form attached?

- Yes
- No

If no, please indicate the reason. _____

14. List the medications the client was taking prior to onset of the SAE:

15. List all medications administered for management of the SAE:

16. Please indicate below what official of the Ministry and/or clinical site has been notified of the severe adverse event. (Provide name of person, title, contact address, phone, and e-mail address, and date of notification.)

Person: _____

Title: _____

Contact address: _____

Phone: _____

E-mail address: _____

Date of notification: _____

Name(s) and Signature(s) of Jhpiego Staff Person Filing This Report

Contact information of person completing this form:

Name: _____

Address: _____

E-mail: _____

Phone: _____

Sponsoring organization project country: _____

Project name: _____

Funding source for the project: _____

Did you witness this incident?

Yes

No

PRINTED NAME

SIGNATURE

DATE

PRINTED NAME

SIGNATURE

DATE

For use by the Country Program Leadership

I have reviewed the report of the incident and confirm the completeness and accuracy of the patient record for internal reporting of a severe adverse event. The in-country team and I agree to respond to any question that might arise regarding this patient/client.

PRINTED NAME

SIGNATURE

DATE

Field Office Technical Director

PRINTED NAME

SIGNATURE

DATE

Country Office Director

