

IPPF Medical Bulletin

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IMAP Statement on voluntary surgical sterilization

Introduction

Surgical sterilization is well established for both men and women in some countries, and female sterilization has been the most common method of family planning for decades. According to United Nations estimates, in 2005, 262 million people of reproductive age were using sterilization as their method of contraception. Of these, 225 million relied on female sterilization and 37 million on vasectomy, accounting for 34% and 5.6%, respectively, of all contraceptive use.¹ Sterilization is an important component of a balanced contraceptive method mix. It offers highly effective protection against pregnancy, while carrying a very low risk of complications when performed according to accepted medical standards, and eliminates the need for long-term contraceptive supplies. Male and female sterilization can be performed as an outpatient procedure with safe and simple techniques. Since this form of contraception is intended to be permanent, informed choice is crucial.

Male or female sterilization does not protect against sexually transmitted infections, including HIV. Condoms should always be used correctly and consistently to prevent STI/HIV transmission, in addition to any other method of contraception.

Counselling

Participation of both partners in the counselling session is desirable, but should not be a condition for the provision of sterilization. When considering this method, a couple must also decide which partner would be sterilized. Vasectomy is simpler, safer, and probably more effective than female sterilization, and the male partner should be informed and encouraged to consider this option. Counselling should allow men and women to make informed choices with regard to their fertility and sexual and reproductive health, so it is important that alternative contraceptive options are offered.

Counselling should include:

- Information and provision of the long-acting reversible contraceptive (LARC) methods
- Emphasis on the intended irreversibility of the procedure
- The low probability of method failure (under 2%)
- The possibility of regret
- What happens during the operation, including types of locally available anaesthesia
- The information that sterilization does not protect against STI/HIV, and that condoms should be used correctly and consistently, in addition to other chosen methods of contraception, to prevent STI/HIV acquisition.

The decision to be sterilized should be made with sufficient time for proper consideration, not when the woman is under emotional stress, such as around the time of an abortion or immediately postpartum. Antenatal clients can be informed of this choice and other contraceptive methods, in order to allow sufficient time for the final choice after childbirth.

No man or woman should be forced to have sterilization – it should never, for example, be a precondition for providing an abortion service. Counselling should ensure informed and voluntary choice, and an informed consent should be obtained and documented prior to the procedure. Service providers should be aware of their national sterilization laws and legal consent requirements.

The client has the right to withdraw consent at any time prior to, or during, the procedure. The opportunity to review the decision and to change his/her mind before the procedure helps to ensure that the client's choice is voluntary and reduces the probability of regret after the operation. A waiting interval of a few days is recommended when possible, although it should not be a requirement. During this time, adequate contraception should be ensured.

Male sterilization

Surgical techniques

Traditional incision vasectomy (standard procedure) has been used for half a century and is a proven method that is simple, inexpensive and effective. Worldwide, an estimated 31 million couples currently rely on vasectomy for contraception. In this simple procedure, each vas deferens is either occluded or cut, so that spermatozoa cannot enter the ejaculate. It is usually performed using local anaesthesia. The operation is not effective immediately, so another method of contraception is needed until the semen is spermatozoa-free or, where semen analysis is not available, for three months.

A widely used modification of standard vasectomy is the **'no-scalpel' technique**. This technique avoids scrotal incisions and the need for skin-stitching. It is less invasive than the incision approach because tissue trauma or blood vessel injury caused by sharp or blind dissection is avoided. However, service providers, even those experienced in standard vasectomy, must obtain training before using the no-scalpel technique.

Efficacy

Vasectomy is a highly effective method of contraception when correctly performed and unprotected intercourse is avoided for three months after the procedure.² Pregnancy rates associated with vasectomy are reported as 0–2 per 100 operations, and most studies report failure rates of less than 1%.³ The efficacy of no-scalpel vasectomy has been reported as 98% at 24 months post-operatively.⁴ Spontaneous recanalization of the vas deferens is the most common cause of failure. It usually occurs when granulomas form at the vasectomy site, usually soon after surgery, occasionally after several years. Early recanalization is identified by post-vasectomy spermatozoa counts. The pregnancy rate due to late recanalization is approximately 1 in 2,000. Most failures occur early and are due to faulty surgical technique or the practice of unprotected intercourse while spermatozoa remain in the seminal fluid.

Complications

Immediate post-operative complications of vasectomy include bleeding, haematoma (collection of blood beneath the skin), and infection. Haematomas occur in approximately 2% of men. Studies consistently suggest that the incidence of haematoma is directly proportional to surgical skill and experience with the vasectomy procedure. The most significant, but rare, early complications are scrotal haematoma and local infection, which have been reported to occur in under 2% of procedures.

There are certain delayed complications, such as orchitis and granulomas, which are rare. There is no relationship between vasectomy and the risk of developing any of the urological cancers. The balance of the evidence suggests that vasectomy is not a risk factor for prostate cancer and does not cause testicular cancer. There is no evidence linking vasectomy to lower sexual performance.

Medical eligibility criteria

IPPF and other international organizations have collaborated with the World Health Organization (WHO) in the development of medical eligibility criteria for the use of contraceptive methods (last reviewed in 2008).

There is no medical condition that would absolutely restrict a person's eligibility for sterilization.

Table 1. Medical conditions requiring caution, delay, or special precautions for the provision of male sterilization

Caution	Delay	Special precautions
Conducted in routine setting with extra precautions	Until the condition is evaluated and/or corrected	Client informed of the increased risks. Should be performed in well equipped facility
*Young age	Local infection	Inguinal hernia
Depressive disorders	Untreated STI	Coagulation disorders
Diabetes	Filariasis, elephantiasis	AIDS-related illness
Previous scrotal surgery	Systemic infection, gastro-enteritis	
Large varicocele and hydrocele	Intrascrotal mass	
Cryptorchidism		

From WHO Medical Eligibility Criteria⁵

Female sterilization

Timing of the procedure

A woman can choose to be sterilized within one week of delivery or coincident with caesarean section (postpartum), within one week after abortion (post-abortion), or at any other time (interval). Postpartum sterilization is popular because it can be performed during hospitalization for vaginal delivery or caesarean section, saves a return visit, which may be inconvenient because of other commitments, and allows a single simultaneous recovery period for the delivery and surgical procedure. Otherwise, it is sensible to wait until at least six weeks postpartum, when the involution of the uterus is complete.

Surgical techniques for female sterilization

The two most widely used surgical techniques for approaching the Fallopian tubes are mini-laparotomy and laparoscopy. Both work by cutting or blocking the Fallopian tubes so that eggs released from the ovaries cannot move down the tubes and meet the spermatozoa.

Minilaparotomy

The Fallopian tubes are approached via a small abdominal incision and brought to the incision to be cut or blocked using surgical, electrocautery, or banding techniques. This is the method used for postpartum sterilization; it is also suitable for interval and post-abortion sterilization and appropriate for most family planning programmes.

Laparoscopy

Laparoscopy is a less invasive procedure, but requires costly equipment and specialized training. It is usually performed by an obstetrician-gynaecologist, in a hospital with specialized equipment and staff. The procedure involves several small abdominal incisions and the use of a small thin tube with a lens in it (laparoscope). The laparoscope enables the doctor to see and block or cut the Fallopian tubes.

Transcervical sterilization

This is a safe, effective, but very expensive method. Special coils with fibrosis-inducing fibres (e.g. Essure, TM) are placed in the Fallopian tubes at the cornua, under direct visualization using a hysteroscope (a small thin tube with a lens in it placed through the cervix to visualize the uterine cavity). Placement is accomplished under local anaesthesia in about 20 minutes. Since complete tubal closure occurs over a variable time period, an additional contraceptive method is required for at least three months after the procedure. A hysterosalpingogram (HSG), to confirm closure of the Fallopian tubes, is recommended three months after the procedure. There are ongoing studies to determine the need for HSG.

Other methods

Sterilization via colpotomy or culdoscopy has a higher rate of major complications (such as pelvic infection) than sterilization via the abdominal routes. Therefore, these methods are not recommended for routine use in surgical contraception services.

Non-surgical methods, such as the transcervical insertion of quinacrine, are experimental and should not be used.

Efficacy

Although tubal sterilization is a highly effective method, failures are more common than previously thought, and can occur for at least 10 years after the procedure. Over 10 years the rate is about 2 pregnancies per 100 women. If a pregnancy occurs after ligation there is an increased risk it will be ectopic, but ligation substantially decreases the overall risk of pregnancy, including ectopic. This possibility should be ruled out for all women who become pregnant after sterilization. Methods of tubal occlusion vary

in efficacy, but pregnancy rates are low for all techniques. Postpartum tubal ligation has been shown more effective than interval sterilization.⁶ Minilaparotomy and the Pomeroy technique (tubal ligation and resection) can be readily used in under-resourced settings. If facilities and trained personnel are available, laparoscopy and bipolar electrocoagulation could be used.⁷

Complications

Early complications for both minilaparotomy and laparoscopy include anaesthetic accidents, haematoma, wound infection, pelvic infection, and intraperitoneal haemorrhage. Occasionally, there is trauma to intra-abdominal viscera or blood vessels. With laparoscopy, puncture of large blood vessels and burns to the bowel during electrocoagulation are rare (but potentially life-threatening) complications.

Although changes in menstrual patterns have been reported subsequent to sterilization, there is no evidence that sterilization is a causal factor. Total menstrual blood loss is unaltered.

Non-contraceptive benefits

Female sterilization has been associated with a reduced risk of ovarian cancer and pelvic inflammatory disease.⁸

Medical eligibility criteria

There is no medical condition that would absolutely restrict a person's eligibility for sterilization.

Special situations

Abnormal vaginal bleeding

Irregular bleeding patterns are common among healthy women and should not be a reason to delay sterilization. However, if vaginal bleeding raises suspicion of pregnancy or disease, it should be fully investigated before surgery.

Malignant disease of the genital tract

Most women with cancer of the genital tract do not need sterilization, because the treatment for malignancies usually makes further pregnancies impossible. While undergoing treatment, women should discuss their fertility situation with the service provider and adopt a temporary method of contraception if required. Women with successfully treated premalignant disease of the cervix generally preserve their fertility and can have a sterilization procedure once treatment has been completed.

People living with HIV

People living with HIV should be offered the full range of locally available contraceptive methods. Contraceptive counselling should include information about the risk of mother-to-child transmission of HIV, which varies according to local availability of antiretroviral therapy; this may influence the client's choice concerning sterilization. Universal precautions should be applied for all sterilization procedures performed, irrespective of the HIV status of the person, and HIV testing should not be a prerequisite for the procedure. People who are HIV-positive and choose sterilization must not be denied the procedure. Whichever contraceptive method is chosen, the consistent use of condoms should be recommended to diminish the spread of HIV and reduce exposure to HIV and other STIs.

People with disabilities

For people with disabilities who are unable to make a decision for themselves, the possibility of sterilization should be considered carefully by the legal guardian and a team of professionals (e.g. psychiatrists, psychologists and social workers) with the guidance of local law and the professional medico-legal code. The sexual and reproductive health rights of these clients must be upheld.

Table 2. Medical conditions requiring caution, delay, or special precautions for the provision of female sterilization

Caution	Delay	Special precautions
Conducted in routine setting with extra precautions	Until the condition is evaluated and/or corrected	Client informed of the increased risks. Should be performed in well equipped facility
*Young age	Pregnancy	Uterine rupture or perforation
Depressive disorders	Active pelvic infection	Coagulation disorders
Diabetes	7 to 42 days postpartum	AIDS-related illness
Obesity > 30 kg/m2 BMI	Systemic infection, gastro-enteritis	Endometriosis
Hypertension	Severe anaemia	Diabetic neuropathy
History of ischaemic heart disease	Untreated STI	Complicated valvular heart disease
Uterine fibroids	Current ischaemic heart disease	Systemic lupus erythematosus with positive or unknown antiphospholipid antibody status, severe thrombocytopaenia, or on immunosuppressive treatment
Stroke (history of ischaemic cerebrovascular accident)	Current symptomatic gall-bladder disease	Pelvic tuberculosis
Uncomplicated valvular heart disease	Local infection	Hyperthyroidism
Current breast cancer	Acute viral hepatitis	Severe decompensated cirrhosis
Schistosomiasis with fibrosis of the liver	Iron deficiency anaemia with Hb < 7g/dl	Chronic asthma, bronchitis, emphysema or lung infection
Hypothyroidism	Acute bronchitis or pneumonia	Abdominal wall or umbilical hernia
Thalassaemia or sickle cell disease		
Hepatocellular adenoma or hepatoma		
Systemic lupus erythematosus without complications		
Severe nutritional deficiencies		
Kidney disease		
Previous abdominal or pelvic surgery		

From WHO Medical Eligibility Criteria⁵

Regret after sterilization

Studies indicate that regret is common among women sterilized when young, those with low parity or those who subsequently experience change in the family structure. Counselling of all men and women considering sterilization should aim to reduce the possibility of later regret by including sufficient opportunity for clients to discuss the subject.

Reversal

In many places, reversal of sterilization is either not available or prohibitively expensive. When reversal – male or female – is attempted, the probability of success is low. When counselling clients who are considering sterilization, it is important to emphasize that the procedure is intended to be permanent.

Service management issues such as facilities and equipment, clinical records, staff training and work load are addressed in more detail in IPPF's Medical and Service Delivery Guidelines (Chapter 8).

Statement developed by the International Medical Advisory Panel (IMAP) in October 1982 and amended by IMAP in January 1993, June 1999 and May 2009. This Statement is valid for the methods of male and female sterilization described above. IMAP reserves the right to amend this

Statement in the light of further developments in this field, when sufficient scientific information becomes available.

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The ethical responsibilities of conscience

Bernard M. Dickens

The protection of conscience

The 1948 Universal Declaration of Human Rights observes that individuals have a right to act and to refrain from action in accordance with their personal conscience. Legal force is given to this right through the UN International Covenant on Civil and Political Rights. Article 18(1) provides that:

Everyone shall have the right to freedom of thought, conscience and religion. This right shall include freedom to have or to adopt a religion or belief of his choice, and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in worship, observance, practice and teaching.

The expressed freedom of "conscience and religion" confirms that conscience is not dependent on religious belief, but exists as a moral conviction that may or may not coincide with a religious faith. Religion has no monopoly on conscience, or immunity from being held to ethical account for practices such as the common marginalization of women and their exclusion from positions of authority.

The Covenant makes clear that protection of an individual's conscience is not absolute, but that its exercise must respect the conscience of others. Article 18(3) accordingly provides that:

Freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health or morals or the fundamental rights and freedoms of others.

This provision requires that, just as health care providers anticipate respect for their own right of conscience, so they must demonstrate equal respect for their patients' right of conscience.

Professional ethics and conscience

Healthcare providers assume ethical responsibilities to the individuals and communities they offer to serve. This is often expressed as a covenant rather than a contract, although in many settings legal contracts may underpin relationships, such as between providers and patients, providers and healthcare facilities including hospitals and clinics, and providers and health-service funders, in the private and/or public sectors. Providers are engaged in covenants and contracts because of their professional training and qualifications, and their commitments to the ethics or codes of conduct of the authorities that issue their credentials, such as governmental licensing bodies and professional associations. Ethical practice usually includes a provider commitment to a requirement not to abandon patients who have been induced to rely upon their care.

An ethical challenge for providers is to balance professional responsibilities to patients with personal conscientious convictions. The challenge has come to focus on such issues as contraception, contraceptive sterilization, abortion, and some acts in end-of-life care. Since some leaders of religious hierarchies have condemned providers' participation in such services, the challenge to professionalism is not just conscientious objection to participation, but also to being conscientiously committed to undertake participation. For instance, a provider may consider that compliance with a patient's request for contraception, sterilization or abortion is appropriate in the patient's best interests when the provider is practising in a hospital whose religious affiliation makes it hostile to delivery of such care.¹

The legal standard of care to which professionals are held under contract and negligence laws is based on common practice among professional peers, without accommodation of personal beliefs. However, because of the human right to conscience, providers who have conscientious objections to participation in lawful procedures their patients require, including informing patients of medically indicated procedures, will be allowed to withdraw from such procedures, provided that they do so professionally, by referring their patients to non-objecting providers.

Conflict of interest

Providers who would serve their own spiritual interests, by objecting to participation in medical services professionally indicated in their patients' health requirements, face a conflict of interest. This is not unethical if the providers respond to it appropriately: by avoidance (not engaging in clinical medicine or counselling), or by due disclosure (patients know in advance which services will not be delivered by a provider).

Doctors and other health service providers are usually free to decline to accept applicants for care as their patients, on non-discriminatory grounds, without assuming any ethical or legal duty to refer them. Once a provider-patient relationship comes into existence, the provider cannot ethically withdraw from delivery of lawful care which the patient seeks, without referring the patient, in good faith and good time, to another provider who is able and willing to render the indicated care. The duty to make appropriate referral satisfies both the provider's right of conscientious objection, and the patient's right of timely access to requested lawful care.

The ethical duty, to disclose the conflict of interest arising from a provider's conscientious objection to participate in procedures within the scope of practice of professional peers, is owed not only to patients and prospective patients, but also to institutions such as hospitals and clinics in which the provider proposes to become professionally engaged. Such facilities cannot decline to recruit an applicant otherwise suitable for recruitment on the ground of the applicant's conscientious beliefs. That would violate antidiscrimination principles which protect freedom of conscience and religion. Since healthcare facilities' primary duties are to the populations they exist to serve, however, they must ensure sufficient staff to meet this mandate. To ensure timely discharge of their responsibilities, they may make willingness to participate in specified procedures a condition of recruitment. For instance, there must be staff serving in a rape-crisis centre who will provide emergency contraception services. Providers who would object to this procedure are ineligible for recruitment.

The scope of conscience

The right of conscientious objection is an important human right. As such, it serves human dignity. It is not available, however, to non-human agencies,

such as corporations and similar bodies, including healthcare facilities. This was emphasized in 2008 by the Constitutional Court of Colombia, which ruled that senior officers of a government hospital who had failed to provide a pregnant rape victim with the abortion to which she was legally entitled, because of staff members' conscientious objections, were in effect claiming their facility's right of conscientious objection. The Constitutional Court ruled that neither their hospital, nor they as administrative officers, could legally make such a claim, and ordered payment of compensation.²

Consistently with senior courts in other countries and with international human rights tribunals, the Court ruled that the protection of conscience was available to providers who would otherwise be bound to participate directly in procedures to which they objected, but not to peripheral actors. In the abortion context, for instance, objection is available primarily to gynaecologists, anaesthesiologists and operating-room nurses, because their involvement in procedures would be immediate, and also to general medical practitioners who object to writing prescriptions for medication abortions. It is not available, however, to general nurses who tend to patients' pre-operative care and post-operative recovery.

The European Court of Human Rights ruled that pharmacists could not invoke their conscience to refuse to fill prescriptions for contraceptives when they were the sole suppliers of prescription medications to a remote population in France.³ They could not exploit their monopoly on filling prescriptions to deny lawful products to those who rely on them for the drugs they need. Similarly, physicians cannot exploit their legal monopoly on provision of care with the effect of making care unavailable. They, pharmacists and similarly situated providers such as anaesthesiologists, can protect themselves from direct participation in procedures that offend their conscience only when, in good faith, they can refer those who depend on them to other available and willing providers of appropriate services, or to agencies that provide referral services.⁴

The abuse of conscience

A number of states in the U.S.A. have enacted laws that provide a wide spectrum of healthcare employees and related personnel, including ambulance attendants, hospital and clinic administrative and secretarial employees, and medical and nursing students, with rights of non-participation in any care or treatment rendered by healthcare providers or institutions to which they claim a conscientious objection, that they may invoke without prejudice, discrimination or disadvantage.⁵ On the final day of its authority, on 20 January 2009, the Bush administration in the U.S. brought into legal effect similar immunities of healthcare providers which all recipients of funds from the Department of Health and Human Services are obliged to grant. These federal provisions govern performing, participating in, referring for, learning, teaching or administering procedures for abortion, sterilization and contraception, and some forms of terminal care.

Under the cover of protecting healthcare providers against discrimination, these provisions were apparently motivated and supported in order to make such lawful procedures unavailable to dependent patients. One effect is that patients whose care is not religiously or morally contentious, such as safe removal of dead fetuses or of cancerous reproductive organs, may have access only to healthcare professionals who are untrained to perform or participate in necessary procedures, because they or their instructors object to some of the uses to which the training may be put. Such provisions expose the paradox of the unconscionable abuse of conscience.

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