Provincial Administration Western Cape:
Department of Health
Directorate: Programme Development

PROVINCIAL POLICY, STANDARDISED GUIDELINES AND PROTOCOLS ON THE MANAGEMENT OF STERILISATION SERVICES

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PROVINCIAL POLICY ON THE MANAGEMENT OF STERILSATION SERVICES

DEPARTMENT OF HEALTH: WESTERN CAPE PROVINCE

This Circular replaces Circulars H28/1999 and H29/1999 (Interim Policy Guidelines) dated 29 March 1999.

1. PREAMBLE

The Sterilisation Act, 1998 (Act No. 44 of 1998, Government Gazette No.19725) has reference. The Act provides an enabling and supportive legislative framework for sterilisation services in recognition of the individual's reproductive health rights enshrined in The Constitution of the Republic of South Africa, 1996 (Act 108 of 1996).

The National Contraceptive Policy Guidelines recommends that both male and female sterilisation services should be strengthened and expanded to be accessible and promoted to men and women who are certain that they do not wish to have more children.

Validated international data suggests expected lifetime failure rates of:

- 1 in 200 following female sterilisation
- 1 in 2000 following male sterilisation

There is no evidence that local failure rates exceed these levels. Lack of accurate data in recent years makes it impossible to confirm this. Over the past 10 years the total number of sterilisations in the Province has ranged between 9 500 and 11 000 per annum. A significant number of failures are therefore inevitable.

Allegations of negligence should be completely defensible provided that:

- Adequate counselling, including clear explanation about failure risk and irreversibility has occurred and this is documented in the case records.
- Informed consent has been explained and confirmed in writing.
- Adequately trained personnel using well-maintained equipment provide services.
- The operative procedure is clearly and comprehensively documented in writing.

2. AIMS OF THE POLICY

To provide effective guidance for health care workers to:

- Promote and enhance equitable, accessible, cost-effective and user-friendly sterilisation services.
- Ensure clients receive a high quality service based on the best evidence currently available and thus minimise the risk of litigation.

- Protect and promote personal human dignity and particularly for those individuals who are incapable of giving consent or are incompetent to give consent due to severe mental disability, by ensuring that decisions about sterilisation are made in a responsible and considerate manner.

3. MANAGEMENT OF PERSONS CAPABLE OF CONSENTING TO STERILISATION

- Any person 18 years or above who is capable of consenting may be sterilised at his or her request.

- A person capable of consenting may not be sterilised without his/her informed and written consent.

- Partner consent is not a legal requirement. However, individuals in a supportive relationship may choose to consult with each other.

- A person capable of consenting who requests a sterilisation must complete blocks A & B on the "Request for a sterilisation procedure" form (Annexure A, Form I, G.P.-S. 004-9035) in addition to signing the regular consent form. *That is, Form Code: 1904388: Consent To Sterilisation Procedure. Both these forms must remain in the client's facility folder.*

- However, the client must receive adequate counselling in order to make an informed decision before the above-mentioned documentation is completed. (See attached protocol for pre-sterilisation counselling).

- Each facility must submit a record of all the sterilisations performed at the facility on the attached Annexure F form on a monthly basis, via the Regional Health Information Component, to the Deputy Director: Reproductive Health, PO Box 2060, Cape Town, 8000. If no sterilisations were performed during a particular month, a Nil return is required.

Note: *Kindly <u>do not</u> forward the Annexure A form to the Regional health information section or to the Provincial Head Office.*

- Kindly ensure that all pregnancies occurring after sterilisation are reported on the attached prescribed form (Annexure G) and forwarded via the Regional Health Information Component, to the Deputy Director: Reproductive Health, PO Box 2060, Cape Town, 8000.

3.1 RECOMMENDATIONS FOR FEMALE STERILISATION SERVICES

A working group comprising of senior academic staff has compiled the following recommendations adapted from: *Male and Female Sterilisation, Evidenced-based Clinical Guidelines No. 4, Published by the Royal College of O & G in April 1999.*

The aim of these recommendations is to inform managers and service providers so that patients receive a high quality service based on the best evidence currently available, and risk of litigation is minimised.

3.1.2 INDICATIONS AND TIMING FOR STERILISATION

There are no absolute contra-indications to sterilisation of women provided that they voluntarily request the procedure, receive adequate counselling, are capable of understanding and granting informed consent, and are not acting under duress (pressures from partner, family, healthcare or social welfare providers). Provisions within the Sterilisation Act, Act 44 of 1998, cover cases where there is doubt about mental capacity to consent. (Refer to Management of Persons Incapable of Consenting - Point 4 of this document).

Sterilisation is indicated when a woman is certain that she does not wish to conceive in the future and/or who's health would be at risk if she became pregnant and who chooses a permanent method of contraception.

A recommendation to consider sterilisation by a healthcare professional should be part of a range of options offered. As a matter of good practice health professionals should concentrate on factual information, avoiding persuasion or any act that may be deemed coercive, however clear the advantage of their recommended option appears to be.

Tubal occlusion can be performed at any time in the menstrual cycle. Use of effective contraception before the procedure is advisable. A pregnancy test should be performed pre-operatively if pregnancy is suspected (missed or late menstruation).

Care should be exercised in discussions with those taking decisions during pregnancy, particularly considering the outcome of this pregnancy. Tubal occlusion may be performed immediately postpartum or at the time of elective caesarean section if this has been requested, discussed and agreed upon in advance. Otherwise an interval (> 6 weeks) after delivery is recommended before surgery. Sterilisation at the time of emergency caesarean section or ectopic pregnancy is less than ideal, resulting in higher failure rate. Informed consent for sterilisation on the prescribed form should be obtained and signed in addition to consent for other surgical procedure.

3.1.3 PRE-PROCEDURE REQUIREMENTS

Counselling should include discussion about the decision to end fertility with specific reference to age, parity, health of the woman and her children, the stability of her relationship and possible change of circumstances in the future. As a precaution against later regret, additional care must be taken when counselling those under 25 years with few or no children (2 or less) and those not currently in a stable relationship.

Partner consent is not a legal requirement. If a woman is in a relationship it is however preferable if her partner agrees with her decision to be sterilised. Participation of both partners in the counselling session is generally desirable.

A history should be taken and physical examination, including PAP smear, should be performed to assess suitability for anaesthesia and surgery and exclude other conditions that may indicate the need for alternative/additional surgical procedure (e.g. prolapse, fibroids).

3.1.4 SPECIFIC COUNSELLING AND CONSENT ISSUES

Informed consent in English, Afrikaans or Xhosa should be explained, confirmed in writing, and witnessed.

The doctor who performs or supervises a trainee performing a sterilisation, assumes responsibility and is accountable for the procedure even when discussion, examination and consent was undertaken by other healthcare professionals. The operating doctor will need to ensure that these processes have been completed thoroughly. Use of a standardised checklist can assist in this.

Information should be given and documented in patient records for each patient under the following headings:

- **Awareness of Alternative Contraceptive Methods**

  Women requesting sterilisation should know about alternative methods of long-term contraception including comparative failure rates and the advantages and disadvantages of each method. Several long-term reversible methods of contraception are available: These include: progestogen releasing intrauterine system (Mirena®) and IUDs containing more than 250mm^2 copper (Dalcept 375® a 5 year device, CuT380® a 10 year device) which have failure rates equivalent to female serialisation. Mirena® does have additional non-contraceptive advantages. Use of these as cost-effective alternatives to female sterilisation should be made available, promoted and utilised more widely. Both vasectomy and tubal occlusion should be discussed with all patients requesting sterilisation. Women in particular should be aware that vasectomy carries a lower failure rate in terms of post procedure pregnancies and less risk related to the procedure. They should be encouraged to discuss this option with their partner.

- **Reversibility**

  Women seeking sterilisation should be advised that the procedure is intended to be permanent. Reversal procedures are available in the public sector services but only in a few facilities so this option is limited.

- **Post Procedure Pregnancy Rate**

  The failure rate following the procedure should be carefully explained. The risk of pregnancy is approximately 1 in 200 in her lifetime. Pregnancy can occur several years after the procedure. The probability of pregnancy occurring is higher when the procedure is performed in young women (<28 years) and immediately post partum.

- **Risk of Ectopic Pregnancy**

  Women should be informed that post procedure pregnancies may be ectopic. They should be advised to seek medical advice promptly if they think they are pregnant, or have lower abdominal pain and vaginal bleeding.

- **Intended Method of Surgical Procedure**

  Women should be informed of the proposed route of access and method of tubal occlusion to be used and the need for alternative surgery if the intended method is not possible. (e.g. laparotomy)

- **Risk of Operative Complications**

  Women should be informed of the risks of anaesthesia and surgery and the chances of requiring laparotomy if there are complications.

- **Need for Contraception Before and After Surgery**

  Women must be advised to continue to use effective contraception until the day of the procedure. If the combined contraceptive pill is being used, the current packet should be finished. If progestogen only pill is being used this should be continued until seven days after the sterilisation procedure. If a woman has a copper IUD *in situ*, this can be removed at the next period. No precautions can be guaranteed to avoid pre-procedure fertilisation, which may be undetectable.

- **Effect on Long-term Health**

  Women can be reassured that there are no substantial long-term health risks from sterilisation procedures and that tubal occlusion is not associated with an increased risk of heavier or irregular periods.

All verbal counselling should be supported by good quality, accurate written information that is easy to understand.

Note: *A comprehensive Counselling Protocol for Voluntary Surgical Contraception (VSC) is included in this document for your convenience.*

3.1.5 FACILITIES, METHODS AND TRAINING

Laparoscopy is the method of choice in facilities that have the expertise to do it. Mini-laparotomy may be more appropriate in low resource areas, following pregnancy and after previous abdominal surgery. **Culdoscopy should no longer be used as a method of approach.**

Mechanical occlusion with either rings or clips is the method of choice for tubal occlusion. While rings are cheaper, and the device recommended as first choice in the Western Cape Province, clips may be associated with a lower failure rate. **Diathermy should not be used as the primary method of sterilisation but should be available as backup if mechanical methods of tubal occlusion are technically difficult or fail at the time of the procedure.** All equipment including diathermy should be properly maintained. There should be access to facilities to perform laparotomy safely in the event of an emergency.

General anaesthesia is more commonly used, however local anaesthesia is an acceptable alternative. Local anaesthesia should be promoted for the obvious advantages. Local tubal anaesthesia at the time of occlusion should be provided in addition to other forms of post-operative pain relief.

The procedure should be performed as a day case wherever possible.

If any doubt exists regarding the successful occlusion of the fallopian tubes he doctor must inform the patient of this. Confirmation should be obtained with a hystero-salpingogram six weeks following the procedure. The patient must be advised to use an adequate form of contraception until the results are available.

Women should be informed post-operatively about the actual method of tubal occlusion used, and of any complications that occurred during the procedure.

When a patient is admitted for a sterilisation and for whatsoever reason the operation is not carried out, the patient must be informed accordingly both verbally and in writing (copy of letter on file) and given a contraceptive method and rebooked if requested.

Doctors performing laparoscopy independently should be competent and capable of at least two laparoscopic methods of tubal occlusion, including diathermy if mechanical occlusion is not possible. Trainees should perform at least 25 supervised laparoscopic sterilisation procedures before operating without supervision. Doctors performing mini-laparotomy sterilisations should perform a minimum of 10 supervised procedures before independent practice should be considered.

3.1.6 FURTHER AUDIT

It is recommended that a provincial register and audit of pregnancy following sterilisation should be set up. Unit-based registers of sterilisation procedure failures would assist this.

3.2 MALE STERILISATION SERVICES

3.2.1 Introduction

Male sterilization, also called vasectomy, is a permanent surgical contraceptive method for men who do not want more children. The method entails a simple surgical procedure and is performed under local anaesthesia.

Male sterilization is not the same as castration. During vasectomy the testes are not removed. Vasectomy does not interfere with intercourse or affect a man's sexual desire or function. Male sterilization is generally safer, more effective and less expensive than female sterilization. It is a good way for men to share in the responsibility of contraception.

Table 1: Key Characteristics:

Effectiveness	Over 99.8% in the first year after the procedure.
Age limitations	No restrictions
Parity limitations	No absolute restrictions. Incidence of regret is highest among young men with few children so careful counselling is essential
Mode of action	Blockage of the vas deferens (ejaculatory duct) to prevent sperm being released in the ejaculate. Not effective immediately
Common immediate complications/problems	Minor postoperative short-term effects (e.g. discomfort for a few days and scrotal bruising and swelling); bleeding from wound; haematoma; wound infection
Effect on STI risk	Not protective
Drug interaction	None
Return to fertility	Never unless the vas deferens is reconnected

3.3.2 Non-Contraceptive Benefits

None

3.3.3 Medical Eligibility

No medical conditions prevent a man from having a vasectomy. Some conditions and circumstances, however, call for delay, referral or caution. In general these conditions fall into three categories: abnormalities of the genitalia that make the procedure technically more difficult or increase its associated risks; infections which must

be treated prior to the procedure; and certain systemic disorders which require special precautions or possible hospitalisation for the procedure. (See Addendum A-2)

3.3.4 Necessary Pre-operative Procedures

(a) Method-specific counselling

- As per attached counselling protocol.
- If possible, arrange for him to talk with men who have already had vasectomies.

(b) Screening

(As for female sterilization)

3.3.5 Post Operative

Management of Complications:

- Bleeding: control the bleeding
- Heamatoma: determine whether there is infection or an abscess. If there is an abscess, drain it. If there is no abscess or infection, advise warm pad and analgesia.
- Infection: clean if necessary and treat with antibiotics.

3.3.6 Follow-up

- After undergoing the vasectomy procedure it takes about 3 months or 20 ejaculations before the ejaculate becomes sperm-free (i.e. the man is sterile). Clients should be counselled to use a back up contraceptive method in the interim period. Semen analysis at 12 weeks is recommended.
- Clients should be advised to return to the clinic at any time, if they develop complications, have any health concerns, questions or need help.

Vasectomy does not protect against STI/HIV, if there is risk of STI/HIV, the correct and consistent use of condoms is recommended.

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4. MANAGEMENT OF PERSONS INCAPABLE OF CONSENTING OR INCOMPITENT TO CONCENT TO STERILISATION DUE TO SEVERE MENTAL DISABILITY (SECTION 3 OF THE STERILISATION ACT)

In terms of the Sterilisation Act, 1998 (Act No. 44 of 1998), the person in charge of a designated facility must, on the request for the sterilisation of a severely mentally disabled person, convene a panel to assess the appropriateness of the sterilisation.
Circular H29/1999 provided interim policy guidelines for the implementation of the Act and a provincial panel was convened for capacity building, as from March 1999.

4.1 REVISED POLICY GUIDELINES

After evaluation by the central panel and consultation with the regions, it has been decided to decentralise the sterilisation assessment panels, taking into account regional capacity to convene panels.

4.2 DECENTRALISED STERILISATION ASSESSMENT PANELS

Currently the sterilisation assessment panels have been decentralised as follows:

- Groote Schuur Hospital – for referrals from its drainage area,
- Tygerberg Hospital - for referrals from its drainage area, that is, part of the Metropole Region and the Boland/Overberg region for the present, until such time the Boland/Overberg Region has the capacity to convene a panel.
- West Coast/Winelands Region and
- George Hospital – for referrals from the South Cape/Karoo Region.

  Decentralisation within the region to facility level may occur according to the available capacity after consultation with the provincial monitoring committee.

  In cases of uncertainty a regional panel may refer the client to the Groote Schuur Panel for a second opinion.

4.3 PRIVATE FACILITIES

- In accordance with the Act, the manager of a designated private facility must upon request, as prescribed for sterilisation, convene a panel to assess the application. The members of the panel may not be employees of, or have financial interest, in that facility.

- Copies of the completed Annexure A, Form I and Annexure B, Form II must be submitted via the Regional Health Information Component, to the Deputy Director: Reproductive Health, PO Box 2060, Cape Town, 8000.

- Private facilities are also requested to kindly submit a record of <u>all</u> the sterilisations performed at the facility on the attached Annexure F form on a monthly basis, via the Regional Health Information Component, to the Deputy Director: Reproductive Health, PO Box 2060, Cape Town, 8000. If no sterilisations were performed during a particular month, a Nil return is required.

4.4 AIMS OF THE STERILISATION PANELS

The aims of the sterilisation panels are:

- To make well considered, high quality, legal decisions (in accordance with the Act and in the best interest of the mentally disabled individual), regarding sterilisation;
- To consider the difficult social circumstances and ethical issues regarding the mentally disabled individual when reaching a decision;
- To document these deliberations and decisions adequately;
- To simplify the application process and panel assessment as much as possible within the legal framework;
- To build capacity within regions for other health professionals to participate in panel assessments and to decentralise panels to facility level as the capacity increases.

4.5 APPLICATION AND ASSESSMENT PROCESS

- The parent, guardian, curator or spouse who requests the sterilisation of a person who is incapable of consenting due to mental disability or incompetent to consent due to mental illness shall complete blocks A and C of Annexure A, Form 1 (GPS 004-9035) (Appendix 1).

- The health care provider (doctor, community psychiatric nurse in a district or the hospital social worker (where available) or designated person(s) should complete the following:
  - Referral report (Annexure D), which include the following aspects:
  - Psychometric test findings if available;
  - Clinical summaries of admissions to psychiatric hospitals if relevant;
  - Social report, including, reports from schools attended if relevant;
  - Medical report (medical history and gynaecological examination and cervical smear for women) if relevant, and
  - Any other relevant information.

- The completed application forms are forwarded to the Medical Superintendent (designated convenor) of the relevant panel (Groote Schuur Hospital/Tygerberg Hospital/George Hospital or superintendent of the local designated hospital in the West Coast/ Winelands Region).

- The convenor convenes the panel to do the assessment.

- After the assessment, the decision of the panel, together with the completed documentation is returned to the convenor. The convenor must inform the referring agent of the decision and return the documents to the referring agent for further management, as applicable.

- The convenor or the referring agent (depending on local operational plans) arranges a date for the sterilisation operation when applicable.

4.6 CONSTITUTING THE STERILISATION PANEL

According to the Act the Panel must consist of:

- A psychiatrist, or a medical practitioner if no psychiatrist is available,
- A psychologist or social worker,
- A registered nurse.

4.7 RESPONSIBILITY OF THE CONVENER (HOSPITAL SUPERINTENDENT / FACILITY MANAGER)

The responsibility of the convener is to:

- Provide a venue for the panel assessment;
- Ensure that the mentally disabled person and the applicant are present for the assessment;
- Ensure that three copies of the documentation are available;
- Retain one copy of the documentation of the panel assessment;
- Sign Annexure A Form; block E, point 5
- Inform the applicant of the panel decision;
- Return one copy of the completed documentation to the referring agent.
- Ensure that the operation is arranged if relevant.
- Ensure that the Notification of Sterilisation (Annexure B, Form II) is completed in duplicate. Retain one copy and forward the other copy to:

  The Deputy Director: Reproductive Health
  PO Box 2060
  Cape Town
  8000.

4.8 RESPONSIBILITY OF THE STERILISATION PANEL

The responsibility of the sterilisation panel is to:

- Do the assessment and make a decision at the meeting, unless further information is needed;
- Document the interview process;
- Complete block D and E of Annexure A;
- Inform the convenor/superintendent of its decision;
- Retain one copy of the documentation in a central filing system;
- Take responsibility to obtain any further information, if required by the panel, to make a decision.

4.9 DOCUMENTATION

(a) Panel Assessment Documentation:

A copy of all the panel assessment documentation should be kept by:

1. The Facility Superintendent/Manager (Panel Convenor);
2. The Sterilisation Panel (central filing System);
3. Deputy Director: Reproductive Health
4. The Regional Office, if required.

(b) After the Sterilisation is performed:

Annexure B, Form II, must be completed in duplicate and submitted to the medical superintendent, who will forward a copy to the Deputy Director: Reproductive Health (refer to point 5).

NB The above-mentioned notification only pertains to the sterilisation of persons with a mental disability and is <u>not</u> necessary for persons capable of consenting to sterilisation.

(c) Failed Sterilisation:

In the case of any failed sterilisation, the form "Notification of Pregnancy after Sterilisation" must be completed and sent to the Deputy Director: Reproductive Health at the above-mentioned address.

4.10 AVAILABILITY OF FORMS

The forms are obtainable on request from:
Metropole Region, Supply Services, Private Bag X15, Parow, 7500

Telephone: (021) 918 1524/1558
Fax: (021) 945 1919

Some forms are available on the PAWC Intranet. (See the note at the bottom of this page).

4.11 DESIGNATED FACILITIES

Refer to Annexure E for a list of the facilities designated by the MEC for Health, where sterilisation of severely mentally disabled persons may be performed.

4.12 PUBLIC AWARENESS CAMPAIGN

Regions should conduct awareness campaigns around sterilisation aimed at:

- Families and care-givers of mentally disabled persons,
- Health Care providers at all health facilities.

4.13 MONITORING AND EVALUATION

- Previously, panel members and consultants have met twice a year to monitor and evaluate the functioning of the panel.
- In future these meetings will occur annually until further notice.

Kindly ensure that the revised Policy Guidelines are brought to the attention of all concerned and are implemented.

Note: *This and other Reproductive Health policy documents, guidelines and protocols can be found on the PAWC Intranet Website*: **http://pawcnet.wcape.gov.za/policies.asp** (*under Programme Development in the Reproductive Health section*).

Some of the forms, instructions to clients, etc. can be downloaded from this website.

An Afrikaans version of the document will be circulated in the near future.

HEAD OF HEALTH
Date:

FLOW CHART: APPLICATION FOR PANEL ASSESSMENT

Step 1

Ensure application documents are completed as follows:

- Request for sterilisation procedure (Annexure A, Form I);
- Referral report (Annexure D), which includes the following aspects:
  - Psychometric test findings if available;
  - Psychiatric report if relevant;
  - Social report, including school report if relevant;
  - Medical report (medical history and gynaecological examination and cervical smear for women) if relevant and
  - Any other relevant information.

Step 2

Refer for a Panel assessment appointment as follows:

Tygerberg Panel
Refer to:
- Social Worker

Tel: (021)-938 4164
Fax: (021)-931 1451

Groote Schuur Panel
Refer to:
- Secretary

Tel: 021-404 3175
Fax: 021-404 3004

W/W Panel
Refer to:
- Local Hospital Superintendent

George Hospital Panel
Refer to Regional Office:
Mrs. G Terblanch
Tel: (044) 874 2172
Fax: (044) 874 2151

NOTE:
- A legal guardian must accompany the client at all times.
- The responsibility for transport arrangements and cost rest with the referring agency.
- The referring agent will be notified to make an appointment for the operation if the panel approved the sterilisation.

ADDENDUM A-1

MEDICAL ELIGIBILITY CRITERIA FOR FEMALE STERILISATION

CONDITION	NEW EVIDENCE/COMMENTS
ACCEPT – There is no medical reason to deny the procedure to a person with this condition.	
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY	
➢ Age: any age >18 years during a woman's reproductive years	See also Caution category (for young age).
➢ Nulliparous or Parous ➢ Smoking –light or heavy smoker	Counselling requires special care to ensure that an informed choice is being made.
➢ **Gynae/Obstetric Conditions:** - History of ectopic pregnancy, gestational trophoblastic disease - Postpartum (<7 days or >42 days), postoperative - Breastfeeding	
- Heavy, light, prolonged or irregular menstrual bleeding	Sterilisation can be safely performed immediately postpartum.
- Severe dysmenorrhoea - Past PID (with subsequent pregnancy) - Breast disease, except current breast cancer	**There is no impact on lactation if local anaesthesia is used and special separation of mother and child is minimized.**
- Cervical ectropian/intra-epithelial neoplasia (CIN) - Benign ovarian tumours - Sterilisation concurrent with Caesarean Section	A careful pelvic examination must be performed to rule out recurrent or persistent infection and to determine the mobility of the uterus.
➢ **Cardiovascular:** - Major surgery without prolonged immobilization - Varicose veins - Superficial, thrombo-phlebitis - Personal/Family history of thromboembolic disorders (DVT/PE) (1st degree kin)	Concurrent sterilisation does not increase risk of complications in a surgically stable client.
- Known hyperlipidaemias	
➢ **Neurological Conditions:** - Headaches – any type	To reduce the risk of DVT/PE, early ambulation is recommended.

➢ **Chronic Diseases/Other Conditions:** - Diabetes - history of gestational disease or non-vascular disease - Thyroid disease (simple goiter) - Treated or asymptomatic gallbladder disease - Viral Hepatitis (carrier, not active case) - Schistosomiasis (uncomplicated) - Malaria - TB (non pelvic) ➢ **STIs:** - Within last 3 months - Vaginitis without purulent cervicitis - Increased risk of STIs ➢ **HIVAIDS:** - High risk of HIV - HIV positive	Routine screening is not appropriate because of the rarity of these conditions and the high cost of screening. Some types of hyperlipidaemias are risk factors for vascular disease. The category should be assessed according to the type and its severity. If blood glucose is not well controlled, referral to a higher-level facility is recommended Appropriate infection control measures, including universal precautions must be carefully observed. If no symptoms persist following STI Syndromic treatment, sterilisation may be performed. Routine screening is unnecessary. Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures. **The use of condoms is recommended following sterilisation.**
CAUTION – Conduct normally in routine setting, but with extra precautions	
➢ **Young Age** ➢ **Obesity: ≥** 30 kg/m^2 body mass index (BMI) ➢ **Gynae/Obstetric Conditions:** - Past PID (without subsequent pregnancy) - Current breast cancer	**New Evidence:** Studies show that up to 20% of women sterilised at a young age later regret this decision, and that young age is the strongest predicator of regret that can be identified before sterilisation. **Comments:** All women should be counselled about the permanency of sterilisation and the availability of alternative, long-term, highly effective methods. This is of extra concern for the young women. The procedure may be more difficult. There is an increased risk of wound infection and disruption. The condition may require general anaesthesia and may limit respiratory function.

- Uterine fibroids	Depending on the size and location of the fibroids, it might be difficult to localize the tubes and mobilize the uterus.
➢ **Cardiovascular conditions:**	
- History of hypertension/mild hypertension - BP<160/100 - History of ischemic heart disease or stroke (CVA) - Uncomplicated valvular heart disease	Blood pressure should be controlled before surgery. There are increased anaesthesia-related risks and increased risk of cardiac arrhythmia. Blood pressure may be very labile and difficult to control in the early postpartum period. Blood press must be monitored appropriately intra-operatively. The client requires prophalactic antibiotics.
➢ **Chronic diseases/other conditions:**	
- Diabetes insulin or non-insulin-dependent - Hypothyroid - Thalassaemia - Sickle cell disease -	High risk of complications associated with anaesthesia and surgery. With sickle cell there is an increased risk of pulmonary, cardiac or neurological complications and possible increased risk of wound infection.
- Moderate iron deficiency anaemia (Hb between 7 and 10 g/dl) - Mild cirrhosis (compensated), liver tumours, benign (adenoma) or malignant (hepatoma) - Epilepsy - Schistosomiasis with fibrosis of liver - Diaphragmatic hernia	Identify underlying disease. Both preoperative Hb level and operative blood loss are important factors in anaemic women. If peripheral perfusion is inadequate, it may decrease wound healing. Liver function and clotting might be altered. Liver function should be evaluated.
- Kidney disease	Liver function may need to be evaluated. For laparoscopy, the woman may experience acute exacerbation of symptoms induced by raising of the diaphram by pneumo-peritoneum, Trendelenburg position, and decreased venous return from gaseous compression of large vessels.
- Severe nutritional deficiencies ➢ **Concurrent elective abdominal surgery**	Blood clotting may be impaired. There may be increased risk of infection and hypovolemic shock. May cause baseline anaemia, electrolyte disturbances, peripheral neuropathy, and abnormalities in drug metabolism and excretion. There may be an increased risk of wound infection and healing.
DELAY – The procedure is delayed until the condition is evaluated and /or remedied. Alternative temporary methods of contraception should be provided.	

CONDITION	NEW EVIDENCE /COMMENTS
➢ **Gynae/Obstetric Conditions:** - Pregnancy - Postpartum (between day 7 and day 42) - Severe pre-eclampsia / eclampsia - Postpartum/post abortion, sepsis, or fever - Recent complicated delivery - Prolonged ruptured membranes (= >24 hours) - Severe ante- or post-partum/ post-abortal haemorrhage - Severe trauma to the genital tract at time of delivery or abortion - Unexplained vaginal bleeding - PID - current or within the past 3 months - Cervical, endometrial, or ovarian cancer - Malignant gestational trophoblastic disease	There is an increased risk of complications when the uterus has not fully involuted. **There are increased anaesthesia-related risks.** **There is an increased risk of postoperative infection.** There are increased risks of postoperative infection. Client may be anaemic and unable to tolerate further blood loss. There may have been significant blood loss and anaemia. The procedure may be very painful.
➢ **Cardiovascular Conditions:** - Current thromboembolic disorders - Ischaemic heart disease - Major surgery with prolonged immobilization	The treatment generally renders a woman sterile.
➢ **Chronic Diseases/Other Conditions:** - Symptomatic, current gall bladder disease - Active viral hepatitis	The woman is at high risk for anaesthesia- and surgery-related complications.
- Severe iron deficiency anaemia (Hb<7 g/dl)	The woman is at high risk for complications associated with anaesthesia and surgery. Appropriate infection control measures, including universal precautions, must be carefully

	observed.
- Abdominal skin infection - Acute lung disease (bronchitis, pneumonia) - Systemic infections or gastroenteritis - Emergency abdominal surgery (without previous counselling) or associated with infection ➢ **Current STIs including Purulent Cervicitis)**	The underlying disease should be identified. Both preoperative Hb level and operative blood loss are important factors in women with anaemia. If peripheral perfusion is inadequate, it may decrease wound healing. There is an increased risk of postoperative infection. The procedure should be delayed until the condition is remedied. There are increased risks in anaesthesia-related and other peri-operative risks. There are increased risks of postoperative infection, complications from dehydration, and anaesthesia-related complications. There is an increased risk of postoperative infection.
SPECIAL - The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate procedure and anaesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.	
➢ **Gynae/Obstetric Conditions:** - Fixed uterus due to previous surgery or infection - Postpartum/post-abortion uterine rupture or perforation - Endometriosis - Hernia (abdominal wall or umbilical) ➢ **Cardiovascular Conditions**: - Multiple risk factors arterial cardiovascular disease (such as older age, smoking, diabetes and hypertention) - Moderate to severe hypertension (BP>160/100) or vascular disease - Complicated valvular	**Decreased mobility of the uterus and bowel may make closed lapa-roscopy and minilaparotomy difficult and increase the risk of complications.** There may have been significant blood loss or damage to abdominal contents, which may increase risk of infection. If exploratory surgery or laparoscopy is conducted and the client is stable, repair of the problem and TL may be performed concurrently if no additional risk is involved. Hernia repair and TL should be performed concurrently, if possible. . The woman may be at high risk for complications associated with anaesthesia and surgery

heart disease	
➢ **Chronic Disease/Other Conditions:** - Severe cirrhosis - Hyperthyroid	There is a high risk for complications associated with anaesthesia and surgery. If the client has unstable atrial fibrillation or current subacute endocarditis, the procedure should be delayed.
- Blood clotting disorders	The woman is at high risk for complications associated with anaesthesia and surgery.
- Chronic respiratory diseases: asthma, bronchitis, emphysema, lung infection - Known pelvic tuberculosis - Nephropathy/retinopathy / neuropathy - Diabetes with vascular complications and/or diabetes of >20 years' duration	Women with coagulation disorders are at increased risk of haematological complications of surgery. For laparoscopy, the woman may experience acute exacerbation of symptoms induced by raising of the diaphram by pneumo-peritoneum, Trendelenburg position, and decreased venous return from gaseous compression of large vessels.
➢ **AIDS**	If the woman is currently suffering an AIDS-related illness, the procedure should be delayed.

Sterilisation does not protect against STI/HIV, if there is risk of STI/HIV, the correct and consistent use of condoms is recommended, either alone or with another contraceptive method.

Reference:

1. **Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use, second edition, 2000** SHR **Reproductive Health and Research: World Health Organization. Geneva**

Women make their own choices. Respect it!

ADDENDUM A-2

MEDICAL ELIGIBILITY CRITERIA FOR MALE STERILISATION (VASECTOMY)

CONDITION	RATIONALE/COMMENTS
ACCEPT - There is no medical reason to deny the procedure to a person with this condition.	
➢ **Sickle Cell Disease** ➢ **High Risk of HIV** ➢ **HIV Positive**	Routine screening is unnecessary. Appropriate infection prevention procedures, including universal precautions, must be carefully observed with all surgical procedures. The use of condoms is recommended following vasectomy.
CAUTION – Conduct normally in routine setting, but with extra precautions.	
➢ **Previous Scrotal Injury** ➢ **Large Varicocele** ➢ **Large Hydrocele** ➢ **Cryptorchidism** ➢ **Diabetes**	The vas may be difficult/impossible to locate; a single procedure to repair varicocele/hydrocele and do a vasectomy decreases risk of complications. If cryptorchidism is bilateral, and fertility has been demonstrated, it will require extensive surgery to locate the vas, and it becomes special category (S). If unilateral, and fertility has been demonstrated, vasectomy may be performed on the normal side and the spermogram checked, as per routine. If the sperm count continues to be positive, more extensive surgery may be necessary to locate the other vas, and it becomes category S. Diabetics are more likely to get postoperative wound infections. If signs of infection appear, treatment with antibiotics needs to be

	given.
DELAY – The procedure is delayed until the condition is evaluated and /or corrected. Alternative temporary methods of contraception should be provided.	
➢ **Scrotal Skin Infection** ➢ **Balanitis** ➢ **Epididymitis or Orchitis** ➢ **Active STI** ➢ **Acute Systemic Infection or Gastroenteritis** ➢ **Filariasis; Elephantiasis** ➢ **Intra-scrotal Mass**	There is an increased risk of postoperative infection (bullet 1-5).. **The scrotum may be involved in severe elephantiasis, making it impossible to palpate the cord structure and testis.** An intra-scrotal mass may indicate an underlying disease.
SPECIAL - The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate procedure and anaesthesia regimen is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.	
➢ **Inguinal Hernia** ➢ **Coagulation Disorders** ➢ **AIDS**	**Hernia should be repaired first or at the same time as vasectomy.**

Vasectomy does not protect against STI/HIV, if there is risk of STI/HIV, the correct and consistent use of condoms is recommended, either alone or with another contraceptive method.

Reference:

1. **Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use, second edition, 2000. SHR Reproductive Health and Research: World Health Organization. Geneva**

ADDENDUM B-1

INSTRUCTIONS FOR CLIENTS BOOKING FOR
LAPARASCOPIC TUBAL LIGATION (DAY CASE)

DEAR CLIENT

1. You have an appointment to undergo an operation on _____ (date).

2. Please report to _____ Hospital at 7am on that date.

3. Have ***NOTHING*** to eat or drink after midnight. (Any food eaten before anaesthetic can lead to complications). ***THAT EXCLUDES MEDICINES.***

4. Please shave your pubic region and bath before admission.

5. Remove nail polish.

6. **KINDLY INFORM THE ANAESTHETIST IF YOU HAD ANY OF THE FOLLOWING PROBLEMS:**

   a) Allergies – especially to drugs.
   b) Problems with previous operations.
   c) Name of any medicines you are presently taking. ***Continue taking medicine.***
   d) If you have any heart, chest or rheumatic disease, high blood pressure, diabetes, Porphyria or tendency to bleed.

7. Continue your present contraceptive method right up to admission to hospital – it may then be discontinued unless otherwise instructed.

8. Should you develop a cold, flu or sore throat before the operation or are unable to attend, ***PLEASE TEL: ……*** as far in advance as possible – so someone else can be given your booking. ***TRY NOT TO SMOKE FOR AT LEAST 3 DAYS BEFORE OPERATION.***

AFTER THE OPERATION YOU MAY EXPERIENCE:

a) Sore throat, sore shoulders.
b) Sore body and muscle stiffness.
c) Abdominal pains.

These are usually minor and short of duration.

IF YOU HAVE ANY DISCOMFORT remain in bed the first day, after that get up for periods as you feel fit. If you have any severe pain or problems after the operation, please contact the clinic, or emergency unit at Groote Schuur Hospital.

REMINDER:

Once the operation is done it probably cannot be undone and therefore you should not have the operation unless you are sure that you will never want another child.

The chances of a pregnancy after the operation are probably in the order of 1:1000. There is no other known method of contraception, which can give you a more reliable result. The operation is immediately effective.

The operation makes no physical difference whatsoever to your health, or sex desire or sex act.

Wishing you all the best.

AUGUST 2001
ST2/INSLAPARASCOPIC/SO

ADDENDUM B-2

INSTRUCTION FOR MEN BOOKING FOR VASECTOMY:

DEAR CLIENT

You have an appointment to undergo a vasectomy on: _____ (date)

At _____ Hospital at _____ (time).

PRIOR TO THE OPERATION:

Have a light meal before coming to hospital.

Shave yourself on the under-surface of the penis and the front of the scrotum the night before the operation and bath on the morning of the operation.

Wear a pair of clean, close-fitting underpants.

If you are on medication, please take it as usual as it will not interfere with the local anaesthetic, but ***please inform the surgeon of:***

a) The names of medicine you are presently taking;
b) Any known allergies (especially to drugs);
c) Any problems with previous operations;
d) Any heart, chest or rheumatic disease, high blood pressure, diabetes, porphyria or bleeding tendency.

If you are unable to attend for the operation, **please** contact the hospital or clinic.

AFTER THE OPERATION:

Take analgesics as advised if you are uncomfortable after the operation. You should rest for 24 to 48 hours and not undertake any strenuous activity during that time. You may return to work after the operation if you feel fit.

Some bruising and swelling of the scrotum are to be expected. If pain or swelling persist and are troublesome, go to the Emergency Unit of the nearest medical facility. Continue to wear close-fitting underpants for a week to support the scrotum.

Your stitches will become absorbed and ***need not be removed.*** Keep the wound dry for a week. Blot well after bathing.

The operation is not immediately effective and therefore you must have your semen tested. Further details and date for this test will be provided on the day of your operation.

You can start having intercourse after a week, as soon as you feel comfortable after the operation. Regular intercourse is necessary to clear the tubes of sperm. However, as ***THE OPERATION IS NOT IMMEDIATELY EFFECTIVE***, you/your wife must use a reliable contraceptive method for a least 3 months and continue to do so thereafter until you have been informed by the clinic that ***NO SPERM*** is present in your semen.

REMINDER:

Once the operation is done it probably cannot be undone, and therefore you should not have the operation unless you are certain that you will never want another child. You can change your mind at any time before the operation.

There is an ***extremely small chance of pregnancy*** after the operation, but there is no other known method of contraception, which can give you a more reliable result.

The operation will not affect your health, sex desire, sex act, or weight.

Wishing you all the best.

Sterilisation/ma/8/02

ANNEXURE E

Designated Facilities

See attached lists of designated facilities where sterilisation of severely mentally disabled persons may be performed.