SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	VAS/2018/1
Service	Community vasectomy service for NHS Greater Huddersfield and NHS Calderdale CCGs
Commissioner Lead	Greater Huddersfield Clinical Commissioning Group
Provider Lead	
Period	30 months starting 1 October 2018
Date of Review	January 2020

1. Population Needs

1.1 National/local context and evidence base

Sterilisation has become increasingly popular since the late 1960's. Discussion of sterilisation is a routine part of contraceptive advice offered by health professionals. Vasectomy is indicated when a man wishes to make permanent and irreversible their decision that they should never subsequently conceive a child of their own. It is a voluntary act with the request coming from the man wishing to be rendered infertile and the procedure may be offered irrespective of age or marital status.

Sterilisation can be an empowering decision for the right person at the right time however its intended permanency means that the onus is on the health care practitioners involved to ensure that the patient has all the information required in order to make an informed choice (which is also available in other languages/formats if required).

This service specification relates to the provision of a community non-consultant led minimally invasive vasectomy (MIV) service for NHS Greater Huddersfield and NHS Calderdale Clinical Commissioning Groups in accordance with the FSRH Clinical Guidance: Male and Female Sterilisation - September 2014.

Regular updates on latest evidence received and best practice from NICE and other related bodies will be acted upon for the vasectomy service. Current evidence suggests that community services such as these will increase patient choice, improve local access and increase capacity in Greater Huddersfield and Calderdale.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

The service contributes to the following domains of the NHS Outcomes Framework:

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	√

	Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

2.2 Local defined outcomes

Covered elsewhere in this specification.

3. Scope

3.1 Aims and objectives of service

The aim of the service is to provide those patients who wish to have a vasectomy under Local Anaesthetic the choice of having their counselling and procedure undertaken within a local primary or community care setting at a time convenient to them.

The objectives of the service are:

- To provide high quality, cost effective, local community vasectomy services for Calderdale and Greater Huddersfield CCGs.
- To provide services that comply with accepted best practice in line with national and local guidance, relevant accreditations processes, relevant guidelines in clinical practice and robust governance arrangements.
- To provide a complete holistic service user focussed care package including pre and post-operative care, information, advice and counselling
- To ensure consistent and continuous care between health professionals, effective and efficient communication.
- To improve access and convenience for service users
- To improve service user choice

3.2 Service description/care pathway

This specification covers vasectomy counselling and procedure under local anaesthetic for any patient registered with a Calderdale or Greater Huddersfield CCG GP practice in accordance with the pathway attached at Appendix A.

The requirements in terms of training and experience for clinicians providing counselling and undertaking the procedure are set out in section 5.1. Other requirements relating to the service are set out below.

Vasectomy Counselling

Counselling should be provided in line with FSRH guidance[1].

Patient information

The patient should be sent an information leaflet with confirmation of the procedure date. The leaflet should contain information in line with FSRH guidance[2].

Consent

Consent should be obtained by the operating surgeon in line with national guidance and CCG policy. The patient should be fully informed of the treatment proposed and associated risks. The patient should give written consent for the procedure to be carried out and the completed consent form should be sent to the referring practice, so that it can be filed in the patient's lifelong medical record.

Methods employed

[1] Royal College of Obstetricians & Gynaecologists Faculty of Sexual and Reproductive Healthcare **Male and Female Sterilisation** (2014)
[2] As above

The procedure should be undertaken according to the guidance[3], which is as follows:
'The traditional method involves making one or two incisions in the scrotal skin to expose the vas deferens. The vas deferens is then occluded and divided using various techniques.

A relatively new technique to expose the vas, the no-scalpel vasectomy (NSV) developed by Li et al., involves a puncture wound in the scrotal skin to access and occlude the vas. This method was developed to increase the acceptability of vasectomy by eliminating the fear of incision. Following anaesthesia, a specially designed fixation clamp encircles and firmly secures the vas without penetrating the skin. Sharp-tipped dissecting forceps are then used to puncture the skin and vas sheath and to stretch a small opening in the scrotum. The vas is lifted and occluded, as with other vasectomy techniques. The same puncture hole can be used for the opposite vas or a separate puncture can be made.

A number of NSV techniques are reported in the literature. It has been suggested that these techniques should not be referred to as NSV but instead be referred to as minimally invasive vasectomy (MIV). For the purposes of this guideline, the term MIV will be used to encompass NSV and any modified versions of this technique where the skin opening is ≤10 mm, and the dissection area surrounding the vas deferens is minimised and does not require the use of skin sutures. MIV may include the use of a variety of surgical instruments, including a scalpel, to expose the vas'.

Division of the vas on its own is not an acceptable technique because of its failure rate. It should be accompanied by fascial interposition/ diathermy.

Clips should not be used for occluding the vas, as failure rates are unacceptably high.

Anaesthesia

Vasectomy should only be performed under local anaesthetic using pre-defined local anaesthetic agent(s). Anaesthetic agents must be stored in line with the local current Medicines Codes.

Histological examination

Excised portions of vas should only be sent for histological examination if there is any doubt about their identity.

The Provider should have a process in place to identify when a sample has been sent to the lab and results have been received and acted upon accordingly.

Post vasectomy semen analysis

The operating clinician is responsible for advising the patient of the results of post vasectomy semen analysis and any further action required.

Men should be advised to use effective contraception until azoospermia has been confirmed. The way in which azoospermia is confirmed will be line with practice and local protocols.

The Provider should maintain records in order to identify that all necessary sperm samples have been sent to and received back from the lab and that the patient has been informed of the results of the test.
Irrigation of the vas during vasectomy does not reduce failure rates or time to clearance.

Special clearance

In a small minority of men, non-motile sperm persist after vasectomy. In such cases 'special

[3] As above

clearance' to stop contraception may be given when less than 10 000 non-motile sperm/ml are found in a fresh specimen examined at least seven months after vasectomy, as no pregnancies have yet been reported under these circumstances. The numbers of cases where this occurs will be monitored.

If the semen count is still positive after 7 months, the patient will be referred back to their own GP for referral onto secondary care for a repeat of the procedure.
Contingency Planning

It will be the responsibility of the Provider to ensure that the service is sustained during periods of annual leave and sickness

Waiting Times

All patients seen by the service are subject to the 18-week referral to treatment waiting time. Ideally patients will be seen within four weeks of referral. Patients requiring an onward referral to secondary care will be referred within 48hrs.

Complaints

All patients should be provided with details of how to make a complaint. A record of any complaints about the service should be kept together with a note of actions taken to address any of the concerns raised.

Patient records

The Provider must ensure that the details for the patients receiving the service are included in their lifelong record. If the patient is not registered with the Provider, then the Provider must send this information to the patient's registered GP practice for inclusion in the patient notes.

Infection Prevention and Control

The specific requirements relating to infection prevention and control are set out in Appendix B.

Patient/carer experience

- The provider will actively gather patient/carer experience data
- The provider will review patient/carer experience data on a quarterly basis, make recommendations where appropriate and act on them
- The provider will make available to the CCG patient/care experience intelligence when requested

Monitoring

Full records of all procedures should be maintained in such a way that aggregated data and details of individual patients are readily accessible. Practices should regularly audit and peer review minor surgery work. The service should be monitored under the following headings:

- Performance management
- Clinical quality
- Patient experience

Detail of the data to be collected/submitted is outlined at Appendix C.

3.3 Population covered

The service will be available to any patient who is registered with a Calderdale or Greater Huddersfield CCG GP practice

3.4 Any acceptance and exclusion criteria and thresholds

Referrals will be accepted from:

- GP's
- Genito Urinary Medicine (GUM) Clinics
- Contraception and Sexual Health (CASH)
- Any other relevant agencies/clinicians

Surgery should be delayed if the following conditions are present:

- Scrotal skin infection
- Active sexually transmitted disease
- Balanitis Epididymitis
- Orchitis

Surgery should be undertaken with caution if the following are present:

- Previous scrotal surgery
- Hydrocele
- BMI>35
- Drug or alcohol misuse

Exclusions:

- Anybody under the age of 18
- Self-referral
- Lack of consent
- Varicocele
- Inguinal hernia
- Cryptorchidism
- Anticoagulant therapy
- Coagulation disorders
- Lack of capacity to give informed consent
- A history of an allergy to local anaesthetic
- A history of fainting easily
- Those deemed unsuitable for local anaesthetic
- Scrotal skin infection
- Active sexually transmitted disease
- Balanitis
- Epididymitis
- Orchitis

3.5 Interdependence with other services/providers

Key professions that the provider will be expected to develop effective links with include:

- General Practitioners (GPs)
- Secondary care vasectomy service providers
- Accredited andrology services
- Contraceptive and Sexual Health service (CASH)
- Genito-Urinary Medicine (GUM)
- Interpreters
- Any other appropriate service

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

See below

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Royal College of Obstetricians and Gynaecologists Faculty of Sexual and Reproductive Healthcare London. RCOG Press September 2014.
http://www.fsrh.org/pdfs/MaleFemaleSterilisation.pdf

4.3 Applicable local standards

Records to be kept by the Provider and information to be submitted to the CCGs are set out at Appendix C.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements

Counselling should be undertaken by an appropriately trained person.

Clinicians performing the vasectomy should be supported by a suitably trained nurse. Nurses assisting in minor surgery procedures should be appropriately trained and competent, taking into consideration professional accountability and the Nursing and Midwifery Council Guidelines on the scope of professional practice.

The following requirements apply for clinicians undertaking vasectomies in this service:

- Clinicians with no prior surgical experience will be required to undertake 40 procedures following a training programme that conforms to that advocated by the Faculty of Sexual and Reproductive Healthcare.
- Clinicians with no prior surgical vasectomy experience will be required to perform a minimum of 15 satisfactory procedures under supervision prior to being able to practice unsupervised.
- Experienced clinicians with prior surgical vasectomy experience will be required to perform a minimum of 8 satisfactory procedures under supervision prior to being able to practice unsupervised.
- Clinicians who have conducted more than 12 vasectomies in the last 12 months where audit reveals no significant clinical problems will not be required to undergo supervision.

Clinicians performing vasectomies in this service will be required to identify a named consultant to provide mentoring for the specialist aspect of their work. Those staff supporting the clinician should also undertake appraisal and CPD on an annual basis.

Clinicians performing vasectomies in this service should keep their knowledge and skills up to date. It is advised that they should maintain a minimum of the following:

- One operating list per month and 40 operations per year
- Audits of own complications and failure rates [4](see Appendix C)

The local Quality Requirements are set out in Appendix D.

5.2 Applicable CQUIN goals

Not appropriate at this time. The application of any future CQUIN scheme will be funded from within the set rate/tariff for the service i.e. within the financial envelope identified and

[4] Royal College of Obstetricians and Gynaecologists December 2008 (section 3.7)

not in addition to.

6. Payment and Prices

The pricing structure below includes all tests, treatment and analysis required.

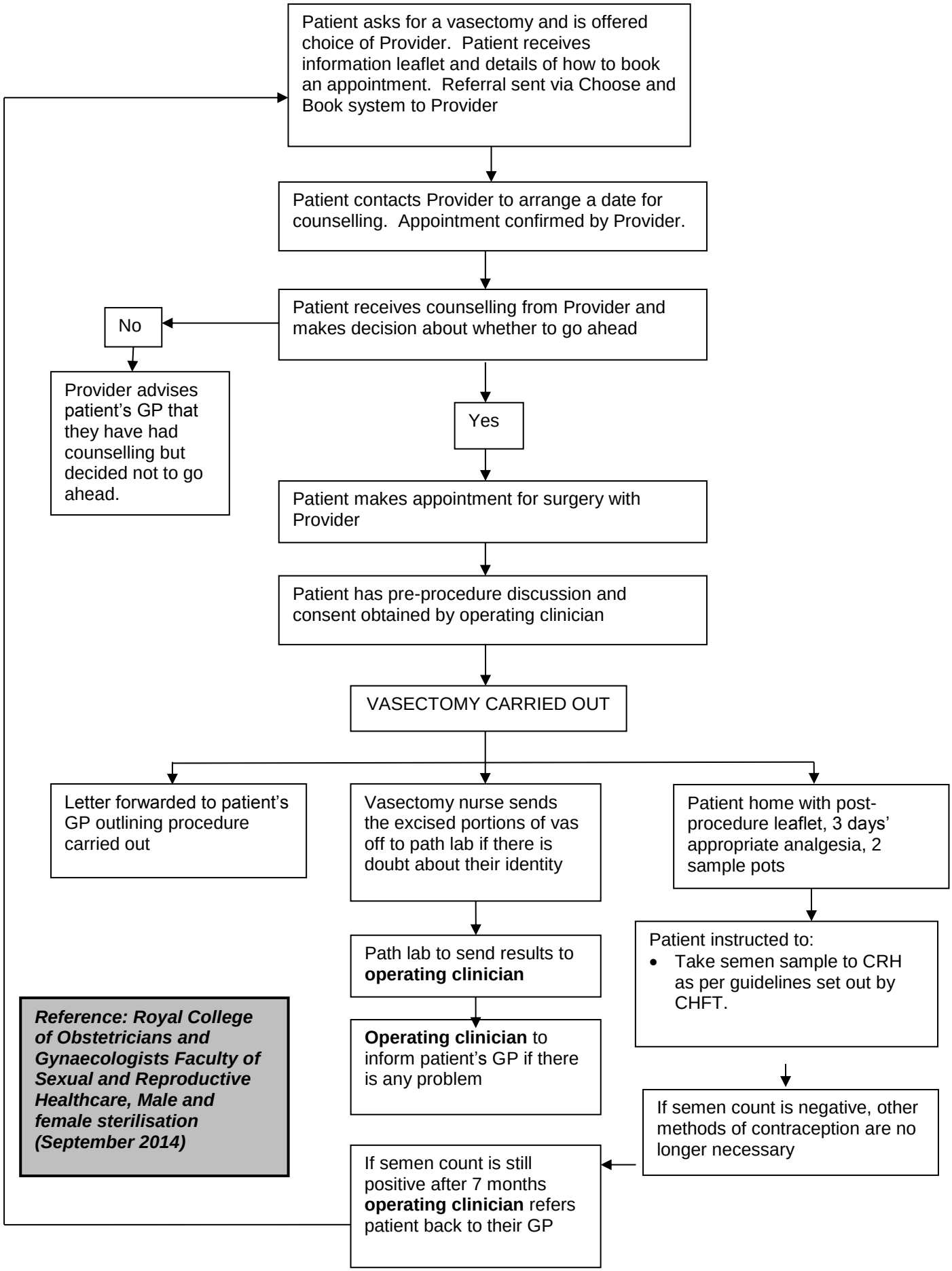
Service Description	Currency	Price
Counselling	Cost per treatment / activity	£10.00
Vasectomy	Cost per treatment / activity	£260.00
Planned Procedure Not Carried Out***		£130.00

*** Where a procedure does not take place due to patient decision at the counselling stage this activity will attract the Counselling only tariff. Planned Procedures Not Carried Out are only payable when the patient has reached the operating area but the operation does not go ahead at that time. These figures will be strictly monitored and the CCG may refuse payment for high levels of activity under this tariff unless exceptionality can be proved.

DNAs (Did Not Attend) will not attract a tariff.

7. Location of Provider Premises

Appendix A - Pathway for vasectomy counselling and procedure



Reference: Royal College of Obstetricians and Gynaecologists Faculty of Sexual and Reproductive Healthcare, Male and female sterilisation (September 2014)

APPENDIX B

Infection Prevention and Control requirements

Expected Outcomes

• Improved or sustained patient experience
•To assist with facilitating improvement in the reduction of healthcare associated infection.
•To provide a safe environment which promotes effective care and optimises health outcomes

Policies

The provider must have written procedures and policies for all staff to follow. The list of policies required can be found in the Health and Social Care Act 2008, the Code of practice on the prevention and control of infections and related guidance (revised 2010) in Part 4 : Guidance Tables. Refer to table 3 for policies appropriate to regulated activities. Staff must be made aware of these policies and procedures.

Audit and Training

The provider should undertake annual infection prevention and control training; an annual infection prevention and control audit, and undertake Essential Steps or equivalent audit process for staff compliance with infection prevention and control procedures. Surveillance of infection rates should be undertaken and provided to the commissioner.

Documentation

Post procedure complications (including signs and symptoms of infection) and advice given on after care should be documented clearly in the patient's record.

Clinical Environment

Size of room

The room should be 18m^2 minimum to accommodate the level 2 service.

Ventilation

The ventilation within the room should be appropriate for the procedure in line with national recommendations.

Furniture, fixtures and fittings

The room should contain the minimum amount of equipment to allow staff to work unhindered. The furniture, fixtures and fittings should be clean and in a good state of repair, and any furniture within the rooms must be wipeable and easy to clean.

Flooring must be seamless and smooth, with coving between the floor and wall to prevent accumulation of dust and dirt in corners and crevices. Any joints must be welded or sealed to prevent accumulation of dirt and damage due to water ingress (HBN 00-10 Part A – Flooring). Walls must be smooth and cleanable with impervious surfaces (HBN 00-10 Part B Walls and Ceilings). Radiators should be painted with oil based 'egg shell' finish paint. In clinical areas, pipework must be concealed. (HBN 00-09: Infection control in the built environment (2013)

Work flow clean/dirty utility rooms

Organisation of the clinical area should be such that areas for clean and dirty procedures are clearly defined and arranged to reduce the risk of cross contamination. Clean and dirty utility rooms are required. The clean utility room is for storing sterile supplies and consumables. Empty supplies trolleys and dressings/instrument trolleys will be held within this room and restocked from here. This

room is required to be a minimum of 6m square with a compliant clinical hand wash basin. A dirty utility room of the same dimensions is required to hold waste sacks prior to their removal; small quantities of used items may be stored in this room e.g. used instruments prior to re- processing. (Health Building Note 00-03 Clinical and clinical support spaces (Jan 2010).

Cleaning standards

Cleaning of the environment must conform to the national specification for cleanliness as detailed in the National specifications for cleanliness in the NHS; Guidance on setting and measuring performance outcomes in primary care medical and dental premises (August 2010). Lighting should be of a suitable construction that allows easy cleaning and does not allow a build-up of dust. It should be cleaned at the end of each day using detergent and water. Central heating radiators can quickly build up high levels of dust so it is important that they are cleaned on a regular basis. Curtains should be avoided but where they are used, they should be washed on a regular basis (usually every 6 months) or when visibly soiled. Double glazed room vision panels with integral blinds are recommended. Where window blinds are in situ these must be fully cleanable and included on the cleaning schedule.

Management of health care waste

The provider must adhere to Department of Health Safe Management of Healthcare Waste (Current Version) and have an up to date policy on the safe disposal of healthcare waste.

Hand washing

Facilities for surgical hand antisepsis should be provided. This will include provision of a recessed scrub sink, antimicrobial solution and sterile hand towels for hand drying.

Skin preparation

The risk of post procedure site infection is minimised through effective use of skin preparations. Antiseptics should be supplied in ready to use single use containers or sachets due to increased risk of contamination from using multiple use containers. The type of preparation should be influenced by the condition of the skin and patients' allergies. Skin preparations solutions should be kept in a locked cupboard to adhere to CoSHH regulations where applicable.

Protective clothing

Personal protective equipment (PPE) includes sterile and non-sterile gloves, disposable plastic aprons and protective eye wear. PPE must be available in the treatment room / minor surgery area and be worn in accordance with standard precautions and health and safety guidelines. Personal protective equipment must be CE marked where appropriate i.e. gloves and eye protection. Scrub suits minimise the transfer of microorganisms and should be available for use when undertaking the procedures.

Traceability of sterile surgical equipment and decontamination

The provider must be able to provide assurance that a means of tracing sterile surgical equipment is in place. If CE marked single use instrumentation are not utilised, then decontamination of reusable medical devices which are compliant with MDD93/42/EEC guidance i.e., Sterile Services Department registered with the MHRA must be assured. Policies to confirm the processes above should be available.

Screening for MRSA

Routine screening for MRSA colonisation is not required. However, patients with a previous history of MRSA may warrant screening pre-operatively. If an individual is found to be colonised then suppression treatment should be prescribed. Treatment should be completed as near to the date of the procedure as possible. Risk assessments should be documented in the patient's notes. Re-screening is not required.

References

The Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance (revised 2010)

Health Building Note 00-09: Infection Control in the Built Environment 2013

Health Building Note 00-10: Part A -Flooring, Part B – walls and ceilings and Part C – Sanitary assemblies (2103)

Health Building Note 00-03: Clinical and clinical support spaces (2010).

HTM 03-01 specialised ventilation for healthcare premises.

NHS Estates – Infection Control in Built Environments HMSO2002

Health & Safety Executive 1999 CoSHH Regulations

Department of Health Safe Management of Healthcare Waste (Version 2; March 2011) Health Services Advisory Committee of the Health & Safety Commission - Safe Disposal of Clinical Waste

Health and Safety at Work Act

Medical Devices Regulations 2002.Decontamination of Instruments and Medical Devices

National specifications for cleanliness in the NHS; Guidance on setting and measuring performance outcomes in primary care medical and dental premises (August 2010)

APPENDIX C

Records to be kept by the Provider

Monitoring

1. Performance (data to be submitted monthly to the CCG)

- Numbers of patients referred by GP practice
- Waiting time from Provider receiving referral to procedure
- Number of patients waiting more than 10 weeks since their referral was received by their provider (at end of month)
- Number of DNAs
- Number of procedures cancelled with reasons for this including circumstances where the patient decided not to continue after the pre-operative consultation
- Number of patients who received post-vasectomy semen analysis

2. Data capture for audit of clinical quality

Immediately pre-op

- Confirmation of details and other pre-op discussions and counselling
- Confirmation of valid signed consent
- Pre-op assessment to confirm fitness for anaesthesia and procedure according to local guidelines
- Discussion of what is involved in the procedure and possible complications
- Discussion of post op pain and care

Immediately post op

- Name of surgeon taking responsibility and name of nurse assisting
- Ease of access to the vas
- Additional procedure or unexpected events/complications
- Discharge letter to the referring GP
- Patient informed of method used and any intra-op findings or events
- Contact point for post –op questions as per the patient information leaflet**.**

The CCG will advise the provider of the audit requirements.

3. Patient experience

A record of all complaints about the service together with a log of action taken as a result should be kept by the practice and form part of the quality reporting. Also, patient survey to be managed by the provider by giving patients questionnaire immediately on discharge.

4. Incident Reporting

Any incident relating to the vasectomy service will be reported to the relevant CCG in accordance with that CCG's incident reporting procedures. Examples of reportable incidents include, but are not limited to:

- Complications during the procedure: e.g. excessive bleeding, pain.
- Post op complications: e.g. haematoma, infection, sperm granuloma.
- Adverse patient reactions: e.g. fainting, allergic reaction.
- Defective equipment
- Failure of the procedure.

The Provider will undertake Significant Event Analysis on incidents relating to the vasectomy service.

APPENDIX D

Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
All patients will provide informed written consent/ indemnity form	100%	Quarterly Quality Report and Audit	As per General Conditions – Contract Management
Complication rates for short term adverse events: Patients requiring unplanned/ emergency follow-up due to the following complications: Excessive pain Haematoma Sperm granuloma Infection	 Not reported in more than 6% of cases Not reported in more than 1% of cases Not reported in more than 5% of cases Not reported in more than 1% of cases	Quarterly Quality Report and Audits	As per General Conditions – Contract Management
98% success rate each year based on the semenology test	98%	Quarterly Quality Report and Audit	As per General Conditions – Contract Management
90% of patients reporting satisfaction of the service	90%	Patient Satisfaction Results	As per General Conditions – Contract Management
Patients to be seen within 30mins of their appointment time	85%	Quarterly Quality Report	As per General Conditions – Contract Management