Service Specifications

Service Specification No.	NKCCG Vasectomy V4
Service	Community Vasectomy Service for North Kirklees CCG
Commissioner Lead	Edward Njuguna
Provider Lead	***[to be added in for individual contracts]***
Period	30 September 2018 to 31st March 2021
Date of Review	To be confirmed

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 high quality, safe community vasectomy service consisting of counselling and no-scalpel procedure, in accordance with the following clinical guidelines:

- Faculty of Sexual and Reproductive Healthcare Clinical Guidance (September 2014). The FSRH guidelines can be found at http://www.fsrh.org/pdfs/MaleFemaleSterilisation.pdf

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 North Kirklees CCG.
- 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 North Kirklees 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.

The service will provide an option of either a one stage or two stage vasectomy procedure but will promote the two stage process for vasectomy as this ensures the patient has a cooling off period before having permanent sterilisation. Where a one staged procedure is offered by the provider they should ensure that appropriate counselling has been carried out by the referrer in accordance with the (RCOG guidelines).

Access to the service

The service will be listed on the e-Referral system and accept all clinically appropriate referrals. The Provider will make it known on e-Referral through the development of their Directory of Service (DOS) that they provide the No Scalpel vasectomy techniques.

Referrals will be accepted from:

- GP's
- Integrated Sexual Health Services

Inappropriate referrals will be returned to source of referral within one week. Service users

who self-refer inappropriately will be advised to see their GP. Patients who are not currently registered with a GP will be advised to do so.

The service clinics may be provided between core hours (8:00am-6:30pm) but where possible there should also be out of hours provision in order to meet patient need and provide patient choice.

Vasectomy Counselling and pre-operative assessment

Patients should be offered an appointment for pre-operative assessment and counselling no later than 4 weeks following referral. Counselling should be provided in line with national and FSRH clinical guidelines (September 2014)

Where the pre-op counselling is provided by the provider and not the referrer the Provider will offer an appointment for the procedure no earlier than 1 week, and no later than 6 weeks after the pre-operative assessment to ensure a cooling off period is allowed.

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 guidelines. The information given to the patient must include sufficient detail regarding the procedure, expected outcomes, risks and potential complications to allow the patient to make an informed decision. Alternatively this may be given to the patient at the time of pre-op counselling by the referrer.

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 operating surgeon will need to ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the patient does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution.

The patient should give written consent for the procedure to be carried out.

The pre-sterilisation information and advice should be given at a suitable interval prior to the procedure (in line with RCOG guidelines) and a copy of the completed consent form should be sent to the referring practice (with the provider working towards electronic transfer of information), so that it can be filed in the patient's lifelong medical record. The provider will retain the original signed consent for governance purposes.

Vasectomy procedure

The methodology used to perform the vasectomy should be in line with current best practice and guidelines as set out below:

- Except when technical considerations dictate otherwise, a no-scalpel approach should be used to identify the vas, as this result in a lower rate of early complications[1].
- 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.

[1] http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004112.pub4/abstract

Medicines Optimisation
The service provider shall ensure that any prescribing follows the current recommendations of the commissioner and shall ensure the safe and legal storage, dispensing, disposal of medicines and prescriptions are adhered to.

The service provider shall ensure that where medications are used and prescriptions are written they conform to the commissioner's drugs formulary.

The provider has full responsibility for the cost of any drugs used/prescribed within the service and are included within the tariff costs.

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.

Transfer of Care
The provider must ensure robust processes are in place for the rapid transfer to specialties within secondary care where the patient's condition warrants this transfer. These protocols must be agreed between the service provider and the secondary care provider and attached to the contract. These protocols will form part of the services audit requirements.

The service provider must ensure all clinical staff are trained and competent to manage patients in the event of cardiac arrest, respiratory arrest, perforated bowel or anaphylaxis.

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.

Pathology
The service provider must contract with an accredited histopathology provider and ensure appropriate sample turnaround times. Where the provider has sent a specimen for histology, the result and any planned action should be communicated to the GP and any unexpected result managed appropriately by the provider.

All histology costs will be borne by the provider and are included within the tariff costs.

Post vasectomy semen analysis
The provider must arrange for post vasectomy testing between 12 and 16 weeks following the procedure which must be processed in line with local lab protocols.

The service provider must contract with an accredited recognised NHS laboratory testing provider and ensure appropriate sample turnaround times.

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.

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. Irrigation of the vas during vasectomy does not reduce failure rates or time to clearance

All diagnostic costs will be borne by the provider and are included within the tariff costs.

Special clearance
In a small minority of men, non-motile sperm persist after vasectomy. In such cases 'special clearance' to stop contraception may be given when less than 100,000 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

Management and Leadership
There is a requirement for the provider to satisfy the commissioner that they have an organisational structure that clearly identifies responsibilities and accountabilities in the following areas:

- Managerial leadership
- Professional leadership
- Clinical leadership
- Clinical governance
- Corporate governance.

Waiting Times
All patients seen by the service are subject to the 18-week referral to treatment waiting time. Therefore patients will be offered a pre-operative assessment 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. 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
- The information gathered on patient/carer experience data should be taken into account when reviewing standards as part of clinical audit.

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 Appendices C and D.

3.3 Population covered

The service will be available to any patient who is registered with a North Kirklees GP.

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
- Service user refusal of local anaesthesia
- 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 laboratory 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)

The provider shall be aware of and involved in the following networks and programmes as appropriate:

- Andrology
- Microbiology
- Infection Control
- Code of Practice for the Prevention and Control of Healthcare Associated Infections14
- The Health and Social Care Act 2008
- The environment for the procedure must include completion of the Infection Prevention Quality Improvement Tool (QIT) for treatment rooms
- Be CQC compliant – If there are any areas which are identified as non-compliant, the commissioner will need to be informed.

Suspected Cancer Referrals

Where Providers have reason to believe through examination, receipt of pathology/histology results or otherwise that the patient displays symptoms or signs that may indicate cancer, the Provider shall;

a) make a direct referral to the appropriate service under the two-week cancer referral guidelines on the appropriate form in line with NICE CG97 – referral guidelines for suspected cancer (2005);

b) a copy of the referral should be sent to the patient's GP indicating reasons for referral;

c) Cases of suspected cancer should NOT be first referred back to the patient's GP for them to make the referral, as this introduces unnecessary and inappropriate delay. Once referral is made, patients GP should be informed.

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

Scalpel vs no-scalpel incision for vasectomy. Cochrane Systematic Review, published 30th March 2014.
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004112.pub4/abstract

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

European Association of Urology Guidelines on Vasectomy. Gert R Dohle, Thorsten Diemer, Zsolt Kopa, Csilla Krausz, Aleksander Giwercman, Andreas Jungwirth European Urology 31 2012 159-163 http://www.europeanurology.com/article/S0302-2838(11)01101-8/pdf/European+Association+of+Urology+Guidelines+on+Vasectomy

Canadian Urological Association (CUA) J 2016, 10(7-8):E274-8.
http://dx.doi.org/10.5489/cuaj.4017

4.3 Applicable local standards

Records to be kept by the Provider and information to be submitted to the CCG are set out at Appendix C.
The provider will be expected to provide evidence that the facility is fit for purpose in that it complies with national and local guidelines for minor surgery.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

Counselling and pre-operative assessment should be undertaken by an appropriately trained person and in line with FSRH guidelines.

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 [2](see Appendix C)

The local Quality Requirements are set out in Appendix D.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

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 not in addition to.

6. Location of Provider Premises

6.1 Locations of Service Delivery

The provider will operate in a location(s) that are accessible and convenient for public access across North Kirklees.

6.2 Days and Hours of Operation

The service should be available at times that are convenient for the population of North Kirklees, including those who work which will include appointments out of normal working hours. The provider will take into account the Vasectomy Services in North Kirklees; Engagement Report (April 2015), when planning service provision.

7. Individual Service User placement

Not applicable

8. Fee for service

The total cost of the service will include:

- Patient focussed health care questions that function as an initial triage system.
- Pre-operative assessment, counselling and sexual health advice
- Patient literature in different languages
- Interpreters
- One or two stage vasectomy procedure under local anaesthetic
- All post-operative follow up care – planned and emergency
- Cost of any drugs used/prescribed within the service
- Histopathology testing (where required)

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

- Semenology testing – all appointments and equipment for each test required
- Disclaimer forms

Item	Fee
Counselling appointment only	£10
Procedure (including, post-operative testing and notifications)	£260
Planned Procedure Not Carried Out***	£130

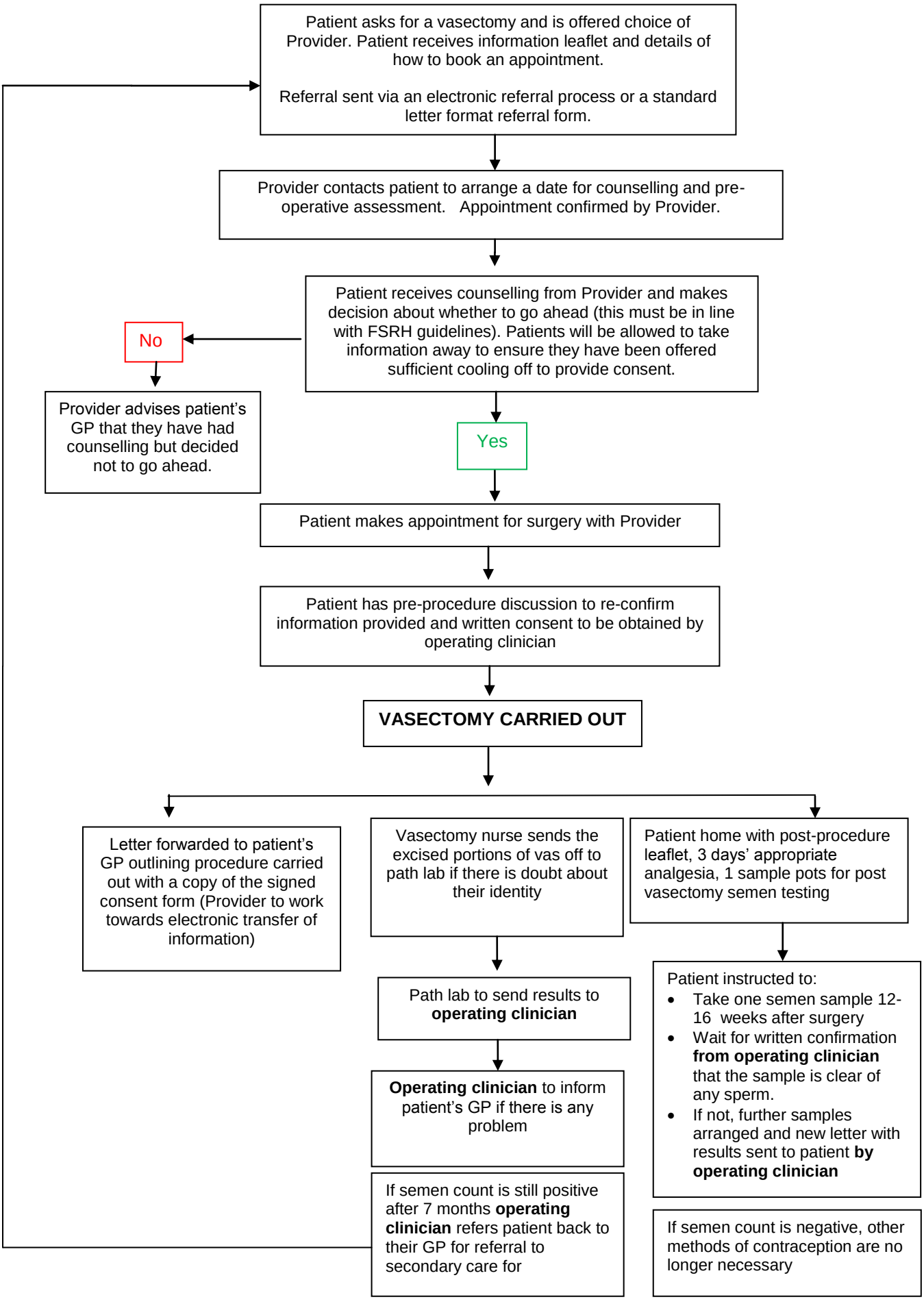
Notes:

- The pricing structure includes all tests, treatments and analysis required.
- There will be no payments for DNA's.
- *** 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.

9. Expected activity levels

This service is being commissioned through the Any Qualified Provider route, and therefore all contracts are zero contracts with no expected level of activity. However, to give some overall context, the number of vasectomies undertaken under local unaesthetic in 2017/18 was 49 counselling and 41 procedures.

Appendix A - Pathway for vasectomy counselling and procedure



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 that 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, Code of practice on the prevention and control of infections and related guidance (January 2015) 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

A minor procedures room should be a minimum 18m-20m^2 to enable a workspace for the practitioner and an assistant.

Ventilation

Environmental air changes

In order to ensure that the clinical environment is safe for procedures to be undertaken, and remains dust free a number of changes of the air within the environment are required. There should be a minimum of 10 air changes per hour which should be provided via a mechanical system.

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 wipe-able 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 (2011) 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 micro organisms 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

Department of Health -The Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance (January 2015)

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).

Department of Health - HTM 03-01 (2007) specialised ventilation for healthcare premises.

NHS Estates – Infection Control in Built Environments HMSO2002

Health & Safety Executive 1999 CoSHH Regulations

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)

Department of Health (2013) Health Building Note 11-01 Facilities for Primary and Community Care Services

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