

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	3
<b>Service</b>	Community Vasectomy Service
<b>Commissioner Lead</b>	REDACTED
<b>Provider Lead</b>	REDACTED
<b>Period</b>	1 <sup>st</sup> January 2024
<b>Date of Review</b>	May 2023 (Revised March 2024)

#### 1. Population Needs

##### 1.1 National/local context and evidence base

Sterilisation has become increasingly popular since the late 1960's. 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 is irrespective of age or marriage. A recommendation to consider sterilisation by a Professional should generally be part of a range of options offered for information or as a result of a particular circumstances or opportunities.

In the UK between 2000-2010, there has been a downward trend in the number of vasectomies carried out in hospital settings but an increase in the number of procedures being carried out in other settings. In England the total number of vasectomies performed in all health settings was 41,100 in 2000/2001 and 18,000 in 2010/11. A reduction of 56.2%.

During 2014/15, 11,113 procedures were performed, and the number stabilised until 2019/20 at around 11-12,000 per year.

In 2020/21, the number fell to 4,486, which is 63% less than 2019/20.

Vasectomy usage is between 17-21% in the UK and the average age is 35.

Up to 6% of men elect to have the vasectomy reversed. This number is down by 81.2% since 2019/21.

References:

Faculty of Sexual & Reproductive Healthcare (Royal College of Obstetricians & Gynecologists): Male and Female Sterilisation 2014

Sexual & Reproductive Health Services, England (contraception) 2020/21

#### 2. Outcomes

##### 2.1 NHS Outcomes Framework Domains & Indicators

<b>Domain 1</b>	<b>Preventing people from dying prematurely</b>	
<b>Domain 2</b>	<b>Enhancing quality of life for people with long-term conditions</b>	
<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health or following injury</b>	
<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	
<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	

##### 2.2 Local defined outcomes

- Patients will receive an effective quality vasectomy procedure with complications rates in line with the Royal College of Gynecologists and Obstetricians in a community location of their choice.
- Provide a pre-operative individualized assessment including a process of counselling and consent with full information about the advantages, disadvantages, and permanency of the procedure.

### **3. Scope**

#### **3.1 Aims and objectives of Service**

The service will provide a quality and safe one or two stage vasectomy procedure under local anaesthetic in a primary care setting to all adult males who request it and are of sound mind, not acting under external duress and are registered with an NHS Nottingham and Nottinghamshire General Practitioner (GP) and that they are fully counselled as to the pros and cons of complications and reversibility.

##### **Objectives**

- To provide quality local community vasectomy services within Nottingham City PBP, South Nottinghamshire PBP and Mid-Nottinghamshire ICB and Bassetlaw.
- To provide services that comply with accepted best practice, relevant guidelines in clinical practice and robust governance arrangements.
- To provide a complete holistic patient focused care package, including pre and post-operative care, information, advice and counselling.
- To provide an opportunity for advice around sexual health and testicular self-examination.
- To ensure consistent and continuous care between health professionals, and effective and efficient communication.

#### **3.2 Service description/care pathway**

##### **Access to the service**

The service will:

- Be a provider on e-RS or working towards this with a planned implementation date.
- Provide and implement a standard referral form, which will include specific patient focused health care questions that function as an initial triage system.
- Referrals that are not appropriate for a community service to be returned to source of referral within one week. Patients who self-refer inappropriately will be advised to see their General Practitioner. Patients who are not currently registered with a General Practitioner will be advised to do so.
- Ensure that a range of appointment times are offered including evening and weekends to suit men of working age.

##### **Support, Advice and Assessment Appointment**

Offer a pre-operative appointment within two weeks of receipt of referral for patients having a two-stage process.

Vasectomy should be discussed in detail with all men requesting sterilization. Clinical guidelines for sterilisation are [cec-ceu-guidance-sterilisation-cpd-sep-2014 \(1\).pdf](#)

Pre-operative individualised assessment must include a process of counselling and consent. Counselling and advice on sterilisation will also include a full range of information about and access to other long term reversible methods of contraception. This should include information on the advantages, disadvantages and relative failure rates of each method.

Provide individual patient care based on a holistic assessment. All verbal counselling will be supported by accurate, impartial printed or recorded information (in translation, where appropriate), which the person requesting vasectomy may take away and read before the procedure.

The operating doctor 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.

Men will be informed that vasectomy has an associated failure rate and that pregnancies can occur several years after vasectomy. Failure rate for vasectomy will be quoted as approximately 1 in every 2000 after clearance has been given.

Although men must understand that this procedure is intended to be permanent, they will be given information of the success associated with reversal should it be necessary.

Men should be informed that reversal operations or intracytoplasmic sperm injections are rarely available on the National Health Service.

Men will also be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association of an increased risk of prostate cancer is at present likely to be considered to be non-causative. Men will be informed of the risk of chronic testicular pain after vasectomy.

Counselling should also consider cultural, religious, psychosocial, psychosexual and other psychological issues some of which may have implications beyond fertility. Healthcare Professionals will concentrate on factual information and avoid persuasion or any act that may be deemed coercive, however clear the advantage of their recommended option appears to be.

Additional care will be taken when counselling patients that;

- Are under the age of 30 years.
- Have few or no children already (few usually relates to two or fewer)
- Are not in a relationship
- Not in a mutually faithful relationship or in a crisis relationship
- May be making the decision as a reaction to a loss of a relationship
- Who may be at risk of coercion by their partner, family or health or social welfare professional
- Timing relating to abortion or childbirth

A history will be taken, and an examination will be performed.

Offer an appointment for the procedure no earlier than 2 weeks, and no later than 4 weeks after the pre-operative assessment to ensure a cooling off period is allowed.

Due to the permanency of the procedure, if there are concerns about a person's mental capacity to give informed consent, guidance from the Mental capacity Act (2007) [Mental Health Act 2007 \(legislation.gov.uk\)](#) and Making Decisions, the guide for people who work in Health and Social Care (2005) must be adhered to.

### **Vasectomy Procedure**

The clinician who performs or supervises a trainee performing a vasectomy takes responsibility for the procedure even when discussion, examination and consent were undertaken by other healthcare professionals.

All Practitioners must have been trained to the standard advocated by the Faculty of Family Planning and reproductive Health Care (FFPRHC) and evidence of this must be seen by the Commissioner.

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

The operating clinician will ensure they are not accepting full responsibility for a procedure that they may have objections in principle or for which they lack the necessary competence.

Promote the two-stage process to vasectomy as this ensures the patient has a two week cooling off period before having the permanent sterilisation.

Clinicians will be competent in the no scalpel procedure. Vasectomy will be performed under local anaesthetic. 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.

Division of the vas on its own is not an acceptable technique because of its failure rate. It should be accompanied by fascial interposition or diathermy. Clips will not be used for occluding the vas, as failure rates are unacceptably high.

Excised portions of the vas will only be sent to histological examination if there is any doubt about their identity.

Offer a one stop approach only if the patient requests it and it is deemed appropriate for that patient following a comprehensive telephone consultation by the surgeon and accompanying written information. A two-week cooling off period between pre-operative information/assessment and the procedure must still be enforced.

Discuss in detail an Indemnity Form that they will be asked to sign. This relieves the provider of any responsibility if the patient fails to comply with semenology testing and a pregnancy occurs.

### **Post procedure care**

Provide post vasectomy care including emergency contact numbers (when and who to contact), pain relief, wound care, resuming normal activities including sexual intercourse, contraception prior to clearance and semenology testing.

Men must continue to use effective contraception until azoospermia has been confirmed.

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

Advise patients on how to comply with semenology testing and supply all necessary equipment in advance of the 16 and 20 week target. Inform patients that they will require at least two consecutive clear semenology test results at 16 and 20 weeks post vasectomy before being considered successful. Emphasise at each stage of the pathway that it is the patient's responsibility to arrange an appointment for semenology testing. The provider will forward semenology results to the patient and their General Practitioner to confirm 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 10,000/ml 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.

A register of failed vasectomies and post-operative complications will be maintained. A data submission will be required detailing failures and complications and shared with the commissioner on a monthly basis using agreed pro-forma.

### **Patient Safety**

Comply with policies and procedures on:

- Infection Prevention and Control
- Complaints and compliments
- Management and reporting of all incidents, including serious untoward incidences (SUI's) and near misses
- Never Events occurrences
- Risk assessment and risk management
- Information Governance incl. GDPR
- Meeting the duties of equality legislation
- Safeguarding Adults
- Data protection
- Patient complaints
- Quality Assurance/ maintaining good practice
- Faculty of Family Planning & Re-productive Health Care Standards
- Clinical and Professional Development (CPD), supervision and training
- NHS Nottingham City PwSI (Practitioner with Special Interest) Accreditation process
- Nottinghamshire County Accreditation process

Practitioners who are being trained to perform vasectomies should ensure their training conforms to that advocated by the Faculty of Family Planning and Reproductive Health Care (FFPRHC). Clinicians with no

prior experience should be supervised for 10 operating sessions or 40 procedures while doctors with relevant prior surgical experience should perform 8 supervised procedures.

Operators will be able to demonstrate appropriate training or experience and planned appropriate access to secondary care advice and services when necessary.

The Provider will be expected to demonstrate the regularity of the personal development proposed for all members of staff on an annual basis.

The Provider and operative premises will be CQC registered and must ensure that they are aware of, compliant with, and can provide evidence if required to demonstrate compliance with any relevant Care Quality Commission guidance.

Providers must ensure that they have sufficient and relevant indemnity and insurance cover including clinical/medical and malpractice.

### **Confidentiality**

The service must be, and be known to be, strictly confidential. A written Confidentiality Policy should be prominently displayed and made available to service users. Staff should be able to demonstrate an understanding of the Policy and process and be able to communicate this to clients using the service.

Confidentiality must be maintained throughout the patients visit, including the minimal use of names in public areas, such as the reception or waiting areas. In order to maintain confidentiality, no information should be sent to the client's home address unless the client expressly wishes this. Care should be taken to ensure that information is not shared with anyone else, including the clients General Practitioner, without the client's consent. Issues of child protection overrule the right to confidentiality; however, the client should be informed if other agencies are to be involved.

The Service Provider will be expected to demonstrate that the collection, storage and transfer of information to other services, including that in electronic format is secure and complies with any data protection requirements.

### **Consent**

The Service Provider will be expected to operate a policy for obtaining consent that complies in all respects with the requirements of National Minimum Standards and the Private and Voluntary Healthcare (England) Regulations 2001 [here](#)

Competent consent is understood in terms of the client's ability to understand the choices and their consequences, including the nature, purpose and possible risk of any treatment (or non-treatment). In assessing competence the Service Provider needs to refer to the Department of Health (DOH) Reference Guide to Consent for Examination or Treatment (2009) [here](#)

### **Service User Experience**

All clients having the procedure should be asked to complete an anonymous pre and post procedure satisfaction survey. The completed surveys should be collated and put into a report to the commissioner for purposes of improving quality and service development. The provider will undertake additional patient satisfaction surveys annually. The information gathered by the patient satisfaction survey should be taken into account when reviewing standards as part of clinical audit.

The Service Provider should put in place and maintain throughout the episode of care an effective representation and complaints procedure and have systems in place, which monitor the incident and outcome of all complaints and investigations regarding the service.

All complaints should be reported to the commissioner as soon as possible, but in any event within two working days. Records should include the nature of the complaint, the individual member of staff involved, the contact details of the complainant, the date and time of both the complaint and the date of the incident and such records should be maintained for a period of ten years.

Untoward incidents and near misses should be reported to the Commissioner immediately. All major complications should be audited together with deviations from planned care.

User experience feedback/questionnaire will be offered to each and reported back at the quarterly review meeting.

### **Monitoring Staff Quality**

Clinical audit should be undertaken twice a year. Professional and support staff should be involved in the audit of organisational care. Professional staff should undertake interdisciplinary clinical audit and receive clinical supervision.

The commissioner will provide details of the referral process and details of the booking service to GPs, Community Contraceptive and Sexual Health Services, GUM Clinics, and any other relevant agencies.

### **Response Time, Detail and Prioritisation**

Complete an initial triage assessment of the referral to ensure the patient appears suitable for a community vasectomy service within one week of receipt of the referral.

Offer an appointment within two weeks of receipt of the referral. The service provider will not cancel appointments.

Referrals that are not appropriate for a community service to be returned to source of referral within one week. Patients who self-refer inappropriately will be advised to see their General Practitioner. Patients who are not currently registered with a General Practitioner will be advised to do so.

### **Discharge Procedure (Care Transfer)**

Information should be given to the client on discharge, which explains the likely course of recovery, including pain and bleeding and with sufficient information to allow another practitioner elsewhere to deal with any complications. Symptoms indicating deviations from the normal course of recovery must be explained and the client advised how and when to seek medical help. Clients should have a list of those complications that require urgent medical consultation and should be given a 24 hour telephone helpline number to ring if they have concerns. Urgent clinical assessment and emergency admission must be available if necessary.

This should be supported by written information, which must be available in languages appropriate to clients using the service. In most cases the local NHS Hospital Trust will deal with emergency readmissions.

Staff should be secured to stay beyond their contractual hours, where necessary, and this must be incorporated into the overall unit cost.

### **Promotion and support of self-care**

The service will promote a culture of encouraging informed decisions regarding healthcare. The aim will be to facilitate self-care and patient/carer empowerment.

### **Information provided to patients and carers**

Patients and carers will receive information on what they can expect from the provider, details of appointments, chaperone facilities, confidentiality issues and contact details for the clinicians.

Patients and carers will be informed of the vasectomy procedure, the implications, the possible benefits and risks involved.

Patients will be informed of the rationale for all onward referrals ensuring patients maintain their right to make choices.

All information will be available in a variety of communication formats to ensure that all those with visual or hearing difficulties or whose first language is not English will not be disadvantaged. Professional interpreters will be used as appropriate.

The provider will signpost to other services per the agreed pathway.

### **Costs of Service**

The total cost of the service will include:

- Patient focused health care questions that function as an initial triage system.
- A physical and medical assessment
- Pre-operative 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
- Semenology testing – all appointments and equipment for each test required
- Disclaimer forms

### **Price of Service**

Counselling appointment only i.e. patient not suitable or decides against having the procedure	
Counselling appointment plus operation (total cost includes all post operation testing and notification)	
The pricing structure includes all tests, counselling, treatments and analysis required	

**Patients who do not attend for their appointment (DNAs) or unable to attend on the day (UTA): as in Secondary Care, no payment will be made to Providers for DNAs or UTAs in any part of the service. Payment will only be made against actual activity carried out.**

### **3.3 Population covered**

Patients registered with a GP practice in Nottinghamshire and Bassetlaw PBP.

### **3.4 Any acceptance and exclusion criteria and thresholds**

- All adult males who request it, are of sound mind, not acting under external duress and are registered with a Nottingham and Nottinghamshire ICB (GP), and do not have any of the exclusion criteria and are appropriately counselled as to the pros and cons of complications and reversibility.
- Open access referrals, referrals will be proactively encouraged from patients, GP's, other appropriate clinicians, the Health Shop, Genito Urinary Medicine (GUM) Clinics and Contraception and Sexual Health (CASH) and any other relevant agencies.

### **Exclusion Criteria**

- Lack of consent
- Previous scrotal surgery
- Hydrocele / varicocele
- Inguinal hernia
- Cryptorchidism
- Gross obesity: BMI>35
- Anticoagulant therapy
- Coagulation disorders
- Drug or alcohol misuse
- Mental instability
- A history of an allergy to local anaesthetic
- A history of fainting easily
- Patient refusal of local anaesthesia
- Those deemed unsuitable for local anaesthetic
- Scrotal skin infection
- Active sexually transmitted disease

- Balanitis
- Epididymitis
- Orchitis

Patients who fall within the exclusion criteria will be signposted to appropriate services or their registered GP for further advice.

### **3.5 Interdependence with other services/providers**

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

- General Practitioners
- Secondary Care Vasectomy Service Providers
- Accredited Andrology Services
- Contraception and Sexual Health (CASH)
- Genito-Urinary Medicine (GUM)
- The Health Shop
- Walk In Centres
- Interpreters
- Any other appropriate service

The provider shall be aware of and involved in the below networks and programs as appropriate:

- Andrology
- Microbiology
- Infection Control

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g., NICE)**

- NICE Clinical Guidelines 139. Infection: prevention and control of healthcare associated infections in primary and community care.
- All Providers will have CQC registration for surgical procedures.

### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)**

- Male and Female Sterilisation, Evidence-based Clinical Guideline Number 4, Royal College of Obstetricians and Gynaecologists. January 2004.

### **4.3 Applicable local standards**

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])**

### **5.2 Applicable CQUIN goals (See Schedule 4 Part [E])**

Not applicable



## 6. Location of Provider Premises

### The Provider's Premises are located at:

The Service is available across Nottinghamshire at: -

#### **Mansfield**

Nottingham Road Clinic,  
195 Nottingham Road,  
Mansfield  
NG18 4AA

#### **Balderton**

Balderton Primary Care Centre  
Lowfield Lane  
Balderton  
Newark  
Nottingham  
NG23 3HJ

#### **Bramcote**

2A Hanley Avenue  
Bramcote  
Nottingham  
NG9 3HF

#### **Carlton**

Park House Medical Centre  
61 Burton Road  
Carlton  
Nottingham  
NG4 3DQ

#### **West Bridgford**

Musters Medical Practice  
Embankment Primary Care Centre  
50-60 Wilford Lane  
West Bridgford  
Nottingham  
NG2 7SD