The Cooden Medical Group

Inspection report

Little Common Road
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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Overall summary

This service is rated as Requires improvement overall.

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection of The Cooden Medical Group on 5 July 2022 under Section 60 of the Health and Social Care Act 2008. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. This was the provider's first inspection of the service since it registered with the Care Quality Commission (CQC).

Throughout the COVID-19 pandemic the Care Quality Commission (CQC) has continued to regulate and respond to risk. However, taking into account the circumstances arising as a result of the pandemic, and in order to reduce risk, we have conducted our inspections differently.

This inspection was carried out in a way which enabled us to spend a minimum amount of time on site. This was with consent from the provider and in line with all data protection and information governance requirements.

This included:

- Speaking with staff in person, on the telephone and using video conferencing.
- Requesting documentary evidence from the provider.
- A site visit.

We carried out an announced site visit to the service on 5 July 2022. Prior to our visit we requested documentary evidence electronically from the provider. We spoke to staff on the telephone and using video conferencing prior to and following our site visit.

The Cooden Medical Group is an independent service led by the medical director, a consultant interventional radiologist. The service specialises in the provision of minimally invasive varicose vein treatments, performed under local anaesthetic and ultrasound guidance, including radio-frequency ablation and foam sclerotherapy. The service also provides practising privileges to a range of consultants and GPs with special interests, who work under the governance of The Cooden Medical Group to deliver services in women's health, dermatology, minor surgical procedures such as lesion excision and upper blepharoplasty (to remove excess skin or fat from the eyelids), and a sub-contracted NHS commissioned vasectomy service. Musculoskeletal (MSK) and joint injection services are provided from a London-based satellite clinic only.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some exemptions from regulation by CQC which relate to particular types of regulated

Overall summary

activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Cooden Medical Group provides a range of non-surgical aesthetic interventions, for example, cosmetic botox injections, dermal fillers and skin rejuvenation treatments, which are not within CQC scope of registration. Therefore, we did not inspect or report on these services.

The Cooden Medical Group is registered with the Care Quality Commission to provide the following regulated activities: Treatment of disease, disorder or injury, Diagnostic and screening procedures and Surgical procedures. Prior to our inspection we identified that the provider had been providing services which included the insertion and removal of intrauterine contraceptive devices. This activity requires the provider to be registered for the regulated activity Family planning services, which the provider was not registered to provide. The provider immediately submitted an application to register to provide the regulated activity and discontinued carrying out the activity in the meantime.

The medical director is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are registered persons. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Our key findings were:

- Medical staff had the relevant skills, knowledge and experience to deliver the care and treatment offered by the service.
- There were processes in place for the training and performance review of some staff. However, monitoring of training records for staff employed on a sessional basis was incomplete.
- Recruitment checks had been carried out in accordance with regulations.
- There were appropriate arrangements to manage medical emergencies and suitable emergency medicines and equipment in place.
- There were some safeguarding systems and processes to keep people safe. However, staff had not received training in the safeguarding of children and there was no documented policy on the safeguarding of children.
- Arrangements for chaperoning were effectively managed.
- There had been insufficient action taken to identify and address some legionella and fire safety risks. Staff had not participated in fire drills.
- Best practice guidance was followed in providing treatment to patients. For example, varicose vein treatments were offered in line with NICE guidance; excised lesions were routinely sent for histological review.
- There were some processes to assess the risk of, and prevent, detect and control the spread of infection. However, staff immunisations were not monitored in line with current guidance.
- Medicines were stored securely, however fridge temperature monitoring processes did not ensure the correct temperature range for their safe storage.
- Policies provided up to date, relevant and sufficient information, to provide effective guidance to staff.
- There was a lack of clinical audit across some specialties but regular auditing of clinical record keeping processes.
- Clinical record keeping was clear, comprehensive and complete.
- There were effective governance and risk assessment processes in the reporting and managing of incidents.
- Staff dealt with patients with kindness and respect and involved them in decisions about their care.
- Staff worked well together as a team and all felt supported to carry out their roles. There was a strong team ethos and culture of working together.
- The service encouraged and valued feedback from patients and staff. Feedback from patients was positive.

The areas where the provider **must** make improvements as they are in breach of regulations are:

Overall summary

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

(Please see the specific details on action required at the end of this report).

The areas where the provider should make improvements are:

- Implement ongoing review of the risk of local anaesthetic toxicity and arrangements to manage associated medical emergencies.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team was led by a CQC lead inspector and included a GP specialist advisor and a radiographer specialist advisor.

Background to The Cooden Medical Group

The Cooden Medical Group specialises in the provision of minimally invasive varicose vein treatments, performed under local anaesthetic and ultrasound guidance, including radio-frequency ablation and foam sclerotherapy. The service also provides practising privileges to a range of consultants who work under the governance of The Cooden Medical Group to deliver services in women's health, dermatology, minor surgical procedures such as lesion excision and upper blepharoplasty and a sub-contracted NHS commissioned vasectomy service. Musculoskeletal (MSK) and joint injection services are provided from a London-based satellite clinic only.

The service also provides non-regulated aesthetic treatments, for example, cosmetic botox injections, dermal fillers and skin rejuvenation treatments, which are not within CQC scope of registration.

The Registered Provider is The Cooden Medical Group.

The Cooden Medical Group is located at Little Common Road, Bexhill On Sea, Dorking Road, East Sussex, TN39 4SB.

The clinic opening times are:

Monday to Saturday 9.00 – 6.00pm

The service also operates from two satellite clinics:

Cooden Medical of Harley Street, 96 Harley Street, Marylebone, London W1G 7HY. Varicose vein and MSK services are provided, approximately once per week.

The Cooden Clinic, Castle House, Orchard Street Mews, Orchard Street, Canterbury, Kent CT2 8AP. Varicose vein treatments are provided, approximately once per month.

We did not visit either of the service's two satellite locations as part of our inspection.

The staff team is comprised of a business operations manager who is supported by three administrators who undertake coordinator and receptionist roles. The service employs two registered nurses on a sessional basis and a therapist who undertakes a clinical assistant role. Eight consultants, including the medical director, plus two GPs with special interests, provide specialist consultations and treatments on a sessional basis, under the governance and control of The Cooden Medical Group. Clinical specialisms include vascular surgery, radiology, urology, women's health and cosmetic surgery.

The service is run from self-contained, single storey premises which are owned by the provider. The premises include a suite of consultation and treatment rooms, a reception and waiting area. Access to the premises at street level, is available to patients with limited mobility. Toilet facilities are located on the ground floor.

How we inspected this service

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Requires Improvement

Are services safe?

The service had some systems to keep people safe and safeguarded from abuse.

- The service had systems and processes to safeguard vulnerable adults from abuse. The provider's safeguarding adult's policy provided appropriate guidance for staff. Staff we spoke with had a clear understanding as to who was the safeguarding lead within the service and how to raise safeguarding concerns about a patient. Our review of training records confirmed that all staff had received training in the safeguarding of vulnerable adults at a level appropriate to their role.
- Treatment was offered to those aged over 18 years of age and no children were treated by the service. However, in the event that children may attend the service whilst accompanying an adult, or staff may have contact with adults who may pose a risk to children, some staff had not received training in the safeguarding of children. There was no documented policy on the safeguarding of children to provide guidance to staff.
- The provider carried out all required staff checks at the time of recruitment and all required ongoing monitoring, such as professional registration status and medical indemnity confirmation. Disclosure and Barring Service (DBS) checks were undertaken for all staff. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).
- We saw there was signage on display within the service which invited patients to request a chaperone. All staff who acted as chaperones were trained for the role and had undergone a DBS check.
- There were mainly effective systems to manage infection prevention and control within the service. Cleaning and monitoring schedules were in place for clinical areas. All staff had received training in infection prevention and control. An audit of infection prevention processes had been undertaken in January 2022. However, the provider was unable to demonstrate that they held appropriate records relating to staff immunisations.
- We reviewed the service's immunisation and health clearance policy dated June 2022. The policy reflected current guidance in relation to staff immunisation requirements. The policy stated that the service would monitor the vaccination status of all team members. Our review of immunisation records confirmed there were no immunisation records held relating to non-clinical staff. A record of only Hepatitis B status and COVID vaccination was held for one doctor who had been recently recruited. There were variable immunisation records available relating to varicella, tetanus, polio, diphtheria and MMR (measles, mumps, rubella) in line with current guidance, for other staff members. Therefore, staff records we reviewed were not in line with national guidance or the provider's policy on monitoring the immunisation status of staff.
- The service performed minor surgical procedures for which they used single-use, disposable items. There were sufficient stocks of personal protective equipment, including masks, aprons and gloves, available to staff. There were sufficient supplies of consumables such as ultrasonic gel and ultrasound probe covers, to support ultrasound services delivered.
- There were systems for safely managing healthcare waste, including sharp items. We saw that clinical waste disposal was available in clinical rooms. Bins used to dispose of sharps items were signed, dated and not over-filled. There were suitable arrangements in place for the collection of healthcare waste by a waste management company.
- The service had some systems to manage health and safety risks within the premises, such as fire safety and legionella. Legionella risk assessments were carried out and resulting actions had been completed. (Legionella is a particular bacterium which can contaminate water systems in buildings). Water systems were deemed low risk in relation to legionella bacteria growth & exposure. Staff undertook monthly monitoring of water temperatures to mitigate the risks associated with legionella, as recommended within their legionella risk assessment. However, some hot water temperatures had been recorded as below the required minimum for a period of three months prior to our inspection. This had not been reported to or identified by leaders and no action had been taken to respond to the low temperatures.
- There were documented risk assessments in place to manage risks associated with the premises and general environment. We noted that one staff member had undertaken health and safety officer training. There was a documented fire evacuation plan in place. There was guidance and information, including risk assessments, available to staff to support the control of substances hazardous to health (COSHH).

Requires Improvement

Are services safe?

- The provider had carried some assessment of fire safety risks. However, the fire risk assessment for the premises had been undertaken by a staff member who had not been trained to adequately assess the risks. There were no actions arising from the risk assessment, which was insufficient to assess all possible risks. For example, there was no assessment of premises signage, fire evacuation procedures, staff training or the monitoring of fire safety equipment. The risk assessment had not identified that staff had not participated in regular fire drills.
- However, there was appropriate fire-fighting equipment located within the premises which was regularly serviced and maintained. We noted that fire alarm and emergency lighting testing was carried out on a monthly basis. Fire extinguishers had been serviced in July 2021. Staff had undertaken some fire safety training.
- The provider ensured that facilities and equipment were safe. Equipment was maintained according to manufacturers' instructions. For example, we saw that ultrasound equipment used in the delivery of vascular and musculoskeletal services was subject to regular servicing and maintenance. We reviewed records to confirm that electrical equipment had undergone portable appliance testing in July 2021. There was a current electrical safety report for the premises.

Risks to patients

There were systems in place to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff required to meet patient needs. Clinical staff working on a sessional basis were scheduled according to patient demand.
- There were planned induction processes in place and a plan of required training for staff to complete as part of the induction process. Induction plans were tailored to meet the needs of the individual staff member and their role.
- There were processes for monitoring patients following their treatment. Where patients underwent excision of a lesion, there were processes for sending dermatology samples for histology and receiving results for review. Samples were recorded in a histology log and all samples were tracked when dispatched. The clinician reviewed the results and dictated a letter to be sent to the patient and their NHS GP. They made onward referrals to secondary care services if these were required. Patients who underwent varicose vein or vasectomy treatments received a call from the service the day following their treatment to confirm their well-being. Varicose vein patients received a second call one week later and attended for a follow up review with the clinician eight weeks following treatment.
- Staff told us that where patients presented as complex cases, for example vascular patients, there were opportunities for informal discussions with clinicians working within the same specialty, in order to review treatment options.
- Staff told us that all patients would receive appropriate support and review in the event of concerns or complications following their treatment. Patients would be promptly reviewed within the service if required.
- The service implemented inclusive pricing which meant that patients who were required to attend follow up appointments for example, for review of a wound or to monitor the efficacy of treatment, were not charged for follow up appointments. This encouraged patients to attend for review and promoted optimum treatment outcomes for patients.
- We reviewed arrangements within the service to respond to medical emergencies. We found there were appropriate supplies of emergency medicines available to staff in the event of a medical emergency. There was oxygen and a defibrillator available on the premises which were subject to regular checks.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. Staff had received basic life support training which was annually updated. Some sessional staff had completed intermediate life support training.
- Clinicians administered tumescent anaesthesia to patients undergoing treatments for varicose veins, in order to manage their pain. (Tumescent anaesthesia involves the injection of a very dilute local anaesthetic solution, into tissue, until it becomes firm and tense (tumescent)).
- We found that there were appropriate protocols in place for the mixing and administration of the tumescent anaesthesia to ensure its safe use. Clinicians closely monitored the dosage of local anaesthetic administered to patients, in line with the service's protocols, in order to minimise the risk of local anaesthetic toxicity. The service had

adequately assessed the risks associated with the management of severe local anaesthetic toxicity which may occur following the administration of local anaesthetic medicines. They did not hold a supply of lipid emulsion which may be used to mitigate the toxic effects of local anaesthetic. However, the provider had clearly set out their rationale for this decision based upon the nature and setting of the service.

- The service implemented use of the World Health Organisation (WHO) surgical safety checklist to improve the safety of patients undergoing a surgical procedure. (The checklist serves to remind the surgical team of important checks to be performed before and after the surgical procedure in order to reduce adverse events.)
- Staff had received guidance and training in the identification of red flag signs, or symptoms of sepsis in patients.
- The service had a first aid kit in place which was appropriately stocked, and its' contents were regularly checked.
- There were appropriate professional indemnity arrangements in place for clinical staff.
- The provider had in place public and employer's liability insurance policies.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

- We reviewed clinical records relating to 15 patients who had received treatment across all specialties delivered within the service.
- Individual care records were written and managed in a way that kept patients safe. Clear, accurate and contemporaneous patient records were consistently kept. Treatment planning and information were fully documented.
- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. The provider had developed templates to ensure consistency of clinical record keeping.
- Digital photographs of affected areas were taken where appropriate to enhance clinical record keeping and to promote comparisons before and after treatment. Photographic records were stored securely on the provider's electronic records system.
- Duplex ultrasound was used, in line with best practice guidance, to confirm the diagnosis of varicose veins, prior to the development of a personalised treatment plan.
- Consent processes were comprehensive and consistently applied. There was a documented consent policy. We reviewed the consent form templates developed by the provider for use with patients undergoing a procedure. Patient records clearly documented the consent process and discussions between the practitioner and patient.
- The service had effective systems for sharing information with staff and other agencies, for example, the patient's NHS GP, to enable them to deliver safe care and treatment.
- Clinicians made appropriate and timely referrals in line with protocols and up to date evidence-based guidance. For example, for patients requiring onward referral to secondary care services for more complex vascular disease or skin cancer treatment.
- Clinical records were stored on a secure, password-protected, electronic system. Hand-written records were stored securely in locked cupboards within a locked room.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

Safe and appropriate use of medicines

The service had some systems for the appropriate and safe handling of medicines.

- The service kept prescription stationery securely and monitored its use. There were systems and arrangements for managing the safe handling of medicines and prescribing practices in a way which minimised risks to patients.

Requires Improvement

Are services safe?

- The service undertook infrequent prescribing but ensured that when required, staff prescribed and administered medicines to patients, and gave advice on medicines, in line with legal requirements and current national guidance.
- Medicines requiring refrigeration were stored in a lockable fridge. The fridge had a freezer compartment, which meant it was unsuitable for the purpose of storing medicines. We found medicines stored directly against the sides of the freezer compartment which were at risk of being subject to very low temperatures. Temperature monitoring records confirmed twice daily checks of the fridge temperatures. Staff had recorded the actual temperature of the fridge at the time of monitoring, as well as the highest and lowest temperatures during a given period. However, we found that fridge temperature monitoring records had highlighted temperatures falling significantly outside of the recommended minimum and maximum range, of between two and eight degrees centigrade, for prolonged periods between March and July 2022. We noted the lowest temperatures were repeatedly recorded as minus 4.4 degrees centigrade and the highest were recorded as either 11 or 12.1 degrees centigrade. No action had been taken prior to our inspection, to report the findings or to ensure that those medicines, stored outside of the recommended range, were safe for use.
- Appropriate processes were in place for the ordering, receipt and monitoring of stock medicines held and staff kept accurate records of those medicines.
- Emergency medicines were readily available and in date and supplies were regularly checked. There were documented records of those checks.

Track record on safety and incidents

- There were some monitoring and auditing processes in place to provide assurance to leaders that systems were operating as intended. There were risk assessments in place in relation to safety issues to support the management of health and safety within the premises.
- Managers responded promptly when safety concerns were identified. For example, we noted that the service had acted to recruit a new cleaning company due to concerns regarding standards of work. Sharps bins had been relocated in response to findings of an infection control audit.
- However, monitoring and auditing processes within the service had not always effectively identified safety issues. For example, the premises fire risk assessment had not identified that staff had not participated in regular fire drills; medicines fridge temperature monitoring had not identified medicines were stored outside of the recommended range for safe storage.

Lessons learned and improvements made

The service had systems to ensure they learned when things went wrong.

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There were adequate systems for reviewing and investigating when things went wrong. The service had recorded seven incidents within the 12 months preceding our inspection. There was a relatively low threshold for incident reporting which promoted a culture of openness and transparency and ensured timely and appropriate action was taken to make changes where necessary.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. For example, staff told us that where one patient had not been fully satisfied with the outcome of their treatment, they were encouraged to attend the service to discuss their concerns in person with the manager and clinician and offered additional treatment.
- The service had systems in place for knowing about notifiable safety incidents. The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team.

Good

Are services effective?

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence-based practice.

- Clinicians employed by the service across all specialties, had high levels of skills, knowledge and experience to deliver the care and treatment offered by the service. Clinicians kept up to date with current evidence-based practice. We found that clinicians assessed needs and delivered care and treatment in line with relevant current legislation, standards and guidance. For example, the medical director was a consultant interventional radiologist who specialised in minimally invasive varicose vein treatments. They were supported by consultant vascular surgeons employed on a sessional basis and delivered varicose vein treatments in line with National Institute for Health and Care Excellence (NICE) guidance and using current technologies. Duplex ultrasound was used, in line with best practice guidance, to confirm the diagnosis of varicose veins and ensured tailored and individual treatment planning. Clinical staff providing dermatology services had received specialist dermatology training and followed best practice guidance, such as that provided by the British Association of Dermatologists (BAD).
- We reviewed clinical records relating to 15 patients who had received treatment within the service across all specialties. We found there was a consistent approach to clinical record keeping and risks to the patient were comprehensively assessed, discussed and documented. Clear, accurate and contemporaneous clinical records were kept. Treatment planning and diagnostic information were fully documented.
- The service ensured they provided information to support patients' understanding of their treatment, including pre- and post-treatment advice and support. Staff within the service provide a telephone call to patients on the day following treatment to ensure their well-being and to answer any queries. In the event of concerns or complications, patients were able to access post treatment support via follow up appointments and also on the telephone.
- Staff assessed and managed patients' pain where appropriate. Patients were prescribed local anaesthetic medicines prior to some procedures, where appropriate. For example, patients undergoing treatments for varicose veins, vasectomy and excision of lesions.
- We saw no evidence of discrimination when making care and treatment decisions.

Monitoring care and treatment

The service was able to demonstrate some quality improvement activity.

- The service used information about care and treatment to assess the need to make improvements.
- Staff employed on a sessional basis under practising privileges, were subject to some review of their performance within the service. The service undertook regular auditing of clinical record keeping processes across all specialties. However, formal monitoring of clinical decision-making and patient treatment outcomes was not applied consistently across all specialities.
- The service provided vasectomy treatments, as a sub-contractor for the delivery of an NHS commissioned community vasectomy service. The provider was required contractually to monitor and report on a wide range of key performance indicators for this service. These included for example, infection rates; staff sharps injuries; patient satisfaction rates; patient safety incidents; complaints; waiting times for triage of the initial referral, for pre-operative consultation and for surgery.
- For other specialities, such as women's health, dermatology, musculoskeletal and vascular services, there were less formal processes under which patient clinical treatment outcomes were monitored.
- Managers undertook a monthly audit of clinical record keeping processes across all services. This included monitoring for example, recording of medical history, treatment planning, patient consent to treatment and cost of treatment.

Good

Are services effective?

- However, where doctors worked under practising privileges, outside of the vasectomy service, there was no formal review of an individual clinician's performance or auditing of their clinical decision making or patient treatment outcomes, other than review of their clinical record keeping. There was no formal review of their practising privileges status or appraisal of their performance.
- Managers collated key information about the service to provide a monthly operational report. This included for example, financial performance, service information, clinical updates, training undertaken and marketing activity. The report was discussed within a monthly operational meeting and information shared as appropriate with wider team members. For example, staff told us that the medical director discussed key aspects of the operational report with doctors working under practising privileges.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- Staff had the appropriate skills and training to carry out their roles. There were planned induction processes in place. There was a plan of required training for staff to complete as part of the induction process.
- The provider understood the learning needs of staff and provided protected time and training to meet them for those employed directly by the service. The service granted practising privileges to experienced and highly trained consultants across several specialties and GPs with special interests. Whilst those clinicians were also employed within the NHS and supported in ensuring training requirements were kept up to date by their NHS employer, the provider had not always ensured that records of their skills, qualifications and training were maintained by the service. For example, we reviewed the personnel records of three consultants employed under practising privileges and found there were no records of their required annual update training held. Immediately following our inspection, the provider sent us completed records of training for those staff members.
- There was regular review of individual performance of staff employed by the service. Staff underwent monthly one-to-one review meetings with the service manager and annual appraisal. Staff who had completed their probationary period were subject to a probationary review. Clinical staff employed on a sessional basis were required to provide evidence of their professional external appraisal summary to the provider but did not undergo an internal appraisal by the service.
- The service held records which confirmed medical professionals were registered with the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) and were up to date with revalidation.

Coordinating patient care and information sharing

- Patients who used the service received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services where appropriate.
- Our review of care records confirmed that before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, previous medical and medicines history.
- Patient information was shared routinely where a patient had provided their consent, and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.
- All patients were asked for consent to share details of their consultation and treatment, with their registered GP, when they registered with the service. Clinicians routinely dictated letters to be typed and sent to the patient's GP, following consultation or treatment, where the patient had given their consent. We noted for example, that findings of diagnostic ultrasound scans and surgical treatments were routinely shared with the patient's GP. An external typing service was employed to ensure communications were processed in a timely manner.
- There were effective arrangements for following up on patients where their care involved other services, for example there were processes for tracking histology results following lesion excision.

Supporting patients to live healthier lives

Good

Are services effective?

- Patients were provided with information about procedures, including the benefits and risks of treatments provided. The service provided comprehensive pre- and post-treatment advice and support to patients. For example, patients undergoing treatment of varicose veins were provided with detailed literature to explain their procedure and advice to support their recovery period.
- Patients received a support telephone call from the service on the day following their treatment and one week later, to ensure their well-being. Varicose vein patients attended for a follow up review of their treatment eight weeks later.
- In the event that patients presented with concerns or complications post treatment, appropriate support and advice was provided. Staff told us that patients would be promptly reviewed within the service if required.
- Where patients' needs could not be met by the service, staff told us they redirected them to the most appropriate service for their needs. For example, staff told us that if they were concerned about a suspicious lesion, they would decline to treat the patient and would refer the patient back to their GP or directly onto a secondary care pathway. Patients who underwent a vasectomy procedure were monitored by a specialist fertility unit to ensure a successful treatment outcome.
- Where lesions were removed or treated within the service, samples were routinely sent for histology. Processes were in place to ensure the recording and tracking of samples sent for histological review. Staff told us that the treating clinician reviewed all results prior to patients being notified of the outcome.

Consent to care and treatment

The service had processes to ensure consent to care and treatment was obtained in line with legislation and guidance.

- Staff we spoke with understood the requirements of legislation and guidance when considering consent and decision making. Staff had completed training in the Mental Capacity Act 2005. Staff described processes for the assessment of patients' suitability for treatment which included their psychological well-being, mental capacity and vulnerability. Staff told us they would not agree to treat patients about whom they had any concerns.
- There was a documented consent policy. Consent processes were comprehensive and consistently applied. Patient records we reviewed clearly documented the consent process and discussions between the practitioner and patient.

Good

Are services caring?

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- Staff understood patients' personal, cultural, social and religious needs. They displayed a welcoming, understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information in relation to their care and treatment.
- The service actively invited feedback on the quality of care patients received. The provider sought regular and ongoing feedback from all patients attending the service via a feedback form. We saw that feedback forms and a posting box were accessible within the patient waiting area. The service reviewed and collated this feedback on a monthly basis. The provider also continually monitored online feedback. We noted that all online reviews had been acknowledged and responded to by the provider. All feedback was shared with the staff team via team meetings and on the staff notice board.
- Feedback from patients was positive about the way staff treated people. For example, patients commented that staff made them feel at ease and were professional and helpful.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- The service ensured that patients were provided with all the information they required to make decisions about their treatment prior to treatment commencing. The service provided comprehensive verbal and written pre- and post-treatment advice and support to patients.
- Patients were contacted by staff on the day following treatment in order to manage their expectations, answer any queries and confirm their well-being.
- Information about pricing was available to patients on the service's website and within the service. Patients were provided with individual quotations for their treatment following their first consultation.
- We saw that the service provided comprehensive information about the service and treatments offered, on their website and within the reception and waiting area. We noted that information on display within the patient waiting area included for example, the provider's quality policy, complaints procedure and treatment information booklets.
- Translation services were available for patients who did not have English as a first language. There was a hearing loop in place and reception staff could support patients in its use.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of maintaining people's dignity and respect. Patients were collected from the waiting area by the clinician and escorted into the consultation room.
- Consultations and treatments took place behind closed doors and conversations could not be overheard. Staff knocked and waited before entering a room, to maintain patients' privacy and dignity.
- Chaperones were available should a patient choose to have one. All staff who provided chaperoning services had undergone required employment checks and received training to carry out the role.
- Reception staff were aware that if patients wanted to discuss sensitive issues or appeared distressed, they could offer them a private room to discuss their needs.

Good

Are services caring?

- Staff complied with the service's information governance arrangements. Processes ensured that all confidential electronic information was stored securely on computers. All patient records and information kept as hard copies was stored in locked cupboards within a locked room. Staff working in the reception area operated a clear desk policy and hard copy documents were promptly locked away.

Good

Are services responsive to people's needs?

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- The provider understood the needs of their patients and arranged services in response to those needs. Doctors across a range of specialties were scheduled to provide services according to patient demand. Appointments were available to patients on an ad hoc basis at two satellite locations, according to patient need. These included for varicose vein treatments and musculoskeletal services.
- Feedback collected by the service was used to make improvements to the patient experience. Staff told us for example, that in response to feedback, music was provided in the treatment room to provide a more relaxing environment for patients undergoing a vasectomy procedure.
- The facilities and premises were well maintained, inviting and were appropriate for the services and treatments delivered.
- Reasonable adjustments had been made so that people in vulnerable circumstances could access and use services on an equal basis to others. For example, there was a hearing loop and translation support services were available.
- Patients were directed to local NHS services if they required assistance when the service was closed.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

- Patients had timely access to initial assessment, test results, diagnosis and treatment. Appointments could be booked in person or by telephone.
- Initial consultations could be requested via a contact form on the provider's website.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients with the most urgent needs had their care and treatment prioritised.
- Referrals to other services were undertaken in a timely way and were managed appropriately.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- The service had a complaints policy in place and information about how to make a complaint or raise concerns was available for patients to read in the reception area and on the provider's website.
- The service had received four complaints within the previous 12 months.
- There was evidence that complaints had been discussed and the learning shared across the organisation. Complaints were discussed at regular team and operational meetings.
- Managers told us that where patients made a complaint, they aimed to meet them in person to discuss their concerns. We saw evidence of this and found that patients had received timely and appropriate responses to their complaints.
- The service clearly informed patients of further action that may be available to them should they not be satisfied with the response to their complaint. The service's written complaints policy included up to date information to support patients should their complaint remained unresolved.

Requires Improvement

Are services well-led?

Leadership capacity and capability:

Leaders demonstrated the capacity and skills to deliver high-quality, sustainable care.

- Leaders demonstrated the capacity to implement systems and processes to support the delivery of high-quality care. Leaders had awareness and understanding of the issues and priorities relating to the quality and future of the service.
- Leaders within the service were visible and approachable. They worked closely with the small team of staff and others and told us they prioritised compassionate and inclusive leadership.
- There was a staffing structure in place across the service and staff were aware of their individual roles and responsibilities. The provider had identified individual members of staff to assume lead roles in key areas. For example, safeguarding and infection prevention and control. The provider had effective processes to develop leadership capacity and skills, including planning for the future leadership of the service.
- There were formal and informal lines of communication between staff working within the service. Staff we spoke with felt well supported and valued. Staff told us they had regular one-to-one interaction with managers due to the small nature of the service and we saw evidence of documented one-to-one meetings. Staff spoke of team meetings they attended, and we saw records of those meetings.

Vision and strategy

- There was a clear vision and set of values. The service had a realistic strategy and supporting business plans to achieve their priorities.
- The service developed its vision, values and strategy jointly with staff and external partners. For example, commissioners of the NHS vasectomy service and clinicians providing services under practising privileges arrangements.
- Staff were aware of and understood the vision, values and strategy of the organisation and their role in achieving them. We saw that staff at all levels were fully engaged in ensuring the promotion of optimum outcomes for patients.
- The service monitored progress against delivery of the strategy.

Culture

There were systems and processes to support a culture of high-quality sustainable care.

- Leaders and managers encouraged behaviour and performance consistent with the vision and values.
- Staff felt respected, supported and valued. The service focused on the needs of patients.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There had been no serious incidents in the past 12 months. Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour, and these were embedded in corporate policies.
- There were processes for providing all staff with the development they needed. Staff employed by the service had received regular review of their performance in the form of regular one-to-one review and annual appraisal. There were clear opportunities for staff to progress within the organisation.
- Clinical staff were supported to meet the requirements of professional revalidation where necessary.
- There was a strong emphasis on the safety and well-being of all staff. We saw records which confirmed all staff had participated in regular one-to-one review meetings with their line manager.
- The service actively promoted equality and diversity. Staff had received equality and diversity training. Staff felt they were treated equally.

Requires Improvement

Are services well-led?

- There was a culture of promoting positive relationships and prompt and effective communications between staff. Staff meetings were held regularly. Organisational communications were shared effectively across the team.

Governance arrangements

Responsibilities, roles and systems of accountability to support good governance and management were not always effective.

- Structures, processes and systems to support good governance and management were clearly set out and understood for many areas of the service.
- The operations manager had regular update meetings with the medical director, to discuss and review the service.
- There was an effective staff meeting structure and systems for cascading information within the organisation.
- The provider utilised the services of an external supplier to provide support to develop and implement governance processes and policy development.
- Leaders had mainly established appropriate policies, procedures and activities to ensure safety, and assure themselves they were operating as intended. However, there were some instances where processes were not operating as intended and did not ensure safe care and treatment. For example, fridge temperature monitoring processes did not ensure the safe storage of medicines requiring refrigeration; fire safety processes did not ensure staff had participated in fire drills; staff immunisations were not monitored in line with current guidance or the provider's own policy; processes for monitoring the risk of legionella were not fully actioned; there was a lack of monitoring of training completed for staff employed on a sessional basis.
- The service collated key information about the service to provide a monthly operational report and undertook regular auditing of clinical record keeping processes across all specialties. However, formal monitoring of clinical decision-making and patient treatment outcomes was not applied consistently across all specialities.
- As a sub-contractor for the delivery of an NHS commissioned community vasectomy service, the provider was required contractually to monitor and report on a wide range of key performance indicators for this service.
- For other specialities, such as women's health, dermatology, musculoskeletal and vascular services, there were less formal processes under which patient clinical treatment outcomes were monitored. There was no formal review of an individual clinician's performance or auditing of their clinical decision making or patient treatment outcomes, other than review of their clinical record keeping. There was no formal review of their practising privileges status or appraisal of their performance.
- Staff clearly understood their individual roles and responsibilities and were well supported by the service manager in fulfilling those roles. Appropriate role-specific guidance was provided for staff. For example, there was a comprehensive guide to support reception staff in their role which covered areas such as pricing, appointment scheduling, clinic protocols and frequently asked questions.
- There were arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems. All patients were allocated a unique identifier code.
- The service submitted data or notifications to external organisations as required.

Managing risks, issues and performance

There were some processes for managing risks, issues and performance.

- There were some governance processes to ensure leaders were able to identify, understand, monitor and address current and future risks including risks to patient safety.
- There was clear evidence of a commitment to change services to improve quality where necessary. Immediately following our inspection, and in response to initial feedback of our findings, the provider took prompt action to begin to address the findings.

Requires Improvement

Are services well-led?

- The service had some processes to manage current and future performance. However, the performance of some clinical staff was subject to only limited review of their consultations and patient treatment outcomes.
- Leaders had oversight of safety alerts, incidents, and complaints. There was a system for recording and acting upon significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- Auditing of patient records was undertaken to review compliance with the provider's expected standards of clinical record keeping.

Appropriate and accurate information

The service acted upon appropriate and accurate information.

- Quality and operational information was used to monitor performance and drive improvement.
- The service used feedback from patients combined with performance information, to drive improvement.
- The provider carried out all required staff checks at the time of recruitment and all required ongoing monitoring, such as professional registration status and medical indemnity confirmation.
- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. Clear, accurate and contemporaneous patient records were kept. Treatment planning and treatment records were fully documented.
- Staff told us they had attended regular staff meetings. We saw documented evidence of staff meetings, where for example, updates, patient feedback and complaints had been discussed, and outcomes and learning from the meetings cascaded to staff.
- There were arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems. Processes ensured that all confidential electronic information was stored securely on computers. Staff accessed electronic records via a two-stage authentication process. All patient information kept as hard copies was stored in locked cupboards within a locked room. Staff demonstrated a good understanding of information governance processes.
- The provider ensured document management protocols were followed, which included version control, author and review dates.

Engagement with patients, the public, staff and external partners

The service involved patients, staff and external partners to support sustainable services.

- The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them to shape services and organisational culture.
- The service was transparent, collaborative and open with stakeholders about performance.
- All patients were asked to provide feedback following their treatment at the service. Concerns raised were acknowledged and responded to promptly. Where necessary a further follow up telephone call or meeting took place in order to resolve concerns.
- Staff could describe the systems in place for them to give feedback. Staff felt confident in providing feedback to managers. The staff team worked closely together and had both formal and informal opportunities to provide feedback through staff meetings, appraisals and discussion.

Continuous improvement and innovation

There was evidence of systems and processes for learning, continuous improvement and innovation.

Requires Improvement

Are services well-led?

- There was a focus on continuous learning and improvement.
- The service made use of internal and external reviews of incidents and complaints. Learning was shared and used to make improvements.
- Leaders and managers encouraged staff to review individual and team objectives, processes and performance.
- There were systems to support improvement and innovation and to drive improvement.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider had not done all that was reasonably practicable to ensure care and treatment was provided in a safe way for service users. In particular: • To ensure staff have access to policy guidance and training in the safeguarding of children. • To ensure staff participate in regular fire drills. • To ensure appropriate records are held relating to staff immunisations, in line with current guidance. • To implement fridge temperature monitoring processes which ensure the correct temperature range for the safe storage of medicines. This was in breach of regulation 12 (1)(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider was unable to demonstrate that systems and processes were implemented effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities. In particular: • To adequately assess and monitor risks to ensure premises are safe and suitable for use, with regard to the management of legionella and fire safety. • To ensure review of clinicians' performance and auditing of their clinical decision making and patient treatment outcomes across all specialties.

This section is primarily information for the provider

Requirement notices

- To ensure monitoring of training completed for staff employed on a sessional basis.

This was in breach of regulation 17(1)(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.