The Cooden Medical Group

Inspection report

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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 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 (carried over from previous inspection)

Are services responsive? – Good (carried over from previous inspection)

Are services well-led? – Requires improvement

We previously carried out a comprehensive inspection of The Cooden Medical Group on 5 July 2022. We identified breaches of regulation 12 (Safe care and treatment) and regulation 17 (Good governance) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and issued requirement notices. The service was rated as requires improvement for providing safe and well-led services and good for providing effective, caring and responsive services. The service was rated as requires improvement overall.

We carried out this announced comprehensive inspection of The Cooden Medical Group on 20 March 2023 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. At this inspection we checked that the service was providing safe, effective and well-led services. Our ratings of good for caring and responsive services are carried over from the previous inspection.

How we carried out the inspection:

This inspection was carried out in a way which enabled us to spend a minimum amount of time on site.

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 20 March 2023. 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 a GP 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

Overall summary

excision and upper blepharoplasty (to remove excess skin or fat from the eyelids), and a sub-contracted NHS commissioned vasectomy service. The provider had recently ceased providing musculoskeletal (MSK) and joint injection services from a London-based satellite clinic. Varicose vein treatments are also provided from a satellite location in Kent, on one half-day session per month.

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 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.

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:

- There were safeguarding systems and processes to keep people safe. However, some staff had not completed training in the safeguarding of children and vulnerable adults at an appropriate level to support their role, in line with current guidance.
- There were processes in place for the training and performance review of staff.
- There were improved processes for ensuring recruitment checks of clinical consultants were undertaken. However, there was a lack of recruitment records for one lead member of staff.
- Arrangements for chaperoning were displayed. However, the offer and attendance of a chaperone was not recorded within the patient's clinical record.
- There were appropriate arrangements to manage medical emergencies and suitable emergency medicines and equipment in place.
- Medicines requiring refrigeration were stored safely. Policies and processes to support the administration of local anaesthesia, including the management of local anaesthetic toxicity, had been reviewed.
- There were governance and monitoring processes to ensure the safety of premises at the provider's main location, including improvements to fire safety processes. However, there was a lack of monitoring of the premises and safety arrangements at satellite locations.
- 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, some staff immunisations were not monitored in line with current guidance.
- Policies provided up to date, relevant and sufficient information, to provide effective guidance to staff.
- Planning had been undertaken to develop an enhanced programme of clinical governance processes, including development of a Medical Advisory Committee, but not yet fully implemented.
- There was some monitoring of clinical record keeping however, outcomes had not always been shared with clinicians or acted upon.
- Incident recording forms did not always clearly capture the nature of the incident or learning outcomes.

Overall summary

- Staff dealt with patients with kindness and respect and involved them in decisions about their care.
- Staff worked well together as a team and felt supported to carry out their roles.
- 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:

- 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:

- Review processes to ensure the offer and attendance of a chaperone is recorded within the patient's clinical record.
- Promote the full completion of incident recording forms and monitor compliance.
- Develop equipment servicing schedules, for treatment couches and ultrasound equipment.
- Continue to monitor hot water temperatures and respond to temperatures which fall outside of the required range, to reduce the risks associated with Legionella bacteria.

Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

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. Varicose vein treatments are also provided from a satellite location in Kent, on one half-day session per month.

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, East Sussex, TN39 4SB.

The clinic opening times are:

Monday to Saturday 9.00 – 5.00pm

The service also operates from one satellite clinic:

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 the service's satellite location 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. There are 11 consultants, including the medical director, plus one GP with a special interest, who 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, cardiology, 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 some systems and processes to safeguard children and vulnerable adults from abuse. The provider's safeguarding policy provided appropriate guidance for staff. The policy had been revised since our last inspection to include guidance on the safeguarding of children. Staff we spoke with had a clear understanding as to how to raise safeguarding concerns about a patient.
- However, we found not all staff had received training in the safeguarding of vulnerable adults at an appropriate level to support 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, including the safeguarding lead, had not received training in the safeguarding of children at a level appropriate to their role, in line with current guidance and competency frameworks.
- At the time of inspection, it was unclear what level of safeguarding training staff had completed. The level of training was not included in the provider's overarching monitoring of completed training and had not been given consideration or risk assessed. The training which administration staff, including the safeguarding lead, had received, was not attributed to a specific level. Following our inspection the provider sent us a group certificate for the administration team, which the trainer had re-issued with level 2 training indicated for adult and child safeguarding. Consultants working under practising privileges had undertaken training in the safeguarding of children and vulnerable adults to level 2 only.
- The provider had carried out the majority of required staff checks at the time of recruitment, and all required ongoing monitoring, such as professional registration status, external appraisal 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). However, there was a lack of records to demonstrate staff recruitment checks had been carried out in accordance with regulations for one lead management role, to which an existing staff member had been newly appointed since our last inspection. There were no recruitment records held on file apart from a DBS check. The staff member had not been issued with a contract of employment or job description which reflected their new role.
- 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. However, we found the offer and attendance of a chaperone was not recorded within the patient's clinical record. This may have provided protection to staff and the patient if an accusation of improper behaviour was later made. Where there was no record of who acted as chaperone, it may be difficult to confirm who witnessed the examination.
- 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 June 2022 and all required actions completed.
- At our previous inspection we found that staff immunisations were not monitored in line with national guidance or the provider's own policy. There were no immunisation records held relating to non-clinical staff. There were variable immunisation records held for clinical staff members.
- At this inspection we found there were full immunisation records held for clinical consultants working under practising privileges. However, there was a lack of immunisation records held for other staff, including nursing and administration staff who had direct contact with patients. This was in contradiction to the provider's immunisation and health clearance policy which set out the immunisation monitoring requirements of all team members. We noted in one instance, where a staff member had been unable to provide immunisation records, no attempt had been made to check their immune status or undertake an assessment of risks associated with their role.

Requires Improvement

Are services safe?

- 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 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.
- At our previous inspection we found some hot water temperatures had been recorded as significantly 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. At this inspection we found that hot water temperatures continued to be recorded at levels below the required minimum. The provider had undertaken more frequent sampling of water samples to test for legionella bacteria in order to mitigate the risks associated with the low hot water temperatures. Following our inspection, the provider employed a contractor to adjust their hot water system and told us that this had increased the temperatures to within the required range.
- There were documented risk assessments in place to manage risks associated with the premises and general environment. We noted one staff member had undertaken health and safety officer training. There was guidance and information, including risk assessments, available to staff to support the control of substances hazardous to health (COSHH).
- At our last inspection we found there was a documented fire evacuation plan in place. However, the fire risk assessment for the premises was insufficient to assess all possible risks. At this inspection we saw the provider had employed a specialist contractor to undertake a full assessment of fire safety arrangements within the premises in September 2022. We saw all required actions had been completed.
- There was appropriate fire-fighting equipment located within the premises which was regularly serviced and maintained. We noted fire alarm and emergency lighting testing was carried out on a monthly basis. Fire extinguishers had been serviced in July 2022. Staff had undertaken fire safety training and had participated in regular fire drills since our last inspection.
- We found the provider had not undertaken checks to assure themselves of the safety of the premises and environment at their satellite location. For example, infection prevention and control arrangements, health and safety risks, risks associated with legionella bacteria and fire safety arrangements, had not been monitored. Staff told us they did not hold any records relating to recent monitoring of safety arrangements at their satellite location, where they leased a room for the provision of varicose vein treatments on a sessional basis. Following our inspection, the provider sent us evidence that they had sought some assurances from the host location in relation to health and safety and risk monitoring processes. However, this information required further exploration and monitoring by the provider.
- Equipment and facilities appeared to be of a high standard and were well maintained. However, there was a lack of planned scheduling for servicing of some equipment. For example, we saw ultrasound equipment used in the delivery of vascular services was booked for servicing and maintenance in April 2023 due to a non-urgent error occurring. However, the provider was unable to confirm the required frequency of servicing as recommended by the manufacturer. The provider was unable to demonstrate when the treatment couch, used for vascular and other minor surgical procedures, had last undergone servicing and maintenance. We reviewed records to confirm electrical equipment had undergone portable appliance testing in July 2022. There was a current electrical safety report for the premises.

Risks to patients

Requires Improvement

Are services safe?

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 processes for monitoring patients following their treatment. Where patients underwent excision of a lesion or cervical screening, there were processes for sending samples for analysis 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, where the patient had given their consent. Clinicians 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.
- We saw patients received appropriate support and were promptly reviewed within the service when post-treatment complications occurred.
- 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.
- The service implemented inclusive pricing which meant 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 there were appropriate protocols in place for the mixing and administration of the tumescent anaesthesia to ensure it was safely used. The provider had reviewed and updated these since our last inspection to ensure appropriate guidance to staff and promote standardised practices.
- 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, which may occur as a rare complication following the administration of local anaesthetic medicines. The review of protocols included the development of guidelines for the identification and management of local anaesthetic toxicity and the introduction of a supply of lipid emulsion within the service since our last inspection, which may be used to mitigate the toxic effects of local anaesthetic.
- 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.)
- 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.

Requires Improvement

Are services safe?

- We reviewed clinical records relating to 13 patients who had received treatment across all specialties delivered within the service.
- 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.
- Individual care records we looked at were written and managed in a way that kept patients safe. Clear, accurate and contemporaneous patient records were consistently kept.
- Digital photographs of affected areas were taken where appropriate, with patient consent, 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.
- 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 systems for the appropriate and safe handling of medicines.

- 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.
- 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.
- At our previous inspection we found medicines requiring refrigeration were not stored in a fridge suitable for that purpose. Fridge temperature monitoring processes did not ensure that medicines were stored within the required temperature range or were safe for use. At this inspection we saw medicines requiring refrigeration were now stored in a suitable refrigerator which was appropriately monitored to ensure a safe temperature range was maintained.
- 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 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 promptly to arrange servicing of an ultrasound machine when a minor error was identified; the temperature of the treatment room was reviewed and maintained at a lower temperature during varicose vein procedures following one patient experiencing a fainting episode; one patient was seen immediately within the service in response to post-operative complications.

Requires Improvement

Are services safe?

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 14 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. However, we noted incident reporting forms were not always completed in a way which clearly set out the nature of the incident, the actions taken or the identified learning. Staff told us that more detailed information about the incident and actions taken, may be recorded in the patient's clinical record where this was appropriate.
- The service also maintained a summary log of all reported incidents and monitored themes and incident rates per clinician. Incidents were discussed and reviewed within team and management meetings, and we saw minutes of those meetings. A quarterly report of incidents and activities was produced that formed the basis of a quarterly meeting of managers with the medical director.
- 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, we saw letters of explanation and apology, as well as a financial refund, had been provided to one patient who had been dissatisfied with the outcome of their pre-treatment diagnostic appointment and had declined to return to the service for further treatment.
- The service had systems in place to be informed 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 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 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 13 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. Treatment planning and diagnostic information were fully documented.
- 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. At our last inspection we saw the service undertook regular monthly auditing of clinical record keeping processes across all specialties. This included monitoring for example, recording of medical history, treatment planning, patient consent to treatment and cost of treatment.
- At this inspection however, we noted that auditing of clinical record keeping was not consistent and had last taken place in June 2022. Outcomes of those audits had not been shared with clinicians, nor action planning undertaken to identify or address the reasons for concerns, including gaps in some clinical records. Leaders within the service told us they were not aware of the outcomes of those audits. However, our review of patient clinical records did not identify any similar patterns or incomplete records.
- At our previous inspection we found 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 therefore 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. However, for specialities such as women's health, dermatology, cosmetic and vascular services, there was a lack of formal processes under which patient clinical treatment outcomes were monitored and no formal review of an individual clinician's performance or auditing of their clinical decision making.
- At this inspection we found the provider continued to be required to monitor and report on a range of key performance indicators in relation to their vasectomy service. The provider had begun to develop a broader clinical governance

framework across all specialties. The framework had enabled the provider to begin to further develop risk and incident management processes and to monitor the incident rate per clinician. We saw this monitoring was in the early stages. The development of key performance indicators, auditing of clinical decision making and patient treatment outcomes within each speciality remained outstanding and was planned for full implementation within 2023.

- Managers collated key information about the service to provide a monthly operational report to the medical director. This included for example, financial performance, service information, clinical updates, training undertaken and marketing activity. The report was discussed within an operational meeting and information shared as appropriate with wider team members.

Effective staffing

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

- Staff mainly 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. Induction plans were tailored to meet the needs of the individual staff member and their role.
- 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 one GP with a special interest. Those clinicians were also employed within the NHS and generally supported in ensuring training requirements were kept up to date by their NHS employer. However, at our previous inspection we found that the provider had not always ensured that records of their skills, qualifications and training were held or monitored by the service.
- At this inspection we found there were improved processes for monitoring the completed training of staff granted practising privileges. However, we found that some staff had not received training in the safeguarding of vulnerable adults or children at a level appropriate to their role, in line with current guidance and competency frameworks. The level of training completed had not been monitored or risk assessed by the provider.
- There was regular review of individual performance of administration 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. At our previous inspection we found sessional clinicians did not undergo an internal appraisal or formal review of their practising privileges within the service, and this had not been fully addressed at this inspection.
- 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.

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. Patients were promptly reviewed within the service when 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 necessary, 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, or cervical screening was undertaken, samples were routinely sent for histology. Processes were in place to ensure the recording and tracking of samples sent for analysis. 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 and mental capacity. 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.

Requires Improvement

Are services well-led?

Leadership capacity and capability:

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

- Since our previous inspection, the provider had established a new leadership and management structure, with the capacity to implement systems and processes to support the delivery of high-quality care. Leaders had begun to implement processes to address the issues and priorities relating to the quality and future of the service.
- 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.
- Leaders within the service were visible and approachable. They worked closely with the small team of staff and told us they prioritised compassionate and inclusive leadership.
- 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. Leaders told us they had developed a schedule of meetings of their Medical Advisory Committee, to start in June 2023 which would include consultants working under practising privileges. Those meetings were planned to review progress and determine strategic developments for the group.
- Staff were aware of and understood the vision, values and strategy of the organisation and their role in achieving them. 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. However, levels of training in the safeguarding of children and vulnerable adults required across the staff team, had not been fully assessed. Administration 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.
- 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 or fully embedded.

- The provider had appointed a lead for clinical governance within the service since our last inspection, who worked closely with the newly appointed operations lead.
- Structures, processes and systems to support good governance and management were clearly set out and understood for many areas of the service. However, some processes were not always effective or fully embedded.
- The provider had developed a governance overview document since our previous inspection which set out the strategic aims and planned approach to governance for the service. We saw that this approach included: patient feedback and patient-centred care; risk and incident management; activity and performance review; the team and their needs; leadership and accountability. We saw that the provider had made some progress towards achieving these aims, but other actions had not yet been implemented.
- A schedule of management review meetings had been introduced which included a weekly leads meeting and quarterly meetings between the group medical director and the governance and operations leads, to review quality indicators and progress against strategic aims. Meetings followed a set agenda which reflected the identified strands of governance.
- At our previous inspection we found 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. However, across other specialties, there was no formal review of an individual clinician's performance or auditing of their clinical decision making or patient treatment outcomes. There was no formal review of a clinician's practising privileges status within the service.
- At this inspection we saw that revised governance processes had enabled the provider to begin to monitor incident rates and themes per clinician. A quarterly report of incidents and activities was produced that contributed to a review meeting of the managers with the medical director.
- We saw that within the provider's governance overview document, it was noted that undesirable outcomes had historically been identified opportunistically. The provider had stated that work was being undertaken to develop a group 'Portfolio of Practice' which would set out standards for procedures and key performance indicators for auditing of treatment outcomes within each speciality. The provider had stated that the measurement programme was not yet embedded and was planned for development and implementation during 2023. Appraisal of each clinician's performance or review of their practising privileges status had also not been fully addressed.
- At our previous inspection we found auditing of patient records was undertaken to review compliance with the provider's expected standards of clinical record keeping.
- At this inspection we found that auditing of clinical record keeping had not been maintained and was not documented as part of the provider's revised governance framework. We saw that clinical record keeping had last been audited in June 2022. Outcomes of those audits had not been shared with clinicians, nor action planning undertaken to identify or address the reasons for gaps in some clinical records at that time. The audits had been completed by a staff member on leave from their employment at the time of our inspection. Leaders within the service told us they had not been aware of the outcomes of those audits.
- Leaders had established appropriate policies, procedures and activities to ensure safety. However, there were some instances where processes were not operating as intended, for example, staff immunisations were not monitored in line with current guidance or the provider's own policy.

Requires Improvement

Are services well-led?

- 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.
- 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. The provider had taken action to fully address some of the findings of our previous inspection. There were some areas which required further action, development or embedding.
- There were systems for cascading information across the wider staff team via weekly huddles led by the operations manager. We noted that a first written update by the clinical governance lead had been sent to the staff team immediately prior to our inspection visit, in the form of a newsletter. This outlined the progress made towards governance objectives within the service and outlined areas for further development.
- Leaders had oversight of safety alerts, incidents, and complaints and monitoring processes had been enhanced since our last inspection. There was a system for recording and acting upon significant events. The service maintained a summary log of all reported incidents and monitored themes and incident rates per clinician. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There was evidence that complaints had been fully reviewed, the learning shared across the service and used to effect change. Complaints were discussed at regular team and operational meetings. Patients received timely and appropriate responses to their complaints.
- We found there was a lack of monitoring of the premises and safety arrangements in place at the provider's satellite location where the provider leased a room for the provision of varicose vein treatments on a sessional basis.

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 planned further use of feedback from patients, combined with performance information, to drive improvement. Leaders told us they had identified 2 recent patients who had agreed to work with them in their planning and review of services, to shape future service development.
- The provider mainly 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. However, we found there was a lack of records held for one staff member, including a job description and contract of employment relating to a new role within the service.
- Individual care records we reviewed 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.

Requires Improvement

Are services well-led?

- 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, the 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 views and concerns from the public, patients, staff and external partners. They 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 some evidence of systems and processes for learning, continuous improvement and innovation.

- Leaders told us there was a focus on continuous learning and improvement. However, some governance and monitoring processes required further development.
- The service made use of internal and external reviews of incidents and complaints. However, some learning was not always shared and used to make improvements.
- Leaders and managers encouraged staff to review individual and team objectives, processes and performance.
- There were some 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 Surgical procedures Treatment of disease, disorder or injury	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 receive training in the safeguarding of vulnerable adults and children an appropriate level to support their role, in line with current guidance. • To ensure the monitoring of staff immunisations in line with current guidance. • To ensure required recruitment checks are carried out for all staff. 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 Surgical procedures Treatment of disease, disorder or injury	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 ensure review of clinicians' performance and auditing of their clinical decision making and patient treatment outcomes across all specialties. • To ensure monitoring of patient records to review compliance with the provider's expected standards of clinical record keeping and provide feedback on outcomes.

This section is primarily information for the provider

Requirement notices

- To ensure shared learning across all aspects of clinical governance to promote improvements.
- To ensure governance and monitoring processes to provide assurance to leaders that premises leased for the delivery of services at satellite locations are safe and suitable for use.

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