Queens Clinic

Inspection report

75 Wimpole Street
London
W1G 9RT
Tel: 07740944473

Date of inspection visit: 16 and 24 January 2024
Date of publication: 12/03/2024

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	Inadequate
Are services safe?	Inadequate
Are services effective?	Inadequate
Are services caring?	Inspected but not rated
Are services responsive to people's needs?	Good
Are services well-led?	Inadequate

Overall summary

This service is rated as inadequate overall. The service had previously been inspected on 13 February 2020, 9 February 2021, 2 September 2021, 30 November 2021, 2 September 2022 and 30 September 2022, and in each case, there were breaches of CQC regulations.

Following the inspection on 30 September 2022, the service was rated as inadequate overall, and in the effective and well led key questions. The safe key question was rated as requires improvement, and the responsive and caring key questions were rated as good. The service was found to be in breach of regulations 17 and 18 of Health and Social Care Act (HSCA) (RA) 2014 and warning notices were put in place. The specific issues found at the inspection of 30 September 2022 were:

- During surgical procedures undertaken under local anaesthetic, the surgeon was the only regulated health professional present, which had not been risk assessed.
- Some clinical records were either incomplete or unclear.
- The service had not undertaken any two cycle or outcome-based audits.
- Consent procedures at the service were not adequate.
- A lack of explicit detail in clinical records meant that it was not possible to ascertain what procedures had been carried out.
- Staff at the service had not been appraised.
- The service had not developed leadership and governance procedures to address breaches of CQC regulations identified in previous inspections.
- There was a lack of clear clinical governance procedures at the service to show that the service was providing safe and effective care.

We carried out an announced comprehensive inspection of Queens Clinic on 16 and 24 January 2024, to review the breaches of regulation. We found that the breaches of regulation from the previous inspection had not been addressed, and other issues of concern were found. Following this inspection, the service is rated as inadequate overall and the key questions are rated as:

Are services safe? – Inadequate

Are services effective? – Inadequate

Are services caring? – Not rated

Are services responsive? – Good

Are services well-led? – Inadequate

Our key findings from this inspection were:

- The service had some systems to manage risk. However, the service was not following safeguarding best practice and its own safeguarding policy. In addition, the service had limited quality improvement mechanisms in place, so it was unclear how the service was determining if the care was of sufficient standard, and that incidents were not being missed.
- The service undertook procedures under local anaesthetic, but in the event of an adverse reaction to local anaesthetic, the lead clinician was the only person available to manage this. The lack of a second clinician had not been adequately risk assessed.
- The service had not reviewed the effectiveness and appropriateness of the care it provided.

Overall summary

- A review of clinical records and consent forms found we were not consistently able to ascertain what procedures had been undertaken, or what consent process had been followed, including the explanation of risks and provision of information. In some instances, attendances at the clinic were not accompanied by a consultation note. There were also examples where it was unclear what protocols and guidance the provider had followed in providing treatment.
- Staff treated people with compassion, kindness, dignity and respect.
- Patients were able to access care and treatment from the service. An adequate complaints system was in place.
- Governance systems, particularly those that ensured safe and effective care, were ineffective and unclear.

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

- Ensure systems and processes are established and operated effectively to ensure compliance with the requirements of safe care and treatment.
- Ensure systems and processes are established and operated effectively to ensure compliance with the requirements of good governance.
- Ensure systems and processes are established and operated effectively to ensure compliance with the requirements of good staffing.

This service was placed in special measures in September 2022. Insufficient improvements have been made such that there remains a rating of inadequate overall and for the safe, effective and well led key questions. Therefore we are taking action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration if they do not improve.

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**.** The team included an obstetrics and gynaecology specialist adviser, and a second CQC inspector.

Background to Queens Clinic

Queens Clinic is a private gynaecological service located on the second floor at 75-76 Wimpole Street, Marylebone, London, W1G 9RT. The building entrance lobby is accessed via steps from the pavement. Wheelchair access is via a ramp at the front of the building (patients are advised of this and a member of staff is available to assist patients). The service is easily accessible by public transport and is a short walk from Bond Street. There are two consultation rooms, one minor operations room, one reception room and a waiting area for patients.

The service is staffed by a lead clinician, who is the sole owner of the business, and registered manager. At the time of the inspection, the service also employed a health care assistant (HCA), and a single administrative members of staff.

The opening hours are 9am to 9pm, Monday to Friday and between 9am to 6pm on Saturdays. Patients have access to the lead clinician by phone for out of hours emergencies.

The service provides private consultations to adults. A variety of services are offered including gynaecological diagnostic and minor surgery procedures.

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.

Inadequate

Are services safe?

We rated the service as inadequate for providing safe services.

At our previous comprehensive inspection on 30 September 2022 we found the service was not providing safe services, this was because:

- We noted that during surgical procedures undertaken under local anaesthetic, the surgeon was the only regulated health professional present. The service had not adequately risk assessed not routinely having a second clinician available.
- When we reviewed clinical records and consent forms, we saw examples where it was not possible to ascertain what procedures had been undertaken, and/or what consent process had been followed, including the explanation of risks and provision of information.

We carried out this announced comprehensive inspection on 16 and 24 January 2024 where we found the concerns from the inspection in 2022 had not been addressed, and other breaches of CQC regulations were identified which continued to expose patients to a significant risk of harm. Specifically:

- We noted that during surgical procedures undertaken under local anaesthetic, the surgeon continued to be the only regulated health professional present. The service had not adequately risk assessed not routinely having a second clinician available.
- When we reviewed clinical records and consent forms, we continued to see examples where it was not possible to ascertain what procedures had been undertaken, and/or what consent process had been followed, including the explanation of risks and provision of information.
- The clinical records system at the service could only be interrogated by patient name. On this basis, if a patient was treated on site with a medicine about which there was a subsequent alert, there would be no way to identify them on the database.
- The service was not following its own safeguarding of adults policy and protocol.
- We saw that in some instances, medicines had been prescribed without a clear rationale in the medical record.

Safety systems and processes

The service did not have clear systems to keep people safe and safeguarded from abuse.

- The service did not support patients and protect them from neglect and abuse, and did not work in line with its own safeguarding adults process and procedure. Our interviews with staff and review of records demonstrated that the provider was not following guidelines in relation to female genital mutilation (FGM) as outlined in their own policy. The policy stated that a full documented assessment was needed to determine whether there was a risk, and if so whether or not, referral needed to be made either to report a crime, or to safeguard the needs of the individual and their family. The service was not undertaking risk assessments, and as a consequence had not assured itself that either the patient or family would be protected from harm.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. 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.
- All staff received up-to-date safeguarding and safety training appropriate to their role.
- There was an effective system to manage infection prevention and control.
- The provider ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions. There were systems for safely managing healthcare waste.

Inadequate

Are services safe?

- The provider carried out appropriate environmental risk assessments, which took into account the profile of people using the service and those who may be accompanying them.
- The provider conducted some safety risk assessments. Staff received information relating to premises risk assessments from the service as part of their induction and refresher training.

Risks to patients

There were not systems to assess, monitor and manage risks to patient safety.

- We noted that during surgical procedures undertaken under local anaesthetic, the surgeon was the only regulated health professional present. In surgical procedures carried out under local anaesthetic in the NHS, a regulated and registered nurse would also be required. Best practice is that either a second regulated professional needed to be present, or the absence of such a clinician should be risk assessed. The presence of only the lead clinician for such procedures had not been adequately risk assessed by the service. We discussed the risk factors with the lead clinician, who did not consider the lack of a second regulated clinician to be a risk.
- There was an effective induction system for agency staff tailored to their role.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. They knew how to identify and manage patients with severe infections, for example sepsis.
- There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly. If items recommended in national guidance were not kept, there was an appropriate risk assessment to inform this decision.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place.

Information to deliver safe care and treatment

Staff did not have the information they needed to deliver safe care and treatment to patients.

- A review of clinical records and consent forms found that CQC were not consistently able to ascertain what procedures had been undertaken, or what consent process had been followed, including the explanation of risks and provision of information. In some instances, attendances at the clinic were not accompanied by a consultation note. There were also examples where it was unclear what protocols the provider had followed in providing treatment. For example, records confirmed that a patient attended for vaginal rejuvenation but the consent form did not contain details of the procedure. This procedure was not routinely offered by the NHS in the UK, and so it was unclear what guidance the clinician had followed. We asked the clinician whether or not this was a cosmetic procedure, which the clinician said it was not, and that it was clinically indicated. However, the patient record reflected a cosmetic reason. We noted that if this was a cosmetic procedure, the clinician would need to be accredited and registered for cosmetic surgery, which he was not.
- We were told that the service had moved from paper based to an electronic records system. However, paper records were being used and then uploaded to the database. We saw that there was a backlog of uploading paper notes to the electronic database. We saw a large (approximately two-inch thick) stack of papers that were still to be uploaded onto the database from two months prior to the inspection. These records were therefore not part of a contemporaneous records database.
- There was no clear process to ensure that information was shared with a patient's GP. We were told that patient records were not routinely shared with patients' GPs, and when they were, this was not noted on the database.

Safe and appropriate use of medicines

Inadequate

Are services safe?

We saw some evidence of reliable systems for appropriate and safe handling of medicines. However, some medical records did not contain sufficient information on the rationale for prescribing.

- There were systems and arrangements for managing medicines. The service kept prescription stationery securely and monitored its use.
- The service does not prescribe Schedule 2 and 3 controlled drugs (medicines that have the highest level of control due to their risk of misuse and dependence).
- Staff prescribed, administered or supplied medicines to patients and gave advice on medicines in line with legal requirements and current national guidance in some cases. For example, we reviewed a record where a patient had been prescribed misoprostol, a medicine that is used for either gastric ulcer prevention, labour induction or termination of pregnancy. The history taken by the clinician included conflicting information, and there was therefore no clear rationale in the records as to why this had been prescribed.

Track record on safety and incidents

The service did not have a good safety record.

- The service had limited systems in place to monitor and review activity. It was therefore difficult to ascertain how risk management protocols were triggered at the service.

Lessons learned and improvements made

The service had some systems in place for when things went wrong. However, the database used by the service prohibited clear searches in the event of a safety alert.

- There was a system for recording and acting on significant events. However, the service had not raised any clinical incidents in the last year, so we were unable to see how this worked in practice.
- All 3 staff at the service told us that the only way to interrogate the patient record system was by the patients' names and that there was no way to search by, for example, medication, condition, surgical procedure or patients' date of birth. As a consequence, the database could not be searched in relation to a safety alert, or to assist in outcome-based audits. Our concern was that on this basis, if a patient was treated on site with a medicine about which there was a subsequent alert, there would be no way to identify them on the database.
- Staff told us that they understood their duty to raise concerns and report incidents and near misses.

Inadequate

Are services effective?

We rated effective as Inadequate because:

At our previous comprehensive inspection on 30 September 2022 we found the service was not providing effective services, this was because:

- The service had not completed any 2 cycle audits to either assure that care being provided was safe, or to demonstrate quality improvement. The lack of 2 cycle audits was first raised in an inspection by CQC of the service in February 2020, and a lack of 2 cycle audits was also subsequently raised in inspections in February 2021, and November 2021.
- Consent procedures at the service were not adequate. Consent forms did not detail discussions of risk or management options with patients, or information sharing.
- A lack of explicit detail in clinical records meant that it was not possible to ascertain what procedures had been carried out.
- Staff at the service had not been appraised.

At the time of the inspection visit on 16 and 24 January 2024, most of these issues had still not been addressed. In addition, other breaches of CQC regulations were identified. Specifically:

- A continued failure to complete audits sufficient to provide assurance that safe care was being provided and to demonstrate quality improvement.
- Consent procedures at the service continued to be inadequate. Consent forms did not detail discussions of risk or management options with patients, or information sharing.
- A continued lack of sufficient detail in clinical records meant that it was not possible to ascertain what procedures had been carried out.
- For procedures or treatments where there were no National Institute for Health and Care Excellence (NICE guidelines), it was unclear what processes the service was following.
- Clinicians at the service were undertaking procedures for which they could not show qualification and/or accreditation.
- There had been a significant reduction in staffing since the last CQC inspection, and staff told us that they were unclear how work was covered in their absence.

Effective needs assessment, care and treatment

The provider did not have systems to keep clinicians up to date with current evidence-based practice. We saw evidence that clinicians did not assess needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service).

- During a review of clinical records, we noted that it was not possible to identify procedures that had been undertaken. For example, a patient had attended 5 times in an 11 day period. At each consultation, the patient was provided with a transvaginal ultrasound. There was no clinical rationale in the clinical record for repeating this procedure multiple times over such a short period of time.
- For procedures or treatments where there were no NICE guidelines, it was unclear what processes the service was following. For example, a patient attended for vaginal rejuvenation. Procedures of this kind are not routinely offered by the NHS in the UK and are therefore not covered by National Institute for Health and Care Excellence (NICE) guidelines. The provider was not able to detail what guidance the clinician was following.
- Clinical records did not contain sufficient relevant information to determine whether or not clinicians had made an appropriate diagnosis, or were managing the patient in line with guidelines.
- We saw no evidence of discrimination when making care and treatment decisions.

Monitoring care and treatment

Inadequate

Are services effective?

The service was not actively involved in quality improvement activity.

- The service had provided clinical notes audits undertaken by the same clinician that had treated the patients.
- The service had not completed any outcome, surgical or condition-based audits to either show that the service was safe, or show quality improvement.

Effective staffing

Some staff had the skills, knowledge and experience to carry out their roles, but at the time of the inspection, staffing was at a lower level than at previous inspection visits.

- Some staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. However, we noted that clinicians at the service were undertaking procedures for which they could not show qualification and/or accreditation. For example, a patient attended for a colposcopy. The clinician was not accredited by the British Society of Colposcopy and Cervical Pathologists and no training record was provided detailing their competence for this procedure. The clinician later told CQC that they no longer undertook this procedure, but did not give a date from when they had ceased undertaking it.
- At the time of the previous CQC inspection, the service had employed 3 health care assistants (HCAs), with clinical staff supported by a service manager, a clinic manager, a deputy manager, plus two further administrative members of staff. At the time of this inspection, there was 1 HCA and a receptionist in place. We asked a member of staff how work would be covered when they were on leave, and they said that they did not know.
- Relevant professionals were registered with the General Medical Council (GMC) and were up to date with revalidation.
- The provider understood the learning needs of staff and provided protected time and training to meet them. Some up to date records of skills, qualifications and training were maintained, but these did not relate to clinical care provided by clinical staff.

Coordinating patient care and information sharing

Staff worked together, and worked well with other organisations, to deliver effective care and treatment in some areas. However, the service was not documenting where relevant information was shared with patients' GPs.

- Before providing treatment, clinicians at the service told us that they ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. However, this was not consistently clearly documented.
- The provider said that all patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. However, this was not detailed in clinical records. The service told us that the correspondence that was sent to patients and their general practitioners was in a password protected format.
- The provider had risk assessed some of the treatments offered and followed NICE guidelines where they were in place. However, the service had not risk assessed procedures provided outside of this guidance.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients, and supporting them to manage their own health and maximise their independence.

- Where appropriate, staff gave people advice so they could self-care.

Inadequate

Are services effective?

Consent to care and treatment

The service did not obtain consent to care and treatment in line with legislation and guidance.

- Clinical staff did not follow or adhere to the requirements of legislation and guidance when considering consent and decision making. For example, in one case, a patient asked that no swab be sent to the laboratory. There was only limited information detailing discussions of risk factors relating to this decision with the patient.
- The consent forms used were not procedure specific. The consent form had several procedures listed on the same form whereby the planned procedure was ticked. This process lacked clarity, and meant that consent forms contained potentially conflicting information.
- Clinical records did not show that clinical staff supported patients in making decisions.

Inspected but not rated

Are services caring?

At the time of the inspection, we were unable to review sufficient information to rate the service for providing caring services.

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the quality of clinical care patients received, although feedback from patients was provided on an individual basis and had not been collated. The majority of patients were satisfied with the service.
- We did not receive specific feedback from patients, however we noted that patients' comments on the website were positive about the way staff treated people.
- The service gave patients timely support and information.

Involvement in decisions about care and treatment

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

- Staff told us that interpretation services were available for patients who did not have English as a first language. Patients were also told about multi-lingual staff who might be able to support them.
- Communication aids were not available for patients who were hard of hearing or had vision impairment.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff knew 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 responsive to people's needs?

We rated responsive as Good because:

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 facilities and premises were appropriate for the services delivered.
- The provider understood the needs of their patients. For example, patients could contact the doctor out of hours Monday to Friday and all-day Saturday and Sunday, or when he was on leave.
- Reasonable adjustments had been made so that people with physical disabilities such as wheelchair users could access and use services.

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.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients with the most urgent needs had their care and treatment prioritised.
- Patients reported that the appointment system was easy to use.

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.

- Information about how to make a complaint or raise concerns was available. Staff treated patients who made complaints compassionately.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service had complaint policy and procedures in place, but reported that they had not received any complaints in the past 3 years. In the absence of specific incidents, CQC was not able to review how this system worked in practice.

Inadequate

Are services well-led?

We rated well-led as Inadequate because:

At our previous comprehensive inspection on 30 September 2022 we found the service was not providing well led services, this was because:

- The service had not developed leadership and governance procedures to address breaches of CQC regulations identified in previous inspections.
- The lack of effective audits had been noted in 3 previous CQC inspection reports, but the service had not taken steps to address this concern.
- There was a lack of clear clinical governance procedures at the service to show that the service was providing safe and effective care.

At the time of the inspection visit on 16 and 24 January 2024, these issues had not been addressed, but other breaches of CQC regulations were identified. Specifically:

- The service had not improved or developed leadership and governance procedures to address breaches of CQC regulations identified in previous inspections.
- The service continued to have a lack of effective audits, and risk assessments for undertaking procedure under local anaesthetic without a second regulated clinician. This had been noted in previous CQC inspection reports but the service had not taken steps to address these issues.
- There continued to be a lack of clear clinical governance procedures at the service to show that the service was providing safe and effective care.
- Policies at the service were generic with a view to them having been adapted to the service need. This had not been undertaken in full.
- At the time of the inspection the provider was not registered for the CQC regulated activity of surgical procedures, which is required for the surgical services provided. The provider told us that they would immediately cease surgical procedures pending registration for this regulated activity.

Leadership capacity and capability

Leaders did not have the capacity and skills to deliver high-quality, sustainable care.

- The provider did not have a service manager at the time of the inspection, and as such it was unclear who had responsibility for the operational management of the clinic.
- The provider had not implemented clear clinical governance systems and protocols to ensure safe and effective care.
- There were fewer staff in post at this inspection, than when we visited in September 2022, and the 1 member of administrative staff was new to post. It was therefore not possible to determine if the provider at the service was supportive to staff.

Vision and strategy

The was not clinically focussed at delivering high quality care for patients.

- It was unclear how the service was measuring the service's vision aim of delivering high quality care for patients.
- The service did not have a clear strategy at the time of the inspection.

Culture

Inadequate

Are services well-led?

- At previous CQC inspections, we spoke with people who either worked at the clinic or had worked there in the past. They told us that there was a non-supportive culture at the service. At the time of the inspection the majority of staff were new starters, so it was not possible to determine if this culture had changed.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.

Governance arrangements

There were limited roles and systems of accountability to support good governance and management.

- Structures, processes and systems to support good governance and management were effective in some areas such as , but not in driving improvement at the service. The service had no effective quality assessment and improvement systems in place for its clinical case, and clinical records reviews showed that best practice was not being followed.
- Clinical processes and procedures at the services had not been sufficiently risk assessed to assure that safe and effective processes were being provided.
- Staff told us that they were clear on their roles and accountabilities.
- Policies at the service were generic with a view to them having been adapted to the service need. Although some adaptions had been made, the safeguarding and incident policies did not include contact details, or details of processes that should be followed. The complaints policy also made repeated reference to NHS processes, which were not relevant to this service. The provider later told the CQC team that there were some other documents that a consultant who had been working as a practice manager at the service had been developing. We noted that these contained some further details, but specific information was still missing, and the policies were not in general use.
- At the time of our inspection the provider was not registered for the CQC regulated activity of surgical procedures, which is required given the services provided.

Managing risks, issues and performance

There did not have processes for managing risks, issues and performance.

- The service did not have a clear risk management strategy and a risk register in place and it was unclear how clinical risks were being identified.
- The service did not have clear protocols on what procedures should be in place at the clinic and how they should be undertaken. This applies to colposcopy, cosmetic surgery and systems to support surgery under local anaesthetic.
- Leaders had limited oversight of safety alerts, incidents, and complaints, although none had been submitted in the last year.
- The provider had plans in place and had trained staff for major incidents.

Appropriate and accurate information

The service did not have appropriate and accurate information, which put patients at the potential risk of harm.

- The service did not use quality and operational information to ensure and improve performance. There were no clear mechanisms whereby quality and sustainability could be discussed.
- The clinical records reviewed did not contain sufficient information about procedures undertaken and assessment of and discussions with patients.
- The service did not submit data or notifications to external organisations as required. For example, the service had not followed its own safeguarding of adults policy and procedure when required.

Engagement with patients, the public, staff and external partners

Inadequate

Are services well-led?

The service involved patients, the public, staff and external partners to support high-quality sustainable services.

- The service sought customer feedback from patients.

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 Family planning services Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing **How the regulation was not being met:** • At the time of the previous CQC inspection, the service had employed three health care assistants (HCAs), with clinical staff supported by a service manager, a clinic manager, a deputy manager, plus two further administrative members of staff. At the time of this inspection, there was one HCA and a receptionist in place, at a time when the number of patients was similar. We asked one member of staff how work would be covered when they were on leave, and they said that they did not know. This was in breach of regulation 18(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met.

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** • We noted that during surgical procedures undertaken under local anaesthetic, the surgeon continued to be the only regulated health professional present. The service had not adequately risk assessed not routinely having a second clinician available. • The clinical records system at the service could only be interrogated by patient name. On this basis, if a patient was treated on site with a medicine about which there was a subsequent alert, there would be no way to identify them on the database. • A continued lack of complete audits sufficient to provide assurance that safe care was being provided and to demonstrate quality improvement. • Consent forms did not detail discussions of risk or management options with patients, or information sharing. • A continued lack of sufficient detail in clinical records meant that it was not possible to ascertain what procedures had been carried out. • For procedures or treatments where there were no National Institute for Health and Care Excellence (NICE guidelines), it was unclear what processes the service was following. • Clinicians at the service were undertaking procedures for which they could not show qualification and/or accreditation. • The service had not improved or developed leadership and governance procedures to address breaches of CQC regulations identified in previous inspections. • There continued to be a lack of clear clinical governance procedures at the service to show that the service was providing safe and effective care. • Policies at the service were generic with a view to them having been adapted to the service need. This had not been undertaken in full.

This section is primarily information for the provider

Enforcement actions

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

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met:** • When we reviewed clinical records and consent forms, we saw examples where it was not possible to ascertain what procedures had been undertaken, and/or what consent process had been followed, including the explanation of risks and provision of information. • The service was not following its own safeguarding of adults policy and protocol. • We saw that in some instances, medicines had been prescribed without a clear rationale in the medical record. This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.