Regency International Clinic Ltd

Regency Clinic - City of London

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	Inadequate
Are services safe?	Inadequate
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this service stayed the same. We rated it as inadequate because:

- The service did not have a process to identify when equipment was last cleaned.
- The service did not have any evidence of checks being completed for the automated external defibrillator. The equipment also did not have an inventory log or a weekly checklist.
- The service had out of date single use disposable medical equipment.
- The service had dirty equipment that had been recorded as sterilised.
- Although the service had a contract with a sterilisation company, the packaging of sterilised equipment had unclear dates written on them.
- The service had expired medicines in the lead consultants' office (Co-amoxiclav).
- The service did not have an adequate process to manage risks or plans in place to reduce their impact. This included plans to cope with unexpected events.
- The service did not have a documented vision, set of values, or strategy developed with all relevant stakeholders.
- Although the service has made some improvements in their governance processes since the last inspection, further improvement was still required to ensure there was effective oversight and assurance for these processes.
- Although staff told us they assessed patients' pain levels, we did not see any evidence of pain assessments using recognised pain tools in patient records or in the service.
- The service did not have suitable recruitment processes in place to ensure staff had the appropriate checks completed prior to their employment.

However:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The service had enough staff to care for patients and keep them safe. Staff had training in key skills and understood how to protect patients from abuse.
- Records were clear, up to date, stored securely and easily available to all staff providing care.
- Staff knew what incidents to report and how to report them.
- Most staff had knowledge or understanding of duty of candour.

Although the provider made improvements to address the previous concerns, we still found several areas of concerns within Regulation 12 and Regulation 17.

Following this inspection in November 2022, the concerns identified resulted in an urgent suspension of all regulated activities imposed for a period of three months through a Section 31 Notice of Decision.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inadequate 	

Summary of findings

Contents

Summary of this inspection

Background to Regency Clinic - City of London

Regency Clinic – City of London is an independent healthcare provider offering a range of "one-stop" gynaecology services and day case operations such as female genital surgery, trans-cervical fallopian tube unblocking, colposcopy, hysteroscopy and diagnostic ultrasound.

It is operated by Regency International Clinic Ltd. The service provides surgical and outpatient services. All surgical procedures are carried out on a day case basis. The service has an operating theatre that is also used for diagnostic imaging and a recovery area with two beds for day case patients.

We have inspected the service six times since 28 February 2018. Following an inspection on 25 August 2021 the service was urgently suspended under Section 31 of the Health and Social Care Act 2008. The service was placed into special measures.

Following an inspection on 12 July 2022, the service demonstrated they had met all the requirements of the suspension notice. The suspension was therefore removed.

This inspection was carried out on 28 November 2022. This was a routine focused inspection to review the inadequate ratings for safe and well-led and to consider whether the service was in a position to exit special measures.

Due to concerns highlighted in this report, we served a notice to the provider using our powers under Section 31 of the Health and Social Care Act 2008, suspending their registration for three months. Following the three month suspension, a further inspection will be carried out. If improvements have not been sustained, we will consider cancelling the services registration.

How we carried out this inspection

This inspection was carried out by two CQC inspectors and a specialist advisor. We interviewed the registered manager and lead consultant. We reviewed documents including training records, policies and risk assessments. We visited all parts of the service including the theatre and recovery areas. We reviewed equipment and checked on infection prevention and control.

We carried out the short notice announced inspection on 28 November 2022. We were not able to speak with patients as there were no appointments/day cases scheduled for that day.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Summary of this inspection

Action the service MUST take to improve:

- The service must embed and strengthen governance processes in order to have better oversight and assurance of the service. (Regulation 17(1))
- The service must have a clinician who has completed advanced life support (ALS) training on sight during opening hours. (Regulation 12(2)(c))
- The service must ensure the resuscitation trolley is locked appropriately and regularly checked. (Regulation 12(2)(e))
- The service must ensure pain assessments are carried out using recognised pain tools. (Regulation 17)(2)(c))
- The service must monitor performance using appropriate data in order to make improvements for service users. (Regulation 17(2)(b))

Action the service SHOULD take to improve:

- The service should ensure that they have the right mechanisms to ensure appropriate management of medicines. (Regulation 12(2)(g))
- The service should have a process to record when equipment has been cleaned. (Regulation 12(2)(e))
- The service should have a patient eligibility criteria for the treatments offered. (Regulation 12(2)(a))

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inadequate	Not inspected	Not inspected	Not inspected	Inadequate	Inadequate
Overall	Inadequate	Not inspected	Not inspected	Not inspected	Inadequate	Inadequate

Inadequate

Surgery

Safe	Inadequate
Well-led	Inadequate

Are Surgery safe?

Inadequate

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. The training was delivered via an e-learning platform and some modules were face to face. The service had three permanent non-clinical staff members (practice manager, business manager and one receptionist) and one permanent clinical staff member (lead consultant). Following the inspection, we requested training records of bank staff members. However, we have not received this information so could not be assured the bank staff members had completed the required training.

The service provided us with a copy of the training matrix that identified what training staff had to complete and how often this needed to be completed. Managers told us they monitored mandatory training and alerted staff when they needed to update their training. Mandatory training records for all permanent staff and found that all staff had up-to-date training. These included infection prevention control, moving and handling, and basic life support.

Safeguarding

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff had access to the service's safeguarding policy in the policy folder and online on the service's computer system. Following the inspection, the service provided a copy of the safeguarding policy. This was version controlled and the next review date was 17 November 2025.

The Safeguarding Policy did not contain any links to national guidance or list the contact details for the local authorities. However, the Female Genital Mutilation (FGM) policy was attached to the Safeguarding Policy and did have links to organisations for advice and listed the contact details for the local authorities.

The lead consultant was the safeguarding lead for the service. The lead consultant had completed Level 3 for both Safeguarding Adults and Safeguarding Children. All staff had completed mandatory safeguarding training.

The service provided mandatory training records for all staff. We did not see evidence that staff had completed training on Female Genital Mutilation (FGM). However, in a staff meeting on 6 November 2021 there was a discussion in relation to the completion of FGM training. The consultant had completed an FGM e-learning course and clinical staff had FGM training on the same day.

One member of staff did not have a Disclosure and Barring Service certificate (DBS). We found the service had only requested and accepted one reference for this member of staff. The service did not have a system in place to complete safe staffing checks. However, following the inspection, the service provided a copy of all staff members DBS certificates which were in date.

Cleanliness, infection control and hygiene

The service kept the premises visibly clean however equipment appeared dirty with no assurance regarding date of sterilisation. The service did not have adequate control measures to protect patients, themselves and others from infection.

The premises was visibly clean and had suitable furnishings which were clean and well-maintained. However, we found evidence of sterilised equipment that appeared dirty with no assurance regarding date of sterilisation. The equipment we saw looked rusted or as though they had blood on them. This meant the equipment was not clean, had been contaminated and posed a risk to service users if they were used.

The packaging of sterilised equipment had unclear dates written on them. This meant it was not clear whether the equipment was in or out of date for use. We were told that the service outsourced sterilisation for non-disposable instruments. We were told all equipment used in the last six months was single use (disposable). The service provided us with the service level agreement (SLA) for the provision of ethylene oxide sterilisation and testing services for the service. The service also provided the annual contract review which was signed by the service on 21 February 2022.

Staff followed infection control principles including the use of personal protective equipment (PPE). Hand gel was available in reception and in each clinical area. The service had personal protective equipment (PPE), including aprons and gloves available and these were seen in the service and theatre areas. There were no treatments taking place during our inspection which meant we were unable to observe or assess staff infection control and hand hygiene practice.

There was antibacterial soap available at all the sinks and each sink had handwashing guidelines displayed.

The service provided their Infection Control Policy which was version controlled and in date. The policy provided information on hand washing, sharps management and clinical waste management.

Staff told us they had an external domestic cleaning company who came weekly. The service provided evidence of the cleaning service contact for four months. The service also provided copies of the last six months of cleaning audits completed for each room. These were up to date.

Staff told us they cleaned equipment after patient contact. However, the service did not have a process for recording when equipment had been cleaned. We requested a cleaning audit for the cleaning of equipment and the service told us they did not have a cleaning audit for equipment.

The pre-assessment and recovery room had disposable curtains, and all except one were dated 17 August 2022. There was one curtain in the recovery room which did not have a date on.

The service had three toilets on site of which one was a disabled toilet. All the toilets were clean, and each toilet had a red emergency pull cord available.

The service changing room had a small shower, toilets and staff lockers. These were visibly clean and there was a cleaning log for the staff changing room.

Inadequate

Surgery

The service provided a completed infection prevention and control (IPC) checklist. The checklist included 8 categories of infection control and health and safety. Infection control checks covered prevention of blood-borne virus exposure, decontamination, hand hygiene and environmental design and cleaning. Where issues were identified, staff took the appropriate action to ensure it was resolved.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe.

The service had a reception area which was visibly clean. The reception area had two chairs in the waiting area and a small kitchenette for staff to make drinks. Staff informed us refreshments were offered to patients.

The reception area had a patient notice board which included information about sepsis management, GDPR and a chaperone request.

We found there was no evidence of checks being completed for the automated external defibrillator. The equipment did not have an inventory log or a weekly checklist. We spoke with the lead consultant who told us checks were completed weekly but failed to provide evidence to confirm this on inspection. However, following the inspection, the service provided evidence of the monthly automated external defibrillator check for October 2022 and November 2022.

We found the resuscitation trolley was inappropriately locked. A quick release tamper proof tag was not in place. The resuscitation trolley had a padlock in place that required three numbers to open. There was no system to ensure that all staff knew the code. This meant service users may be exposed to a risk of harm should there be an emergency situation on site.

The service provided their Resuscitation Policy which was version controlled and in date. The policy included information of the local hospital and contact details to use. This included details to call 999, 112 and/or direct numbers at Homerton University Hospital Trust.

The service had oxygen cylinders which were stored securely with the resuscitation trolley and in the theatre. Both cylinders were due to expire on 1 December 2022. The lead clinician told us the cylinders were due to be replaced on 30 November 2022.

We found out of date single use disposable medical equipment in the storage room. We found two large boxes containing Gallipots (sterile pots) which were out of date with an expiry date of October 2022. We also found out of date single use disposable medical equipment in the theatre. For example, the Sims Speculum and wound care pack with gloves were dated September 2022.

The service had safe arrangements for the handling, storage and disposal of clinical waste, including sharps bins. Staff disposed of clinical waste safely and we found the clinical waste bin was not overfilled and labelled clearly. The service had contracted an external company for waste management.

The service had three fire extinguishers all of which were in date with their service checks. We were provided with the certificate for fire safety checks.

There was a radiation warning notice in place outside of the surgical theatre when diagnostic imaging took place.

Inadequate

Surgery

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks.

The lead consultant had completed training on Resuscitation: Adult Basic Life support including safe use of automated external defibrillator (AEDs).

The lead consultant attended an Advanced Life Support Course in March 2022 and successfully completed the associated resuscitation skills, high-quality CPR and defibrillation assessments. However, the lead consultant did not pass the CASTest assessment and did not achieve the required standard to pass the course. The course was rescheduled for February 2023.

Non-clinical staff had completed training for First Aid in the workplace which was in date. Administration staff had completed Resuscitation: Adult Basic Life Support - including safe use of AEDs which was in date.

The service provided their Health and Safety Policy which was version controlled and the next review date was 11 November 2025.

The service also provided a Significant Event Monitoring and Analysis Template which was version controlled and the next review date was 18 November 2025. This detailed the types of significant events which could trigger an analysis of the event.

A nationally recognised tool was used to identify deteriorating patients and escalate them appropriately. The service provided their Deteriorating Patient Policy and Procedure which was version controlled and in date.

The service provided a private service to patients on request, during the inspection, we found the service did not have a patient eligibility criteria. Following the inspection, we received further information about the eligibility criteria but this was not embedded in a policy. This meant it was unclear how the service assessed a patient's eligibility for the treatments offered and there was a lack of clarity for patients who wished to access the service.

The service was compliant with the 5 steps to safer surgery, World Health Organisation (WHO) surgical checklist. The service had embedded a modified version of the WHO surgical checklist for surgery.

All staff members had completed fire safety training. However, the service had not completed any test fire drills. Staff we spoke with could not provide us with detailed about when the last test fire drill was completed. We asked for any audit details to evidence previous test fire drills, but the service was unable to provide any further information. Following the inspection, the service provided information about a test fire drill completed on 30 November 2022, two days after our inspection.

Staffing

The service had enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm.

The service had permanent staffing including one lead consultant, a registered manager, business manager, and one administrator. The service had one permanent clinical staff member who was the lead consultant. The practice manager worked part-time in a hybrid role.

Inadequate

Surgery

The service relied on bank and agency nurses to deliver services. Although the service did not have any permanent nursing staff, managers told us they only used one regular bank nurse. We requested further information about bank staff. However, the service did not provide this information.

We requested documentation to illustrate how staffing levels were calculated and managed. The service provided information about their current staffing but did not provide information about how their staffing levels were calculated.

The service provided their Staff Induction Policy which was version controlled and in date. The policy included three induction programme checklists for a receptionist, practice nurse and doctor.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Staff used paper-based records which were stored securely, and staff could access them easily. We reviewed seven patient notes all of which had undergone Hysterosalpingogram (HSG). All the records were in good condition, legible and secure.

The seven patient notes each had a recorded drugs chart which was clear. Each of the patient records had a completed pre-assessment.

Patient notes had been completed in a logical and comprehensive way. We saw evidence of completed WHO checklists, Venous thromboembolism (VTE) risk assessments, preoperative self-questionnaires assessments, post-operative observations and COVID questionnaire. However, we did not see pain scores recorded in the notes. The service provided us with their Pain Assessment and Management Policy. However, this was the first version and had been approved by the lead consultant on 1 December 2022.

The service also provided a patient information leaflet which provided patients with advice on pain relief after surgery. We were told this information leaflet was given to all patients following surgery.

Not all patient discharge summaries had been completed. Completed discharge summaries were not tailored to the patient.

Medicines

The service did not use systems and processes to administer and store medications. The service did not have systems or processes in place to record medicines.

The service was registered to stock and administer Controlled Drugs (CDs) although there were none on site during our inspection.

Medicines were locked away in the medicine's cabinet in the lead consultant's office. We reviewed a random sample of medications and found three out of four boxes of antibiotics (Co-amoxiclav) were out of date. The lead consultant told us medications were checked on a weekly basis, however no evidence of these checks were provided on inspection.

Following the inspection, the service provided a copy of their November 2022 drugs and medicines stock rotation checker spreadsheet. The document included information about the use by date, lot/batch number of medications and how many tablets/packets there were.

Inadequate

Surgery

The provider told us there were no pharmacy audits and the pharmacy only attended to deliver the medications.

The service provided a list of the audits they completed. The service did not complete medications management audits.

Staff stored and managed prescribing documents safely. Prescription forms were stored in a locked cupboard in the consultation room with controlled access. The prescription forms we saw were completed in full.

Incidents

Staff knew what incidents to report and how to report them. Most staff had knowledge or understanding of duty of candour.

The service reported zero serious incidents and zero clinical incidents between November 2021 and November 2022. Therefore, the service could not provide evidence of any escalations.

Most staff understood the duty of candour and demonstrated knowledge of their responsibilities. The duty of candour is guidance for being open and honest with people when things go wrong, such as after an incident or accident. There had been no previous incidents in which this needed to be used but an up to date policy was in place. The policy was version controlled and the next review date was 17 November 2025.

During our inspection, we were told staff meetings included shared learning about complaints received from patients. The minutes from these meetings were distributed to staff and printed and stored in a folder.

Are Surgery well-led?

Inadequate

Leadership

Although leaders were visible and approachable in the service for patients and staff, they did not understand and manage the priorities and issues the service faced.

We spoke with permanent staff who described the lead consultant as approachable and visible.

The service had recently employed a practice manager from September 2022.

The Fit and Proper Persons Policy was version controlled and in date.

The service employed a practice manager part-time in a hybrid role to undertake administrative tasks, review policies and procedures and implement checklists ensuring they were up to date. We were told the leadership and governance were the weak points of the service. The practice manager told us being on site once a week would be sufficient to make the improvements required.

We held interviews with the leadership team. There was a lack of understanding of why processes should be in place and followed. They did not show a complete understanding of the depth of challenge the service faced.

Inadequate

Surgery

Vision and Strategy

The service did not have a documented vision, set of values, or strategy, developed with all relevant stakeholders.

At the time of inspection, the service did not have a documented strategy. The vision was not on the service's website. Staff were not aware of the strategy or vision.

Following the inspection, the service provided a short single page document explaining their vision. This document stated the service's values to be accountable, fair, professional, innovative and caring to patients.

The provider told us the long-term goal was to expand the regulated activities and employ additional members of staff. For example, employ a full-time nurse.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff described the environment as friendly and told us they felt they could raise concerns or make suggestions for the service. Staff told us they enjoyed working at the service.

Staff told us there were yearly appraisals. The service was provided by a small team of four permanent staff. The business manager would complete the appraisal for the receptionist, the practice manager would complete the one for the business manager, the lead consultant would complete the practice manager's appraisal. The lead consultant had a responsible officer who oversaw their appraisal and validation.

Staff we spoke with felt supported and said there was good team working.

Following the inspection, the service provided their Complaints Policy. This was version controlled and in date. The policy included information on how patients could complain, the action to be taken upon receipt of a complaint and the investigation and responses to complaints.

Governance

Although the service had made some improvements in their governance processes, further improvements were still required to ensure there was effective oversight and assurance for these processes.

The service provided a detailed clinical governance structure/framework. A Governance and Monitoring Policy was in place and was version controlled and in date. However, the policy included a link to a framework which did not exist.

The service had governance processes in place for medicines and single use medical equipment, but these were not effective. There was no process in place for the service to monitor and manage sterile equipment. Although the service had a contract with an external service for the sterilisation of equipment, we could not be assured the equipment had been repackaged and dated correctly. We raised this with the provider during the inspection, but we were not assured of the process.

The service did not have a system in place to complete safe staffing checks. We found that recruitment processes were not in place to ensure the proper persons were employed by the service.

Inadequate

Surgery

The service provided their annual audit plan. This included the annual audits for patient satisfaction survey, employee satisfaction survey and GDPR audit. However, the service did not have any clinical guidance or standard operating procedures based on national guidance for the treatments provided by the service.

Management of risk, issues and performance

Leaders did not use systems to manage performance effectively. They did not have an adequate process in place to identify risks and issues or identify actions to reduce their impact.

The risk register was updated by the registered manager after our inspection on 30 November 2022. From the information provided by the service, we could not be assured when the risk register was reviewed prior to this date. The register stated that the risks listed on the register were next to be reviewed on 30 May 2023. The top three risks identified by the leadership team when we spoke with them, did not reflect what was documented on the service's risk register.

We reviewed meeting minutes for two staff meetings and two clinical governance meetings. Risk was discussed in these meetings. However, these meetings did not discuss each risk in any detail or any mitigation for these risks.

The service had a service level agreement (SLA) with a local NHS Trust for the agreed transfer of care procedure between the service and the Trust.

The service also told us they had implemented a system of receiving notifications about relevant updates and innovations i.e. CQC newsletters, NICE updates and MRHRA alerts.

The service had in place monthly team meetings and clinical governance meetings. The team meetings discussed the risk register, the audits that were required to be completed and the upcoming CQC inspection. We saw the minutes of these meetings were on the shared drive for all staff to access.

Information Management

Staff could find the data they needed, in easily accessible formats. However, the service's website and information leaflets had not been updated to reflect the changes to the services provided.

Staff had access to all the information they needed as computer stations were available to access the intranet and internet. Staff were aware of how to use and store confidential information. The service used paper-based records and we found paper records were stored securely.

Staff we spoke with told us the information technology (IT) system was reliable and secure.

The service's website included incorrect staff details. For example, the website listed a charge nurse.

The reception area did not have any information leaflets for patients.

The reception area displayed the current CQC ratings.

Engagement

Leaders and staff engaged with patients and staff.

Inadequate

Surgery

The clinical governance meeting concentrated on the clinical activity and also discussed complaints and any learning points from this.

Staff told us staff satisfaction surveys were completed yearly. The most recent staff survey was completed in November 2022. The staff satisfaction survey showed staff members felt satisfied with their role and had a feeling of personal accomplishment.

The service had incorporated a patient suggestion feedback form located in the reception area. Staff told us they had not received any feedback from patients. However, if they were to receive feedback from patients this would be actioned.

Learning, continuous improvement and innovation

The service provided limited examples of continuous improvement and innovation.

The service received one complaint on 10 October 2022. The service reviewed the complaint and there was shared learning in team meetings.

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. 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 17 HSCA (RA) Regulations 2014 Good governance • The service must embed and strengthen governance processes in order to have better oversight and assurance of the service. (Regulation 17(1)) • The service must ensure pain assessments are carried out using recognised pain tools. (Regulation 17)(2)(c)) • The service must monitor performance using appropriate data in order to make improvements for service users. (Regulation 17(2)(b))

Regulated activity	Regulation
Surgical procedures Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service must have a clinician who has completed advanced life support (ALS) training on sight during opening hours. (Regulation 12(2)(c)) • The service must ensure the resuscitation trolley is locked appropriately and regularly checked. (Regulation 12(2)(e))