Clifton Lane Clinic

Quality Report

Clifton Lane
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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Summary of findings

Letter from the Chief Inspector of Hospitals

Clifton Lane Clinic is operated by Clifton Lane Clinic Ltd. The hospital specialised in cosmetic surgery procedures. Facilities included; one ward, one operating theatre and outpatient and diagnostic facilities.

In response to information received via enquiries from members of the public, we carried out an unannounced responsive inspection of the hospital. In line with the intelligence we had received, we inspected the safe and well-led domains in surgery using our comprehensive inspection methodology.

We carried out the unannounced inspection on 2 March 2017. We then returned to the hospital for an announced follow up on 15 March 2017.

We regulate cosmetic surgery services but we do not currently have a legal duty to rate them. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following issues that the service provider needs to improve:

- Incidents were appropriately reported, but we found limited evidence to show that incidents were robustly investigated or that learning was effectively shared.
- Some equipment was not regularly checked, and even when checking was confirmed as being complete, we found checks had not been accurate.
- The theatre environment was not clean and there were environmental risks.
- There was no formal guidance in place to assist clinical staff in determining the acuity or suitability of patients for surgery.
- Take home medication was not appropriately labelled and we found some gaps in medication fridge temperatures being monitored.
- There was no formal agreement in place for the transfer of critically ill patients and there were gaps in the policy concerning the identification of critically ill patients.
- There was also no formal agreement in place concerning the cover arrangements for offsite consultants and anaesthetists by local colleagues when they were unable to return to the hospital.
- Governance processes were not robust and there was a lack of assurance and leadership on governance issues. Hospital wide governance, medical advisory committee and staff meetings did not take place in line with hospital policies or at regular intervals.
- There was a lack of engagement from staff in governance processes, particularly in relation to representation from theatres.
- There was no proactive management of risk and no formal risk register in place for the service.
- We saw that audit activities were not always effective and poor audit outcomes were not escalated or acted upon by the hospital leadership.

We also found the following areas of good practice:

- Medications were appropriately stored and dispensed.
- Staff had appropriate life support training in place and suitable medical cover was available on site for patients undergoing surgery.

Summary of findings

- Records were of a good standard and we saw evidence that safe care was being provided.
- Surgical site infection rates were in line with what we would expect and were appropriately recorded and investigated.
- Staff spoke positively about the new hospital manager and felt that the service was improving.
- We saw that patient feedback was positive.
- The hospital was also an early adopter of the NHS Digital Implant Registry.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with a warning notice in regard to good governance and requirement notices in regard to theatre staffing and the theatre environment. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Contents

Clifton Lane Clinic

Services we looked at
Surgery

Summary of this inspection

Background to Clifton Lane Clinic

Clifton Lane Clinic is operated by Clifton Lane Clinic Ltd. The hospital was registered with CQC in December 2013. It is a private hospital in Rotherham, South Yorkshire. The hospital formed part of a wider clinical group that provided cosmetic surgery services for patients in the North West and Yorkshire (New Birkdale Clinic). The hospital is registered with the CQC to provide surgery and diagnostic and screening procedures.

The hospital has not had a registered manager in post since July 2016. At the time of the inspection, a new manager had requested that they be registered by the CQC in August 2016. However, this application was still outstanding at the time of our inspection.

The hospital consisted of an outpatient consultation area, a ward with five bedrooms and an operating theatre.

In response to information received via enquiries from members of the public, we carried out an unannounced responsive inspection of the hospital. The enquiries raised concerns about the safety of cosmetic surgery being performed at the hospital and the governance structures and processes which it had in place.

When we attended the hospital on 2 March 2017 there were no planned procedures due to take place owing to a fault with theatre equipment. We were able to speak with staff and review patient and hospital records. However, we were unable to access or observe medications. On our return visit on 15 March 2017, we were able to.

The hospital also offers some wider cosmetic procedures, such as ophthalmic treatments. We did not inspect these services.

Our inspection team

The team that inspected the service on 2 March 2017 comprised a CQC inspection manager, two CQC inspectors, a specialist advisor with expertise in theatre management and a CQC clinical fellow with expertise in cosmetic surgery. On the follow up visit on 15 March 2017, the inspection team consisted of a CQC inspector and a specialist CQC pharmacy inspector.

During the inspection, we visited theatre and the ward. We spoke with three staff; the ward sister, the hospital manager, and the theatre manager. There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The hospital had not previously been inspected.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service provider needs to improve:

Incidents were appropriately reported, but we found limited evidence to show that incidents were robustly investigated or that learning was effectively shared. Some equipment was not regularly checked, and even when checking was confirmed as being complete, we found checks had not been accurate. The theatre environment was not clean and there were environmental risks. There was no formal guidance in place to assist clinical staff in determining the acuity or suitability of patients for surgery. Take home medication was not appropriately labelled and we found some gaps in medication fridge temperatures being monitored. We saw entries had been made in the controlled drug record book which were not in accordance with the hospital policy There was no formal agreement in place for the transfer of critically ill patients and there were gaps in the policy concerning the identification of critically ill patients. There was also no formal agreement in place concerning the cover arrangements for offsite consultants and anaesthetists by local colleagues when they were unable to return to the hospital. Staffing in theatres did not comply with relevant national guidance.

We also found the following areas of good practice:

We saw that medications were appropriately stored and dispensed. Staff had appropriate life support training in place and suitable medical cover was available on site for patients undergoing surgery. Records were of a good standard and we saw evidence that safe care was being provided. Surgical site infection rates were in line with what we would expect and were appropriately recorded and investigated.

Are services well-led?

We do not currently have a legal duty to rate cosmetic surgery services. We found the following issues that the service provider needs to improve:

Governance processes were not robust and there was a lack of assurance and leadership on governance issues. Hospital wide governance, medical advisory committee and staff meetings did not take place in line with hospital policies or at regular intervals. There was a lack of engagement from staff in governance processes, particularly in relation to representation from theatres. There was no

Summary of this inspection

proactive management of risk and no formal risk register in place for the service. We saw that audit activities were not always effective and poor audit outcomes were not escalated or acted upon by the hospital leadership.

We also found the following areas of good practice:

Staff spoke positively about the new hospital manager and felt that the service was improving. We saw that patient feedback was positive. The hospital was also an early adopter of the NHS Digital Implant Registry.

Detailed findings from this inspection

Surgery

Safe	
Well-led	

Are surgery services safe?

Incidents

- We saw that incidents were reported in line with the hospitals policy via an electronic reporting system.
- Following our unannounced inspected we requested evidence of all incidents reported in the past 12 months and all investigation reports completed within the past 12 months. We received information to show that 12 incidents had been reported between July 2016 and February 2017. No serious incidents were reported in this period and there was no pattern or trend to the incidents identified.
- However, we received no investigation reports for that period. We also did not see any evidence of robust action planning following incidents being reported. The information provided failed to demonstrate that incidents had been investigated and actions taken to prevent recurrence. There was a lack of systems and processes to ensure the effective recording, investigation, and learning from incidents.

Cleanliness, infection control and hygiene

- Infection rates reported by the hospital were in line with what we would expect to see, with five of 107 cosmetic procedures (4.7%) resulting in an infection. We saw that these were incident reported and that steps had been taken by clinical staff to consider the source of the infection and to provide appropriate treatment.
- We saw visible signs of contaminants in the theatre. The operating table had visible signs of fluids and human tissue present. The operating table covering was torn, making it difficult to clean. Beneath the padding on the arms of the operating table, there were signs of rust as well as rust being present on the wheels and lower portions of trolleys in use in the theatre.
- We also observed dust present between the theatre ceiling tiles and on top of pipework in the theatre area.
- We brought this to the attention of the hospital manager and a deep clean of theatres was completed the following day, prior to any further procedures taking place. On our return visit, we observed that theatre had been subject to a deep clean and that new arms had been ordered for the operating table. The theatre operating table and theatre environment appeared visibly clean, with no staining or fluids visible.
- However, there was still visible rust on theatre trolleys and the footwear we were provided with to wear into theatres was stained with blood/iodine solution. This meant that we were not assured that the environmental risks had been fully accounted for by the deep clean.
- Sharps bins were in use and we saw that these were appropriately labelled and not overfilled.

Environment and equipment

- During our visit on 2 March 2017 the theatre environment was noted to have experienced a rise in temperature. This was being actively investigated and the hospital had taken appropriate steps to transfer any patients requiring any surgery to a Liverpool site.
- Resuscitation equipment was available and we saw that this contained appropriate equipment. We saw that a check of the resuscitation drug box was made on the day that theatre lists operated. However, we did not see any wider evidence to confirm that the resuscitation trolley was checked in full to ensure all equipment and items were in date.
- We also saw that single use equipment (forceps, laryngoscope and scissors) were contained in the resuscitation trolleys out of their packaging. This meant that the expiry date of the equipment could not be confirmed and it could not be confirmed that this equipment was clean; the scissors having visible signs of contaminant on them.
- We brought this to the attention of the hospital manager. On our return visit, we saw that single use equipment on the resuscitation trolley in theatre was appropriately sealed and labelled.

- There was an appropriate cupboard for the storage and control of substances hazardous to health (COSHH) materials.
- There was a visible defect in the flooring in the recovery area. In addition, no emergency call bell was available in recovery to allow staff to alert other staff when a patients condition deteriorated. Oxygen and suction in the recovery area had been checked and was fully operational.
- Oxygen cylinders were appropriately stored and were in date.
- Anaesthetic equipment was not checked on days when theatre lists did not take place and we saw no evidence that the difficult airway trolley was regularly checked or maintained.

Medicines

- Medicines were stored safely and securely with access restricted to authorised staff. There were adequate supplies of medicines and equipment for use in an emergency, and a process was in place to ensure these were fit for use. Medical records we reviewed identified that medicines had been appropriately prescribed and dispensed by staff.
- However, we saw entries had been made in the controlled drug record book which were not in accordance with the hospital policy. For example, figures had been over-written or crossed out, some entries only contained one signature, the amount given and wasted was not always recorded accurately, and some entries did not state which patient medicines had been administered to.
- We inspected medicines which were given to patients to take away from the hospital and found they were not labelled in accordance with legislation and best practice recommendations. For example, labels did not state the quantity of medicines supplied, the address of the clinic, or the words 'keep out of the reach of children'.
- A meeting of the MAC in January 2016 identified that an independent pharmacist had been engaged to attend MAC meetings and to conduct spot check audits of medicines. No such audits had been completed at the time of our inspection.
- Medicines requiring refrigeration were stored securely, and temperatures were monitored daily in line with national guidance. However, temperatures had not been recorded on four days in January 2017 when the operating theatre had been in use which was not in accordance with the hospital's medicines management policy.

Records

- We reviewed six sets of medical records. These were of a good standard and contained appropriate information and details in relation to pre-assessment, operative practice, patient observation and anaesthetic records. We were satisfied that these documented that safe care was being provided.
- The records we reviewed contained completed documentation to show that surgery had taken place in line with World Health Organisation guidance.
- We saw that the theatre log book was up to date with appropriate entries to confirm the details of procedures that had taken place. The implant register was also appropriately completed and we saw that the service was moving towards completion of the digital cosmetic and implant registry introduced in NHS care.

Safeguarding

- The hospital manager confirmed that staff had undergone appropriate adult safeguarding training and that this was logged on the electronic system.
- We saw that safeguarding processes were set out to staff via the use of flowcharts in clinical areas.

Mandatory training

- The hospital manager told us that mandatory training files were up to date and that staff were able to access face to face and online learning. A log of mandatory training was kept electronically to show compliance.
- We reviewed six staff training files and saw that evidence of completion of mandatory training modules was present. This included certificates to show compliance with training in areas such as infection prevention and control, blood transfusion and safeguarding.
- However, there was not a consistent approach to what training certificates were contained within each file. A minority of files contained evidence of all training

sessions attended, whilst others did not contain the same range of certification, despite mandatory training having been noted as completed. This meant that we could not be assured that the full range of training had been completed by all staff.

Assessing and responding to patient risk (theatres, ward care and post-operative care)

- Registered medical officer (RMO) cover was provided via an external company and all RMOs held advanced life support certification. We saw that appropriate numbers of theatre staff also held intermediate life support certification. In addition to the RMO cover and anaesthetists we were assured that appropriate life support experience was available to patients undergoing surgery.
- We saw and were told that the hospital policy did not contain any specific ASA grade (a grading system to identify how medically fit patients are before surgery) at which surgery would not be considered. However, we saw that minutes of the medical advisory committee (MAC) from May 2016 identified that patients graded ASA three or above, or over seventy five years old, should not be accepted for elective surgery.
- We asked the hospital manager to provide us with copies of service level agreements or standard operating procedures for the transfer of critically ill patients. The manager confirmed that the hospital did not have a formal contract or standard operating procedure in place with local providers to facilitate the transfer of critically ill patients. Instead, staff told us that there was an informal relationship and understanding with local NHS trusts in regard to the transfer of critically ill patients.
- We identified gaps within the hospital's policy documents concerning the transfer of critically ill patients, for example the policy did not identify the definition of a critically ill patient, there was no clear assessment criteria, and no reference to any early warning score triggers.

Nursing and support staffing

- We saw that staffing of the ward was routinely one registered nurse and two health care assistants. Staff told us that an additional nurse was in the process of being recruited to allow for an increase in establishment numbers.
- Staffing in theatres did not comply with Association of Perioperative Practice guidance (2014). We observed that only one nurse was rostered to work within recovery and occasions when only one scrub nurse was rostered to work in theatre (in both instances, the guidance states that there should be a minimum of two staff members).
- Staff also confirmed that there was not always a surgical first assistant available and that staff were 'doubling up' to cover these duties and scrub. This was not in line with Perioperative Care Collaboration guidance (2012) and no policy was in place to provide support or training to staff and consider liability. This is because registered healthcare practitioners acting as surgical first assistants without appropriate training may be in breach of their professional registration.

Medical staffing

- The RMO was routinely on site for theatre lists and was able to provide medical cover up to the point of discharge. The RMO was on site for day lists, but would stay overnight if patients required overnight care.
- The hospital routinely used the same four consultants to carry out surgical work. Consultants would attend the hospital for outpatient appointments and surgical lists.
- We saw that the availability of medical staff following procedures was discussed at the medical advisory committee in May 2016. This suggested that medical staff should be within 30 minutes to one hour travel of the hospital in case of emergencies following a procedure. We did not see that a formal policy was in place to confirm this arrangement.
- The hospital manager told us that anaesthetists were also available on call following theatre lists. However, as some anaesthetists travelled from Liverpool there was an informal agreement in place with local anaesthetists that they would provide on-call cover once a list was complete. This had been discussed at the MAC, but no formal process or policy was in place to reflect this arrangement.

Surgery

Emergency awareness and training

- The hospital manager told us that there were documented major incident plans within the hospital. We saw that an incident where the days' theatre list had needed to be cancelled due to an equipment problem was appropriately managed.
- We saw evidence of fire safety training having been completed by hospital staff.

Are surgery services well-led?

Vision and strategy for this this core service

- There was a vision in place linked into the wider group structure of New Birkdale Clinic in which the hospital operated.
- The hospital manager said that he had a vision to allow the hospital to become more autonomous from current arrangements whereby some aspects of its practice (for example, financial arrangements) were controlled via the wider group.
- The hospital manager explained that work was underway to improve the relationship the hospital had with local contractors and suppliers in order to allow it better access to services and skills.

Governance, risk management and quality measurement (and service overall if this is the main service provided)

- There were governance structures in place at the hospital, which included a MAC, governance, and clinical team meetings. We asked the hospital manager how frequently these meetings should take place. They understood that MAC and governance meetings should take place on a quarterly basis and that clinical team meetings were to be held monthly.
- We reviewed the minutes of the MAC meetings. These contained appropriate discussions around hospital business, including clinical incidents, risk and complaints.
- However, we saw that there was a lack of regular meetings of the MAC with four meetings taking place between the period January 2016 to March 2017; on 8 January 2016, 29 April 2016, 25 May 2016 and the last meeting taking place on 22 November 2016.
- There was a lack of regular governance meetings within the hospital, with the last three governance meetings taking place on 8 January 2016, 29 April 2016, and 22 November 2016.
- There was a lack of regular clinical team meetings within the hospital, with a seven month gap between the last team meeting taking place on 16 February 2017 and the prior meeting on 22 July 2016.
- There was a lack of attendance at MAC, governance and staff meetings by theatre staff. Between the period January 2016 to March 2017, theatre staff were noted to have attended; one of four MAC meetings (November 2016), one of three clinical governance meetings (in November 2016), and no clinical staff meetings.
- Risk assessments were in place for theatres and the ward. These had been completed in mid-2016 and covered a range of established risks, including items such as; needle stick injuries, patient identification, falls, scalding. These were intended to form an annual assessment of risk and any mitigating actions.
- However, there was no risk register in place to enable the ongoing assessment, monitoring and improvement of services. The risk assessments that had been undertaken for generic risks were only updated annually and there was no proactive management or recording of any ongoing operational concerns. Risks identified to us by staff around capital investment requirements were not risk assessed.
- We saw that audits and checklists were in place in regard to controlled drugs, resuscitation equipment, cleaning, and theatre procedures. These had been completed appropriately, with only a small number of omissions between January 2016 and March 2016. However, we found discrepancies with findings identified in the hospital's audits and what we observed during our inspection.
- Audits of controlled drugs completed by the theatre manager in November 2016 and February 2017 failed to identity errors that we found in the control drug book during our inspection. Following a data request, a further audit of controlled drugs had been carried out by hospital management on 22 February 2017. This audit also identified similar shortfalls to that which we found during the inspection. No actions or outcomes had been generated from the audit to drive forward

improvements, and the hospital manager told us that the controlled drugs accountable officer (CDAO) had not been informed of the negative findings in accordance with the hospital's policy.

- In addition, an end of theatre day checklist for 28 February 2017 (the last operating day prior to our inspection) identified theatres as clean. However, on our visit on 2 March 2017 we observed human tissue and fluids still visible on equipment in theatres.
- We were not assured that audits were robust and accurately captured the appropriate data. We were provided with no evidence that discrepancies in audit results had been escalated and appropriate action had been taken to address these issues.

Leadership / culture of service related to this core service

- Staff felt that the hospital manager and ward sister had made a positive impact on the service since joining the hospital in the previous 12 months.
- We saw that there was a lack of engagement from theatres in the wider hospital governance. Staff told us that they did feel that there was a divide between theatres and the remaining hospital services.
- The hospital manager explained that he would escalate issues to the company owner. However, we did not see evidence that issues that had/should have been escalated (for example, in relation to the controlled drugs audit) had been acted on.
- Staff explained that they sometimes felt that they lost resources to the other sites that formed part of the New Birkdale Clinic and that the hospital was seen as a lower priority site.

Public and staff engagement (local and service level if this is the main core service)

- The hospital collected feedback from patients via feedback cards. We saw that feedback was reviewed and that the feedback received was positive.
- Any negative feedback was logged and we saw that this was considered and responded to by senior hospital staff.
- We observed staff interacting with patients to obtain feedback.
- We did not see any examples of staff feedback being regularly requested or acted on when received.

Innovation, improvement and sustainability (local and service level if this is the main core service)

- We saw that the service was an early adopter in the use of the NHS Digital Implant Registry.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

The hospital MUST ensure that appropriate governance systems and processes are established and operated effectively to ensure assess, monitor, mitigate, evaluate and improve the quality and safety of services it provides.

The hospital MUST ensure that the theatre environment and equipment used in theatres is clean.

The hospital MUST ensure that sufficient numbers of suitably qualified, competent, skilled and experienced persons are deployed.

The hospital MUST ensure that an agreement and appropriate policy is in place in regard to the identification and transfer of critically ill patients.

Action the provider SHOULD take to improve

The hospital SHOULD ensure that equipment is regularly checked.

The hospital SHOULD ensure that single use equipment is appropriately stored and labelled.

The hospital SHOULD ensure that take home medicines are appropriately labelled.

The hospital SHOULD ensure that medication fridge temperatures are appropriately monitored.

The hospital SHOULD ensure that there is a consistent approach to the storage and recording of mandatory training records.

The hospital SHOULD ensure that a suitable policy is in place to guide staff in assessing the suitability and acuity of patients attending for surgery.

The hospital SHOULD ensure that a formal agreement is in place concerning the cover arrangements in place for offsite consultants and anaesthetists by local colleagues.

The hospital SHOULD ensure that staff feedback is sought on the service.

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	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment **Regulation 15 HSCA 2008 (Regulated Activities) Regulations 2014: Premises and Equipment** **The provider did not ensure that all premises and equipment used by the service provider were clean and properly maintained.** Regulation 15 (1)(a)(e)

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing **Regulation 18 HSCA 2008 (Regulated Activities) Regulations 2014: Staffing** **The provider did not ensure that sufficient numbers of suitably qualified, competent, skilled and experienced persons were deployed.** Regulation 18(1)

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	Regulation 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014: Good governance The provider did not fully assess, monitor the quality and safety of service provided Regulation 17(2)(a) The provider did not fully assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others Regulation 17(2)(b) The provider did not fully evaluate and improve practice in respect of the processing of information Regulation 17(2)(f)