

# MYA Cosmetic Surgery Limited MYA St Luke's Hospital

## Quality Report

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2015

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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

MYA St Luke's Hospital was acquired by MYA Cosmetic Surgery Limited in May 2014. This location had not been previously inspected by the Care Quality Commission (CQC) and the inspection was part of our regular inspection programme. We inspected the location over three days between 29 September 2015 and 1 October 2015. The inspection was announced to the provider a number of weeks before and followed our comprehensive inspection methodology.

The inspection team was led by a CQC inspection manager, supported by CQC inspectors including a pharmacy inspector. In addition, the inspection team had a number of clinically qualified specialist professional advisors in the fields of plastic surgery, anaesthesia and surgical nursing.

We have not published a rating for this service. CQC does not currently have a legal duty to award ratings for those hospitals that provide solely or mainly cosmetic surgery services.

### **Are services safe at this hospital**

The services at MYA St Luke's Hospital had good systems and processes in place to protect patients from avoidable harm. Managers and staff had good systems to report incidents and were encouraged to learn from these and make improvements. There were enough medical and nursing staff to provide care and treatment for patients. Staff were competent and well trained but there was a high turnover of staff and frequent use of staff from nursing agencies.

Patients received good clinical practice; they were protected from potential hazards, such as infections or having to have the operation repeated. There were agreements in place with local NHS hospitals to transfer patients who became ill.

### **Are services effective at this hospital**

The service provided care and treatment in accordance with evidence based practice and nationally recognised standards. Patients were provided with good information that allowed them to make informed decisions about surgery.

Most patients were positive about the cosmetic results of their surgery. The hospital was proactive in sharing its results with other providers in the sector and with the public. There were rigorous processes in place before a surgeon was given practicing rights at the hospital.

### **Are services caring at this hospital**

Staff at this hospital treated patients with care and compassion and provided patient-focused care that met individual needs. The vast majority of the patients we spoke with were very satisfied with their treatment and the outcomes. However, patients were not always clear about the point at which they could cancel their treatment and receive a refund of their deposit if they changed their mind.

### **Are services responsive at this hospital**

The hospital had good processes in place to ensure that it only selected patients who were physically and mentally suited to have cosmetic surgery. We found a number of examples where surgery had been declined because the patients did not meet the clinical suitability and exclusion criteria, or were not supported medically from their relevant specialists/GPs. However, the hospital was not addressing delays in outpatient clinics caused by surgeons arriving late.

### **Are services well-led at this hospital**

There was generally good leadership at the hospital. However, we were concerned that the Medical Director did not have time to fully lead the medical services in the two days each month he spent in the hospital, although he carried out aspects of the role remotely, and was contactable at all times for any urgent and routine medical assistance and advice.

# Summary of findings

The hospital needed to further develop its clinical governance structures and ensure a clearer connection with the medical advisory committee. We were concerned that the MAC only met twice a year. It was not clear to see how key issues linked into the hospital's medical advisory committee. The hospital showed innovation in the way it used social media to reach out to people.

Our key findings were as follows:

- Staff understood how to report incidents and did so promptly and consistently. Managers then investigated incidents in a clear and rigorous way. They shared any lessons learned from these with all staff. There was a low number of infections.
- The hospital employed enough medical and nursing staff to meet patients needs and protect them from avoidable harm. However, too many of these staff were from nursing agencies and do not work at the hospital all the time. The hospital reduced this risk by using agency staff who worked regularly at the hospital.
- Theatre and ward staff had emergency on-call rotas; however, the hospital did not have a formal on-call rota for anaesthetists, and surgeons were responsible for agreeing cover.
- The limited size of the second theatre increased the risk of infection during invasive surgery. To date, there have been no incidents of patients contracting infections.
- Clinical staff at the hospital followed national guidance and good practice on cosmetic surgery when they treated patients.
- Staff were competent and well trained to care for patients. This meant that the right procedures were followed, and staff knew what to do in different circumstances, including emergencies.
- The staff at the hospital cared for and treated patients with compassion.
- The hospital did not have a clear cancellation policy setting out when patients could get their deposit back, if they changed their minds.
- Surgeons were arriving late at their outpatients clinic which meant some patients waited too long to be seen.
- Managers of the hospital had a clear vision of its purpose and future development.
- Managers had set up a number of clinical governance processes, which were working, but needed further development. For example, the Infection Prevention and Control Committee had not yet held a meeting.

We saw areas of outstanding practice including:

- The way the hospital used social media to reach out to patients. This means potential and actual patients could access information, and make comments using the internet.

However, there were also areas of poor practice where the provider needs to make improvements.

The provider must:

- Review and improve the governance processes of the hospital to ensure clinical risks are properly managed.

The provider should:

- Reduce the time that patients are waiting to see the surgeons in outpatients
- Develop a formal on-call rota for anaesthetists and surgeons.
- Ensure that pre-printed medicine labels contain the hospital contact details
- Review the ability of the medical director to carry out this role in the two days per month allowed for that purpose

# Summary of findings

- Review the use of theatre two for invasive surgery and the potential risk of infection to patients
- Make sure the cancellation policy is clear to all patients, and clearly sets out the 'cooling off' period.

Professor Sir Mike Richards

**Chief Inspector of Hospitals**

# Summary of findings

## Our judgements about each of the main services

### Service

#### Surgery

### Rating Summary of each main service

The MYA St Luke's Hospital opened in May 2014 and provides elective cosmetic surgical procedures to male and female patients primarily between the ages of 18 and 35 years. The hospital carries out most of its cosmetic surgical procedures Monday to Friday and is able to provide inpatient care seven days a week. The Hospital admits patients using direct and indirect referral systems. The indirect referrals come from consultations carried out in MYA clinics across the UK. The hospital carried out 2,483 cosmetic procedures between July 2014 and June 2015 and saw 2672 patients within the outpatient service. The hospital has 11 bedrooms split into six single and five double bed rooms, and provides 24-hour nursing and medical cover.

# Summary of findings

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# MYA St Luke's Hospital

## Services we looked at

Surgery

# Summary of this inspection

## Background to MYA Cosmetic Surgery Limited MYA St Luke's Hospital

MYA St Luke's Hospital is operated by MYA Cosmetic Surgery Limited and forms part of a collection of ten clinical sites around the country. Outpatient consultations can take place within all ten sites dependant on the patient's catchment area.

They have two further operating sites which are registered to perform Vaser Liposuction; MYA Manchester and Birmingham Clinics. MYA Cosmetic Surgery have in place service level agreements and operating contracts with three off site facilities; The First Trust Hospital in

Preston, The Natural Look Clinic in Doncaster and The Aesthetic Surgery Clinic in Chiswick, where they perform further cosmetic surgery. The main patient focus is on female patients aged between 18 and 35 years.

The inpatients wards had 16 beds, spilt into six single and five double rooms. There are a number of outpatient consultation and treatment rooms. We inspected all of the public and clinically related areas of the hospital, including theatres, wards and outpatient areas.

The registered manager since July 2015 is a clinical nurse Mrs Heather-Louise Ferguson.

## Our inspection team

Our inspection team was led by:

**Inspection Manager :** David Harris, Care Quality Commission

The team included: CQC inspectors and a number of specialists: a reconstructive aesthetic fellow, a clinical lead (elective surgical care), a consultant anaesthetist and an independent healthcare director of nursing.

## How we carried out this inspection

To understand the patients' experiences of care, we always ask the following five questions of every service and provider:

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

Before visiting, we reviewed a range of information and asked other organisations to share information about the hospital. These included NHS hospitals in the area, information on the hospitals websites, and reports and enquiries made with CQC since the hospital opened in May 2014.

The inspection took place on 29/30 September and 1 October 2015. We spoke with a range of staff at the hospital, including nurses, doctors, consultant surgeons, and administrative and clerical staff. We also spoke with staff individually as requested. We observed how people were being cared for, talked with patients and/or family members, and reviewed patients' records of personal care and treatment. We would like to thank all staff, patients, carers and other stakeholders for sharing their views and experiences of the quality of care and treatment at MYA St Luke's Hospital.

We observed care and treatment, looked at 10 care records, and reviewed the information submitted by the provider. We visited the pre-assessment areas, wards, operating theatres and recovery areas. We spoke with 17 patients, and their relatives, as well as 41 members of staff.



# Summary of this inspection

## Information about MYA Cosmetic Surgery Limited MYA St Luke's Hospital

The MYA St Luke's Hospital opened in May 2014 and provides elective cosmetic surgical procedures to male and female patients primarily between the ages of 18 and 35 years. The hospital carries out most of its cosmetic surgical procedures Monday to Friday and is able to provide inpatient care seven days a week.

The Hospital admits patients using direct and indirect referral systems. The indirect referrals come from

consultations carried out in MYA clinics across the UK. The hospital carried out 2,483 cosmetic procedures between July 2014 and June 2015 and saw 2672 patients within the outpatient service. The hospital has 11 bedrooms split into six single and five double bed rooms, and provides 24-hour nursing and medical cover.

# 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?

The services at MYA St Luke's Hospital had good systems and processes in place to protect patients from avoidable harm. Managers and staff had good systems to report incidents and were encouraged to learn from these and make improvements. There were enough medical and nursing staff to provide care and treatment for patients. Staff were competent and well trained but there was a high turnover of staff and frequent use of staff from nursing agencies.

Patients received good clinical practice; they were protected from potential hazards, such as infections or having to have the operation repeated. There were agreements in place with local NHS hospitals to transfer patients who became ill.

### Are services effective?

The service provided care and treatment in accordance with evidence based practice and nationally recognised standards. Patients were provided with good information that allowed them to make informed decisions about surgery.

Most patients were positive about the cosmetic results of their surgery. The hospital was proactive in sharing its results with other providers in the sector and with the public. There were rigorous processes in place before a surgeon was given practicing rights at the hospital.

### Are services caring?

Staff at this hospital treated patients with care and compassion and provided patient-focused care that met individual needs. The vast majority of the patients we spoke with were very satisfied with their treatment and the outcomes. However, patients were not always clear about the point at which they could cancel their treatment and receive a refund of their deposit if they changed their mind.

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The hospital had good processes in place to ensure that it only selected patients who were physically and mentally suited to have cosmetic surgery. We found a number of examples where surgery had been declined because the patients did not meet the clinical suitability and exclusion criteria, or were not supported medically from their relevant specialists/GPs. However, the hospital was not addressing delays in outpatient clinics caused by surgeons arriving late.

# Summary of this inspection

## Are services well-led?

There was generally good leadership at the hospital. However, we were concerned that the Medical Director did not have time to fully lead the medical services in the two days each month he spent in the hospital, although he carried out aspects of the role remotely, and was contactable at all times for any urgent and routine medical assistance and advice. The hospital needed to further develop its clinical governance structures and ensure a clearer connection with the medical advisory committee. We were concerned that the MAC only met twice a year. It was not clear to see how key issues linked into the hospital's medical advisory committee. The hospital showed innovation in the way it used social media to reach out to people.

## Detailed findings from this inspection

# Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Information about the service

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The Hospital admits patients using direct and indirect referral systems. The indirect referrals come from consultations carried out in MYA clinics across the UK. The hospital carried out 2,483 cosmetic procedures between July 2014 and June 2015 and saw 2672 patients within the outpatient service. The hospital has 11 bedrooms split into six single and five double bed rooms, and provides 24-hour nursing and medical cover.

## Summary of findings

MYA St Luke's Hospital had good systems and processes in place to protect patients from avoidable harm, although there was an increased risk of infection for patients who undergo invasive surgery because of the limited size of its smaller operating theatre. However, the hospital reduced the risk by improving the airflow system in theatre two. There have been no incidents of patients contracting infections.

The hospital had good clinical practice, which complied with national standards and the vast majority of patients had good surgical outcomes. Staff cared for patients and supported them with good information that allowed them to make informed decisions about surgery.

Staff were competent and well trained, but there were high levels of turnover and use of agency staff. Managers displayed good leadership, but they were still developing key processes around clinical risk and infection control.

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## Are surgery services safe?

The hospital had good systems and processes in place to protect patients from avoidable harm. Staff knew how to report incidents. Where an incident occurred, senior ward staff investigated this and made changes to hospital procedures to prevent it happening again. The small size of operating theatre two increases the infection risk to patients during invasive surgery; it also increases the risk in the case of a medical emergency, as there was limited space for emergency equipment. The risk assessment process for the use of this theatre should have been more robust and inclusive.

The hospital had good processes in place for selecting low-risk patients and keeping them safe during their stay. There were enough doctors and nurses to respond to patients whose health deteriorated.

### Incidents

- The hospital had not reported any 'never' events between July 2014 and June 2015. Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures had been implemented by a hospital.
- We reviewed an appraisal document for one of the surgeons dated 17 November 2014. We found a reference to a 'never' event, which had occurred at another hospital where the surgeon had used the wrong implant during a surgical procedure. The clinical supervisor investigated the error and agreed changes in practice with the surgeon, for all his operations, wherever they took place. This included recording the size of the implant when the surgeon marked the site on the patient prior to surgery. We observed nursing staff and the surgeon checking the implants used for three procedures.
- The hospital had a process in place to guide staff on how to report any incidents. Staff told us they reported incidents via the electronic reporting system and they had received training. Training records we examined confirmed this. Staff told us that incident reporting training was included in the staff induction programme which all staff attended when they started working for the hospital.

- The hospital reported 91 clinical incidents between July 2014 and June 2015, which included one serious incident that required investigation. Senior staff had escalated and investigated the incidents we examined. Staff within the theatre suite referred to an incident following surgery and the actions taken.

### Safety thermometer or equivalent (how does the service monitor safety and use results)

- This hospital, unlike NHS trusts, is not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE). However, the evidence provided demonstrated 100% compliance with monitoring and reporting of VTE assessments.
- Minutes from the clinical governance committee (CGC) meeting dated 19 August 2015 highlighted a patient that had developed a pulmonary embolism five days after a surgical procedure. The hospital had completed an investigation which we examined. The minutes stated clinical staff had completed the correct protocol. Staff had given the patient information on deep vein thrombosis (DVT) on discharge.
- The hospital records and monitors performance for hand hygiene and infection control. This ensured that the risk of infection was reduced.

### Cleanliness, infection control and hygiene

- The provider had an Infection Prevention and Control (IPC) policy, drafted on 25 August 2015, but they had not ratified it at the time of our inspection.
- The provider appointed a lead nurse for IPC in May 2015. At the time of the inspection, they were waiting to attend formal IPC training due to the recurring cancellation by the provider of the previously booked accredited course. The infection control lead nurse told us that she had support from the infection control lead at a local NHS trust.
- The provider had an annual IPC audit programme in place. The programme included quarterly hand hygiene and the clinical areas such as wards, clinics and theatres.
- The provider did not report any incidence of Clostridium difficile; however, they reported three cases of MRSA between July 2014 and June 2015. All patients were screened for existing infections prior to attending for

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their operations. Staff told us that these cases were found at pre-assessment and documentation confirmed that surgery had been postponed until each patient was clear of infection. The provider information submitted did not identify any surgical site infections (SSI). This meant the hospital protected patients from cross-infection.

- Minutes from the clinical governance committee meeting dated 19 August 2015 identified 11 cases of post-operative infection noted at follow-up clinic appointments. The minutes did not state how many of these cases required further surgical intervention or implant replacement. The medical advisory committee (MAC) was to follow this up at their next meeting on 24 September 2015. The minutes of the September 2015 MAC meeting were not available at the time of our inspection.
- The patient areas, wards and theatres were visibly clean and well maintained. The hospital managers had cleaning schedules in place and audits had shown that cleaning had been correctly completed 100% of the time. The infection control lead stated that there were plans to update the housekeeping policy to achieve consistency throughout the hospital.
- Patients we spoke with felt the standards of cleanliness and hygiene were good and their rooms were clean and well presented.
- Personal protective equipment was available to all staff and there were notices in all areas highlighting the correct method for hand washing. Hand gel was also available and we observed staff regularly washed their hands and using hand gel where applicable. Sharps bins were in place, dated and stored off the floor in all the areas we visited.
- The hospital's two operating theatres are on the second floor. The main theatre (theatre one) was clean and well maintained, although we did note some paint flaking on one wall. There was adequate room for equipment and staff.
- However, the second theatre (theatre two) was next to the lift and could be accessed from the corridor via a secure keypad access straight into the operating theatre. Only members of the direct theatre and cardiac arrest team had entrance codes to allow access. The lift

also had secure access codes to the second floor limiting the permissions to staff only, or approved persons. Theatre two did not have a preparation or anaesthetic room.

- There was limited space in theatre two, which could potentially allow for contamination from water, and the ability for trolley drapes to touch walls during surgical operations, which could possibly put patients at risk from infection.
- We also saw a case where, due to limited space, post-induction of anaesthesia, the operating table needed to be turned to allow adequate access by the surgeon.
- We examined a risk assessment undertaken by the hospital in July 2015 covering the use of theatre two. The theatre was traditionally used for vaser Liposuction and closed rhinoplasty surgery, but was now being used for breast augmentation and open rhinoplasty surgery.
- An assessment carried out by Air Sentry confirmed that theatre two is an ultra-clean theatre with a modern clinical airflow system. Hospital managers and the medical director told us they felt the risk to patients presented by the small operating theatre had been adequately mitigated by a system of more robust procedures. For example, the laying out of instruments happened under an ultra-clean canopy, and theatre nurses knew not to open the instrument pack whilst the patient was being put to sleep.
- One surgeon we spoke with, told us that he did not do breast augmentation in theatre two, and did not think it a suitable environment for that type of operation. We were unable to find any record that the risk had been discussed at any of the MAC meetings or that senior staff had sought an independent expert opinion.
- There was no evidence that any patients had suffered harm or been infected due to being specifically operated on in theatre two.
- There was a service level agreement in place with an external company to provide sterile services. They stated that they did not have any concerns regarding the quality of the sterile services provided. We saw that all sterile reusable instruments were traceable and stored appropriately.

## Environment and equipment

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- Resuscitation equipment was in place and accessible in the ward and theatres in the event of an emergency. The resuscitation trolleys within the ward, theatres and recovery areas were sealed and checked daily and our checks confirmed this. Each theatre had equipment available to support patients who had difficulty breathing.
- Guidance recommends that there should be enough room to ensure that if an emergency occurs there is space for the additional equipment that may be required. The Hospital has undertaken training scenarios to ensure that there is the appropriate available space to allow for any further emergency equipment to be present within the theatre to ensure patient safety.
- All sterile surgical instruments were stored within the theatre suite and were easily accessible to all staff within theatre one. This was more difficult for staff using theatre two due its small size. All sterile instrument sets were checked prior to opening, to ensure the packaging was intact and sterility had not been breached.
- Staff had sufficient equipment available and there were appropriate maintenance contracts in place. The equipment we checked had been 'portable appliance tested' (PAT) tested within the last year.

## Medicines

- All medicine storage environments were visibly clean and lockable to prevent unauthorised access.
- The controlled drug (CD) cabinets we examined were compliant with CD regulations. The most hazardous drugs were securely stored to prevent unauthorised access.
- We found that the systems for ordering, expiry date checking, and for managing the use of CDs were satisfactory and that the use of CDs was properly controlled.
- The pre-printed dispensing labels for use on discharge medicines given to patients to take home did not include the name and address of the person who supplied them, as required by the Human Medicines Regulations 2012, however, the Hospital did discharge

all patients with a MYA out of hours emergency card and a discharge leaflet, which had the direct ward phone number. This also included the name of the Hospital within it.

- The systems in place for recording and managing the temperatures of rooms and fridges where medicines were stored were unsatisfactory. Staff did not know how to reset the thermometers or what procedures to follow when the temperature readings were out of range.
- An external pharmacist had undertaken regular medicines audits.
- We reviewed a CD audit, dated 30 June 2015, which showed 78% compliance. A follow up action plan and re-audit showed an improvement to 96% compliance.
- The hospital medicine management policy and the safe management of controlled drugs policy were up to date and due for review in September 2016.

## Records

- All 10 patient records we looked at were legible, signed and dated. Theatre staff record details, such as pre-, peri- and post-operative care. However, we noted that three of the records reviewed were not in any sequence and did not follow the patient journey from admission, to theatre and post-operative care. Ward staff printed care notes as individual pages and inserted them into a folder. This presented a risk of pages being lost and information being missed.
- The care plans for the 10 records we reviewed were complete and included risk assessments such as pain, falls, Waterlow (pressure ulcer risk), VTE, and discharge planning. Ward staff had carried out regular hourly comfort checks on all patients and recorded these in the care plans. Nursing staff regularly monitored patients and provided them with food and drink if they needed it.
- As part of the patient pathway, staff used the national early warning score (NEWS) to highlight any deterioration in the patient's condition. The level of observations carried out matched the early warning system. The Resident Medical Officer (RMO) and surgical consultants responded to concerns raised by nursing staff about patients.



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- The RMO reviewed all patients at least daily and followed the plan of care prescribed by the surgeon. The RMOs reviews were documented, although some signatures were illegible and did not have the name of the doctor printed clearly underneath. Surgeons were reviewing patients after their operations, but were not always recording these reviews in the patients notes.
- The hospital managed its own patient records and all notes were scanned onto the computer system following the patients discharge. The notes from patients seen in other clinics are scanned and available if they decide to have surgery at the hospital.
- All the patients' notes contained a completed World Health Organisation (WHO) five-point safety checklist.

## Safeguarding

- The provider had a safeguarding children and vulnerable adults policy dated 20 August 2015 which referenced up-to-date guidance and legislation. The policy contained a flow chart which identified the safeguarding lead but did not contain contact details of the social services designated lead. However, their contact details were on a poster in the main waiting area, which is referred to within the flow chart. Staff were aware of the provider's safeguarding policy. They knew how to access the policy and the designated lead at the London location.
- The provider had reported two safeguarding concerns from June 2014 to July 2015. Staff described a case where concerns were raised during consultations with a patient co-ordinator, as the patient's partner spoke for the patient and appeared to exert inappropriate influence. Hospital managers arranged additional consultations to ensure the surgery was in the patient's best interest and as a result the surgery did not take place.
- Staff attended annual training for safeguarding children and adults. The provider's mandatory training records showed that 100% of clinical staff had completed level 3 adult safeguarding.

## Mandatory training

- There was a list of the mandatory training included in the provider's training policy. The hospital delivered training either face-to-face or by e-learning, and records were stored on a new computer system that generated

reminders when staff were due for annual updates. Mandatory training included manual handling, equality and diversity, risk assessment, infection control, basic life support (BLS), intermediate life support (ILS), fire safety, safeguarding children and safeguarding vulnerable adults.

- The hospitals had a mandatory training target of 90%. Training records for clinical and non-clinical staff showed that between 83-96% of staff had completed mandatory training. Staff were given time within the duty rota to complete training.
- Staff had to undertake short tests that had to be passed to ensure that training and new policies had been understood and confirmation was sent to their managers.

## Assessing and responding to patient risk

- Theatre used a surgical safety check list based on the WHO guidance. Theatre staff completed the WHO safety check list, from the ward to the theatre for three patients we observed. We checked 10 other medical notes and found that the checklists were fully completed in all cases.
- Ward and theatre staff were aware of, and used, NEWS to assist in the identification of patients with deteriorating conditions. Patient notes we examined contained guidance for staff on the NEWS scoring system, and detailed the actions required. Staff we spoke to were familiar with using the NEWS tool and how to escalate concerns.
- There was RMO cover on site 24/7 to support patient care and respond to any concerns raised by nursing staff. The surgeon and anaesthetist checked all patients prior to leaving the hospital and provided the RMO with a care plan which was documented within the notes.
- Theatre and ward staff had emergency on-call rotas; however, the hospital did not have a formal on-call rota for anaesthetists, and surgeons were responsible for agreeing cover.
- The hospital did not provide high dependency or intensive care. Managers at the hospital had negotiated an agreement with a local NHS trust to take patients in an emergency, and transfer would be by the London Ambulance Service.

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- The hospital had a service level agreement with another independent hospital locally to supply blood for transfusion if required.
- Nursing staff and medical handovers occurred at the beginning of each shift. We observed the handovers and found them to be comprehensive and covered all key issues including current patients, new patients and staffing levels.

## Nursing staffing

- The ward staffing levels were in line with current Royal College of Nursing 2012 Safer Staffing guidelines. Although staff reported concerns relating to the staffing levels at night. The number of qualified nurses was dependent on the number of patients. For example, if there were four patients or less the ward had one qualified nurse and the support of a healthcare assistant. This is in line with the safer staffing levels 1:4 ratio. This was increased if the acuity of the patient required additional staffing, either agency or bank staff would be used.
- At night if there were less than four patients the clinical staff team consisted of one RMO, one RN and one HCA. In a risk assessment dated 30 July 2015, undertaken by the Hospital, they highlighted the fact that this increased the risk to patients in the event of an emergency, and that there should be two RNs on duty at all times. Managers had implemented this recommendation with immediate effect during our inspection.
- The ward establishment currently stood at nine whole time equivalents (WTE), with a vacancy rate of 25%. The hospital regularly used bank and agency staff and the duty rotas we saw confirmed this. The ratio of registered nurses to healthcare assistants was 3:1.
- The ward manager was responsible for producing the duty rotas and where possible the rota was completed a month in advance. The use of bank and agency staff varied from 20-39% across the hospital; managers had improved recruitment within the ward and theatre areas.
- The current establishment for nursing in theatres was 11(WTE), and there was one WTE vacancy. The use of agency staff was high at 40% from July 2014 to June 2015. The clinical manager told us that this was due to

using agency staff to fill the operating department practitioner (ODP) role, which was difficult to fill. High use of agency staff who might be unfamiliar with the hospitals procedure increases the risk to patients. However, staff used, worked regularly at the hospital and rotas provided confirmed this.

- Information submitted by the provider states that there had been a high turnover of staff at 40% in 2014; however, figures now show that 83% of theatre staff have been employed for over one year. The clinical nurse manager, who was new in post, told us that the workforce had stabilised, and staff we spoke with said they were happy working at the hospital.
- The hospital had an out of hours emergency theatre nursing on call team, which included the appropriate skill mix of qualified theatre staff to open the theatre.
- The staffing levels in theatre during all surgical procedures were compliant with recommendations from the Association for Perioperative Practice (AFPP).

## Surgical staffing

- Consultant surgeons led the service and they were expected to review their patients on a daily basis. This was always the case; however, not all the patient records had a record of this occurring.
- Nursing staff told us that patients' individual surgeons would attend the hospital if a patient review was requested by the RMO. However, there was no formal rota and the informal cover arrangements were not documented.
- There was 24/7 RMO cover for the ward. The duty rotas provided confirmed the RMOs worked 24 hours a day for two weeks at a time. There was an on call room on the ward for the RMOs to use when they were resident and on site for their two week cover period.
- The RMO attended ward handovers and daily bed meetings for patients. The surgeons were present the majority of the time on a daily basis. Patients who may require additional medical support were supported initially by the RMO who liaised with the surgeon responsible for the individual patients care. Seven surgeons usually operate at the hospital.
- There was no formal on-call anaesthetic rota to cover emergencies or returns to theatre that may arise

# Surgery

following surgical procedures. The surgeon who performed the operation was responsible for obtaining anaesthetic support if a patient needed to return to theatre. Minutes confirmed a discussion took place, regarding having an anaesthetic emergency on call rota during the clinical governance and quality meeting (CGCQ) on the 19 August 2015, and would be discussed further at the medical advisory meeting (MAC) on the 24 September 2015.

- Anaesthetist's did not leave the hospital until the patient had returned to the ward and recovered from the anaesthetic. The surgeons also saw the patient prior to leaving the hospital to ensure they were stable.

## Major incident awareness and training

- Staff we spoke with were able to describe what actions they would take in the case of an emergency such as a serious fire.
- Fire safety was part of the mandatory training cycle and all the staff we spoke with told us they had received training in the last 12 months.
- The hospital had a business continuity plan in place. For example, this included the availability of two hours battery power in the event of a loss of mains power.
- The hospital has only one lift. This would delay evacuation in the event of an emergency other than fire. Hospital managers had produced a risk assessment to reduce the risk of this issue.

## Are surgery services effective?

The service provided care and treatment in accordance with evidence based practice and nationally recognised standards. We observed that clinical staff followed established clinical practice and guidelines.

The rates of a patient being returned to theatre, re-admitted or transferred to an acute hospital because their health had deteriorated were low. We found that staff were competent and well trained. The hospital did not undertake surgery without contacting patients' GPs for their relevant clinical history.

## Evidence-based care and treatment

- Nurses and surgeons delivered care in line with the relevant National Institute for Health and Care

Excellence (NICE) and Royal College guidelines, as well as taking account of individual surgeons' preferences. The hospital had patient pathways and protocols, based on national guidance, that were used to deliver care to patients receiving cosmetic procedures.

- The medical director and senior nursing staff had audited clinical notes on a monthly basis. The medical director had a good knowledge of the results of recent audits of clinical notes. For example, he was aware of omissions surgeons had made, and had spoken with the individuals concerned to ensure improvement.
- The provider had introduced a new computer system, and all the policies were being reformatted and stored electronically. There were arrangements in place for the review and updating of clinical and non-clinical policies.

## Pain relief

- Nursing staff kept records that showed the level of pain was assessed regularly. The records had a copy of the pain tool for staff to use.
- Anaesthetists prescribed pain relief prior to surgery, and this was reviewed by the surgeon. The RMOs worked with nursing staff to ensure the pain relief prescribed was effective when they reviewed patients prior to discharge, or if patients stayed overnight.
- Clinical staff regularly asked patients what their pain level was, and were not kept waiting for analgesia. The ten sets of medical notes we reviewed showed that patients had been given regular pain relief after their operations.
- The anaesthetist reviewed all patients prior to leaving the recovery area, to ensure they were comfortable. At the stage of pre-operative nursing assessment and at discharge, patients were provided with a contact number of the emergency phone line, which had a dedicated registered nurse to advise clinically, and offer support to all patients out of the hospital hours

## Nutrition and hydration

- Nursing staff on the wards used a Malnutrition Universal Screening Tool (MUST), to assess patients for the risks of dehydration or malnutrition on admission. We reviewed ten sets of notes and found that MUST assessments had been completed in all cases.

# Surgery

- Nursing staff had recorded food and fluid intake on the wards following operations, and all patients were given food and fluids before they left.
- Nursing staff had undertaken regular 'comfort rounds' which included patients being offered hot and cold drinks and food.
- The hospital only provided cold food as the hospital did not have on-site catering facilities and all food was brought into the hospital. Staff provided patients with tea and toast as well as offering a choice of sandwiches.
- Some patients we spoke with told us that there were long waits prior to the start of their operation, which had impacted on the length of time they had been without food.
- Staff used a fluid balance chart to record all fluids given intravenously (through a vein) and urine produced by patients.

## Patient outcomes

- The hospital had completed 2,483 inpatient surgical cases between July 2014 and June 2015.
- Information provided showed that there was a low incidence of patients returning to theatre or being readmitted post discharge. One patient had an unplanned return to theatre and 10 patients were readmitted within 29 days of discharge between July 2014 and June 2015. The hospital reported that 668 of the 1,642 day-case procedures were converted to inpatient stays between July 2014 and June 2015.
- Staff gave patients clear instructions about managing their surgical wounds and any follow up appointments that were required.

## Competent staff

- There were processes in place to ensure staff employed by the hospital had access to regular appraisals and opportunities for professional development. Hospital staff told us they had recently received appraisals. Information provided by the hospital showed that the majority of staff had received their annual appraisal. The hospital had completed regular appraisals of its medical staff.
- All new staff completed an induction training programme. The induction and probationary period

included achieving the required level of competency, using the computer system and the hospital policies and procedures. Clinical staff were expected to complete additional training during their three-month probationary period to ensure they had the necessary skills for their role. The ward manager had provided support to a newly appointed nurse we spoke with. We looked at a completed competency booklet which included understanding the treatment, and types of cosmetic procedures that the provider carried out.

- Short tests were carried out to ensure staff were aware of any new policies or procedures. Managers discussed test results with staff at their supervision meetings.
- There was no written orientation booklet used for agency staff. However all agency staff completed a documented induction checklist, and staff worked alongside the agency staff, to ensure they were familiarised with the layout of the clinical areas and all emergency equipment.
- Senior managers and the head office human resources department ensured that professional registration and validation of qualification were undertaken for all staff. Medical staff holding practicing privileges had all undertaken revalidation, and the medical director was the appointed responsible officer. This was confirmed in records we examined.

## Multidisciplinary working

- Staff working within theatres and on the wards told us that there was good working relationships between staff groups, including medical, nursing operating department practitioners, maintenance and portering staff.
- We observed that staff in theatres and on the wards worked well together. The clinical manager told us there were links with external services such as an NHS trust which provided resuscitation training and advice on infection prevention and control. The hospital had a service level agreement with a local private hospital that provided blood in an emergency. Sterile services were contracted out to another provider.

# Surgery

- The patient co-ordinators' liaised with patients GPs to provide medical history prior to carrying out surgical operations. Managers ensured that, if a medical history was not obtained or agreed to by the patient, the surgery would not take place.
- Managers made sure that in all cases, discharge summaries were sent to the patients GPs. This ensured that patients GPs were able to provide on-going care.

## Seven-day services

- There was a 24/7 on-call RMO to cover surgical inpatient care.
- They undertook operations at weekends if there was a patient need for it.
- The hospital maintained nursing cover as per the Royal College staffing levels, consisting of one registered nurse to four patients.
- Consultant surgeons were expected to be available 24 hours a day, seven days a week, if their patients required review, or, if they were not available, they were expected to have arranged cover by another surgeon.

## Access to information

- The hospital kept its policies and national guidance on the intranet which was accessible to staff at all times. Staff we spoke with were able to show us where the policies could be found and had knowledge of them.
- Medical notes were available to clinical staff for all patients. Audits showed that notes were available 100% of the time.
- Blood tests and other diagnostic results were available to clinical staff as required.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff told us they did not have patients who lacked capacity and did not demonstrate that they understood their responsibilities in relation to the Mental Capacity Act. Confirmation of patient medical history was obtained from the patients GP prior to surgery being agreed, to ensure patients did not have an underlying psychiatric or medical history. If patients refused to

allow their GPs to be contacted, they were excluded from having cosmetic surgery with the provider as a safety measure. All the patients we spoke to confirmed that their GPs had been contacted.

- Prior to any surgery all patients underwent an initial medical history assessment and completed a health questionnaire, to ensure they were fully conversant with details of their operation, and that there are no underlying risks to their mental and physical health. If there was a history of any mental or physical health, the provider engaged with the patient's GP and if required, a specialist practitioner, to allow them to fully investigate the appropriateness and fitness for surgery.
- There was a hospital consent policy available to staff on the intranet.
- The patient's consultant surgeon obtained consent on the day of surgery.
- There were checks that consent had been obtained, on the ward, on arrival in theatre, and before the administration of anaesthesia, in line with the WHO surgical safety check list and best practice guidance. The 10 sets of notes we reviewed confirmed that all consent to surgical procedure forms were signed, dated and legible.

## Are surgery services caring?

Staff were caring and professional. All staff treated patients with dignity and respect and were emotionally supported through making the decisions relating to their cosmetic surgery.

The vast majority of the patients we spoke with told us they were happy with the care they had received at the hospital. One person told us, "All staff were caring and patient with me." A number of patients we spoke with were unclear about how long they had to 'cool off' once they had paid their deposit.

## Compassionate care

- We observed staff were professional and treated patients and their relatives with respect. Staff made sure that care was delivered promptly and with compassion. Staff we spoke with were aware of the need to maintain patient dignity, and patients told us that staff were attentive and kind.



# Surgery

- Patients described the care as 'very good', and told us that staff provided full explanations of their surgery, treatment and discharge plans. One patient told us that she had expected to be discharged on the day of her surgery, but was too unwell to go home. Without any hesitation, the nursing and medical staff made arrangements for her to stay overnight. Another patient said, "All staff were caring and patient with me. All the staff listened to any questions I had and took their time to explain anything to me".
- The most recent friends and family test (FFT) confirmed 85% of patients were very satisfied with their care, although the response rate was low at less than 30%.
- We received 29 completed CQC comment cards with one negative comment, and three with mixed comments, mostly relating to waiting times to see the surgeons in outpatients, and delays in going to theatre for operations. Positive comments included, "from start to finish the service and facilities were 5 star, would highly recommend! My results were amazing"

## Understanding and involvement of patients and those close to them

- The hospital allocated each patient a named patient co-ordinator from initial contact, to provide support and answer any questions the patient had. The patient co-ordinators gave support on non-clinical issues such as appointments and costs. Where patients required clinical advice, either a consultation or a telephone conversation was arranged with a member of the medical or nursing staff. Relatives and friends were included in the consultations where appropriate.
- From the time patients decided to go ahead with their surgery and paid their deposit, there is a 14-day 'cooling off' period. The patients we spoke with were uncertain about the cooling off period, and some did not know they could change their minds after the deposit had been paid.
- The hospital offered patients as many free consultations as necessary, either with the same surgeon, or an alternative, to ensure patients were happy with the procedure.
- Patients and their relatives told us they felt involved in the decision making process, and were given

information about the type of implant that would be used if they were having breast augmentation. Patients were able to describe the clinical risks of their operations.

## Emotional support

- Both clinical and non-clinical staff were aware of the importance of providing emotional support and advice. We observed positive interactions between patients, patient co-ordinators and clinical staff.
- The contractual terms of treatment for patients included support and consultation for three years after surgery.

## Are surgery services responsive?

The hospital had a clear focus on its core patient group of women aged between 18 and 35 years. It understood the specific risks of this group, and ensures clinical staff reduce the risks of inappropriate surgery.

Patient coordinators effectively managed the patient journey, and were well thought of by the patients we spoke with. There were delays in outpatients due to the poor time keeping of a small number of surgeons. The hospital did not have a plan in place to improve performance in this area.

## Service planning and delivery to meet the needs of local people

- The hospital focused on cosmetic procedures mainly breast augmentation for females aged between 18-35 years of age. The hospital carried out 1440 breast augmentations from July 2014 to June 2015.
- Surgical cases were booked directly, or were referrals from other MYA clinics across the UK. The patient co-ordinators told us that they responded to enquiries made via the MYA website or by patients calling the provider directly. The hospital had a team of 10 patient co-ordinators. The hospital intended to increase the numbers of patient co-ordinators from 10 to 12 to ensure a more timely response to enquiries.
- Each patient co-ordinator had a portfolio of patients which provided individuals with a named contact within the organisation to meet individual patient needs. This enabled a patient to speak to the same person at the hospital.

# Surgery

- Despite receiving a number of complaints, senior managers had made no analysis of waiting time performance, and the time a patient went into see the surgeon in the outpatient clinic was not recorded. This meant that specific information with regards to the performance of individual surgeons was not available to form the basis of an improvement plan. We found that some of the surgeons were arriving significantly late for their outpatient clinics.
- There were two operating theatres and surgical procedures were carried out seven days a week to assist with service planning.
- As the hospital provided private elective surgery, admissions to the surgical inpatient wards were planned in advance. The majority of patients were treated as inpatient day cases and of 1,642 cases, 668 remained overnight between July 2014 to June 2015.
- The range of cosmetic surgical procedures was limited to approximately nine different procedures. This is in line with the specialties of the surgeons using the hospital with practicing privileges.

## Access and flow

- Patients we spoke with told us that they had not experienced any delays in setting operation dates, and the hospital gave them their operation dates within approximately two weeks of seeing the surgeon, and deciding to proceed with their surgery.
- Staff confirmed that dates for surgical procedures were usually given after the two week 'cooling off' period, although some patients wanted their surgery as soon as possible depending on the surgeon's availability.
- Ward tried to keep patients informed with approximate times that they would be going to theatre for their operation but occasionally delays did occur.
- The provider monitored theatre over runs as well as patients that had unplanned returns to theatre. Overruns occurred and occasionally resulted in operations being cancelled.
- There were minimal reported discharge delays as the majority of patients were day surgery or stayed one night.

- Managers told us that the biggest challenge for them was making sure that they chose the right patients for surgery. For example patients for breast augmentation must have a body mass index (BMI) between 18 and 35.
- The hospital had a process for psychology reviews which formed part of their exclusion criteria. All patients completed a medical history questionnaire ahead of their first appointment with the patient co-ordinator, clinical staff checked this at pre-assessment, and a letter was sent to the GP making them aware of the patient's intention to have cosmetic surgery.

## Meeting people's individual needs

- Clinical staff provided patients with written information relating to their surgical procedure and had access to their named patient co-ordinators and clinical staff, if required, to discuss any medical concerns. Patients could also have as many consultations prior to their surgery as they required and free follow up appointments for three years after surgery.
- The hospital gave patients who had breast augmentation (implants) the manufacturer's booklet, which identified the serial number of the implant, and an explanation from the manufacturer about the type and size of the implant used. Staff recorded the serial number of the implant in the patient's records.
- The patient's discharge plan included advice specific to the procedure that had been undertaken, as well as information relating to any pain relief or antibiotics that patients were given to take home.
- Patients told us that staff provided support both before and after the operation, and met their individual needs. One patient said "I had a patient co-ordinator who kept in contact and nothing was too much trouble."
- The front entrance was wheelchair friendly and the doors opened automatically. The ward bedrooms are on the first floor and there was lift access for patients with specific mobility needs. Some bedrooms were along a narrow corridor but patients requiring easier access due to reduced mobility were allocated rooms adjacent to the nursing station which provided easy access.

## Learning from complaints and concerns

# Surgery

- There was a complaints policy and procedure in place, the admission staff provided this to all patients as part of the inpatient information pack.
- The provider kept a log of all complaints and provided a summary of complaints received from January 2015 to August 2015. The summary stated the provider had received 36 complaints; 22% related to delays in admission and communication issues. The remaining 28 complaints (2.1% of the 1,342 procedures carried out at the location) related directly to the treatment patients received. The hospital had not responded to two complaints within the agreed 20 working days as indicated within the provider's complaints policy due to further investigation being required. Six of the complaints progressed to stage two of the complaints process and none of the complaints went for independent review.
- The summary provided details of the trends and the action taken to prevent recurrence. For example the provider had staggered admission times to prevent delays following admissions.
- The CGCQ meeting discussed complaints, although minutes did not detail trends or actions taken. However, the theatre and ward areas displayed information on their activities such as complaints.
- Hospital staff, wherever possible, tried to resolve any issues with patients prior to a written complaint being made. Manager had an expectation that any concerns raised by patients on the ward or in the clinics would be immediately addressed by staff, and reported and dealt with by a manager, and if possible, resolved immediately to the patients satisfaction.

## Are surgery services well-led?

The management team worked well together locally. The hospital lacked formal rigour and key clinical meetings were not taking place. The medical director was not attending all the key meetings nor was he able to provide enough leadership in the two days a month he is available

The hospitals senior managers had a clear vision for running and developing the hospital for their specific patient group. Key clinical processes and meeting were not taking place at the time of our inspection, for example infection control and clinical risk meetings. Senior

management had not ensured that the medical advisory committee (MAC) was fully linked to the other meetings, meaning clinical risks were not clearly visible and discussed at the MAC.

The hospital was innovative in using social media to keep prospective and actual patients informed and giving them a platform to share their experiences of the hospital.

## Vision and strategy for this core service

- The registered manager and the nominated individual told us that the vision and strategy for the organisation was to:
- Be a market leader in the cosmetic surgery sector
- Focus on a specific age group of 18-35 year old females requiring breast augmentation
- Partner with other quality providers and build a quality service which is patient centred and an aspirational brand
- Staff we spoke with told us they believed the service offered was patient centred, and the provider offered a quality service, although, they were not aware of a formal strategy for the organisation.

## Governance, risk management and quality measurement for this core service

- The provider has used this location since May 2014 and had implemented a governance structure which is being developed. The Clinical Governance and Quality Assurance policy dated 24 August 2015 outlined the terms of reference and agenda topics to be discussed at meetings such as Infection Prevention and Control Committee (IPCC). The IPCC had not met at the time of our inspection.
- We reviewed a selection of CGCQ meeting minutes from February 2015 to August 2015. These were held approximately every six weeks. We noted that there was no identifiable chair, and the title of the group varied from Clinical Governance Committee to Clinical Governance and Quality Meeting. The medical director was recorded as attending 50% of the meetings that we reviewed, despite the terms of reference stating he should attend all of them.
- The topics discussed included complaints, infection control, policies, incidents and practising privileges.



# Surgery

Managers had not documented in any detail, any of topics discussed. For example, on 19 August 2015, the minutes referred to the WHO and medical records audits without any quantitative data to explain the findings. The meeting minutes were available to all staff, and accessible via a computer shared drive to inform them of the progress and discussions undertaken at the CGCQ.

- All CGCQ meeting minutes were supported by an action plan, although we saw that reviewing the infection and prevention policy was first identified as an action in the May 2015 CGCQ meeting minutes, and this was still to be completed in August 2015. The lead for infection prevention and control told us that this was still awaiting completion at the time of our inspection.
- Senior clinical staff were not discussing or updating the risk register at the meetings of the CGCQ in February 2015, May 2015 or July 2015. In the minutes of the 19 August 2015 meeting, it was stated that the risk register was being updated but no items were discussed. Some staff we spoke with were aware of the risk register and the need to carry out a risk assessment to identify the impact on patient safety. Senior managers told us items such as staffing and single lift access for the disposal of theatre clinical waste were key concerns. The risk register did contain staffing but the single lift which was used to take patients to and from theatres and to transport clinical waste did not appear on the register.
- Issues from the CGCQ were discussed and escalated to the medical advisory committee (MAC) which was held twice a year. Managers provided us with the minutes from the meeting held on the 24 February 2015 and the agenda for the 24 September 2015. We noted that the CGCQ was held on the 25 February, the day after the MAC and therefore any issues requiring discussion would need to be carried over until the September 2015 MAC meeting.
- The MAC discussed issues including patient protocols, equipment, practicing privilege and revalidation. The MAC was not discussing incidents or 'never' events.
- Managers held meetings with their staff in each department, and managers were represented at the

CGCQ meeting. Minutes submitted for the Clinic Service Integrated Committee for 29 July 2015 showed that items discussed included incidents. Audit and training were taken forward to the CGCQ on 19 August 2015.

- The hospital ensured that all staff registration statuses were verified and there was a process in place for overseeing and verifying doctor revalidation, continuing practice development and their reviewing practicing privileges.

## **Leadership / culture of service related to this core service**

- Staff across the hospital reported that the senior management team were visible and easily accessible if they needed to discuss an issue or make suggestions on improving the service.
- Staff reported that there was good departmental manager support and they felt listened to and appreciated. A newly appointed clinical nurse manager supported the clinical teams within the theatre and the ward staff.
- The hospital contracts the medical director to work at the hospital for two days a month. However he told us he works many more hours than his formal contract.
- We spoke with six medical staff who reported good working relationships with the senior management team, although, the medical director is not on site very often, and some of the medical staff felt there was a lack of involvement on a clinical level and providing feedback on incidents.

## **Public and staff engagement**

- The provider carried out patient satisfaction surveys to gain information from patients about their experiences. The provider also engaged with people on social media sites such as twitter and Facebook. The provider's website also offered 'live chat' and an open forum to gain public engagement and opinion.
- The nominated individual told us that compliments and concerns were highlighted and responded to by staff. Patients could access a named patient co-ordinator by telephone or via email, and all contacts were followed up and logged on the computer system. We observed this in practice.

## **Innovation, improvement and sustainability**

# Surgery

- Staff we spoke with gave an example of a change they had suggested to their manager to support patients having revision surgery, to improve the contact between patients and the hospital, which had been implemented.
- The hospital is innovative in using social media. They have developed a chat room where patients can share experiences about their care at the hospital.

# Outstanding practice and areas for improvement

## Outstanding practice

- The Hospital uses social media to provide information to patients and to give them an open platform on which they can share their experiences of care at the hospital.

## Areas for improvement

### Action the provider **MUST** take to improve

- The provider must consider the arrangements for managing risk which involves all clinical staff. This must include appropriate arrangements for assessing risks posed by the environment, practices and procedures.

### Action the provider **SHOULD** take to improve

- The pre-printed dispensing labels for use on discharge medicines given to patients to take home, should include the name and address of the person who supplies the medicinal product as required by the Human Medicines Regulations 2012.

- Reduce outpatient delays.
- Develop a formal on-call rota for anaesthetists and surgeons.
- Review the ability of the medical director to discharge his role in the two days allowed for that purpose.
- Make sure the cancellation policy is clear to all 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
Surgical procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17(2)(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);</p> <p>The provider did not have a comprehensive system for identifying, reviewing and reducing clinical risks faced by patients.</p> <p>The provider must consider the arrangements for managing risk which involves all clinical staff. This must include appropriate arrangements for assessing risks posed by the environment, practices and procedures.</p> <p>Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17 Good Governance.</p>