The Foscote Private Hospital

Quality Report

2 Foscote Rise
Banbury
Oxon
OX16 9XP
Tel:01295 252281
Website:www.thefoscotehospital.co.uk

Date of inspection visit: 19 August 2015
Date of publication: 12/11/2015

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

The Foscote Hospital opened in Banbury, Oxfordshire, in 1981. The hospital has recently come out of a 10 year management contract with a large healthcare company and has returned to being independently managed. The Foscote Private Hospital is a charitable trust providing services to patients in Banbury, Oxfordshire and the surrounding areas of Northants, Warwickshire, Gloucestershire and Buckinghamshire. The hospital provides surgical and medical treatments for patients. The on-site facilities include an endoscopy suite, an operating theatre with laminar air-flow and consulting rooms supported by an imaging department offering X-ray and ultrasound. There are 12 patient bedrooms with en-suite.

We undertook a comprehensive inspection of The Foscote Private Hospital in July 2015. At this inspection we judged safety, effective and well-led as inadequate for the surgical service. This was because the staffing levels, the skills and training levels, working practices in the operating department and medicines that were not always safely managed. There was not a consistent approach to the use of national guidance to ensure patients received effective care and treatment. In the operating department staff were undertaking roles which they were either not qualified or assessed as competent to perform.

Governance practices to monitor risk and quality were not embedded across the whole hospital, including in the endoscopy department and theatres. The quality of the service was not being monitored effectively through audit and some working practices were out of line with hospital policies and national guidance. Risks were not adequately identified, assessed or managed.

In July 2015, we served three warning notices against the hospital; under standards for ''staffing'' and ''safe care and treatment'' for the regulated activity surgical procedures. The third notice was served under ''governance'' for the regulated activities surgical procedures and treatment of disease, disorder or injury. The warning notices required the hospital to take immediate action to improve the safety of patient care.

We undertook this unannounced focused inspection of The Foscote Private Hospital to follow-up on the warning notices served.

The inspection took place on 19 August 2015. The inspection team of four included two CQC inspectors and two specialist advisors who were a nurse theatre manager and a governance lead.

Following the comprehensive inspection conducted on the 7 and 8 July 2015 we rated this service as inadequate. After the focused inspection there was not sufficient evidence to change the rating applied at the comprehensive inspection, therefore these ratings will stand. Some improvements had been made as documented in the report, but there had been insufficient changes in the six week period since the comprehensive inspection for these changes to be fully embedded. We concentrated on specific areas of noncompliance identified during the comprehensive inspection. The service will have a further comprehensive inspection when ratings will be applied.

Our key findings were as follows:

- During the inspection we found that the hospital had made improvements, but there remained concerns around the effectiveness of the governance procedures and processes and some operational practices in theatre to keep patients safe.
- Staffing levels in the operating theatre were not consistently in line with national guidance. The Five Steps to Safer Surgery checklist was being used but was not always completed appropriately as part of normal practice
- Medicines management had improved
- Staff had received training to safely use equipment.

Summary of findings

- Polices referenced relevant national guidance, but staff did not demonstrate a clear understanding of why national guidance should be adhered to ensure the patient was receiving the 'best' care and treatment, such as completion of the Five Steps to Safer Surgery.
- A training programme had been introduced for staff acting as surgical first assistant (SFA). Competency assessments were in place for the staff in the operating department.
- Governance processes were not effective in monitoring the risk and quality of providing the service. The hospital clinical audit programme had not been agreed and the business risk register was under development.

Importantly, the hospital must ensure:

- Staffing levels in the operating theatre are in line with current national guidance at all times.
- Staff in the operating theatre fully comply with the five steps of safer surgery.
- Instrument counts in the operating theatre fully comply with national guidance and hospital policy.
- There is a written policy to support staff undertaking dual roles in the operating theatre to ensure staff work safely and in line with national guidance.
- There is clear guidance and staff understand their responsibility under the 'Duty of Candour.'
- Working practices in the operating theatre reflect the hospital policy and procedures and are in line with current national guidance.
- The effectiveness of the clinical governance group is reviewed and there is robust monitoring of safety and quality of the service, that risks are identified, that timely actions are taken to manage risks and that decision-making is recorded clearly.
- There is an effective and comprehensive audit programme and audit of practices in the operating department.
- The risk register reflects the current risks faced by the hospital.

In addition the provider should ensure:

- There are clear procedures and processes to follow if temperature and humidity readings are not within normal limits, once a patient is in the operating theatre.
- Staff fully understand the procedure to follow if there are concerns about an adult's welfare.
- Staff are deemed competent to sign off competencies for other staff within the operating department.
- Storage arrangements for the transfer board in the operating department are appropriate.
- Staff competencies are appropriately assessed, including the competencies of staff from other providers, to confirm they are competent for their roles.

Professor Sir Mike Richards

Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery		At our inspection in July 2015, we rated safety as 'inadequate'. This was because the staffing levels, the skills and training levels, working practices in the operating department and medicines that were not always safely managed. There was not a consistent approach to the use of national guidance to ensure patients received effective care and treatment. In the operating department staff were undertaking roles which they were either not qualified or assessed as competent to perform. Governance practices to monitor risk and quality were not embedded across the whole hospital, including in the endoscopy department and theatres. The quality of the service was not being monitored effectively through audit and some working practices were out of line with hospital policies and national guidance. Risks were not adequately identified, assessed or managed. **During this inspection** we found staff in the operating theatre had made improvements, with the support of senior management, but there were still areas where safety needed to be assured. Governance procedures and processes were not effective in the operating department or across the hospital as whole. Theatre staffing did not always meet national guidance. Instrument counts were completed, but the Five Steps to Safer Surgery was not yet part of normal practice. Medicines management had improved and staff had received training to safely use equipment. Policies referenced relevant national guidance, but staff did not fully appreciate the benefit of this guidance in respect of the treatment outcomes for the patient. A training programme had been introduced for staff acting as surgical first assistant (SFA). Competency assessments were in place for the staff in the operating department.

Summary of findings

Contents

The Foscote Private Hospital

Services we looked at
Surgery

Summary of this inspection

Background to The Foscote Private Hospital

The Foscote Hospital opened in Banbury, Oxfordshire, in 1981. The hospital has recently come out of a 10 year management contract with a large healthcare company and has returned to being independently managed.

The Foscote Private Hospital is a charitable trust providing services to patients in Banbury, Oxfordshire and the surrounding areas of Northants, Warwickshire, Gloucestershire and Buckinghamshire. The hospital provides surgical and medical treatments for patients. The on-site facilities include an endoscopy suite, an operating theatre with laminar air-flow and consulting rooms supported by an imaging department offering X-ray and ultrasound. There are 12 patient bedrooms with en-suite.

We undertook a comprehensive inspection of The Foscote Private Hospital in July 2015. At this inspection we judged safety, effective and well-led as inadequate for the surgical service. This was because the staffing levels, the skills and training levels, working practices in the operating department and medicines that were not always safely managed. There was not a consistent approach to the use of national guidance to ensure patients received effective care and treatment. In the operating department staff were undertaking roles which they were either not qualified or assessed as competent to perform.

Governance practices to monitor risk and quality were not embedded across the whole hospital, including in the endoscopy department and theatres. The quality of the service was not being monitored effectively through audit and some working practices were out of line with hospital policies and national guidance. Risks were not adequately identified, assessed or managed

In summary, the operating theatre was not staffed appropriately in line with national guidance and hospital policy. Staff in the operating department undertook the role of surgical first assistant without sufficient training or competency assessment and under took two roles referred as dual rolling without the required risk assessments and policies. Medicines were not safely managed in the operating department and audible instrument counts were not completed during surgical procedures. Audits were not taking place to monitor practice against hospital policies. There was no evidence that the risk of not complying with policies and procedures had been considered.

In July 2015, we served three warning notices against the hospital; under ''staffing'' and ''safe care and treatment'' for the regulated activity surgical procedures. The third notice was served under ''governance'' for the regulated activities surgical procedures and treatment of disease, disorder or injury. The warning notices required the hospital to take immediate action to improve the safety of patient care and address the staffing levels and training needs of staff in the operating department. Changes were required to governance processes to identify, assess and manage issues around quality and risk at the hospital.

We undertook this unannounced focused inspection of The Foscote Private Hospital to follow-up on the warning notices served.

The registered manager is Karen Ruth Thompson (Ruth) who has been in post since October 2014 when the hospital returned to independent status.

Our inspection team

Our inspection team was led by:

Inspection Manager: Lisa Cook, Care Quality Commission (CQC)

The inspection team of four included two CQC inspectors and two specialist advisors who were a nurse theatre manager and a governance lead.

Summary of this inspection

Why we carried out this inspection

We carried out this inspection to follow up on concerns identified during the comprehensive inspection July 2015

How we carried out this inspection

To get to the heart of 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 we held about the hospital. We carried out an unannounced inspection visit on 19 August 2015.

During this focused inspection we assessed the surgical service, focussing on the safe, effective and well-led domains. The overall governance processes for the hospital were also reviewed and reported on as part of the well-led domain. We spoke with staff, observed patient care in the operating department, reviewed patients' records of personal care and treatment and reviewed hospital policies.

We would like to thank all staff, for sharing their views and experiences of the quality of care and treatment at The Foscote Private Hospital.

Detailed findings from this inspection

Surgery

Safe	
Effective	
Well-led	

Information about the service

Surgery is the primary inpatient activity of the Foscote Private Hospital. Cosmetic surgery,), general surgery, gynaecology, ophthalmology, oral and maxillofacial surgery, orthopaedics and urology surgery are provided. There were 1,124 admissions for surgery from April 2014 to March 2015. The three most commonly performed procedures were hernia procedures (199), phacoemulsification of lens with implants (104) and arthroscopic knee procedures (89).

The hospital has one operating theatre with a single-bedded recovery area. There are 12 patient rooms over two floors; all the rooms are single with an en-suite.

There is a pre-operative assessment clinic room and a bookings and administration office.

During the focused inspection we inspected the operating department. We spoke with seven staff, including nurses, an operating department practitioner, an anaesthetist and a member of the administration team. We also spoke with the hospital manager, Matron and the ward sister. We reviewed two sets of patient records and four personnel files. We observed care in the operating theatre. We assessed the surgical service, focussing on the safe, effective and well-led domains. The overall governance processes for the hospital were also reviewed and reported on as part of the well-led domain.

Summary of findings

At our inspection in July 2015, we rated safety as 'inadequate'. This was because the staffing levels, the skills and training levels, working practices in the operating department and medicines that were not always safely managed. There was not a consistent approach to the use of national guidance to ensure patients received effective care and treatment. In the operating department staff were undertaking roles which they were either not qualified or assessed as competent to perform.

Governance practices to monitor risk and quality were not embedded across the whole hospital, including in the endoscopy department and theatres. The quality of the service was not being monitored effectively through audit and some working practices were out of line with hospital policies and national guidance. Risks were not adequately identified, assessed or managed.

During this inspection we found staff in the operating theatre had made improvements, with the support of senior management, but there were still areas where safety needed to be assured. Governance procedures and processes were not effective in the operating department or across the hospital as whole.

Theatre staffing did not always meet national guidance. Instrument counts were completed, but the Five Steps to Safer Surgery was not yet part of normal practice. Medicines management had improved and staff had received training to safely use equipment.

Policies referenced relevant national guidance, but staff did not fully appreciate the benefit of this guidance in respect of the treatment outcomes for the patient. A training programme had been introduced for staff acting as surgical first assistant (SFA). Competency assessments were in place for the staff in the operating department.

Surgery

Are surgery services safe?

By safe we mean that people are protected from abuse and avoidable harm.

At our inspection in July 2015, we found a number of concerns relating to keeping patients safe, staffing levels were not in line with national guidance and staff were undertaking a dual role without a risk assessment being completed. Staff were not conducting instrument counts and theatre staff were not fully participating in the Five Steps to Safer Surgery, designed to protect patients from harm. Out-of-date medicines were also found. Staff had not received training on how to use the equipment in theatre to ensure they were competent.

During this inspection we found staff in the operating theatre had made improvements, with the support of senior management, but there were still areas where safety needed to be assured. Staffing levels in the operating theatre were not consistently in line with national guidance. The risks of not staffing the operating theatre in line with guidance and hospital policy were reported to have been considered, however these were not formally documented. There was no policy to support staff undertaking a dual role, although a risk assessment for some dual role procedures had been completed.

The cleaning records for the anaesthetic area and operating theatre had been up dated using guidance from The Association for Perioperative Practice (AfPP) Standards and Recommendations for Safe Perioperative Practice (2011) and The Health Act (2006). However, infection control practices that had the potential to place patients at risk were observed for example leaving the patient transfer board on the floor.

The Five Steps to Safer Surgery checklist was still not being completed in full for each patient. Instrument counts were now taking place, with a policy for staff to follow. However, the practice was not yet fully embedded. Staff were not engaging with all the steps of the Five Steps to Safer Surgery, to ensure patient safety.

Staff had limited understanding of duty of candour and found it difficult to define a safeguarding incident.

Staff had received training on the equipment used in theatre and a log of service dates and the date of the next service was now maintained. Daily equipment checks were now taking place to ensure equipment was in good condition. No out-of-date items of single use equipment were found.

Medicines were all in date and stocks were checked weekly.

Duty of Candour

- The Duty of Candour legislation requires healthcare providers to disclose safety incidents that result in moderate or severe harm, or death. Any reportable or suspected patient safety incident falling within these categories must be investigated and reported to the patient, and any other 'relevant person', within 10 days. Organisations have a duty to provide patients and their families with information and support when a reportable incident has, or may have occurred.
- Staff remained unclear around the exact meaning of the Duty of Candour, but one staff member described the importance of being open with the patient and their family and offering an apology.
- Training was being sourced for staff to attend, however the time line for this had not been agreed.

Cleanliness, infection control and hygiene

- At our inspection in July 2015, we saw evidence of completed cleaning matrixes for the anaesthetic and recovery areas.
- During this inspection we saw updated cleaning records for the anaesthetic area and operating theatre. These new records had been compiled using guidance from The Association for Perioperative Practice (AfPP) Standards and Recommendations for Safe Perioperative Practice (2011) and The Health Act (2006). The rationale and actions were clearly identified. The weekly housekeeping records for theatre were compete, signed and dated. Walls, lights and high surfaces were all cleaned weekly as part of the standard list, to maintain good standards of cleanliness and hygiene.
- However, during our observation in theatre, we noted a number of concerns relating to hygiene and infection prevention and control. The patient transfer board, used to move patients between trolleys was on the floor, therefore, it could not be guaranteed that the board was clean prior to use with a patient. Also, a member of staff was seen to remove their gloves before their theatre gown, after an operation was completed, therefore,

creating a potential infection, hygiene and cleanliness risk. Two notices in theatre were not laminated therefore, it was not possible to wipe the signs to keep them clean.

Environment and equipment

- At our inspection in July 2015, surgical item counts were not taking place, placing patients at risk through unintended retained objects. This practice was not in line with hospital policy ''Policy for peri-operative swab, instrument and needle count'' (2013) nor guidance from the AfPP (Accountable items, swab, instrument and needle count (2012)). Staff did not demonstrate an understanding of the reasons why these checks should take place or their importance. It was difficult to locate current information on the contracts and servicing for equipment used in the operating department. Also, staff had not received training on the use of this equipment. There was no evidence of daily equipment checks being conducted in theatres to ensure all equipment was available and safe to use. Out-of-date items were found on the resuscitation trolley.
- During this inspection staff described the process they now followed for counting of items used during a procedure, including the count being verbal and undertaken by two members of staff, counting in unison. Staff were aware of the process to follow should an object not be accounted for in the final count. A new policy had been introduced ''Policy for peri-operative swab, sharp and instrument count'', there was no date or version control and the document had not been approved or ratified. Relevant national guidance was referenced in the document and included an audit tool to be used to monitor staff adherence with the policy. No audits had yet been undertaken.
- We observed a full count taking place correctly pre-operatively, for one patient, following the guidance in the policy and from the AfPP. For a second patient, the initial count was performed, but two additional instruments were missed from the count and were not recorded on the board used to capture this information. However, these two instruments were included in the final instrument count. Therefore best practice was not observed for the recording of additional instruments. Swabs and red ties were counted correctly.
- The final count did not take place with a silent focus or engagement from other staff in the operating theatre. The scrub practitioner and circulating practitioner completed the count, but it was difficult to hear them due to other staff talking. Therefore, there was the potential for errors to be made or items to be missed from the count, putting the patient at risk. Staff were also not demonstrating a thorough implementation of the procedures and processes which they described to us.
- All equipment had been logged onto a central system, managed by an external company. This system could be accessed by the hospital manager, the finance lead and estates manager. The company were responsible for arranging renewal of contracts and servicing for equipment. One piece of equipment checked had a sticker showing item has recently been serviced and when the next service was due, this was cross checked with the electronic log and the data matched. The paper records for servicing of equipment were kept in the theatre office, staff we spoke with knew where to locate these, in the absence of the manager.
- Staff had begun to receive training on the use of the equipment. A log of attendance for each training session had been kept and staff were signed off against a number of competencies to confirm they had the knowledge and skills to use the equipment safely.
- A daily check had been introduced from the beginning of August, with a written list kept, showing that the equipment required for each theatre list had been checked and was available. If a piece of equipment was not needed the box was not ticked. It was raised with staff that this process needed to be clearer, as it could be assumed that someone had forgotten to check that particular piece of equipment. An end of theatre checklist had also been compiled clearly identifying tasks which needed to be completed once the theatre session had finished.
- Daily checks and recording of the relative humidity in theatres had been introduced alongside the daily checks of the theatre temperature, to ensure a comfortable environment for both patients and staff and to minimise infection risks. Records checked showed these had been completed for all but one day. Staff were clear that they needed to raise any concerns to a more senior member of staff if these initial daily readings were abnormal.
- There was a flowchart in place with steps to follow should the reading not be within the expected range.

The flowchart for the temperature check did not include whether the patient should be sent for or not if the reading was outside the normal range, this was included on the humidity flowchart.

- Staff told us and we saw from a review of records the temperature and humidity in theatre were recorded in the patient's care pathway, whilst they were in theatre undergoing a procedure. However, it was not clear what procedure theatre staff should follow if any of these readings were abnormal during this time.
- All items on the trolley had been reviewed and out-of-date items and excess stock removed. A new checklist was being used and was fully completed, signed and dated. No out-of-date items were found on the trolley. There was greater assurance that in an emergency a patient could be fully supported.

Medicines

- In July 2015, we found out-of-dates medicines in the anaesthetic room, putting patients at risk. For ease of access the drugs cupboard was kept unlocked, with the outside door from the anaesthetic room to the corridor kept locked, to limit access to those outside of the department. No risk assessment had been completed to support this practice and to identify the procedure to follow in an emergency.
- During this inspection we checked the drugs cupboard. No out-of-date items were found. A checklist had been introduced, listing all drugs and their expiry date. Stock was rotated as required, to ensure the oldest item was used first. Weekly checks had been completed and a medicines management audit undertaken. The findings, actions and responsible person were clear. The current audit showed 97% compliance against the criteria assessed, but had identified the seal was not intact on the anaphylaxis kit. Action had been taken and the pharmaceutical company contacted for a new seal.
- Staff told us that the drugs cupboard in the anaesthetic room was now kept locked at all times, with the anaesthetic nurse responsible for the keys. Emergency drugs were taken into theatre prior to a session starting. The door to the anaesthetic room was unlocked, which we saw during our inspection. Staff told that the keys were always kept in the department, to ensure the drugs cupboard could always be accessed during an operating session.
- The hospital had agreed a contract with a new external provider for its pharmacy service which included support all aspects of medicines management, for the whole hospital.

Safeguarding

- In July 2015, during our comprehensive inspection, staff were unable to describe what the different types of abuse were.
- During this inspection we spoke with three staff who confirmed they had received safeguarding adults training. They were not clear or confident to speak about what constituted a safeguarding incident, including the different types of abuse.

Assessing and responding to patient risk

- At our inspection in July 2015, we observed the Five Steps to Safer Surgery were not consistently being adhered to by theatre staff. The five steps are designed to reduce harm to the patient and improve safety.
- During our inspection staff told us they were now using the Five Steps to Safer Surgery checklist during all theatre sessions for each patient. There was a ''Safer Surgery'' policy in use, but there was no standard operating procedure with this, to indicate who leads each stage of the checklist, when and where it happens and that a silent focus should be adopted.
- We observed the team briefing prior to the start of the surgical list, which was completed appropriately. The sign in was observed for one case, the patient name and procedure were checked, but not cross checked against the consent form. The consultant went to scrub during the sign in. The steps for time out were not read out aloud, as indicated on the World Health Organisation (WHO) checklist, the anaesthetic practitioner was seen to tick the boxes on the checklist, without consultation with other staff. Sign out was completed, but there was no silent focus from the team. For another patient, the time out was completed out loud and in full, but there was no silent focus. The surgeon was stopped from scrubbing to participate in the time out for this patient.
- The operating department planned to audit their compliance with the WHO checklist, no audits had yet been undertaken.
- Training records showed that five staff had watched a training video on completion of the WHO checklist. Staff also told us that they had been supported and observed on the five steps, by a trained mentor, who had recently

joined the staff team at the hospital as a surgical first assistant. Despite the changes implemented, there was evidence that the process was still not fully embedded and part of standard practice by staff to keep patients safe.

Nursing staffing

- During our inspection in July 2015, we observed that minimum staffing levels were not being maintained at all times in the operating theatre in accordance with guidance from the AfPP (Staffing for patients in the perioperative environment 2014). The guidance advises one qualified anaesthetic assistant practitioner for each session involving an anaesthetic, two qualified scrub practitioners as a basic requirement for each session, unless there is only one planned case, one trained circulating practitioner for each session, one qualified post anaesthetic recovery practitioner for the immediate post-operative period. The minimum staffing requirements inside theatre is four staff, with five for major surgery such as orthopaedic lists.
- Staff were also undertaking the role of scrub practitioner and surgical first assistant, referred to as dual rolling. The Perioperative Care Collaborative Position (PCCP) Statement Surgical First Assistant (2012) states that a practitioner undertaking the role of the SFA must be an additional member of the team. The practitioner acting as the scrub practitioner must manage the intraoperative care required by the patients and must not assume additional duties, such as those of the SFA. In the event that an employer considers that a dual role is required (for example, in minor surgery), then this decision should be endorsed by a policy that fully supports this practice and should also be based on a risk assessment of each situation in order to ensure patient safety. No risk assessments had been completed and there was no hospital policy to support this practice.
- An external audit had been conducted by the AfPP in July 2015, at the request of the hospital. One of the key recommendations of the audit was that the staffing model should be reviewed to ensure that minimum national staffing standards were in place.
- During this inspection we reviewed the hospital ''Staffing Policy'', which stated the recommendations from the AfPP guidance for calculating the staffing establishment. We also reviewed the ''Surgical First Assistant (SFA)'' policy and risk assessments which had been completed on procedures requiring and not requiring a surgical first assistant, the latter being when a dual role would be appropriate. The SFA policy did include the skills, knowledge and competencies required to act as SFA, however, it did not contain anything about staff undertaking a dual role. This was not in line with the PCCP guidance, which states that staff should not undertake a dual role if there is no policy in place.
- Risk assessment for the dual role had been completed which covered six procedures where staff could undertake this role and advised a risk assessment was to be completed for any procedure not listed.
- The Staffing and Surgical First Assistant policies and risk assessments for the dual role had not been approved or ratified. This was particularly important to ensure that senior staff and the legal team were happy with the procedures considered suitable for a dual role and that vicarious liability had been agreed for these.
- We observed one session in theatre, which was staffed correctly in accordance with the guidance, based on the procedures which were being performed.
- We reviewed the staffing rotas and planned procedure lists for a three week period. It was difficult to reconcile the planned staffing with the surgery lists as it was not clear on the rota, which role staff were undertaking. Also, because all dual procedures had not been listed on the risk assessment, it was not clear when the SFA would be undertaking a dual role, which affected the minimum number of staff required.
- The rotas showed that for eight out of 12 days the theatres was not staffed in accordance with the guidance or hospital policy. This was predominantly around the number of scrub practitioners. This was regularly reduced to one, which created a potential risk if two staff were unexpectedly needed in recovery, this would leave theatre short of staff.
- The hospital manager told us that staffing levels were being risk assessed in advanced against the booked theatre sessions and records were kept in the operating department. The theatre manager said they mentally considered the risks, but these were not formally documented anywhere.
- There was no evidence that planned versus actual staffing levels were captured and reported on. Staff we spoke with said they did not report staffing shortages as an incident, but they would raise concerns with their manager. To date there had been no reported incidents

based on staffing levels in the operating theatres, however, there remained a potential risk to patients, through theatres regularly not being staffed to the minimum guidance.

Are surgery services effective?

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

At our inspection in July 2015, staff did not demonstrate a comprehensive awareness of national guidance and hospital policies. Some of the practices we observed were not in line with these. Staff in the operating department were acting in the role of surgical first assistant (SFA), without appropriate training. Staff that did not have a recognised qualification or competency package were assisting the anaesthetist. There was no competency based training in place for staff in the operating department.

During this inspection, we found an increased use of national guidance in the development of hospital polices to establish evidence based care and treatment for patients. However, staff did not fully appreciate the benefit of this guidance in respect of the treatment outcomes for patients.

A policy and training programme was in place to support staff undertaking the role of SFA. Staff acting as an anaesthetic practitioner had an appropriate level of training for this role. Competency assessments were in place for all staff, for the different roles they undertook in the operating department.

Evidence-based care and treatment

- At our inspection in July 2015, there was no formal system to review practices against national guidance, including guidance from the National Institute of Heath and Care Excellence (NICE). Staff told us that these would be considered when a policy or procedure was being reviewed but this was not a formalised process. This was confirmed by the clinical governance lead.
- During this inspection we reviewed a number of polices which had been newly created or rewritten. The policies all contained references to relevant national guidance. We observed practises which were reflective of current guidance, for example, instrument counts were now taking place in the operating theatre, staff acting as a SFA, were undertaking a recognised training programme. However, there was no policy for staff undertaking a dual role as recommended by national guidance.
- Staff were aware of national guidance, but did not demonstrate a clear understanding of why this should be adhered to ensure the patient was receiving the 'best' care and treatment, such as completion of the Five Steps to Safer Surgery.

Competent staff

- At our inspection in July 2015, nurses in the operating department were acting in the role of surgical first assistant (SFA) without the required qualification or competency assessments. Staff supporting the anaesthetist did not have a recognised qualification or competency assessment.
- During this inspection we saw improvements had been made to ensure staff were competent for the roles they undertook.
- The Perioperative Care Collaboration (PCC) states that the role of SFA must be undertaken by someone who has successfully achieved a programme of study that has been benchmarked against nationally recognised competencies underpinning the knowledge and skills required for the role. The role of SFA must be included in the person's job description and the employer should address the issue of indemnity cover.
- Two members of staff from the operating department were in the process of completing training to undertake the role of SFA. They were following a nationally recognised competency package, had weekly support from a mentor and clinical supervision from a consultant. Their job descriptions had been amended and staff were aware of their responsibility to have suitable indemnity insurance in place, however evidence for this was not available on the day we visited. This was also covered in the hospital policy ''Surgical First Assistant (SFA), July 2015''. This policy listed which duties staff could undertake as a SFA. Staff were therefore working in line with national guidance and hospital policy and would be able evidence they were competent to undertake the role once they had completed the training programme.
- The Surgical First Assist policy also included a checklist of documents which needed to be provided by staff working at, but not employed by the hospital, in the role

of SFA. We reviewed the file for one agency staff member. Not all of the required documents were in this file. The theatre manager told us that the agency were responsible for checking staff qualifications, there was no written evidence in the file. The hospital therefore did not have documentary evidence of relevant qualifications as stated in their policy and assurance that the agency staff member was competent for the role they would undertake.

- A statement on'' Assistance for the Anaesthetist (2010)'' from the Association of Anaesthetists of Great Britain and Ireland (AAGBI) states ''The Anaesthetic Assistant role should be undertaken by a registered practitioner who has achieved those competencies specified in the curriculum of the College of Operating Department Practitioners (CODP)''.
- We saw evidence to confirm that two out of three staff supporting the anaesthetist had a recognised qualification or competency package. We were told that a third member of staff had achieved their competencies at another provider; there was no evidence of this in their personnel file.
- All staff now had their own theatre standards pack and competency pack, which were seen and reviewed. Staff competencies were relevant to the role they undertook, such as theatre environment and patient safety, surgical phase and post-operative phase. Staff had performed an initial self-assessment, with review and sign off by a more senior member of the department. It was not clear how this member of staff had been deemed competent to undertake the role of assessor.

Are surgery services well-led?

By well led, we mean that the leadership, management and governance of the organisation assures the delivery of high quality person-centred care, supports learning and innovation, and promotes an open and fair culture.

At our inspection in July 2015, the quality of the service was not being effectively monitored through audit. Practices were being undertaken that were not reflective of the hospital policies and neither were they in line with current national guidance. The governance process was not fully effective so risks were not being adequately identified, assessed or managed. Minutes of meetings did not capture the decision-making process or demonstrate how decisions were reached. There was no formal analysis of the reported incidents to identify trends which could be used as an aid to learning and delivering a quality service. Health and safety risk assessments had been completed but there was no service-specific or hospital-wide risk register.

During this inspection,

We found there was evidence that some staff in the operating department were responsive to the changes which needed to be made, but further work was needed to address the 'custom and practice' culture of the operating department.

The clinical governance committee was not an environment where challenge took place. Policies and procedures referred to as 'standard operating procedures,' were being reviewed and developed, however policies which were described as 'in use' had not been formally ratified and adopted. Scrub practitioners were undertaking a dual role without a policy to support this practice which was not in line with national guidance. There was no established monitoring of practice against policy to ensure that a quality risk managed service was being provided.

Governance, risk management and quality measurement for this core service

- At our inspection in July 2015, procedures were taking place in the operating theatre that were not reflective of the hospital's policies and procedures. No audits had been undertaken to monitor practice against hospital policy. No external audit had been completed for the operating department and there had been no challenge to practices which were not reflective of current guidance.
- There was an established governance structure which defined who reported to the clinical governance committee. This included medicine management group; radiation protection advisor; infection control committee; safety health and environment group; pathology lead; blood transfusion lead; training and development lead; policy steering group and information and security lead
- We reviewed the minutes of the clinical governance meeting 21 July 2015. The minutes included a slot for each group, committee or individual to submit a report.

The minutes contained a list of bullet points and did not contain any evidence of discussion or debate to demonstrate how decisions were reached. This mirrored the findings of the comprehensive inspection.

- The hospital manager and Matron both told us that the role of the clinical governance committee was under review. It was now mandatory for heads of departments to attend this meeting. The plan was to develop the group to be a forum for open challenge and debate. This was not reflected in the minutes and had not yet become embedded.
- A report from the clinical governance meeting should then be submitted to the senior managers meeting. However, the senior managers meeting had taken place before the clinical governance meeting. The hospital manager had introduced a quality and risk month end report. On review this included most of the statistical information that was also discussed at the following clinical governance meeting.
- We were told by the hospital manager and Matron a review was being conducted of the hospitals audit plan. It was acknowledged that this had become routine without challenge or review of the focus of the audits. A new audit plan had not been agreed so was not available for us to review.
- An external body had visited and completed an audit of the operating department 14 and 15 July 2015. The audit had identified areas of concerns reflective of the findings of the commission comprehensive inspection conducted 7 and 8 July 2015.
- One of the key recommendations was the need for further review as soon as possible once surgery had recommenced, so practices could be observed in theatre to ensure adequate changes had occurred. Although operations had recommenced there had not been a further audit.
- The audit also highlighted the need for clinical audit after a period of six to nine months to provide the senior management team with a level of assurance. There were no clear plans for the re audit of the operating department.
- The external audit had included a brief review of the endoscopy service. A more in-depth review was due to take place in a month's time, initial recommendations included the development of more in depth procedures and review of current risk assessments which were in place.
- During this inspection we found that some change to practises in the operating theatre had occurred. Attempts were being made to ensure practises, designed to ensure patient safety were reflected in policies and local standard operating procedures and were then adhered to .
- An example was instrument counts taking place between two members of staff, verbally and in unison, in line with the Policy for peri-operative swab, sharp and instrument count, however, two instruments were missed from the initial count and there was noise from other staff during the final count, against the guidance in the policy.
- Audits, designed to monitor adherence to the policy had been developed but had not yet been completed, therefore no formal assessment of adherence with the policy had been undertaken.
- The policy for the surgical first assistant (SFA) had been reviewed; however the dual role aspect, where a member of staff undertakes two roles at the same time, such as scrub practitioner and SFA had been removed from the policy. This meant that staff were undertaking a role that was not supported by a hospital policy. This did not follow guidance from The Perioperative Care Collaborative Position (PCCP) Statement Surgical First Assistant (2012) which states that ''In the event that an employer considers that a dual role is required (for example, in minor surgery), then this decision should be endorsed by a policy that fully supports this practice and should also be based on a risk assessment of each situation in order to ensure patient safety.''
- There was no standard operating procedure to ensure the Five Steps to Safer Surgery and WHO surgical safety checklist were implemented fully and with involvement of all members of the team, both nursing and medical staff. Staff did not demonstrate that they recognised the value of these tools to monitor and maintain patient safety and to use them to identify improvements which could be made to their service.
- A review of policies and procedures, known as standard operating procedures, for the operating department was on going. A number of polices had been reviewed and standard operating procedures written; however these had not been submitted to the policy steering group for ratification and approval. In some case we were told that polices that had not been reviewed by the policy steering group were the ones in use, these policies were

not dated, for example the 'staffing policy'. We requested the terms of reference for the policy steering group to clarify the membership and the role of the group but none were available.

- A flow chart had been produced to demonstrate the path a review of a policy or standard operating procedure (SOP) should follow. This included a review against latest guidance; approval or more information required and to be resubmitted to the policy steering group; clinical governance ratification and submission to the relevant policy folder. The flow chart did not indicate what would trigger a review of a policy or a SOP. We asked the manager and Matron and they both confirmed that any themes emerging from accident and incidents or complaints could trigger the review of a policy.
- The hospital manager told us that the department leads would now be required to ensure that any guidance relevant to their practice was reviewed and monitored. Any required amendments were to be bought to the attention of the governance committee. Department leads were aware of the additional responsibility; however they were not clear about where this would be discussed.
- At the comprehensive inspection there were two books to record clinical and non clinical incidents respectively. There was no formal analysis of the reported incidents to identify trends which could be used as an aid to learning and delivering a quality service. While the hospital continued to use two books there was still no evidence of analysis of trends. To address this spread sheet was under development so that all accidents and incidents could be recorded in one place, which would in turn enable a review using key words, when looking for possible trends.
- The spread sheet used for tracking when equipment had been serviced had been amended and up dated to include all equipment in the hospital, including the operating department equipment. . This enabled the provider to monitor when equipment was last serviced and the due date for the next service.
- In July 2015 the medicines management audit was not effective as we found out-of-date medicine in the operating theatre that had expired in April and May. One medicines management audit had been completed since this inspection for the operating department. This was more effective as had identified a broken seal on the anaphylaxis kit which had been addressed.
- At the time of the comprehensive inspection there was no hospital risk register. To address this a hospital wide risk register was being developed. The aim was to ensure all department risk registers were stored together in one place, which could be accessed by everyone. A business risk registered would then be added. This was work in progress and the business risk registered had not been developed.
- At our inspection in July 2015, no audit data was collected by the hospital on patient comfort scores, or on individual consultant completion rates and polyp detection rates for Endoscopy procedures, to demonstrate continuous quality assurance for the service.
- During this inspection, the hospital manager told us that this information had previously been audited by the consultant, but the information was now held by the Endoscopy unit. The audits would be reviewed and the results discussed at the clinical governance meetings.

Leadership of service

- Senior staff were proud of how the team within the operating department had worked together and the changes they had implemented.
- A member of the medical team told us that regular communication had been received from the senior management team, after the initial CQC inspection, which was informative and clear on the changes which needed to be made, such as training for surgical first assistants (SFA).
- The role of the trustees was being reviewed as there had been a business and financial focus. The hospital manager was reviewing and amending the terms of reference for the board of trustees with the aim of expending their responsibilities for quality. The terms of reference had not been agreed and adopted and therefore the impact of the change was not known.

Culture within the service

- A number of staff in the operating department told us that the morale was improving, after the initial 'grief' and disappointment which they felt. The team had worked well together and a number of changes had been put in place immediately.
- Some, but not all staff, felt empowered and encouraged to make changes and improve the quality of the service offered to patients.

- Staff commented that they were now following procedures that they should have used before. Staff reported feeling more confident to speak out and challenge poor practice, however, this was not observed during the session in theatre, where the Five Steps to Safer Surgery were not completed in full or with a silent focus.
- The report from the AfPP highlighted the cultural issues within the department and that changes had to be made from what was considered 'custom and practice' to ensure safe care was provided to patients, in line with national guidance and hospital policies.

Staff engagement

- The minutes were seen from a recent operating department team meeting. These included the provisional outcomes from the initial inspection and aspects which needed to be addressed promptly.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

The provider must ensure:

- Staffing levels in the operating theatre is in line with current national guidance at all times.
- Staff in the operating theatre fully comply with the five steps of safer surgery.
- Instrument counts in the operating theatre fully comply with national guidance and hospital policy.
- There is a written policy to support staff undertaking dual roles in the operating theatre to ensure staff work safely and in line with national guidance.
- There is clear guidance and staff understand their responsibility under the 'Duty of Candour.'
- Working practices in the operating theatre reflect the hospital policy and procedures and are in line with current national guidance.
- The effectiveness of the clinical governance group is reviewed and there is robust monitoring of safety and quality of the service, that risks are identified, that timely actions are taken to manage risks and that decision-making is recorded clearly.
- There is an effective and comprehensive audit program and audit of practices in the operating department.
- The risk register reflects the current risks faced by the hospital.

Action the provider SHOULD take to improve

The provider should ensure:

- There are clear procedures and processes to follow if temperature and humidity readings are not within normal limits, once a patient is in the operating theatre.
- Staff fully understand the procedure to follow if there are concerns about an adult's welfare.
- Staff are deemed competent to sign off competencies for other staff within the operating department.
- Storage arrangements for the transfer board in the operating department are appropriate.
- Staff competencies are appropriately assessed, including the competencies of staff from other providers, to confirm they are competent for their roles.

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	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The operating department theatre was not consistently staffed in line with guidance from the Association for Perioperative Practice 2011 or the hospitals policy. Regulation 18 (1)

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • Patients were being placed at risk because instrument counts in the operating theatre did not fully comply with national guidance and hospital policy. • The scrub practitioner was undertaking a dual role without a policies in place to support this practice in line with national guidance. • Staff in the operating theatre did not fully comply with the five steps of safer surgery **Regulation 12 (1), 2 (b) (c)**

Regulated activity	Regulation
	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour • Staff did not understand their responsibilities under Duty of Candour and there was not a formal process for staff to follow.

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
	Regulation 17 HSCA (RA) Regulations 2014 Good governance **A warning notice was served under Regulation 17 1, 2. (a) (b) (f)** • Practices were taking place in the operating theatre which were not supported by policies and procedures. • There had been no follow-up service specific audit or review of the operating department since the hospital had recommenced operating. • Policies in the operating department were in use but they had not been through a ratification and approval process • There was no formal analysis of the reported incidents to identify trends which could be used as an aid to learning and delivering a quality service. • The minutes of the clinical governance meetings reviewed did not contain evidence of clear discussion on findings from audits, incidents or complaints.