This report describes our judgement of the quality of care at this trust. It is based on a combination of what we found when we inspected and information given to us from patients, the public and other organisations. The ratings below are from the last inspection; the trust was not re-rated during this inspection as it was a focused follow up inspection to assess progress against the warning notice.

Overall rating for this trust

<table>
<thead>
<tr>
<th>Service Area</th>
<th>Rating</th>
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</thead>
<tbody>
<tr>
<td>Are services at this trust safe?</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Are services at this trust effective?</td>
<td>Requires Improvement</td>
</tr>
<tr>
<td>Are services at this trust caring?</td>
<td>Good</td>
</tr>
<tr>
<td>Are services at this trust responsive?</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Are services at this trust well-led?</td>
<td>Inadequate</td>
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</tbody>
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Letter from the Chief Inspector of Hospitals

Following our last inspection in July 2017, we rated Royal Cornwall Hospitals NHS Trust as inadequate overall and the trust was placed in special measures on 5 October 2017. Surgery, maternity and gynaecology, end of life and outpatient services were rated as inadequate. Critical care and children and young people’s services were rated as good. These ratings were aggregated with the findings from the core services we inspected in January 2017.

We had serious concerns that systems to assess, monitor, and mitigate risks to patients receiving care and treatment were not operating effectively. We also had concerns that governance systems and processes were not operating effectively. We served the trust with a Warning Notice under Section 29A of the Health and Social Care Act 2008, on 29 August 2017. The notice required the trust to make significant improvements by 30 November 2017. We conducted a further follow-up inspection between 15 and 17 January 2018 and found the requirements of the warning notice had not been met. As a result, we issued a further Warning Notice under Section 29A of the Health and Social Care Act 2008 on 1
March 2018. The notice required the trust to make significant improvements by 13 April 2018. This unannounced follow-up inspection was conducted on 26 and 27 June 2018 and looked only at those areas detailed in the warning notice in safe, responsive and well-led. We did not look at caring or effectiveness. The above ratings were not reassessed as part of this inspection. The inspection focused solely on the issues identified in the warning notice where significant improvement was required, as set out under the relevant headings below:

**Surgery:**
- The systems and processes for ensuring patients were risk-assessed prior to surgery had not been embedded across the surgical division. The theatre scheduling policy had been produced and at the time of our last visit was in draft form awaiting approval.
- We were not assured there was a clear auditable trail of the risk assessment of patients prior to surgery. The request for an additional session form did not provide a trail of the decisions made or confirmation the theatre, staffing and equipment were appropriate.
- We were not assured safety briefings and debriefings were being completed, or that systems and processes for safety briefings were fully embedded across the theatre suites.
- Not all of the theatre team were in attendance at the safety briefings.
- The trust had a recovery plan for improving their referral to treatment time performance. Funding had been agreed to provide additional consultants for the rota. However, the trust performance against the 18-weeks referral to treatment time was still well below the national targets. Waits for patients had increased and were expected to continue to increase for the remainder of the financial year.

**Critical care:**
- Many patients were still being delayed for long periods of time when becoming medically fit for transfer.
- Half of discharges overnight from critical care were as a result of patient beds not being available on wards.
- Bed occupancy of the critical care unit remained high and had only slightly improved since our last inspection. Occupancy rates had reduced from 95% to 90%. However, they were still higher than the recommended levels as stated by the Royal College of Anaesthetists.

**Maternity:**
- Modified Early Obstetric Warning System (MEOWS) charts were not being completed accurately and escalation was not occurring in all cases as required.
- The MEOWS audit did not identify these issues and provided false assurance of compliance. The refreshed MEOWS chart did not include clear timescales for escalation that were capable of being monitored.
- The newly introduced monthly documentation audit highlighted poor compliance with record keeping in a number of key areas relating to patient safety. We were not assured prompt actions were being taken to address the poor compliance identified by the documentation audit as there was no evidence to suggest these patient safety issues were being given sufficient priority, or that actions were being followed through and monitored.
- There was no policy for managing women requiring level two high dependency care and the trust did not have any integrated care pathways or similar guidance for pre-emptively managing some typical conditions requiring or potentially requiring level two care.
- The systems and processes for assembling a second emergency theatre team in maternity were not sufficient and had not been tested. The newly developed standard operating procedure did not address the key concerns raised about potential delays in assembling a second team in an emergency. There was no process to clearly identify or allocate in advance a second response team at all times, and no process to ensure a timely response.
- There was not an effective process in place to ensure staff were not alone with a patient at any time in maternity theatre one. This, combined with the lack of an emergency call bell, posed a risk that staff could not summon emergency help.
- There was not sufficient assurance that controls were in place to audit the completion of the World Health Organisation Surgical Safety Checklist within maternity theatres. The safety briefing and debriefing were only recently introduced and had not yet been formally audited.
• There was not an effective process to ensure community midwives had the correct equipment at all times for use in emergencies, while waiting to transfer a patient to hospital.
• A comprehensive risk assessment of the training and wider needs of community midwives when managing emergencies in the community had not been undertaken.
• There was insufficient oversight of the reporting of delayed transfers of care from community midwifery. All transfers, apart from women in labour, had been excluded from the monitoring reports. This meant the reports did not show the full extent of transfers, or any potential problems, for example with delays in transferring post-natal women in an emergency.
• There was not an effective system to ensure all women booked for a home birth had home visits or risk assessments carried out, or documented, as required at 36 weeks of pregnancy.

Outpatients and diagnostic imaging (Fracture clinic):
• Environmental issues and infection prevention and control issues within the fracture clinic remained a risk to patient safety. There were still armchairs in use which were ripped, and wooden furnishings with deep chips. We also found no action had been taken to rectify issues with air flow and high temperatures.
• Children’s safeguarding concerns remained a risk. Although a children’s area had been made within a waiting room, it was not screened off or separated from adults. The trust told inspectors children were booked separately to adults, although we found processes around this were not being followed.

Governance – trust-wide:
• There were not effective systems and processes in place to ensure continual evaluation and improvement of services.
• There were not effective systems and processes to ensure equipment was of good repair, serviced, maintained, tested or calibrated across the whole organisation. Although systems and processes were being implemented, the trust was still not able to produce assurance reports on the status of equipment.
• Governance systems and processes for the management of incidents and never events were still not operating effectively and we were concerned about their sustainability.
• The trust was still failing to comply with the requirements for duty of candour.

During this inspection we found the trust had made significant improvements against the requirements in the warning notice and had fully met the requirements in surgery, maternity and outpatients. Please see summary of findings section below.

Some further work was required in critical care and trust-wide with governance. However, we found there were quality improvement plans in place, which were subject to external scrutiny on a monthly basis to address any deficits. The trust had also secured external support from subject matter experts and system partners. We were assured that where requirements had not been fully met, improvements had been made and comprehensive plans were in place to ensure ongoing and sustainable improvement. In addition, a full comprehensive inspection is planned to take place in September 2018 where these issues will be followed up to ensure further progress has been made.

Professor Edward Baker
Chief Inspector of Hospitals

Background to Royal Cornwall Hospitals NHS Trust

The Royal Cornwall Hospitals NHS Trust is the principal provider of acute care services in the county of Cornwall. The trust is not a Foundation Trust and performance is monitored by NHS Improvement (NHSI). The trust serves a population of around 532,273 people, a figure that can be doubled by holidaymakers during the busiest times of the year.
Please refer to the previous full inspection report from July 2017 for further background information, and detailed information about the services we inspected if required.

Our inspection team

Our inspection team was led by:

Julie Foster, Inspection Manager, and was overseen by Mary Cridge, Head of Hospital Inspections, Care Quality Commission.

The team included three CQC inspectors and an assistant inspector.

How we carried out this inspection

We conducted this unannounced follow-up inspection on 26 to 27 June 2018. We visited maternity, surgery theatres and wards, critical care, the fracture clinic and the medical physics and clinical technology directorates. We did not inspect all key questions across the areas we visited, but focused on those areas highlighted in the warning notice as requiring significant improvement. We looked at specific concerns under the safe, responsive and well-led questions only. The ratings were not reassessed as part of this inspection.

During our visit we spoke with approximately 20 staff, including medical staff, nursing staff, theatre staff, managers, and associate and clinical directors. We looked at ten patients’ records.

Summary of findings

This was a follow-up inspection to assess whether the trust had made sufficient progress in response to the Section 29A Warning Notice issued on 1 March 2018. We did not inspect all of the key questions, and only focused on those areas detailed in the warning notice. We found significant improvement had been made in all areas of concern and although the requirements had not been fully met, there were comprehensive plans in place and support secured for ongoing and sustainable improvement.

The ratings were not reviewed due to the limited focus of this inspection.

At this inspection we found:

Surgery:

- The requirements of the warning notice had been met and significant improvements had been made in relation to the safety of patients.
- A new theatre scheduling policy had been produced and approved and was in use across the trust. This supported how patients were risk-assessed prior to surgery, including last minute changes.
- The request for an additional session form, to risk assess patients prior to surgery, now provided an auditable trail of the decisions made. This included the confirmation that the theatre, staffing and equipment were appropriate. This form included requests for suitable theatres, suitable theatre teams, suitable anaesthetists, and the correct equipment.
- There was now an automated safety brief and debrief, which had replaced the previous paper-based system. We saw evidence that briefings and debriefings were being completed with the full theatre team in attendance, and the new systems were being rolled out across theatres following a successful trial.
- The trust had a recovery plan for improving referral to treatment time performance, which had been developed in conjunction and agreement with commissioners. There was an agreed trajectory that was being worked towards to reduce the waiting times by April 2019. We found the improvements being implemented had resulted in this trajectory being achieved and were in fact being slightly exceeded.
Critical care:
- An increased emphasis on the prioritisation of discharges had resulted in an improving position. Out of hours and delayed discharges in the main continued to be as a result of factors outside the control of critical care, for example the lack of on-site beds and side rooms and other hospital repatriation.

  However:
  - Although bed occupancy was improving and plans were in place to improve it further, it remained higher than the recommended levels as stated by the Royal College of Anaesthetists.

Maternity:
- Significant improvements had been made in relation to Modified Early Obstetric Warning System (MEOWS) charts and processes to manage deteriorating women.
- We found prompt action was being taken to address concerns arising from poor documentation audit results and these were being monitored for effectiveness.
- A policy had been developed and implemented for managing women requiring high dependency care.
- The standard operating procedure for assembling a second theatre team in an emergency had been improved.
- An emergency call bell had been installed in theatre one.
- World Health Organisation (WHO) Surgical Safety Checklists were being completed and formally audited within maternity theatres.
- Systems and processes were in place to ensure community midwives had access to the correct equipment for managing emergencies, a comprehensive risk assessment in relation to community midwives’ training needs had been carried out, and training plans were being delivered.
- Delayed transfer of care audits were improved and provided the necessary information for full oversight of the cause of any delays.
- We found evidence that all women booked for home births had a risk assessment completed at 36 weeks gestation.

Fracture clinic:
- Environmental issues and infection prevention and control issues within the fracture clinic had been resolved. All chairs had been replaced and wooden furnishings with deep chips had been replaced with plastic cladding.
- We found action had been taken to rectify issues with air flow and high temperatures.
- Children’s safeguarding concerns had been resolved. An area had been designated as the children’s waiting area. Processes to book separate appointments for children were being followed.

Governance – trust-wide:
- The trust had commissioned an external review of governance, including the systems and processes for continual evaluation and improvement of services. These were being implemented at the time of our inspection.
- Considerable progress had been achieved in ensuring oversight of medical devices. Processes were embedded and governance structures were effective. The system was fully implemented and accurate, and the trust had the capability to produce automated reports regarding servicing and maintenance of equipment. The trust could monitor its performance against key performance indicators.
- There was an improvement in systems and processes for identifying, reviewing and grading of harm and impact from incidents. Further progress was expected as additional staff had been recruited to support the governance lead.
- There was ongoing performance management of duty of candour. While the trust was still failing to meet the 100% compliance requirement for duty of candour, a full-time post had been created to oversee the duty of candour process, and improvements had been made to the supporting systems and processes.
Are services at this trust safe?

Not re-rated

We inspected safe in surgery, maternity and outpatients. We found the requirements of the warning notice had been met in all areas.

Surgery:

At our last inspection we were concerned about the safety of patients for the reasons stated in the chief inspector’s letter above.

Further improvements had been made in relation to patient safety and the requirements of the warning notice had been met. We found:

- Significant improvements had been made in relation to the safety of patients.
- A new theatre scheduling policy had been produced and approved and was in use across the trust. This supported how patients were risk-assessed prior to surgery, including last minute changes.
- The request for an additional session form, to risk assess patients prior to surgery, now provided an audit trail of the decisions made. This included the confirmation that the theatre, staffing and equipment were appropriate. This form included requests for suitable theatres, suitable theatre teams, suitable anaesthetists, and the correct equipment.
- There was now an automated safety brief and debrief, which had replaced the previous paper-based system. We saw evidence that briefings and debriefings were being completed with the full theatre team in attendance, and the new systems were being rolled out across theatres following a successful trial.
- The trust had a recovery plan for referral to treatment time performance improvement, which had been developed in conjunction and agreement with commissioners. There was an agreed trajectory that was being worked towards to reduce the waiting times by April 2019. We found the improvements being implemented had resulted in this trajectory being achieved and were in fact being slightly exceeded.

Detailed findings

- We saw evidence from audits, and heard from staff, that the completion of safety briefings and debriefings were being completed. We saw evidence that safety briefings were fully attended by the theatre teams. There was now an automated safety brief and debrief, which had replaced the previous paper-based system.
- The new system allowed theatre teams to score each theatre list or session from one to five, and then add comments to justify those scores. For example, anything that needed to improve, and the staff experience of the day. We saw an example where a lower score had been recorded due to the lack of some theatre packs. The information was collated and shared the following day as part of the safety briefing.
- The system was being introduced in a staged process across the different theatres to ensure any issues could be addressed and dealt with. At the time of the inspection the system was in use in West Cornwall and another set of theatres were in the middle of a two-week trial. The managers explained how they were working to ensure the systems were sustainable before rolling it out across all the remaining theatres. This was an improvement since our last inspection although still being implemented.
- There were two scrub staff and two theatre assistants tasked with collecting patients. Nursing staff and theatre managers explained how they did not send for patients until the safety briefing had been completed. This could add extra time but ensured all staff were present for the briefing.
- The World Health Organisation (WHO) Surgical Safety Checklist and NHS Five Steps to Safer Surgery sign in, time out and sign out were being completed in full. These were now being done electronically, which improved the efficiency and ease of the auditing process. The automated system recorded whether the check had been completed. Any identified issues could be followed up by the theatre managers. For example, cardioversion was done in the anaesthetic room, not completed in the theatre, and therefore was not on the system. It was then added to the electronic system, which is why it appeared the WHO checklist had not been completed. A daily
report was produced by the electronic system every morning, which identified any possible WHO checklist fails. These were then investigated by the theatre managers. We saw the latest compliance figure was recorded on the system as between 98 and 99%. The new system was less time consuming and provided greater assurance.

- We saw the new theatre scheduling policy, which had been produced but not approved at the time of our previous inspection, had now been approved and was in use across the trust. This supported how patients were risk-assessed prior to surgery, including last minute changes.
- We saw the request for an additional session form, to risk assess patients prior to surgery, now provided an auditable trail of the decisions made. This included the confirmation that the theatre, staffing and equipment were appropriate. This form included requests for suitable theatres, suitable theatre teams, suitable anaesthetists, and the correct equipment. Any additional sessions needed to be signed off or declined by a divisional manager, who made the final decision. We saw an example of a completed form, where a request for an additional list was declined because there was no suitable theatre team.
- We saw improvements had been made to the clinical risk assessing and prioritising of patients who were experiencing extended waits. Improvements had been made to the risk assessment process for patients waiting for surgery. Surgery lists were now locked and unable to be changed seven days prior to the surgery session. The locked lists were given to the theatre managers to ensure the right staff and equipment were in place. Only theatre managers had the authority to unlock the lists and make changes. The operating surgeon would also confirm the list was satisfactory.
- All the information was monitored and recorded through the electronic recording system. Reports were produced for directorate managers showing which operating lists were confirmed. At the time of the inspection, compliance with the new process was recorded and audited overall at 74%. However, within this were some low scores for trauma and orthopaedics at 37% and ophthalmology at 54%. The division had a target of 100% compliance by the end of June 2018.
- We spoke with theatre managers who were positive about the new system. They felt the theatre staff had ownership of the risk assessing process, which helped prevent harm.
- The trust had provided details of a recovery plan for improving referral to treatment time performance. This had been developed in conjunction and agreement with commissioners. There was an agreed trajectory that was being worked towards to reduce the waiting times by April 2019. We found the improvements being implemented had resulted in this trajectory being achieved and were in fact being slightly exceeded.

Maternity

At our last inspection we were concerned about the safety of patients for the reasons stated in the chief inspector’s letter above.

Further improvements had been made in relation to patient safety and the requirements of the warning notice had been met. We found:

- Significant improvements had been made in relation to Modified Early Obstetric Warning System (MEOWS) charts and processes to manage deteriorating women.
- We found prompt action was being taken to address concerns arising from poor documentation audit results and these were being monitored for effectiveness.
- A guideline had been developed and implemented for managing women requiring high dependency care.
- The standard operating procedure for assembling a second theatre team in an emergency had been improved.
- An emergency call bell had been installed in theatre one.
- World Health Organisation (WHO) Surgical Safety Checklists were being completed and formally audited within maternity theatres.
- Systems and processes were in place to ensure community midwives had access to the correct equipment for managing emergencies, a comprehensive risk assessment in relation to community midwives’ training needs had been carried out and training plans were being delivered.
- Delayed transfer of care audits were improved and provided the necessary information for full oversight of the cause of any delays.
• We found evidence all women booked for home births had a risk assessment completed at 36 weeks gestation.

Detailed findings

• Significant improvements had been made in relation to Modified Early Obstetric Warning System (MEOWS) charts and processes to manage deteriorating women; the **MEOWS in Detecting The Seriously Ill and Deteriorating Woman** guideline had been reviewed, updated and ratified through the appropriate committees in line with trust policy. Senior midwives confirmed they had been consulted on the changes to the guidelines and all maternity staff had the opportunity to comment. An external peer review had been commissioned to review the new guidance and processes. The new charts reflected the guidance, and included timescales for escalation. The escalation time for those patients scoring seven or above was being reviewed in light of feedback given to the trust.

• The maternity team had developed a sticker for use when a MEOWS score needed escalating and the use of this was being monitored and audited. In the notes we reviewed, we saw this sticker was being used when and as required.

• At our last inspection, we found the MEOWS audit was not capturing all required elements, for example if a MEOWS chart was present in the notes it was deemed compliant for audit purposes, even if it had not been fully completed. At this inspection, we found the audit form had been amended to capture all required elements and this meant improvement from these audits was measurable and meaningful. We saw that where staff had raised concerns about the audit template, it had been reviewed again, and missing items added, or wording clarified. This template had been amended six times since our last inspection, which reflected a commitment to getting it right.

• We found evidence the new MEOWS charts and escalation process had been implemented in the clinical areas. We saw a daily snapshot audit was being conducted across the clinical areas, the findings from this were being reviewed weekly, and feedback was being given to the teams. There was evidence that compliance with the use and escalation of MEOWS was steadily increasing, and much improved across all areas. For April 2018, the MEOWS audit had been 100% compliant for Wheat Rose (antenatal ward), Wheat Fortune (postnatal ward) and delivery suite. We were assured prompt action was being taken when compliance slipped and we were able to track this through in terms of what action had been taken.

• Action had also been taken in response to concerns that there was insufficient equipment to undertake the oxygen saturation monitoring required for calculating a full MEOWS score, and we found equipment had been purchased and was available in the clinical areas.

• At our last inspection we found the monthly documentation audit had highlighted non-compliance in a number of key patient safety areas, and we were not assured that prompt or sufficient action was being taken to address these. Since then, the audit template had been reviewed, and a number of issues identified with data collection that were providing incorrect results had been rectified. For example, where an assessment was being recorded electronically and not in the patient record, the audit form was being marked as non-compliant, even if it had not been fully completed. At this inspection, we found the audit form had been amended to capture all required elements and this meant improvement from these audits was measurable and meaningful. We saw that where staff had raised concerns about the audit template, it had been reviewed again, and missing items added, or wording clarified. This template had been amended six times since our last inspection, which reflected a commitment to getting it right.

• The results were still falling short of the trust's 90% compliance target in a number of areas, for example postnatal record keeping at 69% and intrapartum record keeping at 85%, but evidence from the reviews demonstrated these were being acted upon and were steadily improving month on month. For example, we saw an analysis of the monthly audits was being completed and a dashboard had been created to show the results monthly. This enabled trends and actions to be identified. We found evidence the results of the audit, and any non-compliance, were being cascaded appropriately as per the action plan, either face to face, at safety huddles, team meetings or via email. We saw posters were being created and displayed in response to concerns, to remind staff of priority areas.

• In addition, documentation audit results and the dashboard had been added as standing agenda items at the newly formed Maternity Governance Meeting, which was being held monthly.

• At our last inspection we identified the maternity service did not have a guideline for managing women requiring high dependency care, and there were no supporting integrated care pathways or similar for staff guidance. During this inspection we found there was a policy in place; **Severely Ill Obstetric woman, High Dependency (HDU) care - Early Recognition and Management** (2018), which had been ratified by the appropriate committees in line with trust policy. This guideline
aligned with other local guidance, including management of deteriorating patients and MEOWS scoring.

- There was still further work to do in reviewing potential gaps with integrated care pathways or similar specific condition guidance. We were advised this work had commenced with external support and was being picked up as part of the overall maternity improvement plan. We were assured the minimum safety guidance and policies required were in place. A further five guidelines relating to severely ill women had been reviewed, updated and ratified in March 2018. Each case where high dependency care was required would be managed by the multidisciplinary team and clear and specific instructions given and documented on a case by case basis, with input from external specialities as necessary.

- At our last inspection we were concerned systems and processes for assembling a second emergency theatre team were not sufficient and had not been tested. There was a standard operating procedure (SOP) in place, but this did not set out how a second team would be allocated in advance or how the service could ensure a timely response in the event of an emergency. The SOP had been updated and included much clearer guidance on assembling a second team. There was still no process for allocating a second team in advance, and the process for alerting the second team out of hours was manual and reliant on making a number of phone calls, and waiting for a response. However, the service had made some changes in that the management of maternity theatres was being taken over by the central theatres. The initial phase of the transition was completed at the end of May 2018, which involved all theatre staff being brought under the management of central theatres. There was a plan in progress to bring the operational practices in line, which meant teams would be allocated in advance and available at all times in an emergency. This was due for completion by the end of July 2018.

- Meanwhile, we saw evidence that a simulation emergency drill had taken place to test the existing process for opening a second theatre and assembling a second team, and the learning from this was discussed and disseminated to staff. The service had also developed an audit form for completion each time the second theatre had been used for an emergency, which documented and reviewed the time staff were called, and the time they arrived. This had been done for each case where the second theatre had been used since our last inspection. No delays had been identified for these cases and it was being kept under review.

- At our last inspection we found there was no emergency call bell in theatre one, and no process to ensure staff were never alone with a patient in theatre one at any time. During this inspection, we found an emergency call bell had been installed and we tested this was in working order. There was a process in place to ensure staff would not be left alone in theatre at any time. Any staff checked in for a theatre case who then had to leave for any reason would state this clearly to inform the theatre team at all times.

- At our last inspection we were not satisfied the World Health Organisation (WHO) Surgical Safety Checklists were being completed or formally audited within maternity theatres. During this inspection, we found they were being completed and monitored monthly at the Women, Children & Sexual Health Divisional Board meetings. We saw the compliance rates had been steadily increasing and had risen from 69% in December 2017 to 91% in February 2018 and 100% in May 2018. Where non-compliance had been identified, we could see actions had been taken to address the issues.

- Community midwives working rurally did not have the correct equipment to manage emergencies while waiting for an ambulance to arrive at our last inspection. This time we found the Community Midwifery Equipment guideline had been implemented and contained a detailed list of equipment and medicines that may be required, along with individual responsibilities for ensuring this equipment was in date and replaced at specified times. This included items that may be required at home births, birthing units and during ambulance transfer.

- We found 75 equipment bags had been issued to community midwives, and photographic guidance had been disseminated on how to stock these bags. This meant all staff would be able to locate what they needed in an emergency. A checklist had been developed to ensure community midwives were checking their equipment and medicines expiry monthly, and the team leaders were responsible for collating this evidence and submitting it to the community matron for assurance. This was also being monitored through the Women, Children & Sexual Health Divisional Board meetings until all teams were fully compliant and the new systems were embedded in practice. Emergency grab bags had also been provided for all birthing units and these were being checked weekly.
We were concerned at our last inspection that a comprehensive risk assessment of the training needs of community staff, when managing an emergency, had not been completed. This time, we found a risk assessment had been completed and recorded on the risk register. An additional five training requirements had been recorded for community midwives, and we saw these deficits were being addressed through detailed training plans. The improvement plan for maternity stated 95% staff were to be competent by the end of March 2019. For example, all community midwives were on target to have completed cannulation training by the end of July 2018. We also found guidance for community staff managing emergencies had been strengthened, and additional community specific training had been added to the annual training days.

At our last inspection we found there was insufficient oversight of the reporting of delayed transfers of care from the community. During this inspection, we found this had improved. The maternity service had amended its data collection tool to include all transfers into the hospital from the community, which meant a much more accurate picture was available. The ‘transfer in’ rates were below the national averages. The audit report from April 2018 on transfer of care showed that where delays in transfer had occurred, they were outside of the control of the maternity service. Concerns had been communicated to the third party involved and information had been requested to explain the cause of the delay. We were assured the maternity service had taken significant steps in relation to equipment and training for community midwives to mitigate, as far as possible, any delays in providing emergency treatment in the community.

Systems and processes to ensure all women booked for a home birth had a risk assessment at 36 weeks gestation had been improved to ensure the data was being captured, and this was being monitored. We found evidence to show all women had received an appropriate risk assessment.

Fracture clinic:

At our last inspection we were concerned about the safety of patients for the reasons stated in the chief inspector’s letter above.

Further improvements had been made in relation to patient safety and the requirements of the warning notice had been met. We found:

- Environmental issues and infection prevention and control issues within the fracture clinic had been resolved. All chairs had been replaced and wooden furnishings with deep chips had been replaced with plastic cladding. We found action had been taken to rectify issues with air flow and high temperatures.
- Children’s safeguarding concerns had also been resolved. An area had been designated as the children’s waiting area. Processes to book separate appointments for children were being followed effectively.

Detailed findings:

- During this inspection we found new seating in place and the air flow system had been modified.
- All old chairs had been replaced with new, more comfortable chairs, which were covered in wipeable material to meet infection control standards.
- The ventilation system had been modified to improve the volume and temperature of fresh air supplied to the area. The works included the replacement of the original fan within the air handling unit and a larger, more efficient inverter controlled fan. This took the air volume up to the maximum capacity of the ductwork within the department. A cooling coil was also installed within the air handling unit to allow the air being supplied to the department to be cooled. The system was balanced in terms of distribution and enabled the management of temperatures. Alarms were set to flag with the estates department if the air temperature reached 25 degrees Celsius. This was in line with the upper summertime limit given in the Heating and Ventilation Health Technical Memorandum (HTM03-01) Specialised ventilation for healthcare premises, therefore allowing time to enact the actions contained within the ventilation standard operating procedure.
- Temperatures were monitored weekly by the estates department, provided to the directorate manager and outpatient sister and included as part of the dashboard data. We saw the temperature had not exceeded 23 degrees Celsius.
• One patient said it was “much cooler” than a previous visit to the clinic. We noticed the temperature was very comfortable during our visit on a very warm and sunny day.

• As a result of an infection prevention and control review undertaken on 4 April 2018, further improvements were carried out. These included:
  o The ‘trim’ of the desk at reception had been replaced with plastic cladding.
  o Screw holes evident in the flooring in the waiting area had been filled.
  o The X-ray room, although not originally included, had been redecorated.
  o The water fountain in the adult area had been repaired by the supplier and was in use during our inspection.
  o The blockage in the sink and waste hopper in the domestic cupboard had been resolved.
  o Exposed screw heads on the bookcase in the new children's waiting area had been capped.

• Since our last inspection we found significant improvement to the environment of the fracture clinic and the risks to patient safety had been resolved.

• Improvement works had been completed during March and April. In addition to the new seating, a number of leg stools of various heights were available for those patients who needed to keep their leg elevated and free from harm of being knocked.

• A number of minor repairs had been carried out, along with the replacement of the first section of flooring when entering from the main corridor. Carpets had also been replaced with vinyl in the sister’s office.

• The vast majority of the area had been repainted in white to give a brighter and cooler feel.

• The walls in the vicinity of the bin store at the entrance from the main corridor had been clad with plastic to protect them from further damage.

• It was proposed that, in the medium term (next 2 to 3 years), a new location should be identified for the fracture clinic away from the hospital site. This would be linked with the service re-design work progressing under the models of care within the wider health network.

• During our last inspection we found risks to safeguard children remained as a result of the lack of a separate waiting area for children and the lack of adherence to the processes in place for children only appointments. During this inspection we found these risks had been resolved.

• The area for children to wait had been moved next to the reception and was partially partitioned off with a viewing pane through to reception. The location was chosen after reviewing the guidance of Health Building Note (HBN23) Hospital Accommodation for Children and Young People.

• There was clear signage to make it clear this was a children only waiting area, with accompanying adults.

• There were new seats made of wipeable material, a toy box, books, a small table and chairs and wall art. There was a children and young people’s friends and family questionnaire in which they were asked to rate how much they agreed with the question “I would say this is a good service for my friends and family to be looked after in if they needed similar treatment or care to me.” Options ranged from “I agree a lot” to “I disagree a lot”. Children were also asked to draw a picture of their visit, what was good about their visit, and what could be better. Previous comments were displayed on a notice board.

• Procedures were in place for the management of appointments for paediatric patients (under 16 years old) attending the fracture clinic. This ensured children were treated separately from adult patients in line with safeguarding guidance.

• Paediatric patients requiring new and follow-up appointments were offered appointments in the appointment slots between 8.50am and 9.40am inclusive to manage them separately from adult patients. The only exceptions to this were for patient choice or clinical reasons.

• A standard operating procedure (SOP) had been revised and re-launched on 26 March 2018. It set out the booking procedure for children only slots at the start of clinic and clarified the responsibilities of staff. The SOP had been further re-issued on 6 April 2018 to revise the age to under 16 (previously it had been 16 and under).

• Administrative and clinical staff had been briefed on the SOP. This had been cascaded by e-mail to all staff, in person to reception staff, and through safety briefings to fracture clinic nursing staff. All staff we spoke with were aware of the requirements.

• A dashboard had been developed to monitor compliance with the SOP, both retrospectively and prospectively. Daily reports and weekly audits were completed to demonstrate compliance and effectiveness.
A target had been set for 95% of paediatric patients to be seen in a defined appointment slot. Data showed compliance was at 86.5% for March 2018. Following the revision to the SOP there had been an improvement with data from April to June 2018 showing an average of 94.8% compliance. Data for early April ranged from 66.7% to 88.9%, and had improved to 100% compliance in May and June.

There was a target for no adult patients to be seen in defined paediatric appointment slots. In March 2018 there were 128 adults booked into the paediatric appointment slots. In order to address this, a review of future appointments had been introduced to ensure any adult appointments which had been booked in error in the defined time period could be rescheduled. The review also confirmed paediatric patients booked outside the defined time period had been offered an appointment in the defined time period. This was documented. Any staff who continued to book appointments in error would be identified and appropriate action taken to ensure compliance. There was an expectation that all adult appointments booked in the defined time period would be eliminated from 9 April 2018. Data for early April showed nine adult patients in defined slots. Since then, on all but one occasion, 100% compliance had been achieved.

Compliance was also monitored of offers of appointments to paediatric patients within defined appointment slots. Against a target of 100%, performance in early April 2018 ranged from 56.3% to 83.3%, with 100% compliance achieved from 5 April 2018.

Exceptions in the reports were identified, escalated accordingly and reviewed. Compliance was monitored at divisional governance meetings as a standing agenda item and actions were monitored.

A small number of adults might be referred to the department from other services during the time period reserved for children, or might arrive early for their appointment. These patients would be asked to wait in the adult waiting area furthest from the children’s waiting area.

Are services at this trust responsive?

Not re-rated

We inspected responsive in critical care. We found significant improvements had been made, although further work was required to further reduce the bed occupancy levels.

At our last inspection we were concerned about responsiveness in critical care for the reasons stated in the chief inspector’s letter above.

During this inspection we found:

- An increased emphasis on the prioritisation of discharges had resulted in an improving position. Out of hours discharge delays in the main continued to be as a result of factors outside the control of critical care, for example lack of on-site beds and side rooms and other hospital repatriation.

However:

- Although bed occupancy was improving and plans were in place to improve further, it remained higher than the recommended levels as stated by the Royal College of Anaesthetists.

Detailed findings:

- There had been a continued emphasis on reducing bed occupancy levels. The senior nurse on duty, in discussion with the duty consultant, was the final decision-maker of the unit’s capacity at any given time.

- The critical care unit was funded and staffed for an average of six level three beds and nine level two beds. All bed spaces were able to accept patients at any level of care, allowing flexible admissions. There were times when there were more than six level three patients, but the additional nursing workload of level three patients would reduce the capacity for level two patients. This meant the total capacity would depend on a combination of the number of nurses and the level of the patients. Acuity of patients was unusually high on the day we inspected the unit, with nine level three patients and four level two patients. As a result of the high level of acuity, it was not possible to discharge patients to the wards.

- The decision to admit a patient to critical care electively following planned surgery was made by the consultant surgeon at the time of booking and/or by the consultant anaesthetist at the pre-
assessments. Appropriate patients would, in general, be those identified as high risk using an objective scoring system. Consultants were encouraged to liaise with the critical care consultant in all cases of uncertainty, or where the referral did not meet objective criteria.

- All elective bookings were made electronically, using the booking diary, up to a maximum of two per day. This allowed the booker to see other elective bookings and ensure they were evenly spaced throughout the day and week. The electronic booking system enabled a six-week forward review, which avoided overbooking and enabled the unit to pre-plan staffing requirements in advance.
- The designated clinical director for surgery would have the final decision regarding clinical priority in liaison with the critical care consultant. Where a critical care bed was mandatory to the success of the procedure, the procedure would not be started before the availability of the bed was confirmed.
- Referrals for emergency admission or assessment would be consultant to consultant. In the first instance, advice might be sought from the critical care outreach team, or from the senior anaesthetic trainee on duty. The decision to admit to critical care would be made on an individual patient basis. Every effort was made to ensure an "emergency bed" (an empty bed that was already staffed and prepared) was available at all times.
- Performance on occupancy showed a month on month reduction since January 2018. In January the total occupancy was 113%, in February it was 97% and for March it was 88%. However, this was still higher than the recommended levels of 70% as stated by the Royal College of Anaesthetists.
- Since the introduction of a revised standard operating procedure (SOP) in March 2018 there had been an increase in the prioritisation of critical care discharges.
- The critical care nurse in charge and the duty consultant identified all patients who were stable for transfer to a ward or recovery. A flowchart detailed the processes for discharge and those responsible for completing them, including the completion of a discharge planning aide memoire, discharge summary and handover.
- The aide memoire was fully embedded across the unit to focus staff on the preparation of a patient for discharge. This included documentation such as risk assessments; discharge summaries being up-to-date and drug prescription. Patient preparation included the removal of the arterial line, consideration of the need for a pressure-relieving mattress, moving onto a ward bed as soon as possible, and removal of monitoring. Other considerations included informing relatives, enough oxygen for the transfer, informing the equipment library if a patient transferred with a vacuum pump, and the patient diary outcome.
- There was a flowchart detailing processes and the person responsible for escalation of bed requirements to the clinical site manager, head of patient flow and the chief operating officer. Escalation measures were reported on the electronic incident reporting system.
- Gold control (command centre to oversee flow across the hospital) actions had supported the critical care team to deliver appropriate and timely discharge. Critical care information was provided at the site bed meeting and critical care staff would routinely attend bed meetings (subject to patient dependency, acuity and staffing on the unit).
- Following a review of 12 months’ admission and discharge data it had been agreed a minimum of three critical care discharges per day were prioritised over emergency department 12-hour or decision to admit breaches. There was also an aim to discharge patients as early in the day as possible and ideally before 1pm, which would give medical and nursing teams the time to implement care plans and review investigations. Staff confirmed they were constantly mindful to achieve this where possible.
- Data demonstrated a reduction in delayed discharges following the implementation of the SOP. There was a consistent improvement in discharges delayed by more than 24 hours. Performance data on transfers in and out of critical care was collected on a dashboard. A themed analysis of discharge from the unit was undertaken every week. A root cause analysis of all delays over 24 hours was reported routinely to the unit’s business meeting, divisional performance meeting and board meeting. This was further analysed by the matron to identify key themes around compliance.
- Critical care key performance indicators (KPIs) were included for review via the quality improvement delivery board. Evidence of reductions in delayed transfers of care of more than 24 hours was shown in the dashboard comparison between 2016, 2017 and 2018. In 2016 the average was 18, in 2017 it was 21 and data for January to March 2018 showed an average of 13.
Many of these delayed discharges continued to be caused by wider hospital flow rather than the responsiveness of critical care.

The revised SOP included a section about avoiding out of hours discharges. This reminded staff it was poor practice to discharge patients at night and any discharges after 10pm should be delayed until the next day. Furthermore, staff were reminded adequate handover to medical and nursing staff was not possible at night and staffing levels overnight were not appropriate for initial assessment and orientation to the high patient needs of this group. The guidance also explained overnight discharges represented very poor patient experience and could compound the disorientation and distress experienced by patients who might have undergone prolonged sedation and invasive procedures. It was also recommended that sufficient critical care discharges took precedence over other admissions to medical and surgical beds to ensure ‘forced’ overnight discharges did not happen. If a patient had to be discharged at night to accommodate an emergency admission, the decision to do so was made by the on-call consultant. It was reported as an incident on the electronic incident reporting system.

All staff in critical care were informed via twice daily safety briefings and email to escalate to the site team if discharges were not confirmed by 8pm. A reminder message for staff was displayed at 8.15pm on the unit’s computers.

Since the implementation of the revised SOP on 19 March 2018 there had been a reduction in overnight discharges. Performance data on transfers out of critical care was collected on a dashboard and analysed as mentioned above.

A review of performance was carried out for two weeks from the implementation of the SOP. During this period there were no overnight discharges and there was an improved trajectory going forward. However, during the month of May there had been an unexpected spate of five overnight discharges. These were stroke patients and the reason for the delay was cited as the lack of stroke nurses on the stroke ward.

The team recognised there was further work to do to avoid overnight discharges. There were plans to implement a ‘safer bundle’ shortly after our inspection. This is a practical tool to reduce delays and incorporates a 5pm senior review to identify and request potential beds for the following day.

The focus for the team going forward was to continue to monitor the delayed admission data, with the long term aim to continue to reduce the number of delayed admissions and optimise flow through the unit. Following the elimination of 24-hour delays the team aimed to work towards minimising four hour delays and to monitor readmission rate and post discharge reviews.

The team said they were pleased the profile of the unit had been raised across the trust and recognised their thought processes and those of the site team had changed. They were, however, disappointed a business case to increase capacity from 15 to 17 beds in line with national standards had not been approved.

Are services at this trust well-led?

Not rated

We inspected well-led at trust-wide level in relation to the specific concerns we highlighted in the warning notice as detailed in the chief inspector’s letter at the start of this report. During this inspection we found the trust had made significant improvements against the requirements in the warning notice and had quality improvement plans in place, which were subject to external scrutiny on a monthly basis to address any deficits. The trust had also secured external support from subject matter experts and system partners. We were assured that where requirements had not been fully met, significant improvements had been made and comprehensive plans were in place to ensure ongoing and sustainable improvement. In addition, a full comprehensive inspection is planned to take place in September 2018 where these issues will be followed up to ensure further progress has been made.

During this inspection we found:

- The trust had commissioned an external review of governance, including the systems and processes for continual evaluation and improvement of services. These were being implemented at the time of our inspection.
- There was an improvement in systems and processes for identifying, reviewing and grading of harm and impact from incidents. Further progress was expected as additional staff had been recruited to support the governance lead.
• There was ongoing performance management of duty of candour. While the trust was still failing to meet the 100% compliance requirement for duty of candour, a full time post had been created to oversee the duty of candour process, and improvements had been made to the supporting systems and processes.
• Considerable progress had been achieved in ensuring oversight of medical devices. Processes were embedded and governance structures were effective. The system was fully implemented and accurate, and the trust had the capability to produce automated reports regarding servicing and maintenance of equipment. The trust could monitor its performance against key performance indicators.

**Detailed findings**

• A new base level had been set for all of the clinical governance key performance indicators (KPIs) and was subject to a data quality assurance process. The trust was confident in the accuracy of the data and was using the revised governance KPI dashboard to improve compliance through the monthly divisional performance meetings. Progress was monitored by the re-established quality governance committee (QGC) reporting into the board quality assurance committee.
• The QGC reviewed, scrutinised and challenged the effectiveness of the trust’s annual clinical programmes. It oversaw the development of policy and procedure and acted as the main interface between divisions and the board on all matters relating to quality, including clinical effectiveness, patient safety and patient experience. The QGC met monthly for two hours. We saw the terms of reference of the QGC where the key activities were listed.
• The Executive Serious Incident Review Panel (ESIRP) was established prior to the re-development of the QGC, and in the revised structure the ESIPR reported into the QGC. The panel met fortnightly and provided operational oversight of the effectiveness of the trust’s processes for management and assurance of patient safety incidents in line with national guidelines. This included reporting, investigating, learning and acting on such incidents or events.
• At our previous inspection we found there were shortfalls in identifying, reviewing and grading of harm and impact from incidents. There were also some incidents which were not assigned the correct categorisation. In some cases, incidents were not reviewed or investigated in a timely manner, with limited effective senior-level oversight of incidents. At this inspection visit we found improvements had been made, with further progress expected as additional staff had been recruited to support the governance lead.
• There was daily executive or divisional performance management of all incidents, 24 and 72 hour reports and 60 day reports. There had been retrospective performance management of incidents from February to April 2018. Core areas of performance were improving towards achievement of trajectories in June and July 2018. Incidents had been prioritised by themes or risk for learning and escalation.
• Data showed an 80% reduction in overdue incidents in four weeks. There had been a 33% increase in the timely delivery of 24-hour reports. The delay for 24-hour reporting had reduced from an average of 20 days to four days. The time taken to appoint an investigating officer had reduced from an average of 33 to two days. The trust had increased their list of investigating officers to over 100.
• We saw evidence learning was shared, with safety notices being produced and displayed or distributed across the trust. For example, an issue with venous thromboembolism (VTE) at one surgical location led to a presentation which was fed back to governance specialty meetings.
• Divisional support had also increased. For example, in surgery there were four matrons in post plus one vacancy. Each had one day a week assigned for governance work. This involved dealing with the backlog of incidents, complaints and duty of candour issues. There was one matron a day within the division who was designated to look at incidents.
• There had been retrospective performance management of duty of candour from April 2017 to January 2018. There were three stages of the improvement programme; the first two phases had been in place for over two months and had made significant inroads into the backlog and current performance. The third phase involved the review of potential non-compliance of duty of candour for 2017/18. A total of 323 incidents had been identified for review, in addition to those already reviewed, of which 72 were serious incidents. Currently only 55 were evidenced on trust systems as complying with duty of candour. A task and finish group were reviewing these and identifying all cases where duty of candour requirements were outstanding and appropriate.
• There had been ongoing performance management of duty of candour. Since 1 May 2018 proactive management had been applied to all cases. 51 potential duty of candour cases had been identified. In 31 of these, duty of candour had been applied and all were subject to active management, achieving 61% compliance with a commitment in line with the legal obligation to reach 100%. Performance escalation was conducted twice weekly, at weekly hard reset meetings and at divisional governance boards.
• A new duty of candour recording field and dashboard had recently been added to the electronic incident reporting system. The purpose was to make the duty of candour process simpler and also mandatory on a ‘comply or explain’ basis.
• There were ongoing actions. These included incident triage where potential serious incidents and moderate incidents were escalated to handlers and divisional governance leads with a reminder of duty of candour compliance. There was a central electronic log of all potentially notifiable incidents and these were reviewed weekly and communicated to divisions for follow-up.
• An interim duty of candour officer had been appointed to support the improvement in duty of candour performance.
• Information about the importance of duty of candour had been cascaded to staff through additional training sessions and by email from the medical director and the chief nurse.
• During our previous inspection in January 2018 we saw progress had been made to ensure the trust had oversight and assurances of equipment and medical devices on-site. Although we saw significant improvement, the processes were not yet fully implemented or embedded to enable us to comment on how effective this had been, or to test the system.
• During this inspection we found considerable progress had been achieved in ensuring oversight of medical devices. Processes were embedded and governance structures were effective. The system was fully implemented and accurate and the trust had the capability to produce automated reports regarding servicing and maintenance of equipment. The trust could monitor its performance against key performance indicators.
• There had been significant progress with the radio frequency identification (RFID) tagging of medical devices. The accuracy of the asset register and the ability to track and locate equipment had improved. Information had been captured about assets, including the last service and next due service dates. At the time of our inspection, 90% of assets listed on the historic asset inventory had been audited.
• The medical physics and clinical technology directorate (MPCT) was the designated single provider of maintenance assurance information.
• All non-consumable and non-implantable medical devices were entered onto the trust asset management system. MPCT administered the database for all trust devices, which held the following information: generic name; manufacturer; model/type; asset number; department/location; purchase cost and date if known; maintenance history. The system was a single authoritative inventory for medical devices, as well as the single repository for recording all maintenance activity.
• Third party maintenance contracts had been recorded on the trust’s electronic asset management software. The trust was assured of the external suppliers’ delivery against the contract. 87% of external assets had identified support in place.
• Medical devices in use across the trust had a variety of different ‘support solutions’, but were primarily categorised by: the maintenance provided through a manufacturer or other contracted third party provider, maintenance provided in-house by the medical physics and clinical technology directorate (MPCT) or a combination of both.
• Equipment was categorised into three core groups: critical care (including anaesthesia and renal); monitoring and treatment; and heavy engineering. Each group was broken down into device type category and then into separate assets.
• Certain categories of device required only basic functional checks to be carried out by the user, rather than any scheduled maintenance by MPCT. Although these were not included in the calculation of key performance indicator figures, numbers of these items were included in the report as they could be quite numerous and it provided a wider picture of the likelihood of any particular item of equipment in a clinical area being ‘in compliance’.
• In addition to divisional reports there was an additional category of “Unspecified”, which contained items that were trust-wide assets, as opposed to belonging exclusively within a
particular division or ward. These tended to move around the trust, for example beds and gas flow regulators.

- The labelling process had been overhauled to make it simpler for staff. Labels with the message "Do not use after (insert date)" were now in use and were seen during the inspection.
- Pivotal to understanding the issues of equipment management, both at trust committees and at divisional level, was the provision of structured service and maintenance assurance (SMA) reports. SMA reports were generated by MPCT on a monthly basis using data generated from the central inventory of equipment (asset register). It provided a single graphical snapshot of total compliance and a breakdown of data by support solution. It also reported maintenance conducted in-house by MPCT and maintenance contracted to manufacturers or other third party providers. These were provided to divisional associate directors and divisional governance leads. A trust-level summary SMA report was presented to the medical equipment board.
- The asset management system was able to forecast and schedule routine maintenance activity.
- The medical equipment board reviewed and approved key performance indicators (KPIs) for equipment maintenance, compliance and standard assurance report templates for reporting performance against KPIs.
- The radio frequency identification (RFID) tagging process had been accelerated to improve the data quality of the trust asset list. A set of challenging KPIs targeted devices according to their risk:
  - KPI 1 provided a snapshot of the number and proportion of devices in compliance with their servicing regime. The percentage compliance dictated a risk designation of red, amber or green. Built into this algorithm was a defined tolerance level of 30 days for medium and high risk categories to enable appropriate logistical arrangements to be made for the service. There was no tolerance period for very high risk devices.
  - KPI 2 defined compliance in terms of a graduated and increasing tolerance level. This KPI was specifically designed to show any areas or categories of equipment that might be falling out of compliance to its servicing schedule by a significant margin, in order to trigger targeted investigation and possible rectification.

- We saw the current performance reports for divisions with agreed KPI monitoring, and the sub-committee board minutes of oversight process and risk management. Data from April to June 2018 showed an improvement for internally maintained assets with very high risk equipment achieving 100% compliance. Compliance for high and medium risk devices was currently above projection rates. Extra resources had been deployed specifically at the very high and high risk equipment to reduce the backlog.
- Data for externally maintained devices showed sudden variations as large maintenance contracts were captured and the asset base changed. Managers were confident this would level out as the work continued.
- The medical device and equipment management policy had been updated and outlined the approach to the procurement, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices, as well as to medical device training. This ensured medical devices were used safely, competently and effectively for the best care of patients.
- The medical director had overall responsibility for the safe management of medical devices and compliance with relevant regulations. The medical equipment board was responsible for ensuring adequate governance was in place around the control of medical devices. It provided assurance to the trust management group about the safe use of medical devices, and oversaw issues relating to their maintenance, training, procurement and risk and safety. On an on-going basis the medical equipment board met to review compliance and continued to work to improve medical device governance.
- The medical device safety officer (MDSO) reviewed all incidents reported involving medical devices for the identification of trends, requirement of reporting to the Medicines and Healthcare products Regulatory Agency (MHRA), and to further investigate (or assist with investigation) where required. A regular summary of these incidents was provided for review by the medical equipment board. Any reports made to the MHRA were kept on a central record by the MDSO.
- Ward and department managers were responsible for the safe use of medical devices within their location.
- The medical physics and clinical technology directorate (MPCT) was working closely with the procurement group following the revamp of the procurement process. A simple on-line standard
form had been developed to ensure those responsible for the purchase of devices were aware of the technical and revenue implications of their choice of equipment. This helped to keep maintenance and revenue costs to a minimum.

- Prior to ordering any new medical device the following factors were considered: clinical requirements; maintenance strategy, costs and implications; safety; compatibility with other devices; patient needs; whole life cost; training requirements; standardisation / preferred devices; and decontamination procedures. Standardisation of common types of equipment reduced operator confusion, made training easier, improved equipment availability and took advantage of the cost saving from bulk purchasing.

- There were procedures for accepting new equipment, which included checks, identifying devices with a unique number and entering the details into the trust’s asset management system.

- In accordance with the MHRA guidance Managing Medical Devices (2015), the trust had established a strategic rolling replacement programme for medical equipment funded through capital monies. Oversight was provided by the medical director.

- Improvements had been made to the risk assessment tool on the electronic incident reporting system to enable medical device risks to be identified. Risks were maintained on the risk register and an action plan was drawn up to mitigate the risks. There were four open entries on the risk register: increase maintenance coordination and communication between clinical areas and the MPCT; completion of radio frequency tagging to track the location of medical devices; completion of current recruitment cycle to vacant posts; and the completion of the refurbishment of the disused toilet block to provide equipment servicing space.

- The detailed breakdown of non-maintained assets to divisions enabled them to identify high patient or service continuity risk assets and to prioritise these. They were also added to divisional risk registers. The divisional focus was to develop action plans for their identified priorities within ‘very high risk’ and ‘high risk’ categories. Updates were communicated to staff via medical devices newsletters.

- Recruitment of two additional technicians had been completed to support the workstreams. An investment request had been submitted for an additional post to ensure the team had the capacity to maintain equipment following completion of the tagging process.

- The refurbishment of a room previously used as a toilet had been completed to provide additional workshop space. There were also plans to create an additional space.

- The future key focus for the team was to continue to provide reports to maintain assurance and risk-based maintenance. The team would also be working on efficiency while maintaining technical integrity.

- The managers would continue to work collaboratively with other trusts across the region.