Royal Cornwall Hospitals NHS Trust

Quality report

Treliske
Truro
Cornwall
TR1 3LJ

Tel: 01872 250000
www.rcht.nhs.uk

Date of inspection visit:
15 - 17 January 2018

Date of publication:
<xxxx> 2018

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 rated during this inspection as it was a focused follow up inspection to assess progress against the warning notice.

Overall rating for this trust	Inadequate
Are services at this trust safe?	Inadequate
Are services at this trust effective?	Requires improvement
Are services at this trust caring?	Good
Are services at this trust responsive?	Inadequate
Are services at this trust well-led?	Inadequate

Letter from the Chief Inspector of Hospitals

Following our last inspection in July 2017, we rated Royal Cornwall Hospitals NHS Trust as inadequate overall. Surgery, maternity and gynaecology, end of life and outpatient services were rated as inadequate and 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.

The trust responded on 30 November 2017 with a single, integrated CQC Action Plan that incorporated all of the 'must do/should do' provisions arising from the January 2017 and July 2017 CQC inspection reports, in addition to the specific concerns included within the warning notice.

We conducted this follow-up inspection on 15 to 17 January 2018. The inspection was unannounced and this time we did not inspect all of the key questions, and only focused on those areas detailed in the warning notice in safe, responsive and well-led. We decided not to look at caring or effectiveness. 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 identifying, reviewing and the grading of harm and impact from incidents were not effective and incidents were not assigned the correct categorisation. In many cases, incidents, including serious incidents, were not reviewed or investigated in a timely manner, and there was no effective senior-level oversight of incidents.
- The trust was an outlier for never events, and staff had not been provided with the correct list of incidents that should be categorised as a never event, or had not acted on them accordingly.
- Surgery services were not meeting the incomplete pathway referral to treatment times for all of the surgical specialties. Patients requiring emergency surgery were sometimes delayed unnecessarily.
- Systems and processes for ensuring patients were risk assessed prior to surgery were not operating effectively. There was no assurance when changes to theatre lists were made that patients were being allocated to the most suitable theatre or team.
- Safety briefings were not always undertaken prior to the start of a case/theatre list.
- Systems and processes did not ensure compliance with the World Health Organisation (WHO) Five Steps to Safer Surgery checklist. WHO surgical safety checklists were not always fully completed or audited.
- There were not effective systems and processes to ensure that equipment was of good repair, had been serviced, maintained, tested or calibrated across the whole organisation. Safety checks on equipment were not carried out by planned dates.

Critical Care Unit:

- There were high levels of delayed and out of hours patient discharges from the critical care unit which were worse than the national average. There were high occupancy rates above recommended levels and national averages. These concerns were raised in our inspection in January 2016 and despite action plans having been completed since the inspections in January 2016 and January 2017, the actions taken had not resolved the issues or mitigated the associated risks.

Maternity:

- Systems and processes in maternity to identify and manage deteriorating women did not operate effectively. Use of the Modified Early Obstetric Warning System (MEOWS) was inconsistent and ineffective.
- Systems and processes to manage the care of women identified as needing or potentially needing high dependency (level two critical care) care did not operate effectively. There were insufficient midwives with the relevant training, skills, experience or competency to care for high-dependency women, and there was a lack of guidance for staff.
- The second obstetric operating theatre (used at times when the main obstetric operating theatre was in use, and occasionally for emergencies) did not meet minimum standards required of an operating theatre. It had not been fully risk assessed so as to put the necessary controls in place to protect mothers and babies from the risk of harm.
- There were no formal arrangements to ensure there were suitable numbers of staff available to provide cover for a second obstetric operating theatre.
- There were no systems and processes to ensure lone working community midwives were able to respond to emergency situations. The training provided to community midwives had not been adapted to reflect the complexities of working in a community setting.

Services for children and young people:

- There were not always sufficient numbers of staff with the skills, knowledge and experience to meet patients' needs. There were no formal or long term systems and processes to ensure there were sufficient numbers of registered nurses (Child Branch) deployed to meet the needs

of children and young people in the emergency department at all times.

Outpatients and diagnostic imaging:

- The systems and processes for monitoring and managing non-admitted cardiology and ophthalmology patients were not effective. There were increasing waiting lists and patient demand. There was evidence of harm to patients on the waiting list.
- There was no assurance that the specialist lead, or senior management had sufficient oversight or that there were effective systems to mitigate or address the risks of potential loss of sight to patients waiting for appointments or treatment.
- There was a reporting backlog for 24 hour cardiac recording tapes and echocardiograms for approximately 150 patients, with no effective system to address this backlog.
- The fracture clinic waiting room was not of sufficient size to accommodate patients who needed to elevate limbs safely or comfortably. Children were at risk because they were not able to wait in a separate waiting room away from other adults. This was a safeguarding concern.

Governance – trust-wide:

- Governance systems and processes were not operating effectively.
- Systems and processes to manage confidentiality were not operating effectively.
- Systems and processes to ensure the 'Being Open Policy', which included guidance for staff on how to respond when duty of candour was triggered, were not operating effectively.
- Systems and processes to address poor behaviour, grievances and performance management related issues were not operating effectively.

The trust had achieved progress in addressing our concerns; however, there was still work to do. We judged that the requirements of the warning notice had not been fully met, apart from within services for children and young people, where they had been fully met.

We found:

Surgery:

- There was a focus on incidents to manage the backlog, and review the processes in place. However, there were problems assigning investigators and tracking progress of investigations. Furthermore, the effectiveness of the system was dependent on individuals with no contingency cover in the event of absence.
- The trust had one reported never event since our last inspection. Learning from previous never events, although some time after the incidents, had been delivered as part of a surgical services shared learning event.
- Effective systems and processes had been or were being implemented to ensure equipment was of good repair, serviced, maintained, tested or calibrated across the whole organisation. Once systems were fully embedded, the trust would have the capability to produce assurance reports on the status of its equipment, which was maintained both internally and externally.
- A theatre scheduling policy had been produced and was in draft form. This supported how patients were risk assessed prior to surgery, to include last minute changes. This policy was yet to be approved and embedded across the surgical division.
- The request for an additional session form, to risk assess patients prior to surgery, did not provide a clear auditable trail of the decisions made and confirmation the theatre, staffing and equipment were appropriate.
- The completion of safety briefings and debriefings, although an improving picture, were still not compliant. This still needed embedding across the theatre suites, particularly the completion of debriefings. Furthermore, not all of the theatre team were in attendance at the briefings. For example, theatre assistants may be collecting patients, or the briefing started before trainees arrived. Some staff also left theatres before the debriefing.
- Overall, the World Health Organisation Surgical Safety Checklist and NHS Five Steps to Safer Surgery sign in, time out and sign out, were being completed in full. Improved processes for auditing had been introduced both quantitatively and qualitatively.
- Concerns were raised by staff about 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.

- Nurse Staffing remained a challenge for the trust. However, the trust were trying to improve recruitment and manage safe staffing levels on a daily basis with appropriate escalation processes.
- The trust had a recovery plan for referral to treatment time performance improvement. 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.
- Patients waiting for more than 52 weeks were increasing from August 2017 to January 2018. However, they were projected to decrease in February 2018 and be at zero in March 2018. The patients waiting more than 52 weeks for surgery were being assessed for clinical risk and prioritisation.
- There was a clear real-time oversight of emergency patients and patients were prioritised by risk assessing each person on the list. This process was still being embedded to ensure data was accurately captured.
- Additional capacity for emergency patients had been implemented.
- Data for emergency patients being seen in surgery was captured and analysed to identify if there was capability for service improvement. For example, where patients were incorrectly prioritised the trust had identified the need for education to staff to ensure prioritisation was accurate.
- Cancellations of surgery were being monitored daily, and cross-referenced with the cancer pathway. However, the trust was still experiencing cancellations of cancer patients, particularly at the time of winter pressures impacting on bed availability.

Critical care:

- Many patients were still being delayed for long periods of time when becoming medically fit for transfer. Data provided by the trust showed that common themes of delayed discharges were a lack of side rooms on wards, understaffing on wards or lack of available beds.
- Half of discharges overnight were as a result of patient beds not being available on wards. Other overnight discharges were as a result of other acute trust repatriations of patients, and changes in clinical decisions affecting timely patient discharge.
- Bed occupancy of the critical care unit remained high and had only slightly improved since the 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.

However,

- The critical care unit could provide evidence that it was consistently being responsive to patients' needs by discharging them to a medical bed as soon as the bed became available. Processes, such as pre-emptive flow meetings and planning patient discharges were embedded within the unit.

Maternity:

- Theatre two was not meeting current minimum theatre standards for its air change rate, preparation space, and minimum floor area or recovery facilities. However, the trust was constrained by a building that was 50 years old, compounded by limited capacity to relocate the theatre.
- There was a risk that staff could not summon emergency help from theatre one (main maternity theatre) as there was no emergency call bell, or process to ensure staff were not alone with a patient at any time.
- There was no process to ensure community midwives had the correct equipment at all times for use in emergencies, while waiting to transfer a patient to hospital.
- Modified Early Obstetric Warning System (MEOWS) charts were not being completed accurately. The newly introduced monthly documentation audit highlighted poor compliance with record keeping in a number of key areas. We were not assured prompt actions were being taken to address the poor compliance identified by the documentation audit.
- When patients were discharged, their loose leaf papers were not always being secured to the hospital records. Some did not contain the patient name or hospital number, which increased the risk of them becoming separated or misfiled.
- A comprehensive risk assessment of the training and wider needs of community midwives when

managing emergencies in the community had not been undertaken as requested.
- Reporting of delayed transfer of care from the community excluded a number of transfers and we were not assured that sufficient oversight of this process existed.
- We found that not all women booked for a home birth had home visits or risk assessments carried out or documented as required at 36 weeks of pregnancy.
- Systems and processes for managing deteriorating women had been implemented but they remained ineffective and further work was needed.
- There was no policy for women requiring level two high dependency care, and there were gaps in clinical guidance for some key conditions that may require high dependency care.
- The systems and processes for assembling a second emergency theatre team were not sufficient and had not been tested.

However,

- An external risk assessment had been undertaken and some remedial alterations in theatre two were completed. An operational group had been set up to focus on managing the risks and a strategic outline case containing options for solutions had been submitted to the board.
- There were controls to manage the key risks, as far as possible, in theatre two.
- Patients' records were mostly securely stored in lockable trolleys.
- The trust had responded to our concerns about monitoring the quality and standard of record keeping and had introduced a monthly documentation audit. This served to indicate the areas of weakness in record keeping.
- The annual training for community midwives had been adapted to cover the key emergencies they were likely to encounter when lone working, or waiting for an ambulance. There was a dedicated day-long course scheduled to cover community emergencies.
- The trust had implemented and strengthened the process for ensuring a priority response from the ambulance service for community emergencies, and we saw this was being used.
- The trust had developed a policy for MEOWS and had aligned other key policies to ensure guidance for scoring MEOWS was consistent.
- There was a system to ensure high dependency (HDU) trained midwives were allocated to each shift and this was working well. Additional HDU training was planned and ongoing.

Services for children and young people:

- There was appropriate and sufficient staffing cover arrangements in the paediatric area of the Emergency Department. We were satisfied that systems and processes ensured cover at all times. We found the requirements of the warning notice had been fully met for this service.

Outpatients and diagnostic imaging:

- 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 that 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 that children were booked separately to adults, although we found processes around this were not being followed.

However:

- Risks to cardiac and ophthalmology patients waiting for appointments were being appropriately assessed and managed according to clinical need. All patients were risk assessed routinely if they were waiting longer than expected for an appointment.
- During this inspection we found an effective process for the management of echo and cardiac event recordings. Additional time was available to reduce further risks. If demand became unmanageable there was a contract with an external organisation who provided support.
- Backlogs in both ophthalmology and cardiology had reduced and there were plans to ensure that management of backlogs was sustainable.

Governance – trust-wide:

- The trust was still failing to comply with the requirements for duty of candour.
- Governance systems and processes for the management of incidents and never events were still not operating effectively and we were concerned about their sustainability.

However,

- Overall, patient records and confidential information was being held securely, and were mostly held in locked patient record trolleys.
- The trust had made progress with the investigation of grievance cases. Although they had not yet met the trust target, they were showing improvement where the time to complete investigations was reducing.
- Polices were updated to reflect changes to improve the systems and processes for recording, monitoring and risk assessing cases. The changes were still being embedded.

The trust must:

- Improve in a sustainable way the systems and end to end processes for managing incidents, and sharing the learning from those incidents.
- Ensure all staff from the theatre list team attend the safety briefing and safety debriefing. Consider the timings of the morning emergency theatre list meeting and the theatre morning huddle to ensure the theatre nurses can attend both in full.
- Complete World Health Organisation surgical safety checklists for all patients in theatre, to include patients returning from recovery.
- Review the request for additional session document and ensure the sign off for approval of the operation identifies appropriate theatre, staffing and equipment is available for the patient. Include any risks considered when making this decision, to enable a clear audit trail of decisions.
- Continue to review the recovery plan and resource to reduce the number of patients waiting over 18 weeks from referral to treatment across surgical specialities.
- Ensure completion, monitoring and reporting of the World Health Organisation Surgical Safety Checklist within maternity theatres. The safety briefing and debriefing must be formally embedded and audited.
- Continue to progress the business case for the second obstetric theatre and mitigate the associated risks in the interim.
- Ensure staff in the main obstetric theatre can summon emergency help when needed and there are systems to ensure staff are not alone when in theatre with a patient.
- Conduct a comprehensive risk assessment around community midwives in terms of their training needs, equipment and lone working.
- Ensure risk assessments are being carried out for women requesting home births and that documentation of these is recorded accurately.
- Continue to implement the MEOWS policies and procedures and ensure these are being completed and escalated appropriately.
- Develop, implement and monitor guidance for staff when caring for women requiring level two high dependency care.
- Review the systems and process for securing a second emergency obstetric theatre team to include ensuring the right staff with the right competencies are available at all times.
- Make improvements to the fracture clinic environment to reduce risks to patients. This includes addressing the environmental, and infection prevention and control concerns around the waiting room.
- Make improvements to safeguard children in the waiting room of the fracture clinic.
- Continue to ensure actions around the management of ophthalmology backlogs are completed in a timely way to ensure timely management of patients in a backlog.
- Improve flow throughout the hospital to reduce the number of delayed and out of hours discharges from critical care.
- Improve flow throughout the hospital to reduce bed occupancy levels in critical care to bring them in line with the recommendations of the Royal College of Anaesthetists.
- Develop, implement and monitor comprehensive systems and processes for complying with its obligations under duty of candour.

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, supported by Dan Thorogood, Inspection Manager and Mary Cridge, Head of Hospital Inspections, Care Quality Commission.

The team included four CQC inspectors, an assistant inspector, and one specialist advisor. In addition, the inspection team was joined by a deputy director of nursing from NHS England.

How we carried out this inspection

We conducted this follow up inspection, unannounced, on 15 to 17 January 2018. We visited maternity, surgery theatres and wards, outpatient department and the paediatric area in the emergency department. 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 78 staff, including medical staff, nursing staff, theatre staff, managers, and associate and clinical directors. We looked at 44 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 in August 2017. We inspected the main Royal Cornwall Hospital site and did not revisit St Michael's Hospital or West Cornwall Hospital. We did not inspect all of the key questions, and only focused on those areas detailed in the warning notice in safe, responsive and well-led. We decided not to look at caring or effectiveness.

We judged that insufficient progress had been made in maternity, surgery, critical care, outpatients and governance and the requirements of the warning notice had not been fully met. We found the requirements of the warning notice had been met in the services for children and young people. The ratings were not reviewed due to the limited focus of this inspection.

At this inspection we continued to have serious concerns that:

- systems to assess, monitor, and mitigate risks to patients receiving care and treatment in maternity and surgery were not operating effectively.
- governance systems and processes were not operating effectively in critical care and the fracture clinic to support significant and sustained improvement.
- systems and processes to ensure equipment was of good repair, serviced, maintained, tested or calibrated across the whole organisation were not operating effectively
- governance systems and processes for the management of incidents and never events were not operating effectively and were not sustainable.

- systems and processes to comply with the requirements of duty of candour were not operating effectively.

We served the trust with a second Section 29A Warning Notice on 1 March 2018. The notice required the trust to make significant improvements by 13 April 2018.

At this inspection we found:

Surgery:

- There was a focus on incidents to manage the backlog, and review the processes in place. However, there were problems assigning investigators and tracking progress of investigations. Furthermore, the effectiveness of the system was dependent on individuals with no contingency cover in the event of absence.
- The trust had one reported never event since our last inspection. Learning from previous never events, although some time after the incidents, had been delivered as part of a surgical services shared learning event.
- Effective systems and processes had been or were being implemented to ensure equipment was of good repair, serviced, maintained, tested or calibrated across the whole organisation. Once systems were fully embedded, the trust would have the capability to produce assurance reports on the status of its equipment, which was maintained both internally and externally.
- A theatre scheduling policy had been produced and was in draft form. This supported how patients were risk assessed prior to surgery, to include last minute changes. This policy was yet to be approved and embedded across the surgical division.
- The request for an additional session form, to risk assess patients prior to surgery, did not provide a clear auditable trail of the decisions made and confirmation the theatre, staffing and equipment were appropriate.
- The completion of safety briefings and debriefings, although an improving picture, were still not compliant. This still needed embedding across the theatre suites, particularly the completion of debriefings. Furthermore, not all of the theatre team were in attendance at the briefings. For example, theatre assistants may be collecting patients, or the briefing started before trainees arrived. Some staff also left before the debriefing.
- Overall, the World Health Organisation Surgical Safety Checklist and NHS Five Steps to Safer Surgery sign in, time out and sign out, were being completed in full. Improved processes for auditing had been introduced both quantitatively and qualitatively.
- Concerns were raised by staff about 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.
- Nurse Staffing remained a challenge for the trust. However, the trust were trying to improve recruitment and manage safe staffing levels on a daily basis with appropriate escalation processes.
- The trust had a recovery plan for referral to treatment time performance improvement. 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.
- The patients waiting for more than 52 weeks were increasing from August 2017 to January 2018. However, they were projected to decrease in February 2018 and be at zero in March 2018. The patients waiting more than 52 weeks for surgery were being assessed for clinical risk and prioritisation.
- There was a clear real-time oversight of emergency patients and patients were prioritised by risk assessing each person on the list. This process was still being embedded to ensure data was accurately captured.
- Additional capacity for emergency patients had been implemented.
- Data for emergency patients being seen in surgery was captured and analysed to identify if there was capability for service improvement. For example, where patients were incorrectly prioritised the trust had identified the need for education to staff to ensure prioritisation was accurate.
- Cancellations of surgery were being monitored daily, and cross-referenced with the cancer pathway. However, the trust was still experiencing cancellations of cancer patients, particularly at the time of winter pressures impacting on bed availability.

Critical care:

- Many patients were still being delayed for long periods of time when becoming medically fit for transfer. Data provided by the trust showed that common themes of delayed discharges were a lack of side rooms on wards, understaffing on wards or lack of available beds.
- Half of discharges overnight were as a result of patient beds not being available on wards. Other overnight discharges were as a result of other acute trust repatriations of patients, and changes in clinical decisions affecting timely patient discharge.
- Bed occupancy of the critical care unit remained high and had only slightly improved since the 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.

However,

- The critical care unit could provide evidence that it was consistently being responsive to patients' needs by discharging them to a medical bed as soon as the bed became available. Processes, such as pre-emptive flow meetings and planning patient discharges were embedded within the unit.

Maternity:

- Theatre two was not meeting current minimum theatre standards for its air change rate, preparation space, and minimum floor area or recovery facilities. However, the trust was constrained by a building that was 50 years old, compounded by limited capacity to relocate the theatre.
- There was a risk that staff could not summon emergency help from theatre one as there was no emergency call bell, or process to ensure staff were not alone with a patient at any time.
- There was no process to ensure community midwives had the correct equipment at all times for use in emergencies, while waiting to transfer a patient to hospital.
- Modified Early Obstetric Warning System (MEOWS) charts were not being completed accurately. The newly introduced monthly documentation audit highlighted poor compliance with record keeping in a number of key areas. We were not assured prompt actions were being taken to address the poor compliance identified by the documentation audit.
- When patients were discharged, their loose leaf papers were not always being secured to the hospital records. Some did not contain the patient name or hospital number, which increased the risk of them becoming separated or misfiled.
- A comprehensive risk assessment of the training and wider needs of community midwives when managing emergencies in the community had not been undertaken as requested.
- Reporting of delayed transfer of care from the community excluded a number of transfers and we were not assured that sufficient oversight of this process existed.
- We found that not all women booked for a home birth had home visits or risk assessments carried out or documented as required at 36 weeks of pregnancy.
- Systems and processes for managing deteriorating women had been implemented but they remained ineffective and further work was needed.
- There was no policy for women requiring level two high dependency care, and there were gaps in clinical guidance for some key conditions that may require high dependency care.
- The systems and processes for assembling a second emergency theatre team were not sufficient and had not been tested.

However,

- An external risk assessment had been undertaken and some remedial alterations in theatre two were completed. An operational group had been set up to focus on managing the risks and a strategic outline case containing options for solutions had been submitted to the board.
- There were controls to manage the key risks, as far as possible, in theatre two.
- Patients' records were mostly securely stored in lockable trolleys.
- The trust had responded to our concerns about monitoring the quality and standard of record keeping and had introduced a monthly documentation audit. This served to indicate the areas of weakness in record keeping.
- The annual training for community midwives had been adapted to cover the key emergencies they were likely to encounter when lone working, or waiting for an ambulance. There was a dedicated day-long course scheduled to cover community emergencies.
- The trust had implemented and strengthened the process for ensuring a priority response from the ambulance service for community emergencies, and we saw this was being used.
- The trust had developed a policy for MEOWS and had aligned other key policies to ensure guidance for scoring MEOWS was consistent.

- There was a system to ensure high dependency (HDU) trained midwives were allocated to each shift and this was working well. Additional HDU training was planned and ongoing.

Services for children and young people:

- There was appropriate and sufficient staffing cover arrangements in the paediatric area of the Emergency Department. We were satisfied that systems and processes ensured cover at all times. We found the requirements of the warning notice had been fully met for this service.

Outpatients and diagnostic imaging:

- 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 that 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 that children were booked separately to adults, although we found processes around this were not being followed.

However:

- Risks to cardiac and ophthalmology patients waiting for appointments were being appropriately assessed and managed according to clinical need. All patients were risk assessed routinely if they were waiting longer than expected for an appointment.
- During this inspection we found an effective process for the management of echo and cardiac event recordings. Additional time was available to reduce further risks. If demand became unmanageable there was a contract with an external organisation who provided support.
- Backlogs in both ophthalmology and cardiology had reduced and there were plans to ensure that management of backlogs was sustainable.

Governance – trust-wide:

- The trust was still failing to comply with the requirements for duty of candour.
- Governance systems and processes for the management of incidents and never events were still not operating effectively and we were concerned about their sustainability.

However,

- Overall, patient records and confidential information was being held securely, and were mostly held in locked patient record trolleys.
- The trust had made progress with the investigation of grievance cases. Although they had not yet met the trust target, they were showing improvement where the time to complete investigations was reducing.
- Polices were updated to reflect changes to improve the systems and processes for recording, monitoring and risk assessing cases. The changes were still being embedded.

Are services at this trust safe?

Inspected not rated

We inspected safe in surgery, maternity, outpatients and services for children and young people. We found the requirements of the warning notice had not been fully met, apart from in services for children and young people, where we judged they had been fully met.

Surgery:

At our last inspection we were concerned about the safety of patients for the following reasons:

- The systems and processes in place for identifying, reviewing and the grading of harm and impact from incidents were not effective and incidents were not assigned the correct categorisation. In many cases incidents, including serious incidents, were not reviewed or investigated in a timely manner, and there was no effective corporate oversight of incidents.
- The trust was an outlier for never events, and staff had not been provided with the correct list of

incidents that should be categorised as a never event, or have not acted on them accordingly.

- Surgery services were not meeting the incomplete pathway referral to treatment times for all of the surgical specialties. Patients requiring emergency surgery were sometimes delayed unnecessarily.
- Systems and processes for ensuring patients were risk assessed prior to surgery were not operating effectively and there was no assurance when changes to theatre lists were made that patients were being allocated to the most suitable theatre or team.
- Safety briefings were not always undertaken prior to the start of a case/theatre list.
- Systems and processes in place did not ensure compliance with the World Health Organisation (WHO) Five Steps to Safer Surgery checklist. WHO surgical safety checklists were not always fully completed or audited.
- Concerns were raised by staff about 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 were not effective systems and processes in place to ensure that equipment was of good repair, had been serviced, maintained, tested or calibrated across the whole organisation. Safety checks on equipment are not carried out by planned dates.

During this inspection we found:

- There was a focus on incidents to deliver the backlog, and review the processes in place. However, there were problems assigning investigators and tracking progress of investigations. Furthermore, the effectiveness of the system was dependent on individuals with no contingency in place to cover in the event of absence.
- The trust had one reported never event since our last inspection. Learning from previous never events, although some time after the incidents, had been delivered as part of a surgical services shared learning event.
- Effective systems and processes had been or were being implemented to ensure equipment was of good repair, serviced, maintained, tested or calibrated across the whole organisation. Once systems were fully embedded, the trust would have the capability to produce assurance reports on the status of their equipment, which was maintained both internally and externally.
- A theatre scheduling policy had been produced and was in draft form. This supported how patients were risk assessed prior to surgery, to include last minute changes. This policy was yet to be approved and embedded across the surgical division.
- The request for additional session form, to risk assess patients prior to surgery, did not provide a clear auditable trail of the decisions made and confirmation the theatre, staffing and equipment were appropriate.
- The completion of safety briefings and debriefings although an improving picture were still not compliant, this still needed embedding across the theatre suites particularly the completion of debriefings. Furthermore, not all of the theatre team were in attendance at the briefings, for example theatre assistants may be collecting patients or the briefing starts before trainees arrive. Some staff also left theatres before the debriefing.
- Overall, the World Health Organisation Surgical Safety Checklist and five steps to safer surgery sign in, time out and sign out, were being completed in full. Improved processes for auditing had been introduced both quantitatively and qualitatively.
- Concerns were raised by staff about 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.
- Nurse staffing remained a challenge for the trust. However, the trust were trying to improve recruitment and manage safe staffing levels on a daily basis with appropriate escalation processes in place.
- The trust had a recovery plan for referral to treatment time performance improvement. 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.
- The patients waiting more than 52 weeks were increasing from August 2017 to January 2018, however they were projected to decrease in February 2018 and be at zero in March 2018. The patients waiting more than 52 weeks for surgery were being assessed for clinical risk and prioritisation.

- There was a clear real time oversight of emergency patients and patients were prioritised by risk assessing each person on the list. This process was still being embedded to ensure data was accurately captured.
- Additional capacity for emergency patients had been implemented.
- Data for emergency patients being seen in surgery was captured and analysed to identify if there was capability for service improvement. For example where patients were incorrectly prioritised the Trust had identified the need for education to staff to ensure prioritisation is accurate.
- Cancellations of surgery were being monitored daily and cross-referenced with the cancer pathway. However, the trust was still experiencing cancellations of cancer patients, particularly at the time of winter pressures impacting on bed availability.

Detailed findings

Incidents

- Since the last inspection, there had been a focus on managing the backlog of incidents. Significant work had been completed to clear the backlog of investigations of serious incidents, but we were concerned this would not be sustained. The trust had employed an interim senior manager and was using an external company to improve the process of serious incident investigation, and to reduce the backlog. While the backlog had been tackled, and work to improve the process had taken place, the interim manager left the trust, as planned, in January 2018. We asked the trust how the serious incident workload would be managed to ensure a backlog would not start to build again. At that time they were unable to confirm what structures would be put in place to manage this. The interim manager's planned leaving date had been known about for some months, but no permanent solution had been identified and discussions had only started the week they left.
- The trust's clinical lead for serious incidents was given three hours a week to carry out this role. Two hours were spent in a weekly meeting, and the third hour was spent preparing for this meeting. Their remaining time was spent working clinically. They did not have the capacity to undertake this role and therefore had to find additional time to support investigating officers, mentor new investigating officers, and work within the new governance structure to support the divisions.
- The clinical lead for serious incidents and associate director for clinical governance reviewed all potential serious incidents. A standard operating procedure had been developed centrally to address the changes in policy and oversight. This had been shared with divisional senior management teams and cascaded through their governance arrangements.
- There was a raised awareness of the importance of governance and processes were embedding. A surgery specialty governance meeting was held monthly looking at themes and trends. Issues were escalated to the divisional board and back to the specialty. The responsibility for managing incidents was being cascaded to the divisions, but concerns remained about capacity for the divisions to manage this change.
- However, there were problems assigning investigators and tracking progress of investigations. Furthermore, the effectiveness of the system was dependent on individuals with no contingency to provide cover in the event of absence.
- The structure and function of the incident reporting system had been implemented from 1 December 2017. Staff said the system was easier to understand and there was an emphasis on education, support and accountability. The system was still too new to determine how effective it was and the trust could not be assured that learning and actions were being shared and completed promptly. We saw no evidence that outcomes of actions implemented following an incident were being monitored or reported on.
- New policies and procedures for incident reporting did not contain any guidance for staff in terms of never events.
- We were told random audits of the grading of incidents had been commenced in December 2017 and findings would be shared with divisions. These were not available at the time of our inspection.
- Incident reporting refresher training for staff at induction, including duty of candour, and mandatory refresher training was planned from January 2018 as part of the 'Patient Safety Culture' core training. Clinically led daily review of incidents to identify potential serious incidents, as well as themes and trends of concern, had also been introduced.
- A new questionnaire had been devised to send to patients or relevant persons who had been involved with a serious incident investigation to get their feedback on how they found the process. This had not been sent out to anyone at the time of our inspection.

- During this inspection we were not assured sufficient learning had taken place around serious incidents we were aware of in theatre because not all staff were aware of the learning that had taken place, or any changes resulting from the serious incidents.
- In our previous inspection, we identified the trust was not able to demonstrate sufficient or rapid learning as a result of never events. We attended the first of the surgical services sharing learning events during our inspection. These events were planned to be held monthly, and a 70% attendance from staff was expected. There were five specialty presentations to review three never events, one downgraded never event, and one serious incident from 2017. Two of these were about trauma and orthopaedics relating to wrong-sided implant and retained metalwork. One related to anaesthetics, about administration of a wrong-side block. One was in ophthalmology, and about the wrong-side eye preparation. The other was a serious incident in ophthalmology about giant cell arteritis. Attendees were from a multi-disciplinary forum and there was opportunity to look at contributory factors and themes, share learning and discuss how things had changed or could be done differently. We spoke to some staff who attended who spoke positively about the information and learning gained from this event.
- There had been one reported never event since our last inspection between 10 July 2017 and 15 January 2018. However, we were aware of three cases which may have met the criteria for a never event. These had not been reported as discussions were ongoing at the trust to decide if they were never events or not. This raised concerns about the timeliness of investigating and reporting, and the culture of waiting to report, rather than reporting and downgrading the incident where relevant.
- We reviewed an incident report for surgical wards and theatres covering incidents from 1 November to 31 December 2017. There were 343 incidents.

Environment and equipment

- Our previous inspection found there were not effective systems and processes to ensure equipment was of good repair, had been serviced, maintained, tested or calibrated across the whole organisation. The trust did not have an accurate medical equipment asset register.
- There was a lack of knowledge of where equipment was, which impacted on the trust's ability to provide accurate assurance reports regarding equipment servicing.
- The trust did not maintain records of maintenance which was being carried out by third-party contractors.
- During this inspection we saw a lot of 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 has been, or to test the system.
- Once the system was fully implemented and accurate, the trust would have the capability to produce automated reports regarding servicing and maintenance of equipment. The trust would be able to monitor its performance against key performance indicators.
- The medical devices and clinical technology team had recruited additional staff to ensure it was able to carry out the servicing of equipment in a timely manner and centrally manage and maintain records of third party maintenance.
- The medical devices and clinical technology team had identified a centralised single point asset register to collect assurance information regarding the maintenance of medical devices. This would enable assurance reports to be produced. This covered all medical devices under contract with third parties and maintenance carried out in-house.
- The asset register, with an estimated 20,000 items, was expected to be complete and accurate in April 2018. This was designed to ensure clear information was captured about all assets, including the last service and next due service dates.
- Third party maintenance contracts were being recorded on the trust's electronic asset management software. Once this was complete, this would enable the trust to be assured of the external supplier's delivery against the contract. Staff reported improved relationships with suppliers.
- Our previous inspection identified safety checks on equipment were not carried out by planned dates, in particular anaesthetic machines and anaesthetic syringe pumps. During our inspection we checked a number of anaesthetic machines and anaesthetic syringe pumps in theatres. We noted all were clearly labelled to identify they were in date of their servicing and maintenance. The trust provided evidence of 100% compliance of planned preventative maintenance for anaesthetic machines, which were now being classified as a very high risk device on the asset register. For anaesthetic syringe pumps, classified as high risk devices, 97% were compliant with their planned

preventative maintenance, one anaesthetic syringe pump showed on the record as out-of-date, but was currently unable to be located.

- To ensure the department was able to meet the demands of servicing and maintaining anaesthetic machines, a business case had been approved and an additional anaesthetic machine had been purchased. This enabled a machine to be out for service without this compromising the availability of anaesthetic machines in theatres.
- The trust was introducing tagging of all medical equipment to enable an accurate asset register to be maintained, and to allow the team to successfully track and locate assets. This was being rolled out at the time of our inspection. The asset register would not be fully reflective of active assets until this tagging audit was completed.
- In our previous inspection, the clinical equipment asset list supplied for surgical services at West Cornwall Hospital showed 77 out of 104 pieces of equipment had no date of last service or date to indicate when servicing was next due.
- The trust completed an audit of equipment in theatres at West Cornwall Hospital. This audit revealed assets still listed on the asset register were no longer in use or not found, as well as assets which had not been captured on any inventory. We saw evidence that the gaps in maintenance were being addressed. Assets which were maintained by clinical technology, or manufacturer maintained, had dates of the last planned preventative maintenance and date of due planned preventative maintenance recorded, with those which were overdue flagged. Information was being obtained for assets requiring external contract support. Assets only requiring a user check were also clearly identified.
- In our previous inspection, we were not provided with evidence that the risks associated with testing or servicing equipment on the theatre or anaesthetic risk register, or the trust corporate risk register.
- During the 2018 inspection we saw evidence of risks identified and recorded by the medical devices and clinical technology team on their local risk register. There were seven active risks relating to equipment, servicing and maintenance. Two extreme risks were escalated to the corporate risk register.
- The medical devices' group was now being provided with the responsibility to ensure medical device governance and review risks, and were now named the medical devices oversight group. The purpose of this group was to provide assurance to the trust regarding safety, suitability, availability and safe use of all medical devices in use across the trust, in line with key performance indicators. We saw evidence of updated terms of reference for this group. This group met on the 15 January 2018 to discuss the feedback from our previous inspection and to change the terms of reference and governance arrangements. The group were next planned to meet on the 13 March 2018. The medical devices oversight group would then report to the medical director. A sub-group, the integrated medical equipment planning group, had also been formed. This provided evidence of the progress the trust was making in ensuring oversight of medical devices. However, the process was yet to be embedded and the groups would only be fully effective once the asset register was complete and accurate.

Assessing and responding to patient risk

- In our previous inspection, we raised concerns about the systems and processes for ensuring patients were risk assessed prior to surgery. There was no guidance available to staff to set standards by which a patient should be allocated to a particular list in a particular operating theatre. This meant at times patients were operated on in an inappropriate theatre, without the required level of skilled staff or equipment. There was no guidance for staff about risk assessment or allocation of patients, nor an authorisation process where last minute changes were made, or for allocating emergencies.
- Since our last inspection, a theatre scheduling policy, including standard operating procedures and guidelines, had been developed. The theatre scheduling policy included risk assessment, criteria on allocation of theatre lists, management of emergency situations, authorisation process, last minute changes and alterations to the operating theatre lists' schedule. The key objectives were to ensure information was as visible as possible and theatre teams took ownership to ensure the right specialty was in the right place. We reviewed the draft policy. This policy was awaiting ratification by the divisional board.
- The theatre scheduling policy included how short notice urgent requests were considered once a request for an additional session form was completed. This enabled information to include

speciality, location, staff availability and complexity of the planned operating procedure to be considered for an informed decision to be made. This was to ensure the theatre was fully resourced with the appropriately skilled team in an appropriate and safe environment. A flow chart was included within the theatre scheduling policy.

- The request for an additional session form (also referred to as the theatre pro-forma) used to risk assesses short notice surgeries, had only been used once since implementation. We were told the future plan was to audit the use of the theatre pro-forma to ensure appropriate theatre allocations. We saw an example of the completed form, this included the speciality, primary surgeon, planned procedure, patient acuity, surgical class, and known comorbidities. The document was then completed as 'session approved' and signed by the approver, who in this case was the operational manager for theatres. The document did not identify or have a record of which theatre and list this patient had been assigned to, and whether the staffing and equipment was appropriate for the case. The current form did not have a clear auditable trail of the decision made and why this was made based on risk assessing the patient and their surgery.
- We saw standard practice in theatre one in the Tower Suite for an ophthalmology operating list where the unexpected absence of a paediatric anaesthetist was managed appropriately. The list was delayed to ensure a paediatric anaesthetist was available.
- In our previous inspection, both theatre staff and senior leaders told us safety briefings were not always undertaken prior to the start of a case or theatre list, despite being introduced in September 2016. Audits failed to demonstrate safety briefings were being carried out and there was no assurance these were working effectively.
- Since our last inspection, the theatres introduced a standard format for theatre safety briefings. This began with a morning safety huddle for the nursing teams in each theatre suite, led by the nurse in charge. The safety huddle covered staffing, equipment and daily plans for each theatre in the suite. This was also an opportunity to discuss any learning from incidents or issues from the previous day, or to raise any important information.
- During this inspection we observed one safety huddle in Trelawney suite and one safety huddle in the Tower Suite. We found staff were well engaged in this process and most nursing staff attended. This was with the exception of the staff who were in attendance at the emergency theatre meeting who came late to the safety huddle. Key messages were shared with the teams. This included, for example, key information about individual patients, complaints, infection control issues, promptness in attending briefings, and a reminder about audit, and training that afternoon.
- In September 2017, a revised theatre list briefing and debriefing tool was implemented. The briefing was completed before the start of any theatre list and was led by the operating surgeon or a designated member of the theatre team. The end of list debrief was completed at the end of the operating theatre list. All team members attended both the brief and debrief, and this was recorded. The completed list was returned to the department coordinator. This provided an oversight of compliance to ensure any issues for learning were identified and included in the following morning's safety huddle.
- Completion of the theatre briefing and debriefing was audited. The October 2017 data showed there were still improvements required within the majority of theatres on the Royal Cornwall Hospital site with compliance varying from 0% to 91%.
    - November 2017 data for the 13 theatres across the Tower Suite, Trelawney and Newlyn showed three theatres were partially compliant with 90-99% completion, and 10 theatres were non-compliant and below 90%.
    - In December 2017, all 13 theatres were non-compliant with compliance variable between 33% and 88%.
    - However, there was an overall improvement from 51% in November to 74% in December across all the trust's surgical theatres.

  We were told the low compliance the data captured appeared to be a result of failure to save documentation, and did not correlate directly with an incomplete briefing and debriefing. The department managers were addressing this, identifying named individuals in each area who would have access and be responsible for the document upload. The division had plans to move the recording and documentation of the theatre brief and debrief to an electronic system, which would allow more streamlined reporting and daily escalation of failures to complete for immediate action.
- We observed four safety briefings during our inspection. Although the checklist was followed in all safety briefings and the team were fully engaged, we did identify differences with the depth and discussion held by the teams. We did note good practice in theatre five Tower Suite. This included

a well-performed safety briefing where each patient was discussed in detail and the whole team were involved. During the briefing, the theatre phone was ringing. The senior operating surgeon stopped the briefing to enable someone from the team to take the call. The briefing restarted once everyone was fully engaged. Also in theatre six Trelawney Suite, the team recognised their team would be changing through the day and a second safety briefing would be required.

- Best practice was not always being followed as not all staff were in attendance at the safety briefing. Staff told us not all of the theatre team attended all briefings as one member of the team would often be collecting the patient. In these instances, the theatre assistant would collect the patient so not to delay the list. This would be written on the briefing and the theatre assistant would be informed of briefing information on their return.
- Staff told us they had seen an improvement with completion of safety briefings but they were still in the process of embedding and the quality of the briefing was dependent on the teams. Staff told us briefings would sometimes start before trainees arrived, and therefore the team needed to be clear on who was going to be in the theatre so they could ensure they only started briefings with the full team present.
- Not all of the theatre team were in attendance in safety debriefings. Staff told us theatre debriefings were still not always being completed and could be a challenge if some of the team left before it was completed. There were occasions when the debriefing did not happen as staff had finished their shift and had left for the day, or the medical team were seeing other patients on the wards.
- We also saw on completed safety debriefings recordings when staff were not present, for example, an anaesthetist or surgeon. An electronic system safety briefing method was being trialled. This had been trialled in theatres at West Cornwall Hospital and theatre 12 at Royal Cornwall Hospital. We were told feedback had been positive. The electronic system method would enable a report to be completed daily on compliance and identify any issues or non-compliance so this could be discussed with the relevant teams or theatre suites as soon as possible.
- Our last inspection found systems were not in place to ensure compliance with the World Health Organisation (WHO) surgical safety checklist and the NHS Five Steps to Safer Surgery. WHO surgical safety checklists were not always fully completed or audited. We found examples where these were not fully completed, to include failure to mark the surgical site. There were also records of personnel changes in the operating theatre after completion of the WHO surgical safety checklist.
- From 18 October 2017, the trust created and implemented an additional field within the theatre electronic record. This required all staff to check and confirm all patients have had a WHO surgical safety checklist completed and recorded as part of the theatre process. Recovery staff then reviewed for completeness the WHO surgical safety checklist following every procedure and returned to the theatre team any incomplete checklists for immediate action. The trust had identified a trend in the non-complete forms and this was due to the lack of the senior operating surgeon's signature. Staff were reminded to ensure forms were complete, but this process was still embedding.
- Data across theatres in Royal Cornwall Hospital, St Michael's Hospital and West Cornwall Hospital showed 99.82% compliance in November 2017 and 99.63% compliance in December 2017 for completion of the WHO surgical safety checklist. Data was not available for maternity theatres as they did not utilise the electronic system. This meant there was no assurance of compliance within maternity theatres.
- We spoke to staff during our inspection who felt there had been a change in culture and a real emphasis on the completion of the WHO surgical safety checklist and the NHS Five Steps to Safer Surgery. All staff were confident this was being completed in the surgical theatres. Some staff did mention the sign out was sometimes completed without checking if there was anything the team wanted to input or waiting for everyone to be fully engaged and participated. There were also concerns raised by staff about the non-completion of the checklist and particularly safety briefings and debriefings within the maternity theatres.
- We reviewed 14 patient care records for patients who were post-surgery. The WHO surgical safety checklist and the NHS Five Steps to Safer Surgery sign in, time out and sign out were completed in full in 13 care records. One case was complete with the exception of recording a "yes or no" for any known allergies.
- For one patient they had a WHO surgical safety checklist completed in full for their first procedure. However, the patient came in from recovery with an urgent bleeding aneurysm. It was recorded on the checklist "patient known to some staff from earlier operation (identity known) operation is in

best interest". The sign in and time out were therefore not completed and only the sign out was completed. This did not follow the World Health Organisation guidelines and the recording in the notes "some staff" suggests the team had changed since the previous procedure.

- The trust had external input from NHS Improvement to support it and improve on the culture for the completion of the WHO surgical safety checklist and the NHS Five Steps to Safer Surgery. The trust planned to invite NHS Improvement to return and check their progress.
- Staff were aware it was a compulsory requirement to complete the WHO surgical safety checklist and there was a constant message across the division to comply. This was monitored as part of ongoing staff performance and where there were persistent errors staff would be subject to the performance disciplinary process.
- At the time of our previous inspection the audits of compliance with the WHO surgical safety checklist and the NHS Five Steps to Safer Surgery showed completion between 95% and 99% from May 2016 through to May 2017. However, some senior managers questioned the validity of the audits, telling us staff carried out the audits in their own areas and selected lists and theatres to audit where compliance was expected to be high. This was recorded as a concern in the surgical governance and business meetings on 28 June 2017. Therefore, there was no assurance that underperforming areas or risk were being identified.
- The trust continued to complete direct observation audits of practice by the senior theatre team, and this was now done in another area or department. As a further development to provide independent audit scrutiny the trust were working with their volunteer coordinators to develop a volunteer patient safety audit role. The volunteers would observe practice of the WHO surgical safety checklist. This was planned to be operational by 31 March 2018.
- We were provided with the October and November 2017 monthly WHO compliance reports in an old template. During October 2017, there were 260 direct observations of the WHO process during the audit achieving 95% compliance at the Royal Cornwall Hospital, 97% compliance at St Michael's Hospital and 83% compliance at West Cornwall Hospital, with overall 95% compliance, against a 95% trust target.
- The quantitative audit reviewed 120 forms and 87% showed the WHO surgical safety checklists were fully compliant against a 100% trust target. During November 2017 there were 249 direct observations of the WHO process during the audit, Royal Cornwall Hospital achieved 95% compliance, St Michael's Hospital achieved 100% compliance and West Cornwall Hospital 86% compliance, with overall 94% compliance, against a 95% trust target. The quantitative audit results for November reviewed 95 WHO surgical safety checklists and 97% were fully compliant against a 100% trust target. Although this report recorded why compliance was not met, the report did not clearly identify the learning and action from the audits.
- The maternity delivery suite WHO surgical safety checklist was captured within the monthly audits. In the October 2017 report there were 10 qualitative and two quantitative audits which were 100% compliant. In November 2017, forms were received a month late for the delivery suite so were not included within the report. We were told for January 2018, there were 10 qualitative checks and four quantitative checks completed, although the report was yet to be produced. The maternity department had only started using the safety briefing and debriefing in the middle of January and therefore had not yet formally audited this process.
- A new template had been produced to continue to capture WHO compliance and provide a monthly report for all surgical theatres. The monthly report assured the surgical directorate that standards were being met by all theatres. This reported on safety huddles, operating list briefing and debriefing, quantitative WHO (target 100%), qualitative WHO (target 95%), and reported on actions. We reviewed the blank template but a full report in this template had not yet been completed.
- We were told the current method for completing observational WHO surgical safety checklist audits required administrative time to ensure results were typed up or paper copies were scanned and uploaded. The trust planned to create an electronic app to enable audits to be completed and data to be analysed in a timely manner.
- A trend identified in the observational audits were distractions. We were told this was difficult due to different people's perception of what counted as distraction or full engagement. We saw a direct correlation with a trend identified from an audit; the team were marked down for not being fully engaged as someone was moving. The team were being reminded of this within their morning safety huddle. A theatre manager told us they were trying to empower people in theatre to tell the team to stop if a distraction was noted.

- As part of the trust's timeline for improvement, we were told the distribution of display of the NHS Five Steps to Safer Surgery audit information had been revised so all staff could see the department's progress towards target. However, during the inspection in Tower Suite and Trelawney suite, we did not see up-to-date information of department compliance with the WHO surgical safety checklist and the NHS Five Steps to Safer Surgery. In Trelawney Suite the 'how are we doing' board data for WHO surgical safety checklist was from May 2017.
- During this inspection, we also heard there was some disparity between how well systems had embedded across the Trelawney theatres and those in the Tower. The theatre manager for Trelawney Suite also told us about plans to ensure consistency. They were currently assessing roles, responsibilities, competencies and training requirements with an aim that all staff knew the basics and could move across both theatre suites if required. This would be beneficial to ensure emergency patients could be seen in a timely manner in theatres if staff at least knew how to set up an emergency theatre, and also help with theatre staffing.

Surgical staffing

- Our previous inspections identified there were not always sufficient numbers of staff with the skills, knowledge and experience to meet patient's needs.
- The trust still faced challenges with staffing. Staffing risks were captured on the surgical services risk register. A resource plan had been developed to address key vacancies identified by the division. This included the number of vacancies, retirees, turnover and 12-month retention. This information helped when planning recruitment activity priorities to achieve a target of a maximum 6% vacancy gap by July 2018.
- The trust were reviewing how it could attract people and were holding and delivering recruitment events and campaigns. The trust had been successful in filling vacancies for band two and band three roles, which was the area of focus.
- We reviewed medical and nursing staffing for surgical wards and theatres across the three hospital sites for November and December 2017. The trust were hopeful they would see an improvement on this data in 2018 with the recruitment of both medical and nursing staff. For both medical and nursing staff:
    - In November 2017 there was a gap of 12.1 whole time equivalent staff when comparing the planned versus actual staffing. This included the use of 47.8 whole time equivalent bank and 17.7 whole time equivalent agency and locums.
    - For December 2017 there was a small gap of 0.7 whole time equivalent staff when comparing the planned versus actual staffing, this included the use of 55.3 whole time equivalent bank and 15.6 whole time equivalent agency and locums.
- For the medical workforce, 10 consultants had been recruited since August 2017. The trust was developing a clinical fellow programme combining clinical work with educational/research and project opportunities to help fill rota gaps and attract medical staff. This was planned to be advertised in February 2018.
- At the time of our inspection, the medical staffing establishment for the surgical division was 302.5 whole time equivalent, there were 262.5 whole time equivalent in post. The resulted in a current vacancy rate of 40.2 whole time equivalent (13.3%).
- The management of the medical workforce had improved and capacity could be identified through implementation of an electronic roster, including the management of job planning. Specialist nursing roles were being developed to offer additional support to the medical team.
- Staffing nursing vacancies were still present across the surgical division, the trust was trying to recruit to these posts. For nursing staff across surgical wards at the Royal Cornwall Hospital, there were 38.2 whole time equivalent vacancies, with the highest vacancies in the Trauma Unit and surgical admission unit/theatre direct. For theatres at Royal Cornwall Hospital, there were 1.7 whole time equivalent vacancies in theatres, 4.9 whole time equivalent vacancies in recovery and 6 whole time equivalent vacancies in anaesthetics.
- Safe staffing levels were monitored through a staffing tool. This ensured oversight of clinical areas and helped to ensure safe staffing levels. The tool was based on national criteria and local representation of what was needed. Data was inputted twice daily at 11am and before the night shift. Management staff were able to review shift management pictorially on a 'staffing wheel' which identified areas without full cover. This helped to identify where staff could be redeployed. The surgical admissions lounge and theatre direct were not included, as most patients using these areas were day cases and staffing was therefore based on statistics and the number of theatre

lists.

- The ‘surgical pool’ was introduced on the 14 March 2016 and was set up to allow for eight whole time equivalent band two healthcare assistants who were able to work both day and night shifts. This resource would be allocated to the highest areas of acuity to support extra capacity areas, or where enhanced care was required. Redeployment of staff in the surgical pool was decided using daily safe care discussions. This could include non-surgical areas in the hospital. The surgical pool had also been used to fill vacancies where staff could be transferred from the surgical pool to wards. The associate director nursing for surgical services told us they had experienced a higher turnover in wards, and were therefore recruiting to the surgical pool with planned start dates over the next two months (February and March 2018).
- A ‘winter pool’ was also in place to provide additional staffing capacity and block booking of agency staff. This enabled more consistency in the workforce. The winter pool plan, which the trust had previously stood down the week before our inspection, had been reinstated at the time of our inspection on 15 January 2018.
- Talking to staff on surgical wards and in theatres, on the whole they felt staffing was appropriate and safe, and some staff reported improvements in staffing since our inspection in July 2017. However, staff did comment on recent challenges from winter pressures, with increased numbers of patients and sickness absence amongst staff. Staff also commented how weekends differed to week days for staffing numbers on wards but the number and acuity of patients was still the same on some wards. They said this was being reviewed and addressed by the ward sister.
- Staff were aware of the escalation process to raise concerns about the staffing levels and safety concerns and were able to tell us about instances where this had been done. For example, where a patient required enhanced care this had been escalated to the site coordinator and additional staffing capacity was provided.
- On our evening visit on 15 January 2018, we noticed Pendennis ward was particularly pressurised. The ward was one healthcare assistant down, and had an increased acuity of patients (patients had additional needs) and an emergency on the ward. Patient call bells were continually ringing and the staff were unable to meet the patient demands in a timely manner. We discussed this the following day with a matron who explained they were eight healthcare assistants short across the trust and this affected their capacity to transfer staff across to help. This had been escalated to the Associate Director of Nursing and Director of Nursing to identify the difficulties of staffing. Staffing was reviewed at 7pm by the on-call manager and prioritised. On Pendennis ward, a second patient was taken particularly poorly and the ward phoned the site coordinator, and a healthcare assistant was redeployed. The matron further explained how some discussions were required to ensure, where possible, staff were reporting sickness in a timely manner.

Maternity

At our last inspection we were concerned about the safety of patients for the following reasons:

- The second obstetric operating theatre (used at times when the main obstetric operating theatre was in use, and occasionally for emergencies) did not meet minimum standards required of an operating theatre and had not been fully risk assessed so as to put the necessary controls in place to protect mothers and babies from the risk of harm.
- There were no formal arrangements to ensure there were suitable numbers of staff available to provide cover for a second obstetric operating theatre.
- Systems and processes to manage the care of women identified as needing or potentially needing high dependency (level two critical care) did not operate effectively. There were insufficient numbers of midwives with the relevant training, skills, experience or competency to care for high dependency women, and there was a lack of guidance for staff.
- There were no systems and processes to ensure that lone working community midwives were able to respond to emergency situations. The training provided to community midwives had not been adapted to reflect the complexities of working in a community setting.
- Systems and processes in maternity to identify and manage deteriorating women did not operate effectively and the use of the Modified Early Obstetric Warning System (MEOWS) was inconsistent and ineffective.

During this inspection we found:

- Theatre two was not meeting current minimum theatre standards for its air change rate, preparation space, and minimum floor area or recovery facilities. However, the trust was constrained by a building that was 50 years old, compounded by limited capacity to relocate the theatre.
- There was a risk that staff could not summon emergency help from theatre one (main maternity theatre) as there was no emergency call bell, or process to ensure staff were not alone with a patient at any time.
- There was no process to ensure community midwives had the correct equipment at all times for use in emergencies, while waiting to transfer a patient to hospital.
- Modified Early Obstetric Warning System (MEOWS) charts were not being completed accurately. The newly introduced monthly documentation audit highlighted poor compliance with record keeping in a number of key areas. We were not assured prompt actions were being taken to address the poor compliance identified by the documentation audit.
- When patients were discharged, their loose leaf papers were not always being secured to the hospital records. Some did not contain the patient name or hospital number, which increased the risk of them becoming separated or misfiled.
- A comprehensive risk assessment of the training and wider needs of community midwives when managing emergencies in the community had not been undertaken as requested.
- Reporting of delayed transfer of care from the community excluded a number of transfers and we were not assured that sufficient oversight of this process existed.
- We found that not all women booked for a home birth had home visits or risk assessments carried out or documented as required at 36 weeks of pregnancy.
- Systems and processes for managing deteriorating women had been implemented but they remained ineffective and further work was needed.
- There was no policy for women requiring level two high dependency care, and there were gaps in clinical guidance for some key conditions that may require high dependency care.
- The systems and processes for assembling a second emergency theatre team were not sufficient and had not been tested.

However,

- An external risk assessment had been undertaken and some remedial alterations in theatre two were completed. An operational group had been set up to focus on managing the risks and a strategic outline case containing options for solutions had been submitted to the board.
- There were controls to manage the key risks, as far as possible, in theatre two.
- Patients' records were mostly securely stored in lockable trolleys.
- The trust had responded to our concerns about monitoring the quality and standard of record keeping and had introduced a monthly documentation audit. This served to indicate the areas of weakness in record keeping.
- The annual training for community midwives had been adapted to cover the key emergencies they were likely to encounter when lone working, or waiting for an ambulance. There was a dedicated day-long course scheduled to cover community emergencies.
- The trust had implemented and strengthened the process for ensuring a priority response from the ambulance service for community emergencies and we saw this was being used.
- The trust had developed a policy for MEOWS and had aligned other key policies to ensure guidance for scoring MEOWS was consistent.
- There was a system to ensure high dependency (HDU) trained midwives were allocated to each shift and this was working well. Additional HDU training was planned and ongoing.

Detailed findings

Environment and equipment

- The delivery suite had a main theatre and a second back up theatre, which was a converted delivery room. This room was being used on rare occasions as an emergency theatre, but mostly it was being used for minor surgical procedures that were required to be done in a sterile theatre environment. As a delivery room it had supplementary upgrade works including the provision of an examination lamp and a pressurised ventilation regime.
- At the last inspection we had concerns about the safety of patients being operated on in this room.

There was a very small floor area, the room was very cramped, and the area for the surgical team to scrub was too close to the bed area. There was no preparation room to ensure the safe preparation of instruments which posed infection control risks. There was limited space for vital equipment, for example, resuscitaires, or emergency equipment, and there was no dedicated recovery area. When we visited during the last inspection, we found the door to theatre two propped open, and some key equipment was not present in the room. We asked to see a full risk assessment, but the trust had not carried one out. We were therefore not assured the trust was fully aware of the risks, or that it was doing all it could to minimise the risk of harm.

- In response to our warning notice, the trust took immediate action to secure a comprehensive external risk assessment. This highlighted concerns with regard to:
    - The air change rate of 18 changes per hour, which was less than stipulated for a theatre environment at 25 changes per hour.
    - Infection control as theatre instruments were being carried across a corridor due to the lack of a preparation room.
    - The environment as there was peeling paint and inappropriate ceiling tiles, and the proximity of the sink to the surgical field was insufficient to prevent the spread of infection.
    - The lack of a surgeon's control panel and a full specification theatre light, with back up in case of a power cut.
    - The room was 21 square metres, but to meet theatre standards, it should be a minimum of 50 square metres.

- During our follow up inspection, which was unannounced, we found that a number of remedial works had been carried out, and some of the concerns highlighted above, for example, lighting, had been addressed. The doors to the theatre were closed, and there was a cleaning regime in place. The trust had maximised to the best of its ability, without a total new build, the air change rate in theatre, although this was still not meeting required standards. Improvements had been made to the ventilation system as there were ongoing concerns about the risk of prolonged staff exposure to noxious gases, and further improvements were scheduled to be completed by May 2018.
- We saw the risk register (entry 6421) contained a list of risks with associated mitigation and controls. However, the trust had been severely constrained by a 50 year-old building and limited capacity to expand the theatre area or to effectively redesign the area.
- A project team had been assembled to look at the issues in theatre two, and held meetings every two weeks. We saw minutes from these meetings where the issues and concerns were discussed and actions put in place. We saw a number of those actions had been completed. For example, a strategic outline case was developed to include the various options open to the trust to bring theatre two up to the required standards. This was presented to the trust board for approval to develop a business case to consider a new build, as this was deemed to be the only feasible option in light of the limitations mentioned above. This business case was being progressed during our inspection.
- We remained concerned about the lack of a safe preparation space in theatre two, and the potential for the spread of infection as a result of this. We were also concerned about infection prevention and control due to some of the larger equipment being stored outside of the theatre in a non-theatre environment. We do, however, acknowledge that the trust is limited with what it can do within the constraints of the current building. As an additional control, the trust had improved its process for compliance with pre-operative antibiotic provision, and had implemented a system to screen all major postoperative cases carried out in theatre two for infection. We were told all emergency cases using theatre two would be audited to ensure continued learning.
- During the inspection, we followed up on a serious incident in theatre one which was the main maternity theatre. We found there was no way for staff to call for help from this theatre as there was no emergency call bell. The incident had occurred some months before, and the investigation was ongoing. However, some key staff we spoke to had not been made aware of this particular incident or risk. Although we were told a call bell was on order, the immediate risk of a repeated serious incident had not been addressed. While we were told it was rare for staff to be alone in theatre one, actions had not been taken to ensure this never happened.
- The warning notice raised concerns about how community midwives were supported to manage emergencies in the community. We asked the trust to undertake a comprehensive risk assessment to look at the wider risks associated with the community. During this inspection, we requested evidence of how equipment was managed in the community. This was to ensure community

midwives, who may be dealing with an emergency while waiting to transfer the patient to hospital, had the correct equipment. We were informed by the trust that it had developed an equipment list in December 2017, but this had not yet been audited. We were provided with a blank audit form, which was not an equipment list, and there was no process to ensure midwives had access to the correct equipment. The trust had not conducted a risk assessment with regard to what equipment was required as a minimum in an emergency, how this would be stored or maintained. There was no inventory of what equipment was in circulation and no guidance on this for community staff. We were therefore not assured that community midwives had the correct equipment to hand when required in an emergency.

Records

- During our last inspection, we were concerned about confidentiality of patient records across the trust. In maternity, we found during this inspection that all patient records were now stored confidentially and securely in lockable trolleys. However, we reviewed five sets of notes awaiting return to medical records from patients who had been discharged. Within these were loose leaf papers containing patient information that had not been secured within the notes. This meant there was a risk of some patient information becoming lost, or separated from the main records. Some of the loose leaf papers did not contain patient names or hospital numbers, which increased the risk of these becoming separated and incorrectly filed in another patient's notes.
- During our last inspection, we were concerned that there was no process for auditing documentation or ensuring the standard and quality of record keeping was maintained. Since our warning notice, the trust had implemented a monthly documentation audit, which was reported monthly to the maternity forum, which was good progress. We saw the minutes for these meetings, but aside from a high level summary in the patient safety newsletters, we were not assured that prompt actions were being taken to address the findings from these audits.
- The documentation audit presented to the Maternity Forum in December 2017 showed poor compliance against a number of key requirements. In particular, it showed that completion of Modified Early Obstetric Warning System (MEOWS) charts on admission, and following delivery were both at 60% compliance. The documentation audit for January 2018 showed a significant deterioration in MEOWS charts being completed on admission. This was down to 27% compliance, with charts being completed following delivery increasing to 73% compliance. These audits did not record any actions as to how the issues identified with MEOWS completion, or in a number of other key areas were going to be addressed.
- While we acknowledge that the MEOWS chart was a change in practice and still embedding, the documentation audits from November, December 2017, and January 2018 highlighted worrying trends in relation to accurate completion or documentation of risk assessments. An example of this related to assessments for venous thrombo-embolism (VTE), which were recorded in November as 6% compliant, in December as 8.5% compliant, and in January as 20% compliant.
- In relation to secure storage, the documentation audit for November 2017 showed that recordings taken during labour of the baby's heart rate (cardiotocographs - CTGs) were not completed or stored securely in the purpose made envelope provided in 80% of cases, and in 33% of cases during December 2017. The patient safety newsletter from December 2017 highlighted a case review where a CTG was missing, but had not communicated the poor compliance rates around storage of CTGs from the documentation audit.

Mandatory training

- During our last inspection, we raised concerns about the training provided to lone working community midwives. These had not been adapted to ensure they had the necessary skills and competency to manage emergency situations while waiting for an ambulance. We asked that a full risk assessment be undertaken to ascertain what those training needs were, including minimum requirements to be able to safely manage any emergency in the community. As evidence, we were provided with a risk register entry focusing on training midwives to insert a cannula (a plastic tube inserted with a needle to enable fluids to be given). The trust had not undertaken a full risk assessment of the wider risks as requested. Therefore, we could not be assured that the current training on offer to lone working community midwives was sufficient.
- However, the trust had made some progress. The annual practical obstetric multi-professional training (PROMPT) had been amended to include community-specific emergencies. We found that two cohorts of community midwives at the time of our inspection had been through this course,

which included input from a local paramedic. Feedback from this course was positive. More courses were booked and the training report detailed plans to ensure full attendance and follow up for non-attendance.

- The trust had also liaised with an external training company to provide a community specific training day focusing on community emergencies. This was planned for September 2018, as this was the first date available, and then four-yearly updates would be scheduled.
- We were provided with the content and programme for the annual maternity update days, which had been very well attended and received. However, we noted that these were not intended to include obstetric emergencies, and were more focused on other key learning such as screening, bereavement and blood transfusions.

Assessing and responding to patient risk

- Concerns around delayed transfer of care into an acute setting were raised as part of the warning notice. We were told by the trust that a new standard operating procedure (SOP) was in place, and we saw this was the case. The SOP gave clear guidance for midwives as to how to ensure that an ambulance was not diverted in a life-threatening situation, to another priority incident. This was recognised as a possibility as the ambulance service would know patients were being attended by a healthcare professional. We also saw that this process had been used by the community midwives. The trust told us they were monitoring any delays from the community to hospital to ensure any trends were identified and acted upon quickly.
- We were told that transfer rates and timings were being closely monitored through a monthly audit. The monthly audit findings were then pulled into an annual clinical audit report 'Maternity Community Transfers'. We saw this audit which covered the period between April 2017 and September 2017. The trust told us there had been no incidents recorded of delayed ambulance transfers in an emergency community situation since April 2017 when the community transfer audit commenced.
- However, on reviewing the audit report, we found it had excluded all cases of transfer where the patient was postnatal, all cases involving transfer of a baby, all cases where the woman was not in labour, for example, where a midwife had been called in the antenatal period. It also excluded all cases where the woman had not intended to deliver at home, including babies born early or women in premature labour. This meant that out of 58 transfers in the five month period, only 33 were considered or reviewed as part of this audit. Of those, there were four cases where transfer data had not been recorded. In another case, a call had been upgraded in urgency from a red to a purple, but it was not clear when this occurred, so the auditor was unable to ascertain how long the delay had been. A red call should be responded to within 30 minutes and a purple call within 10 minutes; in this case the time was recorded as 45 minutes. No actions had been included as part of this audit to investigate why this information had not been recorded or to improve data collection to ensure delays could be accurately monitored. We therefore did not have assurance that all cases where patients were requiring transfer into the hospital were being monitored, and we were not assured that all delays were being recorded or reported.
- Where a home birth was planned, we saw that during November 2017 and January 2018, home visits and risk assessments had not been carried out, or not documented at 36 weeks in 100% of cases. This had been highlighted in the documentation audits, but we could not track any actions that had been taken to address this risk, and these findings had not fed into the risk register entry for community related risks.
- We were concerned about community midwives managing emergencies in the community. The trust told us it would develop and ratify a Patient Group Direction (PGD) for the Misoprostol (a drug used to control postnatal bleeding) for use in the community by December 2017. When we visited in January 2018, this had not been ratified or rolled out. We were informed that there were no plans to consider developing or rolling out training for the community midwives on use of this drug until the PGD had been ratified. This meant that the trust had not met its own stated target for implementing this safety measure. There was no clear understanding at the time of our inspection as to how this drug would be safely and securely stored for community use or access.
- We were concerned at the last inspection about the lack of community specific guidance for managing emergencies; the trust had reviewed three key obstetric emergency policies to include reference to the community and had developed a policy for managing babies born before arrival at hospital.
- During our last inspection we found that systems and processes in maternity to identify and

manage deteriorating women did not operate effectively and the use of the Modified Early Obstetric Warning System (MEOWS) was inconsistent and ineffective. We found that the trust had made some progress; a policy had been developed and ratified for the use of MEOWS. A new MEOWS chart had been developed and we saw this in use. There had been some delay in implementing this due to problems with an external printing agency and the completed form arrived the week before our inspection.

- We reviewed a total of 20 patient records; 19 had MEOWS charts. Of these, only one MEOWS chart had been fully and accurately completed and escalated according to the guidance. In nine cases, MEOWS charts had not been fully completed and some parameters had not been recorded, for example, respirations or temperature. This meant that the scores entered were not correctly calculated. A further five MEOWS charts, where escalation was indicated, did not have the required actions documented so it was not clear if escalation had occurred. Three charts had a score over four, which in line with the sepsis policy meant those women should have been screened for sepsis; however we could not see that this had been done. Six MEOWS charts indicating increased frequency of observations had not been completed within the expected timescales.
- The new guidance stipulated that any patient scoring three in any one parameter, or five or above in total, should have urgent assessment by a clinician with core competencies to assess acutely ill patients. It was not clear to staff we spoke with if this meant an obstetrician or a midwife. There were no minimum timescales set out for this review, and therefore it was difficult to monitor or measure. Some staff said this would be immediate whereas others said it could be within an hour. This was further confused by the timescale set for patients scoring over seven, who required "emergency assessment by a clinical team", and the instruction to inform outreach if this review had not taken place within 30 minutes.
- We were provided with a document called 'maternal level 2 critical care', which stated that level two care was indicated if the MEOWS score was eight or over, but this was not included on the MEOWS chart or in the guidance.
- Some staff we spoke with did not think that all parameters were necessary for all women, for example, oxygen saturations, and therefore had not been completing the charts fully. Of those staff we spoke with, training had not been provided on how to complete or escalate the MEOWS scores.
- During our last inspection, we raised concerns about the lack of policy for women requiring level two high dependency care (HDU), and the lack of other guidance or integrated care pathways for some key conditions to pre-emptively manage deteriorating women. During this inspection, we were told that an HDU policy had not yet been developed but there were plans to do so. We were told there were no integrated care pathways for a number of conditions where women may require HDU care. It was acknowledged by senior managers that there remained gaps in clinical guidance. For example, this included management of thromboembolic disease, thrombocytopenia, placenta praevia and suspected placenta accreta or epilepsy. We were therefore not assured that staff had sufficient clinical guidance for managing HDU patients, or that minimum clinical standards had been set that were capable of being monitored for best practice.

Staffing

- We raised concerns at the last inspection about the lack of HDU trained staff on the delivery suite which posed a risk to mothers requiring high dependency care. As a result of the warning notice, the trust had made very good progress in ensuring that there was adequate cover across all shifts. We saw that the staff rota now indicated who was trained on which shift, and advanced planning factored the need for a member of staff with HDU training to be allocated on duty at all times. This was working well with the majority of shifts fully covered. Staff we spoke to said this had been a positive change, and even though it had meant some staff working extra shifts to cover and more inflexibility in them being able to swap shifts, they knew this was a short term measure and were keen to ensure this continued until more staff were trained.
- The trust had allocated a number of midwives to attend further HDU training, and we saw evidence that midwives had enrolled on this course. Following concerns raised by midwives that the course needed more obstetric input, the trust had proactively taken steps to liaise with the course provider and adapt the training to ensure the midwives got the training they required. In addition, the trust had planned to include a half day annual update for HDU skills for those midwives who had undertaken the HDU training.
- During the last inspection we raised concerns about the lack of a dedicated second theatre team and the risk of potential delays in an emergency situation. Following the warning notice, the trust

developed a standard operating procedure (SOP) and added this as a risk to the risk register. However, the SOP was a list of which staff should be contacted in the case of second theatre team being needed. This meant that no actual change in practice had been implemented. No roles or responsibilities were allocated, and staff we asked said the delivery suite coordinator would be responsible for making the calls. This did not serve to reduce any potential delay in contacting or assembling a second theatre team. In addition, we were told that the delivery coordinator was not always surplus to staffing numbers, and we saw that on four occasions during December 2017, the delivery suite coordinator had not been surplus to staffing numbers as would be usual, so may not have been available to make those calls.

- The SOP set out a requirement to have a second team assembled within 10 minutes for a category one caesarean section. Staff did not feel this was realistic given there was not a fast bleep system set up, or an allocated rota for a second team. Staff would often have to come across from the main site, or in some cases from home, if a second obstetric anaesthetist was required out of hours. The SOP had not been tested and no testing had been undertaken to see if it would work in practice. Staff told us as it was so rare for a second theatre to be needed in an emergency situation, it was not necessary to test the process. We were therefore, not assured there was sufficient appreciation of the need to be practiced for potential life threatening situations, particularly when they did not occur frequently.
- The SOP did not cover obtaining all staff required for a second emergency team. It did not mention recovery nurses, and there was no process for allocating additional scrub nurses or theatre runners. Staff told us they would try to pull additional staff from main theatres, or midwives and midwifery assistants from the wards. In an emergency situation this would add to any potential delay as there was no process for pre-allocating a second on call team. We asked for evidence that all staff working in maternity theatres had undertaken training to do so and were appropriately skilled. We were provided with a blank template for theatre competencies, and the trust told us it did not have a record of which staff had completed this competency, and which had not. We were told that staff on the wards did not routinely complete this competency, and that staff being pulled from the wards to assist were expected to say so if they did not feel competent. This did not assure us there was an adequate or monitored system in place to staff a second theatre safely at all times.
- We saw the lack of a second theatre team had been added to the risk register (entry 6421). This initially had a high score of eight, but following production of the SOP, this had been reduced to four. One of the stated risks was “recovery staff will not be adequately supported to recover patients due to only one recovery nurse available which could lead to post anaesthetic problems and harm the patient.” Mitigation for this was stated as “there would always be a second nurse/midwife to support the recovery nurse.” However, as stated above, this process has not been included in the SOP, and there was no evidence that this had been formally agreed with the main theatre team.
- We requested the full risk assessment for lone working in the community. We were provided with an entry on the risk register (entry 5673) with a high residual score of six. However, no risks were detailed or described on the entry. The controls in place were listed as “lone worker policy, ability to call 999 for back up and the provision of mobile phones to all community midwives.” We were not assured that all risks had been considered or fully mitigated.

Services for children and young people:

At our last inspection in July 2017 we were concerned about the safety of children and young people for the following reasons:

- There were insufficient numbers of suitably qualified nursing staff in the paediatric area of the emergency department (ED) to provide safe care at all times.
- There were no formal processes to ensure appropriate cover was in place in the department at all times, particularly during periods when the qualified nurse was temporarily absent from the department.
- There were not always sufficient numbers of staff with the skills, knowledge and experience to meet patients’ needs. There were no formal or long-term systems and processes to ensure there were sufficient numbers of registered nurses (Child Branch) deployed to meet the needs of children and young people in the emergency department at all times.

During this inspection we found:

- There was appropriate and sufficient staffing cover arrangements in the paediatric area of the ED, and we were satisfied there were systems and processes to ensure this cover at all times. We found the requirements in the warning notice had been met.

Detailed findings:

Assessing and responding to patient risk

- Further to the Section 29A Warning Notice there were a number of areas where we required evidence that the trust was taking immediate action to be assured that any risks were being identified and managed in the interim, and before the improvement as required in the warning notice had been completed. These actions included a risk assessment for paediatric staffing in the paediatric area of the emergency department (ED) and evidence that there were two paediatric trained staff on duty at all times.
- The trust had completed and evaluated patient risk assessments. We saw the risk entry relating to the paediatric staffing within the medicine division's risk register and the two comprehensive operational risk assessments. The first was based on the staffing model in place at the time of the July 2017, inspection and the second was based on the model implemented on 10 August 2017.
- Based on these risk assessments the trust took immediate action to staff the paediatric area of the ED with two appropriately trained nurses at all times day and night and had continued to do so.

Nursing staffing

- There were adequate nursing staff levels to safely meet the needs of children and young people at all times in the paediatric area of the ED.
- There was a standard operating procedure (SOP) which outlined the process for managing the rota, roles and responsibilities of staff. This included when transferring patients onto wards and the specific escalation process when the area was crowded. This SOP was ratified at the ED clinical governance meeting on 6 September 2017, although implementation was commenced in August through safety briefings, team meetings and email communications in order to raise awareness and ensure compliance.
- We saw the standards and practice for safe staffing levels, which stated there were to be two trained nurses within the paediatric area of the ED, with at least one nurse throughout the 24 hour period who held a paediatric qualification.
- There was a substantive team of qualified children's nurses led by a band seven nurse solely based within the paediatric area. Additional recruitment was required to sustain the rota and there were plans to recruit 5.4 whole time equivalent (WTE) paediatric nurses to increase staffing levels. One of these was planned to be a rotational post between the paediatric area of the ED and the paediatric division. Recruitment was ongoing at the time of our inspection and 1.8 WTE additional staff were in post with a further 0.8 WTE recruited. Until recruitment was completed, the second trained nurse would either be a qualified children's nurse, or a registered nurse with enhanced paediatric training / skills. These included paediatric life support, safeguarding children level three, and education on recognising the sick child as laid out in the Royal College of Nursing standards.
- From the rotas for the period from 10 August 2017 to the week of the inspection (week commencing 15 January 2018), we saw evidence that there were plans for two paediatric trained staff to be on duty at all times. The rotas showed the level of training / experience of the registered nurses on the rota in order to ensure that all staff at all times were clear on the staffing of that dedicated area. In addition, there was a table indicating the qualifications, training and experience of each named nurse in relation to paediatrics.
- Data from the rotas for the period from August to October 2017, showed the rate of compliance achieved with two registered children's nurses was 33% for August, 58% for September and 90% for October. Compliance achieved with two nurses (one registered children's nurse and one registered nurse with paediatric life support and safeguarding children level three competencies or paediatric experience) was 65% for August, 40% for September and 10% October. This data demonstrated that as the two registered children's nurse levels were increasing, the one registered children's nurse levels were decreasing as would be expected. We were, therefore, assured that progress was being made in ensuring that there would be two registered children's nurses on duty in the paediatric area of the ED.

- Paediatrics was identified separately on the ED rota to ensure all shifts were planned and covered by appropriately qualified nurses. There was a process for managing the nursing staff roster in the paediatric area. The lead nurse compiled the roster ensuring every shift had a registered children's nurse on duty as a minimum. Where shifts could not be covered by two registered children's nurses a registered nurse with enhanced paediatric skills was appointed. Any future gaps would be filled with appropriately trained staff from child health, bank staff, the block booking of agency nurses and overtime shifts.
- Every morning the ED matron and the paediatric matron (child health division) jointly looked at the next 72-hours cover for the paediatric area in order to assure themselves that there was safe staffing compliant with national standards. If this standard was not met at any time, the incident was reported on the electronic reporting system and was escalated to the associate director of nursing within the medicine division to investigate.
- During the evening of 15 January 2018, we visited the paediatric area in ED and found that the shift was not staffed with two paediatric trained nurses due to staff absence. At this time one nurse was supported by a health care assistant. Staff assured us that this situation rarely occurred and this was supported by evidence contained in the rotas referred to above. This was reported as an incident and a risk assessment had been completed where additional controls were recorded. These included informing the band seven nurse shift coordinator who monitored the acuity and dependency of patients in the paediatric area and. With assistance from the clinical site team, they moved staff from other areas with additional paediatric skills. The situation had also been escalated to the on-call manager.
- Training was planned and booked to ensure that by December 2018, all band seven nurses would be trained in advanced paediatric life support; all paediatric band fives and sixes would be trained in paediatric life support; and a nominated selection of adult band fives would be trained in paediatric life support.
- All seriously unwell children would be cared for in the resuscitation department by a registered children's nurse until the Paediatric Emergency Response Team (PERT) arrived to care for the child.
- There was an escalation procedure for children likely to be admitted. At times when the paediatric area had a surge of patients, or when the time to be seen was greater than three hours and the patients were likely to be admitted to the paediatric unit, patients would be discussed with the paediatric registrar on call to discuss the possibility of transferring the patient to the paediatric observation unit to be assessed. A paediatric consultant was available on a hotline between the times of 9:30am to 9pm Monday to Friday and on call outside of these hours to discuss overcrowding and long waiting times in the department.
- Paediatric patients needing admission were transferred by a nurse or health care assistant who had the skills and training appropriate to the patient's condition. There was a paediatric transfer guideline contained in the standard operating procedure which outlined the instructions to ensure the safe and timely transfer to the paediatric wards.
- For short periods of time, for example, during breaks, or when one nurse needed to leave the paediatric area to collect equipment or to make use of other clinical areas within ED, one appropriately trained nurse was present in the paediatric area. The absence was communicated to the nurse in charge of the ED department and only occurred when activity allowed.
- In the event of the paediatric area of the ED being overcrowded, for example, when all four trolleys were occupied due to clinical need, and / or waiting time was at capacity, there were a number of actions to be taken. There were outlined in the ED paediatric area crowding action card. Actions included reviewing staffing and assessing if resources could be allocated to support the paediatric area. Also escalation to the ED matron and the divisional nurse in hours to obtain support from other areas, and out of hours via the site coordinator and the duty manager.
- Actions also included ensuring the room set aside for breastfeeding women was available as a back-up for assessment of ambulatory patients and senior assessment of waiting children. Parents were kept aware of the situation and patient information leaflets were distributed to inform parents of the waiting time in the paediatric area. All actions were recorded in patients' records.
- At the last inspection, we found that not all areas had access to a call bell. During this inspection we saw there were call bells and emergency call bells in each of the rooms, toilets and play area which could be heard outside of the paediatric department. There was also an intercom at the nurses' station which could be heard throughout ED and could be used to call for assistance.
- Managers advised us that activity in the paediatric area between 10pm and 8am was being

monitored. A sustainable long-term plan was being developed with the paediatric service to maximise the use of staff and resources whilst maintaining patient safety.

Outpatients and diagnostic imaging:

At our last inspection in July 2017 we were concerned about the safety of outpatient services for the following reasons:

- The fracture clinic waiting room was not of sufficient size to accommodate patients who needed to elevate limbs safely or comfortably. Children were at risk because they were not able to wait in a separate waiting room away from other adults. This was a safeguarding concern.

During this inspection we found:

- 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 that 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 that children were booked separately to adults although we found processes around this were not being followed.

Detailed findings:

Infection prevention and control

- In June 2017, we found that the environment in the fracture clinic did not promote cleanliness, infection control and hygiene. Issues included armchairs needing replacement and there were issues with air flow and high temperatures. During this inspection we found that no changes had been made to the environment and the risks to infection prevention and control remained.

Environment and equipment

- In July 2017, we found that the environment of the fracture clinic did not always keep people safe. During that inspection we found that patients who had to keep a leg elevated due to the nature of their fracture were at risk of having their leg knocked into because there was no provision to protect them. During this inspection we found that there was no change to the waiting area and the risks remained.
- The 'quality improvement plan' for the fracture clinic stated that new seating had been designed and ordered in October 2017 for delivery in December 2017. Staff we spoke with in the fracture clinic stated that the new chairs had only just been ordered in the last week of December. There was also no indication within the 'quality improvement plan' that air flow had been considered as a risk requiring improvement.
- A business case was produced in November 2017 to potentially relocate the fracture clinic to another part of the hospital site which was being developed and managed by the estates team and the service lead.

Safeguarding

- In June 2017, we found that the design of the fracture clinic did not always keep people safe. We found that there was no separate waiting area for children. During this inspection we found that although a waiting area for children (with toys and games) was placed at the far end of the waiting room, it was not screened off from adults. This meant the risks to safeguarding children remained.
- Processes had been introduced since the last inspection to book children into the first hour of the clinic to separate them from adult patients. However, we found this was not being followed. We found that during the first hour of the clinic there were four children and ten adults booked. We spoke with a member of staff who said that although they knew about the process they would book children into any available slot.
- The 'quality improvement plan' for the fracture clinic said that patient and carer feedback would be collected to ensure that the designed processes were meeting patients' needs. We spoke with staff

in the fracture clinic who said that this was not happening and that the only feedback collected was through the volunteers called 'friends of the hospital' who came to the clinic once a month.
- The 'quality improvement plan' also stated that screens to separate the children's and adults area would be in place by November 2017. However, we found no screens in place.

Assessing and responding to patient risk

- In July 2017, we found that processes to assess and respond to patient risk did not ensure patients were kept safe, particularly in the management of patients on waiting lists and backlogs of delayed patients. During this inspection we found this greatly improved.
- At the last inspection we found approximately 150 echo and cardiac event recordings were in a backlog waiting to be reviewed by a consultant. During this inspection we found that there was no backlog of recording tapes and the backlog had been addressed. Additional doctor time had been allocated to ensure that tapes were reviewed in a timely way. We found that most tapes were reviewed within four weeks which was better than the national target of six weeks. A system of outsourcing to an external provided for all tapes waiting over four weeks acted as a failsafe to ensure all tapes were reviewed in a timely way. In the last month, only four tapes had gone to an external provider as all others had been reviewed within the four-week timeframe.
- All cardiology patients were risk assessed based on an improved risk assessment process. We found that all patients when referred to the service were routinely assessed to identify risks and to potentially identify alternative clinical pathways. All patients who went over their 'to be seen' date were reviewed on a monthly basis to identify alternative pathways or to book an appointment.
- In July 2017, we found that there was insufficient assurance in ophthalmology to monitor the ongoing risks of patients waiting for an appointment. During this inspection we found that all patients had been risk assessed against a standard operating procedure to identify who was at highest risk of harm. Since the last inspection there had been two serious incidents relating to ophthalmology, neither of which were as a result of waiting too long for an appointment.

Are services at this trust responsive?

Inspected not rated

We inspected responsive in surgery, critical care and outpatients. We found the requirements of the warning notice had not been fully met.

Surgery:

At our last inspection we were concerned about the responsiveness of the service for the following reasons:

- Surgery services were not meeting the incomplete pathway referral to treatment times for all of the surgical specialties.
- Improvements were required in access to surgery for emergency patients. Emergency surgery was sometimes delayed unnecessarily.
- Twelve patients with cancer had their operation cancelled from January to September 2017.

During this inspection we found:

- The trust had a recovery plan for referral to treatment time performance improvement. Funding had been agreed to provide additional consultant resource. However, the trust performance for 18 weeks referral to treatment time was still well below the national targets and waits for patients had increased and were expected to continue to increase for the remainder of the financial year.
- The patients waiting more than 52 weeks for surgery were increasing from August 2017 to January 2018, however they were projected to decrease in February 2018 and be at zero in March 2018. These patients were being assessed for clinical risk and prioritisation.
- There was a clear real time oversight of emergency patients and patients were prioritised by risk assessing each person on the list. This was still being embedded to ensure data was accurately captured.
- Additional capacity for emergency patients had been implemented.

- Data for emergency patients being seen in surgery was captured and analysed to identify if there was capability for service improvement. For example where patients were incorrectly prioritised the Trust had identified the need for education to staff to ensure prioritisation is accurate.
- Cancellations were being monitored daily and cross-referenced with the cancer pathway. However, the trust were still experiencing cancellations of cancer patients, particularly at the time of winter pressures impacting on bed availability.

Detailed findings

Access and flow

- Previously surgery services were not meeting the incomplete pathway referral to treatment times for all of the surgical specialties. At the time of this inspection this was still not being met.
- The trust completed a referral to treatment time recovery plan. A trajectory showed continued decline on referral to treatment time performance until additional consultants were employed. Funding had been agreed for additional the consultants to include the specialties of general surgery, trauma and orthopaedics, oral surgery and urology. Start dates were variable from the end of 2017 to early 2018. The trust expected this to enable additional clinics and an increase in surgical procedures to reduce waiting times. The trust was reviewing performance and noting key actions required and exception reporting (gaps in service). The exception reporting mainly related to consultant resource, for example consultant sickness, maternity or locum availability.
- The trust were prioritising patients waiting longer than 52 weeks. Harm review panels were taking place to assess harm for all specialities with long referral to treatment time delays.
- We reviewed data for August, September and October 2017 and projected from November 2017 to March 2018, for referral to treatment time for admitted patients breaching 18 weeks backlog. This showed waiting times for routine patients had or would increase. This was because available capacity was being focused on urgent and high risk patients. The pattern was expected to continue until the end of March 2018. The non-admitted backlog showed a similar performance.
- Data for referral to treatment time for performance for incomplete pathways across the specialities showed the trust were continuing to not meet the national 92% target. For August 2017, the trust performance was at 88.3% and this was declining through to October 2017 at 85.2%. It was projected to continue to decline through to March 2018. Trauma and orthopaedics, vascular, cardiology, dermatology and neurology had some of the longest waiting times or projected waiting times.
- Data for the number of patients waiting 52 weeks was also projected to increase until January 2018. However, it was then projected to decrease in February 2018, in line with additional consultants being appointed and additional clinic time, and be at zero for March 2018. The projections for October and November 2017 had been accurate at the time of our inspection, and data showed there were 88 patients waiting in both December and January with a projection of 42 patients for February. The patients who were waiting for more than 52 weeks were being assessed for clinical risk and prioritisation in theatre scheduling meetings.
- In our previous inspection improvements were required in access to surgery for emergency patients. Emergency surgery was sometimes delayed unnecessarily.
- Patients booked for emergency surgery were already being assigned a clinical priority to define waiting times, which was implemented in April 2017. In October 2017, the trust used the electronic whiteboard to rate (red, amber, and green) patient waiting times for the emergency theatre. During this inspection the electronic whiteboard was visible in theatres to see emergency patients in real time and their waits. We were told there was work and education needed to ensure clinicians were adding accurate prioritisation of patients to ensure the validity of data.
- With staff being able to visually see the electronic white boards they were encouraged, particularly the theatre leads, to pull across from the emergency list if they had capacity in their theatre or if there was a priority emergency case for the team's speciality. We saw this happen during our inspection where a vascular surgeon saw an emergency patient during another surgeon's list.
- The electronic whiteboards were also being used to communicate to theatre any immediate action information. For example, if there was an emergency situation or any immediate learning from an incident which had occurred.
- The trust recognised the need to create extra emergency theatre capacity. As a result a full day (8.5 hours) emergency theatre list was run every Friday in one theatre since 24 November 2017.

- An emergency list multidisciplinary team meeting was held every morning, to which all specialities were invited. This was led by the anaesthetist and the team present would assess the priority for patients based on risk.
- We reviewed emergency theatre data for November and December 2017. For December 2017, the average waiting times for patients were all within targets specified at booking. For November 2017, the average waiting times for immediate (within one hour) and urgent operations (within three hours) were outside of the target time specified at booking. Exception reporting was completed for all cases which did not achieve the target wait times, on review these appeared appropriate. For example, in November, of the seven immediate cases, two were delayed. One because specialist equipment was required and not available immediately at the time the case was listed, and one was an incorrect listing. For 19 urgent cases in November, six were delayed due to other patients taking priority, the previous patient taking longer than anticipated in surgery, a patient being surgically unfit. There was also an incorrect listing which was not an emergency patient.
- Going forward, once new systems were embedded the trust aimed for emergency patient wait times and breaches to be monitored, reported and governed by the theatre operational group. Key performance indicators had been agreed to enable monthly monitoring.
- A theatre scheduling meeting was held weekly, reviewing the rota electronic system in real time for sessions up to six weeks in advance. For example, this live document could show changes to specialities, where surgeons were not available, open sessions, sessions without an anaesthetist and cancelled sessions. Endoscopy and imaging were also in attendance at the theatre scheduling meeting.
- A theatre scheduling policy was currently in draft form waiting to be ratified at the divisional board. Staff told us the processes in this policy were mostly being followed already prior to the July inspection. However, there was no formal document. One significant improvement to the process and included within the policy, would be to release the anaesthetic rota four weeks prior to the list.
- All theatre lists on the electronic system were 'locked' 48 hours prior to the list, with the exception of the emergency pool. This meant they were agreed and should not be changed. This was done to encourage communication between bookers and the theatre team at short notice. The new theatre scheduling policy detailed that operating theatre sessions would be locked to prevent short notice changes one week prior to the day of the surgery, to provide assurance any adjustments were communicated and agreed.
- Our previous inspection noted twelve patients with cancer had their operation cancelled from January to September 2017, with six on the day of their booked operation. The trust investigated the 12 patients cancelled and identified reasons for cancellation. This included no high dependency unit or bed cancellations, other patients taking priority, surgeon sickness, requirement of additional specialist resources and administration errors. The trust planned to monitor cancellation data monthly including undertaking a root cause analysis. The critical care improvement plan and theatre scheduling policy were hoping to reduce these cancellations. However, data did not show any improvements in critical care at the time of our inspection.
- Operation cancellations were being monitored daily and these were being cross-referenced with the cancer pathway. The cancellations were being reviewed for trends and themes. The trust were aiming to reduce the number of cancellations occurring on the day of planned surgery by reviewing the following day's list and cancelling any patients so they were aware the day before. This had been particularly important over the last month with the winter pressures experienced at the trust.
- The trust had seen improvements in the number of cancer patients being cancelled for their surgery, however in late November 2017 and January 2018, this had increased due to the winter pressures the trust was facing. Between 1 October 2017 to 17 January 2018, there had been six cancellations of surgery for patients with cancer. The reasons included: two due to no ward bed available, one due to no high dependency unit bed available, one due to equipment not available, one due to consultant on sick leave, and one due to insufficient time to complete the procedure. Three out of the six had been cancelled on the day of the surgery. All patients were treated at a later date, on average across the six cases this was 19 days later.

Critical care:

At our last inspection in July 2017 we were concerned about the responsiveness of critical care services for the following reasons:

- There were high levels of delayed and out of hours patient discharges from the critical care unit

which were worse than the national average. There were also high occupancy rates above recommended levels and national averages. These concerns were raised in our inspection in January 2016 and despite action plans having been completed since the inspections in January 2016 and January 2017, the actions taken had not resolved the issues or mitigated the associated risks.

During this inspection we found:

The discharge of patients from the critical care unit had improved and was more timely when beds became available. The unit could provide evidence that it was consistently being responsive to patients' needs by discharging them to a medical bed as soon as the bed became available. Processes, such as pre-emptive flow meetings and discharge pro-formas were embedded within the unit.

However,

- Many patients were still being delayed for long periods of time when becoming medically fit for transfer due to a lack of side rooms on wards, understaffing on wards or a lack of available beds.
- Half of discharges overnight were as a result of patient beds not being available on wards. Other overnight discharges were as a result of other acute trust repatriations of patients, and changes in clinical decisions affecting timely patient discharge.
- Bed occupancy of the critical care unit remained high and had only slightly improved since the last inspection. Occupancy rates had reduced from 95% to 90%. However, were still higher than the recommended levels as stated by the Royal College of Anaesthetists.

Detailed findings:

Access and flow

- During the inspection in July 2017, there were a high number of delayed discharges. We found during this inspection that the number of delayed discharges had not improved.
    - Between January and June 2017, there was an average of 82 delayed discharges per month, with 60 being greater than four hours and 22 being greater than 24 hours.
    - Between July 2017 and December 2017, there was an average of 82 delayed discharges per month, with 62 per month being greater than four hours and 20 being greater than 24 hours.
- Many of these delayed discharges were attributable to wider hospital flow rather than the responsiveness of critical care. For example, between 13 November 2017 and 14 January 2018, only six patients had transfers delayed longer than an hour once a ward bed became available. Delays in discharge were raised with the trust as a requirement notice in January 2017 within the medicine report. All of these occasions within critical care were investigated and themes were identified to improve this further.
- Of the patients delayed over 24 hours between 13 November 2017 and 14 January 2018, 19 were delayed due to lack of side rooms on wards, staffing availability on wards, or specialist beds. Of these patients, 13 were due to lack of beds on wards and the remaining was due to repatriation to other specialist units. The unit was in regular communication with bed managers and the chief operating officer to report when this occurred.
- Staff in critical care met at 5pm every evening to plan upcoming patient discharges in advance. Managers told inspectors there was an increased support from consultants to improve discharge timeliness and forward planning with wards to ensure discharges happened. Staff were using a 'transfer aid memoir' which was used to start the discharge process as soon as a patient became well enough to be transferred. These processes were ongoing throughout the last inspection but were embedded and working more effectively during this inspection.
- Staff attended bed meetings to get exposure to the hospital wide flow challenges and to put into perspective their contribution to effective patient flow. This was an improvement since the last inspection.
- During the inspection in July 2017, there were a high number of discharges overnight. We found during this inspection that the number of discharges overnight had reduced slightly.
    - In the first six months of 2017, an average of 13 patients were discharged per month between 10pm and 5am.

    - In the second six months of 2017, an average of 11 patients were discharged per month between 10pm and 5am.
- Many of these overnight discharges were attributable to factors outside the control of critical care. Delays in discharge were raised with the trust as a requirement notice in January 2017 within the medicine report. Between 23 October 2017 and 31 December 2017, there were 17 discharges overnight. Of these discharges four were due to repatriation to paediatric specialist units, four were due to a change in clinical decisions delaying discharge and the others were due to delays in beds being available.
- During the inspection in July 2017, bed occupancy was found to be high. It averaged 95% in 2016, which was significantly higher (worse than) than the 70% as recommended by the Royal College of Anaesthetists. In 2017, overall occupancy had reduced to 90% but was still higher than recommended.
- Inspectors were told about a business case to extend the size of the critical care unit to 17 beds which would improve capacity. However, this plan had been submitted in June 2016 and limited progress had been made since the last CQC inspection.

Outpatients and diagnostic imaging:

At our last inspection in July 2017 we were concerned about the responsiveness of outpatient services for the following reasons:

- The systems and processes for monitoring and managing non-admitted cardiology and ophthalmology patients were not effective. There were increasing waiting lists and patient demand. There was evidence of harm to patients on the waiting list.
- There was no assurance that the specialist lead, or senior management had sufficient oversight or that there were effective systems to mitigate or address the risks of potential loss of sight to patients waiting for appointments or treatment.
- There was a reporting backlog for 24 hour cardiac recording tapes and echocardiograms for approximately 150 patients, with no effective system to address this backlog.

During this inspection we found:

- Risks to cardiac and ophthalmology patients waiting for appointments were being appropriately assessed and managed according to clinical need. All patients were risk assessed routinely if they were waiting longer than expected for an appointment.
- During this inspection we found an effective process for the management of echo and cardiac event recordings. Additional time was available to reduce further risks. If demand became unmanageable there was a contract with an external organisation who provided support.
- Backlogs in both ophthalmology and cardiology had reduced and there were plans to ensure that management of backlogs was sustainable.

Detailed findings:

Access and flow

- In July 2017, we found there were large numbers of new and follow up patients waiting longer past their 'to be seen dates' in cardiology. During this inspection we found waiting times had improved, due to better processes and the recruitment of three additional consultant cardiologists. Cardiology patients waiting more than 18 weeks for their first appointment had reduced from 140 in July 2017 to just one in December 2017 (attributed by the trust to the patient's choice). Cardiology follow-up patients waiting past their 'to be seen' dates had also reduced from 650 in April 2017, to 400 in December 2017 with a continuing improving trajectory.
- In July 2017, we found there were large numbers of ophthalmology patients waiting for treatment. There had been a review of the service for glaucoma and wet age-related macular degeneration (WARM) to identify if pathways could be shortened to reduce waiting times.
- With regards to WARM patients, additional staffing and a consistent six-day service had been introduced to manage the demand. In June 2017, there were 225 patients awaiting WARM treatment, but in December we found no patients waiting past their referral date for treatment.
- Two additional doctors had been appointed to manage glaucoma patients and additional time had

been built into job plans to reduce the backlog. This had an impact on reducing the size of the backlog. In June 2017 the backlog was 235 patients and had reduced to 157 patients. Also, the average waiting times for patients had come down from 12 weeks in July 2017 to nine weeks in December 2017.

- However, the trust had identified that the backlog was not being managed quickly enough. It was identified that 80 additional 'virtual clinics' were needed per week to manage the demand. This was due to begin a month following this inspection through a contract with a third-party.

Are services at this trust well-led?

Inspected but not rated

We inspected well led at trust wide level in relation to the specific concerns we highlighted in the warning notice. We found progress had been made in some areas, but we judged the requirements in the warning notice had not been fully met.

At our last inspection we had some concerns within the well-led domain:

- Governance systems and processes were not operating effectively.
- Systems and processes to manage confidentiality were not operating effectively.
- Systems and processes to ensure the 'Being Open Policy' which includes guidance for staff on how to respond when duty of candour was triggered were not operating effectively.
- Systems and processes to address poor behaviour, grievances and performance management related issues were not operating effectively.

During this inspection we found:

- Governance systems and processes for the management of incidents were still not operating effectively and there were concerns around sustainability (see section on incident management under surgery above).
- The trust was still failing to comply with the requirements for duty of candour.

However:

- Overall, patient records and confidential information was being held securely, and were mostly held in locked patient record trolleys.
- The trust had made progress with the investigation of grievance cases. Although they had not yet met the trust target, they were showing improvement where the time to complete investigations was reducing.
- Polices were updated to reflect changes to improve the systems and processes for recording, monitoring and risk assessing cases. The changes were still being embedded.

Detailed findings

Governance, risk management and quality measurement

Duty of Candour

- The trust was failing to comply with the requirements of the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- We reviewed five serious incident investigations and the associated patient records and letters. We found no evidence that duty of candour had been met in three of these, and the trust was unable to provide any evidence of this. The other two did not appear to meet the thresholds required for duty of candour to be implemented. Although there was some evidence of conversations taking place with patients and or relevant persons, these did not include an apology or honest explanation of what had happened.
- The trust did not have a suitable process for recording duty of candour. We were told duty of candour conversations were recorded in patient notes, and follow-up letters were stored locally, usually within the patient's notes. This process did not provide the trust with any assurance that duty of candour was being complied with and no audits of care records had been completed to

confirm duty of candour had been implemented following moderate harm or serious incidents. We were told the trust's electronic incident reporting system had been upgraded to include a mandatory field about duty of candour and a facility to upload the initial letter to the patient or relevant person. The clinical lead for serious incidents told us this was live on the system, but when we went through the live system in the emergency department we found the field was not available. We were told by one staff member that the field had previously been there, but following the most recent upgrade it had disappeared.

- We asked the trust to provide us with any duty of candour letters uploaded to the electronic system since it had been upgraded. The trust responded to advise that only one incident had been reported with the duty of candour field being marked as complete; however, this incident did not have a letter uploaded.
- In two of the three 72-hour reports where moderate or serious harm had been identified, under the duty of candour section there were comments that the patient or the family had not been informed of the incident because it would have caused them further distress. This failed to meet the requirements of the duty of candour and gave us significant concerns about the trust's desire to have a truly open and honest culture.
- A new information pack had been introduced to help investigating officers complete their investigations. The pack was relatively new, but had been rolled out to staff. The pack contained information about duty of candour, including what was required to be done, how this should be recorded and what timescales applied. However, the supporting standard operating procedure gave a target of 80% for compliance with duty of candour. We asked the interim manager why 80% had been set as a target, given the duty of candour is a regulatory requirement and therefore requires 100% compliance. They were unable to articulate clearly the reasons for the lower target, but suggested it might have been an initial target to work towards once the evidence was being captured effectively on the incident reporting system. We were therefore not assured the trust had a clear understanding of the regulation and plan to meet the requirements 100% of the time.

Confidentiality

- During previous inspections we identified there were not effective processes to ensure confidentiality was maintained, as records were not held securely at all times.
- Systems and processes were now in place to ensure confidentiality was maintained at all times. Locked trolleys for the storage of patient current medical records were available on all wards and the policy to monitor information and records was reviewed, updated and disseminated.
- There was an increased awareness of the correct storage of patient records and this was seen as a priority for managers and staff. An instruction had been issued by the chief nurse, deputy medical director and chief operating officer to all staff reminding them of their responsibility to adhere to the correct storage and advising of potential disciplinary proceedings that may occur if this was not followed. A newsletter had also been issued to staff to advise them of wider confidentially issues and correct information governance procedures. Posters had been placed in each clinical area to remind staff to store patient records safely. Safe storage of medical records was included as part of the 'hot topic series' and we saw this was included on the screensavers of the televisions situated on the wards.
- Matrons included storage of medical records as part of their weekly checks and there was also monthly auditing in clinical areas.
- During our inspection and walk around on surgical wards we found records were mostly held securely and locked trolleys were in use. However, we did find a few instances where records were not fully secure. On Pendennis ward a cupboard containing patients' notes had been left unlocked and patient notes were also found on a shelf in a staff office where the door was left unlocked. In Wheal Coates ward patient's notes were left out on the nursing desk and the discharge notes drawer was left unlocked. Our visit was in the evening and staff were not visible in these areas and therefore there was a risk unauthorised persons or members of the public could access people's confidential information.
- In maternity, we found patient records were stored securely in lockable trolleys; however notes for patients who had been discharged were not secured, and we found loose paperwork tucked in the front cover of those files. Some did not contain patient names or identifiers and this meant they could become separated and misfiled.

Culture within the service

- In our previous inspection we identified systems and processes to address poor behaviour, grievances and performance management related issues were not operating effectively. Grievances were not always being addressed in a timely manner and some cases were not addressed for a matter of months.
- Since our last inspection the trust told us they had introduced weekly team reviews by the employee relations team and developed a new case management database. Reports were sent to the deputy director of human resources (HR) and HR business partners on a daily basis to follow up any cases with the relevant line managers and to increase the awareness of case actions to improve momentum.
- The new database captured employee relations issues, including informal matters and allowed tracking of status, time and division so that cases were not overlooked when reviewing time frames and prioritising resources to ensure the timeliness of actions.
- We were also told where delays were caused by a lack of investigation resources then external investigators would be sourced. The trust was engaging with these investigators.
- The human resources director updated us on progress whereby grievance cases were taking 18 weeks to clear previously. At the time of this inspection the trust had reduced this to 13 weeks with an aim to be at eight weeks, with a trajectory for this. A case tracker had been introduced to manage cases and be able to report on progress. However, this was still a work in progress and not yet embedded.
- Looking at a snapshot in time to monitor progress in April 2017 the average time for the completion of grievance investigations was 99 days (14 weeks), in August 2017 this reduced to 77 days (11 weeks), and in January 2018 the cases were open for an average of 47 days (six weeks).
- The trust had reviewed the management of cases to identify inconsistent practice to record keeping. Policies were updated in line with outcomes of this review.
- The grievance and disputes policy, procedure and guidance changes included; a reduction in time-scales to more closely mirror Advisory Conciliation and Arbitration Service guidance; the introduction of recording devices used to record formal grievance meetings; improved recording and monitoring system; inclusion of suspension risk assessment form; inclusion of overlapping employee relations issues impact assessment tool and the use of external investigators.
- The disciplinary policy was reviewed and ‘unnecessary steps’ were removed to reduce time frames and the number of people involved in the process.
- A risk assessment analysis document had been introduced for counter allegations that required a review of whether it was appropriate to continue with performance management, disciplinary or investigations. The risk assessment ensured decisions did not impact on patient or staff safety. An anonymised example risk assessment for suspension was provided as evidence in response to a reported incident. Following the risk analysis a decision was made to avoid the risk and exclude the staff member.
- A professional standards report was shared with the people and organisational development committee. This report provided information of employee relation trends, complex cases and matters that related to professionally registered staff who were being managed in accordance with maintaining high professional standards, disciplinary policy and capability policy. The report also provided an update of any referrals made to professional bodies or any lapses in professional registration. A quarterly report was submitted to the trust board through the people and organisational development committee.
- We were provided with a professional standards report for December 2017 covering all cases live during September, October and November 2017.

This section is primarily information for the provider

Enforcement actions (s.29A Warning notice)

Action we have told the provider to take

The table below shows why there is a need for significant improvements in the quality of healthcare. The provider must send CQC a report that says what action they are going to take to make the significant improvements.

Why there is a need for significant improvement	Where these improvements need to happen
The trust must take action to address serious failings to ensure quality care and treatment and safety of patients.	**Systems to assess, monitor, and mitigate risks to patients receiving care and treatment are not operating effectively.** Ensure Modified Early Obstetric Warning System (MEOWS) charts are being completed accurately and escalation is occurring in all cases as required. Ensure the MEOWS audit includes clear timescales for escalation that are capable of being monitored. Ensure there is compliance with the newly introduced monthly documentation audit in respect of record keeping in a number of key areas relating to patient safety. Ensure patient safety issues are being given sufficient priority, or that actions are being followed through and monitored. Ensure there is a policy for managing women requiring level 2 high dependency care and an integrated care pathway or similar guidance for pre-emptively managing some typical conditions requiring or potentially requiring level 2 care. Ensure there are sufficient systems and processes for assembling a second emergency theatre team in maternity and they have been tested. Ensure there is a process to clearly identify or allocate in advance a second theatre response team at all times, and there is a process to ensure a timely response. Ensure there is an effective process to ensure staff are not alone with a patient at any time in maternity theatre one. Ensure there is sufficient assurance that controls are in place to audit the completion of the World Health Organisation Surgical Safety Checklist within maternity theatres.

	Ensure there is an effective process to ensure community midwives have the correct equipment at all times for use in emergencies, while waiting to transfer a patient to hospital. Undertake a comprehensive risk assessment of the training and wider needs of community midwives when managing emergencies in the community. Provide assurance of sufficient oversight of the reporting of delayed transfers of care from community midwifery. Ensure there are effective systems to ensure that all women booked for a home birth have home visits or risk assessments carried out, or documented, as required at 36 weeks of pregnancy. Ensure systems and processes for ensuring patients are risk assessed prior to surgery are embedded across the surgical division. Provide assurance that there is a clear auditable trail of the risk assessment of patients prior to surgery. Provide assurance that systems and processes for safety briefings are fully embedded across the theatre suites, particularly the completion of debriefings. Adhere to the trust recovery plan for referral to treatment time performance improvement against the 18 weeks referral to treatment time. **Governance systems and processes are not operating effectively.** Ensure there are effective systems and processes in place to ensure continual evaluation and improvement of services. Ensure action is taken to address the environmental issues and infection prevention and control issues within the fracture clinic. Ensure action is taken to rectify issues with air flow and high temperatures in the fracture clinic. Provide assurance that a suitable area is available for children waiting for an outpatient appointment. Ensure the process where appointments for children could be booked separately to adults is followed. Ensure there are effective systems and processes to ensure equipment is of good repair, serviced, maintained, tested or calibrated across the whole

	organisation. Ensure there are effective and sustainable governance systems and processes for the management of incidents and never events. Ensure that adequate systems and processes are in place such that duty of candour is appropriately applied in a timely way in all relevant cases.