Royal Devon and Exeter NHS Foundation Trust

Evidence appendix

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This evidence appendix provides the supporting evidence that enabled us to come to our judgements of the quality of service provided by this trust. It is based on a combination of information provided to us by the trust, nationally available data, what we found when we inspected, and information given to us from patients, the public and other organisations. For a summary of our inspection findings, see the inspection report for this trust.

Facts and data about this trust

We carried out an unannounced focused inspection of the surgical division of Royal Devon and Exeter NHS Foundation Trust on 21 December 2017. The aim of the inspection was to see if the hospital had taken the necessary action and made the required changes following a number of never events within the surgical division. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. Each never event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a never event.

During this focused inspection we concentrated on specific key lines of enquiry within the 'safe' and 'well led' domains. This meant we could assess the trust's learning and changes to practice in response to the never events. We did not inspect the effective, caring or responsive domains.

We did not look at the core service as a whole and therefore the overall rating for surgery remains good.

We will continue to monitor the performance of this service and inspect it again, as part of our ongoing new phase NHS programme.

Details of sites and locations registered with CQC

- Axminster Hospital
- Crediton Hospital
- East Devon Satellite Kidney Unit
- Exeter Community Hospital
- Exmouth Hospital
- Honiton Hospital
- Mardon Neuro-Rehabilitation Centre

- Okehampton Hospital
- Ottery St Mary Hospital
- RD&E Hospital, Heavitree
- RD&E Hospital, Wonford
- Seaton Hospital
- South Devon Satellite Kidney Unit
- Tiverton District Hospital
- Victoria Hospital, Sidmouth

Specialist services provided at the trust

The standard specialties at the trust include orthopaedics, maternity and neonatology, cancer services, renal services and the Mardo Neuro-rehabilitation centre.

Background to the trust

Royal Devon and Exeter NHS Foundation Trust is a teaching hospital providing specialist and acute hospital services to a core population of about 460,000 people in Exeter, East and Mid Devon.

The main hospital sites are at Wonford and Heavitree in Exeter. The trust is also registered to provide services at a number of local community hospitals.

The trust provides a full range of acute clinical services. The Wonford and Heavitree hospital sites have over 800 beds combined. There are around 300,000 outpatient attendances and over 120,000 day case or inpatient admissions per year, with additional activity delivered in local communities. The trust employs over 8,000 staff.

Acute services

Surgery

Facts and data about this service

The hospital undertakes surgical procedures from the main Wonford site, the Heavitree day case unit and four community day case units. During our inspection, we did not visit any community locations such as community hospitals or the Heavitree day case unit.

The surgical division at the main Wonford site provides emergency inpatient surgical treatment, elective (planned) inpatient surgical treatment and day case surgery across a range of specialities. These include acute surgery, trauma and orthopaedics, general, thoracic surgery, ENT (ear, nose and throat), plastic surgery, breast surgery and ophthalmic surgery.

The trust undertakes approximately 8,500 elective procedures per month and 2,500 emergency surgical procedures a month. The hospital has four theatre suites. The main theatres have 10 operating theatres, the Princess Elizabeth Orthopaedic Centre has five operating theatres, the West of England Eye Unit has two and the Centre for Women's Health (maternity, gynaecology and women's surgery) has three operating theatres.

During the unannounced visit, we visited the following surgical departments:

- The West of England Eye Unit
- Theatres including: Ophthalmology, ENT and colorectal theatre.

During the inspection visit, the inspection team:

- observed staff giving care

- reviewed 15 patient records
- looked at trust policies
- looked at performance information and data about the trust
- spoke with 33 members of staff of different grades including consultants, doctors, nurses, operating department practitioners (OPDs) and theatre managers.
- met with consultants, matrons, the director of the surgery division, the assistant director of nursing the medical director anddeputy chief executive/chief nurse .

The care quality commission last inspected the hospital in November 2015 and rated the surgery division as good overall with safe rated as requires improvement. This inspection focused on the changes the trust had made following a series of never events.

Is the service safe?

Assessing and responding to patient risk

Risks to people were safely monitored. Daily safety briefings in each theatre were undertaken to highlight any patient that may be deemed at risk. The briefing followed the World Health Organisation (WHO) standards and was appropriate to the case being undertaken**.** A record of the theatre briefing checklist was also maintained. We reviewed 20 of these records.These were all completed, signed and dated with additional notes to highlight risks discussed. These included possible complications such as unstable fractures.

The National Patient Safety Agency five steps to safer surgery was followed as part of the World Health Organisation (WHO) surgical safety checklist, in all operations we viewed. The purpose of the checklist is to check all safety elements of a patient's operation before proceeding. This included, for example, checking for the correct patient, the correct operating site, and to ensure all staff were clear in their roles and responsibilities. We observed six WHO checklists being completed. Each stage of the WHO checklist was completed with all staff involved and paying attention in five of the six observations. It was evident that the different stages of the WHO checklist (sign in, time out and sign out) was embedded and formed part of the working routine in the operating theatres. However, during one of the observations, although each part of the WHO pathway was carried out, we observed this was done as quickly as possible. This did not provide us with the assurance that processes were always effective.

However, areas of the checklist requiring completion prior to the patient attending theatre were not always fully completed. We reviewed and discussed a checklist performed on the ward prior to the patient entering the operating theatre. We noticed there was one question (preoperative daily medication), which had not been answered by ward staff. There was also one question from the section 'sign out from ward', which had not been completed. Also, the section relating to 'operation site marked and confirmed as correct using notes and consent form' had not been completed at the correct stage of the process. When we raised this, staff confirmed that these should have been completed before progressing on to the next stage of the WHO surgical checklist. All other sections had been completed in full.

Monthly audits were undertaken looking at five steps to safer surgery. There was positive compliance with the target of five audits being undertaken per month, being achieved for all months apart from September 2017 between January to December 2017. We reviewed the completion of the five steps to safer surgery audits between July and December 2017. The results were:July 2017: Seven audits completed

- August 2017: Seven audits completed
- September 2017: Four audits completed
- October 2017: Five audits completed
- November 2017: Five audits completed
- December 2017: Six audits completed

Each of these audits was then reviewed at the five steps to safe surgery audit meeting. Each negative feedback was discussed with actions agreed on how to address areas of poor compliance.

Compliance with the WHO checklist was good. Between January to December 2017 compliance was at 95%. Records of completed WHO checklists were stored in patients' records. We reviewed 15 sets of records and found the WHO checklist to be fully completed, dated and signed. However, during the inspection we noticed one aspect of the WHO 'time out' section was not completed at the time of 'time out,' prior to commencement of surgery. The person responsible for leading the 'time out' did not sign as required. When we checked this later, the section had been completed retrospectively and signed but not by the member of staff leading the time out section. We were therefore not assured that the correct stages had been followed and something had not been missed.

In the general theatre suite, the daily safety brief meeting had only been introduced in December 2017 and had not been completely embedded into practice. Meetings were held every morning and attended by team leaders from each theatre, surgeons and the theatre coordinator. They covered a range of topics such as staffing, theatre lists, relevant trust communications, reported incidents from the previous day and any infection control concerns. Records of the daily meeting were maintained. There were plans to audit these for completion and to evaluate and alter the process according to the outcome of the audit. The safety briefing meetings were introduced on 4 December 2017 as a trial. This was as a result of positive feedback from the day case unit, where this practice was already embedded. We reviewed completed meeting records and found there was one day where there was no record of a meeting held, and only one record was incomplete between 4 December and 21 December 2017.

National Safety Standards for Invasive Procedures (NatSSIPs) were embedded in the organisation. NatSSIPs provide a framework for the production of Local Safety Standards for Invasive Procedures (LocSSIPs). These are important as the role of LocSSIPs are to improve patient safety and minimise harm. Dedicated LocSSIP checklists were in place for ophthalmology procedures, ultrasound guided procedures and cystoscopy. There was a clearly defined action plan of procedures still awaiting a LocSSIP, for example kidney biopsies and chest drain insertions, and the current position of their development documented.

Staff were able to seek support from senior staff in situations where risks were identified. We were informed staff were supported to challenge where they felt there was risk, regardless of role or seniority. We observed a member of staff voicing their concern to a consultant regarding insufficient information about a patient's allergy status. We felt this was not given sufficient attention by the consultant who seemed anxious to proceed with a busy theatre list. However, the nurse recognised their responsibility in ensuring the patient's safety, and telephoned the ward to ask for confirmation of the missing data. We also observed how staff addressed issues relating to potential breaches of infection control measures, and the actions taken when instruments or equipment was not working effectively. Staff removed the equipment immediately and completed appropriate documentation for repairs or replacements.

Appropriate risk assessments and actions were carried out and taken in line with guidance from the National Institute for Health and Care Excellence (CG65, 2016). We reviewed 15 sets of records. In 12 out of 15 records, a patient's temperature was recorded on arrival in recovery. Hypothermia (low body temperature) before, during and after surgery is associated with preventable complications and poor patient outcomes. In 14 of the 15 records we reviewed, patients' preoperative medicine had been documented and administered.

Incidents

The surgical division managed patient safety incidents well and took appropriate action in response to significant incidents. In accordance with the Serious Incident Framework (NHS England, 2015), the trust reported seven never events, which met the reporting criteria set by NHS England between May 2015 and December 2017. Two additional serious incidents were under investigation at the time of our inspection.

Of these seven never events and the two under investigation, seven occurred within the surgical division:

- Three were in the ophthalmology department
- One was in the endoscopy unit
- One was in the oral and maxillofacial department
- One was in the orthopaedic day surgery
- One was within spinal speciality
- One was in the critical care unit

The remaining never event was in maternity.

Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. Each never event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a never event.

Staff reported incidents and near misses using the trust's electronic incident reporting system. However, two of the never events were identified through the complaints procedure but were investigated in line with national guidance for investigating serious incidents. Each reported serious incident was followed up by an initial 72 hour report. These reports were reviewed in a 'safety huddle' within the governance department, where decisions about further investigation and reporting were made.

There was an investigation of each incident following NHS guidance for examining and reporting serious incidents. An investigation lead was appointed to carry out the investigation and the trust held a list of all staff who had received training in the investigation of serious incidents. It was acknowledged investigating incidents was time consuming and staff allocated to carrying out serious incident reviews could be allocated non-clinical time if required. This ensured investigations were in-depth and completed in a timely manner. Action plans were identified for each event. For example, following a wrong site surgery in the ophthalmology department an action plan was identified. The action to improve practice included ensuring when only one eye required laser treatment, only that eye should be dilated. Each action had a clearly defined person responsible for its completion and the date this should be achieved.

There was learning from the never events and changes to practice as a result. During our inspection, staff shared examples of change to practice. For example, in ophthalmology, following insertion of an incorrect lens, the unit had added an additional box to the checklist and to the whiteboard (a display board in theatres used during surgery to display important information about the procedure) which identified the strength of the lens required for the procedure. Staff informed us only one lens would be opened and this would only occur when these boxes were completed. Changes had also been made within ENT theatres. These included the addition of visual reminders displayed on the door leading out of the operating theatre to ensure additional awareness. Changes had also been made to documentation to ensure all disposable items that were not an instrument were included in the 'swab count' at the end of surgical procedures.

Actions to prevent incidents occurring again were identified and then shared within the speciality. Staff members were clearly able to explain the actions and changes to practice. This information was shared through newsletters, team meetings and audit days. We were informed during audit days staff were encouraged to raise any incident or concern they had been involved with and the learning that had occurred following this. However, learning from incidents was not shared specifically with all the practice educators within recovery and theatres. This meant an opportunity to share learning with all members of staff responsible for teaching within the operating theatre environment was lost.

Effective sharing of learning across specialties did not occur. Although staff we spoke with were able to tell us about the never events that had occurred in their speciality, they were not aware of the never events in other specialities. This meant we were not assured the learning from these had been shared effectively to ensure similar incidents did not occur in other specialities.

Staff were encouraged to be open and honest to report incidents. Nearly all staff we spoke with told us they were encouraged to raise incidents and there was a no blame policy. They all knew how to use the reporting system and said it was easy to use. Staff reported incidents and near misses. The surgical division summarised in a surgical newsletter that 49 surgical safety incidents or near misses had been reported on the electronic incident reporting system between July 2016 and June 2017.

When incidents were reported, feedback provided to staff was informative. Staff we spoke with informed us they always received feedback following an incident being raised. If they wanted more comprehensive feedback they could click a button to request this. If they did this, they then received the action taken and the recommendations to change of practice which may have occurred.

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.The trust's root cause analysis report contained a section for duty of candour. We looked at two examples of duty of candour letters sent. They included an apology and a clear outline of the next stages and timeframes for the investigation.

Staff had a variable awareness of the regulation. Some staff were unaware of duty of candour. However, all staff said if an incident occurred they would be open and honest with the patient and ensure the appropriate escalation occurred. Staff were introduced to duty of candour as part of their induction, however staff told us they received no additional training or updates.

Is the service effective?

We did not inspect this area of the service, as this was a focused inspection specifically looking at areas of safe and well-led.

Is the service caring?

We did not inspect this area of the service, as this was a focused inspection specifically looking at areas of safe and well-led.

Is the service responsive?

We did not inspect this area of the service, as this was a focused inspection specifically looking at areas of safe and well-led.

Is the service well-led?

Leadership

Leaders recognised the challenges surrounding the never events and changes required. All leaders we spoke with reported they were disappointed the never events had occurred and they were driven to ensure they did not occur again.

Leaders had undertaken an internal thematic review of the never events to determine if there were additional trends or learning could be gained. However, this review was undertaken by staff within the hospital. We asked leaders at different levels if an external review was considered. Leaders stated they were confident in the internal processes and stated no trends were identified. However, we were not assured an internal review would give the unbiased insight into the culture of the operating theatres an external investigation would provide. Leaders told us they had recently been in contact with another healthcare organisation that had undertaken an external

review of their theatres. This report had been shared with a view to determine if any learning could be gained.

Single speciality leaders in the surgical division were approachable. Staff reported they could approach their speciality leaders and they listened. However, many staff reported they did not often see the divisional leaders, the medical director or the deputy chief executive/chief nurse within their departments.

Leaders were receptive to change. Each never event had a clear action plan with a nominated person responsible for ensuring the actions were completed. Audits were undertaken to confirm these changes had been embedded and compliance was maintained. However, we were not assured all learning that could be shared between specialities had been identified.

Leaders had not identified there was cross learning from the incident relating to a retained foreign object. It was felt this incident occurred due to the extremely small size of the foreign object. However, learning relating to the counting of objects in and out were relevant across all specialities and divisions.

Culture

Staff felt supported, respected and valued. Staff we spoke with said they felt comfortable raising concerns and when they did they were listened to. We heard examples of changes to staffing levels following concerns raised about the workload, and how it was not sustainable for one person. This led to an additional job role being created so the workload could be shared.

There was a culture which encouraged openness and honesty at all levels within the organisation. Leaders and staff understood the importance of staff being able to raise concerns without fear of retribution. We heard an example where staff had raised concerns about other staff members' outcomes. Appropriate action was taken to ensure the safety of patients.

Action was taken to address areas of poor performance. When a clinician's practice was deemed to not fit the standards required, action was taken to ensure change to practice occurred and patient safety was maintained.

There was evidence of team working and cooperative, supportive and appreciative relationships among staff. Staff felt comfortable in challenging each other and also asking for help. We observed friendly and professional relationships amongst staff.

The senior divisional management team stated they were proud of the response to the never events. The management team stated there were robust processes to ensure initial investigation of incidents (72 hour report) and opportunities for debriefing staff in a supportive and constructive manner. Senior leaders spoke of staff responses to the never events and the effectiveness of bringing staff together for immediate debriefing. In one incident, all staff were recalled within one hour to ensure staff were reassured the patient was well and to support staff that were visibly upset by the experience. Managers explained there was a culture of ensuring the best and safest care for patients at all times amongst all staff. Managerswere proud of the involvement and contributions of all staff in the investigation of the never events.

Staff felt positive and proud to work in the hospital. All staff we spoke with reported they enjoyed and were proud to work in Royal Devon and Exeter Hospital. A lot of staff we spoke with had worked in the hospital for many years and this was due to their pride at working in an environment with a positive culture.

Governance

There were some effective structures, processes and systems of accountability to support the delivery of good quality and sustainable services. There was a clear governance structure, which enabled the never events to be reported, escalated and acted on. All current actions were reported to and reviewed by the safety and risk committee.

We did not speak with any members of the Board during the inspection but we were told the Board were fully aware of the never events and were supportive of the actions taken by the trust in

response. We looked at the minutes of three public board meetings from February to May 2017 and found no challenge from the board in relation to the never events. We found this challenge in the minutes of other meetings attended by board members.

All levels of governance and management functioned effectively and interacted with each other appropriately. Information about incidents was shared with managers through weekly speciality/business meetings. Managers also attended divisional governance meetings and speciality governance meetings. Learning was shared with staff through weekly communications and in staff meetings. For example, the anaesthetics and theatre teams had a half day meeting eight times a year. This was used for auditing, teaching and educational purposes.

The governance structure did not always ensure learning was shared effectively between surgical specialities. Some leaders acknowledged there was an element of 'silo' working, although they stated if there was systematic learning then this would be shared .Staff we spoke with were able to tell us about the never events within their own speciality but not about those that occurred within others. We were therefore not assured the required learning and change to practice were implemented to prevent the never event occurring again in all specialities.

Meeting minutes demonstrated incidents and shared learning were discussed. We reviewed minutes of speciality governance meetings for ophthalmology, spinal surgery, breast services, acute surgery, ENT (earn, nose and throat), orthodontics, oral & maxillofacial surgery and anaesthetics/theatres. Minutes of meetings were well organised and had similar set agenda items. We found reference to speciality specific never events but minutes of meetings did not evidence there was cross-speciality awareness or shared learning.

We heard of plans to enhance communication with staff through 'video blogging' as it was recognised existing communication pathways (email and intranet hub) were not always the best way of reaching out to staff.

Processes had been developed to train staff in human factors. Human factors training focuses on optimising human performance through better understanding of the behaviour of individuals with others and their environment. The majority of staff we spoke with in theatres had received this training. However, this level of training was not found amongst staff within the ophthalmology/eye unit. During discussion with leaders, it seemed they had not given sufficient consideration to the value of human factors for staff in the ophthalmology/eye unit even though there had been three never events in this department since 2015.

The trust had effective structures, processes and systems to ensure compliance with the national agenda for national safety standards for invasive procedures. The thematic review of the never events had driven the agenda to ensure local safety standards for invasive procedures. In March 2017, an additional work stream was set up to ensure invasive procedures were reviewed and were compliant with evidence-based practice. The trust had a designated lead for ensuring invasive procedures were in line with national standards. Each surgical speciality had a nominated lead to drive the development of speciality specific safety standards. There was involvement from doctors, nurses and operating department practitioners in the development of the safety standards. Local safety standards were reviewed to a predefined schedule of every two or three years . Where gaps were identified, action was taken to ensure a local safety standard/standard operating procedures was signed off by the trusts division's safety and risk committee. When new safety standards were introduced or developed, this was shared with staff in meetings (predominantly monthly audit meetings) and in the theratre newsletter. We asked how compliance with the safety standards was monitored. Leaders told us each safety standard included an element of auditing. However, the auditing process to ensure a complete overview of compliance and the effectiveness of the local safety standard was not yet embedded.

During the inspection we reviewed patients' records and noticed patients' consent for surgery was obtained on the day of surgery. This was not in line with recommendations from the Royal College of Surgeons: Consent, Supported decision-making: A guide to good practice 2016, which recommends consent should be obtained prior to surgery to ensure patients have sufficient time and information to make an informed decision. The recommended practice also ensures additional consideration is given to those patients who lack mental capacity, have learning disabilities and to

children and young people. We discussed this with leaders who acknowledged best practice guidance. However, they stated this was not always possible due to the need for extended time for appointments in the pre-assessment clinic prior to surgery.

Staff at all levels were clear about their roles and understood what they were accountable for, and to who. We spoke with staff with varying seniority and they were clear about the roles they played in the changes made to practice following the never events within their speciality.