Care Quality Commission

Royal Cornwall Hospitals NHS Trust

Royal Cornwall Hospital

Inspection report

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Ratings

Overall rating for this service	Inspected but not rated
Are services safe?	**Inspected but not rated**
Are services well-led?	**Inspected but not rated**

Our findings

Overall summary of services at Royal Cornwall Hospital

Inspected but not rated

We carried out a short notice announced focused inspection of the surgical care group of Royal Cornwall Hospitals NHS Trust (RCHT) on the 9 and 10 December 2020.

The aim of the inspection was to see if the trust had taken the necessary action and made the required changes following six never events between February 2020 and September 2020, within the surgical care group, and one never event in medical services. The trust had a further incident in September 2020 which did not meet the never event criteria but was declared as a never event by the hospital. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, these 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.

The never events happened over three locations,

February 2020. Retained swab, Breast Surgery theatres at St Michaels Hospital.

May 2020. Wrong site surgery, Dermatology West Cornwall Hospital.

June 2020. Wrong site surgery, Dermatology Unit Royal Cornwall Hospital.

May 2020. Partial retained wire, Cardiac Catheter Laboratories Royal Cornwall Hospital.

September 2020. Incorrect lens fitted, Ophthalmology Theatre Royal Cornwall Hospital.

September 2020. Wrong medicine given, Emergency Department Royal Cornwall Hospital.

October 2020. Wrong site surgery, Dermatology Unit Royal Cornwall Hospital.

During this focused inspection we concentrated on specific key lines of enquiry within the ‘safe’ and ‘well led’ domains for surgery. 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 and therefore we did not change the rating for surgery which remains requires improvement overall. This is because the safe and responsive domains were rated as requires improvement when we inspected these in November 2019. As a result of that inspection the trust overall was rated as requires improvement. We will continue to monitor the performance of this service. With the risks relating to Covid-19 still present, we’ll draw from the best of our existing methodologies and adapt them to work in the current environment. We are clear that our focus will continue to be on services where we have concerns about quality and/or safety, and we’ll continue to take appropriate action to protect people if necessary.

Our findings

Royal Cornwall Hospitals NHS Trust (RCHT) is the main provider of acute hospital and specialist services for most of the population of Cornwall and the Isles of Scilly, approximately 500,000 people. The population can more than double during busy holiday periods. The trust employs approximately 5,000 staff.

The trust delivers care from three main sites – Royal Cornwall Hospital in Truro, St Michael's Hospital in Hayle, and West Cornwall Hospital in Penzance. The trust also provides outpatient, maternity and clinical imaging services at community hospitals at other locations across Cornwall & the Isles of Scilly.

The trust has seven care groups which include medicine, clinical support, general surgery and cancer services, women, children and sexual health, anaesthetics, critical care and theatres, specialist services and surgery, and urgent, emergency and trauma. The surgical care group at the Royal Cornwall Hospital provides emergency inpatient surgical treatment, elective (planned) inpatient surgical treatment and day case surgery across a range of specialities. These services include acute surgery, trauma and orthopaedics, general, thoracic, ENT (ear, nose and throat), plastic, breast and ophthalmic surgery.

The Royal Cornwall Hospital Trust has undertaken approximately 51,458 elective procedures and 24,496 emergency surgical procedures from January 2020 to November 2020.

The hospital has three main theatre suites Trelawney, Newlyn, and Tower theatres.

We inspected areas of the surgical care group at Royal Cornwall Hospital. These included Trelawney, Newlyn and Tower theatres, recovery areas and two surgical wards. We also visited the Cardiac Catheter Laboratory the Cardiac Investigations Unit, and the Dermatology Unit. A team of one manager, two inspectors, and two specialist advisors spoke with 35 nursing staff and seven medical staff, three health care assistants and three administrative staff. We took part in five virtual interviews with staff. We looked at 12 sets of patient notes and reviewed audit data and policies and processes. At this inspection because of the risks caused by Covid-19, we did not speak to patients and relatives.

Following the inspection, we took regulatory enforcement action as a result of our findings in surgical care services. We issued a Warning Notice under section 29A of the Health and Social Care Act 2008. This means that we asked the trust to make significant improvements in the quality of healthcare it provides. Further details can be found at the end of the report.

You can find further information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

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Inspected but not rated

- Compliance with the World Health Organisation (The WHO Surgical Safety Checklist is a simple tool designed to improve the safety of surgical procedures by bringing together the whole operating team (surgeons, anaesthesia providers and nurses) to perform key safety checks during vital phases of perioperative care). We found the checklist had improved following a trust review of safety incidents, but the required actions in response had not been managed in a timely way to ensure patient safety.
- Not all relevant audits were completed. Audit data showed varying levels of compliance and staff were not aware of the audit outcomes and learning was not triggered by these audits.
- Staff had not received adequate training in a timely way in response to the never events.
- Safety systems which had been implemented as part of never event learning did not always consider the impact on staff and the wider safety implications, in relation to dermatology.
- Managers had not identified the gaps in learning between the specialities and across the trust and had not ensured that actions from incidents were implemented and monitored for effectiveness in a timely way.
- Governance procedures were not effective throughout the service to guarantee that changes and learning ensured patient safety across the trust. Quality Improvement processes had been implemented but were in their infancy.
- Staff followed current national practice to check patients had the correct medicines.
- Staff felt respected, supported and valued. The service had an open culture where patients, their families and staff could raise concerns without fear.

Is the service safe?

Inspected but not rated

- Compliance with World Health Organisation (WHO) Checklist had improved following a safety review of safety incidents, but responses had not been managed in a timely way to ensure patient safety. Mandatory WHO training for all theatre staff had been discontinued.
- We saw that when safety systems had been implemented as part of never event learning the impact on staff and the wider safety implications had not always been considered.
- Staff recognised and reported incidents and near misses but effective sharing of learning across specialties did not occur to ensure patient safety. Managers investigated incidents but did not use the communication systems to share lessons in a timely way learned with the whole team and the wider service. Managers had not identified the gaps in cross care group and trust wide learning and had not ensured actions from incidents were implemented and monitored for effectiveness in a timely way.
- Staff followed current national practice to check patients had the correct medicines.

Assessing and Responding to Risk

Compliance with World Health Organisation (WHO) Checklist had improved following review of safety incidents, but the response had not been managed in a timely way to ensure patient safety.

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Risks to patients were discussed daily and shared with staff across theatre suites. Daily safety huddles in the theatre departments were undertaken to highlight any issues with patient risks, staffing, theatre lists, reported incidents from the previous day and any infection control concerns. This meeting also provided a forum for any relevant hospital updates. Minutes were taken and available to all staff and provided an audit trail for areas discussed. Prior to Covid-19 this process involved all staff, apart from surgeons, anaesthetists and the Central Sterile Service Department. During Covid-19 this had been attended by two staff from each theatre who returned to their allocated theatres to share the information. We spoke with recovery staff who confirmed that patient handovers included all necessary key information to keep patients safe.

As part of the five steps to safer surgery a daily briefing in each theatre was undertaken at the beginning of each operating list to highlight any patient that may be deemed at risk, to discuss specific equipment requirements, and any issues which may impact the list. In these briefings we observed notes made on the paper operating list, the questions asked were from memory. No physical prompts were used which could lead to inconsistency of the content discussed or missed information. Following the inspection, the trust told us the briefing and debriefing checklist was captured on the electronic system and there were set questions. However, this practice was not observed during our inspection.

The National Patient Safety Agency five steps to safer surgery was followed as part of the World Health Organisation (WHO) surgical safety checklist, in the 14 sign-in checklists we viewed. The purpose of the checklist was to ensure all safety elements of a patient's operation before induction of anaesthesia. These checks included, for example, checking for the correct patient, ensuring the consent form had been completed and the operating site had been marked.

During the timeout section before the start of surgery. We saw that if a new member of the team not at the original briefing joined, introductions were completed again to ensure the theatre team knew who was available and who held what role. During all stages of the 5 steps to safer surgery, staff were engaged and participating in the process, at the sign-in, timeout and sign out stages. The documentation was signed and dated to provide an audit trail.

We looked at the WHO checklist in detail for the six procedures observed and a further eight sets of notes. We saw in the ophthalmology theatres, systems to prevent the reoccurrence of the never event had been implemented, and further WHO training for staff had been planned to start in early 2021. The trust had looked for best practice from other hospitals to benchmark their service and had made a change to records as a result. We also saw in the Cardiac Catheter Laboratory a new check had been added to the WHO checklist to include if wires used had been checked on removal from the patient. All five records seen in the Cardiac Catheter Laboratory had included this check, written by hand, and there were plans for new forms to be printed to include this check, but no timescales for this were known to staff.

Across other specialities appropriate WHO checklists were in use with updates already incorporated for example in adult orthopaedics theatre, in relation to metal work removal. We observed that a paediatric patient in the orthopaedic theatre had a paediatric specific checklist. However, it was not specific to the specialty for example orthopaedics, so staff were having to remember to ask from memory certain additional checks. This was not safe and consistent practice as a lack of written prompt meant risks could be missed. No debriefing at the end of the lists was observed due to the limited time we were on site.

Some actions relating to the never events had not been implemented. For example, the updating of the peri-operative care plan to include two signatures for the swab count was considered but no action was taken. The Association for Perioperative Practice 2016 Chapter 8 Clinical Guidelines 8.1 Accountable Items, Swab, Instrument and Needle Count Recommendation 8.1.62 states "A copy of the count sheet should be retained in the patient's notes indicating the names of the scrub and circulating staff responsible for the final count. Where electronic records are utilised, the record should indicate the names of the scrub and circulating staff responsible for the final count."

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The current electronic learning for staff provided by the trust, does not state that the swab check requires two staff signatures of the scrub and circulating staff responsible. We observed three swab counts as part of the WHO checklist procedure. In each case staff recorded the swab count on a paper and electronic record but each of those systems had a shortfall in information. Staff documented the swab counts on the electronic record. The only field which was mandatory for staff to complete was if the count was correct or incorrect. The record did not require the names of staff completing the checks to be added to the system. Therefore, the record could be closed without including staff names and so would not provide an audit trail if the information was needed later. The written record enabled only one signature despite two staff having competed the checks therefore did not leave a full audit trail of the information, should it be needed later.

There was inconsistent practice in relation to The Association for Perioperative Practice 2016 Chapter 8 Clinical Guidelines 8.1 Accountable Items, Swab, Instrument and Needle Count and there was an inconsistency in how the standard was being met and recorded by staff. The trusts Generic Theatre Practice Standards Clinical Guideline V3.0 November 2019, stated, “Swab instrument, needle and sharps count record must be made electronically and in the patient’s record.”

Staff we spoke with said it was up to the scrub staff discretion regarding what was counted. Staff told us this was also based on historical practice and no updates had been provided.

The Association for Perioperative Practice 2016. Accountable Items, Swab, Instrument and Needle Count Standard states, “There is a safe and consistent process in place to ensure that all items used during perioperative or interventional procedures are accounted for during the procedure and are reconciled at the end, in order to prevent items being unintentionally retained at the surgical site, in a body cavity, or within any other material (for example, drapes, personal linen).”

Following an investigation of the retained swab never event, an action plan was completed and learning actions included. The Quality Assurance report of 23/09/2020 noted, “There should be quarterly audit of the xxx system across all RCHT theatre suites to evidence that names of staff who conducted the count are entered and ongoing education of staff to ensure completion.” No timescales were provided for completion of training or audits. At the time of the inspection, we saw no evidence that the action indicated above were being consistently followed, in line with the relevant standards.

Mandatory WHO training for all theatre staff had been discontinued in early 2020. As part of never event learning updated WHO training we were told by governances leads for the surgical care group, that this was to start being rolled out again. We found during this visit that dermatology staff had received this updated training but not all other theatre staff had started the training, and this could create a risk to patient safety. The trust staff told us there was currently no formal training for the WHO checklist in the trust. New staff had been trained by staff within theatres during their local induction. The quality of the WHO checklist was overseen by senior team leaders, theatre managers and the WHO audit process. Following the never events in 2020 it had been recognised by governance leads that this needed to be improved to provide further assurance of completion. Evolving plans are that all staff involved with the WHO checklist will undergo annualised training. This had commenced and will be monitored through Electronic Staff Record and staff performance reviews. Electronic learning for the WHO safer surgery checklist had been created in November 2020 and so there was a time lapse between mandatory and updated training being available for staff.

Training for the WHO checklist had been provided in Dermatology, and staff said they benefitted from this. Staff in dermatology outpatients reflected that since the training they recognised their previous practices of the WHO checklist had not been robust, and they felt the training improved patient safety. We observed staff completing the “silent cockpit

approach" (this requires staff to focus strict attention during critical phases of a procedure) to patient safety checks. We also were informed that prior to the training the morning briefing meetings were not standard practice in the dermatology outpatient procedure room. More time had now been allocated to ensure that a briefing meeting and debrief were implemented. However, staff told us that although agreed, this practice had not yet happened. Prior to the training swab counts, and instrument checks had not been completed, but this had now started in this theatre.

Safety systems had been implemented as part of never event learning, but they did not always consider the impact on staff or safety. We saw in the dermatology outpatient procedure room; actions had been taken to mitigate risks of wrong site surgery. However, these were potentially increasing the risk of errors occurring. For example, the implemented extra check of site marking, involved asking doctors to leave clinic appointments to check patient site markings in nurse led clinics. Some patients were seen in outpatients' clinics by a doctor and then referred to the nurse led clinic to have the procedure later. Photographs of the site for excision were taken at the initial clinic referral and used to verify the surgery site on the day of surgery. Following the wrong site surgery never event, doctors were asked to leave their clinics, and attend the nurse led theatre to verify the site of surgery and mark the location. This marking process would be on a patient the doctor had never met before and they would be required to review notes and carefully establish the site of surgery. This meant the responsibility for that specific action then lay with that doctor. Staff told us there were sometimes issues in identifying the correct area for surgery, as the clinical photo was missing. This additional process was a distraction for the doctors and was not providing a good experience for the patients both in theatre and for those waiting in the outpatient clinic to see the doctors.

Additional time had not been considered for the increased safety checks needed for each procedure. We observed that increased safety checks to reduce the risks of wrong site surgery and increased cleaning caused by Covid-19, meant the time slots in dermatology of 30 and 45 minutes caused undue pressure on staff. This resulted in increased risks to patients. Staff told us that after the never event senior staff had discussed with them about an increase of time slots to 45 to 75 minutes, but while this would appear to have been agreed no action had taken place and staff were still having to comply with the 30-to-45-minute time slots. Staff told us the outcome to patients was a rushed service and delays to appointment times.

From November 2017 audit processes changed to an electronic audit completed at the time of surgery and recorded completion of the WHO process in all areas apart from Endoscopy and Cardiac Catheter Laboratory. There was a disconnect between identifying safety concerns, making action plans and ensuring those actions had been successfully implemented. Monthly audits of the WHO checklist were undertaken looking at five steps to safer surgery. We were told by staff that the audits only looked at a small number of records.

We reviewed the results of the WHO audit from January to October 2020.The quantitative compliance ranged from 100% to 88% in May 2020. However, compliance in relation to the qualitative declined from 99% to 49% between April and May 2020. This picked up in June and July. However, it did not break down the areas within the WHO checklist to enable clarity of what had been audited and the areas identified as requiring improvement. This audit was to help assure the trust Executive Team that standards were being met across all theatres. Audit data showed variable levels of compliance. The audits showed that one WHO prelist brief and debrief form was audited for each theatre list undertaken. The trust advised that all paper records in theatres are audited by the recovery team as part of their processes, this was recorded on the electronic system. This audit was not seen as part of the inspection. The areas included for audit were the safety huddle, the operating list briefing and debriefing.

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Staff told us they reviewed five WHO records per theatre each month. This was completed by theatre staff reviewing their own practice and so lacked any external or independency oversight. This was a very low percentage of the total surgeries performed. Staff also confirmed they were not aware of the audit outcomes and learning was not triggered by these audits.

There was some evidence of Local Safety Standards for Invasive Procedures (LocSSIPs). We reviewed a small sample of six documents across Urology, Cancer services, Cardiac Catheter Lab and Theatres. It was noted for the Generic Theatre Practice Standards Clinical Guidelines V3.0 November 2019 and the Cardiac Catheter Lab Surgical Standards Clinical Guidelines V2.0 April 2019, these had not been updated to reflect any of the recent never event learning. These are important to improve patient safety and minimise harm.

Consent was not managed in line with good practice guidance. During the inspection we reviewed 12 patients' records and saw 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 had sufficient time and information to make an informed decision. The recommended practice also ensured additional consideration was given to those patients who lacked mental capacity, have learning disabilities and to children and young people. We saw for three patients' consent was discussed as part of a telephone assessment but in the remaining cases this was not recorded. As part of the WHO checklist, we observed during timeout that the scrub staff would read the consent form out loud and seek verbal confirmation from the surgeon.

Staff were able to seek support from senior staff in situations where risks were identified.

Following the WHO training staff told us they felt more able to raise concerns and to challenge where they felt there was a risk, regardless of role or seniority. Staff told us they felt more informed and empowered. As part of the inspection, we requested to attend and observe a WHO procedure in outpatients dermatology department. At the time a silent cockpit check was being completed. We were appropriately advised twice that we could not enter, and we should not be disturbing this process. Another example seen in a different theatre was, at the end of a procedure the staff were carrying out a count and the surgeon was rushing to sign out, staff asked him to wait until they had finished the count.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

Staff now followed current national practice to check patients had the correct medicines.

A never event involving administration of an oral medicine via an intravenous (IV) route in the emergency department (ED) been reported and investigated. The ED pharmacist and medicines safety officer (MSO) were fully involved in the incident review and identification of learning from this never event. Governance processes were followed with the report signed off as final, not all actions had been completed, but were being worked through. Focus was on the more immediate actions with those requiring immediate attention being completed first.

The ED pharmacist led the implementation of internal recommendations to reduce the risk of a similar event occurring. External recommendations included working with medical schools to improve trainee doctor medicines administration training and competence.

We were assured that action was being taken to prevent the likelihood of this event recurring. However, learning from the incident needed to be shared with other sites within the trust.

Incidents

Staff recognised and reported incidents and near misses. Managers investigated incidents but did not always share lessons learned in a timely way with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.

The surgical care group took appropriate action in response to significant incidents, but the action taken was not immediate and could have been taken sooner to ensure patient safety. For example, updates in training and practices to prevent reoccurrence. 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. A further incident which did not meet the criteria had been considered significant by the trust and so treated as a never event.

Staff reported incidents and near misses using the trust's electronic incident reporting system.

There was a clear understanding of incident reporting among staff and a no blame culture. Staff demonstrated the incident reporting process and told us they could request feedback. Staff told us the trust promoted incident reporting as a positive action. Information provided by the trust showed there has been a rise in incident reporting, overdue incidents and serious incidents and concise actions since July 2020.

Never Events

Never Events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each Never Event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a Never Event.

The trust had seven never events which happened over three locations:

February 2020. Retained swab, Breast Surgery theatres at St Michaels Hospital.

May 2020. Wrong site surgery, Dermatology West Cornwall Hospital.

June 2020. Wrong site surgery, Dermatology Unit Royal Cornwall Hospital.

May 2020. Partial retained wire, Cardiac Catheter Laboratories Royal Cornwall Hospital.

September 2020. Incorrect lens fitted, Ophthalmology Theatre Royal Cornwall Hospital.

September 2020. Wrong medicine given, Emergency Department Royal Cornwall Hospital.

October 2020. Wrong site surgery, Dermatology Unit Royal Cornwall Hospital.

There was an investigation of each incident and debriefs were undertaken in each department to gain a better understanding of what had gone wrong. An investigation lead was appointed to carry out the investigation and an initial

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72-hour report was produced. Following this a full investigation and final report was produced with recommendations and an action plan. The action plan identified allocation of responsibility and timescale for action. The investigating officer for dermatology also reviewed a previous never event and other historic dermatology serious incidents for comparison.

There was some learning from the never events and some changes to practice as a result. During our inspection, staff shared examples of change to practice. Action plans were identified for each event and staff showed us how the checking procedures in ophthalmology had been changed. We also saw the WHO checklist in the cardiac catheter laboratory had been amended to include an extra wire check. We were advised that the standard operating procedure for dermatology was being updated as a result of changes made following the never events but there was no date for implementation.

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

Staff were encouraged to be open and honest and to report incidents. All staff we spoke with told us they were encouraged to raise incidents and there was a no blame culture. Staff we spoke with said they could request feedback following an incident being raised.

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 investigation process included confirmation that duty of candour had been applied.

All staff we asked demonstrated a clear understanding of the duty of candour and their own responsibility to be open and honest.

Is the service well-led?

Inspected but not rated

- Leaders had not identified the gaps in cross care group and trust wide learning. They had also not ensured that actions from incidents were implemented and monitored for effectiveness in a timely way.
- The governance structures did not always ensure information and learning was shared effectively between surgical specialities and other locations in the trust.
- Staff felt respected, supported and valued. The service had an open culture where patients, their families and staff could raise concerns without fear.

Leadership

Leaders understood and managed the priorities and issues the service faced, however, they had not identified the gaps in cross speciality and trust wide learning. Leaders did not recognise the risks of the self-assessment review of the training needs of staff.

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Leaders recognised the challenges surrounding the never events and changes were required to ensure patient safety. Staff told us one of the issues around the WHO checklist and subsequent never events was as a result of staff not feeling able to speak up if they had concerns. A new culture and improvement lead role had been implemented to drive change. The staff member in this role had already started to make inroads into identifying the issues and the direction needed for leadership, but this work was in its infancy.

Staff told us speciality leaders in the surgical care groups were approachable and they felt more listened to in recent months. Theatre staff were not aware of who most members of the trust board were, except for the Chief Executive Officer (CEO). Staff referred to her by first name and several staff spoke positively that the CEO had visited theatres and spent time with them. Staff told us that as a result of the CEO visiting and discussions at that time, a new process for dealing with the red tag around the swabs had been identified (swabs were bundled in packs of five secured with a red tag and incorporated into the swab count). The changes had been made at theatre level, but when speaking to staff they told us that this had not been recognised by any policy or standard operating procedure. The trust sent us the Surgical Practice Standards Clinical Guidelines V4.0 December 2019 which included information in relation to dealing with the red tags in a count. It was clear that staff we spoke with were unaware of supportive guidance in relation to this.

Leaders had not identified the gaps in cross speciality and trust wide learning. There was no clear insight by leaders into the gaps in shared learning. Not all managers had shared the never events and the subsequent changes to the wider care groups and trust locations as staff had limited knowledge of the never events.

Leaders had undertaken an internal thematic review of the never events to determine if there were additional trends or learning which could be gained. A review of staff skills had taken place and training had been provided. Firstly, in dermatology, but with plans for further roll out training for ophthalmology and cardiology. We were advised this was taking a lot of logistical planning as it involved training a whole team for half a day. Theatres and all interventional spaces teams would also be provided with this training.

The review of staff skills had been a self-assessment format, which did not provide assurance of a consistent benchmarking of skills had been used. Leaders had not recognised this as a risk, but staff were clear about the risks of this process. They explained staff may have considered themselves competent but because a lack of observational audit to standardise practice, different levels of ability had been accepted. Staff explained that a structured induction for new staff had been implemented. However, the induction was provided by staff who had not been assessed as competent, so the induction may not be effective or of the correct standard. Staff described the risk as teaching custom and practice, when that may not be correct practice. Staff did not advise they had informed the trust of this issue.

Culture

Staff felt respected, supported and valued. The service had an open culture where staff could raise concerns without fear.

Staff told us felt supported, respected and valued. Staff felt positive and proud to work in the hospital and told us they felt they were a good team and benefitted from excellent clinical skills.

Staff told us they felt morale was low, mostly caused by the impact of Covid-19 and increased workloads, but they considered that a culture change seemed to be happening with staff starting to feel more empowered and able to speak up. Freedom to Speak up Guardians and safety champions were available in the trust to support staff. There was evidence of team working and cooperative, supportive and appreciative relationships among staff, but many staff told us they were overwhelmed by the workload and the changes needed to improve patient safety.

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. Staff we spoke with said they felt comfortable raising concerns and felt they were listened to. However, some staff told us they felt under pressure to meet an increasing workload and this affected aspect of safe practice. They told us they absorbed increased workload because they felt this was their role, but the impact put strain on them, and the services provided. For example, we saw in dermatology outpatients the nursing staff were allocated to two doctors each. Staff told us this was sometimes problematic if the doctor had to leave patients to find nursing staff, so reducing patient experience and creating increased pressure on staff.

There was evidence of team working and cooperative, supportive and appreciative relationships among staff. Staff felt comfortable in asking for help. We observed friendly and professional relationships amongst staff. Staff at all levels were clear about their roles and understood what they were accountable for, and to who. They recognised change was needed as a result of the never events to ensure patient safety.

Governance

Governance structures and the communication within them were not effective to ensure that changes and learning supported patient safety across the trust.

The governance structure did not always ensure information and learning was shared effectively between surgical specialities and locations in the trust. Theatre staff were managed by theatre managers as part of a triumvirate of a general manager, head of nursing and clinical director. They were answerable to the operations lead, who reported in turn to the trust board.

The Board were fully aware of the never events and were supportive of the actions being taken. We looked at the minutes of three public board meetings from July 2020, October 2020 and November 2020, and found reference to challenge from the board in relation to the never events.

There were governance structures at each location, which enabled the never events to be reported and escalated. All current actions were reported to and reviewed by the quality assurance committee. However, there were gaps in communication and in the governance structures which did not ensure communication between all surgical specialities and all locations of the trust were enabled. Staff we spoke with were not all able to tell us about the never events within their own speciality and those that occurred elsewhere. We were therefore not assured the required learning and change to practice were implemented to prevent any never event occurring again.

Information about incidents was not shared across surgical specialities or locations through governance processes or any staff communications. There was a governance structure for the trust which did not consistently incorporate West Cornwall Hospital and St Michaels Hospital. For example, a never event occurred on the West Cornwall Hospital site in May 2020 (undertaken by a Royal Cornwall Hospital team), the senior team at West Cornwall Hospital were not made aware of the never event until the internal summit held November 2020.

A never event took place at Royal Cornwall Hospital in September 2020. We were told the team at West Cornwall Hospital were made aware of the ophthalmology never event by a visiting doctor to West Cornwall Hospital and not by the trust governance structures. Information could have been shared and learning implemented earlier to prevent the risk of reoccurrence.

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There was a disconnect between staff and the senior leadership teams. Governance and management interacted with each other appropriately but information about incidents while shared with managers through weekly speciality/ business meetings, care group governance meetings and speciality governance meetings, was not disseminated to staff working in theatres and surgical areas.

We reviewed minutes from the daily safety huddles from September 2020 to December 2020 and they did not evidence any communication or learning from never events across the trust.

We looked at staff meeting minutes across the surgical care group and they did not demonstrate incidents and shared learning. There was only one reference to the WHO in October 2020 anaesthetic team minutes.

Senior governance meeting minutes demonstrated incidents and shared learning were discussed. We reviewed weekly governance huddle meeting minutes from October into November 2020 and saw that the never events were included. Teams were waiting for the final Ophthalmology report for discussion.

Theatres undertook never event debriefs to look at what could be improved, and a weekly governance huddle looked at what went well and why. This was used to embed safe and positive learning. A monthly governance audit half day meeting was held to review audit data. A newsletter was being launched to circulate the positives to celebrate good work and share the information more widely. This had not yet been completed. We spoke with staff in the surgical areas visited and they consistently confirmed that they were not aware of never events in other surgical specialities and learning taken from those events was not used to support safety practice in other parts of the trust.

The trust senior staff told us that “critical friends” were to be used to visit theatres and review practices using an external perspective, for scrutiny and challenge. Critical Friends are staff from other departments of the trust with some surgical insight which enabled them to observe practice and provide an external perspective.

Quality Improvement processes had been implemented but were in their infancy. Some information gathering had taken place and a substantial action plan had been completed. The trust was using quality improvement methodology to support the spread and sustainability of learning. A training session had been held in December 2020 which had looked at the use of the WHO checklist, human factors and scrub practice. It had been recognised that the WHO checklist and the practice of questioning and raising concerns about the WHO checklist had in some places been poor and staff recognised the risks of this. Staff spoke positively about the training provided and one staff described the WHO checklist training as “an eye opener,” and other staff told us patient safety had improved as a result.

The Quality Summit was also held in November 2020 to further support the development of a substantial action plan. The internal quality summit saw representation from across all Care Groups, including those where a never event occurred. From this meeting, further cross cutting themes were identified, and a paper presented to board.

There was an incident review and learning group which had looked at information sharing and shared presentations across some of the care groups.

Staff recognised the difficulty with having a large action plan and were looking to manage the changes effectively rather than be overwhelmed with the task. Dermatology staff told us that on their action plan 27 changes were recorded. Staff talked about feeling positive about the training and support but felt overwhelmed by the number of changes needed

and the work needed. The extensive dermatology action plan was being reviewed every two weeks with a review of evidence of actions completed. The quality improvement meeting was used to sign off action plans. Some of the plans had been closed but further to the third dermatology never event these closed actions had been reopened to ensure a wider scope of learning.

An Incident Review and Learning Group which had looked at information sharing and shared presentations across some of the care groups. We were told by senior staff that never events and serious incidents learning was disseminated to staff through daily huddles across wards and theatres. These huddles were recorded, and notes were held in the department to enable staff not on that shift to be able to access the information. A further governance huddle was held each Monday afternoon.

Processes had been developed to train staff in human factors. Human factors training focussed on optimising performance by better understanding the behaviour of individuals and the environmental factors involved. This training had not yet been implemented in all areas of practice and at the time of the inspection had only been completed by the dermatology team. However, there was a delay in the training reaching all the required staff groups in a timely way. There was a risk that if not all staff completed this training, they may not have the correct knowledge and skills, potentially, increasing the risk of errors occurring.

Areas for improvement

The trust must:

- Ensure that actions taken to mitigate further risks of never events occurring do not have the potential to increase risk.
- Ensure that staff receive timely and adequate training in response to the never events
- Ensure that there is a system and process whereby there is a complete programme of theatre audits which includes sharing outcomes and learning across the multi-disciplinary team.
- Ensure that there is a clear governance structure to enable learning to be shared more widely across the trusts and to its other locations to guarantee patient safety.
- Ensure that actions taken in response to the never events are actioned in a timely way to ensure patient safety and to prevent re occurrence.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, inspection manager, one other CQC inspector and two specialist advisors with a surgical background. The inspection team was overseen by Amanda Williams, Head of Hospital Inspection.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Surgical procedures	S29A Warning Notice