Royal Cornwall Hospitals NHS Trust

St Michael's Hospital

Inspection report

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Date of inspection visit: 15 and 16 June 2021
Date of publication: 20/08/2021

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 St Michael's Hospital

Inspected but not rated

We carried out a short notice focused inspection of the Surgical Care Groups of the trust on 15 and 16 June 2021.

We inspected one surgical area of St Michael's Hospital on the 16 June 2021 as part of that inspection. This was because at our last inspection in December 2020, we identified concerns which led to the trust being served a Warning Notice under Section 29A of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The aim of the inspection was to see if the trust has made the required improvements. At this inspection, we found that the trust had made a number of improvements and had met the requirements of all aspects of the S29A Warning Notice.

During this focused inspection we concentrated on specific key lines of enquiry within the 'safe' and 'well led' key questions for surgery. This meant we could assess the trust's actions and improvements in response to the Warning Notice. We did not inspect the effective, caring or responsive key questions and therefore did not change the rating for surgery at St Michael's Hospital, which remains good overall. We will continue to monitor the performance of this service.

The trust is the main provider of acute hospital and specialist services for most of the population of Cornwall and the Isles of Scilly, about 500,000 people. The population can more than double during busy holiday periods. The trust employs about 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 and 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. St Michael's Hospital is managed as a separate site and does not sit within those trust care groups. Elective surgery is provided at St Michael's Hospital and West Cornwall Hospital.

The trust had undertaken 30,160 elective procedures and 14,441 emergency surgical procedures from January to June 2021.

St Michael's hospital has one theatre suite, this includes four operating theatres, a recovery area and two surgical wards. We inspected some of the surgical areas at St Michael's Hospital. This included one theatre and two surgical wards. The inspection team included a lead inspector and a second inspector.

See the surgery section for our detailed findings.

How we carried out the inspection

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.

Surgery

Inspected but not rated

At the last inspection in December 2020, the trust was served a Warning Notice because:

- Governance was not effective throughout the service to ensure that changes and learning supported patient safety across the trust. The response to the never events had not been managed in a timely way to ensure patient safety.
- Not all relevant audits were completed. Audits data showed varying levels of compliance. Staff were not aware of audit outcomes and learning was not triggered by these audits.
- Staff had not received adequate training in response to never events.
- Actions taken to mitigate further risks of never events occurring had the potential to increase the risk in the short term.

At this inspection in June 2021 we found:

- The trust had made significant improvements since our last inspection in December 2020.
- Compliance with the World Health Organisation (WHO) Checklist had improved, and further improvements were in progress to ensure sustainable improvements. The WHO Surgical Safety Checklist is a simple tool designed to improve the safety of surgical procedures by bringing together the whole operating team to perform key safety checks during vital phases of perioperative care.
- Managers responded to incidents and shared information in a timely way.
- The programme of audits had been reviewed and there is a targeted audit schedule. A safer surgery group had been implemented to review audit findings and share learning with the wider hospital team.
- Compliance with training had improved with over 80% of staff having completed the WHO checklist and Human Factor training. There was an ongoing programme to ensure the rest of the workforce completed the training.
- Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together across all hospital sites for the benefit of patients and had access to good information.
- Further improvements had been implemented to ensure actions to mitigate further risks of Never Events did not increase risk in the short term.
- Leaders understood and managed the priorities and issues the service faced. Actions had been taken to improve communication and ensure more joined up working between Royal Cornwall Hospital, St Michael's Hospital and West Cornwall Hospital.
- Governance structures and communication within them had improved to ensure changes and learning supported patient safety across the trust.
- Staff felt respected, supported and valued. The service had an open culture where staff could raise concerns without fear.
- Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. Staff assessed risks to patients, acted on them and, in most cases, kept good records. They managed medicines well. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.

However:

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- Peri-operative documentation was not always completed fully and consistently.
- Although the trust provided assurance that the WHO checklist was being updated to include a patient safety alert, the updated documents had not been in circulation yet.
- Relevant information about allergies was not written on the board in theatres.

Is the service safe?

Inspected but not rated

Mandatory training

The service provided mandatory training and had implemented WHO checklist and Human Factor training across the Surgical Care Groups. It encouraged all staff to complete these training packages.

WHO checklist and Human Factor training had been rolled out to all staff who were involved with patients who underwent invasive procedures across all Care Groups, including bank staff. A trust performance report as at 15 June 2021 showed:

- 82% of applicable staff had completed the WHO checklist training.
- 89% of applicable staff had completed the Human Factors training.

This was an improvement since our last inspection where only staff working in the dermatology department had received the WHO checklist training.

For staff working in non-invasive areas, such as the surgical wards, they were required to complete patient safety training. The clinical lead for culture change and improvement told us as at 4 June 2021, 44% of staff had completed this training. They had oversight of the training record and sent out weekly reports to department leads to ensure staff who needed the training were booked appropriately.

Staff were required to complete this training annually. There was a process to restrict staff practice if they did not maintain training of these subjects.

The quality of the WHO checklist was overseen by senior team leaders, theatre managers and the WHO audit process.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration. However, there were gaps in record keeping which the trust recognised and was addressing.

Risks to patients were discussed daily and shared with staff across theatre suites. Daily safety huddles in theatre departments were undertaken to highlight any issues with patient risks, staffing, theatre lists, reported incidents from the previous day and infection control concerns. This meeting provided a forum for relevant hospital updates. Minutes were taken and available to all staff and provided an audit trail for areas discussed. Staff confirmed patient handovers included all necessary key information to keep patients safe.

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As part of the five steps to safer surgery a daily briefing in each theatre was undertaken at the beginning of each operating list. This was to highlight any patient who may be deemed at risk, to discuss specific equipment requirements, and issues which may impact the list. 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 eight sign-in checklists we reviewed. 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 that the operating site had been marked. Staff performed and documented checks well in the three cases we observed. For example, staff observed a "silent cockpit" approach which ensured everyone was listening and focused as each part of the checklist were completed.

Staff shared key information to keep patients safe when handing over their care to others.

Peri-operative care booklets were used to ensure that important clinical and safety information was easily available. Staff in theatre and recovery rooms told us that information sharing between areas was good. We observed a patient's whole peri-operative journey and saw handovers that effectively communicated the patient's ongoing needs.

However, documents and information on theatre boards were not always completed fully and consistently. For example, information about allergies was recorded in the notes and shared during the "sign" part of the WHO checklist. However, we observed in the theatre we visited these were not recorded on the whiteboard in theatre. Key document templates had been updated but were not in circulation yet. We also found information was not fully completed in the three peri-operative care booklets we reviewed. For example, the pre-operative checklist had not been fully completed to indicate that the questions asked within this section of the checklist had been answered. The trust recognised this problem and had redesigned the surgical care documents. They had collated information from different care groups to understand why some sections were not always completed and whether it was necessary to have these. They aimed to streamline and standardise these documents where possible. Senior managers would be monitoring whether the changes improved compliance through their monthly audits.

At this inspection we looked at how changes and improvements were managed between all of the trust's hospital sites across Cornwall. For example, at West Cornwall Hospital we saw a newly updated peri-operative care booklet in use. This had additional boxes on the "patient care in theatre" page where the theatre scrub practitioner and circulating practitioner signed and printed their names. This demonstrated that the trust had met the requirements of the Section 29A Warning Notice issued on 21 December 2020, which required the trust to maintain a written record of two signatures for the scrub count.

However, in St Michael's Hospital and The Royal Cornwall Hospital these documents had not been updated. We were told this change was being implemented trust wide and updated care booklets were approved for issue and would soon be in use. We noted in the minutes from the Quality Assurance Committee on the 23 June 2021 (one week after our inspection), this had been discussed and confirmed that five out six peri-operative care booklets had been updated and published. The one outstanding was in relation to cataract surgery where additional changes were being made following a further revision to the WHO checklist.

Theatre staff had to add the names of the scrub and circulating practitioners to the electronic record of care before the record could be closed. These records were monitored and if staff had failed to enter their names, a notification would be sent to theatre managers the following morning prompting them that a record was incomplete and to review these. This was an improvement since the last inspection where records could be closed without staff adding their names to it and did not provide an audit trail if the information was needed later.

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Daily reports were circulated to ensure governance leads were sighted on issues and concerns in real time. The trust had also updated their Scrub Practice Standards Clinical Guideline in February 2021 indicating that the perioperative document must be fully completed and signed, naming the scrub and circulating practitioners. This was to be retained in the patient's medical record.

An audit process had been implemented since March 2021 to understand areas of improvement in completing peri-operative booklets throughout the patient's journey in surgical care. A first audit had been undertaken which looked at the quality of record keeping in 50 sets of notes across different care groups. This audit identified several areas of improvement in the quality of record keeping between the wards to recovery areas. Actions from these audits would be discussed and agreed at the Safer Surgery Group meeting, which we noted was the following day of our inspection and was on the agenda. There were plans to re-audit within three months to check the actions were effective. The purpose of the Safer Surgery Group was to ensure learning and actions was shared across the different care groups. This audit process had improved since our last inspection as the information was gathered by the governance lead for Anaesthetics, Critical Care and Theatres which ensured independent oversight, compared to our last inspection where we identified this was lacking.

We reviewed results of the WHO checklist audit from March to May 2021 which demonstrated improvement in practices. The quantitative compliance (measured by the quantity of something rather than its quality) ranged from 90% to 100% in that period. Compliance in relation to the qualitative compliance (measured by the quality of something rather than its quantity) increased from 61% to 100% between March and May 2021. This was an improvement from the same period in 2020. This audit was to help assure the trust Executive Team that standards were being met across all theatres. The audit areas included the safety huddle, operating list briefing and debriefing. This audit relied on information being gathered by the nurse or matron in charge from each theatre. This audit was a peer assessment within clinical areas overseen by the Theatre Manager or Nurse in Charge. Leaders told us the additional WHO checklist training and Human Factor training had provided staff working in the Surgical Care Groups refreshed understanding on the expectations of peer assessments. The trust had implemented further spot audit checks on those areas of the WHO checklist peer assessment to ensure independent oversight. We were told by leaders that eventually both audits would be brought together to provide a clearer view of assurance. We noted action plans were drawn from the independent process to ensure actions were implemented and learning was shared.

Never event

Never events are serious patient safety incidents that should not happen if healthcare providers follow guidance on how to prevent them. Each never event has the potential to cause serious patient harm or death, but neither need to have happened to be a never event.

When we inspected in December 2020 the trust had reported seven recent never events across its three locations between February and October 2020. Since we last inspected the trust had two further never events, both at its Royal Cornwall Hospital site:

- One in February 2021 which was a wrong site surgery carried out in the interventional radiology department. (Interventional radiology refers to minimally invasive, image-guided medical treatments).
- June 2021 was an overdose of insulin administered due to the use of an incorrect device in anaesthetics.

Nearly all staff we spoke with knew about a recent never event and all staff knew about those which related to their own role or specialty.

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The trust had improved communication of never events with staff. We saw evidence that the trust made sure learning from never events was communicated quickly across all staff grades and sites. For example, a trust wide briefing on the safer administration of insulin by clinical staff was issued within a week of reporting the latest never event.

At this inspection we looked at how changes and improvements were managed between all the trust's hospital sites across Cornwall. Staff in St Michael's Hospital told us about the recent overdose of insulin never event, that happened at the Royal Cornwall Hospital. Staff in the Post Anaesthetic Care Unit (PACU) showed us how 'pop ups' on trust computers communicate safety information such as never events.

Staff in all sites confirmed they also received safety information through management emails and leaders 'vlogs' (Vlog stands for a video blog or video log, and refers to a type of blog where most or all of the content is in a video format) but they expressed concern that they did not always have time to log in to see these. Trust managers would soon be placing new communication screens throughout theatre departments. The screens would be linked and could be updated remotely to show the latest safety messages.

There was an investigation of each incident and debriefs were undertaken to gain a better understanding of what had gone wrong. Investigation leads were appointed and after initial investigations, 72-hour reports were published. Following a full investigation into the wrong site surgery never event, a final report was produced with recommendations and an action plan to identify allocation of responsibility and timescale for actions. The final investigation report for the insulin never event was being written, as it only happened 18 days before our inspection.

There was some learning from these never events and some changes to practice as a result. For example, following the interventional radiology never event, five learning points were identified. These included:

- Clinicians undertaking the procedure to prepare together so key information is reviewed prior to starting the procedure.
- When concerns are raised, for everyone to pause and check information before proceeding.
- Ensuring clinicians taking written consent capture sufficient information for the patient and the team to validate the procedure, site and, when specifically required, the side.
- Consent form to be seen and procedure confirmed verbally in the room as part of WHO final checks.
- Referral information to be seen and procedure confirmed verbally in the room as part of WHO final checks.

Medicines

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

Systems had been improved to ensure correct syringes were available to administer medicine for the treatment of diabetic patients. This was in response to a never event and had been implemented across all sites. The communication was an improvement since the last inspection when key information about a medicine never event had not been shared across the trust.

The service had systems to ensure staff knew about safety alerts and incidents. This meant patients received their medicines safely. Staff followed current national practice to check patients had correct medicines.

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Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. However, managers had not ensured that actions from a patient safety alert were implemented and monitored in a timely manner.

Staff knew what incidents to report and how to report them. All staff were able to describe systems and process to report incidents. They told us the trust encouraged them to report incidents and there was a no blame culture.

Managers shared learning about incidents and never events with staff and across the trust. We saw evidence of this in minutes of meetings and "pop-ups" on computer screens.

Staff understood the duty of candour. They were open and transparent and gave patients and families a full explanation if and when things went wrong. 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.

Staff received feedback from investigation of incidents, both internal and external to the service.

Staff met to discuss the feedback and identify where improvements could be made to patient care. There was evidence that changes had been made as a result of feedback. For example, in dermatology, processes had been improved to avoid the need for doctors to leave their clinic and check surgery sites. A "body-map" form had been introduced to ensure nurses and doctors only operated on the correct surgical site. More time had been allocated to ensure clinical staff completed all safety checks prior to, during and post-surgery.

Managers investigated incidents thoroughly. Patients and their families were involved in these investigations. Managers debriefed and supported staff after any serious incident.

However, two of the three hospitals (Royal Cornwall Hospital and St Michael's Hospital) we visited had not included specific questions around a national patient safety alert issued in 2017 on their checklists. These questions were asked to ensure that patients' intravenous cannula were free from residual anaesthetic medicines before they left theatre. An intravenous cannula is a thin tube that healthcare staff insert into a person's vein. Healthcare staff use them to administer medicine. NHS England required all theatre departments in England to add these questions to their surgical safety checklists by 9 August 2018. In theatres, cannula flushing was recorded on the electronic system but not the checklist. While the trust had advanced plans to issue new surgical safety checklists, these were not fully implemented at the time of our inspection. They explained this was due to using the opportunity to review and improve existing documents. The safer surgery group signed off the improved checklist on 18 June 2021 and the minutes from the Quality Assurance Committee on the 23 June 2021 (one week after our inspection), confirmed that five out of six perioperative care booklets had been updated and were published. The one outstanding was in relation to cataract surgery where additional changes were being made following a further revision to the WHO checklist. Further evidence sent by the trust showed that the documents were available to all departments and there was a two-week turnaround for all departments to update their stationery.

Surgery

Is the service well-led?

Inspected but not rated

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills.

Leaders recognised challenges surrounding never events, changes required to ensure patient safety and comply with the Warning Notice served at the last inspection. The role of the new Clinical Lead for Culture Change and Improvement was embedded, and they were driving improvement in invasive procedures across the Royal Cornwall Hospital, including the Surgical Care Groups.

Staff told us there was a notable positive change in communication shared across the Surgical Care Groups and hospital sites. This was an improvement since our last inspection where staff could not demonstrate they were aware of information about never events and learning from these.

A monthly quality assurance committee was attended by executive and non-executive directors. Actions from our previous inspection and never events were reviewed and discussed. We noted that leaders challenged actions overdue and encouraged accountable teams to focus on these. This gave the leadership team oversight of actions and their progress.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff we spoke with said they were encouraged to raise concerns and to speak up. They told us that Human Factors and the WHO checklist training had increased their confidence to speak up if they had a concern. We saw posters and messages were sent to staff by the trust, to encourage them to speak up if they had concerns.

Staff at St Michael's Hospital told us there was increased anxiety when surgical wards were converted to medical wards in response to the COVID-19 pandemic. However, they also told us they had support from the medical team and they worked well together.

There was evidence of team working and cooperative, supportive and appreciative relationships among staff. Staff felt comfortable 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.

The duty of candour is a regulatory duty that relates to openness and transparency. It 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 of the recent never events confirmed that duty of candour had been applied.

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Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The governance arrangements had improved since our last inspection. Leaders could demonstrate oversight of issues and actions.

Gaps in training, skills assessments and sharing of information had been addressed since the last inspection. We saw evidence the trust had prioritised the WHO checklist and Human Factor training, and significant improvements had been made in this area.

Skills assessment had improved and competency packs for staff had been reviewed and developed. At our last inspection staff skills were assessed using self-assessment tools. At this visit we found the practice education team were implementing systems to independently assess staff skills. Leads monitored staff compliance and we saw 12 out of 13 staff members working in theatres had completed the revised competency assessments. We were told by the theatre management team there were plans to recruit one additional member of staff to support this team with skills and competency assessment.

A new governance lead for St Michael's and West Cornwall Hospital had been appointed. Feedback from staff was positive about this new role. Staff felt more connected with the main trust site at Royal Cornwall Hospital. The hospital manager, clinical director and head of nursing at both hospitals had seen a significant improvement in how the hospitals linked with each other to share information and learning. Staff told us the governance lead was visible and approachable.

Oversight of audit results had improved since our last inspection. Governance leads monitored audits and ensured the annual audit programme was completed. They used this information to review practice and identify where improvements were needed.

The service used a range of meetings to manage current risks, issues and performance. These included weekly governance huddles, monthly safer surgery group meetings and quality assurance committee meetings.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The clinical lead for culture change and improvements had clear plans to ensure staff maintained training and skills. They had delivered the majority of the Human Factors training and were now starting to implement Train the Trainer courses so that there were sufficient trainers available throughout the trust.

Weekly governance huddles were held. This meant there was oversight of risks, actions and performance. A Safer Surgery Group had been implemented with representation across the care groups, including governance leads to keep oversight of required improvements and actions.

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To help assure the trust's Executive Team that standards were being met across all theatres, audit processes had been implemented. For example, an audit process had been introduced since March 2021 to understand areas of improvement in completing peri-operative booklets throughout the patient's journey in surgical care. A separate monthly WHO checklist audit was undertaken.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The Governance Lead for General Surgery and Cancer had identified a need to check knowledge and understanding of high-profile incidents, and governance information across wards and clinical areas. As such a spot audit check was being developed to then be shared across further Care Groups for development. At the time of our inspection the criteria for this audit was awaiting sign off. This had been highlighted at weekly governance huddles as a concern for several months and had been delayed due to Covid-19 pressures. However, this was now back on track and due to be implemented as soon as the sign off process had been completed.

Areas for improvement

We told the trust that it should take action because there were areas where it should make improvements to comply with a minor breach that did not justify regulatory action, to prevent beaching a legal requirement, or to improve service quality.

SHOULDS

Surgical care service

- The trust should ensure their new peri-operative documentations are implemented across all the surgical Care Groups immediately to include the patient safety alert, "confirming removal or flushing of lines and cannula after procedures 9 November 2017." (Regulation 12).
- The trust should ensure it reviews the COVID-19 guidelines for "amber" and "green" patients so that it can be followed consistently in all urgent cases. (Regulation 12)

This is required as part of Regulation 12 on managing risks to patients, but we considered that it would be disproportionate for these two findings to result in a judgement of a breach of the regulation overall at the location.

- The trust should continue to review and implement improvements so that information is recorded consistently. This is relation to peri-operative documentation packs and information about allergies on white boards in theatres.
- The trust should continue to encourage uptake of the WHO checklist and Human Factor training, to improve compliance.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a second CQC inspector. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection.