Review of compliance

Royal Cornwall Hospitals Trust **Royal Cornwall Hospital**	
Region:	South West
Location address:	Royal Cornwall Hospital Treliske Truro Cornwall TR1 3LJ
Type of service:	Acute Hospital registered for the following regulated activities: Treatment of disease, disorder or injury Assessment or medical treatment of persons detained under the Mental Health Act 1983 Surgical procedures Diagnostic or screening procedures Management of supply of blood and blood derived products etc. Maternity and midwifery services Termination of pregnancies

	Family planning.
Publication date:	June 2011
Overview of the service:	Royal Cornwall Hospital is situated in Truro, Cornwall. It is part of the Royal Cornwall Hospitals Trust (RCHT) which also consists of West Cornwall Hospital (Penzance), St Michaels Hospital (Hayle), Penrice Birthing Unit, at St Austell Hospital (provision of approximately 750 beds between them) and RCHT Headquarters who manage community services at other sites throughout Cornwall. This is an acute hospital with services such as a 24 hour accident and emergency department, maternity unit, outpatient services, imaging and laboratory facilities. The hospital serves a local population of around 450,000 which is often doubled by holiday makers during the busiest times of the year.

Summary of our findings
for the essential standards of quality and safety

What we found overall

We found that Royal Cornwall Hospital was not meeting one or more essential standards. Improvements were needed.

The summary below describes why we carried out the review, what we found and any action required.

Why we carried out this review

We carried out this review as part of our routine schedule of planned reviews.

We carried out this review because concerns were identified in relation to:

- Consent to care and treatment
- Care and welfare of people who use services
- Supporting workers
- Assessing and monitoring the quality of service provision

How we carried out this review

This review was carried out under section 62 of the Health & Social Care Act 2008 following information gained from NPSA (National Patient Safety Agency) notifications (that the Trust have to submit and that then feed into Care Quality Commission's Quality Review Profile), Cornwall and Isles of Scilly Primary Care Trust and the Trust themselves. We found that between November 2009 and April 2011 the Trust had experienced five "never events" within the operating theatre areas of the hospital. 'Never events' are serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented.

A site visit took place on 25 May 2011 and was unannounced. We were accompanied by a professional clinical advisor to the Care Quality Commission (CQC). The visit consisted of going to operating theatres 1, 2, 4, 6, 7, 9, 10 and the emergency theatre at Royal Cornwall Hospital. We were reviewing the regulated activity of surgical procedures only.

We met with staff including anaesthetists, health care assistants, specialist nurses, operating department practitioners, registered nurses, surgeons, doctors on trainee programmes, the new matron and the medical director. We met the Chief Executive,

Medical Director and the Director of Nursing, amongst other heads of department at the end of the site visit.

Our visit consisted of speaking with staff, looking at records and observing theatre practices.

What people told us

Because we were reviewing practice in the operating theatres we did not speak to many people who use the service. The very small number of people we did speak with said staff had explained what was going to happen pre and post surgery and that they had been treated very well.

What we found about the standards we reviewed and how well Royal Cornwall Hospital was meeting them

Outcome 2: Before people are given any examination, care, treatment or support, they should be asked if they agree to it

The service has suitable arrangements for gaining and acting in accordance with people's consent. This ensures that people receive the care and support they have agreed to.

- Overall, we found that Royal Cornwall Hospital was meeting this essential standard.

Outcome 4: People should get safe and appropriate care that meets their needs and supports their rights

Patients are at an increased risk because important safety check-lists are not consistently being completed or used effectively in the operating theatres at the Royal Cornwall Hospital.

Patients are at risk of receiving inappropriate care and treatment because information is inconsistently recorded.

- Overall, we found that improvements were needed for this essential standard.

Outcome 11: People should be safe from harm from unsafe or unsuitable equipment

Some equipment is in need of repair or replacement. Areas where tape or gloves have been used to repair or improvise could increase the risk of infection or pressure area damage for patients.

Equipment is provided in sufficient quantities and was being used properly.

- Overall, we found that the Royal Cornwall Hospital was meeting this essential standard but, to maintain this, we suggested that some improvements were made.

Outcome 13: There should be enough members of staff to keep people safe and meet their health and welfare needs

The staff working in all of the theatres had a range of skills and experience.

There is not always sufficient numbers of appropriate staff which could sometimes put the safety of patients at risk.

- Overall, we found that the Royal Cornwall Hospital was meeting this essential standard but, to maintain this, we suggested that some improvements were made.

Outcome 14: Staff should be properly trained and supervised, and have the chance to develop and improve their skills

Staff with poor morale, feeling undervalued and under pressure are more at risk of making mistakes putting the safety of patients undergoing surgery at risk. Although changes are being made, further improvements are needed to improve the safety for patients undergoing surgery.

- Overall, we found that the Royal Cornwall Hospital was meeting this essential standard but, to maintain this, we suggested that some improvements were made.

Outcome 16: The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

A culture of reacting to problems rather than monitoring and preventing them, mean that some patients receiving surgery are still at an increased risk of receiving unsafe care and treatment.

- Overall, we found that improvements were needed for this essential standard.

Action we have asked the service to take

We have asked the provider to send us a report within **14** days of them receiving this report, setting out the action they will take to improve. We will check to make sure that the improvements have been made.

Where we have concerns, we have a range of enforcement powers we can use to protect the safety and welfare of people who use this service. Any regulatory decision that CQC takes is open to challenge by a registered person through a variety of

internal and external appeal processes. We will publish a further report on any action we have taken.

What we found
for each essential standard of quality and safety we reviewed

The following pages detail our findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

We will have reached one of the following judgements for each essential standard.

Compliant means that people who use services are experiencing the outcomes relating to the essential standard.

A **minor concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard.

A **moderate concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard and there is an impact on their health and wellbeing because of this.

A **major concern** means that people who use services are not experiencing the outcomes relating to this essential standard and are not protected from unsafe or inappropriate care, treatment and support.

Where we identify compliance, no further action is taken. Where we have concerns, the most appropriate action is taken to ensure that the necessary improvements are made. Where there are a number of concerns, we may look at them together to decide the level of action to take.

More information about each of the outcomes can be found in the *Guidance about compliance: Essential standards of quality and safety*.

Outcome 2:
Consent to care and treatment

What the outcome says

This is what people who use services should expect.

People who use services:

- Where they are able, give valid consent to the examination, care, treatment and support they receive.
- Understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed.
- Can be confident that their human rights are respected and taken into account.

What we found

Our judgement

The provider is compliant with outcome 2: Consent to care and treatment

Our findings

What people who use the service experienced and told us

We were told, by patients, that people had been asked for their consent to surgery and that procedures to be carried out had been fully explained.

During one ‘time out’ period (safety checks performed before the start of the operation) observed, consent was discussed in detail as it had involved ‘best interests’ meetings taking place prior to consent being gained.

One consent form seen had two options for surgery on it. This varied from the procedure written on the board in the theatre. In discussion with staff it was confirmed that they had checked with the surgeon and that what was written on the board was the procedure to be carried out. This may be misleading for staff.

We observed that pre operative checks ensure that consent forms had been signed and staff confirmed verbally with the patient what procedure they were going to have.

Our judgement

The service has suitable arrangements for gaining and acting in accordance with people's consent. This ensures that people receive the care and support they have agreed to.

Outcome 4:
Care and welfare of people who use services

What the outcome says

This is what people who use services should expect.

People who use services:

- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

What we found

Our judgement

There are major concerns with outcome 4: Care and welfare of people who use services

Our findings

What people who use the service experienced and told us

During our site visit we saw numerous examples where surgical safety checks were not being carried out in a satisfactory or consistent way within operating theatres at the hospital. This is despite five 'Never Events' occurring in the operating theatre departments since 2009, (the most recent being in April 2011), subsequent internal investigations by the hospital and actions plans developed as a result of these. 'Never Events' are serious, largely preventable, safety incidents that should not happen if the available preventative measures have been put into place.

Royal Cornwall Hospital sometimes use an adapted version of the World Health Organisation (WHO) surgical safety checklist recommended by the National Patient Safety Agency (NPSA). The surgical safety checklist consists of safety checks done at various stages of the person's journey through the operating theatre. The WHO state that these checks should be clear, formal and read out loud.

Staff told us they thought they were very good at performing surgical safety checks but said it did depend on which staff were on duty as to how well the checks were done.

Our observations found that staff are not following the WHO guidelines and do not always refer to the hospitals adapted checklist. As a result they do not complete all core checks which meant there was an increased risk to some patients because important checks are not completed at an appropriate time or not communicated to all team members.

Staff told us that there is a 'Department meeting' each morning where the theatre list is discussed with complications and important information discussed. Staff told us that Surgeons and Anaesthetists are not always included in this meeting.

A detailed 'sign in' check should be performed before the anaesthetic is given to the patient. We saw an example where airway, estimated blood loss and equipment checks were not performed. The remaining checks were also not clearly communicated.

Just before the operation commences a 'time out' check is conducted where staff make sure the next stage of the checklist is complete. During our observations time out checks were not clear and in one case chaotic with a quiet time not being adhered to. This meant that important information was missed or needed to be repeated.

During the eight 'time out' checks we saw none were clear or formally done. Four checks did not introduce the staff present in theatre and three did not discuss antibiotic therapies. Two checks did not discuss prevention measures for pressure sores. One of these was on an elderly person where no padding or hip protection was used under a hip despite the person being at very high risk of developing pressure sores. In the same case specific pressure relieving equipment was not used on other parts of the body. Incontinence pads were used for padding, which may crease and further the risk of pressure sores developing. Theatre staff also identified that the person had an artificial hip in place which they had not been informed about and were also delayed starting because they had not been informed that ward staff had not performed all pre operative checks, meaning operating staff had to get further equipment. This meant the person was waiting for an extra five minutes with specialist anaesthetic in process, which could have worn off needing further anaesthetic.

During another time out check the surgeon was 'scrubbing up' (washing his hands and putting on sterile gown and gloves) so missed the majority of the surgical safety check. Possible critical events or risks were not discussed and the name of the procedure was not announced to the theatre team as expected according to the WHO checklist and hospital checklist. The consent form for this patient varied very slightly to the procedure on the board. This lack of clarity could lead to errors being made. This operation was being carried out by a registrar grade surgeon. The assistant was also acting as a scrub nurse. We were told this was acceptable practice for the routine procedure being carried out. However, this theatre was short of an extra member of staff to compensate for this, meaning staff were rushing to achieve all tasks and perform all checks. For this patient, there was no 'sign out' check performed. The surgeon asked if the swabs were present, wrote his notes

and left the theatre. The anaesthetist did not give clear instructions for recovery.

During the five time out checks seen, only one ‘anticipated critical events’ was communicated. Two were not done and two were covered in a single question of ‘Any risks identified?’

During another ‘time out’ check, when the quiet time was not being adhered to, a member of staff later had to ask about checks he had missed.

Following the surgery there should be a ‘sign out’ check performed before any member of the operating team leaves theatre. Checks should be done to confirm that the name of the procedure has been recorded, that the swab and needle counts are correct and any specimens have been labelled. Instructions for the recovery period, including checks, specific to different types of surgery are also shared at this time. During our observation we saw no formal sign out checks being conducted in any case where we were present.

The way swabs were collected and counted varied across the different theatres we saw. This inconsistency puts people at risk because staff that move from one theatre to another will be unfamiliar with each system and so are more likely to make mistakes.

Prior to one operation the surgeon pointed out that the typed theatre list was incorrect in one case. He said that the theatre lists are typed by booking clerks from information given to them from the relevant clinic where the patient was assessed. We spoke to a booking clerk who confirmed that that is how the theatre lists are compiled. The surgeon said he checked the consent form, which he knew was correct. He also spoke with the patient and their representative, once he had noticed the discrepancy to confirm exactly what procedure was to be carried out. He corrected the theatre list himself with a pen.

Our judgement

Patients are at an increased risk because important safety check-lists are not consistently being completed or used effectively in the operating theatres at the Royal Cornwall Hospital.

Patients are at an increased risk as the consent forms, typed theatre lists and information on the white boards in the operating theatre do not always say the same thing,

Outcome 11:
Safety, availability and suitability of equipment

What the outcome says

This is what people should expect.

People who use services and people who work in or visit the premises:

- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

What we found

Our judgement

There are minor concerns with outcome 11: Safety, availability and suitability of equipment

Our findings

What people who use the service experienced and told us

We saw worn pieces of equipment that had been repaired with surgical tape. This can be an infection control risk and can increase the risk of a person developing pressure sores if a limb is rubbing against a ridge of tape.

Other operating theatre table positioning devices were being covered by surgical gloves. This also could increase the risk of pressure sores developing should a person be in contact of a crease in the glove. Staff explained that requests for the correct covers has been requested but not purchased meaning they had to improvise.

Our judgement

Some equipment is in need of repair or replacement. Areas where tape or gloves have been used to repair or improvise could increase the risk of infection or pressure area damage for patients.

Outcome 13: Staffing

What the outcome says

This is what people who use services should expect.

People who use services:

- Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.

What we found

Our judgement

There are minor concerns with outcome 13: Staffing

Our findings

What people who use the service experienced and told us

We were told by nurses and consultants that there is a stable team of staff in the operating theatres with low turnover and virtually the same staff 'week on week' which makes for 'a very safe situation'. Four staff told us staffing had been 'an issue' in recent months. Staff said a shortage of well trained skilled staff was often an issue.

We were told that the departments sometimes have to use bank nursing and support staff specifically employed to work across all Royal Cornwall Hospitals Trust sites) staff and that although they are often experienced in the particular departments this is not always the case and then it puts extra pressure on the regular staff within the unit.

We saw medical students and student nurses present during some cases we observed. Staff said they enjoyed having students but found that they could not always offer as much time to them when they were short of staff.

One operation was being carried out by a registrar grade surgeon. The assistant was also acting as a scrub nurse. We were told this was acceptable practice for the routine procedure being carried out. A more senior grade surgeon was available within the department. However, this theatre was short of an extra member of staff to compensate for this.

Staff said, despite re grading of some nursing staff going on, normally morale and team work was very good within the theatres. Staff said they felt part of a team and could move between theatres with maintaining particular interest in specific types of surgery. For example one member of staff said they felt confident to work within all trauma theatres but was used for specialist hand surgery.

Senior staff indicated that staff numbers were correct but there was an issue about staff rostering and skill mix. We were told that interviews for theatre staff were taking place on the day of the inspection visit.

We saw one of the theatre managers answering the telephone frequently. Some of these calls did not need an experienced practitioner to answer them. They took her away from other jobs that were more relevant to her role. We saw support staff standing around waiting for patients to arrive in the department.

The paediatric dental day case unit was very well set up for children with a very stable group of clinicians who behaved very professionally in a paediatric environment.

Our judgement

The safety of patients is sometimes put at risk due to reduced staffing levels and skill mix that could be improved.

Outcome 14:
Supporting workers

What the outcome says

This is what people who use services should expect.

People who use services:

- Are safe and their health and welfare needs are met by competent staff.

What we found

Our judgement

There are minor concerns with outcome 14: Supporting workers

Our findings

What people who use the service experienced and told us

Understanding of the occurrence of never events at the hospital varied between staff we spoke with. Two staff told us they had been told about the retained swabs during one of the team briefings with a reminder to double check swabs at the end of surgery. One anaesthetist said he had been informed at a clinical governance meeting and an operating department assistant said they had received an email. consultants had heard about previous 'never events' and one was not aware of any of the 'never events'. No staff knew about the cluster of 'never events' therefore no one understood there was a theatre safety issue.

Not all staff felt valued. We were told that some nurses were being interviewed as part of a re-grading process and this had had some effect on staff morale, especially as some staff had had their interviews five weeks ago and still did not know the outcome. Other staff said that requests for equipment were not acted upon and others said there were concerns about skill mix.

Staff told us that they fell under pressure to complete the paperwork and the computer system whilst the operation is ongoing. One person was pleased that the operation being observed was a training operation as it would be slower and therefore there would be more time to complete the documentation.

We were told that the staff working in the theatres have access to relevant training,

support each other and get ongoing support form theatre managers

Other evidence

There has been no formal training for all grades of staff within the operating theatre departments in relation to the implementation and use of the WHO checklist and how that can prevent ‘never events’ occurring.

Our judgement

Poor morale, feeling undervalued and under pressure staff are more at risk of making mistakes putting the safety of patients undergoing surgery at risk. Although changes are being made, further improvements are needed to improve the safety for patients undergoing surgery.

Outcome 16:
Assessing and monitoring the quality of service provision

What the outcome says

This is what people who use services should expect.

People who use services:

- Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

What we found

Our judgement

There are moderate concerns with outcome 16: Assessing and monitoring the quality of service provision

Our findings

What people who use the service experienced and told us

Staff told us that they use a sticker, in the patient's notes, to sign to show that the WHO safety checks had been done. All patients' notes we saw had stickers signed to say the WHO checklist had been done.

A computer system is used to record that the checks have been done and that swab checks have been done and are correct. The system does not record the quality of this check or details of what it included. This means that audits may not pick up poor practice.

One consultant said that he believes in the computerised system but did not think it was sufficient to cover the WHO checklist. Another said he used to do a more rigorous checklist until, the computerised system took over. Another added that there are far too many similar checks done too early before the patient reaches the theatre, meaning that the important checks are not done when they really need to be by the people who need to do them such as the anaesthetist, surgeon and nurse.

All of the staff knew about the WHO checklist. The NPSA 'five steps to safer

surgery', to be used in conjunction with the WHO surgical safety checklist was displayed on the wall in each theatre we visited. The staff had adapted it in their own way and in so doing had left out important parts of it.

Other evidence

Reports received before our visit informed us that an internal investigation had taken place with every 'never event' reported but these had not been linked together to ascertain whether there may be systemic issues within the operating theatre departments.

Our judgement

A culture of reacting to problems rather than monitoring and preventing them, mean that some patients receiving surgery are still at an increased risk of receiving unsafe care and treatment.

Action
we have asked the provider to take

Improvement actions

The table below shows where improvements should be made so that the service provider **maintains** compliance with the essential standards of quality and safety.

Regulated activity	Regulation	Outcome
Surgical procedures	16	11
	Why we have concerns: Some equipment is in need of repair or replacement. Areas where tape or gloves have been used to repair or improvise could increase the risk of infection or pressure area damage for patients.	
Surgical procedures	22	13
	Why we have concerns: The safety of patients is sometimes put at risk due to reduced staffing levels and skill mix that could be improved.	
Surgical procedures	**23**	14
	Why we have concerns: Poor morale, feeling undervalued and under pressure staff are more at risk of making mistakes putting the safety of patients undergoing surgery at risk. Although changes are being made, further improvements are needed to improve the safety for patients undergoing surgery.	

The provider must send CQC a report about how they are going to maintain compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The provider's report should be sent within **14** days of this report being received.

CQC should be informed in writing when these improvement actions are complete.

Compliance actions

The table below shows the essential standards of quality and safety that **are not being met**. Action must be taken to achieve compliance.

Regulated activity	Regulation	Outcome
Surgical procedures	10 - (2) (c) (i) (ii)	Outcome 16: Assessing and monitoring the quality of service provision
	How the regulation is not being met: A culture of reacting to problems rather than monitoring and preventing them, mean that some patients receiving surgery are still at an increased risk of receiving unsafe care and treatment.	

The provider must send CQC a report that says what action they are going to take to achieve compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The provider's report should be sent to us within **14** days of this report being received.

Where a provider has already sent us a report about any of the above compliance actions, they do not need to include them in any new report sent to us after this review of compliance.

CQC should be informed in writing when these compliance actions are complete.

What is a review of compliance?

By law, providers of certain adult social care and health care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The Care Quality Commission (CQC) has written guidance about what people who use services should experience when providers are meeting essential standards, called *Guidance about compliance: Essential standards of quality and safety*.

CQC licenses services if they meet essential standards and will constantly monitor whether they continue to do so. We formally review services when we receive information that is of concern and as a result decide we need to check whether a service is still meeting one or more of the essential standards. We also formally review them at least every two years to check whether a service is meeting all of the essential standards in each of their locations. Our reviews include checking all available information and intelligence we hold about a provider. We may seek further information by contacting people who use services, public representative groups and organisations such as other regulators. We may also ask for further information from the provider and carry out a visit with direct observations of care.

When making our judgements about whether services are meeting essential standards, we decide whether we need to take further regulatory action. This might include discussions with the provider about how they could improve. We only use this approach where issues can be resolved quickly, easily and where there is no immediate risk of serious harm to people.

Where we have concerns that providers are not meeting essential standards, or where we judge that they are not going to keep meeting them, we may also set improvement actions or compliance actions, or take enforcement action:

Improvement actions: These are actions a provider should take so that they **maintain** continuous compliance with essential standards. Where a provider is complying with essential standards, but we are concerned that they will not be able to maintain this, we ask them to send us a report describing the improvements they will make to enable them to do so.

Compliance actions: These are actions a provider must take so that they **achieve** compliance with the essential standards. Where a provider is not meeting the essential standards but people are not at immediate risk of serious harm, we ask them to send us a report that says what they will do to make sure they comply. We monitor the implementation of action plans in these reports and, if necessary, take further action to make sure that essential standards are met.

Enforcement action: These are actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers are set out in the law and mean that we can take swift, targeted action where services are failing people.

Information for the reader

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Care Quality Commission

Website	www.cqc.org.uk
Telephone	03000 616161
Email address	enquiries@cqc.org.uk
Postal address	Care Quality Commission Citygate Gallowgate Newcastle upon Tyne NE1 4PA