Royal Devon University Healthcare NHS Foundation Trust

Letter / Reviews

Reference Number: F4923
Date of Response: 11/11/2022

Further to your Freedom of Information Act request, please find the Trust's response, in **blue bold text** below:

Royal Devon's Eastern FOI Office Response

1) Please send the letter sent by the trust to Devon Integrated Care Board regarding its performance management of operational pressures. Reference to the letter can be found on page 6 of 297 within the trust's public board papers for August 2022 (link here): https://royaldevon.nhs.uk/media/jkxjgvvz/royal-devon-board-papers-08-2022.pdf

   This information is not held by the Trust.

   Further to the Board meeting in August 2022 a decision was made not to send the recommended letter to the ICS regarding the performance management of operational pressures. As a result, a letter was not written and therefore the requested information does not exist.

2) Please send the thematic review which was commissioned following an increase in never events during the last 12 months at the trust. Reference to the review can be found on page on page 151 of 297 of the trust's public board papers for August 2022 (link here): https://royaldevon.nhs.uk/media/jkxjgvvz/royal-devon-board-papers-08-2022.pdf

   This information is held by the Trust.

   The Trust has carefully considered your request and is releasing a copy of the review, a copy of which is attached. Please note that the following exemptions apply where redactions have been applied as the information contains personal data.

   Section 40(2) personal data
   The review contains details of each incident which includes the personal data of the patients involved and is exempt under Section 40 (2) of the Freedom of Information Act.

   The Trust believes that the release of such information meets the definition of personal data and disclosing the information would contravene Principle (a) as set out in Article 5 of the UK GDPR as the processing would not be lawful, fair and transparent. As such release of the information would be likely to cause distress to the individuals concerned.

3) Please state who or which organisation carried out the thematic review referred to in Question 2 and the amount paid to them for doing so?

This information is held by the Trust.

The Review of Never Events was undertaken by the Trust Risk Manager. This was conducted as part of their substantive role and resulted in no additional costs to the organisation.

4) Please send the full reviews of spinal services and cardiology services (with any appropriate redactions made), which are referenced on page 149 of 297 of the trust's public board papers for August 2022 (link here): https://royaldevon.nhs.uk/media/jkxjgvvz/royal-devon-board-papers-08-2022.pdf

This information is held by the Trust.

The Trust has carefully considered your request and is releasing to you summaries of the two reviews requested, please find attached documents. However, it declines release of this information in its full format into the public domain, this would not be appropriate as the following exemptions apply:

Section 40(2) – Personal information
The reviews contain high levels of personal information throughout the information requested which is exempt under Section 40 (2) of the Freedom of Information Act.

The personal data of individual members of the review team, patient information within clinical record reviews and Trust staff involved in the review and working in the relevant services is exempt from disclosure in compliance with the UK GDPR. These individuals would not expect to have this published into the public domain.

The documents contain a significant amount of personal data, including the names of all those involved in the review. The reviews also contain the opinions of individuals staff who work in the services under review, these open honest opinions were provided in confidence to support improvements in patient care and it would not be expected that these would be released publicly. In addition the reviews contain detailed summaries of clinical records, although these have been pseudonymised within the report to ensure a level of confidentiality they have not been fully anonymised and so release into the public domain may cause distress to those patients who are able to recognise themselves from the reports.

The Trust believes that the release of such sensitive information meets the definition of personal data and disclosing the information would contravene Principle (a) as set out in Article 5 of the UK GDPR as the processing would not be lawful, fair and transparent. As such release of the information would be likely to cause distress to the individuals concerned.

Section 36 (2) (b)&(c) – Prejudicial to effective conduct of public affairs

In accordance with Section 36(2) (b)&(c) of the Freedom of Information Act 2000, the release of this information would, or would be likely to prejudice the effective conduct of public affairs and inhibit the free and frank provision of advice, and the free and frank exchange of views for the purposes of deliberation.

The Trust needs to be able to have free and frank discussion about delivery of services to our patients to understand any concerns and make improvements where required, to do that we need everyone involved to be free to express their opinions and to enable quality involvement. Ultimately the ability to have free and frank advice and exchange of views allows the Trust to make improvement in how we conduct the running of the public authority in providing and improving patient care.

In applying the exemption under Section 36(2) (b)&(c) we have balanced the public interest in withholding the information against the public interest in disclosure. The public interest test favours withholding the information in full for the following reasons:

Public interest considerations for disclosure

- Promoting accountability and transparency of our Trust and for decisions and actions taken by us
- Promoting accountability and transparency in the spending of public money
- Bringing to light information affecting public health and safety
- Allowing individuals and other organisations to understand decisions made by our Trust which affect their lives
- Furthering the understanding and participation in the public debate of these issues

Public interest considerations favouring withholding the information

- There is a potential risk that staff may not wish to participate in future review work if the report is released and creates an environment where objective discussion of the recommendations is not possible.
- The review and subsequent report were not commissioned on the basis that this information would be for anything other than internal consumption. Trust willingness to invite external organisations to conduct reviews would likely be undermined if this report were disclosed.
- The Trust must have some ‘safe space’ in order to review and examine its services.
- We have a duty of confidentiality and privacy for our staff and patients and disclosure would allow identification of both.

Decision

There is a public interest in withholding this information in it full content from release under Section 36(1a) & (2b) of the FOIA, as its release would, or would be likely to prejudice the conduct of public affairs of the Department of Health and our Trust.

Although the Trust declines the release of the full review documentation requested, it has identified that it is in the public interest to have an understanding and overview of the contents of the review. We are therefore providing a summary of the reviews and the actions taken to make improvements.

5) Please state who or which organisation(s) carried out the reviews referred to in Question 4 and the amount paid to them for doing so?

This information is held by the Trust.

The Invited Service Review for spinal surgical service was undertaken by the Royal College of Surgeons of England at a cost of £35,400.

The Invited Service Review for the cardiology service was undertaken by the Royal College of Physicians at a cost of £41,856.

NHS
Royal Devon
University Healthcare
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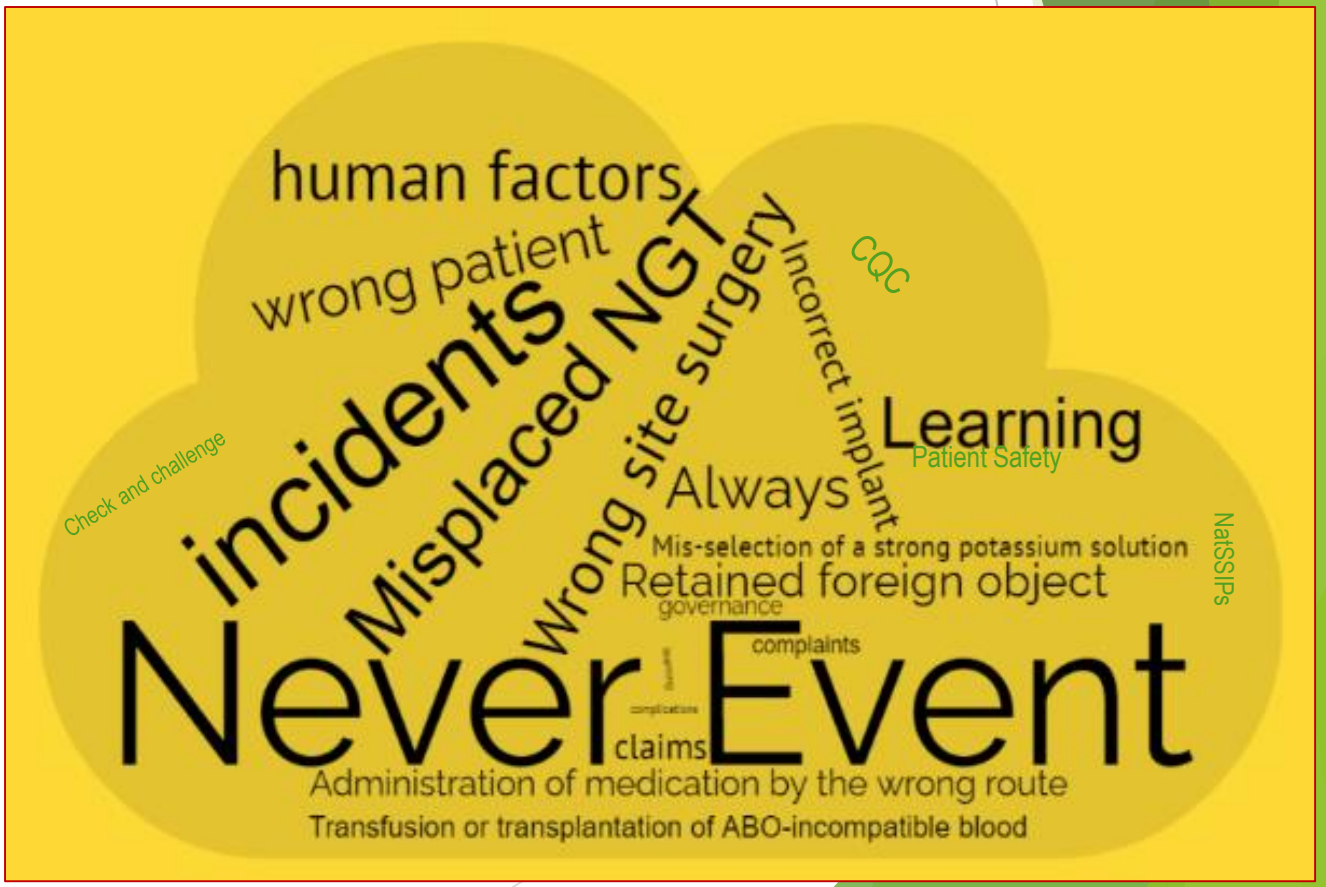
Safety and Risk Committee
Learning from Never Events

July 2022

[redacted]
Trust Risk Manager



The term "**Never Event**" was first introduced in 2001 in response to particularly shocking medical errors — wrong site surgery — that should never occur.

Over time, the term has become more widely used in the NHS to describe entirely preventable serious incidents that potentially or actually cause harm to patients or jeopardise patient safety. These patient safety incidents are considered to have been prevented had the healthcare provider properly implemented existing national guidance and safety recommendations.

The current Never Event List published in 2018 (last updated February 2021) identifies 15 incidents that are required to reported under the national Never Event Policy and Framework.

1 April 2021 - 31 March 2022

- Wrong Site Surgery **171**
- Retained Foreign Object Post procedure **98**
- Wrong Implant/ Prothesis **47**

Serious Incidents Reported

407 met the definition of a Never Event

29 did not meet the definition of a Never Event

Provisional Never Event Report

Local Context

In 2021, 15,785 patient safety incidents were reported at the Eastern services. Of these, six incidents were reported as Never Events.

Incident Date	Incident type	Severity of Harm	Service
June 2021	Retained swab	Moderate	East
June 2021	Wrong side block	No Harm	East
July 2021	Misplaced NGT	No Harm	East
Oct 2021	Transfusion of ABO-incompatible blood components	No Harm	East
Oct 2021	Wrong patient received block	No Harm	East
Oct 2021	Wrong side block	No Harm	East
Dec 2021	Wrong side block	Minor	North
April 2022	Wrong side block	No harm	North
May 2022	Wrong lesion removed	Minor	East

Case 1 – July 2021

Learning – Misplaced NG tube

The Incident

[redacted]

Contributory Factors

- RNs out of date with NGT competencies.
- Direct supervision not given for staff without current competency.
- Despite several conversations regarding which feed to prescribe, no-one enquired whether the position of the NGT had been confirmed.

Lessons learned

- **There is no routine practice of frontline safety critical communication which would have provided an opportunity for clarity on the position of the NG tube.**
- **A local induction programme was not in place at the time in Recovery.**
- **The Trust NGT policy is not up to date in that it refers to paper records and not EPIC.**
- **At the time EPIC did not have a box for Doctors to document position of an NGT.**
- **Confusion amongst Recovery staff regarding what constitutes an incident and timely reporting.**

Key Points

- It is important to have a system in place that ensures staff caring for patients are supervised if they have not achieved the competency required.
- The staff member inserting the NGT must complete the NG avatar in EPIC or ensure that this is done with all the correct information in a timely manner.
- The investigation found variability in the degree of support provided by senior Recovery staff when approached for assistance by junior colleagues.

Patient harm?	None

Case 2 –June 2021

Learning – Retained Swab

The Incident

[redacted]

Contributory Factors

Patient had a postpartum haemorrhage, an emergency situation requiring rapid action to control the bleeding.

No field on the delivery summary to record a swab count for a vaginal birth and instrumental delivery.

There is no requirement detailed in the local instrumental delivery, postpartum haemorrhage or perineal suturing guideline to undertake a swab count.

Lessons learned

- **The use of swabs during procedures should be accounted for pre and post procedure irrespective of location taking place in.**
- **All types of deliveries where a pack is used containing swabs must have a mandatory swab count documented.**

Key Points

- Swab counts were not carried out following delivery, but all swabs were accounted for from the theatre suturing pack, therefore it is most likely that the swab came from the instrumental delivery pack.
- All swabs should be counted when a pack is opened.
- EPIC to be updated to introduce additional fields within the delivery summary.

Patient harm?	Moderate

Case 3 – October 2021

Learning – Wrong Patient FIB

Contributory Factors

- No formal positive patient identification undertaken (Dr referred to patient as 'the fractured NOF' and nursing staff directed Dr to Bed X – neither checked the other's assumption of the patient concerned and no formal check was undertaken.
- LA not prescribed on Epic, no scanning of the patient and the medication to prompt correct patient identification prior to administering the FIB.
- The Clinical Guideline for Performing a Fascia Iliaca Block in Adults with a Hip Fracture 2018 (updated April 2020) had not been updated to reflect the changes in practice since the introduction of the EPR. Previous guideline included an FIB Safety Checklist which was no longer in use. The guidelines should refer to electronic documentation including prescribing the LA on the MAR and scanning both the patient and the medication prior to administration.

Lessons learned

- **The patient was not positively identified by the Doctor prior to the administration of the FIB. Undertaking positive patient identification would have avoided this incident.**
- **There is inconsistent practice in the prescribing of LA used for FIBs. If the medication had been prescribed this would have prompted scanning of the medication and patient and flagged an error.**
- **Junior doctors are not widely aware of the Clinical Guideline for Performing a Fascia Iliaca Block in Adults with a Hip Fracture 2018 (updated April 2020).**

Key Points

- Differing practice between ED doctors and Orthopaedic doctors (no common guidelines).
- Change of usual location (trauma ward not ED).
- Practice of calling patient by their condition or bedspace number, not their name.
- No formal patient ID check as required by LocSSIP and the Patient Identification Policy.
- End of a busy night shift – interruptions.
- New Jr Drs unaware of LocSSIP guideline due to inadequate induction process.
- Out of date guidelines.
- Both patients had a painful hip although Patient 2's was not fractured.
- No harm and Patient 2 happy with pain relief, but Patient 1 did not receive her FIB!

The Incident

[redacted]

Patient harm?	None

Case 4 –July 2021

Learning – Wrong Side Block

Contributory Factors

- Human Factors – distractions in the anaesthetic room, time pressures with theatre over running.
- The Consultant Anaesthetist was dual supervising two very similar lists.
- The anaesthetist was not actively involved in the sign in process.
- Visual cues of posters stating STOP BEFORE YOU BLOCK removed due to Covid.
- Change of list order resulting in an incorrect printed list in the anaesthetic room.

Lessons learned

- **The STOP BEFORE YOU BLOCK step was missed.**
- **It is important to remain vigilant at all times, particularly when risk factors for human error are present.**
- **Visual cues are important as reminders.**
- **Anaesthetists to encourage and be open to Stop Before You Block prompts from other healthcare professionals.**

Key Points

Stop Before You Block did not occur because the anaesthetic team were distracted as there were time pressures, and the anaesthetic was challenging and had not gone as planned.

A wrong sided block is the most common ‘wrong sided surgery’.

Patient harm? **None**

The Incident

[redacted]

Case 5 –December 2021

Learning – Wrong Side Nerve Root Injection

Contributory Factors

- The patient was not marked prior to the procedure. This was not practice at the time of the incident. *Mandatory marking has since been implemented.*
- Due to space/access required for the xray machine, the patient is required to lie with their head at the foot of the theatre trolley.
- The surgeon, theatre staff and the patient participate in the 'Time out' checks (which includes laterality). Because the patient participates and in order to reduce their time lying prone, Time Out is undertaken *before* the patient turns over.

Lessons learned

- **There was no local guideline in place to cover this invasive procedure as required by the national guidance *(NatSSIPs: National Safety Standards for Invasive Procedures 2015)* which requires Trusts to implement local safety standards (LocSSIPs) – including patient marking.**
- **There was limited awareness by staff of NatSSIPs and the essential requirements, e.g. site marking for *all* invasive procedures, in theatres *and* procedure rooms.**
- Without skin marking there is no reference point once the patient has turned over.
- A Stop Before You Block check was not undertaken and is considered to fall within the anaesthetist's domain, rather than that of the orthopaedic surgeon and was not considered appropriate for this procedure.

Key Points

A wrong sided block is the most common 'wrong sided surgery'.

Patient harm?	Minor

The Incident

[redacted]

Case 6 – October 2021

Blood Transfusion – incorrectly issued ABO incompatible units of cryoprecipitate

* BMS = Biomedical Scientist

The Incident

[redacted]

Care and Service Delivery Issues

- Communication – an informal conversation should not have been used to influence practice. A conversation between 2 staff members was unclear and resulted in a misunderstanding of steps to be taken for issuing cryoprecipitate.
- There was no process for consent or instruction from a consultant to issue group O to non-group O patients.
- There is no local competency to assess BMS* knowledge and understanding of appropriate choice of group for issuing plasma components.
- The SOP was not consulted at any point during the issuing process.

Contributory Factors

- There was an assumption based on comments made by a more experienced member of staff.
- 2 units of cryoprecipitate had been incorrectly stored in FFP drawer of the freezer. Had these been in the correct drawer the patient would not have been issued incorrect cryoprecipitate.

Lessons learned

- **The regular competency assessment process should specifically include understanding and theoretical knowledge of ABO incompatibility for all blood components. *A proficiency exercise has now been completed by all BMS staff including situational and theoretical elements*.**
- **Outside formal handover reliance should not be placed on informal conversations where the full facts of the situation may not be known to all parties. It is the responsibility of the BMS releasing the components to understand the processes and blood group compatibilities. If staff are unsure of the correct course of action they should refer to the SOP, call the second-on BMS or the haematologist on call. *Human factors training including the importance of speaking up and clarity in conversations is being rolled out*.**

Patient harm?	None

Wider System Issues

Environment

Each of the cases occurred in a busy environment at a time when the wider organisation was under extreme pressure, **distractions** in the environment played a key part in contributing factors identified.

Communication

From national initiatives to local policy or standard operating procedures, confirming actions passed in conversation offer safety barriers based on **safety critical communication** principles; if used these would have afforded the space to confirm a site, a number, a patient's identity, position or action required.

Checklists

Inconsistent implementation of national initiatives such as Stop Before you Block, a swab count or Local Standards for Invasive Procedures (LocSSIPs)

Safety Critical Communication

Each one of the countless necessary communication points between individuals in healthcare represents an unwelcome opportunity for a patient safety event. Taking a few seconds or minutes to confirm information ensures effective communication and maintains patient safety.

Confirming information becomes more vital when a system is under pressure. Regardless of training and competence, policies or procedures, **staff need to feel empowered and psychologically safe to speak up or initiate a pause to confirm information or raise concerns.**

Creating the right climate, mindset and behaviours within teams to build psychological safety is inextricably linked to effective leadership.

Action: Psychological safety

In 2020 the Trust launched a psychological safety and staff wellbeing resource for managers. The People, Workforce Planning and Wellbeing Committee has maintained oversight of the continued development of this work.

There have been some local initiatives to explore nurturing psychological safety in specific areas.

In the immediate wake of the six Never Events there was a recognition that the pace at which teams were working was a significant feature, and a series of communications was aimed at highlighting the need for awareness and signposting wellbeing support.

As the national patient safety strategy is implemented, its success will be dependent on significant changes in patient safety culture and patient safety systems. The structural changes required to meet the aims of Insight, Involvement, and Improvement are in the planning phases. It is anticipated these changes will reinforce a just culture, where staff will feel confident they will be treated fairly when something goes wrong and that their voice counts.

Action: LocSSIPS

The Patient Safety Group has overseen the development of a comprehensive LocSSIP programme since the publication of the NatSSIPs in 2015. In 2021, the Trust became part of a regional collaborative to review and share best practice.

Variations in content have been reduced/refined with the implementation of EPIC.

The Healthcare Safety Investigation Branch (HSIB) has published a national learning report into never events that concludes some...

> "*... barriers were neither strong nor systemic. These events are therefore not wholly preventable and do not fit the current definition of Never Events.*" and recommends:

1. Revision of the Never Events list to remove events that do not have strong and systemic safety barriers;
2. Safety barriers to avoid incidents are developed where possible; and
3. Standardisation of the NatSSIPs.

Action: Stop Before You Block

An audit of practice is due to be completed by the end of July 2022. This is one aspect of much broader work planned.

The introduction of the “Prep-Stop-Block” approach will require system redesign and changes to the Anaesthetic Sign In process and checklist.

Oversight of this work is being maintained by the Safer Surgery Group.

Education for all professional groups has been commenced. The next available opportunity to take this work forward will be at the September 2022 audit half day. This will be used to provide a session for all disciplines involved in the process to facilitate the further MDT learning required to consolidate best practice.

Recommendations: Further Action

Implementation of the Patient Safety Strategy

Establish the governance structures to deliver the requirements of the Patients Safety Strategy. This will support a shift in culture of reporting and learning from incidents, this in turn will positively alter perceptions of psychological Safety.

Safety Critical Communication

A Trustwide human factors training programme to be developed which will incorporate the principles of safety critical communication.

LocSSIPs

The development of LocSSIPs in Northern services to form part of the wider ongoing integration work for the safety agenda with clear line of accountability and responsibilities for work established as part of the governance structures for the Patient Safety Strategy.

Any Questions

Royal Devon University Healthcare NHS Foundation Trust

Summary of the Invited service review for Spinal Services

In April 2022, the Royal Devon and Exeter NHS Foundation Trust merged with the Northern Devon Healthcare NHS Trust to become the Royal Devon University Healthcare NHS Foundation Trust. The Spinal services that are referred to in the reports are now part of the Eastern services, based at the Royal Devon & Exeter Hospital, Exeter.

The Trust actively sought the independent review and welcomed the subsequent report and recommendations. The Spinal service continues to embrace the reviews recommendations, and the opportunities to demonstrate its commitment to implementing improvements for the benefit of patients.

Spinal services review:

In March 2020, the Trust asked the Royal College of Surgeons to carry out an invited service review of its Spinal Surgery service.

The Review was asked to focus on:

- Pre-operative care
- Perioperative care
- Clinical governance arrangements
- Team working

The review was carried out in September 2020 and involved:

- Review of background documentation and data
- Clinical record review of patient records
- Interviews with members of the team and other relevant staff

The report was provided to the Trust in January 2021 made 29 recommendations. Nine of these recommendations were categorised as requiring immediate action, and all of which have been completed.

The recommendations can be themed in the following categories:

- Clinical and managerial leadership and team working
- Clinical governance arrangements
- Compliance with organisational policies
- Documentation
- Review of local processes
- Standardised pathways

Following the report and recommendations, a comprehensive action plan was developed which has been robustly monitored via the Trust's governance performance system.

The Royal College of Surgeons have been provided with updates on the progress of the action plans and have concluded that no further follow up is required.

Royal Devon University Healthcare
NHS Foundation Trust

Summary of the Invited service review for Cardiology Services

In April 2022, the Royal Devon and Exeter NHS Foundation Trust merged with the Northern Devon Healthcare NHS Trust to become the Royal Devon University Healthcare NHS Foundation Trust. The Cardiology services that are referred to in the reports are now part of the Eastern services, based at the Royal Devon & Exeter Hospital, Exeter.

The Trust actively sought the independent review and welcomed the subsequent report and recommendations. The Cardiology service continues to embrace the reviews recommendations, and the opportunities to demonstrate its commitment to implementing improvements for the benefit of patients.

In June 2020, the Trust commissioned the Royal College of Physicians to undertake an invited review of its Cardiology service.

The Review was asked to focus on:

- Clinical governance arrangements
- Leadership and team working
- Management of care
- Service design and provision of cardiology services

The review was carried out in September 2020 and involved:

- Review of background documentation and data
- Clinical record review of patient records
- Interviews with members of the team and other relevant staff

The report was provided to the Trust in March 2021 and made 25 recommendations. Six of these recommendations were categorised as requiring immediate action, and all of which have been completed.

The themes of the recommendations included:

- Admission capacity and accommodation
- Clinical and managerial leadership and team working
- Clinical governance arrangements
- Clinical protocols and pathways
- Compliance with organisational policies
- Documentation

Following the report and recommendations, a comprehensive action plan was developed which has been robustly monitored via the Trust's governance performance system.

The Royal College of Physicians have been provided with updates on the progress of the actions and have confirmed that no further updates are required.