Health Services Safety Investigations Body

Investigation report

Administering a wrong site nerve block

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Theme:
Checking, Surgical

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Contents

A note of acknowledgement

Summary

1. Background

  1.1. Nerve blocks

  1.2. Stop Before You Block

  1.3. Other national guidance

  1.4. National information on nerve blocks

2. The reference incident

3. Involvement of HSIB

  3.1. Referral of the reference incident

3.2. Decision to investigate

3.3. Investigation process and methodology

4. Analysis of the treatment in relation to guidance

4.1. Stop Before You Block (SBYB)

4.2. Distractions in the anaesthetic environment

5. Findings and analysis from the wider investigation

5.1. Stop Before You Block

5.2. Distractions in the anaesthetic environment

6. Summary of HSIB Findings

6.1. Findings

6.2. Safety recommendations

6.3. Safety observations

7. Appendices

Appendix A

Appendix B

8. Glossary

Endnotes

A note of acknowledgement

We would like to thank Mr Awcock, the patient whose experience is detailed in this report, for the practical assistance he willingly provided to the investigation team.

Summary

The reference incident

Mr Awcock, a 69-year-old man, attended a specialist NHS orthopaedic treatment centre for elective surgery on his right ankle. This included a plan to administer anaesthetic nerve blocks (injections to block pain in a specific region of the body) and a general anaesthetic as part of the procedure.

Before the procedure commenced, the ‘sign-in’ stage of the World Health Organization Safer Surgery Checklist was completed by the consultant, the registrar, and the operating department practitioner. The ‘sign-in’ includes anaesthetic checks. A ‘Stop Before You Block' (SBYB) check was then completed for the first nerve block (a popliteal nerve block [1]). The first nerve block was administered by the registrar whilst Mr Awcock was awake and in the prone position (lying on his front). Mr Awcock was then repositioned to the supine position (lying on his back) and given a general anaesthetic.

Following induction of anaesthesia, it was noted that Mr Awcock’s blood oxygen saturation levels were decreasing. In response, the registrar and the operating department practitioner focused on repositioning the laryngeal mask airway (LMA) to address the oxygen saturation issue. While the airway intervention was ongoing, the consultant proceeded with the second nerve block (a saphenous nerve block [2]). Following the administration of the local anaesthetic, it was realised the second nerve block had been carried out on the left leg in error.

The national investigation

The Trust conducted its own local investigation and informed HSIB about the incident for consideration as a national investigation. After gathering additional information and assessing the incident against HSIB’s investigation criteria the decision was made to progress to a national investigation.

The national investigation focused on:

- The SBYB process and its use nationally.
- Specific distractions arising from the reference incident that impacted on the anaesthetic team.

The investigation sought to identify opportunities and systemic remedies to reduce the risk of wrong site anaesthetic blocks occurring.

Although the investigation and the report focus primarily on wrong site anaesthetic blocks, the findings, safety recommendations and safety observation may be beneficial when considering the development of other national patient safety initiatives.

Findings

- It is unclear whether SBYB in its current form has had any impact on the incidence of wrong site blocks.
- The SBYB guidance does not provide sufficient clarity or direction on how SBYB should be used in practice. Consequently, there is significant variation in SBYB practice and its uptake amongst clinical staff.
- No evaluation of SBYB practice has taken place to confirm how SBYB is working in practice and whether local variations or alternate approaches to SBYB improve its effectiveness.
- A consistent approach to training and supervision in SBYB is not incorporated into anaesthetic specialist training.
- There is an opportunity for an additional safety barrier if a patient is awake and able to engage with clinicians during the block procedure.
- Drawing on human factors principles, it would be expected that changes to the position of patients between blocks and administering multiple blocks would increase the risk of a wrong site block.
- The current variability of how SBYB is understood and practised means that SBYB does not always form a strong systemic protective barrier to wrong site blocks occurring.

HSIB makes the following safety recommendations:

Recommendation 2018/012:
The Royal College of Anaesthetists establishes a specialist working group to evaluate the current practices used to reduce wrong site block incidents. This group should consider how safety initiatives to reduce wrong site blocks can be standardised in anaesthesia training and practice.

It is recommended that the specialist working group consider the impact of: the patient's state of consciousness, changes in a patient's position and the prevalence of wrong site block incidents compared to the number of blocks administered.

Recommendation 2018/013:
The Royal College of Anaesthetists ensures any further work identified by the specialist working group to reduce wrong site block incidents is subject to human factors-based testing and evaluation.

The investigation makes the following safety observation:

The development of patient safety initiatives should incorporate human factors and safety science specialism. This can help ensure that appropriate planning, testing, and evaluation take place to ensure a strong evidential basis for patient safety initiatives.

HSIB has directed safety recommendations to Royal College of Anaesthetists, who are expected to respond within 90 days of the publication of this report. HSIB will publish their responses.

1. Background

1.1. Nerve blocks

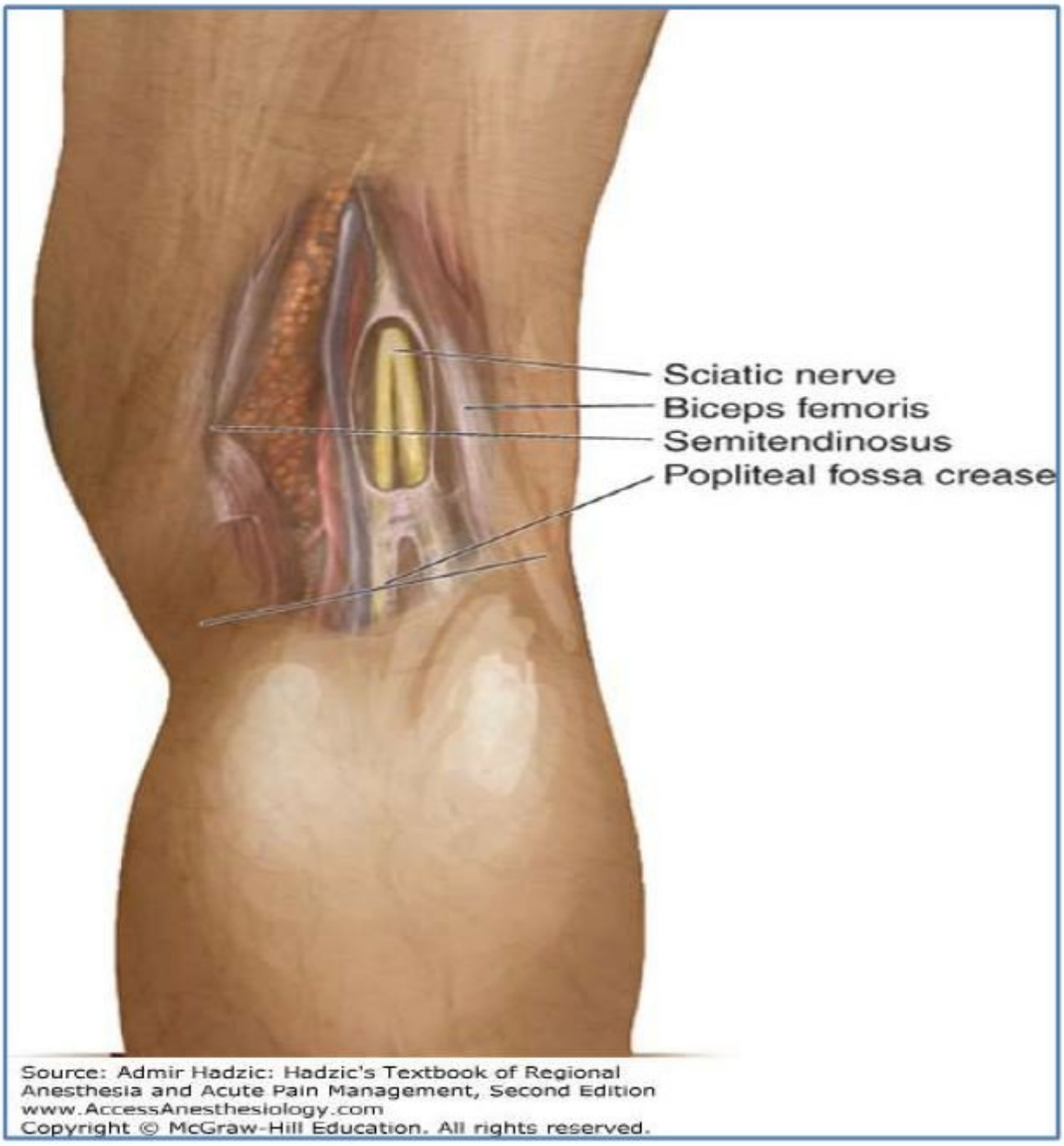
1.1.1. Nerve blocks are a type of regional analgesia in which local anaesthetic is injected near a specific nerve or bundle of nerves to block the sensation of pain. Ultrasound equipment is often used to help determine the correct location for the injection. When used in surgery, the benefits include improved post-operative pain control, a reduced need for strong pain medication post procedure and an earlier discharge from hospital.

1.1.2. Complications [3] from an unnecessary block may include:

- Nerve damage.
- Local anaesthetic toxicity.
- Delayed treatment, particularly if administered in a pain clinic outpatient setting due to the requirement to wait before administration to the correct site.
- Delayed hospital discharge due to reduced mobility or dexterity.

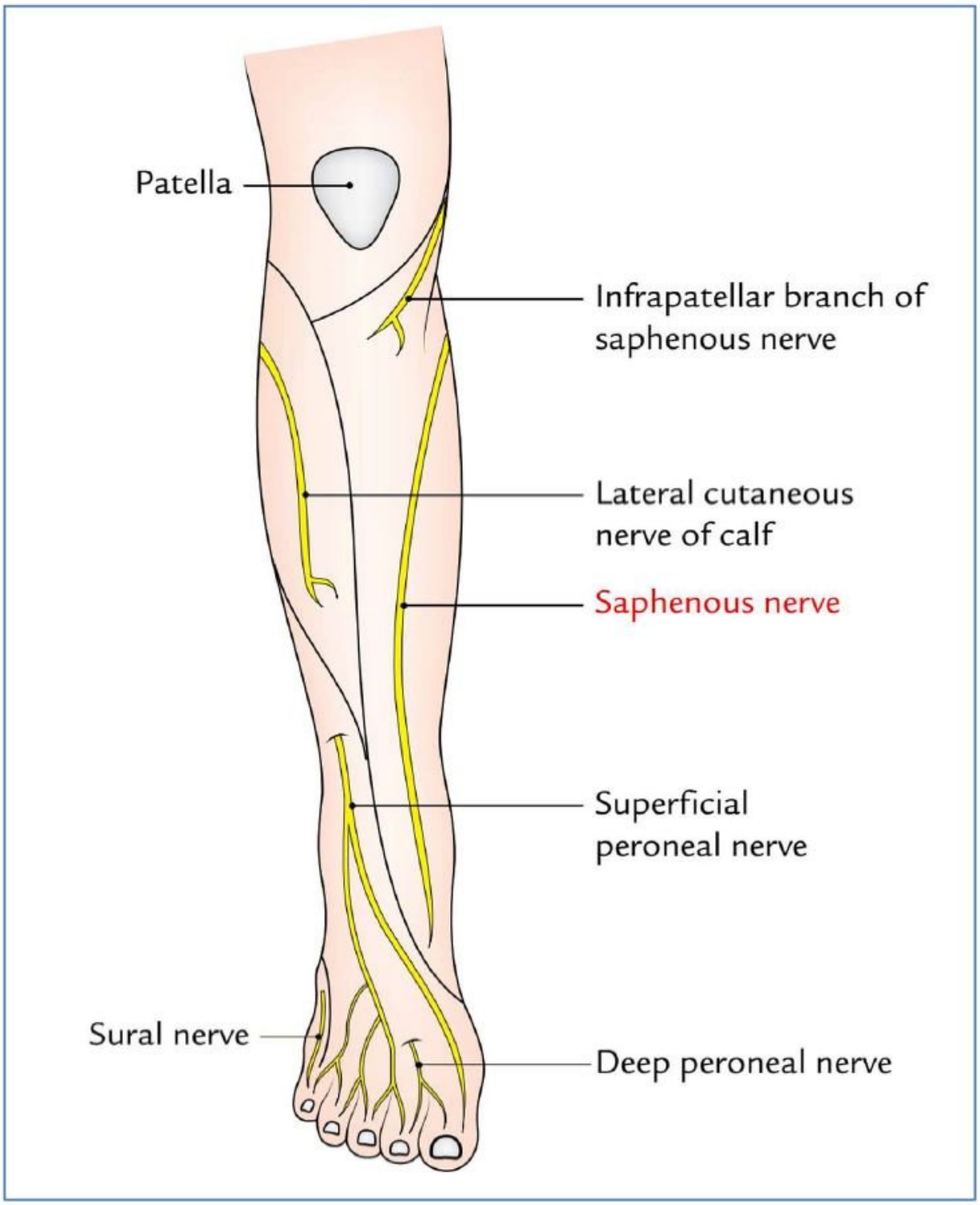
1.1.3. A popliteal nerve block is a block of the sciatic nerve at the level of the popliteal fossa (a shallow depression located at the back of the knee joint). It provides regional anaesthesia and post-operative pain relief and is used in a variety of lower limb surgeries (Figure 1).

Figure 1: Popliteal fossa [4]



1.1.4. A saphenous nerve block is a block of a sensory branch of the femoral nerve (usually administered 10-15 cm above the knee). It is often used as a supplemental block when surgery impacts on the medial (inside) structures of the foot and ankle (Figure 2).

Figure 2: Saphenous nerve [5]



1.2. Stop Before You Block

1.2.1. The national Stop Before You Block (SBYB) campaign was launched in 2011 by the Royal College of Anaesthetists. It provides a toolkit for anaesthetic teams to help prevent wrong site blocks from occurring (Appendix A). Further details on the background of SBYB are contained in Section 5.

1.3. Other national guidance

1.3.1. Since 2010, a number of safety initiatives have been implemented, focusing on reducing the risk of wrong site events, including wrong site blocks. These include:

The Never Event Framework

1.3.2. The Never Event Framework [6] was introduced in the NHS in England in 2009. Never Events are defined as:

‘*Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’.*

The framework ‘is designed to support safety improvements by defining Never Events in a way that means occurrence of a Never Event indicates possible weaknesses in how an organisation manages fundamental safety processes’.

1.3.3. A wrong site nerve block was first classified as a Never Event within the wrong site surgery category in 2015. The framework identified SBYB as a national safety requirement that provides a strong, systemic barrier against wrong site blocks occurring.

WHO Surgical Safety Checklist

1.3.4. In 2010, the World Health Organization Surgical Safety Checklist [7] (the WHO checklist) was mandated for all patients in the NHS undergoing a surgical procedure. Some NHS Trusts have made amendments to the checklist to include a specific reference to nerve block marking. The use of SBYB was supported as part of the WHO checklist ‘sign-in’ which takes place prior to the induction of anaesthesia.

NatSSIPs and LocSSIPs

1.3.5. The introduction by NHS England in 2015 of National Safety Standards for Invasive Procedures (NatSSIPs) [8] provides a framework for producing Local Safety Standards for Invasive Procedures (LocSSIPs). It was intended LocSSIPs should be created by cross-professional clinical teams to standardise key elements of procedural care across all clinical environments where invasive procedures occur.

1.4. National information on nerve blocks

1.4.1. The NHS Strategic Executive Information System (StEIS) allows information on wrong site interventions to be collated. Analysis of StEIS data was undertaken to identify the number of wrong site interventions reported nationally between April 2016 and March 2017. It identified 192 reported incidents of wider wrong site intervention, of which approximately 29 incidents involved wrong site anaesthetic block.

1.4.2. The cause of the wrong site interventions was categorised based on the incident description contained within StEIS. This identified common themes prevalent in both wrong site intervention incidents and wrong site block incidents. For wrong site block incidents, these were:

- Deviation from SBYB guidance.
- Distractions in the anaesthetic environment.

1.4.3. Underpinning this was a broader reference to the importance of culture in the environments where incidents were reported.

2. The reference incident

2.1.1. Mr Awcock was 69 years of age when he attended a specialist orthopaedic treatment centre at an acute NHS Trust for elective surgery on his right ankle. The senior anaesthetic trainee (the registrar) discussed the procedure with Mr Awcock as part of the pre-operative assessment. This included a plan to administer either an ankle nerve block, or a popliteal nerve block, and a general anaesthetic as part of the operation.

2.1.2. During the team briefing, at which the consultant was present, it was decided that a popliteal nerve block would be administered followed by a saphenous nerve block; two blocks would be given rather than one. This was the consultant's normal practice to help control postoperative pain. This was discussed with Mr Awcock and his consent was obtained.

2.1.3. The surgical site was marked and an anti-embolic below knee (TED) stocking was put on the left leg (non-operative leg). Local policies were in place to indicate the site of the nerve block should also be marked with blue tape.

2.1.4. A WHO checklist was completed before Mr Awcock's procedure started. This included an addition made by the Trust to check that the site of a regional anaesthetic block had been marked. This was noted as being complete, despite the block site not being marked.

2.1.5. A Stop Before You Block (SBYB) check was also completed for the first popliteal nerve block (back of the leg above the knee joint). This was performed by the registrar under the supervision of the consultant. This procedure was undertaken while Mr Awcock was awake, in the prone position (lying on his front). Mr Awcock was then repositioned to the supine position (lying on his back) and a general anaesthetic was administered.

2.1.6. Following induction of anaesthesia, it was noted that Mr Awcock's blood oxygen saturation levels were decreasing. In response, the registrar and the operating department practitioner focussed on repositioning the laryngeal mask airway (LMA) to address the oxygen saturation issue. The consultant also administered a dose of muscle relaxant to assist with this process.

2.1.7. While the airway intervention was in progress, the consultant proceeded with the saphenous nerve block (front of the leg and above the knee). The consultant positioned the block needle and asked the ODP to administer the injection; this was necessary because the consultant was holding both the block needle and ultrasound probe at this point. An SBYB check was not carried out for the second block.

2.1.8. Following administration of the local anaesthetic, the ODP identified that the saphenous nerve block had been carried out on the left leg in error. Consequently, Mr Awcock did not receive the saphenous nerve block to his right leg (the correct leg) due to concerns about local anaesthetic toxicity.

2.1.9. In response to the incident, the Trust's serious incident investigation identified the following safety actions:

- At the anaesthetic quality and safety meeting, the Trust discussed any possible additional steps that could be taken to reduce the risk of omitting the SBYB checks.
- The Trust reviewed the use of the additional safety net of nerve block site marking to ensure there was acceptance and consistent agreed practice by all relevant staff. This included discussion about: when the marking is placed, clarity regarding use of the block site question on the WHO checklist sign-in section, and if documentation was necessary to record when block site marking was declined.
- The consultant involved agreed to change his practice to perform both nerve blocks with the patient awake. This change of practice was shared with consultant colleagues to facilitate standardisation across the team.
- The Trust considered how the use of surgical drapes could aid identification of the unaffected leg. The Trust was also to discuss and agree consistent practice regarding the use of an additional safety net (for example, a surgical drape) to identify the area which was not being treated.

- The Trust arranged refresher training within the musculoskeletal directorate of its ‘Understanding of human factors and its role in reducing risk of patient safety incidents’ training.
- The Trust planned to ‘raise awareness’ of the continued need for due diligence to avoid wrong site nerve blocks via bulletins, safety huddles and internal forums.

2.1.10. Wrong site nerve blocks expose patients to a greater risk of local anaesthetic toxicity, mobility problems post-surgery and increased length of stay in hospital. In this case, Mr Awcock came to no harm and surgery was able to proceed as planned.

2.1.11. The risk of adverse outcomes to other patients from wrong site blocks remains, despite a national initiative designed to eliminate the risk of performing a wrong site regional block.

3. Involvement of HSIB

3.1. Referral of the reference incident

3.1.1. The Trust contacted HSIB regarding the wrong site block and the possibility of HSIB conducting a national investigation. A scoping investigation was initiated to determine the learning potential of a national investigation.

3.2. Decision to investigate

3.2.1. Following the scoping investigation, the chief investigator authorised a full investigation as the incident met the following criteria:

Outcome Impact – What was, or is, the impact of the safety issue on people and services across the healthcare system?

3.2.2. Wrong site anaesthetic blocks have potential to cause physical and psychological harm. Such events may also create a requirement for further treatment and a loss of confidence in the care that patients may receive in the future.

Systemic Risk - How widespread and how common a safety issue is this across the healthcare system?

3.2.3. Data gathered from the StEIS suggest that, despite existing NHS processes intended to prevent wrong site blocks, such events continued to occur throughout the healthcare system. Although safety initiatives have been developed and implemented to address this issue at both local and national levels, their effectiveness has been difficult to measure.

Learning Potential – What is the potential for a HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

3.2.4. A review of incidents reported to StEIS over a 12-month period identified issues in deviation from national and local guidance intended to prevent wrong site blocks. This suggested there may be complexities associated with the national SBYB process, preventing it from being a strong and effective barrier to such events. It was agreed the investigation would review the SBYB process to better understand why it does not always prevent wrong site blocks occurring.

3.2.5. The national investigation has focused on:

- The SBYB process and its use nationally.
- Specific distractions arising from the reference incident that impacted on the anaesthetic team.

3.2.6. Although the investigation and the report have focused primarily on wrong site anaesthetic blocks, the findings, safety recommendations and safety observation may be beneficial when considering the development of other national patient safety initiatives.

3.3. Investigation process and methodology

3.3.1. A range of methodologies were used in this investigation including:

- Review of patient operating theatre records, Trust policies, procedures and practice regarding SBYB practice at the Trust where the reference incident occurred.
- Interviews with clinical staff involved in the reference incident.
- Observations of regional block practice and/or operating theatre environments at four other NHS Trusts.
- Informal interviews with surgeons, nurses, and support staff at the comparison locations visited.
- Review of StEIS.
- Literature review.
- Interviews and personal communications with relevant national organisations and subject matter experts, both clinical and non-clinical, regarding regional block practice and possible improvements that may help to reduce the occurrence of such events.
- Communication with subject matter experts in the USA regarding regional block practice.
- Use of the Accident Route Matrix (ARM) model.

3.3.2. Given the safety barriers in place to prevent a wrong site block rely on a human checking process, HSIB engaged with human factors experts to consider how additional safety barriers could be implemented.

3.3.3. Although clinical staff have developed technical skills to perform the procedures, there are also non-technical skills that contribute to adverse clinical incidents. Non-technical skills are ‘the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance’ [9]. These include factors such as: situation awareness, decision-making, teamwork, leadership, and coping with stress.

3.3.4. There are limitations to the methodology used in this investigation. The primary limitation is sample size. Compared to the number of staff, Trusts and private facilities carrying out regional anaesthetic blocks, only a small percentage of practice was observed. Any observations of people at work, by other people introduced as ‘conducting research’, or from ‘an external body’ (HSIB) with apparent authority (whether real or perceived) will affect the way people behave.

3.3.5. Witness memory is useful for understanding an individual’s perception of events and exploring other contextual factors. However, witness memory reports are prone to errors as details of events can be forgotten, altered or falsely added into memory.

3.3.6. The findings of this report have been supplemented by insights from subject matter experts and academic literature.

4. Analysis of the treatment in relation to guidance

This section focuses on findings and analysis of Mr Awcock’s treatment specifically in relation to national guidance and local policy. Findings and analysis from the wider investigation can be found in Chapter 5.

4.1. Stop Before You Block (SBYB)

National and local guidance

4.1.1. In November 2010, the Safe Anaesthesia Liaison Group (SALG) published an alert highlighting details and learning points from 67 inadvertent wrong-sided nerve blocks reported via the National Reporting and Learning System (NRLS) [10]. The initial recommendation to address this issue was to check the surgical site had been marked in accordance with the WHO checklist.

4.1.2. Nottingham University Hospitals NHS Trust carried out additional work to analyse incidents of wrong site block within the Trust. It concluded errors had occurred even when the WHO checklist was performed correctly. A local SBYB campaign was developed to provide an additional barrier to this error. This work was refined by the SALG and Regional Anaesthesia-UK. A national SBYB campaign was launched in 2011.

4.1.3. The SBYB process was launched as guidance to clinicians via a toolkit issued by the SALG (Appendix A). This included a standard poster advising of the process and an accompanying guidance document. No further national training was identified or provided to anaesthetists at the time of the roll out of SBYB. Local implementation of SBYB was reliant on NHS Trusts and individual clinicians amending block practice and producing local guidelines for use when administering regional anaesthesia.

4.1.4. The SBYB process was described in the guidance launched with the campaign. The following guidance was issued on how SBYB was to operate:

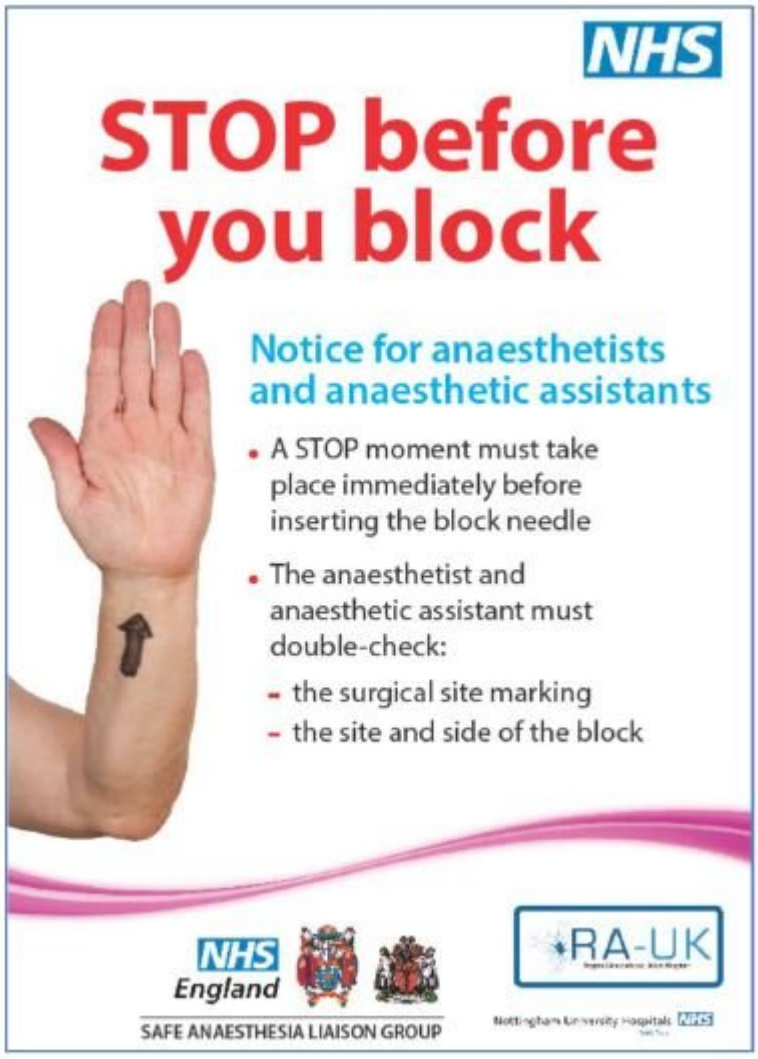
- The WHO ‘sign-in’ is performed as usual. The patient identity, consent form and marking of the correct surgical site are confirmed.
- IMMEDIATELY before needle insertion in the nerve block process the correct site is confirmed again. This involves:
    - Visualising the surgical arrow indicating site of surgery.
    - Asking the patient to confirm the side of surgery (if conscious).
    - Double checking the consent form for operative side (if patient unconscious).

4.1.5. It also identified possible issues that could have an impact on the effectiveness of the SBYB process, including:

- Where there is a delay between the WHO ‘sign-in’ and the performance of the nerve block.
- After turning the patient, when the block site will have ‘moved’ relative to the anaesthetist.
- Where there are obvious distractions in the anaesthetic room.
- Where the WHO surgical site marking may not be immediately visible.

4.1.6. Posters promoting the campaign (Figure 3) were made available and encouraged to be displayed in all anaesthetic rooms where nerve blocks take place. This highlighted the ‘STOP’ moment immediately prior to placing the needle and that there must be a double check of the WHO surgical site marking and the site and side of the block.

Figure 3: Stop Before You Block poster from the toolkit



4.1.7. The success of the campaign was stated in the guidance as relying on all team members being trained and aware of the SBYB process. This included the anaesthetist, anaesthetic nurse, operating department practitioner or anaesthetic physician's assistant. Local additions to the SBYB project were encouraged and suggested further steps included:

- Block site marking by the anaesthetist.
- Smaller versions of the poster attached to nerve stimulators and
- ultrasound machines.
- Local audit of the SBYB process.

4.1.8. The Trust in the reference incident had developed policies and procedures to guide staff in the use of SBYB, which included more detail than the national SBYB guidance. The local Trust guidance stated:

- At the sign-in, the anaesthetist is responsible for confirming if an anaesthetic nerve block is required after confirming the procedure with the patient, consent form and site marking.

- The anaesthetist will then place a sticky label on the intended site of the block. (The purpose of doing this is a recognition there can be a delay between sign-in and performing the block and the label will help reinforce the site required).
- Before performing the actual block, the anaesthetist will ask for a pause (STOP BEFORE YOU BLOCK) with the anaesthetic practitioner to confirm the site again against the sticky label, surgical site marking and consent.
- The label is then removed.
- All ultrasound machines will have a ‘Stop before you block’ flip card, which will require turning over to remind practitioners to carry out the pause before proceeding.
- The anaesthetist and anaesthetic practitioner will record in the [operating] theatre care plan that they have done a ‘Stop before you block’ pause.

4.1.9. The WHO checklist ‘sign-in’ had been amended to include a question asking if the nerve block site is marked. The nerve block site marking question directly follows the surgical site marking question. The Trust confirmed this question was deliberately placed there to allow the nerve block site check to take place at the same time as the check for the surgical site marker.

Reference incident

4.1.10. Mr Awcock attended a specialist orthopaedic treatment centre for elective surgery on his right ankle. This included an anaesthetic plan to administer two nerve blocks.

4.1.11. On the day of his surgery, the surgical site was marked, and a TED stocking was put on the left leg (non-operative leg). Local policies were in place to indicate the site of the nerve block should also be marked with blue tape.

4.1.12. A WHO checklist was completed, before surgery proceeded. This included an addition made by the Trust to check that the site of a regional anaesthetic block had been marked.

4.1.13. An SBYB check was completed for the first popliteal fossa nerve block. An SBYB check was not carried out for the second, saphenous nerve block.

Analysis

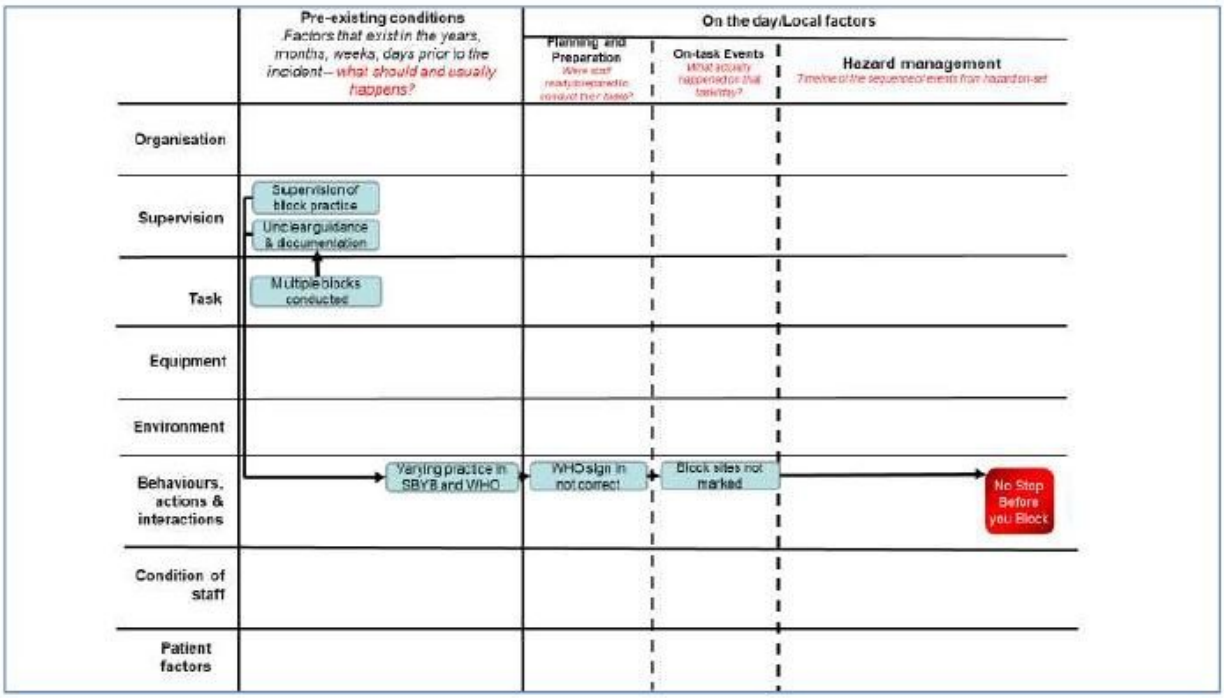
4.1.14. HSIB has considered the contributory factors that led to Mr Awcock receiving a wrong site anaesthetic block. A range of factors have been mapped on to the ARM model to highlight the range of contributory factors which, together, played a role in Mr Awcock’s care.

4.1.15. The ARM supports a human factors approach by providing a framework to plot the subjective and objective data. Factors can be plotted by type and by time of effect. Once complete, the ARM can be read from top to bottom to understand the factors that might influence operator behaviour and operator conditions. Alternatively, it can be read left to right on each row to assess the time at which these factors affected the events.

4.1.16. The full ARM map and further commentary is displayed in Appendix B. This identifies each of the factors identified in the investigation that impacted on Mr Awcock's care. Constituent parts of the model have been separated to comment on specific issues identified within the investigation. It is important to note that the model is intended to be read as a whole to gain a full understanding of the various factors preceding the wrong site block and how the risk of administering a wrong site block could have been detected.

4.1.17. In relation to considerations around the use of SBYB process in Mr Awcock's care, HSIB considered what conditions may have contributed toward deviation from SBYB and local practice (Figure 4).

Figure 4: Deviation ARM model



4.1.18. The Trust had developed policies and procedures to guide staff in the use of SBYB. The guidance provided greater detail than the national SBYB campaign on the steps practitioners should take before administering a nerve block. The local guidance was not clear on the process when multiple blocks were to be administered (nor was the national guidance).

4.1.19. Local documentation did not provide an effective tool to allow clinicians to fully recall and record correct block practice. This included no provision for multiple blocks to be recorded, and there was no prompt for the site of the planned blocks to be recorded in the operating theatre pathway documentation or the anaesthetic record.

4.1.20. The WHO checklist ‘sign-in’ had been amended to include a question checking if the nerve block site is marked. The consultant believed this caused confusion as it could be mistaken for confirmation of the surgical site marking.

4.1.21. The Trust did not actively evaluate how consultants performed SBYB or adhered to local Trust policies or procedures. This is reflected in the varying practice and the tacit acceptance of this omission from the non-consultant staff interviewed. The ODP told the investigation, ‘anaesthetists do sometimes need reminding to carry out the SBYB moment’. Where a consultant chose not to adhere to local policy the ODP suggested this was ‘taken as a given’ and other staff would not insist it be done.

4.1.22. There was variation in practice as to whether the SBYB moment would need to be completed before every block being administered, or whether SBYB was complete following administration of the first block. This was not clear from local guidance or national SBYB guidance in place.

4.1.23. In the reference incident, all the clinical staff involved suggested a second SBYB moment should have taken place before the saphenous nerve block, but common practice, when there were multiple blocks being administered, was that this did not always take place. The consultant explained the team considered they had ‘done that bit and put it aside’. Confusion around this process may have inhibited staff from raising this issue at the time.

4.1.24. Literature identifies a broad range of factors in why policies may not be adhered to [11] and they do not alone form a robust safety barrier. This can include factors such as guidance being unclear or where ‘trivial’ guidance is introduced as a ‘knee jerk’ reaction without testing or engagement with staff.

4.1.25. There is also a range of work highlighting the differences between ‘work as imagined’ (i.e. our mental model of how we would carry out a task), ‘work as prescribed’ (i.e. the guidance or policy in place setting out how to do the task), ‘work as done’ (i.e. how the task is actually performed) and ‘work as disclosed’ (i.e. how we describe and talk about having completed the task) [12].

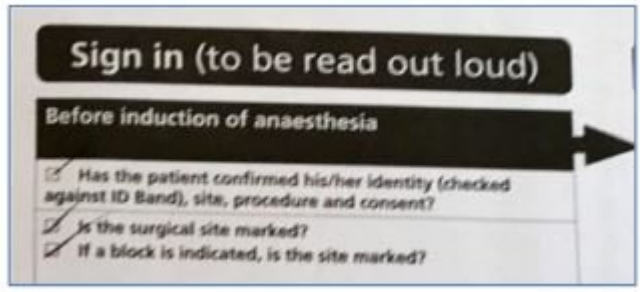
4.1.26. There were recognised variations in practice between anaesthetists at the Trust on whether to use blue tape and when in the SBYB process the blue tape was placed on the patient.

4.1.27. The ODP told the investigation she felt able to prompt anaesthetists regarding the use of a nerve site block tape but did not consider it her role to apply the block site marking without the agreement of the consultant. The ODP was aware not all consultants wished to use this system, ‘some people do, and some people don’t’.

4.1.28. The consultant told the investigation they ‘made an executive decision’ not to make use of the tape on this occasion as the initial SBYB checks led them to believe it would be okay to proceed without it. The registrar was also aware the block site had not been marked but could not comment on why it had not been used.

4.1.29. The WHO checklist was marked to show that block site marking was in place (Figure 5):

Figure 5: Modified WHO checklist for Mr Awcock

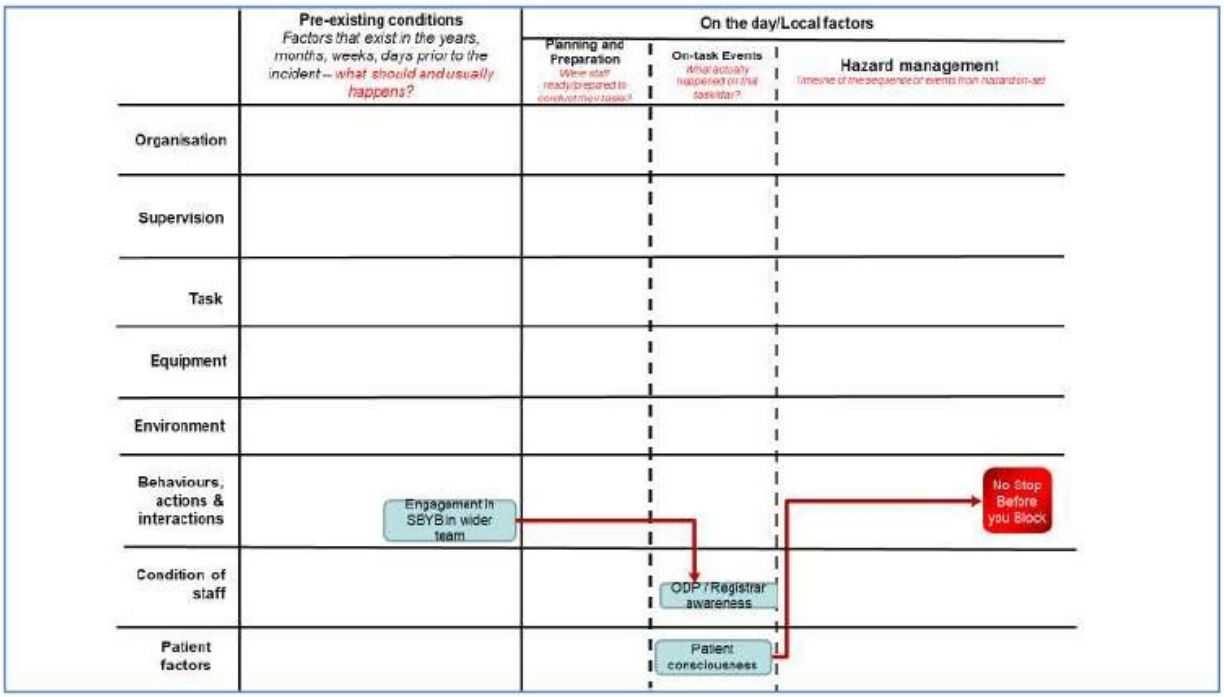


4.1.30. The ODP confirmed, given the existing variation in consultant staff choosing to use site marking, that practice had developed to mark the box if the question had been asked of the consultant; not necessarily to indicate the block site marking was in place. In this case, tape was not used by the consultant, so the ODP proceeded to mark this box as per their usual practice.

4.1.31. Without an active evaluation of block practice in the anaesthetic environment, it is likely any audit of SBYB site marking compliance would have relied on this checklist to identify compliance with the SBYB process.

4.1.32. The investigation also considered the wider engagement of the anaesthetic team and the patient (Figure 6):

Figure 6: Engagement ARM model



4.1.33. The ODP did not believe the Trust's wider anaesthetic staff (outside of the anaesthetists) had been engaged in considering whether the blue tape would be effective in avoiding wrong site block incidents.

4.1.34. Wider engagement with the anaesthetic team in the SBYB process may have acted as an additional safety barrier to the block being administered. They were not involved in any necessary checks prior to the second block being administered. The consultant described this as being 'purely me, I carried on and did the block while everyone else was distracted'.

4.1.35. The registrar confirmed although she was engaged in maintaining Mr Awcock's airway at the time the saphenous block was administered, any spare capacity would have focussed on the ultrasound screen for learning purposes rather than identifying whether the site had been marked.

4.1.36. The ODP had an opportunity to query whether an additional SBYB moment had taken place prior to the injection taking place; they had been asked to assist the consultant in administering the injection. The ODP commented that it 'did not occur' to her that the consultant had not performed a second SBYB moment.

4.1.37. If Mr Awcock had been conscious, this could have also acted as an additional prompt to alert the consultant.

4.1.38. In response to issues identified in the local serious incident investigation the Trust took the following local safety actions regarding the use of SBYB:

- At the anaesthetic quality and safety meeting, the Trust discussed any possible additional steps that could be taken to reduce the risk of omitting the SBYB checks
- The Trust reviewed the use of the additional safety net of nerve block site marking to ensure there was acceptance and consistent agreed practice by all relevant staff. This included discussion about: when the marking is placed, clarity regarding use of the block site question on the WHO checklist sign-in section, and if documentation was necessary to record when block site marking was declined.
- The Trust planned to 'raise awareness of the continued need for due diligence to avoid wrong site nerve blocks' via bulletins, safety huddles and internal forums.

4.1.39. The reference incident demonstrated deviations from SBYB guidance and local Trust policies on the use of site marking, whether a second SBYB moment was required, and the confidence of staff to challenge this without a standard approach being in place for all clinicians. A review of StEIS data identified deviation from guidance as the most common factor in why wrong site blocks occur.

4.2. Distractions in the anaesthetic environment

National and local guidance

4.2.1. In addition to the specific guidance surrounding the use of SBYB, academic research has highlighted the various distractions that impact the effectiveness of surgical and anaesthetic checks[13],[14] (for example, personal issues affecting staff or factors such as interruption or changes in the regular environment in which procedures are performed).

4.2.2. There is also a wider recognition of the role human factors can play in understanding how organisations can take a systems-based approach to these issues[15]. Despite this, there are reports of an implementation gap[16] where the problems arising from distractions in the anaesthetic environment are not always successfully resolved.

The reference incident

4.2.3. The registrar discussed the surgical procedure with Mr Awcock as part of the pre-operative assessment. This included a plan to administer either an ankle nerve block or a popliteal nerve block and a general anaesthetic as part of the operation. During the team brief, at which the consultant was present, it was decided a popliteal nerve block would be administered followed by a saphenous nerve block. Two blocks would be given rather than one. Mr Awcock gave his consent for two blocks to take place.

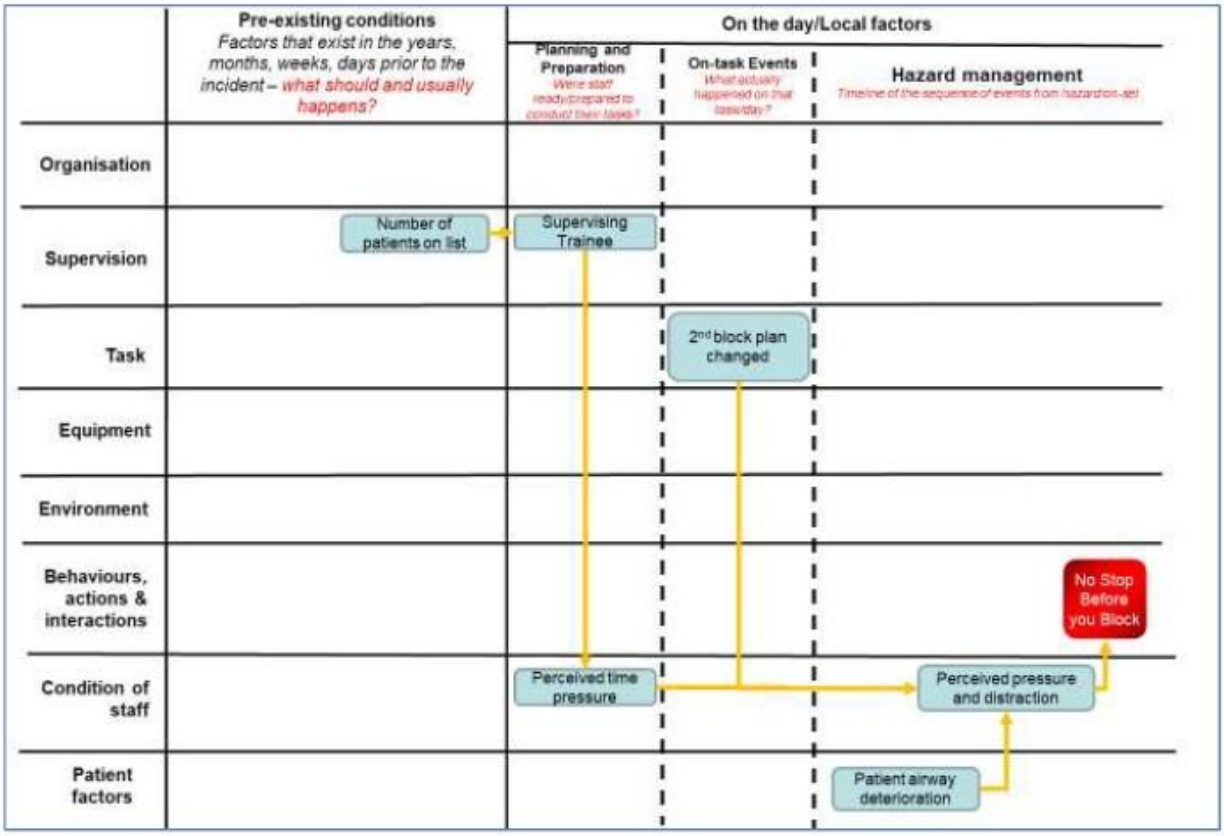
4.2.4. The popliteal fossa nerve block was performed by the registrar under the supervision of the consultant. This procedure was performed while Mr Awcock was awake, in the prone position. Mr Awcock was then repositioned to the supine position and a general anaesthetic was administered.

4.2.5. It was noted that Mr Awcock's blood oxygen saturation levels were decreasing. In response, the registrar and the ODP focussed on repositioning the LMA to address the oxygen saturation issue. To aid in this process, the consultant also administered a dose of muscle relaxant. While the airway intervention was continuing, the consultant then proceeded with the saphenous nerve block. The consultant sited the block needle and asked the ODP to administer the injection. This was required as the consultant was holding both the block needle and ultrasound probe at this point.

Analysis

4.2.6. The investigation considered factors that contributed to Mr Awcock receiving a wrong site block and those relating to distraction have been mapped onto the ARM model (Figure 7):

Figure 7: Distraction ARM model



4.2.7. There were six patients planned for the elective list that morning; Mr Awcock was second on the list. The consultant performed the list once or twice a month and the number of patients on the list was not abnormal. Mr Awcock was the only patient to require repositioning and two blocks.

4.2.8. The consultant was supervising the practice of the registrar. Supervision was an additional task requiring the consultant's attention and focus. This was particularly true for the popliteal block as this is more technically challenging and the consultant was 'anxious' it proceeded smoothly.

4.2.9. The initial plan for Mr Awcock's procedure was that a single nerve block would be administered; however, when the consultant considered Mr Awcock's care in the surgical time out, the plan was changed to administer two anaesthetic blocks. This was agreed and communicated to Mr Awcock.

4.2.10. The plan was for the registrar to administer both anaesthetic blocks under supervision from the consultant. The registrar had not been involved in many cases where the patient had been repositioned from prone to supine. The ODP also reflected, usually when more than one injection was given, the patient would be supine for all.

4.2.11. The popliteal block was administered by the registrar as planned and Mr Awcock was then administered a general anaesthetic. Mr Awcock required more sedation to induce a deeper level of unconsciousness. The oxygen levels in Mr Awcock's blood were also lower than expected. This was a recognised problem resulting from the seal around the LMA leaking slightly. The registrar and ODP were engaged in resolving this situation.

4.2.12. Following a discussion between the registrar and the consultant, it was agreed the LMA should be taken out, a muscle relaxant administered and the airway re-positioned. The consultant and registrar waited for the muscle relaxant to take effect, prior to the airway being re-positioned. There was discussion regarding whether the registrar or the consultant would administer the saphenous nerve block. It was agreed the consultant would proceed with the nerve block allowing the registrar and ODP to monitor Mr Awcock's airway. This resulted in the ODP only assisting the consultant with the saphenous block at the injection stage, after the needle insertion.

4.2.13. The consultant's recollection was that their attention had been on ensuring that Mr Awcock's airway and oxygen saturations were satisfactorily maintained once it became apparent that the oxygen saturation levels were not optimal. The consultant said this distraction also contributed to the omission to undertake the second SBYB check, as they 'temporarily lost situation awareness'. However, this may also have been a negative impact of task switching between the block and concerns about managing Mr Awcock's airway.

4.2.14. A perceived time pressure was created when it was identified that Mr Awcock's LMA needed to be repositioned to improve his oxygen saturation levels. The perception of a time pressure was different between the clinical staff. The ODP believed they 'were not under that much of a time constraint'. The consultant considered he was 'losing momentum in the list' and was mindful of the orthopaedic team waiting in the operating theatre.

4.2.15. The registrar said, 'turnover of lists is a concern,' and, 'the more rushed you feel, the more likely you are to make a mistake'. The registrar outlined how staff working in the anaesthetic room often performed duties in parallel, rather than in a linear fashion. This was due to the pressure to undertake all tasks as promptly as possible. They considered that working in parallel potentially increased the risk of error as the opportunity for double-checking by staff was reduced.

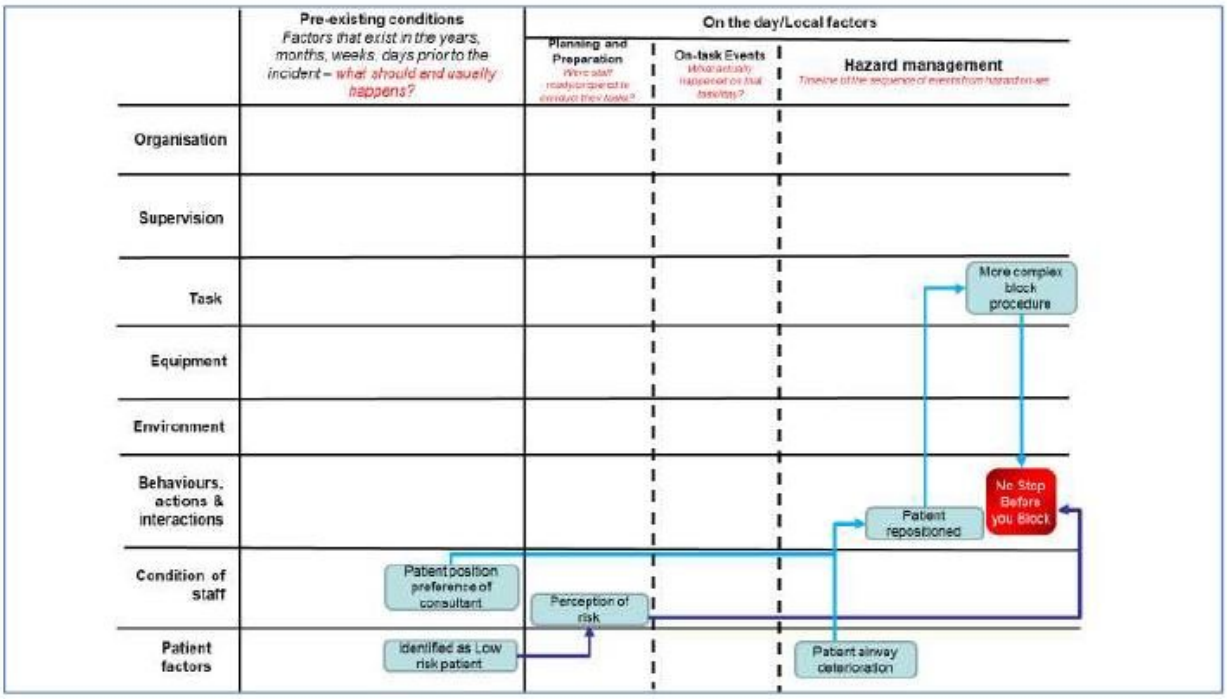
4.2.16. The national task force review of Never Events in 2014 also highlighted time pressure as a source of error in the literature regarding preventable surgical adverse events [17]. HSIB's investigation report on the implantation of wrong prostheses during joint replacement surgery [I2017/10] highlighted that actual time pressure is not as important as the perception of time pressure felt by clinical staff. The report acknowledged that there is a trade-off between efficiency and effectiveness on one hand, and thoroughness on the other.

4.2.17. In practice this could lead to staff experiencing conflicting pressures to balance the benefits of safety actions against the effectiveness or timeliness of some clinical processes.

4.2.18. Mr Awcock's airway issue impacted on several factors that contributed to the anaesthetic team being distracted. Clinical staff sought to resolve these difficulties as a priority. This compromised their ability to focus on the block process and make sure the necessary checks had been completed.

4.2.19. There were also some factors in Mr Awcock's procedure that created additional distractions that would not normally occur with less technically challenging blocks (Figure 8).

Figure 8: Complexity ARM model



4.2.20. The decision on the number of anaesthetic blocks a patient receives is the responsibility of the consultant. The consultant was involved in this operating theatre list once or twice a month and multiple blocks were not always required. SBYB checks were completed prior to the popliteal block being administered. There was a delay between the popliteal and saphenous block being administered due to the need to reposition Mr Awcock, administer a general anaesthetic and manage the airway issue.

4.2.21. Once the SBYB checks had been completed for the first block, the consultant considered the team may have mentally disengaged, feeling this process had been completed. The consultant said that he was ‘anxious and nervous about the [popliteal] block’ as it was a ‘high risk, difficult, challenging’ procedure. However, the saphenous block was ‘technically much easier’. The consultant explained the popliteal block ‘went really, really well’ and as such ‘you immediately relax, switch off a little bit’.

4.2.22. There was an inconsistent approach within the Trust to how these blocks were performed, with the ODP commenting that from her experience at the Trust ‘some anaesthetists may not even do [the saphenous nerve block]’.

4.2.23. Mr Awcock was repositioned from prone (for his popliteal block) to supine (for his saphenous block). A general anaesthetic was administered between the two blocks taking place.

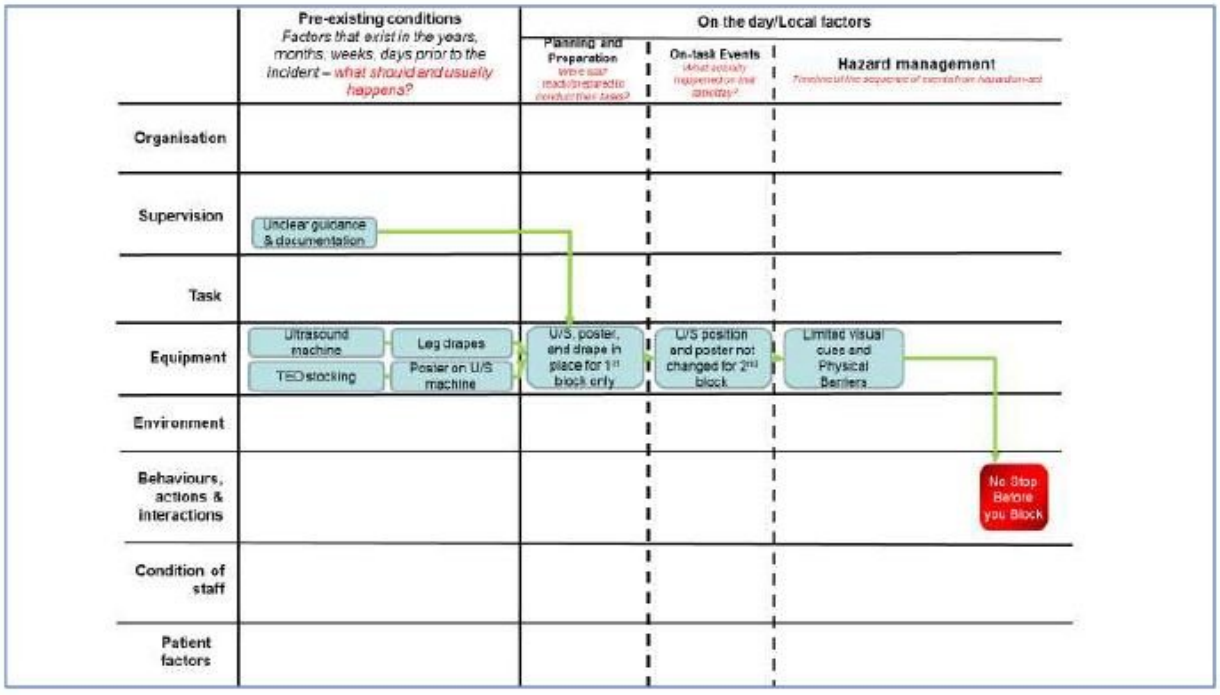
4.2.24. It was the consultant's preference for Mr Awcock to be turned from prone to supine, and for a general anaesthetic to be administered between the blocks. This was a relatively infrequent procedure and the consultant commented that the 'normal pattern or flow of the day was interrupted' and the clinical team 'did something we don't normally do'. This also created a delay between the first and second block being administered. It was at this time Mr Awcock's breathing difficulties developed.

4.2.25. The registrar explained, 'working with different consultants you see different techniques' regarding the positioning and sedation level of patients in such procedures. The ODP also indicated in her experience 'some people would do [the saphenous block] awake'.

4.2.26. Mr Awcock was considered a low risk patient and, when complications with his airway were encountered, it was unexpected and added to the complexity of the task being performed.

4.2.27. There were also a range of physical or visual cues in place to reduce the risk of a wrong site block. However, these barriers were ineffective in assisting the clinical team identifying the hazard at the time of the saphenous block (Figure 9):

Figure 9: Physical barrier ARM model



4.2.28. Trust and national guidance did not set out requirements for staff for procedures where multiple blocks were required.

4.2.29. The ultrasound machine was deliberately placed on the correct side of Mr Awcock for the popliteal block procedure. It acted as a visual cue to the correct side for the block to be administered. In addition, an SBYB poster was displayed on the ultrasound machine, covering the screen, as a reminder to carry out an SBYB moment. The surgical drape was also placed to ensure that the surgical site marking was visible.

4.2.30. The Trust's recommended practice of covering the ultrasound screen (with the SBYB poster) after the first nerve block did not take place and was, on this occasion, missing as a prompt for the second nerve block.

4.2.31. The ODP's account says that once a patient has turned into a supine position, the recommended practice would be to move the ultrasound machine to the other side of the patient. The ultrasound screen would then be covered again with the SBYB poster in accordance with Trust guidance. The consent form would be re-checked and SBYB checks then carried out with the anaesthetist.

4.2.32. On this occasion, however, the ODP was required to assist the registrar with the airway complication and was standing by Mr Awcock's head when the consultant moved to the side of Mr Awcock to administer the second nerve block. The ODP was unable to relocate the ultrasound machine or re-cover the ultrasound screen with the SBYB poster.

4.2.33. The ODP's previous experience with multiple blocks had been that they were completed in quick succession, and the ultrasound screen remained uncovered throughout.

4.2.34. There was no consistent practice at the reference incident Trust regarding the use of a surgical drape to help identify the unaffected leg. The ODP explained her personal practice was to uncover both legs prior to a block taking place so that the surgical site marking could be seen. The ODP did this with Mr Awcock prior to his popliteal block. However, it was the registrar's usual practice to use the surgical drape to cover the unaffected leg, and so they repositioned the surgical drape prior to administering the popliteal block.

4.2.35. Once Mr Awcock was turned onto his back for the second nerve block his surgical drape should have been repositioned. The ODP was managing Mr Awcock's airway and was therefore unable to reposition the surgical drape, as per her usual practice. The TED stocking was still in place up to the knee on Mr Awcock's non-operative leg, but below the site of the saphenous nerve block. The surgical site arrow may still have been visible; however, the task focus of administering the saphenous block may have resulted in a narrowing of the consultant's attention so that the surgical site arrow was not seen.

4.2.36. In response to issues identified in the local serious incident investigation, the Trust took the following local safety actions regarding the distractions leading to this incident:

- The consultant involved agreed to change their practice to perform both nerve blocks with the patient awake. This change of practice was shared with consultant colleagues to facilitate standardisation across the team.
- The Trust considered how the use of a drape could aid identification of the unaffected leg. The Trust was also to discuss and agree consistent practise regarding the use of an additional safety net (for example, a drape) to identify the area which was not being treated.
- The Trust arranged refresher training within the musculoskeletal directorate of its 'Understanding of human factors and its role in reducing risk of patient safety incidents' training'.

4.2.37. The investigation identified that complications managing the airway and the technical complexity of the block procedures taking place distracted the team from the routine nerve block process. The investigation's review of StEIS data identified distraction as the second most commonly reported factor in why wrong site blocks occur.

5. Findings and analysis from the wider investigation

This section focuses on findings and analysis from the wider investigation. Findings and analysis with specific regard to Mr Awcock's treatment are outlined in Section 4.

5.1. Stop Before You Block

SBYB in practice

5.1.1. There has been no large-scale study to consider how SBYB is used in practice. Some small-scale studies [18], [19] have taken place. These studies indicate the uptake of the SBYB initiative is not universal amongst anaesthetists, but do not provide any data for why this is the case.

5.1.2. A recent study in 2017 by Hopping et al [20] gathered responses from approximately 200 anaesthetists in six NHS Trusts in the Midlands. Over 90 per cent of anaesthetists reported that they performed a SBYB moment. However, 41 per cent were considered to perform the moment too early to usefully serve as a 'stop' moment just before injection. Approximately 10 per cent reported that they did not use SBYB regularly. This included two per cent who did not use SBYB, even though they had previously performed a wrong site block.

5.1.3. This is further supported by evidence collected via StEIS, which identified incidents where the SBYB process was not followed or there was significant deviation from the SBYB or local protocols.

5.1.4. A 2011 survey by Simmons and Brits [21] received 152 responses of which 14 reported they marked the anaesthetic site separately from the WHO marking. This is an addition to SBYB suggested in SBYB guidance. The investigation is not aware of any further block site marking studies since this time.

5.1.5. SBYB guidance suggests that further barriers such as block site marking may be incorporated into local guidance. Many Trusts (including the reference Trust) have developed local guidelines for administering a regional nerve block. A re-survey of the Simmons and Brits cohort in 2013 by Lie and Naylor [22] received 244 responses, of which 146 staff (60 per cent) reported they were aware of relevant local guidelines in their organisation.

Engagement of the anaesthetic team

5.1.6. SBYB forms part of the perioperative pathway and posters are displayed in many anaesthetic areas. The investigation observed some posters were displayed out of the vision of staff administering anaesthetic blocks or were reported as becoming '*part of the wallpaper'* due to their positioning and the length of time on display.

5.1.7. The SBYB guidance suggests all members of the anaesthetic team need to be familiar with the process. However, the issued guidance poster only refers to the role of the anaesthetist and 'anaesthetic assistant' (the ODP) in performing a check. Academic research has highlighted there has been little focus on the wider engagement of the ODP and any other staff in the checking process [23].

5.1.8. Wider research recommends that the senior anaesthetic clinician needs to be engaged in the checking process to ensure greater effectiveness [24]. There may also be cultural limitations on placing responsibility for monitoring checks on other staff groups. In the reference incident, staff commented on the positive safety culture at the Trust. However, the ODP and registrar did not challenge the consultant when block site marking was not used.

5.1.9. The investigation subject matter experts commented that to deliver an effective SBYB moment requires a shared understanding of the purpose and process to be followed. Academic research also highlights the importance of collaboration in improving the leadership and culture within anaesthetic teams [25].

5.1.10. The investigation recognises that in addition to anaesthetists, anaesthetic blocks may be performed by some other medical specialities and are often supported by non-medical staff (for example, nurses and ODPs). Engagement of these staff may allow additional insight into how block practice can be developed and implemented in a variety of clinical environments.

5.1.11. The data contained in the limited studies available is supported by staff comments received during the investigation reference site visits and from incident narratives provided in StEIS. It is evident that there is variable uptake and understanding of national SBYB guidance.

Impact of SBYB on wrong site nerve blocks

5.1.12. The investigation has not identified any national evaluation on the prevalence of wrong site blocks.

5.1.13. In 2009, prior to the SBYB initiative being introduced, 27 wrong site blocks were reported via StEIS. In comparison, data from StEIS between April 2016 and March 2017 suggests that there were approximately 29 reported incidences of wrong site block in this period.

5.1.14. Academic research [26] has identified that the rate of wrong site block incidents has remained steady at a rate of approximately 1 in every 6,250 procedures since the introduction of SBYB. The investigation acknowledges the difficulty in identifying base line figures to benchmark the success of SBYB due to recognition that wrong site block incidents may be under-reported. This also provides a challenge in identifying where SBYB has assisted in averting incidents or ‘near misses’. The lack of reliable comparative data means it was difficult to determine the impact of the current SBYB initiative on the incidence of wrong site block.

Local initiatives

5.1.15. Observations from other Trusts conducting similar procedures and from academic literature identified a range of local initiatives prepared by Trusts to aid the SBYB process. These initiatives are set out in local Trust protocols in the same way as is reflected in the reference incident.

5.1.16. In the reference incident, additional processes had been adopted to include: reference to SBYB in pathway documentation, site marking in the WHO checklist, the use of posters on ultrasound machines and use of blue tape to mark the block site.

5.1.17. On review of wider practice other interventions have included, but are not limited to:

- Use of pen marking.
- Making a variety of symbols/letters on block sites.

- Different types of SBYB stickers [27].
- Decisions not to mark the block site separately.
- ‘Block boxes’ [28].

5.1.18. The range of interventions demonstrated the various approaches Trusts and clinicians have taken to enhance or improve how SBYB is conducted. Marking of the anaesthetic site is supported by SBYB guidance; however, this guidance is not specific in how the site should be marked or whether the use of stickers is appropriate. This has led to the development of local variations to overcome the limitations in the current scope of the SBYB guidance.

5.1.19. In the reference incident, a contributing factor to the wrong site block was a local variation between anaesthetists in the application of the blue marking tape. Investigation subject matter experts explained that the ability to develop local procedures around SBYB was intended to allow local factors to be considered when implementing the SBYB process. However, the reference incident demonstrated that further variation may also exist between individual clinicians operating within local variations to the SBYB process.

5.1.20. Without appropriate testing and evaluation of local practice variations there cannot be a clear evidential basis to determine whether these variations are effective in improving SBYB processes or patient safety.

5.1.21. The investigation considered other approaches that have been proposed to reduce the risk of wrong site nerve blocks being carried out.

Mock Before You Block [29]

5.1.22. The Mock Before You Block proposal is based on a psychological approach to the block task. The approach requires an anaesthetist to prepare an additional empty syringe (no needle) or empty needle sheath. A finger or the tip of an ultrasound probe may also be used. A mock block is then performed by touching the skin and seeking verbal confirmation that the mock block is on the correct side. Only after this is confirmed would the actual injection be given.

5.1.23. This initiative is not supported by all clinicians [30], with questions raised as to whether a further procedural step in the SBYB process would be effective in this form.

5.1.24. The proposal does provide consideration of psychological factors when considering whether the initiative can be effective. This includes the potential importance of considering how the psychological perceptions for ‘action’ and for ‘identification’ differ and may impact on the effectiveness of any initiative that is heavily reliant on human operators.

Regional Block Checklist [31]

5.1.25. The American Society of Regional Anaesthesia (ASRA) has approached the issue of wrong site blocks by creating a nine-point checklist to aid anaesthetists. This was developed in 2014 and provides a more formalised breakdown than SBYB of the process steps to be followed before the block needle is inserted. As with SBYB, guidance from ASRA encourages institutions to adapt the checklist to meet localised need. The increased detail contained within the ASRA checklist allows for key elements in the process to be clear when institutions adapt or amend the checklist. The investigation engaged in discussions with a subject matter expert from the USA with respect to their block checklists.

5.1.26. A block checklist used by the subject matter expert from the USA was displayed on the wall within the anaesthetic environments of his hospital and anywhere a patient may undergo a block. He also stated that no documentation is completed within the records at the time the process outlined in the checklist is being completed. Instead, post-operatively, a note is made to confirm the checklist procedure was used. This was intended to ensure staff did not see the checklist as just a '*document to be completed*' but were instead fully engaged in the process of completing the checks.

5.1.27. Clay-Williams and colleagues have called for a wider consideration of how checklists are used in healthcare to make sure they are as effective as possible in promoting patient safety [32]. The checklist (or any patient safety tool alone) can be only one of multiple safety barriers designed to prevent an incident occurring.

Technological interventions

5.1.28. The investigation was made aware of a SBYB device [33] which is in the early stages of development by a group of clinicians.

5.1.29. This device registers when the needle touches the skin. At this point there is an audible warning to remind the anaesthetist to confirm the block site. The audible warning must be acknowledged to allow the device to perform the secondary function to register injection pressure.

5.1.30. The rationale behind this is by '*giving the clinician something useful in return*' (i.e. pressure monitoring functions) to encourage greater compliance with the SBYB process. However, the device has not yet undergone any testing to determine its usefulness, usability, or effectiveness in a clinical environment.

Block environment

5.1.31. The investigation considered the ability for NHS Trusts to standardise the environments in which anaesthetic blocks take place. Some NHS Trusts have already developed separate block rooms [34] or have nominated block anaesthetists to further standardise processes.

5.1.32. The block room is intended to be the sole anaesthetic room in operating theatres where anaesthetic blocks are administered. This allows for a consistent set up of equipment and a familiar environment for the clinicians performing blocks. In addition, the investigation's human factors expert commented that this allowed clinicians to focus on administering regional blocks and provided a further psychological cue to ensure block practice is followed. The human factors expert also supported the advantages of a single room/standardised set up for blocks, where possible, to allow the greatest opportunity for consistent practice to develop.

Developing effective interventions

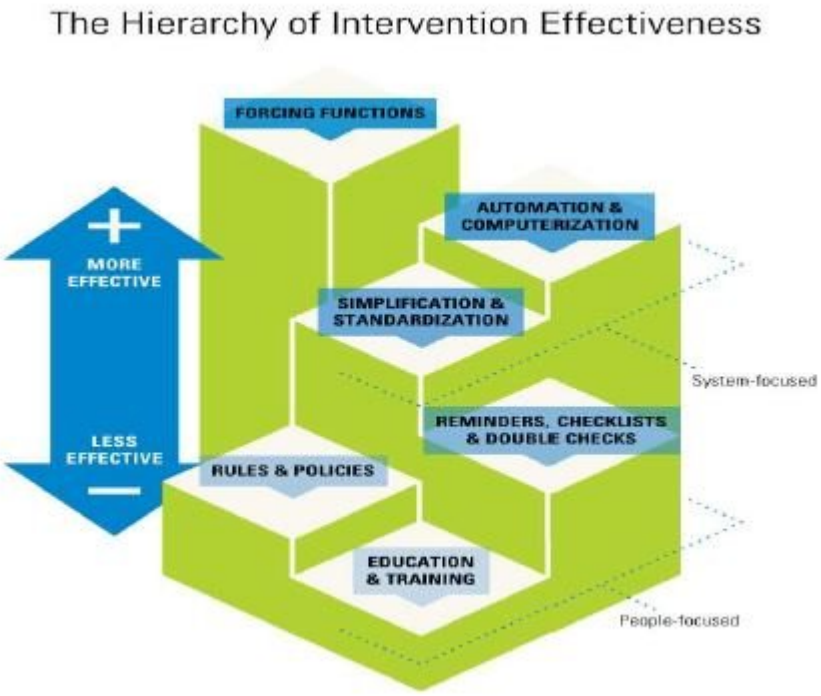
5.1.33. The SBYB process relies on interactions between individuals in the anaesthetic environment to ensure its effectiveness and on clinicians remembering to carry out the SBYB process. The variations observed in local practice may offer some additional aids to provide further safety barriers. However, the strength of these barriers is not always understood.

5.1.34. The Hierarchy of Intervention Effectiveness (Figure 10) is a theory that rates the effectiveness of a range of interventions when seeking to make improvement or eliminate risk [35]. It is widely accepted and has been adapted to mitigate risk and improvement projects within healthcare. It sets out system-based recommendations which will have a higher likelihood of mitigating risk because they do not rely on individual human attention or vigilance.

5.1.35. There is still a place for human-based actions to reduce risk, however, these actions are 'weaker' than system-based solutions. No single approach will eliminate safety incidents. An understanding of the mix and relative strengths of different approaches can help to build a range of effective barriers to safety incidents.

5.1.36. The investigation considered the safety actions taken by the Trust in the reference incident. Each intervention falls within the people-focused spectrum of the hierarchy.

Figure 10: The Hierarchy of Intervention Effectiveness [36]



5.1.37. The investigation also considered the current national approach to SBYB. It is evident that, despite efforts to create system focused barriers, there has been an emphasis on people-focused solutions to implement and embed SBYB practice. The investigation has seen no national consideration of whether any forcing functions (any task, activity or event that forces you to take a specific action) or automation could be introduced to assist in embedding SBYB.

5.1.38. There was an intention that SBYB would allow simplification and standardisation of block practice for anaesthetic staff. This has not been the case. Instead, there appears to be significant variation in SBYB practice between clinicians and between various NHS Trusts. This has impacted on the effectiveness of reminders, checklists and double-checks to embed consistent practice in SBYB processes and weakens the ability for these processes to act as stronger, system-orientated barriers to safety incidents.

5.1.39. SBYB was launched as guidance and a toolkit for clinicians. Although reference to completing SBYB is contained in NatSSIPS, the variation in how it is interpreted and practiced prevents it from effectively being enforced as a ‘rule or policy’.

5.1.40. The launch of SBYB was not accompanied by any specific training package for anaesthetists. The investigation understands anaesthetists in training are required to demonstrate SBYB when being supervised in practice performing regional nerve blocks. However, supervision is dependent on individual consultants/senior clinicians. With the variation in practice around SBYB, it is likely that there is a variation in how SBYB is supervised and

signed off. There is no standard part of the Royal College of Anaesthetists curriculum that enables a consistent evaluation of whether SBYB is carried out as intended by trainee anaesthetists throughout England.

Summary

5.1.41. The SBYB initiative and local interventions observed and described at comparison sites have not undergone rigorous human factors testing, evaluation and audit to determine if they are effective and practicable in reducing the incidence of wrong site block in the clinical environment.

5.1.42. Academic work warns of the risk that patient safety initiatives are being developed without appropriate evaluation, with further risks and limitations occurring when local variations to practice are developed in the same manner [37].

5.1.43. Carthey [38] et al recommends a human factors approach is used to develop any changes or amendments to the SBYB process. They recommend a focus not just on the limitations of current SBYB guidance, but also the adoption of a Safety II approach to consider where good practice exists. Safety II involves not just learning from when things go wrong, but also learning from when things go right. By engaging clinical staff in the process and making them aware of the evident benefits of SBYB, it is more likely amendments to SBYB process can be successful and allow for greater standardisation in how SBYB is performed in England.

5.1.44. Additional human factors training and developing leadership skills within the anaesthetic team can act as an additional barrier to safety incidents occurring. It is also beneficial to ensure safety is embedded in the culture. Frequent evaluation of the culture in practice (for example, by observation and safety culture surveys) is required to share and embed positive practice in relation to SBYB or any future initiative to reduce wrong site anaesthetic blocks.

The investigation makes the following safety observation:

> The development of patient safety initiatives should incorporate human factors and safety science specialism. This can help ensure that appropriate planning, testing, and evaluation take place to ensure a strong evidential basis for patient safety initiatives.

5.2. Distractions in the anaesthetic environment

Patient airway and consciousness

5.2.1. A patient's condition can deteriorate in the anaesthetic room. This can occur at any point, even if the patient is seemingly low risk and healthy (as in Mr Awcock's case) and whether they are awake, sedated, or placed under general anaesthetic.

5.2.2. Distractions are described as a risk to successfully completing the SBYB process [39]. The management of deterioration in the patient can move the focus away from the SBYB process. Once this focus is lost, it may not be regained even when the deterioration is resolved. The shift away from the primary task increases the chances of an error occurring [40].

5.2.3. The investigation understands there has been debate within the anaesthetic community about whether nerve blocks should be performed awake, sedated or under general anaesthetic. Some consider that a patient who is awake can report any neuropathic symptoms when a block is taking place. Conversely, there are concerns a conscious patient may involuntarily move and impact on the nerve block taking place. Most studies on a patient's consciousness level during a nerve block are within paediatric anaesthesia. The limited studies available in the adult patient appear to support a clinical benefit to patients being awake or sedated (as opposed to under general anaesthetic) where possible [41].

5.2.4. Literature is also supportive of patients being awake and involved in the verification of their procedure, where possible [42]. The investigation's subject matter experts have reflected that there are limitations to patients confirming information with medical practitioners (or more broadly with authority figures) and this should not be relied on as the sole source of confirmation of the block site. A conscious patient should instead be considered a further safety barrier, who may assist in alerting the anaesthetic team to any wrong site errors.

Changing patient position

5.2.5. The human factors expert and subject matter expert from the USA considered the increased risk of a wrong site block when a patient's position is changed. They commented that this can create confusion about the correct block site for the reasons highlighted in the reference incident, particularly when a patient is placed from a prone to supine position.

5.2.6. Academic research by Taha & Ahmed highlights there are alternate approaches to providing a popliteal nerve blocks from the supine position [43]. Further academic studies have demonstrated the effectiveness of the nerve block was not impacted by the patient remaining in the supine position [44]; both nerve blocks can safely be administered whilst the patient is on their back.

Multiple blocks

5.2.7. The decision to administer multiple blocks was made by the consultant in the reference incident. Human factors and safety science suggest the chance of a wrong site block occurring will increase when multiple blocks are being administered. The investigation is unaware of any studies or evaluation into the benefits of multiple blocks, weighed against additional risks involved in the procedure and the effectiveness of some of the mitigating factors outlined above.

HSIB makes the following safety recommendations:

Recommendation 2018/012:

That the Royal College of Anaesthetists establishes a specialist working group to evaluate the current practices used to reduce wrong site block incidents. This group should consider how safety initiatives to reduce wrong site blocks can be standardised in anaesthesia training and practice.

It is recommended that the specialist working group consider the impact of: the patient's state of consciousness, changes in a patient's position and the prevalence of wrong site block incidents compared to the number of blocks administered.

Recommendation 2018/013:

That the Royal College of Anaesthetists ensures any further work identified by the specialist working group to reduce wrong site block incidents is subject to human factors-based testing and evaluation.

Patient documentation

5.2.8. There is evidence that events earlier in the patient's pathway to the operating theatre can have a direct impact on incidents taking place. The investigation identified incidents reported via StEIS where anaesthetic blocks have been administered to the 'correct' location (as set out in patient records and consent forms) but where the location of the block was incorrectly recorded earlier on in the patient pathway. In such cases, it is unlikely an effective SBYB moment would act as a barrier against a wrong site block being administered.

5.2.9. A systematic review and fault tree analysis for wrong site surgery [45] points to most of the record keeping relying on human transcription and verification. Transcription errors in documents prior to the day of surgery are key vulnerabilities. The study identified errors occurring prior to the day of surgery were subject to less verification requirements, creating the potential for an initial error to propagate through the system leading up to the day of surgery.

5.2.10. Patient pathway documentation can be amended to ensure additional information is available to assist clinicians in identifying the correct number, site and side for anaesthetic blocks. Alongside an approach to barrier management highlighted in academic research [46], this may increase the reliability of processes within the pre-operative pathway.

6. Summary of HSIB Findings

6.1. Findings

- It is unclear whether SBYB in its current form has had any impact on the incidence of wrong site blocks.
- The SBYB guidance does not provide sufficient clarity or direction on how SBYB should be used in practice. Consequently, there is significant variation in SBYB practice and its uptake amongst clinical staff.
- No evaluation of SBYB practice has taken place to confirm how SBYB is working in practice and whether local variations or alternate approaches to SBYB improve its effectiveness.
- A consistent approach to training and supervision in SBYB is not incorporated into anaesthetic specialist training.
- There is an opportunity for an additional safety barrier if a patient is awake and able to engage with clinicians during the block procedure.
- Drawing on human factors principles, it would be expected that changes to the position of patients between blocks and administering multiple blocks would increase the risk of a wrong site block.
- The current variability in how SBYB is understood and practised means SBYB does not always form a strong systemic protective barrier to wrong site blocks occurring.

6.2. Safety recommendations

HSIB makes the following safety recommendations:

Recommendation 2018/012: The Royal College of Anaesthetists establishes a specialist working group to evaluate the current practices used to reduce wrong site block incidents. This group should consider how safety initiatives to reduce wrong site blocks can be standardised in anaesthesia training and practice.

It is recommended that the specialist working group consider the impact of: the patient's state of consciousness, changes in a patient's position and the prevalence of wrong site block incidents compared to the number of blocks administered.

Recommendation 2018/013: The Royal College of Anaesthetists ensures any further work identified by the specialist working group to reduce wrong site block incidents is subject to human factors-based testing and evaluation.

6.3. Safety observations

The investigation makes the following safety observation:

The development of patient safety initiatives should incorporate human factors and safety science specialism. This can help ensure that appropriate planning, testing, and evaluation take place to ensure a strong evidential basis for patient safety initiatives.

7. Appendices

Appendix A

Stop Before You Block guidance

NHS England

SAFE ANAESTHESIA LIAISON GROUP

Nottingham University Hospitals NHS

RA-UK

STOP BEFORE YOU BLOCK CAMPAIGN

We introduce a national patient safety initiative called Stop Before You Block. The campaign is aimed at reducing the incidence of inadvertent wrong-sided nerve block during regional anaesthesia.

BACKGROUND

Inadvertent wrong-sided peripheral nerve blocks are uncommon but can have serious consequences including complications from the unnecessary block such as nerve injury and local anaesthetic toxicity. Hospital discharge may also be delayed due to reduced mobility or dexterity. At worst, a wrong-sided nerve block may lead the team to continue to wrong-site surgery.

NHS England describe a 'Never Event' as a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.[1] In 2015 wrong-sided nerve blocks were classified by NHS England as 'Never Events', in recognition that they are unacceptable, and preventative measures are required to help reduce their incidence.

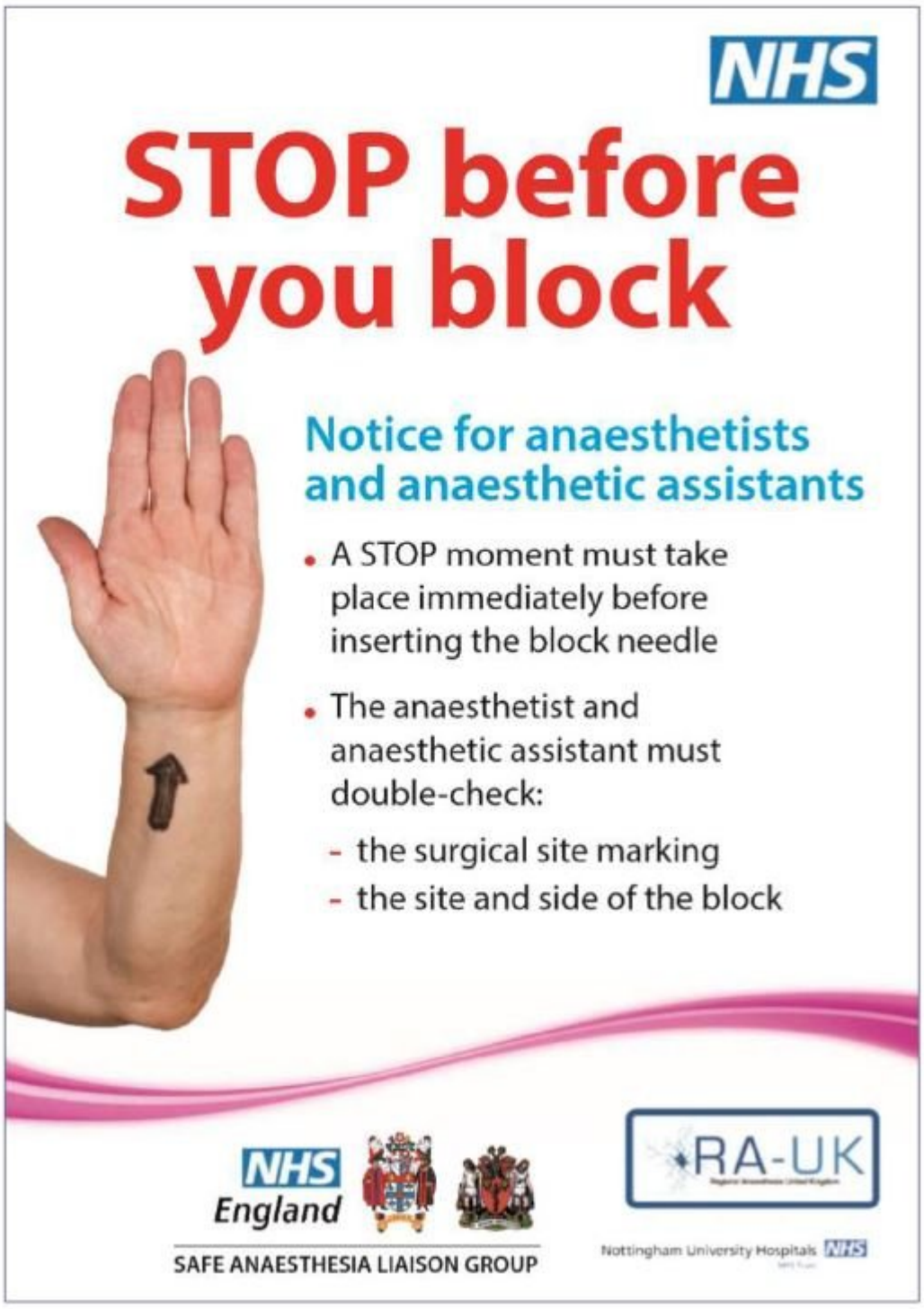
In November 2010, the Safe Anaesthesia Liaison Group (SALG) published an alert highlighting details and learning points from 67 inadvertent wrong-sided nerve blocks reported via the National Reporting and Learning Service (NRLS) over a 15-month period.[2] The recommendation from this alert was to check that the surgical site had been marked by the surgical team before performing a peripheral nerve block, as per the World Health Organization (WHO) checklist.[3]

At Nottingham University Hospitals NHS Trust, we had already conducted a local investigation in response to 5 reported wrong-sided blocks during a 12-month period. Analysis revealed that in ALL of these cases the surgical site had been marked appropriately and the WHO 'sign in' performed correctly. We identified several important factors contributing to the performance of the wrong-sided nerve blocks that were common in most cases. These included:

- Distraction in the anaesthetic room
- Time delay between the WHO sign and performance of the nerve block (e.g. a femoral block performed after a difficult and time-consuming spinal anaesthetic)
- Covering-up of the surgical mark with blankets in an attempt to keep the patient warm

These factors were also found to be recurring themes throughout the 67 incident reports received by the NRLS.

We felt that the initial advice from the SALG, whilst important, needed to be bolder and therefore introduced a local STOP BEFORE YOU BLOCK campaign. We requested that anaesthetists and operating department personnel conduct an additional 'stop moment'; in addition to the WHO checklist, IMMEDIATELY BEFORE NEEDLE INSERTION when performing a peripheral nerve block. The conduct of the STOP BEFORE YOU BLOCK process is described below.



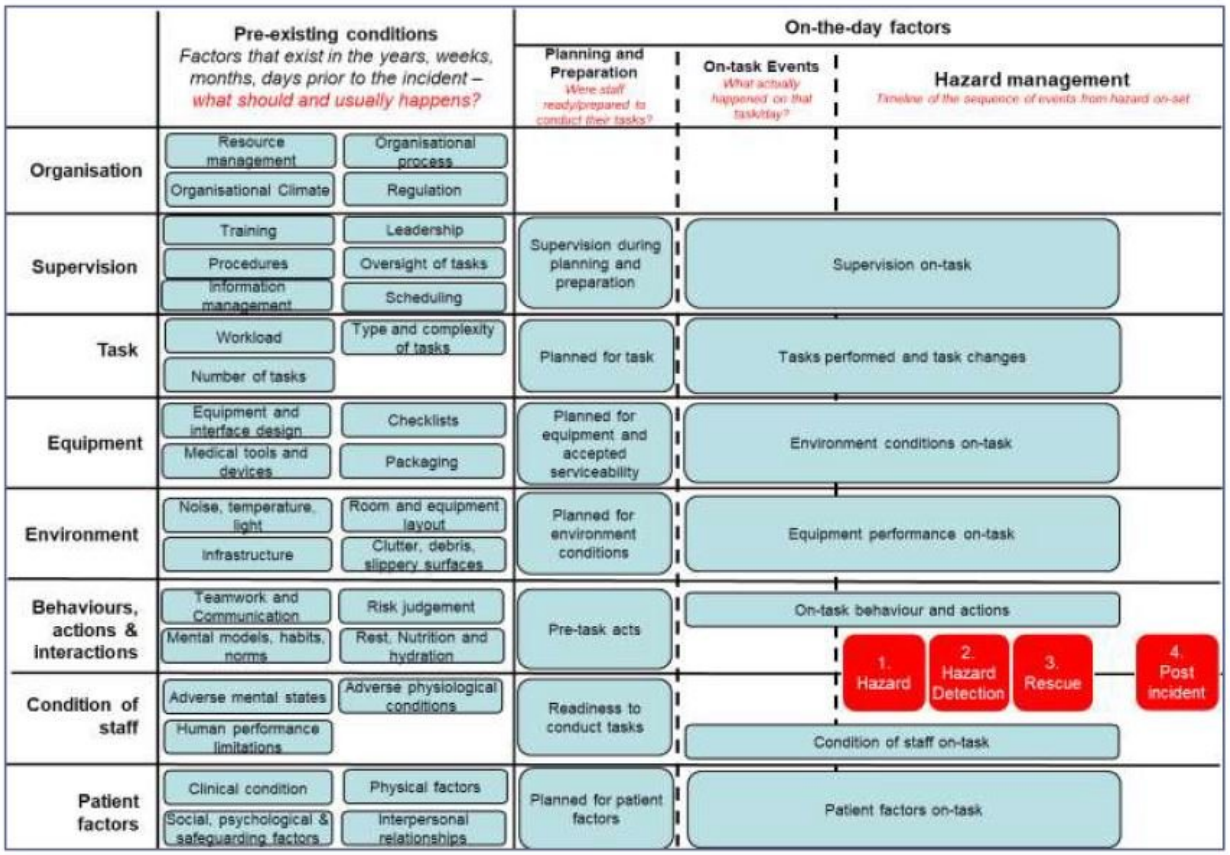
Appendix B

Analysis of the Trigger Event using the Accident Route Matrix Model (ARM)

The ARM is a human factors investigation tool, created in 2009, to support military human factors air investigations [1], [2], [3]. The ARM is based on the Swiss Cheese Model [4] and the Human Factors Analysis and Classification System [5]. In addition, more than 30 actual air accident investigations were used to both develop the framework and refine it. The ARM enables evidence to be plotted by both type (factors at the organisation, supervision,

equipment, environment or operator level) and by time of effect (factors that occurred prior to the day of the incident or factors that occurred on the day of the incident). HSIB has worked with our own human factors specialists to modify the ARM for use in healthcare investigations. A generic HSIB modified ARM is shown in Figure A.

Figure A: HSIB's Accident Route Matrix modified from Harris, 2011 [52]



The aim of the ARM is to identify which factors, and at which point each factor, contributed to the following:

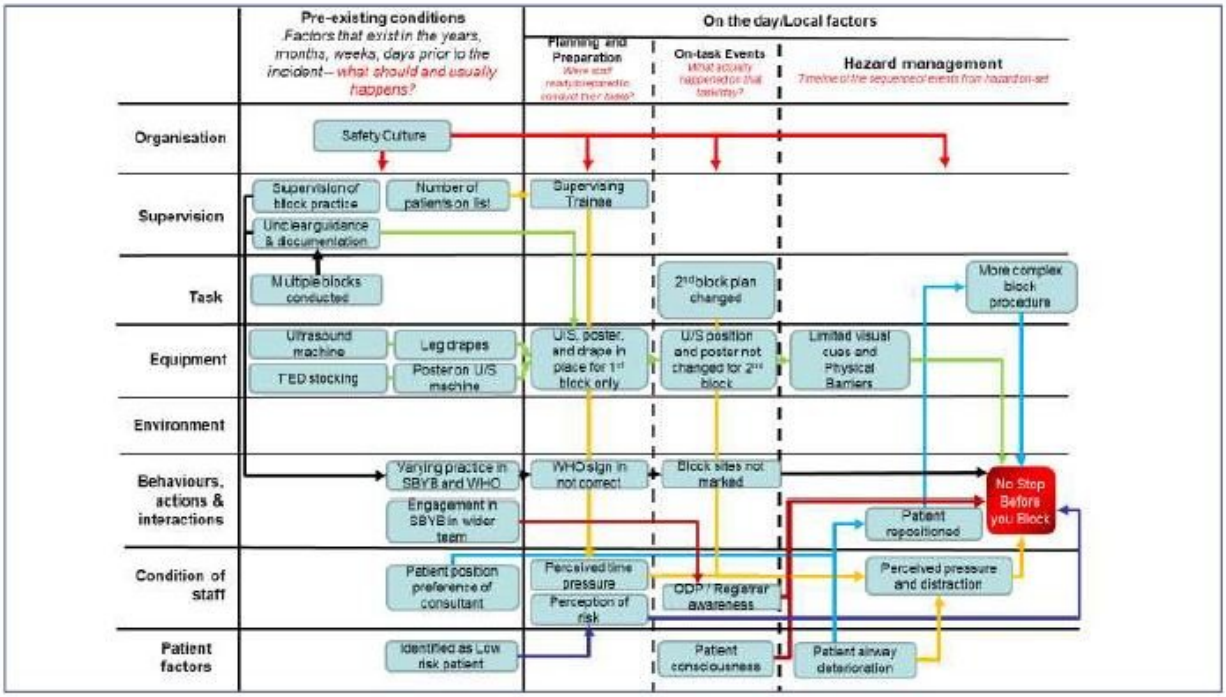
- Hazard **–** The hazardous situation in which the patient and/or staff were in.
- Hazard Detection **–** How, when, where and by whom, the hazardous situation was detected (if detected).
- Rescue **–** The response and actions taken to deal with the hazardous situation.

HSIB's modified ARM can also identify factors post-incident. For example, how the Trust dealt with the patient and family after the incident or how staff are supported after a traumatic event. Links can be drawn to show interrelationship between related factors and common themes.

In this case, the ARM model was used to identify the factors that led to and contributed to no SBYB being carried out for the second block on Mr Awcock.

The ARM model should be read in full to appreciate the various factors throughout a system that contributed to the incident. The ARM for Mr Awcock's wrong site block is presented below (Figure B):

Figure B: ARM model for Mr Awcock's care



8. Glossary

ARM	Accident Route Matrix, the human factors tool used by HSIB in the investigation
ASRA	American Society of Regional Anaesthesia
Consultant	The consultant is a senior doctor in anaesthetics who had completed a minimum period of specialty training in their speciality area. The consultant in the reference incident had 14 years' experience.
HSIB	Healthcare Safety Investigation Branch
ODP	Operating department practitioner
LocSSIPs	Local Safety Standards for Invasive Procedures
LMA	Laryngeal Airway Mask
NatSSIPs	National Safety Standards for Invasive Procedures
NRLS	National Reporting and Learning System
RA-UK	

	Regional Anaesthesia UK. RA-UK is the UK division of the European Society of Regional Anaesthesia and is the UK specialist society for anaesthetists interested in the field of regional anaesthesia.
Registrar	The registrar is a specialist trainee in critical care and anaesthetics. They were NHS grade ST6; they had completed six of seven years specialist training
SALG	Safe Anaesthesia Liaison Group. SALG is a multiagency group formed of three core members: the Royal College of Anaesthetists, the Association of Anaesthetists of Great Britain and Ireland and NHS Improvement. Its purpose is to highlight potential or existing patient safety issues which fall within the anaesthesia care pathway.
SBYB	Stop Before You Block
StEIS	Strategic Executive Information System
TED stocking	Anti-embolic below knee stocking
The Trust	The NHS Trust where the reference incident occurred
WHO	World Health Organization

Endnotes

[1] This is a block to the sciatic nerve (the nerve that carries sensation and runs from the back to the lower limb) above the popliteal fossa (area on the back of the leg behind the knee).

[2] This is a block to the saphenous nerve (a sensory branch of the femoral nerve) and is usually administered 10-15 cm above the knee.

[3] Further details of risks and complications are available at: **https://www.rcoa.ac.uk/system/files/13-NerveDamagePeripheralNB2017.pdf**

[4] Image taken from: **https://accessanesthesiology.mhmedical.com/content.aspx?bookid=2070&sectionid=157607838**

[5] Image taken from: **https://www.earthslab.com/anatomy/saphenous-nerve/**

[6] **https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf**

[7] Further information on the WHO checklist is available at: **www.nrls.npsa.nhs.uk/resources/?entryid45=59860**

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