NHS Improvement

Surgical Never Events

Learning from 38 cases occurring in English hospitals between April 2016 and March 2017

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We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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Summary

Never Events are patient safety incidents that are considered preventable when national guidance or safety recommendations that provide strong systemic protective barriers are implemented by healthcare providers.

Starting in 2012, NHS England began a programme of work to understand why surgical Never Events persist despite the requirement in the NHS to use the World Health Organization (WHO) surgical safety checklist and the five steps to safer surgery. A key recommendation from this programme was the development of national standards to be introduced in all areas of healthcare where patients undergo invasive procedures, and in 2016 NHS England launched the national safety standards for invasive procedures (NatSSIPs).

NHS Improvement commissioned this report as part of the evaluation process for the implementation of NatSSIPs. It presents an analysis of the local investigation reports into 38 surgical Never Events from across England that occurred between April 2016 and March 2017 (the last full year with data available). No further data was collected for the analysis. This report follows on from similar reviews of nine cases in 2012 and 23 cases in 2014, enabling the tracking of similarities and differences over time.

The cases analysed here include 20 of surgery at the wrong site; four of the wrong implant being inserted; and 14 of retained foreign objects. It is important to note that these cases represent a small fraction of the total number of interventional procedures undertaken in the NHS and independent sector during the year in question.

The main contributory factors identified in the Never Event investigations are set out in this report together with a summary of the different actions taken by organisations to prevent recurrence. It is clear from this analysis that some challenges remain to the prevention of reoccurrence. These are given in detail in Section 8 and include:

- how to create a receptive team culture during interventional procedures: one where questioning related to safety is welcomed, advice listened to and acted on, and all staff are encouraged to speak up when they have concerns

- reducing the risks and enhancing awareness of safety in situations where team members are unfamiliar with each other or with the environment, equipment or procedure
- developing the use of safety checks, so that they are done because all those participating realise their importance, not because they have been mandated.

NHS Improvement considers Never Events to be ‘red flags’; they highlight potential weaknesses in how an organisation manages fundamental safety processes. The investigation reports reviewed held little evidence that the organisations had fully considered their approach to the implementation of relevant national guidance: this is an area for further work. Several trusts had already introduced human factors training before the Never Event occurred and were able to include the learning from the investigation in future training. It would be beneficial to know more from these trusts about their human factors training and its impact, and to share their learning across the NHS.

Other areas with potential for improvement include:

- **Interruptions and distractions:** these were described as leading to a loss of situational awareness in several cases – reducing these and recognising how they impact on concentration remain a challenge, despite what has been learned from research and from other industries.
- **Site marking:** more work is needed to identify the best way to mark surgical sites for: hand and foot surgery; angiograms that are side specific; dermatology; and pain injections.
- **Reducing transcription errors:** removing the need to copy information from one piece of paper to another or from paper to computer remains a challenge. Several cases highlighted that a transcription error may be copied onto all other records including the theatre list.
- **Counting:** following a Never Event many trusts have added items to their count policies, but these additions and the reasons for them are not shared across the NHS. It would be helpful to find out what trusts now include in their count policies and why, and for this information to be disseminated across trusts.
- **Equipment with covers or caps that come apart:** several of the cases raised the question of how to handle covers and caps that are passed across the surgical field. Some trusts have withdrawn certain items from use,

replacing them with other more robust kit. Sharing the actions taken by these trusts so that others can implement similar checks should be considered.

- **Design:** manufacturers of medical implants, components and devices need to add visual cues to clearly display side and size on their packaging and, if possible, the device itself. The medical device/implant industry should consider using a common size indicator and colour code for left and right labelling and packaging. Similarly, manufacturers need to consider designing visual cues for equipment and supplies that are wholly inserted into the surgical field, to help prevent retention of foreign objects.
- **Reducing choice of implants and components:** lack of familiarity with implants, equipment and consumables was the cause of some of the Never Events reviewed. Reducing the number of different types available would increase staff familiarity with what is being used, as well as reducing the training load.
- **Size and side compatible components:** where multiple components are used that need to be both size and side compatible, systems and procedures are needed to check compatibility before each component is used. This remains a challenge and solutions varied.

1. Introduction

Never Events are patient safety incidents that are considered preventable when national guidance or safety recommendations that provide strong systemic protective barriers [1] are implemented by healthcare providers. Their prevalence remains low in relation to the total volume of surgery undertaken in the NHS: about one in every 20,000 procedures. In some cases the impact is minimal but in others it can be devastating. Many affected patients need another procedure or to take antibiotics or pain relief medication, but some are permanently harmed.

Starting in 2012, NHS England began a programme of work to understand why certain surgical incidents persist despite the requirement in the NHS to use the World Health Organization (WHO) surgical safety checklist and the five steps to safer surgery. A task force was set up nationally to review why such events were happening, to learn from these and to make recommendations. A key recommendation was the development of national standards to be introduced in all areas of healthcare where patients undergo invasive procedures. A clinically-led group was established at a national level to prepare these standards and in 2016 NHS England launched the national safety standards for invasive procedures (NatSSIPs). Each NHS organisation undertaking invasive procedures was required to develop local versions of these national standards – called local safety standards for invasive procedures (LocSSIPs) – but with limited scope for amendment to ensure local relevance.

NHS Improvement commissioned this report as part of the evaluation process for the implementation of NatSSIPs to assess their impact and to discover issues not addressed by these standards. NHS Improvement considers Never Events to be ‘red flags’; they highlight potential weaknesses in how an organisation manages fundamental safety processes. Therefore, whenever a Never Event occurs, regardless of the outcome, a full systems-based investigation is required, including of the approach the organisation took to the implementation of national guidance [1].

This report presents an analysis of the investigation reports into 38 surgical Never Events from across England that occurred between April 2016 and March 2017: 20 cases of wrong site surgery; four of the wrong implant being inserted; and 14 of retained foreign objects.

Example Never Event: retained guide wire

A severely ill patient was admitted to the coronary care unit where their condition deteriorated rapidly. The doctor needed to administer emergency drugs by intravenous infusion. Accessing the patient's veins was difficult so the doctor inserted an emergency central line through a vein in the patient's leg using a technique that required a guide wire. The doctor was under pressure due to the patient's condition and wanted to check immediately that the sheath was in the femoral vein, so they quickly aspirated blood and then flushed the sheath ready for use – forgetting to remove the guide wire. The flush pushed the guide wire into the patient's vein and it travelled around their body and lodged near their heart. The fact that the guide wire had been retained was not noticed until three weeks later when the patient was transferred for heart surgery. The guide wire was removed successfully by a specialist team after two attempts.

The purpose of this work was to:

- identify the causes of these events using a human factors approach
- identify the common systems and design issues
- assess the evidence of implementation of NatSSIPs, in particular the gaps in implementation
- develop a method for ongoing review to track implementation/adoption of the national standards over time through a longitudinal analysis of a sample of incidents.

This review follows on from similar reviews of nine cases in 2012 [2] and 23 cases in 2014 [3], enabling the tracking of similarities and differences over time and as the national standards are implemented.

This analysis is not intended to offer a comprehensive report of what happened over the year in terms of all surgical Never Events in England; instead it offers an analysis for the purpose of learning.

1.1. Facts and figures

In 2016/17 there were 189 cases of wrong site surgery; 114 of retained foreign objects post procedure; and 53 of the wrong implant/prosthesis being used [4].

- Of the wrong site surgery cases, 30 involved use of the wrong site for a nerve block, 46 removal of the wrong tooth; and 14 removal of the wrong skin lesion.
- Of the cases of retained foreign objects, 32 involved retention of vaginal swabs; 23 of surgical swabs; 17 of central line or chest drain guide wires; and five of specimen retrieval bags.
- Of the wrong implant/prosthesis inserted, 25 were for hips or knees and 21 were intraocular lenses.

1.2. Definitions and examples

1.2.1. Wrong site surgery

Wrong site surgery was defined in 2016/17 as: “A surgical intervention performed on the wrong patient or wrong site (for example, wrong knee, wrong eye, wrong limb, wrong tooth or wrong organ); the incident is detected at any time after the start of the procedure” [5].

This includes:

- “Wrong level spinal surgery and interventions that are considered surgical but may be done outside of a surgical environment, eg wrong site block (unless being undertaken as a pain control procedure), biopsy, interventional radiology procedures, cardiology procedures, drain insertion and line insertion, eg [peripherally inserted central catheter] PICC/Hickman lines.”

But excludes:

- “Interventions where the wrong site is selected because of unknown/unexpected abnormalities in the patient’s anatomy. This should be documented in the patient’s notes.
- Incidents where the wrong site surgery is due to incorrect laboratory reports/results or incorrect referral letters.”

Example: Wrong site surgery

As part of her treatment for breast cancer, a patient had a lymph node removed in her armpit. Surgery was performed on the wrong side.

What happened?

- The surgeon wrote down the wrong side for the procedure during a busy multidisciplinary team meeting when the laboratory results for both sides were discussed.
- The surgeon's notes, including the error, were typed up by the administrator, put in the medical notes and fed into the operating list schedule.
- The patient had a benign lump on the opposite side to where surgery was intended. When the patient was examined before the procedure, the surgeon followed what was written in the patient's notes and felt a lump in the 'wrong' side.
- The WHO safe surgery checklist was undertaken pre-procedure but the imaging and histology results were not reviewed; only the patient's records were considered.
- The error was found when the results of the test on the node removed came back as 'benign'.
- The patient was readmitted and the correct procedure undertaken.

1.2.2. Wrong implant/prosthesis

Wrong implant/prosthesis surgery was defined in 2016/17 as: "Surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the surgical plan either before or during the procedure and the incident is detected at any time after the implant/prosthesis is placed in the patient" [5].

This excluded:

- "Where the implant/prosthesis placed in the patient is intentionally different from the surgical plan, where this is based on clinical judgement at the time of the procedure.

- Where the implant/prosthesis placed in the patient is intentionally planned and placed but later found to be suboptimal."

Example: Wrong prosthesis

A patient had surgery to repair a complex arm fracture. During surgery the circulating nurse picked a plate from the drawer where both left and right-sided plates were kept. The plates had become mixed in the drawer and the wrong one was picked and inserted.

What happened?

- The way in which left and right-sided implants were stored created the conditions for the selection error.
- The trust's policy for checking implants before use was not adhered to.
- The circulating nurse, the scrub practitioner and the surgeon all failed to check that the plate selected was for the correct side.

1.2.3. Retained foreign objects after a surgical/invasive procedure

The definition of a retained object in 2016/17 relates to the definition of a surgical or invasive procedure: "Surgical/invasive procedure includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside of the surgical environment, eg central line placement in ward areas" [5].

Retained foreign objects are defined as: "any items that should be subject to a formal counting/checking process at the commencement of the procedure and a counting/checking process before the procedure is completed (such as swabs, needles, instruments and guide wires) except where:

- Items that are not subject to the formal counting/checking process are inserted any time before the procedure, with the intention of removing them during the procedure and they are not removed.
- Items are inserted during the procedure that are subject to the counting/checking process, but are intentionally retained after completion of the

procedure, with removal planned for a later time or date and clearly recorded in the patient's notes.

- Items are known to be missing before the completion of the procedure and may be within the patient (eg screw fragments, drill bits) but where further action to locate and/or retrieve would be impossible or be more damaging than retention."

Example: Retained foreign object

The patient had surgery for a bunion (a hallux valgus procedure) during which a small guide wire was used. The end of the guide wire broke off and was retained in the patient's foot. The patient returned to the outpatient clinic, and the broken piece of wire was identified on X-ray and then removed.

What happened?

- Small guide wires were not included in the list of things counted during this type of surgery.
- The length of the guide wire was not measured on retrieval so the fact that it had broken off was not detected.

2. Methods

2.1. Sample selection

NHS Improvement requested incident investigation reports from each of the four regions of the English NHS such that the overall sample was 10% of all surgical Never Events that took place in 2016/17. Reports were submitted from organisations of all sizes, both teaching and non-teaching, and from across England.

NHS Improvement selected the cases from a list of those occurring in the time period but without knowing the detail of the trust, the case or the investigation. The selection process ensured a spread across England and included the independent sector. This can be regarded as a stratified, random sample where the stratification occurred across NHS regions. However, since the number of cases is small, it is not possible to draw statistical conclusions. Nor can it be concluded that this is a truly representative sample; but it does offer a good indication of the causes underlying surgical Never Events in England and the lessons that can be drawn from them. Also, the findings are consistent with previous reports reviewing Never Event cases in 2012 and 2014 [2, 3].

Twenty cases related to wrong site/procedure/patient surgery; four to wrong prosthesis/implants; and 14 to retained foreign objects. There was a spread of cases across specialties too.

2.2. Analysis of contributory factors

The purpose of the work as set out by NHS Improvement was to identify the:

- causes of these events using a human factors approach
- common systems and design issues.

Each report was reviewed and analysed. No further data was collected for the analysis. The contributory factors were identified, in so far as the local investigation had described or implied them, and grouped in a spreadsheet using the headings in the ‘London protocol’ [6] as set out in Table 1. This is a well-validated incident analysis framework, based on the principles of ‘system-level’ safety thinking, and was used in the previous two reviews of Never Events, allowing for comparisons. It also allowed for the clinical human factors to be identified.

Human factors, often referred to as ergonomics, is an established scientific discipline used in many other safety critical industries. While most errors in healthcare are considered to be due to poorly designed systems, it is important to understand the human–system interactions and their impact on risk and safety. This includes an understanding of the influence of equipment and workplace design on human performance; the impact of the organisational and team characteristics on safety-related behaviour; and the impact of non-technical skills on a person's work. Non-technical skills are "the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance" [7]. These include: situation awareness, decision-making, teamwork, leadership and coping with stress [8].

- **Situation awareness:**
  - not gathering enough information
  - overlooking anomalies
  - not checking 'mental pictures' with others
  - not recognising increased risks.
- **Decision-making:**
  - proceeding with the task rather than checking when uncertain
  - over-reliance on assumptions as to correct location such as prepositioned patients.
- **Teamwork:**
  - failures in the team to speak up;
  - inadequate exchange of information to ensure a shared understanding of what was going to be done.

Clinical human factors are defined as factors that enhance clinical performance through an understanding of the effects on human behaviour of teamwork, tasks, equipment, workspace, culture and organisation, with the application of that knowledge in clinical settings (see Clinical Human Factors Group).

The causes identified were then analysed under each heading and described. The actions taken were also identified, recorded and grouped according to the type of action taken. The cases were then summarised (see Appendix 1 for details).

Table 1: The London protocol for classifying the contributory factors in healthcare adverse events (Taylor-Adams et al (2004) [6])

Factor type	Influencing/contributory factors
Institutional context	Economic and regulatory context National guidelines and policies
Organisational and management factors	Trust financial resources and constraints Organisational structure Trust policy standards and goals Safety culture and priorities
Work environment factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Design of the work space including noise levels
Team factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc)
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors

Findings

Sections 3 to 7 set out the contributory factors for the 20 cases of wrong site, wrong procedure and wrong patient surgery; the four cases of the wrong implant being used; and the 14 cases of retained foreign objects. These are grouped using the framework described in Section 2 with a short commentary. The differences from and similarities with the cases reviewed in 2014 are then described, followed by a summary of the actions taken as a result of these Never Events. Finally, the overarching themes for future prevention are set out.

Appendix 2 summarises the contributory factors by type of Never Event against those in the London protocol.

3. Wrong site surgery

Twenty cases of wrong site, wrong procedure and wrong patient were analysed (Table 2). The wrong patient and wrong procedure cases were both in ophthalmology. Of the remaining 18, three involved anaesthetics; four were in general/specialist surgery; and five were in orthopaedics.

Table 2: Summary of cases of wrong site surgery

Never Event	No	Specialty	Description
Wrong patient	1	Ophthalmology	The patient had unnecessary laser eye surgery
Wrong operation	2	Ophthalmology	During surgery to correct an eye condition the wrong procedure was undertaken
Wrong site or side	3	Anaesthetics	A nerve block was administered on the wrong side
	4	Anaesthetics	A pain-relieving injection was given into the wrong hip joint
	5	Anaesthetics	A central line was inserted in the wrong place
	6	Dental	The wrong tooth was extracted
	7	Dermatology	The wrong naevus was removed
	8	Endoscopy	The scope was inserted by mistake into the cervix
	9	Gynaecology	A cyst was removed from the wrong side
	10	Orthopaedics	During surgery for a hand injury, the wrong finger was operated on
	11	Orthopaedics	The surgeon made an incision at the wrong site when due to perform surgery for a trigger thumb
	12	Orthopaedics	The surgeon made an incision at the wrong site for trigger finger surgery
	13	Orthopaedics	The patient's arthroscopy started on the wrong knee

Never Event	No	Specialty	Description
	14	Orthopaedics	The surgeon made an incision in the wrong space when due to perform surgery on a patient's toes
	15	Radiology	The patient had a diagnostic angiogram performed on the wrong leg
	16	Surgery	Venous ablation was started on the wrong leg
	17	Surgery	The wrong rib was removed during complex surgery
	18	Surgery	The patient had a growth removed from the wrong side
	19	Surgery	Surgery to clear lymph nodes in the armpit was carried out on the wrong side
	20	Urology	A stent was placed in the wrong ureter

3.1. Institutional context

No contributory factors or root causes relating to the national, economic or regulatory context were reported for any of the 20 cases.

3.2. Organisation and management factors

Three organisational system issues were identified: the arrangements for pooled operating lists; errors in recording side during multidisciplinary team (MDT) meetings; and mixed paper and electronic records.

3.2.1. Pooled operating lists

A pooled operating list is one where patients who have previously seen a different surgeon in the outpatient clinic are placed on a common operating list. This is often done where the procedure is considered straightforward, such as cataract surgery or the removal of moles (naevus). The surgeon who operates is unlikely to have seen the patient until the day of surgery, when they meet the patient to ask for consent to undertake the procedure.

Three cases identified the need for consideration of the systems and procedures for managing patients on pooled lists – for example, the need for each patient on a

pooled list to have a clear treatment plan, written in their notes, confirmed and signed by the listing surgeon, and including the site, the side, the procedure and all required calculations (such as the degree of muscle realignment in squint surgery). This treatment plan would then be used by the operating surgeon in the consent process and the surgery. Giving a copy of this treatment plan to the patient in advance of the surgery would add another layer of checking if they were able to refer to it when signing the consent form.

3.2.2. Multidisciplinary meetings

In cancer MDT meetings many patients are discussed. Each will have a similar condition and require similar surgery but either on the left or right side. In the case analysed here, the surgeon recorded the required procedure but the wrong side for surgery on the MDT sheet during the meeting. No checking mechanisms were in place; hence the MDT sheet was transcribed into typewritten notes on the same day by the co-ordinator and e-mailed to all members of the MDT. This error then transferred to other written communication such as the theatre list. The error was further obscured by the fact that the patient had lumps on both sides (one benign), so the error was not noted during examination before surgery.

3.2.3. Medical records

Three cases involved the availability and accuracy of medical records. One case occurred during a period of transition to electronic patient records: at the time the trust was operating with a mix of paper and electronic records. It was evident from the report that the transfer to full electronic records was unlikely to be completed for some time. Here, the paper records were incomplete and hence incorrect, since the most recent correspondence, including the treatment plan, had been placed in the electronic record.

In another case, the postoperative note stating the first surgery had been completed and on which leg had not been filed in the notes by the time the patient returned for their second procedure. The only letter in the notes was from the first referral and the side it mentioned was taken as the side for the second procedure.

3.2.4. Training

In only one case was the syllabus of a training programme described as a factor, specifically the content of training for non-medical staff undertaking endoscopies. There is a known risk with female sigmoidoscopy of the scope entering the wrong

orifice. The findings from this case recommend that this is covered in training – including how to detect the error during the procedure.

3.2.5. Safety culture

In three cases the nursing staff did not feel able to speak up about their concerns. Two involved new or junior nursing staff and one related to experienced theatre staff not feeling able to speak up during a procedure that they were unfamiliar with. In two cases safety processes were described as not being embedded in routine practice.

3.3. Work environment factors

3.3.1. Design and layout

In one case the design and location of the whiteboard was described as a factor. Here the patient's procedure details were written on the whiteboard but the size of the writing was described as too small for the person undertaking the procedure to read from where they were operating.

In two cases – both involving outpatient procedures – the layout of the treatment area was described as a contributory factor. In one noise could be heard from the waiting area and other members of the nursing and medical team were able to interrupt. In another case the same waiting area served for different procedures and tests, and patients did not take their notes to the different outpatient areas.

3.3.2. Equipment

Equipment failure occurred in the case of wrong site central line insertion. The equipment lost power as it had not been adequately charged before use. The investigation report did not name this equipment or explain why it had not been adequately charged, but it did imply that failure of the device was a significant contributory factor.[1]

3.3.3. Time to undertake safety checks

Time available for safety checks was raised as an issue in six cases where these checks were either not done or not done properly.

[1] From reading the investigation report, this equipment was either that used for ultrasound guidance to insert the central line, or the transducer used to check central venous pressure.

In four cases ‘ambitious scheduling’ on theatre lists was cited as a cause; in another, patients had been added to an already full list and in two the surgeons’ schedules were an issue, such that they felt under pressure for time and failed to complete the necessary checks.

3.4. Team factors

3.4.1. Team communication failures during checks

In three cases staff being busy with other tasks contributed to communication failures.

- “The anaesthetic assistant had to leave theatre to get some drugs for the patient – drugs that should have been given on the ward prior to arrival in theatre – hence they were not present for the ‘time out’.”
- “Staff were distracted at knife to skin – the operating department practitioner (ODP) was in the anaesthetic room; another staff member was away for a break; the scrub practitioner was drawing up local anaesthetic, supported by the circulating staff member.”
- “During an extraction process the dental nurse was focused on monitoring the neighbouring tooth for damage to fillings so was unable to provide a second check that the dentist was on the correct tooth.”

In the case of the urological stent being placed on the wrong side, there was a failure of teamwork. The radiographer had not been present for the WHO checklist and the ‘time out’ and, when they joined the procedure, spoke up and questioned the side. Their questioning was heard by the nursing staff but no-one picked it up and supported the radiographer. As a result the radiographer did not pursue their questioning believing that the procedure must have changed.

In two cases the team were described as on autopilot.

- “The team were working using highly rehearsed actions (autopilot) in high volume, rapid turnover surgery. The surgical pauses and checks designed to enable ‘conscious control’ at critical points were conducted – but not at the optimal time.” (thumb operation)
- “This was an experienced theatre team who are familiar with each other and the checking process but there was a danger of familiarity leading to a loss of situational awareness (autopilot).” (finger surgery)

Other examples involving the whole team were:

- “The whole team were present but not engaged in the pre-procedure ‘time out’.”
- “There were five opportunities for the team to notice and correct the error through the surgical checks, reviewing the correspondence and imaging compared to the site marking but all failed.” (removal of a growth)

3.4.2. Written communication

Written communication was a contributory factor in eight cases. In one the documentation was described as “poor throughout”. In several cases the theatre list was wrong.

- “The waiting list referral did not specify the side and since this information was used for listing the procedure, no side was stated on the theatre list.” (growth removal)
- “Inconsistencies on the theatre list, numerous abbreviations used for laterality documented as R, Rt and Right.” (toe surgery)

In the case of the wrong operation, the patient, side and site were correctly identified during a surgical pause before the eye surgery. However, staff in the waiting list department had inadvertently put incorrect additional information on the operating list sheet. This error was transferred to the theatre whiteboard and then included in the surgeon’s calculations, leading to the wrong surgery being carried out.

In other cases there were discrepancies in the notes.

- “The name of the procedure on the WHO checklist was ‘excision vulvar lesion’ and not ‘incision and drainage of left labial cyst’ as written on the consent form.”
- “There was a discrepancy between the referral letter, the imaging and the site marking with regard to side for surgery and this was not picked up in theatre.”
- “The radiographer confirmed the patient’s details using a sticker from the notes which had the wrong side recorded on it. The request card did have the correct side recorded but was not referred to, so the error was not noticed.”

3.5. Individual (staff) factors

Individual (staff) factors were often difficult to distinguish from those relating to the whole team. Where they could be, these factors were usually due to the individual working in an environment whose custom and practice created ‘error traps’.

3.5.1. Cognitive factors

Unlike for the cases analysed in 2014, cognitive factors leading to a loss of situational awareness were identified in the current cases (suggesting local investigators are now more aware of such factors). Of note are the cases where ‘automaticity’ was cited as a factor: staff undertaking checks and checklists by rote and not listening to what was said; or surgeons described as operating in ‘automatic’ mode when working through a list of the same procedure.

- “Doctors are routinely allocated lists of the same procedure, carrying out 10 similar procedures one after the other. This repetition may have led to lack of concentration from over-familiarity with the task, resulting in human error.” (laser eye surgery)
- “The surgeon was on autopilot and was guided by the patient’s anatomy which indicated that the digit in question needed surgery. This was despite the WHO checklist being completed, including a ‘time out’ immediately prior to the incision.”
- “The surgeon did not recall hearing the radiographer question the site of the procedure, since they were completely focused on the procedure.” (urology)

In one case the surgeon was present for the safety checks but had been distracted just beforehand with a worry about how to sort out staffing for the weekend shifts. Their loss of concentration may have been the reason the wrong procedure was done despite the safety checklists being performed, including a ‘time out’ just before the incision.

3.5.2. Knowledge, skills and experience

Knowledge and skills featured in two cases. The endoscopy case is described above (see Section 3.2.4). In another the theatre staff had been trained in the organisation’s records management policy.

The surgeons for three cases were described as being at an early stage in their training, and their inexperience was considered a possible contributory factor.

However, it is noteworthy that in most of the cases analysed here, experienced consultants and nursing staff were also involved.

3.5.3. Not complying with policies and procedures for checking

In several cases policies and procedures were not fully complied with. The reasons for this varied but often were due to departmental custom and practice: for example, not marking all sites for pain injections in the pain management service.

Not doing checks with the patient at consent or at the time of surgery was a factor, in particular not cross-checking with the records but being led by the patient.

- “All the correspondence said ‘right’ but when asked, the patient exposed their left shoulder. The surgeon marked the site exposed by the patient without reference to the correspondence.” (the patient had growths on both sides)

Another cause of policies and procedures not being followed related to people not being present for some part of the checking process.

- “The surgeon was not present for the complete ‘time out’ process and did not look for the surgical mark on the limb when applying the tourniquet.”
- “The consultant anaesthetist was not present for the ‘sign in’. When they arrived in the anaesthetic room, the trainee and ODP who had completed the ‘sign in’ left to undertake other tasks. The consultant (contrary to the policy) did not undertake a check themselves prior to preparing the leg for the nerve block.”
- “The consultant left the operating table to look at the patient’s records following the ‘time out’, despite the images being on display. The surgical site was not rechecked or verbalised after the consultant returned and immediately prior to skin incision.”

Failing to undertake adequate checks led to a central line being inserted at the wrong site. In this case the patient deteriorated during the surgery and the anaesthetist was under pressure; the correct positioning of the guide wire was not adequately checked before insertion of the large bore multi-lumen CVP line.

3.6. Task factors

Task factors predominantly involved site marking. The relevant cases are considered together, including those where local policies and procedures were not followed.

3.6.1. Site marking

Site marking was an issue in nine cases. In one the surgical site mark was not close enough to the operation site and was not visible to the theatre staff. In another, the correspondence said ‘right’ but when the surgeon asked the patient to show the site, they exposed their left side. The surgeon marked the site exposed by the patient without referring to the medical records for site verification.

Hand and foot surgery

Site marking for hand and foot surgery featured in four cases. In one case of hand surgery there was concern about the site mark causing a tattoo if it were too close to the incision line. In two trusts the investigation found that hand and foot surgeons differed in how they marked the surgical site and most did not fulfil the site marking policy requirements. The following are examples.

- “There was an arrow and the initials of the surgery (TT for trigger thumb) marked on the hand; however, when the hand was positioned neither mark could be seen.”
- “Only the left dorsal aspect of the hand was marked so when the hand was turned over there was no clear mark on the correct digit.” (finger surgery)
- “The surgeon could not see the site marking because the fingers had curled further following the anaesthetic.”
- “Varied forms of site marking were used in toe surgery including a line and a circle.”

Pain management joint injections

In the case analysed here, the pain service’s custom and practice at the time of the incident was not to mark all injection sites before the procedure. In addition, a safe site surgery document had not been completed for pain procedure patients and each injection site did not have a separate ‘time out’.

Site marking for angiograms

The Royal College of Radiologists recommends that sites for angiograms should not be routinely marked, since access to the coronary arteries can be gained from both sides. A lack of site marking was considered a factor in one case analysed here, although the fact that the WHO safe surgery checklist was not used was considered a more important failing.

Surgery involving the ribs

Marking the exact rib is not considered possible due to the surgical method – the surgeon finds the rib internally using anatomical features. Use of anatomical markers and imaging during surgery was suggested as a way to improve accuracy in future.

Site marking for the removal of lesions

Locating a particular lesion on a patient's back from among many others was problematic in terms of site marking and verification using checklists. The surgical safety checklist was described in this case as insufficiently detailed to help prevent wrong site excision. There was no 'sign in', 'time out' or box to indicate that the site had been checked with the patient.

3.6.2. Failure to follow trust policies and procedures for safe site surgery

A failure to follow local policies and procedures for checking the site, the side and the patient, including failure to use the WHO checklist, featured in many of the cases. In one trust the overlap and redundancy in the ward 'sign out', the theatre 'sign in' and the 'time out' pre-procedure were a source of frustration. Because of this staff had adapted the process to make it less time-consuming, and in doing so inadvertently created conditions where important steps in the process were routinely adapted or ignored.

Other cases were as follows:

- "No documented team brief or debrief at the start and end of the procedure, and the whiteboard was not used to display the proposed procedure or provide a visual check or prompt for the team."
- "Lack of adherence to the formal system to verify the correct site of surgery in the preoperative setting."
- "A key step in the safety checklist for dental extraction was not carried out."

- “The WHO safety checklist was not undertaken as the radiologist did not consider an angiogram to be a surgical procedure.”

In two cases no safety checklists were used routinely. One involved foot surgery where no surgical site verification checklist was in place. Another involved laser eye surgery where no pre-procedure checklist was used.

Time out

In addition to problems created by some staff not being present at the ‘time out’, the timing of the ‘time out’ relative to when surgery was started was an issue.

- “The surgeon did not mark the incision line until after the ‘time out’ had been completed.” (finger)
- “The time-out occurred before skin preparation and draping – meaning that time passed before the incision was made.”
- “The ‘stop before you block’ time out did not happen immediately before the anaesthetic nerve block was administered.”

In the case involving hand surgery, the surgeon was using a new technique. Two different medications had to be administered separately – a local anaesthetic and a coagulant to stop bleeding. The surgeon administered both separately but did not use a ‘stop before you block’ process.

3.7. Patient factors

In nine cases the patient’s condition/anatomy was a factor. In seven, the surgeon was incorrectly guided by a similar condition elsewhere on the patient’s body: for example, operating on the ‘wrong’ side.

- “The patient had a growth on both shoulders.”
- “The patient had a lump on both sides.”
- “The patient had multiple lesions on their back.”
- “The surgeon was guided by the patient’s anatomy which indicated surgery was required on a different finger to that intended.”
- “The patient required multiple pain-relieving injections to multiple sites on both sides.”
- “The patient’s teeth were similar in size and both had similar large fillings.”

Poor communication with the patient when confirming and/or marking the site for surgery was a factor in four cases. These included one case where the patient did not speak up to say the side marked was the one on which they had previously had surgery, and another where the patient asked to be examined before surgery to confirm the site and the continued requirement for the surgery, but this was declined by the surgeon.

4. Wrong implant or prosthesis

Four cases were analysed of patients having the wrong implant inserted during surgery (Table 3). These included two wrong sized implants, one in ophthalmology where the wrong strength lens was inserted during cataract surgery and another in orthopaedics where the wrong size of hip joint component was used. Two cases involved the selection and use of a wrong sided bearing or plate – that is, use of one designed for the left side on the right.

Table 3: Summary of cases of wrong prosthesis/implant

Never Event	No	Specialty	Description
Wrong implant	21	Ophthalmology	The patient had the wrong strength lens inserted during cataract surgery
	22	Orthopaedics	The wrong sized hip implant was used – different from the size of the other components used
	23	Orthopaedics	The wrong sided bearing was inserted during knee replacement surgery
	24	Orthopaedics	A left-sided plate was inserted to repair a fracture in the right arm

4.1. Institutional context

No factors relating to national guidance or the economic and regulatory context were identified as causes.

4.2. Organisation and management factors

The safety culture was cited in two of the four cases. In one the checking processes were insufficiently embedded in routine clinical practice in the theatre. In the second case the nursing staff did not feel able to speak up and challenge the surgeon's behaviour when they were put under pressure to open the implant packaging to "get on and finish the list".

4.3. Work/environment

4.3.1. Design and labelling of packaging

Several different components are used in hip replacement surgery, all of which need to be size compatible. In the case analysed here, the design and labelling of the packaging for each individual component provided the latent conditions for error. The packaging for each component had a lot of text on it but that indicating left or right was in a very small typeface.

4.3.2. Storage of different sided components

The storage of right and left-handed components in the same drawer created the conditions for error in another case. Here, the left and right-handed plates, usually stored on the appropriate side of the drawer for their use, became mixed up. The person selecting the component simply picked from the usual side of the drawer, assuming this to be correct – a failure in the checking process that followed meant the error was not detected.

4.4. Team factors

The team factors mainly related to a failure in the team to follow trust guidelines and policies, and are covered in Section 4.6 on ‘task factors’.

In one case a failure to follow the checking procedures was compounded by the scrub practitioner being distracted at a critical point; when the wrong sized ‘impactor’ was handed to the surgeon. The size of the individual components used during the surgery had not been recorded on the whiteboard. As a result, when there was a staff change over, the person joining the team had no written record of the sizes of the components already used and relied solely on what the surgeon asked for.

In the case of the wrong knee implant, a medical representative from the prosthesis manufacturer joined the surgery once it was underway but after the safe surgery checklists and ‘sign in’ procedures had been done. The representative had been asked (appropriately) to assist the team in the use of the implant. However, the team deferred to the medical representative’s knowledge and allowed them to select the components. As a result the usual selection checks were not undertaken and the wrong implant was inserted.

4.5. Individual (staff) factors

Knowledge and skills were a factor in one case. The surgeon failed to recognise that their inability to satisfactorily fit or locate the replacement hip joint may have been because the sizes of the components used were in compatible. Had they spoken up about the failure to locate the joint, the sizing on the packaging could have been rechecked.

In one case the surgeon's attitude was such that the nursing staff did not feel able to speak up.

4.6. Task factors

In all cases there was a failure to follow local policies and procedures for selecting, checking and cross-checking implants before use.

A transcription error in the case of insertion of the wrong strength intraocular lens may have been picked up if the guidelines for checking had been followed. In this case poor handwriting led to a '2' being transcribed onto a different sheet as a '7'. The two sheets should have been compared and checked but in this case the box on the WHO surgical safety checklist confirming the correct sized lens was left empty.

Other cases included:

- "Failure to follow guidelines for selecting and for collecting a patient-specific intraocular lens."
- "Failure to follow correct checking process for implants – no cross-checking/double checking of the size of femoral head selected with the size of liner used."
- "No final compatibility check of all used implants prior to skin closure: contrary to trust policy."
- "Implant not checked correctly by the circulating nurse, scrub practitioner or surgeon."
- "Inadequate checking of the components – over reliance on the medical representative for these tasks which should have been the responsibility of the circulating nurse."

4.7. Patient factors

Patient factors did not arise in these cases.

5. Retained foreign objects

Fourteen cases of retained foreign objects were analysed (Table 4): three retained guide wires, three retained swabs and eight retained objects. Of the eight retained objects, three involved laparoscopic surgery.

Three of the cases involved women in labour. These highlighted issues specific to maternity services, including staff regularly undertaking procedures on their own; and the importance of accurate handover in stressful situations such as transferring women to theatre for emergency caesarean sections.

5.1. Institutional context

These factors relate to national guidance and the regulatory context. The institutional context was not considered to have contributed to any of the 14 incidents.

5.2. Organisation and management factors

The organisation and management factors included staff training; confusing and overlapping trust policies; staff shortages; and the safety culture in the organisation and in certain departments and teams.

5.2.1. Staff training

Training was cited as a factor in two cases. One case raised the question of how staff are kept up to date with equipment they infrequently use. The second case raised issues of when doctors receive simulation training in techniques involving the use of guide wires. In this case core trainees but not foundation trainees had received simulation training in the specific technique to insert a chest drain.

Table 4: Summary of cases of retained foreign objects

	No	Specialty	Type of procedure	What was retained
Guide wires	25	Cardiology	Femoral vein access for emergency infusion	The entire guide wire was flushed into the vein
	26	Orthopaedics	Foot surgery	Part of a small guide wire broke off and was retained
	27	Emergency medicine	Insertion of a chest drain	The entire guide wire was retained
Swabs	28	ENT	Sinus surgery	Two strips of ribbon gauze were retained in one nostril
	29	Obstetrics/ midwifery	Forceps delivery followed by repair in theatre	Vaginal swab retained
	30	Cardiac surgery	Mitral valve surgery	Small swab retained behind the heart – used to elevate the valve during surgery
Foreign objects	31	Orthopaedics	Repair of complex fracture	An unused guiding 'turret' remained attached to the plate
	32	Ophthalmology	Eyelid surgery	A corneal shield was left under the eyelid, having been inserted to protect the surface of the eye during surgery
	33	Plastic surgery	Abdominal surgery	A 4-cm plastic drain cap entered the wound cavity and was retained
	34	Midwifery	Perineal repair	Needle and suture material was left in the wound site
	35	Obstetrics/ midwifery	Emergency caesarean section	A fetal scalp electrode was retained in the vagina, having been attached to the baby's head during labour
	36	Gynaecology	Laparoscopic abdominal hysterectomy	The broken end of the forceps used to retract the bowel was retained
	37	Surgery	Laparoscopic emergency appendicectomy converted to open	A laparoscopic retrieval bag was retained following conversion to open surgery
	38	Surgery	Laparoscopic surgery for bleeding duodenal ulcer	A stainless steel spring from the suction device was retained

5.2.2. Confusing trust polices

Confusing trust polices were found in two cases. In one overlapping trust policies were being used ‘subject to various amendments and changes’, although the investigation team reported that despite this, the requirement to do the WHO checklist was unambiguous. In the other case, staff worked across the trust’s two hospitals but each site had different clinical policies for managing pneumothorax.

Policies relating to specific tasks, such as counting, are covered in Section 3.1.6.

5.2.3. Staff shortages

Staff shortages were an issue in one case: the midwife was the only permanent member of staff on duty. The trust policy for calling in additional help was not followed in this case; those required to implement it thought it added to the problems covering shifts later in the week.

5.2.4. Safety culture

Safety culture was highlighted as a factor in three cases.

- “Some theatre nursing staff found it difficult to speak up, for example to ask for a surgical pause.”
- “A standardised approach to counting was not embedded in practice across the maternity services.”
- “There was toleration of poor adherence to expected practice regarding documentation in obstetric theatres.”

5.3. Work/environment factors

Environment factors mainly related to the design and use of instruments and equipment.

5.3.1. Equipment functioning/breakage

Three cases involved equipment breaking or coming apart.

- “The forceps snapped at the hinge joint of the grasper. They were three years old and were expected to last five to eight years, but had been damaged.”

- “The suction device had been assembled incorrectly and during the surgery the device came apart.”
- “The guide wire fractured and the end came off.”

5.3.2. Usage outside of manufacturer’s guidance

In one case the equipment was described as possibly having been used outside the manufacturer’s guidance in terms of the force applied to it.

5.3.3. Equipment design

The design and use of specific equipment featured in three cases.

- “The surgeon used a bag with no 'endocatch'. This type of bag is fully inserted and has no external 'tail' to indicate its use. These bags are much stronger than those with an endocatch and less likely to break, reducing the risk of the contents being spilled.”
- “The equipment was not designed to force the operator to remove the guide wire before proceeding.”
- “There was no clear way of telling that the end of the guide wire had come off.”

Problems with the layout of the theatre whiteboard was mentioned as a contributory factor in one case where there was “no specific area on the whiteboard to record swabs in situ on arrival in theatre”. However, in four cases the redesign of theatre whiteboards was included as a solution to counting failures: for example, by including preprinted columns and specific sections for items to be included in future counts.

5.3.4. Work environment

In two cases the work environment was a factor.

- “The case was moved from a specialty theatre into main theatres where staff were unfamiliar with the procedure, the equipment and with each other.”
- “The locks on the maternity ward doors meant that midwives had to leave their patients to answer the door, causing interruptions during procedures.”

In the second case, the midwife was doing several tasks at once and could not focus completely on the perineal repair. She had to leave the room twice during the procedure, once to answer the door, which interrupted the count.

5.4. Team factors

Communication failure was a major factor in the cases analysed, both written and verbal.

5.4.1. Verbal communication

Verbal communication was a factor in six cases.

- “No communication to the team from the surgeon that the corneal shield had been inserted so it was not recorded anywhere.”
- “The surgeon assumed the retrieval bag would have been included on the white board for the count hence there was no verbal instruction to record this.”
- “The surgeon did not notify the scrub practitioner that the instrument had come apart and that they had put it back together so there was no opportunity for the team to consider if all parts had been retrieved.”
- “Poor communication between the midwife and surgeon, prior to surgery commencing. The surgeon was described as focused on the urgent requirement to deliver the baby.”
- “There were interruptions throughout by another member of the surgical team (the consultant) coming in to check everything was OK. This could have distracted the trainee undertaking the surgery and/or the supervising surgeon.”
- “There was a newly qualified nurse scrubbed for experience who was passing things between the surgeon and scrub practitioner and this interrupted the chain of communication.”

5.4.2. Written communication/documentation

Written communication was a factor in six cases.

- “The in-situ swab was confirmed in theatre by the surgeon and scrub practitioner but there was a collective failure to ensure this was recorded on the theatre white board at the start of the procedure.”

- “The fetal scalp electrode cable had been cut at some point but this was not documented nor was it communicated to the operating team.”
- “Swab type (gauze) and the number of pieces cut and used had to be recorded on the whiteboard but not side or site.”
- “The swab was correctly documented at handover to the theatre team, but not recorded on the theatre white board at the start of the procedure.”
- “The final retained swab was not recorded in the notes.”

The shortage of staff on the maternity unit that led to a retained foreign object was also in part down to communication failures: poor handover between the day and night shift managers, and poor communication between the midwives in charge of the different wards/units in the hospital meant one midwife struggled on under the impression that nothing more could be done.

5.4.3. Staff changes during procedures

Staff changes were an issue in two cases. Here the staff assisting in the final count had neither been present at the start of the procedure nor involved in the initial count. This was against standard operating procedures. They assisted for speed and convenience in terms of completing the procedure, since those involved in the first count were no longer available to help.

5.5. Individual (staff) factors

5.5.1. Knowledge, competence and confidence

Lack of knowledge was a factor in three cases. In one, the scrub practitioner lacked knowledge of the surgery being performed and had not worked with the surgeon before; in another the scrub practitioner lacked knowledge about the type of equipment being used; and in another the trainee had neither used the equipment before nor been trained in its use, and the more senior doctor had been trained some years before.

In two cases, competence was assumed to be greater than it was when workload was high and the supervisor had to be called away, leaving the junior member of staff to complete a task alone.

5.5.2. Cognitive factors

Cognitive factors contributed to an object being retained in five cases. These included distractions and mental stress leading to a loss of situational awareness.

- “A guide wire was flushed into the femoral vein – the patient had deteriorated and needed a life-saving infusion.”
- “The surgeon was described as focused on the urgent requirement to deliver the baby.”
- “The decision to convert to an open procedure was taken at a critical point and this was considered to have distracted the team, leading to a loss of situational awareness in relation to the insertion of a retrieval bag.”
- “The inaccurate intra-operative swab count was thought to have been caused by a distraction.”

5.5.3. Failing to comply with policies and procedures

Failing to comply with policies and procedures featured in five cases, four relating to the count (see Section 5.6), and one to the record-keeping policy not being followed during a caesarean section, attributed to toleration of poor adherence to expected practice in the department (see Section 5.2.4). Failure to check the completeness of equipment following a procedure was a factor in three cases (see Section 5.6).

5.6. Task factors

Task factors predominantly related to there being inadequate policies, procedures and standards for certain tasks. For example, in the case of a perineal repair by a midwife in the birthing room, the policy for searching for and escalating the case of a missing item was unclear. The midwife searched for vicinity for the items, convinced herself that she had disposed of things in the sharps bin and moved on to other work.

5.6.1. Policies for what is and what is not counted

Policies for what is and what is not counted during a procedure were cited as a factor in six cases:

- turrets not included in count policy
- consumables not included in count policy
- count policy opaque on disposable covers (two cases)

- laparoscopic retrieval bags not included in count policy
- small guide wires not included in count policy.

Dealing with covers for drains and other surgical items, such as trocars, was highlighted in two cases. Issues raised are how covers and caps are counted and how items with covers and caps are passed across the surgical field: in one case a cap fell unnoticed into the wound cavity.

- “There were no standards for how waste items are returned across the surgical field, such as trocar sheaths, cut ends of drains, drain covers, k-wires, etc.”
- “Drain covers – and covers for other things such as trocars – were not included in the count policy.”

5.6.2. Policies and procedures for checking equipment integrity

Whether and how surgical equipment should be checked for integrity after a procedure was raised by three cases. In one the end of a pair of forceps broke off but this was not evident until the forceps were opened in the central sterile supplies department (CSSD). In another a suction device came apart during a procedure and was incorrectly reassembled, with a spring left inside the patient.

- “There was no policy or procedure relating to checking the integrity of equipment at the end of surgical cases (eg forceps).”
- “Instruments that are constructed prior to surgery were not required to be dismantled following use to check they were intact.”
- “Guide wires were not measured on retrieval to confirm they had not broken.”

5.6.3. Need for visual cues

In addition to items missing from the count policy, visual cues were absent in two cases: one where ribbon gauze was placed fully into a nostril without leaving a small tail showing, and another where the laparoscopic retrieval bag was fully inserted with no external sign of use.

Efforts to prevent the retention of guide wires focused on introducing visual cues on trolleys to prompt their replacement on the trolley and measurement of their length. To prevent retention of entire guide wires, switching to equipment that forces the

operator to remove the guide wire before proceeding was considered important, although cost is an issue here.

- “No policy or standard practice to document that an introducing guide wire has been removed and is on the trolley at the end of the procedure.”
- “No chest drain checklist.”

In three cases the retained object was missed when images were reviewed.

- “The drain was clear on the ultrasound scan but not the cover since it looked like part of the drain.”
- “An image intensifier was used to take serial X-rays during the procedure to ensure the removal of all bone fragments. The turret was detectable on these images, but the surgeons were only looking for bone fragments.”
- “The retained guide wire was clear on the X-ray but the doctors did not see it since they were looking for problems in the lungs.”

5.6.4. Failure to follow trust policies and procedures for safe surgery

Not undertaking or not completing the WHO surgical safety checklist and ‘sign out’ procedures were cited as factors in all three maternity cases. In one the checklist was not completed before the induction of anaesthesia; in another the checklist was only partially completed, with questions relating to the retained object being left unanswered; and in another the sign-out procedure was not completed.

In three cases the count policy was not followed, in two because of who was involved in the final count.

- “The final count involved a nurse who was unfamiliar with the procedure and who had not been involved in the initial count and who had not been in the theatre during the procedure.”
- “The nurse who assisted with the first count was busy moving equipment and did not participate in the final count.”
- “The count was undertaken by the circulating nurse who had not been present for the entire procedure.”

5.7. Patient factors

Six cases involved patient factors, including the need to reassure the patient during the surgery, the complexity of the procedure, the patient's anatomy and the development of an emergency situation (three cases).

- "The patient had a complex fracture which required a plate to be used with more screw holes and turrets than the usual one used for this type of procedure."
- "The patient was anxious about the surgery and the scrub practitioner spent time at the start of the procedure offering reassurance, this was a distraction for the scrub practitioner."
- "Labour had commenced and the baby's head was visible and a fetal scalp electrode was attached; the mother's condition then deteriorated requiring an emergency caesarean section."
- "The patient had difficult anatomy requiring use of a retractor with some force needing to be applied."
- "The patient was very unwell with peritonitis, requiring a very complex laparoscopic appendicectomy which had to be converted to open surgery."
- The collapse of the patient required an emergency life-saving infusion; hence an emergency femoral vein cannulation was undertaken in a stressful situation.

6. Comparison with the cases analysed in 2014

There was a noticeable improvement in the quality of the investigation reports compared to those reviewed in 2012 and 2014, with more contributing factors described in the 2016/17 reports. However, there was little evidence in the most recent investigation reports that organisations have fully considered any governance issues associated with the implementation of relevant national guidance.

Note: in 2014 no cases of wrong implant/prosthesis were analysed, only cases of wrong site and retained foreign objects.

6.1. What remains the same in the 2016/17 reports?

The lack of a safety culture and staff not feeling able to speak up when they have concerns remain issues (see Section 8 for further information).

Interruptions and distractions persist and cause a loss of situational awareness. In some services the prevailing custom and practice continues not to embed safety checks in routine practice.

The purpose of the pre-procedure ‘time out’ continues not to be well understood, with this final check still often not being done in a way that prompts a final confirmatory check of the procedure and the site or side.

Specific to wrong site surgery, time pressures continue to create conditions where staff take short cuts, leading to ‘error traps’.

The issues in maternity and obstetric care remained similar in the 2016/17 reports. They include failures to follow trust policies and procedures; a lack of communication about retained items; and issues relating to staff undertaking procedures such as perineal repairs alone.

The issues surrounding retained guide wires were also similar: doctors not trained in the techniques; no systems to check if guide wires have broken off; and equipment designs that allow guide wires to disappear inside the patient, not designs that ‘force’ removal before the operator can proceed.

The need to check the integrity of equipment after use and before closure remains an issue, particularly for equipment that can come apart.

Poor communication remained an issue in the 2016/17 reports, specifically doctors not telling others about the equipment used or intentionally retained items.

Finally, the need to improve the design of theatre whiteboards to help with the count was an even greater issue in the 2016/17 reports.

6.2. What has changed?

In the 2016/17 reports the duty of candour was evident, with all patients informed about the incident and involved in some way in the investigation, and the report shared with them.

Of note, the 2016/17 reports raised issues relating to human factors and situational awareness, such as staff working on autopilot. Less blame was attached to individuals for not recognising issues and there was more awareness of human factors.

The 2014 analysis recognised inadequate site marking as a root cause of surgical Never Events; with no local policies and procedures for how sites should be marked. By 2016/17 such policies and procedures were in place but reports indicate other root causes have emerged. For example, in several cases the site mark was not visible at the time of incision, such as when the back of the hand was marked but the incision was made with the palm of the hand facing upwards.

In 2014 the WHO checklist was not used routinely and often surgeons were not present for this. In the 2016/17 cases, the WHO checklist was used routinely but often poorly. Safety checks such as ‘sign in’ and ‘time out’ were undertaken more often in the 2016/17 reports, but all staff were often not present for all checks.

There were no cases of the surgeon leaving before the count had been completed in the 2016/17 reports and no cases of staff not knowing what the count policy was. Fewer cases attributed cause to the count policy not being followed.

The 2016/17 reports call for new items to be included in the count policy in future including:

- disposable covers

- items such as trocars and k-wires
- turrets
- retrieval bags
- consumables such as corneal shields
- the length of guide wires.

More cases of interruptions and distractions were noted in the 2016/17 reports.

The need for visual equipment cues to act as reminders was more evident in this series of reports: for example, the ‘tails’ of inserted items to be left showing.

7. Actions taken to prevent recurrence

All case reports included an action plan drawn from the investigation and analysis. These varied in length from half a page to several pages. Evidence of implementation was usually given in the form of an audit but no reports examined whether action had improved safety.

> "Formulating corrective actions is more difficult than finding problems, and follow-up on outcomes is rare. A sign of the incomplete adoption of recommendations is that despite having recently completed an RCA [root cause analysis] for a specific incident, hospitals commonly experience repeat events, which is a reminder of words attributed to Einstein: Insanity is doing the same thing and expecting a different result." [9]

This section begins with the actions commonly taken in response to surgical Never Events and then looks at the specific issues for each type of surgical Never Event.

7.1. Actions common across the 38 cases

7.1.1. Safety culture

Junior staff continue to find it difficult to raise concerns and bring them to the surgeon's attention. Actions often involved speaking to individuals and teams of nurses, not considering if the culture in the operating environment hinders staff from feeling able to speak up. None of the action plans involved working with surgeons or other senior operating department staff to encourage speaking up and listening.

7.1.2. Individual learning

Inappropriate staff attitudes were noted to be addressed by line managers.

Individual reflection was encouraged and undertaken in some cases: in some this involved further supervised practice. In one case that did not include reflective practice by the operator involved in the trust's action plan, the clinical commissioning group required confirmation of this.

With only the investigation reports and action plans to go on it is impossible to say what is meant by ‘reflective practice’ or whether it was appropriate. However, this phrase does appear in action plans where a trust wants to convey the message to the family that the people involved have learnt from what happened, despite it having connotations of individual error rather than systems failure.

7.1.3. Training/induction

Training and induction featured in the action plans of 22 cases. Several organisations had programmes of human factors training that were being rolled out and these were amended to incorporate learning from the Never Event (no details were provided).

Other trusts had set up specific training for theatre staff on checking and on the health records policies. In one trust induction was amended to cover concerns about having a mix of paper and electronic records and the risk this posed. In another, training and induction for agency nursing staff were amended to include the checking processes and the need to check different sources of information to make sure side, site and size all match.

To address wrong implant/prosthesis, training was instigated in the use of certain equipment such as surgical plates and laparoscopic retrieval bags, largely to increase familiarity with components.

One trust introduced training for all doctors who insert chest drains. Arrangements were made in another for new doctors to have induction in the dangers of using equipment involving guide wires (especially with the Seldinger technique).

7.1.4. Raising awareness

For all cases learning was shared. This ranged from team discussions to emails and presentations at clinical governance meetings.

One trust issued an internal patient safety alert warning about retained laparoscopic retrieval bags, another launched a new ‘pause for the gauze’ campaign and another began a poster campaign warning about the risk of retained guide wires.

The usual ‘inform all relevant staff’ also featured frequently.

7.1.5. Audit

Many organisations audited the implementation of actions, particularly safety checks in theatres. However, it was not clear whether these audits would tell the trust whether the actions had improved patient safety.

7.1.6. NatSSIPs/LocSSIPs/new policies and procedures

One trust introduced new policies and procedures for pooled operating lists to ensure all patients had treatment plans. Another trust had an action to “develop and implement standard operating procedures for stop before you block’’.

Another trust was considering the development of a local guideline in orthopaedics for ‘wide awake local anaesthesia no tourniquet’ (WALANT) procedures to preserve the usefulness, applicability and relevance of the surgical checking procedures in these cases.

LocSSIPs were mentioned as follows:

- “LocSSIPs to be developed for pain management injections to include site marking and whether a separate ‘time out’ should take place before each injection.”
- “LocSSIP to be developed for invasive anaesthetic nerve blocks.”
- “Introduction of LocSSIPs for maternity invasive procedures including instrumental delivery in the room.”
- “Safety count section of LocSSIP policy expanded to include new items.”
- “Insertion of central lines to be included in new LocSSIPs.”

7.2. Actions to prevent wrong site surgery

Actions to reduce recurrence mainly focused on safety checks/’sign in’ and ‘time out’, and site marking.

7.2.1. Stop before you block

One trust relaunched the ‘stop before you block’ procedure across all theatres. Another introduced a two-person check before the administration of anaesthetic.

7.2.2. Site marking

Actions relating to site marking were recommended in seven cases, including work to resolve the variation in practice for marking fingers and thumbs, and consultation on the feasibility of a standard method for marking toes. In addition, one organisation was developing standard operating procedures (SOPs) for the optimal way to mark closed injuries.

In dermatology, the feasibility of using new photographic software in the clinic (Fotoware) was being investigated by one trust; this allows images to be recorded and made available to the surgeon at the time of the procedure. The trust was also looking into the feasibility of using a patient's smart phone to take images of naevi to be removed.

For patients having multiple joint injections for pain management, new procedures were introduced such that all sites (with a left and right side) would be marked.

For rib surgery, the use of imaging was being investigated to enhance intraoperative accuracy.

7.2.3. Safety checks

Many of the cases resulted in changes to the safety checks, 'sign in' and 'time out', for example:

- "new agreed checklist introduced for dental extraction"
- "if radiographers/radiologists are to join a procedure to assist, they must be there for the WHO checklist"
- "revised checklist to include the name of the operation and the site (written on)"
- "the WHO checklist to be amended to include date and signature".

One trust introduced the requirement for all radiologists to complete the WHO safety checklist when undertaking interventional procedures.

The action in the trust with mixed paper and electronic records was to 'ensure' preoperative checks included clinical details taken from the core patient database and not just hand-held paper records. There was clearly no easy solution during the lengthy transition to full electronic medical records, and the trust also instituted

training at induction for new staff to make them aware of the dangers inherent in the trust from using both electronic and paper records.

A new unified MDT form was introduced in cancer services as well as a pause after each case to confirm the accuracy of the information recorded, to reduce reliance on one person only.

7.2.4. Time out/immediate preoperative checks

The purpose of the immediate preoperative checks in some of the cases appeared not to be fully appreciated; they were done because they had to be, not for conscious control and focus at a crucial point in the surgical process.

It was not evident that the actions taken by trusts would address this issue. For example, one trust introduced an additional pause point directly before skin incision that involved the scrub practitioner and surgeon confirming site, side and procedure were as documented on the consent form. Another introduced the requirement to check the operating list at the 'time out', but in other trusts the operating list was inaccurate which contributed to the error.

Other actions included:

- "consideration of a loud verbal declaration of side and procedure before commencing and confirmation with imaging"
- "WHO checklist time-out change from the question: has the incision line been marked correctly? to Has the correct surgical site been marked accurately?"
- "preoperative team verification introduced to reduce reliance on the surgeon alone"
- "scrub team to write surgical site on the scrub trolley list and confirm the verbal instruction and act as a visual reminder when the incision line is drawn".

There were also very general actions and it was unclear how they were to be implemented, such as "time out must be performed immediately before knife to skin".

7.2.5. Consent

Four cases involved actions around consent. In one surgery went ahead at a site different from that indicated on the consent form and the surgeons were asked to attend update training on the consent process. Others included:

- “known risk of the wrong rib being removed to be discussed when taking consent”
- “consent form to include site and side of surgery”.

7.2.6. Documentation/theatre lists

In one case a reminder was sent that only recognised abbreviations could be used in patient documentation and on theatre lists (orthopaedics).

The case of mixed paper and electronic records was clearly hard to resolve, and letters and emails were sent to remind surgeons to check everything, including the imaging and pathology forms, and the electronic and paper records.

Three cases involved issues with the theatre list. In one the throughput and type of cases were reviewed to ensure sufficient time was available for safety checks and safe procedures. In another the theatre lists were reviewed to see if unnecessary information could be removed to provide greater focus on the planned procedure and associated laterality. Another introduced the requirement to use the waiting list booking form only to list a procedure – this included laterality, etc.

7.3. Actions specific to preventing wrong implants/prosthesis

The actions specific to preventing wrong implants and prosthesis included changes in how items were stored and selected, and in the way checks were done pre-implantation. The following sections highlight these actions.

7.3.1. Implants

- “Storing left and right-handed implants in separate locations that are clearly marked.”
- “Reducing the volume and variety of unfamiliar instrumentation and implants available. This was done by setting up a weekly meeting specifically to

review and rationalise implants and theatre equipment loaned to the trust by medical representatives."

7.3.2. Safety checks/sign in/time out

- "Addition to the 'sign in' checklist, a check between the ward staff and the theatre staff that the IOL selection sheet and the biometry calculation page match."
- "Introduction of a way to call all staff to attention when the 'time out' is about to be performed."
- "Confirming the role of the anaesthetist during the 'sign in' and 'time out' checks, so they join in and help with confirmation of size, site, etc."
- "Introduction of new procedure such that the skin preparation material is not handed to the surgeon until after the 'time out' has been completed."

7.3.3. Compatibility checks

- "To keep a record of size compatibility for hip replacements, a laminated sheet was introduced to record the size of each component handed to the surgeon and used."
- "The size of each component is now recorded on the whiteboard. In this trust a SOP was introduced for implant checking."
- "Real-time data entry of each implant component was being researched, to scan the bar codes and link this directly with the National Joint Registry for the patient. At present it was noted that bar code reading is not possible for this."
- "In one trust, amendments have been made to their checking policy to make it explicit that medical company representatives must not be involved in checking size or site."

7.3.4. Accrediting medical representatives

The trust where, guided by a medical representative, a component was wrongly selected had an action to join a trained medical representatives programme. Under these programmes company representatives must sign up and be trained/regulated or they will not be granted access to the trust and its theatres. The programme generates a register so that theatres can check if a representative is on it. Representatives must wear 'who are you' identity badges.

7.4. Actions specific to preventing retained foreign objects

7.4.1. Equipment

Where equipment had broken off and parts had been unintentionally retained inside the patient, actions taken by trusts involved:

- removing similar items from use and checking them
- looking for alternative equipment that would be more robust, such as single-use alternatives
- identifying which pieces should have extra checks post procedure and what these checks should involve.

Trusts were looking for tried and tested solutions and were doing this by emailing and phoning people in neighbouring organisations.

7.4.2. Count policy

In several cases items were added to the count policy, including:

- disposable covers
- items such as trocars and k-wires
- turrets
- retrieval bags
- consumables such as corneal shields
- length of guide wires.

7.4.3. Whiteboards

The use of the whiteboard in the count is important, particularly for recording items such as consumables, lengths and site of gauze used (ENT). A new area for recording ‘swabs in situ from room’ is needed.

7.4.4. Safety checks, briefings and handovers

One trust introduced a checklist for chest drain insertions.

In maternity services, communication during handover from the labour room to theatres for an emergency caesarean section remains problematic.

In ophthalmology, checking a patient's eye before discharge was introduced as a requirement, to ensure corneal shields were removed.

7.4.5. Supervision

Supervision of junior doctors was increased in those trusts where guide wires had been retained.

The supernumerary status of student midwives and their supervision during busy periods were addressed in the trust where a suture needle was retained.

7.4.6. Staffing

Staffing featured in two cases. For the one in ENT, this revolved around the need to have teams for each specialty and for waiting list cases. For the maternity case where a suture needle was retained, the staffing of maternity services during busy periods was reviewed.

7.4.7. Documentation

Documentation was changed in three cases:

- "formal documentation in the clinical notes that the Seldinger introducing guide wire has been removed and is on the trolley at the end of the procedure"
- "amendment to the perioperative care plan to include 'swabs in situ from the room'"
- "a complete review of maternity documentation with the introduction of the communication tool called SBAR (situation, background, assessment, recommendation)".

7.4.8. Imaging

The trust at which a guide wire was retained following the insertion of a chest drain made it a requirement for a radiographer to review all chest X-rays taken after a guide wire was retained. This was to give an independent view of whether or not the guide wire was visible.

8. Challenges for prevention in future

This section draws together the main challenges identified in the cases, to highlight the further work needed to prevent surgical Never Events in future.

Perhaps the key challenge is for organisations to find out if their solutions have indeed reduced the identified risk.

> "The RCA process is designed to answer three basic questions: what happened, why did it happen, and what can be done to prevent it from happening again? What is missing in medicine is a fourth question: has the risk of recurrence actually been reduced? The fact that it generally is not known whether risk has been reduced is causing concern that some of the considerable resources and efforts expended on RCA are being wasted." (Wu et al 2008 [9])

As set out in the introduction to this report, NHS Improvement considers Never Events to be 'red flags' – indicators of potential weaknesses in how an organisation manages fundamental safety processes. Their investigation should therefore examine the organisation's approach to implementing national guidance [1]. There was little evidence in the reviewed investigation reports that the organisations had fully considered any governance issues associated with the implementation of relevant national guidance: this is an area for further work.

8.1. Sharing solutions

In many cases the action plans involved staff getting in touch with other trusts to find out what they were doing differently and, rather on the off chance, perhaps find something that works for their trust. There is clearly a need for more effective ways of sharing problems and solutions across trusts: for example, when issues relating to medical devices are identified, what alternatives do other trusts use and what is included in their count policies, etc. Also, sharing lessons from issuing internal alerts or starting campaigns such as 'pause for the gauze' would help trusts determine whether similar activities locally would work for them.

8.2. Safety culture and speaking up

The cases described here highlight the continued challenge of creating a receptive team climate during interventional procedures, where questioning related to safety is welcomed, listened to and acted on, and where all staff present are encouraged to speak up when they have concerns. Both experienced and less experienced staff described how they did not feel able to speak up despite having concerns.

> "A critical characteristic of effective teams in any setting is when each member is willing to speak up to share thoughts and ideas to improve processes. In spite of attempts by healthcare systems to encourage employees to speak up, employee silence remains a common cause of communication breakdowns, contributing to errors and suboptimal care delivery. Nurses in particular have reported low confidence in their communication abilities, and cite the belief that speaking up will not make a difference." (Morrow et al 2016 [10])

Research has found that all grades and groups of staff weigh up the risks and benefits of speaking up. Often, not speaking up relates to the complex socialisation process in healthcare; authority gradients; and past experiences of disruptive and rude behaviour [11]. Caring leaders who engage in specific behaviours that foster speaking up are needed, with peer support and an organisational commitment to safe care.

'Speaking up' is not just about those supporting the surgeon raising their concerns; it extends to the surgeon feeling able to ask for advice, taking a 'time out' when something seems wrong – a pause for thought – and if necessary asking for things to be checked, such as the size of components used.

8.3. Safety checks and handover

Much work has been done in the last 10 years to develop safety checklists and to improve handover. However, concern remains about how these checklists have been implemented and how they are used. In the cases reviewed safety checks were described as being performed by rote, not as a stop point for situational awareness. In some cases local policies and procedures were not followed for selecting, checking and cross-checking implants before their use, with a variety of reasons for this. In addition, it was often difficult to ensure the right people were present for each safety check (sign in, time out, first and last count, etc).

The challenge is to understand better why safety checks are not being used in certain circumstances; or not being used as intended; or not being used by the intended team members. This may be due to local working arrangements or checklist fatigue, or because use of the checklists has been mandated but those using them do not fully understand their purpose and importance.

> "I fear that regulating (checklists) may actually anchor you into bad practices." Peter Prononvost (Rice 2014 [12])

Several cases revolved around the surgeon being guided by the patient's anatomy and not checking the medical records: in hand surgery some patients had the same condition on more than one finger; and in lymph node and shoulder surgery patients had a lump on both sides.

Where someone is asked to join a procedure to assist after the operation has started and all safety checks have been completed – for example, a radiographer – the challenge is to ensure they are briefed on the procedure and the site or side before they begin their work.

Also, the following issues arose from these cases:

- "How to increase the reliability of handover regarding retained objects, in critical situations, in particular from the labour suite to theatre."
- "How to enhance safety consciousness and reduce risk in situations where teams are not familiar with each other or with the theatre they are working in, and are not familiar with the equipment or the procedure."

8.4. Resolving time pressures

In several cases time pressures led to safety checks not being done correctly or being done too quickly. The challenge is to maintain throughput but also to do safety checks in a timely and meaningful way.

In several cases different staff were involved in the first and final counts, often for speed and convenience. The challenge remains to enable an accurate count under time pressures.

8.5. Interruptions and distractions

> "Humans frequently engage in repetitive tasks that require minimal attention. These highly practiced and seemingly automatic behaviours are particularly susceptible to attention or memory failures, especially if one is interrupted or distracted during the process." (Diller et al 2014 [13])

Interruptions and distractions were described as leading to a loss of situational awareness. Reducing these and recognising how they impact on concentration remains a challenge, despite what we know from research and from other industries – for example, the 'sterile cockpit' in aviation [7].

8.6. Fixation and focus

In several of the cases a deterioration in the patient's condition that required particular concentration and focus from the surgeon was described in the reports as leading to a loss of situational awareness. Research has shown that unexpected intraoperative factors are one of the strongest risk factors for retained foreign objects [14].

8.7. Training in human factors

Several trusts had already introduced human factors training and reported having developed this to include the learning from Never Events. It would be beneficial to find out more from these trusts about this training – its content and its impact – and to share this learning across the NHS.

8.8. Site marking

More work is needed nationally to guide trusts on the best way to mark surgical sites in the following areas: hand and foot surgery; side-specific angiograms; dermatology; and pain injections.

8.9. Counting

Many trusts have changed their count policies to include additional items following Never Events, but these additions and the reasons for them are not shared across the NHS. It would be helpful to find out what trusts now include in their count policies and why, and for this information to be disseminated across trusts.

Many trusts have redesigned their white boards to improve the accuracy of counting. Often specialty-specific designs are used, to include items only used in that theatre. Consideration should be given to sharing these designs and learning from what works.

8.10. Pooled operating lists

The cases highlight the need for each patient on a pooled list (or a list where the surgeon is unlikely to have seen the patient beforehand in the outpatient setting) to have a treatment plan completed in advance by the listing surgeon. This should include the procedure, the site, the side and the direction of surgery (eg divergent or convergent for ocular surgery). It should also include any necessary calculations, such as the degree of muscle realignment in surgery to correct a squint.

8.11. Mixed paper and electronic records

Trusts operating with a mix of paper and electronic records urgently need to consider the patient safety risks inherent in this arrangement. Safety assessments and risk reduction strategies are needed, as well as drawing the attention of current and new staff to the need to look at all the trust's patient information systems.

8.12. Reducing transcription errors

Reducing transcription errors remains a challenge. Information is regularly copied by hand from one record to another. This may be from the electronic or paper patient record onto a sticker for a test; from an intraocular lens calculation sheet to the lens selection sheet; from the notes to an imaging request card; or from the notes to the operating list schedule and/or whiteboard. Also, where the electronic patient record and theatre IT system or radiology IT system are not connected, information has to be transferred by hand. Often the procedure on the consent form is written in by hand, copied from the patient record. A recent study of wrong intraocular lens (IOL) events in the UK found one in seven to have involved a transcription error [15].

One case in particular highlighted the error prone conditions of transcription: one error went on to be copied onto all other records including the theatre list.

Consideration should be given to writing numbers in words where these are critical to patient outcome and are likely to be transcribed. The NatSSIPs already include the requirement not to use abbreviations, especially for left and right.

8.13. Trust policies and guidelines

Trust operational policies and clinical guidelines featured in several cases: they were not up to date or were unclear or differed between the trust's sites. These differences only came to light when there was a Never Event. Trusts should have systems and procedures for regular review and updating of all policies, procedures and guidelines, including removal of anything outdated and simplification and reduction of those remaining.

8.14. Equipment with covers/caps and that come apart

As a result of incidents involving such equipment, trusts have drawn up lists of the theatre equipment to be checked for integrity and when. Some have also removed certain items from use, replacing them with more robust kit. Consideration should be given to ways of sharing the actions taken by these trusts so that others can implement similar checks.

The question of how to handle covers and caps that are passed across the surgical field was raised by several cases.

8.15. Design

There is a challenge for the manufacturers of medical implants, components and devices that are for one side only, to include bold visual cues on the packaging and ideally the device too that, for example, identify the side the device is for. Consideration should be given across the medical device/implant industry to a common size of indication and colour code for left and right labelling and packaging.

There is a similar design challenge for the prevention of retained foreign objects. For example, how to include visual cues on equipment and supplies that are wholly inserted into the surgical field. Can all laparoscopic retrieval bags have an external tail? Is there a design solution to indicating when a guide wire has broken? What are the best ways to ensure that a guide wire is removed before a drain or line is inserted?

8.16. Storage

Hospitals should examine how they store 'sided' implants. These need to be separated into clearly labelled and distinguishable containers for left and right.

8.17. Size and side compatible components

Where multiple components are used that need to be compatible in size and side, there must be systems and procedures to check this compatibility before each component is used (NatSSIPs 4.10.1 and 4.10.2). This remains a challenge and solutions have included asking staff to say out loud the size and side when handing the component to the surgeon and for the surgeon to say these on receipt; and recording the size and side of each component used on the white board with a final check of compatibility before skin closure.

The cases examined here represent a small fraction of the total number of successful operations to insert implants and prostheses. It is vital to learn from successful cases: for example, how size compatibility is checked, and for this learning to be shared.

8.18. Reducing choice of implants and components

Lack of familiarity with equipment and consumables was the cause in some cases. Reducing the number of different types of equipment and consumables available would reduce the likelihood of staff being unfamiliar with what is being used. It would also reduce the training load. Reducing the selection of implants and components available in a trust would similarly reduce the chance staff are unfamiliar with their use.

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Appendix 1: Summary of cases

Wrong patient

Wrong patient for laser eye surgery

The patient attended for follow-up after cataract surgery and required optical coherence tomography (OCT) to one eye. They were sent to the waiting room for this procedure, a waiting room also used for laser eye surgery.

The specialist nurse kept hold of the patient's notes in another area. The doctor doing the laser eye surgery had a set of notes for a patient with the same first name and who required surgery on the other eye. The doctor went into the common waiting room and called the patient using their first name only. The patient requiring OCT went into the room. The doctor explained the procedure and despite the patient saying they were there for their other eye, the laser surgery was performed on the wrong eye. Fortunately the patient suffered no lasting harm.

What happened?

- The surgeon did not formally check the patient's identity before carrying out the procedure.
- Patients were not routinely consented for laser eye surgery immediately before it was carried out.
- Patients' notes did not follow them around the unit as they went for different tests.
- Allocated time on the list for laser procedures was short, reducing the time the surgeon had with the patient to carry out essential checks.

Wrong procedure

Wrong procedure for correcting a squint

The patient had elective surgery to correct a divergent squint. The wrong procedure (convergent) was undertaken which made the squint worse. Further surgery was required to correct the mistake.

What happened?

- The additional information on the operating list information sheet, completed by the staff in the waiting list department, was incorrect. This incorrect information was transcribed onto the theatre whiteboard and used by the surgeon to calculate the adjustment to the eye muscle.
- The words ‘resection’ and ‘recession’ were transposed on the white board.
- This was a pooled operating list so the consultant who performed the operation only met the patient on the day of the surgery.
- The surgeon who initially saw the patient and listed them for surgery did not include an operative plan in the patient’s notes. This would have assisted the surgeon who did the operation. Better planning for pooled operating lists was an important action from this case.

Wrong site surgery

Wrong site nerve block

The patient was admitted for surgery on their left leg. The leg was marked with an arrow by the surgeon (on the ward before the operation) and the patient was seen by the anaesthetist. ‘Sign in’ was completed by a trainee and the ODP in the anaesthetic room. The consultant anaesthetist then arrived and was told the ‘sign in’ had been completed. A general anaesthetic was then given. The ODP and trainee left the room to collect other equipment and drugs. Working alone, the consultant mistakenly prepared the wrong leg for a nerve block and administered the block.

The consultant anaesthetist realised before the ‘STOP check’ (‘time out’) stage of the WHO safer surgery checklist that the nerve block had been performed on the

incorrect leg. The nerve block and surgical procedure were then carried out on the correct leg and the patient came to no harm.

What happened?

- The consultant anaesthetist was not present for the 'sign in'. They did not undertake a check themselves before preparing the leg for the nerve block.
- The 'sign in' was done by the trainee while the surgeon was in recovery with the previous patient, to maintain flow through theatres and not delay things.
- The failsafe 'stop before you block' procedure did not happen immediately before the anaesthetic nerve block was administered. 'Stop before you block' had not been formalised in a SOP which meant that the process had yet to be fully adopted, implemented and embedded in everyday practice by all members of the anaesthetic team.

Wrong site hip injection

The patient was given pain-relieving injections at multiple sites on both their left and right sides. The site for the hip injection was not marked and it was performed on the wrong side.

What happened?

- Not all injection sites were marked before the injections were given. This was custom and practice in the pain service at the time of the incident.
- Information was incorrectly transcribed: the radiology request card stated right not left hip.
- There was no separate 'time out' for each injection site.
- At the time of the incident, a safe site surgery document had not been completed for pain procedure patients.
- The white board on which patient procedure details were written was small and to one side of the anaesthetist, so it was difficult for them to read from where they were working.

- The patient was sedated so was unable to identify/communicate that the injection was being administered to the wrong site.
- Documentation was poor with gaps throughout.

Wrong site central line insertion

During anaesthesia for an emergency laparotomy on a pregnant woman, the consultant anaesthetist inadvertently placed the central line in the right carotid artery. The patient developed left hemiparesis. They were transferred to a tertiary centre for surgical removal of the central line. The mother then delivered prematurely and her baby died.

What happened?

- The procedure was urgent. During surgery the patient became hypotensive and required noradrenaline due to placental perfusion issues. As she was septic the decision was made to insert a central line.
- Insertion of a right internal jugular line was initially attempted under ultrasound guidance during the operation (under drapes). This was technically very challenging and compounded by a loss of ultrasound guidance.
- The correct position of the guide wire was not adequately checked before the insertion of a large bore multi-lumen central venous pressure line. There was no pressure transduction check before noradrenaline infusion started.
- There was an identified power failure: the device had not been connected to the mains and had limited battery life (the report was unclear about what this device was).

Wrong tooth extracted

The patient attended hospital with facial pain and an abscess was diagnosed. Tooth extraction was agreed. The dental extraction checklist was not completed in full by the trainee and the wrong tooth was extracted. The patient went on to have the correct tooth extracted.

What happened?

- The patient had swelling around two teeth that were similar in appearance – each had been restored with large fillings.
- During the extraction the dental nurse was monitoring the neighbouring tooth for damage to the fillings so was unable to provide a second check that the dentist was on the correct tooth.
- A key step in the safety checklist for dental extraction was not carried out: apply an instrument to the tooth and say out loud which tooth is to be extracted, with the nurse checking this.
- This was the first time the trainee had used the checklist: they had only been in the department a week.

Wrong site surgery – dermatology

The patient had the wrong naevus removed from their back. The correct lesion was removed the next day.

What happened?

- The clinic documentation was clear and included a diagram of the lesion to be excised. This was not checked at the time of surgery. However, the diagram and description of the lesion were not considered explicit enough, given that a different clinician would be performing the excision.
- The usual procedure for checking the excision site with the patient was not followed – there was no written protocol for how to do this, but usual practice was to use a mirror.
- The surgical environment (outpatients) was not protected from interruptions.
- The WHO safer surgical checklist was not completed.
- The nurse surgical safety checklist was insufficiently detailed to help prevent wrong site excisions: for example, no time in, time out, site checked with patient.

Biopsies taken from the cervix instead of the bowel following incorrect endoscope insertion

The patient was undergoing a flexible sigmoidoscopy for rectal bleeding but the endoscope was inserted into her cervix not her bowel. Biopsies were taken from the wrong organ. This error was noted the following day and the patient underwent the correct procedure soon afterwards.

What happened?

- Patients are laid on their side for this procedure and considerable lubrication is applied to the scope. Female anatomy means there is a risk of the scope slipping and entering the wrong orifice.
- The endoscopist was not trained in gynaecology and since the bowel can look very different in different people, they did not consider that the endoscope was in the wrong place.
- Routine identification of the cervix is not included in an endoscopist's training programme.

Wrong site surgery for a gynaecological cyst

The patient had a Bartholin's cyst on their right side removed. This was identified in theatre, but the patient had only consented to the removal of a cyst on the left side.

What happened?

- The name of procedure on the WHO checklist was 'excision vulvar lesion' and not 'incision and drainage of left labial cyst' as written on the consent form.
- The patient asked if the cyst could be examined before surgery as it felt different. However, the surgeons considered that it would be in the patient's best interest to proceed as this cyst was likely to reoccur and could be a problem in future.
- The consultant examined the patient in theatre and was unable to see or feel a cyst on the left. However, it was obvious that there was a Bartholin's cyst on the right side. As this cyst was likely to cause a problem in the

future, both surgeons present thought that it was appropriate to remove this while the patient was under general anaesthesia.

Wrong finger operated on

The patient suffered an injury to their ring finger and was brought in for urgent surgery. The finger to be operated on was marked on the back of the hand, but before surgery the hand was turned over, so the markings were no longer visible. With the hand turned over, the index finger was mistakenly operated on. The error was noticed when the patient was in the recovery room and they consented to have the correct procedure done immediately.

What happened?

- The patient had a closed injury so there were no external signs of where it was.
- Only the left dorsal aspect of the hand was marked so when the hand was turned over there was no clear mark to identify the correct digit.
- During the WHO checklist the team identified a different error on the theatre list; the wrong hand was down to be operated on. This was checked and corrected.
- The whole theatre team participated in the ‘time out’ but did not notice the incision line had not been drawn. This was an experienced theatre team familiar with each other and the checking process. The danger of familiarity leading to a loss of situational awareness (autopilot) was recognised.
- The WHO checklist does not ask specifically if the incision line has been marked correctly.
- The surgeon did not mark the incision line until after the ‘time out’ had been completed.

Trigger thumb surgery due but carpal tunnel syndrome incision made

A patient was due to have a trigger thumb release procedure but the surgeon made an incision for carpal tunnel surgery. The patient had not had local anaesthetic for

this incision and was immediately in pain, alerting the surgeon to the error. More local anaesthetic was administered and the incision line stitched. The correct surgery was then undertaken.

What happened?

- An arrow and the acronym for the surgery (TT for trigger thumb) were marked on the hand, but when the hand was positioned for surgery neither mark could be seen.
- Marking the site of the incision is considered to carry a risk of 'tattooing' in the eventual scar line.
- The new theatre scrub practitioner did not feel confident enough to speak up.
- There was a 'time out' before skin preparation and draping, but there was then an interval before the incision was made, contributing to the failure (no 'unassailable mental cue').
- Staff – including the surgeon – were performing highly rehearsed actions (autopilot) in high volume, rapid turnover surgery.
- There was considerable overlap and redundancy (for the local anaesthetic cases) in the ward 'sign out', theatre 'sign in' and 'time out' pre-procedure. The staff had therefore adapted the process to make things less onerous and less time-consuming. This had inadvertently created conditions where important steps in the process were routinely adapted or ignored.

Wrong site incision for trigger finger release surgery

The patient required surgery for the release of several digits, with operation on two planned for this surgery. These were marked by the surgeon on the ward. Despite the WHO 'sign in' and 'time out' being performed, the surgeon initially made an incision on a wrong digit but realised the error and stopped. The correct digits were then operated on.

What happened?

- The surgeon could not see the site marking because the fingers had curled further following the anaesthetic.
- The surgeon was guided by the patient's anatomy which indicated that the digit in question needed surgery. This was despite the WHO checklist being completed, including a 'time out' immediately before the incision.
- The theatre team were attentive but did not have time to intervene before the incision was made.
- The surgeon had been distracted immediately before the procedure with phone calls and questions about staffing for the weekend.
- Other cases had been added to the list so there were time pressures with this case.

Arthroscopy started on the wrong side

The patient's arthroscopy was started on the wrong knee. This error was recognised by the anaesthetist and the procedure stopped. The correct knee was then operated on.

What happened?

- The surgical site mark was not close enough to the operation site and so was not easily visible after draping. In addition, the wrong knee was partially exposed as the patient was moved onto the operating table.
- The surgeon did not look for the surgical mark on the limb when applying the tourniquet.
- The surgeon was not present for the 'sign in' or the 'time out'.
- The whole team were not engaged in the pre-procedure 'time out' – the first circulating nurse read out 'left leg' but the second circulating nurse was holding the right leg. The first nurse asked if this was the correct leg but this did not alert anyone to the error. The scrub practitioner went on to prep the wrong leg.

- The WHO surgical safety process was not embedded in routine practice and several aspects were either not conducted or done by the wrong people.

Surgery on the wrong toe

A patient was admitted for elective surgery on their toe. By mistake the consultant surgeon made a small incision at the 3/4 space rather than at the 2/3 space. The error was identified by the circulating practitioner who stopped the surgeon proceeding. The patient was left with a small scar over the 3/4 space.

What happened?

- Scheduling was very ambitious with quick turnaround of cases.
- There were inconsistencies on the theatre list, with numerous abbreviations used for laterality – R, Rt and Right.
- The foot surgeons used various surgical site markings.
- There was no surgical site verification checklist and not all staff were present at the 'time out'.
- The hard copy of the operating list was not used at the 'time out' to clarify procedure site and side.
- The consultant left the operating table following the 'time out' to recheck the images to seek clarity on the proposed surgery. The surgical site was not rechecked or verbalised by the consultant after they returned to the operating table.
- Staff were distracted at knife to skin – the ODP was in the anaesthetic room, another staff member was away for a break and the scrub practitioner was drawing up local anaesthetic.
- The whiteboard was not fully used to display the proposed procedure and act as a visual prompt/check for the team.

Diagnostic angiogram performed on the wrong leg

The patient was due to have a diagnostic angiogram on their right leg, but it was performed on their left leg. The error was noticed during the procedure and the patient informed. The correct procedure was then undertaken.

What happened?

- Patients undergoing angiograms do not routinely have the site marked (this is in keeping with Royal College of Radiologists' recommendations).
- The radiographer confirmed the patient's details using a sticker from the notes, which had incorrect information on it, and not the request card, which contained the correct information.
- The WHO safety checklist was not undertaken as the radiologist did not consider an angiogram to be a surgical procedure, rather a diagnostic procedure.
- The junior nurse did not feel confident enough to speak up about not using the WHO checklist.

Wrong site venous ablation

The patient was listed and consented for surgery on the left leg; they had previously had the same surgery on the right leg. Surgery was attempted on the wrong leg. When asked by the consultant, the patient, who was under local anaesthetic, confirmed that the right leg had already been operated on. The procedure was then switched to the left leg.

What happened?

- Following the first surgery, on the right leg, the consultant requested the patient be relisted for surgery 'on the other leg'. They then cut and pasted information about the type of surgery to be performed from the previous theatre list – including that it was to be on the right. The waiting list co-ordinator copied these patient details onto the theatre system, which led to the incorrect listing of the patient for surgery on the right side.

- The postoperative note saying the first surgery had been completed was not in the notes when the patient returned – the last letter in the notes was from the first referral stating the surgery was to be on the right.
- Only the paper record and not the computer database was checked before consent for the second procedure (operation notes were on the computer and not filed in the paper record), so mistakenly the patient was consented for surgery on the right side. They did not mention their previous surgery on this side when being prepped for surgery on the same side.
- Due to the trust being in the process of moving over to electronic records, case notes were no longer complete and adequate for use on their own.

Removal of wrong rib bone

The right first rib should have been removed but the second was taken out by mistake. The patient went on to have further surgery to remove the correct rib. During the first surgery the WHO checklist was undertaken and the correct side was marked. However, it is difficult to mark the exact rib.

What happened?

- Removal of the wrong rib is a known risk in this type of surgery but this was not discussed when the patient was consented for the surgery.
- The patient had a complex anatomy in this region.
- It is difficult to mark the exact rib. The cavity created requires the surgeon to find the rib using internal anatomical features. It was noted that imaging could be used in future for intraoperative accuracy.

Surgery on the wrong shoulder

The patient had surgery to remove a lipoma (growth) from one shoulder. They were unaware that they had a similar growth on the other shoulder. Surgery removed the growth from the wrong shoulder and the patient subsequently had surgery to remove the lipoma from the correct shoulder.

What happened?

- The surgeon was operating on a ‘pooled list’ so had not seen the patient before the day of surgery.
- All the correspondence said ‘right’ but when asked the patient exposed their left shoulder. The surgeon marked the site exposed by the patient.
- The consent form did not indicate the side for surgery despite two opportunities for this to be included.
- The waiting list referral did not specify the side and hence this was not stated on the operating list.
- There was a discrepancy between the referral letter, the imaging and the site marking regarding side for surgery, and this was not picked up in theatre.
- There were five opportunities for the error to be corrected through a review of the correspondence and imaging compared to the site marking but none was taken.

Wrong side axillary node clearance for breast cancer

The patient was due to have a right-sided axillary node clearance procedure for metastatic breast cancer. This was carried out on the wrong side. The error was detected 10 days later at the MDT meeting. The patient was informed and then underwent the correct procedure.

What happened?

- During the MDT meeting, the surgeon documented the wrong side for the procedure, despite drawing a diagram showing the correct side. The hand-written notes were then typed and emailed to everyone. The error was included in correspondence to the GP and to the waiting list team, who scheduled the surgery on the wrong side. Consent was then taken by the surgeon for the wrong side.
- There were time pressures at the MDT meeting when up to 40 patients were discussed. The histology of both the patient’s breasts was discussed at the meeting and this may have contributed to the error.

- There were time pressures for the surgeon on the day of surgery, which meant they felt rushed when seeing patients pre-procedure.
- The patient also had a lump (a benign cyst) on the left side which was felt by the surgeon at site marking.

Wrong side urology stent insertion

The patient was listed, the consent form signed and the site marked for a left stent insertion. All the WHO safety checks were performed with all present at the start of the procedure. But the surgeon inserted the scope and then the stent on the wrong side. During the 'sign out' the error was recognised. While the patient was still anaesthetised the incorrectly placed stent was removed and the correct procedure was performed. The patient had some pain on the right side postoperatively but made a full recovery.

What happened?

- The procedure took place on a day when the surgeon was very busy and felt under pressure – ward round, on call and operating list.
- The radiographer questioned the site of the procedure but no-one picked this up, so they assumed the procedure had changed to bilateral stenting and did not pursue their questioning. The surgeon did not recall hearing the radiographer; they were focused on the procedure.
- Nursing staff heard the radiographer's question but did not support the challenge.
- Staff described some occasions when they found challenging colleagues difficult: for example, when interventions being performed were out of their scope of practice.

Wrong prosthesis/implant

Wrong strength lens inserted during cataract surgery

The patient had the wrong strength intraocular lens (IOL) inserted during cataract surgery, resulting in blurred vision. When transcribing information from the biometry

calculation sheet to the lens selection sheet, a 7 was entered in the IOL power box when it should have been a 2. This discrepancy was not picked up in either the checking process for selection or the checking process before the lens was inserted. A second procedure was required to insert the correct lens.

What happened?

- Handwriting was poor so the 2 looked like a 7.
- The surgeon and scrub practitioner did not look at the biometry calculation sheet, relying solely on what was written on the IOL selection sheet.
- The whole WHO surgical safety checklist was not completed.

Wrong size hip implant – liner and femoral head of different sizes

The patient underwent an elective hip replacement. During the surgery the checking processes failed and the patient had a liner fitted that was incompatible with the size of the femoral head. The patient had to undergo a second operation to correct this.

What happened?

- The size of the different hip joint components used was not recorded on the white board during surgery.
- The scrub practitioner was distracted at a crucial point in the surgery and with no information on the whiteboard regarding the size of components already used, they handed the wrong sized impactor to the surgeon.
- The size of the selected femoral head was not checked against the size of liner used.
- There were staff changes during the procedure. The staff member who selected the liner left the theatre and a new person selected the femoral head for the surgeon. With no information on the whiteboard about sizes already used, the second member of staff relied on what the surgeon asked for.
- The surgeon did not stop to question things when they could not satisfactorily relocate the hip joint.

- There was no final compatibility check of all implants used before skin closure. This was contrary to trust policy.

Left-sided bearing inserted on the right during knee replacement

During a uni-compartmental (or partial) knee replacement a left-sided bearing was used rather than a right-sided bearing. Due to the complexity of the procedure the medical company representative joined the theatre team to advise the surgeon on the use of the implant. There was over-reliance on the knowledge and expertise of the company representative such that they selected the implants and in doing so, bypassed the checks normally done by the circulating nurse. The patient mobilised well after the surgery and was informed of the error and the chance of dislocation but did not undergo further surgery.

What happened?

- The representative joined the theatre after the WHO checklist had been completed.
- The representative selected the components to be used, bypassing the usual checking procedures.
- Three individually packaged components had to be selected. The packaging for each included a lot of text but that indicating left or right was very small.

Right-sided plate inserted during an open reduction and repair of a left wrist fracture

The patient had surgery to repair a wrist fracture. During surgery the circulating nurse picked a plate from the drawer where both left and right-sided plates were stored. The surgeon was in a hurry and had put pressure on the staff to speed up. The circulating nurse checked the type of implant but not the side with the surgeon and scrub practitioner. When the error was detected the patient was informed but they did not require further surgery.

What happened?

- Left and right-sided plates were stored in the same drawer. They were usually stored on the appropriate side of the drawer (that is left-sided plates on the left side and vice versa) but not in this case.
- The implant was not checked correctly by the circulating nurse, scrub practitioner or surgeon – there was a failure to check and confirm the plate was of the correct side.
- The nursing staff felt under pressure to open the implant and to finish the case since the surgeon was pressed for time.
- The nursing staff did not feel able to challenge the surgeon's behaviour.

Retained foreign objects

Guide wires

A guide wire not removed before an emergency infusion was flushed into the patient, migrating to the left subclavian vein

The patient was severely ill when admitted to the coronary care unit. Suddenly their blood pressure fell. Intravenous access was difficult, so the doctor inserted an emergency central line into the right femoral vein using the Seldinger technique.[2] They were under pressure due to the condition of the patient and wanted to check quickly that the sheath was in the femoral vein, so aspirated blood immediately and then flushed the sheath, forgetting to remove the guide wire. The retention of the wire was not noticed by the doctor. The investigators considered the guide wire had been pushed further into the vein as the sheath was introduced, so it did not protrude through the sheath and hence was not visible to the doctor. The guide wire was clearly visible on a chest X-ray taken later that night, but was not noticed by the doctor who was only looking for signs of pulmonary oedema. The chest X-ray was reviewed several times after this by others and again the wire was missed: the consultant cardiologist was not looking for a wire but for signs of lung consolidation

[2] In the Seldinger technique a needle is inserted into a vein attached to a 10 mL syringe. When blood is sucked back into the syringe, confirming the needle is in the vein, the syringe is removed and a guide wire is introduced through the needle into the vein. The needle is then removed, leaving the guide wire in the vein. An indwelling sheath and access port is then passed over the wire into the vein (21 cm long in total). The guide wire should at this point emerge through the sheath and be removed before the port is closed.

and pneumonia; the radiologist considered the wire to be external to the patient. The patient was transferred to another hospital for further surgery and the wire was seen immediately by the receiving doctors on the X-ray. It was then removed.

What happened?

- The collapse of the patient required an emergency lifesaving infusion, hence the emergency femoral vein cannulation.
- The doctor made an error in the rush to gain central access – the patient was in extremis.
- It was not policy or standard practice to document the removal of an introducing guide wire and that it was on the trolley at the end of the procedure.

Broken off end of guide wire was retained in patient's foot

During a hallux valgus procedure (bunion surgery) the end of a guide wire broke off and was retained in the patient's foot. The retained piece was found six weeks postoperatively when the patient returned to outpatients complaining of pain in the plantar aspect of their foot. A short piece of a guide wire was seen on X-ray and removed.

What happened?

- Small guide wires were not included in the count – although even if they had been, this may not have alerted the team to the fractured wire.
- Guide wires were not measured on retrieval.

Guide wire retained following chest drain insertion

The patient was admitted as an emergency with left-sided chest pain. An X-ray confirmed a pneumothorax and a chest drain was inserted using the Seldinger technique. The foundation year 2 (FY2) doctor was left to complete the procedure when the senior doctor was called away to another more serious case. The assisting nurse also left the area to get more morphine for the patient and, rather than waiting

for them to return, the doctor proceeded with the insertion alone. The doctor noted that after insertion the drain was performing the task it was inserted to do. Half an hour later a post-drain insertion X-ray was taken and reviewed by another doctor, who noted the guide wire within the drain but not visible externally. The patient was admitted for surgery to remove the guide wire. They had to stay in hospital for a week longer than would otherwise have been the case.

What happened?

- The equipment design did not 'force' the operator to remove the guide wire before proceeding.
- There was no chest drain checklist.
- The more senior doctor assumed the FY2 doctor was competent to perform the procedure alone. The FY2 doctor did not wait for the assisting nurse to return.
- The department was busy and the staff felt pressurised.
- Simulation training in the Seldinger technique was provided for core trainees but not foundation year trainees.
- Each hospital in the trust had different policies for managing pneumothorax.

Swabs

Two strips of ribbon gauze retained in patient's nasal cavity following endoscopic sinus surgery

The case was moved from the head and neck theatre to the general theatres due to pressures elsewhere in the trust. Staff sickness meant a nurse from another specialty was asked to cover the list. The scrub practitioner had not previously worked with the surgeon. There was a full team brief before the list with all present. The surgeon used 22-cm strips of gauze (cut from a roll) to apply Moffat's solution, which causes restriction of the vessels in the nose to minimise bleeding. The surgeon then used a different type of swab (a patty) soaked in a different solution and this was also placed in a pot on the trolley. Two types of swab were purposefully used to distinguish which were soaked in which solution. The patties were taken from a pack so were included in the routine swab count. The gauze was cut from a roll and its use should have been written on the whiteboard.

The circulating nurse helped at the start of the procedure but then left. The gauze was cut by the scrub practitioner and the healthcare assistant (HCA) wrote this on the whiteboard. After the surgery was complete, the final count was undertaken with the circulating nurse – they had returned but were not familiar with this type of surgery. The HCA who had done the first count was busy doing something else so did not participate in the final count – contrary to the SOPs. The retained gauze was found by the patient following discharge home. They returned and had it removed.

What happened?

- A newly qualified nurse scrubbed for experience passed things between the surgeon and scrub practitioner – interrupting the direct chain of communication.
- The final count involved a nurse who was unfamiliar with the procedure and had not been involved in the initial count or in theatre during the procedure – against SOPs.
- It was not standard procedure for the ribbon gauze to be left with a piece showing from the nostril.
- Swab type (gauze) and the number of pieces cut and used needed to be recorded on the whiteboard but not side or site.

Retained vaginal swab following a forceps delivery with episiotomy

There were concerns about fetal wellbeing during labour and the decision was made to assist delivery in the room. A baby was delivered by forceps and required resuscitation but not admission to the neonatal unit. The mother was found to have suffered a fourth-degree tear with blood loss and a swab was inserted into her vagina. She was transferred to theatre for the repair. This swab was documented by the midwife in the notes and included in the pre-theatre and in-theatre checklists, but not recorded on the theatre whiteboard – so not considered at ‘sign in’ or ‘sign out’. During the procedure more swabs were used and documented. At the end of the procedure a swab was inserted high in the vagina for removal later. It appears that the first swab was removed and another one inserted at the end of the procedure, but the swab count only considered the swabs used during the procedure and one left in the vagina was overlooked. The WHO ‘sign out’ procedure was not properly completed. The patient was referred back by her GP and returned several times,

eventually with abdominal pain, discharge and urinary incontinence. The retained swab was found five weeks after the birth.

What happened?

- The swab was correctly documented at handover to the theatre team, but not recorded on the theatre white board at the start of the procedure.
- There was no specific area on the obstetric theatre whiteboard to record swabs in situ on arrival.
- The WHO 'sign out' procedure was not properly completed.
- The final intentionally retained swab was not recorded in the notes.

Retained swab following mitral valve repair

The patient underwent a mitral valve repair, a procedure that uses many swabs. The surgery was uneventful although at one point a particular type of swab was unaccounted for but then found, which may have caused a distraction. The retained swab had been placed behind the heart to elevate the valve before repair. The final swab and instrument counts were recorded as correct. The 'time out' and 'sign out' were recorded and described by staff as uneventful. Staffing levels and skills mix were appropriate for the procedure. The retained swab was noticed on X-ray by the consultant radiologist 12 days post-surgery.

The investigation failed to identify why the swab was retained, but human error caused by a distraction during the procedure was thought most likely. The patient had a further procedure to remove the swab and made a full recovery.

Plates, covers and consumables

Retained guiding 'turret'

A patient was admitted with a complex displaced fracture requiring open reduction and internal fixation. The fracture required the use of a non-standard plate which had multiple screw holes, each with a guiding 'turret' to help the surgeon drill and place each screw at the correct angle. After placing the screw, the 'turret' is removed. One of the holes in the plate was not used and its turret was retained. This was detected on the postoperative X-ray and the patient required a second operation to remove it.

What happened?

- The plate used was different from usual, with more holes and turrets.
- Turrets were not part of the routine swab, instrument and needle count.
- The supervising surgeon's and scrub practitioner's training in using this plate was several years ago and the trainee undertaking the surgery had not been trained in its use.
- Interruptions throughout from another member of the surgical team coming in to check everything was okay were distracting.
- There was no surgical pause before the wound was closed.
- An image intensifier was used to take X-rays during the procedure to ensure all bone fragments were removed. The turret could be seen on these images, but the surgeons were only looking for bone fragments.

Retained corneal shield after upper eyelid surgery

A corneal shield was inserted under the eyelid to protect the surface of the patient's eye during surgery, but this was not recorded on the whiteboard as an additional item and therefore excluded from the count. The surgery went well and the WHO checklist 'sign out' was completed, with the instrument, needle and swab count marked as correct. The patient's eye remained closed due to the significant amount of local anaesthetic that had been injected, so it was not checked before the patient went home. The next day the patient returned with a sore eye and on examination the corneal shield was found and removed. Fortunately there was no lasting damage.

What happened?

- Consumables such as the corneal shield were not included in the trust's count policy and were not routinely counted.
- The surgeon did not tell anyone that they had inserted a corneal shield, so it was not listed on the whiteboard as an item whose removal should be checked at the end of the procedure.

- The patient was anxious about the surgery and the scrub practitioner spent time at the start of the procedure offering reassurance; this may have distracted them from recording items.

Retained drain cover

To close a patient's wound at the end of abdominal surgery, they were placed in a jack-knife position and drains inserted on either side and stitched in place. The surgery went well and the WHO checklist and SOPs were followed. The patient was transferred to the recovery area and monitored. Dark blood was seen to have drained on one side and an ultrasound scan was done to rule out a haematoma. Monitoring continued and the patient was discharged home five days after surgery. A retained 4-cm plastic drain cap was discovered five days later when the patient attended a dressing clinic. This was removed during a second hospital admission and the patient had several courses of antibiotics before recovering.

What happened?

- The trust's count policy was not clear on disposable covers in general; drain covers were not included in the count.
- There were no standards for handing items to surgeons or returning them to the scrub practitioner across the surgical field.
- There were no standards for returning waste items across the surgical field, such as the cut ends of drains and drain covers.

Suture material and needle retained following perineal repair

The mother required a perineal repair. There was a shortage of staff on the midwifery unit and the midwife was under pressure to complete the repair since another woman in labour was about to arrive. The midwife was also supervising a student midwife who interrupted her several times during the repair. On completion of the suturing and after counting the swabs but before the final count, the midwife had to leave the room to answer the door to let someone in. On returning the final safety count had been completed and the midwife realised the needle was missing. The immediate area was checked and without it being found the midwife convinced

herself she had disposed of it in the sharps bin when answering the door. About 10 hours later the mother told the staff she was in discomfort and on examination suture material was found to have been left in place with the needle attached. The consultant trimmed the sutures and removed the needle. No further action was required.

What happened?

- Staff shortage: the midwife was the only permanent midwife on duty and she felt responsible for all activity in the unit, including supervising a student midwife.
- The midwife was doing several tasks at once and could not focus completely on the perineal repair. She was interrupted several times, including having to leave the room to answer the door before the final count.
- Handover between the day and night shift about the staff shortage in the maternity service was poor and the problem was not resolved.
- Following trust policy for calling in community midwives to assist was not considered practical by the senior midwives on duty since it would create staffing problems in the community later in the week.
- The loss of the needle was not escalated. The count policy did not include detailed instruction on how to search for lost items or how to escalate the loss once it was confirmed.
- A standardised approach to counting was not found to be embedded in practice across the maternity service.

A fetal scalp electrode (FSE) was retained after a caesarean section

The woman was admitted to the birth centre in early labour and transferred to the labour ward as her blood pressure was of concern. There were signs of fetal distress so a FSE was placed on the baby's head. Later in the labour, the decision was made to perform an emergency caesarean section. This was done under a general anaesthetic and a healthy baby was delivered. Several days later the mother, now at home, found the fetal scalp electrode had been left in her vagina.

What happened?

- When preparing the patient for theatre, the midwife did not document the placement of the FSE.
- The FSE cable had been cut at some point but this was neither documented nor communicated to the operating team.
- It was unclear whose responsibility it was to check that the FSE had been removed: the surgeon assumed it was the midwife's.
- Before starting surgery, the surgeon was described as focused on the urgent need to deliver the baby – leading to communication not being good on other issues, such as the retained FSE.
- The WHO surgical safety checklist was not completed before the induction of anaesthesia.
- The record keeping policy was not followed during the operation and the checklist question 'has the FSE been removed?' was left blank.
- Poor adherence to expected practice regarding documentation was generally tolerated in the department; this laxity was described in the investigation as not attributable to time pressures.
- Trust policies were subject to various amendments and changes, and overlapping polices were in operation.

Laparoscopic surgery

Broken piece of surgical instrument (forceps) retained during a laparoscopic procedure

The patient was the only one on the list. There was a team briefing in theatre before the patient arrived. The 'sign in' part of the checklist was then completed with all present. The scrub practitioner checked the instruments were correct and functional. Johannes forceps were placed on the tray and the jaws opened and closed – nothing untoward was reported. During the procedure the bowel needed to be retracted for a clearer view of the operating area, so the Johannes forceps were requested and used. On completion of the surgery all instruments were withdrawn and handed to the scrub practitioner. It was not normal practice to open and close the forceps at this point, so no problems were identified. The WHO 'sign out' check was performed correctly and final closure was completed. Later in the day the CSSD staff checked

the integrity of equipment before repacking it and discovered the damaged forceps. An abdominal X-ray clearly showed the retained piece of the forceps. The patient returned to theatre soon afterwards, the item was removed and the patient was discharged home two days later.

What happened?

- The forceps had snapped at the hinge joint of the grasper.
- The forceps were three years old and were expected to last five to eight years.
- Instruments put together before surgery were not required to be dismantled following use to check they were intact – in fact, there was no requirement to check the integrity of equipment at the end of surgical cases.
- The patient's anatomy required a retractor to be used with some force. Forceps will only take a certain force but the staff using them were not aware of this limitation or the manufacturer's guidance on this.

Retained laparoscopic retrieval bag during emergency appendicectomy

The patient had an emergency laparoscopic appendicectomy but during the procedure it became necessary to convert this to open surgery. At the start of the procedure the scrub practitioner asked the circulating nurse to pass them a retrieval bag so that it would be available if needed. The bag was opened and put on the sterile trolley but not added to the count list on the board. The bag was used in the early part of the surgery but its use was not recorded. At the end of the procedure, the final count was completed and documented as correct, and the patient was discharged a few days later. They were readmitted a month later with abdominal pain and a CT scan indicated an abscess around a possible foreign object. The laparoscopic retrieval bag was removed and the patient made a full recovery.

What happened?

- The scrub practitioner was not familiar with the type of retrieval bag passed to them. It was different from those normally used and did not have an

'endocatch' which would have kept it externally connected via a suture during the surgery.

- The nurse did not expect the bag to be fully inserted, instead thinking part of it would be externally connected.
- The surgeon used this type of bag since it is more robust when friable and fragmented tissue needs to be removed in one go.
- The surgeon assumed the bag would be included on the board for the count.
- Trust policy about what was counted was not explicit in detailing those items that should be counted in addition to instruments, swabs and sharps. Laparoscopic retrieval bags were not included in the trust's count policy
- The decision to convert to an open procedure was taken at a critical point and this may have led to a loss of situational awareness in relation to the retrieval bag.
- The circulating nurse conducted the final count but had not been present for the entire procedure so was unaware that the retrieval bag had been opened and placed on the trolley.

Stainless steel spring from a suction device retained during laparoscopic surgery for a bleeding duodenal ulcer

The patient had an emergency laparotomy. During use a stainless steel suction device came apart. The surgeon reassembled the device and continued to use it, without the scrub practitioner being made aware of this. The CSSD later informed the scrub practitioner that a spring was missing from the device. After a thorough search, including through the waste bags, the surgeon was informed and an X-ray was requested. This confirmed the spring's retention in the abdominal cavity. The patient had further surgery to remove the spring.

What happened?

- The suction device had not been assembled correctly and during the surgery it came apart. The investigation report did not mention anything about who assembled the equipment or when this was done.

- The surgeon put the device back together but was unaware that it should contain a spring. It was not unusual for surgeons to resolve problems with suction equipment during surgery: for example, if it blocked.
- The surgeon did not notify the scrub practitioner that the device had been reassembled so the team had no opportunity to consider whether there were missing parts.

Appendix 2: Contributory factors across the types of Never Events

Factor types	Wrong site surgery	Wrong implant/prosthesis	Retained foreign object
Institutional context	None	None	None
Organisational and management factors	• Safety culture – staff not speaking up • Checks not embedded in routine practice • Pooled operating lists • Training • Transcription errors copied across documentation • Medical records not complete	• Safety culture – staff not speaking up • Checks not embedded in routine practice	• Safety culture – staff not speaking up • Checks not embedded in routine practice • Training • Confusing trust policies • Staff shortages
Work environment factors	• Design and layout (including white boards) • Equipment failure • Insufficient time to undertake checks	• Design and labelling of packaging • Storage of left and right components	• Equipment breakage • Equipment design (guide wires, white boards) • Work environment

Team factors	• Communication failures • Interruptions and distractions • Autopilot mode • Written communication failures	• Medical company representative joined the team but was not present at the start for the safety checks	• Communication failures • Interruptions and distractions • Written documentation – no recording of swabs, etc • Staff changes during procedures
Individual (staff) factors	• Cognitive factors leading to loss of situational awareness • Knowledge and skills • Not complying with check policies	• Knowledge and skills • Attitude of surgeon	• Cognitive factors leading to loss of situational awareness • Knowledge, competence • Not complying with count policies
Task factors	• Site marking visibility • Policies and procedures for site marking not followed • 'Time out' not done properly	• Policies and procedures for selecting and checking not followed • Transcription errors	• Policies for what is and is not counted • No policies for checking integrity of equipment • Visual cues needed • Safe surgery checks not performed
Patient factors	• Anatomy • Communication failures with the patient	None	• Anatomy • Development of an emergency situation requiring urgent action

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