Surgical 'Never Events'

Learning from 23 cases in London Hospitals

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1. Introduction

Surgery continues to be the most dangerous context in acute care in England with regards to the occurrence of adverse events. Indeed, when looking at some of the most serious types of adverse event, 'never events', the majority occur in the operating theatre. Whilst the prevalence of surgical never events remains low in relation to the total surgical load in the NHS (occurring in around 1 in every 20,000 procedures), their impact can be devastating. As such NHS England have launched a recent programme of work focussed on understanding why these avoidable events continue to occur at a steady pace and how we can create the conditions whereby they live up to their name.

As part of this focused effort, NHS England commissioned the current report which presents an analysis of the investigations into 23 surgical 'never events' from across London Trusts which took place between April 2012 and March 2013. These include 17 cases of retained objects and 6 cases of wrong site surgery.

Using the recent analysis of 9 wrong site surgeries conducted by the Clinical Human Factors Group as a basis,[1] the primary aim of the analysis that we present here was to identify common lessons from the investigations and to identify the human factors at the core of these events. We anticipated that different types of care delivery problems might underlie the occurrence of retained objects and wrong site surgeries. For instance, whereas wrong site surgery may commonly originate in events occurring during the pre-operative phase of the surgical pathway, retained objects may be more likely influenced by errors occurring later on, for example during counts and shift change-overs.

The secondary aim of this review was to conduct a thematic analysis of the *actions* taken by Trusts following these events. This, to our knowledge, has not been attempted previously.

In bringing our findings together we hope that this report will aid London NHS Trusts in learning from these 'never events' and making improvements to prevent their occurrence.

1.1 Surgical 'Never Events': Facts and Figures

There are now 25 'never events' recognised by NHS England. The criteria for an adverse event being classified as a 'never event' are as follows:

- The 'never event' may or does result in severe harm or death to patients or the public

- There is evidence that the 'never event' has occurred in the past, that it is a known source of risk (from data sources: National Reporting and Learning System (www.nrls.npsa.nhs.uk) and other Serious and Untoward Incident reporting systems)
- There is existing national guidance and/or national safety recommendations on how the 'never event' can be prevented, along with support for implementation.
- The 'never event' is preventable if the national guidance and/or national safety recommendations are implemented
- Occurrence of the 'never event' can be easily identified, defined and measured on an ongoing basis

Some types of 'never events' hold high *potential* for significant harm to patients, and are designated as 'never events' regardless of the actual degree of harm that occurred.

We set out below the NHS England definitions of the two types of 'never events' reviewed in this report:

Wrong site surgery:

A surgical intervention performed on the wrong site (e.g., wrong knee, wrong eye, wrong patient, wrong limb, or wrong organ); the incident is detected at any time after the start of the operation and the patient requires further surgery, on the correct site, and/or may have complications following the wrong surgery.

- Includes biopsy, radiological procedures and drain insertion, where the intervention is considered surgical.
- Excludes wrong site anaesthetic block.
- 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.

Example: Case 1 – wrong-site surgery
A mechanical thrombectomy and angioplasty due to be performed on the right leg was carried out on the left leg. The patient subsequently had a further procedure on the correct leg under a second general anaesthetic later the same day.
What happened?

- *The patient's anatomy was such that the original planned procedure had to be changed requiring access from the other side*
- *The consent form was not completed correctly and was amended later*
- *It is unclear whether the WHO Checklist was used*
- *The side was not marked with permanent marker*
- *The doctor changed the method of the procedure from direct entry to entry from the other side and did not adequately communicate this with the theatre team.*

- *The consultant asked a nurse to turn the patient around but did not check this had happened*
- *The other staff present (radiologist, scrub nurse) did not speak up about the side*

Retained foreign object post-procedure:

Unintended retention of a foreign object in a patient after surgical intervention – including interventional radiology, cardiology and vaginal birth.

- Includes swabs, needles, implants, fragments of screws, instruments and guidewires.
- Excludes where any relevant objects are found to be missing prior to the completion of the surgical intervention and may be within the patient, but where further action to locate and/or retrieve would be more damaging than retention, or impossible. This must be documented in the patient's notes and the patient informed.

Example: Case 2 – retained foreign object

A swab was left inside a patient following a double renal transplant. The swab was discovered during a surgical follow-up procedure 4-months later, located 4-5cm from the upper transplanted kidney. It had not been picked up in a number of radiological tests that had been performed in the interim.

What happened?

- *There was a lot of blood loss during the initial procedure requiring a large number of swabs*
- *The swab count was incorrect*
- *There was a change in scrub practitioner between the first and final counts and the team did not perform an adequate swab count at this stage.*
- *The swab count policy does not specify any involvement or 'hands-off' by the surgical team when nursing staff swap over during a case*

How are 'never event' data generated?

In April 2013, NHS England became responsible for the 'never events' policy framework. Such incidents were previously collected by the National Reporting and Learning Service (NRLS) and STEIS systems by the Patient Safety Team at NHS England. Although efforts were made at each year's end to identify the number of 'never events' duplicated via both the

NRLS and STEIS, an accurate assessment of overlap (and therefore the total number of 'never events' reported to either or both systems) has historically been difficult.

To avoid this, any possible 'never events' reported via NRLS since April 2013 have been passed by NHS England to commissioners, who are asked to discuss with the relevant provider organisations and either establish that an incident was not actually a 'never event', or if it was to ensure that it is reported on the STEIS system. This process means that (once this confirmation has been received) STEIS can be considered as a reliable and complete data source for these incidents.

As of the 12th December 2013, provisional quarterly data on the number of 'never events' occurring at each hospital Trust in England are being published so that patients, healthcare professionals, managers, stakeholders and the public become aware and understand them. Until this change, data had been published only annually, and only at national, aggregated level. The new dataset is currently available on the NHS England website (www.england.nhs.uk) and will be updated monthly.

Recent Surgical 'Never Event' Data: England

<u>April-Sept 2013:</u> (NB: 6 monthly data collated by NHS England)

- 148 'never events' in total, 127 of which were surgical.
- Retained foreign objects = 69 (27 vaginal swabs/tampons, 11 surgical swabs, 4 throat packs)
- Wrong site surgeries = 37 (much more variable in type; most common was wrong tooth in dental procedures, n=4)
- Wrong implant/prosthesis = 21 (4 incorrect ophthalmic lens, 4 wrong knee prostheses)

<u>April 2012-March 31st 2013:</u> (NB: annual data from STEIS)

- 290 'never events' in total, 255 of which were surgical
- Retained foreign objects = 130 (47 vaginal swabs/tampons, 34 surgical swabs, 11 instruments)
- Wrong site surgeries = 83 (26 wrong side, 21 wrong tooth, 12 wrong procedure)
- Wrong implant/prosthesis = 42 (29 incorrect ophthalmic lens, 6 knee prostheses)

2. Methods

Incident investigation reports for surgical 'never events' occurring between April 1st 2012 and March 31st 2013 were requested from all London Trusts who had reported any by NHS England. At the time of writing of this report (March-May 2014), 10 Trusts had provided us with access to retained object reports (17 reports in total) and 4 Trusts had provided us with access to wrong-site surgery reports (6 reports in total).

The reports were analysed by 4 experts in patient safety (the authors of this report).

Each incident was summarised (see appendix for detail) and its contributory factors were identified using the 'London Protocol'.[2] This is a well-validated incident analysis framework, which adopts a systems view of error. Within the London Protocol, factors that contribute to errors/incidents are categorised as follows (see Table 1 for details):

- Institutional factors
- Organisational factors
- Work/environment factors
- Team factors
- Individual (staff) factors
- Task/technology factors
- Patient factors

We included contributory factors identified in the reports by the original investigators as well as factors that our analysis team identified and considered significant.

FACTOR TYPES	INFLUENCING CONTRIBUTORY FACTORS
Institutional Context	Economic and regulatory context National health service executive Clinical negligence scheme for trusts
Organisational and Management Factors	Financial resources & constraints Organisational structure 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 Administrative and managerial support
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 & seriousness) Language and communication Personality and social factors

Table 1. Factors contributing to errors and patient safety incidents based on the London Protocol

A similar analysis was carried out for the actions taken in response to the incidents (as recorded in the 'Actions' list within each of the reports). Since there is no existing framework for categorising post-incident actions, we reviewed all of the actions taken and grouped them into the following emergent themes:

- Reinforcement of existing practice
- Training and education
- Audit
- New/revised Trust policy/guideline
- New system/process
- Dissemination
- External report or investigation (e.g., MHRA)
- Investigation/action with individual/s involved

To ensure accuracy, reliability and comprehensiveness in the analysis and categorisation of contributing factors and actions taken, all reported incidents were first analysed by one member of the research team and subsequently cross-checked by a second member of the team, who had been kept blinded to the analysis until that point.

3. Findings

3.1. Contributory Factors

These were analysed using the framework presented in Table 1 above. In the following sections, we describe our findings regarding contributing factors for the retained foreign objects first, followed by the wrong-site procedures.

3.2. Retained objects: contributory factors

On average four different types of contributory factor per retained object incident were identified. Task/technology factors contributed to the majority (15/17) of the cases reviewed. Team and individual staff factors were also common (Figure 1).

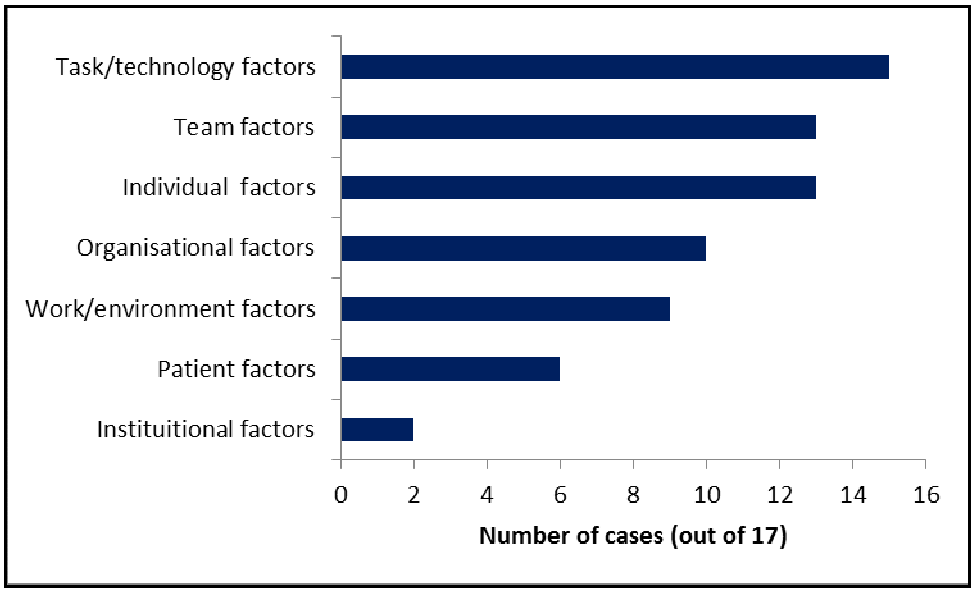

Figure 1: Contributory factors for retained objects – Frequency analysis

In what follows, we present a summary of the factors as analysed:

3.2.1. Institutional context factors

In one case it was recognised that there was no national guidance relating to guidewire removal despite it being recognised as a problem by the NPSA – this was considered to have contributed to the incident.

3.2.2. Organisation and management factors

The organisation and management factors included lack of training in policies and procedures or procedures not being embedded in every day practice. In one case a Trust policy was considered “aspirational” resulting in the policy never actually being followed. The organisational safety culture was also a problem in a number of instances.

Poor organisation/management of training was regularly identified as a contributory factor:

- Surgeons treated differently to the rest of the operating theatre team, thereby receiving no instruction/training in new swab count policy
- Agency midwife not familiar with new documentation in the Trust
- Trust training programme for line insertion not running due to training lead on maternity leave (and no alternative available)

Policy standards were an issue specifically in maternity services, with poorly embedded procedures being identified as contributing to incidents in a number of cases:

- WHO Checklist not embedded in maternity practice
- Guidance for perineal suturing not embedded in practice – especially swab count procedures and the need for good documentation

Safety culture was an issue in several cases where staff did not speak up or challenge others, often surgeons:

- Not challenging senior surgeons/doctors when they leave the patient without checking the swab count (this applied to nurses, midwives, trainee obstetricians and trainee surgeons)
- Failure to speak up when staff knew there is a swab missing but the surgeon was closing the skin
- Lack of leadership and ownership of the WHO Surgical Safety Checklist
- Failure to notify senior staff (consultant) when there were difficulties, e.g., obtaining the correct images and going ahead and closing when a swab is unaccounted for

3.2.3. Work environment factors

Environmental factors included ergonomic issues, related both to the design of instruments and also more broadly to the operating theatre layout. Instrument design was a factor in one case where the end of a proctoscope dislodged and remained inside the patient. In this case the equipment was reported to the MHRA as not fit for purpose. In other incidents the following factors were found:

- Poor design of equipment – vascaths and guidewires permitting guidewire to remain in-situ
- Poor design of theatre table prevented correct X-ray being taken
- View of white board obscured by theatre door
- No column on whiteboard for additional items to be recorded

Time pressure and interruptions/distractions were reported as environmental factors in several cases, e.g., surgeons and obstetricians having to finish cases quickly to get to another or for the theatre to be used for an emergency. The incorrect skills mix for the

complexity of procedures was recognised as a factor in incidents involving care delivery out of hours when staffing levels were sub-optimal.

- Numerous interruptions about cases of high acuity during the procedure – prioritisation of cases meant delay in carrying out perineal repair
- Exceptionally busy maternity unit
- Time pressure on theatre team due to emergency case needing that theatre
- CEPOD theatre busy so laparotomy to remove swab was not done until next day
- Managing multiple demands and high workload meant team leader was scrubbed for another case and could not act on missing swab until her case was completed
- No review of available staffing to manage the theatre over-run and nothing done to prevent staff changeover in the middle of the case that over-ran

3.2.4. Team factors

Team structure was an issue where there was staff movement and disruption during cases. This was a common contributory factor, particularly when there was insufficient time for a comprehensive handover with the surgeon involved – e.g., in cases that ran late when some staff had to leave to collect children from school:

- Staff disruption, nurses being moved or changed during cases with poor handover
- Poor planning for staff changes – some staff leaving mid-procedure with no chance for surgeon to pause for the count at the point of handover

Poorly defined responsibilities or lack of clarity over who was responsible for the final swab count also caused problems:

- Multiple doctors involved in a procedure with no-one thinking they were accountable for the final swab count
- Poorly defined responsibilities for when swab count is incorrect

Poor teamwork and non-technical skills were specifically identified as contributing to a number of cases. For instance, regarding leadership:

- Nurses accepted that line was not working for an extended period of time without escalating to the consultant
- Not speaking up (see safety culture under 'organisational and management' factors)

Further on teamworking, problems were identified regarding written and verbal communication:

- SpR inserted a tampon without communicating with theatre staff and did not use a clip to secure the tail so this was not visible

- Surgeon intentionally left swab inside patient for pressure but failed to tell anyone and did not document this
- No communication with theatre coordinator about planning staff for a late running theatre
- Confirmation written in the theatre care plan that swab count was correct when in reality it was not
- Poor overall documentation of care

3.2.5. Individual (staff) factors

There were many cases where the contributory factors related to the competence of individual members of staff, often due to poor communication skills, lack of training, poor documentation or leaving before a procedure was completed. The first group of these relate to swab counts:

Staff failing to comply with policies and procedures:

- Failure to comply with the swab count policy
- Failure to use new swab trays purchased to assist with counting

Staff leaving before checks completed:

- Failure to check swab count after suturing completed and doctor left before count checked
- Consultant left theatre and did not give instructions as to what to do if X-ray did not locate retained swab

Lack of knowledge and skills were often identified as a gap in training:

- Only the nurses were trained in the new swab count policy and even those trained were uncertain about some aspects of the new policy. The surgeons received no training or instruction.
- Staff joining the Trust outside normal start date missed training in swab count

Staff failing to check the completeness of equipment on withdrawal from a patient was a factor in several cases:

- Surgeon failed to check completeness of equipment inserted when withdrawn – disposable procto-scope used and part was left inside patient
- Poor knowledge – did not know what to do when line was not working properly
- Failure to check guidewire had been removed and failure to detect this on X-ray

In other cases, an individual's decision to use non-standard equipment (e.g., pads and packs) was found to have contributed to a retained object:

- Abdominal pads only used by one consultant – SpR had not used one before. Pad used but not put on the whiteboard for them to be counted.
- Misjudgement by surgeon in using non-standard nasal pack. Pack not secured to prevent patient swallowing it.

3.2.6. Task factors

A frequent issue with task-related contributing factors was a policy or procedure not being followed. In one case the nurses had been trained in the new swab count policy but none of the surgeons had received training. In maternity services the use of tampons was a particular problem with doctors not following policies or there not being a policy for counting and ensuring tampon removal. Some examples are listed below:

Availability of policies and procedures:

- No policies for use of tampons in maternity services – frequent issue
- No policy for involving the surgical team in the swab count handover between scrub nurses
- Procedures for swab counting out of date
- No policy for action after swab count incorrect but cannot find swab after imaging in theatre
- No clear escalation policy when instrument retained
- Guide wire removal – no line insertion checklist or protocol as to what to do if line isn't working properly – no visual, verbal or documentary process to confirm that guide wire has been removed – reliant on memory

Use of existing policies and procedures:

- Swab count policies not being followed – sometimes resulting in counts being recorded as correct when they were not
- Poor record keeping- illegible notes, lack of signatures etc
- Surgical counts not added to the white-board until staff shift change half way through the case
- Not following policy for antibiotic use following known retained swab

Improper and variable use of the WHO Surgical Safety Checklist was a common task related factor. At times the checks were omitted altogether (particularly at Sign-out, at the end of procedures); at other times individual team-members were missing when the checks were undertaken or checks were completed apparently without team awareness and/or focus:

- Failure to use the WHO Checklist with all present, particularly failure to sign out
- WHO Checklist in patients notes but entirely blank i.e. not completed

- Failure to comply with the locally adapted Checklist

There was clearly a problem with surgical procedures taking place in a non-theatre environment – e.g., in a delivery room or a radiology room. Often in these cases the usual swab count equipment is not available and staff were unclear how to proceed.

The over-reliance on X-rays to identify retained swabs was a contributory factor where these X-rays gave staff a false sense of security. There was also lack of awareness and policy around the actions that should be taken when a missing swab/instrument was identified.

3.2.7. Patient Factors

Six cases involved patient factors. These varied from anatomical issues to blood loss during surgery and unexpected problems requiring additional packs to those used in the planned procedure. Examples of these issues are set out here:

- A prolapsed cervix made it more difficult to identify a retained swab during a vaginal examination
- The nasal cavity had to be packed following surgery, this was unexpected and not part of the planned procedure

In one case the large amount of blood loss resulted in numerous swabs and packs being used during the procedure and the pressure of the situation led to the swab count going awry.

3.3. Wrong Site Surgery: contributory factors

On average there were 6 different types of contributory factor per case of wrong-site surgery. Team, individual staff, task and patient related factors accounted for most of our findings (Figure 2). Institutional factors did not contribute to any of the cases reviewed.

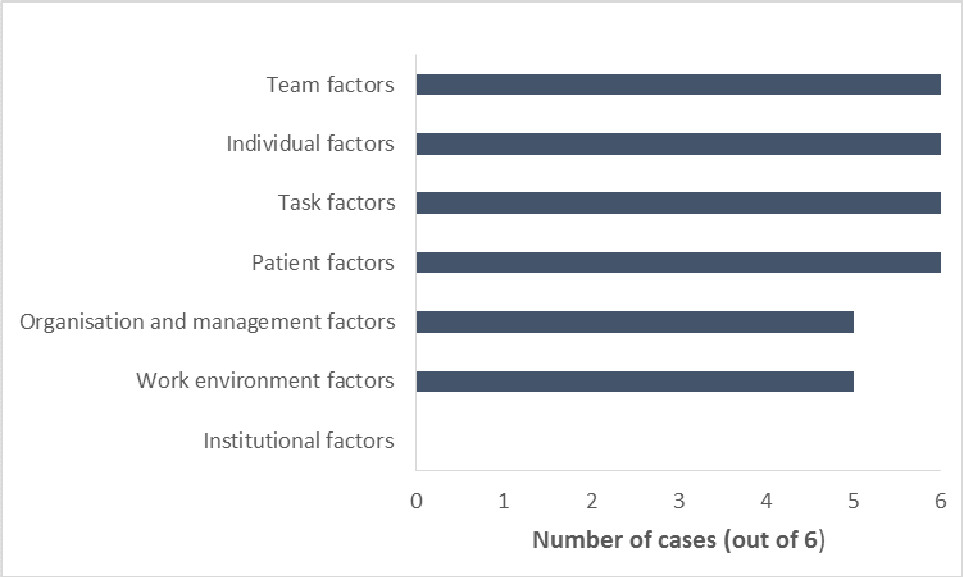

Figure 2: Contributory factors for wrong site surgery – Frequency analysis

A summary of the identified factors is presented in the sections below.

3.3.1. Institutional Context

There were no such factors found for these cases.

3.3.2. Organisation and management factors

Policy standards were an issue in dental services with a number of recommended checking procedures not being embedded in standard practice:

- The department's guidelines for performing minor oral surgery did not include the use of a pre-operative checklist

Lack of a proactive safety culture was a contributory factor in several of the cases, for example where staff did not speak up to ask about the side to be operated on. The lack of learning from previous similar incident was also a contributory factor related to safety

culture. In one particular case implementation of previous recommendations for counting the teeth prior to the procedure were 'patchy':

- Lack of learning from a previous similar incident 5 years prior to this one. The recommendation following the previous incident was to incorporate best practice in teeth counting prior to procedures but implementation in practice was patchy.

3.3.3. Work environment factors

Interruptions/distractions featured in 2 of the wrong site cases reviewed. In one case there were up to 13 staff-members present in the operating theatre prior to the case commencing. Not all of these were theatre staff and this added to the overall 'chaotic' feeling in the theatre:

- There were interruptions during the procedure which were a source of stress to the consultant undertaking the procedure

In another case, locating equipment contributed towards the chaotic environment:

- The equipment needed for this case was all available but staff had difficulty locating it as only one of the four paediatric nurses has experience of working in the emergency theatre. This meant that there was a lot of staff movement locating equipment prior to commencement of the case.

Time pressure was a clear problem in one case but interestingly it did not contribute to one of the other incidents (as specifically stated on the incident report form):

- The registrar usually has a second person check when marking the patient (although there is no Trust expectation for this); however due to the time critical nature of this surgery he did not on this occasion.
- No time pressure – list lighter than usual with one of four patients cancelled

Staffing levels and skills mix featured strongly in one case involving a paediatric patient requiring neurosurgery, where only adult trained staff were available and there was a lack of specialty specific experience:

- There was lack of nursing staff experienced in neurosurgical-trauma present at the time this incident occurred.
- The consultant anaesthetist was working with an operating department assistant and an anaesthetic registrar who were unfamiliar with paediatric patients, and so the consultant anaesthetist had to gather, draw up and mix drug infusions for the patient. This meant he was not in theatre at the point when 'time out' should have occurred.

3.3.4. Team factors

Poor team working in general was identified as a problem:

- During the incident there was lack of team working, with staff focusing on their own individual tasks without reference to colleagues

Poor communication was a specific problem underlying all of the wrong-site cases reviewed:

- The doctor changed the method of the procedure from direct entry to entry from the other side and did not adequately communicate this with the theatre team.
- The consultant asked a nurse to turn the patient round but didn't check this had happened when returning to undertake the procedure
- Theatre staff did not receive any communication that the patient was on the way to theatres from A&E; this meant that the time available for them to prepare for the case was very limited.
- There was not a clear handover of the patient to the paediatric theatre staff with regards to the patient and his injury
- The white board discussion in the morning was informal and did not lead to an update on the board of the clinical decisions

Written communication was also a problem. Documentation was commonly of poor quality, inaccurate or absent:

- The consent form was not filled in correctly and was then amended which should not have happened.
- WHO Checklist incorrectly said 'site marking not applicable'
- Failure of staff to plot MEWs scores which would have stimulated escalation and review of her condition several times.
- Poor documentation throughout – no timed entries in notes and illegible signatures.
- Abbreviating the side of the procedure on consent form
- No written consent in place
- The white board in theatre was not updated following Consultant A's discussion with the renal team confirming a Liver biopsy was required

Another aspect of teamwork, poor leadership, was a contributory factor in a number of cases. Usually this involved senior team members being absent. In two cases no consultant surgeon was present to deal with critically ill patients. Appropriate nursing leadership was also lacking in a number of cases:

- There was no clear nurse in charge or nursing leadership in the operating theatre during the set up for the case which meant that overall coordination of the theatre was not managed.

- The consultant surgeon was not present during the procedure – there was confusion over the account of why. An SHO started the procedure – it should have been a more senior surgeon, if not the consultant, given that she (i.e. patient) was pregnant
- The adult theatre co-ordinator did not take the lead in the absence of a specified paediatric nurse in charge due to the fact that this was a paediatric case.

Further, ill-defined team structure and poor coordination between different care-teams was identified in three of the cases. For example, in one case involving a pregnant lady requiring surgery, there was a profound lack of clarity around the appropriate involvement of both the obstetric and surgical teams:

- The adult nursing team clearly saw this as a paediatric case and had limited involvement even though they had more experience with emergency neurosurgical cases.
- Lack of clarity between obstetric and surgical teams as to who was following up Mrs A. Surgeons left obstetricians to lead on surgical management. The fact that she was seen on the obstetric ward as a surgical 'outlier' meant that no consultant took overall control of her care.
- Two separate interventional teams were in charge of the patient during the same day. No formal handover occurred.

3.3.5. Individual (staff) factors

Problems involving an individual member of staff often focused on inadequate knowledge, skills and/or experience, resulting in poor decision making:

- Failure to identify a plausible differential diagnosis on first admission (thrush was diagnosed which was at odds with patient presentation). Poor notes by SHO did not document concerns.
- Mrs A was discharged despite still having tachycardia
- The paediatric theatre co-ordinator on duty was new to paediatrics and had little paediatric trauma experience.

Sometimes this was a result of the most-appropriate member of staff not being willing or able to participate in the case:

- The most experienced paediatric theatre nurse (band 5) present refused to scrub for this case even though she had been instructed to do so by the band 6 adult theatre co-ordinator. She instead allocated a junior and inexperienced nurse to scrub.

The doctor's physical and mental health was a factor in one of the cases reviewed:

- Operating Dr (DFY2) had recent bereavement and incident review implied loss of confidence

Active mistakes and lapses also occurred:

- The incorrect site was marked by the neurosurgical registrar
- Details of the patient's requirement for a liver biopsy to be carried out first (rather than renal) were documented in the patient's written record; however this record were not consulted prior to consent being taken for the renal biopsy.

3.3.6. Task factors

Availability of protocols and procedures was a problem, particularly in dental cases. There was a clear lack of protocol with regards to marking the side and tooth/teeth to be extracted and double-checking the correct tooth with an assistant. Furthermore, the use of safety checklists within dental surgery is not standard – which was mentioned as a contributor. Examples of lacking protocols/procedures include:

- There was no procedure for marking the side/site
- No protocol or procedure for reporting wrong site/wrong tissue or organ removal or unexpected findings by histopathology to consultant in charge of the patients care.
- No checklist in place in the department
- No double-checking in place (which is also ergonomically difficult, as only the doctor had adequate view of teeth to be operate on)
- No formal 'counting teeth out loud' protocol in place

In one general surgery case in which an ovary had been removed instead of an appendix, the histologists recorded the event days before it was communicated to the clinical team managing the patient. This was due to a lack of a procedure for doing so.

More commonly, protocols and policies were in place, but were not used in the intended manner. This was particularly the case with regards to use of the WHO Surgical Safety Checklist (which was not used in 4/6 cases of wrong site surgery we analysed, and was used inappropriately in 1/6 cases). Marking of the surgical site, despite being a long standing practice in certain specialties, was also omitted at times:

- The 'Time out' section of the WHO Checklist (immediately prior to incision) was not completed as per policy prior to the initial incision being made.
- There was no pre-procedure pause to check the side with others present
- Side of the procedure not marked
- The side was not marked with a permanent marker
- There were assumptions made by many members of the team that the 'Time out' had been completed when they were not present in the operating theatre

3.3.7. Patient factors

Patient factors played a role in all six of the wrong-site surgeries reviewed. These included unusual anatomy (which meant that the patient's position had to be changed potentially contributing towards the wrong side being operated on), critical condition (meaning that the team were operating under stressful conditions) and the patient needing more than one procedure. In one case, the patient actually consented to the wrong procedure being performed:

- The patient's anatomy was such that the original planned procedure had to be changed requiring a different entry point
- Patient was pregnant and had appendicitis.
- UL6 and UL7 looked clinically very similar (dental surgery incident)
- Food remnants on right tonsil making pathology difficult to see
- The patient was critically unwell and unstable as a result the team were working in a highly stressed situation
- The patient had a complicated clinical history with lesions in both the kidney and liver. The patient's clinical presentation supported the need for a renal biopsy.
- The patient gave informed consent for a renal biopsy prior to the procedure.

3.4. Summary and recommendations

Human Factors-related problems

Our analysis of these surgical 'never events' across London NHS Trusts highlights firstly that these incidents are multifactorial in nature and secondly that there are some commonalities in the factors identified as contributing to these incidents – many of which reflect key human factors failures:

- **Failures in teamworking**, including verbal and written communication and leadership. These contributed to problems being created or being identified by some members of clinical teams but ignored by others, and thus not resolved before reaching the patient.
- Specific communication failures including **failure to 'speak up', poor handovers of care, and failure to openly communicate with other members of the multidisciplinary team** (e.g., nurses communicating with doctors, or trainee doctors communicating with their consultants)
- **Failure to appropriately use evidence-based interventions** that can prevent wrong site procedures and retained objects – the WHO Checklist was a good example. The Checklist was introduced in the NHS in 2009 with intended 'full implementation' by 2010;[3] however, it is often carried out in a 'tick-box' manner (i.e., the focus being on

getting the form filled in rather than conducting a team safety discussion in the spirit intended) or not at all,[4] or it is not applied within areas where interventions are taking place but are not designated as 'operating theatres'.

- **Time pressure, lack of adequate staffing levels, and interruptions/distractions within clinical areas** while care is being provided were all linked to a higher likelihood of protocols or best practice not being used at all or not being used appropriately.

We also found **systemic organisational contributions, including lack of a proactive safety culture**. These organisational failures include treating different staff members differently; and relying on external/agency staff without ensuring that they can work safely and consistently with best practice and organisational standards.

There are also lessons to be learnt that are specific to each type of incident analysed – we review these below.

Recommendations stemming from wrong site procedures

Regarding wrong site procedures, multiple doctors/teams involved with a patient is a risk factor – due to numerous handovers required, which increase the risk of information loss. Surgical site marking[5] and double-checking[6] are good practices, but in some places they are not implemented or are likely to be skipped if under time pressure or due to lack of staff – which adds a risk factor for wrong site procedures.

Recommendations that emerge from our analyses include the following:

- **Surgical site marking** should always be performed and double checked
- **Proactive and coordinated surgical and nursing leadership** at the start of a case is critical (including in conducting the WHO Checklist 'Time out' part appropriately)
- **Dental procedures require review and improvement – to include standard procedures** for marking and consenting patients

Recommendations stemming from retained objects

Regarding retained objects, a key risk factor is the usefulness and use of available protocols. We identified 'non-compliance' with protocols as a contributor to the incidents – however, some of the protocols appeared not applicable or confusing. For obstetric cases, clarification of whether tampons are to be considered swabs is required – so it becomes clear that counting protocols apply to them too. On some occasions a protocol was lacking (e.g., regarding what to do once a retained object had been identified or how to treat guide-

wires). Other risk factors that emerged for retained objects included shift handovers mid-procedure, which appears to significantly increase retained object risk; poor equipment design and poor layout of workspace (e.g., of the operating theatre), and finally the abundance of interruptions which can distract a team.

Recommendations that emerge from this type of incident include:

- **National guidance on guidewire removal** is required
- **Tampons should be considered swabs** and treated in the same manner in all settings (i.e., similar counting protocols applied)
- **Training of new staff members and agency staff in safety critical policies and procedures** should be routinely and uniformly provided before they start work
- **Harmonising swab count policies across London Trusts** would reduce the risk associated with temporary staff being unfamiliar with these policies in the different hospitals they work in
- Avoidance of retained swabs is not just a nurse's responsibility; **correct and documented swab counting should involve and be owned by the entire team** and this should be reflected in policies and procedures and associated training
- **The operating/senior surgeon should not leave theatre prior to counts being completed and the WHO Checklist 'Sign out' part being carried out** appropriately
- **Non-standard equipment should not be used** unless the whole team are comfortable with its use and staff are appropriately trained in its use

4. Actions taken by trusts following a 'Never Event'

In this section, we summarise the reported actions taken by trusts following both retained objects and wrong-site surgeries.

All investigation reports included an action plan. The general format for these was to re-list each of the recommendations from the investigation and to assign in a column next to it the corresponding action/s to be taken for achieving the improvement. Most reports also listed the member/s of staff accountable, the due date for action completion, and the action's priority status. Some also included a confirmed completion date and a description of the outcome measure (i.e., how it will be evident that the action was completed); however, the latter were usually limited to there being immediate evidence for the action rather than any measurable impact on service provision – e.g., '*the discussion will be reflected in the minutes of the meeting*' or '*the theatre board will have been moved*'. In other reports it was not mentioned at all if, when or how completion of the actions would be ascertained.

The most common actions across both retained objects (Figure 3) and wrong site surgery incidents (Figure 4) were dissemination and reinforcing current practice. Interestingly, in only six of the 23 cases was it recorded that the patient or family were to be given a copy of the report or contacted after the investigation.

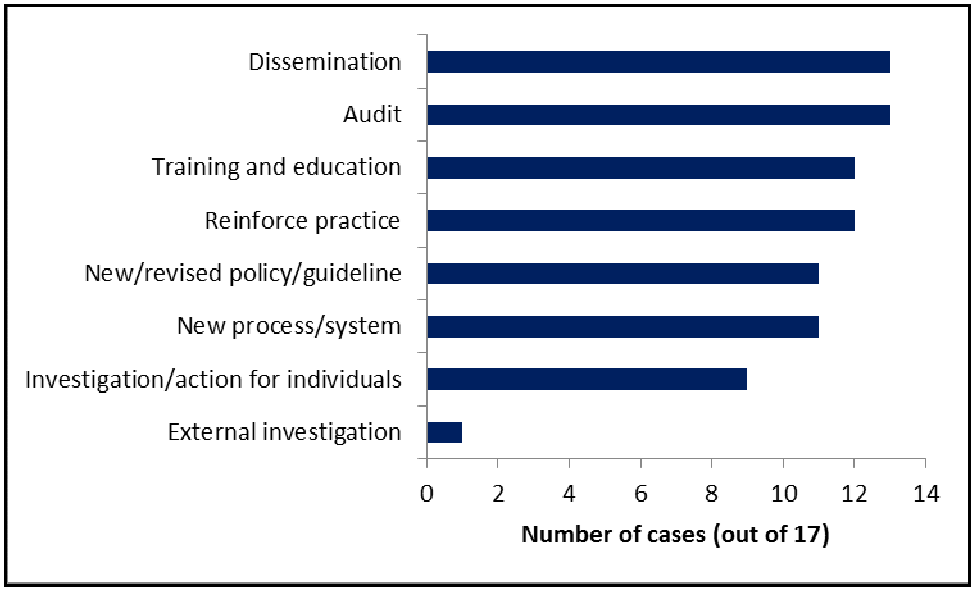

Figure 3: Actions following investigations of retained objects incidents – Frequency analysis

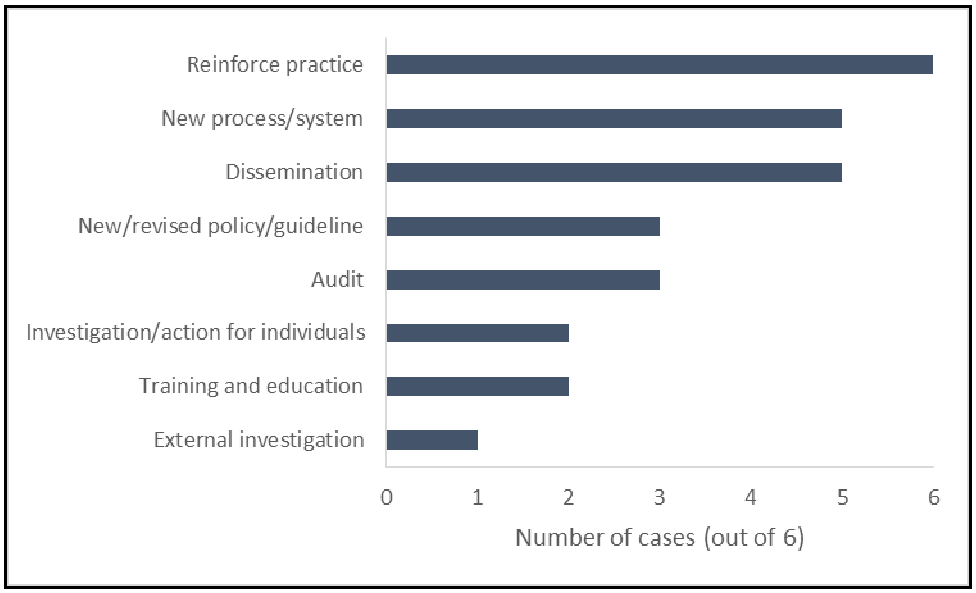

Figure 4: Actions following investigations of wrong site surgery incidents – Frequency analysis

In what follows, we summarise and comment on the 'action' categories that we found in the reports:

4.1. Reinforce practice

Frustration was discernible in the investigation reports where staff had failed to follow a policy or procedure. The response to this was often to reinforce practice without being clear about how this would be done or who would do it, for example '*reinforce antibiotic use following retained swab*' or '*multidisciplinary approach to be reinforced throughout unit - with focus on planning, consenting and checking*'. There were also statements in the action plans saying for example '*embed WHO Checklist*' and '*Safe Surgery Checklist must be completed and filed in the notes*' and '*no surgeon is to undertake the procedure unless trained by the designated Consultant Colorectal Surgeon*'.

Learning points were included in some reports but these did not then appear in the action plans. For example in one report it was stated: '*staff handovers should be agreed in advance with the team to ensure they are carried out at a convenient time to pause for the swab count*' but no specific action was listed in the follow up action plan to enable this to happen. There were further similar examples of this pattern – including:

Asking staff to read policies:

- All staff to confirm they have read and understood new policy

- Written confirmation from every surgeon and obstetrician that they have read (or been trained in) the new policy

Asking for practice to be reinforced with no-one responsible for doing this and no methods given:

- Reinforce new swab counting procedure in email and newsletters
- Reinforce antibiotic use following retained swab
- Reinforce need for immediate X-ray if line not functioning correctly
- Reinforce the need not to use abbreviations in laterality of site of marking
- Where there has been a wrong site or wrong procedure, an incident form must be filled in.
- Counting (teeth) aloud should be reinforced as standard practice
- The whiteboard discussions/safety briefing held each morning must include a formal review of the procedures to be carried out and assurance given that the procedure documented on the board accurately reflects the procedure to be carried out

Recommending further staff instruction:

- Everyone will be instructed that use of non-standard nasal packs is not acceptable practice
- All staff using this equipment must be made aware of the fact that the end can come off and be retained in the patient
- Theatre manager to reiterate to all theatre staff the need for clear communication and documentation
- Inform all staff that perform suturing that they are responsible for swabs before, during and after the procedure (unclear who would do this)
- There must be clear communication to all theatre users of this accountability and a reminder that there is an overall team responsibility for ensuring that each section of the checklist is completed for every case

4.2. Training and education

Training and education was a common action to prevent recurrence of the 'never events', particularly those involving retained objects. In several cases there was feedback directly to individuals with the offer of educational support and training where necessary.

In one case the CEO, medical director and nursing director were asked to discuss how to support and develop clinical leadership in practice, with consideration of employing an external mentoring service for consultants.

In terms of formal training, one case was used as a practical example during training sessions. Following another incident, the swab count policy was built into simulation drills based training for specific groups of staff, whilst in another Trust the swab count policy was introduced into the mandatory training for all staff. The following give other examples:

- Include a section on swab counting and communications between midwives and doctors in risk management training
- Trust training and education on central venous catheters to emphasis appropriate control of guidewires, not just infection prevention. New formal training to include a two-person process with verbal and visual confirmation of guidewire removal.

Assessing staff competence:

- All maternity staff to complete and return an assessment of the count policy to ensure they understand it

Local induction training:

- All staff, regardless of start date to attend local induction that includes education about the swab count policy and to sign a local induction checklist to say they understand and will comply with the policy
- Add section into medical staff induction book on swab count
- More formalised induction week for junior doctors including asking them to observe good counting practices
- All directorates must address the expected standards of documentation as part of induction and mandatory training
- Better working relationships and practices could be fostered by the inclusion of obstetric anaesthetists on mandatory training sessions and emergency skills/drills training and by having joint rounds, especially on labour ward and HDU.

4.3. Audit

Forms of audit and checking were often introduced to ensure that practice matches policy on an ongoing basis. This was less about “putting things right” and more about checking that things were being done appropriately on an ongoing basis. In one case there was a wider review of variation in practice of swab usage and counting within a maternity service. The following give examples of the types of audits introduced following the ‘never events’:

- Audit of maternity documentation regarding swab count
- Regular audits of compliance with WHO Checklist and swab count policy
- Ongoing audit and spot checks of swab counting/checking procedures

- Ongoing monthly audit of swab counts and documentation accuracy following episiotomy
- Audit 40 sets of notes regarding perineal repair documentation both in theatre and on delivery suite to provide assurance of compliance with guideline
- Theatre manager and education nurse to perform regular spot checks of nursing documentation.
- Audit of radiology consent forms
- Audit of the use of the WHO Checklist in radiology Department
- Adoption of the Adult emergency services: Acute medicine and emergency general surgery Commissioning Standards – once implemented performance against the standards should be audited and action plans drawn up to tackle any shortfalls
- Undertake audit to ensure site marking policy implemented and practiced
- Audit of documentation to ensure no abbreviations used in laterality of site marking

4.4. New or revised Trust policy or guideline

New policies or guidelines were often introduced or existing ones were revised. In one case the WHO Checklist was adapted and re-launched with the inclusion of a final 'Sign out' to be confirmed by the scrub nurse and operating surgeon. A new checklist was introduced in one organisation to resolve the problem of a retained guidewire following a CV line insertion and a working group was set up to look at line insertion training and assessment

Standard operating procedures were often introduced to clarify roles and responsibilities, e.g., what should happen following the discovery of a missing swab. The following give examples of new policies and guidelines introduced as a response to a 'never event':

- Theatre count policy to be reviewed and updated, to include clearly defined responsibilities for decision making, actions and documentation requirements needed in a situation when a swab, instrument or needle remains unaccounted for following X-ray imaging
- Amend maternity services protocol to explicitly state that the doctor who performs the suturing is responsible for final correct swab count
- New maternity adapted count policy to be implemented and include instructions for tampon use
- Develop structured handover guidance in the revised maternity swab count policy
- The laboratory SOP's (standard operating procedures) should reflect the need to relay crucial clinical information to clinical teams in a timely manner when they impact on a patients care and treatment. There should be an agreed protocol of when to contact clinicians about an unexpected result.
- Correct surgical site marking policy to be written

4.5. New systems and processes

Further to policies, a range of new systems and processes were introduced in organisations to address some of the contributory factors, particularly in response to wrong site surgeries. These were notable in maternity services, where several Trusts recognised the need to bring maternity services into line with the policies and procedures they have in theatres and to introduce new systems for swab counts in delivery rooms.

In terms of redesigning systems, whiteboards were put in all delivery rooms in one Trust and elsewhere those that could not be seen during procedures were moved. In one Trust all tampons and small swabs were removed from the delivery and suture packs in the maternity unit to force a change in practice. Forms and notes were also altered to leave space for double checking and signatures following swab counts. Other examples include:

- Review approval process for changes in theatre lists to include late starts and over runs in theatre, develop a standard operating procedure as required
- Format of the 'Record of Perineal Repair/Trauma' proforma documentation to be amended to highlight tampon use
- Develop new flowchart for checking processes, to make current procedure very explicit to all staff
- New escalation process if there is any deviation in practice

For site marking the use of indelible markers was introduced and made mandatory – e.g., in interventional radiology suites.

4.6. Dissemination

Methods for wide dissemination of the investigation findings were listed in the action plans of 18 of the 23 cases that we reviewed. Often this specified how this should be done – e.g., through audit days, multi-disciplinary team meetings (MDT's) and governance meetings. In some cases the investigation report was anonymised and circulated to the team. Newsletters, emails, letters to staff-members and the use of Trust intranet were all modes employed for dissemination.

Some examples of dissemination plans include:

Within obstetrics/midwifery:

- Midwifery lead to discuss the findings of the investigation and reflection of involvement
- Clarify and communicate across sites the clinical indicators for the use of tampons

Within operating theatres:

- Relevant divisions to identify appropriate MDT or audit meetings for the theatre Practice Educators to attend and present the changes to the swab count policy
- Theatre Practice Educators to present the changes to the swab count policy to Divisions MDT or audit meetings when requested by the divisions
- The incident and recommendation will be shared at the multi professional theatre meeting and the divisional quality and risk meeting. Wider learning will be undertaken via the Trust Clinical Quality and Risk Committee.

4.7. External investigation

In one case, the equipment failure that was identified as part of the 'never event' was reported to the MHRA and the manufacturer. Another case resulted in a comprehensive external review.

4.8. Investigation or actions with individuals involved

In a number of cases there was further action taken with the individuals involved. This included a formal investigation of the practice of all nursing staff involved in an incident and a formal investigation of the practice of all surgical staff involved. Often the action was to feedback to the individuals and offer support from educational or other supervisors – some examples:

- All staff involved in this case to be referred to their educational supervisor, line manager or similar to discuss expected standards and identify any training deficits. Learning plans should be audited.
- Surgical registrars to meet with their educational supervisors to discuss the report of the case, in particular their standards of record keeping and engagement in the governance process.
- It is recommended that a debrief session is held, facilitated by one of the lead investigators, with all staff involved in this incident

In one case there was action taken when two members of staff, including a consultant, failed to engage in the incident investigation.

4.9. Summary and recommendations

The practice of including an 'action plan' should be part of all comprehensive incident investigations and is standard across industries outside healthcare: without a list of specific

actions it is unclear how, and unlikely that, any recommendations will be satisfied and benefits to care delivery will be achieved. A positive finding of our analysis was that action plans were included as a component of all 23 incident reports that we reviewed. We did, however, identify some areas for improvement. Further, some of the actions were proactive and specific. These included revisions and additions to policies and guidelines where insufficiencies were identified; the development of new processes (e.g., better documentation or new processes for escalating care); and training and education (whether ensuring all mandatory training had been completed or making additions to training programmes to address the weaknesses detected).

Overall, however, we found that the 'actions' included within incident reports were often weaker than the root cause analysis itself. One of the main failures was the use of the conditional tense and firm statements. Many actions fell into the category of 'reinforcement of practice' and would be described as 'statements' rather than 'actions'. For example, reports often stated '*there should be a clear process governing who is responsible for x, y or z' or 'a new system is needed for x, y or z*' or '*all nursing staff should be reminded to read the policy around x, y or z'*. It may be that the investigation report is being used to make recommendations for action to be approved before an action plan that can be delivered is put in place. In this case this should be clearly set out to avoid confusion. Exhorting staff to read a policy or instructing them that certain things are unacceptable may work in the short term but is unlikely to be sustainable in the long term. Interestingly, one report included several statements saying that certain things should be considered, such as '*consider adoption of written consent and WHO Checklist*' – this was surprising given that the Checklist should have been in place already at the time of the incident/investigation.

Audits were a popular response, but it was often unclear how these data would be utilised or fed-back to management and/or the frontline. Moreover, audits tended to be somewhat limited in scope – generally limited to recording *if* processes/guidelines were being utilised as opposed to *how* they were being utilised. Audits that assess the quality of the implementation of processes/policies rather than recording in a binary fashion whether they are 'being used or not' are more informative. For example, with regards to the WHO Checklist, tools are available for assessing the quality of its use (over and above the simplistic 'was it done' question) which can provide more information regarding problematic areas, barriers to use or indeed strengths. Such audits usually provide more instructive and influential data for feeding back to frontline clinical groups and management.

Looking across all incidents, the approach to generating action plans appeared to be more geared towards addressing weaknesses and deficiencies in the *system* rather than blaming or taking punitive action towards *individuals* (aside from the occasional cases where

individual members of staff were clearly in breach of expected professional behaviour or had demonstrated a marked deficiency in knowledge/skill). This is encouraging and demonstrates the evolution of a 'systems approach' within healthcare that avoids individual blame and assesses system-wide influences on error.[7] It was also encouraging that dissemination of the incident reports featured highly on the list of actions for most of the report we analysed – organisational learning remains a weakness in healthcare and only through effective dissemination within a hospital can this start to change. Various different modes of dissemination were listed, ranging from the circulation of emails and newsletters through to sharing the incident and learning at audit days or at inter-disciplinary forums. In our experience the latter should be favoured given that emails and letters are frequently ignored and verbal feedback tends to generate more scope for discussion and debate.

Importantly, while dissemination within hospital Trusts was being demonstrated, we would highlight the lack of explicit sharing with patients and relatives from the action plans that we reviewed – a finding that replicates national data in England.[8] Seeing that adverse events are being investigated and lessons are being learnt is a big part of the processes of acceptance and recovery for patients. Hospitals have a duty of care to patients who have been involved in 'never events' , and also to their families or carers, to explain what happened and why and to share the action plan that ought to stop a similar incident from happening again in the future. 'Never events' and patient safety incidents leave patients psychologically vulnerable or traumatised,[9] and the response process on the part of the Trust ought to acknowledge and address this. The response process should always include addressing the patient's needs and identify who and how should do this.

A final observation was that actions plans were weak in areas with regards to their measurability. For example, intended impacts on care delivery were poorly described and it was often unclear whether 'completion dates' had been met. It was also unclear how many of the actions were going to be monitored, and, particularly with regard to the introduction of 'new systems or processes', how potential negative effects as well as positive effects would be captured and evaluated. There is clearly an issue here for further work in NHS Trusts to help with plans to implement and monitor change over time and not as a 'one-off' reaction to a serious incident.

Our summary recommendations based on our review of action plans are as follows:

- Actions should be *SMART* (Specific, Measureable, Assignable (to an individual or group of people), Realistic and Time-related (i.e., a completion date is assigned and monitored)
- Audits should focus on the 'how' as well as the 'if' – i.e., measuring the quality of implementation of procedures/processes, not just compliance vs non-compliance.
- It should be specified how audit data will be utilised and fed back to frontline staff-members.
- A 'systems approach' should remain the central premise on which investigation reports are structured, and this should be made clear across the organisation to foster a culture for reporting and learning from 'never events'.
- Dissemination should remain a focus; wherever Trusts opt for emails/newsletters, these should be reinforced with verbal feedback during inter-disciplinary meetings to generate discussion and accelerate learning.
- Investigation reports should be shared with patients to allow a sense of 'closure' for the patients/families involved in a 'never event' (if necessary a modified version of the report can be provided).
- It should be made clear in specific terms on the incident report form how an action will be monitored and its completion recorded.
- Where it is necessary to reinforce practice the approach to achieving this should be made explicit; how this is expected to address the problem and drive change should be thought out and described (such that actions are not 'knee-jerk' reactions). These responses should be accompanied by longer-term strategies for improvement.
- Action plans should be tailored to address issues at all levels of the organisation rather than focusing solely on frontline care.

5. Conclusions

The events analysed in this report demonstrate that patient safety needs to be tackled across a NHS organisation at all levels and in all departments.

Beyond our specific recommendations earlier, this report highlights a number of 'systems issues' that require reflection and a measured ongoing response and review – including:

- Equipment purchase and use
- Information and records management
- Job plans, protocols and procedures
- The work environment (especially where invasive procedures take place)
- Work design (e.g., staff breaks and interruptions)
- Teamworking and team culture throughout an organisation – including within and between clinical teams and units
- Communication – staff to patient; between teams and staff groups; and with management
- Organisational issues (such as unrealistic expectations, staffing levels, staff skills mix (especially in relation to temporary staff), time pressure and heavy workloads)

Overall, the majority of the global human factors issues as well as the more incident-specific problems highlighted by these incidents are not novel – they have been raised before in incident investigations, and they have been extensively investigated in the past decade, both in the UK and internationally. For some of them there is a vast evidence base that covers a number of specialities. The contribution of these factors to the incidents analysed here shows how catastrophic they can be on a 'bad day' – i.e., when multiple factors align and harm reaches the patient before it can be stopped. There is an extensive evidence base on the effectiveness of some key interventions that we have recommended (including the WHO Checklist, when correctly applied) and an emerging evidence base indicating other interventions for the future (e.g., limitations of unnecessary interruptions during procedures).

All of the above suggests that there are well identified solutions that can be put into place – or that should already be in place. We take the view that the way that some of these interventions have historically been applied within the NHS has been rather thoughtless, often 'top down' and without taking into account professional sensitivities and pride.[11] A

checklist, no matter how well-designed, or intentioned, appearing one day within an operating theatre with the expectation that it will be used appropriately and it will stop wrong site 'never events' is one such example – but there are many others.

There is currently a wealth of information available about human factors and about how to change and improve clinical and organisational systems and we recommend that this literature/evidence is considered together with the recommendations made in this report in order for NHS England, London Region, to develop a systems-wide approach to improving patient safety across the capital.

We would further argue that whereas a decade ago we faced an 'evidence gap' we are now beyond this point – we are now facing an 'implementation gap' – whereby we know how to improve care and safety, yet the implementation of patient safety interventions is poor and as such detrimental to their effectiveness. Some of the key recommendations of this report, including all of those relating to global human factors issues, are fundamentally behavioural and attitudinal – in other words, they require some change in behaviour. For this to be done effectively senior organisational leadership is required. This practically means that there needs to be good and open communication between the management and the frontline and a shared building of the organisational priorities. This also requires adequate vision within NHS organisations beyond immediate funding concerns that allows time to train, develop and retain staff-members.

Summary of requirements & recommendations

Wrong site procedures:

- Surgical site marking should always be performed and double-checked
- Proactive and coordinated surgical and nursing leadership at the start of a case is critical (including in conducting the WHO Checklist 'Time out' part appropriately)
- Dental procedures require review and improvement – to include standard procedures for marking and consenting patients

Retained instruments:

- National guidance on guidewire removal is required
- Tampons should be considered swabs and treated in the same manner in all settings (i.e., similar counting protocols applied)
- Training of new staff members and agency staff in safety critical policies and procedures should be routinely and uniformly provided before they start work
- Harmonising swab count policies across Trusts would reduce the risk associated with temporary staff being unfamiliar with these policies in the different hospitals they work in
- Avoidance of retained swabs is not just a nurse's responsibility; correct and documented swab counting should involve and be owned by the entire team and this should be reflected in policies and procedures and associated training
- The operating/senior surgeon should not leave theatre prior to counts being completed and the WHO Checklist 'Sign out' part being carried out appropriately
- Non-standard equipment should not be used unless the whole team are comfortable with its use and staff are appropriately trained in its use

Incident investigation reports and actions:

- Actions should be SMART (Specific, Measureable, Assignable (to an individual or group of people), Realistic and Time-related (i.e., a completion date is assigned and monitored)
- Audits should focus on the 'how' as well as the 'if' – i.e., measuring the quality of

implementation of procedures/processes, not just compliance vs non-compliance.

- It should be specified how audit data will be utilised and fed back to frontline staff-members.

- A 'systems approach' should remain the central premise on which investigation reports are structured, and this should be made clear across the organisation to foster a culture for reporting and learning from 'never events'.

- Dissemination should remain a focus; wherever Trusts opt for emails/newsletters, these should be reinforced with verbal feedback during inter-disciplinary meetings to generate discussion and accelerate learning.

- Investigation reports should be shared with patients to allow a sense of 'closure' for the patients/families involved in a 'never event' (if necessary a modified version of the report can be provided).

- It should be made clear in specific terms on the incident report form how an action will be monitored and its completion recorded.

- Where it is necessary to reinforce practice the approach to achieving this should be made explicit; how this is expected to address the problem and drive change should be thought out and described (such that actions are not 'knee-jerk' reactions). These responses should be accompanied by longer-term strategies for improvement.

- Action plans should be tailored to address issues at all levels of the organisation rather than focusing solely on frontline care.

Overall recommendation:

There is currently a wealth of information available about human factors and about how to change and improve clinical and organisational systems.

We strongly recommend that this literature/evidence be considered, together with the recommendations made in this report, in order for NHS England, London Region, to develop a systems-wide approach to improving patient safety across the capital.

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APPENDIX

Case Summaries: Retained Objects

Case 1.
An abdominal pad was left inside a patient following an elective Total Abdominal Hysterectomy and Bilateral-Salpingo-Oophrectomy. The SpR who performed the procedure realised what had happened when writing the operation notes. The patient was brought back to theatre from recovery, re-opened and the pad was removed.
What happened?

- *The WHO Surgical Safety Checklist was not used at any point.*
- *The swab count was not written on the theatre white board until a new circulating nurse joined the team mid-way through the procedure. She was unaware an abdominal pad had been used and therefore did not add it to the count.*
- *Use of abdominal pads is not standard for this procedure but was requested by the consultant. The SpR had never used an abdominal pad before.*
- *The use of an abdominal pad was poorly communicated throughout the team.*
- *The swab count procedure was out of date*

Case 2.
A swab was left inside a patient following a double renal transplant. The swab was discovered during a surgical follow-up procedure 4-months later, located 4-5cm from the upper transplanted kidney. It had not been picked up in a number of radiological tests that had been performed in the interim.
What happened?

- *There was a lot of blood loss during the initial procedure requiring a large number of swabs*
- *The swab count was incorrect*
- *There was a change in scrub practitioner between the first and final counts and the team did not perform an adequate swab count at this stage.*
- *The swab count policy does not specify any involvement or 'hands-off' by the surgical team when nursing staff swap over during a case*

Case 3.
A tampon was left in a patient following an instrumental delivery with episiotomy. Five days later she told the community midwife that she had felt unwell following the delivery and had removed a tampon after feeling something congested within her vagina. The midwife alerted the hospital and the woman was put on antibiotics.
What happened?

- *A pre and post suturing swab count was completed but not signed by both healthcare professionals present*
- *The member of medical staff involved reported poor documentation*
- *Guidance for perineal suturing is not embedded in the practice of midwives and doctors*
- *Role definitions were poorly clarified and understood.*

Case 4.
A nasal pack was swallowed by a patient following an elective procedure of the post nasal space. When the patient was examined in recovery with the intention of removing the pack, it was no longer visible and it was confirmed that it had not been removed. Immediate chest x-ray and nasal endoscopy, and a later head and neck x-ray the next day following discharge could not locate the pack. Radiological review of the chest x-ray later confirmed that the nasal pack had been swallowed. The patient was informed and a follow-up abdominal x-ray arranged.
What happened?

- *There was a lot of bleeding and an unexpected requirement to pack the nasal cavity following biopsy*
- *A non-standard nasal pack was used. There was misjudgement around this decision by the Consultant ENT surgeon and a lack of challenge by theatre nurses.*
- *The pack was not adequately secured to prevent the patient from swallowing it*
- There was inadequate handover between theatre and recovery nurses.

Case 5.
A right internal jugular vein guide-wire was retained in a patient undergoing alcoholic hepatitis treatment in ICU. It was not picked up on a post-procedure chest x-ray but was identified on a CT chest/abdo/pelvis x-ray performed the following day. In retrospect the wire was visible in the chest x-ray from the previous day. The wire was removed by interventional radiology.
What happened?

- *There is no formal sign-off for competency to insert guide-wires*
- *Guide-wire placement is usually considered a single-person task with no standardised procedures to check line removal.*
- *There was a failure to check the guide-wire had been removed and a failure to identify it on the initial chest x-ray.*
- *There is no national guidance on guide-wire removal despite it being acknowledged as an area of risk.*

Case 6.
A guide-wire was retained in the right jugular vein of a young woman following the ineffective insertion of a femoral dialysis catheter (vascath). After several attempts at reinsertion a new vascath was inserted into the left jugular. A chest x-ray performed the next day picked up the retained guide-wire in the right jugular which was removed endovascularly in a two-hour procedure.
What happened?

- *There was no clear protocol to follow when the initial line was identified not to be working*
- *Neither the nursing staff or the Registrar informed the consultant that the initial line was not working well for a prolonged period of time*
- *The Trust's training programme on line insertion was not running at the time of the incident because the trainer was on maternity leave*
- *There were distractions and competing priorities when inserting the line*
- *The vascath equipment was poorly designed and allowed the guide-wire to remain in-situ*

Case 7.

A swab was left inside a patient following a liver resection. The missing swab was identified at the first count before closure but could not be found. Several x-rays were taken but not at the preferred view (AP) due to the configuration of the operating table- the swab could not be seen. The charge nurse notified the HPB? team leader about the missing swab and insufficient xrays who contacted the registrar some hours later. The correct AP x-ray was performed the following morning and revealed a swab in the upper abdomen which was removed by laparotomy the following day.

What happened?

- *The consultant left the junior to complete the operation despite knowing about the missing swab*
- *Poor design of operating theatre prevented correct positioning of the x-ray machine*
- *Failure to notify the consultant that there was difficulty in obtaining the correct x-rays*
- *There was over reliance on the initial inadequate x-rays which gave a false send of security*
- *No policy regarding actions to take if the swab count is incomplete following imaging in theatre*

Case 8.

A swab was left inside a patient following heavy bleeding during an episiotomy. 17 days later the patient presented to A&E at a different hospital with purulent vaginal discharge. Examination revealed a retained swab, which was removed under general anaesthetic the next day. IV antibiotics were administered.

What happened?

- *The final count was recorded as 'correct' by the SpR following the episiotomy – erroneous swab counting procedure*
- *A swab was used instead of the appropriate vaginal pack.*
- *The SpR stated that the swab had been left in the patient intentionally with instructions to the midwife to remove it on transfer to the maternity care unit. There was no documentation of this*
- *Multiple doctors were involved in the patients care which confused accountability for removal of the swab*

Case 9.

A swab was left inside a patient following a rescue cerclage procedure. The swab count was marked as correct by the theatre nurse and runner, and signed by the scrub nurse. The patient was subsequently catheterised. Two days later the patient returned complaining of pressure. Speculum examination revealed retained swab, which was removed - IV antibiotics were started. Two days later, the pt ruptured her membranes, the stitch was removed and termination of pregnancy discussed.

What happened?

- *Subsequent case in theatre was indicated as an emergency which put pressure on the team*
- *The WHO Checklist was found in patient notes but was entirely blank*
- *There was a shift change during the procedure meaning that different runners started and finished the swab count.*
- *There was no request for catheterisation during the procedure, this came later and more swabs were used, but no additional swab count was completed*
- *The relevant forms only allowed one signed check of the swabs, regardless of how many counts had taken place during the procedure*

Case 10.

A swab was left inside a patient following an episiotomy. On post-delivery review the next day the patient told the midwife that she has seen 'something like a tampon' sticking out of the vagina. The midwife found a swab on examination which was immediately removed.

What happened?

- *The SpR appeared to have intentionally left the swab in for pressure; however, this was not documented.*
- *Poor communication regarding the swab between the SpR and the midwife/patient*
- *The new protocol for swab counting in the hospital's maternity department (2 people counting and checking swabs have been removed) was not followed.*
- *Agency midwife involved was not familiar with the swab count procedure*
- *Antibiotics were not started when the retained swab was found*

Case 11.
A swab was left inside a patient following and instrumental delivery with episiotomy. 2 days later the community midwife thought the episiotomy wound looked infected and advised a GP visit. The patient went to the GP for antibiotics. The patient was visited again 4 and 11 days post-delivery, and at the latter was advised immediate transfer to A&E as the perineum was severely infected. A retained swab was found in A&E and removed.
What happened?

- *The swab count procedure was not followed.*
- *The doctor left the delivery suite before checking the count was correct and the midwife did not perform a count post-suturing.*
- *The midwife did not challenge the doctor when leaving early*

Case 12.
A swab was left inside a patient following an anterior resection and nephrectomy. Towards the end of the first laparotomy closure it was noted a small swab was missing. Despite a manual search and abdominal X-rays performed in theatre the missing swab could not be located, and the wound was closed. Two days later the patient deteriorated. A CT scan revealed a collection of fluid at the site of the left nephrectomy. The patient was returned to theatre and the missing swab was found at the pole of the spleen.
What happened?

- *The complex surgery required the use of small swabs*
- *At the time of the incident the process to be carried out following a missing swab was unclear*
- *The investigation team concluded that appropriate actions had been taken.*

Case 13.
The plastic end of a proctoscope was left inside a patient following hemorpex ligation of haemorrhoids under spinal anaesthesia. The following morning the patient reported to the Nurse that he had passed a 'plastic end' and handed it to her. The Specialist Registrar who had performed the surgery explained to the patient that this was the end part of the proctoscope which had dislodged from the main body. Review by the consultant concluded no harm had been caused.
What happened?

- *The completed WHO Checklist could not be found in the patient's notes*
- *The surgeon and the team did not check if the equipment used was retrieved fully intact.*
- *The end of the proctoscope was not secure and was dislodged at the end of the surgery- equipment not fit for use.*

Case 14.
A swab was left inside a patient following an elective juxtarenal abdominal aortic aneurysm repair. 2 days later a rise in c.reactive protein was noted. Intravenous antibiotics had been commenced post operatively. 2 weeks later the patient complained of feeling nauseas and tired and an examination found a slightly tender supra-pubic region. A CT scan was performed which revealed a retained surgical swab which was removed the following day.
What happened?

- *Failure to comply with Trust swab count procedure, including no pause for 4 of the 5 counts.*
- *There was a failure to confirm the swab count with the surgeon.*
- *The 'sign-out' of the WHO Checklist was not completed.*
- *There was no formal training for surgeons around the new swab count procedure*
- *The culture was that surgeons did not take on board the nurses request to pause for counts*

Case 15.
A swab was left inside a patient following an episiotomy repair. The episiotomy had been delayed due to emergencies in theatre. The repair was completed and the patient was discharged home a few days later. The retained vaginal swab was reported by the community midwifery service.
What happened?

- *Prolapsed cervix may have made it difficult to identify the retained swab*
- *Failure to comply with the locally adapted WHO Checklist*
- *Lack of clarity regarding surgical procedures conducted in a non-surgical setting e.g. where to document swab counts and how to handover patients*
- *Staff did not use the new swabs trays which had individual compartments to aid counting*
- *There were numerous interruptions during the episode of care*
- *The ST1 performing the procedure had not been introduced to the swab count policy*

Case 16.

A tampon was left inside a patient following an episiotomy repair. The patient and her baby were discharged home 2 days later. The following day the woman attended the hospital having passed a vaginal tampon. She was reviewed by the doctors and admitted for a septic screen and IV antibiotics. She was discharged two days later.

What happened?

- *At the time of the incident there was no maternity specific swab count procedure in place*
- *The usual procedure for tampon use was not followed*
- *The registrar inserted the tampon without informing the theatre staff or using a clip to secure the tampon. The tampon was therefore not included in the count*
- *There was no documentation of the use of a tampon*
- *The 'record of perineal repair/trauma' proforma was not completed*

Case 17.

A drain tip and a swab were left inside a patient following an elective aortic valve replacement. Three days later the drain inserted during the procedure was removed and it was noted that the tip remained inside the patient. A CT scan was performed which showed the tip of the drain and a surgical swab. The swab had previously been misinterpreted by the radiographer as the drain. A further surgical procedure was performed the same day and the drain tip and swab were removed.

What happened?

- A new swab count procedure had been introduced and the nurses were still being trained in its use. The surgeons received no training.
- The swab count procedure was not followed, including not using the hanging bags for the final count and failing to confirm the counts between the nurse and surgeon.
- There was a change in scrub nurse mid-procedure for which there was no advanced warning or preparation, meaning that the surgeons could not pause at the point of handover
- Insufficient time was allocated for the procedure on the theatre list which meant there were inadequate staff

Case Summaries: Wrong site surgery

Case 1.
A mechanical thrombectomy and angioplasty due to be performed on the right leg was carried out on the left leg. The patient subsequently had a further procedure on the correct leg under a second general anaesthetic later the same day.
What happened?

- *The patient's anatomy was such that the original planned procedure had to be changed requiring access from a different entry point*
- *The consent form was not completed correctly and was amended later*
- *It is unclear whether the WHO Checklist was used*
- *The side was not marked with permanent marker*
- *The doctor changed the method of the procedure from direct entry to entry from the other side and did not adequately communicate this with the theatre team.*
- *The consultant asked a nurse to turn the patient around but did not check this had happened*
- *The other staff present (radiologist, scrub nurse) did not speak up about the side*

Case 2.
A woman in her fifth pregnancy presenting with appendicitis had an ovary removed instead of her appendix. Her post-operative recovery was lengthy but she was discharged 8 days later. 12 days later she was seen by her GP and prescribed Amoxicillin for a possible wound infection. 3 days later she was readmitted to hospital with a history of abdominal pain. Previous blood and histopathology results were reviewed by the on-call consultant who noted that the supposed appendix was in fact an ovary. The patient underwent percutaneous drainage of an intra-abdominal collection under ultrasound guidance, following which she went into premature labour and delivered a stillborn infant. During her labour her condition deteriorated and she was diagnosed with severe sepsis secondary to peritonitis and appendicitis. The next day she underwent an appendicectomy and abscess drainage but died on the operating table. The cause of death was multi-organ failure secondary to overwhelming sepsis.
What happened?

- *There was no one consultant in charge of the care of the patient*
- *There was poor coordination between the surgical and obstetric teams*
- *There was no procedure in place for reporting unexpected histopathology to the consultant in charge of the patient – thus the wrong site was not reported*
- *Patient was discharged initially despite being tachycardic*
- *There was a failure of staff to plot MEOWs scores which would have led to escalation of the patient on a number of occasions*
- *The consultant surgeon was not present for the initial attempted appendicectomy.*

Case 3.
A dental patient came was admitted for removal of upper left 6 molar (UL6), but had the UL7 molar removed. The wrong tooth procedure was acknowledged immediately, and the correct procedure was carried out immediately afterwards.
What happened?

- *There was no written consent form or checklist in place in the department*
- *There was no formal 'counting teeth out loud' procedure in place*
- *The operating doctor had a recent bereavement and loss of confidence*
- *There was no double checking with assisting doctor*
- *There was a lack of learning following a similar incident 5 years previous*

Case 4.
A left tonsillotomy was performed instead of a right tonsillotomy. Immediately after the procedure in the recovery room, the patient alerted staff that incorrect side had been operated on and a plan was made for operative treatment on the correct side.
What happened?

- *The side of the procedure was not marked on the patient*
- *There was no Trust policy for surgical marking for this procedure*
- *The procedure was correctly recorded on consent form but word 'right' was abbreviated to 'R'.*
- *During the procedure the right tonsil was covered with food making pathology difficult to see*

Case 5.
A right-sided incision was made on a paediatric patient requiring a left sided craniotomy. The error was quickly identified, the incorrect incision closed and the operation continued on the left site.
What happened?

- *The patient was critically unwell and the team were working under stressed conditions*
- *The incorrect site was marked by the registrar*
- *There was no second doctors available to double check the marking of the patient*
- *The 'time-out' section of the WHO Checklist was not completed*
- *Due to shift changes, the most experienced paediatric nurse refused to scrub for the case despite being instructed to by the theatre coordinator which meant that the nursing staff were relatively inexperienced*
- *No consultant was present at the start of the case and there was no clear nursing leadership*

Case 6.

A patient underwent a renal biopsy instead of a liver biopsy. The patient had lesions in the liver and the kidney, however during a white board discussion it was agreed by the interventional team that biopsy of the liver would be more appropriate in the first instance. Following the incorrect procedure the patient asked if he would also be having liver biopsy. At this point the SpR rang the interventional consultant and realised that the wrong biopsy had been done. The patient had a liver biopsy the next day.

What happened?

- *The patient's clinical condition supported the need for a renal biopsy*
- *The white board in theatre was not updated following the discussion with the interventional team confirming a liver biopsy was required*
- *Two separate interventional teams were in charge of the patient during the same day. No formal handover occurred.*