Toft Report - external review of ‘Never Events’ that occurred at Oxford University Hospitals NHS Trust during the period 13 September 2013 to 26 March 2015

Professor Brian Toft OBE, Professor Emeritus of Patient Safety at Coventry University and Visiting Professor of Patient Safety at Brighton and Sussex Medical School was commissioned by Sir Jonathan Michael, then Chief Executive of Oxford University Hospitals, to carry out an external review. The subject of investigation was the Root Cause Analysis Investigation Reports into seven Never Events reported by Oxford University Hospitals in financial year 2014/15 (one of which related to an error in the previous financial year).

The Terms of Reference of the review did not include a requirement to reinvestigate the Never Events, but to comment on the quality, findings, and recommendations of the investigations, and if appropriate to make more general comments on any themes whether previously identified or not.

The attached report therefore summarises conclusions and recommendations of External Review of ‘Never Events’ that occurred at Oxford University Hospitals NHS Trust during the period 13 September 2013 to 26 March 2015.

The review concludes that no evidence has been found to suggest that a patient safety problem exists within the Trust with the evidence strongly suggesting that the Trust has a proactive safety culture. Professor Toft concludes that the Trust’s commitment to openness with respect to Serious Untoward Incidents and ‘Never Events’ is exemplary. In Professor Toft’s opinion, five of the seven Never Events that the Trust declared are judged not to meet the NHS England criteria for a Never Event.

The report was brought to the Trust Board in January 2016 (and can be found in the Board papers along with an accompanying Trust Board paper www.ouh.nhs.uk/about/trust-board/2016/january/documents/TB2016.07-never-event-review.pdf). The Board adopted the recommendations in the Board paper which were to receive the report, to endorse the proposed response to the report’s recommendations that can be found in the Board papers and to publish the report on the Trust’s website.

External Review of ‘Never Events’ that occurred at Oxford University Hospitals NHS Trust during the period 13 September 2013 to 26 March 2015

Professor Brian Toft OBE

October 2015
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Executive summary

The starting point for the Trust and External Reviewer is that patient safety is paramount. As a result as issues have come to light during the review the Trust have started to put in place the necessary processes to support the recommendations made by the author of this report.

Seven patients attended Oxford University Hospitals NHS Trust (Trust), for their healthcare needs between 13 September 2013 and 26 March 2015, and unintentionally suffered serious adverse incidents (SUI) later classified by the Trust as ‘Never Events’. Although remedial actions were taken quickly following each of the ‘Never Events’ it became a matter of concern to the senior management of the Trust that such serious untoward incidents continued to occur. Therefore Sir Jonathan Michael, Chief Executive of the Trust decided to commission this External Review of the Root Cause Analysis Investigation Reports produced following those SUIs to provide an opinion on the robustness of the investigations and ascertain if any further lessons might be drawn.

For an SUI to be characterised as a ‘Never Event’ national guidance or national safety recommendations must have been published, which if implemented, would have prevented the serious adverse incident from taking place. Or, putting it another way, a serious untoward incident should only be classed as a ‘Never Event’ where the national guidance or safety recommendations issued have not been implemented by the Trust concerned and that is the reason for the SUI occurring. Thus where a provider of healthcare services has implemented all recommended steps and an SUI still occurs then it should not be classified as a ‘Never Event’.

Applying the national criteria for the categorisation of ‘Never Events’ to each of the seven SUI’s reported by the Trust revealed that five of the SUI’s did not meet the conditions to be classified in such a way while two did. The Never Event declaration for these incidents was discussed with and agreed by commissioners and regulators (The NHS Trust Development Agency, NHS England, and Oxford Clinical Commissioning Group) at the time of reporting of the events.

Although the reports of the investigations into the serious untoward incidents, which are the subject of this External Review are of variable quality, they do not raise any concerns. Whilst the appropriateness and timescale of the improvements set out in the Trusts overarching ‘Never Event’ action plan appear appropriate. In addition, no

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3 Confidential report Datix: W48452, W56416, W45903, W64277, W54592, W60304 and W65370


6 Confidential report Datix: W48452, W56416, W64277, W54592, W60304, W45903 and W65370

7 Confidential report Datix: W48452, W56416, W54592, W60304 and W65370

8 Confidential report Datix: W45903 and W64277
evidence has been found to suggest that a patient safety problem exists within the Trust with the evidence strongly suggesting that the Trusts has a proactive safety culture. However, where there appears to be room for improvement recommendations have been made in those respects.

Recommendations have also been formulated for consideration by NHS England.

Finally it should be noted that Systems Theory and human fallibility predict that in an open sociotechnical system, such as healthcare, regardless of what precautions are taken there is always the possibility that a serious untoward incident could occur. Thus, when implemented, the recommendations made in this report, will help to reduce the risk of patients experiencing serious untoward incidents. However, what they cannot do is guarantee that such events will not recur.

Professor Brian Toft OBE
BA (Hons), Dip Comp Sci (Cantab), LLM, PhD,
ICDDS Dipl, FIIRSM, Hon FICPEM, FRSA

Principal
Risk Partnerships
Professor Emeritus of Patient Safety
Coventry University
and
Visiting Professor of Patient Safety
Brighton and Sussex Medical School

October 2015
Section 1: Introduction

Between 13 September 2013 and 26 March 2015 seven patients, who attended Oxford University Hospitals NHS Trust (Trust) to have their healthcare needs addressed, experienced inadvertent serious untoward incidents\(^9\) (SUI) subsequently classified by the Trust as ‘Never Events’.\(^10\) Three of the ‘Never Events’ concerned an item of medical equipment being inadvertently left in the patient’s body after the completion of a medical procedure.\(^11\) However, it should be noted that, in one of the SUI’s\(^12\) there is no evidence to suggest that the Trust was at fault but because of the circumstances surrounding the SUI in the spirit of ‘openness’\(^13\) it was reported as though it had occurred at the Trust. Three of the SUI’s were the result of a surgical procedure being unintentionally performed on the wrong part of the patient’s body.\(^14\) While the seventh concerned a nasogastric feeding tube that was unknowingly misplaced in the patient’s lung rather than their stomach.\(^15\)

When an item of medical equipment is inadvertently left in a patient post-operatively, (‘Retained foreign object post-procedure’),\(^16\) or the wrong part of a patient’s body has been operated on (‘Wrong site surgery’),\(^17\) providing the circumstances do not meet exclusionary criteria,\(^18\) such incidents are classified in two different but related ways. First, they are defined nationally as a ‘Serious Incident’\(^19\) and secondly as a ‘Never Event’.\(^20\) As a consequence, these types of incident are always subject to a ‘Root Cause Analysis’ investigation\(^21\) (RCA) in an effort to identify why and how the incident occurred and to learn lessons that could prevent such a serious incident from recurring.

In an attempt to ascertain how robust the investigations of the ‘Never Events’ noted above had been Sir Jonathan Michael, Chief Executive of the Trust, decided to

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\(^11\) Confidential report Datix: W48452

\(^12\) Confidential report Datix: W48452


\(^14\) Confidential report Datix: W54592, W60304 and W65370

\(^15\) Confidential report Datix: W45903

\(^16\) Please note that the nomenclature used to define the type of ‘Never Event’ where an item of medical equipment is inadvertently left in a patient’s body has changed on a number of occasions since the policy was first implemented. For the purposes of this External Review the type of ‘Never Event’ discussed in this report is categorised as ‘Retained foreign object post-procedure’, NHS England, 2013 at: [http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf](http://www.england.nhs.uk/wp-content/uploads/2013/12/nev-ev-list-1314-clar.pdf) accessed 11 October 2015

\(^17\) Ibid, p.3


commission this External Review of the reports of the investigations that were produced following those SUI’s.\textsuperscript{22}

**Terms of Reference**

‘…the purpose of the Review will be:

‘1. To provide assurance to the Trust Board and external stakeholders of:

‘a. The robustness of the SIRI investigations undertaken for each of the seven Never Events

‘b. The appropriateness and timescales of the improvements and actions set out in the action plans and in the overarching Never Event action plan

‘2. To determine whether additional common factors, not already identified in the Trust’s internal thematic analysis, are involved in the genesis of the seven Never Events

‘3. To identify any additional improvement actions, beyond those already in train, that the Trust should consider to minimise risk of recurrence of similar Never events.\textsuperscript{23}

**Acknowledgments**

I would like to thank the following for their help during this External Review, Tracey Jones, Christopher Evans, Neil Scotchmer and Debbie Dudek.

**Methodology**

Each of the seven reports of the SUI investigations\textsuperscript{24} was read by the author of this report and where necessary additional information was sought from the Trust. However, no interviews have been conducted and thus the critique of each of the root cause investigation is in effect based on the report produced by the investigator or investigators.

The author of this report recently completed similar exercises for Sheffield Teaching Hospitals NHS Foundation Trust\textsuperscript{25} and Wrightington, Wigan and Leigh NHS Foundation Trust (WWL).\textsuperscript{26} Therefore as several elements of the Sheffield and WWL reports are also germane to the evaluation undertaken in this report, in order to conserve NHS resources, where appropriate, that work has been drawn upon.

\textsuperscript{22} Confidential report Datix: W48452, W56416, W64277, W54592, W60304, W45903 and W65370

\textsuperscript{23} Letter of appointment and Terms of Reference, e-mail 3 July 2015

\textsuperscript{24} Confidential report Datix: W48452, W56416 and W64277, W54592, W60304, W45903 and W65370


\textsuperscript{26} Confidential Report: Toft, B., External Review of ‘Never Events’ that occurred at Wrightington, Wigan and Leigh NHS Foundation Trust in the period October 2012 to August 2014
Cognitive biases

A cognitive bias is an influence that can affect the judgement of human beings without the person or group of people affected being aware that such a psychological mechanism has operated, i.e. it can occur unconsciously. The author of this External Review however was explicitly cognizant of the National Patient Safety Agency (NPSA) caveat regarding such biases and that:

‘Care should be taken to avoid the following:

‘Hindsight bias is when actions that should have been taken in the time leading up to an incident seem obvious because all the facts become clear ‘after the event’. This leads to judgement and assumptions around the staff closest to the incident.

‘Outcome bias is when the outcome of the incident influences the way it is analysed, for example when an incident leads to a death it is considered very differently from an incident that leads to no harm, even when the type of incident is exactly the same. When people are judged one way when the outcome is poor and another way when the outcome is good, accountability becomes inconsistent and unfair’.

The relevance of taking cognitive biases explicitly into account, particularly where it is thought poor clinical practice might be involved, is clearly spelt out by Crosby who argues that, ‘Bias is pervasive in the analysis of medical occurrences and may result in findings against caregivers which are unfair’.

Additionally, through the explicit use of a critical approach to the collection and analysis of the data the author also sought to minimize the potential negative effects of ‘Confirmation Bias’ which can cause healthcare and ‘lay’ professionals to unconsciously:

‘…seek only evidence that can be used to confirm hypotheses... [This] confirmatory bias not only causes one to seek predominantly confirmatory evidence but influences data interpretation as well’.

While Klein observes that:

‘Confirmatory bias has been shown to affect peer-reviewers’ assessments of manuscripts. Mahoney sent fictitious manuscripts with identical methods

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30 Crosby, E ‘Medical malpractice and anesthesiology: literature review and role of the expert witness’, Canadian Journal of Anesthesia, Vol. 54, p.227
but different results to reviewers. Reviewers gave significantly better ratings to the methods section when the results supported their pre-existing beliefs. ‘Once again, doctors are not immune to confirmatory bias. In taking medical histories, doctors often ask questions that solicit information confirming early judgments. Even worse, they may stop asking questions because they reach an early conclusion, thus failing to unearth key data. More generally, the interpretation of information obtained towards the end of a medical work-up might be biased by earlier judgments’\(^{32}\).

Thus, the Reviews have been conducted bearing in mind the conclusion drawn by Kaptchuk that:

‘…a view that science is totally objective is mythical, and ignores the human element of medical inquiry. Awareness of subjectivity will make assessment of evidence more honest, rational and reasonable.’\(^{33}\)

Readers of this report who are interested in the topic of cognitive biases with respect to healthcare should note that there is a growing body of literature on the subject. The ‘BMJ’ and the journal ‘Quality and Safety in Health Care’ web sites both carry papers on the topic.\(^{34}\)

**Perception**

Human judgement is a complex phenomenon and it is affected by myriad factors, with Simon and Newell suggesting that man:

‘…is a mirror of the universe in which he lives, and all that he knows shapes his psychology, not just in superficial ways but almost indefinitely and subject only to a few basic constraints.’\(^{35}\)

While Rolfe argues that the:

‘…human observer sees the world in relation to his past experience. In consequence, what he perceives is partly determined by what he expects to see…’\(^{36}\)

Similarly, Levitt and March have observed that:

‘Routines are based on interpretations of the past more than anticipations of the future. They adapt to experience incrementally in response to feedback about outcomes’.\(^{37}\)

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33 Kaptchuk, T. J. ‘Effect of interpretive bias on research evidence’, BMJ, Volume 326, 28 June, 2003, p.1455
34 This section of the report draws heavily upon Toft, B., Independent review of the orthopaedic knee surgery undertaken by visiting Scandinavian Consultant Orthopaedic Surgeons at the Weston NHS Treatment Centre for comparison with the findings of the British Orthopaedic Association with respect to the same cohort of patients, South West Strategic Health Authority, Published in electronic form at: [http://www.chfg.org/wp-content/uploads/2011/05/Westonreport.pdf](http://www.chfg.org/wp-content/uploads/2011/05/Westonreport.pdf) pp.47 – 49. accessed 11 October 2015
With Berger and Luckmann coming to the conclusion that reality is socially constructed and hence, for human beings perception is all. Thus as Flyvbjerg and colleagues have observed ‘…if people define situations as real they are real in their consequences…’

Therefore where people are successful in their professional lives, unless there is robust evidence to the contrary, they have no reason to question their behaviour or the procedures which they use. Moreover Miller notes:

‘Failure teaches leaders valuable lessons, but good results only reinforce their preconceptions and tether them more firmly to their "tried-and-true" recipes’.

Hence, human beings would appear to have expectations regarding what is likely to happen in a frequently encountered situation. Therefore, when an individual or team of professionals carry out a particular task, what guides their choice of what to address will be their knowledge of what has happened in the past. Thus, success in any field of endeavour may lead to an individual and/or team unintentionally failing to perceive they have made an error. Especially in situations where they do not perceive there is any persuasive evidence to suggest anything is amiss.

System theory

The foundations of systems thinking are to be found embedded in Greek philosophy. However it was not until the 1930’s that systems thinking gained explicit recognition through the work of biologist Karl Ludwig von Bertalanffy and his development of General Systems Theory (GST). GST is an approach that moved away from the scientific paradigm of reductionism and mechanistic relationships to that of holism and adaptive entities. Thus instead of reducing an entity to its constituent parts (subsystems) and studying them in isolation GST is concerned with the nature of the organisational arrangements that connects the elements together to form the whole and the behaviour of the total system. It is this systems approach which has been adopted with regard to the critiques which follow.

Besides developing GST von Bertalanffy also introduced the concept of an ‘open’ as opposed to a ‘closed’ system arguing that:

‘A System is closed if no material enters or leaves it; it is open if there is import and export, and, therefore, changes of the components. Living systems are open systems, maintaining themselves in exchange of materials with environment, and in continuous building up and breaking down of their components…If a steady state is reached in an open system, it is independent of the initial conditions and determined only by the systems parameters…This is called equifinality as found in many organismic processes, e.g. in growth. In contrast to closed physico-chemical systems, the same final state can therefore be reached

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Hence a closed system, for example, a car engine, has a finite number of actions that it can perform from an initial starting position. In contrast, Systems Theory predicts that in any open system, in this case an healthcare organisation (Trust), the system can arrive at a given end state from different starting conditions and via different routes. Thus it can be argued, that there are an infinite number of equally likely ways by which an organisation (or a person) can arrive at or be responsible for an accident, i.e. a serious untoward incident. Consequently, it is impossible for anyone to identify the totality of the risks and the pathways which might lead to a patient being inadvertently harmed.

Empirical evidence to support this contention comes from a letter written to The Honourable Mike Gavel of the United States Senate, when the Comptroller General of the United States reported, in relation to the Senators concerns over the confidence that could be placed on quantitative reliability predictions, regarding the possibility of a catastrophic nuclear accidents that:

‘As far as we could learn during this brief review, DOD [Department of Defence] and NASA officials can offer little guidance as to how very rare failures or catastrophic accidents to systems can be anticipated, avoided or predicted ...NASA goes to extraordinary lengths--reliability cost is hardly an object--to prevent disasters in manned space vehicles...Still, three astronauts were lost in one vehicle. The Soviets suffered similar losses in other attempts. No one can tell if and when such catastrophic failures will be repeated’.

The deaths referred to by the Comptroller were those of the Apollo space capsule crew who perished in a fire during practice drills in January 1967 and the crew of the Soyuz XI space capsule who died following the capsules decompression during re-entry June 1971. Since the writing of that letter other examples have only too clearly illustrated our inability to accurately predict the probability of a disaster occurring. For example, the tragic loss of the space shuttles Challenger and Columbia, the nuclear industry disasters at Chernobyl and Fukushima Daiichi. While the world of civil aviation has suffered many unforeseen tragedies including the ‘Germanwings’

42 Beishon, J., ‘Systems’, Technology Foundation Course Unit 1, Course T100, The Open University Press, 1976, p.27
Airbus A320 which was deliberately crashed into the Alps by the pilot and the infamous disappearance of Malaysia Airlines MH370 while on a flight from Kuala Lumpur to Beijing.

In a medical context the alleged failure of senior managers at the Care Quality Commission regarding the untoward events which took place at the University Hospitals of Morecambe Bay NHS Foundation Trust or the breakdown in patient care which took place at Mid Staffordshire NHS Foundation Trust was not predicted. Similarly, the series of inadvertent errors which led to a child’s treatable brain tumor not being diagnosed in time or those which led to the death of a patient who was deprived of oxygen during an attempted operation also do not appear to have been foreseen.

**Serious untoward incidents**

Toft and Reynolds, Reason, Turner and Pidgeon and others have all comprehensively argued that the precursor conditions required for the creation of any SUI may lie cloaked in the social and technical fabric of an organisation for many years before an adverse incident occurs. Similarly, an organisation’s culture, i.e. the commonly accepted way of behaving within any given organisational setting, does not spring into existence overnight as an established phenomenon. It takes time for the complex sets of individual and collective perceptions to develop and coalesce into a system of commonly shared values.

Therefore the actions that individuals take within an organisation are determined by their subjective understanding of any particular situation. Thus people try to make sense of their organisational settings and then act in the belief that the assumptions that they have made are facts: ‘It is therefore imperative to understand the organisational setting in which the adverse incident[s] took place.’ Hence, the

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organisational contexts in which the seven ‘Never Events’ noted earlier will be briefly described later in this report.

**Comments**

Cognitive biases affect all human beings to a lesser or greater extent and an explicit attempt has been made to take cognizance of such psychological phenomena in the preparation of this report.

Systems Theory suggests that risk free medical treatment is impossible to achieve in practice because healthcare organisations and people can behave in unpredictable and unlimited ways. In addition, human beings are fallible and therefore errors are inevitable. The World Health Organisation (WHO) explicitly recognising this latter issue, as for example, in their guidance to healthcare professionals on how to reduce the risk of patients inadvertently retaining foreign objects following surgical/invasive procedures. The WHO observing that, ‘Manual counting methods are not fool-proof, as they are subject to human error’.

In addition, since no one can prespecify their own ignorance although all the recognised potential pathways to a serious adverse incident may appear to have been addressed, in open systems there are always other unidentified routes by which the same serious untoward incident could occur.

The aim of the ‘Never Event’ policy ‘….is to reduce the incidence of never events to zero’. Unfortunately Systems Theory and our inability to prevent all human error suggest that it will be impossible to achieve. Nevertheless as Berwick observed in his report:

‘While “Zero Harm” is a bold and worthy aspiration, the scientifically correct goal is “continual reduction”. All in the NHS should understand that safety is a continually emerging property [of open systems], and that the battle for safety is never “won”; rather, it is always in progress’.

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66 Confidential report Datix: W48452, W56416 and W64277, W54592, W60304, W45903 and W65370


71 Beishon, J, ‘Systems’, Technology Foundation Course Unit 1, Course T100, The Open University Press, 1976, p.27


Thus, ‘…whilst perfect safety is always likely to be a utopian vision that does not mean society should not attempt to approach it as closely as possible.’

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Section 2: ‘Never Events’

In his report ‘High quality care for all’… Professor the Lord Darzi proposed that the concept of ‘Never Events’ should be introduced into the NHS in England stating that:

‘In some parts of the United States, events that are serious and largely preventable such as ‘wrong-site’ surgery have been designated ‘Never Events’, and payment withheld when they occur. The NPSA [National Patient Safety Agency] will work with stakeholders in this country to draw up its own list of ‘Never Events’.66

Thus following wide stakeholder involvement the NPSA published a ‘Never Event’ policy and framework for its implementation.77 ‘Never Events’ being defined as:

‘Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers’78

The core list of eight ‘Never Events’ selected by the Department of Health was based upon the following criteria:

• The Never Event may or does result in severe harm or death to patients and/or the public.

• There is evidence that the Never Event has occurred in the past, that it is a known source of risk (data sources: NPSA Reporting and Learning System, 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’.79

Taken together the definition and the criteria used by the Department of Health, subsequently adopted by NHS England, 80 makes it clear that the type of serious

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76 Ibid, p.45, para.56
untoward incidents selected as ‘Never Events’ should generally not occur if national guidance or national safety recommendations have been implemented. Thus:

‘If a provider takes every recommended step to prevent occurrence and an incident still occurs this argues strongly that the incident was not preventable and therefore not a “never event”’.

However while the fundamental criteria for identifying a ‘Never Event’ has remained the same, the specific terminology and description for defining one in relation to foreign objects being inadvertently left in a patient’s body following a surgical/interventional procedure, has been modified on a number of occasions. For example, in the original list of core ‘Never Events’ issued in 2009 this type of serious untoward incident was categorized as a ‘Retained instrument post-operation’ and described as follows:

‘One or more instruments are unintentionally retained following an operative procedure, and an operation or other invasive procedure is needed to remove this, and/or there are complications to the patient arising from its continued presence. This Never Event does not include interventional radiology or cardiology procedures, and the definition of instrument does not include guide wires, screws, swabs or other similar material’.

Whereas, effectively the same ‘Never Event’ (patient retains a foreign object - using a higher level of analysis) is re-classified in the 2013 - 2014 list of ‘Never Events’ as a ‘Retained foreign object post-procedure’ and depicted in the following way:

‘Retention of a foreign object in a patient after a surgical/invasive procedure.

‘Surgical/invasive procedure’ includes interventional radiology, cardiology, and interventions related to vaginal birth.

‘Foreign object’ includes 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 guidewires) except where:

‘Items are inserted during the procedure but are intentionally retained after completion of the procedure, with removal planned for a later time or date.

‘Items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further

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action to locate and/or retrieve would be impossible or be more damaging than retention.

‘Items were inserted at an earlier date or time and not removed as planned during a later surgical/invasive procedure’.

Thus changes have been made with respect to the nomenclature used and the way in which patient foreign object retention ‘Never Events’ have been described. For example, in the 2009 list of ‘Never Events’ the definition of ‘Retained instrument post-operation’ as can be observed above, does not include swabs or throat packs whereas the 2010 - 2011 list does. Therefore, if a patient had retained a swab or throat pack in 2009 that incident would not have been classified as a ‘Never Event’ whereas in 2010 - 2011 it would.

On the other hand, part of the definition of a ‘Retained foreign object post-procedure’ incident used in the 2013 -2014 list of ‘Never Events’ provides an exception in that if:

‘Items were inserted at an earlier date or time and not removed as planned during a later surgical/invasive procedure’.

Thus a retained foreign object incident which meets the 2013 -2014 exception rule would not to be classified as a ‘Never Event’. Whereas, a serious untoward incident which occurred in previous years, under exactly the same circumstances as that in 2013 -2014, would have been classified as a ‘Never Event’.

‘Never Events’ understandably often bring public concern in their wake however such publicity risks undermining the confidence of patients in healthcare professionals and damaging the morale of those involved with healthcare. Indeed, NHS England has stated that, ‘They are intolerable and inexcusable’ (emphasis in the original). It is therefore extremely important that where serious untoward incidents have been classified as ‘Never Events’ there should be no doubt whatsoever that they qualify for that ignoble rubric.

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Guidance: prevention of patients retaining a foreign object post procedure

To date the following organisations have not published a detailed ‘good practice’ protocol advising NHS Trusts on how to reduce the risks of patients inadvertently retaining swabs, instruments, needles and other miscellaneous items used in surgical/invasive procedures except in very specific circumstances:


It should be noted however that NICE has published basic guidance on reducing the risk of swabs being retained following perineal repairs which states that, ‘Equipment should be checked and swabs and needles counted before and after the procedure’.

The NPSA has also published specific national guidance on how the risks of a patient retaining a throat pack following surgical/interventional procedures can be reduced. As well as advice on how the risk of swabs being retained after a vaginal birth and perineal suturing can be reduced. But neither they nor any other national body appear to have published formal detailed guidance on how to prevent swabs, instruments, needles or other sundry items that are used in the vast majority of surgical/invasive procedures from being inadvertently retained within patients' bodies.

The World Health Organisation (WHO) on the other hand has published some general guidance on the topic of foreign object retention by patients. However, that advice was generated by them drawing upon the recommendations made by a number of professional bodies including the United Kingdom based Association of Perioperative Practice (AfPP).

The AfPP provided detailed guidance in 2007 on how the risk of a foreign object being inadvertently left in a patient’s body might be reduced and a poster entitled ‘Swab, needles and instrument counts: Managing the risk’ was published based on that advice. The guidance was subsequently updated in the AfPP 'Standards and Recommendations for Safe Perioperative Practice’.
and recommendations for safe perioperative Practice'.

In October 2012 the AFPP’s updated guidance was published once more in a poster format but the title changed to ‘Accountable items, swab, instruments and needle counts’.

The intended audience of the AFPP ‘good practice’ posters on reducing the risk of foreign objects being retained within a patient’s body is aimed, in the first instance, at assisting their members. The AFPP have never nor do they now consider their advice to be ‘national guidance’ as not all those employed in perioperative practice are members of the AFPP. However, the AFPP guidance posters are freely available and can be downloaded from the ‘standards and guidance’ section of their website by anyone.

It should be noted that, both the 2007 and 2012 versions of the AFPP guidance posters are the subject of copyright and consequently the information contained within them cannot be copied verbatim without extensive acknowledgements to the source documents. Therefore where AFPP’s recommendations have been incorporated in to Trusts local guidance document it would appear that the information has been rephrased to avoid copyright issues.

In both their guidance posters on trying to prevent the retention of foreign object by patients following surgical/invasive procedures the AFPP observe:

‘Although UK statute law does not dictate what system or method of accountable items, swab, instrument and needles counts should be performed within a perioperative environment, as healthcare practitioners, the law is quite clear in that we all have a ‘duty of care’ to the patient’.

Thus, authoritative detailed guidelines or standards produced or endorsed by a national body on how the risks associated with patients’ inadvertently retaining foreign objects can be reduced might be of assistance to patients, NHS Trusts and the courts particularly in cases where medical negligence has been alleged. For as Harwood observed two decades ago professional guidelines, ‘… determine what the medical profession believes ought to done in a variety of different situations’.

104, 105, 106, 107, 108, 109, 110, 111

104, 105, 106, 107, 108, 109, 110, 111
While the ‘NHS England Surgical Never Events Task Force’ recommended that:

‘NHS England develops a coherent framework of national standards, and mandates provider compliance with the national standards’.\(^{112}\)

Critique: retained foreign object post procedure ‘Never Event’

The research carried out for a review undertaken by the author of this report for Sheffield Teaching Hospitals NHS Found Trust\(^{113}\) uncovered what appears to be an oversight by the Department of Health and NHS England with respect to the criteria used to categorise a serious untoward Incident as a ‘Never Event’. Part of the fundamental criteria for a patient safety incident to be classified as a ‘Never Event’, as noted earlier, is that:

‘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’.\(^{114}\)

Thus it is clear that for a serious untoward incident to be classified as a ‘Never Event’ some form of national guidance\(^{115}\) must have been published to assist NHS Trusts in managing the risks associated with the different types of ‘Never Event’. And, although the wording is slightly different from the 2009 – 2010 list of ‘Never Events’ above the same intent can be seen in the current 2013 -2014 list of ‘Never Events’. The document stating that amongst other criteria for a serious untoward incident to be consider a ‘Never Event’ there must be:

‘…existing national guidance or safety recommendations, which if followed, would have prevented this type of never event from occurring (for example, for ‘Retained foreign object post procedure’ the referenced national guidance is related to the peri-operative counting and checking processes that would be expected to occur at the time of the procedure, including suturing after a vaginal birth).’\(^{116}\)


\(^{115}\) The phrase ‘national guidance’ is not defined in any of the Department of Health or NHS England ‘Never Event’ documents cited in this report. It is however assumed that the term ‘national guidance’ is used to denote that the advice must have been produced or publicly endorsed by an appropriate government institution such as the Department of Health, NHS England, National Patient Safety Agency, National Institute for Care and Excellence or Medicines, Healthcare Products Regulatory Agency or the Care Quality Commission to have such status.

However, while there is national guidance to reduce the risk of ‘Retained foreign objects post procedure’ for vaginal births and perineal suturing as noted earlier, there is none with regard to reducing the risks to patients retaining swabs, instruments, needles and miscellaneous items used in surgical/invasive procedures.

Evidence to support this assertion comes in an answer provided by NHS England, with respect to a question the author of this report asked under the Freedom of Information Act 2000 (FOIA), regarding national guidance to the NHS on the subject of retained foreign objects by patients.

‘I can confirm that NHS England has not published a model protocol which explicitly states what procedural checks should be undertaken by staff in an operating theatre to prevent swabs, instruments, needles and other miscellaneous items used in surgery from being retained in a patient’s body.’

In addition, NHS England when again asked under the provisions of the FOIA by the author of this report, as to what the national guidance or national safety recommendations were that the Department of Health and NHS England was referring to with respect to the core list of eight ‘Never Events’, replied that:

‘The current policy framework and list of never events clearly identifies relevant national guidance for each never event and the relevant links are as follows:

Accessed 11 October 2015

Accessed 11 October 2015

However, the guidance cited in the documents, found using the internet links provided by NHS England in their response to the FOIA request, with regard to reducing the risk of patients retaining foreign objects such as swabs, instruments, needles and other miscellaneous items, is that produced by the AfPP for its members. However, as noted earlier, the AfPP advice is not deemed by them or it would appear by the Care Quality Commission, Health Education England and the

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119Toft, B., request under the Freedom of Information Act 2000 to NHS England regarding the national guidance provided to the NHS with respect to retained foreign object in patients – E-mail sent 4 December 2013

120..., Re: Freedom of Information request (Our Ref: SDR – 178285) – E-mail received 23 December 2013

121Toft, B., request under the Freedom of Information Act 2000 to NHS England regarding what national guidance was provided to the NHS with respect to the eight core ‘Never Events’ – E-mail sent 14 January 2014

122..., Re: Freedom of Information request (Our Ref: SDR - 195131) – E-mail received 4 February 2014

Department of Health to be national guidance\(^{124}\) as, for example, that published by the NPSA, NICE or NHS England.

Thus since no detailed national guidance or national safety recommendations have been produced with regard to reducing the risk of patients inadvertently retaining a whole range of foreign objects, then clearly where such incidents occur they do not meet the required ‘Never Event’ criteria. Therefore logically, none of the serious patient safety incidents discussed in this report, which fit the category ‘Retained instrument post-operation’, but for which there is no national guidance or national safety recommendations, should have been categorised as a ‘Never Events’. This is not to imply that such incidents are not very serious because they are. But to contend that such patient safety incidents currently do not and never have met the criteria specified for ‘Never Events’ by either the Department of Health\(^{125}\) or NHS England.

As there never has been any legal or detailed national guidance prescribing the actions needed to reduce the risk of patients retaining a foreign objects, such as swabs, instruments, needles and other miscellaneous items, NHS Trusts have developed their own ‘good practice’ guidance protocols\(^{126}\) to manage those risks. Thus the majority of the guidance used by healthcare professionals with respect to reducing the risk of patients’ inadvertently retaining foreign objects at the Trust has been developed in house.\(^{127}\) The guidance produced by the Trust however has been updated twice in the light of a serious untoward incidents that have taken place.\(^{128}\)

With respect to ‘Never Events’ it should be remembered that the ‘Never Event’ framework is an important part of the Standard NHS Contract\(^{131}\) which states that, ‘…[t]he provider must ensure Never Events do not occur…’.\(^{132}\) As a result where a

\(^{124}\) Personal communication from Sue Lord, President, Association of Perioperative Practice, 15 January 2014 in a telephone interview Ms Lord stated that the information produced by the AfPP with respect to accountable items is not considered by the AfPP to be national guidance but solely as advice for their members. This is because the AfPP have approached the Care Quality Commission, Health Education England and the Department of Health with regard to having their guidance on reducing the risk of patient’s retaining foreign objects recognised as national guidance and their request has been refused on each occasion. In a telephone enquiry to the AfPP on the 28 September 2015 the Chief Executive of the AfPP confirmed that the position was unchanged.


\(^{126}\) See for example the current guidance entitled: Theatre Education & Training Lead, Surgical Count Policy, V.1, Surgical & Specialist Services, Wrightington, Wigan and Leigh NHS Foundation Trust , January 2013

\(^{127}\) The guidance was updated following SIRI 2012-003 Never Event Churchill Theatres, 9 January 2012 and SIRI 2012-025 - Never Event, 29 March 2012

\(^{128}\) See for example the current guidance entitled: Theatre Education & Training Lead, Surgical Count Policy, V.1, Surgical & Specialist Services, Wrightington, Wigan and Leigh NHS Foundation Trust, January 2013


A serious untoward incident is classified as a ‘Never Event’. Trusts face the following financial penalty:

‘...recovery by the Responsible Commissioner of the costs to that Commissioner of the procedure or episode (or, where these cannot be accurately established, £2,000) plus any additional charges incurred by that Commissioner (whether under this Contract or otherwise) for any corrective procedure or necessary care in consequence of the Never Event’.

Hence, all published national guidance with regard to the prevention of ‘Never Events’ must be implemented by the Trust if it wishes to avoid the financial consequences associated with all such serious untoward incidents as it is a contractual obligation. On the other hand, if a serious untoward incident occurs but national guidance or safety recommendations have not been published and all recommended steps have been implemented then that SUI is not a ‘Never Event’ and the Trust should not be penalised.

It should be noted that the model for commissioning ‘Never Events’, as suggested by the Department of Health, has not been implemented by the Trust at the present time.

Reduction of the risk of SUI’s occurring during invasive procedures at the Trust

The instructions to surgical and operating theatres teams on how to reduce the risk of a patient suffering from SUI’s during invasive procedures at the Trust is to be found in two standardised documents one entitled: The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy and the ‘WHO Checklist’ which is part of the NPSA ‘Five Steps to Safer Surgery’ process.

Comments

Providing the relevant national guidance or safety recommendations have been implemented and all recommended steps have been taken at an NHS England Trust a serious untoward patient safety incident should not be classified as a ‘Never Event’.

The nomenclature and description of a serious untoward incident ‘Never Event’ where patients inadvertently retain a foreign object following a surgical/invasive procedure:

135 Telephone discussion with SM1 28 September 2015
136 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, 19 February 2014 - its use is mandatory.
137 The WHO checklist has been customised by the Trust for a number of invasive procedures and its use is mandatory.
138 How to Guide - Five Steps to Safer Surgery, National Patient Safety Agency, December 2010 at: http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/NRLS-1291-How_to_guide_fi~urgery-2010.12.20-v1%5B1%5D.pdf accessed 11 October 2015. This process has been implemented by the Trust save for the ‘Debriefing’ step at the end of an operating list which remains voluntary – 10 August 2015 e-mail from SM2 to Professor Toft
procedure has changed over time. Thus, although a patient has inadvertently retained a foreign object it may not have been classified as a ‘Never Event’ because the definition at the time it occurred did not encompass the specific circumstances in which it took place. Similarly, an incident originally classified as a retained foreign object ‘Never Event’ might, because of a change in the definition, no longer qualify for that classification.

National guidance has been published by NICE and the NPSA to reduce the risk of patients inadvertently retaining foreign objects following perineal suturing. The NPSA has also published national guidance on how to reduce the risk of a patient inadvertently retaining a throat pack and on the ‘Five Steps to Safer Surgery’ process which includes the use of the ‘WHO Safer Surgery Checklist’.

National guidance has not however been published on how to reduce the risk of patients in England inadvertently retaining swabs, instruments, needles and other sundry items used in surgical/invasive procedures with respect to the ‘Never Event’ ‘Retained foreign object post-procedure’.

The guidance published by the AfPP140 and cited in Department of Health and NHS England documents in relation to the ‘Retained foreign object post-procedure’ does not constitute formal national guidance since the purpose of the AfPP recommendations is to advise their members. Notwithstanding that the Care Quality Commission, Health Education England and Department of Health have all refused to confer national guidance status on the AfPP’s recommendations.

Hence at the present time there is no published detailed legal or national guidance on how NHS England Trusts should manage the risk of patients inadvertently retaining foreign objects except in three specific cases, i.e. vaginal births, perineal suturing and throat packs. It would appear therefore that two out of the three SUI’s which have occurred at the Trust in the ‘Retained foreign object post-operation’ category should not have been classified as ‘Never Events’. This is because they did not fulfil the criteria stipulated by the Department of Health or NHS England to be categorised in such a way. All such events are of course serious untoward incidents and should always be fully investigated.143

The provisions set out in the NHS Standard Contract regarding ‘Never Events’ make the implementation of national guidance regarding such incidents a contractual obligation which if not performed has and will continue to result in the Trust sustaining financial penalties in the form of unrecoverable costs.

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139 As advised by the Department of Health or NHS England
142 Ibid
At the present time all the procedures in place at the Trust to reduce the risk of patients inadvertently retaining foreign objects in the Trusts main Operating Theatre complexes are from a corporate governance perspective mandatory.\textsuperscript{144}

The model suggested by NHS England for the commissioning of ‘Never Events’,\textsuperscript{145} as with other NHS Trusts,\textsuperscript{146} has not been implemented by the Trust at the present time.\textsuperscript{147}

Although attempts have been made to stop patients from suffering from inadvertent SUI’s at the Trust, they have continued to take place.\textsuperscript{148} This, it could be argued, is tentative empirical evidence to support the concept of ‘equifinality’ discussed earlier and the unrelenting nature of human fallibility.

\textsuperscript{144} Telephone discussion with SM1 28 September 2015
\textsuperscript{147} Telephone discussion with SM1 26 September 2015
\textsuperscript{148} For example, SUI’s at the Trust where a patient has inadvertently retained a foreign object following an invasive procedure as in Confidential report Datix: W64277
Section 3: Never Event incidents at the Trust

There are three documents by which the Trust seeks to reduce the risk of patients’ inadvertently experiencing SUI’s of the types discussed in this report. These are the ‘WHO Checklist’ which has been appropriately adapted and standardised;149 the instructions provided in the ‘The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy’150 and the ‘Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes’.151

As noted earlier during the period 13 September 2015 to 26 March 2015 seven patients at the Trust were categorised as having suffered ‘Never Events’. Three of the ‘Never Events’ were categorised as Retained foreign object post-operation152 three as ‘Wrong site surgery’153 and one as a ‘Misplaced naso- or oro-gastric tubes’.154

It should also be noted that if a SUI is not identified at the time it occurs, then trying to get healthcare professionals to accurately recall what occurred sometime later is fraught with problems. Not least of all because they have no frame of reference. Therefore memories of what actually took place are frequently indistinct.155 Thus, on some occasions, it is not possible for an investigating panel to identify the root cause(s) of a particular serious untoward incident or a ‘Never Event’.

A brief summary with observations based on the Root Cause Analysis Investigation reports of the seven ‘Never Events’ which have occurred at the Trust156 is presented below.

‘Never event’ 1: retained guidewire following a PCI157

On the 13 September 2013 a patient was admitted as an emergency to the John Radcliffe Hospital, Oxford, complaining of severe pain in his chest. Diagnosed as suffering from an acute myocardial infarction, i.e. a heart attack.158 The patient underwent a Percutaneous Coronary Intervention (PCI) in the Cardiac Angiography Suite. Consultant ‘A’ carried out the PCI using fluoroscopy160 with the

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149 Telephone discussion with SM1 28 September 2015
150 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, 19 February 2014 - its use is mandatory.
152 Confidential report Datix: W48452,W56416 and W64277
153 Confidential report Datix: W54592, W60304 and W65370
154 Confidential report Datix: W45903
156 Investigation reports sent to the author of this report by SM1
157 Confidential report Datix: W48452
The PCI was carried out successfully using a right radial artery approach and the patient made a good recovery.

The patient was scheduled to have an elective PCI follow up procedure on the 25 October 2013 at the Heart Centre, John Radcliffe Hospital, Oxford. However the patient decided that he would prefer to have the follow up elective PCI procedure carried out by Consultant ‘B’ at the Manor Hospital, Oxford which is a private healthcare facility.

On the 2 October 2013 Consultant ‘B’ started to undertake the elective follow up PCI procedure on the patient using the same route as Consultant ‘A’, i.e. a right radial artery approach. However apparently this technique was aborted due to the anatomy of the blood vessel and Consultant ‘B’ switched to a femoral approach instead. The PCI procedure was then completed by Consultant ‘B’ without any further problems and the patient appeared make an uneventful recovery.

On the 24 June 2014 the patient was referred to the Churchill Hospital, Oxford to have a chest X-ray by his General Practitioner (GP) with respect to a medical complaint he had developed which was unconnected with his heart condition. A report on his chest X-ray stated that a length of wire could be seen retained in the blood vessels of the patient’s right upper arm and chest.

The patient contacted Consultant ‘B’ on the 28 June 2014 who in turn contacted the patient’s GP and an Interventional Radiologist, Consultant ‘C’. On the 15 July 2014 an unsuccessful attempt was made by Consultant ‘C’ at the Manor Hospital, Oxford to remove the wire retained within the patient’s body.

Subsequently, on the 21 July 2014 the patient wrote a letter of complaint to the Trust regarding the retained wire and this is when the SUI came to light. However there was no evidence offered by the patient to suggest that the PCI procedure carried out in the Cardiac Angiography Suite, John Radcliffe Hospital, Oxford was the cause of him inadvertently retaining a wire.

Consultant ‘B’ referred the patient to a Vascular Surgeon for removal of the wire. At the time the investigating team wrote their report the wire was still retained within the patient’s body however he appeared to have suffered no physical harm.

Although there was absolutely no evidence to suggest that the patient had inadvertently suffered an iatrogenic injury while being treated at the Trust in the spirit of openness, the Trust reported that a ‘Never Event - Retained foreign object post-procedure’ SUI had occurred to the NHS Oxfordshire Clinical Commissioning Group and an investigation into the circumstances surrounding this event was initiated.

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163 Sometime after the final interview took place with Consultant ‘A’ on the 15 September 2014
Root causes

At the time the original report of this SUI was written no evidence had been found linking the actions of Consultant ‘A’ and his Scrub Nurse to the SUI. However this fact is not mentioned in the report. It should be noted therefore that the root cause of the SUI which has been suggested by the investigation team may be inaccurate.

It is proposed by the investigation team that the root cause of this SUI occurred because ‘[t]here is no process to visually check that all the devices used in the procedure have been removed’. However, as noted above, this is conjecture since the PCI procedure conducted by Consultant ‘A’ may have been flawless. On the other hand if the SUI was caused as a result of negligent action by Consultant ‘A’ and his Scrub Nurse then the root cause suggested by the investigation team is likely to have contributed to the event taking place.

However even if there had been a process in place to check that all the devices used in the PCI procedure had been removed from the patient, unless the process mandated that each of the guidewires which had been used in the procedure should be physically checked for mechanical integrity, it is highly unlikely this SUI would have been identified.

Should Consultant ‘A’ and his Scrub Nurse be responsible for the patient inadvertently retaining a guidewire then they clearly failed to ‘perceive’ that a guidewire or a fragment of guidewire had been retained within the patient’s body i.e. inadvertent ‘human error’ also played a part in the SUI occurring. Thus a second potential root cause of this SUI, it can be argued, would be a loss of ‘situational awareness’ by Consultant ‘A’ and his Scrub Nurse due to an inadvertent perceptual failure. Evidence to support this conclusion can be found in the work of Grieg et al who argue that, ‘…perceptual failures are a cause of loss of situational awareness in practice’.

Once inserted, the part of a guidewire protruding from a patient is, according to the investigation team, always ‘…firmly held by operator or nurse to ensure they do not go further into the patient’. Thus if the guidewire should, as the expert Cardiologist called in to provide an opinion suspects, turn out to be a complete short ‘Radial Introducer Wire’ (RIW), rather than a fragment of a long guidewire.

166 Sometime after the final interview took place with Consultant ‘A’ on the 15 September 2014
167 Confidential report Datix: W48452
168 Confidential report Datix: W48452, p.4
173 Confidential report Datix: W48452 pp.2-3
174 Confidential report Datix: W48452, p.3
175 Confidential report Datix: W48452, p.3
then another possible root cause of this incident is that either the Operator or the Scrub Nurse inadvertently lost their grip on the RIW without realising it. The RIW could then be drawn into patient’s radial artery and swept along in their circulation until it came to rest at the point it was found on the chest X-ray.

It has very recently been established that the patient had inadvertently retained a piece of long guidewire as opposed to a RIW. However, the critique of the original investigation report remains germane to this report.

As it now transpires that the wire retained within the patient’s body is a fragment of a long guidewire another potential root cause of the incident could be the way in which the Operator withdrew it from the patient once the procedure had been completed. While yet another possible root cause is that there was a physical flaw in the material used to construct the guidewire thus affecting its mechanical strength. Hence as the guidewire was withdrawn by the Operator it is possible that it broke at a weak point.

Another potential root cause for this SUI occurring is that once a PCI procedure has been completed patients do not routinely have a plain X-ray taken to check whether any of the equipment used in the procedure has been inadvertently retained. It will be recalled that the guidewire retained within the patient’s body was identified because it could be seen on the plain chest X-ray that his GP had requested.

As there is no evidence to suggest that Consultant ‘A’ and his Scrub Nurse were responsible for the SUI that occurred to the patient then the potential root causes of this SUI discussed above also apply to the elective PCI procedure undertaken at Manor Hospital, Oxford by Consultant ‘B’.

Lessons learned

The investigation reports rightly states that a lesson to be learned is:

*The importance of making sure that medical devices used during a procedure are accounted for and intact at the end of the procedure*. However another lesson that can be drawn, providing Consultant ‘A’ and his Scrub Nurse were responsible for this SUI occurring, is that it was caused, in part, by inadvertent human error, i.e. the members of staff performing the PCI procedure lost their situational awareness due to an inadvertent perceptual failure.

Recommendations

The first and second recommendations made by the investigation team align with the findings of the ‘Concise Investigation Report’ these are:

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178 27 July 2015 - e-mail from SM1 to Professor Toft
179 27 July 2015 - e-mail from SM1 to Professor Toft – stating the piece of guidewire inadvertently retained within the patient’s body was from a long guidewire.
180 22 July 2015, telephone discussion with SM2
181 Confidential report ‘Lessons Learned’, Datix: W48452, p.4
182 Confidential report Datix: W48452
'1. The OUH NHS Trust could consider developing a standardised process (SOP) for guide wire management during PCI and similar interventions: This may include 2 person visual checks and/or radiographic screening'.

'2. Ensure that all consultant staff within the Cardiology, Cardiac and Thoracic Surgery and Radiology Directorates attend incident identification and risk awareness training'.

The third recommendation made is:

'3. Complete an incident decision tree for each of the clinicians involved'.

The ‘Incident Decision Tree’ was developed by the National Patient Safety Agency:

‘…to help National Health Service (NHS) managers in the United Kingdom determine a fair and consistent course of action toward staff involved in patient safety incidents’.183

However, there is no evidence to suggest that the PCI procedure which led to the patient inadvertently retaining a guidewire was caused by the actions of the staff who work in the Cardiac Angiography Suite at the Trust. Although it is clear one of the PCI procedures did lead to the patient inadvertently retaining a guidewire of some description it could just as easily have been the PCI procedure undertaken at Manor Hospital, Oxford. Thus to recommend that an ‘Incident Decision Tree’ analysis be undertaken for all the clinicians involved is inappropriate, in the opinion of the author of this report, because not all the clinicians involved in the two separate PCI procedures can be held responsible for this SUI.

Given the above discussion on root causes in relation to the original report184 a number of additional recommendations might have been made such as:

- All medical equipment to be used in a PCI procedure or similar interventions must be inspected prior to use so as to ascertain whether any damage has been sustained whilst in transit.

- The WHO checklist should be amended so that the mechanical integrity of all medical equipment used in a PCI procedure or similar intervention must be checked immediately upon their removal from a patient. This is to ensure that they are still intact.

- The method used by which Operators remove guidewires from patients should be evaluated to ensure that excessive mechanical loads are not inadvertently placed on the guidewire during removal.

- All Operators undertaking a PCI procedure or similar intervention should


184 Confidential report Datix: W48452
monitor the removal of medical equipment from patients using fluoroscopic images so that potential or actual problems can be identified at the earliest moment.

Comments

As discussed earlier for an SUI to be reported as a ‘Never Event’ it must meet the NHS England definition which is that ‘[i]nidents are considered to be never events if:

‘...There is existing national guidance or safety recommendations, which if followed, would have prevented this type of never event from occurring…’\(^{185}\)

At the time this SUI occurred, as discussed earlier, there was no national guidance or safety recommendations that had been made publicly available by any national body such as NICE or the NPSA to prevent this type of SUI, i.e. ‘Retained foreign object post-procedure’.\(^{186}\)

Therefore, in the opinion of the author of this report, this SUI has been inadvertently classified as a ‘Never Event’.

In addition, as noted earlier guidance provided by the Department of Health to NHS Trusts and adopted by NHS England\(^{187}\) states that:

"“Never events” are by definition largely preventable if a provider takes every recommended step to prevent occurrence and an incident still occur this argues strongly that the incident was not preventable and therefore not a “never event”."\(^{188}\)

As the report of this SUI\(^{189}\) did not discuss any safety procedures the Operator might have carried out while undertaking the PCI procedure the author of this report made further enquires as to what safety precautions were employed. It was found that the ‘WHO Surgical Safety Checklist: for Radiological Interventions ONLY’\(^{190}\) had been correctly completed during the PCI procedure, as were all other safety precautions. Hence, it would appear that given the NHS England definition of a ‘Never Event’ this SUI appears to have been inadvertently categorised as ‘Never Event’ as the Operator carried out all the recommended national guidance and safety precautions\(^{191}\) but these did not prevent the SUI from occurring.

It should also be noted that while the ‘Sign out’ section of the WHO document does contain a field which asks ‘Have all pieces of invasive equipment used been...


\(^{191}\) 4 August 2015 –E-mail from SM2 to Professor Toft
the prompt did not prevent the patient from inadvertently retaining a foreign object post-procedure. This is because further enquiries by the author of this report have also established that it was a piece of long guidewire which was inadvertently retained within the patient’s body\textsuperscript{192} not a whole guidewire. Thus without the Operator or their assistant physically measuring the length of the long guidewire withdrawn from the patient it would not be possible for them to know that a piece of it had been inadvertently retained. Moreover the prompt in the ‘Sign out’ section on the WHO checklist does not ask Operators to check the length of the guidewires withdrawn or that they are intact.

Although this SUI has been reported by the Trust to the NHS Oxfordshire Clinical Commissioning Group\textsuperscript{193} as a ‘Never Event’ the ‘Concise Investigation Report’ of this SUI\textsuperscript{194} does not identify the incident in such a way. There is no discussion of ‘Never Events’ in the report which may mean that the investigating team was not aware that the report should have explicitly classified the SUI as a ‘Never Event’. This in turn would account for why a ‘Concise Investigation Report’ form (Level 1 – concise investigation) was used to report the circumstances surrounding the SUI rather than the more detailed ‘Root Cause Analysis Investigation Report’ form (Level 2 – comprehensive investigation). Thus this SUI was investigated at the wrong level of detail, i.e. Level 1 rather than Level 2.

However with respect to the investigation being conducted at Level 1 it has now been established that:

‘In respect of the reporting as a never even the sequence was as follows – a complaint was received and a local investigation was carried out using the concise format. On completion this was decided to be a serious incident and never event and at that time was reported on STEIS with the level one investigation supplied to the relevant commissioners’.\textsuperscript{195}

But even if the SUI had been investigated at the correct level it would still have been allocated the wrong classification because it does not meet the criteria of a ‘Never Event’ as discussed earlier.

It is perhaps interesting to note that the National Patient Safety Agency in September 2011 stated that:

‘Despite published evidence of incidences of guidewire retention, no formal national guidance has been developed that addresses the issues commonly identified, particularly regarding the humans factors issues involved’.\textsuperscript{196}

\textsuperscript{192} 27 July 2015 - e-mail from SM1 to Professor Toft
\textsuperscript{193} Details about the Oxfordshire Clinical Commissioning Group can be found on their website at: http://www.oxfordshireccg.nhs.uk/
\textsuperscript{194} Confidential report Datix: W48452
\textsuperscript{195} 27 July 2015 - e-mail from SM1 to Professor Toft
At the present time the observation made by the National Patient Safety Agency in 2011 is still accurate.\textsuperscript{197}

The report\textsuperscript{198} also raises questions which are not answered, for example, it is stated that the ‘…imaging of the forearm does not exceed beyond the elbow’.\textsuperscript{199} Does this mean that Consultant ‘B’ did not advance the guidewires he used any further than the patient’s elbow? In which case why did Consultant ‘B’ personally arrange for an attempt to be made to remove the wire retained in the patient’s right upper arm and chest by Consultant ‘C’ on the 15 July 2015 at Manor Hospital if he knew he had never advanced the long guide wire that far?

Similarly the report of the investigation states that the ‘…radial route was abandoned, due to the anatomy of the blood vessel…’\textsuperscript{200} But there is no discussion in the investigation report about what the anatomical feature of the blood vessel was that caused Consultant ‘B’ to switch to the femoral route. Nor does the report state which blood vessel was involved or where the anatomical problem with the patient’s blood vessel was located within his person.

In the opinion of the author of this report this SUI should not have been reported to the NHS Oxfordshire Clinical Commissioning Group as a ‘Never Event’. This is not only because of the reasons rehearsed earlier but because there is no evidence to suggest that the Trust’s employees are responsible for the SUI that the patient has sustained.

The date that report was submitted to the NHS Oxfordshire Clinical Commissioning Group is absent from the document.

As a result of further enquiries made by the author of this report it is now known that wire retained within the patient’s body was a fragment of a long guidewire.\textsuperscript{201} However there is still no evidence that it was the PCI procedure undertaken by Consultant ‘A’ which led to the patient inadvertently retaining a piece of long guidewire.

The author of this report found difficulty in following the development of the SUI because of the order in which the information is presented in the ‘Concise Investigation Report’ form.

The ‘Concise Investigation Report’ form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which makes it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also have resulted in data not being presented in a report which could mean important lessons have not been learned.

\textsuperscript{197} Advised by a Consultant cardiologist and an extensive search on the internet
\textsuperscript{198} Confidential report ‘Facts’, Datix: W48452
\textsuperscript{199} Confidential report ‘Facts’, Datix: W48452 p.3
\textsuperscript{200} Confidential report ‘Chronology’, Datix: W48452 p.1
\textsuperscript{201} 27 July 2015 - e-mail from SM1 to Professor Toft
‘Never event’ 2: wrong premolar extracted

On the 31 October 2014 a patient was referred by an external Orthodontic Practice to the Department of Oral and Maxillofacial Surgery and Dental Departments of Orthodontics and Restorative Dentistry at the John Radcliffe Hospital. The patient’s Dentist having referred her to the Orthodontist so that her orthodontic treatment needs could be assessed.

The patient was examined in the pre-operative Dentoalveolar clinic by a Consultant Orthodontist and a Consultant in Oral and Maxillofacial Surgery on the 10 June 2014. It was jointly decided by the two consultants who examined the patient that four teeth would be extracted under General Anaesthetic. The teeth to be extracted were the:

- Upper right second molar
- Upper right canine.
- Upper left first premolar
- Lower right second premolar

The external Orthodontist was sent a letter from the Consultant Orthodontist at the John Radcliff Hospital informing him of the proposed treatment plan.

Subsequently the patient was admitted to the Day Case Surgical Unit on the 3 October 2014 for the extraction of four teeth under General Anaesthetic. The operating surgeon who had not met the patient before took her informed consent which was counter signed by her mother. The consent form stated, “Removal of upper right 2nd molar, canine, upper left 1st premolar + lower right 2nd premolar. In addition, Palmer dental notation was used to identify the teeth to be extracted. The consent form recording that the teeth to be extracted were ‘73/4’. ‘5’

Following the completion of a generic form of the WHO checklist four of the patient’s teeth were extracted. The patient made an uneventful recovery. However at a follow up appointment on the 24 October 2014 the patient’s Orthodontist realised that the lower left second premolar had been extracted instead of the lower right second premolar. The Trust was then informed that the wrong tooth had been extracted. Hence the patient had inadvertently suffered a serious untoward incident (SUI) which was categorised as a ‘Never event – wrong site surgery’.

Root causes

The authors of the investigation report correctly identify that one of the root causes of this incident occurred because of ‘Human Error; the surgeon identified the wrong tooth’. However, the investigators did not identify that the ‘human error’
experienced by the operating surgeon was a ‘perceptual error’\textsuperscript{206} which caused him to lose ‘situational awareness’\textsuperscript{207}. Which might be the reason they did not explore why a perceptual failure took place and try to ascertain at what point in the dental operation the wrong tooth was extracted.

In the ‘Care and service delivery problems’\textsuperscript{208} section of their report the investigators note that: ‘A generic WHO checklist is used in Dental extractions. This does not prompt the practitioner to identify the correct tooth for extraction to the team’.\textsuperscript{209} Therefore the failure of the WHO checklist to ‘prompt the practitioner’, it could be argued, is also one of the root causes for the incident occurring.

Similarly, it can be argued, that because there is no method at the moment to be able to distinctively mark the teeth to be extracted this could also be considered another root cause of the adverse event taking place.

While the failure to have a second independent person check the tooth to be extracted is the correct one it could also be deemed to be a root cause of the incident.

The report of the investigation states that:

\begin{quote}
‘The operation note completed following this surgery however, noted “73/4 Under GA” had been \(\textit{\small /5}\) “performed which is not what was recorded on the patient consent as the planned surgery”.\textsuperscript{210}
\end{quote}

Indeed, the planned surgery, as noted above, using Palmer notation was to have been: 73/4’. But as can be observed in the notation used after the operation (in \(\textit{\small /5}\) italics above) the numeral ‘5’ is on the right hand side of the \(\textit{\small /}\) (forward slash) and not the left where it should have been. Hence the operating surgeon seems to have been well aware of the position and types of teeth he had extracted from the patient’s mouth.

The question is why, when completing his post-operative notes, the operating surgeon did not perceive that the dental notation he used to describe the location and types of teeth he had extracted did not match the pre-operative notation. This issue however is not addressed in the report. Although it might have been one of the root causes of this SUI occurring.

\textsuperscript{208} Confidential report Datix: W54592/ID 61290 p.10
\textsuperscript{209} Confidential report Datix: W54592/ID 61290 p.10
\textsuperscript{210} Confidential report Datix: W54592/ID 61290 p.9
In a similar vein the investigators have not provided a description of the checking process used by the operating surgeon during the extractions to try to ensure that the tooth he was about to remove was the correct one. Hence, when reading the report it is impossible to know whether there were other root causes which were missed because the level of detail required to make such a determination is absent from the report.

Lessons learned

The investigation reports states that:

‘The need for higher vigilance during dental extractions to ensure the correct tooth is extracted is required.

‘The practitioner performing the procedure had not met the patient prior to the day of surgery, which resulted in a lack of opportunity for the patient and the operating surgeon to discuss the plan, and so for the surgeon to have a potential memory of previous discussions with the patient and parent regarding the planned extraction’.211

With respect to the exhortation made above for ‘higher vigilance’ when dental extractions are taking place. Odukoya and Chui have observed that there is:

‘…significant evidence in human factors literature shows that reliance on vigilance to catch errors is unreliable…’.212 Similarly, Porto has concluded that, ‘…getting it right the first time and noticing when it is wrong – require the vigilance of the individual, a skill at which humans are generally unreliable’.213 While Donaldson notes that ‘Individuals cannot remain vigilant for long periods of time’.214

Thus while an operating surgeon will always need to exercise vigilance another lesson to be drawn from this incident is that the caution expected of a healthcare professional should not be relied upon where an error free performance is required. Rather mechanisms such as technology aids where available, mandatory protocols and checklists should be used so that reliance on the vigilance of the operating surgeon is reduced to ‘as low as reasonably practicable’ (ALARP).215

Another lesson that might be drawn is that because there is no method for distinctly marking teeth for extraction then more than one technique should be used to identify the tooth or teeth to be removed. Thus lowering the risk of erroneous extractions.

211 , Confidential report -‘Lessons Learned’, Datix: W54592 p.11
As with the ‘Root Causes’ there is not sufficient detail in the report to judge whether all the lesson that could be drawn from this incident have been learned.

**Recommendations**

The recommendations made by the investigators\(^{216}\) should, when implemented, reduce the likelihood of another incident of a similar nature occurring.

However, an additional recommendation which might also reduce the likelihood of a wrong extraction has been made by Lee \textit{et al} who have suggested that:

‘A patient-mirror is a good method to identify and verify which tooth is going to be removed’.\(^{217}\)

While another recommendation which could also be made is for the pre-operation Palmer notation stating which tooth or teeth are to be extracted to be independently compared with the post-operative notation of the teeth actually removed to ensure they are the same. In this way provided the original Palmer notation was correct:

‘When the wrongsite tooth extraction is identified immediately, reimplantation with subsequent endodontic therapy may enable retention of the involved tooth’.\(^{218}\)

Therefore if it were to prove possible to re-implant a wrongly extracted ‘\textit{sound}’\(^{219}\) tooth this would be of significant benefit to a patient.

**Comments**

As noted above guidance provided by the Department of Health and subsequently adopted by NHS England regarding ‘\textit{Never Events}’\(^{220}\) states that:

‘\textit{Never events are a sub-set of Serious Incidents and are defined as ‘serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers}’."\(^{221}\)

While other guidance adopted by NHS England clarifies the above definition by stating that:

‘\textit{If a provider takes every recommended step to prevent occurrence and}

\[^{216}\text{Confidential report - ‘Recommendations’, Datix: W54592 p.11}\]
\[^{219}\text{The word ‘\textit{sound}’ is used to denote a tooth which under normal circumstances would not extracted in the foreseeable future. The distinction is made because it is possible for the wrong tooth to be extracted but not be re-implanted for}\]
an incident still occurs this argues strongly that the incident was not preventable and therefore not a “never event”.

Hence given the operating dental surgeon appears to have carried out all the recommended safety precautions noted in the NHS England guidance prior to operating and yet the incident still occurred, it would seem that this SUI was inadvertently categorised as a ‘Never Event’.

The list of ‘Root causes’, ‘Lessons learned’ and ‘Recommendations’ in the report could be extended.

The categories of ‘Contributory factors’ and ‘Care and service delivery problems’ are not tightly defined. As a consequence different investigators could categorize the same phenomenon as a ‘Contributory factor’ or a ‘Care and service delivery problem’ hence making pattern recognition difficult when looking for common features of the same or disparate events.

There is not sufficient information in the report on the circumstances surrounding this SUI to enable an independent reviewer to decide whether all the root causes have been identified and all potential lessons learned. This may be because the ‘Root Cause Analysis Investigation Report’ form appears to coerce investigators to review the SUI so parsimoniously that the form of the narrative is staccato. This also makes it difficult for a reader to readily identify data relating to the underlying causes of the SUI.

Under the heading ‘Brief incident description’ in the ‘Executive Summary’ of the investigation report the authors state that, ‘The lower left premolar was removed instead of the planned lower right premolar’. This is a typographical error. The text should read “The lower left second premolar was removed instead of the planned lower right premolar”.

In the section of the investigation report headed ‘Incident description and consequences’ under the subheading ‘Incident description’ the authors state that:

‘The Dentist’s main concern was the failing root treatment in her lower left first molar and enquired whether its extraction could be incorporated into the Orthodontic plan’.

While the statement is correct it gives the impression that the lower left first molar will be extracted as part of the Orthodontic plan. However, following enquiries made by the author of this report it has been established that the patient’s ‘…lower left first

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223 The operating surgeon carried out the WHO checklist procedure and there is no mention in the report of him failing to carry out any of the other safety checks that are required prior to extracting a tooth.


225 Confidential report Datix: W54592

226 Confidential report Datix: W54592, p.2

227 Confidential report ‘Chronology’, Datix: W54592, p.9

228 Ibid, p.5
molar had been ‘lost’ i.e. the root had failed and it had fallen out prior to her first attendance at the John Radcliff Hospital. Thus the text is not only misleading but also unnecessary.

A disciplinary ‘Incident Decision Tree’ analysis was performed for this SUI but the result is not recorded in the report of the investigation.

The author of this report found difficulty in following the development of the SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form. Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and that could lead to lessons not being learned.

‘Never Event’ 3: misplaced nasogastric tube

An 81 year old female patient was admitted to the Emergency Assessment Unit at Horton General Hospital, Oxford on the 3 October 2014 with suspected sepsis from a urinary tract infection. The patient was subsequently transferred to Juniper Ward (an acute general ward) at the hospital on the 5 October 2015. The patient was a diabetic and dependent upon insulin. In addition, after falling ill she had become withdrawn showing little interest in eating or drinking and had problems swallowing.

On the 6 October 2015 the patient underwent an ultrasound examination of her liver which showed she had multiple gall stones and it was presumed that these were the cause of her intermittent sepsis. Antibiotics were started to combat the supposed infection. However maintaining the patient’s blood glucose was difficult because of the assumed infection and the fact she was not eating or drinking. As a result the patient was assessed and it was decided that she should be fed using a fine bore nasogastric tube (FBNGT).

The original Root Cause Analysis Investigation Report of this serious adverse incident (SUI) contains details about the patient’s medical condition and hospital movements which, in the opinion of the author of this report, are unnecessary for the purposes of this critique and therefore will not be recounted here.

On Saturday 1 November 2015 the patient’s FBNGT became blocked and was removed by a nurse. A replacement FBNGT was inserted early in the evening of the 1 November 2015 (the time is not recorded in the Trusts report) by two nurses. Once the nurses were of the opinion that the replacement FBNGT had been correctly sited an attempt was made to obtain aspirate from the nasogastric tube, i.e. extract an amount of the liquid contents of the patient’s stomach. If aspirate is

229 21 August 2015 – E-mail from SM1 to Professor Toft
231 Confidential report Datix: W45903
233 Confidential report Datix: W45903
obtained and has a pH\(^{234}\) of 5.0 or less then feed, medication or water can be administered to the patient using the FBNGT.\(^\text{235}\)

However since aspirate could not be obtained the nurses asked a foundation year Doctor covering the ward to request that an X-ray be taken to confirm that the FBNGT was situated in the patient’s stomach. The patient was X-rayed early in the evening of Saturday 1 November 2015 (the time the X-ray was taken is not recorded in the report of this SUI).

At 18:30hrs 1 November 2015 the nurse caring for the patient who had her FBNGT replaced bleeped the foundation year Doctor as she had been called away from the ward to work in another part of the hospital. The nurse asked the foundation year Doctor to review the X-ray that had been taken to confirm that the FBNGT was correctly positioned in the patient’s stomach. However, the foundation year Doctor was attending to another patient who was acutely unwell at the time and therefore she could not leave the patient to review the FBNGT X-ray film. Hence she reviewed the X-ray which showed the position of the FBNGT in the patient’s body using the Trusts picture archive computer communication system (PACS).\(^\text{236}\)

Whilst reviewing the X-ray which showed the position of the FBNGT in the patient’s body the foundation year Doctor was interrupted in relation to the patient who was acutely unwell and did not look at the X-ray again. Subsequently the foundation year Doctor informed the nurse that the FBNGT was in the correct position and the patient was fed at 19:00hrs 1 November 2015.

Later that evening the foundation year Doctor returned to the ward, where the patient who’s FBNGT had been replaced was located, and documented that the FBNGT was in the correct position. With the advantage of hindsight the foundation year Doctor did recall that “…there was something slightly strange about the CXR [chest X-ray]; however, in her clinical opinion (at the time) the tip of the tube was in the stomach”.\(^\text{237}\)

At 22:00hrs 1 November 2015 the patient was administered medications and a half feed flush by the night nurse who also performed blood glucose measurements. Pressure area care was also provided. The night nurse informed the investigating team that “…the patient did not communicate verbally, however appeared to follow the nurse with her eyes”.\(^\text{238}\) The second half of the patient’s feed flush was administered by the same night nurse at 23:00hrs 1 November 2015. The night nurse stating at interview that other than the half feed flush at 23:00hrs there were no other events to report.

The investigation report observes that following the entry in the patient’s medical notes at 23:00hrs 1 November 2015:


\(^{237}\) Confidential report Datic: W45903, p.13

\(^{238}\) Confidential report Datic: W45903, p.14
'The next entry recorded in the patient’s medical record is at 02:10hrs on 2nd November 2014, this retrospectively records the care that had been given on the previous evening. There is no reference in the records that the patient showed any signs of respiratory distress including coughing, wheezing, noisy breath sounds or increased respiratory effort. This entry also notes that the patient was found unresponsive in bed at 02:10hrs...A medical officer was called to certify her death.'

As a consequence the Trust declared that a ‘Never Event - Misplaced naso- or orogastric tubes’ SUI had occurred and an investigation into the circumstances surrounding the tragedy commenced.

Preamble

The critique of this ‘Never Event’ has been particularly challenging and time consuming. The reason for this is, because of an inadvertent misunderstanding, the author of this report was only initially provided with the report of the investigation and not all the documentation which pertains to this ‘Never Event’.

On attempting to evaluate the findings of the investigation report against the Trusts formal documented procedure for the siting of nasogastric tubes questions were raised that the report of the investigation did not appear to answer. As a result additional documentation was made available which, along with other enquires, has resulted in the author of this report having confidence that the principal root causes of this ‘Never Event’ have now been identified.

The review which follows was initially based on the assumption that the nurses and foundation year Doctor involved in this ‘Never Event’ would be familiar with the details of the Trusts written ‘Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes’ (FBNGT). However, as the analysis below demonstrates when the evidence of what occurred is compared to the requirements of the Trusts FBNGT procedural document it eventually forces that assumption to be challenged.

Root causes

The report of the investigation into this ‘Never Event’ states the root causes of the SUI was that:

239 Confidential report Datix: W45903, p.14
241 Confidential report Datix: W45903,
244 Confidential report Datix: W45903
‘A clinician, who had not been trained in reviewing chest X-rays to confirm placement of a fine bore nasogastric tube, incorrectly interpreted the chest x-ray taken on 1st November stating that the tube was in the patient’s stomach when it was in the left lung. Feed was administered into the tube leading to the patient’s demise’.246

However, the root causes identified by the investigation team are, in the opinion of the author of this report, incomplete. This is because there are other root causes to this ‘Never Event’ that do not appear to have been identified. In the first instance the investigation report states that ‘The foundation year Doctor was not aware of the Trust’s Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Tubes’.247 However the investigation team do not appear to have been aware that the Trust’s ‘Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes’248 extant at the time the SUI took place states:

‘52. Medical staff will be able to access e-learning module for X-Ray interpretation of nasogastric feeding tubes at www.trainingngt.co.uk. The lead consultant responsible must ensure that medical practitioners in their team have undertaken the learning module and have been assessed as competent’.249

There is however no evidence in the report of the investigation250 that the foundation year Doctor’s lead consultant informed her of the requirements she had to meet before interpreting X-rays taken to confirm the position of a FBNGT. Hence the root cause of the SUI as identified by the investigation team with regard to the foundation year Doctor would appear to be erroneous. This is because there is another root cause, i.e. the circumstances which led to the foundation year Doctor not being aware of the training and assessment that she needed to undertake before interpreting X-rays taken for the purpose of confirming the position of an FBNGT in a patient.

In addition, it can be argued, that the misinterpretation of the FBNGT X-ray by the foundation year Doctor may not have been made had she not been interrupted and called away to care for an acutely unwell patient. For as Turner observes when discussing the underlying causes of socio-technical systems251 disasters:

‘…when some hazard or problem was perceived, action taken to deal with that problem distracted attention from the problems which eventually caused trouble. In other words, a contributory factor to the disasters was the attention paid to some well-defined problem or source of danger which

246 Confidential report – Datix: W45903, p.15
247 Confidential report Datix: W45903, p.3
249 Ibid, p.28
250 Confidential report Datix: W45903
was dealt with, but which distracted attention from another dangerous but ill-structured problem in the background\(^{252}\)

Therefore, as the foundation year Doctor had been in the process of reviewing the patient’s FBNGT X-ray when called to attend to the acutely unwell patient it is quite possible she was unconsciously captured by what Turner has called the ‘decoy phenomenon’\(^{253}\) discussed above. Which would be another root cause of this SUI.

In addition, the Trusts ‘Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes’\(^{254}\) states:

\begin{quote}
‘Timing of inserting fine bore NG tubes\end{quote}

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19. Placement of fine bore nasogastric feeding tube is rarely urgent thus should only be inserted during the day time while there is senior medical and nursing cover. However it is acceptable in exceptional circumstances to have a fine bore NG tube inserted out of hours where a competent person is available to interpret and confirm the correct position of the fine bore NG tube in a timely fashion. In these exceptional circumstances the rationale should be clearly documented in the patient’s medical notes\(^{255}\) (Author emphasis)
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Thus given that 1 November 2014 was a Saturday the replacement procedure of the FBNGT took place ‘out of hours’.\(^{256}\) However the report of the investigation makes no mention of there being ‘exceptional circumstances’ documented in the patient’s medical notes. In addition, there was no competent person available to interpret and confirm that the FBNGT was in the correct position. Therefore, it can be argued, given the lack of evidence to the contrary in the investigation report,\(^{257}\) that the patient’s FBNGT should not have been replaced and that it was an erroneous decision to proceed with the FBNGT replacement procedure which was the root cause of this ‘Never Event’ taking place.

In addition, the Trusts procedure regarding FBNGT\(^{258}\) also states that:

\begin{quote}
The Trust will also make certain that all medical and nursing staff understand their role and their accountability for undertaking appropriate training and achieving the competencies required\(^{259}\)
\end{quote}


\(^{253}\) Ibid


\(^{256}\) 13 August 2015 – e-mail to Professor Toft from a Trust employee

\(^{257}\) Confidential report Datix: W45903,


\(^{259}\) Ibid p.23
However, it would appear that the foundation year Doctor did not:

…understand their [her] role and their [her] accountability for undertaking appropriate training and achieving the competencies required.\(^{260}\)

Nor, it can be argued, did the nurses involved in this SUI given the Trusts, own written instruction not to perform the insertion of an FBNGT ‘out of hours’ other than in exceptional circumstances.

Thus the Trust appears to have failed in its stated aim to make:

‘…certain that all medical and nursing staff understand their role and their accountability for undertaking appropriate training and achieving the competencies required’.\(^{261}\)

The Trusts failure to ensure that the medical and nursing staff were competent to carry out the task of correctly replacing or, depending on the circumstances prevailing at the time, not replacing a FBNGT appears to have occurred because those responsible\(^{262}\) for the system of training staff in these matters\(^{263}\) did not perform as envisaged. Thus another root cause of this ‘Never Event’ taking place would seem to be that the systems in place for ensuring ‘…that patients within the Trust receive safe and effective fine bore NG tube feeding with minimal risk and incidents’\(^{264}\) did not perform effectively.

Furthermore the Trusts procedural document in relation to FBNGT\(^{265}\) also states that:

‘Repeat checks

‘29. The fine bore NG tube position should be confirmed, by staff deemed competent, following initial insertion and thereafter before administering feed, water, or medications…’\(^{266}\) (Author emphasis)

Similarly ‘Appendix 2: Nasogastric Feeding Tube Position Record’ states that:

‘Nasogastric feeding tubes should always be checked for correct position:

‘Following initial tube insertion

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\(^{260}\) Ibid p.23  
^{261}\) Ibid p.23  


^{265}\) Ibid, p.26
‘Before starting the feed, each bolus feed or drug administration.’\textsuperscript{267} (Author emphasis)

The form used to document when ‘Repeat Position Checks’ have been undertaken asks for, amongst other data, the ‘Date Time’ the check is undertaken, ‘first visible marker’, ‘aspirate obtained and ‘pH of aspirate’.\textsuperscript{268}

In the ‘Discussion’ section of the investigation report it is stated that, ‘[a]t 22:00hrs the night shift nurse attended the patient to administer medications …’\textsuperscript{269} However the investigation report makes no mention of a repeat position check being undertaken by the nurse who administered the medications to the patient. As a consequence the question arises was the required repeat position check undertaken by the nurse at 22:00hrs 1 November 2015 and if not why not? However, the report of the investigation does not discuss this issue although it might have been one of the root causes of this ‘Never Event’ occurring.

Finally, the Trusts procedural document on FBNGT extant at the time of this ‘Never Event’ occurring states:

‘It is the Trust guidance that patients requiring fine bore nasogastric (NG) tube feeding will be correctly assessed for this method of enteral nutrition, have the fine bore NG tube inserted by a fully trained and competent practitioner and that the patient will receive their fine bore NG tube feeding in a safe manner following confirmation of tube placement.’\textsuperscript{270} (Author emphasis)

The above statement regarding the training of staff is also reinforced later in the Trusts procedural document relating to FBNGT\textsuperscript{271} in the section headed:

‘Staff Responsibilities

‘9. Staff undertaking this procedure should have had appropriate training and be deemed competent. All practitioners are personally responsible for updating and maintaining their competency.’\textsuperscript{272}

Appendix 4\textsuperscript{273} of the Trusts ‘Procedure for the Insertion, Use and Care of Fine Bore

\begin{thebibliography}{9}
\bibitem{272} Ibid, p.24
\end{thebibliography}
Nasogastric Feeding Tubes\textsuperscript{274} provides a specimen form which contains all the various competencies to be assessed and signed off before an individual may insert a FBNGT into a patient as noted above. The investigating team did attempt to ascertain whether the nurse who sited the replacement FBNGT was qualified to undertake the procedure observing that:

‘The nurse had been working for the Trust for five years and had moved to the ward some six months prior to the incident. She reports having inserted many nasogastric feeding tubes, however did not recall any specific difficulty inserting the feeding tube into the patient on 1st November. Her training for tube insertion predated the new “competencies model” required by band five nurses commencing employment with the Trust. As the nurse had worked in other areas of the Trust, she had frequently been required to carry out nasogastric feeding of patients in previous positions’.\textsuperscript{275}

However that said on the 31 January 2012 in response to an ‘Alert’ issued by the National Patient Safety Agency concerning the death of patients caused by misplaced FBNGTs the Trust introduced a policy entitled, ‘Procedure for the Insertion, Use and Care of Nasogastric Feeding Tubes’ to combat the problem. The Trust avowing that:

‘Policy statement

1. It is the policy of the Trust that patients requiring nasogastric nutrition will be correctly assessed and that they will then receive safe and effective nasogastric feeding’.\textsuperscript{276}

Later in the Trusts policy document on FBNGTs the following instruction is given:

‘Insertion of Nasogastric tubes

28. This should only be performed by an appropriately trained practitioner who has completed the competency framework on insertion of NG tubes (Appendix 4).

29. The trained practitioner should carry out the procedure as described in Procedure for insertion of fine bore Naso-gastric tubes (Appendix 5).’\textsuperscript{277}

Thus as the FBNGT procedure had the status of policy, compliance with its strictures was mandatory. Thus the nurse who sited the patient’s FBNGT should have undergone the necessary training and have successfully passed the ‘Nurse Competences’\textsuperscript{278} as required by the policy. Yet the actions of the nurses and

\textsuperscript{274} Ibid, p.21
\textsuperscript{275} Confidential report Datix: W45903, p.12
\textsuperscript{276} Enteral Nutrition Clinical Nurse Specialist, Clinical Nurse Manager Vascular Access, Procedure for the Insertion, Use and Care of Nasogastric Feeding Tubes, Oxford University Hospitals, January 2012, p.3
\textsuperscript{277} Ibid, p.5
\textsuperscript{278} Ibid, p.16
foundation year Doctor strongly suggested that they were not aware of the Trusts FBNGT procedure. Hence the question was raised were they in fact aware of the Trusts FBNGT procedure.

With the hindsight provided through additional documentation it can be observed that the investigation team failed to identify that:

'It was apparent that the two nurses who gave evidence at the Inquest and [name of foundation year Doctor] were unaware of the OUH policy of January 2012 entitled “procedure for the Insertion, Use and Care of Nasogastric Feeding Tubes.”'\(^{279}\)

Indeed enquiries made following the release of the extra documentation and additional enquires made by the author of this report have unambiguously revealed that ‘[t]he nurse who placed the NG tube had not completed the appendix four competency at the time of the incident.'\(^{280}\) Similarly, ‘…nor had the observing nurse…completed the appendix four competency at the time of the incident'.\(^{281}\) It is also clear from the findings of the investigation that the foundation year Doctor was not aware that she had to undergo training and be assessed as competent before interpreting a patient’s X-ray for the purposes of confirming the position of a FBNGT. Which is not surprising since it has now been established that the foundation year Doctors lead consultant:

‘…was not aware of this (FBNGT) policy in detail and had had no discussion in relation to it with the doctor prior to the incident’.\(^{282}\)

The reason why the foundation year Doctor’s lead consultant was not aware of the Trusts FBNGT procedure, it can be argued, is because:

There is some ambiguity regarding the definition of ‘lead consultant’ in this context. The [lead consultant for the foundation year Doctor] has interpreted this as the lead consultant for the policy rather than for the doctor although is not clear who this would be'.\(^{283}\)

Therefore ‘given that no one can prespecify their own ignorance’\(^{284}\) it is not surprising that the two nurses involved with siting the patient’s FBNGT and the foundation year Doctor were unaware of the criteria that had to be met before a FBNGT could be inserted ‘out of hours’. Hence the root causes of this SUI, it can be argued, was the failure of the Trusts clinical policy alerting, distribution and training system to perform as envisaged. Evidence to support this contention can be drawn from the conclusion drawn by the Senior Coroner for Oxfordshire who stated that:

\(^{278}\) Senior Coroner – Regulation 28: report to prevent future deaths, dated 8 May 2015, item 1
\(^{280}\) 20 August 2015 – e-mail to Professor Toft from SM1
\(^{281}\) 4 September 2015 –email to professor Toft from SM3
\(^{282}\) 7 September 2015 – e-mail to Professor Toft by SM3
\(^{283}\) Ibid
‘The impression I obtained from the evidence is that whilst a policy or procedure is produced they may not be sufficiently disseminated to the nurses and doctors...It would assist if this process could be reviewed and explained to me’.285

With regard to the nurse who inadvertently misplaced the FBNGT and the foundation year Doctor who unintentionally misinterpreted the FBNGT confirmation X-ray, it can also be argued that they were also victims of the Trusts failed clinical policy alerting, distribution and training system rather than root causes of this ‘Never Event’.

Lessons learned

The lessons cited as being learned by the investigation team in their report are in alignment with their account of the circumstances leading up to this SUI. However, with respect to the first lesson drawn by the investigation team that:

‘Medical staff who interpret chest x-rays to confirm the position of nasogastric tubes should be trained to undertake this task’.286

As noted above it is explicitly stated in both the 2012 and 2014 versions of the Trusts FBNGT written procedures that:

‘Medical staff will be able to access e-learning module for X-Ray interpretation of nasogastric feeding tubes at www.trainingngt.co.uk. The lead consultant responsible must ensure that medical practitioners in their team have undertaken the learning module and have been assessed as competent’287

Thus the lesson drawn by the investigation team regarding the training of medical staff to interpret X-rays taken to confirm the position of FBNGT’s is misleading. This is because the report gives the impression that the investigation team has identified a safety activity previously unknown to the Trust. Whereas the training of medical staff in the interpretation of X-rays for the purposes of confirming the position of an FBNGT was explicitly incorporated into the Trusts FBNGT procedure. Another lesson identified by the investigation team was that:

‘Not all staff were aware of the Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Tubes, although it is available on the Trust’s intranet. There should be wide dissemination of this document so all staff that insert FBNGT and administer feeds and medication via this route are aware of the Trust procedure and where it can be found’.288

285 Senior Coroner, ‘Coroners Concerns’, Regulation 28: report to prevent future deaths, dated 8 May 2015, item 4
286 Confidential report Datix: W45903, p.15
However while the investigation team recognised that not all the staff were aware of Trusts FBNGT procedure and that as a consequence it should be distributed more widely. They do not appear to have recognised that another lesson which could be drawn from their conclusion is that the Trusts policy/guidance alert, distribution and training system did not work as intended and it was that failure which played a pivotal role in the creation of this SUI.

The investigation team also drew the lesson that:

‘Elderly patients may not exhibit a strong cough reflex and therefore the absence of pronounced coughing cannot be relied upon to assume that the feeding tube has not passed into the lungs.

However, the supporting information supplied by the National Patient Safety Agency (NPSA) with respect to their 2011 Alert on misplaced nasogastric feeding tubes\textsuperscript{289} states that:

‘Traditional bedside methods: Observing for respiratory signs or symptoms such as coughing, dyspnoea, or cyanosis does not provide evidence of tube misplacement into the airway’\textsuperscript{290} (Emphasis in the original)

Thus the lesson drawn by the investigation team with regard to a patient not exhibiting a cough when being fitted with an FBNGT had been published by the NPSA before this SUI took place. Therefore since that information was issued by the NPSA it should, in the opinion of the author of this report, have been incorporated into the Trusts FBNGT procedure.

However the caveat concerning respiratory signs is not contained in either of the Trusts FBNGT procedure documents\textsuperscript{291}. Similarly, it should also be noted, that the NPSA published a Rapid Response Report (RRR) entitled \textit{Harm from flushing of nasogastric tubes before confirmation of placement} on the 22 March 2012.\textsuperscript{292}

However, none of the information contained within the NPSA RRR is drawn upon in the text of the Trusts FBNGT procedure nor is the NPSA RRR cited in the ‘References’ section of that document\textsuperscript{293}

Thus another lesson that could be drawn is that on occasions not all the relevant information regarding patient safety alerts from a national source is incorporated into the Trusts local clinical policy/guidance documents.

\textsuperscript{290} Ibid, p.13
\textsuperscript{292} \ldots, ‘Harm from flushing of nasogastric tubes before confirmation of placement’, NPSA/2012/RRR001, National Patient Safety Agency, 22 March 2012 at: \url{http://www.nrls.npsa.nhs.uk/resources/?entryid45=133441} accessed 11 October 2015
Recommendations

The recommendations made by the investigation team are consistent with their narrative on the circumstances surrounding this SUI. However recommendation 2 commences by stating that:

‘All medical staff who are involved in interpreting CXR to confirm positioning of FBNGT should be adequately trained’.294

As noted earlier, such training for medical staff is a requirement of both the 2012 and 2014 Trusts written procedure for the insertion of FBNGT. Similarly, recommendation 3 states:

‘All frontline nursing staff must complete a competency based training package relating to the insertion and care of nasogastric tubes’.295

Yet again, as discussed above, such training for nurses is stipulated in both the 2012 and 2014 Trusts written procedure regarding the use of FBNGT’s. Thus, it can be argued, both of these recommendations were unnecessary.

However an additional recommendation that could have been made, before the Coroners observation, is that since the Trusts alert, distribution and training system for local clinical policy/guidance documents did not work as expected a review of the current system should be undertaken as soon as possible to ascertain why it failed.

As discussed above the NPSA, in addition to their patient safety alert, published supporting information stating that when inserting an FBNGT staff should not take the absence of respiratory distress by a patient as evidence that the tube is correctly sited.296 However this information is not in either of the Trusts documents regarding FBNGT’s.297 Similarly the NPSA’s RRR on the Harm from flushing of nasogastric tubes before confirmation of placement has not been cited in the Trusts 2014 FBNGT procedure. Thus another recommendation which could be made is that before the Trusts releases a local clinical policy/guidance document based upon national policy or guidance an independent check must be undertaken to ensure that all the relevant information from such documents has been included.

Comments

This SUI was correctly declared as a ‘Never Event - Misplaced naso- or oro-gastric tubes’.298

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295 Ibid
Due to inadvertent human error a nurse did misplace the FBNGT and the foundation year Doctor did unintentionally misinterpret the patient’s FBNGT X-ray but, in the opinion of the author of this report, these were not the root cause of this ‘Never Event’. The root cause of this SUI, it can be strongly argued, was the failure of the Trusts alert, distribution and training system for local clinical policy/guidance documents.

This is because if the nurse had been aware that FBNGT’s can only be inserted in exceptional circumstances when out of hours then advice would have been sought from a senior nursing or medical colleague. Similarly, if the foundation year Doctor had known she needed to be assessed as competent before being allowed to interpret X-rays taken for the purpose of confirming the position of a FBNGT then she would not have undertaken the task of interpreting the patient’s FBNGT X-ray. Rather she would have asked a medical colleague who had been assessed as competent to undertake the task and the SUI should not have occurred.

The list of ‘Root causes’, ‘Lessons learned’ and ‘Recommendations’ could be extended.

Although this was a ‘Never Event’ the report of the investigation does not discuss whether an NPSA ‘Incident Decision Tree Analysis’ was undertaken.

The e-learning module for the X-ray interpretation of FBNGT which is noted in the Trusts FBNGT procedure is not available at the internet address (www.trainingngt.co.uk) provided in the document.

It is ambiguous as to precisely who the phrase ‘lead consultant’ refers to in paragraph 52 of the Trusts FBNGT procedure which states that:

‘The lead consultant responsible must ensure that medical practitioners in their team have undertaken the learning module and have been assessed as competent’.

The report of the investigation raises questions which it does not answer for example it is stated that:

‘The next entry recorded in the patient’s medical record is at 02:10hrs on 2nd November 2014, this retrospectively records the care that had been given on the previous evening’.

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302 Ibid

303 Confidential report Datix: W45903, p.14
However the report does not provide any rationale as to why the night nurse did not keep a contemporaneous record of the care she was providing to the patient.

In the ‘Action Plan’ section of the report of the investigation it is stated that:

‘There is no mandatory assessment of competence relating to nasogastric feeding for nurses who commenced working for the Trust prior to the introduction of the current band five nursing competencies’.\(^{304}\)

However the Trusts FBNGT procedure introduced in 2012\(^{305}\) was a policy and therefore it was mandatory for all nurses to complete and be assessed on the competencies set out in Appendix 4\(^{306}\) of that document. The status of the Trusts FBNGT published in 2014\(^{307}\) appears to be unclear. However, in the opinion of the author of this report, the Trusts FBNGT procedure should be policy, i.e. compliance should be mandatory as should all Trust safety protocols.

The investigation team state that one of the contributory factor to this ‘Never Event’ was that:

‘…the doctor interpreted the chest x-ray remotely by computer (i.e. the foundation doctor was on an adjacent ward at the time and did not examine or sight the patient when reviewing the chest x-ray)’.\(^{308}\)

However there is no explanation in the report of this investigation as to why interpreting the patient’s FBNGT X-ray on PACS by the foundation year doctor was a contributory factor to this ‘Never Event’.

Although the investigation team included the Trusts FBNGT procedure\(^{309}\) as Appendix 1 in the report it would appear that they did not recognise the provisions in it which led to the identification of a different root cause by the author of this report to the one which they proposed.

The author of this report found difficulty in following the development of this SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form.

Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also

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\(^{304}\) Confidential report Datix: W45903, p.19

\(^{305}\) Enteral Nutrition Clinical Nurse Specialist, Clinical Nurse Manager Vascular Access, Procedure for the Insertion, Use and Care of Nasogastric Feeding Tubes, Oxford University Hospitals, January 2012

\(^{306}\) Ibid, pp.16 -17


\(^{308}\) Ibid, pp.16 -17

have resulted in data not being presented which could lead to lessons not being learned.

‘Never Event’ 4: retained midline catheter guide wire

On the 14 November a 24 year old man suffering from an infective exacerbation of Cystic Fibrosis was admitted to the infectious diseases ward at the Churchill Hospital, Oxford because he was feeling unwell. It was decided that a midline catheter should be inserted into his arm the following day so that intravenous antibiotics could be administered to treat his medical condition.

As planned, on the 15 November 2015 an Advanced Nurse Practitioner (ANP) arrived at the patient’s bedside with all the medical equipment required to insert a midline catheter. It should be noted that there is no dedicated standard pack of medical equipment for this procedure or documentation and it is performed by a single ANP.

In the first instance the ANP attempted to insert the midline catheter into the patient’s right arm but found, having done so, that she could not flush the catheter as required by the procedure and so she removed it. A second attempt to insert a midline catheter into the patient’s left arm was successful however and the patient was discharged to home the following day.

On the 20 November 2014 the patient rang the Churchill Hospital to report that the antibiotics he was self-administering through the midline catheter were not as effective as anticipated and that he felt ill. An appointment was made for the patient to attend the Respiratory Day Case Unit at the Churchill Hospital the following day.

On the 21 November 2015 while discussing his medical condition with a consultant in the Respiratory Day Case Unit the patient reported that he was experiencing pain in his right upper arm. The pain in his arm was subsequently diagnosed as phlebitis. However as his medical condition was not improving as expected he was admitted to the hospital.

Because the pain in the patient’s right upper arm did not subside he underwent an investigative ultrasound scan on the 24 November 2015. The ultrasound scan revealed that the guidewire used in the unsuccessful attempt to insert a midline catheter in his right arm had inadvertently been retained within the patient’s body and this was the reason for the pain he was experiencing.

This serious untoward incident (SUI) was reported on Datix and classified as a ‘Never Event - Retained foreign object post-procedure’. On the 25 November

309 Confidential report Datix: W56416
313 Confidential report Datix: W56416
2014 a Consultant Vascular Surgeon at the Churchill Hospital, operating at the patient’s bedside, removed the guidewire from his right arm intact. The patient has suffered no lasting ill effects.

At interview the ANP reported that she had used the ‘Seldinger’ technique\textsuperscript{316} to introduce the midline catheter into the patient’s right arm (unsuccessfully) and left arm (successful). The technique:

...involves inserting a needle into the vein, passing a guidewire through the needle, removing the needle, then threading the small plastic tube onto the guidewire and into the vein. This is the recognized technique for line insertion. The guidewire should be secured throughout the procedure between the operator’s fingers or between the operator’s fingers and the patient’s skin, as there is the possibility that it could be lost into the patient’s circulation'.\textsuperscript{317}

The ANP also reported that during the first unsuccessful attempt to insert the midline catheter into the patient’s right arm she did not recall losing sight of the guidewire or it slipping from her grasp. She did however recall that after the procedure was completed she only disposed of one guidewire and not two.\textsuperscript{318} The investigation report on this SUI suggests that the guidewire might have been drawn into the patient’s vein when the ANP reached for a piece of equipment.\textsuperscript{319}

The ANP also noted at interview that there were a number of interruptions and distractions while she carried out the midline catheter procedures. For example, a domestic assistant entered the curtained off area around the patient’s bed to offer him a cup of tea and the patient’s nurse came in to take down his intravenous antibiotics. In addition, the ANP was also subject to time constraints. She was scheduled to provide care for another patient in the near future and thus ‘...the practitioner may have felt under pressure to insert the line quickly’.\textsuperscript{320} It was also noted in the report of the investigation that during the period that this SUI took place that:

‘... it was an exceptionally busy period for the CF [Cystic Fibrosis] service during November, both for the inpatient and outpatient service. As a result, the clinical teams, both nursing and medical were stretched to their capacity in supporting competing demands’.\textsuperscript{321}

Finally, while the ANP documented her successful insertion of a midline catheter in the patient’s left arm this was not completed for the failed attempt in the patient’s right arm.

\textsuperscript{317} Confidential report Datix: W56416, p.9
\textsuperscript{318} Confidential report Datix: W56416, p.9
\textsuperscript{319} Confidential report Datix: W56416, p.9
\textsuperscript{320} Ibid, p.10
\textsuperscript{321} Ibid, p.10
Root causes

The investigation report of this ‘Never Event’ concluded that the root causes were that:

‘An error was made by the operator who lost sight and hold of the guidewire during the insertion. There was no systematic check to ensure that the guidewire was present and intact at the completion of the line insertion’. 322

However, as noted above, at interview the ANP noted that while undertaking the midline catheter insertion procedures there were a number of interruptions and distractions. 323 It should be noted therefore that in a study into drug administration errors in the United Kingdom it was concluded that one of the ‘Main causes of drug errors… [was the]… ‘Interuption and distraction of nurses during drug administration’. 324 While the Institute for Safe Medication Practices in the United States in a ‘Safety Alert’ stated that:

‘Distractions and interruptions include anything that draws away, disturbs, or diverts attention from the current desired task, forcing attention on a new task at least temporarily. Attending to the new task increases the risk of an error with one or both of the tasks because the stress of the distraction or interruption causes cognitive fatigue, which leads to omissions, mental slips or lapses, and mistakes’. 325

Similarly, the National Nursing Research Unit has concluded that:

‘Interruptions affect staff cognitively, interfering with working memory, causing lack of focus (3) and invoking feelings of frustration and stress’. 326

While the Report of the NHS England Never Events Taskforce’ observes that one of the ‘Sources of error consistently recognised [is that of]… unplanned events and distractions that disrupt work flow…’ 327

Thus another root cause of this SUI, it can be argued, was that an interruption caused the ANP to lose her ‘situational awareness’328 when undertaking the removal of the midline catheter in the patient’s right arm, which she then inadvertently failed

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322 Ibid, p.12
323 Ibid, p.9
325 „„, ‘Side tracks on the safety express. Interruptions lead to errors and unfinished… Wait, what was I doing?’. ISMO Medication Safety Alert!, 29 November 2012 at: https://www.ismp.org/newsletters/acuteCare/showArticle.aspx?id=37 accessed 11 October 2015
to ‘perceive’.\textsuperscript{329} Evidence to support this conclusion can be found in the work of Grieg \textit{et al} who argue that, ‘…perceptual failures are a cause of loss of situational awareness in practice’.\textsuperscript{330}

\section*{Lessons learned}

The investigation reports rightly states that some of the lessons to be learned from this SUI are:

\begin{quote}
‘\textit{Interruption during line insertion increases the risk of errors.}'
\end{quote}

\begin{quote}
‘\textit{Standardization of equipment assists staff, by pattern recognition, to notice if any equipment is missing.}'
\end{quote}

\begin{quote}
‘\textit{Performing line insertion as a singlehanded practitioner is challenging. Should unexpected events arise with the equipment or patient the practitioner may become distracted from the line insertion, increasing the risk of errors}’.\textsuperscript{331}
\end{quote}

However another lesson that could be drawn is that this SUI was caused, in part, by inadvertent human error, i.e. the ANP performing the midline catheter procedure lost her situational awareness due to an inadvertent perceptual failure.

A further lesson that might be drawn from this SUI is one that was previously discussed in ‘\textit{Never event} 2: wrong premolar extracted\textsuperscript{332}, i.e. that the vigilance expected of a healthcare professional should not be relied upon where error free performance is required. Rather mechanisms such as technological aides, mandatory protocols and checklists should be developed so that reliance solely on the vigilance of a healthcare practitioner working on their own to catch errors is reduced to as low as reasonably practicable.

\section*{Recommendations}

The recommendations of the investigator align with their findings.

However, another recommendation which might be made where midline catheter insertions are undertaken at the bedside is that warning signs stating ‘\textit{Keep out – clinical procedure in progress}’ should be placed on either side of a patient’s bed to prevent unwanted interruptions and distractions.

While it is recorded in the ‘\textit{Recommendation}’ box of the ‘\textit{Action Plan}’ that:

\begin{quote}
‘\textit{A review of the feasibility of a dedicated room for sterile procedures in}
\end{quote}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{329} ‘\textit{Perceive}’, Oxford Dictionaries, \url{http://www.oxforddictionaries.com/definition/english/perceive} accessed 11 October 2015
\item \textsuperscript{331} Confidential report – Datix: W56416, p.12
\item \textsuperscript{332} ‘\textit{Never event} 2: wrong premolar extracted, confidential report Datix: W54592
\end{itemize}
\end{footnotesize}
the outpatient setting should be made available. For inpatients, a similar review should be undertaken’.333

The above recommendation is not recorded in the ‘Recommendation’ section of the SUI report.334

Comments

This was a SUI, but as rehearsed in arguments earlier, in the opinion of the author of this report, it was not a ‘Never Event.’

The list of ‘Root causes’, ‘Lessons learned’ and ‘Recommendations’ associated with this SUI could be extend.

At interview the ANP recalled only disposing of one guidewire following the two midline catheter procedures she had carried out. However the report of this SUI does not explore that finding.

Similarly the ANP stated that she did not document the unsuccessful attempt to insert a midline catheter in the patient’s right arm but the report of the SUI does not discuss why that occurred.

The report of this SUI states that the ANP was subjected to time pressure because she had to care for another patient in the very near future and that the Cystic Fibrosis service was stretched to its limits. This however is an undesirable situation for the United Kingdom Health and Safety Executive observe that:

‘Work-related stress is a major cause of occupational ill health, poor productivity and human error. It can result in sickness absence, high staff turnover and poor performance and a possible increase in accidents due to human error’.335

Similarly, the ‘Report of the NHS England Never Events Taskforce’ observes that ‘…time pressures and the use of ‘work arounds’ to manage work pressure…’ are well-known sources of error.336 Hence, it can be argued, that the work environment in which the midline catheter procedures were carried out may have been partly responsible for the ANP failing to perceive that she had lost situational awareness.

A disciplinary ‘Incident Decision Tree’337 analysis was performed for this SUI but the result is not recorded in the report of the investigation.

333 Confidential report – Datix: W56416, p.15
334 Confidential report – Datix: W56416, p.15
The author of this report found difficulty in following the development of the SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form.

Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and that could lead to lessons not being learned.

‘Never Event’ 5: wrong tooth removal

On the 1 December 2014 a 14 year old patient was referred to the Department of Maxillofacial Surgery, John Radcliffe Hospital, Oxford (Department) by his Specialist Orthodontist for a treatment plan which would incorporate the exposure of two teeth and extraction of four other teeth. The teeth planned for extraction were:

- Upper Right Canine (URC)
- Upper Left Canine (ULC)
- Upper Right 4 (UR4)
- Upper Left 4 (UL4)

However in December 2014 the waiting time for a new outpatient appointment in the Department was four months. As a consequence the patient’s father contacted a colleague in the Department to ‘…see if the process could be expedited’. Subsequently the consultant booked the patient to be examined by him on the 6 January 2015 during his on call week in the Department’s Trauma Clinic.

Because he was on call the day of the patient’s appointment the consultant was very busy. At some point during the dental examination the consultant using Zsigmondy-Palmer dental notation recorded in the patient’s clinic notes that teeth C/C should be extracted. However this was an inadvertent transcription error because the dental notation used erroneously indicated that the patient was to have the Lower Right 4 (LR4) and Lower Left 4 (LL4) teeth extracted. Whereas the patient’s Specialist Orthodontist, as noted earlier, had requested that the Upper right 4 (UR4) and Upper Left 4 (UL4) teeth be removed.

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338 Confidential report Datix: W60304
339 Ibid,
Consequently when the consultant, drawing upon his Trauma Clinic notes, wrote a letter to the Orthodontic Clinic with his management plan it was the wrongly transcribed configuration of teeth which he scheduled for extraction.

On the day of the patient’s dental operation, Monday 13 January 2015, while the Trauma Clinic notes and the letter to the clinic by the consultant, both of which contained the transcription error, were checked by a foundation year 2 Doctor the initial referral letter was not. The patient’s X-rays had been checked the previous night.

On the day of the patient’s operation an anaesthetist was absent from the Department due to ill health and as a consequence the consultant was busy trying to find a replacement. Therefore the consultant also delegated the task of obtaining the patients consent for their dental surgery to the foundation year 2 Doctor.

Drawing upon the consent form, which had the dental procedure to be undertaken written in full and also in dental notation\textsuperscript{342}, the foundation year 2 Doctor provided the patient and his father with a full explanation of the procedure and the serious or frequent risks involved. No concerns were raised by either the father or the patient about what they had been told and both signed the consent form.

The World Health Organisation safety checklist\textsuperscript{343} was performed as required prior to the operation commencing after which the patient’s dental surgery was performed according to the consultant’s unintended erroneous management plan.

Subsequently the patient’s Specialist Orthodontist wrote to the consultant who performed the dental surgery on the 21 January 2015 to inform him that the Lower Right 4 (LR4) and Lower Left 4 (LL4) had been extracted from the uncrowded lower arch in error. While the Upper Right 4 (UR4) and Upper Left 4 (UL4) in the crowded arch remained in place. The letter also noted that the patient would now need additional dental surgery and orthodontic treatment. Thus the Trusts declared that a serious untoward incident (SUI) ‘Never Event’ ‘Wrong site surgery’\textsuperscript{344} had occurred.

**Root causes**

The report of the investigation correctly states that the root cause of this SUI was ‘Human Error; this incident was caused by a Transcription Error by the Consultant in the OPD (Out Patient Department)’.\textsuperscript{345} However, as for example in ‘Never Event’ 2: wrong premolar extracted\textsuperscript{346} the investigator did not identify that the ‘human error’ experienced by the consultant was a ‘perceptual error’\textsuperscript{347} which caused him to lose


\textsuperscript{345} Confidential report Datix: W60304, p.12

\textsuperscript{346} Confidential report Datix: W54592

‘situational awareness’ and it was that which lead to the consultant not perceiving he had made a transcription error.

Again, as in ‘Never Event’ 2: wrong premolar extracted, it can be argued, that because there is no method at the moment to be able to distinctively mark the teeth to be extracted this could also be considered another root cause of the adverse event taking place.

In the report of the investigation it states that the foundation year 2 Doctor did not check the initial referral letter to the Department but relied upon the notes made by the consultant in the Trauma Clinic and the letter he sent to the Orthodontic Clinic containing the patient’s management plan. Hence an argument can be made that another root cause of this SUI was the lack of an explicit cross-check to ensure that all the documents regarding a patient dental surgery, including the initial letter of referral, record exactly the same treatment plan.

It is also noted in the report of the investigation that the patient’s consultant was occupied with trying to find an anaesthetist to replace the one whose illness had prevented him from coming to work. As a consequence:

‘The Consultant did not therefore personally consent the patient which is unfortunate as his usual practice is to cross check the initial referral letter when consenting such patients and this may have revealed the previous error.’

Therefore another root cause it could be said was that of the consultant not being present at the time when the patient’s consent was taken.

Lessons learned

The investigator rightly notes in the lesson learned section of the investigation report that there was a need for ‘human factor’ training and that Trauma Clinics should not be used when a patient is not suffering from trauma. However, it is also stated in that section that there was a ‘…need to document teeth in a consistent, clear and concise way’. Yet the report of the investigation observes that when the foundation year 2 Doctor reviewed the patient’s notes:

‘…which included the clinic letter and clinic notes and then the procedure was completed both in full and in dental abbreviations on the consent form’.

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349 Confidential report Datix: W54592
350 Confidential report Datix: W60304, p.2
351 Confidential report Datix: W60304, p.7
352 Ibid, p.12
353 Confidential report Datix: W60304, p.3
354 Ibid,p.6
Hence there would appear to be no evidence to suggest that the teeth of the patient involved in this SUI or of other any other dental patient undergoing treatment in the Department did not have their teeth documented in a ‘consistent, clear and concise way’. Therefore it is unclear as to why this lesson has been drawn.

However another lesson that might be drawn is that all the documents regarding a patient’s dental treatment, including the initial referral letter should be cross-checked to ensure that there are no inconsistencies in them with respect to a patient’s treatment.

**Recommendations**

The recommendations made in the report of the investigation are appropriate given the discussion of the circumstances surrounding this SUI. It should be noted however that Recommendation 4 states that:

‘The Department should implement a system whereby all documentation regarding teeth is annotated in 2 ways:

‘I. In full writing.
‘II. In Dental terminology’.

However as noted in the section on ‘Lesson learned’ above there is no explicit evidence in the report of the investigation that the Department was not already documenting teeth in the way suggested by the recommendation. Thus the reason why this recommendation has been made is unclear.

**Comments**

As noted in ‘“Never Event” 2: wrong premolar extracted’ part of the guidance provided by the Department of Health and adopted by NHS England states that:

“Never events” are by definition largely preventable if a provider takes every recommended step to prevent occurrence and an incident still occur this argues strongly that the incident was not preventable and therefore not a “never event”’.

Hence, given the operating dental surgeon appears to have carried out all the recommended safety precautions it would seem that the incident was inadvertently wrongly categorised as a ‘Never Event’.

The list of ‘Root causes’ and ‘Lessons learned’ could be extended.

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355 Confidential report Datix: W60304, p.13
356 Confidential report Datix: W54592, p.6
359 The operating surgeon carried out the WHO checklist procedure and there is no mention in the report of him failing to carry out any of the other safety checks that are required prior to extracting the patient’s teeth.
It is not clear why the investigator has drawn the conclusion that the Department is not using two types of notation to document teeth to be extracted, i.e. using the Zsigmondy-Palmer dental notation\textsuperscript{360} and written in full. When the report states that the teeth to be extracted were written out in full and Zsigmondy-Palmer dental notation was also used.\textsuperscript{361}

The investigator implies that the consultant was very busy when he examined the patient in the Trauma Clinic\textsuperscript{362} but does not explicitly state how long the patient had to wait past his appointment time before being examined. Had the investigator done so it may have been possible to formulate a hypothesis as to what caused the consultant not to perceive he had made a transcription error.

In the report of the investigation ‘Executive Summary’\textsuperscript{363} not all of the teeth to be extracted from the patient were explicitly noted. But they are in the ‘Incident description and consequences’\textsuperscript{364} section of the report which the author of this report found confusing. Similarly another confusing matter is that the report of the investigation states that, ‘[o]n the 21 January 2015 the patients Orthodontist wrote to the Consultant (who performed the surgery)...’\textsuperscript{365} As a consequence it is unclear as to whether it was the consultant who booked the patient in for his dental examination and examined him, but did not consent him, that undertook the dental surgery or whether it was performed by an entirely different consultant.

In the ‘Lesson learned’\textsuperscript{366} section of the ‘Executive Summary’ of the report of the investigation\textsuperscript{367} it does not state that Trauma Clinics should not be used for normal appointments as detailed in the main report.\textsuperscript{368}

The investigator notes that the patients X-ray were checked the night before their dental operations but does not say who undertook that task. Nor does the report of the investigation discuss the process used to check the patients X-rays. In addition, if the patient’s top arch was known to be ‘crowded’ and the bottom arch ‘uncrowded’ why did the person checking the X-ray not recognise that two of the four teeth to be extracted were to be removed from the ‘uncrowded’ arch. The report of the investigation however is silent on these matters.

In ‘Never Event’ 2: *wrong premolar extracted*\textsuperscript{369} it was recommended that a pictorial diagram of a patient’s jaw be incorporated into the WHO checklist and that any teeth to be extracted should marked on that diagram.\textsuperscript{370} It is therefore crucial if the recommendation of a pictorial jaw is incorporated in the WHO checklist that

\textsuperscript{360}…, Dental Charting, National Examining Board for Dental Nurses – National Diploma Examination at: \url{http://nebdn.org/sites/default/files/NEBDN%20Dental%20Charting%20Book%20APRIL%202015.pdf} p.1 accessed 11 October 2015
\textsuperscript{361}Confidential report Datix: W60304, p.5
\textsuperscript{362}Confidential report Datix: W60304, p.6
\textsuperscript{363}Confidential report Datix: W60304, p.2
\textsuperscript{364}Confidential report Datix: W60304, 12
\textsuperscript{365}Ibid, p.6
\textsuperscript{366}Confidential report Datix: W60304, p.2
\textsuperscript{367}Confidential report Datix: W60304
\textsuperscript{368}Confidential report Datix: W54592, p.3
\textsuperscript{369}The recommendation to include a pictorial jaw into the WHO checklist had not been implemented at the time of this SUI.
extraction are not marked on it until after all the documents relating to a patient’s dental surgery have been cross-checked for any inconsistencies in their treatment. The report of the investigation does not state whether an ‘Incident decision Tree’ was completed for this SUI.

The author of this report found difficulty in following the development of this SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form. Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and that could lead to lessons not being learned.

‘Never Event’ 6: retained swab

On the 18 March 2015 a female patient had a Total Abdominal Hysterectomy and Bilateral Salpingo-oophorectomy in operating theatre 10 of the Churchill operating theatre complex, Churchill Hospital, Oxford. Prior to the operation the WHO checklist procedure was undertaken and following its completion the patient’s surgery commenced.

A consultant surgeon carried out the Total Abdominal Hysterectomy and Bilateral Salpingo-oophorectomy part of the operation. After which he handed over the role of lead surgeon to a surgical clinical fellow 1 (SCF1) so he could perform an omentectomy and close the patient’s abdomen with the assistance of surgical clinical fellow 2 (SCF2). The consultant surgeon then descubbed but remained in the operating theatre until SCF1 completed the omentectomy and he was satisfied that there was no bleeding. After which he left the operating theatre but remained within the theatre suite.

The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures document used in all Oxford University Hospitals operating theatres (count policy) states that:

‘When we undertake counts

‘Three counts must occur – before the start of the procedure, at the start of closure of bodily cavity, and at skin closure.’

The count policy also notes that:

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372 Confidential report Datix: W64277
375 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014
376 Ibid, p.25
Where a department supports students in the perioperative environment (pre-registered nursing and midwifery students, student ODP’s or student assistant theatre practitioners), they should have supernumerary status until they have been deemed competent to assist with the count. When competent, this count should be conducted with a registered member of the perioperative team. Whenever possible this should be the designated mentor/assessor of the registered student. Documentary evidence of the assessment must be available.377

The first of the two mandatory closing counts was undertaken by the scrub nurse and the supernumerary student Operating Department Practitioner (ODP) who was being supervised by the circulating nurse. This first closing count revealed that a swab was missing SCF1 and SCF2 were informed of the situation and a search for the swab commenced. The swab was subsequently found in the patient abdominal cavity and removed.

Once the missing swab had been found SCF1 and SCF 2 started to close the patient’s abdominal cavity. At some point during this procedure the scrub nurse and the student ODP recall one of the surgeons requesting a swab which was handed to him. However, neither surgeon could recall putting a swab into the patient’s abdomen while closing the wound.

Having found the missing swab the scrub nurse, student ODP and the circulating re-started their first closing count as per the Trust counting policy.378 It was recognised by the scrub staff that the re-started first closing count took longer than normal. This was because the items of medical equipment on the trolley needed to be reorganised before the count could begin and the ODP student was not as fast as a fully trained member of staff. The report of the investigation stating that:

‘“The surgical clinical fellow 1 described: We waited and asked if the count was correct. The scrub nurse confirmed ‘yes my count is correct’”. The scrub nurse described “I was nearing the end of the instrument count at this stage. I confirmed that the count was correct”. The student ODP describes the scrub nurse having said ‘closing count correct’.”379

It was at this point that there was an inadvertent loss of situational awareness380, 381 by the surgical team and scrub staff. This was because the count to which the scrub nurse referred to as ‘correct’ was the restarted first closing count while the surgical team thought it was the final closing count. Hence at this point the surgical team and the scrub staff suffered a significant perceptual failure382 for neither group realised that their situational awareness had become asynchronous.

377 Ibid, p.5
378 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014, p.18
379 Confidential report Datix: W64277, p.17
380 Ibid
Thus the surgical team thought that the final closing count had been successfully completed and therefore proceeded to close the skin at the site of the patient’s operation. While the scrub staff knew that a second final closing count would be required. In the event the scrub staff did not complete the second and final closing count which revealed that a swab was missing until after the surgical team had closed the patient’s skin.

The report of the investigation provides a wealth of details surrounding the actions of the medical and non-medical staff from just before the surgical clinical fellow closed the patient’s skin until it was found that a second swab was missing. However, as those details are not strictly required for the purposes of this report they have not been recounted here.

Subsequent to the scrub staff reporting that their final closing count had identified that a swab was missing a plain X-ray was taken of the patient’s operation site. The swab was found to be in the patient’s abdomen. The patient was given an apology and the inadvertently retained swab was removed in a second operation performed shortly afterwards.

At interview it was found that neither of the surgical clinical fellows had read the Trust count policy\textsuperscript{383} nor did it form any part of their training or induction into Churchill operating theatres. Thus SCF1 and SCF2 were completely unaware that the closing count undertaken during in an operation in Churchill operating theatres consisted of two separate counts. The report of the investigation noted that:

‘Surgical clinical fellow 2 has stated in his interview that this area of knowledge [count policy] is transferrable between institutions but on questioning he believed that instruments should be counted at the final closing count and not at the first closing count which could lead to incorrect assumptions about the time each count could take and compound any errors due to the use of non-specific language by staff conveying information about the count’.

While:

‘…surgical clinical fellow 2 stated: “We don’t say first or second count. The final count is usually at the time of skin closure, but not in this case.” and surgical clinical fellow 1 stated “We waited and asked if the count was correct. The scrub nurse confirmed ‘yes my count is correct’.”

Thus the two surgical clinical fellows inadvertently held inaccurate assumptions about the situational context in which the final closing count would be carried out. However, as Van Maanen observed:

“A newcomer assumes that he knows what the organization is about, assumes others in the setting have the same idea, and practically never bothers to check out these assumptions.”\textsuperscript{384}

\textsuperscript{383} Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014

\textsuperscript{384} Toft, B., External Inquiry into the adverse incident that occurred at Queens Medical Centre Nottingham 4th January 2001’ published by the Department of Health, April 2001 at:

Thus, as noted earlier in ‘Never Event’ 3: misplaced nasogastric tube\textsuperscript{385} ‘given that no one can prespecify their own ignorance’\textsuperscript{386} it is not surprising that the two surgical clinical fellows were unaware of the closing count process. The report of the investigation also observes that:

‘The scrub nurse recalls “I was still doing my [first] count when the surgeon asked for the skin clips. Another circulating practitioner was stood at the table and opened the skin clips. I took the clips and made them available to the surgeon. I was nearing the end of the instrument count at this stage. I confirmed that the [first] count was correct.” In giving the staples to the surgical team an opportunity to pause before final closing and detect the communication error was lost. From this point forward the surgeons are further ahead in the procedure than the scrub nurse and this difference in timing is key to the late detection of the retained swab’.

Thus as the patient had inadvertently retained a swab the Trust declared that a ‘Never Event - Retained foreign object post-procedure’\textsuperscript{387} SUI had occurred and an investigation into the circumstances surrounding the event was initiated.

Root causes

The investigation team in their report rightly state that the root causes of this SUI are that:

‘The skin was closed and the operation finished prior to the final closing count being conducted due to the surgical team mistakenly believing they had been told that the final closing count was complete and correct. This related to lack of training of the surgical team which should have been implemented after previous Never Event investigations’\textsuperscript{388}

However, the Trust count policy\textsuperscript{389} states that:

‘10.4. The Clinical Directors are responsible for ensuring that all Surgeons and Anaesthetists within their Directorates are aware of the content of this policy’\textsuperscript{390} (Emphasis in the original)

Yet the surgical clinical fellows were not aware of the count policy or its contents.\textsuperscript{391} Hence, it might be said that as with “Never Event’ 3: misplaced nasogastric tube”\textsuperscript{392}

\textsuperscript{385} Confidential report Datix: W45903


\textsuperscript{388} Confidential report Datix: W45903, p.24

\textsuperscript{389} Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014

\textsuperscript{390} Confidential report Datix: W45903, p.8

\textsuperscript{391} Ibid

\textsuperscript{392} It will be recalled that the Trusts policy/guidance alert, distribution and training system also did not work as intended in: Confidential report – Datix: W45903, ‘Never Event’ 3: misplaced nasogastric tube’
the Trusts policy/guidance alert, distribution and training system did not work as intended and this was also a root cause of the SUI taking place.

In addition, the count policy also contains an instruction that:

‘Swabs should be in full view of the operating surgeon where applicable throughout a clinically invasive procedure, except on the occasion that a throat pack is to be concealed behind the patient’s tongue, as in dural oral surgery…’

Thus both the operating surgeon (SCF1) and SCF2 appear to have experienced a perceptual failure causing them to lose situation awareness with respect to the location of the swabs inadvertently retained within the patient’s body. This could be considered to be another root cause of the SUI taking place. However, it should be noted, that it can be extremely challenging, if not impossible to perceive items such as swabs particularly where they are ‘…blood soaked and compressed’.

It is interesting to note that although the investigation team correctly identified in the body of their report that there had been an inadvertent loss of ‘situational awareness’ which led to the SUI occurring that phrase is not used in the ‘Root causes’ section of their report.

In addition, the investigation team correctly identified in the body of their report that the SUI occurred, in part, because the '[m]edical and nursing staff used non-specific language to describe the counts' yet it would appear that the utterance was not considered to be a 'root cause' of the SUI. Whereas, given the crucial role that the failed communication had in the production of the SUI, it can be argued, that it should have been explicitly included in the ‘Root causes’ section of the investigation report. Particularly as there is a specific recommendation to address that issue in the report.

Lessons learned

The lessons learned by the investigation team are aligned with the description of the circumstances surrounding this SUI.

However another lesson which can be drawn from this SUI is that the Trusts policy/guidance alert, distribution and training system with regard to the Trusts count policy did not work as intended.

It is stated in the ‘Root causes’ section of the report into this SUI that, in part, it

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393 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014, p.14


395 Confidential report Datix: W45903, p.17

396 Ibid, p.17


occurred because there had been a ‘…lack of training of the surgical team which should have been implemented after previous Never Event investigations’. Thus a further lesson to be drawn from this SUI is that the Trusts’ system for implementing the lessons learned from ‘Never Events’ does not always work as intended following investigations. As a result on this occasion the Trust suffered from a ‘failure of hindsight’.

While another lesson that might be drawn from this SUI is one previously discussed in ‘Never event’ 2: wrong premolar extracted and ‘Never Event’ 4: retained midline catheter guide wire i.e. the caution expected of a healthcare professional should not be solely relied upon where error free performance is required. Rather a technology like radiofrequency markers to detect swabs used during invasive procedures should be used so that reliance on the vigilance of a healthcare practitioner to catch their own errors is reduced.

Recommendations

The recommendations made in the Root Causes Analysis Investigation Report are consistent with the evidence presented. However additional recommendations that might be considered are a review of the Trusts’ policy/guidance alert, distribution and training system with regard to the count policy should be undertaken and the Trusts’ system for implementing the lessons learned from ‘Never Events’ ought to be reviewed to ascertain why it also did not work as intended.

Another recommendation which could be made is that the Trust ‘…should evaluate and consider the use of adjunct technologies in conjunction with manual counting’ of swabs. Thereby reducing reliance upon the vigilance of healthcare practitioners to prevent this particular type of ‘Never Event’.

Comments

As evidenced earlier, no advice has been published or explicitly endorsed as national guidance by any NHS organisation on how the risks to patients inadvertently retaining swabs, instruments, needles and other miscellaneous items used in surgical/invasive procedures might be reduced. Thus at a surface level of analysis this SUI would not appear to be a ‘Never Event’. However in this SUI, at least in part, the root cause of this incident taking place was because of a ‘…lack of training

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399 Confidential report Datix: W45903, p.24
400 See ‘Appendix Six – Action Plan, item 9’, SIRI 2012-003 Never Event Churchill Theatres
402 ‘Never event’ 2: wrong premolar extracted, confidential report Datix: W54592
403 Confidential report Datix: W56416
405 Confidential report Datix: W45903
of the surgical team which should have been implemented after previous Never Event investigations’. Thus given ‘Never Events’ are defined as:

‘Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers’

Hence if the training on the count policy had been implemented by the Trust as recommended, it can be argued, that the misunderstanding between the surgical and scrub staff would not have taken place and the SUI would not have occurred. Therefore as not all the available preventative measures were implemented, i.e. the recommended training of all surgeons on the count policy, this serious untoward incident, in the opinion of the author of this report, does meet the criteria to be placed in the category of a ‘Never Event’.

The list of ‘Root causes’, ‘Lesson learned’ and ‘Recommendations’ associated with this ‘Never Event’ could be extended.

The Trusts policy/guidance alert, distribution and training system and that for implementing the lessons learned from ‘Never Events’ failed to work as expected. Recent advances in the use of radiofrequency technology to help detect swabs used during invasive procedures would help reduce reliance on the vigilance of healthcare practitioners and the risks of them being inadvertently retained within the patient’s body.

Although not directly germane to this ‘Never Event’ it should be noted that the ‘Throat Pack’ section of the Trust count policy does not correspond to the national guidance provided by the NPSA Alert ‘Reducing the risk of retained throat packs after surgery’. This is because the NPSA Alert requires a visually-based indicator to be used to show that a patient has a throat pack in place whereas the Trusts count policy does not.

In a similar vein it should be noted that the Trusts count policy does not contain any of the national guidance provided by the NPSA Rapid Response Report ‘Reducing risks of tourniquets left on after finger and toe surgery’.

The report of the investigation states that one of its purposes is to use the NPSA Decision Incident Tree to assess if there were any actions by staff which might be

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407 Confidential report Datix: W45903, p.24
410 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, version 2, 19 February 2014, pp.14-15
deemed culpable. However the findings of that assessment are not provided in the report.

Once again the author of this report found difficulty in following the development of this SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form.

Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and that could lead to lessons not being learned.

‘Never Event’ 7: wrong level spinal surgery

Prior to having an operation in the Nuffield Orthopaedic Centre, Oxford on 26 March 2015 the patient had a Magnetic Resonance Imaging (MRI) scan and a plain X-ray taken to help identify the precise site on his skin where lumbar decompression back surgery and transforaminal lumbar interbody fusion at spinal disk level L4/5 would commence. However, it should be noted that, there is no published national or international protocol at the present time which will unerringly prevent a consultant surgeon from inadvertently operating on the wrong level of a patient’s spine from the one intended.

Before the operation commenced the skin on the patient’s spine was marked by the consultant orthopaedic spinal surgeon with a pen as recommended by the National Patient Safety Agency. However it needs to be recognised that the technique of marking a patient’s spine prior to surgery is not infallible. A joint international project on surgical site marking warned that skin marking on its own is not a prevention strategy and does not replace the need for preoperative and time-out checks.

Datix: W65370


Joint Commission International, Haute Autorité de Santé et Coordination pour l’Evaluation des Pratiques Professionnelles les en santé en Rhône-Alpes, Guide to surgical site marking at: http://www.aezq.de/patientensicherheit/h5s/high-5s-
However the ‘WHO checklist’ was also completed in line with Trust policy hence all national guidance with respect to patient safety was implemented prior to the patient’s spinal surgery commencing.

In trying to establish where the patient’s level L4/5 vertebra was in relation to his external anatomy the two consultant surgeons undertaking the operation examined the MRI scan\(^\text{424}\) and the plain X-ray\(^\text{425}\) that had been taken of the patient’s spine. These images showed that the patient had an anatomical abnormality known as sacral lumbarisation which means that the lumbar spine has characteristics that make it look like the sacral spine or the other way round. This anatomical feature is seen in approximately 4% of the population.\(^\text{426}\) This made the identification of L5/S1 more difficult than would have been in the case of a patient who did not have the anomaly.

The level at which the surgery was to be performed on the patient was determined pre-operatively based on the MRI scan and the plain X-ray. Both of these images showed a well-defined disk space at L5/S1 and it was decided that this would be the starting point from which the patient’s vertebra would be counted until reaching disk space L4/5.\(^\text{427}\) However, not only did the consultant surgeons count the vertebra externally to locate the patient’s L4/5 disk space during the operation they also used a fluoroscopic image intensifier\(^\text{428}\) to aid in the process. The images of the patient’s spine produced by the fluoroscopic image intensifier did not however reveal the same level of anatomical detail\(^\text{429}\) as the MRI scan or plain X-ray. This is a known limitation of the technology.

Thus the consultant surgeons having perceived the well-defined disk at L5/S1 on the MRI scan and plain X-ray reasoned that if they identified the last ‘obvious’ lumbar disk and operated at one level above then they would be operating at the correct spinal level.\(^\text{430}\) Therefore the consultant surgeons having identified what they thought was level L4/5 the surgery commenced. During the operation the patient suffered from an inadvertent dural tear\(^\text{431}\) which the consultant surgeons repaired. Nevertheless the patient made an uneventful recovery following his operation.

Subsequently the patient reported numbness around his perineum\(^\text{432}\) and a MRI scan was performed. The MRI scan revealed that the operation on the patient’s spine had been undertaken at level L3/4 a level one higher than that intended. As a consequence, the patient had a second spinal procedure carried out on 3 April 2015 at level L4/5 as originally planned.

\(^{424}\) See appendix 1
\(^{425}\) See appendix 2
\(^{427}\) See appendix 1 and 2
\(^{429}\) See appendix 3
\(^{430}\) See appendix 1and 2
On being informed that surgery had been performed on the patient’s spine at the wrong level the Trust declared that a ‘Never event - Wrong site surgery’ had occurred.

The patient’s subsequent recovery was hindered by the need to drain a haematoma in the operating theatre on 9 April 2015 but he did fully recover.

**Root causes**

The report of the investigation correctly states that the root causes of this SUI was ‘…a failure to correctly interpret the CII [fluoroscopic image intensifier] images given the known limitations of this technology’. However, the investigators did not explicitly identify that it was a ‘perceptual error’ which caused the consultant surgeons to lose ‘situational awareness’ and therefore failed to realise that they were operating at the wrong level, i.e. L3/4 and not L4/5. This is also likely to be the reason the investigators did not explore why the consultant surgeons failed to correctly interpret the CII images.

Conversely, it can be argued, that a second root cause was the technology used to locate the patient’s disk space L5/S1, i.e. the fluoroscopic image intensifier was the root cause of this SUI since the images it produced apparently failed to show the patient’s disk space L5/S1 at all.

At interview the consultant surgeons stated that it had been difficult to get a clear fluoroscopic image of the patient’s spine but both were confident that the operative level chosen was correct. This account was supported by the scrub nurse who said that at no time during the operation had there been any disagreement between the consultant surgeons regarding the site of the operation.

Thus both consultant surgeons agreed on the spinal level at which the operation was to be carried out based upon their individual perception of the fluoroscopic image thereby confirming each other’s opinion. Hence, a third root cause for the SUI taking place could be ‘confirmation bias’ whose characteristics were discussed earlier.

It might also be asserted that another root cause, as noted earlier, is because there is no extant national or international protocol which, if implemented, will always ensure that spinal surgery is performed at the correct level.

**Lesson learned**

The lesson learned are in agreement with the narrative provided by the investigators regarding the circumstances surrounding this SUI.

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433 Confidential report Datix: W65370
434 Confidential report Datix: W65370, p.16
437 See appendix 3
Recommendations

The recommendations cited in the investigation report when implemented should lead to a reduction in the risk of a similar SUI occurring.\(^{438}\)

A further recommendation which could be made however is that the Trust should investigate the possibility of obtaining the vertebra level check software that has very recently been developed in the Department of Computer Science, Johns Hopkins University in the United States.\(^{439}\)

Comments

The investigators noted that:

‘There was some calcification on the L5/S1 disc which may have made it appear more like bone (as opposed to a gelatinous disc) with the CII images’.\(^{440}\)

When discussing the calcification of soft tissue Abramson and Miller note that:

‘Soft-tissue calcification is an abnormal accumulation of lime salts in tissue in amounts which are demonstrable on microscopic, roentgenographic and even naked eye examination’.\(^{441}\)

Thus given the calcification on the L5/S1 disc appeared as bone on the fluoroscopic intensifier image, i.e. the L5/S1 spinal disc vanishes on the fluoroscopic image, it can be argued that the amount of calcium present on the patient’s spinal disk fits Abramson and Miller’s definition of ‘abnormal’.

In addition, neither the MRI scan nor the plain X-ray revealed the presence of the calcium on the patient’s spinal disk. Therefore there was no indication to the consultant surgeons that the fluoroscopic intensifier images would not clearly show the disc space L5/S1 that was to be used as the ‘marker’ from which the count to spinal disc L4/5 was to be commenced. Thus the calcification was unknown to them and therefore unexpected.

The relevant list of ‘Never Events’ states with respect to classifying an SUI as wrong site surgery that it:

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\(^{438}\) Confidential report Datix: W65370, p.17


\(^{440}\) Confidential report Datix: W65370, p.16

‘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’.442

Therefore as the calcification on the patient’s L5/S1 was unknown and unexpected and also appears to fit Abramson and Miller’s definition of ‘abnormal’ then it can be argued that this SUI was inadvertently classified as a ‘Never Event’. As there is a discussion in the report of the investigation regarding the calcification of the patient’s L5/S1 disk it is assumed that fact was documented in the patient’s notes.

Moreover, as noted earlier NHS England states that:

‘Never events are a sub-set of Serious Incidents and are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers’.443

While other guidance adopted by NHS England clarifies the above definition by stating that:

‘If a provider takes every recommended step to prevent occurrence and an incident still occurs this argues strongly that the incident was not preventable and therefore not a “never event”’.444

Hence given the consultant surgeons appear to have carried out all the recommended safety precautions445 noted in the NHS England guidance prior to operating and yet the SUI still occurred, it would seem that it was inadvertently categorised as a ‘Never Event’ on that basis also.

Furthermore the report of the investigation states that:

The deputy medical director, medical director and head of clinical governance reviewed the incident and agreed that this met Never Event criteria as stated in the Never Events List 2015/2016. This incident was identified as meeting the first definition on the list under the head “wrong site surgery”. The list clearly states that wrong level spinal surgery is included as a Never Event.446

However, this SUI447 occurred on the 26 March 2015 and the ‘Never Event’ list for 2015/16 was not published until 27 March 2015.448 Thus the circumstances

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445 The operating surgeons marked the skin as required by the NPSA guidance and carried out the WHO checklist procedure and there is no mention in the report of them failing to carry out any of the other safety checks that are required prior operating.

446 Confidential report Datix: W65370, p.15

447 Confidential report Datix: W65370

surrounding this SUI should have been compared to the ‘Never Event’ criteria published on the 12 December 2013 because that was the ‘Never Event’ list in force at the time the SUI occurred.449

Perhaps more importantly the ‘Never Event’ list whose criteria was operating at the time of the SUI occurred, unlike the 2015/16 ‘Never Event’ list, does not mention spinal surgery. Thus it would appear this SUI has also been inadvertently classified as a ‘Never Event’ because the criteria from the wrong ‘Never Event’ list was applied.

In addition, one of the provisions of the revised policy and framework for ‘Never Event’ published by NHS England on the 27 March 2015 which is currently in force states that:

‘Never Events are a particular type of serious incident that meet all the following criteria:

4.2.1 They are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers2 are available at a national level, and should have been implemented by all healthcare providers…’451 (Emphasis in the original)

However, as noted earlier, the evidence demonstrates that no national guidance or safety recommendations have been published that ‘provide strong systemic barriers’ to ensure that spinal surgery is always performed at the correct level.452 Therefore on that basis, it can be argued, this SUI also does not meet the new NHS England revised policy criteria to be classified as a ‘Never Event’.453

The list of ‘Root causes’ and ‘Recommendations’ could be extended.

There is no indication in the report of the investigation as to whether a disciplinary ‘Incident Decision Tree’454 analysis was performed for this SUI.

The recently developed software at John Hopkins University in the United States to accurately identify the correct spinal level at which a patient should have their surgery performed would appear to be a significant breakthrough in patient safety technology.
The author of this report found difficulty in following the development of the SUI because of the order in which the information is presented in the Root Cause Analysis Investigation Report form.

Additionally the form appears to coerce investigator/s to review the SUI so parsimoniously that the form of the narrative is staccato which made it difficult to readily identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and that could lead to lessons not being learned.

**Observations**

The reports of the investigations reviewed above (‘Never Events’: 1-7) are of variable quality. For example, root causes are not always articulated in a clear and concise way or in some cases do not appear to have been identified. However, this may be due to the investigator or investigators not being trained or not having sufficient experience. Some of the reports also raise issues that are then not addressed which may mean that not all the lessons that could have been drawn from a given serious untoward incident are learned.

There is also very little in the way of evidence provided in the text to support assertions made in the investigation reports, i.e. there are few quotes from the documents to which an investigator or investigation panel have referred or the verbatim replies of the healthcare professionals interviewed during an the investigation to support the conclusions that have been drawn. It would also appear that an investigator or investigators do not always check the current criteria governing the classification of a serious untoward incident as a ‘Never Event’.

The evidence suggests that inadvertent human error was, at least in part, one of the root causes of the seven SUI’s that are the subject of this External Review.\(^{455}\) However while human error was implied in five of the investigation reports it was only explicitly identified in two of them.\(^{456}\) In addition, a number of dysfunctional human factors which may have had a bearing on the eventuation of some of the SUI’s were not identified in the reports of the investigations concerned.\(^{457}\)

There are a number of typographical errors and omissions in some of the investigation reports. In one case the report of an investigation states that the patient had a completely different medical condition to that cited in the local briefing memorandum provide by the Trust Legal Advisor following the Inquest.\(^{458}\)

Although a disciplinary ‘Incident Decision Tree’ analysis is mentioned in several of the SUI reports, the results of the evaluation are not provided.

The Trusts alert, distribution and training system for local policy/guidance document

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\(^{455}\) Confidential report Datix: W48452, W56416, W64277 W54592, W60304, W65370 and W45903

\(^{456}\) Confidential report Datix: W54592 and W60304

\(^{457}\) For example, in ‘Never Event’ 2 it was a ‘perceptual failure’ that led to a loss of ‘situational awareness’, in ‘Never Event’ 3 the ‘decoy phenomenon’ may have played apart, while in Never Event 4 interruptions and distraction were present and in Never Event 7 ‘confirmation bias’ might have assisted in producing the SUI.

\(^{458}\) ‘Never Event’ 3: misplaced nasogastric tube
has failed to operate as intended on a number of occasions. In addition, the content of some policy documents has been incorrect or ambiguous.\textsuperscript{459}

The structure of the Root Cause Analysis Investigation report form makes it difficult to quickly pull together the essential details of why and how a particular serious untoward incident occurred.

The categories of ‘Contributory factors’ and ‘Care and service delivery problems’ are not tightly defined.\textsuperscript{460} As a consequence different investigators could categorize the same phenomenon as a ‘Contributory factor’ or a ‘Care and service delivery problem’ hence making pattern recognition difficult when looking for common features of the same or disparate events.

In addition, the structure of the Root Cause Analysis Investigation form also appears to coerce investigators into describing the events of the SUI which has occurred so parsimoniously that the narrative is staccato and this makes it difficult to identify data relating to the underlying causes. Notwithstanding it may also result in data not being presented in a report and this could lead to lessons not being learned.

However, it should be noted that the robustness of the investigations and quality of the ‘Never Events’ reports is similar to those of other NHS Trusts that the author of this report has reviewed\textsuperscript{461} and do not give rise for concern.

A brief review of NHS England data on ‘Never Events’ from 1 April 2014 until 31 March 2015 revealed that during the period there were 102 cases in NHS England Trusts where patients inadvertently retained foreign object following their operation.\textsuperscript{462} When the sub-categories for this type of SUI, which are relevant to this External Review, were examined it was revealed that there were 16 surgical swabs and 15 guide wires that were inadvertently retained within the bodies of patients’ during that period.

There were also 126 cases in NHS England where surgery was performed on the wrong site.\textsuperscript{463} An examination of the sub-categories for this type of SUI, relevant to this External Review, established that there were 27 cases where the wrong tooth or teeth were extracted and 8 cases where spinal surgery was performed at the wrong level.\textsuperscript{464}

With regard to the total number of ‘Never Events’ reported by the Trust in the period

\footnotesize{\textsuperscript{459} For example, in the report Datix: W49503 the Trust document ‘Procedure for the insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes,’ version 2, 26 September 2014 states that a web link will take the reader to an e-learning module on the siting of nasogastric tubes. However the web link did not lead to such an e-learning module. In addition, the phrase ‘lead consultant’ in the same document was ambiguous.


\textsuperscript{461} See for example, Toft, B. External Review of Never Events in Interventional Procedures co-commissioned by Sheffield Teaching Hospitals NHS Foundation Trust and Sheffield Clinical Commissioning Group, Sheffield Teaching Hospitals NHS Foundation Trust, January 2015 at: http://www.sth.nhs.uk/clientfiles/File/External%20review%20%20redacted%20version%20at%20the%20request%20of%20patients.pdf


\textsuperscript{463} Ibid

\textsuperscript{464} Ibid, p.8}
covered by the NHS England data. Three NHS Trusts, not including Oxford, experienced six ‘Never Events’, one Trust had seven, another Trust suffered eight and one Trust had nine ‘Never Events’. The total number of NHS England Trusts that experienced at least one ‘Never Event’ was 142.

Hence, there does not appear to be an atypical pattern with respect to the type or the number of SUI’s that have occurred at the Trust, including the two very recent incidents and the one which came to light as a result of a claim being made by a patient. Indeed, the Trust has a culture of openness in relation to serious adverse incidents and ‘Never Events’ which is outstanding.

Furthermore, the reports of the investigations into the SUI’s discussed above do not reveal a pattern of behaviour which suggests that the Trust has a systemic problem with patient safety. No member of the Trust has been involved in more than one of the ‘Never Events’ reviewed. Each of the ‘Never Events’ which took place did so due to a unique set of circumstances prevailing at the time. They also appear to have taken place at random over the period covered by the External Review.

Of the seven Root Cause Analysis Investigation ‘Never Event’ reports that have been reviewed only two of the SUI’s fit the published criteria for an SUI to be categorised as a ‘Never Event’. This is because for an SUI to be classified as a ‘Never Event’ there should be ‘existing national guidance or safety recommendations, which if followed, would have prevented the incident from occurring’. Therefore as no national guidance or safety recommendations have been published with respect to three of the SUI’s where patients’ inadvertently retained foreign object post-procedure, those SUI’s do not match the NHS England definition of a ‘Never Events’ and appear to have been inadvertently wrongly classified.

In one of those cases however a Trust recommendation had already been made which, if it had been implemented, would have prevented the SUI from occurring and thus it was correctly classified as a ‘Never Event’. However of the two other SUI’s in the Trust where a foreign body was inadvertently retained within a patient’s body there is no evidence to suggest that the Trust was responsible for one of them occurring.

As noted earlier the Department of Health has stated that where a provider takes all

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465 Telephone discussion with SM1 22 September 2015
466 Confidential report Datix: W48452, W56416, W64277 W54592, W60304, W65370 and W45903
467 13 September 2013 to 26 March 2015 and when the recent adverse events are taken into consideration up to 22 September 2015
468 Confidential report Datix: W48452, W56416, W64277 W54592, W60304, W65370 and W45903
469 Confidential report Datix: W45903 and W64277
472 Confidential report Datix: W48452 and W56416
474 Confidential report Datix: W48452
steps to prevent an SUI but it still occurs then this ‘…argues strongly that the incident was not preventable and therefore not a ‘never event’’. Hence in the three SUI’s where surgery was performed at the wrong site and yet every safety precaution that could be taken was implemented then given the Department of Health’s guidance it would seem that these SUI’s were inadvertently classified as ‘Never Events’.

Thus, in the opinion of the author of this report, five out of the seven SUI’s categorised as ‘Never Events’ and reported by the Trust because of their exemplary culture of openness were inadvertently misclassified.

From a corporate governance perspective some of the Trusts safety protocols appear to be seen as guidance rather than mandatory.

This External Review also found that the NPSA Safer Practice Notice, ‘Reducing the Risks of retained throat packs after surgery’, issued in April 2009 and the guidance provided by Rapid Response Report (RRR) ‘Reducing risk of tourniquets left on after finger and toe surgery’ again issued by the NPSA in December 2009 has not been incorporated into ‘The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy’. Similarly the NPSA published a RRR entitled Harm from flushing of nasogastric tubes before confirmation of placement on the 22 March 2012. However, none of the information contained within the NPSA RRR is drawn upon in the text of the Trusts FBNGT procedure nor is the NPSA RRR cited in the ‘References’ section of that document. The Deputy Medical Director has been informed of this issue.

Health service professionals do not have perfect vigilance therefore adjunct technologies, protocols and checklists could be helpful in preventing patients from suffering inadvertent SUI’s through the inadvertent retention of foreign objects following surgery and spinal surgery being performed at the wrong level.

The evidence is clear that there is no existing national guidance or safety recommendations to prevent a patients’ inadvertently retaining foreign objects or to stop spinal surgery being conducted at the wrong level. Yet the NHS England ‘Never Event’ list 2015/16 cites both types of SUI’s as ‘Never Events’ which would

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476 Confidential report Datix: W54592, W60304 and W65370
477 Confidential report Datix: W48452, W56416, W54592, W60304 and W65370
478 Confidential report Datix: W48452, W56416, W64277 W54592, W60304, W65370 and W45903
479 For example, version 1 of the document Procedure for the insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes, version 2, 26 September 2014 was mandatory. Whereas version 2 is classified as procedure, i.e. guidance.
482 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, 19 February 2014
484 E-mail to Deputy Medical Director 16 September 2015
seem illogical given the past and present national criteria to be used in the categorisation of such events.486

The Department of Health’s model for the commissioning of ‘Never Events’487 from the Trusts Clinical Commissioning Group488 has not been implemented by the Trust at the present time.489

During this External Review of the Root Causes Analysis Investigation reports of the seven SUI’s a number of additional ‘Root causes’, ‘Lessons Learned’ and ‘Recommendations’ have been identified which the Trusts senior management may wish to consider with respect to implementation.
Section 4: conclusions and recommendations

The conclusions that have been drawn from the evidence presented in this report are noted below in plain text, with recommendations shown in bold italic.

Safety culture

The Trusts commitment to openness with respect to SUI’s and ‘Never Events’ is exemplary. Moreover the data published by NHS England shows that ‘Never Events’ are experienced by numerous NHS Trusts and on multiple occasions. Thus, the pattern of serious untoward incidents experienced by the Trust is not unusual. As a consequence the evidence strongly suggest that the Trusts safety culture has the same high priority as in the two other foundation Trusts whose reports of ‘Never Events’ the author of this report has previously reviewed.

However some of the Trusts internal safety documents such as the Procedure for the Insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes designed to help prevent patients suffering serious untoward incidents is classified as guidance and therefore discretionary.

Recommendation 1

All internal guidance with regard to patient safety should be incorporated into the Trust portfolio of policies and thus become mandatory.

System failures

The evidence reviewed strongly suggests that the seven serious untoward incidents that are the subject of this External Review were the result of inadvertent human error and systems failures. However it will be recalled that with respect to the ‘Never Event’ declared in the spirit of openness (Never Event 1: retained guidewire following a PCI) there is no evidence to suggest the Trust was responsible for that SUI occurring.

Investigation of serious untoward incidents at the Trust

The robustness of the investigations carried out into the SUI’s that have been the subject of this External Review do not raise any cause for concern as they mirror similar reports reviewed by the author of this report at other Foundation Trusts.

The appropriateness and timescale of the improvements and actions set out in the action plans in the Trusts overarching ‘Never Event’ action plan appear apposite.
However the structure of the Root Cause Analysis Investigation report forms (RCAIF) used by the Trust, in the opinion of the author of this report, does not lend itself to a reader of such a document rapidly gaining a comprehensive understanding of the circumstances surrounding a serious untoward incident. The RCAIF also appears to encourage investigators to write their reports with such economy that the description of the events which took place is frequently taciturn. This can make it challenging for a reader to identify the facts associated with the underlying causes of an SUI. Moreover this parsimonious approach may unwittingly lead to evidence not being reported thus lessons to be learned and hence recommendations to prevent a recurrence of an SUI may be missed.

**Recommendation 2**

*The Trust should consider moving from the current Root Causes Analysis Investigation report form to a narrative style of report without prescribed headings.*

The categories of ‘Contributory factors’ and ‘Care and service delivery problems’ used in the Root Analysis Investigation Reports are not tightly defined. As a consequence different investigators could categorize the same phenomenon as a ‘Contributory factor’ or a ‘Care and service delivery problem’ hence making pattern recognition difficult when looking for common features of SUI’s.

**Recommendation 3**

*The Trust should consider defining the categories of ‘Contributory factors’ and ‘Care and service delivery problems’ used in the Root Analysis Investigation Report form so that healthcare professionals undertaking investigations at the Trust categorize phenomenon the in the same way. Or alternatively cease to use them.*

**Training**

The reports of the investigations into the serious untoward incidents at the Trust which are the subject of this External Review are of variable quality. There are few references to human factors and there is an absence of evidence to support the conclusions and recommendations which have been drawn. In addition, five of the seven serious untoward incidents discussed in this report were, in the opinion of the author of this report, inadvertently misclassified as ‘Never Events’. In short investigations into serious untoward incidents at the Trust need to take a more forensic approach than at present otherwise it is possible that important lessons could be missed.

**Recommendation 4**

*All members of staff selected to lead or undertake investigations should*

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497 Confidential report Datix: W48452, W54592, W56416, W60304 and W65370
undergo formal training on human factors and how investigations into serious untoward incidents ought to be undertaken. 498

Inadvertent misclassification of ‘Never Events’

It is acknowledged that the regulators, with whom the SUI’s that are the subject of this External Review were discussed, agreed the classification of ‘Never Event’ with the Trust. However, the evidence discussed in this report indicates that five 499 out of the seven 500 were inadvertently misclassified as ‘Never Events’.

Recommendation 5

The Trust’s investigation policy should explicitly state that when an SUI is considered to be a potential ‘Never Event’ the circumstances surrounding it must be compared in detail to the then current definition of a ‘Never Event’ and also to the national policy documents published with respect to ‘Never Events’. Only where an SUI meets all the nationally stated criteria should the Trust classify an incident as a ‘Never Event’.

Recommendation 6

The Trust should enter into discussions with the Commissioner of Services to have the five inadvertently misclassified ‘Never Events’ 501 downgraded to SUI’s.

Recommendation 7

The Trust should enter into discussions with the Commissioners of Services with respect to the recovery of any financial penalties imposed on them through the provisions of the NHS Standard Contract given five of the SUI’s at the Trust 502 appear to have been inadvertently misclassified as ‘Never Events’.

Inadvertent administrative oversights

A number of administrative oversights 503 were made in the reports of investigations such as typographic errors while several of the reports omitted to state what the ‘Incident Decision Tree’ 504 analysis had revealed.

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499 Confidential report Datix: W48452, W54592, W56416, W60304 and W65370
500 Confidential report Datix: W48452, W56416, W64277, W54592, W60304, W45903 and W65370
501 Confidential report Datix: W48452, W54592, W56416, W60304 and W65370
502 Confidential report Datix: W48452, W54592, W56416, W60304 and W65370
503 For example, in the report Datix: W49503 the Trust document ‘Procedure for the insertion, Use and Care of Fine Bore Nasogastric Feeding Tubes,’ version 2, 26 September 2014 states that a web link will take the reader to an e-learning module on the siting of nasogastric tubes. However the web link did not lead to such an e-learning module. In addition, the phrase ‘lead consultant’ in the same document was ambiguous.
Recommendation 8

All Root Causes Analysis Investigation report forms where used should be checked independently for accuracy before being submitted to the person who commissioned the investigation.

One of the SUI’s reviewed eventuated because one part of a recommendation from a previous ‘Never Event’ investigation was inadvertently not implemented.

Recommendation 9

An internal review should be undertaken by the Trusts Governance Team to ensure the Action Plans of all the SUI’s that are the subject of this External Review are, in so far is practicable, completed in full.

The ‘Throat Pack’ section of the Trust document entitled ‘The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth)’ does not correspond to all the provisions of NPSA Alert NPSA/2009/SPN001, ‘Reducing the risk of retained throat packs after surgery’. In addition, the same policy also does not contain the guidance provided by the NPSA Rapid Response Report, NPSA/2009/RRR007, ‘Reducing risks of tourniquets left on after finger and toe surgery’.

In a similar vein none of the guidance contained within NPSA/2012/RRR00 entitled: ‘Harm from flushing of nasogastric tubes before confirmation of placement’ published on the 22 March 2012 has been included in the Trusts procedure for the use of fine bore nasogastric tubes.

Recommendation 10

The Trust should ensure that all the provisions contained in the NPSA guidance documents NPSA/2009/SPN001 ‘Reducing the risk of retained throat packs after surgery’, NPSA/2009/RRR007 ‘Reducing risks of tourniquets left on after finger and toe surgery’ and NPSA/2012/RRR00 entitled: ‘Harm from flushing of nasogastric tubes before confirmation of placement’ are implemented as soon as possible.

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505 Confidential report Datix: W64277- ‘Never Event’ 6: retained swab
506 Action point 9, SIRI 2012-003 Never Event Churchill Theatres, Incident Date: 9 January 2012
507 Confidential report Datix: W48452, W54592, W45930, W56416, W60304, W64277 and W65370
508 Theatre Group, The Counting of Swabs, Instruments, Needles and Miscellaneous items for Surgical Procedures (including childbirth) Policy, Oxford University Hospitals NHS Trust, 19 February 2014
Recommendation 11

A thorough examination of the processes used internally to disseminate patient safety information from outside sources (such as the Patient Safety Domain of NHS England) should be undertaken as a matter of urgency to ascertain why these oversights occurred.

The alert, distribution and training system cited in two local Trust clinical policy/guidance documents failed to ensure that all the healthcare professionals who needed to be aware of their contents received that information.

Recommendation 12

All healthcare professionals whose roles are cited in the alert, distribution and training system devised for the implementation of a local Trust policy/guidance document should be individually informed of the role they are to play by the authors of the document.

Learning from SUI's and ‘Never Events’

This External Review appears to have identified a number of additional root causes, lessons learned and recommendations from the evidence presented in the SUI’s reviewed.

Recommendation 13

The Trusts senior management should review the additional, root causes, lessons learned and the recommendations drawn from the SUI's that were the subject of this External Review to determine their relative benefits with regard to implementation.

The model suggested by the Department of Health for the commissioning of ‘Never Events’, as with other NHS Trusts, has not been implemented by the Trust at this time.

Recommendation 14

The Trust should commence discussions with their Commissioner of Services
with regard to implementing the Department of Health Model for commissioning of ‘Never Events’.

Technology

Human error cannot be completely eliminated but the risk of a patient inadvertently suffering an SUI can be reduced through the use of technology.

**Recommendation 15**

The Trust should investigate the possibility of introducing new technologies such as bar coding or radio-frequency identification to reduce the risks of patients inadvertently retaining foreign objects following surgical/invasive procedures.

Similarly with respect to reducing the risks to patients’ of being operated at the wrong spinal level the Trust should explore the possibility of obtaining the vertebra level check software that has been developed in the Department of Computer Science, Johns Hopkins University in the United States.

A number of issues regarding ‘Never Events’ have come to light during the course of this External review which NHS England should be made aware of as they effect the credibility of the concept.

**Recommendation 16**

The Trust should make a copy of this report available to NHS England so that the issues noted below are brought to their attention.

**National issues**

The Department of Health and NHS England’s criteria for Retained foreign object post-procedure means that only untoward incidents where national guidance on throat packs, vaginal births and perineal suturing has not been followed qualify as ‘Never Events’.

All serious untoward incidents which involve swabs, instruments, needles or other sundry items do not meet the criteria for Retained foreign object post-procedure.

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522 Ibid.
since no national guidance or national safety recommendations to prevent such events has been published.

The guidance cited by the Department of Health and which has been adopted by NHS England, in documentation regarding the prevention of patients inadvertently retaining foreign objects, is that produced by the Association of Perioperative Practitioners (AfPP) and was developed for use by their members. Therefore it has no official national standing. This is evidenced by the fact that the Care Quality Commission, Health Education England and the Department of Health have all refused to endorse the AfPP guidance in this area when requested to do so.

**Recommendation 17**

**NHS England should as a matter of urgency publish their own or publicly endorse the AfPP's guidance on the management of swabs, instruments, needles and sundry items so that the 'Never Event - 'Retained foreign object post-procedure' will also apply where such items are inadvertently retained within a patient's body as recommended by Toft.**

There is evidence which demonstrates that there is no published national guidance or safety recommendations on how to prevent surgery at the wrong spinal level, yet the 'Never Events list 2015/16' for 'Wrong site surgery' states that it, 'Includes wrong level spinal surgery'. Given the past and present published national criteria to be used in the categorisation of a 'Never Event' this is irrational.

**Recommendation 18**

**NHS England should remove the SUI 'wrong spinal level surgery' from its 2015/16 list of 'Never Events.'**

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As discussed earlier the eradication of all human error is unachievable and the property of ‘equifinality’ possessed by an ‘open system’, in this case healthcare, means that it is impossible for a 100% guarantee to be given that any particular serious untoward incidents will never occur.

**Recommendation 19**

**NHS England should re-consider whether it is appropriate to use the concept of a ‘Never Event’ in relation to serious untoward incidents since, as noted by Toft, the unthinkable as well as obvious events can occur.**

In addition, the total number of ‘Never Events’ experienced by NHS England Trusts in the period 1 April 2014 – 31 March 2015 and classified as ‘Retained foreign object post-operation’ was 102. This is approximately 33% of all the ‘Never Events’ which occurred during that period. Such a large percentage of the same type of serious untoward incident being placed into the same ‘Never Event’ category, it can be argued, is likely to gravely undermine the whole idea in the minds of the general public.

**Recommendation 20**

**As recommended by Toft NHS England should re-consider whether it is appropriate to use the concept of a ‘Never Event’ as a category in relation to untoward incidents which are caused through an item of medical equipment being inadvertently left in the body of a patient.**

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Appendix 1: MRI scan image

Image one below, is taken from the MRI which shows the slippage at L4/5 and the disc space at L4/5, L5/S1 and a rudimentary disc at S1/2 (this is not present in most people).
Appendix 2: plain X-ray image

Image two below, a plain X-ray, shows the same features but does not show the rudimentary disc at S1/S2. The x-ray shows a small amount of calcification on the anterior aspect of the L5/S1 disc. This is not apparent on MRI.
Appendix 3: fluoroscopic intensifier image

Image three below, the CII image, does not show the S1/2 rudimentary disc or the previously seen fully formed disc at L5/S1. The darker line seen in the image is one of the screws used to perform the procedure.
### Recommendations from Professor Brian Toft's External Review

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Trust Response</th>
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</thead>
<tbody>
<tr>
<td>1 All internal guidance regarding patient safety should be incorporated into the Trust portfolio of policies and become mandatory.</td>
<td>A review of Trust wide policies is underway and will include actions related to policies which may impact on Never Events</td>
</tr>
<tr>
<td>2 The Trust should move from the current Root Causes Analysis Investigation report to a narrative style of report without prescribed headings</td>
<td>The divisions have been consulted about this recommendation and feel a template is helpful for newer investigators. Guidance is being embedded in the template to support its use. Future emphasis will be on training of and support for investigators</td>
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<td>3 The Trust should define the categories of ‘Contributory factors’ and ‘Care and service delivery problems’ used in the Root Analysis Investigation Report form so that healthcare professionals undertaking investigations categorise the phenomenon in the same way. Or alternatively cease to use them.</td>
<td>Guidance is being embedded in the template to support its use. Future emphasis will be on training of and support for investigators</td>
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<td>4 All members of staff selected to lead or undertake investigations should undergo formal training on human factors and how investigations into serious untoward incidents ought to be undertaken</td>
<td>A review of support to investigators and the RCA training in the Trust is underway via the risk management team. The Trust will consider capacity in current human factors training in OXSTAR and explore opportunities for targeted training for investigators</td>
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<tr>
<td>5 The Trust’s investigation policy should explicitly state that when an SUI is</td>
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<td>Complete</td>
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<td>9  An internal review should be undertaken by the Trust’s Governance Team to ensure the Action Plans of all the SIRIs that were the subject of the External Review are, in so far is practicable, completed in full.</td>
<td>In progress via clinical governance</td>
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<tr>
<td>10 The Trust should ensure that all the provisions contained in the NPSA guidance documents NPSA/2009/SPN001 ‘Reducing the risk of retained</td>
<td>Complete and being incorporated into current policy</td>
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| A thorough examination of the processes used internally to disseminate patient safety information from outside sources (such as the Patient Safety Domain of NHS England) should be undertaken as a matter of urgency to ascertain why these oversights occurred (Re NG tube policy awareness). | Accepted
A survey of staff to explore preferred options for communication is to be conducted and expertise in education from Oxford University to be consulted. Future new policies to be included in the staff monthly update |
<p>| All healthcare professionals whose roles are cited in the alert, distribution and training system devised for the implementation of a local Trust policy/guidance document should be individually informed of the role they are to play by the authors of the document. | A survey of staff to explore preferred options for communication is to be conducted and expertise in education from Oxford University to be consulted. Shelford group quality leads and CQC ‘outstanding’ rated Trusts have been consulted to explore best practice and CQC Future new policies to be included in the staff monthly update |
| The Trust’s senior management should review the additional, root causes, lessons learned and the recommendations drawn from the SIRIs that were the subject of the External Review to determine their relative benefits with regard to implementation. | These will be added to the Trust wide Never Event action plan |</p>
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<td>17</td>
<td>The Trust should make a copy of this report available to NHS England so that the issues noted are brought to their attention. Three further recommendations are made to NHS England regarding publishing their own guidance with respect to retained foreign objects, declassifying wrong level spinal surgery as a Never Event and reconsidering the concept of Never Events.</td>
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