**Title:** Identification of Common Themes from Never Events Data Published by NHS England

**Short Title:** Common Never Events

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**Identification of Common Themes from Never Events Data Published by NHS England**

**Abstract:**

**Background:** Never Events (NE) are serious clinical incidents that cause potentially avoidable harm and impose a significant financial burden on healthcare systems. The purpose of this study was to identify common Never Events.

**Methods:** We analysed the NHS England NE data from 2012-2020 to identify common Never Events category and themes.

**Results:** We identified 51 common NE themes in 4 main categories out of a total of 3247 NE reported during this period. Wrong-site surgery was the most common category (n=1307;40.25%) followed by Retained foreign-objects (n=901;27.75%); Wrong implant or prosthesis (n=425;13.09%); and Non-surgical/infrequent ones (n=614; 18.9%).

 Wrong-side (laterality) and wrong tooth removal were the most common Wrong-site NE accounting for 300 (22.95%) and 263 (20.12%) incidents respectively. There were 197 (15%) wrong-site blocks, 125 (9.56%) wrong procedures, and 96 (7.3%) wrong skin lesions excised.

 Vaginal swabs were the most commonly retained items (276;30.63%) followed by surgical swabs (164;18.20%) and guidewires (152;16.87%). There were 67 (7.44%) incidents of retained parts of instruments and 48 (5.33%) retained instruments. Wrong intraocular lenses (165; 38.82%) were the most common wrong implants followed by wrong hip prostheses (n=94; 22.11%) and wrong knees (n=91; 21.41%).

 Non-surgical events accounted for 18.9% (n=614) of the total incidents. Misplaced naso-or orogastric tubes (n=178;29%) and wrong-route administration of medications were the most common events in this category (n=111;18%), followed by unintentional connection of a patient requiring oxygen to an air flow-meter (n=93; 15%).

**Conclusion:** This paper identifies common NE categories and themes. Awareness of these might help reduce their incidence.

**Key Words:** Never Events, Patient safety, Medical errors

**Introduction:**

 Never Events (NE) are defined as ‘serious incidents which could have been prevented if the currently available safety measures had been implemented’.1, 2 The term was first introduced by the National Quality Forum (NQF) of the United States of America in 2001.3 In the United Kingdom (UK), the term NE was introduced into National Health Service (NHS) in 2009 by the National Patient Safety Agency (NPSA).1

 This enhanced focus has led to a global drive to reduce the incidence of NE. In 2009, the World Health Organisation (WHO) published guidelines on safe surgery - ‘safe surgery saves lives’ - which evolved into the WHO surgical safety checklist.4 In England, efforts towards safer healthcare further involved regular updates of NE lists, the annual publication of NE data, and the introduction of preventive measures and checklists into surgical practice. 5-7

 Despite these measures, NEs have remained a major problem for healthcare systems worldwide. In addition to the obvious adverse consequences for the patients, they are also associated with significant implications for the healthcare professionals involved, who can often be the forgotten second victim of these tragic instances 8. Furthermore, NE can place a heavy reputational and financial burden on healthcare provider organisations.9

 There is currently a paucity of data and awareness regarding the most frequent themes when it comes to NEs. Attempts to identify common NE for individual specialities are often hampered by the low numbers of such events 10, 11. National databases of reported NE can be particularly useful for this purpose. To the best of our knowledge, there is no published analysis of all the NE data within a large national or regional database to identify common themes.

 Lack of this specific knowledge of common NE themes may have hampered our efforts to reduce their incidence. The purpose of this study was to analyse NE data published by NHS England from April 2012 to February 2020 to identify common themes.

**Methods:**

 Within the National Health Service (NHS) of the UK, healthcare professionals are required by regulators to report all adverse clinical incidents, including the ones that meet the criteria for being NE, to the National Reporting and Learning System (NRLS). Each clinical area in each healthcare provider institution has a Clinical Governance (CG) lead, who is responsible for ensuring that these incidents are reported as and when they happen and that, appropriate mechanisms are in place for prevention. The ultimate responsibility rests with the Medical Directors of institutions who are also assisted by the safety leads in this task. General Medical Council (GMC), the regulator of all doctors working in the UK, has further made it clear through its “Duty of Candour” that all doctors should not just report such incidents but also share them transparently with the patients. The system is further overseen by local commissioners who oversee the hospital funds and Care Quality Commission (CQC), who monitor the quality of care provided by the individual trust. Indeed, the penalties for not reporting NEs honestly are harsh for individual doctors, clinical managers, and the institutions involved. Each year, after local incident investigation and national analysis of data, NHS England publishes a final whole-year report.

To avoid any duplicate, any possible 'Never Events' reported via NRLS since April 2013 have been passed by NHS England to commissioners, who were asked to discuss with the relevant provider organisations and either confirm this was not a Never Event or to ensure the incident was reported as a Never Event on the STEIS system. This process means that once this confirmation has been received STEIS can be considered as a reliable and complete data source.

Furthermore, there have been some significant changes to the data collection process over the years. The NE policy and framework and the NE list were revised in March 2015 and the definition of what constituted a NE was amended to include the potential to cause serious harm/death rather than actual harm. The NE list was further revised on 1st February 2018 to include changes to some of the definitions and the addition of new categories of NE. Data from the 2019/2020 report was extracted on 11 March 2020 to cover the period between 1 April 2019 and 29 February 2020 whereas the data for previous years included the month of March within them. All these factors mean that the individual annual reports are not directly comparable.

In this paper, we analyse NHS England NE data from 2012 to 2020. Data were tabulated in four major categories. An attempt was then made to identify common themes in each of the categories. We focussed on themes rather than the absolute numbers of events for two reasons. Firstly, because of the changes in the methodology of the reporting system as detailed above, the annual trends of each individual category may not be reliable and secondly, it can never be guaranteed in any healthcare system that all such events have been reported though we have one of the most robust systems for this in the UK.

 To be able to focus on important themes, NE reported ≤ 5 times during the entire study period were grouped in the miscellaneous category for analysis of wrong-site surgery and non-surgical NEs. While analysing retained objects, all guidewires were grouped together. While analysing retained objects and wrong implants, events reported ≤ 3 times during the entire study period were categorised as miscellaneous**.** For the wrong surgery category, some events that were only reported once during the study period were assigned to appropriate general themes. All this information is also presented below each table for further clarity.

**Results:**

 A total of 3247 NEs reported to NHS England between April 2012 and February 2020 were analysed. We identified 51 common NE themes in 4 main categories. Table 1 shows all the NEs broken down into four main categories. Overall, Wrong-site surgery was the most common NE category (n= 1307; 40.25%) followed by Retained foreign objects (n= 901; 27.7%); Wrong implant or prosthesis (n= 425; 13.09%); and Non-surgical/ infrequent never events (n= 614; 18.9%)

 Table 2 shows the analysis of Wrong-site surgery incidents (n= 1307). We identified 20 major themes in this category. Wrong side (laterality) and wrong tooth removal were the most common wrong-site surgery problems, accounting for 22.95 % (n=300) and 20.12 % (n=263) cases respectively. Since being introduced as a reportable NE in 2015/2016, the wrong site block has been a frequent problem accounting for 15 % of the total (n=197). There were 125 wrong procedures performed accounting for 9.56% of the total wrong-site surgery. Excision of wrong skin lesions has been a frequently reported problem with an overall 96 incidents representing 7.34% of the total.

 Table 3 shows Retained foreign objects (n= 901) categorised into 12 themes according to the object retained. Vaginal swabs were the most commonly retained items (276; 30.63%) followed by surgical swabs (164; 18.20%) and guidewires (152; 16.87%). Additionally, there were 67 incidents of retained parts of broken instruments and 48 retained instruments representing 7.44% and 5.33% of the total retained items.

 Table 4 lists the Wrong implant or prosthesis NE (n= 425) broken down into 7 themes. Wrong intraocular lenses were the most common incidents (165; 38.82%), wrong hip prostheses reported in (94; 22.11%) cases while wrong knee prostheses accounted for (91; 21.41%) cases. There were 16 wrong intrauterine devices and 13 wrong plates and screws representing 3.76% and 3.05% respectively.

 Table 5 lists all the Non-surgical/ infrequent NE (n= 614) broken down into 12 themes. Misplaced naso- or oro-gastric tubes (n=178) and wrong route administration of medications (n=111) were the most common in this category representing 29% and 18% of all the events in this category respectively.

**Discussion:**

 This detailed analysis of 3247 NE reported by NHS England, covering a period of nearly 8 years from March 2012 to February 2020, found 51 common themes in 4 main categories. This is the first such analysis of NE data from anywhere in the world with a specific focus on identifying commonly recurring NE. This knowledge might help reduce their occurrence in the future. If we had included every single NE separately, it would have made our tables too large and distracted us from our main aim of analysing the common themes. So, we grouped the rare events into miscellaneous categories as detailed above in the Methods section. We hope to carry out further focussed analysis of NE in each clinical area and in that analysis, we will also include these rarer NE to identify speciality specific themes.

 There is widespread recognition, and it is also apparent from our analysis that the problem of NE has persisted 12 despite the introduction of measures like the surgical safety checklists. It may be because the checklists can be difficult to implement effectively.13 It may also be because of a lack of awareness of specific pitfalls that then repeat themselves.14 Identification of predisposing factors for each specific NE is beyond the purview of this paper as we have focussed on the identification of themes rather than their prevention in this paper. Usually, all such incidents undergo a thorough Root Cause Analysis (RCA) in the NHS where all contributory factors are examined, and locally appropriate recommendations are made. Individual organisations do report these incidents and NHS England then produces an annual report but poor engagement from clinicians means that this data is not then used to proactively implement preventative measures.

As we can see from the data held by NHS England, this sadly means that the same NE is then repeated from one trust to another. We hope that studies like this will help raise awareness of common NE themes and encourage healthcare professionals to be more vigilant whilst performing procedures known to be at high risk of leading to NEs.

Surgical checklists have been around for almost a decade and though they have many other benefits, it is not certain if they have led to a reduction of NEs. For obvious reasons, this study does not allow us to make any conclusions about the effectiveness of checklists. It is, however, difficult to understand how some of the NE we have noticed would still have happened if a proper checklist was in place and diligently executed by healthcare professionals. It is, however, recognised that checklists by themselves cannot reduce NEs. They need doctors and nurses to engage with them. One of the reasons healthcare professionals do not engage with them is because they feel checklists are unnecessary and a bureaucratic waste of time. We hope studies like this would help change that perception and culture as these events are not that uncommon and many, if not most, clinicians incur the risk of being caught out in their lifetime if adequate systems are not in place and followed.

 The analysis of factors predisposing NE has so far focussed on identifying human factors 15 and broad speciality specific predisposing factors.16 But there has thus far been little emphasis on the identification of specific NE that have often then repeated themselves. For example, excision of the wrong skin lesion is one of the commonest wrong site NE in our dataset with a total of 96 independent events during the study period but authors are not aware of any specific study highlighting this problem and examining the reasons for it. It is probably because of incorrect markings without involving patients or their representatives. But such an analysis has not been carried out as many surgeons, like us, are not even aware of this being a common pitfall.

 Similarly, there were 25 instances of retained specimen retrieval bags in this study but the authors are not aware of any published report of this problem in the peer-reviewed scientific literature. In one such instance that authors are aware of, the problem happened because these bags were not in the theatre count policy, which had not been updated to accommodate this commonly used new item in the laparoscopic era. This was potentially an easily avoidable situation but still happened and keeps on happening in different hospitals simply because surgeons are not aware of this item not being there in their theatre count policies.

 Another common problem worth highlighting is that of guidewires. Increasing use of percutaneous approaches means there is now a range of tubes being used in a variety of clinical areas that have guidewires within them but many of these procedures are carried out in environments where there may not even be formal count policies emphasising perhaps the need to develop policies for the safe performance of these procedures in different clinical areas.

 Following the publication of National Safety Standards for Invasive Procedures (NatSSIPs) on 7th September’ 2015,17 the NHS England issued a stage two alert (Alert Reference Number NHS/PSA/RE/2015/08) on 14th September’ 2015 asking relevant NHS organisations to develop “their own Local Safety Standards for Invasive Procedures (LOCSSIPs) based upon the high-level national standards” 18 with an overarching objective of reducing “Never events”. Amongst other things, the alert asked the organisations providing NHS funded care to “develop and test LocSSIPs based on the relevant NatSSIPs using local insight”. Even though the guidance and the alert were issued several years ago, a recent survey 19 by NHS Improvement showed that this is very much work in progress. Several of the common events highlighted in this study could probably be prevented by the development of LocSSIPs specifically designed for this purpose. We hope that the findings of this study would help National Safety Standards for Invasive Procedures (NatSSIPs) leads in each trust to identify priority areas for the development of Local Safety Standards for Invasive Procedures (LocSSIPs) in their institutions.

**Strengths and Limitations:**

 This is the first in-depth analysis of specific NE events data published by NHS England. Themes identified in this analysis might help increase awareness of specific pitfalls and encourage further research into their predisposing factors.

 There are several limitations to this study. First of all, and as mentioned above, the data from year to year are not strictly comparable and should not be used to indicate trends over the study period. This is because of various changes in methodologies of data collection and definition of NE by NHS England during the entire study period. Secondly, we are unable to comment on causative factors as that data has not been reported and is likely to be buried within the individual clinical incidents. Thirdly, to be able to focus on important themes, we clubbed many infrequently reported incidents into the Miscellaneous category. Focussed work by specialities should take that into account and probably start with the raw data itself to not miss any. Finally, we cannot be absolutely certain that the data includes all NE occurring within NHS England during this time period. Though there are safeguards in place to deter underreporting and harsh penalties for medical professionals and institutions who fail to comply, one can never be completely confident that all such incidents have been reported and recorded. That is why we have focussed on identifying important themes rather than focussing on the numbers of individual events annually. Authors, therefore, feel occasional failure to report NE would not significantly undermine the value of our study.

**Conclusions:**

This detailed analysis of published Never Events data by NHS England over a period of 8 years from April 2012 to February 2020 identified 51 common themes in 4 main categories. Awareness of these themes might help reduce their incidence and allow for focussed work to reduce their incidence as well as the development of specific LocSSIPs.

**Conflict of Interest Statement:** The authors declare that they have no conflict of interest.

**Statement of Human and Animal Rights:** Not Applicable

**Statement of Informed Consent:** Not Applicable

**Author Contribution:** Author 1 performed the data collection and analysis, and drafted the manuscript. Author 6 conceived the idea for this study, assisted with data collection and analysis, and manuscript writing. All other authors helped with determining methodology, provided feedback at every stage, and critically reviewed the manuscript. All authors have seen and approved the final manuscript.

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**Abbreviations:**

**NE:** Never Event(s)

**IOM:** Institute of Medicine

**USA:** United States of America

**UK:** United Kingdom

**NHS:** National Health Service

**NPSA:** National Patient Safety Agency

**WHO:** World Health Organisation

**NRLS:** National Reporting and Learning System

**STEIS:** Strategic Executive Information System

**NatSSIPs:** National Safety Standards for Invasive Procedures

**LocSSIPs:** Local Safety Standards for Invasive Procedures