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Common general surgical never events: analysis of NHS England never event data

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Abstract

Background: There is little available data on common general surgical never events (NEs). Lack of this information may have affected our attempts to reduce the incidence of these potentially serious clinical incidents.
Objectives: The purpose of this study was to identify common general surgical NEs from the data held by the National Health Service (NHS) England.
Methods: We analysed the NHS England NE data from April 2012 to February 2020 to identify common general surgical NEs.
Results: There was a total of 797 general surgical NEs identified under three main categories such as wrong-site surgery ($n = 427$; 53.58%), retained items post-procedure ($n = 355$; 44.54%) and wrong implant/prosthesis ($n = 15$; 1.88%). We identified a total of 56 common general surgical themes—25 each in the wrong-site surgery and retained foreign body categories and six in wrong implants category.
Wrong skin condition surgery was the commonest wrong-site surgery ($n = 117$; 27.4%). There were 18 wrong-side chest drains (4.2%) and 18 (4.2%) wrong-side angioplasty/angiograms. There were seven (1.6%) instances of confusion in pilonidal/perianal/perineal surgeries and six (1.4%) instances of biopsy of the cervix rather than the colon or rectum.
Retained surgical swabs were the most common retained items ($n = 165$; 46.5%). There were 28 (7.9%) laparoscopic retrieval bags with or without the specimen, 26 (7.3%) chest drain guide wires, 26 (7.3%) surgical needles and 9 (2.5%) surgical drains. Wrong stents were the most common ($n = 9$; 60%) wrong implants followed by wrong breast implants ($n = 2$; 13.3%).
Conclusion: This study found 56 common general surgical NEs. This information is not available to surgeons around the world. Increased awareness of these common themes of NEs may allow for

the adoption of more effective and specific safeguards and ultimately help reduce their incidence.

Key words: never events, patient safety, medical errors, medical claims

Introduction

'Never events' (NEs) are patient safety incidents that are deemed wholly preventable if accepted safety norms have been implemented by healthcare providers [1]. They have the potential to cause serious patient harm or death and as such are regarded as highly important benchmarks for the safety of healthcare provided by an institution.

One of the most established safety norms in the surgical world is the 'Safe Surgery' checklist developed by the World Health Organization [2]. Use of safety checklists is associated with a reduction in the deaths after inpatient surgery [3]. However, its usefulness in the prevention of NEs is less clear, and NEs continue to represent a major challenge for the surgical community [4].

Within the UK, there is an ongoing national drive to expand the safety framework beyond just surgical procedures to include all invasive procedures [1, 5]. It is recommended that individual healthcare institutions should develop their own Local Safety Standards for Invasive Procedures based on the National Safety Standards for Invasive procedures [1]. However, despite these measures, NEs continue to happen [1, 6], and published data from the National Health Service (NHS) England suggest no apparent decline in their frequency [7]. At the same time, the data reveal many NE themes that are unfortunately repeated from one place to the other.

General surgery accounts for a significant proportion, if not the majority, of NEs [8]. Although the NHS England releases annual NE reports, in their current form, they do not allow busy clinicians to easily recognize incidents relevant to their speciality. The reports include all the incidents covering all medical and surgical specialties and do not break them down into specialties. Additionally, they list individual incidents under three main categories such as wrong-site surgery, retained items post-procedures and wrong implants or prostheses, which in itself does not allow for the easy identification of common pitfalls. All these factors make it very difficult for individual clinicians to know which specific incidents are relevant to their speciality and routine work.

There has thus far been no attempt to identify common and recurring general surgical NEs in the scientific literature. Such data, if available, may alert general surgeons to the common pitfalls and may allow for timely implementation of necessary safeguards in their practice. The purpose of this study was to analyse general surgical NEs from the data held by the NHS England to identify common themes. Increased awareness of these common themes might help reduce their incidence.

Methods

Within the NHS of the UK, reporting of all adverse clinical incidents including NEs is mandatory. All incidents need to be reported to the National Reporting and Learning System (NRLS). Each clinical area in each healthcare provider institution has a clinical governance lead, who is responsible for ensuring 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 the Care Quality Commission, 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 duplication, any possible 'Never Events' reported via NRLS since April 2013 have been passed on by NHS England to commissioners, who were asked to discuss with the relevant provider organizations 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 a reliable and complete data source. NHS England has 854 hospitals in 217 different trusts within its jurisdiction [9, 10].

We analysed NHS England NE data from April 2012 to February 2020. All general surgical NEs were separately identified by two authors (IO and KM). Any discrepancy was resolved by discussion with co-authors. The authors applied a broad definition of general surgery to include all procedures or invasive procedures that could be performed by a general surgeon or a sub-specialist in theatre or outside the theatre in some part of the world, as we aimed to identify all potential general surgical themes from the data set. Data were tabulated in three main categories and then we attempted to identify common themes in each of these categories. Our themes development process took into account many factors such as the anatomical considerations, the nature of the procedure, setting of the incidents and the equipment or instruments involved if any.

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 an NE was amended to include the potential to cause serious harm/death rather than actual harm. The NE list was further revised on 1 February 2018 to include changes to some of the definitions and the addition of new categories of NEs. 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 extended up to 31 March. All these factors mean that the individual annual reports are not directly comparable and any analysis of trends over time would be meaningless.

Definitions

Wrong-site surgery: Surgical operation or invasive procedure performed on the wrong site and not the intended site.

Retained items post-procedure: Any item unintentionally left behind after completion of the procedure and subject to a formal counting/checking process.
Wrong implant or prosthesis: Foreign object that has been inserted to perform a function as part of the invasive procedure or operation but did not meet the predetermined specifications required.
Wrong skin condition surgery: Surgery on the wrong skin or subcutaneous tissue lesion, which might include excision or biopsy from a wrong lesion, site or side.
Wrong laterality: Performing the surgical operation on the opposite side of the body intended (e.g. right side as opposed to the left side).
Wrong procedure: Performing a different surgical procedure to the one intended.
Wrong digit surgery: Procedure or incision performed on the wrong finger or toe (including nails).
Wrong patient procedure: Performing the intended surgical procedure on another patient not meant to have the procedure.
Wrong incision: Performing skin incision on a wrong site or side without completing the procedure on the wrong site or side.
Wrong scope: Performing a different endoscopic procedure or examination to the intended one.

Results

We identified 797 general surgical NEs

(Figure 1 presents most significant themes) out of a total of 3247 [6] NEs held in the data set. This represented 24.5% of the total events. The number of general surgical NEs ranged from 84 to 122 per year. Wrong-site surgery was the most common NEs ($n = 427$; 53.6%), followed by retained items post-procedure and wrong implant/prosthesis ($n = 355$; 44.5% and 15; 1.9%) respectively (Table 1).

If we had included every single NE separately, it would have made our tables too large and also distracted us from our main aim of analysing the common themes. Therefore, NEs that happened only once during the study period, and could not be aligned with any other theme, were grouped in the miscellaneous category in tables.

Table 2 shows 25 wrong-site surgery themes from amongst a total of 427 NEs in this category. Wrong skin condition surgery was the commonest in this category ($n = 117$; 27.4%). Amongst other significant themes were wrong finger surgery ($n = 26$; 6.1%); wrong-side chest drains ($n = 18$; 4.2%); wrong-side angioplasty/angiograms (n = 18; 4.2%) and wrong incisions ($n = 15$; 3.5%).

Table 3 shows 25 common themes of retained items post-procedure from amongst a total of 355 NEs in this category. Retained surgical swabs were the most commonly retained items ($n = 165$; 46.5%). Amongst other significant ones, there were 28 (7.9%) organ retrieval bags (or part of) with or without the specimen, 26 (7.3%) chest drain guide wires, 26 (7.3%) surgical needles (or part of) and 9 (2.5%) surgical drains (or part of).

Table 4 shows six themes of wrong implants/prostheses from amongst a total of 15 NEs in this category. Wrong stents ($n = 9$; 60%) were the most common followed by wrong breast implants ($n = 2$; 13.3%).

Discussion

Statement of principal findings

In this first analysis of NEs reported to NHS England from April 2012 to February 2020 with a special focus on general surgery, we identified 797 general surgical incidents. After analysis, we identified 56 meaningful themes. Like other data sets [11] on this topic, NHS England divides the data it holds into three main categories of wrong-site surgery, retained foreign body and wrong implants. It does not attempt to separate data according to speciality or themes. These factors limit the usefulness of this data set as in the real-world doctors and nurses generally work in a specific clinical area.

Over the study period, the number of the procedures and interventions performed within the NHS England has increased from 10 594 814 in 2012–2013 to 12 281 985 in 2019–2020. General surgical branches accounted for more than 2 000 000 procedures and interventions including vascular, breast, colorectal and hepatobiliary subspecialties in 2019–2020 [12–14]. Authors, therefore, feel general surgical NEs involve a small per cent of the total procedures performed. At the same time, the absence of a denominator in the published data by NHS England does not allow us to make any scientific deduction about their approximate annual incidence.

Interpretation within the context of the wider literature

Wain *et al*. were only able to identify 79 surgical NEs in their large analysis [8] of 20 432 patient admissions, and only 47 of them were in 'general surgery' patients. In another study [15], there were only 26 'general surgery' NEs. Such low numbers also preclude the identification of any common themes. This is probably why no attempt has thus far been made to identify common general surgical never events themes.

Our study shows that within the commonly recognized three main categories, certain NEs happen more commonly. For example, a large number of incidents ($n = 117$) involved surgery on the wrong skin lesion. This could be potentially due to several reasons. Skin and subcutaneous lesions are usually not subjected to strict laterality specifications [16]. Moreover, the majority of these procedures are performed under a local anaesthetic which can distort the lesion [17]. Finally, patients can present with multiple lesions of the same pathology like multiple lipomatosis, sebaceous cysts or neurofibromas, leaving room for confusion [18]. Other possible explanations

Table 1 All general surgical NEs

	2012–2013	2013–2014	2014–2015	2015–2016	2016–2017	2017–2018	2018–2019	2019–2020	Total
Wrong-site surgery	54	62	51	48	51	55	50	56	427
Retained items post-procedure	68	47	47	41	42	44	31	35	355
Wrong implant/ prosthesis	0	1	1	1	2	6	3	1	15
Total	122	110	99	90	95	105	84	92	797

Table 2 Wrong-site surgery (25 themes)

Wrong-site surgery	2012–2013	2013–2014	2014–2015	2015–2016	2016–2017	2017–2018	2018–2019	2019–2020	Total
Wrong skin condition surgery ($n = 117$)									
Wrong skin lesion/tag/scar excised	9	3	14	19	14	13	20	14	106
Biopsy of wrong skin lesion			1		2	3	2	3	11
Wrong laterality ($n = 84$)									
Wrong side/laterality (Not otherwise specified)	26	1	3		1	3	1		35
Wrong side chest drains		2	3	5		3	2	3	18
Wrong side angioplasty/angiograms			3	1	4	2	5	3	18
Wrong side/Wrong hernia repair			1	1		2		2	6
Wrong side stent surgery/removal		1			3	1			5
Wrong side of leg/leg surgery/foot surgery		1	1						2
Wrong procedures ($n = 80$)									
Wrong procedure (Not otherwise specified)	12	41						1	54
Wrong-site/side biopsy (Misc): Biopsy from GI tumour rather than kidney/Lung biopsy instead of bowel/Wrong-side breast biopsy/Liver biopsied instead of pancreas			2	1	1	1	1	2	8
Wrong bottom surgery (Pilonidal/Perianal/Perineal/Groin/Haemorrhoid confused)		1		1		2	1	2	7
Biopsy of cervix rather than biopsy of colon/rectum					3	1	1	1	6
Fallopian tube/adipose tissue removed instead of appendix		2	1	1				1	5
Wrong digit surgery ($n = 58$)									
Wrong: finger surgery/finger incision	5[a]		6	2	4	3	5	6	26
Wrong: toe/toes/side of toe surgery/toe incision			5	3	4	1	3	3	19
Wrong toe nail/side of toe nail removed			1		2	1	3	1	8
Wrong breast surgery ($n = 20$)									
Wrong area/lesion breast			3	1	2	4	2	4	16
Wrong breast injection					1	1		2	4
Wrong patient procedure: ($n = 18$)									
Wrong patient surgery: Excision of skin lesion/Biopsy/angiogram intended for another patient			1	7	1	3			12
Wrong pt. endoscopy: OGD/Sigmoidoscopy/Colonoscopy intended for another patient						2	2	2	6
Wrong incisions: Wrong groin incision/Wrong-side angioplasty incision/Wrong incision for hernia repair/Wrong side hernia incision/Wrong side of leg/Wrong foot/Wrong area of arm		4	1	1	3	4	1	1	15
Unnecessary/Additional procedure undertaken	1	5	1	1	3	1			12
Wrong scopes: ($n = 9$)									
OGD instead of flexible sigmoidoscopy/colonoscopy			1	2		1		1	5
Sigmoidoscopy/Colonoscopy instead of cystoscopy/Cystoscopy instead of sigmoidoscopy			1		1	1		1	4
Wrong vein/Wrong-side vein surgery/harvesting/ablation		1		1	1			1	4
Miscellaneous	1		2	1	1	2	1	2	10
Total	54	62	51	48	51	55	50	56	427

[a]Overall number of wrong digit surgery was reported without details/Events that occurred only once in the study period and could not be aligned with any other theme were clubbed together as miscellaneous.

Table 3 Retained items post-procedure (25 themes)

	2012–2013	2013–2014	2014–2015	2015–2016	2016–2017	2017–2018	2018–2019	2019–2020	Total
Surgical swab	34	22	19	18	23	19	12	18	165
Laparoscopic retrieval bag or part of (± specimen)	5	4	3	4	5	5	2		28
Guide wire—chest drain	2	1	6	3	4	3	2	5	26
Surgical needle (or part of)	2	3	6	5	1	3	2	4	26
Instruments ($n = 23$)									
Instruments not otherwise specified	11								11
Microvascular/Vascular/Surgical Clamp		2	1	1		3			7
Surgical forceps		2					1	2	5
Surgical drain/part of/inserter cover	4				3	1	1		9
Part of/broken instrument ($n = 8$)									
Part of/broken instrument	2								2
Screw from instrument			1	1					2
Part of forceps					1	1			2
Scalpel blade/part of			1	1					2
Glove/Glove remnant	3	2				1	1		7
Guide wire—Different tubes			4	1	1			1	7
Ribbon gauze/Vaseline gauze/gauze roll			1	1	1	1	2		6
Unknown	2	1					1		4
Fragment of plastic		1		1		1			3
Piece of laparoscopic port tubing/Plastic tubing/Silicon tubing	1					1	1		3
Hypodermic needle	1	1	1						3
Cotton wool ball						1	1		2
Dressing used during surgical procedure		1	1						2
Tag from swab			1		1				2
Angioplasty cover								2	2
PEG tube/Insertion device				1				1	2
Plastic sheath vascular ablation procedure						1		1	2
Miscellaneous	1	7	2	4	2	3	5	1	25
	68	47	47	41	42	44	31	35	355

Events that occurred only once in the study period and could not be aligned with any other theme were clubbed together as miscellaneous.

Table 4 Wrong implants and prostheses (six themes)

Wrong implant/prosthesis	2012–2013	2013–2014	2014–2015	2015–2016	2016–2017	2017–2018	2018–2019	2019–2020	Total
Wrong stent		1			1	6	1		9
Wrong breast implant							1	1	2
Wrong vascular graft							1		1
Gastrostomy tube				1					1
Stent used instead of a balloon catheter					1				1
Aortic stent			1						1
Total numbers	0	1	1	1	2	6	3	1	15

could include unclear marking, lack of patient involvement during marking or poor communication within the surgical team [19]. However, identification of all the potential underlying reasons will require further focused work, which has not yet been performed as surgeons are not aware of this being a common NE.

Similarly, wrong-side chest drains ($n = 18$) and wrong-side angioplasty/angiograms ($n = 18$) were common amongst wrong laterality NEs. Once again, there is no prior mention in the surgical literature of these being common NEs, making our study significant. It is unclear if these incidents are more common because the chest and vascular problems are often bilateral or because these procedures are often carried out in environments other than operating theatres where hospitals may not have clear safety protocols and checklists [1, 20]. Once again, the lack of awareness thus far has prevented any detailed examination of the underlying reasons and development of specific strategies for the prevention of these events. There were

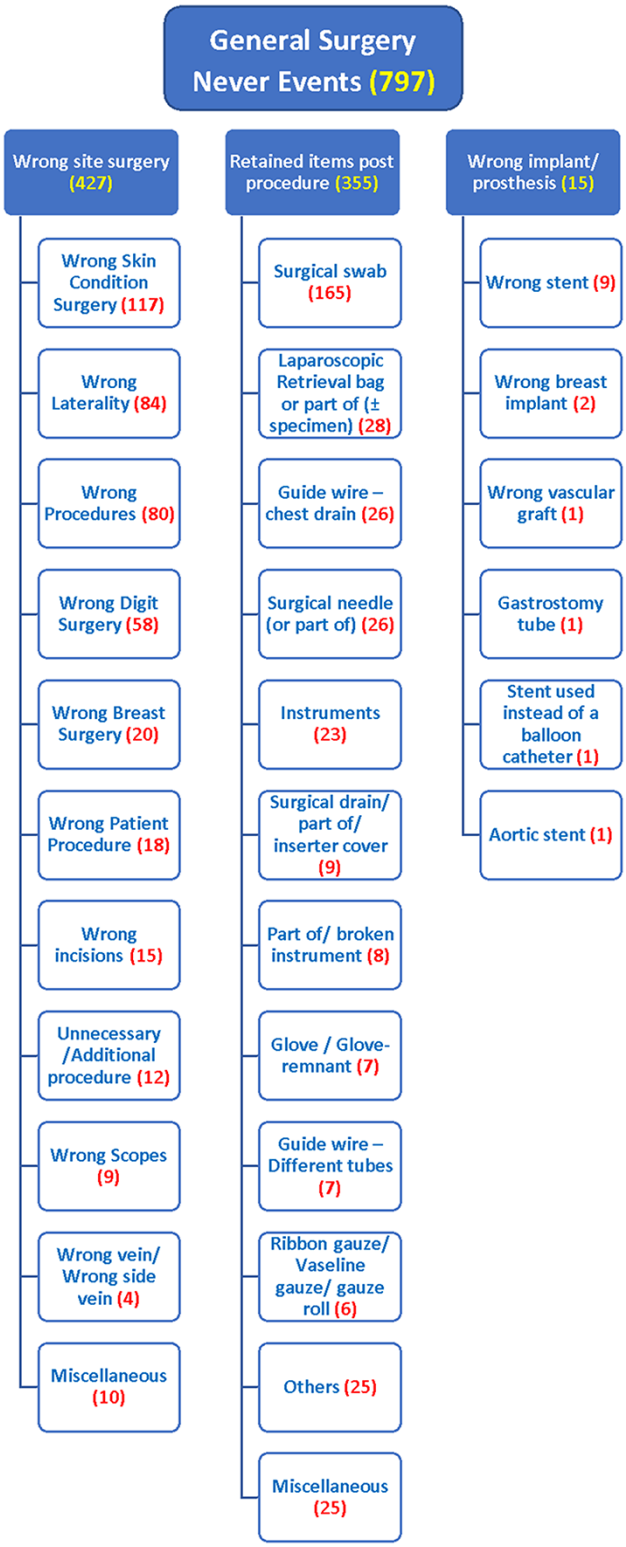

Figure 1 Commonest general surgical NE themes.

further reports of confusion amongst pilonidal, perianal and perineal procedures and upper gastrointestinal endoscopy carried out in place of lower gastrointestinal endoscopy. Awareness of these NEs may make surgeons more careful when dealing with these patients.

Most of the retained items in our study were surgical swabs ($n = 165$). Unfortunately, this database does not contain any information on the possible reasons behind this finding. However, the available evidence points to a limitation of the manual surgical counting process [21]. The use of automated counting utilizing barcoded surgical sponges and radiofrequency detection systems has been suggested to improve the accuracy [22, 23].

Amongst other retained items, there were 28 retained laparoscopic retrieval bags (with or without the specimen). This problem seems very specific to laparoscopic surgery when an item placed inside the abdomen for later removal can be forgotten at the end of the surgery. It may be possible to prevent this by ensuring these bags and any specimens are promptly added to the count during the surgery. There were 26 chest-drain guide wires.

Implications for policy, practice and research

The analysis of NEs of a large national database spanning nearly 8 years has yielded 56 specific general surgical themes. The analysis addressed the common general surgical NEs rather than all the events that a general surgeon can come across in their wider practice of medicine. This specific knowledge may alert general surgical teams around the world to common themes and help them reduce the incidence of these NEs. Our findings may also allow for further focused work for understanding the reasons behind each of these themes, with an overarching aim of developing better preventative strategies.

Strengths and limitations

This is the first analysis of NEs of a large national data set over an extended period. However, there are several weaknesses of this study that need to be recognized. First, any separation of patients according to a specific speciality can be artificial for many patients who are looked after by multidisciplinary teams involving many professionals and specialties in complex hospital environments.

Second, because of the nature of this database, we have no further information on individual NEs in the database. Therefore, we are unable to comment on the underlying reasons. Third, we cannot provide an idea of the rate of individual NEs, as we are not aware of the denominator population. Fourth, because of various factors, as detailed in the 'Methods' section, we cannot make any scientific deductions about trends of each theme over time. Moreover, the data set does not provide information on the completion of the surgical checklists in each patient. Hence, we cannot conclude if these incidents were related to the lack of implementation or the improper implementation of safe surgery checklists.

Furthermore, we cannot be certain that any specific NE actually happened to a general surgery patient. Finally, general surgery is a broad speciality, and its character can be quite different in different countries and often even in different parts of the same country. We have tried to use a very broad definition of general surgery based on the authors' own experiences. We may have missed some NEs from the data set that others could perceive as general surgical events or included those that others might think do not belong here.

Conclusions

This is the first analysis of NEs with a general surgical perspective. We identified 56 common themes. Enhanced awareness of this information could alert busy clinicians on the ground and may allow for further focused work for the prevention and adoption of specific safeguards.

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Author contribution

I.O. performed the data collection and analysis and drafted the manuscript. K.M. conceived the idea for this study, helped with data collection and analysis, and manuscript writing. All other authors helped with determining the methodology, provided feedback at every stage and critically reviewed the manuscript. All authors have read and approved the final manuscript.

Statement of human and animal rights

Not applicable.

Statement of informed consent

Not applicable.

IRB approval

Not applicable.

Data availability

Data are available on the NHS England website.

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