

Why are surgical never events still occurring: A Delphi study research sample across NHS England operating theatres

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ABSTRACT

This paper examines the application of the Surgical Safety Checklist (SSC) within NHS hospital operating theatres England. The aim of the study, through a combination of open-ended questions, was to solicit specific information including views and opinions from operating theatre experts to establish from how the World Health Organisations (WHO) SSC is being applied, and therefore and why intraoperative 'Never Events' continue to occur more than a decade after the SSC was introduced. Participants were from the seven regions identified by NHS England.

The intention of this paper is not to establish definitively whether the quantitatively identified themes; including a lack of training and engagement with human factors explains the increased presence of intraoperative 'Never Events'. However, these themes, when subjected to methodological triangulation with the current literature, do appear consistent, and therefore provide an exploratory approach to inform research intended to improve safety in the operating theatre by informing policy and its application to safe practice ultimately towards quality improvements.

1. Applying the safe surgical checklist

The World Health Organisation (WHO) global guidelines were launched across 132 countries as part of the safe surgery saves life campaign (WHO, 2009; [1,2]). The aim of was to prevent unnecessary death and improve outcomes for surgical patients [3]. The original approach to the SSC identified nineteen separate actions that were compiled into the three steps. However, a further two steps, the team brief and debrief were added in 2010 following feedback from the initial implementation (Shah, 2011). [4] Since their introduction their application has been subject to ongoing commentary. Aiming for simplicity, McConnell et al. [5] suggested the checklist should remain succinct and concise, to avoid checklist fatigue. Harden [6] stressed that the checklist should be customised to fit local practice and should not necessarily take a one size fits all approach. Raman et al. [7] concurred, arguing that checklists should be tailored to specific tasks. Moreover, the use of stock questions could increase inattention rather than ensuring all theatre personnel remain engaged with the checklist.

Despite the introduction of the SSC and ongoing debate within the

literature, the surgical intraoperative 'Never Events' which the SSC was intended to reduce stubbornly remain as a major source of patient harm. A review of the final and provisional data between April 2012 and December 2022 [8–15] has shown that there was 1574 wrong site surgeries, 528 wrong implant/prosthesis and 1053 retained foreign objects post procedure. This is a total of 3155 intra-operative 'Never Events'. Given the continued incidence of 'Never Events' it is essential to explore why surgical (Intra-operative) 'Never Events' (wrong site surgery, wrong implant/prosthesis, and retained foreign objects post procedure), steadfastly occur. The aim of this study was to seek expert opinions from those involved in the implementation and use of the SSC, who through their role within the peri-operative environment, have knowledge and experience that can highlight the circumstances and context central to these events.

The working environment in operating theatres, entails daily time pressures, high workloads, and the potential for catastrophic outcomes when errors occur. The internationally agreed checklists are based upon three principles, simplicity, widespread applicability, and measurability [16]. Theatres were recognised as a hazardous environment by Thomas

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et al. [17] when it was estimated that almost half of adverse events were preventable. The ethos of a checklist is to help identify mistakes before harm is caused to patients. Helmreich [18] reported that checklists are commonly used as a method of both error and safety management to reduce risk. Haynes *et al.* [1] demonstrated a simple checklist can reduce risk of morbidity, mortality and surgical site infection associated with surgery. Checklists not only reinforce communication [5] but also improve communication in multidisciplinary teams.

2. Methodology

The approach to this research study is based upon three Delphi study rounds and one questionnaire. The Delphi research study consisted of an invited sample of NHS England Trust Theatre Managers, Matrons and Educators from across NHS England using a combination of both open and closed questions. Prior to round one of the Delphi studies, a pilot questionnaire containing fifteen questions was sent to seventeen members of the National Performance Advisory Group for – Theatre Managers, Matrons and Educators for several reasons: to see what the responses from the questions yielded; to see if the questions needed to be altered as to ensure meaningful and tangible data was collected; to ensure the questions can be answered honestly, without bias and are a true reflection of today’s current practice inside NHS England operating theatres and to inform the first Delphi Study round.

Gathering the survey data in this way is intended to allow us to gain a consensus of opinion based on our aim of surfacing trends, theme patterns to arrive at a logical understanding of the phenomena research topic. The method used promoted anonymity and avoided direct confrontation amongst experts.

Jones and Hunter [19], described the Delphi technique as seeking the opinion of a group of experts in order to assess the extent of agreement and to resolve disagreements on an issue. Barrett and Heale [20] state that the Delphi technique was first developed in the 1950s in an attempt to gain reliable expert consensus. The Delphi technique is an iterative multistage process, designed to transform opinion into group consensus. If used systematically and rigorously, it can contribute significantly to broadening knowledge with the healthcare profession.

2.1. Delphi study

Round one of the Delphi study commenced on the 21st October 2022 and contained fourteen of the original fifteen pilot questions. Round one began with a structured questionnaire that was based upon the extensive review of the literature with a combination of closed and open-ended questions that solicited specific information about current practice and researched literature that generated ideas and allowed participants freedom in their responses. Careful thought and consideration was given to the wording of the questions to ensure that there was no bias from the author, and not to limit the responses. The same principle applied for rounds two and three. Round two of the Delphi study commenced on the 17th November 2022. All participants was sent the results of the analysis with statistical information presented to indicate areas that have gained collective opinion. Hsu and Sanderson (2007) [21] suggest that the feedback process allows the participants to reassess their initial judgments about the information previously provided. In round two, a consensus began to form. The second stage focused on the theatre checklist and National Safety Standards for Invasive Procedures. Round three of the Delphi study commenced on the 27th December 2022. This stage provided a final opportunity for participants to revise their judgments.

To allow for richer data, all three Delphi rounds were combined into one questionnaire and sent to current members (2022) of the National Performance Advisor Group for theatre managers. In total, thirty-three NHS England Trust senior (Agenda For Change Band’s 7 – 8b) safety expert theatre managers, matrons and educators was asked for their opinion on a series of questions. A diverse mix off backgrounds from

both Operating Department Practitioner’s (ODP) and Registered General Nurse’s (RGN) was recruited.

Ethics approval was granted from the University of Derby, application ETH2223–0074, on the 18th October 2022 and ETH2223–1516 on the 5th December 2022. HRA approval was sought, but not required, application 319,163 on the 18th October 2022.

The Delphi study technique was used as it is a mixed method option aimed at generating expert consensus [22]. (Niederberger and Spranger [23], pp. 3) state that an expert “is either based on their individual scientific/professional expertise or lifeworld experience”. Jones and Hunter [19] suggested that this technique seeks the opinion of a group of experts in order to assess the extent of agreement and to resolve disagreement on an issue. Rowe and Wright [24] advocate that the Delphi technique has proven to be a reliable measurement instrument in developing new concepts and setting direction of future-orientated research. Hasson, Keeney and McKenna [25] study argued for consensus methods such as a Delphi survey technique to be employed to enhance effective decision making in health and social care. This was still supported several years later by Jorm [26] as they recommended that Delphi studies are often used in health sciences to find consensus.

The Delphi technique is an iterative multistage process, designed to transform opinion into group consensus. If used systematically and rigorously, the Delphi can contribute significantly to broadening knowledge with the healthcare profession. Vogel *et al.* [27] suggest that this technique is used to establish consensus across a range of subject areas. Niederberger and Spranger [23] study indicated that the objectives of a Delphi study in health sciences are: identifying the current state of knowledge and improving predictions of possible future circumstances. Jorm [26], Negrinin *et al.* [28] and Junger *et al.* [29] also argued that the method is useful for identifying and formulating standards or guidelines for theoretical and methodological issues. Han *et al.* [30] adds that the Delphi technique is good for developing a measurement tool and identifying indicators. Van Hasselt, Oud and Loonen (2014) [31] suggest the Delphi technique can be used to formulate recommendations for action and prioritising measures.

An expert safety consensus was required from theatre managers, matrons and educators across NHS England. The research gathered data to seek expert opinions of users of the WHO Surgical Safety Checklist and to gain a consensus of opinion based on the end user’s knowledge and expertise. The technique developed an approach which promoted anonymity and avoided direct confrontation amongst experts.

Table 1 details the number of potential NHS Trusts across the seven regions in NHS England.

Of the 223 NHS Trusts in England [32], only 157 NHS Trusts have operating theatres (Supporting Facilities Data, 2019/20 cited in [33]). Across the seven separate regions there are a total of 3282 operating theatres. For the study, we chose to purposefully reduce the number of Trusts and operating theatres. The total number of Trusts included in the study was reduced by twenty-one. Table 2 details the number of Trusts by region and the number of operating theatre.

The rational for excluding the total number of Trusts from the research by twenty-one was due to the following reasons:

Table 1
NHS England Trusts.

Region	Number of Trusts
London	23
Southwest	21
Southeast	22
Midlands	25
East	18
Northwest	26
Northeast & Yorkshire	22
Total	157

Table 2
NHS England trusts by region and the number of operating theatres.

Area	Number of Trusts	Number of operating theatres
London	22	512
Southwest	15	275
Southeast	20	438
Midlands	21	524
East	15	272
Northwest	22	366
Northeast & Yorkshire	21	531
Total	136	2918

- Nine Trusts were not yet in existence between April 2015 – March 2020 at the point that LocSSIPs were first introduced.
- Six Trusts were excluded as a result of only appearing to have one operating theatre therefore meaningful data was difficult to ascertain.
- Two of the Trusts are non-NHS.
- We removed the data from a further Trust because of a possible conflict of interest.
- Three Trusts did not provide any contact details.

Table 3 details the number of participants by NHS England region.

The data was collected between the 27th October 2022 and the 20th January 2023. In total thirty-three NHS England Trusts participated. The study was collected by Qualtrics to ensure anonymity. This equates to 24% (or 33) of eligible NHS Trusts that have operating theatres, as part of routine or emergency patient services. The study took a representative sample. It was an opportunity sample of staff which was determined by the participants volunteering from across NHS England. However, we propose that it is possible to generalise the results for the entire research population – i.e., NHS England. There was a range of hierarchical agenda-for-change bands, age and professional qualification held such as RGN or ODP.

3. Results

3.1. WHO surgical checklist and the steps involved

For any system or process to work, training should occur. However, surprisingly 56% of responses stated that training on how to deliver the checklist was not offered by their organisation, nevertheless, 78% of respondents stated that the guidance from the WHO was clear, and that 78% of participants agreed that all the current five steps are as important as each other. The literature supports the development and alteration of checklists to suit the speciality. Helmio (2012) [34] found that if the WHO checklist is modified, it may influence its efficiency, but if the WHO checklist is too long or difficult, it may have a negative effect or no effect at all. Raman et al. [7] argued that checklists need to be tailored to the specific task being performed: 60% of respondent stated that their Trust has both generic and speciality checklists, and 25% started that only a generic SSC is available. Interestingly, 93% of participants felt that NHS England should provide the WHO SSC electronically to all NHS England Trusts.

The study found that time was not considered a barrier for the

Table 3
Research participants by NHS England region.

Area	Number of Trusts	Actual participants who responded
North East & Yorkshire	21	5
North West	22	8
Midlands	21	4
South West	15	3
South East	20	6
London	22	4
East	15	3

delivery of the checklist amongst the majority of participants, as 83% of respondents felt that there was enough time to undertake the SSC. Previous literature supports this finding as Taylor, Slater and Reznick [35] dispelled the myth of the WHO checklist being ‘time consuming’ by reporting that it took only about two minutes on average. Interestingly, only 29% of Trusts had checklist champions, with the Operating Department Practitioner (ODP) mainly undertaking this role. Treadwell, Lucas and Tsou [36] also concluded that enlisting leaders as local champions is a positive strategy for successful implementation.

To ensure that cyclical learning and continual education occurs, auditing and feedback are critical to examine efficiency and outcomes. 98% of respondents stated that the SSC was audited, and that this occurred monthly at 67% of organisations. Hall [37] proposes that audit may highlight unexpected changes that further identify risk. Feedback was also considered important: 71% of respondents stated that they always feedback if a never event occurs, but only 33% of respondents stated they were aware of how their organisation was doing compared to others in their region. Regarding whether all five/six steps are completed, Table 4 shows which steps are most commonly missed in the view of the expert panel. There could be many reasons or perceived barriers as to why the Surgical Safety Checklist is not always completed. For example, Mahajan [38] found that leadership was required for successful implementation of the Surgical Safety Checklist. Zuckerman et al. [39] also found that a shared vision of active communication was also required. The study found that even though there was steps missed, 89% of respondents indicated that they would speak out if there was a patient safety concern. One final point on this section was that 98% of respondents felt that the NHS needed to revise how the delivery of the SSC was undertaken.

Treadwell et al. [36] found that barriers included surgeon resistance to changing habits, awkwardness of self-introductions and steep interpersonal hierarchy. Ultimately, Gillespie et al. [2] Australian study stated that the most significant barriers to using the SSC were: workflow, limited knowledge about timing, content of checks, a lack of clinical leadership and dissonant attitudes. The research study highlighted this, as the feedback was spread across several headings, but the top three barriers were: Staff attitude 27%; Culture 21% and; Communication 18%.

3.2. NatSSIPs

NatSSIPs was originally launched on the 7th September 2015. The intention was that the mandatory introduction of the WHO Surgical Safety Checklist and the refinement of the three surgical ‘Never Events’; wrong site surgery; wrong implant or prosthesis and retained foreign object post procedure, would lead to a significant reduction in the incidence of ‘Never Events’ in the NHS in England. Despite these initiatives, the data would suggest that this has not been the case, and a marked decrease in ‘Never Events’ has not materialised. In 2018 a survey conducted by NHS Improvement found that the existence and implementation of LocSSIPs was inconsistent and challenging with the main barriers being a lack of time; staff not having protected time to do the work; a lack of multidisciplinary training; not seen as a priority; and lack of internal expertise as well as an understanding of which areas qualify at a trust level. NatSSIPs 2 was launched on the 23rd January

Table 4
Which SSC step is most likely to be missed?.

Possible category	Response rate as a percentage
Team Brief	7%
Sign-In	5%
Prep, Stop, Block	16%
Time-Out/STOP moment	5%
Sign-Out	5%
De-Brief	62%

2023, however, only 44% of respondents either strongly agree or agreed that NatSSIPs have helped. As part of this research, an audit was undertaken by the lead author in November 2021, as part of the literature review, asking if NHS England trusts had implemented NatSSIPs into their operating theatres. A response rate of 58% was achieved. Nonetheless, six trusts had yet to implement NatSSIPs. This was followed up again on the 17th November 2022, when five out of the six Trusts responded, however NatSSIPs still had not been implemented. The number of intra-operative ‘Never Events’ reported at those Trusts totalled sixty between April 2015 and March 2022 (Final and Provisional data) See [table 5](#). 89% of respondents felt that NHS trusts should be held accountable for not introducing NatSSIPs and 82% stated that NatSSIPs training should occur annually.

There was a total of six trusts still to implement NatSSIPs in the operating theatres. They was from the following regions; East (x2), Midlands, Northeast & Yorkshire (x2), and the Southwest. There were too few trusts in this category to allow meaningful comparisons between trusts that have implemented NatSSIPs and those which have not due to a lack of statistical power.

3.3. Staffing and leadership

Staff shortages across the NHS reported by Deakin [40] stand at 110,000, excluding primary care. NHS Funding [41] reported a similar number of 132,1139 vacancies as of the 30th June 2022. The Care Quality Commission reported similar numbers in October 2022, but added that vacancy rate was 9.7%. London has the reported highest vacancy rate with the North-East and Yorkshire consistently having the lowest. The regulator, CQC [42] stated that health and care leaders need to recruit the equivalent of the population of Newcastle, that is 297,000. [Table 6](#) below highlights the number of FTE vacancies in the NHS across the seven regions between January and March 2022.

The UK National press [43] had picked up on a whistleblower expressing concerns around staffing at a large teaching hospital in Sheffield stating that ‘operations are routinely being done with too few nurses and that staff often have too little experience. Most days theatres run on three staff and in some cases two if a staff member takes a break’. This question is wanting to understand from the theatre safety experts, if they are experiencing staff shortages in theatres, that may directly impact on patient safety.

However, the response from the research study detailed in [table 7](#) and are not conclusive to suggest that staff shortages in the operating theatre are impacting on patient safety.

3.4. Training and never events

Sixty-eight percent of respondents stated that time and investment in training on non-technical skills and Human Factors must occur and that

Table 5
Number of Never Events at NHS Trusts yet to implement NatSSIPs [8–15].

Year(Final and Provisional Data)	Wrong site surgery	Wrong Implant/ Prosthesis	Retained foreign object post procedure
April 2015 – March 2016	4	2	4
April 2016 – March 2017	3	0	4
April 2017 – March 2018	2	1	1
April 2018 – March 2019	7	2	2
April 2019 – March 2020	6	1	2
April 2020 – March 2021	4	3	4
April 2021 – March 2022	4	0	4

Table 6
NHS Vacancies by region (Nuffield Trust, 2022).

Region	Percentage of vacancies
London	11%
East	8.25%
Midlands	8.25%
South East	8.25%
North West	6.25%
South West	6.25%
North East & Yorkshire	6%

Table 7
Are staff shortages hampering patient safety.

Possible answer	Response Rate as a percentage
Strongly agree	18%
Agree	18%
Somewhat agree	15%
Neither agree nor disagree	11%
Somewhat disagree	15%
Disagree	16%
Strongly disagree	7%

senior NHS leaders in the organisation should engage with theatres to understand the challenges faced. Degani and Wiener [44] found that the Surgical Safety Checklist is unlikely to be implemented or maintained without the backing of senior leadership within each organisation. Leadership for the successful implementation of the SSC is key, as Conley, Singer and Edmondson’s [45], study of five hospitals reported that engagement of leadership was seen as a key factor in the success of the SSC adoption. Having leaders actively promote the SSC was deemed to be successful, therefore, hospital leaders need to work on all staff’s perception and resistance to change, by educating staff that the hospitals priority, are one of patient safety. Conley, Singer and Edmondson [45], and Smith et al. [46] commented that importantly, communication between hospital leadership and front-line practitioners must be open, honest, and constructive to obtain the ‘buy-in’ necessary for the successful initiative of the checklist. In regard to multidisciplinary team working, 91% of respondents asked for collective training on the Surgical Safety Checklist, Human Factors and simulation sessions and that training should be annual and mandated.

Eighty percent of respondents either strongly agreed or agreed that non-airway surgical fires should be classed as a ‘Never Event’, thus changing the reportable intraoperative ‘Never Events’ category from three to four (note that surgical airway fires caused by a combination of oxygen and the use of a laser don’t meet the definition of a ‘Never Event’, but other types of fires are wholly preventable). There is no national guidance or safety recommendations to prevent fires in the operating theatres, these types of incidents therefore cannot be defined as a ‘Never Event’. Stormont, Anand and Deibert [47] stated that ‘very few fires are unpreventable, and all surgical fires should be considered a Never Event’. Fisher [48] American study stated that the number of surgical fires ranges from 550 – 600 annually which is about as common as incorrect surgical site procedures. Choudhry et al. [49], claimed that of 114 cases identified involving surgical fires, 60% resulted in a median award of \$215,000, (£188,969). In contrast, the National Reporting and Learning System (NRLS) database in England and Wales identified thirty-seven reported surgical fires between January 2012 and December 2018 [50], pp. 18). NHS Resolution [51] reported legal costs and damages of £13.9million from 459 cases relating to clinical negligence caused by surgical burn.

Theatres are a fast paced environment and have great potential of causing inadvertent patient harm. Non-technical skills such as culture, communication, attitudes, team working, leadership and situational awareness are skills that each member of the theatre team uses daily and are vital to mitigating human error. Gordon et al. [52] stated that further

consideration of non-technical skills in education is required. Indeed, Prineas et al. [53] described non-technical skills as a set of generic cognitive and social skills, exhibited by individuals and teams, that play an important role in supporting technical skills when performing complex tasks. According to Prineas, Mosier and Guicciardi [53] non-technical skills are fast becoming an established and indispensable building block of patient safety. Finally, Lock and Novoa (2021) concluded that incidents in healthcare were often due to system complexity and failures in non-technical skills. Casali, Lock and Novoa [54] argued that to start the change, non-technical skills must be recognised as a mandatory. Table 8 highlights respondents view about the teaching of non-technical skills during mandatory training. As can be seen, 95% of respondents replied in agreement that theatre staff should receive non-technical skills training.

In regard to how non-technical skills training should be delivered, 77% of staff stated that training should be a combination of online, practical and simulation. Training in any format, whether via a presentation, e-learning, poster, simulation sessions or video for the introduction of a new tool or technique is important for its success as well as ensuring staff have the correct skills and knowledge, to safely and effectively perform the role. The focus must be on how training and education interventions can actively improve patient safety [55]. The tools at our disposal must be used effectively as to build a long-term, sustainable learning environment. (Health Education England [55], pp. 3) commissioned a report on patient safety and found that “Getting it right involves instilling the right culture from the start of a career in healthcare. Education and training from undergraduate and apprentice level throughout one’s career can not only embed the right approach to preventing and learning from errors but also keeps the mind receptive to new ideas that could improve safety”. (Health Education England [55], pp.40) stated that “Human Factors in healthcare is about enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings”. HEE [55] further expanded and suggested that to build the under-pinning knowledge of patient safety, staff well-being must be recognised as an essential component of clinical human factors, particularly when it comes to the delivery of training.

Eighty-two percent of respondents supported the use of the terminology ‘never event’. This was introduced by Kizer (2001) in reference to shocking medical errors that should never occur. [56]. According to Devlin [57] the Medical Defence Union (MDU) regards the term ‘Never Event’ as a misnomer because we are no closer to eradicating these errors. Devlin [57] further suggests that the word ‘Never’ reinforces the unhelpful concepts of blame and liability and is a distraction. In contrast, Tingle [58] argues that the term should not change or be diluted and argues that when a ‘Never Event’ occurs, it cannot be excused.

4. Discussion

The literature to support understanding the impact of checklist implementation is still emerging. The use of the Delphi method was born out of curiosity to see to what the theatre safety experts (matrons, managers and clinical educators) thought of the current checklist across

Table 8
Should non-technical skills be a part of mandatory training?.

Possible answer	Response rate as a percentage
Strongly agree	57.14%
Agree	28.57%
Somewhat agree	9.52%
Neither agree nor disagree	4.76%
Somewhat disagree	0%
Disagree	0%
Strongly disagree	0%

England since its introduction thirteen years ago and LocSSIPs that was first introduced in 2015.

It was found that, of the Trusts that responded, the absence of formal training and a small number of champions may actually result in poor adherence to the checklist. It can be anticipated that invasive procedures in healthcare globally will continue to rise as new technology and techniques become available. Furthermore, as access to treatments increases for patients with complex and demanding rehabilitation needs the challenges will persist. While clinical outcomes, quality of life and, indeed, life expectancy can be improved and extended, this is only the case if surgery takes place within optimum conditions. The number of ‘Never Events’ continues to remain a persistent patient safety concern. It was also found that the debrief is time critical and therefore results in poor adherence to the checklist. Nevertheless, it was perhaps surprising to discover that time constraints, and the apparent lack of clinical engagement from surgeons are still an issue over a decade after the initial launch. In addition, mandatory annual training on how to deliver the checklist must occur.

In acknowledging that the participant rate was 24%, we cannot claim to know how other Trusts are utilising the SSC. Given the timing and context in which the Delphi study was carried out, it is appreciated that other priorities could have impacted on the ability and willingness to participate. Nevertheless, it was surprising to discover that a lack of leadership and of multidisciplinary team engagement remains an issue, over a decade after the launch. NatSSIPs (2) was re-launched on the 23rd January 2023. Should healthcare providers be held to account for their implementation?

A new patient safety flowchart designed and development based on this research (Fig. 1). The Centre for Peri Operative Care (CPOC) and Patient Safety Learning (PSL) have supported the infographic design and it is being made available to all NHS Trusts in the United Kingdom.

5. Conclusion

To conclude, further work is needed to ensure that the Surgical Safety Checklist is fully accepted and used in operating theatres. It is not possible to determine from the Delphi study round whether the lack of compliance leads to greater risk of ‘Never Events’ occurring. While statistical analysis is important, the study indicates that a greater qualitative understanding is needed of the factors that impact upon the persistence of ‘Never Events’. Given the paucity of the current literature, examples from ‘Never Events’ and the stubbornness of the data to improve should act as a catalyst for further investigation. The intention is not to single out Trusts for criticism based on non-compliance and without greater appreciation of context but instead to encourage all global healthcare providers to adopt standardised safe surgery check lists. Murphy [59] has pointed to poor communication and lack of leadership as being common factors in the causation of procedural mishaps and safe surgery checklists and flowcharts can serve as prompts to improved communication. Rather than criticism, the focus needs to shift from simply understanding adverse events, to the introduction of measures that will prevent them. This will also ensure that the clinical approach to safety is the same, irrespective of the location, time, and resources available.

Similarly, Radcliffe [60] affirms that such standards aim to minimise risks of variation in practice, moreover safety standards are aimed at embedding best practice by maximising consistency, and ensuring harmonisation across organisations. Wali, Halai and Koshal’s [61] paper concludes that high quality training is integral to ensuring that checklists are not mistaken for or treated as a tick-box exercise. Atul Gawande’s [62] checklist manifesto describes how the Surgical Safety Checklist provides reminders of only the most critical and important steps; the ones that even the highly skilled professionals using them could miss.

There is a realisation, that these standards alone cannot prevent ‘Never Events’ from occurring. However, when combined with staff

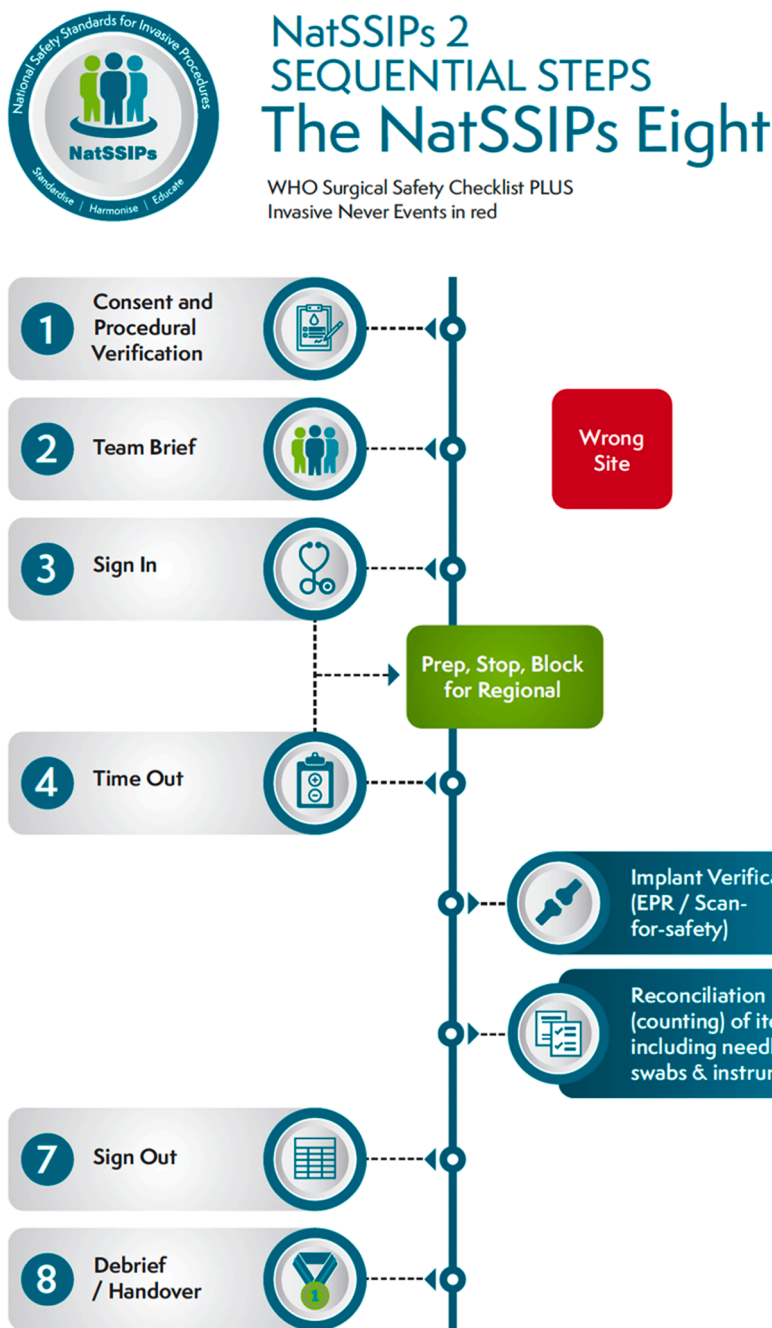


Fig. 1. Patient safety flowchart.

education, the promotion of teamwork, and human factors training, these measures go some way to ensure that the triad designed to standardise, educate and harmonise is complete. Further fine grained qualitative and quantitative investigation is required to explore the issues highlighted regarding the safe and effective delivery of the surgical checklist. These include effectiveness of the theatre checklist itself, Local Safety Standards for Invasive procedures (LocSSIPs) and Human Factors that may impact on performance. Ideally this would include collaborative and interdisciplinary approaches.

The application of LocSSIPs 2 must ensure that the clinical approach to safety remains the same, irrespective of the location, time, and resources available and that healthcare providers are held to account. Radcliffe [60] affirms that such standards aim to minimise risks of variation in practice. Moreover, safety standards are aimed at embedding best practice by minimising the risk of variation, maximising

consistency, and, therefore, ensuring harmonisation across organisations. Teamworking and team learning are essential to achieving this effective implementation. In accordance with Radcliffe [60], we argue that these standards alone cannot prevent ‘Never Events’ from occurring but, when combined with the staff education, the promotion of teamwork, and human factors training, these measures must go some way to ensure that the triad designed to standardise, educate and harmonise is complete.

CRedit authorship contribution statement

Nigel Roberts: Conceptualization, Methodology, Investigation, Writing – original draft. **Stephen Wordsworth:** Supervision, Writing – review & editing. **Edward Stuppel:** Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

- Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat A-HS, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360(5):491–499. <https://doi.org/10.1056/NEJMsa0810119>.
- Gillespie BM, Harbeck EL, Lavin J, et al. Evaluation of a patient safety programme on Surgical Safety Checklist Compliance: a prospective longitudinal study. *BMJ Open Qual*. 2018;7(3), e000362. <https://doi.org/10.1136/bmjopen-2018-000362>.
- Viswanth A, Balint A, Johnson RE, Rosenberg MB, Oreadi D. 'Surgical safety checklists are under utilised in ambulatory oral and maxillofacial surgery. *J Oral Maxillofac Surg*. 2017;07:154. <https://doi.org/10.1016/j.joms.2017.07.154>. Epub 2017 Jul 21.
- Shah J, Fitz-Henry J, Vickers R. Peri-operative care series'. *RCS Advancing surgical standards. Ann R Coll Surg Engl*. 2011;93:501–503. <https://doi.org/10.1308/147870811X565070>.
- McConnell DJ, Fargen KM, Mocco J. 'Surgical checklists: a detailed review of their emergence, development, and relevance to neurosurgical practice. *Surg Neurol Int*. 2012;3:2. <https://doi.org/10.4103/2152-7806.92163>.
- Harden SW. Six things every plastic surgeon needs to know about teamwork training and checklists. *Aesthet Surg J*. 2013;33:443–448. <https://doi.org/10.1177/1090820X13477417>.
- Raman J, Leveson N, Samost AL, et al. When a checklist is not enough: how to improve them and what else is needed. *J Thorac Cardiovasc Surg*. 2016;152(2): 585–592. <https://doi.org/10.1016/j.jtcvs.2016.01.022>.
- NHS (2020) *Never events reported as occurring between 1 April 2019 and 31 March 2020 – Final update*. <https://www.england.nhs.uk/wp-content/uploads/2021/01/Final-update-NE-1-April-2019-31-March-2020.pdf> [Accessed 26th August 2021].
- NHS England (2019) *Provisional publication of Never Events reported as occurring between 1 April 2018 and 31 March 2019*. https://www.england.nhs.uk/wpcontent/uploads/2020/08/Provisional-publication_-_NE_1-April_2018_to_31_March_2019.pdf. [Accessed 11th February 2023].
- NHS ENGLAND (2019-20) *Supporting facilities data, operating theatres in NHS organisations in England, quarter 3 2019-20*. <https://www.england.nhs.uk/statistics/statistical-work%20areas/cancelled-elective-operations/supporting-facilities-data/>. [Accessed 30th January 2023].
- NHS England (2021) (1 APRIL 2020 –28 FEBRUARY 2021) *Provisional publication of never event data reported as occurring 01 April 2020 –28 February 2021*. <https://www.england.nhs.uk/wp-content/uploads/2021/04/Provisional-publication-NE-1-April-28-February-2021.pdf>. [Accessed 28th March 2023].
- NHS England (2021/22) *Provisional 2021/22 data: 1st April 2021 –31st March 2022*. <https://www.england.nhs.uk/wp-content/uploads/2022/05/Provisional-publication-NE-1-April-31-March-2022.pdf>. [Accessed 28th March 2023].
- NHS ENGLAND (2022) *Provisional publication of Never Events reports as occurring between 1 April 2021 and 31 March 2022*. <https://www.england.nhs.uk/wp-content/uploads/2022/05/Provisional-publication-NE-1-April-31-March-2022.pdf>. [Accessed 20th May 2022].
- NHS England and Improvement (2019) *Never events reported as occurring between 1 April 2017 and 31 March 2018 – Final update*. https://www.england.nhs.uk/wpcontent/uploads/2020/08/Annual_NE_report_1_April_2017_to_31_March_2018_FINAL_V5.pdf. [Accessed 28th March 2023].
- NHS Improvement (2018) *Never events reported as occurring between 1 April 2016 and 31 March 2017 – Final update*. https://www.england.nhs.uk/wpcontent/uploads/2020/08/Never_Events_1_April_2016_-_31_March_2017_FINAL_v2.pdf. [Accessed 28th March 2023].
- World Health Organisation. *Implementation Manual WHO Surgical Safety checklist: Safe Surgery Saves Lives*. Geneva: WHO; 2008.
- Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and type of adverse events and negligent care in Utah and Colorado. *Med Care*. 2000;38(3):261–271. <https://doi.org/10.1097/00005650-200003000-00003>.
- Helmreich RL. *Human Factors Aspects of the Air Ontario crash At Dryden*. Toronto, ON: Minister of supply and services; 2000.
- Jones J, Hunter D. Consensus methods for medical and health services research. *BMJ*. 1995;311:376–380. <https://doi.org/10.1136/bmj.311.7001.376>.
- Barrett D, Heale R. What are Delphi studies? *Evid Based Nurs*. 2020;23:68–69. <https://ebn.bmj.com/content/23/3/68> [Accessed 28th February 2023].
- C. Hsu C, Sandford B. The Delphi Technique: making sense of Consensus *Pract Assess, Res Eval*. 2007;12(10):1–7. <https://doi.org/10.7275/pdz9-th90>. <https://scholarworks.unmass.edu/pare/vol12/iss1/10> [Accessed 18th February 2023]
- DICK, B. (2000) *Delphi face to face. Resource papers in action*. <http://www.aral.com.au/resources/delphi.html>. [Accessed 10th February 2023].
- Niederberger M, Spranger J. Delphi Technique in Health Sciences: a Map. *Front Public Health*. 2020;8(457):1–10. <https://doi.org/10.3389/fpubh.2020.00457>. Available at: <https://www.frontiersin.org/articles/10.3389/fpubh.2020.00457/full> [Accessed 7th March 2023].
- Rowe G, Wright G. The Delphi technique as a forecasting tool: issues and analysis. *Int J Forecast*. 1999;15(4):353–375. [https://doi.org/10.1016/S0169-2070\(99\)00018-7](https://doi.org/10.1016/S0169-2070(99)00018-7).
- Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs*. 2000;32(4):1008–1015. Available at: <https://osf.io/rkmbq/download> [Accessed 7th March 2023]. PMID: 11095242.
- Jorm A. Using the Delphi expert consensus method in mental health research. *Aust New Zeal J Psychiatry*. 2015;49(10):887–897. <https://doi.org/10.1177/0004867415600891>.
- Vogal C, Zwolinsky S, Griffiths C, Hobbs M, Henderson E, Wilins E. A Delphi study to build consensus on the definition and use of big data in obesity research. *Int J Obes*. 2019;43:2573–2586. <https://doi.org/10.1038/s41366-018-0313-9>. Available at: [Accessed 7th March 2023].
- Negrini S, Armijo-Olivo S, Patrini M, et al. Methodology of Development of a Reporting Guideline Specific to Rehabilitation. *Am J Phys Med Rehabil*. 2020;99(3): 210–215. <https://doi.org/10.1097/PHM.0000000000001370>.
- Junger S, Payne S, Brearley S, Ploenes V, Radbruch L. Consensus Building in Palliative Care: a Europe-Wide Delphi Study on Common Understanding and Conceptual Differences. *J Pain Symptom Manage*. 2012;44(2):192–205. <https://doi.org/10.1016/j.jpainsymman.2011.09.009>.
- Han H, Dong-Hyun A, Jinhee S, Tae-Yeon H, Sungwon R. Development of Mental Health Indicators in Korea. *Psychiatry Investig*. 2012;9(4):311–318. <https://doi.org/10.4306/pi.2012.9.4.311>.
- Van Hasselt FM, Oud MJT, Loonen AJM. Practical recommendations for improvement of the physical health care of patients with severe mental illness. *Acta Psychiatr Scand*. 2014;131(5):387–396. <https://doi.org/10.1111/acps.12372>. Epub 2014 Dec 11.
- Kingsfund.Org.UK (2021) *Key facts and figures about the NHS*. <https://www.kingsfund.org.uk/audio-video/key-facts-figures-nhs>. [Accessed 30th March 2023].
- NHS England (2020/21) *Provisional 2020/21 data: 1st April 2020 –31st March 2021*. <https://www.england.nhs.uk/wp-content/uploads/2021/05/Provisional-publication-NE-1-April-2020-31-March-2021.pdf>. [Accessed 28th March 2023].
- Helmiö P, Takala A, Aaltonen LM, Blomgren K. WHO Surgical Safety Checklist in otorhinolaryngology-head and neck surgery: specialty-related aspects of check items. *Acta Otolaryngol*. 2012;132(12):1334–1341. <https://doi.org/10.3109/00016489.2012.700121>.
- Taylor B, Slater A, Reznick R. The surgical safety checklist effects are sustained, and team culture is strengthened. *Surgeon*. 2010;8(1):1–4. <https://doi.org/10.1016/j.surge.2009.11.012>.
- Treadwell JR, Lucas S, Tsou A. Surgical checklists: a systematic review of impacts and implementation. *BMJ Qual Saf*. 2014;23(4):299–318. <https://doi.org/10.1136/bmjqs-2012-001797>.
- Hall BH. *The Why and How of Auditing. Auditing made Easy*. Great Britain: Amazon; 2019. ISBN-13:978-0-578-51973-9.
- Mahajan RP. The WHO surgical checklist. *Best Pract Res: Clin Anaesthesiol*. 2011;25(2):161–168. <https://doi.org/10.1016/j.bpa.2011.02.002>.
- Zuckerman SL, Green CS, Carr KR, Dewan MC, Morone PJ, Mocco J. Neurosurgical checklists: a review. *Neurosurg Focus*. 2012;33(5):E2. <https://doi.org/10.3171/2012.9.FOCUS12257>.
- Deakin M. (2022) *NHS Workforce shortages and staff burnout are taking a toll*. <https://www.bmj.com/content/377/bmj.o945>. DOI: <https://doi.org/10.1136/bmj.o945>. [Accessed 5th January 2023].
- NHS FUNDING (2022). *Fund our NHS*. <https://nhsfunding.info/symptoms/10-effects-of-underfunding/staff-shortages-2/>. [Accessed 5th November 2022].
- Care Quality Commission. (2022) *Care sector must recruit equivalent of population of Newcastle as CQC warn of service gridlock*. <https://careappointments.com/care-news/england/187176/care-sector-must-recruit-equivalent-of-population-of-newcastle-as-cqc-warn-of-service-gridlock/>. [Accessed 5th November 2022].
- The Star (2022) *Staff shortages in theatres at Sheffield's Northern General Hospital 'putting lives at risk'*. <https://www.thestar.co.uk/health/staff-shortages-theatres-sheffields-northern-general-hospital-putting-lives-risk-1366003>. [Accessed 5th March 2023].
- Degani A, Wiener E. Cockpit Checklists: concepts, Design and Use. *Hum Factors*. 1993;35(2):345–359. <https://doi.org/10.1177/001872089303500209>.
- M.J.R. Conley D, Singer S, Edmondson L, Berry W, Gawande A. Effective Surgical Safety Checklist Implementation *J Am Coll Surg*. 2011;212(5):873–879. <https://doi.org/10.1016/j.jamcollsurg.2011.01.052>
- Smith EA, Akusoba I, Sabol DM, Stawicki SP, Granson MA, Ellison EC. Surgical safety checklist: productive, nondisruptive, and the "right thing to do. *J Postgrad Med*. 2015;61(3):214–215. <https://doi.org/10.4103/0022-3859.159434>.
- Stormont GM, Anand S, Deibert CM. *Surgical Fire Safety. National Library of Medicine*. StatPearls Publishing LLC; 2022. <https://www.ncbi.nlm.nih.gov/books/NBK544303/> [Accessed 6th March 2023].
- Fisher M. Prevention of Surgical Fires: a Certification Course for Healthcare Providers. *AANA J*. 2015;83(4):271–274. PMID: 26390745.
- J.N.A.C. Choudhry A, Haddad N, Khasawneh M, Cullinane D, Zielinski M. Surgical Fires and Operative Burns: Lessons Learned From a 33-Year Review of Medical Litigation *Am J Surg*. 2017;213(3):558–564. <https://doi.org/10.1016/j.amjsurg.2016.12.006>

- [50] Keeley L. Surgical fires must become 'Never Event'. *Clin Services J*; 2020:18–20. <https://www.clinicalservicesjournal.com/story/33506/surgical-fires-must-become-never-event> [Accessed 24th March 2023].
- [51] NHS Resolution (2019) 'Did you Know? Preventing Surgical Burns'. https://resolution.nhs.uk/wp-content/uploads/2019/10/Did-You-Know_Surgical-burns-Digital-Accessible-1.pdf. [Accessed 1st April 2023].
- [52] Gordon M, Fell CWR, Box H, Farrell M, Stewart A. Learning health 'safety' within non-technical skills interprofessional simulation education: a qualitative study. *Med Educ Online*. 2017;22(1):1–9. <https://doi.org/10.1080/10872981.2017.127838>. <https://www.tandfonline.com/doi/full/10.1080/10872981.2017.127838> [Accessed 26th November 2022].
- [53] Prineas S, Mosier K, Guicciardi S. Non-Technical Skills in Healthcare. In: Donaldson I, Ricciardi W, Sheridan S, Tartaglia R, eds. *Textbook of Patient Safety and Clinical Risk Management*. Cham: Springer; 2021. ISBN:978-3-030-59402-2 https://link.springer.com/chapter/10.1007/978-3-030-59403-9_30#citeas [Accessed 26th November 2022].
- [54] Casali G, Lock G, Novoa NM. Teaching non-technical skill: the patient centered approach. *J Thorac Dis*. 2021;13(3):2044–2053. <https://doi.org/10.21037/jtd.2019.01.48>. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8024801/> [Accessed 26th November 2022].
- [55] Health Education England (2016). Improving Safety through Education and training. Report by the commission on education and training for patient safety. <https://www.hee.nhs.uk/sites/default/files/documents/Improving%20safety%20through%20education%20and%20training.pdf>. [Accessed 1st April 2023].
- [56] Lembitz A, Clarke TJ. Clarifying 'never events' and introducing 'always events'. *Patient Saf Surg*. 2009;3:26. <https://doi.org/10.1186/1754-9493-3-26>.
- [57] Delvin M. No more "Never Events". *BMJ Opinion*; 2021. <https://blogs.bmj.com/bmj/2021/03/26/michael-devlin-no-more-never-events/> [Accessed 20th February 2023].
- [58] Tingle J. Ways of tackling the continuing problem of Never Events. *Br J Nurs*. 2022; 31(12). <https://www.britishjournalofnursing.com/content/patient-safety/ways-of-tackling-the-continuing-problem-of-never-events/> [Accessed 20th November 2022].
- [59] Murphy JFA. Safety standards for invasive procedures. *Ir Med J*. 2016;109(3): 366–367. PMID: 27685814.
- [60] Radcliffe T. 'Say never to never events. *Nurs Stand*. 2016;30(19):64–65. <https://doi.org/10.7748/ns.30.19.64.s47>.
- [61] Wali R, Halai T, Koshal S. WHO surgical safety checklist training: an alternative approach to training in local safety standards for invasive procedures. *Eur J Dent Educ*. 2020;24(1):71–78. <https://doi.org/10.1111/eje.12469>.
- [62] Gawande A. *The Checklist Manifesto: How to Get Things Right*. Metropolitan Books; 2012. ISBN10: 0805091742.