The risk of surgical never events

Risk means different things to different people. Many definitions exist but most have in common some concept of potential harm. No-one is in any doubt that surgery carries risks, and great strides have been made in reducing these. Until relatively recently the focus of risk reduction was through improvements in surgical techniques, safer anaesthesia, improved nursing and rehabilitation. As the surgical episode itself has become more predictable and less risky, the focus has rightly turned to the safety and reliability of the processes of care. Never events are one marker of reliability but stubbornly refuse to live up to their name – so what are the risks?

Safety in health care

There are many facets to safety in health care (Vincent, 2012). Although in general we are interested in whether care will be safe in the future, the only information we have relates to the present and the past. There has historically been a focus on past failures in the process of care, which may or may not have caused harm, identifying weaknesses in current processes to prevent future harm. More recently there has been renewed focus on learning from what goes well and the resilience of teams and organizations – so-called 'Safety II' (Hollnagel, 2013).

Professor Iain K Moppett is Macintosh Professor in the Department of Anaesthesia and Critical Care, Division of Clinical Neuroscience, University of Nottingham and Honorary Consultant Anaesthetist in the Department of Anaesthesia, Queen's Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham NG7 2UH

Mrs Sarah H Moppett is Divisional Nurse in Clinical Support, Queen's Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham

Correspondence to: Professor IK Moppett (lain.moppett@nottingham.ac.uk)

Never events are a special category of incident, defined as serious incidents that:

> **'are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.' (NHS England, 2015a).**

Within surgery there are three such never events: operating on the wrong body part (wrong site surgery), leaving something in the surgical site unintentionally (retained foreign object), and putting the wrong thing in (incorrect implant). Despite the name, never events keep occurring. So what are the risks of surgical never events?

Risks to the patient

In purely quantitative terms, the risks to the patient are relatively small. Surgical never events are infrequent – occurring around once every 17 000 operations in England (Moppett and Moppett, 2016), with similar rates in the USA (Neily et al, 2011). The risk of serious harm is even less frequent – around 1 in 250 000 operations (Moppett and Moppett, 2016) – although sadly this has included at least one death in recent years. Although the list of surgical never events is a cartoonist's heaven – objects left inside, operations on the wrong part of the body, wrong implants inserted – the reality is often rather less dramatic: small portions of gloves left behind or lenses inserted that were not as intended but have no impact on the patient. For an individual patient a never event, and particularly one that causes serious harm, is undoubtedly significant but non-never event harm is a much greater risk.

However, these figures almost certainly underestimate the harm that occurs. However slight the physical harm, some patients inevitably suffer psychological distress. What if they left something else behind? There may certainly be loss of confidence in health care – what about my relative having an operation?

Risks to health-care workers

What of the risk to the health-care workers involved? To the authors' knowledge there have been no systematic studies of the impact of never events on health-care workers, but there is good evidence that there are 'second victims' when serious incidents occur. Seys et al (2013) estimated that second victims had a prevalence of 10–14% following adverse events. The NHS and other health-care organizations have not had a good track record when dealing with the aftermath of incidents for staff. Perceptions of punitive actions by hospitals, regulators and commissioners, threats of litigation and the simple fact that health-care workers do not set out to cause harm all conspire to increase adverse outcomes for staff.

Risks to the organization

Finally, what are the risks to the organization? There are financial consequences with direct financial penalties – commissioners or insurers refusing to pay for some or all of the costs of care. Indirectly, investigating never events appropriately takes a significant amount of resource. At the least, a competent investigation is going to take many hours of work by a senior (expensive) investigating panel along with interviews with involved staff, presentation to risk committees and discussion by hospital boards.

Certainly there are reputational risks. Media, regulators and politicians seem very willing to paint organizations as unsafe when never events occur. Interestingly, the authors could not find any evidence to support this link between never events and organizational safety. The only factor that seems to influence how many never events occur in an organization are its size and the period of time examined. None of the metrics of safety the authors assessed were associated with the risk of never events (Moppett and Moppett, 2016). Undoubtedly, care processes have failed when a never event occurs, but it is rarely (if ever) a single person or single part of the process that has failed. Many parts must

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fail, yet the terminology persists: to quote the NHS Never Event Framework (authors' emphasis):

> **'the NHS should not pay for *care that is so substandard* as to result in a never event.'**

Never events behave as rare random events – currently, it is a matter of when the system will fail, not if. To label such care as 'so substandard' surely misses the point about how and why these occur.

There is an opportunity cost too. The harm caused by never events is relatively low compared with other harms that occur. An excessive focus on a relatively narrow set of incidents risks diverting resources from more important issues. At a deeper level, there is a risk that investigation of never events, or other incidents, keeps too much focus on what went wrong. Despite what some commentators would have us believe, the vast majority of health care produces good outcomes, even with the inevitable errors and mistakes that happen. There is much to be learnt from when health care goes right (Hollnagel, 2013) – what are the factors that make it resilient, that allow us to catch errors before they cause harm?

Positive benefits of never events

Turning back to the concept of risk, wider definitions do not assume that the outcomes of risk are all harmful, just that external forces may result in unanticipated outcomes. So is there any good to come out of this focus on never events? The authors would submit that there are several benefits.

First, the reporting strictures mean that hospitals should feel less exposed when a never event does occur. To report a never event does not mark a hospital out. The authors estimated that the probability of a median-sized trust (~ 24 000 operations/year) having no surgical never events over a 3-year period is around 2%. To have not reported a never event over 2 or 3 years should be the marker of concern.

Second, the investigation process for never events is heavily protocolized and forces hospitals to look further than the individual at the sharp end wielding the knife or performing the swab count. This in turn should help organizations learn about the systems factors that make errors likely to occur. Never events almost universally occur as a result of unusual failures in several parts of the system that, effectively at random, all occur in succession.

Third, although never events receive far more attention than they probably merit, this political focus has led to national initiatives that are likely to have beneficial consequences far beyond never events. The introduction of the World Health Organization Safer Surgery Checklist was partly driven by a desire to reduce never events. The evidence so far is that it reduces harm associated with surgery as a result of effects on non-never event harm (Haugen et al, 2014). More recently, in the NHS one outcome of the Never Events Taskforce was a set of national standards for invasive procedures (NHS England, 2015b). Superficially these look like a set of standard operating procedures to prevent never events, but there is a strong focus on team training, communication and appropriate resources that are likely to have much more impact on non-never event harm.

Finally, if a surgical never event occurs around one in every 17 000 operations, that means that in 16 999 operations the processes, staff and teams worked successfully to make it not happen. No complex process ever runs smoothly, and the resilience of the whole system is a key factor in keeping things safe and efficient. These are golden opportunities for individuals and organizations to learn from when never events do not occur.

Never say never

Never events will always happen – that is the nature of a complex system – and to pretend otherwise is foolhardy. Although they are relatively uncommon they undoubtedly carry adverse risks to patients, staff and health-care organizations. Conversely, health-care professionals and organizations can use them as catalysts to improve. Learning from when never events do not happen may be more useful in the long term than dwelling on failures. **BJHM**

KEY POINTS

- Surgical never events occur once in approximately 17 000 operations.
- Most surgical never events are relatively low harm events, although serious harm can occur.
- Never events carry adverse risks to staff and organizations involved as well.
- The occurrence of never events seems to be related far more to organization size than to any measures of organizational safety.
- Health-care organizations can learn from when never events do not happen as well as when they do.

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BRITISH JOURNAL OF HOSPITAL MEDICINE

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