OPEN ACCESS

The problem with 'never events'

Joanna Zaslow ,[1] Jacqueline Fortier,[2] Gary Garber[3,4]

[1]Evidence Synthesis Unit, Canadian Medical Protective Association, Ottawa, Ontario, Canada
[2]Canadian Medical Protective Association, Ottawa, Ontario, Canada
[3]Safe Medical Care Research, Canadian Medical Protective Association, Ottawa, Ontario, Canada
[4]Department of Medicine, University of Ottawa, Ottawa, Ontario, Canada

Correspondence to
Dr Joanna Zaslow, Evidence Synthesis Unit, Canadian Medical Protective Association, Ottawa, Canada; jzaslow@cmpa.org

Accepted 28 May 2024

'The problem with…' series covers controversial topics related to efforts to improve healthcare quality, including widely recommended, but deceptively difficult strategies for improvement and pervasive problems that seem to resist solution. The series is overseen by Ken Catchpole (Guest Editor) and Kaveh Shojania.

The concept of 'never events' (NEs), introduced in 2002, is used to classify patient safety incidents that should never happen. The term is typically reserved for severe events such as performing surgery on the wrong body part,[1] discharging a baby from the hospital to the wrong parents,[2] or stage 3 or 4 pressure ulcers.[3] The terminology was introduced as a wake-up call for reducing their incidence, but they continue to occur.

Recent systematic reviews have highlighted variability among lists of NEs,[4] or how serious patient safety events in general are defined.[5] Our group recently published a systematic review that identified 12 separate NE frameworks.[4] Despite decades of research and thousands of publications on NEs, there is no universal or official definition for which patient safety events are NEs.

Building on the work of Austin and Provonost,[6] we suggest that the problem with NEs begins at the conceptual level, that is, we do not know how to define them. However, other barriers to reducing or eliminating NEs exist in many different forms. At a systems level, some countries lack independent patient safety authorities,[7] who may help in providing consistency across hospital sites and authority for implementing efforts to address NEs. Where such authorities exist, investigations have highlighted a lack of strong and systematic barriers in hospitals for preventing NEs,[8] which may require leadership to implement policies and procedures to mitigate such risk. At an institutional level, barriers to eliminating NEs can include under-reporting, suboptimal investigations and understanding of causes of patient safety events,[9] and implementing changes that are not effective at reducing NEs. And finally, at the individual level, cognitive biases also contribute to NEs. Issues relating to NEs exist at multiple levels, which highlights the number of impediments to reducing NEs. In this article, we call for efforts to build a shared understanding around what an NE entails.

BACKGROUND

NEs as a concept were first introduced by the National Quality Forum (NQF) in the USA in 2002, when they released a list of what they called serious reportable events (SREs). The purpose of this report was to propose a standardised list of patient safety events which could be used to create state-based reporting systems[10] to establish measurements for assessing the provision of safe care.[11] In a press release accompanying the list, Ken Kizer, the chief executive officer of NQF, claimed their SRE list was comprised of the 'most egregious' efforts that should 'never occur'.[6]

Other organisations quickly followed suit and created their own lists of NEs, including: American organisations such as the Centers for Medicare and Medicaid Services (CMS), the Leapfrog Group, Cigna, Colorado Business Group on Health, University Health Alliance (UHA) Health Insurance; the National Health Service (NHS) in the UK; Observatoire de Medicament, des Dispotifs Medicaux et de l'Innovation Therapeutique (OMEDIT) Pays de la Loire in France; and the Canadian Patient Safety Institute (CPSI). Several groups base their definitions on the NQF's, while others developed their own definitions.

WHAT DOES 'NE' EVEN MEAN?

Standardised language is a necessary part of evidence-based medicine and patient

Linked

► http://dx.doi.org/10.1136/bmjqs-2024-017395

Check for updates

To cite: Zaslow J, Fortier J, Garber G. *BMJ Qual Saf* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjqs-2023-016981

Table 1 : Common Characteristics of Never Events

Characteristics found in never event definitions			
Organisation	**Preventability**	**Harm or severity**	**Accountability or transparency**
NQF[10]	Largely preventable	Serious and adverse	Important for public transparency
CMS[3]	Usually preventable	Serious and/or adverse	Important for public credibility and/or accountability
NHS[1]	Wholly preventable when guidance or safety recommendations have been implemented	Potential to cause serious patient harm or death	Not addressed by this definition
CPSI[2]	Preventable by using organisational checks and balances	Results in serious patient harm or death	Not addressed by this definition
OMEDIT[14]	Preventable	Not addressed by this definition	Not addressed by this definition
Cigna[21]	Not addressed by this definition	Not addressed by this definition	Not addressed by this definition
Leapfrog[13]	Always preventable	Always harmful to patients	Not addressed by this definition
UHA Health Insurance[22]	Preventable	Serious in consequence to patient	Indicate a real problem in the safety and credibility of the facility

CMS, Centers for Medicare and Medicaid Services; CPSI, Canadian Patient Safety Institute; NHS, National Health Service; NQF, National Quality Forum; OMEDIT, Observatoire de Medicament, des Dispotifs Medicaux et de l'Innovation Therapeutique; UHA, University Health Alliance.

safety work; it requires commonly accepted terminology, definitions, values and units.[12] In the case of NEs, we have no common definition. Groups such as hospitals and other care facilities are unable to compare event rates and share quality improvement measures. The effect of this inconsistency is to hinder larger-scale research into NEs. To put it plainly: using the same term without the same meaning makes it hard for patient safety groups to identify trends in other organisations and put lessons learnt into clinical practice.

We have identified three characteristics commonly found in NE definitions, but with varying uses (table 1).

Are they preventable?

Preventability plays a very important role in which events are considered to be NEs and, importantly, the real or perceived role that a physician and the healthcare team has in that event.

The level of preventability for an NE differs based on the organisation—language ranges from 'always preventable'[13] to 'preventable'[14] to 'wholly preventable'[1] to 'largely preventable'[10] to 'usually preventable'.[3] While these might seem like slight degrees of preventability, it has significant implications for the potential occurrence of an NE. For example, if an NE is only largely or usually preventable, that does concede that they may occur and thus the inclusion of never in the name is misleading.

Some organisations claim that NEs are entirely preventable when appropriate measures are in place. The definitions for NHS and CPSI, for example, imply that the policies and procedures set out to prevent NEs are robust. Despite this, NEs continue to occur, and healthcare providers involved in these events may feel at fault when a preventable event happened despite robust policies and procedures. These feelings of fault, however, should be carefully scrutinised as the healthcare environment is extraordinarily complex. Administrators, policymakers and other leaders also play a role, as decisions at a leadership or governance level—such as staffing ratios,[9] workload, culture, and hospital policies and procedures—may affect the likelihood of NEs occurring. While frontline healthcare providers may be closest to the NE when it occurs, the contributing factors go beyond the individual and to the team or systems level.[9] Regardless of where the primary responsibility for the failure of the NE lies, patients and healthcare providers experience harm and shame.[8 15] Defining an NE as one that is fully preventable when safeguards are in place leaves room for the clinician and the healthcare team to be unfairly held (or hold themselves) responsible.

Does harm need to have occurred?

NEs often encompass events that are severe and significant, but does harm need to have occurred in order for it to be considered an NE? For some organisations, like the NQF, CMS, CPSI and others, and NE is a serious event or an event which results in serious patient harm. A serious event can be one which results in outcomes like 'death, loss of body function or disability lasting longer than a week…'.[16] A contrasting definition by the NHS views an NE as something that has the *potential* to cause serious harm, but that harm need not to have occurred.[1] This results in a large gap of harm for NEs—on one end we have harm that causes further hospitalisation or disability, and the other has no requirement for any harm occurring while still falling under the same umbrella of NE.

It should be noted that these definitions of harm make no explicit mention of emotional or psychological harm that can result from the event itself and corresponding loss of trust in healthcare providers. It may be valuable for patient safety organisations to consider ways in which harm can manifest itself beyond the merely physical. Leapfrog, for example, suggests steps that may help to rebuild trust between

patients and care teams after the occurrence of an NE, including speaking openly with the patient and their family about the circumstances that led to the event[17] and validating and addressing concerns.

Should reporting NEs be mandatory?

When NQF developed the initial framework of NEs, public accountability was seen as a necessary part of the work to eliminate NEs. Public accountability or transparency is also mentioned by CMS. For NQF, public accountability requires transparency in alerting the appropriate bodies when NEs occur. Kizer and Stegun liken this to an investigation by an aviation oversight group when a crash has occurred—oversight bodies investigate to determine causes and ways to prevent their reoccurrence.[16]

In contrast, some organisations make no mention of public accountability in their definitions but have chosen in the past to release incident rates as a way to establishing transparency. The initial aim of the NHS NE framework was to provide 'a lever for increasing transparency of organisations and the levels of reporting and learning around these very serious safety incidents'.[8] Public accountability appears to be different for the NQF and NHS—one sees accountability as altering appropriate authorities in the event of an NE, while the other views public transparency as an important factor.

Groups like CPSI, OMEDIT, Cigna and UHA make no mention of public accountability or offer no incident rates.

THE 'NEVER' OF NES

Despite the efforts of many to address NEs, they continue to occur. The organisations identified in this paper all introduced their work on NEs between the years 2002 and 2015. In 2021, the Healthcare Safety Investigation Branch in the UK noted that data on the incidence of NEs show they occur and will likely continue to do so.[8] While some claim that frequency rates of NEs over time may be somewhat 'distorted' due to changing definitions, increased complexity of patients, and the development of new procedures and treatments,[18] NEs such as retained foreign objects after surgery, wrong site surgery or the use of wrong implant/prosthesis continue to occur at similar or increased frequency.[8]

As we saw above, even for some definitions of NEs, it is acknowledged that they may not be preventable. This means that, conceptually, for some frameworks, the definition conflicts with the name of the concept before an event even happens.

WHAT IS THE PROBLEM?

There are two issues at hand, conceptually, in the case of NEs: (1) definitions of NEs vary between organisations to such an extent that there is no unifying thread; and (2) given that NEs continue to occur and given that several organisations do not consider them to be preventable, the 'never' of NEs is a misnomer. Both serve to undercut the strength or power of NEs as a concept.

WHAT SHOULD NES ENTAIL?

With the lack of a constitutive element or essential component in NEs, how do we begin to determine or declare what NEs entail? Hegarty *et al* performed a systematic review of serious reportable patient safety incidents and identified five components or dimensions that were common among these terms: events were (1) largely preventable, (2) had the potential for significant learning; (3) cause serious harm or have the potential to cause harm; (4) are identifiable, measurable and feasible for inclusion in an incident reporting system; and (5) run the risk of recurrence.[5] Hegarty *et al*'s search parameters included NEs but did not exclude other patient safety incidents.

While we do argue for the benefit of standardisation, we acknowledge the challenges inherent to such an undertaking. While there are benefits to standardised language, that does not mean healthcare organisations will change their NE definitions.

Each of the groups identified in this paper has very different structures, purposes and roles within the healthcare system and their work on NEs is motivated by very different purposes, but all share a goal of better healthcare. Government agencies, patient safety groups and insurance companies all strive for a reduction in patient harm but in different ways and with different methods. Irrespective of their different perspectives, all will benefit from a reduction in NEs, whether that be due to less patient harm, insurance payouts or lawsuits. Future work on a universal NE definition should begin with the dimensions identified by Hegarty *et al* and view them through an NE-specific lens. If the ultimate goal of work in NEs is to reduce or eliminate them, patient safety groups should develop consensus-based definitions that are clear, standardised and applied consistently. What makes an NE? What is necessary for an NE to occur? Can an NE be somewhat preventable? Or must they all be wholly preventable? What kind of harm must occur in an NE? Our recent systematic review of NEs identified 125 unique NEs, with 4 most commonly identified events: wrong body part, wrong procedure, unintentionally retained foreign object and wrong patient.[4] While we acknowledge that there are myriad ways to reduce the frequency of NEs, including the development of robust policies and procedures for surgical procedures, we still suggest that working towards a common list of NEs is an important element to improve patient safety. Without a common conceptualisation of a term, the strength of the concept is rendered null and this can impact other efforts to reduce NEs. If we want the work of NEs to have meaning, we need to ensure it is conceptually sound.

'NEs' is a term that is conceptually flawed. We say they should never occur, but they also might not be preventable (and just might be random[19]). And we have failed to even identify any essential component to the events themselves. There is much that can be done with this concept—some (including us) have suggested focusing on a common list of NEs, while others have suggested renaming NEs[20]—here we suggest identifying common characteristics in order to create a new definition. All are important efforts. And the push for each of these shows how much work needs to be done in this area.

- There are multiple challenges to reducing the prevalence of NEs
- The term is currently used with varying definitions and characteristics, which limits collaboration
- Patient safety/healthcare groups should identify the necessary conditions/characteristics for NEs

Contributors JZ designed study methods, conducted analysis, drafted the manuscript, reviewed the manuscript. and is the guarantor of the paper. JF designed study methods and reviewed the manuscript. GG made the overall conception of the study, designed study methods and reviewed the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Joanna Zaslow http://orcid.org/0000-0002-3011-6667

REFERENCES

1 NHS Improvement. Never events policy and framework. London, 2018.
2 Canadian Patient Safety Institute and Health Quality Ontario. Never events for hospital care in Canada: safer care for patients. 2015.
3 Centers for Medicare & Medicaid Services. Eliminating serious, preventable, and costly medical errors - never events. 2006. Available: ELIMINATING SERIOUS, PREVENTABLE, AND COSTLY MEDICAL ERRORS - NEVER EVENTS | CMS [Accessed 17 May 2024].
4 Bowman CL, De Gorter R, Zaslow J, *et al*. Identifying a list of healthcare 'never events' to effect system change: a systematic review and narrative synthesis. *BMJ Open Qual* 2023;12:e002264.
5 Hegarty J, Flaherty SJ, Saab MM, *et al*. An International perspective on definitions and terminology used to describe serious reportable patient safety incidents: a systematic review. *J Patient Saf* 2021;17:e1247–54.
6 Austin JM, Pronovost PJ. 'Never events' and the quest to reduce preventable harm. *Jt Comm J Qual Patient Saf* 2015;41:279–88.
7 Bhatia D, Lynch M, Murmann M, *et al*. *Marchildon Rapid Review: Never Events in Acute Care: Policy Lessons from International Comparisons. Prepared for the Canadian Patient Safety Institute*. Toronto: North American Observatory on Health Systems and Policies, 2021.
8 Healthcare Safety Investigations Branch. Never events: analysis of HSIB's National investigations. 2021.
9 Koleva SI. A literature review exploring common factors contributing to never events in surgery. *J Perioper Pract* 2020;30:256–64.
10 National Quality Forum. Serious Reportable events in Healthcare – 2011 update: A consensus report. 2011. Available: NQF: Serious Reportable Events in Healthcare 2011 (qualityforum.org) [Accessed 17 2024].
11 National Quality Forum. List of Sres. 2024. Available: NQF: List of SREs (qualityforum.org) [Accessed 17 May 2024].
12 Executive Board 118. eHealth: standardized terminology: report by the Secretariat. World Health Organization; 2006. Available: eHealth:standardized terminology: report by the Secretariat (who.int) [Accessed 17 May 2024].
13 The Leapfrog. Leapfrog never events report. 2019. Available: Microsoft Word - Leapfrog Never Events.docx (leapfroggroup.org) [Accessed 17 May 2024].
14 Omedit Pays de la Loire. Les never events. 2021. Available: résentation PowerPoint (omedit-paysdelaloire.fr) [Accessed 17 May 2024].
15 Wu AW, Shapiro J, Harrison R, *et al*. The impact of adverse events on clinicians: what's in a name? *J Patient Saf* 2020;16:65–72.
16 Kizer KW, Stegun MB. Serious Reportable adverse events in health care. In: Henriksen K, Battles JB, Marks ES, eds. *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products)*. Rockville (MD): Agency for Healthcare Research and Quality (US), 2005.
17 Leapfrog Group. Leapfrog hospital survey, never events: fact sheet. 2021. Available: Never Events Fact Sheet.pdf (leapfroggroup.org) [Accessed 17 May 2024].
18 Morgenthaler T, Hopper CM. Getting rid of 'never events' in hospitals. Harvard Business Review; 2015. Available: Getting Rid of "Never Events" in Hospitals (hbr.org) [Accessed 17 May 2024].
19 Moppett IK, Moppett SH. Surgical caseload and the risk of surgical never events in England. *Anaesthesia* 2016;71:17–30.
20 Pandit JJ. Deaths by Horsekick in the Prussian army – and other 'never events' in large organisations. *Anaesthesia* 2016;71:7–11.
21 Cigna. Cigna Reimbursement Policy, Subject: Never Events, 2008. Available: https://static.cigna.com/assets/chcp/secure/pdf/resourceLibrary/clinReimPolsModifiers/R05_Never_Events.pdf [Accessed 17 May 2024].
22 UHA Health Insurance. Never events and hospital acquired conditions. 2012. Available: https://www.uhahealth.com/wp-content/uploads/form_fac_Never-Events-Hospital-Acquired.pdf [Accessed 17 May 2024].