Is the "never event" concept a useful safety management strategy in complex primary healthcare systems?

Paul Bowie[1-3]**, Diane Baylis**[4]**, Julie Price**[4]**, Pallavi Bradshaw**[4]**, Duncan McNab**[1,2,] **Jean Ker**[1]**, Andrew Carson-Stevens**[5]**, Alastair Ross**[6]

[1]NHS Education for Scotland, Edinburgh, Scotland, UK
[2]Institute of Health and Wellbeing, University of Glasgow, Scotland, UK
[3]School of Health and Social Care, Staffordshire University, UK
[4]Medical Protection Society (www.medicalprotection.org), Leeds, England, UK
[5]Division of Population Medicine, School of Medicine, Cardiff University, Wales, UK
[6]Dental School, University of Glasgow, Scotland, UK

Corresponding author:
Professor Paul Bowie
Programme Director (Safety & Improvement)
NHS Education for Scotland
2 Central Quay
GLASGOW
Scotland, UK
G3 8BW

Email: paul.bowie@nes.scot.nhs.uk
Telephone: 0044 +141 223 1463
Twitter: @pbnes

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Abstract

Why is the area important?

A sub-group of rare but serious patient safety incidents, known as 'never events', is judged to be 'avoidable'. There is growing interest in this concept in international care settings, including UK primary care. However, issues have been raised regarding the well-intentioned coupling of 'preventable harm' with zero tolerance 'never events', especially around the lack of evidence for such harm ever being totally preventable.

What is already known and gaps in knowledge?

We consider whether the ideal of reducing preventable harm to 'never' is better for patient safety than, for example, the goal of managing risk materialising into harm to '*as low as reasonably practicable*' which is well-established in other complex socio-technical systems and is demonstrably achievable.

We reflect on the 'never event' concept in the primary care context specifically, although the issues and the polarised opinion highlighted are widely applicable. Recent developments to validate primary care 'never event' lists are summarised and alternative safety management strategies considered e.g. Safety-I and Safety-II

Future areas for advancing research and practice

Despite their rarity, if there is to be a policy focus on 'never events', then specialist training for key workforce members is necessary to enable examination of the complex system interactions and design issues which contribute to such events. The 'never event' term is well-intentioned but largely aspirational – however it is important to question prevailing assumptions about how patient safety can be understood and improved by offering alternative ways of thinking about related complexities.

Keywords:

Patient safety, never events, risk management, systems thinking, primary care

Introduction

Healthcare inherently involves significant clinical and organisational risks. Consequently, a minority of patients are unintentionally harmed across care sectors worldwide [1]. Care providers are repeatedly challenged to improve service quality and minimise or even 'eliminate' preventable harm [2]. While these goals are laudable and unarguable, they are problematic given the competing demands, workload pressures, and resource constraints routinely faced by care teams [3]. New technologies, increasingly complex care processes, rising patient expectations and the litigious environment all interact, to such a degree, that 'sharp end' practitioners often feel powerless to affect system change and sustain meaningful improvement in patient safety.

It is accepted that many serious patient safety incidents are 'avoidable'. The interest in adopting similar safety strategies to other high-risk industries (e.g. nuclear power) suggests there is an optimism that healthcare can improve patient safety. Multiple improvement interventions have been implemented across many care systems internationally. While evidence of impact is limited or equivocal [4], reducing serious preventable harm to patients continues to be a public health concern attracting significant policy and media interest [5].

The periodic media reporting of a group of serious safety incidents, known as 'never events' [7], is an important case in point [16] - a 'never event' is defined as: "…*a serious, largely preventable patient safety incident that should not occur if the available preventable measures were implemented by healthcare workers*" [17]. The phrase 'never event' was coined because of the 'extra psychological charge' it invoked [7]. In some secondary care settings internationally, a formal list of 'never events' is now published, including in England [17]. Recent research has also led to 'validated' lists for general medical practice [18-19] and primary care dentistry [20-21] – although internationally only secondary care systems appear to have formal policies [17, 22-24]. Attention appears to be centred around measurement of event occurrence, rather than proactive improvement efforts informed by systems analysis and re-design.

Fundamental issues have been raised regarding the coupling of 'preventable harm' with zero tolerance 'never events' [25-27]. First, 'preventable' is logically derived from single case reviews, where decisions are made as to whether harm could have been prevented i.e. it was not inevitable given patient acuity, medical knowledge and treatment available etc. But at the statistical, patterned level, there is little or no evidence for such harm ever being preventable. Recurrence of most, if not all the typology of harm, is repeatedly observed [23]. No healthcare system has demonstrated a complete ability to sustainably prevent these incidents. Secondly, 'never event' is an emotive term about a narrower set of rare patient harm events, but it is important to stress that they are 'routine' as reported data demonstrates [7].

Given the serious impacts on people of such events, the policy interest in the concept is understandable. But this article aims to consider whether the ideal of reducing preventable harm to 'never' (or 'zero') is a meaningful goal. We reflect specifically on the 'never event' concept in the primary care context, but stress that the issues debated here are generalizable in all care settings.

We aim, therefore, to:

- define the concept of 'never events' and describe their potential purpose within the primary care context;

- highlight the controversy surrounding the related goal of 'zero harm'; and

- outline what can be practically achieved to better understand and manage the complex system issues within which 'never events' (re-)occur.

Recent Developments in Primary Care

Patient safety research in primary care is severely limited in comparison to the study of this important topic in secondary care settings. This is due in large part to the heterogenous and complex nature of care delivery in many countries and the perception by policy leads that it is a low technology environment where safety is not a significant issue [3,

18]. A systematic review, however, estimates that between 2 to 3 patient safety incidents occur per 100 consultations in primary care – the burden of potential harm is significant given that in the UK, for example, there are over 300 million consultations annually [19]. The patient safety challenges are focused on diagnostic, medication, communication and administrative issues.

Four recent patient safety studies have validated 'never events' lists in primary care settings: In Scottish general practice [18] ten candidate 'never events' was agreed with specific criteria produced to guide 'never event' selection (Box 1). The Medical Protection Society [19] identified 13 additional 'never events', and further studies validated lists for primary care dentistry [20, 21]. Over 50 priority 'never events' are now identified to potentially guide incident reporting and learning (Table 1).

A Window on the System

The 'never event' issue is problematic, engendering emotion and leading to a need for accountability. Frontline staff are overwhelmingly held to account. But there is strong evidence that care systems frequently leave teams with all the responsibility, but a lack of control (e.g. influence, knowledge and resource) to better improve care system designs [29-30], which are often sub-optimal and complex.

For example, six general practice 'never events' involve electronic medical records [18] with known design issues that facilitate 'error-producing conditions' [31-32], particularly when combined with managing high workloads, goal conflicts and safety-efficiency trade-offs. Human-centred re-design of these systems to improve safety can only be actioned nationally. In dentistry, systems-wide issues are highlighted that require similar national attention to improve, for example, clinical guideline adherence and workforce training in safety improvement [21].

"Never Events" and "Zero Harm" Thinking

The 'never event' concept is open to challenge from a safety science perspective [25-27]. In this standpoint, much of healthcare is considered as a 'complex sociotechnical system' - patient safety goals can only be achieved through successful interactions between social, technical, human, organisational, economic and regulatory components of work systems [33]. There may be certain routine tasks or simple, closed processes which can be treated in isolation and for which near 100% compliance or standardisation is feasible. But all tasks take place *in situ* and thus all care episodes are complex i.e. are situated in complex practice. 'Normal accident' theory suggests that serious incidents are inevitable (i.e. harm is not always preventable) in highly complex systems, which cannot be accurately modelled and satisfactorily designed to completely eradicate all risk [34].

'Never events' continue to routinely occur, despite the policy attention, strongly suggesting they are 'normal' in this technical sense; the 'loaded' term may thus be a misnomer, despite the underlying goal (as safe as possible) being an aspiration all would reasonably share. The concept is thus not without controversy and debate is polarised. Shorrock outlines multiple reasons and rationale [27] why this type of thinking may be inherently flawed and counterproductive to improving organisational safety (Box 2).

"*No-one wants an accident or never event. That's obvious. It's not a useful goal though, and it's not a useful way of thinking either. Never/zero is the stuff of never-never land. You can't swear off accidents*" [27]

In contrast, Caffazo suggests that healthcare should '…*strive to reduce the occurrence of never events and other adverse incidents…[and] set a standard that eliminates all harmful events...the debate should not be about a reduction target, but about a target of zero.*' [35] The logic advanced invokes comparisons with what happens in other safety-critical sectors and cites societal expectations when dealing with and reacting to serious harm events that are known to occur but are judged preventable:

"*When we look at other industries' tolerance for adverse risks, it is always zero. Imagine if the airline industry would aim to tolerate a certain number of accidents per year; passengers would refuse to board a plane… …In the end, when dealing with a patient's life and harmful events that are preventable, the benchmark should always be zero, because anything less is not just odd, but is just simply unacceptable…*".

The 'never event' agenda is not a 'fixed target' but a process that focuses attention on single events requiring a high level of professional engagement and action to sustain commitment and improvement – however the (perhaps unintentional) focus appears to be on individual professional accountability, rather than on a *shared responsibility* across all system actors up to and including regulators and government. This arguably over-emphasises the need to motivate clinicians to be more safety-conscious and possibly misunderstands the nature of why things go wrong in complex systems and how people create safety through adaptive performance to fit system conditions [34-36].

Moving forward: what can be done pragmatically?

More research to better understand the phenomena as it occurs within complex healthcare environments is clearly necessary. Adopting a 'systems approach' [37] to 'never events' should be considered essential in defining the boundary and functions of the related work system, the complex socio-technical interactions that take place, and how the current context influences system behaviours and outcomes. It is unclear to what extent systems and design thinking are considered in the care systems where 'never events' policies exist. While a systems approach is promoted in patient safety, what this means in everyday work is not well-defined and a shared understanding of the concept/application is lacking [20, 28, 30].

The following concepts and practices embrace systems thinking and may be helpful for better understanding and controlling the risks associated with serious safety issues in primary care:

Balancing Safety-I and Safety-II Thinking

Safety-I and Safety-II [36] concepts offer a different perspective on how we think safety is created and maintained in complex care systems. This approach may be applied to explain, as far as possible, the intractable safety problems we can encounter in primary care. Orthodox safety methods such as a reliance on incident reporting, measuring safety incidents, root cause analysis, and various quality improvement techniques are suggested as 'Safety-I' approaches in this context. These are thought to be limited in terms of providing a deeper understanding of how safety is dynamically created and managed because they focus on very specific events or care processes in isolation, rather than broader care system performance holistically.

This can lead to a linear focus on 'cause-and-effect' due to the need to 'fix' or action something after the fact [38]. The approach derives from significantly less complex process industries, such as car manufacturing, where discrete fixes can be found after isolating problems; this may have a limited transferability to primary care contexts.

The 'Safety-II' perspective originated in the human factors sub-discipline of resilience engineering and, as such, it adopts the 'systems approach' to studying and modelling human interactions with other elements of a complex sociotechnical system. The goal is to understand how these complex interactions lead to both wanted and unwanted outcomes related to organisational performance and human wellbeing. A key objective is to learn from how things go well in the great majority of cases in healthcare i.e. what can we find out about how everyday success is routinely achieved in these challenging working conditions and so enable the design of more effective changes to improve system resilience and enhance safety and wellbeing. In essence, work success happens in complex, inadequately designed care systems because people continually adjust their performance (e.g. via work-arounds and efficiency-thoroughness-trade-offs [39]) to ensure successful outcomes for patients and themselves – it is the combination of understanding and learning from how this is achieved,

as well as from when things go wrong, that is potentially key to more informed patient safety practices.

Barrier Management Methods

The formal proactive risk assessment of the potential for serious safety incidents to occur is rarely undertaken in primary care. Recent research on the utility of Bowtie Analysis (BTA) as a method for frontline teams to assess the system controls relied upon to protect against the risk of a specific 'never event' is the first to be conducted based on recently published 'good practice' principles [40]. The study reports that BTA can provide a "…*rich understanding of the controls that are expected to be in place to protect against incidents, how they can fail, and how they need to be implemented, supported, and managed. In addition, it can do so without having to make any assumptions about the mechanisms or nature of accident causation*". It concluded that its application was potentially feasible but it was unclear what level of training, support and resources would be needed to implement BTA routinely.

It is worth noting that the BTA criteria applied in high-risk industries to determine what can be considered to be a full system 'barrier', may expose the weaknesses and limitations of the proposed 'strong systemic barriers' (e.g. standardised procedures or cognitive aids) that are claimed will prevent specific secondary care 'never events' if successfully implemented [41]. This topic merits study to evaluate these criteria against the quality of the 'barriers' currently recommended to prevent 'never events'.

Adopting the ALARP Principle

ALARP ("as low as reasonably practicable") is a risk management approach [28] with very limited application in primary care, but is widely used in the regulation and management of safety-critical systems in high-risk industries, where a regulatory framework informs the need to identify, consider and reduce risks in this way. The governing principle of ALARP "…*is to demonstrate that risks have been controlled effectively to a point where the cost of*

further risk reduction would be grossly disproportionate to the expected benefits". While healthcare systems generally lack a similar regulatory framework to implement this principle, viewing the potential for a 'never event' to occur through the ALARP lens may still be useful for care teams and organisations in judging underlying risks and balancing the resource necessary to reduce the risks i.e. the trading-off risk reduction with related costs paradigm is analogous to the routine clinical decision-making that clinicians perform daily.

Safety Cases

In many safety-critical industries, 'safety case' documentation is submitted to regulators to demonstrate that:

1. Specific systems of work have been formally assessed and related hazards and risk identified, and

2. The associated safety management system that is implemented ensures that all risk controls can be reliably applied to a high standard.

The ALARP principle can also be integrated within this approach. While the safety case concept is theoretically described in healthcare, such as in the design and use of medical devices and infusions pumps [42], there is no evidence of such consideration in primary care work systems (e.g. management of clinical test results) in which 'never events' may occur. Clearly there would have to be different regulatory landscapes in healthcare to oversee the implementation of safety cases. However, the concept is not without merit in terms of organisations proactively assessing, identifying and managing known serious risks in this way.

Incident Reporting and Learning

A balanced approach to applying Safety-I and Safety-II principles and methods is recommended. It is still necessary to report and learn from things that go seriously wrong in primary care or had the potential to do so – perhaps with a specific emphasis on 'never events' as a way of demonstrating to the public and the workforce a desire to tackle the

more complex and problematic issues that occur. Engagement of primary care teams in formally reporting safety incidents is historically low internationally [43] (e.g. due to the lack of policy attention and supporting infrastructure), but recent supportive commentary and practical guidance have been published [44-45]. Encouragingly from our experiences some organisations are providing primary care with access to reporting systems traditionally used in secondary care. Recent research also reports development of a systems-based approach to the analysis of 'significant events' in primary care [46].

Conclusion

Despite their rarity, if 'never events' are to be taken seriously in primary care then it is clear that a policy focus on this issue would be required. Key workforce members would need to be upskilled in 'new' safety management practices to examine the complexities of the system interactions and design limitations they are required to function within.

The conjunction of avoidance (preventable) and frequency (zero) terms means that, conceptually, 'never events' are ultimately 'selected events that in theory should never happen but do, from a bigger set of events that in theory can be avoided but are not'.

The term is well-intentioned but ultimately aspirational in many cases, as highlighted in recent commentaries [47-50] which also point out the folly of some harms eradication strategies ('…some harms are inevitable and impossible to eliminate.' [50]) and instead advocate a more realistic focus on becoming better at 'recognising and managing threats to safety'. In summary, the way we think about patient safety is too important not to question assumptions and the potential implications of the various ways in which measured accountability might further its aims.

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Conflict of Interest

The Authors declare that there is no conflict of interest.

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Box 1. Preliminary criteria to inform judgement on 'never event' development [18]

A "never event"…

1. Is known to cause severe harm to a patient, or has the potential to do so AND

2. Is preventable by the healthcare professional, team, or organisation AND

3. Can be clearly and precisely defined AND

4. Can be detected AND

5. Is not the result of an unlawful act

Box 2. Suggested reasons why the 'never event' concept is not useful [27]

Reason	Rationale
1. Never/zero is not SMART (Specific, Measureable, Assignable, Realistic and Time-Related)	*All work improvement objectives should be SMART but the concept fails on most of these criteria*
2. Never/zero is unachievable	*Unfortunate as it is, zero accidents/incidents can never be achieved and never has been, but more particularly so in a complex healthcare system*
3. Never/zero is avoidant	*It is aspirational and anti-goal. It does not necessarily follow that focusing on not doing something will result in that thing not being done.*
4. Never/zero is someone else's agenda	*The agenda is rarely set by frontline staff, who have to balance competing goals with limited resources, and make frequent trade-offs - none of these can be simplified to never/zero.*
5. Never/zero leads to blaming and shaming	*No one goes to work to do a bad job. But it is inevitable that those individuals nearest in time and space to the 'never event' will be blamed, directly or indirectly – particularly by those such as the media, judiciary and public with limited understanding of systems thinking, complexity science and Human Factors/Ergonomics.*
6. Never/zero makes safety language even more negative	*The negative language limits our thinking about what safety actually entails and our ability to learn, while frontline teams know these types of clearly unwanted events are unrealistic*
7. Never/zero does not equal good safety	*It is not a useful goal, what happens to your target (and motivational campaigning etc) when you inevitably have this type of incident in a complex system?*

Table 1. Examples of suggested "never events" for primary care [18-21]

'Never Event'	Primary Care Setting	Research Team
1. Prescribing a drug to a patient that is recorded in the practice system as having previously caused her/him a severe adverse reaction	General medical practice	NHS Education for Scotland
2. A planned referral of a patient, prompted by clinical suspicion of cancer, is not sent	General medical practice	NHS Education for Scotland
3. Prescribing a teratogenic drug to a patient known to be pregnant (unless initiated by a clinical specialist).	General medical practice	NHS Education for Scotland
4. An abnormal investigation result is received by a practice but is not reviewed by a clinician	General medical practice	NHS Education for Scotland
5. Prescribing systemic oestrogen-only Hormone Replacement Therapy for a patient with an intact uterus	General medical practice	NHS Education for Scotland
6. Prescribing Methotrexate daily rather than weekly (unless initiated by a specialist for a specific clinical condition e.g. leukemia)	General medical practice	NHS Education for Scotland
7. Not referring a child suspected to have non-accidental injuries urgently.	General medical practice	Medical Protection
8. Performing a cervical smear without visualising the cervical os.	General medical practice	Medical Protection
9. Medical waste and hazardous substances discarded in an inappropriate manner.	General medical practice	Medical Protection
10. Not updating or checking a patient's medical history prior to undertaking dental	Primary care dentistry	NHS Education for Scotland

extractions.		
11. Omitting to check that treatment plans and radiographs concur with clinical findings before any treatment is commenced	Primary care dentistry	NHS Education for Scotland
12. Undertaking clinical procedures without taking adequate precautions to avoid potential for inhalation or ingestion of crowns or endodontic instruments	Primary care dentistry	NHS Education for Scotland
13. Wrong tooth extracted	Primary care dentistry	University of Edinburgh
14. Jaw fracture during implant placement due to poor treatment plan	Primary care dentistry	University of Edinburgh
15. Treatment provided to the wrong patient	Primary care dentistry	University of Edinburgh
16. Injection of wrong aesthetic solution	Primary care dentistry	University of Edinburgh
17. Retained foreign objects after surgical procedures (excluding root canal procedures)	Primary care dentistry	University of Edinburgh
18. Re-use of disposable items	Primary care dentistry	University of Edinburgh