NHS Improvement

Never Events policy and framework

Revised January 2018

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We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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Foreword

Learning from what goes wrong in healthcare is crucial to preventing future harm, but it requires a culture of openness and honesty to ensure staff, patients, families and carers feel supported to speak up in a constructive way.

The revised Never Events policy and framework are designed to support the NHS to do that, and are part of continuing efforts to build a learning culture and maximise opportunities to keep our patients safe.

Our revision of the framework has been informed by your response to the consultation at the end of 2016. The consultation asked if the previous Never Events policy and framework were fit for purpose, and if the list of incidents continued to reflect the definition of a Never Event – that is, incidents on the list should be avoidable if available preventative measures have been implemented.

One of the key changes we have made in response to what you told us is to remove the option to impose financial sanctions associated with Never Events. We heard that allowing commissioners to impose financial sanctions following Never Events reinforced the perception of a 'blame culture'. Our removal of financial sanctions should not be interpreted as a weakening of effort to prevent Never Events. It is about emphasising the importance of learning from their occurrence, not blaming.

The revised Never Events framework will be aligned with a new Serious Incident framework due to be published later in 2018. We will shortly be launching an engagement exercise around the Serious Incident framework, but the plan to align the two documents will go ahead as Never Events should always be treated as Serious Incidents.

We have also looked at the list of Never Events. A reference group comprising NHS Improvement and NHS England regional quality leads, members of the patient safety team at NHS Improvement and clinical advisors reviewed the list alongside all the new suggestions that were made for Never Events in response to the consultation. Two types of Never Event have been added – unintentional connection of a patient requiring oxygen to an air flowmeter and undetected oesophageal intubation – and the definitions of some existing Never Events have been revised. Further detail is provided in the Never Events list 2018.

This document is a resource for patients, boards and all healthcare clinical and management staff. However, we particularly ask that all board members and other leaders of healthcare organisations consider this revised framework, and that medical and nursing directors in provider and commissioning organisations ensure that all relevant guidance is followed – both to prevent Never Events and to learn from Never Events when they do occur.

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1. Policy statement

1.1. Never Events are incidents that require investigation under the Serious Incident framework. In 2018 the Never Events policy and framework will be merged with the revised Serious Incident framework. Until then, this policy should always be read in conjunction with the current Serious Incident framework.

1.2. The Never Events policy and framework is relevant to all NHS-funded care.

2. Acknowledgements

2.1. The Never Events policy and framework have been revised following a wide consultation of patients, healthcare providers, commissioners, regulatory and supervisory bodies, patient safety experts, professional organisations and royal colleges. We thank everyone for their contribution.

3. Purpose

3.1. Never Events are defined as Serious Incidents that are wholly preventable because 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. Strong systemic protective barriers are defined as barriers that must be successful, reliable and comprehensive safeguards or remedies – for example, a uniquely designed connector that stops a medicine being given by the wrong route. The importance, rationale and good practice use of relevant barriers should be fully understood by and robustly sustained throughout the system, from suppliers, procurers, requisitioners, training units to frontline staff.

3.2. The Never Events policy and framework are designed to provide healthcare workers, clinicians, managers, boards and accountable officers with clarity on their responsibilities and on the principles of Never Events. In particular, these people should know what they are expected to do to prevent Never Events and how they must respond if they occur, including how they report a Never Event.

3.3. Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so this policy and framework provide the NHS with an essential lever for improving patient safety.

3.4. NHS Improvement's vision of high quality, compassionate and constantly improving healthcare requires us to nurture the necessary culture and conditions, including openness and transparency, evidence-based decision-making and a commitment to lifelong learning. As Don Berwick noted: "…standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning."[1]

3.5. The Never Events policy and framework support our vision by requiring honesty, accountability and learning in response to a group of incidents that can be prevented if accepted practice (including available preventative measures) has been implemented.

3.6. In this context, it is important that when a Never Event occurs, regardless of the outcome, the problems in care are identified and analysed through full investigation using a systems-based investigation method (such as root cause analysis – RCA) to understand how and why they occurred (from a systems perspective), as described in the Serious Incident framework. This will mean effective and targeted action can be taken to prevent recurrence.

3.7. Supporting staff to recognise Never Events is essential so that the opportunity to investigate, learn and improve can be identified in a timely way before vital information is lost.

4. Definition

4.1. The types of incident defined as Never Events using the criteria below are listed in the Never Events list 2018.

4.2. Never Events are incidents that meet all the criteria given in 4.3 to 4.6 below, and require full investigation under the Serious Incident framework.

[1] Department of Health (August 2013) *A promise to learn – a commitment to act: improving the safety of patients in England* August 2013. Available at: www.gov.uk/government/publications/berwick-review-into-patient-safety

4.3. Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations[2] that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

4.4. Each Never Event type has the potential to cause serious patient harm or death. However, serious harm[3] or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.

4.5. For each Never Event type, there is evidence that the Never Event has occurred in the past – for example, through reports to the National Reporting and Learning System (NRLS) – and that the risk of recurrence remains.[4]

4.6. Each Never Event type must be able to be clearly defined and its occurrence easily recognised – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

4.7. The Never Event list is reviewed regularly by NHS Improvement.

4.8 The NHS Improvement patient safety team does not act as an arbiter of whether a particular incident is a Never Event. This is agreed between provider and commissioner. The national team can advise on whether a type of Serious Incident qualifies as a Never Event as defined in the framework.

[2] As compiled by NHS Improvement patient safety experts and healthcare professionals, and referenced in the Never Events list 2018. These include: physical barriers (eg equipment that makes it impossible to connect medications via the wrong route); time and place barriers (eg withdrawal of concentrated medications from settings to prevent them being accidentally selected) or systems of double or triple checking where these are supported by visual or computerised warnings, standardised procedures or memory/communication aids. As all human action is vulnerable to human error, particularly where there is a risk of staff becoming overloaded, processes that rely solely on one staff member checking the actions of another or referring to written policies are not strong barriers.

[3] Serious harm: severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care); chronic pain (continuous, long-term pain lasting more than 12 weeks or beyond the time that healing post trauma or surgery should have occurred) or psychological harm; impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is unlikely to be temporary (that is, has lasted or is likely to last for a continuous period of at least 28 days).

[4] As this policy aims to drive patient safety improvement, it excludes incident types eradicated by technical, medical or scientific advances.

5. Learning from incidents

5.1. Learning from incidents requires timely incident reporting in a fair, open and just culture. Blame is not a useful lever for learning because: "…a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring".[5]

6. Organisational leadership

6.1. This policy and framework apply nationally, and all levels of healthcare organisations – from 'ward to board' – must play their part. Ultimately, however, and for clarity, an organisation's leadership is accountable for the occurrence of Never Events and crucially for the organisation's response.

6.2. The chief executive, all board members, other relevant organisation leaders and all relevant teams should know about any Never Event occurring in their organisation, and view each as an opportunity to investigate effectively and take meaningful targeted action(s) that measurably reduces risk of recurrence to improve patient safety. Repeated Never Events, particularly of the same type, signal ongoing problems in systems that previous investigations may not have identified or their recommendations (and resulting actions) have failed to address. Leaders should focus on maintaining systems that prevent Never Events from occurring in the first place. However, leaders must also provide support, investment and attention to enable effective investigation and meaningful improvement action (which measurably reduces the risk of recurrence) when Never Events do occur.

[5] National Patient Safety Agency (2004–2009) *Seven steps to patient safety*. Available at: www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

7. Requirements – when a Never Event is identified

7.1. Never Events are incidents that require full investigation under the Serious Incident framework. The requirements for reporting, principles for investigation, and the roles and responsibilities associated with the management and oversight of other Serious Incidents apply, including the need to fully and meaningfully engage patients, families and carers at the beginning of and throughout any investigation. Further information can be found in the Serious Incident framework.

7.2. As with other incidents that are classified as Serious Incidents, Never Events must be reported to both the strategic executive information system (StEIS) and the NRLS until the new patient safety incident management system is in place. Crucially, reports to both the NRLS and StEIS must clearly label the incident as a Never Event, even if this status is uncertain at the time of reporting (both systems contain a Never Events field). If necessary, and with provider and commissioner agreement, incident reports on StEIS can be retrospectively amended if it is found that the incident did not meet the definition of a Never Event. A clear audit trail explaining the rationale for the change and who authorised this should be recorded.

7.3. Organisational leaders (board or equivalent) are responsible for ensuring that any occurrence of a Never Event is analysed fully using a systems-based investigation method (such as RCA) to understand how and why it occurred (from a systems perspective). Leaders must then ensure that actions which measurably reduce the risk of recurrence are taken. Monitoring processes must support implementation and delivery of effective actions – this is the crucial aspect of this policy and framework.

7.4. Incidence of Never Events must be identified in the commissioner's annual report and the provider's quality accounts (ensuring patient confidentiality). This should include:

- data on the type and number of Never Events, including historical context and related incidents

- the learning stemming from the incidents, with a particular focus on the system changes made to reduce the probability of recurrence
- how learning has been shared at all levels in the organisation and externally.

7.5. In some instances Never Events may be identified some time after they occurred. While delayed identification is not a factor in determining whether or not an incident is a Never Event, it may have a bearing on the improvements deemed necessary following investigation (eg where subsequent procedural changes mean that additional action may be unnecessary).

7.6. Where a Never Event is discovered by one organisation but appears to be the responsibility of another, the 'discovering' organisation should inform the originating organisation and is not required to report the incident as its own.

7.7. Some definitions of Never Events have changed in this revision of the framework. Where incidents that used to meet the definition of a Never Event but no longer do so (for example, wrong level spinal surgery) are identified after publication of the new framework, they should not be reported as Never Events even if they occurred before publication. Previously reported Never Events, even if they no longer meet the definition of a Never Event, should not be retrospectively downgraded.

7.8. As a general rule, local healthcare organisations should consider the status of the incident at the time it occurred, particularly whether it met the Never Event criteria. If the incident pre-dated clear, easy to apply guidance on prevention or the introduction of the Never Event framework in 2009, it is not a Never Event. But if such guidance was available at the time but not acted on, the incident could be considered a Never Event in all but name, and treated appropriately.

8. Failure to report a Never Event

8.1. Failure to report a Never Event is unacceptable and can signal cultural and safety failings in an organisation. The reporting and investigation of Never Events may be an indicator of the organisation's attitude to patient safety

and openness. As noted by Sir Liam Donaldson: “to err is human, to cover up is unforgivable, and to fail to learn is inexcusable”.[6]

8.2 In some circumstances it may not be apparent that an incident is a Never Event until there has been some degree of investigation. In these circumstances, the possibility that a Never Event has occurred should be reported as soon as it is identified.

8.3. Failure to report a Never Event should be thoroughly investigated by the relevant organisational lead, with support from commissioners as required, to understand what prevented the recognition and/or reporting of the incident. This may lead to efforts to develop knowledge/awareness about incident reporting (and Never Events more specifically) and/or broader initiatives to measure and improve reporting culture as part of a wider safety culture in the organisation. If the failure to report was a deliberate act, this is likely to constitute a serious failing by the staff and organisation involved and will likely constitute a breach of Care Quality Commission (CQC) requirements (regulations 16 and 18 of the CQC (Registration) Regulations 2009).

[6] Sir Liam Donaldson, speaking at the launch of the World Alliance for Patient Safety, Washington, DC, 27 October 2004, calling to mind and adding to the comments made by Susan Sheridan (the wife and mother of victims of medical error).

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