NHS England

# Draft revised Never Events Policy Framework for consultation



| NHS England INFORMATION READER BOX | | |
|---|---|---|
| **Directorate** | | |
| Medical | Commissioning Operations | Patients and Information |
| **Nursing** | Trans. & Corp. Ops. | Commissioning Strategy |
| Finance | | |

| **Publications Gateway Reference:** | **02320** |
|---|---|
| **Document Purpose** | Consultations |
| **Document Name** | Draft revised Never Events Policy Framework for consultation |
| **Author** | NHS England/Patient Safety Domain |
| **Publication Date** | 06 October 2014 |
| **Target Audience** | CCG Clinical Leads, CCG Accountable Officers, Medical Directors, Directors of Nursing, NHS England Area Directors, GPs |
| **Additional Circulation List** | |
| **Description** | A core team of patient safety experts and health professionals have produced the initial draft of the revised framework, including professional organisations and NHS England staff in regional and area offices. Feedback received in consultation on the Standard Contract was also used to update sections of the policy. We are now seeking wider views and opinions on the proposed changes via the public consultation. The consultation closes on 31 October 2014. Responses will then be analysed and we will aim to publish the final revised Never Events Policy Framework by the end of the year, along with a summary of the consultation's findings. |
| **Cross Reference** | The never events policy framework |
| **Superseded Docs** (if applicable) | |
| **Action Required** | Review and feedback. |
| **Timing / Deadlines** (if applicable) | **By 31 October 2014** |
| **Contact Details for further information** | Joan Russell<br>Head of Patient Safety<br>Skipton House<br>80 London Road<br>London SE1 6LH<br>07736 814478 |

## Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet

# Draft revised Never Events Policy Framework for consultation

Version number: 1

First published: 06 October 2014

Prepared by: NHS England Patient Safety Domain in partnership with professional organisations and NHS England staff in regional and area offices.



Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.

# Contents

# 1 Purpose

1.1 This policy provides guidance for healthcare workers, clinicians, managers, boards and accountable officers, concerning responsibilities and appropriate responses to never events.

1.2 Our shared vision of high quality, compassionate, and constantly-improving health care requires NHS England 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]

1.3 The never events policy supports our vision by requiring honesty, accountability and learning in response to a group of serious incidents that should be avoidable if available preventative measures have been implemented.

1.4 'Never events' do not necessarily specify the worst class of serious incident or grant a particular incident type a higher priority, nor does this label ensure proper investigation of incidents and learning – this is better addressed through the Serious Incident framework. However, as never events may highlight potential weaknesses in how an organisation manages fundamental safety processes, this policy provides the NHS with an essential lever for improving patient safety.

1.5 This policy will continue to evolve in response to wider changes in healthcare, and debate about its content will remain emotive. Within this context, it is notable that while most serious incidents are preventable to varying degrees, classifying incident types as never events will not prevent their occurrence. However, in focusing greater scrutiny on these preventable incidents the policy aims to drive patient safety improvement more widely.



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

1.6 Whilst recognising and classifying incidents as never events is essential for their continued reduction, the reporting of all incident types remains critical to achieving our vision.

## 2 Definition

2.1 Never events are a particular type of serious incident that meet the following criteria:

2.1.1 Never events should not occur if national guidance or safety recommendations that provide strong organisational barriers[2] have been implemented by all healthcare providers.

2.1.2 The intent of this policy is to improve patient safety, so although severe harm or death is not required for a *particular* incident to be a never event, the list of designated never events does not include those where potential for significant patient harm or death is remote or unlikely.

2.1.3 There is evidence that the category of never event has occurred in the past, for example through reports to the National Reporting and Learning System (NRLS), and a risk of recurrence remains. As the aim of this policy is to drive patient safety improvement, it excludes those incident types that have been eradicated by technical, medical, or scientific advances.

2.1.4 Occurrence of the never event is easily recognised and clearly defined – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

2.2 The 14 types of incident that meet these criteria are listed in an appendix to this document, which will be updated annually by NHS England.



[2] These include: physical barriers (e.g. special equipment that makes it impossible to connect medications via the wrong route); time and place barriers (e.g. withdrawal of concentrated medication from settings to prevent accidental selection) or systems of double or triple checking, 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 Background

3.1 This document refreshes the policy first developed by the National Patient Safety Agency in 2009, and updated by the Department of Health in 2011 (when the list was expanded to 25 never events).

3.2 Never events are a subset of serious incidents and therefore, this policy should always be read in conjunction with the Serious Incident Framework.

3.3 Learning lessons from incidents requires timely incident reporting, which in turn requires a fair, open, and just culture that abandons blame as a tool. In part this is 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." [3]

3.4 Failure to report a never event is unacceptable and a potential sign of cultural and safety failings in an organisation. The reporting and analysis of never events is therefore a probable indicator of the organisational attitude towards patient safety and openness. As has been noted by Sir Liam Donaldson, "to err is human, to cover up is unforgivable, and to fail to learn is inexcusable".[4]

3.5 This policy is set nationally, and all sections of healthcare organisations - from 'ward to board' - must play their part. Ultimately however, and for the sake of clarity, it is the leadership of an organisation who is held accountable for the occurrence of never events and crucially, for the organisation's response.

3.6 Occurrence of a single never event may be taken as a sign by the Chief Executive or relevant organisational leader that he/she must take immediate steps to ensure that patient safety systems and procedures are reviewed,



[3] National Patient Safety Agency, '*Seven Steps to Patient Safety*'', 2004 – 2009. Available at http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

[4] 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).

ensuring that any changes required are implemented to prevent recurrence. Repeated never events, particularly of the same type, may demonstrate a failure of the organisation's leadership to take patient safety seriously.

# 4 Roles and responsibilities

The following section summarises policy requirements when a never event is suspected (as described in greater detail in the Serious Incident Framework).

4.1 Providers - Managing the response to never events is a critical component of corporate and clinical governance. Providers must establish effective governance mechanisms to ensure the following:

4.1.1 Timely reporting and liaison with their commissioning bodies.

4.1.2 Compliance with reporting and liaison requirements with agencies such as Monitor, Care Quality Commission (CQC), Public Health England, Health and Safety Executive, and coroners. Never events are clearly defined as serious incidents and therefore, must be reported to the CQC. This obligation can be met by reporting the never event to the NRLS.

4.1.3 Arranging and resourcing investigations in response to never events, including processes to ensure the following:

- Early, meaningful and sensitive engagement with affected patients and/or their families/carers from the point that the never event is identified, through investigation and action planning, to closure of the incident. Information should be shared in line with *Being Open* guidance, the statutory duty of candour, and the contractual duty of candour.
- Investigations are undertaken by appropriately trained and resourced staff and/or teams that are sufficiently removed from the incident to be able to provide an objective view.
- Investigations follow a systems-based methodology to ensure root causes, and focused actions and learning are identified.
- Staff involved in the never event are supported and treated fairly, with reference to the NPSA Incident Decision Tree, and with the primary focus of investigation remaining on the wider organisational barriers.

- Access to subject matter experts, communications expertise, administrative support and/or additional resources as required.
- Monitoring action plans until fully implemented, with oversight by organisation leaders.
- Quality assurance processes to ensure completion of high quality investigation reports and action plans to enable timely learning, and to prevent recurrence.
- Mechanisms and effective communication to facilitate the sharing of lessons learned across the organisation and more widely where required.

4.2 NHS England – as the national commissioning body, NHS England has overall policy responsibility for never events and patient safety in general. Its role in relation to never events is twofold:

4.2.1 Leading and enabling the commissioning system NHS England Area Teams (and London Regional Office) maintain oversight and surveillance of never event investigations undertaken in NHS-Funded care, as part of their role in assuring effective operation of the commissioning system. In Clinical Commissioning Group (CCG)-commissioned care, Area Teams assure CCG systems for managing never events via the CCG assurance process. Regional teams are also responsible (upon request) for advising commissioners on investigation types and where relevant, determining whether wider, independent investigations (e.g. into service configuration) are needed in response to ever events and if so, commissioning those investigations.

4.2.2 Direct Commissioning - NHS England directly commission a range of services (e.g. GPs, community pharmacy, offender health), and is therefore responsible for holding providers to account for never events that occur in their directly commissioned care. In particular, Area Teams are responsible for closing and assuring never event investigations.

4.3 The never events policy is included in the NHS Standard Contract to ensure commissioners and providers (both NHS, and independent providers of NHS care) discuss and agree a shared understanding for application of the policy. This also helps ensure a nationally consistent response to never events, as set

out in this guidance, and annual review of the never events list as part of the annual Standard Contract consultation.

## 5 Requirements - when a never event is suspected

5.1 The following table summarises policy requirements when a never event is suspected (as described in greater detail in the Serious Incident Framework. Please also refer to local procedures):


| |
|---|
| Inform patient/family/carer as soon as possible.<br>Report within two working days to NRLS and STEIS* (and thus CQC). |
| Discuss and agree never event with commissioner and Area Team (AT) |
| Conduct investigation (root cause analysis, significant event audit) |
| Review learning and implementation plan with commissioner and AT |
| Consider never event reports and implications at public board meeting |
| Share appropriate learning with NRLS |
| Include NE numbers and type in annual reports and quality accounts |

* Where organisations do not have direct access to the National Reporting and Learning System (NRLS) and Strategic Executive Information System (StEIS), alternative arrangements are in place, via commissioners.

5.2 The patient/family/carer must be informed as soon as possible following a never event (or potential never event) and details of the conversation must be documented in the patient records; disclosure must not be delayed while never event status is determined. All staff should be familiar with related requirements of *Being Open*[5], and the *Duty of Candour* which requires providers to be open with patients when things go wrong (from October 2014 for

[5] National Patient Safety Agency, '*Being Open: communicating patient safety incidents with patients, their families and carers'*, November 2009, available at: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726.

all NHS Trusts, Foundation Trusts and special health authorities, and by April 2015 for all other providers). Service Condition 35 of the 2014/15 NHS Standard Contract sets out provider requirements in relation to the Duty of Candour. The Care Quality Commission (CQC) may use its enforcement powers in cases of failure to comply.

5.3 The incident should be reported on the organisation's local risk management system. For both clear and suspected never events, a Level 2 (Comprehensive) Investigation should be undertaken as set out in the Serious Incident Framework,[6] and reported on StEIS as a never event within two working days of occurrence or identification. The incident report should be uploaded to the NRLS as soon as possible, ideally within the same timescale, although it is acknowledged uploading of data to the NRLS is often carried in batches and may therefore be less frequent.

5.4 Never events must be reported to both StEIS and to the NRLS until a single system has been developed to integrate the two systems.[7] Crucially, reports to both systems must clearly label the incident as a never event even where there is uncertainty at the time of reporting (in the StEIS 'never events' field, and in NRLS using the words 'never event' in the free text field). If necessary, incident reports on StEIS can be retrospectively amended to downgrade from a never event (a clear audit trail explaining the rationale for the change and who authorised is required).

5.5 Never events must be highlighted to the relevant commissioner within two working days as per the Serious Incidents Framework. While this may be automatic with StEIS/local incident reporting, timely personal contact between relevant directors should follow. Where there is doubt about an incident's status, the commissioner and provider must agree categorisation with urgency (while advice may be sought from NHS England, this decision rests with the commissioner and provider).



[6] Footnote to be updated following consultation and publication of the revised serious incident framework.
[7] Data is reported by NHS England here: http://www.england.nhs.uk/ourwork/patientsafety/never-events/ne-data/.

5.6 Response to a never event should be coordinated by the medical or nursing director (or accountable leader with delegated responsibility) as soon as a potential never event is identified. This includes: leading on final confirmation of never event status; organising the investigation; discussion with external parties, including patients/representatives and commissioners; identifying underlying contributory factors; and implementation of required actions and learning. It is not appropriate for this task to be delegated to junior staff.

5.7 Investigation teams should be multidisciplinary and include representation from each professional group involved. If necessary, organisations should seek additional training to ensure staff are able to undertake appropriately detailed investigations, in line with human factors principles and relevant methodologies (e.g. root cause analysis, significant event audit).

5.8 Organisational leaders (board or equivalent) are responsible for ensuring that all relevant learning is captured and implemented effectively - this is the most crucial aspect of this policy. Learning outcomes should be monitored through established monitoring structures and processes.

5.9 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, where possible:

- Data on the type and number of never events, including historical context and related incidents.
- The learning derived from the incidents, with a particular focus on the system changes that have been made to reduce the probability of recurrence.
- How learning has been shared at all levels within the organisation, and externally.

5.10 In some instances never events may be discovered some time after the incident occurred. While delayed discovery is not a factor in determining whether an incident is a never event, it may have a bearing on the improvements deemed necessary following investigation (e.g. where subsequent procedural changes mean that additional action may be unnecessary).

5.11 Where a never event is discovered by one organisation but appears to be the responsibility of another, the 'discovering' organisation should make all reasonable effort to inform the originating organisation, and is not required to report the incident as their own.

# 6 Failure to declare or report a never event

6.1 Failure to report a never event which subsequently comes to light through a third party route, (e.g. a coroner's inquest, media report, or patient complaint) is a serious failing on the part of staff involved and the organisation, and is likely to constitute a breach of CQC requirements (*Regulation 16 and 18 of the CQC (Registration) Regulations 2009*) and Service Condition 33 of the 2014/15 NHS Standard Contract, which sets out provider responsibilities for reporting incidents.

6.2 In some circumstances, it may not be apparent that a never event has occurred until some degree of investigation has occurred. In these circumstances, the possibility that a never event has occurred should be reported as soon as it is recognised.

6.3 For any failure to report a never event, commissioners should consider using the full range of powers afforded via the NHS Standard Contract, including the following remedial actions:

- A detailed review and analysis of the circumstances leading to the failure to recognise and/or report the incident; relevant training (where indicated); and consideration of disciplinary action against individuals where there is evidence of deliberate non-disclosure.
- Cost recovery where there has been a failure in relation to declare or report (see section 7 below).
- Requiring the provider's chief executive to deliver full written and verbal explanations of the failure to report, the circumstances of the incident and the actions taken in response, in public to the CCG board and to the relevant patient (subject to their agreement).

- Continued monitoring of agreed actions and use of powers to intervene (as per the NHS Standard Contract), where satisfactory progress is not made and patients remain at risk.

# 7 Cost Recovery

7.1 It may be appropriate for commissioners to recover costs in relation to never events in particular circumstances.

- Failure to declare or report a never event within specified timeframes (e.g. where there is evidence that there were opportunities for the organisation to identify and report the incident)
- In response to never event clusters (two or more never events of the same type) where there is evidence that organisations have failed to support learning or implement actions plans drafted in response to past never events. Cost recovery is only appropriate in this circumstance if adequate time has passed for embedding learning and implementing past recommendations

7.2 Recovery by the Responsible Commissioner of the costs to that Commissioner of the procedure or episode (or, where these cannot be accurately established, £2,000) plus any additional charges incurred by that Commissioner (whether under this Contract or otherwise) for any corrective procedure or necessary care in consequence of the never event. . This is in keeping with the principle of appropriate remedy or 'putting things right'

7.3 Commissioners are also encouraged to apply discretion and/or waive their right to recover costs when early open disclosure to patient and commissioner has occurred.