NHS England

Revised Never Events Policy and Framework

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

Publications Gateway Reference:	**03199**
Document Purpose	Policy
Document Name	Revised Never Events Policy and Framework
Author	NHS England Patient Safety Domain
Publication Date	27 March 2015
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of Nursing
Additional Circulation List	
Description	The Revised Never Events Policy and Framework provides clarity for staff providing and commissioning NHS funded services who may be involved in identifying, investigating or managing Never Events. It is relevant to all NHS funded care.
Cross Reference	Serious Incident Framework
Superseded Docs (if applicable)	The Never Events Policy Framework - October 2012
Action Required	Implement policy within organisations providing NHS funded care
Timing / Deadlines (if applicable)	**To be implemented from 1 April 2015**
Contact Details for further information	Patient Safety Domain NHS England Skipton House 80 London Road London SE1 6LH

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. **NB:** The NHS Commissioning Board (NHS CB) was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the NHS Commissioning Board has used the name NHS England for operational purposes."

Revised Never Events Policy and Framework

Version number: 1

First published: 27 March 2015

Prepared by: NHS England Patient Safety Domain

Contents

Foreword from Dr Mike Durkin...…….5

1 Policy Statement……6
2 Acknowledgements……...6
3 Purpose……...6
4 Definition……7
5 Background……..…8
6 Roles and responsibilities……9
7 Requirements – when a never event is suspected……12
8 Failure to report a never event……...16
9 Cost Recovery……...17

Appendix 1 The Never Events List 2015/16……..19
Appendix 2 Rationale for amendments to the Never Events List……...29

Foreword

There is universal agreement on the need to protect patients from avoidable harm. How this can be achieved is often more complex. In the case of Never Events, despite there being defined processes and procedures to prevent them, on occasions they continue to occur, often with tragic consequences for patients, their families and the staff involved. From the data we publish on Never Events it is clear we have work to do to eradicate these serious incidents. We must investigate the reasons why they occur, learn from them, and take revised action to prevent them at both a local and national level.

This will require root cause analysis which will not only examine issues such as compliance with, and the robustness of, local processes and procedures; but also the role of human factors. This is an organisational responsibility that covers all NHS funded care and calls for lessons to be learned and solutions to be applied within a culture of openness rather than blame.

The rationale behind a type of serious incident being included on the Never Events list is that there are barriers to prevent it from occurring and guidance is in place to ensure it should never happen. However, it is acknowledged that the effective implementation of such procedures and guidance relies heavily on both the organisation and the workforce within it. It is therefore recommended that all organisations involved in the management of Never Events pay particular attention to the principles of human factors. Further information can be found at http://patientsafety.health.org.uk/sites/default/files/human_factors_in_healthcare_trainer_manual_en_march_2013.pdf.

We are also working at a national level to help prevent these incidents. NHS England commissioned a Surgical Never Events Taskforce to examine and clarify the reasons for the persistence of Never Events in the operating theatre environment, where they are most commonly reported. The taskforce produced a report in February 2014 making a number of recommendations, which we are now working towards putting into practice. This includes the development of the concept of new national and local safety standards for the continuous improvement of the safety of patients undergoing invasive procedures.

This revised Never Events Policy and Framework follows consultation with a wide range of stakeholders and offers a useful reference point for boards, clinicians, staff and patients. Feedback from stakeholders has helped us redefine our policy on Never Events and refine the Never Events list, with the focus always remaining on learning and improvement. It should be remembered that Never Events are types of serious incidents and that while this framework sits separate to the Serious Incidents Framework, the two should be considered in conjunction with one another.

Never Events are key indicators that there have been failures to put in place the required systemic barriers to error and their occurrence can tell commissioners something fundamental about the quality, care and safety processes in an organisation. Therefore, the framework is a key lever for commissioners and NHS England supports the commissioning system to continuously improve quality by reviewing the framework and ensuring that it is fit for purpose. We ask that all boards consider this refreshed framework and that medical and nursing directors within provider and commissioning organisations, take a lead to ensure that work is taken forward to continue improving the way we identify, investigate and learn from incidents to help eradicate Never Events from NHS care.

Dr Mike Durkin
Director of Patient Safety
NHS England

1 Policy statement

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

1.2 It aims to provide clarity for staff providing and commissioning NHS funded services who may be involved in identifying, investigating or managing Never Events. It is relevant to all NHS funded care.

2 Acknowledgements

2.1 This policy and framework has been developed by the NHS England Patient Safety Domain following a wide consultation with patients, healthcare providers, commissioners, regulatory and supervisory bodies, patient safety experts, professional organisations and Colleges.

2.2 The Patient Safety Domain sincerely thank the core team of commissioners and providers who were involved in reviewing the consultation feedback and who significantly contributed to the development of this policy and framework.

3 Purpose

3.1 Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so this policy and framework provides the NHS with an essential lever for improving patient safety. Regardless of the outcome of an individual Never Event, Never Events are always considered serious incidents as described in the Serious Incident Framework.

3.2 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]

3.3 The Never Events policy and framework 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.

3.4 This policy and framework 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 and framework aims to drive patient safety improvement more widely.

3.5 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.

4 Definition

4.1 The types of incident defined as Never Events using the definition below, are listed in an appendix to this document.

4.2 Never Events are a particular type of serious incident that meet **all** the following criteria:

4.2.1 They are **wholly preventable**, where guidance or safety recommendations that provide strong systemic protective barriers[2] **are available at a national level, and should** have been implemented by all healthcare providers.

---

[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.*

[2] As compiled by NHS England patient safety experts and health professionals and referenced in the Never Event list, 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 only where 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.

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

4.2.3 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[4].

4.2.4 **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.

4.3 It is anticipated the Never Event list will be reviewed annually by NHS England.

5 Background

5.1 Learning lessons from incidents requires timely incident reporting, which in turn requires a fair, open, and just culture that rejects 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."* [5]

5.2 Failure to report a Never Event is unacceptable and a potential sign of cultural and safety failings in an organisation. The reporting and investigation of Never

[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 of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery) or psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).
[4] 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.
[5] 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/

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"*.[6]

5.3 This policy and framework 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.

5.4 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, 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.

6 Roles and responsibilities

The following section summarises the policy requirements when a Never Event is identified. Never Events are Serious Incidents and the principles guiding the roles and responsibilities of the Providers and Commissioners will be the same across both types of incident. (Also see section three of the Serious Incident Framework)

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

[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).

6.1 **Providers of NHS funded care**

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:

- 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 and the 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 contributory factors, 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[7]. The primary focus of the investigation should be on identifying underlying factors that contributed to the Never Event occurring, including understanding why the relevant barriers were not properly in place to prevent the Never Event.
- Access to subject matter experts, communications expertise, administrative support and/or additional resources as required.
- Quality assurance processes to ensure completion of high quality investigation reports and action plans to enable timely learning, and to prevent recurrence.
- Monitoring action plans until fully implemented, with oversight by organisation leaders.

[7] The Incident Decision Tree aims to help the NHS move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. NHS England is currently redeveloping the Incident Decision Tree with a plan to relaunch early 2015/16

- Mechanisms and effective communication to facilitate the sharing of lessons learned across the organisation and more widely where required.

6.1.1 Providers must also establish effective governance mechanisms to ensure the following:

- Timely reporting and liaison with their commissioning bodies.
- Compliance with reporting and liaison requirements with agencies such as Monitor, the Trust Development Authority, the Care Quality Commission (CQC), Public Health England, the Health and Safety Executive, and coroners. Never Events are clearly defined as serious incidents and therefore, must be reported to the CQC[8]

6.2 Commissioners of NHS funded care: NHS England

NHS England are committed to ensuring that learning from Never Events is the primary purpose of reporting and investigating them.

NHS England's role in relation to Never Events is twofold:

- Leading and enabling the commissioning system. NHS England's sub - regions maintain oversight and surveillance of Never Events in NHS-Funded care, as part of their role in assuring effective operation of the commissioning system. In Clinical Commissioning Group (CCG)-commissioned care, sub - regions assure CCG systems for managing Never Events via the CCG assurance process. Sub - regions 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 Never Events and if so, commissioning those investigations.

[8] The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2010, available at http://www.legislation.gov.uk/uksi/2010/781/contents/made

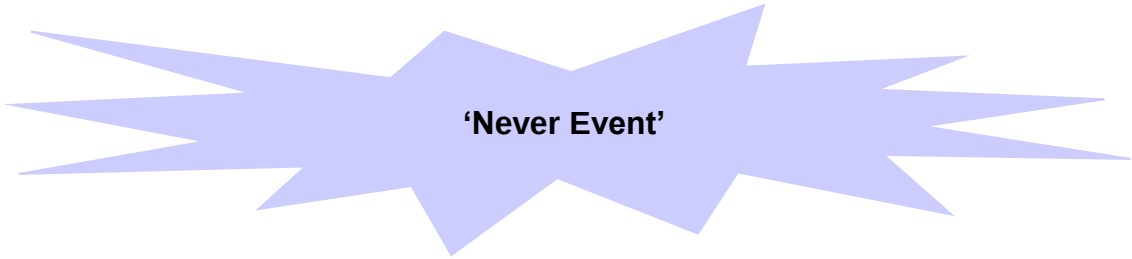
- Direct Commissioning - NHS England directly commission a range of services (e.g. GPs, community pharmacy, offender health), and are therefore responsible for holding providers to account for Never Events that occur in their directly commissioned care. In particular, sub - regions are responsible for assuring and closing Never Event investigations.

Commissioners may close incidents on StEIS once they are assured the action plan is in place and is being monitored to completion

6.3 The Never Events Policy and Framework is referred to in the NHS Standard Contract to ensure commissioners and providers 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 policy and framework, and supports the annual review of the Never Events list as part of the annual Standard Contract consultation.

7 Requirements - when a Never Event is identified

7.1 The following table summarises the requirements when a Never Event is identified. Specific timeframes are described in more detail in the Serious Incident Framework.



Inform organisational leaders that a Never Event has occurred following local policy

Inform patient/family/carer as soon as possible following ‘Being Open’ principles.

Discuss and agree Never Event with commissioner.
Report on StEIS & NRLS*

Conduct investigation using systematic methodology e.g. RCA/ SEA

Review learning and implementation plan with commissioner

Consider Never Event reports and implications at public board meeting

Share appropriate learning on StEIS and NRLS

Include Never Event types and numbers in annual reports and quality accounts

*Where organisations do not have direct access to the Strategic Executive Information System (StEIS), alternative arrangements will be in place, via commissioners to submit a report onto this system

7.2 The patient/family/carer must be informed as soon as possible when a Never Event occurs. 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*[9], and the *Duty of Candour* [10]

7.3 The incident should be reported on the provider's local risk management system and on StEIS within two working days of identification. Never Events must be reported to both StEIS and to the NRLS until a single system has been developed to integrate the two systems. Crucially, reports to both systems must clearly label the incident as a Never Event even where there is uncertainty at the time of reporting (both systems contain a Never Events field). If necessary, and following agreement of provider and commissioner, incident reports on StEIS can be retrospectively amended to downgrade from a Never Event ensuring a clear audit trail explaining the rationale for the change and who authorised is recorded.

7.4 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.

7.5 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 whether a Never Event has occurred, the commissioner and provider must agree categorisation

[9] 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.
Investigation resources - http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60180

[10] The Department of Health introduced fundamental Standards, the Duty of Candour and the fit and proper person requirement as CQC registration requirements. The measures will be implemented in a phased approach. For further details visit: https://www.gov.uk/government/consultations/fundamental-standards-for-health-and-social-care-providers. It requires providers to notify anyone who has been subject (or someone lawfully acting on their behalf, such as families and carers) to an incident involving moderate or severe harm or death. This notification must include an appropriate apology and information relating to the incident. Failure to do so may lead to regulatory action

(while advice may be sought from NHS England, this decision rests with the commissioner and provider).

7.6 The response to a Never Event should be coordinated by the medical or nursing director (or accountable leader with delegated responsibility) as soon as a 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.

7.7 Never Events must be investigated in line with the Serious Incident Framework. 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).

7.8 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 and framework. Learning outcomes should be monitored through robust monitoring structures and processes.

7.9 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.

7.10 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).

7.11 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 their own.

8 Failure to report a never event

8.1 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 identified

8.2 Failure to report a Never Event which subsequently comes to light through a third party route, (e.g. a coroner's inquest, claim, 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.

8.3 For any failure to report a Never Event where there is evidence that there were opportunities for the provider to identify and report the incident, 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.
- Requiring the provider's chief executive (or equivalent) to deliver full written and verbal explanations of the failure to report a known Never Event, 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.

9 Cost Recovery

9.1 Cost recovery is secondary to the process of reporting Never Events, learning from them via robust investigation, and implementation of that learning to prevent any future occurrence.

9.2 That said, the NHS should not pay for care that is so substandard as to result in a Never Event. For this reason Commissioners should seek to withhold payment for the cost of the episode of care in which a Never Event has occurred and any subsequent costs involved in treating the consequences of a Never Event.

9.3 Commissioners are able to decide to waive these contractual terms depending on individual circumstances, applying the principles of proportionality and taking into account previous performance and the Provider's response to the Never Event occurring. This decision should be taken in discussion with the Provider, although the default should be to recover costs.

9.4 It is possible that for certain Never Events, the costs of the procedure linked to that event could be extremely large, meaning the Commissioner could impose a significant financial penalty on the Provider. We are clear that the principle that Commissioners should apply is that the NHS should not be paying for care that has fallen so short of standards as to result in a Never Event. However, Commissioners may wish to avoid recovering costs where Providers can demonstrate robust action has been taken or where the loss of income would have a detrimental effect on patient care.

9.5 In some cases, the cost of the procedure in which a Never Event has occurred could represent the cost of care over a significant period of time, for example in a

mental health inpatient setting. If the period of care has lasted a number of years, Commissioners could argue for the recovery of costs running to many hundreds of thousands of pounds. This would be disproportionate. Where this may be an issue, Commissioners and Providers should discuss what principles to apply while agreeing contracts. We suggest they agree to cap cost recovery to the equivalent of a month's inpatient stay, or at a monetary level of, for example, £15,000.

9.6 Similarly the costs of treating the long-term consequences of a Never Event could run to extremely high sums. Again, a cap or limit should be decided upon before contracts are agreed. Where the subsequent treatment is by a Provider other than that in which the original error occurred, it is the original Provider that should be subject to any cost recovery.

9.7 There is no reason why contractual agreements that are not covered by the NHS Standard Contracts should not also include the national list of Never Events as part of their contractual terms where relevant. Primary Care and Social Care Providers will undertake some activities associated with a number of the Never Events, and so all contracts for NHS services should reflect the aspects of this policy that are relevant.

9.8 Where the standard contracts refer to the cost of the procedure (acute, community and ambulance services), this value should be equal to the latest reference cost for the relevant Healthcare Resource Group (HRG) associated with the procedure/care during which the Never Event occurred. Where relevant reference cost data is not available or the care is commissioned in other contractual units, Commissioners and Providers should, prior to finalising contracts, agree alternative cost recovery mechanisms, using for example, the costs associated with the relevant contractual unit up to the value of an appropriate cap. Cost recovery in mental health and learning disability settings should be equal to the cost of one month of care provision based on the Provider's annual average daily rate costs, or a pre-agreed value.

Appendix 1 – The Never Events List 2015/16

The following never events list is the list that all organisations providing NHS care should use. It is applicable for all incidents that occur on or after 1 April 2015.

SURGICAL
1. Wrong site surgery
A surgical intervention performed on the wrong patient or wrong site (for example wrong knee, wrong eye, wrong limb, wrong tooth or wrong organ); the incident is detected at any time after the start of the procedure. • Includes wrong level spinal surgery and interventions that are considered surgical but may be done outside of a surgical environment e.g. wrong site block (unless being undertaken as a pain control procedure), biopsy, interventional radiology procedures, cardiology procedures, drain insertion and line insertion e.g. PICC/ Hickman lines. • Excludes interventions where the wrong site is selected because of unknown/unexpected abnormalities in the patient's anatomy. This should be documented in the patient's notes. • Excludes incidents where the wrong site surgery is due to incorrect laboratory reports/ results or incorrect referral letters **Setting:** All patients receiving NHS funded care. **Guidance:** - *Safer Practice Notice – Standardising Wristbands improves patient safety, 2007,* available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824 - *Patient Safety Alert – WHO Surgical Safety Checklist, 2009,* available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/ - *How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901 *- Safe Anaesthesia Liaison Group – Stop before you block 2011* https://www.rcoa.ac.uk/sites/default/files/CSQ-PS-sbyb-supporting.pdf *-Standards for providing a 24 hour interventional radiology service, 2008, The Royal College of Radiologists.* Available at http://www.rcr.ac.uk/docs/radiology/pdf/Stand_24hr_IR_provision.pdf
2. Wrong implant/prosthesis
Surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the surgical plan either prior to or during the

procedure and the incident is detected at any time after the implant/prosthesis is placed in the patient.

- Excludes where the implant/prosthesis placed in the patient is intentionally different from the surgical plan, where this is based on clinical judgement at the time of the procedure
- Excludes where the implant/prosthesis placed in the patient is intentionally planned and placed but later found to be suboptimal.

Setting: All patients receiving NHS funded care.

Guidance:
- *Safer Practice Notice – Standardising Wristbands improves patient safety, 2007,* available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824
- *Patient Safety Alert – WHO Surgical Safety Checklist, 2009,* available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/
- *Safer Surgery Checklist for Cataract Surgery,* 2010, available at http://www.rcophth.ac.uk/page.asp?section=365&sectionTitle=Information+
- *How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901

3. Retained foreign object post-procedure

Retention of a foreign object in a patient after a surgical/invasive procedure.

'Surgical/invasive procedure' includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside of the surgical environment e.g. central line placement in ward areas

'Foreign object' includes any items that should be subject to a formal counting /checking process at the commencement of the procedure and a counting /checking process before the procedure is completed (such as swabs, needles, instruments and guide wires) **except where:**

- Items are inserted any time before the procedure that are not subject to the formal counting/checking process, with the intention of removing them during the procedure and they are not removed
- Items are inserted during the procedure that are subject to the counting/ checking process, but are intentionally retained after completion of the procedure, with removal planned for a later time or date and clearly recorded in the patients notes

- Items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further action to locate and/or retrieve would be impossible or be more damaging than retention

See the **Appendix A on page 11** for examples of correct application of this never event definition.

Settings: All patients receiving NHS funded care.

Guidance:
- *Standards and recommendations for safe perioperative practice*, 2007, available at http://www.afpp.org.uk/news/safe-practice-highlighted-in-new-afpp-publication
Accountable items, swab, instrument and needle count, AfPP 2012, available at http://www.afpp.org.uk/careers/Standards-Guidance
- *Patient Safety Alert – WHO Surgical Safety Checklist, 2009,* available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/
- *How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901
- *Reducing the risk of retained throat packs after surgery*, 2009, available at -http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59853
-*Reducing the risk of retained swabs after vaginal birth and perineal suturing,* 2010, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=74113
- *Risk of harm from retained guide wires following central venous access*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132829
- *Tracking subsequent removal of intentionally retained swabs*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132834&p=2

MEDICATION

4. Mis – selection of a strong potassium containing solution

Mis - selection refers to:

- When a patient intravenously receives a strong[11] potassium solution rather than an intended different medication

Setting: All patients receiving NHS funded care.

Guidance:
- *Patient safety alert – Potassium chloride concentrate solutions, 2002 (updated 2003),* available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882

[11] ≥10% potassium w/v (e.g. ≥ 0.1g/ml potassium chloride, 1.3mmol/ml potassium chloride)

5. Wrong route administration of medication

The patient receives one of the following:

- Intravenous chemotherapy administered via the intrathecal route
- Oral/enteral medication or feed/flush administered by any parenteral route
- Intravenous administration of a medicine intended to be administered via the epidural route

Setting: All patients receiving NHS funded care.

Guidance:
- HSC2008/001: Updated national guidance on the safe administration of intrathecal chemotherapy, 2008, available at *http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_086870*

- Rapid Response Report NPSA/2008/RRR004 using vinca alkaloid minibags (adult/adolescent units), 2008, available at *http://www.nrls.npsa.nhs.uk/resources/?entryid45=59890*

- Minimising Risks of Mismatching Spinal, Epidural and Regional Devices with Incompatible Connectors, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132897

- Patient safety alert on non-Luer spinal (intrathecal) devices for chemotherapy 2014. available at http://www.england.nhs.uk/2014/02/20/psa-spinal-chemo/

- Patient Safety Alert NPSA/2007/19 - Promoting safer measurement and administration of liquid medicines via oral and other enteral routes, 2007, available at *http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808*

- Patient Safety Alert NPSA/2007/21, Safer practice with epidural injections and infusions, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807

6. Overdose of Insulin due to abbreviations or incorrect device

Overdose refers to:

- When a patient receives a tenfold or greater overdose of insulin because a prescriber abbreviates the words ‘unit’ or ‘international units’ , despite the care setting having an electronic prescribing system in place
- When a health care professional fails to use a specific insulin administration device i.e. does not use an insulin syringe or insulin pen to measure insulin

Setting: All patients receiving NHS funded care.

Guidance:
- *Rapid response report – Safer administration of insulin*, 2010, available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287Diabetes: insulin, use it safely Patient information booklet 03 January 2011 - NHS Diabetes and Kidney Care

Available at
http://www.nhsiq.nhs.uk/resource-search/publications/nhs-dakc-insulin-use-it-safely.aspx

Insulin use safety: Patient Safety Resource Centre The Health Foundation
Available at

http://patientsafety.health.org.uk/area-of-care/diabetes/insulin-use-safety

7. Overdose of methotrexate for non-cancer treatment

Overdose refers to

- When a patient receives methotrexate ,via any route, for non-cancer treatment which results in more than the intended weekly dose being taken, despite the care setting having an electronic prescribing and administration system , or in primary care an electronic prescribing and dispensing system, in place

Setting: All patients receiving NHS funded care.

Guidance:
- *Patient safety alert - Improving compliance with oral methotrexate guidelines*, 2006, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800

8. Mis – selection of high strength midazolam during conscious sedation

Mis - selection refers to

- When a patient receives an overdose due to the selection of a high strength midazolam preparation (5mg/ml or 2mg/ml) rather than the 1mg/ml preparation, in a clinical area performing conscious sedation.
- Excludes clinical areas where the use of high strength midazolam is appropriate. These are generally only in general anaesthesia, intensive care, palliative care, or where its use has been formally risk assessed within an organisation.

Setting: All healthcare premises.

Guidance:

- Rapid Response Report - Reducing risk of overdose with midazolam injection in adults, 2008, available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59896&p=2

- Safe sedation, analgesia and anaesthesia with the radiology department, 2003, available at http://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=186

- Over sedation for emergency procedures in isolated locations, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=94848

MENTAL HEALTH

9. Failure to install functional collapsible shower or curtain rails

Involves either;

- failure of collapsible curtain or shower rails to collapse when an inpatient suicide is attempted/ successful.
- failure to install collapsible rails and an inpatient suicide is attempted/successful using these non-collapsible rails

Setting: All mental health inpatient premises.

Guidance:
Health Building Note (HBN)03-01 – Adult Acute Mental health Units, 2006, available at https://www.gov.uk/government/publications/best-practice-design-and-planning-adult-acute-mental-health-units
- NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems, 2002, available at http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Estatesalerts/DH_4122863?PageOperation=email- *Clinical guideline 16 – self-harm: the short term physical and psychological management and prevention of self-harm in primary and secondary care,* 2004, available at www.nice.org.uk/guidance/CG16

GENERAL
10. Falls from poorly restricted windows
A patient falling from poorly restricted window. • Applies to windows “within reach” of patients. This means windows (including the window sill) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to assist in climbing out of the window. • Includes windows located in facilities/areas where healthcare is provided and where patients can and do access. • Includes where patients deliberately or accidentally fall from a window where a restrictor has been fitted but previously damaged or disabled, but does not include events where a patient deliberately disables a restrictor or breaks the window immediately before the fall. • Includes where patients are able to deliberately overcome a window restrictor by hand or using commonly available flat bladed instruments as well as the ‘key’ provided. **Setting:** All patients receiving NHS funded care **Guidance:** - *Health Building Note (HBN) 00-10 Part D: Windows and associated hardware*, available via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/273867/20131223_HBN_00-10_PartD_FINAL_published_version.pdf - *DH(2014)/003 – Window restrictors of cable and socket design, 2014, available at https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102246* - *Risk of falling from windows*, available at http://www.hse.gov.uk/healthservices/falls-windows.htm
11. Chest or neck entrapment in bedrails
Entrapment of a patient’s chest or neck within bedrails, or between bedrails, bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance

Setting: All settings providing NHS funded healthcare, including NHS funded patients in care home settings, and equipment provided by the NHS for use in patients' own homes.

Guidance:
- *Safer practice notice – Using bedrails safely and effectively,* 2007, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59815
- *DB 2006(06) v 2.1 Safe use of bed rails,* Dec 2013, available at http://www.mhra.gov.uk/home/groups/dts-bs/documents/publication/con2025397.pdf
- *Local Authority Circular - Bed Rail Risk Management,* 2003, available at http://www.hse.gov.uk/lau/lacs/79-8.htm
- *Safe use of bedrails*, available at http://www.hse.gov.uk/healthservices/bed-rails.htm

12. Transfusion or transplantation of ABO-incompatible blood components or organs

Unintentional transfusion of ABO-incompatible blood components.

- Excludes where ABO-incompatible blood components are deliberately transfused with appropriate management.

Unintentional ABO mismatched solid organ transplantation.

- Excluded are scenarios in which clinically appropriate ABO incompatible solid organs are transplanted deliberately
- In this context, 'incompatible' antibodies must be clinically significant. If the recipient has donor specific anti-ABO antibodies and is therefore, likely to have an immune reaction to a specific ABO compatible organ then it would be a never event to transplant that organ inadvertently and without appropriate management.

Setting: All patients receiving NHS funded care.

Guidance:
- *Safer Practice Notice – Right Patient, Right Blood*, 2006, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59805
- *SHOT Lessons for clinical staff,* 2007, available at http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-lessons-for-clinical-staff-website.pdf
- *SHOT Lessons for Clinical Staff* 2009, available at http://www.shotuk.org/wp-content/uploads/2010/12/Lessons-for-Clinical-Staff-Dec-2010.pdf
- *BSHI and BTS Guidelines for the Detection and Characterisation of Clinically Relevant Antibodies in Allotransplantation,* 2010, available at http://www.bts.org.uk/Documents/Guidelines/Active/A6.pdf
- *Antibody incompatible transplant guidelines*, 2011, available at http://www.bts.org.uk/Documents/Guidelines/Active/AiT%20guidelines%20Jan%202011%20FINAL.pdf
- *Patient Safety Alert – WHO Surgical Safety Checklist,* 2009, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59860

13. Misplaced naso- or oro-gastric tubes

Misplacement and use of a naso- or oro-gastric tube in the pleura or respiratory tract where the misplacement of the tube is not detected prior to commencement of feeding, flush or medication administration.

Setting: All patients receiving NHS funded care.

Guidance:
- *Patient safety alert – Reducing harm caused by misplaced nasogastric feeding tubes,* 2005, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59794
- *Patient safety alert – Reducing harm caused by misplaced naso and orogastric feeding tubes in babies under the care of neonatal units*, 2005, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59798&q=0%c2%acnasogastric%c2%ac
- *Reducing the harm caused by misplaced naso-gastric feeding tubes in adults, children and infants*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=129640&p=2
- *Harm from flushing of naso-gastric tubes before confirmation of placement*, 2012. available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=133441

Patient safety alert on placement devices for nasogastric tube insertion - http://www.england.nhs.uk/2013/12/05/psa-ng-tube/

14. Scalding of patients

Patient being scalded by water used for washing/bathing

- Excludes scalds from water being used for purposes other than washing/bathing (e.g. from kettles)

Settings: All patients receiving NHS funded care.

Guidance:
- *Health Technical Memorandum 04-01 - The control of* Legionella*, hygiene, "safe" hot water, cold water and drinking water systems*, 2006, available via https://www.gov.uk/government/publications/hot-and-cold-water-supply-storage-and-distribution-systems-for-healthcare-premises
- *Health Building Note 00-10 Part C - Sanitary assemblies,* 2013, available via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148497/HBN_00-10_Part_C_Final.pdf
- *Scalding risks from hot water in health and social care LAC: 79/5,* 2007, available at http://www.hse.gov.uk/lau/lacs/79-5.htm
- *Scalding and burning*, available at http://www.hse.gov.uk/healthservices/scalding-burning.htm

Appendix A: Retained foreign object post procedure

Earlier definitions of the never event type 'Retained foreign object post operation' were not consistently applied, so examples are provided below to assist consistent application of the current clarified definition. The examples below are intended solely as **illustrative examples of the principles of the definition**, not a complete list of circumstances where the definition applies.

Note that the principles of the definition relate to items that should be subject to a formal counting or checking process at the commencement of the procedure and a counting or checking process before the procedure is completed. The size of the retained foreign object and the potential for harm from the retained foreign object is irrelevant to its designation as a never event.

Circumstances	**Does this fit the never event definition?**
A patient underwent gynaecological surgery and had a vaginal pack/vaginal tampon intentionally left in place at the end of surgery, with removal planned for 48 hours after surgery. Unfortunately, the planned removal did not take place, and the error was only brought to light after the patient was sent home and she went to her GP complaining of vaginal discomfort and discharge. He examined her and found the pack.	This does not meet the definition of a never event, as the vaginal pack was intentionally retained after the procedure; once outside the controlled counting processes in theatre, the never event principle of being eminently preventable if existing guidance was followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via STEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future.
A patient needed suturing after an episiotomy during vaginal birth. To create a clear view for the suturing procedure, three swabs were placed in the vagina. The intention was to remove these as soon as suturing was complete, but only two swabs were removed. The error was only brought to light when the swab fell out a few days after the patient and her baby went home.	This meets the definition of a never event; the swab was not intentionally retained and all swabs should have been counted at the time of the procedure.
A patient undergoing eye surgery as day case had a pledget (a small swab) inserted under her eyelid an hour pre-operatively to deliver topical medication. The pledget should have been removed during the surgery but was not. The patient telephoned for advice on a painful eye the day after her procedure and when she came back to the unit to be examined the pledget was found and removed.	This does not meet the definition of the never event, as the pledget was inserted outside the controlled counting processes in theatre, therefore the never event principle of being eminently preventable if existing guidance was followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via STEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future.
A patient undergoing eye surgery as day case had a pledget (a small swab) inserted under her eyelid at the beginning of the procedure. The pledget should have been removed at the end of the surgery but was	This meets the definition of a never event; the pledget was not intentionally retained and all pledgets should have been counted at the time of the procedure.

not. The patient telephoned for advice because her eye was painful the day after her procedure and when she came back to the unit to be examined the pledget was found and removed.	
A patient had an interventional cardiology procedure using a guidewire. When the doctor tried to remove the guidewire, it appeared to be stuck. It was left in place so that x-rays could be taken and expert advice sought before its removal was attempted.	This does not meet the definition of the never event, as the guidewire was known to be retained prior to the completion of the procedure, but immediate action to retrieve it would be impossible or be more damaging than retention. This incident is still likely to fit the definition of a Serious Incident and should be reported via STEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future. Additional reporting to the MHRA would also be required if an equipment fault could have been implicated.
A patient had an interventional cardiology procedure using a guidewire. No problems with the procedure were noticed at the time, but when an x-ray was taken for another reason several days later, a broken-off guidewire tip was found lodged in a blood vessel.	This meets the definition of a never event as the guidewire should have been checked for completeness when it was removed at the end of the procedure.

Appendix 2 - Rationale for amendments to the Never Events List (including consideration of October 2014 open consultation)

Action	Never Event	Rationale
Removed	Maternal death due to post-partum haemorrhage after elective caesarean section	The guidance for a post-partum haemorrhage is not considered to be any more robust than for any other major haemorrhage and therefore, does not meet the definition that requires the availability of strong systemic protective barriers to make it wholly preventable. This Never Event was also defined by an outcome (death) that would not in itself reflect how significant the failure of barriers had been, as it could be affected by a number of other factors *313 consultation respondents agreed with the removal of this Never Event and 38 did not.*
Removed	Wrongly manufactured high-risk injectable medication	Note the existing Never Event was not sufficiently specific in terms of its scope, and no Never Events had ever been

		reported under this category. It had been most commonly understood to be encompassing local manufacture of medication within a pharmacy department (though some responses to consultation considered it could or should apply to any reconstitution of high risk medication in a ward area, e.g. setting up a heparin pump). The strong systemic protective barriers required i.e. the national availability of, and the use in all clinical areas, of ready to administer injectable medication products requires a national plan that was beyond the timescales of this review. We recognise the support that inclusion of this Never Event has received and with this in mind we look to undertake an impact assessment with NHS partners that will be reviewed again in 2016 to ensure that this gets a high level of attention as a prime candidate for future inclusion on the list under the appropriate circumstances. It is important to note that the majority of feedback responses were contradictory in that they agreed there were currently no strong barriers to prevent human error, and yet still supported its retention as a Never Event. This may relate to persistent belief amongst pharmacists in the 'perfection myth' (that if individuals strive hard enough not to make error, they will not make errors). *305 consultation respondents agreed with this Never Event and 46 did not, so it will be reviewed next year for inclusion with further information.*
Removed	Opioid overdose of an opioid/opiate-naïve patient	The strong systemic protective barriers to prevent this are not strong enough at present as they rely on the provision of clinical guidance and the education and training of health professionals only *313 consultation respondents agreed with the removal of this Never Event and 38 did not.*
Removed	Escape of a transferred prisoner	This was removed from the list as the barriers to prevent this are not strong enough. It was felt that they are treated as a serious incident and investigated and this is the important issue. *During the consultation 154 from 174 responses agreed that it should be removed as a never event*
Removed	Wrong gas administered	The guidance relating to the administration of gases does not represent a sufficiently strong systemic protective barrier to

		prevent inappropriate administration – hence this category does not meet the Never Event criteria *296 consultation respondents agreed with the removal of this Never Event and 55 did not.*
Removed	Failure to monitor and respond to oxygen saturation	The overwhelming majority of respondents agreed with removal of this incident as a Never Event However there was some discomfort about removing this, most notably from the Royal College of Anaesthetists. They felt that as pulse oximetry is so commonly used now that it should remain but be renamed as 'Failure to respond to oxygen saturation'. A small number of others commented that although the current barriers are weak, keeping it as a Never Event but working on strengthening the barriers was the way forward. On evaluation however, the current barriers which are the use of standard operating procedures, the implementation and use of protocols and guidelines, education and awareness were not felt to be strong enough to prevent the incident occurring, and therefore the incident did not fit the required criteria to remain a Never Event *142 consultation responses agreed that it should be removed and 31 disagreed.*
Removed	Air embolism	The barriers relating to air embolism are not considered to represent a sufficiently strong barrier to protect against inappropriate administration – hence this category does not meet the Never Event criteria. *321 consultation respondents agreed with the removal of this Never Event and 30 did not.*
Removed	Misidentification of patients	A majority of respondents agreed with removal of this incident as a Never Event. However there was some discomfort about removing this as it was suggested that removing from the list would remove any incentive for change. There was a mixed response regarding whether the barriers were strong enough and supported further work on developing stronger barriers. The core team considered this in detail and felt that as wrong identification of patients was often picked up through other Never Events, most notably Wrong Site Surgery that it should be removed from the list at this time *285 consultation responses agreed that this should be removed and 66 disagreed.*

Merged	Wrong route medication, was: Wrong route chemo Wrong route oral/enteral treatment Intravenous admin of epidural medication	Merged for simplification *339 consultation respondents agreed with these changes and 12 did not.*
Merged	Transfusion or transplantation of ABO-incompatible blood components or organs, was; Transfusion of ABO incompatible blood components Transplantation of ABO incompatible organs	Merged for simplification. The changes in the ABO incident relate to the appropriate risk assessment of administration of ABO incompatible products (which happens in very high risk patients that are appropriately managed by specialists). *341 consultation respondents agreed with these changes and 10 did not.*