



# Expanding the list of “never events”

*Policy proposals for engagement*

## Expanding the list of “never events”

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<b>Description</b>	The Government proposed in the recent White Paper to expand the current list of incidents that are considered to be "never events" and to allow cost recovery when these "never events" occur. The purpose of this paper is to engage external partners and seek comments and suggestions on the draft list of events and on the framework for recovering costs when they occur
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# Expanding the list of “never events”

## *Policy proposals for engagement*

**Prepared by the Patient Safety policy team**

## Contents

1. Introduction and background.....	4
2. The “never event” criteria and the current national list.....	7
3. Expanding the national list of “never events” .....	8
4. The expanded list of “never events” .....	9
5. The “never event” contractual framework .....	19
6. Costs and Benefits .....	21
7. Confidentiality of Your Response .....	23
8. References .....	24

## 1. Introduction and background

“Never events” are defined as ‘serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers’<sup>1</sup>.

*High Quality Care For All* published in June 2008<sup>2</sup> proposed that a “never events” policy be introduced for the NHS in England from April 2009. The National Patient Safety Agency (NPSA) subsequently co-produced a set of criteria for defining “never events” and agreed a core list of eight events, alongside a policy framework<sup>3</sup>, to assist commissioners in implementing the “never event” proposals.

From April 2009 to March 2010, the framework provided a lever for increasing the transparency of organisations and the levels of reporting and learning around these very serious safety incidents. This provided an increased impetus for reducing and preventing their incidence, and encouraged commissioners to work with their providers to actively improve the safety of the care people receive.

In March 2010, the NPSA published *‘Never Events – Framework: Update for 2010-11’*<sup>4</sup>. This outlined how existing arrangements for “never events” should continue, taking account of policy developments, but also refined the core list of “never events” and described new arrangements, specified in *‘The operating framework for the NHS in England 2010/11’*<sup>5</sup>, for how PCTs should seek to recover the costs of any procedure/treatment where a “never event” occurs. The NPSA have also now produced an annual report providing a summary of the first 12 months of the “never event” framework available at [www.nrls.npsa.nhs.uk/neverevents/](http://www.nrls.npsa.nhs.uk/neverevents/)

In July 2010, the Government committed to build on these changes and to proceed with work to impose contractual penalties for an extended list of “never events”<sup>6</sup>.

This paper has been produced by the Department of Health in order to engage the NHS and our external partners in the process for expanding the national list of “never events” and implementing contractual penalties where “never events” occur.

## Expanding the list of “never events”

The Government wishes to maintain and increase the focus on safety in the NHS, especially through encouraging the reporting of patient safety incidents and ensuring that lessons are learned and implemented. However, it is also clear that serious failure will not be tolerated, especially where there are clear guidelines and procedures in place to support organisations in preventing serious incidents. Therefore, where serious failings still occur, organisations will be subject to sanctions, emphasising a firm approach to “never events”.

Commissioners and providers are currently free to negotiate their own locally agreed quality requirements in addition to the quality requirements set centrally, which could include local “never events”, along with any appropriate locally agreed contractual arrangements as they see fit. There are examples around the country where local health care communities have embraced this idea. These do not replace the requirement to use the national core “never events”.

This current paper is only concerned with the national core list of “never events” and does not seek to change these local arrangements. However for the purposes of simplicity we propose that locally determined “never events” should not duplicate nationally determined ones and suggest that the national event should take precedence. If you have any comments about this position however, please feed them back via the routes explained below.

Equally, this paper is not seeking to amend the arrangements set out in the current “never event” Framework for how organisations are expected to work together to report “never events” to each other and to the public in their annual reports and to fully investigate and share learning from events that occur. Organisations should continue to follow the arrangements as set out for all core, national “never events”.

In this document, the Department has produced an expanded list of “never events” and is proposing revisions to the NHS standard contracts (acute hospital, mental health and learning disability , community and ambulance services). We are looking for clinicians, managers, commissioners, subject experts and other interested parties to review the list we have produced and make suggestions for amendments in the context of the clear criteria that have been defined. The engagement process will run online at <http://neverevents.dh.gov.uk> where people can comment directly on the proposals. You can also submit comments to [neverevents@dh.gsi.gov.uk](mailto:neverevents@dh.gsi.gov.uk).

## Expanding the list of “never events”

This engagement process is open to all, however we are most actively seeking input from clinicians and other professionals due to the technical nature of the NHS contracting system and the requirement for detailed subject knowledge in order to assess the suitability of the suggested “never events” and to propose additions or amendments. The engagement process will run for 6 weeks from 8 October 2010 until 19 November, after which we will refine our proposals according to the comments received and produce a final version of the “never event” list and associated contractual framework. We will look to incorporate the policy arrangements in the 2011/12 NHS Operating Framework and 2011/12 NHS Standard Contracts, subject to Ministerial agreement and the financial context and priorities determined by the forthcoming Spending Review. Any queries about this process should be addressed to [neverevents@dh.gsi.gov.uk](mailto:neverevents@dh.gsi.gov.uk).

## 2. The “never event” criteria and the current national list

The Government is clear that the current criteria for defining “never events” are the correct basis for expanding the list. To be a “never event”, an incident must fulfill the following criteria;

- The incident has clear potential for or has caused severe harm/death.
- There is evidence of occurrence in the past (i.e. it is a known source of risk).
- There is existing national guidance and/or national safety recommendations on how the event can be prevented and support for implementation.
- The event is largely preventable if the guidance is implemented.
- Occurrence can be easily defined, identified and continually measured.

Their occurrence is a clear indicator of an organisation which has not put in place the right systems and processes to prevent the incidents from happening and thereby prevent harmful outcomes. It is also an indicator of how safe the organisation is and the patient safety culture within that setting. The current “core eight” list of “never events” is:

- Wrong site surgery.
- Retained instrument post-operation.
- Wrong route administration of chemotherapy.
- Misplaced naso or orogastric tube not detected prior to use.
- Inpatient suicide using non-collapsible rails.
- Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners (not included in the previous contractual list).
- In-hospital maternal death from post-partum haemorrhage after elective caesarean section.
- Intravenous administration of mis-selected concentrated potassium chloride.

The new list we are proposing contains or builds on the previous core list and we are seeking comments and suggestions on all the proposed “never events” including those contained in the previous core list. It should be noted that “never events” and serious untoward incidents (SUIs) are not mutually exclusive. It is inevitable by their nature that all “never events” are SUIs, but not all SUIs are “never events”. The definition and reporting of SUIs was discussed in the recent “*National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*”<sup>7</sup>.



### 3. Expanding the national list of “never events”

Expanding the list of “never events” will be done according to, and consistent with, the criteria outlined earlier.

There are a number of sources for suggested additional “never events” including the list used by the National Quality Forum in the United States of America, lists used locally by NHS organisations in England, and suggestions from clinical and other experts with the Department and the National Patient Safety Agency.

The Department has used all of these to propose a revised “never event” list comprising 22 events in total, including those already on the list but in some cases suggesting amendments. These are not final and we are seeking comments on the types of incidents listed, their definitions and suitability as “never events”, and whether there are other events suitable for inclusion that we have missed.

- **Do you agree that the list of events and the definitions that we have produced below should be used for the new “never event” list and that they are consistent with the “never event” criteria outlined earlier?**
- **Do you agree with the inclusion of the events listed below but have suggestions for amending the scope and/or definition of the events?**
- **Do you have any additional suggestions for events and/or definitions to be included on the “never event” list?**

#### 4. The expanded list of “never events”

“Never event”	Characteristics/Definition
Wrong site surgery	<p>Currently included in core eight.</p> <p>A surgical intervention performed on the wrong site (for example wrong knee, wrong eye, wrong patient, wrong limb, or wrong organ); the incident is detected at any time after the start of the operation and the patient requires further surgery, on the correct site, and/or may have complications following the wrong surgery. This incident should also includes the placement of incorrect implants and replacement joints.</p> <p>Guidance/Alerts:            - <i>Safer Practice Notice – Standardising Wristbands improves patient safety, 2007</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824</a>            - <i>Patient Safety Alert – WHO Surgical Safety Checklist, 2009</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/">http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/</a></p>
Retained instrument post-operation	<p>Currently included in core eight.</p> <p>One or more instruments or swabs, or a throat pack, are unintentionally retained following an operative procedure, and an operation or other invasive procedure is needed to remove this, and/or there are complications to the patient arising from its continued presence. This Never Event does not include interventional radiology or cardiology procedures, and the definition of instrument does not include guidewires, screws, or other similar material. It does not include retained swabs after non-operative vaginal delivery.</p> <p>Proposal:            We propose expanding this event to include any unintended retention of a foreign object (including any swabs, but</p>

## Expanding the list of “never events”

	<p>excluding needles and bits of screws) in a patient after surgery or other procedure including interventional radiology, cardiology and vaginal delivery, but excluding items deliberately retained.</p> <p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>Standards and recommendations for safe perioperative practice</i>, 2007, available at <a href="http://www.afpp.org.uk/news/safe-practice-highlighted-in-new-afpp-publication">http://www.afpp.org.uk/news/safe-practice-highlighted-in-new-afpp-publication</a></li> <li>- <i>Swab, instrument and needle counts: Managing the risk</i>, 2005, available at <a href="http://www.afpp.org.uk/filegrab/swabcountposter.pdf?ref=57">http://www.afpp.org.uk/filegrab/swabcountposter.pdf?ref=57</a></li> <li>- <i>Patient Safety Alert – WHO Surgical Safety Checklist, 2009</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/">http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/</a></li> </ul>
<p>Wrong route administration of chemotherapy</p>	<p>Currently included in core eight.</p> <p>Intravenous or other chemotherapy (for example, vincristine) that is correctly prescribed but administered via the wrong route (usually into the intrathecal space).</p> <p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>HSC2008/001: Updated national guidance on the safe administration of intrathecal chemotherapy</i>, available at <a href="http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/healthservicecirculars/dh_086870">http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/healthservicecirculars/dh_086870</a></li> <li>- <i>Rapid Response Report NPSA/2008/RRR004 using vinca alkaloid minibags (adult/adolescent units)</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59890">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59890</a></li> </ul>
<p>Misplaced naso or orogastric tube not detected prior to use</p>	<p>Currently included in core eight.</p> <p>Naso or orogastric tube placed in the respiratory tract rather than the gastrointestinal tract and not detected prior to commencing feeding or other use.</p> <p>Proposal;</p> <p>We propose extending this event to misplaced tube used for enteral feeding not detected prior to use, so that it will include</p>

Expanding the list of “never events”

	<p>naso- or oro-jejunal tubes misplaced in the respiratory tract.</p> <p>Guidance/Alerts:  <i>- Patient safety alert – Reducing harm caused by misplaced nasogastric feeding tubes, 2005, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59794">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59794</a></i>  <i>- Patient safety alert – Reducing harm caused by misplaced naso and orogastric feeding tubes in babies under the care of neonatal units, 2005, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59798&amp;q=0%c2%acnasogastric%c2%ac">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59798&amp;q=0%c2%acnasogastric%c2%ac</a></i></p>
<p>Inpatient suicide using non-collapsible rails</p>	<p>Currently included in core eight.</p> <p>Suicide using non collapsible curtain or shower rails by an inpatient in an acute mental health setting.</p> <p>Guidance/Alerts:  <i>- NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems, available at <a href="http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4122863">http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4122863</a></i>  <i>- NHSE (2004) 10: Bed cubicle rails, shower curtain rails and curtain rails in psychiatric in-patients settings, available at <a href="http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4119476">www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_4119476</a></i>  <i>- 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 <a href="http://www.nice.org.uk/guidance/CG16">www.nice.org.uk/guidance/CG16</a></i>  <i>- DH (2007)08: Cubicle curtain track rails (anti-ligature), available at <a href="http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_076400">http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_076400</a></i></p>
<p>Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred</p>	<p>Currently included in core eight but not penalised under the NHS Standard Contracts.</p> <p>A patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment subject to Ministry of Justice restriction directions.</p>

Expanding the list of “never events”

<p>prisoners</p>	<p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>Standards for medium secure units, 2007</i>, available at <a href="http://www.rcpsych.ac.uk/pdf/Final%20Standards%20for%20Medium%20Secure%20Units%20PDF.pdf">www.rcpsych.ac.uk/pdf/Final%20Standards%20for%20Medium%20Secure%20Units%20PDF.pdf</a></li> <li>- <i>Best Practice Guidance: Specification for adult medium-secure services, 2007</i>, available at <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078744">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078744</a></li> </ul>
<p>In-hospital maternal death from post-partum haemorrhage after elective caesarean section</p>	<p>Currently included in core eight.</p> <p>In-hospital death of a mother as a result of a haemorrhage following elective caesarean section, excluding cases where imaging has identified placenta accreta.</p> <p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>The role of emergency and elective interventional radiology in postpartum haemorrhage, good practice No. 6, 2007</i>, available at <a href="http://www.rcog.org.uk/womens-health/clinical-guidance/role-emergency-and-elective-interventional-radiology-postpartum-haem">http://www.rcog.org.uk/womens-health/clinical-guidance/role-emergency-and-elective-interventional-radiology-postpartum-haem</a></li> <li>- <i>Saving mothers' lives: Reviewing maternal deaths to make motherhood safer – 2003-2005, 2007</i>, available at <a href="http://www.cemach.org.uk/getattachment/927cf18a-735a-47a0-9200-cdea103781c7/saving-mothers--lives-2003-2005_full.aspx">www.cemach.org.uk/getattachment/927cf18a-735a-47a0-9200-cdea103781c7/saving-mothers--lives-2003-2005_full.aspx</a></li> <li>- <i>Patient Safety alert – WHO safer surgery checklist, 2009</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/">http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/</a></li> </ul>
<p>Intravenous administration of mis-selected concentrated potassium chloride</p>	<p>Currently included in core eight.</p> <p>Intravenous administration of mis-selected concentrated potassium chloride.</p> <p>Proposal:</p> <p>We propose amending this event to “Maladministration of concentrated KCl”, which will include intravenous administration of mis-selected concentrated potassium chloride and over-infusion of concentrated potassium chloride where the concentration administered has the potential to cause severe harm or death.</p>

Expanding the list of “never events”

	<p>Guidance/Alerts:  - <i>Patient safety alert – Potassium chloride concentrate solutions, 2002 (updated 2003)</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882</a></p>
<p>Death or serious injury arising from the inadvertent administration of ABO/HLA-incompatible blood or blood products or transplant of ABO/HLA incompatible organs</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts:  - <i>Safer Practice Notice – Right Patient, Right Blood, 2006</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59805">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59805</a>  - <i>SHOT Lessons for clinical staff, 2007</i>, available at <a href="http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-lessons-for-clinical-staff-website.pdf">http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-lessons-for-clinical-staff-website.pdf</a></p>
<p>Death or serious disability associated with entrapment in bedrails whilst being cared for in a healthcare facility</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts:  - <i>Safer practice notice – Using bedrails safely and effectively, 2007</i>, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59815">http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59815</a>  - <i>DB 2006(06) Safe use of bed rails, 2006</i>, available at <a href="http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&amp;dDocName=CON2025397&amp;RevisionSelectionMethod=Latest Released">http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&amp;dDocName=CON2025397&amp;RevisionSelectionMethod=Latest Released</a>  - <i>Local Authority Circular - Bed Rail Risk Management, 2003</i>, available at <a href="http://www.hse.gov.uk/lau/lacs/79-8.htm">http://www.hse.gov.uk/lau/lacs/79-8.htm</a></p>
<p>Death or serious injury as a result of a healthcare professional's prescribing, preparing or</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts:  - <i>Rapid response report – Safer administration of insulin, 2010</i>, available at <a href="http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287">http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287</a></p>

## Expanding the list of “never events”

<p>administration of insulin in overdose, or his or her failure to prescribe or administer insulin when clinically indicated in a healthcare setting.</p>	<ul style="list-style-type: none"> <li>- <i>NHS Diabetes – Safe use of insulin, 2010</i>, available at <a href="http://www.diabetes.nhs.uk/safe_use_of_insulin/">http://www.diabetes.nhs.uk/safe_use_of_insulin/</a></li> <li>- <i>NHSIII Toolkit – Think Glucose, 2008</i>, available at <a href="http://www.institute.nhs.uk/thinkglucose">www.institute.nhs.uk/thinkglucose</a></li> <li>- <i>NHS Diabetes guidance - The Hospital Management of Hypoglycaemia in Adults with Diabetes Mellitus, 2010</i>, available at <a href="http://www.diabetes.nhs.uk/document.php?o=1037">http://www.diabetes.nhs.uk/document.php?o=1037</a></li> </ul>
<p>Death or serious injury arising from failure to recognise and act on critical oxygen saturation levels in a patient undergoing general anaesthesia.</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Intended to capture difficult intubation as well as monitoring issues.</p> <p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>Recommendations for the Standards of Monitoring During Anaesthesia and Recovery (4)</i>, 2007, available at <a href="http://www.aagbi.org/publications/guidelines/docs/standardsofmonitoring07.pdf">http://www.aagbi.org/publications/guidelines/docs/standardsofmonitoring07.pdf</a></li> </ul>
<p>Death or serious injury associated with the use of wrongly prepared high risk<sup>8</sup> injectable medication, including dose, when the error occurs in the healthcare facility preparing and administering the medication</p>	<p>New proposal.</p> <p>All care settings.</p> <p>The intention is to capture where high risk medication is incorrectly formulated within a healthcare facility, not where an error has occurred outside the facility administering the medication, for example during its manufacture elsewhere.</p> <p>Guidance/Alerts:</p> <ul style="list-style-type: none"> <li>- <i>Patient Safety Alert - Promoting safer use of injectable medicines</i>, 2007, available at <a href="http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59812&amp;p=4">http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59812&amp;p=4</a></li> </ul>
<p>Death or serious injury associated</p>	<p>New proposal.</p>

## Expanding the list of “never events”

<p>with intravascular air embolism that occurs while being cared for in a healthcare facility</p>	<p>All care settings.</p> <p>Guidance/Alerts: While fundamental to the training of clinicians hence a lack of additional alerts to date, avoidance of air embolism is to be the subject of a forthcoming evidence based guideline from the Society of Acute Medicine.</p>
<p>Death or occurrence of kernicterus associated with failure to identify and treat hyperbilirubinemia in neonates</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts: - <i>NICE Guidance – Recognition and management of neonatal jaundice</i>, 2010, available at <a href="http://guidance.nice.org.uk/CG98">http://guidance.nice.org.uk/CG98</a></p>
<p>Death or severe injury as a result of the administration of the wrong gas or failure to administer the correct gas at all through a line designated for oxygen in a healthcare facility</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts: - <i>Rapid Response Report - Oxygen Safety in Hospitals</i>, 2009, available at <a href="http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=62811">http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=62811</a> - <i>NHSE SN (2003) 02: Medical liquid oxygen supply systems</i>, 2003, available at <a href="http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4121320.pdf">http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4121320.pdf</a> - <i>NHSE SN (2003) 01: Oxygen cylinder manifolds used to supply oxygen for patient use</i>, 2003, available at <a href="http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4121317.pdf">http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4121317.pdf</a> - <i>DH (2008) 06 - Medical air plant</i>, 2008, available at <a href="http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087060.pdf">http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087060.pdf</a></p>
<p>Daily administration of oral methotrexate for non-cancer</p>	<p>New proposal.</p> <p>All care settings.</p>



## Expanding the list of “never events”

<p>treatment or provision of oral methotrexate for non-cancer treatment with the instruction to take daily.</p>	<p>Note this event explicitly excludes administration or provision of oral methotrexate on a weekly basis, for example in the treatment of vasculitis.</p> <p>Guidance/Alerts:          - <i>Patient safety alert - Improving compliance with oral methotrexate guidelines</i>, 2006, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800</a></p>
<p>Death or serious injury arising from overdose with opioid medicines where the dose of opioid given was inappropriate to the patient’s condition and needs</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Where the opioid dose may have contributed to the patient’s death but the drug was given in good faith at a dose considered appropriate for the clinical need, based on current evidence and the patient’s history, then the never event does not apply.</p> <p>Guidance/Alerts:          - <i>Rapid Response Report – Reducing dosing errors with opioid medicines</i>, 2008, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888</a></p>
<p>Death or serious injury arising from overdose of midazolam injection.</p>	<p>New proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts:          - <i>Rapid Response Report - Reducing risk of overdose with midazolam injection in adults</i>, 2008, available at <a href="http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59896&amp;p=2">http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59896&amp;p=2</a></p>
<p>Death or serious disability while being physically restrained in any mental healthcare</p>	<p>New Proposal.</p> <p>Mental health settings.</p> <p>Guidance/Alerts:          - <i>NICE guidance - The short-term management of disturbed/violent behaviour in in-patient psychiatric settings</i></p>

Expanding the list of “never events”

<p>setting including mental healthcare settings within prisons.</p>	<p>and emergency departments, 2005, available at <a href="http://guidance.nice.org.uk/CG25">http://guidance.nice.org.uk/CG25</a>          - <i>Mental Health Act Code of Practice on Restraint</i>, 2008, available at <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084597">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084597</a></p>
<p>Death or serious injury resulting from falls from unrestricted windows.</p>	<p>New proposal.</p> <p>Organisations providing care for mental health patients, elderly and confused patients and children.</p> <p>A patient either deliberately or accidentally falls from an unrestricted window (including where a restrictor has been fitted but subsequently damaged or disabled) where there is a foreseeable risk of falling, resulting in death or serious injury.</p> <p>Main care setting: Organisations providing care for mental health patients, elderly and confused patients and children.</p> <p>Guidance/Alerts:          - <i>Health Technical Memorandum (HTM) 55: Windows</i>          - <i>DH(2007)09 – Window restrictors</i>, 2007 available at <a href="http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalasset/@dh/@en/documents/digitalasset/dh_080164.pdf">http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalasset/@dh/@en/documents/digitalasset/dh_080164.pdf</a></p>
<p>Death or serious injury caused by administration of oral/enteral medication, feed or flush intravenously or intrathecally; or caused by intravenous medication administered intrathecally or vice versa</p>	<p>New Proposal.</p> <p>All care settings.</p> <p>Guidance/Alerts:          - <i>Patient Safety Alert - Promoting safer measurement and administration of liquid medicines via oral and other enteral routes</i>, 2007, available at <a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808</a></p>

## Expanding the list of “never events”

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## 5. The “never event” contractual framework

As the Government made clear in *‘Equity and Excellence: Liberating the NHS’*, the NHS needs a comprehensive, transparent and sustainable structure of payment for performance that ensures payment reflects quality. Payments and the ‘currencies’ they are based on will be structured in the way that is most relevant to the service being provided, and will be conditional on achieving quality goals. If providers deliver care that is of poor quality, then commissioners will be able to impose contractual penalties.

In this context, the “never event” framework is clear that where a “never event” occurs during a commissioned episode of care, the commissioner should recover the cost of that episode of care and, in addition, there should be no charge to the commissioner for any corrective procedure/operation that is required. Where there is in-hospital death, the commissioner can recover the cost of the episode of care if appropriate, or the cost of the care to date within the financial year for the ongoing patient episode.

Cost recovery is intended as a lever to encourage providers to ensure that “never events” do not happen. Recovery of money is not in any way intended for use as ‘compensation’ for a “never event” occurring. Recovery of costs does not in any way affect the provider’s liability with respect to criminal or clinical negligence proceedings.

Commissioners will be able to waive the cost recovery process according to individual circumstances and local agreement. This should be the result of an open dialogue between the commissioner and the provider, where the circumstances of the particular event are taken into account, including the actions that the provider has taken in response to the event.

Importantly, cost recovery does not replace any separate regulatory requirements such as the process of registration with the CQC and compliance with minimum standards. The payment system should align with and support best practice but is not, nor should become, a regulatory mechanism. The CQC should use information on “never events” to inform its regulatory processes and, following a “never event”, should take any enforcement action it deems appropriate. This action could include imposing additional financial penalties such as fines, where a review of compliance following a ‘never event’ provides evidence of non-compliance with Essential Standards of Quality and Safety. Any such review should of course take into

## Expanding the list of “never events”

account the local response to the ‘never event’, such as cost recovery, and any evidence of learning.

Most importantly though, and consistent with the current arrangements<sup>9</sup>, there must be a robust and rapid process of reporting, learning and improvement following a “never event”. Each “never event” should be reported to the relevant Primary Care Trust/commissioner and to the National Reporting and Learning System at the NPSA. Each “never event” should be the subject of an investigation of its root causes, learning should be implemented and the systems for future prevention strengthened. Commissioners should give high priority to the learning gained from investigation and the actions put in place by providers after a “never event”. The reporting and review of events between commissioners and providers should include evidence of discussion with the affected patient and/ or carers consistent with the NPSA’s *‘Being Open’* framework<sup>10</sup>.

In future years, these principles will still apply, but in the context of a restructured NHS. This means that providers will be required to report the incidence of “never events” to the commissioner of the care in which the event took place (either the National Commissioning Board or the relevant GP Commissioning Consortium). The incident must also be reported to the National Reporting and Learning System, which will sit with the National Commissioning Board.

- **Do you agree with cost recovery for all providers, given that some incidents relate to short term, low cost interventions and others relate to long-term care where cost recovery could be many thousands of pounds? This could disproportionately affect small providers.**
- **Do you have alternative suggestions for the contractual framework?**

## 6. Costs and Benefits

At this stage, given the final list of “never events” has not been determined, a full impact analysis of the proposals has not been provided. We are able to discuss the likely impacts of the proposals, however.

The costs of these proposals will take a variety of forms. One impact should be to incentivise the NHS to further prevent these “never events”. This process of prevention could be argued to incur costs to the NHS, although these are not possible to quantify because the cost of prevention for each event will vary due to the very different nature of the interventions required for each event and also because different providers will have different systems and methods of prevention already in place. Therefore, the actions they need to take will vary.

It could also be argued that prevention of these events should happen already given the existence of relevant alerts and clinical guidance, which should already have been implemented. All providers are subject to the same requirements to provide safe care and that they must comply with all relevant patient safety standards and alerts (regardless of the status of “never events”). One of the criteria for the definition of a never event is that clear guidance and/or principles exist, which, if followed by providers, will prevent the event from happening. All providers must implement such guidance and, given that the obligation to do so sits outside the policy on “never events”, any associated costs could be considered as separate to this policy proposal.

Similarly, while there will be an increase in the reporting of “never events” due to expanding the list, this should not increase the costs associated with reporting these events because they are all serious incidents, and as such should already be reported to commissioners and the NPSA.

The impact of cost recovery will be borne by providers, but will be cost neutral to the NHS as a whole as the recovered money will be returned to the commissioner for reinvestment in NHS services. Estimating the impact of cost recovery is difficult given the varying costs associated with dealing with each event and the varying costs of the care episode in which a particular event could occur. It is also possible that the number of events will reduce immediately anyway simply due to the impact of categorising these events as “never events” and the increased scrutiny this would bring.

## Expanding the list of “never events”

However, to give providers an idea of the potential impact, we have conducted a very rough analysis of the potential number of “never events” that might occur if the proposed list of events below were made “never events”. Our analysis suggests there would be between 300 and 400 “never events” per year at present (using information from the NPSA and other published sources). This suggests there would be between one or two events per NHS provider (assuming 240 NHS providers - 169 NHS Acute and specialist trusts, 57 mental health trusts, 11 ambulance trusts and 3 learning disability/other trusts). This compares to data from the NPSA’s annual report on “never events” for 2009/10 indicating there were 111 events in 2009/10. This is obviously a crude estimation, however, as Trusts vary widely in the number of patients they care for and therefore the risk that a serious errors will occur. Equally, some trusts will be better at preventing safety incidents than others.

The benefits of these proposals to the NHS include the savings associated with not having to treat patients for the consequences of any “never events” that are prevented, plus the savings associated with reducing the legal action that could result from errors. As an illustration, in 2009/10, over £2.1m was paid in relation to clinical negligence claims where wrong site surgery formed part of the claim, according to the NHS Litigation Authority (note that part of this sum will be for losses relating to other aspects of the claims). There will also be a resulting ‘reputational’ benefit for the NHS as it is seen to apply even more stringent safety standards and further demonstrate its lack of tolerance for serious safety incidents.

Most importantly, however, and fundamental to the concept of “never events” is the impact on patients of ensuring these events never happen. This has the key benefit for individuals and their families and friends of not having to endure the potentially devastating and long-term impacts of a very serious safety incident. Depending on the incident, occurrence of a “never event” could lead to death, serious long-term disability, a significantly prolonged period in hospital, further intrusive and unpleasant treatments and interventions, significant emotional and mental trauma, and wider consequences for quality of life, ability to work, family life and long-term well being. For all these reasons, reducing the incidence of these events will be of huge benefit to patients and their families and should be the overriding consideration when reviewing these proposals.

## 7. Confidentiality of Your Response

We manage the information you provide in response to this engagement exercise in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.



## 8. References

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<sup>1</sup> National Patient Safety Agency, ‘Never Events – Framework: Update for 2010-11’, March 2010. Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=68518>

<sup>2</sup> Department of Health. *High quality care for all – NHS next stage review final report*, June 2008. Available at: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085825](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825)

<sup>3</sup> National Patient Safety Agency, *The Never Events Framework 2009./10*, February 2009. Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59859&q=0%ac2%acnever+events%ac2%ac>

<sup>4</sup> National Patient Safety Agency, ‘Never Events – Framework: Update for 2010-11’, March 2010. Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=68518>

<sup>5</sup> Department of Health, ‘*The operating framework for the NHS in England 2010/11*’, December 2009. Available at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_110107](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110107)

<sup>6</sup> Department of Health, ‘*Equity and Excellence: Liberating the NHS*’, July 2010. Available at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_117353](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353)

<sup>7</sup> National Patient Safety Agency, *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*, March 2010, available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173>

<sup>8</sup> High risk as defined using the NPSA High Risk Medication Risk Assessment Tool, 2007, available at <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60097&type=full&servicetype=Attachment>

<sup>9</sup> National Patient Safety Agency, ‘Never Events – Framework: Update for 2010-11’, March 2010. Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=68518>

<sup>10</sup> NPSA, ‘*Being Open: communicating patient safety incidents with patients, their families and carers*’, November 2009, Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077>