

The "never events" list 2011/12

Policy framework for use in the NHS



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The list of "never events" 2011/12

Policy framework for use in the NHS

Prepared by the Patient Safety policy team

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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'¹.

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 an indication that an organisation may have 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 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, in July 2010, the Government committed to proceed with work to extend the list of "never events"² for use in the NHS.

A set of proposals were 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 to seek views on the contractual framework that should support the policy. Around 210 individuals and organisations, including providers and commissioners, both within the NHS and outside it, responded to the proposals. This final list of events reflects much of that feedback and reflects the patient safety incidents that should be considered as unacceptable in the NHS.

2. What you told us

We received a total of 210 formal comments following publication of the proposed expanded list in October. Overall, these demonstrated that there is broad support for the concept of "never events";

- "I am in total agreement [with] all the proposed areas as outlined in the document on the extended list of Never Events and with the arrangements for PCTs to apply financial penalties where breaches have occurred."
- "All the comments we received on this consultation, from both the professional and the lay/patient perspective, were supportive of the concept of expanding the list of 'never events' as proposed... There was also general agreement for the proposed penalty system."
- "We have been utilising the broad concept of the never event to be creative with our teams and get them to run Foresight activity, creating a culture of prevention in relation to patient safety and quality... This is a welcome way of working and is well owned by teams who identify near misses and respond with a never event explored using RCA methodologies"
- "I agree with this initiative in principle. It has resulted in significant improvements in patient safety in my hospital. For example, we had a death associated with feed being given into the lungs some time ago. We have now revised and tightened our procedures, at least in part due to the "never event" process. It serves to concentrate attention to clinical risk and forces managers to take it seriously."

However, it is fair to say that the majority of respondents, while supportive in principle, had specific concerns with the inclusion or definition of one or more of the events on the list. We have taken these constructive comments on board as far as possible. Some events have been reworded, some removed and others added following suggestions from respondents and we believe that the final list therefore represents a consensus view (see final list on page 17). It reflects concerns expressed by respondents, but will obviously not satisfy all viewpoints.

2.1 Concerns with the broader concept of "never events" and the framework.

Some organisations and individuals have deep-seated concerns about the use of a "never events" framework. Concerns included the following;

- "The impression for many reading this list is that the NHS...seems to be aiming to blame and punish individuals and individual organisations for defects for which the NHS itself may be in part responsible. History has shown that issuing an edict that demands that something must not happen is not a clever way of stopping it happening...Punishing them when avoidable problems occur is unlikely to be as successful as rewarding them for making changes that will lead to a decrease in avoidable problems. The "never event" approach is not in keeping with a blame-free culture."
- "The expansion into such a higher number may...detract from the status of the never event."
- "Overall we are not convinced that imposing cost recovery would actually change individual practice in such a way that would reduce the occurrence of 'never events' but would instead merely create additional burdens and bureaucracy. Any sort of punitive approach has a big risk of discouraging accident reporting and openness."
- 'the extended list of proposed "never events" risks causing more harm than good to patient care, from the psychiatrist's perspective at least. Furthermore, it may severely and unfairly penalise mental health services providers for isolated incidents."

We appreciate that some may hold differing views on the use of a "never event" list, and indeed expanding it, but we do not share these views and have made clear that we wish to increase the focus on safety. This includes defining errors that deserve particular focus and scrutiny, due to their devastating impact and their preventability.

2.2 Preventability and the concept of "never".

Concerns about whether particular events are truly preventable were repeated a number of times. "Never" is obviously an aspiration. Some of the comments we received following the publication of the draft list of "never events" questioned the use of the word "never" when, demonstrably, these events do happen³. The point is that they should not happen and all efforts must be made to prevent the mistakes that led to one "never event" being repeated. This means that the overriding concern for the NHS in implementing the "never event" policy is to report these events when they occur and to learn from the mistakes that were made.

In the real world we accept that there is the possibility that unforeseen scenarios could mean that a "never event" may not have been preventable. For example, it has been argued that there may be cases of post-partum haemorrhage after elective caesarean section in individuals with multiple complex co-morbidities (e.g. high body-mass index, undetected placental praevia, previous multiple caesarean sections etc) where death could result despite state-of-the-art care being provided by a fully staffed and equipped specialist tertiary referral centre. If, in individual cases, it can be shown that completely unanticipated or unpreventable circumstances led to an event occurring, we would suggest the commissioner and provider should agree not to classify it as a "never event".

The key consideration is that commissioners and providers should discuss fully the circumstances of the event and whatever the decision, ensure lessons are learned and implemented. Commissioners and providers should also discuss potential issues such as these before events occur to ensure all parties understand how the "never event" list should be applied.

2.3 Cost recovery

Many respondents raised concerns with the principle of cost recovery. They variously argued that any recovery of costs was punitive and had the potential for discouraging reporting of incidents, perpetuating the blame culture and reducing openness. There were also concerns that the principle of recovering the costs of the procedure in which the "never event" occurred and the costs of any care needed to treat the consequences of the "never event", could mean the recovery of very large sums of money in some cases and very small sums in others. Potentially an event leading to death of a patient would be 'punished' less severely than an event in which severe harm was caused and the patient required a large amount of treatment and care as a result.

We must be clear that cost recovery is not about punishment. It is about maintaining the principle that the NHS needs a comprehensive, transparent and sustainable structure of payment for performance that ensures payment reflects quality. If providers deliver care that is of poor quality, then the option should exist to ensure the taxpayer does not have to pay for that care. As stated earlier, the underlying principle of the "never events" list is about ensuring

organisations report and learn from these extremely serious incidents and strengthen the systems for prevention in the future. Cost recovery is secondary to that.

Commissioners and providers should therefore seek to identify in as simple terms as possible, what the care episode was in which the error occurred and what subsequent treatment was required as a direct result (if appropriate). They can then recover those costs. They should not be looking to forensically examine every possible aspect of care for links to the event in order to recover those costs. Equally they should not view this simply as an opportunity to recover the costs of many months of care due to a "never event" occurring at some point during that care. This misses the point of the "never events" policy, which is about reporting and learning. Cost recovery must be proportionate and appropriate.

To ensure cost recovery is proportionate, commissioners should consider using caps on the maximum amount of money they recover. For certain "never events", it may not be possible to distinguish the costs of the relevant procedure from the extremely large costs of a significant period of care, such as the cost of a long period of mental health inpatient care. This means the commissioner could impose a very large financial penalty on the provider. Commissioners should avoid recovering costs to the point where the loss of income could have a detrimental effect on patient care. Where there is the potential for this to be an issue, commissioners and providers should discuss what principles to apply in advance, 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, $\pounds10,000$.

Commissioners also have the discretion to waive cost recovery if they agree with the provider that this is appropriate. For example, if they are satisfied that there is evidence of transparency and that the provider is taking swift, robust and appropriate action to prevent recurrence of the error, they could reduce or not impose any cost recovery at all.

Alternative systems of imposing flat rate 'fines' for "never events" or sliding scales of financial penalties based on the impact of the "never event" were considered. These however undermine the principle that the "never event" policy is not primarily about punishment; it is firstly about reporting and learning to strengthen the systems for prevention, and only secondarily about not paying for poor quality. These fining systems also present their own problems with determining appropriate levels of repayment for each event. It therefore makes

sense to allow commissioners simply to not pay for care associated with "never events" if appropriate.

2.4 Other concerns

Some respondents have queried the fact that a few of the "never events" do not stipulate that death or severe harm must have resulted from the incident for it to count. This is a deliberate feature. Some errors are so preventable and have such potential for harm, that even if harm is avoided, their incidence should still be classified as a "never event".

For all other "never events" there is a single definition of 'severe harm' taken from the National Patient Safety Agency's '*Seven Steps to Patient Safety; The Full Reference Guide*⁴. Severe Harm is defined as;

Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. Permanent harm, directly related to the incident and not related to the natural course of the patient's illness or underlying condition, is defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ, or brain damage.

Concerns were raised by some respondents that some providers will be unwilling to take on complex cases or treat the seriously ill for fear that a "never event" may result. This is an unacceptable interpretation of the policy. "Never events" are by definition largely preventable. If a provider takes every recommended step to prevent occurrence and an incident still occurs, this argues strongly that the incident was not preventable and therefore not a "never event". Commissioners and providers should agree before implementing the framework how they will ensure that complex cases will be considered and reviewed both before and after any procedures are performed to ensure that there is no disincentive to providing the care that seriously ill patients need.

Many respondents also highlighted that the list is heavily acute care focused and called for the inclusion of events that apply to social care and primary care for example. There is no reason why those responsible for commissioning services in these areas should not use appropriate

"never events" from the national list to assist them in commissioning for quality and safety in these services, or devise their own local "never events".

The reason for the focus on the events listed is, in part, because the acute sector has the most highly developed reporting and learning culture, meaning that we know more about what goes wrong in this sector than many of the others and also, crucially, how these mistakes can be avoided. In addition, the principal mechanism for applying the "never events" framework in the NHS is through the standard contracts for acute hospitals, mental health and learning disability services, ambulance services and community services. It remains our longer-term ambition to embed the concept of "never events" more fully in all sectors of NHS provision

Related to this, many respondents asked for more clarity on the care settings to which specific "never events" apply. The "never event" list only applies to NHS-funded care, although providers are free to use the list for privately funded care as well. We have stated an event applies to 'all healthcare <u>settings</u>' where there is no need to restrict the application of the "never event" to any particular location, service or specialty. 'All' therefore refers to any healthcare setting where the care is being funded by the NHS and that is covered by one of the standard contracts (acute, mental health and learning disability, community and ambulance services). It explicitly includes mental health settings and care of those at home by NHS services.

Where we have stated the "never event" applies to 'all healthcare <u>premises</u>', this excludes care provided outside of healthcare facilities, for example at a patient's home. This is because either the relevant care is not provided outside healthcare facilities, or because the circumstances involved in safety incidents in these locations are different from those in more traditional care settings (for example the roles of formal and informal carers), and available guidance does not apply.

In some cases, there is the potential for the event to apply in multiple care settings, but the available guidance and preventative measures only apply to certain settings. In these cases, we have specified the settings where it is reasonable for the event to apply. For example, the suicide via non-collapsible rails event could theoretically apply to any care setting with curtain and shower rails, but the previously issued guidance specifies that it is inpatient mental health settings that must ensure collapsible rail are fitted and so it would be inappropriate and

disproportionate to specify that this event applies to all settings. Commissioners and providers are free to expand the settings to which any of the "never events" apply if they feel this is appropriate.

The "never events" apply across all age groups unless otherwise specified.

3. Implementing the expanded list

Commissioners and providers are now familiar with the concept of "never events" and they have been used in the NHS since April 2009. This section describes the principles and processes that commissioners and providers should use to implement the "never event" policy.

The fundamental and unarguable motivation behind the "never events" policy is to ensure as far as possible that these events never happen.

"Never" means that individuals and their families and friends do not have to endure the potentially devastating and long-term impacts of a very serious safety incident.

"Never" means avoiding incidents that cause death, serious long-term disability, significantly prolonged stays 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.

As discussed earlier "never" is an aspiration. These errors should not happen and all efforts must be made to prevent these mistakes from being repeated. This means that the overriding concern for the NHS in implementing the "never event" policy is to discuss these events when they occur and to learn from the mistakes that were made.

Commissioners and providers should use the national list of "never events" to discuss and agree a shared understanding of the roles, responsibilities and processes that they will follow when a "never event" occurs, including incorporating these arrangements into their contracts. Discussion and openness between commissioners and providers around Serious Untoward Incidents, including "never events", should continue to be part of contract fulfillment and lie at the heart of ensuring safety for patients treated by the NHS.

To aid this discussion, the process that commissioners and providers should follow when a "never event" occurs should include the following key steps;

 Providers should immediately inform patients and/or their families that a serious incident has occurred according to the principles of the 'Being Open' policy⁵, including offering appropriate support to patients/their families and the staff involved who may also be affected by the incident.

- Providers must discuss a possible "never event" with their commissioners and, through the NPSA, report to the Care Quality Commission as part of their existing requirements to report Serious Untoward Incidents^{6,7}.
- Providers should carry out an analysis of the underlying root causes of the event and discuss learning and preventative action with their commissioner, sharing any learning with the NPSA as appropriate.
- Commissioners and providers should discuss and, if appropriate, put in place arrangements for the commissioner to recover the costs of the procedure in which the "never event" occurred and any necessary treatment that results from this event.
- Commissioners should publish the numbers and types of "never events" that have been reported to them on an annual basis.

There are some events that could count as more than one event under the new "never event" list. For example, misidentification of a patient following a failure to use wristbands correctly could lead to wrong site surgery being the inappropriate treatment that the patient receives. If there is a single error that could be categorised as either one of two distinct "never events", only one "never event" has actually occurred. Commissioners and providers should discuss the most appropriate classification. If on the other hand two separate events occur, for example wrong site surgery and retention of a foreign object in the same surgical procedure, this should be counted as two separate "never events".

3.1 Agreeing roles, responsibilities and processes.

In 2010/11, commissioners used the national list of "never events" as part of their contract agreements with providers and were able to recover the costs of any procedure in which a "never event" occurred and if appropriate the costs associated with treating the consequences of that "never event". These arrangements continue. Before April 2011, commissioners and providers should discuss the arrangements for implementing the expanded list of "never events", building on the arrangements that already exist.

There are a number of issues that commissioners and providers may wish to consider when discussing the expanded list of "never events";

- The arrangements for implementing the guidance and alerts that are specific to the prevention of each "never event" should be reviewed to ensure preventative measures are in place, or action is being taken to address any concerns.
- Commissioners and providers should agree which events are relevant to them as some are specific to certain care settings or services.
- Commissioners and providers should agree processes for determining when a "never event" has and has not occurred, including resolving any disputes. As a simple rule we would suggest that if an incident cannot be easily demonstrated to be a "never event", then it probably is not, as "never events" should be easily identifiable.
- Commissioners and providers should agree how they will determine whether cost recovery is appropriate. For example commissioners may agree to waive cost recovery if they are satisfied that a provider is taking rapid and responsive action to deal with the causes of a "never event" and to prevent recurrence. Equally waiving cost recovery may be appropriate where the reduction in income involved could further damage patient care.
- Commissioners and providers should discuss and agree any variations to the principles of recovering the cost of the procedure in which the "never event" occurred and whether a cap on cost recovery is appropriate.
- The "never events" policy must not lead to providers being unwilling to provide appropriate care for patients for fear of a "never event" occurring. In response to our earlier proposals, some contributors raised the possibility that providers such as tertiary referral centres treating patients with complex co-morbidities may be discouraged from accepting referrals due to the increased risks of a possible "never event" occurring. Providers and commissioners should discuss arrangements for ensuring that complex cases that could result in an apparent "never event" that is actually not preventable because of complex and multiple co-morbidities, should be exempt from the policy. All such events should still be reported and investigated according to best practice and existing regulatory requirements.

3.2 Agreeing contractual terms for recovering costs

The NHS standard contracts for acute, mental health and learning disabilities, community and ambulance services mandate the inclusion of the national list of "never events" with clearly defined consequences of breach, i.e. cost recovery. The Table of Never Events for the standard contracts is set out at Annex 1 of this document.

As stated earlier, commissioners are free to decide to impose or 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.

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 be considered 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.

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, £10000.

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.

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 those commissioners who wish to ensure patient safety is improved in these sectors may wish to adapt the contents of this document for those sectors. 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 costs, or a pre-agreed value.

As in previous years, commissioners and providers are currently free to negotiate their own "never events" in addition to the "never events" set centrally, along with any appropriate locally agreed contractual arrangements as they see fit. These locally defined "never events" should still fit with the criteria as set out on page 4. There are examples around the country where local health care communities have embraced this idea. However for the purposes of simplicity the locally determined "never events" should not duplicate nationally determined ones and the national event should take precedence. Locally agreed "never events" should also be distinguished from the national events in any reporting to ensure clarity.

3.3 How "never events" fit with the wider regulatory system

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 may use information on "never events" to inform its regulatory processes in conjunction with other indicators and, following a "never event", may 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 account the local response to the "never event", such as cost recovery, and evidence of learning.

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 "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, securing provision of which is intended to be the responsibility of the NHS Commissioning Board in the future.

3.4 Dispute resolution

Neither the Department or the NPSA will act as arbiters of whether a particular incident is a "never event". This is solely for agreement between the provider and the commissioner. If both parties are unable to agree on whether an event is a "never event", or what level of cost recovery is appropriate, they could always seek independent mediation from another NHS body or independent mediation service. However if this occurs, it is our view that both parties will have failed to understand the basic principles of the "never events" framework. Patients and the public will rightly be concerned with any process that focuses on who is and isn't correct and which wastes public resources rather than focusing on improving the care that is provided.

Ultimately it is not imperative to determine if something is or isn't a "never event" but it is imperative that the incident is identified, reported and learning is put in place to prevent the incident happening again.

4. The "never event" list

The expanded "never event" list is, in the view of the Department, a reasonable list of events that are unacceptable and eminently preventable in the NHS. It is the list that all organisations providing NHS care should work from.

SURGICAL

1. Wrong site surgery

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.

- Includes biopsy, radiological procedures and drain insertion, where the intervention is considered surgical.
- Excludes wrong site anaesthetic block.
- 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.

Setting: All healthcare premises.

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/

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 operating plan either prior to or during the procedure. The incident is detected at any time after the implant/prosthesis is placed in the patient and the patient requires further surgery to replace the incorrect implant/prosthesis and/or suffers complications following the surgery.

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

Setting: All healthcare premises.

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/?entryid45=59824
Safer Surgery Checklist for Cataract Surgery, 2009, available at http://www.rcophth.ac.uk/core/core_picker/download.asp?id=375

3. Retained foreign object post-operation

Unintended retention of a foreign object in a patient after surgical intervention, including interventional radiology, cardiology and vaginal birth.

- Includes swabs, needles, implants, fragments of screws, instruments and guidewires.
- Excludes where any relevant objects are found to be missing prior to the completion
 of the surgical intervention and may be within the patient, but where further action to
 locate and/or retrieve would be more damaging than retention, or impossible. This
 must be documented in the patient's notes and the patient informed.

Settings: All healthcare premises.

Guidance:

Standards and recommendations for safe perioperative practice, 2007, available at http://www.afpp.org.uk/news/safe-practice-highlighted-in-new-afpp-publication
 Swab, instrument and needle counts: Managing the risk, 2005, available at http://www.afpp.org.uk/filegrab/07Swabandinstrumentcount.pdf?ref=1040
 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/

MEDICATION EVENTS

4. Wrongly prepared high-risk injectable medication

Death or severe harm as a result of a wrongly prepared high-risk injectable medication.

- High-risk injectable medicines are identified using the NPSA's risk assessment tool^{*}. A list of high-risk medicines has been prepared by the NHS Aseptic Pharmacy Services Group using this tool[†]. Organisations should have their own list of high-risk medications for the purposes of the "never event" policy, which may vary from the NHS Aseptic Pharmacy Services Group list, depending on local circumstances.
- A high risk injectable medicine is considered wrongly prepared if it was not;
 - prepared in accordance with the manufacturer's Specification of Product Characteristics;
 - prepared in accordance with a protocol formally agreed by the local organisation (for example for off-label or unlicensed product use);
 - prepared in accordance with patient specific directions of a prescriber in an urgent or emergency situation and supported by evidence or expert advice.
- This event excludes any incidents that are covered by other "never events".
- Where death or severe harm cannot be attributed to incorrect preparation, treat as a Serious Untoward Incident.

Setting: All healthcare settings.

Guidance:

- Patient Safety Alert - Promoting safer use of injectable medicines, 2007, available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59812&p=4

^{*} 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 [†] Pharmaceutical Aseptic Services Group. Example risk assessment of injectable medicines. 2007. Available at http://www.civas.co.uk/

5. Maladministration of potassium-containing solutions

Death or severe harm as a result of maladministration of a potassium-containing solution. Maladministration refers to;

- selection of strong[‡] potassium solution instead of intended other medication,
- wrong route administration, for example a solution intended for central venous catheter administration given peripherally,
- infusion at a rate greater than intended.

Setting: All healthcare settings.

Guidance:

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

- Standard Operating Protocol fact sheet; Managing Concentrated Injectable Medicines, part of the WHO High 5's project, available at <u>https://www.high5s.org/bin/view/Main/WebHome</u>

6. Wrong route administration of chemotherapy

Intravenous or other chemotherapy (for example, vincristine) that is correctly prescribed but administered via the wrong route (usually into the intrathecal space).

Setting: All healthcare premises.

Guidance:

- HSC2008/001: Updated national guidance on the safe administration of intrathecal chemotherapy, available at

http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/healthservicecirculars/d h 086870

- Rapid Response Report NPSA/2008/RRR004 using vinca alkaloid minibags (adult/adolescent units), available at

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59890

7. Wrong route administration of oral/enteral treatment

Death or severe harm as a result of oral/enteral medication, feed or flush administered by

 $^{\ddagger} \ge 10\%$ potassium w/v (eg ≥ 0.1 mg/ml potassium chloride, 1.3mmol/ml potassium chloride)

any parenteral route.

Setting: All healthcare settings.

Guidance:

- 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

8. Intravenous administration of epidural medication

Death or severe harm as a result of intravenous administration of epidural medication.

 A broader "never event" covering intravenous administration of intrathecal medication or intrathecal administration of intravenous medication is intended once the deadlines for Patient Safety Alert 004A and B actions have passed.

Setting: All healthcare premises.

Guidance:

Patient Safety Alert NPSA/2007/21, Safer practice with epidural injections and infusions, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807
 Safer spinal (intrathecal), epidural and regional devices - Parts A and B, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807

9. Maladministration of Insulin

Death or severe harm as a result of maladministration of insulin by a health professional.

Maladministration in this instance refers to when a health professional

- uses any abbreviation for the words 'unit' or 'units' when prescribing insulin in writing,
- issues an unclear or misinterpreted verbal instruction to a colleague,
- fails to use a specific insulin administration device e.g. an insulin syringe or insulin pen to draw up or administer insulin, or
- fails to give insulin when correctly prescribed.

Setting: All healthcare settings.

Guidance:

- Rapid response report – Safer administration of insulin, 2010, available at <u>http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287</u>

- NHS Diabetes – Safe use of insulin, 2010, available at http://www.diabetes.nhs.uk/safe use of insulin/

- NHSIII Toolkit – Think Glucose, 2008, available at <u>www.institute.nhs.uk/thinkglucose</u> - NHS Diabetes guidance - The Hospital Management of Hypoglycaemia in Adults with Diabetes Mellitus, 2010, available at

http://www.diabetes.org.uk/About_us/Our_Views/Care_recommendations/The-hospitalmanagement-of-Hypoglycaemia-in-adults-with-Diabetes-Mellitus/

10. Overdose of midazolam during conscious sedation

Death or severe harm as a result of overdose of midazolam injection following use of high strength midazolam (5mg/ml or 2mg/ml) for conscious sedation.

- Excludes areas where use of high strength midazolam is appropriate. These are specifically only in general anaesthesia, intensive care, palliative care, or where its use has been formally risk assessed.
- Excludes paediatric care.

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/medicationsafety/?entryid45=59896&p=2

- Guidelines for nursing care in interventional radiology, 2006, available at http://www.rcr.ac.uk/docs/radiology/pdf/GuidelinesforNursing.pdf

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

11. Opioid overdose of an opioid-naïve patient

Death or severe harm as a result of an overdose of an opioid given to a patient who was opioid naïve. Specifically this means:

- Where a dose is used that is not consistent with the dosing protocol agreed by the healthcare organisation, or the manufacturer's recommended dosage for opioid-naïve patients*.
- Where the prescriber fails to ensure they were familiar with the therapeutic characteristics of the opioid prescribed.
- Excluded are cases where the patient was already receiving opioid medication.

Setting: All healthcare settings.

Guidance:

Rapid Response Report – Reducing dosing errors with opioid medicines, 2008, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888
 *Specific Product Characteristics available at www.medicines.org.uk

12. Inappropriate administration of daily oral methotrexate

Prescription, supply or administration of daily oral methotrexate to a patient for non-cancer treatment including supply to the patient with the instruction to take daily.

- Excludes cancer treatment with daily oral methotrexate
- Excludes where the error is intercepted before the patient is supplied with the medication.

Setting: All healthcare settings.

Guidance:

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

MENTAL HEALTH

13. Suicide using non-collapsible rails

Death or severe harm to a mental health inpatient as a result of a suicide attempt using noncollapsible curtain or shower rails.

Setting: All mental health inpatient premises.

Guidance:

- NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems, available at

http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_41228

- NHSE (2004) 10: Bed cubicle rails, shower curtain rails and curtain rails in psychiatric inpatients settings, available at

www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh 4119476

- 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

- DH (2007)08: Cubicle curtain track rails (anti-ligature), available at

http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_07640

14. Escape of a transferred prisoner

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.

Setting: All medium and high secure mental health inpatient premises.

Guidance:

- Standards for medium secure units, 2007, available at

www.rcpsych.ac.uk/pdf/Final%20Standards%20for%20Medium%20Secure%20Units%20PD F.pdf

- Best Practice Guidance: Specification for adult medium-secure services, 2007, available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidan_ce/DH_078744

GENERAL HEALTHCARE

15. Falls from unrestricted windows

Death or severe harm as a result of a patient falling from an unrestricted 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.

Setting: All healthcare premises.

Guidance:

Health Technical Memorandum (HTM) 55: Windows, available via <u>http://www.spaceforhealth.nhs.uk/England/space-health</u>
DH(2007)09 – Window restrictors, 2007, available at <u>http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080164.pdf</u>

16. Entrapment in bedrails

Death or severe harm as a result of entrapment of an adult in bedrails that do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) dimensional guidance.

Setting: All adult inpatient care premises.

Guidance:

Safer practice notice – Using bedrails safely and effectively, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59815
 DB 2006(06) Safe use of bed rails, 2006, available at

http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025348

- Local Authority Circular - Bed Rail Risk Management, 2003, available at <u>http://www.hse.gov.uk/lau/lacs/79-8.htm</u>

17. Transfusion of ABO-incompatible blood components

Death or severe harm as a result of the inadvertent transfusion of ABO-incompatible blood components.

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

Setting: All healthcare premises.

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/2010/03/SHOT-lessons-for-clinical-staff-website.pdf

18. Transplantation of ABO or HLA-incompatible organs

Death or severe harm as a result of inadvertent HLA (Human Leukocyte Antigen) or ABO antibody-incompatible solid organ transplantation, where the antibodies are of clinical significance.

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

Setting: All healthcare premises.

Guidance:

 BSHI and BTS Guidelines for the Detection and Characterisation of Clinically Relevant Antibodies in Allotransplantation, 2010, available at <u>http://bts.demo.eibs.co.uk/transplantation/standards-and-guidelines/</u>
 Antibody incompatible transplant guidelines, 2006, available at <u>http://bts.demo.eibs.co.uk/transplantation/standards-and-guidelines/</u>
 Patient Safety Alert – WHO Surgical Safety Checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/

19. Misplaced naso- or oro-gastric tubes

Death or severe harm as a result of a naso- or oro-gastric tube being misplaced in the respiratory tract.

Setting: All healthcare premises.

Guidance:

- Patient safety alert – Reducing harm caused by misplaced nasogastric feeding tubes, 2005, available at <u>http://www.nrls.npsa.nhs.uk/resources/?entryid45=59794</u>

- 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&g=0%c2%acnasogastric%c2%ac-asogastric%c2%c2%ac-asogastric%c2%c2%c2%ac-asogastric%c2%c2%c2%c2%c2%c2%c2%c2%c2%c

20. Wrong gas administered

Death or severe harm as a result of the administration of the wrong gas, or failure to

administer any gas, through a line designated for Medical Gas Pipeline Systems (MGPS) or

through a line connected directly to a portable gas cylinder.

Setting: All healthcare premises.

Guidance:

Health Technical Memorandum 02-01 parts A & B, 2006, available at https://publications.spaceforhealth.nhs.uk/?option=com_documents&task=new_pubs&Itemid =1®ion=England
Rapid Response Report - Oxygen Safety in Hospitals, 2009, available at http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=62811
NHSE SN (2003) 02: Medical liquid oxygen supply systems, 2003, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digital asset/dh_4121320.pdf
NHSE SN (2003) 01: Oxygen cylinder manifolds used to supply oxygen for patient use, 2003, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digital asset/dh_4121317.pdf
DH (2008) 06 - Medical air plant, 2008, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digital asset/dh_4121317.pdf
DH (2008) 06 - Medical air plant, 2008, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digital asset/dh_4121317.pdf

21. Failure to monitor and respond to oxygen saturation

Death or severe harm as a result of failure to monitor or respond to oxygen saturation levels in a patient undergoing general or regional anaesthesia, or conscious sedation for a healthcare procedure (e.g. endoscopy).

• Includes failure to physically have monitoring in place, and failure to act on relevant information from monitoring oxygen saturation.

- Excludes where action is taken in response to recorded adverse oxygen saturation levels, but this fails to prevent death or severe harm for other reasons (e.g. pre-existing problems with oxygenation that cannot be resolved).
- Excludes incidents where the accepted limitations of monitoring equipment mean that adverse readings may be artefactual (e.g. shock/vasoconstriction).

Setting: All healthcare premises.

Guidance:

Recommendations for the Standards of Monitoring During Anaesthesia and Recovery (4), 2007, available at http://www.aagbi.org/publications/guidelines/docs/standardsofmonitoring07.pdf
Royal College of Anaesthetists, Guidance on the provision of anaesthetic care in the non-theatre environment, revised 2010, available at http://www.rcoa.ac.uk/docs/GPAS-ANTE.pdf
British Society of Gastroenterology, Guidelines on safety and sedation during endoscopic procedures, 2003, available at http://www.bsg.org.uk/clinical-guidelines/endoscopy/guidelines-on-safety-and-sedation-during-endoscopic-procedures.html
Academy of Royal Medical Colleges, Implementing and ensuring safe sedation practice for healthcare procedures in adults. Report of an intercollegiate working party chaired by the Royal College of Anaesthetists, 2001, available at http://www.rcoa.ac.uk/docs/safesedationpractice.pdf

22. Air embolism

Death or severe harm as a result of intravascular air embolism introduced during

intravascular infusion/bolus administration or through a haemodialysis circuit.

- Excludes the introduction of air emboli through other routes. This therefore excludes
 introduction via surgical intervention (particularly Ear, Nose and Throat surgery and
 neurosurgery), during foam scleropathy and during the <u>insertion</u> of a central venous
 catheter.
- Introduction of an air embolism <u>after</u> the insertion of a central venous catheter, through the line, and during its removal, is included.
- Excludes where the introduction of the air embolism was caused by the actions of the patient.

Settings: All healthcare premises.

Guidance:

- Section 9.8 - Air Embolism, RCN; Standards for Infusion Therapy, 2010, available at http://www.rcn.org.uk/____data/assets/pdf_file/0005/78593/002179.pdf

Avoidance of air embolism is part of basic training of clinicians, hence a lack of additional alerts to date. However, this is to be the subject of a forthcoming evidence based guideline from the Society of Acute Medicine. More information and basic instruction is available from the following medical texts;

- pp 366-372, Lippincott's Nursing Procedures, Lippincott, Williams and Wilkins - pp254-256, Clinical Dialysis, Nissenson AR and Fine RN

23. Misidentification of patients

Death or severe harm as a result of administration of the wrong treatment following inpatient misidentification due to a failure to use standard wristband (or identity band) identification processes.

Failure to use standard wristband identification processes means;

- failure to use patient wristbands that meet the NPSA's design requirements,
- failure to include the four core patient identifiers on wristbands last name, first name, date of birth and NHS number,
- failure to follow clear and consistent processes for producing, applying and checking patient wristbands,
- printing several labels with patient details at one time.

This event excludes where the patient refuses to wear a wristband despite a clear explanation of the risks of not doing so, or where it has been documented that the patient cannot wear a wristband due to their clinical condition or treatment, or in emergency care environments where high patient turnover, insufficient patient identity information, or the need for rapid treatment can delay wristband use.

Setting: All healthcare premises.

Guidance:

- Patient Identifiers for Identity Bands: Information standard; Information Standards Board for Health and Social Care - DSCN 04/2009, March 2009, available at http://www.isb.nhs.uk/library/standard/175

- Safer Practice Notice – Standardising Wristbands improves patient safety, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824

- Safer practice notice – Safer Patient Identification, 2005, available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/patient-admission-transfer-

discharge/?entryid45=59799

24. Severe scalding of patients

Death or severe harm as a result of a patient being scalded by water used for washing/bathing.

• Excludes scalds from water being used for purposes other than washing/bathing (eg from kettles)

Settings: All healthcare premises.

Guidance:

- Health Technical Memorandum 04-01 - The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems, 2006, available from

http://www.spaceforhealth.nhs.uk/

- Hospital Technical Memorandum HTM64 (Sanitary assemblies), 2006, available from http://www.spaceforhealth.nhs.uk/

- NHS Model Engineering Specification D08 (Thermostatic Mixing Valves – healthcare premises), 1999, available from http://www.spaceforhealth.nhs.uk/

- 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

MATERNITY

25. Maternal death due to post partum haemorrhage after elective caesarean section

In-hospital death of a mother as a result of haemorrhage following elective caesarean section.

- Excludes cases where placenta accreta is found, or where there is a pre-existing bleeding disorder, or the mother refuses blood components for any reason.
- Excludes emergency caesarean section and where a scheduled elective caesarean section is brought forward.

Setting: All healthcare premises.

Guidance

The role of emergency and elective interventional radiology in postpartum haemorrhage, good practice No. 6, 2007, available at http://www.rcog.org.uk/womens-health/clinical-guidance/role-emergency-and-elective-interventional-radiology-postpartum-haem
 Saving mothers' lives: Reviewing maternal deaths to make motherhood safer – 2003-2005,

2007, available at <u>http://www.cemach.org.uk/Publications-Press-Releases/Report-</u> Publications/Maternal-Mortality.aspx

- Patient Safety alert – WHO safer surgery checklist, 2009, available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/

- BCSH Guidelines on the Management of Massive Blood Loss, 2006, available at

http://www.bcshguidelines.com/documents/massive_bloodloss_bjh_2006.pdf

5. Glossary of terms

Never event – a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers

Severe harm – Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. Permanent harm, directly related to the incident and not related to the natural course of the patient's illness or underlying condition, is defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ, or brain damage.

All healthcare settings – all locations where the care is being funded by the NHS and that is covered by one of the standard contracts (acute, mental health and learning disability, community and ambulance services). It explicitly includes mental health settings and care of those at home by NHS services.

All healthcare premises – all locations comprising dedicated healthcare facilities delivering NHS-funded care that is covered by one of the standard contracts (acute, mental health and learning disability, community and ambulance services). This specifically excludes any care provided outside of dedicated healthcare facilities, for example at a patient's home or in other irregular surroundings.

Root Cause Analysis – A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Serious Untoward Incident/Serious incident for investigation - an incident that occurred in relation to NHS-funded services and care resulting in one of the following:

 Unexpected or avoidable death of one or more patients, staff, visitors or members of the public;

- Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure;
- Allegations of abuse;
- o Adverse media coverage or public concern about the organisation or the wider NHS;

Annex 1 - Table of "never events" for the standard contracts

"Never event"	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
Wrong site surgery	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Wrong implant/prosthesis	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Retained foreign object post-operation	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Wrongly prepared high-risk injectable medication	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Maladministration of potassium-containing solutions	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Wrong route administration of chemotherapy	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care

"Never event"	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		Performance Report	
Wrong route administration of oral/enteral treatment	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Intravenous administration of epidural medication	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Maladministration of Insulin	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Overdose of midazolam during conscious sedation	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Opioid overdose of an opioid-naïve Patient	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Inappropriate administration of daily oral methotrexate	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any

"Never event"	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		monthly Service Quality Performance Report	corrective procedure or care
Suicide using non- collapsible rails	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Escape of a transferred prisoner	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Falls from unrestricted windows	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Entrapment in bedrails	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Transfusion of ABO- incompatible blood components	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Transplantation of ABO or HLA- incompatible organs	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to

"Never event"	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		Incidents reports and monthly Service Quality Performance Report	Commissioner for any corrective procedure or care
Misplaced naso- or oro-gastric tubes	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Wrong gas administered	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Failure to monitor and respond to oxygen saturation	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Air embolism	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Misidentification of Patients	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care
Severe scalding of Patients	>0	Review of reports submitted to National Patient Safety Agency (or	In accordance with applicable Guidance, recovery of the cost of the

"Never event"	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		successor body)/Serious Incidents reports and monthly Service Quality Performance Report	procedure and no charge to Commissioner for any corrective procedure or care
Maternal death due to post partum haemorrhage after elective caesarean section	>0	Review of reports submitted to National Patient Safety Agency (or successor body)/Serious Incidents reports and monthly Service Quality Performance Report	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to Commissioner for any corrective procedure or care

References

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

² Department of Health, *'Equity and Excellence: Liberating the NHS'*, July 2010. Available at <u>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance</u> /DH 117353

³ National Patient Safety Agency, *Never Events Annual Report 2009/10*, October 2010, available at http://www.nrls.npsa.nhs.uk/resources/collections/never-events/?entryid45=83319

⁴ National Patient Safety Agency, '*Seven Steps to Patient Safety; The Full Reference Guide,* second print, August 2004, available at <u>http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/</u>

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

⁶ Care Quality Commission, *Essential Standards of Quality and Safety,* March 2010, available at

http://www.cqc.org.uk/ db/ documents/Essential standards of quality and safety March 20 10 FINAL.pdf

⁷ 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