NHS England

Revised Never Events Policy and Framework – Frequently asked Questions

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

Publications Gateway Reference:	**03330**
Document Purpose	Guidance
Document Name	FAQs on the Revised Never Events Policy and Framework
Author	NHS England Patient Safety Domain
Publication Date	27 March 2015
Target Audience	To be published on the NHS England website
Additional Circulation List	
Description	The FAQs provide supporting information around the implementation of the revised Never Events Policy and Framework published March 2015.
Cross Reference	Revised Never Events Policy and Framework
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	
Contact Details for further information	Patient Safety Domain NHS England Skipton House 80 London Road London SE1 6LH

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet. **NB:** The NHS Commissioning Board (NHS CB) was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the NHS Commissioning Board has used the name NHS England for operational purposes.

The Never Events List 2015/16 – Frequently Asked Questions

Why are there now only 14 Never Events when there were 25 last year?

There are two main reasons for this:

Firstly the purpose and definition of a Never Event has been revised in the latest version of the Framework. This is to provide greater emphasis that a Never Event arises from failure of strong systemic protective barriers. Several of the previous Never Events do not meet the updated definition. These are:

- Opioid overdose of an opioid/opiate-naïve patient
- Escape of a transferred prisoner
- Wrong gas administered
- Failure to monitor and respond to oxygen saturation
- Air embolism
- Misidentification of patients
- Wrongly manufactured high-risk injectable medication [1]
- Maternal death due to post-partum haemorrhage after elective caesarean section

This does not mean they are not considered to be patient safety priorities but that they do not meet the revised definition of a Never Event. If they are serious incidents, they should still be managed using the Serious Incident Framework.

Secondly, several of the Never Events have been merged for the purpose of simplification. Wrong route chemotherapy, wrong route oral/enteral treatment and intravenous administration of epidural medication have been merged into wrong route administration of medication. Transfusion of ABO incompatible blood components and transplantation of ABO incompatible organs have been merged into transfusion or transplantation of ABO-incompatible blood components or organs.

Have any of the criteria for the current Never Events been changed?

Yes - it is important to review each Never Event on the list as some of the definitions have been revised, and /or the health care setting has changed. Where appropriate the guidance has also been updated.

Why has the outcome of death or severe harm been removed from the current list of Never Events?

The definition of a Never Event has changed. Although each Never Event type has the potential to cause serious patient harm or death, harm is not required to have occurred for an incident to be categorised as a Never Event.

[1] This Never Event was removed from the list for 2015/16 as the strong systemic protective barriers that are required e.g. national availability and use of ready to administer products in clinical areas, requires a national plan that was beyond the timescales of this review.

Does the wrong tooth extraction apply to milk teeth?

No – although the strong systemic protective barriers exist to prevent this incident from occurring, there is no known risk of serious harm or death.

Does the wrong tooth extraction apply to the inadvertent removal of teeth (with dental caries) which would have been removed at a future appointment?

Yes, as the strong systemic protective barriers exist to prevent this incident from occurring even though it may be planned to remove the tooth in the future.

The treatment that is undertaken should not deviate from the consent for treatment. However, there may be occasion's e.g. special care dentistry where examination of patients may be compromised, it may be necessary to have an open consent to allow for appropriate extractions and restorations once the patient is sedated and accessible.

Should the immediate re - implantation of a tooth removed in error be reported as a Never event?

Yes - as the strong systemic protective barriers exist to prevent this incident from occurring and it is not known if the re implantation will be successful.

Why does the wrong site surgery Never Event exclude incidents where the wrong site surgery is due to incorrect laboratory reports or results?

Although it is recognised that there are strong systemic protective barriers in place to prevent wrong site surgery during the perioperative period, national guidance isn't currently available to sufficiently prevent the risk of incorrect laboratory reports or results occurring.

Why does the wrong site surgery Never Event exclude incidents where wrong site blocks are undertaken as a pain control procedure relating to a long term medical condition?

Although it is recognised that there are strong systemic protective barriers in place to prevent wrong site blocks during the perioperative period, national guidance isn't currently available to sufficiently prevent the risk of wrong site blocks being undertaken as a pain control procedure relating to a long term medical condition.

What counts as the start of surgery for wrong site surgery?

The start of surgery should be considered the point at which the patient's physiology begins to be permanently altered. This includes for example the beginning of any incision that will result in scarring and require time to heal and recover from.

Should the implantation of wrong Intra ocular (IOL) lenses be reported as a Never Event, if there is not a high risk of serious harm or death?

Yes - there are strong systemic protective barriers that exist to prevent the wrong IOL lens being implanted. Although it is recognised that in the majority of cases a wrong IOL lens can be exchanged for the optimal one with minimal risk to the patient or an adverse outcome, there is still the potential for serious harm/ complications for some patients.

What about incidents where an instrument component, fragment, or the whole instrument is retained inside the patient, and its location is known to the surgeon,

but it is considered more problematic or harmful to retrieve it than leave it even though the surgeon knows exactly where it is? Is this a Never Event?

No - where the location of an object is known, for example when part of a drill bit breaks off during surgery but it is considered too difficult or harmful to retrieve even though the location is clear, then this will not count as a retained instrument Never Event, provided the patient is informed and the incident recorded in their notes. Again, this does not remove the need to investigate the incident and implement any learning to prevent its recurrence.

What about where an instrument is used in a procedure and unintentionally sheds components during the procedure but this is not detected. Is this a Never Event?

No – this is not a Never Event as in these circumstances; it is not subject to a formal counting/ checking process

Does the 'falls from poorly restricted windows' Never Event include incidents when

- **the Provider has not put a restrictor in place, in accordance with guidance**
- **the restrictor is poorly fitted/the restrictor is damaged and has not been repaired?**

Yes - In these circumstances the fall is a Never Event, except where the individual deliberately forces the window open by damaging the restrictor immediately before the incident.

Is the Never Event relating to entrapment in bed rails now only relevant to a patient's chest or neck?

Yes - the current national guidance on the safe use of bed rails, published by the MHRA, is specifically relevant to preventing chest and neck entrapment.

Has the Never Event relating to misplaced naso or oro gastric tubes changed?

Yes - the definition of this Never Event has been revised to clarify that it is when a patient is fed via a naso or oro gastric tube into the respiratory tract, regardless of the harm to the patient.

Why has a new Never Event that has been proposed as part of the consultation not been included in the list?

The criteria for a never event are that they must:

- Be wholly preventable, where guidance or safety recommendations are available at a national level, that provide strong systemic protective barriers have been implemented by all healthcare providers.
- Have the potential to cause serious patient harm or death.
- Have occurred in the past, for example through reports to (NRLS),
- Be easily recognised and clearly defined

All proposals were assessed against these criteria but if the proposal did not fully meet them a new Never Event was not considered.

What is meant by strong systemic protective barriers?

Strong systemic protective barriers can be further defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use is known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike.

Will there be an opportunity for new Never Events to be developed in the future?

Yes - it is anticipated that the Never Events list will be reviewed on an annual basis. If the evidence becomes available to support its inclusion as a Never Event, this will provide the potential opportunity for guidance to be developed and the systemic protective barriers to be assessed. It will also provide the opportunity for new Never Events to be identified.

What happens when a new Never Event that has been proposed as part of the consultation has not been included in the list and is unlikely to meet the definition of a Never Event in the future?

If the incident concerned is a serious incident then it should be reported/ managed appropriately using the Serious Incident Framework.

This is because when the revised criteria for a Never Event was applied to the overdose of insulin (due to the use of abbreviations), and methotrexate the systemic protective barriers were not strong enough in care settings where electronic barriers did not exist. For example even though most acute hospitals do have a pre-printed insulin prescription to try and prevent prescribers using the abbreviations “iu” or “u” this is certainly not true in all care settings, notably care homes. In addition the pre-printed prescriptions is not in itself a reliably strong enough barrier to prevent a potential 10 fold dosing error as prescribers can still prescribe insulin on general prescriptions.

So what does my organisation, that does not have an electronic prescribing, dispensing and administration systems in place do if they have a patient safety incident involving overdose of methotrexate for non-cancer treatment, or insulin due to the use of abbreviations?

They should report it to the NRLS in the normal manner and investigate it as a serious incident if the harm was severe or the patient died as a consequence. The introduction of electronic prescribing, dispensing and administration systems is an evidence based method to reduce patient harms due to medicines and all NHS organisations should be moving towards this goal as soon as possible

Why do two of the medication Never Events appear to only include care settings that have electronic prescribing, dispensing and administration systems in place?

This is because when the revised criteria for a Never Event criteria was applied to the overdose of Insulin, due to the use of abbreviations, and methotrexate the systemic protective barriers were not strong enough in care settings where electronic barriers did not exist. For example even though most acute hospitals do have a pre-printed insulin prescription to try and prevent prescribers using the abbreviations “iu” or “u” this is certainly not true in all care settings. In addition the pre-printed prescriptions are not alone a reliably strong enough barrier to prevent a potential 10 fold dosing error as prescribers can still prescribe insulin on general prescriptions.

What should Commissioners and Providers do if they cannot agree on whether something is or is not a Never Event?

Neither the Department of Health nor NHS England Central Patient Safety Team will act as arbiters of whether a particular incident is a Never Event. This is solely for agreement between the Provider and the Commissioner.

Does it matter if an incident is discovered a long time after it happened, or at a different organisation to where it happened?

Never Events may, on occasion, be discovered some time, even years, after the incident itself occurred. The delay between the incident and its discovery is not in itself a factor in determining whether an incident is a Never Event or not. It may however, have a bearing on the improvements that are deemed necessary following investigation of the Never Event, for example where changes in procedures since the incident mean that additional actions may no longer be necessary.

Similarly, where an incident is discovered by one organisation, but appears to be the responsibility of another, this is still a Never Event. It must however be recorded and responded to by the organisation where the incident occurred provided they are identifiable. The 'discovering' organisation does not have to report the incident as their own but should endeavour to inform the originating organisation.

What about incidents that are Never Events now, but which occurred some time ago before they were designated as Never Events and are only recently discovered?

These circumstances are going to be rare and each case must be considered individually and the Never Event status agreed by the Commissioner and relevant Provider. It should also be remembered that provided appropriate preventative measures have been put in place since the incident, debating the nature of a historical event is unlikely to have practical benefit. However, as a general rule, local health care organisations should consider the status of the incident at the time and in particular whether it met the Never Event criteria at the time that it occurred. If the incident pre-dated the availability of clear, easy to apply guidance to prevent the incident or the introduction of the Never Event framework in 2009, then it's not a Never Event. If however there was clear guidance on how to prevent it and this was not put in place, then it could be considered a Never Event in all but name, and treated appropriately.

What happened to the revised cost recovery approach that was suggested as part of the consultation period in October?

During the Never Events Policy and Framework consultation in October it was proposed that cost recovery is limited to instances where there is a failure to report a Never Event or where there are repeated Never Events indicating an organisation has failed to learn from previous incidents. It is recognised that the Framework must support an emphasis on learning and create a system to support this and the consultation responses supported this approach. Unfortunately it presented a number of operational challenges in terms of implementation that would not be ready for April 2015, so this remains a key area of focus for the coming year.

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

Action	Never Event	Rationale
Removed	Maternal death due to post-partum haemorrhage after elective caesarean section	The guidance for a post-partum haemorrhage is not considered to be any more robust than for any other major haemorrhage and therefore, does not meet the definition that requires the availability of strong systemic protective barriers to make it wholly preventable. This Never Event was also defined by an outcome (death) that would not in itself reflect how significant the failure of barriers had been, as it could be affected by a number of other factors *313 consultation respondents agreed with the removal of this Never Event and 38 did not.*
Removed	Wrongly manufactured high-risk injectable medication	Note the existing Never Event was not sufficiently specific in terms of its scope, and no Never Events had ever been reported under this category. It had been most commonly understood to be encompassing local manufacture of medication within a pharmacy department (though some responses to consultation considered it could or should apply to any reconstitution of high risk medication in a ward area, e.g. setting up a heparin pump). The strong systemic protective barriers required i.e. the national availability of, and the use in all clinical areas, of ready to administer injectable medication products requires a national plan that was beyond the timescales of this review. We recognise the support that inclusion of this Never Event has received and with this in mind we look to undertake an impact assessment with NHS partners that will be reviewed again in 2016 to ensure that this gets a high level of attention as a prime candidate for future inclusion on the list under the appropriate circumstances. It is important to note that the majority of feedback responses were contradictory in that

		they agreed there were currently no strong barriers to prevent human error, and yet still supported its retention as a Never Event. This may relate to persistent belief amongst pharmacists in the 'perfection myth' (that if individuals strive hard enough not to make error, they will not make errors). *305 consultation respondents agreed with this Never Event and 46 did not, so it will be reviewed next year for inclusion with further information.*
Removed	Opioid overdose of an opioid/opiate-naïve patient	The strong systemic protective barriers to prevent this are not strong enough at present as they rely on the provision of clinical guidance and the education and training of health professionals only *313 consultation respondents agreed with the removal of this Never Event and 38 did not.*
Removed	Escape of a transferred prisoner	This was removed from the list as the barriers to prevent this are not strong enough. It was felt that they are treated as a serious incident and investigated and this is the important issue. *During the consultation 154 from 174 responses agreed that it should be removed as a never event*
Removed	Wrong gas administered	The guidance relating to the administration of gases does not represent a sufficiently strong systemic protective barrier to prevent inappropriate administration – hence this category does not meet the Never Event criteria *296 consultation respondents agreed with the removal of this Never Event and 55 did not.*
Removed	Failure to monitor and respond to oxygen saturation	The overwhelming majority of respondents agreed with removal of this incident as a Never Event However there was some discomfort about removing this, most notably from the Royal College of Anaesthetists. They felt that

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

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