To:	**Trust Board**
From:	**MEDICAL DIRECTOR**
Date:	**29 NOVEMBER 2012**
CQC regulation:	**ALL**

Title:	**Thematic review of never events**

Author/Responsible Director: Dr K Harris – Medical Director

Purpose of the Report: To provide the Trust Board with an update on the Trust's thematic review of never events.

The Report is provided to the Board for:

Decision		Discussion	
Assurance	√	Endorsement	

Summary / Key Points:

Summary of never events, lessons learned, and next steps.

Recommendations:

The Trust Board is invited to receive and note the report.

Considered at another UHL corporate Committee ? yes – GRMC 26 November 2012

Strategic Risk Register N/A	**Performance KPIs year to date** N/A

Resource Implications (eg Financial, HR)
N/A

Assurance Implications
Yes

Patient and Public Involvement (PPI) Implications
N/A

Equality Impact
N/A

Information exempt from Disclosure
N/A

Requirement for further review ? reported to the GRMC each month through the patient safety report.

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: **TRUST BOARD**

DATE: **29TH NOVEMBER 2012**

REPORT BY: **MEDICAL DIRECTOR**

SUBJECT: **UPDATE ON THEMATIC REVIEW OF NEVER EVENTS**

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1. INTRODUCTION

1.1 Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

1.2 Incidents are considered to be never events if:-

- The incident either resulted in severe harm or death or had the potential to cause severe harm or death.
- There is evidence that the never event has occurred in the past and is a known source of risk (for example through reports to the National Reporting and Learning System or other serious incident reporting system).
- There is existing national guidance or safety recommendations, which if followed, would have prevented the incident from occurring.
- Occurrence of the never event can be easily identified, defined and measured on an ongoing basis.

1.3 The term should not be used for incidents that do not meet these criteria. Attached at Appendix 1 is the revised never event policy framework document, published 29 October 2012.

1.4 **The aim of the Never Event policy is to reduce the incidence of never events to zero. They are intolerable and inexcusable**.

2. HEADLINES FROM THE REVISED FRAMEWORK

2.1 Reporting Never Events is a legal requirement under CQC regulations and must be reported to the CQC. This obligation can be met by reporting the Never Event to the National Reporting and Learning Service (NRLS) which UHL already do.

2.2 Board, Chief Executives and Accountable Officers of each organisation are responsible for ensuring the implementation and adherence to the Never Events Framework and reporting processes as described in section 3 of the attached policy.

2.3 Failure to report a Never Event or possible Never Event which subsequently comes to light through a third party route, for example a Coroner's inquest, media report or patient complain, will be viewed as an extremely serious failing on the part of the staff involved as well as the organisation.

2.4 Failure to report is more likely to be symptomatic of the culture of an organisation, rather than the result of an individual's action. Therefore responsibility rests with the Board and Senior Managers, rather than a single individual.

2.5 The failure to declare or report is viewed as an extremely serious failing on the part of the staff involved as well as the organisation.

2.6 Possible as well as actual Never Event must be reported on to STEIS to enable the Commissioners and the SHA to track the response to the incident.

2.7 Any failure to report should be referred to the CQC immediately, by the Provider or the Commissioner.

2.8 Commissioners should treat failures to report very seriously with the full range of powers afforded to them including suspension or termination of services delivered by the Provider.

2.9 Cost recovery is secondary to the process of report Never Events and learning from them, but Commissioners should seek to withhold payments for the episode of care in which a Never Event has occurred.

3. UHL NEVER EVENTS

3.1 Attached at Appendix **2** is the updated Thematic Review of Never Events within UHL.

3.2 A further Never Event was reported in October 2012 which relates to Retained Foreign Object Post Operation. See Appendix **3** for details.

4. UPDATE ON NEVER EVENT WORK STREAMS

4.1 Following the Thematic Review of Never Events, there have been two meetings held to discuss the lessons and actions required. An update is provided below:-

- Marking the Operation Site. Dr. Tim Bourne has sourced a potential marker pen that cannot be easily removed by surgical preparation.
- Procurement have been approached to progress purchase.

- Next steps will be to agree with Divisions a list of Consultants who need to be supplied with a pen and information regarding national good practice regarding skin marking.

4.2 Adhering to the WHO Safer Surgical Check List

- Team briefing guidance has been updated and shared with all theatre users.
- The safer surgery checklist has been shared and discussed at CBU Quality and Safety meetings.
- The Head of Nursing for CSD is exploring the possibility of incorporating any issues raised in theatre following surgery to be incorporated in to ORMIS.
- A time out immediately before a procedure commences has been introduced (pause time between draping and knife to skin).

4.3 Adherence to National/Trust Policy and/or Procedures

- A review of appropriate local policies is underway in theatres to ensure they comply with guidance and ensure all disciplines of staff are aware of their responsibilities.

4.4 The SHA "Review and Thematic Analysis of Maternity Never Events 2011/12" document has been received and noted by the Trust.

The Women's CBU has reviewed the report and has considered and implemented the recommendations.

5. RECOMMENDATIONS

5.1 Trust board are invited to note:-

i The new Never Events Framework document.
ii The work being undertaken within UHL, which will include a programme to inform all staff of the Never Event policy framework.
iii The Trust's intention to reduce Never Events within the organisation to zero.

Moira Durbridge,
Director of Safety Risk
November 2012

The never events policy framework

An update to the never events policy

Foreword

Protecting patients from avoidable harm is something on which there is universal agreement. How we achieve this is often more complex. With never events, there are clearly defined processes and procedures to follow to help ensure that these incidents do not happen. Yet despite such processes and procedures some of the never events listed in this policy framework have still occurred.

The numbers of never events reported in the NHS in the last two years, as detailed in Annex 1, demonstrate there is plenty of work to do to eradicate these incidents. We must, therefore, work together to understand why they occurred in order that we can continue to improve patient safety.

This will require root cause analysis which will not only examine such issues as compliance with, and the robustness of, relevant processes and procedures but also the role of human factors and how, if possible, these can be mitigated against to reduce the risk of recurrence further.

It also requires vigilance and the need to identify where the risk of a never event occurring exists before a patient is harmed, so-called ‘prevented never events’.

This Framework has been revised through consultation with stakeholders and offers a useful reference point for Boards, clinicians, staff and patients. It does not alter the basic principles of the never events policy and does not amend the types of incident included on the list. It does however clarify a couple of areas that caused some uncertainty and provides a comprehensive set of frequently asked questions to clarify some of the issues that health care providers and commissioners have raised. It also updates the references and guidance that underpin the never events list.

We strongly recommend that all Boards consider this refreshed Framework and that Medical and Nursing Directors take a lead to ensure that work is taken forward to improve patient safety and eradicate never events from health care.

Jane Cummings

Chief Nursing Officer

Professor Sir Bruce Keogh

NHS Medical Director

DH INFORMATION READER BOX

Policy	Clinical	Estates
HR / Workforce	Commissioner Development	IM & T
Management	Provider Development	Finance
Planning / Performance	Improvement and Efficiency	Social Care / Partnership Working

Document Purpose	Policy
Gateway Reference	17891
Title	The Never Events Policy Framework: an update to the never events policy
Author	Department of Health / Patient Safety
Publication Date	**29 October 2012**
Target Audience	PCT Cluster CEs, NHS Trust CEs, SHA Cluster CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, PCT Cluster Chairs, NHS Trust Board Chairs, Special HA CEs, Directors of Finance, Allied Health Professionals, GPs, Emergency Care Leads
Circulation List	
Description	The Never Events Policy Framework has been revised and updated through consultation with stakeholders to address areas of uncertainty and provide greater clarity about never events and the response to them. It offers a useful reference point for Boards, clinicians, staff and patients. This replaces the "List of Never Events 2011/12"
Cross Ref	The Never Events list 2011/12 and 2012/13
Superseded Docs	The Never Events List 2011/12
Action Required	N/A
Timing	**N/A**
Contact Details	Patient Safety Room 62A, Skipton House 80 London Road, London SE1 6LH 020 7972 3893
For Recipient's Use	

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Contents

1 Introduction

1.1 Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers[1].

1.2 Incidents are considered to be never events if :

- The incident either resulted in severe harm or death or had the potential to cause severe harm or death[2].
- There is evidence that the never event has occurred in the past and is a known source of risk (for example through reports to the National Reporting and Learning System or other serious incident reporting system).
- There is existing national guidance or safety recommendations, which if followed, would have prevented the incident from occurring.
- Occurrence of the never event can be easily identified, defined and measured on an ongoing basis.

1.3 The term should not be used for incidents that do not meet these criteria. The twenty-five types of incident that currently meet these criteria are listed in Section 8.

1.4 This document refreshes the current national policy on never events for the NHS in England. It builds on the never events frameworks developed by the National Patient Safety Agency since 2009/10 and is designed to provide healthcare workers, clinicians, managers, boards and accountable officers with clarity about their responsibilities. In particular, it is designed to be clear about what they are expected to do in terms of preventing never events and how they must respond to them if they should occur, including providing more clarity on reporting.

1.5 The aim of this policy is to reduce the incidence of never events to zero. They are intolerable and inexcusable.

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

[2] For some types of never event, there does not have to have been actual severe harm or death for the incident to be classed as a never event. The never events criteria require that the type of incident has the potential to cause severe harm or death. For some never events, an incident in which neither severe harm or death results is still a never event, for example wrong site surgery. For other types of never event, severe harm or death must result for the incident to be classed as a never event, for example maladministration of insulin.

1.6 When a never event occurs, the first step must be to understand why it happened and seek to learn from it, not simply to apportion unfair blame to an individual.

1.7 Failure to learn the lessons of a single never event or a prevented never event could be perceived as organisational failure on grounds of patient safety for which Board leaders, particularly the Chief Executive and Medical and Nurse Directors are accountable.

2 Background to the never events list

2.1 There are twenty-five never events specified in the NHS in England (see section 8). This list was expanded in 2011 from the original eight never events defined by the NPSA in 2009 following engagement with the NHS, patients and the public.

2.2 This framework maintains the current list as specified in the NHS Standard Contract for 2012/13[3].

2.3 The never events list provides a lever for those in the NHS to improve patient safety through greater focus, scrutiny, transparency and accountability when serious patient safety incidents occur. The existence of the never events list is a key driver in ensuring unrelenting focus on the eradication of these largely preventable and serious incidents.

2.4 The occurrence of a never event indicates a failure of protective systems and processes.

2.5 The analysis and reporting of never events is an indicator of the organisational attitude towards patient safety.

2.6 The never event list has been compiled to encourage greater organisational focus on specific serious safety issues. It does not exist to focus or divert blame onto individuals. Organisations must create a fair, open and just culture that does not seek simply to blame on individuals, but encourages reporting and asks why incidents occurred. This is because:

"…the causes of a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring." [4]

2.7 Occasionally never events are the result of poor practice by an individual rather than the system in which they work. These instances are rare, but the Incident Decision Tree

[3] Department of Health, '*NHS Standard Contracts for 2012/13*', December 2011. Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131988

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

developed by the NPSA can help managers and senior clinicians determine if it is appropriate to take action concerning an individual[5].

2.8 Never events are a particular type of patient safety incident, focus on which should form part of wider safety improvement efforts to reduce the number of patient safety incidents in health care. Ultimately it does not matter whether an incident matches a never event definition; patients must be protected from avoidable harm.

2.9 One of the key principles of patient safety improvement is that of incident reporting. This is therefore vital in the context of never events. Reporting is the first stage in learning the lessons from an incident and ensuring it can never happen again. Failure to report a never event is simply unacceptable and a sign of real cultural and safety failings in an organisation. As has been noted by Sir Liam Donaldson, "*to err is human, to cover up is unforgivable, and to fail to learn is inexcusable*".

2.10 Reporting serious incidents is a legal requirement under CQC regulations. Never events are clearly defined as serious incidents requiring reporting and therefore must be reported to the CQC, although this obligation can be met by reporting the never event to the National Reporting and Learning Service (NRLS, see paragraph 3.4). This requirement continues regardless of the organisational changes within the NHS.

2.11 Driving the incidence of never events to zero requires the concerted effort and focus of all those working in NHS-funded services. While the policy framework can be set nationally, it is those providing NHS-funded care that are accountable for the services they deliver. From ward to board, all sections of an organisation must play their part. However, ultimately, and for the sake of clarity, it must be the leadership of an organisation who are held accountable for any never events that occur in that organisation, and crucially for the response that organisation makes to the never event.

2.12 Failure to prevent a single never event should be taken as a clear sign by the Chief Executive that he/she must take steps quickly to ensure that procedures and systems to improve patient safety are reviewed, ensuring that any changes required are implemented to prevent recurrence of that event.

2.13 Repeated never events, particularly if they are the same type of incident, could demonstrate a failure of the organisation's leadership, particularly clinical leadership, to take patient safety seriously.

[5] National Patient Safety Agency '*Incident Decision Tree*' 2004. Available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900

3 Roles and Responsibilities

3.1 Boards, Chief Executives and Accountable Officers of each organisation undertaking NHS-funded services must ensure that:

- their staff are aware of this framework and its contents; all identified preventative measures are in place to prevent the occurrence of relevant never events across the whole organisation;
- they create an fair, open and just culture where staff are encouraged and supported to report incidents and the 'blame' culture is avoided (for more information see the NPSA's *Seven Steps to Patient Safety*[6]);
- processes are in place for staff to know how and when to report a never event and know how an incident is designated as a never event
- their staff are aware that it is their professional and moral responsibility to raise safety concerns with their line manager, or more senior managers if necessary, in order to enable the organisation to rectify the risks;
- procedures are in place for all prevented never events(see section 5) and actual never events to be reported to, and discussed by, the organisation's Board (or other accountable body);
- all staff are aware of the principles of the '*Being Open*' policy framework, their professional code of conduct with respect to protecting patients, (where applicable) reporting and disclosing incidents and the Duty of Candour
- all relevant staff are aware of the need for all prevented never event and actual never events to be reported to and discussed with the Commissioner of the relevant care episode;
- relevant staff to know that if in doubt they report an incident as a never event and then downgrade it later if investigation proves it not to be;
- all relevant staff to know that an investigation using Root Cause Analysis, as recommended by the NPSA, is initiated within 24 hours of an incident being identified and reported;

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

- all relevant staff are aware of the obligations that exist under the CQC registration requirements in terms of reporting serious incidents such as never events and the relevant guidance for responding to and reporting serious incidents[7];
- this awareness includes the requirement to report never events to both the Strategic Executive Information System (STEIS) and the National Reporting and Learning Service (NRLS) ensuring the fact that the incident is a never event is flagged/specified appropriately;
- relevant staff are also aware of the requirements for reporting never events to the NHS Trust Development Authority (NTDA) once it is established, and to Monitor, for non-FTs and FTs respectively;
- they establish a mutual understanding with their Commissioners of the principles determining which never events should be reported and reviewed;
- they establish a mutual understanding with their Commissioners of the principles and practicalities of any cost recovery associated with never events;
- never events are a standing agenda item for Board meetings (where there are no incidents to discuss, this should be made explicit)
- they understand their obligations with respect to the publication of information on never event occurrence via their Commissioner, through public Board papers (given the obligation to discuss never events) and in annual Quality Accounts.

3.2 A key component of the never events framework is its inclusion in the NHS Standard Contract, which ensures that never events are discussed as part of the contract negotiation process. This also ensures that each provider is contractually required to respond to never events in a nationally consistent manner, as set out in the relevant guidance (i.e. this document). It is therefore, important that Commissioners and Providers, whether NHS Providers or independent (which provide NHS care), discuss and agree a shared understanding for implementation of the never event framework during the contract negotiation phase each year. This negotiation should follow the below model;

[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

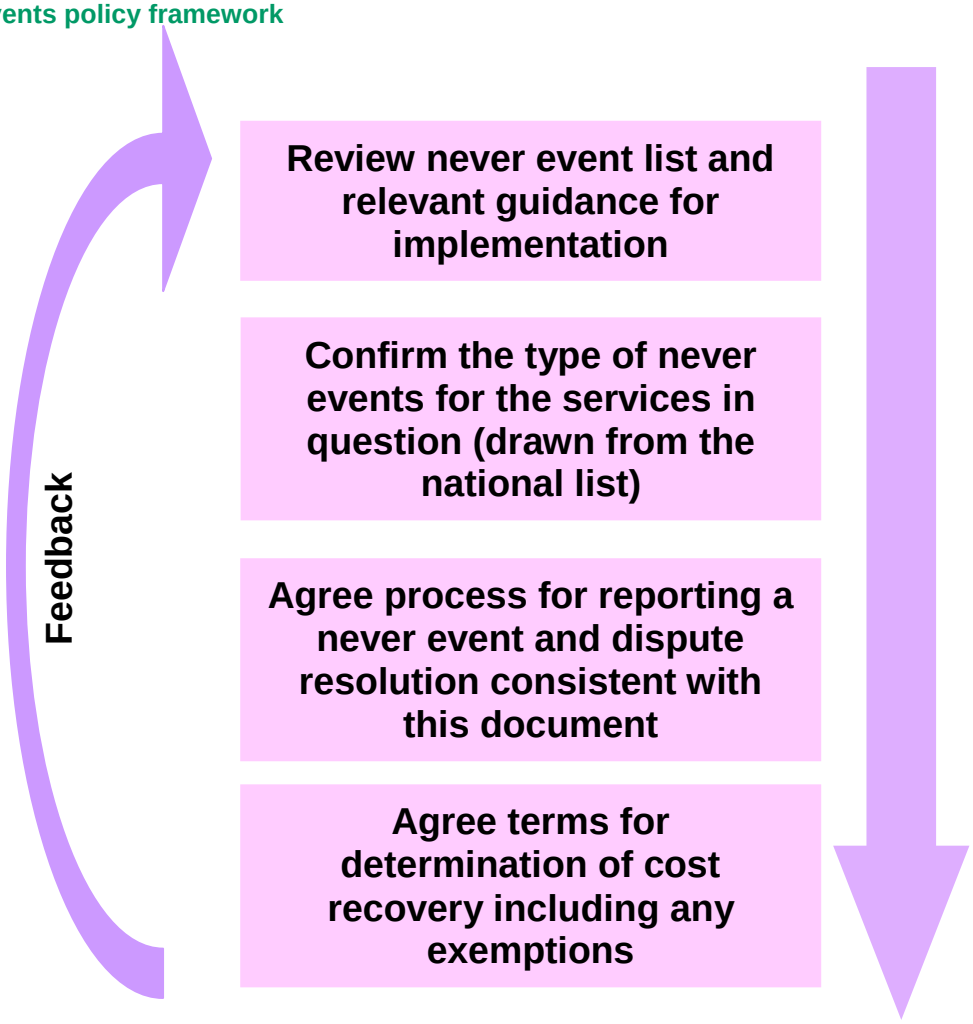

Figure 1. The commissioning process for never events

3.3 The existence of a never events framework and the associated processes does not replace other regulatory requirements such as registration with the CQC or compliance with essential standards.

3.4 Never events are defined in guidance[8] as 'Grade 2' serious incidents requiring investigation and should be reported to the CQC via the NRLS (even where there may be 'no harm'). They should be reported to the NRLS and also be recorded on the Strategic Executive Information System (STEIS) - (see 4.3). Reports to the NRLS should make clear a never event is being reported in the free text field. The CQC may use information on never events to inform its regulatory processes in conjunction with other indicators. Following a never event, the CQC may take any enforcement action it deems appropriate.

[8] 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

3.5 In the context of the structural changes underway in the NHS these principles will need to be kept under review, particularly during the period of transition as PCTs and SHAs disappear and the NHS Commissioning Board and NHS Trust Development Authority become established.

3.6 The NRLS and STEIS will provide a platform for incident reporting as well as being the source of data for analysis of trends and risks in relation to never events. Information derived from the NRLS and examined by the NHS Commmissioning Board's Patient Safety Division is utilised to provide the NHS with the resources and support necessary to reduce the risk of never events. The NRLS is the source of the data used to produce many of the recommendations and guidance that trusts should use to prevent the occurrence of never events.

3.7 In time, the NHS Commissioning Board will assume responsibility for national never events policy. It will maintain and update the never events framework as the new NHS embeds and takes shape and will be responsible for ensuring the policy framework fits with the wider system. It will also be reponsible for ensuring the NHS responds to, and learns from, patient safety incidents including never events, particularly where problems are highlighted through repeated similar incidents. It will also be responsible for the strategic approach to patient safety including, in time, the rationalisation of the reporting systems that exist in order to deliver a single effective system for reporting, managing, learning from and responding to incidents.

3.8 Previously there has been local leeway for Commissioners and Providers to agree local never events and the policy for how to respond to them. This has caused confusion in relation to the national policy. In future, if local healthcare economies wish to designate particular patient safety incidents for more intense scrutiny that are not covered by the national never events policy, they should not refer to these as never events.The term never events should be reserved for incidents fitting the national criteria and the various definitions for a never events. Locally agreed never events are no longer compatible with the national never events policy.

4. What should happen when a never event is suspected

4.1 The following summarises the process to be undertaken when a never event is suspected;

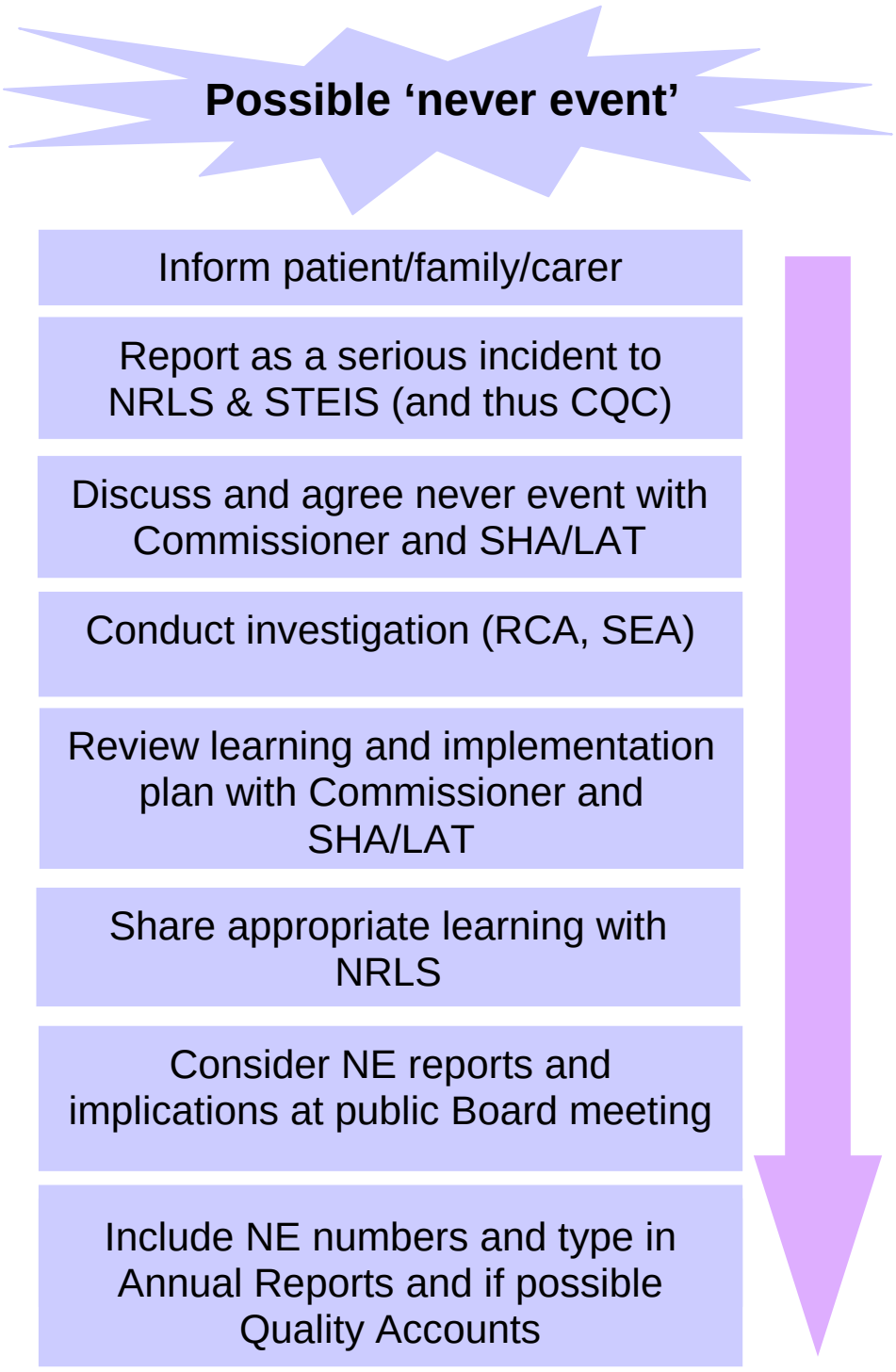

Figure 3. What to do when a never event is suspected.

STEIS	Strategic Executive Incident System
RCA	Root Cause Analysis
SEA	Significant Event Audit
NE	Never event
SHA/LAT	Strategic Health Authority/Local Area Team (when established)

4.2 The first step in this process is to inform the patient and/or their family or representative that a patient safety incident has occurred and that it is potentially a never event. This must take place as soon as possible after the incident and should not be delayed while the status of the incident as a never event or not is determined. If the status is unclear, this should be explained to the patient/their representative. The communication of a patient safety incident to a patient or their representative is described in detail in *Being Open*[9] and all staff should be familiar with these requirements as well as the outcome of any policy changes arising from the consultation on the proposed Duty of Candour.

4.3 The incident should be reported to the organisation's local risk management system as with all identified patient safety incidents. At this point consideration should be given as to whether the incident is a never event. If there is a possibility that it is, or if it is clear that it is, the incident should be assumed to be a never event, given a Grade 2 status for serious incident requiring investigation purposes (see *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*[10]*)*, and reported to STEIS as a never event within 2 working days of occurring or being identified. The incident report should be uploaded to the NRLS as soon as possible, ideally within the same timescale, although it is acknowledged uploading of data to the NRLS is often carried in batches and may therefore be less frequent than this.

4.4 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.

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

[10] 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

4.5 It is vital that all never events are reported both to STEIS and to the NRLS until a single system has been developed to integrate the two systems into one. Analysis of the numbers and types of never events reported to STEIS and to the NRLS indicates there is some confusion across NHS organisations about reporting never events to these two systems. Annex 1 provides an overview of the numbers and types of never events reported to both NRLS and STEIS. This demonstrates that reporting is not consistent to both systems and that reporting behaviour differs across organisations. All organisations should review their use of these systems and ensure their reporting is consistent with this and other relevant guidance, principally the current *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*[11].

4.6 Crucially, incident reports to both systems must clearly label the incident as a never event even if there is some uncertainty at the time the report is made. STEIS now contains a 'never events' field which should be used to indicate never event status. Incident reports to NRLS should also make clear the never event status of the incident in the free text field by using the words 'never event'. If necessary, incident reports on STEIS can be retrospectively amended to downgrade an incident from a never event if subsequent investigation shows this is necessary. A clear audit trail explaining the rationale for the change and who authorised it must be maintained.

4.7 Given the duplicative nature of these reporting processes and the potential for conflicting records of never events being held on discrete systems, there is a specific intention to develop a single national reporting system for use in the NHS. This will not replace organisations' own local risk management systems but will reduce the opportunity for confusion created by disparate regional and national systems. This work will be included in the wider programme to modernise the national reporting and learning system.

4.8 Never events must be highlighted to the relevant Commissioner within two working days as per the *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*. This may be automatic with STEIS/local incident management system reporting but good practice would dictate that personal contact between the relevant

[11] 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

Directors should take place in a timely manner. In cases where there is uncertainty around the status of an incident as a never event, Providers and Commissioners must come to a conclusion as a matter of urgency. It is important that where there is doubt about the status of an incident, the Commissioner and Provider discuss this and agree the categorisation according to the details set out in the never events list. Until April 2013, Providers and Commissioners should agree the status of an incident with their SHA. Advice may also be sought through peer review or from the NPSA (NHS Commissioning Board's Patient Safety Division), but the final decision will always rest with the Commissioner and Provider.

4.9 The FAQ section at the end of this document provides the answers to some queries that have arisen with respect to agreeing the status of some particular never events.

4.10 The nature of never events dictates that the Medical or Nursing Director (or clinical leader with delegated responsibility) should coordinate the organisation's response to the incident. They should become involved at an early stage, as soon as potential never event status is identified. They should be responsible for leading on final confirmation of the never event status, organising the investigation, discussion with the Commissioner and other external parties, including the patient or their representative, reporting to the Board, developing relevant learning from the incident and identifying the underlying contributory factors such as the Human Factors, and implementation of required actions. It is not appropriate for this task to be delegated ad hoc to more junior staff. If necessary, organisations should seek additional training to ensure staff are able to undertake appropriately detailed investigations that reflect the principles of human factors and relevant investigation methodologies (e.g. Root Cause Analysis, Significant Event Audit).

4.11 Providers should follow the detailed procedures set out in the *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*[12] for Grade 2 serious incidents. Those at the top of an organisation are responsible for ensuring that all relevant learning is captured and implemented effectively to prevent recurrence of the never event. It is the process of commissioning and carrying out a high quality investigation and then translating the findings of that investigation into effective learning and therefore prevention, that is the most crucial aspect of the never events framework.

[12] 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

4.12 Outcomes from this process of learning should be monitored through routine monitoring structures and processes.

4.13 After this process is complete, the Commissioner and Provider should discuss cost recovery. This is covered in more detail below.

4.14 The final stage is to ensure that the incidence of a never event is captured in the Commissioner's annual report and the Provider's Quality Accounts if possible (ensuring patient confidentiality is protected). This information should capture as far as possible;

- The type of incidents.
- The learning derived from the incidents, with a particular focus on the system changes that have been made to reduce the probability of it occurring again.
- Data on the total number of never events, including the historical context and related incidents such as prevented never events if appropriate.
- That learning has been shared more widely than the organisation.

5 Prevented never events

5.1 Prevented never events provide vital warning signs to Provider organisations that the potential for actual never events exists in their organisation. In that respect they are possibly the most powerful signal that action needs to be taken and can be the most important factor in preventing the devastating consequences of an actual never event.

5.2 Prevented never events are defined as incidents that may have been never events had action not been taken to avoid an incident meeting the never events criteria and where such action is not part of the specified preventative action detailed in the relevant associated guidance or safety recommendations. For example, it is a prevented never event where an opioid naïve patient receives an opioid overdose, but the error is rescued and severe harm or death is prevented through rapid naloxone administration. This is also an actual patient safety incident and should be reported as such, but is not an actual never event and so is not subject to cost recovery, for example.

5.3 Where appropriate available preventative measures are implemented and prevent an incident and/or near miss, this is not an incident.

5.4 Prevented never events are not the same as no or low harm never events. There are some never events where death or severe harm does not need to result for a never event to have occurred. Wrong site surgery for example could simply involve a small initial incision at the beginning of a surgical procedure. If a member of a surgical team halts the surgery following this error and no serious harm results, the incident is still a wrong site surgery never event, not a prevented never event. This is because the required checks and procedures cannot have been implemented correctly and the patient still requires further surgery on the correct site. The potential for harm in this scenario coupled with the very preventable nature of the incident warrants this being treated as a never event. It is not a prevented never event just because severe harm or death did not result, unless the definition of the specific never event category requires death or severe harm to have resulted in order to meet the definition.

5.5 Prevented never events such as those described should, in essence, be treated as seriously as actual never events except for the purposes of national reporting, cost recovery and publication of never events numbers. They should be reported both internally

to the organisation's leadership and externally to the Commissioner (although they should not be labelled as never events on the NRLS or STEIS systems). They must be investigated using appropriately robust protocols (SEA or RCA) and the learning from these prevented never events must be used as part of the preventative process to ensure actual never events do not occur. They should form part of the regular patient safety reports to organisational leadership and/or the Board who are accountable and responsible for ensuring these warning signs are not ignored. These processes should be agreed with Commissioners.

5.6 Clearly, this is a complex area and each potential prevented never event must be considered carefully and individually before taking appropriate action. The reason for outlining these steps is to emphasise the power of responding to prevented never events in avoiding the devastating consequences of an actual never event. When reviewing an incident that may be a prevented never event Providers and Commissioners should refer to the appropriate preventative guidance, particularly NPSA guidance, and the *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*.

6 Failure to declare or report a never event

6.1 Failure to report a never event which subsequently comes to light through a third party route, for example a Coroner's Inquest, media report, patient complaint or other soft intelligence, is an extremely serious failing on the part of the staff involved as well as the organisation. It is likely to constitute a breach of CQC regulation requirements (*Regulation 16 and 18 of the Care Quality Commission (Registration) Regulations 2009*). It also breaches NHS Standard Contract Section E Clause 25, which requires the appropriate reporting of serious incidents and patient safety incidents to the Commissioner and CQC.

6.2 Reporting a possible or actual never event to the NRLS alone does not fulfil all the reporting requirements that exist. The organisation should also report the incident on STEIS which ensures the commissioners and the regional NHS leadership are able to track the response to the incident.

6.3 Once it is established that a patient safety incident has occurred, it may still take time and some degree of investigation to establish if it is a never event. It may therefore also take some time to report the incident as a never event to the appropriate systems. As mentioned earlier, if there is some doubt about whether an incident is a never event, but the possibility has been recognised, then it should be reported as a never event immediately. If, however, even the possibility that an incident is a never event is not immediately recognised, there must be some allowances in terms of the timescales for reporting.

6.4 The *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation* sets out the timescales for investigating serious incidents. This states that an investigation into a grade 2 serious incident, which is what a never event is, should take no more than 60 working days from the point that the incident is recognised and notified to the commissioner/SHA. Therefore, it will be considered a failure to report a never event appropriately, where an incident has not been formally reported to the incident reporting systems (STEIS and NRLS) as a never event more than 60 days after the incident is first notified to the local risk management system, and it is subsequently established to be a never event through another route (e.g. a Coroner's inquest, patient complaint, media story etc.).

6.5 Any such failure to declare or report a never event should be referred to the CQC immediately to allow it to consider the issue and undertake the action it deems appropriate. This should be done by the Provider or Commissioner. In exceptional circumstances, the SHA would report this failure to the CQC.

6.6 Commissioners should also treat such breaches very seriously, using the full range of powers afforded to them via the Standard Contract. This must involve the development of a remedial action plan including, where possible;

- requiring a detailed review and analysis of the circumstances leading to the failure to recognise, declare and report such an event. The plan may require additional training in relation to serious incidents, never events and their reporting, and even the possibility of disciplinary action against individuals where there is evidence of deliberate non-disclosure;
- requiring the Provider Chief Executive to deliver full written and verbal explanations of the failure to declare and report the never event, the circumstances of the incident and the actions taken in response, in public to the PCT cluster/CCG Board and to the relevant patient/patient representative (subject to their agreement); and
- recovery of appropriate costs related to the never event and its consequences.

6.7 Failure to declare or report is much more likely to be symptomatic of the culture of an organisation, rather than being the result of the isolated action of an individual. In this scenario where there are cultural issues, the responsibility rests with the Board and senior managers rather than a single individual. This should be considered when developing any remedial action plan.

6.8 Commissioners should vigorously pursue compliance with the action plan and if necessary invoke further sanctions up to and including suspension or termination of services delivered by the relevant Provider if an incident was knowingly not declared or reported and patients remain at risk.

7 Cost Recovery

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

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

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

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

7.5 In some cases, the cost of the procedure in which a never event has occurred could represent the cost of care over a significant period of time, for example in a mental health inpatient setting. If the period of care has lasted a number of years, Commissioners could argue for the recovery of costs running to many hundreds of thousands of pounds. This would be disproportionate. Where this may be an issue, Commissioners and Providers should discuss what principles to apply while agreeing contracts. We suggest they agree to cap cost recovery to the equivalent of a month's inpatient stay, or at a monetary level of, for example, £15,000.

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

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

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

8 The never events list

The following never events list is the list that all organisations providing NHS care should work from.

The never events list has been updated since February 2011 with minor amendments to two of the never event definitions. The changes are to

- never event number 18, 'Transplantation of ABO incompatible organs as a result of error'
- never event number 23, 'Misidentification of patients'.

This is the revised list and definitions for use in the NHS from 2012/13;

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/ *- How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901
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/clinical-specialty/surgery/
- *Safer Surgery Checklist for Cataract Surgery,* 2010, available at http://www.rcophth.ac.uk/page.asp?section=365&sectionTitle=Information+
- *How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901

3. Retained foreign object post-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://learning.afpp.org.uk/documents/SwabA2Poster2007.pdf
- *Patient Safety Alert – WHO Surgical Safety Checklist, 2009,* available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/
- *How to Guide to the five steps to safer surgery', 2010,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=92901

- *Reducing the risk of retained throat packs after surgery*, 2009, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59853
- *Risk of harm from retained guidewires following central venous access*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132829
- *Tracking subsequent removal of intentionally retained swabs*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132834&p=2

MEDICATION 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[13]. A list of high-risk medicines has been prepared by the NHS Aseptic Pharmacy Services Group using this tool[14]. Organisations should have their own list of high-risk medications for the purposes of the never events policy, which may vary from the NHS Aseptic Pharmacy Services Group list, depending on local circumstances.
- The patient receives a wrongly prepared high risk injectable medication 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
- *Multiple use of single use injectable medicines*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=130185

[13] 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
[14] Pharmaceutical Aseptic Services Group. Example risk assessment of injectable medicines. 2007. Available at http://www.civas.co.uk/

5. Maladministration of a potassium-containing solution

Death or severe harm as a result of maladministration of a potassium-containing solution.

Maladministration refers to;

- selection of strong[15] 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 https://www.high5s.org/bin/view/Main/WebHome

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,* 2008, available at http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/healthservicecirculars/dh_086870
- *Rapid Response Report NPSA/2008/RRR004 using vinca alkaloid minibags (adult/adolescent units)*, 2008, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59890
- *Minimising Risks of Mismatching Spinal, Epidural and Regional Devices with Incompatible Connectors, 2011,* available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132897
- *Safer spinal (intrathecal), epidural and regional devices*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=94529

7. Wrong route administration of oral/enteral treatment

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

Setting: All healthcare settings.

Guidance:
- *Patient Safety Alert NPSA/2007/19 - Promoting safer measurement and administration of liquid medicines via*

[15] ≥10% potassium w/v (eg ≥ 0.1g/ml potassium chloride, 1.3mmol/ml potassium chloride)

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 both parts A (updated) and B of the *Safer spinal (intrathecal), epidural and regional devices* patient safety alert have passed.

Setting: All healthcare premises.

Guidance:
- *Patient Safety Alert NPSA/2007/21, Safer practice with epidural injections and infusions*, 2007, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59807
- *Safer spinal (intrathecal), epidural and regional devices*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=94529
- *Minimising Risks of Mismatching Spinal, Epidural and Regional Devices with Incompatible Connectors*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132897

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 http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74287
- *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 www.institute.nhs.uk/thinkglucose
- *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-hospital-management-of-Hypoglycaemia-in-adults-with-Diabetes-Mellitus/*
- *The adult patient’s passport to safer use of insulin,* 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=130397&p=2

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/medication-safety/?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
- *Over sedation for emergency procedures in isolated locations*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=94848
- *Prevention of Harm with Buccal Midazolam*, 2012, available at http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=132975

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
- *Intravenous morphine administration on neonatal units*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=130181&p=2
- *Opioids in palliative care: safe and effective prescribing of strong opioids for pain in palliative care of adults*, 2012, available at http://guidance.nice.org.uk/CG140
- *End of life care for adults quality standard*, 2012, available at

http://www.nice.org.uk/guidance/qualitystandards/endoflifecare/home.jsp
- *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 http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800

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 non collapsible curtain or shower rails.

Setting: All mental health inpatient premises.

Guidance:
- *NHSE SN (2002) 01: Cubicle rail suspension system with load release support systems,* 2002, available at http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Estatesalerts/DH_4122863?PageOperation=email
- *NHSE (2004) 10: Bed cubicle rails, shower curtain rails and curtain rails in psychiatric in-patients settings,* 2004, 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),* 2007, available at http://www.dh.gov.uk/en/publicationsandstatistics/lettersandcirculars/estatesalerts/dh_076400

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 http://www.rcpsych.ac.uk/pdf/Final%20Standards%20for%20Medium%20Secure%20Units%20PDF.pdf
- *Best Practice Guidance: Specification for adult medium-secure services*, 2007, available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/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 http://www.spaceforhealth.nhs.uk/England/space-health (login required)
- *DH(2007)09 – Window restrictors,* 2007, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_080164.pdf
- *Risk of falling from windows*, available at http://www.hse.gov.uk/healthservices/falls-windows.htm

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/home/idcplg?IdcService=GET_FILE&dDocName=CON2025397&RevisionSelectionMethod=LatestReleased
- *Local Authority Circular - Bed Rail Risk Management,* 2003, available at http://www.hse.gov.uk/lau/lacs/79-8.htm
- *Safe use of bedrails*, available at http://www.hse.gov.uk/healthservices/bed-rails.htm

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/2010/12/Lessons-for-Clinical-Staff-Dec-2010.pdf

18. Transplantation of ABO incompatible organs as a result of error

Death or severe harm arising from inadvertent ABO mismatched solid organ transplantation.

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

Setting: All healthcare premises.

Guidance:
- *BSHI and BTS Guidelines for the Detection and Characterisation of Clinically Relevant Antibodies in Allotransplantation,* 2010, available at http://www.bshi.org.uk/pdf/BSHI_BTS_guidelines_2010.pdf
- *Antibody incompatible transplant guidelines*, 2011, available at http://www.bts.org.uk/transplantation/standards-and-guidelines/
- *Patient Safety Alert – WHO Surgical Safety Checklist,* 2009*,* available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59860

19. Misplaced naso- or oro-gastric tubes

Death or severe harm due to a misplaced naso- or oro-gastric tube being used where the misplacement of the tube is not detected prior to commencement of feeding, flush or medication administration.

- Where appropriate checks are conducted and documented and demonstrate that the tube is in the correct place, but the tube is subsequently found to have become misplaced, for example after becoming dislodged, provided there has been regular checking of tube placement, this is not a never event.

Setting: All healthcare premises.

Guidance:
- *Patient safety alert – Reducing harm caused by misplaced nasogastric feeding tubes,* 2005, available at

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

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 via https://publications.spaceforhealth.nhs.uk/?option=com_documents&task=new_pubs&Itemid=1&region=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/digitalasset/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/digitalasset/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/digitalasset/dh_087060.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 2011, available at http://www.rcoa.ac.uk/node/766
-*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://aomrc.org.uk/publications/reports-a-guidance.html
- *Over sedation for emergency procedures in isolated locations*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=94848

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 insertion of a central venous catheter.

- Introduction of an air embolism after 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:
- *Risk of air embolism when removing central lines*, 2011, available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=132830
- *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. 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 does not apply to those units where wristbands are not used, for example some mental health inpatient units (this requires local agreement).

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 (e.g. 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 via https://publications.spaceforhealth.nhs.uk/index.php?option=com_documents&task=list_search&Itemid=1 (login required)
- *Hospital Technical Memorandum HTM64 (Sanitary assemblies),* 2006, available from *http://www.spaceforhealth.nhs.uk/* (login required)
- *NHS Model Engineering Specification D08 (Thermostatic Mixing Valves – healthcare premises)*, 1999, available from *http://www.spaceforhealth.nhs.uk/* (login required)
- *Scalding risks from hot water in health and social care LAC: 79/5,* 2007, available at http://www.hse.gov.uk/lau/lacs/79-5.htm
- *Scalding and burning*, available at http://www.hse.gov.uk/healthservices/scalding-burning.htm

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 – 2006-2008,* 2011, available at http://onlinelibrary.wiley.com/doi/10.1111/bjo.2011.118.issue-s1/issuetoc
- *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

9 FAQs

General

Is there any local flexibility about classifying something as a never event where it appears to meet the definition of the never events but there are genuine mitigating circumstances that render the incident non-preventable?

It is difficult to imagine a scenario in which a never event turns out to be non-preventable given the definitions have been carefully designed to not include any non-preventable incidents. That said, it is for local Commissioners and Providers to decide between them whether an incident matches one of the never events definitions. They should not of course amend the list of never events or their definitions for their own purposes.

Is there any local flexibility about the application of cost recovery?

Yes, although the default position should be to undertake cost recovery.

How should a Commissioner apply cost recovery where for example an incident takes place in one Provider's facilities, but where the responsible clinician or team is employed by another Provider?

It is the responsibility of the Provider who employs the clinician or team responsible for the never event even if it occurs on another Provider's premises.

What about prevented never events?

These are vitally important and should be treated as never events (and therefore Grade 2 serious incidents under the *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation)* for the purposes of investigation and implementation of learning to prevent actual never events. The consequences of a never event can be so devastating that it is vital that the opportunity to prevent future never events that is offered by a prevented never event cannot be ignored.

What about complex cases with multiple co-morbidities where this increases the chances of a complication leading to a never event?

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 through the investigation 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.

What age groups do never events apply to?

All age groups unless otherwise specified.

What about where a single incident could be classified as two types of never events?

There are some events that could count as more than one event under the never events 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.

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 or the NHSCB 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 is not 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.

What should happen in scenarios where a coroner's inquest determines that a death resulted from natural causes when it had appeared to be a never event?

If the never events definition in question requires death or severe harm to have resulted, and a coroner (or indeed other investigation) demonstrates the death was not caused by the error, this is not a never event. If death or severe harm is not required as part of the never events definition, the official cause of death is irrelevant. Where investigations demonstrate a never event has not actually occurred, incident reports and records should be amended accordingly, including any published data if feasible and appropriate.

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.

If the originating Provider cannot be identified, then the responsible originating Commissioner should report the incident as a never event, but making clear that it is unable to determine the originating organisation. They should consider how to improve their record keeping. If neither the originating organisation or originating Commissioner can be identified, then no practical action can result from recording the incident as a never event locally. The ‘discovering’ organisation should as a matter of good practice ensure that it has procedures in place to prevent a similar incident, but it should not record the incident as a never event occurring within its care. It should still report the incident to the NRLS to ensure that the incident is captured nationally for learning purposes, but making clear they are not the responsible 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 (paragraph 1.2) at the time that it occurred. So, for example, at the time of the incident, was the event likely to cause severe harm or death and was clearly preventable by following the guidance, support and safety recommendations available at the time? If the incident pre-dated the availability of clear, easy to apply guidance to prevent the incident, then it’s probably 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.

If an incident has occurred that doesn't exactly match one of the never events listed, does that mean the care provided was appropriate or safe?

Not necessarily. There will be many incidents, similar to the never events described, that still represent poor or unsafe care and which breach acceptable standards, but which aren't specifically never events. Just because the never event definitions provided do not match the circumstances of the incident exactly does not mean that the care provided was safe. Incidents that occur may still breach acceptable standards of safety while not matching a description in the never events list. Equally, the lists of relevant guidance are not necessarily exhaustive. There may well be additional standards and guidance that should be followed that are not listed and failure to follow those additional standards represents unacceptable care.

Specific never events definitions

Does death or severe harm have to occur for it to be a never event?

No. For several of the never events there is no need for severe harm or death to have resulted from the incident. For example, wrong site surgery and wrong route chemotherapy incidents have such devastating potential effects, and are preventable if the relevant procedures are correctly followed, that they constitute never events.

Does wrong tooth extraction count as wrong site surgery?

The definition of the wrong site surgery never event relies on the procedure being undertaken being considered ‘surgical’ by those involved. There is no easy definition of what is and is not surgical, but there are some factors that Providers and Commissioners may wish to consider when looking at an incident:

- Does the procedure involve sedation and/or general anaesthesia?
- Does the procedure involve permanent alteration of the patient’s physiology?
- Does the patient consider the procedure surgical?
- Will scarring result from the procedure (no matter how minor) or the procedure to take time to heal from?

If the answer to all or most of the above is yes, then it is likely the procedure is surgical and therefore could involve a wrong site surgery never event.

Therefore there are likely to be some tooth extraction procedures that are surgical and others that are not.

What about wrong site surgery where there is no real harm, for example removal of the wrong abscess in the presence of multiple abscesses?

Where the incorrect procedure was undertaken, even if it is very similar to the intended procedure, this is a clear signal that the appropriate preventative actions were either not undertaken correctly or not undertaken at all. In the abscess example, why was the incorrect abscess removed? Regardless of the harm that results, this incident is a never event as it clearly demonstrates a failure in the appropriate safety procedures which in other circumstances could result in severe harm or death.

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 in the wrong location. This includes for example the beginning of any incision or any other procedure that will result in scarring and require time to heal and recover from.

Does it matter if the wrong implant/prosthesis is not removed, for example if the patient chooses not to undergo corrective surgery or there is no actual harm?

Technically if there is no actual harm and the patient does not want any further intervention then this is not a never event. However this is a prevented never event and is only not an actual never event due to strict interpretation of the definition. The point is that the mistake was made in the first place which indicates a failure in the relevant preventative procedures. This must be addressed. If the patient refuses further surgery due to a reluctance born of the original mistake but they are clinically disadvantaged by the use of the wrong implant/prosthesis as compared to the condition they would be in if the correct implant/prosthesis were used, this counts as a 'complication' and therefore is a never event.

What about where an instrument used in a procedure unintentionally sheds components during the procedure but this is not detectable, or removal of the foreign object is more dangerous than retention?

In these circumstances, if the relevant objects are found to be missing prior to the completion of the surgical intervention and may be within the patient, but further action to locate and/or retrieve them would be more damaging than retention, or impossible, the incident is not a never event but must be documented in the patient's notes and the patient informed. Additionally this does not remove the need to investigate the incident and implement any learning to prevent its recurrence.

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? Does this constitute 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.

Is the "falls from unrestricted windows" never event intended to include where the Provider has not complied with the relevant guidance and not put a restrictor in place where they should, and/or 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.

Does it count if feeding is commenced through a mis-placed naso or oro-gastric tube but no death or severe harm results?

No, this is not a never event under the current definition as neither severe harm nor death has resulted from the error. This is clearly a prevented never event and should be treated as a never event for the purposes of reporting, investigation and learning, but should not be labelled as a never event in STEIS or to the NRLS, should not be

reported as a never event by the Commissioner in their annual report, and not subject to cost recovery.

Does the misidentification of patients due to the failure to use a wristband never event apply in those settings where a decision has been taken for all patients not to wear a wristband, for example in some mental health units?

No. Where an organisation or setting has made a clear and auditable decision for the benefit of its patients not to use wristband identification, this never event definition cannot apply.

10 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

Incidents are considered to be never events if they meet the following criteria;

- The incident may or does result in severe harm or death (note for some never events there does not have to have been severe harm or death for the incident to be a “never event).
- There is evidence that the never event has occurred in the past and that it is a known source of risk (for example through reports to the National Reporting and Learning Service or other serious incident reporting system).
- There is existing national guidance and/or national safety recommendations on how the event can be prevented as well as support for implementation of the relevant preventative measures.
- The event is preventable if the national guidance and/or national safety recommendations are implemented.
- Occurrence of the never event can be easily identified, defined and measured on an ongoing basis.

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 also looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Significant Event Audit - A process in which individual episodes (when there has been a significant occurrence either beneficial or deleterious) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care, and to indicate any changes that might lead to future improvements[16].

Serious Untoward Incident/Serious Incident Requiring 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;
- Adverse media coverage or public concern about the organisation or the wider NHS

Prevented never event - incidents which may have been never events had action not been taken to avoid an incident meeting the never events criteria, where such action is not part of

[16] National Patient Safety Agency, *Significant Event Audit* guidance. October 2008. Available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=61500

the specified preventative action detailed in the relevant associated guidance or safety recommendations.

Annex 1 – Never events reported to the NRLS and SHAs in 2010/11 and 2011/12

The tables below provides the number of never events reported to SHAs using the 'STEIS' system and the number of incidents reported to the NRLS and flagged as never events for 2010/11 and 2011/12. These figures should be read alongside the comprehensive explanatory notes that follow given the potential for misunderstanding.

Table A. 1. Never events reported to SHAs and the NRLS in 2010/11

Never Event	Number of never events reported to SHAs 2010/11	Number of Incidents flagged as never events in the NRLS 2010/11
Wrong site surgery	60	19
Retained instrument post-operation	67	22
Intravenous administration of mis-selected concentrated potassium chloride	<10	<10
Wrong route administration of chemotherapy	0	0
Inpatient suicide using non-collapsible rails	0	0
Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners	<10	0
Misplaced naso or orogastric tube not detected prior to use	31	11
In-hospital maternal death from post-partum haemorrhage after elective caesarean section	<10	<10
Total	**166**	**56**

Table A. 2. Never events reported to SHAs and the NRLS in 2011/12

Never Event	Number of never events reported to SHAs 2011/12	Number of Incidents flagged as never events in the NRLS 2011/12
Wrong site surgery	70	41
Wrong implant/prosthesis	41	15
Retained foreign object post-operation	161	86
Wrongly prepared high-risk injectable medication	0	0
Maladministration of potassium-containing solutions	<10	<10
Wrong route administration of chemotherapy	<10	0
Wrong route administration of oral/enteral treatment	<10	0
Intravenous administration of epidural medication	0	0
Maladministration of Insulin	<10	0
Overdose of midazolam during conscious sedation	<10	0
Opioid overdose of an opioid-naïve Patient	0	0
Inappropriate administration of daily oral methotrexate	<10	<10
Suicide using non-collapsible rails	0	0
Escape of a transferred prisoner	<10	0
Falls from unrestricted windows	<10	<10
Entrapment in bedrails	0	0
Transfusion of ABO-incompatible blood components	<10	0
Transplantation of ABO incompatible organs as a result of error	0	0
Misplaced naso- or oro-gastric tubes	23	15
Wrong gas administered	0	0
Failure to monitor and respond to oxygen saturation	0	0
Air embolism	<10	<10
Misidentification of Patients	<10	0
Severe scalding of Patients	0	0
Maternal death due to post partum haemorrhage after elective caesarean section	0	0
Total	**326**	**163**

Notes on the never events data

Where records indicate fewer than 10 incidents of a certain type of never event, the exact number is not provided. This is consistent with the previous publication policy applied to never event data by the NPSA. Never events are very rare and as such reporting low numbers of a particular type incident may represent patient identifiable information when combined with other data or information. The total number of never events provided includes all incidents reported.

From 2010/11, NPSA asked NHS organisations to clearly identify incident reports relating to never events in the free text of their incident report to the NRLS. The NRLS data was therefore derived by carrying out a search for the term 'never events' in the free text of all the NRLS incident reports. In addition, probable never events identified from regular reviews of incidents reported to the NRLS as involving severe harm or death have been included.

Searching the NRLS for incidents flagged as never events relies on reporters to identify and flag never events appropriately, and is unlikely to find all reported never events. It was decided therefore that separate data on incident reports categorised as never events in local serious incident reporting systems should also be obtained from SHAs.

As detailed in the main document, the data from STEIS and the NRLS are not directly comparable due to differences in the way incidents are identified and reported as never events to the two systems. These data sets overlap to a large extent (i.e. most of the incidents reported to the NRLS are also reported to the SHAs) but there is some unique reporting to the two systems.

For example, 19 of the 163 never events recorded on the NRLS for 2011/12 are not recorded within the SHA data set for the same year. Some organisations, such as NHS Foundation Trusts, are under no obligation to report incidents to SHAs, which may go some way to explaining this discrepancy. Equally, the SHA data set contains incidents classified as never events locally but not found during the search of the NRLS. This may in part be due to these incidents not being flagged as never events in reports to the NRLS and therefore not detected during the exercise to search the NRLS. Other incidents may simply not have been reported to the NRLS. While it is a CQC registration requirement to report incidents involving severe harm and death to the CQC, and this can be done via reporting to the NRLS, it is not a specific legal requirement to report all never events, including those that do not involve severe harm or

death, to the NRLS. Organisations may report directly to CQC, or, in the case of incidents that do not involve severe harm and death, may not report them to the CQC at all. While it is strongly recommended that they do, reporting of never events that do not involve severe harm or death is only compulsory to the relevant commissioner, as set out in the NHS Standard Contract.

The differences in data collections between the SHA and NRLS data, and the amendments made to the never events list definitions between 2009/10, 2010/11 and 2011/12, mean that direct comparison of the total number of never events between years is not appropriate. The data cannot be used to draw conclusions about changes in the number of never events or to make assertions about trends in the safety of NHS services. For example, between 2010/11 and 2011/12, the definition of 'retained foreign object' was expanded to include swabs retained following vaginal birth. This has resulted in a significant increase in the number of incidents being captured within the 'retained foreign object' definition. This does not necessarily mean that there have been more of these incidents, and could be that they are now being reported as never events.

For clarity, the SHA figures are likely to be the more accurate number. SHAs will see relatively few serious incident reports compared with the million-plus incidents (of all kinds) reported to the NRLS annually. Therefore, SHAs are able to follow-up serious incident reports with the relevant Trust. This additional scrutiny can ensure that never events are identified, reported and responded to appropriately.

SHA and NRLS data was accurate as of August 2012. Incidents can be discovered and reported some time after they have occurred and therefore the above data may change as additional incidents are reported. Equally, investigation of an incident may result in it being 'downgraded' and found to not be a never event. Therefore, the above data is subject to change.

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Annex 2 – Table of never events for the standard contracts

Never Events	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 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

Never Events	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
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 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

The never events policy framework

Never Events	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
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 incompatible organs as a result of error	>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
Misplaced naso- or oro-gastric tubes	>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

Never Events	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		Incidents reports and monthly Service Quality Performance Report	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 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
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	In accordance with applicable Guidance, recovery of the cost of the procedure and no charge to

The never events policy framework

Never Events	Threshold	Method of Measurement	Never Event Consequence (per occurrence)
		monthly Service Quality Performance Report	Commissioner for any corrective procedure or care

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT BY: **DIRECTOR OF SAFETY AND RISK**

SUBJECT: **THEMATIC REVIEW OF NEVER EVENTS AT UHL**

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1. INTRODUCTION

1.1 Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

1.2 Introduced on the 1st April 2009 there were 8 events initially listed. There are now 25 "Never Events" on the expanded list. This includes the original 8, some of which have been modified, and builds on the draft list published in October 2010. The list is as follows:-

- Wrong site surgery.
- Wrong implant/prosthesis.
- Retained foreign object post operation.
- Wrongly prepared high-risk injectable medication.
- Mal-administration of potassium containing solutions.
- Wrong route administration of oral/enteral treatment.
- Wrong route administration of chemotherapy.
- Intravenous administration of epidural medication.
- Mal-administration of insulin.
- Overdose of Midazolam during conscious sedation.
- Opiod overdose of an opoid-naïve patient.
- Inappropriate administration of daily oral Methotrexate.
- Suicide using non-collapsible rails.
- Escape of a transferred prisoner.
- Falls from unrestricted windows.
- Entrapment in bed rails.
- Transfusion of ABO-incompatible blood components.
- Transplantation of ABO or HLA incompatible organs.
- Misplaced naso or oro-gastric tubes.
- Wrong gas administered.
- Failure to monitor and respond to oxygen saturation.
- Air embolism.
- Misidentification of patients.
- Severe scalding of patients.
- Maternal death due to post partum haemorrhage after elective Caesarean section.

1.3 Primary Care Trusts are required to monitor the occurrence of Never Events within the services they commission and publicly report them on an annual basis.

1.4 This paper details the findings of a review undertaken of the 9 Never Events reported by UHL NHS Trust since 2009, which were investigated by the Divisional and Corporate Patient Safety Team.

2. THE CASES

2.1 Case 1 – Retained Blade Post Operation – Musculo-Skeletal (November 2009)

The patient underwent a routine left total hip replacement. During the early stages of the procedure it was noticed that a number 23 blade was missing from the long blade handle. It was immediately brought to the attention of the surgeon and searches were made in the operative site and within the theatre without success. The surgeon closed the wound and arranged for the patient to be x-rayed in recover, where it was noted to be in the soft tissues around the left hip. The patient was taken back to theatre for retrieval of the blade.

What Happened?

- There was a failure to follow the "Management of Surgical Swabs Needles and other Accountable Items within the Operating Theatre Policy and Procedures" (patient should have been x-rayed before leaving theatre).
- The surgeon deviated from the above policy because he believed it certain that the blade could not be in the wound and must have fallen to the floor, despite searching for the blade and it not being found.
- The theatre team suggested to the surgeon that an x-ray be performed in the theatre before closure of the wound, but this was declined.

2.2 Case 2 – Wrong Site Knee Surgery – Musculo-Skeletal (February 2010)

The patient was taken to theatre for a right knee arthroscopy. The correct knee was marked and the consent form correctly completed, but the procedure was commenced on the left knee. The Health Care Theatre Assistant recognised the error and spoke up. The procedure was stopped and the right knee investigated as required.

What Happened?

- The person operating was not the same as the person taking consent and marking the site.
- The site marking was not prominent or undertaken in accordance with the policy.
- The WHO Surgical Safety Checklist was not used in this theatre and there was no time out or verbal check of the site for surgery or position of the table before the procedure started.
- The scrub nurse rotated the table for the left knee which caused confusion. The nurse then left the theatre and did not return until the procedure had started.
- Additional theatre staff joined the team during the procedure but were not briefed.

2.3 Case 3– Retained Surgical Swab – General and ENT Surgery (March 2010)

The patient had an oesophagogastrectomy and anastomosis of oesophagus to the stomach. All swab counts were documented as being correct at the final count. Post-operatively the patient complained of abdominal pain which did not settle. Eight days post-operatively an x-ray identified a large abdominal swab which was removed the next day from behind the spleen.

What Happened?

- There was a failure to follow the "Management of Surgical Swabs, Instruments, Needles and Other Accountable Items within the Operating Theatre Policy and Procedures". (The swab placed in the body cavity was not recorded on the board in theatre and the swab counts did not detect the retained swab and was therefore inaccurate).
- The surgery performed was highly complex and required two separate surgical teams to operate at the same time, with the abdomen and neck incisions being undertaken synchronously, increasing the risk in terms of tracking swabs.
- All disciplines of theatre staff (surgeon, operating department practitioner (ODP) and scrub practitioner) directly involved in the surgery were at the level where they required supervision.
- There was a miscount of surgical swabs and failure to perform a count when one of the scrub practitioners returned to theatre following a break.
- There was no verbal acknowledgement of the swab going in to the patient's cavity, and no record made on the theatre white board.
- There was a single circulating practitioner to support 2 surgical teams, creating pressure on all involved.

2.4 Case 4 – Wrong Route Chemotherapy – Oncology (April 2011)

The haematology patient was admitted for combination chemotherapy treatment (intravenous and intrathecal). Intravenous Cytarabine was prepared. Two qualified nurses completed the necessary checks at the bedside in accordance with Cytoxic Policy but failed to identify during checking the route of administration. The drug was administered subcutaneously rather than intravenously.

What Happened?

- There was a failure to adhere in full to the checking procedure during the administration of the drug i.e. the route was not checked.
- There is a national requirement, reflected in the local Trust policy, that all intravenous chemotherapy must be administered prior to any intrathecal drugs being released from pharmacy. The nurses felt some pressure to administer the IV drug promptly to allow the patient to go to theatre for the intrathecal drugs.
- The patient was on an oncology ward as there were no beds in haematology.

2.5 Case 5 – Retained Vaginal Swab – Maternity (June 2011)

The patient had a forceps delivery in obstetric theatres for poor progress in the second stage of labour. Approximately three day spost discharge, the patient felt unwell and contacted her G.P. who prescribed antibiotics. The patient continued to feel unwell and was experiencing offensive vaginal discharge. Further antibiotics were prescribed and as there was no improvement, the patient visited her G.P. surgery who examined her and reportedly removed a maternity pad sized swab from the vagina.

What Happened?

- The pre and post swab, instrument and needle counts were completed and were correct before, during and following delivery.
- The patient was catheterised following delivery but at no time were any swabs inserted in to the vagina.
- Post natal examination of the perineum was undertaken on three occasions and appropriate referral to the G.P. as lochia described as offensive.
- No root causes were identified as the swab removed by the G.P. had not been returned for inspection and therefore it was impossible to determine which procedure it might be related to.

2.6 Case 6 – Wrong Lens Implant – Ophthalmology (April 2012)

The patient was admitted for elective cataract surgery (as a day case) to the left eye, including a replacement lens. The wrong strength lens was implanted. This was identified once the patient was in the recovery area, and following discussion with the patient, the decision was made to go back in to theatre and replace it with one of the correct power. No additional local anaesthetic was required.

What Happened?

- The WHO Safer Surgery Checklist was used and completed correctly. This clarifies the name, D.O.B, procedure, and site. (details regarding prosthesis are not required as part of the WHO Safer Surgery Checklist).
- There was a deviation from standard procedure as a theatre assistant selected the lens for implant instead of the surgeon.
- There was a deviation from standard procedure as there was more than one lens in the theatre at the same time.
- The standard procedure was not formally documented.
- Details of the lens to be implanted was not documented on the white board in theatre.
- There was a failure in the checking process immediately prior to implantation to ensure that the correct prosthesis had been selected.

2.7 Case 7 – Wrong Site Surgery to Finger – Musculo-Skeletal (April 2012)

A patient with diffuse osteoarthritis of the distal interphalangeal joints of most digits of both hands was scheduled for fusion of the left middle finger. Surgery was commenced on the index finger of the left hand. The mistake was immediately noticed by the assisting trainee and the procedure stopped. Surgery continued on the correct finger.

What Happened?

- Consent was confirmed by the operating consultant on the ward prior to theatre, in the presence of his registrar.
- Operative marking was undertaken using a permanent marker by the registrar, who was present in theatre at the time of the procedure.
- The WHO Safer Surgical Checklist was completed prior to the patient being prepared or draped.
- It was visually difficult to distinguish the digits of the hand due to the deformities caused by the osteoarthritis.
- The marking on the finger nail of the affected digit became either washed off or obscured by the Betadine skin preparation.

- There was a failure to undertake a definitive “STOP” to check and verbalise “loud and clear” the correct operation and site.

2.8 Case 8 - Wrong Dental Extraction – Maxillo-Facial (May 2012)

The patient was consented for extraction under general anaesthetic of upper right 6, lower right 7and upper left 6. Dental extraction was undertaken by two Senior House Officers. Instead of removing the upper right 6, they removed the upper left 7, leaving 6 in place.

What Happened?

This investigation is not yet complete however preliminary findings are:-

- The Who check list was used and correct instructions written on the whiteboard in theatre
- Due to previous dental extractions a human error occurred in the identification of the Upper Right 6 tooth.
- There is no reliable method of marking teeth prior to surgery.
- The extractions were undertaken by 2 separate surgeons.

2.9 Case 9 – Miss-placed or Displaced Naso-Gastric Tube – Medicine (July 2012)

The patient was experiencing continued inability to swallow oral fluids and so a naso-gastric tube was inserted. There as intolerance of the tube, which was repeatedly pulled out by the patient. A Deprivation of Liberty Safeguard Urgent Authorisation was put in to place and mittens applied to reduce the risk of the tube being removed by the patient, and allow feeding to continue. The recommended testing was undertaken to establish that the tube was in the correct place and feeding recommenced. Following deterioration of the patient an x-ray confirmed that the tube was in the lungs.

What Happened?

This investigation is not yet complete however preliminary findings are:-

- The Policy for placing an NG Tube was followed appropriately.
- The member of staff inserting the tube was experienced.
- Was the patient suitable for having a NG tube sited at all given his clinical condition.

This investigation is now complete and it is not believed that the NG tube had been misplaced. Therefore, a request to remove the Never Event description has been made to the PCT.

2.10 Case 10 – Inappropriate Administration of Daily Oral Methotrexate - Medicine (August 2012)

The patient was admitted to hospital for investigations having taken ill at home. Prior to admission, oral Methotrexate was being taken once weekly for arthritis. This was prescribed by the admitting doctor and a dose was given correctly on the Monday. However, it was given again the next day.

What Happened?

This investigation is not yet complete however preliminary thoughts are:-

- The prescription chart appropriately detailed the Methotrexate dose and "once weekly on a Monday" in the special instructions section. The days of the week when the drug was to be given however were not "crossed through" as is recommended prescribing practice for this drug.
- The prescribing Dr was a Foundation Year 1 Level.
- There appears to be evidence to suggest clinicians did not realise this was a "Never Event".

3. THEMATIC REVIEW

3.1 A review of issues identified within the cases has identified that:-

- On 5 occasions there was deviation from UHL Policy and/or Procedures.
- On 2occasions there was deviation from the WHO Safer Surgery Checklist.
- On 3 occasions the marking of the operative site played a part.
- On 4 occasions staff changes, interruptions or breaks played a part.

Within all cases there were human factors that played a part such as:-

- Situation Awareness e.g. not recognising increasing risks
- Decision making e.g. over-reliance on assumptions as to correct location/dose/route
- Teamwork e.g. failure to speak up when checklist not followed or swab count wrong
- Leadership e.g. not demonstrating compliance with procedure/policy
- Coping with stress e.g. staff new to a procedure or area and dealing with difficult or complex issues
- Coping with fatigue e.g. working in busy, high volume areas.

3.3 These human factors will be considered in future investigations.

4. LESSONS FROM CASES REVIEWED

4.1 Marking the site:-

- The operating surgeon should always be the person who marks the operative site.
- Indelible ink marker pens should always be available and used throughout the Trust.
- As well as marking the operative site, the procedure to be undertaken should be written on also.
- Where the side cannot be marked on the skin, another type of visual clue should be used e.g. a mark on another part of the body that will not be covered by a drape.
- Never allow patients to be anaesthetised without the site being marked on the patient.

4.2 Adhering to the WHO Safer Surgery Checklist:-

- Say the site or side for the surgery out loud when going through the safe surgery checklist.

- All members of the operating team should be there and take full part in the final checklist before the procedure starts.
- The operating surgeon should check out loud the side and the site before proceeding.
- A team brief should be undertaken at the beginning and the end of each case.

4.3 Staff changes, interruptions and distractions:-

- New staff to the team should be introduced to the rest of the team.
- Robust mentorship should take place to ensure new staff are familiar with the policy, procedure, all equipment used and any specific requirements demanded by either the type of surgery or surgeon preference.
- Staff breaks must be managed to ensure consistency in the team involved in the surgery.
- Those staff setting up the theatre equipment for the case must be the same as those present at the start of the procedure.

4.4 Adherence to National/Trust Policy and/or Procedures:-

- Strict adherence to Trust policies such as the "Management of Surgical Swabs, Needles and other Accountable Items within the Operating Theatre", the "Cytoxic Drug Policy" and the WHO Safer Surgery Checklist.

5. NEXT STEPS FOR UHL

5.1 A Never Event task and finish group has been established for UHL with surgical, anaesthetic, corporate and divisional patient safety representation.

5.2 Work streams developed as follows:-

- Further refinement of the WHO Checklist within theatres.
- Review the technique and equipment for marking operative sites.
- Develop an enhanced checking process for implantation of prosthetics.
- Implement a "say it out loud" protocol for drugs and prosthetics.
- Ensure face to face contact by the operating surgeon with the patient prior to anaesthetic.

5.3 A work stream lead has been identified for each of the above and an update will be provided in 2 months time.

5.4 Raise the profile of Never Events across the organisation.

5.5 Share the findings of this paper at all Morbidity and Mortality Meetings via Divisional Quality and Safety Teams/Corporate Patient Safety Teams.

5.6 Present during "Safer Surgery Week" at Friday afternoon Forum (to get best clinician air time)

5.7 Present at Learning from Experience Group (LEG).

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

CORPORATE MEDICAL DIRECTORATE

REPORT TO: **CLINICAL QUALITY REVIEW GROUP**

DATE: **22ND NOVEMBER 2012**

REPORTED BY: **DIRECTOR OF SAFETY AND RISK**

SUBJECT: **NEVER EVENTS**

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1. BACKGROUND

1.1 Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventable measures have been implemented.

2. DETAILS OF EVENT

2.1 Following a laparoscopic right nephrectomy the surgeon was closing the second of three skin wounds when the needle broke and fell off the suture thread. A search was carried out of the floor and drapes and the needle was not found. The ODA left theatre to seek advice and during this time the patient was transferred to recovery. The Patient was subsequently returned to theatre where an x-ray was carried out. The missing part of the needle was found on the other end of the suture. The retained piece of needle was removed from the wound and the patient returned to recovery.

2.1 Due to the type of anaesthetic which includes both general anaesthetic and block there is the ability to lighten the general anaesthetic towards the end of the procedure to enable timely extubation. This process had occurred on this occasion resulting in the need for further general anaesthetic when the patient returned to theatre.

3. ACTION TAKEN

3.1 This incident was reported as a SUI and Never Event as on initial review it was felt it met the criteria for number 3 of the Department of Health's Never Event list 2012/13 i.e. retained foreign object post operation, which includes needles.

3.2 A full RCA approach investigation is being undertaken and will consider both individual and system failures.

3.3 The patient suffered no ill effects following the procedure or the return to theatre. A full explanation and apology was given to the patient's mother by the Consultant Surgeon.

Moira Durbridge
Director of Safety and Risk
November 2011