FREEDOM OF INFORMATION ACT 2000

THE ROYAL CORNWALL HOSPITALS NHS TRUST RESPONSE TO INFORMATION REQUEST

Date Request Received: 04th March 2020 **FOI Ref: 9580**

Requested Information

Under the Freedom of Information Act 2000, I would like to request the following information relating to 'never events' at your trust:

'Never events' are patient safety incidents that are considered preventable when national guidance or safety recommendations that provide strong systemic protective barriers are implemented by healthcare providers [https://improvement.nhs.uk/documents/3213/Learning_from_surgical_Never_Events_FINAL.pdf]

Examples of 'never events' include foreign objects not being removed following surgery and patients being treated with the incorrect procedure.

Please could you tell me:

1) How many 'never events' have occurred at your trust over the past ten years? (please break this down by year and speciality department, and if possible also include information collected for 2020)

2) Details for each of these 'never events'. What happened? Were there any contributing factors?

3) How the issue was resolved for each? (i.e was there any compensation involved and if so what was the total amount paid in compensation for these 'never events' by year and over the past 10 years?)

4) Has NHS England (or another body) issued guidance or any other form of support to prevent the occurrence of 'never events' in the future?

Response

1) During the past 10 calendar years the Royal Cornwall Hospitals Trust had 27 Never events occur

2) Appendix 1 details the Never events occurring across the Royal Cornwall Hospitals Trust during the past 10 calendar years

3) Of the 27 Never events listed in appendix 1, six resulted in a claim being made against the Royal Cornwall Hospitals Trust. Five of the claims received by the Royal Cornwall Hospitals Trust totaled to £67, 000 paid in damages. The Royal Cornwall Hospitals Trust is unable to provide any information on one case as this is still ongoing

The Royal Cornwall Hospitals Trust is unable to disclose the information by year due to the small numbers of cases

4) Please refer to Appendix 2 for the Never Events Framework and List from NHS Improvement used by the Royal Cornwall Hospitals Trust

Attachment(s)
Appendix 1 – Never Events Appendix 2 - Never Events Framework and List

Date Response Sent:
March 2020

FOI Ref 9580 - Appendix 1 Never Events

Specialty	Date reported	Category
Dental Surgery	21-Apr-2011	Wrong Site Surgery
Obstetrics	11-Sep-2012	Retained foreign object
General Surgery	19-Mar-2013	Wrong implant / prosthesis
Dermatology	4-Apr-2013	Wrong Site Surgery
Orthopaedics	8-Oct-2013	Wrong implant / prosthesis
Endocrinology	27-Dec-2013	Administration of medication
Clinical Imaging	14-Feb-2014	Wrong Site Surgery
Dental Surgery	21-Mar-2014	Wrong Site Surgery
Cardiology	7-Apr-2014	Retained foreign object
Cardiology	25-Jun-2014	Retained foreign object
Ophthalmology Surgery	27-Nov-2015	Wrong Site Surgery
Emergency Department	20-Jan-2016	Retained foreign object
Clinical Imaging	24-Mar-2016	Wrong Site Surgery
Breast Surgery	12-Oct-2016	Wrong Site Surgery
Anaesthetics	11-Nov-2016	Wrong Site Surgery
Cardiology	3-Mar-2017	Wrong implant / prosthesis
General Surgery	9-Mar-2017	Retained foreign object
Orthopaedics	5-May-2017	Wrong implant / prosthesis
Orthopaedics	16-May-2017	Retained foreign object
Gastroenterology	16-Jun-2017	Wrong implant / prosthesis
Gastroenterology	12-Jul-2017	Wrong implant / prosthesis
Contraception Clinic	14-Jul-2017	Wrong Site Surgery
Gynaecology	8-Aug-2017	Wrong Site Surgery
Gynaecology	19-Jan-2018	Wrong Site Surgery
Theatres & Recovery	18-May-2018	Retained foreign object
General Surgery	17-Feb-2019	Retained foreign object
Dental Surgery	1-Mar-2019	Wrong Site Surgery

NHS Improvement

Never Events list 2018

January 2018

collaboration trust respect innovation courage compassion

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

Contents

All organisations providing NHS care should use the following list that becomes active on initiation of the updated 2017-19 NHS Standard Contract on 1 February 2018.

Surgical

1. Wrong site surgery

An invasive procedure[1] performed on the wrong patient or at the wrong site (eg wrong knee, eye, limb, tooth). The incident is detected at any time after the start of the procedure.

Includes:

Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (eg peripherally inserted central catheter (PICC)/ Hickman lines). This also includes teeth extracted in error that are immediately reimplanted.

Excludes:

- removal of wrong primary (milk) teeth unless done under a general anaesthetic
- local anaesthetic blocks for dental procedures (exclusion added May 2019)
- interventions where the wrong site is selected because the patient has unknown/unexpected anatomical abnormalities; these should be documented in the patient's notes
- wrong level spinal surgery*
- wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters
- contraceptive hormone implant in the wrong arm.

*Excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident.

[1] The start of an invasive procedure is when a patient's anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Safer Practice Notice – *Wristbands for hospital inpatients improves safety* (2005). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – *Standardising wristbands improves patient safety* (2007). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – *WHO surgical safety checklist* (2009). The key points in the alert are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safe Anaesthesia Liaison Group – *Stop before you block* (2011).
- The Royal College of Radiologists – *Standards for providing a 24 hour interventional radiology service* (2008).
- Faculty of Pain Medicine – *Safety checklist for interventional pain procedures under local anaesthesia or sedation* (2017).
- Royal College of Surgeons (Faculty of General Dental Practice) – *Toolkit for the prevention of wrong tooth extraction* (2017).
- *National safety standards for invasive procedures* (NatSSIPs) (2015).
- Patient Safety Alert – *Supporting the introduction of the national safety standards for invasive procedures* (2015).

2. Wrong implant/prosthesis

Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient.

Excludes:

- placed implant/prosthesis is intentionally different from that specified in the surgical plan, based on clinical judgement at the time of the procedure
- specified implant/prosthesis is placed as planned but later found to be suboptimal

- implant/prosthesis is different from the one specified due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry.

Includes:

- implantation of an intrauterine contraceptive device different from the one in the procedural plan.

See **Appendix A** for examples of correct application of this Never Event definition.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Safer Practice Notice – *Wristbands for hospital inpatients improves safety* (2005). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – *Standardising wristbands improves patient safety* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – WHO surgical safety checklist (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- *National safety standards for invasive procedures* (NatSSIPs) (2015).
- Patient Safety Alert – *Supporting the introduction of the national safety standards for invasive procedures* (2015).

3. Retained foreign object post procedure

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

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

‘Foreign object’ includes any items subject to a formal counting/checking process at the start of the procedure and before its completion (such as for swabs, needles, instruments and guidewires) **except** where items:

- not subject to the formal counting/checking process are inserted any time before the procedure, with the intention of removing them during the procedure but they are not removed
- subject to the counting/checking process are inserted during the procedure and then intentionally retained after its completion, with removal planned for a later time or date as clearly recorded in the patient’s notes
- are known to be missing before completion of the procedure and may be inside the patient (eg screw fragments, drill bits) but action to locate and/or retrieve them is impossible or more damaging than retention.

See **Appendix B** for examples of correct application of this Never Event definition.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *WHO surgical safety checklist* (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – *Reducing the risk of retained throat packs after surgery* (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – *Reducing the risk of retained swabs after vaginal birth and perineal suturing* (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- *National safety standards for invasive procedures* (NatSSIPs) (2015).
- Patient Safety Alert – *Supporting the introduction of the national safety standards for invasive procedures* (2015).

Medication

4. Mis-selection of a strong potassium solution

Mis-selection refers to:

- when a patient is intravenously given a strong[2] potassium solution rather than the intended medication.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *Potassium chloride concentrate solutions* (2002; updated 2003). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

5. Administration of medication by the wrong route

The patient is given one of the following:

- intravenous chemotherapy by the intrathecal route
- oral/enteral medication or feed/flush by any parenteral route
- intravenous administration of an epidural medication that was not intended to be administered by the intravenous route*

* During the transition period for the introduction of NRFit™ devices, the 'intravenous administration of a medicine intended to be administered by the epidural route' cannot be considered a Never Event. An update will be provided when this period ends.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *Promoting safer measurement and administration of liquid medicines via oral and other enteral routes* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

[2] ≥10% potassium w/v (eg ≥0.1 g/mL potassium chloride, 1.3 mmol/mL potassium chloride).

- Patient Safety Alert – *Safer practice with epidural injections and infusions* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

6. Overdose of insulin due to abbreviations or incorrect device

Overdose refers to when:

- a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system[3]
- a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin
- a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Rapid Response Report – *Safer administration of insulin* (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – *Risk of severe harm and death due to withdrawing insulin from pen devices* (2016).

[3] Electronic prescribing, dispensing and administration systems are an evidence-based method to reduce patient harm from medicines. All NHS organisations should introduce them as soon as possible. When the definitions for the insulin and methotrexate overdose Never Events were revised in 2015, it was agreed that those for insulin given in overdose because of the use of abbreviations for 'unit' and for all methotrexate overdose incidents would only apply to care settings with electronic prescribing systems as indicated. The systemic protective barriers for these two types of Never Event were found not to be strong enough in care settings where electronic barriers do not exist. For example, even though most acute hospitals do use a preprinted insulin prescription to try and prevent prescribers using the abbreviations 'iu' or 'u', this is not the case in all care settings. Also, preprinted prescriptions on their own are not a reliably strong enough barrier to prevent a potential 10-fold dosing error as prescribers can still prescribe insulin on general prescriptions.

7. Overdose of methotrexate for non-cancer treatment

Overdose refers to when:

- a patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system[3] (see footnote 3 on previous page).

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *Improving compliance with oral methotrexate guidelines* (2006). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

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

Mis-selection refers to when:

- a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation
- excludes clinical areas where the use of high strength midazolam is appropriate; these are generally only those performing general anaesthesia, intensive care, palliative care, or areas where its use has been formally risk-assessed in the organisation.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Rapid Response Report – *Reducing risk of overdose with midazolam injection in adults* (2008). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

Mental health

9. Failure to install functional collapsible shower or curtain rails

Involves either:

- failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide
- failure to install collapsible rails and an inpatient attempts or completes a suicide using non-collapsible rails.

Setting: All settings providing NHS-funded mental health inpatient care.

National safety requirement:

Health building notes:

- Health building note 03-01 – *Adult acute mental health units* (2013).
- Health building note 03-02 – *Facilities for child and adolescent mental health services (CAMHS)* (2017).

Estates and facilities alerts:

- NHS England SN 01 – *Cubicle rail suspension system with load release support systems* (2002).
- NHS England 03 – *G-rail 2301, window curtain tracking system* (2004).
- NHS England 08 – *Cubicle rail tracking and PVC dustcovers* (2004).
- NHS England 10 – *Bed cubicle rails, shower curtains rails, and curtain rails in psychiatric in-patient settings* (2004).
- Department of Health 08 – *Cubicle curtain track rail* (2007).
- EFA/2010/003 – *Anti-ligature curtain rails (including shower curtains): Risks from incorrect installation or modification* (2010).
- EFA/2010/10 – *Flush fitting anti-ligature curtain rails: ensuring correct installation* (2010).

General

10. Falls from poorly restricted windows

A patient falling from a poorly restricted window.[4] This applies to:

- windows 'within reach' of patients; this means windows (including the window sills) 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 climb out of the window
- windows located in facilities/areas where healthcare is provided and that patients can and do access
- where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before they fall
- where patients can deliberately overcome a window restrictor using their hands or commonly available flat-bladed instruments as well as the 'key' provided.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Health Building Note 00-10 Part D – *Windows and associated hardware*.
- Department of Health Estates and Facilities Alert – *Window restrictors of cable and socket design* (2014).
- Health and Safety Executive *Risk of falling from windows* (2016).

11. Chest or neck entrapment in bed rails

Entrapment of a patient's chest or neck between bedrails or in the bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

Setting: All settings providing NHS-funded care including care homes, and patients' own homes where equipment for their use has been provided by the NHS.

[4] This includes windows where the provider has not put a restrictor in place in accordance with guidance.

National safety requirement:

- Medicines and Healthcare products Regulatory Agency – *Safe use of bed rails* (2013).

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

Unintentional transfusion of ABO-incompatible blood components.

Excludes:

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

Unintentional ABO-mismatched solid organ transplantation.

Excludes:

- situations in which clinically appropriate ABO-incompatible solid organs are deliberately transplanted.

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, the inadvertent transplantation of that organ without appropriate management is a Never Event.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Department of Health CEM/CMO/2017/005 – *Safe transfusion practice: use a bedside checklist* (2017).
- British Society for Histocompatibility and Immunogenetics and British Transplantation Society – *Guidelines for the detection and characterisation of clinically relevant antibodies in allotransplantation* (2014).
- British Transplantation Society – *Guidelines for antibody incompatible transplant* (2015).
- Safer Practice Notice – *Wristbands for hospital inpatients improves safety* (2005). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

- Safer Practice Notice – *Standardising wristbands improves patient safety* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

13. Misplaced naso- or oro-gastric tubes

Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *Nasogastric tube misplacement: continuing risk of death and severe harm* (2016).
- NHS Improvement – *Initial placement checks for nasogastric and orogastric tubes: resource set* (2016).

14. Scalding of patients

Patient scalded by water used for washing/bathing.

Excludes:

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

Setting: All settings providing NHS-funded care.

National safety requirement:

- HTM 04-01 – *Safe water in healthcare premises* (2006, updated 2017).
- Health Building Note 00-10 Part C – *Sanitary assemblies* (2013).
- Health and Safety Executive – *Managing the risks from hot water and surfaces in health and social care* (2012).
- Health and Safety Executive – *Scalding and burning* (2012).

15. Unintentional connection of a patient requiring oxygen to an air flowmeter

This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter.

Excludes:

- unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Patient Safety Alert – *Reducing the risk of oxygen tubing being connected to air flowmeters* (2016).

16. Undetected oesophageal intubation

This Never Event has been temporarily suspended pending further clarification.

Appendix A: Wrong implant/prosthesis

Earlier definitions of the Never Event type ‘wrong implant/ prosthesis’ were not consistently applied with regard to wrong intraocular lenses (IOL). The examples below assist with consistent application of the current clarified definition. They are intended solely as **examples of the principles of the definition**, and are not a complete list of circumstances where the definition applies.

Circumstances	Does this fit the Never Event definition?
A patient attended hospital for a right phacoemulsification and IOL procedure. The surgeon – a senior trainee – discussed the risks and benefits of right cataract surgery and the target refractive outcome with the patient, who consented to the procedure with the aim of achieving an emmetropic (no distance glasses) outcome. A +20.5 dioptre (D) IOL was chosen and the IOL selection sheet was completed accordingly. At the WHO sign in the surgeon confirmed with the team he wanted a +20.5D IOL. A +20.0D IOL was presented during the time out section of the WHO checklist, which was completed by the consultant (not the surgeon), scrub nurse and operating department practitioner. The team did not identify that the lens power did not match that selected on the biometry and IOL selection sheet, and previously stated at the sign in. The senior trainee continued with surgery supervised by the consultant and a +20.0D IOL was implanted in error.	This is a Never Event. The surgeon clearly stated the surgical plan for a +20.5D IOL to the team. A different IOL was inserted.
A patient was admitted for right phacoemulsification and IOL. A toric IOL was planned to correct astigmatism. The IOL power was circled correctly on the biometry sheet and this was also correctly transcribed onto an IOL selection sheet. (continued on next page)	This is a Never Event. The surgeon stated in the surgical plan the wish to implant a certain model of lens but implanted a different model, which could not correct the astigmatism.

The operation was cancelled as the list was running late and the patient was admitted a few days later for surgery by a different consultant. This surgeon confirmed at sign in and again at time out with the surgical team that a 19D model SN6AT (toric) lens was required as detailed in the notes, but did not confirm that a toric lens was required as planned. The lens presented to the surgeon was a 19D SA60AT (non-toric) and this was opened and inserted into the patient's eye.	
A patient attended hospital for a left phaocemulsification and IOL procedure. The surgeon confirmed with the patient that the aim of the procedure was emmetropia and circled a +17.5D IOL on the biometry sheet. The sheet had unexpectedly been printed in a different format, moving the data for the most commonly used IOL from where it normally appeared. This meant the wrong type of IOL was circled, an anterior chamber not a posterior chamber lens. All WHO checks were appropriately completed by the surgeon and the team, and a lens power of +17.5D was confirmed verbally by the surgeon to the team as the surgical plan. A +17.5D posterior chamber lens was inserted. At the postoperative review the patient was noted to be 3.5D hypermetropic and not emmetropic.	This is **not** a never event. The IOL inserted was the one stated in the surgical plan by the consultant. However, this surgical plan was wrong because the surgeon had chosen the power for a posterior chamber lens using data pertaining to an anterior chamber lens.
A patient was admitted for left phacoemulsification and IOL. The surgeon discussed the refractive aim with the patient; emmetropia was agreed and a +22D lens was circled on the biometry sheet. The IOL power was then unclearly transcribed onto an IOL selection sheet and later misread as 27D, not 22D. The surgeon confirmed the IOL as 27D to the team and all checks were completed. It was not noted that the original biometry sheet indicated a 22D IOL. A 27D lens was inserted. The patient was noted postoperatively to be myopic rather than emmetropic.	This is **not** a never event. The IOL inserted was that stated in the surgical plan by the consultant, but the surgical plan was based on information incorrectly transcribed from a poorly written document.

Appendix B: Retained foreign object post procedure

Earlier definitions of the Never Event type ‘retained foreign object post operation’ were not consistently applied. The examples below assist with consistent application of the current clarified definition. They are intended solely as **examples of the principles of the definition**, and are not a complete list of circumstances where the definition applies.

Note that the principles of the definition relate to items that should be subject to a formal counting or checking process at the start of the procedure and before its completion. The size of the retained foreign object and the potential for harm from the retained foreign object are irrelevant to the incident’s designation as a Never Event.

Circumstances	Does this fit the Never Event definition?
A patient underwent gynaecological surgery and a vaginal pack/vaginal tampon was intentionally left in place at the end of surgery, with removal planned for 48 hours after surgery. Unfortunately, the pack was not removed as planned and the patient was sent home with the pack still in place. She went to her GP complaining of vaginal discomfort and discharge. He examined her and found the pack.	This does **not** meet the definition of a Never Event as the vaginal pack was intentionally retained after the procedure. Once outside the controlled counting processes in theatre, the Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events in future.

A patient needed suturing after an episiotomy during a vaginal delivery. To create a clear view for the suturing procedure, three swabs were placed in the patient's vagina, to be removed as soon as suturing was complete. Only two swabs were removed. This error was realised when the swab fell out a few days after the patient and her baby went home.	This meets the definition of a Never Event. The swab was not intentionally retained. The number of swabs inserted and removed should have been counted at the time of the procedure.
A patient undergoing eye surgery as a day case had a pledget (a small swab) inserted under her eyelid an hour preoperatively to deliver topical medication. The pledget should have been removed during surgery but was not. The patient telephoned for advice about her painful eye the day after her procedure. When she returned to the unit to be examined the pledget was found and removed.	This does **not** meet the definition of a Never Event as the pledget was inserted outside the controlled counting processes in theatre. The Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via STEIS and the NRLS, with all possible steps taken to prevent similar events in future.
A patient undergoing eye surgery as a day case had a pledget inserted under her eyelid at the beginning of the procedure. The pledget should have been removed at the end of the surgery but was not. The patient telephoned for advice the day after her procedure because her eye was painful. When she returned to the unit to be examined the pledget was found and removed.	This meets the definition of a Never Event. The pledget was not intentionally retained and the number of pledgets inserted and removed should have been counted at the time of the procedure.
A patient had an interventional cardiology procedure using a guidewire. When the doctor tried to withdraw the guidewire, it appeared to be stuck. It was left in place so that X-rays could be taken and expert advice sought before attempting to remove it.	This does **not** meet the definition of a Never Event as the guidewire was known to be retained before the procedure was completed, and immediate action to retrieve it was impossible or more damaging than retention. (continued)

	This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future. If an equipment fault is likely to be responsible, the incident should also be reported to the MHRA.
A patient had an interventional cardiology procedure using a guidewire. No problems with the procedure were noticed at the time, but an X-ray taken for another reason several days later revealed a broken-off guidewire tip lodged in a blood vessel.	This meets the definition of a Never Event as the guidewire should have been checked for completeness when it was withdrawn at the end of the procedure.

Appendix C: Rationale for amendments to the Never Events list (including consideration of the October 2016 open consultation)

Never Event	Amendment	Rationale
Wrong site surgery	Include pain relief blocks.	New guidance is available from the Faculty of Pain Medicine – *Safety checklist for interventional pain procedures under local anaesthesia or sedation* (2017).
Wrong site surgery	Clarification that the extraction of primary (milk) teeth is excluded unless done under a general anaesthetic.	The extraction of milk teeth is extremely unlikely to result in severe harm/death unless it is done under a general anaesthetic when the potential risks of anaesthesia could apply.
Wrong site surgery	Exclude spinal surgery.	There is no specific guidance available relating to preoperative identification/marking of the spinal level. NHS Improvement will be working with the British Orthopaedic Association to develop guidance.
Wrong site surgery	Exclude contraceptive hormone in the wrong arm.	Severe harm/death is extremely unlikely.
Wrong implant/ prosthesis	Includes the implantation of an intrauterine contraceptive device that differs from the one in the procedural plan.	The existing barriers to prevent implantation of the wrong implant/prosthesis also apply to intrauterine devices.

Wrong implant/ prosthesis	Excludes where the implant/prosthesis differs from the one intended due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data, eg wrong intraocular lens due to wrong biometry or using the wrong dataset from correct biometry.	There are currently no robust barriers to prevent this from occurring.
Overdose of insulin due to abbreviations or incorrect device	Include when a healthcare professional withdraws insulin from an insulin pen or an pen refill and then administers it using a syringe and needle.	New guidance is available in the Patient Safety Alert *Risk of severe harm and death due to withdrawing insulin from pen devices* (2016).
Unintentional connection of a patient requiring oxygen to an air flowmeter	New Never Event.	New guidance is available in the Patient Safety Alert *Reducing the risk of oxygen tubing being connected to air flowmeters* (2016).
Undetected oesophageal intubation	New Never Event.	**This Never Event has been temporarily suspended pending further clarification.**

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This publication can be made available in a number of other formats on request.

 Publication code: CG 20/18

NHS Improvement

Never Events policy and framework

Revised January 2018

collaboration trust respect innovation courage compassion

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

Contents

Foreword

Learning from what goes wrong in healthcare is crucial to preventing future harm, but it requires a culture of openness and honesty to ensure staff, patients, families and carers feel supported to speak up in a constructive way.

The revised Never Events policy and framework are designed to support the NHS to do that, and are part of continuing efforts to build a learning culture and maximise opportunities to keep our patients safe.

Our revision of the framework has been informed by your response to the consultation at the end of 2016. The consultation asked if the previous Never Events policy and framework were fit for purpose, and if the list of incidents continued to reflect the definition of a Never Event – that is, incidents on the list should be avoidable if available preventative measures have been implemented.

One of the key changes we have made in response to what you told us is to remove the option to impose financial sanctions associated with Never Events. We heard that allowing commissioners to impose financial sanctions following Never Events reinforced the perception of a 'blame culture'. Our removal of financial sanctions should not be interpreted as a weakening of effort to prevent Never Events. It is about emphasising the importance of learning from their occurrence, not blaming.

The revised Never Events framework will be aligned with a new Serious Incident framework due to be published later in 2018. We will shortly be launching an engagement exercise around the Serious Incident framework, but the plan to align the two documents will go ahead as Never Events should always be treated as Serious Incidents.

We have also looked at the list of Never Events. A reference group comprising NHS Improvement and NHS England regional quality leads, members of the patient safety team at NHS Improvement and clinical advisors reviewed the list alongside all the new suggestions that were made for Never Events in response to the consultation. Two types of Never Event have been added – unintentional connection of a patient requiring oxygen to an air flowmeter and undetected oesophageal intubation – and the definitions of some existing Never Events have been revised. Further detail is provided in the Never Events list 2018.

This document is a resource for patients, boards and all healthcare clinical and management staff. However, we particularly ask that all board members and other leaders of healthcare organisations consider this revised framework, and that medical and nursing directors in provider and commissioning organisations ensure that all relevant guidance is followed – both to prevent Never Events and to learn from Never Events when they do occur.

Celia Ingham Clark
Interim National Director of Patient Safety
NHS Improvement

1. Policy statement

1.1. Never Events are incidents that require investigation under the Serious Incident framework. In 2018 the Never Events policy and framework will be merged with the revised Serious Incident framework. Until then, this policy should always be read in conjunction with the current Serious Incident framework.

1.2. The Never Events policy and framework is relevant to all NHS-funded care.

2. Acknowledgements

2.1. The Never Events policy and framework have been revised following a wide consultation of patients, healthcare providers, commissioners, regulatory and supervisory bodies, patient safety experts, professional organisations and royal colleges. We thank everyone for their contribution.

3. Purpose

3.1. Never Events are defined as Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. Strong systemic protective barriers are defined as barriers that must be successful, reliable and comprehensive safeguards or remedies – for example, a uniquely designed connector that stops a medicine being given by the wrong route. The importance, rationale and good practice use of relevant barriers should be fully understood by and robustly sustained throughout the system, from suppliers, procurers, requisitioners, training units to frontline staff.

3.2. The Never Events policy and framework are designed to provide healthcare workers, clinicians, managers, boards and accountable officers with clarity on their responsibilities and on the principles of Never Events. In particular, these people should know what they are expected to do to prevent Never Events and how they must respond if they occur, including how they report a Never Event.

3.3. Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so this policy and framework provide the NHS with an essential lever for improving patient safety.

3.4. NHS Improvement's vision of high quality, compassionate and constantly improving healthcare requires us to nurture the necessary culture and conditions, including openness and transparency, evidence-based decision-making and a commitment to lifelong learning. As Don Berwick noted: "…standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning."[1]

3.5. The Never Events policy and framework support our vision by requiring honesty, accountability and learning in response to a group of incidents that can be prevented if accepted practice (including available preventative measures) has been implemented.

3.6. In this context, it is important that when a Never Event occurs, regardless of the outcome, the problems in care are identified and analysed through full investigation using a systems-based investigation method (such as root cause analysis – RCA) to understand how and why they occurred (from a systems perspective), as described in the Serious Incident framework. This will mean effective and targeted action can be taken to prevent recurrence.

3.7. Supporting staff to recognise Never Events is essential so that the opportunity to investigate, learn and improve can be identified in a timely way before vital information is lost.

4. Definition

4.1. The types of incident defined as Never Events using the criteria below are listed in the Never Events list 2018.

4.2. Never Events are incidents that meet all the criteria given in 4.3 to 4.6 below, and require full investigation under the Serious Incident framework.

[1] Department of Health (August 2013) *A promise to learn – a commitment to act: improving the safety of patients in England* August 2013. Available at: www.gov.uk/government/publications/berwick-review-into-patient-safety

4.3. Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations[2] that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

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

4.5. For each Never Event type, there is evidence that the Never Event has occurred in the past – for example, through reports to the National Reporting and Learning System (NRLS) – and that the risk of recurrence remains.[4]

4.6. Each Never Event type must be able to be clearly defined and its occurrence easily recognised – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

4.7. The Never Event list is reviewed regularly by NHS Improvement.

4.8 The NHS Improvement patient safety team does not act as an arbiter of whether a particular incident is a Never Event. This is agreed between provider and commissioner. The national team can advise on whether a type of Serious Incident qualifies as a Never Event as defined in the framework.

[2] As compiled by NHS Improvement patient safety experts and healthcare professionals, and referenced in the Never Events list 2018. These include: physical barriers (eg equipment that makes it impossible to connect medications via the wrong route); time and place barriers (eg withdrawal of concentrated medications from settings to prevent them being accidentally selected) or systems of double or triple checking where these are supported by visual or computerised warnings, standardised procedures or memory/communication aids. As all human action is vulnerable to human error, particularly where there is a risk of staff becoming overloaded, processes that rely solely on one staff member checking the actions of another or referring to written policies are not strong barriers.

[3] Serious harm: severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care); chronic pain (continuous, long-term pain lasting more than 12 weeks or beyond the time that healing post trauma or surgery should have occurred) or psychological harm; impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is unlikely to be temporary (that is, has lasted or is likely to last for a continuous period of at least 28 days).

[4] As this policy aims to drive patient safety improvement, it excludes incident types eradicated by technical, medical or scientific advances.

5. Learning from incidents

5.1. Learning from incidents requires timely incident reporting in a fair, open and just culture. Blame is not a useful lever for learning because: "…a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring".[5]

6. Organisational leadership

6.1. This policy and framework apply nationally, and all levels of healthcare organisations – from 'ward to board' – must play their part. Ultimately, however, and for clarity, an organisation's leadership is accountable for the occurrence of Never Events and crucially for the organisation's response.

6.2. The chief executive, all board members, other relevant organisation leaders and all relevant teams should know about any Never Event occurring in their organisation, and view each as an opportunity to investigate effectively and take meaningful targeted action(s) that measurably reduces risk of recurrence to improve patient safety. Repeated Never Events, particularly of the same type, signal ongoing problems in systems that previous investigations may not have identified or their recommendations (and resulting actions) have failed to address. Leaders should focus on maintaining systems that prevent Never Events from occurring in the first place. However, leaders must also provide support, investment and attention to enable effective investigation and meaningful improvement action (which measurably reduces the risk of recurrence) when Never Events do occur.

[5] National Patient Safety Agency (2004–2009) *Seven steps to patient safety*. Available at: www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

7. Requirements – when a Never Event is identified

7.1. Never Events are incidents that require full investigation under the Serious Incident framework. The requirements for reporting, principles for investigation, and the roles and responsibilities associated with the management and oversight of other Serious Incidents apply, including the need to fully and meaningfully engage patients, families and carers at the beginning of and throughout any investigation. Further information can be found in the Serious Incident framework.

7.2. As with other incidents that are classified as Serious Incidents, Never Events must be reported to both the strategic executive information system (StEIS) and the NRLS until the new patient safety incident management system is in place. Crucially, reports to both the NRLS and StEIS must clearly label the incident as a Never Event, even if this status is uncertain at the time of reporting (both systems contain a Never Events field). If necessary, and with provider and commissioner agreement, incident reports on StEIS can be retrospectively amended if it is found that the incident did not meet the definition of a Never Event. A clear audit trail explaining the rationale for the change and who authorised this should be recorded.

7.3. Organisational leaders (board or equivalent) are responsible for ensuring that any occurrence of a Never Event is analysed fully using a systems-based investigation method (such as RCA) to understand how and why it occurred (from a systems perspective). Leaders must then ensure that actions which measurably reduce the risk of recurrence are taken. Monitoring processes must support implementation and delivery of effective actions – this is the crucial aspect of this policy and framework.

7.4. Incidence of Never Events must be identified in the commissioner's annual report and the provider's quality accounts (ensuring patient confidentiality). This should include:

- data on the type and number of Never Events, including historical context and related incidents

- the learning stemming from the incidents, with a particular focus on the system changes made to reduce the probability of recurrence
- how learning has been shared at all levels in the organisation and externally.

7.5. In some instances Never Events may be identified some time after they occurred. While delayed identification is not a factor in determining whether or not an incident is a Never Event, it may have a bearing on the improvements deemed necessary following investigation (eg where subsequent procedural changes mean that additional action may be unnecessary).

7.6. Where a Never Event is discovered by one organisation but appears to be the responsibility of another, the 'discovering' organisation should inform the originating organisation and is not required to report the incident as its own.

7.7. Some definitions of Never Events have changed in this revision of the framework. Where incidents that used to meet the definition of a Never Event but no longer do so (for example, wrong level spinal surgery) are identified after publication of the new framework, they should not be reported as Never Events even if they occurred before publication. Previously reported Never Events, even if they no longer meet the definition of a Never Event, should not be retrospectively downgraded.

7.8. As a general rule, local healthcare organisations should consider the status of the incident at the time it occurred, particularly whether it met the Never Event criteria. If the incident pre-dated clear, easy to apply guidance on prevention or the introduction of the Never Event framework in 2009, it is not a Never Event. But if such guidance was available at the time but not acted on, the incident could be considered a Never Event in all but name, and treated appropriately.

8. Failure to report a Never Event

8.1. Failure to report a Never Event is unacceptable and can signal cultural and safety failings in an organisation. The reporting and investigation of Never Events may be an indicator of the organisation's attitude to patient safety

and openness. As noted by Sir Liam Donaldson: “to err is human, to cover up is unforgivable, and to fail to learn is inexcusable”.[6]

8.2 In some circumstances it may not be apparent that an incident is a Never Event until there has been some degree of investigation. In these circumstances, the possibility that a Never Event has occurred should be reported as soon as it is identified.

8.3. Failure to report a Never Event should be thoroughly investigated by the relevant organisational lead, with support from commissioners as required, to understand what prevented the recognition and/or reporting of the incident. This may lead to efforts to develop knowledge/awareness about incident reporting (and Never Events more specifically) and/or broader initiatives to measure and improve reporting culture as part of a wider safety culture in the organisation. If the failure to report was a deliberate act, this is likely to constitute a serious failing by the staff and organisation involved and will likely constitute a breach of Care Quality Commission (CQC) requirements (regulations 16 and 18 of the CQC (Registration) Regulations 2009).

[6] Sir Liam Donaldson, speaking at the launch of the World Alliance for Patient Safety, Washington, DC, 27 October 2004, calling to mind and adding to the comments made by Susan Sheridan (the wife and mother of victims of medical error).

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 Publication code: CG 19/18