Never events: an anaesthetic perspective

Siddharth S Adyanthaya MBBS FRCA
Vishal Patil MD FFARCSI

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Key points

- 'Never events' are defined as 'serious, largely preventable patient safety incidents that should not occur if relevant preventive measures have been put in place.'
- Many of these incidents may potentially occur in the perioperative setting.
- Never events are largely deemed to be unacceptable and generate negative publicity.
- Any investigation after a never event should primarily focus on systemic failings rather than apportioning blame to individuals.
- Through effective teamwork anaesthetists are well placed to minimize the number of never events in perioperative practice.

> Always and never are two words you should always remember never to use.
>
> Dr Wendell Johnson, American psychologist (1906–65)

'Never events' are defined as 'serious, largely preventable patient safety incidents that should not occur if relevant preventive measures have been put in place'.[1] The never events policy published by the Department of Health in England has generated considerable discussion since its introduction in 2008. It is important to realize that it is not only here to stay but is likely to evolve and grow, with the list of never events likely to expand in the years to come. This article will provide an overview of the policy including the current list of never events while focusing on those of relevance to anaesthetists and our role in their prevention.

Historical perspective

Though a relatively new development in the UK, the concept of never events has its origins in the National Quality Forum (NQF), which was established in the United States in 1999 as a non-profit, patient advocacy group. In 2002, it produced a list of 27 'Serious Reportable Events' (SRE) under six categories with further updates in 2006 and 2011.[2] The term 'never event' was first coined by Kenneth Kizer, former Chief Executive Officer of the NQF. In 2008, with the primary aim of increasing awareness of the quality agenda the US Centres for Medicare and Medicaid Services adopted a list of 10 hospital acquired conditions from the original list of SRE, which they officially referred to as never events. They subsequently introduced a non-reimbursement policy whenever one of these events occurred. In the same year in the UK, Lord Darzi published 'High-quality care for all: NHS Next Stage Review' in which he noted the US never events policy and proposed the introduction of a similar initiative for the NHS in England. The National Patient Safety Agency (NPSA) in 2010 launched the Never Event Framework and drew up a core list consisting of eight events. The list was subsequently revised, and an expanded list of 25 never events was published in February 2011 (Table 1). For the year 2012/13, minor amendments have been made to the definitions of two of the events.[1]

Never events

Incidents are considered to be never events if they meet the following criteria:[1]

(i) The incident may or does result in severe harm or death (note for some never events the incident does not have to be associated with such extreme outcome). For example a retained instrument or a wrong intraocular lens implant may not cause severe harm or death but is nevertheless a never event.
(ii) The incidents are a known source of risk (e.g. through reports to the National Reporting and Learning Service or other serious incident reporting system).
(iii) There is existing national guidance, safety recommendations or both on how the event can be prevented and also support for implementation of the relevant preventive measures.
(iv) The event is preventable if the national guidance, safety recommendations or both are implemented.
(v) Occurrence of the never event can be easily identified, defined and measured on an ongoing basis.

For the year April 1, 2009 to March 31, 2010, a total of 111 never events were reported. This relates to the initial list of eight events, which are marked with an asterisk in Table 1. Of these, 57 related to wrong site surgery and 41 related to misplaced naso or orogastric tubes. There were no reports of never events related to wrong route of administration of chemotherapy, in-hospital maternal death from post-partum haemorrhage after elective Caesarean section or in-patient suicide associated with non-collapsible rails. The number of incidents reported as never events are expected to be higher in subsequent years because of additions to the list and an increased awareness of the obligation to report their occurrence.

Siddharth S Adyanthaya MBBS FRCA
Specialist Registrar in Anaesthesia
Department of Anaesthesia
Cambridge University Hospitals NHS Foundation Trust
Box 93
Cambridge CB2 0QQ
UK

Vishal Patil MD FFARCSI
Consultant Anaesthetist
Department of Anaesthesia
Cambridge University Hospitals NHS Foundation Trust
Box 93
Cambridge CB2 0QQ
UK
Tel: +44 122 321 6292
Fax: +44 122 321 7223
E-mail: vishal.patil@addenbrookes.nhs.uk
(for correspondence)

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Table 1 The 'never events' list 2012–13

Those of direct relevance to anaesthetists
1. Wrong site surgery—excludes wrong site anaesthetic blocks*
2. Wrong implant/prosthesis
3. Retained foreign object postoperation*
4. Wrongly prepared high-risk injectable medication
5. Maladministration of potassium-containing solutions*
6. Wrong route administration of chemotherapy*
7. Wrong route administration of oral/enteral treatment
8. I.V. administration of epidural medication
9. Maladministration of insulin
10. Overdose of midazolam during conscious sedation
11. Opioid overdose in an opioid-naïve patient
12. Transfusion of ABO incompatible blood components
13. Transplantation of ABO incompatible organs as a result of error
14. Misplaced naso or oro-gastric tubes*
15. Wrong gas administered
16. Failure to monitor or respond to oxygen saturation
17. Air embolism
18. Maternal death because of post-partum haemorrhage after elective Caesarean section*
19. Misidentification of patients
Other never events
1. Inappropriate administration of daily oral methotrexate
2. Suicide using non-collapsible rails*
3. Escape of transferred prisoner*
4. Falls from unrestricted windows
5. Entrapment in bed rails
6. Severe scalding of patients

*Those events which were in the original list of core 'never events'.

After a never event has occurred, various actions should be taken including:

- attempt at immediate restitution of harm to the patient;
- reporting the incident through the hospital's own risk management system;
- onward reporting to the Clinical Commissioning Group and NHS England;
- communication with the patient/carers/relatives in line with the Being Open Policy;[3]
- undertaking a root cause analysis;
- implementing and sharing the lessons learnt including any procedural changes after the root cause analysis.

Never events may act as surrogates of the patient safety culture within healthcare organization. Repeated occurrence of never events may be interpreted as failure of implementation or adherence to guidelines and protocols. When a never event occurs the primary focus should be on the reasons behind such failures rather than on the actions of the individuals involved. The use of the word 'never' though has a negative connotation and indeed patients and public may assume negligence if a patient safety incident is termed as a never event. Hence it is likely that the never event policy will have an impact on medical litigation.

Unlike the situation in the USA, cost recovery after a never event in the NHS is intended to act as a lever to prevent its occurrence. Cost recovery does not affect the provider's liability concerning criminal or clinical negligence and is not intended to be used as compensation for the patient. Healthcare commissioners usually recover the cost of the clinical episode from the provider who is expected to bear the expense for any subsequent corrective procedure. However, commissioners have the discretion to waive cost recovery depending on local arrangements and individual circumstances of the event in question. In this context, 'never' is an aspiration that healthcare providers must embrace, whist working towards reporting and learning from these events.

In addition, cost recovery alone is unlikely to absolve the healthcare provider from further external scrutiny after a never event and it is likely that frequent never events will prompt an investigation by the Care Quality Commission.

The never event policy applies to all NHS-funded care in all healthcare settings including NHS-funded care in the independent sector in England. The never event policy does not apply to private healthcare in the independent sector or to private healthcare delivered in NHS hospitals.

Relevance to anaesthesia, pain, and intensive care medicine

Wrong site surgery

The use of neural blockade techniques performed by chronic pain specialists fall under the criteria of an operative procedure and are hence covered by the never event policy. The 'Stop before you block' campaign will help in preventing these incidents.[4] The participation of the anaesthetists in the WHO surgical safety checklist[5] means they have a shared responsibility in the case of wrong site/side surgery. Though wrong site/side nerve blocks intended for postoperative analgesia are excluded from the current list of never events they may be incorporated in the future.

Wrong implant/prosthesis

Again considering chronic pain practice, insertion of the incorrect type of a spinal cord stimulator may be classified as a never event. There have been instances of the wrong type of PICC (peripherally inserted central catheter) inserted, for example valved instead of non-valved but, because they are not classified as implants or prostheses, they have not as yet been classified as never events.

Retained foreign object post operation

Though retained objects after surgery tend to be associated with surgeons[6] there are regular reports of guide wires retained after central line insertion.[7] The routine use of ultrasound for central line insertion has reduced the need for post-procedure chest X-ray and hence failure to recognize retained guide wires after line insertion. In our own institution, a two-person check to witness and document the removal of all guide wires was introduced after such an incident.

Wrongly prepared high-risk injectable medication

Anaesthetists are frequently involved in administering potentially high-risk medications, for example opioids, benzodiazepines and insulin. They can be identified as high-risk medications by using a risk assessment tool which identifies risk factors such as a narrow therapeutic index, use of a concentrated solution, need for complex calculations in their preparation, part use of a vial or ampoule or use of more than one vial or ampoule and use of a pump or syringe driver or a non-standard giving set. This can be partly addressed by having the pharmacy department or manufacturer prepare the appropriate concentration of the drug. A thorough risk assessment and putting procedures in place to mitigate the risks, including written protocols, will also prevent these types of incidents.

Maladministration of potassium-containing solutions

The maladministration of potassium-containing solutions is a potential hazard well known to anaesthetists and intensivists and has been addressed by previous safety alerts. This has led to an increased awareness and the storing of concentrated solutions of potassium under lock and key.[8] Better design of drug labels will also help prevent this type of incidents by decreasing the potential for misreading drug names.

Wrong route administration of chemotherapy

Wrong route administration of chemotherapeutic agents has happened in the perioperative setting, most notably with intrathecal injection of vincristine. The recommendations of the Toft Inquiry are well known and the use of safer spinal needles with non-Luer lock connectors will prevent these types of incidents.[9]

I.V. administration of epidural medication

Anaesthetists have been involved in the intravascular injections of epidural medications. Maintaining a high level of vigilance, drawing up drugs just before use, using different drug trays with different coloured syringes and labels will mitigate this risk until a design solution is available as devices that use safer connectors that are not compatible with intravascular connectors.

Maladministration of insulin

Increasing numbers of diabetic patients requiring blood glucose control in the perioperative period or in critical care means that anaesthetists/intensivists are able to influence never events because of maladministration of insulin. The commonest error is because of misreading of abbreviations such as 'U' or 'IU' units in insulin prescriptions.[10]

Overdose of midazolam during conscious sedation

Overdose with midazolam during conscious sedation is unlikely to happen in the hands of an experienced anaesthetist. Although as a specialty we cannot be responsible for the actions of non-anaesthetists, we should be involved in coordinating and delivering training in safe sedation practice where colleagues in other specialities practice conscious sedation.[11] There is a concern that if the administration of flumazenil is used as a surrogate marker for overdose of midazolam then care should be taken to ensure that this does not increase the threshold for the use of flumazenil where there is a clear indication to do so. In other words, flumazenil should not be withheld for the fear of its use being looked upon as an automatic admission of a midazolam overdose.

Opioid overdose in an opioid-naïve patient

Opioid overdose in opioid-naïve patients could occur because of an inadvertently large bolus dose or wrong setting of an infusion pump. However, the never events list does not make an allowance for overdose in the setting of deranged physiology leading to alteration in pharmacokinetics and pharmacodynamics such as may occur in renal failure or in patients who are rapid metabolizers of codeine. This never event has implications on management of postoperative pain. It is useful to remember that this never event only applies to opioid-naïve patients. It that context, an opioid overdose in a patient who was recently on remifentanil is still a never event because of the very short context sensitive half-life of remifentanil.

Transfusion of ABO incompatible blood components

The transfusion of ABO incompatible blood groups has become a rarity particularly since the introduction of the Portable Blood Audit Release System. The barcode scanning system for patient identification and blood transfusion is a good example of the use of technology to prevent never events.

Transplantation of ABO incompatible organs

Transplantation of ABO incompatible organs may potentially occur in the perioperative setting with disastrous consequences for the patient and the transplant programme. Anaesthetists should ensure that there are procedures and systems in place to ensure that this is discussed at the time of the WHO Surgical Safety Checklist.

Misplaced naso/oro-gastric tubes

Insertion of naso/oro-gastric tubes is often performed perioperatively and in a critical care setting. During intrabdominal procedures, the position of the tube is often checked and confirmed by the surgical team and by the aspiration of gastrointestinal contents. It is important that this is documented in the medical notes appropriately. This will prevent any subsequent ambiguity about the correct placement of these devices.[12] In cases where nasogastric tube placement has not been confirmed, this should also be documented to ensure pH testing by nursing staff after operation.

Wrong gas administered

Modern anaesthetic machines will normally prevent the administration of the wrong medical gases because of their numerous safety features such as hypoxic linkage. However, it is possible that older versions of anaesthetic machines which lack these safety features may migrate to areas of the hospital such as the emergency department or radiology suites where the risk of the wrong gas being administered may be increased by the potential use of the equipment by non-anaesthetically trained personnel. Clearly, anaesthetic machines should only be used by adequately trained personnel and older machines taken out of service. It should also be remembered that wrong gas delivery could also occur in the setting of inappropriate delivery of high concentrations of oxygen to patients with advanced COPD associated with type II respiratory failure. This never event can also happen because of confusion over air and oxygen flow meters.

Failure to monitor and respond to a falling oxygen saturation reading

This is one of the never events that is likely to cause the greatest debate among the anaesthetic community. There is no definition of the term 'monitor'. According to the AAGBI definition of minimal monitoring standards in anaesthesia, monitoring requires the presence of trained personnel who can provide immediate care to the patient. This opens a whole new set of issues including staffing concerns in the critical care setting or at least the need for remote monitoring when more than one patient is cared for by a single member of staff to ensure appropriate response to a desaturation episode. A recent editorial raised the possibility of this never event defining a failed intubation, in the context of the accompanying desaturation and failing to respond to it by being unable to secure an airway, as a never event.[13]

Air embolism

Air embolism is a known complication of central venous access both on insertion and removal of cannulae. Simple measures such as head down position when removing central lines should be highlighted. The use of obturators in pulmonary artery catheter introducers is a way of preventing air embolism though this may reduce the flow through the line and negate the purpose of its insertion.

Maternal death because of post-partum haemorrhage after elective Caesarean section

This prompted some debate among anaesthetists leading to an exclusion of cases of placenta accreta, where there is a pre-existing coagulation disorder or where the mother refuses blood components. It also excludes emergency Caesarean section. Nonetheless, multidisciplinary management with input from anaesthetists, obstetricians, haematologists, intensivists and intervention radiologists combined with guidelines on management of major haemorrhage, better antenatal care and early referral to tertiary obstetric units makes post-partum maternal death as a result of blood loss a rarity.

Preventing never events

By definition, all never events have existing guidance for their prevention. The use of this guidance, in an environment of a robust safety culture with strong clinical leadership, along with meticulous and conscientious use of checklists and adoption of design and technological solutions has the potential to eliminate never events in the NHS.

Technological solutions such as the barcode scanners and BARS have made blood transfusion extremely safe but that does not preclude a mismatched transfusion due to a manual labelling error at the point of blood collection. In some cases, such as retained guide wires after insertion of vascular lines, it may be practically impossible to find a design solution and hence the need to fall back on a manual two-person check to ensure that guide wires do not remain behind in patients.

Understanding human factors

The Clinical Human Factors Group (www.chfg.org) is a multiprofessional independent campaign group that aims to highlight the understanding of human factors and the significant affect they can have on the safety, quality and productivity in healthcare. In its report entitled 'Never?' it considers the human factors contributing to nine cases of wrong site surgery.[14] It is clear that improved understanding of human factors and acquisition of nontechnical skills, in particular understanding of behavioural biases such as confirmation bias (favouring information that supports our preconceived conclusions), optimism bias (the mistaken belief that one's chances of experiencing a negative event are lower, or a positive event higher, than that of one's peers) and recency bias (thinking that trends and patterns observed in the recent past will continue in the future) will play a vital role in preventing never events.

While the publication of a never events list helps to focus on preventable patient safety incidents, this should not weaken the resolve to investigate, act and learn from other patient safety incidents which are not classified as never events. An example of this would be the inadvertent flushing of residual neuromuscular blocking agents that may be present in an i.v. cannula leading to serious harm.

Overall the publication of the never event list has given a fresh impetus to patient safety in the NHS. There is feedback to suggest that the policy has increased the focus on patient safety within institutions, and has prompted local implementation of patient safety initiatives.[15] It is hoped that it will lead to increased accountability of clinicians and managers, ensuring that the emphasis stays on securing and implementing robust processes and systems and so further decrease the incidence of preventable patient safety incidents.

Declaration of interest

None declared.

References

1. Department of Health. The never events policy framework. Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213046/never-events-policy-framework-update-to-policy.pdf (accessed 20 November 2013)
2. National Quality Forum. Serious reportable events in healthcare: a consensus report. Washington, DC, 2002
3. National Patient Safety Agency. *Being Open: Communicating Patient Safety Incidents with Patients, Their Families and Carers*. Available from http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077 (accessed 20 November 2013)
4. The Royal College of Anaesthetists. Wrong site block. Available from http://www.rcoa.ac.uk/node/346 (accessed 20 November 2013)
5. World Health Organisation. *WHO Surgical Safety Checklist and Implementation Manual*. Available from http://www.who.int/patientsafety/safesurgery/ss_checklist/en/ (accessed 20 November 2013)
6. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003; **348**: 229–35
7. Vannucci A, Jeffcoat A, Ifune C, Salinas C, Duncan JR, Wall M. Retained guidewires after intraoperative placement of central venous catheters. *Anesth Analg* 2013; **117**: 102–8
8. National Patient Safety Agency. Potassium solutions: risks to patients from errors occurring during intravenous administration. Available from http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59882 (accessed 20 November 2013)
9. National Patient Safety Agency. Safer spinal (intrathecal), epidural and regional devices. Available from http://www.nrls.npsa.nhs.uk/alerts/?entryid45=94529 (accessed 20 November 2013)
10. Lamont T, Cousins D, Hillson R, Bischler A, Terblanche M. Safer administration of insulin: summary of a safety report from the National Patient Safety Agency. *BMJ* 2010; **341**: 882–3
11. Lamont T, Matthew L, Cousins D, Green J. Avoiding midazolam overdose: summary of a safety report from the National Patient Safety Agency. *BMJ* 2009; **339**: 1196–7
12. Lamont T, Beaumont C, Fayaz A *et al.* Checking placement of nasogastric feeding tubes in adults (interpretation of x ray images): summary of a safety report from the National Patient Safety Agency. *BMJ* 2011; **342**: 1079–81
13. Harrop-Griffiths W. Never Events. *Anaesthesia* 2011; **66**: 158–62
14. The Clinical Human Factors Group. Never? Available from http://www.chfg.org/wp-content/uploads/2012/03/Never_Events_Corrected_Final_VersionApril12.pdf (accessed 20 November 2013)
15. National Patient Safety Agency. Never Events Annual Report 2009/10. Available from http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83319 (accessed 20 November 2013)

Please see multiple choice questions 1–4.