Introduction

Welcome to the first edition of Nevermore. Our Hospitals are now safer than they have ever been and yet still patients suffer avoidable harm. Whilst we recognise this better now, I am concerned that learning from harm is inconsistent and at times we see events recur with similar or even identical causation.

In 2004 Sir Liam Donaldson launched the World Alliance for Patient Safety with the following statement:

“To err is human, to cover up is unforgivable and to fail to learn is inexcusable”.

For patients who have been harmed, for their families, for the coroner and others who regulate our practice day to day evidencing learning from harm is key. Experience over recent years has taught me how difficult this can be across an organisation and hence the advent of Nevermore.

This newsletter, compiled by the Patient Safety team, is intended to be largely clinical and we will look at harm identified through the Adverse Incident Reporting System (AIRS), Serious Incidents’s (SI’s), complaints, litigation and elsewhere. This is not about blame but learning. I would urge you please to look through the information and consider how it is applicable within your own practice as relatively few such events have implications exclusively for the clinical area in which they occurred.

This first issue focuses exclusively on Never Events and I hope is of interest. By changing our culture of responding to harm we can make our hospitals and care in the community demonstrably safer.

Dr Alastair Turnbull
Medical Director
**Never Events**

Never events are defined as serious, largely preventable patient safety incidents that should not occur if existing national guidance or safety recommendations have been followed.

There are currently 25 categories of Never Events with Retained Foreign Object and Wrong Site Surgery being the most frequently reported.

It is widely believed that these all relate to Death or Serious Harm but that is not the case. There are qualifications to a number of the Never Events so if you think one has occurred in your area please look at the definition carefully and discuss with a member of the Trust Risk and Legal Services Team.

A list of definitions for all the Never Events can be found at [Q:\York Hospitals Trust\SUI\Never Events and Learning\Never Events list 2013 2014.pdf](Q:\York Hospitals Trust\SUI\Never Events and Learning\Never Events list 2013 2014.pdf)

**So has our Trust had any Never Events recently?**

Unfortunately the answer is yes, we have had 4 in the last 16 months.

We have reported into the National Reporting and Learning System (NRLS) 2 incidents of Retained Foreign Object, 1 Wrong Site Surgery and 1 Air Embolus.

Nationally between April 2014 and October 2014 Wrong Site Surgery was the top reported Never Event with 71 identified (16 being wrong tooth removed and 5 wrong lesion). Second highest reported in this period were Retained Foreign Objects at 53, 17 being Vaginal Swabs and 6 Surgical Swabs.

The case studies of our four recent Never Event Incidents are as follows and all are important to reflect on across specialities;
Case study 1 Retained Foreign Object

Definition of a retained foreign object

Retention of a foreign object in a patient after a surgical/invasive procedure. ‘Surgical/invasive procedure’ includes interventional radiology, cardiology, and interventions related to vaginal birth. ‘Foreign object’ includes any items that should be subject to a formal counting / checking process at the commencement of the procedure and a counting / checking process before the procedure is completed (such as swabs, needles, instruments and guidewires) except where:
- Items are inserted during the procedure but are intentionally retained after completion of the procedure, with removal planned for a later time or date
- Items are known to be missing prior to the completion of the procedure and may be within the patient (e.g. screw fragments, drill bits) but where further action to locate and/or retrieve would be impossible or be more damaging than retention
- Items were inserted at an earlier date or time and not removed as planned during a later surgical/invasive procedure.

See the Appendix A on page 15 for examples of correct application of this never event definition.

A small piece of blue plastic from an insulated skid, used during a hip Replacement was found after the patient developed a postoperative infection. The patient was returned to theatre 11 days after the initial operation for surgical debridement and partial exchange of the prosthesis.

The “skids” are used to prevent damage to the head of the prosthesis. They are made from metal but are dipped in a plastic coating during the manufacturing process in order to avoid scratching the head of the prosthesis.

At the time of the incident we had 10 insulated skids at Scarborough Hospital however only 4 of the 10 were in an adequate state of repair.

The sterile services manager has advised that the expansion of metal during the sterilisation process can cause the insulation to crack. It has been confirmed that York theatres do not use these skids. Some clinicians may still choose to use them if it is felt to be the safest way to operate. A new type of skid has been ordered for Scarborough Hospital.

At the time of the incident the GP and patient were notified of the situation but an AIRS form was not completed to advise of the Never Event and there was no documentation in the operation notes relating to the discovered blue plastic.

The event came to light as a result of the patient making a formal complaint.

A number of recommendations were made and the full report can be accessed at Q:\York Hospitals Trust\SUI\Never Events and Learning\Case study 1 SI Report 2013 31733 Final.doc
Lessons learnt;

Equipment must always be checked for faults, cleanliness and completeness of kit both at the sterilisation stage and pre operation.

Incidents as defined in both the Adverse Incident Reporting Policy and the listed Never Events should always be reported and should be flagged using the prompt on the AIRS form if it is deemed to be a Never Event.

The medical record should always contain a full explanation of the procedure including anything untoward as detailed and required by both the Being Open Policy and under the requirements of the Duty of Candour.

Case study 2 Air Embolus

Definition of an 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.

A patient undergoing dialysis felt unwell and developed low blood pressure, an apnoeic episode and seizures. The patient was transferred to ITU and a CT of the head showed a suspected air embolus in the right hemisphere.

Possible diagnosis included air embolus, encephalitis possibly due to gas forming bacteria or recurrent vasculitis.

The patient was intubated, ventilated and treated with anti convulsant drugs, methylprednisolone and antibiotics but subsequently deteriorated and died 9 days later. The cause of death remained unknown and the Coroner was informed.

A Coroners post mortem revealed a patent foramen ovale (PFO) potentially explaining how air could transfer between the right and left sides of the circulation.

The consultant responsible for the care of the patient wrote to the relatives to advise that the event had been declared a Serious Incident under the Never Events category and that a copy of the report would be available to them.

The investigation has not been able to determine the root cause of the incident as all
equipment and techniques were found to be satisfactory.

It is suspected that the cause of death was related to an air embolus from air entering the circulation during dialysis on the day.

Two recommendations were made however and the full report can be accessed at Q:\York Hospitals Trust\SUI\Never Events and Learning\Case study 2 SI 2013 31233 Final.doc

Lessons learnt

In terms of lessons learnt the key issue here is that it was not recognised at the time of the incident that Air Embolus is a Never Event. The investigation did not reveal any deficiencies with equipment or techniques but has reminded staff of the possibility of Air Embolus and reinforced the need for a thorough check of equipment.

It would have also prevented the Trust from being asked questions in an open Coroners Court as to why we have not considered it as a Never Event at the time.

Air embolism remains a significant clinical risk with the use of invasive intravascular devices and all possible safeguards should be taken to prevent it's recurrence.

Case study 3 Retained Foreign Object

A patient underwent a Dacryocystorhinostomy procedure (operation on the tear duct). As part of the procedure a shield (conformer) was placed over the eye to protect it. The conformer was not removed at the end of the procedure and the patient returned the following day with total loss of vision in that eye. The conformer was removed immediately and the patient made a full recovery with no permanent consequences.

The patient received an apology and a copy of the SI investigation report was offered.

The root cause of the incident was found to be failure to complete the WHO checklist although the count at the time did not include conformers.

A number of recommendations were made and the full report can be accessed at Q:\York Hospitals Trust\SUI\Never Events and Learning\Case study 3 SI Report FINAL 11 2 14.doc

Lessons learnt

The WHO checklist must always be followed and all items used in a procedure should be on the count list.
# Case study 4 Wrong site surgery

## Definition of 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.

The patient underwent an excision of persistent urachal sinus and paraumbilical hernia repair at Scarborough Hospital.

On review in clinic a possible further hernia was detected in her caesarean scar. Due to difficulty assessing the hernia clinically, a CT was performed. The CT written report demonstrated “infraumbilical divarication of rectus with protrusion of omental fat”. The patient was seen in clinic and booked for repair of her incisional hernia.

The patient complained of pain over her paraumbilical incision at the initial clerking. There was confusion over the site of the hernia preoperatively and both incisions were marked. After discussion with the patient and review of the CT, the paraumbilical incision was re-explored. No hernia was detected. The patient was discharged home the same day. She re-attended clinic to see the original Consultant who felt the wrong site had been explored.

The CPD listing chosen for the procedure was incorrect.

The root cause of the incident appears to be confusion in the marking of the operating site by the two doctors reviewing the patient.

There was also no evidence or recollection of a consent form and it cannot be determined if this had been completed or had been completed and then lost.

The patient received an apology and was offered a full copy of the SI report.

A number of recommendations were made and a full copy of the report can be accessed at Q:\York Hospitals Trust\SUI\Never Events and Learning\Case study 4 SI 2014 9435 Final May 2014.doc
Conclusion

Of the Never Events we have reported with the exception of the Air Embolus it would appear that failure to follow process and communication were significant contributory factors to things going wrong.

Human factors play a large part when errors occur, such errors can be reduced with a good standard of documentation and checklists.

And finally a reminder about the Duty of Candour which must be applied to every incident rated as moderate or severe harm/death. The Health and Social Care Act (2008) has been amended and new regulations have come into force.

The revised Being Open Policy describes our duty to be open when harm events occur, it incorporates the ‘Duty of Candour’ which is a statutory obligation since November 2014 and reinforces the fundamental obligation to be open and honest in the event of an incident where patient harm has occurred. ALL moderate and severe harms must be handled and reported under Being Open, the pivotal feature of which is early acknowledgement, explanation and apology.

The Health and Social Care Act criminalises NHS bodies that fail to notify and apologise to their patients for incidents that have caused them harm. This includes “any unintended or unexpected incident that occurred in respect of a service user that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in a) death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition; or b) severe harm, moderate harm or prolonged psychological harm to the service user”.

Lessons learnt.

This instance of wrong site surgery is typical in that many small errors contributed to the event. This case also reveals the rare weakness of the WHO checklist, as the listed operation and mark were all compatible with the procedure performed.

In terms of learning there should always be a Consultant surgeon allocated to the operating list who does not have other clinical commitments. If no such person is available the list must be cancelled.

Consent should be carried out prior to admission and patients must be listed accurately for operations. If this is not done then the operation should not proceed. Marking accurately the site of surgery, checking this back with letters etc and with the patients is of fundamental importance.

You should also note that failure to consent, which then leads to harm for the patient is also the subject of a fine which could be anything up to £50K (Section 2 item 11, of the Health and Social Care Act 2008 (updated 2014))
Details of the new Act re Duty of Candour, Section 2 item 20, can be found at
Q:\York Hospitals Trust\SUI\Never Events and Learning\The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.htm

Mrs Elaine Miller
Lead for Patient Safety Learning
January 2015