



PATIENT SAFETY UPDATE

January – March 2017



LEARNING POINTS FROM REPORTED INCIDENTS

January 2017 – March 2017

This document aims to achieve the following:

- Outline the data received, the severity of reported patient harm and the timing and source of reports
- Provide feedback to reporters and encourage further reports
- Provide vignettes for clinicians to use to support learning in their own Trusts and Boards
- Provide expert comments on reported issues
- Encourage staff to contact SALG in order to share their own learning on any of the incidents mentioned below.

The SALG Patient Safety Updates contain important learning from incidents reported to the National Reporting and Learning System (NRLS). The Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) would like to bring these Safety Updates to the attention of as many anaesthetists and their teams as possible. We would like to encourage you to add this Update to the agenda of your next Morbidity and Mortality (M&M) meeting, and we would also like to hear your feedback on the learning points.

Feedback from M&M meetings on how the Patient Safety Update has informed action can be sent to the SALG administrator at SALG@rcoa.ac.uk

be substituted by a procurement department in the assumption that one blood giving set is just like another.

Blood can be delivered by gravity, by external positive pressure on the bag or by downward negative pressure applied by volumetric pumps.[1,2,3] Each method requires its own specific giving set and the market is awash with options; it is easy to see how confusion can arise. There are standards (BS EN ISO 8536-4 and 8536-8) specifying the physical characteristics, performance of each type of giving set and labelling (source of information; British Standards Institution). The standards do not require the giving set to be marked as gravity **only** flow; this may represent a patient safety issue. The user is not always the person who checks the packaging and primes the infusion set. In time critical situations it is not practical or appropriate to read all the packaging information of every item that you use (or someone around you uses) indeed if one did this it would be a dereliction of the responsibility of patient care.

The problem above may have arisen because of a disconnection between the procurement process and the user; the subtlety of giving set specifications may not be understood by procurement staff or the person laying aside new stock or even the person setting up the device. Procurement in many hospitals will change equipment on numerous occasions; this is usually either because of supply issues or for cost reasons. Communication about these changes is often poor, leaving opportunity for potential error. There may be similarities here with drug supplies and pharmacy. Procurement decisions about equipment and drugs could benefit from increased clinical input and engagement.

The Medicines and Healthcare products Regulatory Agency (MHRA) is aware of some of the difficulties associated with labelling and has set up a Labelling Expert Advisory Group to consider these issues in more detail. Its first review is of labelling in interventional radiology.

In addition, following a specific report to it regarding vented caps on intravascular access devices, the MHRA is working with relevant manufacturers to see if patient safety can be enhanced by working together. The solution to the issue may be labelling, but it may also be in the presentation of these devices in the packaging.

MHRA would also be very grateful if anaesthetists and other healthcare professionals would report issues specifically regarding labelling to them. This is in addition to reporting other issues related to patient safety and medical devices. This can be done via the Yellow Card Scheme <https://yellowcard.mhra.gov.uk/>

PLANNING AND PREPARING – KNOWING THE EQUIPMENT

- *Woman anaesthetised for serious and significant post - partum haemorrhage... attempted to give blood under pressure via fluid warmer using blood giving set... barely a trickle could be squeezed through... lots of time and attention was diverted from patient care to trying to figure out the issue. An anaesthetic nurse remembered a previous alert about blood giving sets that could not be pressurised... retrieved the packaging from the bin was marked in the tiniest of writing "gravity flow only". An alternative set was got and care proceeded uneventfully. However, this could have caused a fatal sequence of events. I understand the logic of having gravity only blood sets but in theatre the virtue becomes a latent danger. The packaging is labelled, but I firmly believe that the giving set itself should also bear a clear indication that it is gravity flow only. This would be a failsafe, at present it is a 'fail dangerous'. This is of special importance where such an item could easily*

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1. Nightingale M J, Norfolk D R Pinchon, D J. Current uses of transfusion administration sets: a cause for concern? *Transfusion Medicine* 2010;**20**(5);291-302.
2. Stoneham M D. An evaluation of methods of increasing the flow rate of i.v. fluid administration. *British Journal of Anaesthesia* 1995; **75**:361-365.
3. Technical aspects of transfusion. *JPAC* (<http://bit.ly/2yVKWJt>).

➤ *Patient had likely hypoxic arrest secondary to pneumonia... had been intubated by anaesthetic registrar and was being ventilated with a Water's circuit. Patient had very low oxygen saturations despite apparent 100% oxygen and positive pressure ventilation. Patient arrested a further time secondary to hypoxia. It was then discovered that patient was being ventilated with medical air from piped supply. The medical air and the oxygen outlets were side by side... both with flowmeters attached. It was very difficult to tell, particularly in an emergency situation, which flowmeter was which.*

The Problem: In time-pressured situations it is easy to misread or miss reading the detail on wall mounted terminal valves for pipeline medical gases. Piped medical gas systems are regulated by both ISO (ISO 9170-1:2017 and ISO 15002:2008) and BS standards (BS EN 737-1:1998). The standards have been interpreted by the Department of Health in their Health Technology Memorandum.¹ Valve shape, gas symbol, +/- colour ensure correct assembly of the oxygen/ air flowmeter to the relevant piped gas outlet. The connection from the flowmeter to the mask and tubing is via a fir tree connector; there is no differentiation between oxygen and air at this point of connection. The user has to check backwards to the wall valve / flowmeter connection. This remains a significant latent error in hospitals, that has currently not been engineered out of the system.

Current limited solutions: NHS Improvement in their Patient Safety Alert stage three – directive in 2016 brought this risk to the attention of all hospitals with piped medical gases for a second time and required implementation of the three barriers to human error by 4 July 2017: medical air terminal units (wall outlets) are covered with designated caps in areas where there is no need for medical air, medical air flowmeters are removed from terminal units (wall outlets) and stored in an allocated place when not in active use, air flowmeters are fitted with a labelled, movable flap.² This incident serves as a reminder for departments to ensure they are compliant with the directive.

Possible future engineered solutions: The fir-tree connector is under review as part of the ISO respiratory small-bore connector project and will be covered in ISO 80369-2 when it is published. It is anticipated that the fir-tree will remain but changes will be applied to the patient end connections. SALG will report on this as soon as more detail is available.

1. Health Technical Memorandum 02-01: Medical Gas Pipeline Systems – Part A Design, Installation, Validation and Verification Department of Health 2006 (<http://bit.ly/2xuscES>) (accessed 10/09/2017).
2. Reducing the risk of oxygen tubing being connected to air flowmeter. NHS Improvement October 2016 (<http://bit.ly/2y6lMKo>) (accessed 11/09/2017).

THE DETERIORATING PATIENT – AKI

➤ *Patient was discharged from CICU following a CABG - not documented on CICU patient ready for discharge. Patient developed an acute kidney injury and arrhythmias and returned to CICU... subsequently arrested and died.*

Chronic kidney disease increases the risk of developing acute kidney injury (AKI) whilst acute kidney injury increases the likelihood of developing end stage kidney disease by 13-fold.^{1,2} The NCEPOD report in 2009 stated that less than 50% of cases with AKI had received good care in hospital, that post admission AKI was avoidable in 21% of cases and that there was an unacceptable delay in recognition of AKI in 43% of cases.³

NHS Improvement published a stage 3 directive in 2014 to raise awareness of an agreed national algorithm for the timely detection and diagnosis of AKI.⁴ This has been followed up by a stage 2 alert signposting clinicians to resources supporting the care of patients with AKI.⁵

1. James M. T. et al. Glomerular filtration rate, proteinuria, and the incidence and consequences of acute kidney injury: a cohort study. *Lancet* 2010;376:2096-2103.
2. Ishani A. et al. Acute Kidney Injury Increases Risk of ESRD among elderly. *Journal American Society Nephrology* 2009;20: 223–228.
3. Acute kidney injury: adding insult to injury, National Confidential Enquiry into Patient Outcome and Death 2009. (www.ncepod.org.uk/2009aki.html) (accessed 12/09/2017)
4. Patient Safety Alert. Stage Three: Directive Standardising the early identification of Acute Kidney Injury. NHS Improvement 2014 (<http://bit.ly/2zbyeY2>) (accessed 12/09/2017).
5. Patient Safety Alert. Resources to support the care of patients with acute kidney injury. NHS Improvement 2017 (<http://bit.ly/2gaeb7L>) (accessed 11/09/2017).

ANAESTHESIA SPRINT AUDIT OF PRACTICE (ASAP) 1 – RECURRING THEMES

➤ *Bone cement implantation syndrome patient was hypoxic and hypotensive after the cement was inserted. This resolved to some extent but the patient had to be intubated in recovery and taken to ICU.*

Following local case review, the department identified and reported some good practice points:

- *Identify high risk patient*
- *cement implantation syndrome was not discussed within the surgical or anaesthetic consent process.*

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This should probably be done and documented in patients who are high risk.

- *spinal with plain bupivacaine which was inadequate – heavy marcain may have given a better block and avoided the need for GA.*
 - *communication between the surgical and anaesthetic teams was good however the cementing was not discussed at the WHO check*
 - *the cement curfew did not take place formally we just discussed it around the time of cementing. Guidance should be available in theatre on how exactly this should be done to standardise this.*
- *82 year old female admitted following fall at home with a hip fracture requiring hemiarthroplasty... extensive cardiac PMH on clopidogrel and apixaban. Surgery had been delayed 48 hrs to allow coagulation to normalise. Spinal with sedation advised, patient agreed. Failed to adequately site block. Converted to GA... LMA used, Fentanyl / Propofol / Isoflurane, IPPV Routine anaesthetic for first 45 mins, then persistent desaturation. Gastric contents apparent on removing LMA at end of procedure.*

The AAGBI guideline on bone cement implantation syndrome provides a structured approach to management of the patient requiring cemented hemiarthroplasty following a long bone fragility fracture.^[1] As identified in the local case review, the steps include identification of the at-risk patient, shared team understanding using the WHO safety checklist and following the discipline described in the "Coventry Curfew".²

ASAP reviewed compliance with standards of perioperative care in hip fracture patients in England and Wales. The study concluded that the mode of anaesthesia had no significant impact on the mortality rate. ASAP noted that a supraglottic airway was used in 51% of patients in ASAP and commented that pulmonary aspiration of gastric contents may be reduced by intubation. The inflammatory side effects of mechanical ventilation were also noted. Combined general anaesthesia and spinal anaesthesia was associated with the largest drop in blood pressure.^{3,4}

1. Griffiths R et al. Safe ty guideline: reducing the risk from cemented arthroplasty for hip fracture 2015. Association of Anaesthetists of Great Britain and Ireland, British Orthopaedic Association, British Geriatric Society 2015 (<http://bit.ly/2grfufG>) (accessed 12/09/2017).
2. Scrase A, Horwood G, Sandys S. Coventry, "Cement Curfew": team training for crisis. *Anaesthesia News* 2014;327:8-9.
3. National Hip Fracture Database Anaesthesia Sprint Audit of Practice (ASAP). Association of Anaesthetists of Great Britain and Ireland, Royal College of Physicians 2014 (<http://bit.ly/2kDtGXd>).
4. Whyte S M et al. Outcome by mode of anaesthesia for hip fracture surgery. An observational audit of 65 535 patients in a national dataset. *Anaesthesia* 2014;69(3):224-30.

LARGELY PREVENTABLE SERIOUS ADVERSE EVENTS (NEVER EVENTS)

- *Patient underwent elective surgery for total abdominal hysterectomy... remained in hospital as she was unwell. CT abdomen was requested as abdominal sepsis was suspected... reported that a retained surgical swab was within the abdomen. Patient was scheduled for removal of swab. On opening the abdomen two abdominal swabs were found to have been retained from surgery.*
- *Patient was on nasal high flow oxygen... tachycardia, BP stable without any support. Patient has NG feed running. Received handover from the night staff who mentioned that the patient pulled out NG tube during the night and another one had been reinserted. CXR was taken after NG insertion... night staff informed feed only restarted after confirmation from night registrar that NG tube was in the correct place. Aspiration of the NG tube got 35mls aspirate, checked pH (6.5) and gave morning medicines. Patient saturation is dropping, 89% and patient is slightly uncomfortable. CXR from early morning shows NG tube situated right in the lungs.*

The definition of never events is: serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.¹ It is claimed that never events may highlight potential weaknesses in how an organisation manages fundamental safety processes. References attached provided detail on barriers to wrong position of NG tubes and retained foreign bodies following surgery.^{2,3,4}

1. Revised never events policy and framework NHS England 2015 (<http://bit.ly/2yc8fBF>) (accessed 12/09/2017).
2. Resource set Initial placement checks for nasogastric and orogastric tubes. NHS Improvement 2016 (<http://bit.ly/2wK9B3k>) (accessed 12/09/2017).
3. Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants National Patient Safety Agency. 2011 (<http://bit.ly/2xwxxkm>) (accessed 03/10/2017).
4. National Safety Standards for Invasive Procedures (NatSSIPs) NHS Improvement 2015 (<http://bit.ly/2zbCNla>) (accessed 12/09/2017).

NATIONAL AUDIT PROJECTS 3 AND 4 – RECURRING THEMES

- *Patient admitted for AAA repair under spinal anaesthetic. Post-surgery patient unable to move lower limbs, MRI showed likely spinal haematoma causing compression and myelopathy.*
- *Female admitted with failure to progress during labour... septic with fever. Epidural placed with constant 10ml / h infusion. Failure to progress from 5cm... decision made to do Caesarean. Epidural catheter injected with 20ml bolus and patient collapses followed by cardiac*

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arrest. 2-3 minutes of CPR performed with ROSC and peri-mortem C-section. Patient is now demonstrating decorticate posturing and not waking up.

NAP3 confirmed that vertebral canal haematoma is a very rare complication and the administration of drugs interfering with coagulation is a risk factor. Many of the patients affected were elderly suggesting reduced drug handling was also a factor.¹

Forty-five percent of central neuraxial blocks were performed for obstetric indications but these were under-represented in terms of major complications, as reported in NAP3. One case of obstetric total spinal was described. The report suggests that application of good anaesthetic principles helps avoid significant morbidity due to cardiovascular collapse. The use of a test dose (low volume high dose) is in decline and high volume low dose boluses are the new norm. NAP3 states that *low concentration, high volume, doses of dilute local anaesthetic with fentanyl lend themselves better to a fractionation technique, with the first dose- often in the region of 10ml of 0.1% bupivacaine with fentanyl – acting as its own test for intrathecal placement. There seems no reason why this should be any less safe than the low volume, high concentration test doses of the past, as long as the possibility of accidental spinal administration and a rapid onset of a high block are not forgotten. Indeed, any bolus should be administered accepting that if the epidural catheter has misplaced, it may in effect be a subarachnoid bolus.*¹

1. Cook T M et al. Major complications of central neuraxial block: report on the Third National Audit Project of the Royal College of Anaesthetists. *British Journal Anaesthesia* 2009;102(2):179-90. (www.nationalauditprojects.org.uk/NAP3_home).
2. Cook T M et al. Major complications of airway management in the United Kingdom: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society *British Journal of Anaesthesia* 2011; 106(5): 617–631 (www.rcoa.ac.uk/system/files/CSQ-NAP4-Full.pdf) (accessed 12/09/2017).

LINES

- Patient transferred after AVR for weaning... confused, on Noradrenaline... in renal failure... required a line change and a vascath. Sedated for the procedure and became hypotensive. I supervised the line insertion and felt that the technique was safe. The patient arrested at the end of the procedure and died despite CPR. A post mortem was carried out and the results were made available... a large (1.5L) haemothorax on the same side as the vascath.
- Coroner post-mortem identified bleeding from femoral arterial line in 1b as cause of death. We were not aware of bleeding at the time.

Haemothorax is a recognised complication of central venous cannula insertion. The potential for significant blood into the low pressured pleural space is large. Patients may present with respiratory and or circulatory collapse. The cannula should remain in situ whilst resuscitation proceeds +/- open repair of the vessel involved.¹

Concealed haemorrhage following femoral artery cannulation is a recognised but rare complication; most cases of femoral arterial haemorrhage are visible in the groin but retroperitoneal haemorrhage does not present with the usual sign of a swelling mass. Many cases can be managed conservatively but surgical/radiological intervention may be required.²

1. Association of Anaesthetists of Great Britain and Ireland: Safe vascular access 2016. *Anaesthesia* 2016;71(5):573–585 (<http://bit.ly/2yCYz4u>).
2. Sanjani N. et al. Retroperitoneal Hemorrhage as a Complication of Percutaneous Intervention: Report of 2 Cases and Review of the Literature *Open Cardiovascular Medical Journal* 2013;7:16–22.

SURGICAL COMPLICATION PRESENTING TO THE ANAESTHETIST

- Patient booked on the emergency list for incision and drainage of left breast abscess. Abscess lower right quadrant of left breast, close to the midline. Had ultrasound guided aspiration earlier but unsuccessful due to viscous nature of abscess contents. Plan use of 2nd generation LMA as obese with a BMI 30 and occasional reflux. Induction with fentanyl 100mcg and propofol 200mg, 2nd generation LMA placed immediately. Cardiovascularly stable, easy ventilation with good bilateral chest rise. Moved to theatre and placed on ventilator with age and weight specific settings used. Making respiratory effort, therefore placed on pressure support setting (assist of 10 and pEEP of 5). Tidal volumes of 400ml and respiratory rate 14, sats 97% 50% nitrous oxide, oxygen and sevoflurane. Stimulation from surgery with increased heart rate, increased respiratory rate. Further analgesia given 100mcg of fentanyl apnoeic pressure controlled ventilation. Started to desaturate. Emergency declared when saturation reached 90%, surgery halted. Consultant anaesthetist called and arrived quickly. Concurrently decision to intubate... suxamethonium 100mg given, grade 2b view with Mac 4 blade. Bougie inserted 1st pass size 7.0 cuffed endotracheal tube passed. Tracheal intubation confirmed via end tidal CO₂. On auscultation no air entry in right hemithorax, crackles in left hemithorax. Hyper-resonant right hemithorax. Working diagnosis pneumothorax.

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Pneumothorax during breast surgery is a rare surgical complication. It may arise unexpectedly and it is difficult to diagnose. As such it is important to have a high index of suspicion and a systematic approach to making the diagnosis.^{1,2}

1. T Reekie et al. Diagnosing Intraoperative Pneumothorax in Patients Undergoing Autologous Breast Reconstruction: A Useful Clinical Sign Case Reports in Surgery Volume 2014 (2014), Article ID 308485, 3 pages (<http://dx.doi.org/10.1155/2014/308485>)
2. AK Bacon et al. Crisis management during anaesthesia: pneumothorax. Quality and Safety in Healthcare 2005; 14(3):e18.

APPENDIX: INCIDENT DATA SUMMARY

A total of 12,155 anaesthesia-related incidents were reported during the specified time period. Two incidents were reported using the anaesthetic eForm; 1 (50%) of these incidents were reported to the National Reporting and Learning System (NRLS) within one week of occurrence. 0 (0%) of the incidents reported to the eForm were reported as 'near miss' (harm was prevented from reaching the patient). 12,153 incidents were reported using Local Risk Management Systems (LRMS); 2771 (17.9%) of these incidents were reported within one week. Of the incidents reported via LRMS, 1,279 (10.5%) were reported as near miss.

All incidents reported via the eForm, and all those reported to the LRMS graded as 'death' or 'severe harm', were reviewed by the Patient Safety Team, now part of the Patient Safety Function within NHS England (formerly the NHS Commissioning Board). Consultant anaesthetists from the

RCoA or AAGBI reviewed incidents identified as having potential cause for concern. No information about the Trust was disclosed in this review; only information about the incident. Most incidents reported via the eForm were completed by consultant anaesthetists, although the eForm is available to all members of the perioperative team.

As with any voluntary reporting system, interpretation of data should be undertaken with caution as the data are subject to bias. Many incidents are not reported, and those that are reported may be incomplete having been reported immediately and before the patient outcome is known. Clarity of 'degree of harm' to patients who experience a patient safety incident is an important aspect of data quality.

ANAESTHETIC EFORM

The anaesthetic eForm was designed to allow specific clinical information relating to anaesthetic incidents to be reported by anaesthetists and other members of the anaesthetic team, and can be found at: www.eforms.nrls.nhs.uk/asbreport.

The RCoA and AAGBI continue to work with the NRLS team at Imperial and the patient safety function of NHS England. SALG would like to reinforce that processes for sharing and learning incidents remain firmly in place. Staff are urged to continue to use the eForm (or your local reporting systems) to report patient safety incidents so that trends and incidents can be acted upon and learning maximised. The eForm is particularly useful as it provides a mechanism by which high quality information can be reported rapidly by members of the anaesthesia team and disseminated nationally.

Figure 1 – Degree of Harm (actual incidents)

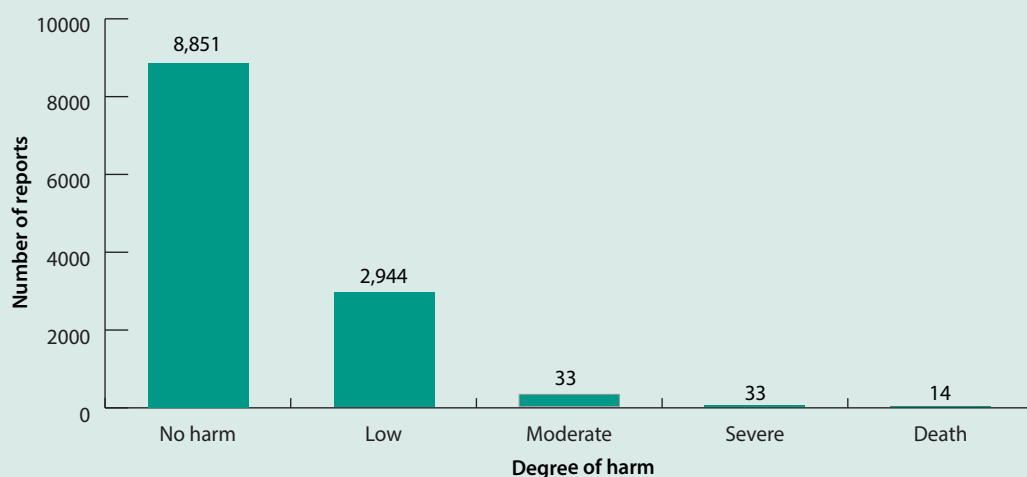


Figure 1 shows the degree of harm incurred by patients within the anaesthetic specialty during the period January– March 2017. 14 deaths were reported through LRMS and none via the anaesthetic eForm.

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Figure 2 – Incidents by incident type

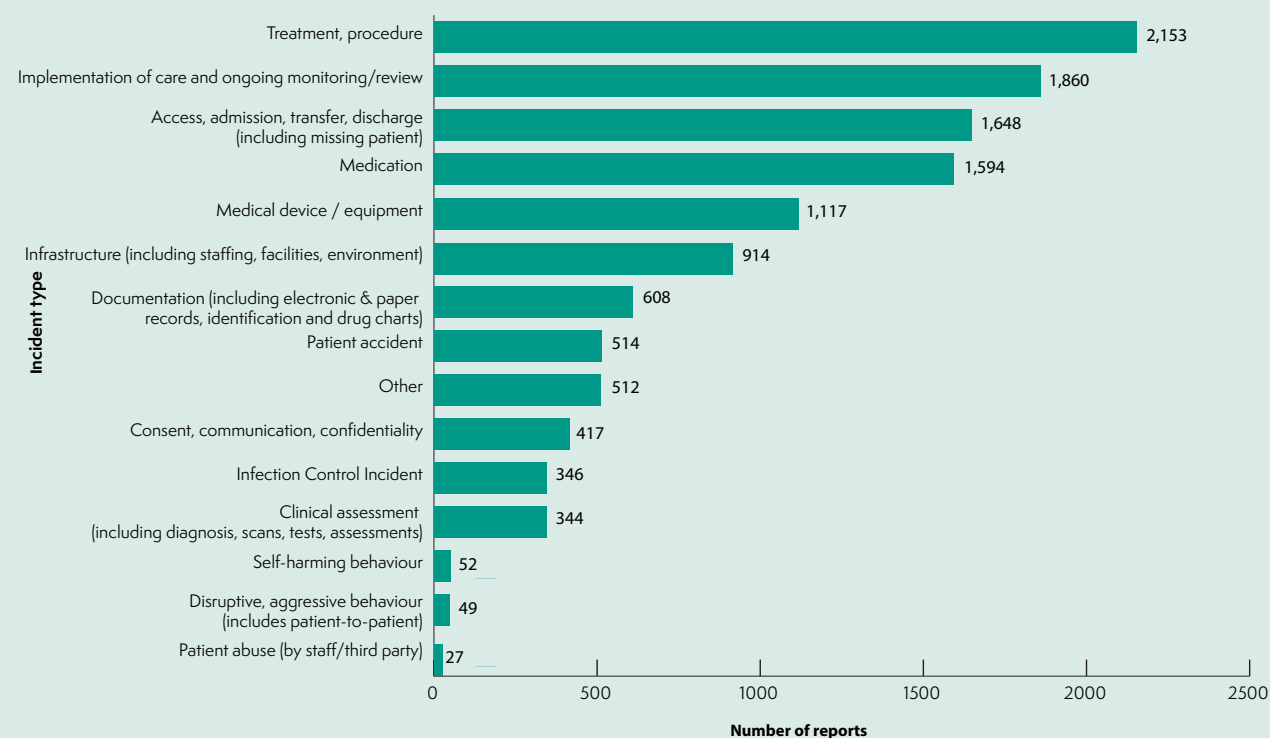


Figure 2 shows the type of incidents that occurred within the anaesthetic specialty that were reported using LRMS or the anaesthetic eForm for the period January– March 2017. The categories were determined at local level.

