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Key findings

- Reporting of life-threatening perioperative anaphylaxis to local reporting systems, and thence to the National Reporting and Learning System (NRLS), occurs in 70% of cases. Reporting is usually by the index anaesthetist.
- Reporting to the UK regulatory system, the Medicines and Healthcare products Regulatory Agency (MHRA), is poor, occurring in fewer than one quarter of cases.
- From a general public health perspective, the potential value of reporting to the MHRA is much greater than that of local reporting.
- Current reporting levels and processes mean that data held by the MHRA are unlikely to be representative of the prevalence of perioperative anaphylaxis, and that data on suspected trigger agents are highly likely to be inaccurate.
- Steps are needed to improve the ease of reporting and to remove barriers to this.
- A lack of feedback from the NRLS and MHRA may negatively impact on reporting rates.
- Combining relevant data from the NRLS and MHRA (taking care to avoid double-reporting of cases) may have considerable benefit.

Reporting systems

“Without principles, practice is a mere routine; the good or ill results of which the cause is not discerned, are equally lost to the progress of Art. The success which cannot explain often leads us into error, and serves only to perpetuate, under the names of experience, a blind conduct, of which we know neither the good nor the evil.”

— Benjamin Travers, Surgeon to the Honourable East India Company, 1812.

In many healthcare settings, data on side effects of medicines and complications of procedures may be limited, and this increases the need for accurate and timely reporting of complications and hazards. Such reporting helps build a safety profile so that complications and hazards can be identified in a manner which is not possible in the practice of individual clinicians or teams.

Reporting, particularly of rare events, provides an opportunity for a better overview and understanding of known complications and hazards associated with a process, and has the potential to detect and enumerate new and unforeseen complications and hazards. Reporting can also identify emerging trends of known complications and hazards, and may also provide clues to aid in further risk reduction where innovative and novel treatments emerge.

Without reporting, as doctors, we are confined to our own limited sphere of knowledge and experience supplemented by reliance on intermittent study of research, which may or may not be focused and which may not provide answers to important patient-safety questions.

Although in the ideal situation there would be no hazards, side effects or complications, the reality with all healthcare is that there will always be risk to some degree. With this in mind, there can be reassurance when reporting can confirm a steady state of complications and hazards that is consistent with known, accepted or benchmarked data. The value of reporting is perhaps best illustrated by the vacuum within which we would operate if no reporting of complications were to take place.

The usefulness of reporting is increased greatly when there is accurate denominator data and known risks have been properly quantified. For example, using registry data it was possible to identify the premature wear and failure of certain types of hip replacement prostheses which had metal-on-metal bearing surfaces. This wear in vivo had not been detected in pre-implantation engineering testing (Fary 2011, Haddad 2013). This led to a series of alerts being issued by the MHRA, the first being in 2010 to alert surgeons to the possibility of emerging problems (MHRA 2010), and subsequent actions to further determine the extent of the problem and, where necessary, to address it – both in terms of identifying patients at risk of problems and in preventing further operations with this technology.

Data generated by reporting can be used for numerous purposes, including:

- Identifying critical incidents which need investigating
- Identifying trends
- Identifying emerging issues
- Audit, for monitoring performance of:
 - The individual
 - The team
 - The healthcare institution
- Monitoring the introduction of new processes or procedures
- Reducing the likelihood of litigation by preventing safety issues going unnoticed
- Fulfilling a doctor's obligation to the GMC (GMC 2014).
- Enabling healthcare institutions to fulfil their obligations to patient safety as determined in the Health and Social Care Act 2008 and other regulatory updates (CQC 2015).

All these activities contribute to the general culture around enhancing patient safety.

However, barriers to reporting are numerous (Vincent 1999, Mahajan 2010, Whitaker 2016) and include:

- A lack of perceived or actual value in the eyes of the potential reporter
- Poor education regarding the value and methods of reporting
- Difficult or time-consuming data entry
- A requirement to enter excessive or unnecessary data
- Absence of feedback from reporting systems
- Failure to provide feedback on what action is to be taken
- Requirements to report to more than one system
- Lack of resources for reporting.

Only a fraction of critical incidents may be reported in many systems (Evans 2006, Kaldjian 2008).

For reporting systems to be effective a number of principles need to be followed (Vincent 2014):

- All incidents which could have led to harm should be reported, (to ensure today's near-miss does not turn out to be tomorrow's disaster)
- Information reported must be:
 - Accurate
 - Timely
 - Succinct/manageable
 - Include everything being requested by the reporting system to ensure consistency
- Data should be reviewed promptly
- Data should be only what is required, and should only need to be entered once
- Data should be analysed regularly to identify trends and emerging hazards

- Action should be undertaken in a timely way where this is deemed necessary
- There should be feedback to the reporters/teams involved. This will vary in detail, but must include some element of what action is to be taken, even if this is just to be mapping of trending and continuing surveillance
- Reporters should have a voice in what is being collected, and be given confidence of its value
- Sufficient resources should be given to reporters to undertake reporting activities.

Reporting improves in a no-blame culture. In the NHS there are plans to improve future reporting, for example, by bar-coding using systems such as 'Scan4Safety', and unique device identifiers (NHS Improvement 2017a).

Numerical analysis

We have made the assumption that responses from Local Coordinators stating that reporting status was 'unknown' indicate that reporting did not occur. The data therefore represent minimum reporting levels.

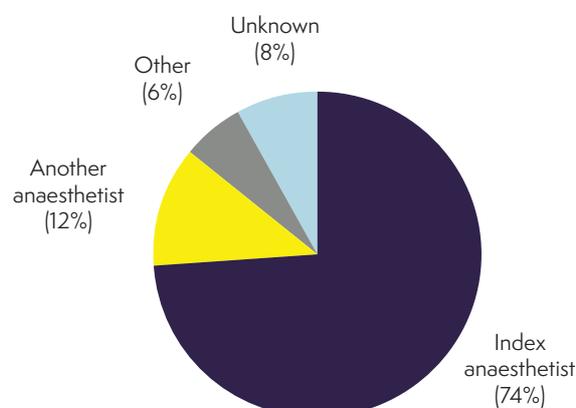
Trust reporting

Seventy per cent of cases included in NAP6 were reported to trust reporting systems (Table 1). In the vast majority of cases this was reported by the index anaesthetist (Figure 1). Others who reported included nursing staff, surgeons, anaesthetic assistants and ICU staff. Of the ten deaths, eight were reported to local incident reporting systems.

Table 1. Reporting to trust/board incident systems

Reported to the trust: Part A	Number	%
Yes	187	70.3%
No	71	26.7%
Unknown/blank	8	3.0%
Total	266	100%

Figure 1. Reports of perioperative anaphylaxis to trust/board reporting systems



Reporting to MHRA

In all cases, reporting to the MHRA occurred in 15.8% of cases before attending the allergy clinic and in 23.7% after the clinic visit (Tables 2 and 3). In children, reporting to the MHRA occurred in 9.1% of cases before attending the allergy clinic and in 18.2% after the clinic visit.

Table 2. Reports to the MHRA before attending the allergy clinic (all cases)

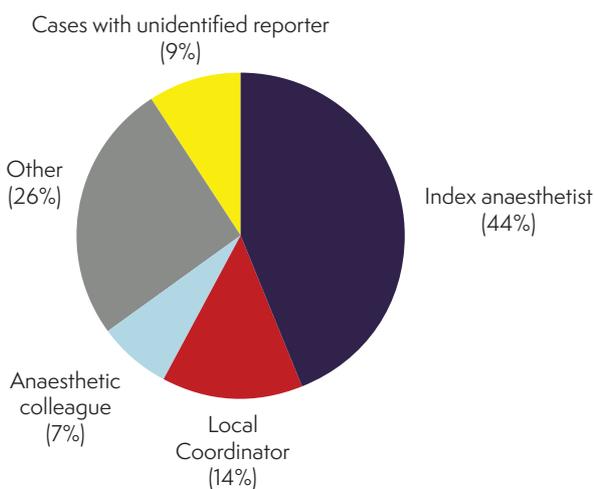
Reported to MHRA before allergy clinic attendance	Number	%
Yes	42	15.8%
No	164	61.7%
Unknown	54	20.3%
Blank	6	2.2%
Total	266	100%

Table 3. Reports to the MHRA after attending the allergy clinic (all cases)

Reported to MHRA after allergy clinic attendance	Number	%
Yes	63	23.7%
No	68	25.6%
Unknown	52	19.6%
Blank	83	31.1%
Total	266	100%

The index anaesthetists were responsible for 44% of reports to the MHRA before allergy clinic assessment and Local Coordinators accounted for another 14% (Figure 2). Others who reported to the MHRA included other anaesthetists (7), pharmacists (2), and ICU doctors (1). Of the ten deaths, three were reported to MHRA.

Figure 2. Individual reporting to MHRA, before allergy clinic attendance



MHRA data

We liaised with the MHRA to determine whether data held by them would be informative. In the year January to December 2016 the MHRA received 901 reports of suspected ‘anaphylactic or anaphylactoid reactions’ via the Yellow Card system. Of these, 464 (51%) could potentially have occurred during the perioperative period, though for some drug groups it is highly likely that many did not – for instance antibiotics may have been administered at any time – and many other drugs included in miscellany are also used in non-perioperative settings. Reports to the MHRA included some likely anomalous reports such as reactions to sevoflurane, sodium chloride, water, steroids, and adrenaline.

We are not aware of the grades of reactions reported, nor the degree of suspicion of anaphylaxis. It is of course inevitable that many of these reactions were not hypersensitivity reactions. It is overall very difficult to compare these data with NAP6 data, and some anomalies are clearly evident. It is however of note that there were significant numbers of reactions to co-amoxiclav (35), teicoplanin (72), amoxicillin (20), rocuronium (34), atracurium (27), suxamethonium (17), chlorhexidine (22), and Patent Blue (17), all of which ranked in the top 11 most frequently reported drugs and between them accounted for 27% of all reports.

Tables 4 and 5 provide a breakdown of these data.

Table 4. Main drug groups reported to the MHRA as causing anaphylactic or anaphylactoid reactions in 2016

Drug group or drug	Number	% of all reports
All drugs	901	-
Potential perioperative drugs	464	51%
		% of all potential perioperative drugs
Antibiotics	237	51%
NMBA	79	17%
Sugammadex	8	1.7%
Induction and maintenance agents	14	3.0%
Opioids and analgesics	33	7.1%
Antiemetics, local anaesthetic and miscellany	53	11.4%
Chlorhexidine	22	4.7%
Patent Blue dye	17	3.7%
Iodine	1	0.2%

Table 5. Drugs of prominence in NAP6 and MHRA datasets compared

	MHRA	% of potential perioperative drugs reported to MHRA	NAP6	% of NAP6 reports with identified trigger
Teicoplanin	72	15.5%	36	18%
Co-amoxiclav	35	7.5%	46	24%
Amoxicillin	20	4.3%	0	0.0%
Piperacillin and tazobactam	18	3.9%	1	0.5%
Gentamicin	15	3.2%	3	1.5%
Flucloxacillin	6	1.3%	2	1.0%
Cefuroxime	7	1.5%	4	2.0%
Rocuronium	34	7.3%	27	13.6%
Atracurium	27	5.8%	23	11.6%
Suxamethonium	17	3.7%	14	7.0%
Mivacurium	1	0.2%	1	0.5%
Sugammadex	8	1.7%	1	0.5%
Propofol	10	2.2%	1	0.5%
Midazolam	2	0.4%	0	0.0%
Thiopental	1	0.2%	0	0.0%
Sevoflurane	1	0.2%	0	0.0%

Discussion

Reporting of serious incidents and near-misses are essential to the understanding of untoward events occurring in healthcare. Without data we are destined to miss opportunities to detect and potentially mitigate issues which could be more common than we perceive. Reporting of untoward events and near-misses is a professional responsibility of all healthcare professionals.

This means that everyone involved in healthcare has a part to play in reporting, and strong leadership in this by medical professionals is essential. There also needs to be a permissive environment and a culture of reporting. This can only be fostered by using data generated as a learning opportunity, and not as part of a vehicle to blame individuals where an error by a healthcare professional is seen to be the root cause of an issue. It is important to start the conversation with 'What happened within the system that facilitated this set of circumstances?', and not 'Who's to blame and how were they allowed to do this?'

The MHRA Yellow Card scheme is for medicines and devices. It can be accessed for reporting online (<https://yellowcard.mhra.gov.uk/>) and by phone, post or app. NHS Improvement also provides guidance on reporting patient-safety incidents (NHS Improvement 2017b).

In the case of perioperative anaphylaxis, there is a danger of multiple reporting and also of incorrect data being reported and recorded. The index anaesthetist may report a case and identify a suspect culprit agent. After attending the allergy clinic and further investigation, the event may or may not be confirmed

as a hypersensitivity reaction and, if confirmed, a causative agent (or agents) may or may not be identified. This may then be reported by the allergy clinic. Ensuring that the MHRA does not have incomplete, duplicate, inaccurate or out-of-date data would require considerably more coordination than currently exists. In NAP6 panel discussions it was noted how little information is received back from the MHRA regarding perioperative (or other) anaphylaxis. This may be a flaw in the current reporting system that makes it inadequate for generating a meaningful and representative picture of perioperative anaphylaxis.

In some respects, the NAP6 reporting of perioperative anaphylaxis could be illustrative of what reporting to the MHRA might ideally be. NAP6 engaged with all NHS hospitals, and received numerous reports of events in which the suspected culprit agent was reported by the anaesthetists, both immediately and then again after allergy clinic investigation, with those reports being systematically linked. NAP6 is providing, through this report, rapid feedback to those reporters, which is potentially of value to the learning process of reporters and departments and may reduce risk to patients. While the MHRA seemingly cannot provide the same level of capture, analysis and feedback as achieved by NAP6 in this project, it may be possible to identify key lessons to be learned, and we make several recommendations below. This topic is also discussed in Chapter 4, The lay perspective.

Overall, reporting at local level for these serious incidents is reasonably good, but it could still be improved. While local information is fed into the National Reporting and Learning System, it is unclear how this is filtered and analysed and what is done with the resultant findings. There appears to be a lack of national reports of such analysis to aid in the learning process.

From data received by NAP6, reporting to the national regulator of drugs and medical devices (MHRA) appears very poor, and it is likely that not only are reporting rates normally lower than during NAP6 (a substantial number of reports made to the MHRA were by NAP6 Local Coordinators), but also that, due to the processes involved, the data collected by MHRA is unlikely to accurately identify causative agents. There is currently very little feedback from the MHRA on this matter.

Recommendations:

National

- MHRA should improve communication with clinicians; for example, providing an annual report which includes perioperative anaphylaxis.

Institutional

- The departmental lead should ensure all cases have been reported to the trust's incident reporting system
- The departmental lead should ensure all cases are reported (by the anaesthetist encountering the reaction, or the departmental lead) to the MHRA as soon as possible after the event, and record the MHRA case identifier for future reference

- The departmental lead should (using the MHRA case identifier) ensure the MHRA record is updated after allergy clinic investigation is completed to ensure the information held is accurate.

Individual

- The departmental lead should be informed of the case
- The MHRA case identifier should be included in the referral to the allergy clinic
- All cases of Grades 3–5 perioperative anaphylaxis should be presented and discussed at local Morbidity and Mortality meetings for purposes of education and familiarisation.

References

CQC 2015: Guidance for providers on meeting the regulations. Care Quality Commission 2015. http://www.cqc.org.uk/sites/default/files/20150324_guidance_providers_meeting_regulations_01.pdf (Accessed 21 Feb 2018).

Evans 2006: Evans SM, Berry JG, Smith BJ, *et al.* Attitudes and barriers to incident reporting: a collaborative hospital study. *Qual Saf Health Care*. 2006; 15: 39-43.

Fary 2011: Fary C, Thomas GER, Taylor A, Beard D, Carr A, Glyn-Jones S. Diagnosing and investigating adverse reactions in metal on metal hip implants. *BMJ* 2011; 343: d7441.

GMC 2013: Good medical practice 2014. General Medical Council 2014. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice> (Accessed 27 Apr 2018).

Haddad 2011: Haddad FS, Thakar RR, Hart AJ *et al.* Metal-on-metal bearings: the evidence so far. *J Bone Joint Surg Br*. 2011; 93: 572-9.

Kaldjian 2008: Kaldjian LC, Jones EW, Wu BJ, Forman-Hoffman VL, Levi BH, Rosenthal GE. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med*. 2008; 168: 40-6.

Mahajan 2010: Mahajan RP. Critical incident reporting and learning. *Br J Anaesth* 2010; 105: 69-75.

MHRA 2010: Medicines and Healthcare products Regulatory Agency. Medical device alert: all metal-on-metal (MoM) hip replacements (MDA/2010/033). 2010. <http://webarchive.nationalarchives.gov.uk/20130513184637/> <http://www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con079162.pdf> (Accessed 21 Feb 2018).

NHS Improvement 2017a: The future of the patient safety incident reporting: upgrading the NRLS. NHS Improvement 2017 <https://improvement.nhs.uk/news-alerts/development-patient-safety-incident-management-system-dpsims/> (Accessed 21 Feb 2018).

NHS Improvement 2017b: Report a patient safety incident. NHS Improvement 2017. <https://improvement.nhs.uk/resources/report-patient-safety-incident/> (Accessed 21 Feb 2018).

Vincent 1999: Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract* 1999; 5: 13-21.

Vincent 2014: Vincent C, Burnett S, Carthey J. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety *BMJ Qual Saf* 2014; 23: 670-7.

Whitaker 2016: Whitaker J. Incident reporting feedback experience in a UK secondary care setting. *RCS Bulletin* 2016; 98: 82-4.