4 The lay perspective

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What we knew before NAP6

Perioperative anaphylaxis, unlike accidental awareness and wrong site surgery, may not be perceived as one of the most feared risks by the 3.5 million patients anaesthetised each year. Media and anecdotal sources would indicate that public awareness and experience of anaphylactic shock is associated with triggers such as nuts, sea foods, penicillin and venom rather than the anaesthetic process. It is probable that the body of public knowledge of perioperative anaphylaxis lies more with those who have experienced it, their families and the patient allergy organisations.

The variability of services that patients receive after life-threatening perioperative anaphylaxis is a matter of concern. Access to and waiting times for clinic appointments to investigate the incidents are hugely variable but generally significantly long and more commonly at least 18 weeks rather than the ideal of six weeks after the event (see Chapter 13, Allergy clinic baseline survey and 14, Investigation). As a result the original treatment that needed to be rescheduled may be delayed while the patient waits for a clinic appointment.

Poor and ineffective communication between clinicians and between clinicians and the patient has been noted in NAP6. The patient needs to know the cause of the event and to be provided with factual written information that they can understand, rather than the clinic letter being written with medical terminology appropriate primarily for the general practitioner (GP). Both the NAP6 Allergy clinic baseline survey and the findings of the main study, reported in Chapters 13 and 14, raise concerns about timeliness of investigation and quality of communications.

The NAP6 survey of existing allergy services (Egner 2017 and reproduced as Chapter 13) provides an accurate backdrop to the patient experience. It notes, "Guidelines exist for the investigation and management of perioperative drug allergy. The distribution and quality of diagnostic services is unknown." "Variation in workload, waiting times, access, staffing and diagnostic approach was noted."

Variation can lead to a 'postcode lottery' referral system for patients. Rare events such as perioperative anaphylaxis mean that clinical experience may be limited, including the necessary protocols and experience for identifying culprits, safe alternatives and communicating effectively to patients. Services may not therefore have the ideal resources to meet the unpredictable demand. This is more specifically seen in the care of children with suspected allergy to anaesthetic drugs (Egner 2017).

NAP6, the patient journey and patient expectations

Preoperative information

In order that the patient can make the right decisions about their care, they require good information about any proposed activity, and consent must be 'informed'. Accordingly, information should be provided about the potential risks and causes of anaphylaxis during anaesthesia. The risk of severe complications such as drug reactions should be discussed before the patient attends for anaesthesia and further explored as necessary at the anaesthetist's preoperative visit. In addition, the surgeon, when taking consent, should discuss the relevant risks of adverse reactions, eg. Patent Blue dye (see Chapter 18, Patent Blue dye). The extent of the conversation will be widened by the questions and fears expressed by the patient. The challenge of providing truly informed consent in this setting has been robustly discussed recently (Chrimes 2018), but that responsibility undoubtedly lies with the clinician (Montgomery 2015, Yentis 2017).

It is not possible to comment on whether information on the incidence of anaphylaxis is currently given during the preoperative period. It is likely that many, or even most, patients will not have been advised of the risks and that relevant information is only provided after the event. Section 9 of the RCoA's Risks Associated with your Anaesthetic (RCoA 2017) clearly explains the risks of perioperative anaphylactic shock without being unduely alarmist.

Reassurance can be given by a risk assessment of the individual patient's situation and by giving information on how quickly and successfully anaphylaxis can be recognised and treated. The patient can be further assured that there is always an anaesthetist there to respond and manage the complication immediately. In this respect the findings of NAP6 (Chapter 11, Immediate management and departmental organisation) can provide considerable reassurance to patients. Providing the patient with this information in advance may also reduce sequelae and complaints. It is not known how many patients are provided with copies of Section 9 (or equivalent information) and equally how many read the information they are given.

Patients' allergy history

In 2014 NICE Clinical Guidance 183 (NICE 2014) provided a stark judgement on the quality of patients' medical notes: "Major issues identified by this guideline include poor clinical documentation of drug allergy and a lack of patient information." The NAP6 survey of existing allergy services (Egner 2017) provides patients with little confidence that the situation has improved since then.

Of the 266 reported cases included in NAP6, 162 (61%) anaesthetic charts noted a previous drug allergy. In two cases an anaesthetist administered a drug of the same class as one which the patient was known to be allergic to. Communication failures contributed to these cases. Examples of a different situation were also reported, in which patients claimed an allergy to a drug and received an alternative to which they were subsequently proven to be allergic, later to discover in the allergy clinic that they were not allergic to the drug that had been avoided. Patients may provide unreliable or incomplete accounts of their past medical history for many reasons. These include pain, stress, cognitive state, previous poor communication, confusion between allergy and intolerance, and rushed consultations to mention only a few. Reducing the likelihood of poor communication of allergy history requires robust processes to improve the reliability of information provided about past allergy, rather than relying solely on the recollection of patients.

Until anaesthetists can put a greater reliance on the allergy history as presented to them, it is important that they have the time to try to establish whether the patient is reporting a true allergy.

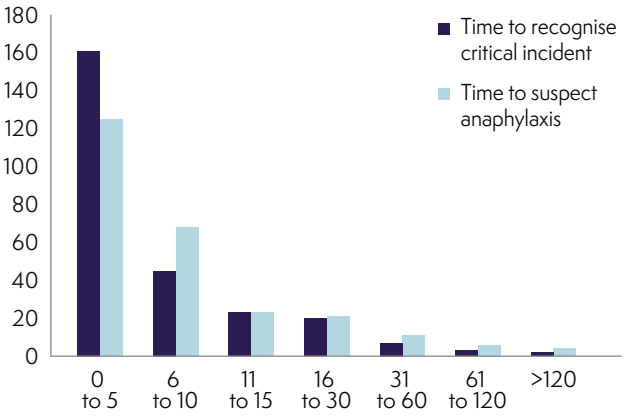
> A patient presented for elective surgery. They reported an allergy to penicillin and received teicoplanin prophylaxis as an alternative. They had an Grade 3 anaphylactic reaction to teiciplanin confirmed by allergy testing, which also determined that the patient was not actually allergic to penicillin.

Improved and more standardised methods of establishing accurate past allergy information at the preoperative assessment would have further benefits. A timely alert to possible problems, such as penicillin allergy, would provide time for any issues to be investigated further prior to elective surgery (see Chapter 15 Antibiotics).

Rapid diagnosis and immediate care

At a risk rate of around 1 in 10,000, (Chapter 6 Main findings), patients can take some solace that perioperative anaphylaxis is rare. Many anaesthetists will never encounter a case in their career. The speed of reaction of anaesthetists to the first symptoms presenting themselves is reassuring. In 66% of 266 cases the anaesthetist recognised the signs of a critical incident and started treatment within 5 minutes. In a further 17% cases treatment was started between 5 and 10 minutes after first presenting signs. In only 5% cases was a delay in starting anaphylaxis-specific treatment reported. In addition in 49% of cases the anaesthetist recognised anaphylaxis as a cause of the incident within 5 minutes of the first clinical sign; anaphylaxis is not always an easy diagnosis as other acute events can present in the same ways as anaphylaxis, eg. low blood pressure due to an acute cardiac problem.

Figure 1. Elapsed time (minutes) between drug administration (suspected trigger agent) and recognition of a critical incident and suspecting anaphylaxis



Unplanned hospital stay and unexpected harm can be concerns held by patients. Data on length of stay was available for most (78%) of patients reported to NAP6. In spite of the life-threatening nature of all the perioperative anaphylaxis reviewed in NAP6 one quarter of these patients had a normal outcome and length of stay was not extended. Thirty-seven percent of these patients had their length of stay increased by one day and 38% by more than this. Delayed discharge and levels of harm are reported in full in Chapter 12.

Providing support and information

It is important that patients are provided with details of the adverse event and advice for future care, as soon as is practical after the incident. Oral advice by itself is inadequate since recall is unreliable. The number of patients given written or written and oral advice by the department of anaesthesia was 131, which is 49% of all cases and 58% of cases where this question was answered. Some anaesthetists voiced disappointment that they had not managed to debrief appropriately with the affected patient. In narrative reports, the most common reason for the anaesthetist not visiting after the event was because the patient had been discharged on the same day or early the next. Best care requires that written advice is given in every case; we have included a template letter from the anaesthetist to the patient, as well as the GP, in Appendix B of Chapter 11.

For the other patients discharged without advice from the anaesthetist, communication depended upon the discharge letter sent to the GP. NAP6 did not seek information on whether departments of anaesthesia offered telephone helpline facilities. Most patients would be unlikely to consider a spontaneous call to the anaesthetist to allay their anxieties.

Forty-two cases were confirmed to have been reported to the Medicines and Healthcare products Regulatory Agency (MHRA) before the allergy clinic appointment and sixty three after the allergy clinic, though there was uncertainty as to who did the reporting this appeared to predominantly be done by anaesthetists. These are surprising low results given the regulatory and pharmacovigilance role undertaken by the MHRA. Patients may benefit from reports of adverse drug reactions to the MHRA as this organisation monitors for trends, and can alert clinicians to change practice as necessary.

The MHRA might also provide improved analysis of reports of anaphylaxis that it receives and these should focus on learning. Publications and communications from organisations need to be accessible to patients as well as clinicians and this includes those from the National Patient Safety Reporting Advisory Review Panel (NatRAP), the Safe Anaesthesia Liaison Group and the AAGBI Safety Committee.

Surprisingly, from a lay perspective at least, only 107 (40%) of patients were known to have been issued with a Medic Alert or other hazard warning card either by the anaesthetist or the allergy clinic.

The Allergy clinic baseline survey (Egner 2017) noted "Poor access to services and patient information provision require attention". It would appear that there is no data available indicating how many patients were referred to an allergy charity or given literature regarding the availability of information and help from an allergy charity.

Investigation – immediate care and allergy clinic

National guidance exists for the immediate care and investigation of suspected perioperative anaphylaxis. Panel review of the NAP6 data shows that collection and analysis of blood samples for mast cell tryptase was insufficient in 16% of cases. In allergy clinics, adherence to published guidelines on investigation of suspected perioperative anaphylaxis was poor (Chapter 14, Investigation).

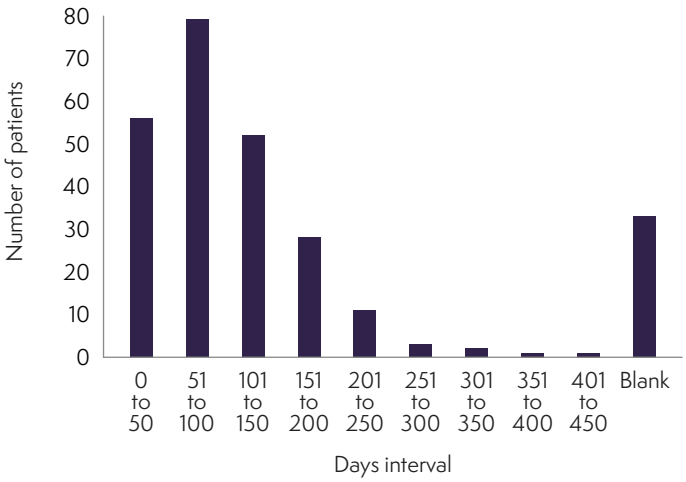
Widespread availability and use of Anaesthetic anaphylaxis investigation packs and patient safety algorithms should improve patient outcomes (Chapter 11, Immediate management and departmental organisation).

Of the 252 patients referred to allergy clinics (98% of survivors), the time taken to be seen was available for 233: the average wait time before they were seen was 101 days. The range was large – 0 days and 450 days. Narratives from the audit indicated that many of the expedited times related to prioritised referrals of cancer surgery – however wait times for urgent cases were not shorter than non-urgent cases. There appears to be a lack of clear pathways for the prioritising and fast tracking of patients who require urgent investigation prior to surgery – accepting that genuinely urgent surgery may need to take place before allergy clinic investigation can be arranged. While there were exceptions (see vignette) these were very infrequent.

An elderly patient presented for elective cancer surgery and had a Grade 4 anaphylactic reaction after induction of anaesthesia. The index anaesthetist communicated with the allergy clinic and the patient was seen in a little over a week. Surgery was rescheduled in a timely manner thereafter.

A young patient presented for elective general surgery. Although the procedure was abandoned at the time of the reaction, it was completed before review in the allergy clinic. The clinic appointment was delayed for over 3 months.

Figure 2. Allergy clinic waiting times (days)



There was a considerable variety in the range of testing carried out by clinics (Chapter 14, Investigation) which may not give rise to the individual patient anxieties but is an important quality issue. Patients should receive care delivered to a set standard wherever they are referred. The standard is set in NICE guidance CG183 (NICE 2015). This issue should be addressed further as part of accreditation and monitoring of clinical standards, currently via IQAS (Improving Quality in Allergy Services).

The clinic investigation and diagnosis of anaphylaxis is, however, extremely complex and although this is guided by nationally and internationally agreed guidelines, the time to patient review is hugely variable and the interpretation of test results includes subjective decision-making. Add to this individual patient circumstances and the variation in practice takes on a different complexion. Some inconsistency of service may therefore reflect the complexities of the investigations and personalisation of consultations rather than major inconsistencies of a service where 'one size fits all' algorithms may not be appropriate.

NAP6 indicates room for improvement in terms of:

- The expediting of and the reduction in variations of wait time for allergy clinic appointments/investigations
- Consistent investigation of perioperative anaphylaxis, adhering to published guidelines including identifying a culprit agent, excluding other possible culprits and identifying safe alternatives to the culprit agent

- Improvements in delivery and clarity of allergy information given to the patient
- Consistency of reporting to MHRA, Trusts and GPs.

Medium to long term patient harm

Information on psychological and physiological sequelae as reported by patients, family members or carers was recorded after the event (Part A) and at allergy clinic review (Part B). Submission of data was limited and so the results may well provide an under estimation of the side effects associated with severe perioperative anaphylaxis. The most commonly reported longer term harm was anxiety about future anaesthetics and sedation: this was reported by 59 patients when Part A was completed and 36 patients when Part B was completed, suggesting some improvement of symptoms over time. Overall there were 104 adverse sequelae reported at the time of filling in form A (67 mild, 29 moderate and 8 severe) reducing to 73 at the time of filling in form B (41 mild, 27 moderate and five severe). Adverse sequelae (other than anxiety) included mood and memory changes, occasional alteration in coordination, mobility or PTSD-like symptoms, and a small number of patients who experienced a myocardial infarction, acute kidney injury or new shortness of breath.

These reports provide us with only limited information about long-term adverse sequelae a patient may experience. In particular there is no data available on the effect of perioperative anaphylaxis on the levels of anxiety patients experience when they actually plan for or present for another operation. In looking at long term adverse sequelae for patients, one area of particular concern meriting further analysis is the impact of perioperative anaphylactic shock on women who have a suffered an incident, while awake, during a caesarean section.

In light of the limited available evidence, there may be benefit in creating methods which enable and promote patients, carers and relatives to report complications following perioperative anaphylaxis through the NHS reporting systems.

Comment

An aspirational recommendation would be that all allergy services, as part of accreditation schemes, should gain expertise in investigation of perioperative anaphylaxis, using clear guideline-based protocols. The question, however, remains if it is pragmatic to invest in such provision at the expense of other health services.

One solution that might improve patient outcomes would be the development of arrangements for remote access to existing drug allergy centres across the UK by those clinicians who rarely receive this type of referral. Advice and expertise might well be obtained via webinar conferences. Additionally such information could be used as part of team learning for doctors, nurses, pharmacists and other health professionals as part of a multidisciplinary approach.

While allergy charities can and do provide support to patients who have suffered a perioperative anaphylactic event, they can only help those who are aware of and seek their advice. In an age of competing medical priorities, it is unlikely that the NHS will be able to provide adequate support to allergy care without significant additional funding. The charitable sector may have something to offer.

Recommendations

Institutional

1. Consent should always be informed. Therefore, patients should be informed of the risk of anaphylaxis preoperatively. Patient information leaflets may be suitable as part of this process.
2. Following a perioperative anaphylactic event and before discharge from hospital the patient should be provided with a letter from their anaesthetist. The *NAP6 template patient letter* is in Chapter 11, Appendix B. This letter should be in addition to the discharge summary and a copy should be sent directly to the patient's GP.
3. The practice of NHS drug allergy clinics should be standardised so that patients and commissioners can expect a consistent service. British Society for Allergy & Clinical Immunology guidelines should be followed. Regulators and inspectors should pay heed to this too.

Research

The effect of a perioperative anaphylactic event on a patient's physical and physiological well-being in both the medium and the long term is not well understood. Research into this topic and dissemination of the outcomes could be of great benefit to patients.

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