

SPECIAL ARTICLE

Anaesthesia, surgery, and life-threatening allergic reactions: protocol and methods of the 6th National Audit Project (NAP6) of the Royal College of Anaesthetists

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Abstract

Background: Anaphylaxis during anaesthesia is a serious complication for patients and anaesthetists.

Methods: The Sixth National Audit Project (NAP6) of the Royal College of Anaesthetists examined the incidence, pre-disposing factors, management, and impact of life-threatening perioperative anaphylaxis in the UK. NAP6 included: a national survey of anaesthetists' experiences and perceptions; a national survey of allergy clinics; a registry collecting detailed reports of all Grade 3–5 perioperative anaphylaxis cases for 1 yr; and a national survey of anaesthetic workload and perioperative allergen exposure. NHS and independent sector (IS) hospitals were approached to participate. Cases were reviewed by a multi-disciplinary expert panel (anaesthetists, intensivists, allergists, immunologists, patient representatives, and stakeholders) using a structured process designed to minimise bias. Clinical management and investigation were compared with published guidelines. This paper describes detailed study methods and reports on project engagement by NHS and IS hospitals. The methodology includes a new classification of perioperative anaphylaxis and a new structured method for classifying suspected anaphylactic events including the degree of certainty with which a causal trigger agent can be attributed.

Results: NHS engagement was complete (100% of hospitals). Independent sector engagement was limited (13% of approached hospitals). We received >500 reports of Grade 3–5 perioperative anaphylaxis, with 266 suitable for analysis. We identified 199 definite or probable culprit agents in 192 cases.

Conclusions: The methods of NAP6 were robust in identifying causative agents of anaphylaxis, and support the accompanying analytical papers.

Keywords: allergy; anaesthesia; anaphylaxis; National Audit Project

Life-threatening allergy during anaesthesia and surgery (perioperative anaphylaxis) is of critical importance to both patients and clinicians with profound impact on patient safety, and in relation to specific subsets of patients or drugs.¹ Data from historical studies or from other geographical locations might not be transferrable to current practice or UK practice, or vice versa. No major prospective study of perioperative anaphylaxis has been performed in the UK.

The National Audit Projects (NAPs) of the Royal College of Anaesthetists (RCOA) have an established role in examining clinically important, rare complications of anaesthesia that are incompletely studied.^{2–7} The established methodology of the NAPs is to perform a national survey or surveys of relevant national activity^{8,9} and establish a national registry for reporting of relevant cases for a time-limited period. This enables an examination of: (i) pre-existing practices and beliefs, (ii) relevant activity (denominator data), (iii) a large cohort of relevant cases (numerator data), and thence (iv) incidence data.

Methods

NAP6 was commissioned by the Health Services Research Centre (HSRC) of the National Institute of Academic Anaesthesia for the RCoA. It is the sixth in a series of 'national audits' (though more correctly described as service evaluations) conducted by the specialty.¹⁰ The topic for NAP6 was selected by open tender for proposals in 2013. There were 91 proposals covering 33 topics.¹¹ The topic of perioperative anaphylaxis was selected by a committee comprised of members of the HSRC executive board. The methodology of NAP6 is similar to, and builds upon, that used for NAP3–5.^{2,3,5}

The intention of the project was to establish:

- (i) What proportion of cases of suspected perioperative anaphylaxis are referred, investigated, or both?

- (ii) What proportion of investigated cases is proven or unproven?
- (iii) How well does management, referral, and investigation match published guidelines?
- (iv) Is there any correlation between drugs used in resuscitation [e.g. epinephrine (adrenaline), alpha agonists, vasopressin] and outcome for severe cases?

The NAP6 project was approved by the Confidentiality Advisory Committee of the NHS Health Research Authority (HRA), National and Local Caldicott Scrutiny Process in Scotland and Privacy Advisory Committee for Northern Ireland. The Confidential Advisory Committee deals with approvals for the handling of patient-identifiable information across the NHS. If such information is required, then approvals are required under Section 251 of its governance procedures. As no patient-identifiable information was used, no section 251 application was necessary. The National Research Ethics Service confirmed it to be a service evaluation, not requiring formal ethical approval. The project received the endorsement of all four Chief Medical Officers of the UK.

All hospitals in the UK performing surgical procedures with anaesthetist involvement were contacted. This included 356 UK NHS hospital centres and 304 independent sector (IS) hospitals believed to perform surgical work. NHS hospitals performing surgery were identified from the RCoA database of hospitals. IS hospitals were contacted using a list provided by the Association of Independent Healthcare Organisations. All NHS centres volunteered a Local Coordinator, a consultant anaesthetist who became responsible for delivering the project at their hospital and for liaising with the central NAP6 team. Several Local Coordinators were responsible for more than one hospital within a Trust (England, Northern Ireland) or Board (Scotland, Wales). During efforts to engage with the IS hospitals, more than 300 hospitals were contacted on several occasions.

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