

SPECIAL ARTICLES

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.

There were four elements to the project. First, a baseline survey collected retrospective data on anaesthetists' previous experiences with perioperative anaphylaxis and their perceptions and patterns of risk-avoidance.⁹ Second, UK allergy clinic services were surveyed to identify clinics that investigated suspected perioperative anaphylaxis and to compare their practices against guidelines.¹² Third, the main prospective study collected anonymised case reports over a 1-yr period. Fourth, a prospective survey, also in 2016, collected comprehensive information on workload, patient characteristics, and patients' exposure to potentially-allergenic drugs and other substances during anaesthesia and surgery.

Local Coordinators were sent detailed information (available at <http://www.nationalauditprojects.org.uk/NAP6-Resources#pt>) and were tasked with disseminating and coordinating all phases of the project locally. All allergy clinics investigating perioperative anaphylaxis were contacted and informed of the project. Materials were made available to enable them to give Local Coordinators detailed information about tests performed and their results when investigating suspected perioperative anaphylaxis.

Baseline surveys

The baseline anaesthesia survey and allergy clinic services survey and methods have been published.^{9,12}

Activity and allergen survey phase

This part of the project was a cross-sectional observational study of NHS hospitals. It collected detailed data on anaesthetic activity (workload), patient characteristics, and drug exposure during anaesthesia care. The detailed methods are described in each paper,^{13,14} but are summarised here for clarity. The Local Coordinator at each participating hospital was invited by email from the NAP6 administrator to organise data collection from every perioperative case involving the care of an anaesthetist. All adult and paediatric cases requiring general anaesthesia, sedation, regional or local anaesthesia, involving an anaesthetist, in all hospital locations, were included. Obstetric cases included epidural pain relief in labour. Cases of sedation or local anaesthesia delivered by a non-anaesthetist were excluded. Routine sedation in intensive care was also excluded.

Each hospital was randomised to collect data on two consecutive days of the week, including Saturday and Sunday, with specialist hospitals (cardiac, neurology, or paediatric centres) block-randomised separately to prevent skewed allocation. The majority of data collection took place between October 13 and 31, 2016.

Each hospital was provided with paper proformas and one proforma was used to collect survey data from each included patient. Once the survey was completed at a hospital, the completed proformas were returned to the study team. Local Coordinators were also asked to record a capture rate at their site to estimate the proportion of relevant cases for which a completed proforma was submitted.

The data from the proformas were transferred to digital form using optical character recognition, and a spreadsheet created for analysis. An annual caseload was estimated by multiplying the number of cases by a scaling factor, which accounted for scaling the 2-day survey to a year and also taking account for missed data and uninterpretable forms. Those analysing the data were blinded as to which NHS site the case originated from.

Registry phase

Local Coordinators were asked to ensure the reporting of all cases of suspected life-threatening perioperative anaphylaxis to the NAP6 team. Anaphylaxis was defined as a severe, life-threatening, generalised or systemic hypersensitivity reaction. Perioperative anaphylaxis was defined as:

Anaphylaxis that occurs in patients undergoing a procedure requiring general or regional anaesthesia or sedation or managed anaesthesia care (anaesthetist monitoring only) under the care of an anaesthetist between the period of first administration of a drug (including pre-medication) and the post-procedure transfer to the ward or critical care.

As we only wished to collect cases of life-threatening anaphylaxis, it was emphasised that only anaphylaxis Grades 3–5 (Table 1) were to be included. Cases were to be included irrespective of age or hospital location, but patients in critical care or the emergency department were excluded unless undergoing procedural general anaesthesia.

Each month, the Local Coordinator was required to provide the central NAP6 team with a 'return' indicating the number of

Table 1 Grading of perioperative hypersensitivity/anaphylaxis used for determining inclusion or exclusion in the Sixth National Audit Project (NAP6) project.

Grade	Features	NAP6
1 Not life-threatening	Rash, erythema, swelling (any of)	Hypersensitivity—excluded
2 Not life-threatening	Unexpected hypotension—not severe (e.g. not requiring treatment), bronchospasm—not severe (e.g. not requiring treatment), or both +/- Grade 1 features	Hypersensitivity—excluded
3 Life-threatening	Unexpected severe hypotension, and or severe bronchospasm, and or swelling with actual or potential airway compromise +/- Grade 1 features	Included if perioperative anaphylaxis suspected
4 Life-threatening	Fulfilling indications for cardiopulmonary resuscitation	Included if perioperative anaphylaxis suspected
5 Fatal	Fatal	Included if perioperative anaphylaxis suspected

reports of suspected life-threatening perioperative anaphylaxis identified that month, using a system developed by the UK obstetric surveillance system¹⁵ and also used in NAP5.⁵ Where no reports were received, the Local Coordinators returned a 'nil' report.

Presentations, posters, and promotional material were provided to each Local Coordinator and the project was widely advertised nationally (Fig. 1). Information provided to Local Coordinators included advice on interpretation of grades of anaphylaxis and a series of 'frequently asked questions', with answers. For example, Local Coordinators were advised to regard hypotension that was mild or required modest doses of a vasopressor or fluid as meeting the definition of Grade 2, whereas hypotension that was profound, sustained, resistant to treatment, or requiring extensive treatment met the criteria for Grade 3.

Reporting cases

Reporting was in two parts. Part A included details of the patient, drugs administered, the clinical features, management and timings relating to the event, outcomes, contributory factors, referral for investigation, and details of reporting of the event and communication to the patient. Local Coordinators were asked to submit Part A as soon as possible after the suspected anaphylactic event. Definitions of clinical features associated with anaphylaxis required to be reported were provided in the webpage supporting information (Supplementary Table S1). Part B was to be completed by the Local Coordinator, after allergy clinic investigation was complete. It included full details of allergy clinic investigations, sought to confirm patient outcomes, and to update the data on reporting to national registries and information given to patients. Part B was not required for fatalities.

Between them, the two parts of the case reporting form collected detailed information on all aspects of the event and patient care. The questions from Form A and Form B are shown in Supplementary material, Appendix 1 and are available at <http://www.nationalauditprojects.org.uk/NAP6-Data-Entry#pt>.

Cases were included if the event occurred between 00:00:00 on November 5, 2015 and 23:59:59 h on November 4, 2016.

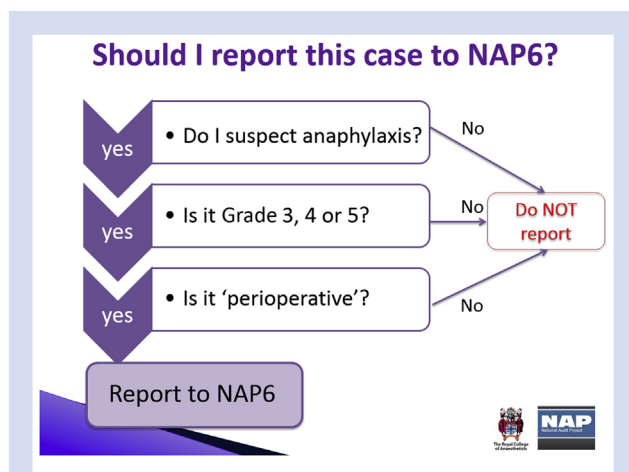


Fig 1. Supporting information on which cases should be reported to the Sixth National Audit Project (NAP6).

Reports were accepted until May 2017 to allow for allergy clinic waiting times.

Case reporting was confidential. When a Local Coordinator or other anaesthetist wished to report a case, they contacted the NAP6 administrator. The reporter was required to confirm: that the case was suspected perioperative Grade 3–5 anaphylaxis, as defined above; that the case occurred in the data collection period; and whether the case took place in an NHS or IS hospital. After confirmation that the case met inclusion criteria, the reporter was issued with a unique identifier and password. These were used to submit case details to a password-protected, secure, and encrypted website. Before accessing the webform, the reporter was required to change their password. Cases arising from NHS and IS hospitals were assigned different number series for easy identification. No patient, clinician, or hospital data were admissible, and the webpages repeatedly reminded reporters not to include such information.

The NAP6 administrator could track progress of reporting (not started; started but incomplete; complete; submitted) but could not access forms. Once completed and submitted, the anonymised form was automatically transferred electronically to the project clinical lead, who was able to raise queries and receive replies about case reports via a blind email (i.e. blinded to where the email went to or from where replies came). No other panel members received reports or had access to the website. In this manner, no panel member was aware of the geographical origin of any case, nor of any individuals involved in managing the case.

A moderator, a consultant anaesthetist with appropriate expertise, was available to discuss cases when there was uncertainty about inclusion. The moderator was not on the review panel and had no contact with the review panel throughout the project.

Review of cases

The NAP6 review panel met monthly to review and classify cases. The panel was comprised of 25 representatives of patient support groups, patient representatives, and clinicians in relevant fields (anaesthesia, critical care, allergy, clinical immunology) representing stakeholder and subspecialty organisations. Clinicians were selected by stakeholder organisations and whilst many had specific expertise in allergy, this was not a requirement for joining the panel.

The panel reviewed each case in detail and in a structured manner, three times. First, the clinical care (Part A) was reviewed by a small group of three to five clinical and patient representative panel members. Second, allergists and clinical immunologists reviewed drug administration and allergy investigations (relevant parts of Part A and all of Part B). Several groups performed these tasks on different cases concurrently. The outputs of the reviews were used to populate a structured output form (Supplementary material, Appendix 2) and spreadsheet for subsequent analysis. When sufficient cases were reviewed, all groups joined into a large panel, of typically 12–15 panel members, and the cases were again reviewed to combine the outputs of the clinical and allergy/immunology reviews and to check and moderate each small group's findings. This process was used in an attempt to avoid 'outcome bias' (where the known poor outcome leads to an unreasonably harsh judgement),¹⁶ 'hindsight bias' (where retrospective review leads to a tendency to believe that an adverse outcome was predictable or avoidable),¹⁷ and 'groupthink' (where a desire to agree within groups leads to a lack of independent scrutiny).¹⁸

In judging quality of care, we referred to guidelines from: the Association of Anaesthetists of Great Britain and Ireland on management of suspected anaphylaxis associated with anaesthesia¹⁹; the Resuscitation Council (UK) on management of anaphylaxis²⁰; the European Resuscitation Council on cardiopulmonary resuscitation²¹; and the British Society for Allergy and Clinical Immunology (BSACI) guidelines on investigation of anaphylaxis during general anaesthesia.²² In addition, the review panel referred, where appropriate to NICE CG183 *Drug allergy: diagnosis and management of drug allergy in adults, children and young people*^{23,24} and NICE CG134 *Anaphylaxis: assessment and referral after emergency treatment*.²⁵ As these guidelines were used to measure deviation from standards of care, NAP6 had a greater genuine 'audit' component than previous NAPs. Overall quality of care (initial management, clinic referral by anaesthetist, and allergy clinic investigation) were also each judged as 'good', 'poor', 'good and poor' or 'unassessable' based on adherence to guidelines and ultimately by panel consensus.

It became rapidly apparent that cardiopulmonary resuscitation (CPR) was frequently not started when there was profound hypotension. We therefore defined a systolic BP below which we judged that CPR should be started, which we set at 50 mmHg (see Discussion). These cases were classified as Grade 4 (Supplementary Table S2). When CPR was not started, we judged this as failure to initiate CPR when indicated and judged this to be a deviation from resuscitation guidelines.

The case report form included specific questions about potential errors related to allergy history or administration of cross reacting substances. Preventability of each case was classified as 'yes', 'no' or 'uncertain', and reasons why the event may have been prevented were recorded.

Patient outcomes were measured in two ways. Individual patient outcomes were captured on the case report form including new anxiety about future anaesthetics, features consistent with post-traumatic stress disorder, change in mood, impaired memory, impaired coordination, impaired mobility, myocardial infarction, heart failure, renal impairment, and stroke. Overall severity of patient outcome, was recorded using a modification of the National Patient Safety Agency classification of severity of harm from patient incidents (Table 2).²⁶ In most cases, Grade 3 anaphylaxis itself

meets the definition of moderate harm. When resuscitation had only involved minimal doses of vasopressor or other drugs and no further action had been taken, the case was deemed to meet the criteria for minimal harm. Apparently permanent sequelae (i.e. persisting symptoms or deficits at follow-up) were recorded as severe harm, as were cardiac arrest and critical care stay >14 days.

Each event was classified as 'allergic anaphylaxis', 'non-allergic anaphylaxis', 'anaphylaxis mechanism uncertain', 'anaphylaxis uncertain' or 'not anaphylaxis' using the classification shown in Table 3. For each classification certainty of classification was recorded as high or intermediate.

In order to classify the type of each event, a definition of mediator release was required. Providing mast cell tryptase samples were taken at appropriate times after the event (broadly: soon after the event and approximately 1–3 h after the event, and a baseline sample either taken before the event or ≥24 h after the event) the following definition was used:

- (i) peak mast cell tryptase $\geq 1.2 \times \text{nadir value} + 2 \mu\text{g L}^{-127}$; or
- (ii) peak mast cell tryptase $\geq 14 \mu\text{g L}^{-1}$ (i.e. >99th centile for normal mast cell tryptase levels)²⁸

This pragmatic definition may not exclude all cases of mastocytosis, but to do so was beyond the capabilities of the project. Where there was clinical or biochemical uncertainty, differential diagnoses other than anaphylaxis were carefully considered by the review panel.

In determining adequacy of allergy clinic investigation, BSACI guidelines^{22,29,30} were used by the immunologists and allergists to set the following rules:

- (i) Where testing for allergy to neuromuscular blocking agent (NMBA) was necessary, given variable access to some NMBA, the NAP6 minimum panel¹² was applied: succinylcholine (suxamethonium), rocuronium, and either atracurium or cis-atracurium should have been tested and at least one safe alternative should have been sought.
- (ii) Chlorhexidine and latex should have been investigated routinely because of the widespread risk of exposure.
- (iii) For skin prick tests (SPTs) and intradermal tests to be judged appropriate, there should be no tests performed that were not indicated. This was to exclude 'scatter-gun' testing being judged as good practice.
- (iv) Allergy to antibiotics, and particularly beta-lactams, could only be excluded if a negative skin test was followed by negative provocation testing

The allergists and immunologists reviewed each case that was confirmed to be anaphylaxis, to determine all possible causative agents (culprits). Reviewing the clinical data and allergy clinical tests, they identified these drugs as having high, intermediate, or low culpability. We recorded 'identified culprits' as follows:

- (i) Definite: where one sole agent was recorded with a high degree of confidence and any other agents with intermediate or low confidence.
- (ii) Probable: (a) where only one agent was recorded with an intermediate degree of confidence and any other agent was identified with low confidence; (b) where two agents were both recorded with a high degree of confidence.
- (iii) Possible: where two agents were recorded with an intermediate degree of confidence and none with a high degree of confidence.

Table 2 Degree of physical harm. Source: NPSA seven steps to patient safety.²³ *First aid, additional therapy or additional medication. Excludes extra stay in hospital, return to surgery or readmission. †Return to surgery, unplanned re-admission, prolonged episode of care as in or out patient or transfer to another area such as intensive care. ‡Permanent lessening of bodily functions, sensory, motor, physiologic or intellectual.

Severity grade	Description (tick against the most severe feature)
Uncertain	Insufficient information
Mild	Minimal harm necessitating extra observation or minor treatment*
Moderate	Significant, but not permanent harm, or moderate increase in treatment† Includes delayed cancer surgery
Severe	Permanent harm because of the incident,‡ also including cardiac arrest; adverse sequelae recorded as "Severe" in Part A or Part B; ICU stay of 14 days or longer
Death	Death as a result of the incident

Table 3 Immunological classification of events in the 6th National Audit Project (NAP6).

Class of event (in addition to history of reaction Grade 3–5)	High certainty	Intermediate certainty
Allergic anaphylaxis (IgE-mediated)	Timeline—within 60 min Evidence of mast cell mediator release—tryptase Evidence of positive sIgE (blood or skin tests)* Differential diagnoses excluded 4/4 criteria; *essential	Timeline—within 60 min Evidence of mast cell mediator release—tryptase Evidence of positive sIgE (blood or skin tests)* Differential diagnoses excluded 3/4 criteria; *essential
Non-allergic anaphylaxis (non-IgE-mediated)	Timeline—within 60 min Evidence of mast cell mediator release—tryptase No evidence of positive sIgE (blood or skin tests) Differential diagnoses excluded 4/4 criteria	Timeline—within 60 min Evidence of mast cell mediator release—tryptase No evidence of positive sIgE (blood or skin tests) Differential diagnoses excluded 3/4 criteria
Anaphylaxis—mechanism uncertain	Timeline—within 60 min Evidence of mast cell mediator release—tryptase Skin tests or blood sIgE not available 3/3 criteria	
Anaphylaxis uncertain	Meeting 2/3 criteria in entry above and/or Differential diagnoses more likely: Airway management Drug side effect Drug overdose Cardiac disease/event	
Not anaphylaxis	Not meeting clinical criteria for diagnosis (as per grading)	

- (iv) Do not count: (a) where more than two agents were recorded with a high degree of confidence; (b) where more than two agents were recorded with an intermediate degree of confidence; (c) where the only agents recorded were identified with a low degree of confidence.

Agents meeting the criteria for definite or probable were considered to be ‘identified culprits’; agents meeting the criteria for possible or do not count, were not.

Approximately 10–12 cases were fully reviewed each day in the early part of the review process, increasing to up to 22 in the latter stages as the panel became more familiar with the process. Because of the high number of cases submitted, we were not able to perform full reviews of all cases. The remaining cases in the main dataset had a shorter review that determined: the diagnosis of anaphylaxis, the grade of anaphylaxis, all potential culprits, and the degree of certainty of ‘identified culprits’.

Results

The results of the Anaesthesia Baseline survey,⁹ Allergy Clinic survey,¹² Anaesthetic Activity survey,¹³ and Allergen survey¹⁴ are each reported separately and are not considered further here (Supplementary material, Appendix 3). There were no technical or security breaches of the website, or concerns about identification of patients, clinicians, or hospitals.

All 356 (100%) NHS hospitals where surgery was undertaken agreed to take part in the project and volunteered a Local Coordinator. These 356 hospitals were served by 282 Local Coordinators. Overall return rate of ‘monthly reports’ from NHS hospitals was 94%, and 84% of NHS hospitals returned all monthly reports.

Responses were considerably fewer from IS hospitals. In total, 41 (13%) IS hospitals volunteered to participate and

these hospitals were included in data collection. Overall return rate of ‘monthly reports’ from these IS hospitals was 70%, and 39% of these IS hospitals returned all monthly reports.

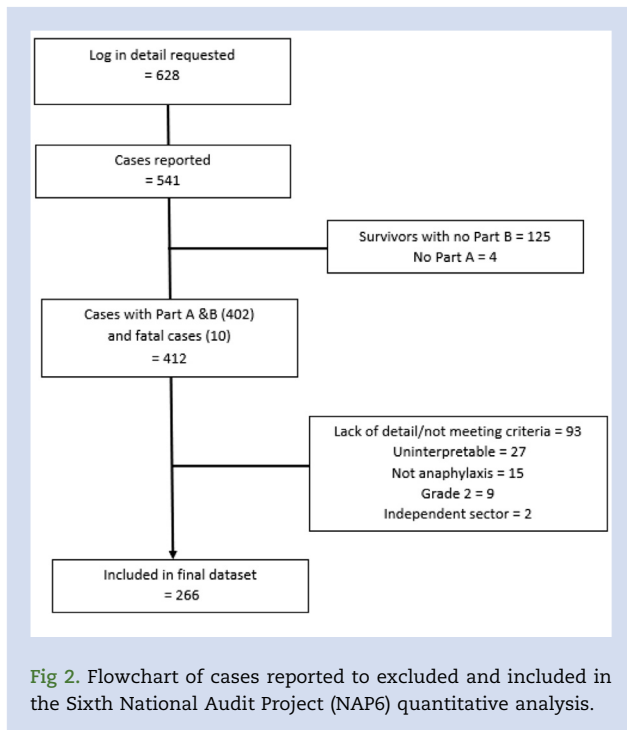
In view of the small number of IS hospitals that agreed to participate, it was decided that this sample would not be representative of practices or events in this healthcare sector and a decision was made to include their data only for examination of isolated events and not for numerical analysis.

The full results of analysis and findings of reports of anaphylaxis are presented in the accompanying papers.^{31,32} We present here the results of the NAP6 process.

There were 628 requests made for login details to the reporting website. A total of 541 cases were submitted: 412 either with Part A and Part B completed or fatalities, 125 survivors with only Part A completed, and four survivors with only Part B completed. Amongst these, there were seven requests for an identifier for the reporting website from IS hospitals but only two cases were fully reported.

Only those cases with Part A and Part B ($n=402$), or deaths ($n=10$) were considered for review. Of these, 93 were not suitable for review because of lack of detail or not meeting entry criteria; 27 were uninterpretable; 15 were not anaphylaxis; nine were excluded as being Grade 2; and two were from IS hospitals. A total of 266 NHS cases (256 survivors with Part A and Part B and 10 fatalities) met inclusion criteria, were interpretable, and were Grade 3–5 anaphylaxis: these formed the main dataset. A total of 217 cases were fully reviewed, including 184 of the main dataset. This included all deaths. The remaining 82 cases underwent shorter review, as described above (Fig. 2).

Amongst the 266 cases in the main dataset, there was an identified culprit in 192 cases. In seven cases, there were two



identified culprits (all because two agents were identified with high confidence) so the total number of identified culprits was 199.

Discussion

NAP6 is the most comprehensive prospective study of perioperative anaphylaxis undertaken to date. It provides prospective data on a large number of cases which have all been subject to structured multidisciplinary expert review. It provides the opportunity to learn about preparedness of hospitals and clinicians, clinical presentation of perioperative anaphylaxis, severity, immediate management, referral for investigation, and outcomes. It provides significant epidemiological data about distribution of anaphylaxis grades, suspected and actual triggers, and non-standard treatments. Further, it provides data on the quality of management and investigation in a 'real world setting' and of communication, between clinicians and to patients.

In order to collect and analyse these data in a meaningful manner, it was important to perform a structured analysis of cases. That structure was underpinned by clear definitions of which events should be included or excluded and also by classification during review. We followed the review process previously used in other NAPs which included multiple, serial, multidisciplinary reviews incorporating patient representation, formal moderation, and a structured output. Review of events that have already happened is always prone to the limitations of 'looking backwards' and this may be exacerbated when the outcome of the event is known.^{16–18} Our processes made every effort to produce balanced judgements, accepting these known limitations.

Anaphylaxis is 'a severe, life-threatening generalised hypersensitivity reaction'.³⁴ Lesser hypersensitivity reactions should not be included in the term anaphylaxis. Unlike many

previous large-scale studies of hypersensitivity, we have focussed only on genuinely life-threatening reactions (i.e. true anaphylaxis). We judged this would enable us to gather the most clinically powerful lessons, to improve engagement in the project, and to increase capture rates. These are also the cases where most is to be gained (or lost) in efforts to improve care.

There are numerous grading scales and definitions of severity of hypersensitivity/anaphylaxis and the cut-offs between grades vary considerably. This has implications for data analysis and comparisons between studies. The 1977 classification by Ring and Messmer³⁵ included four grades with Grade 3 'shock, life-threatening spasm of smooth muscles (bronchi, uterus, etc.)', and Grade 4 'cardiac and/or respiratory arrest'. Garvey and colleagues³⁶ in 2001 described only three grades with the highest grade (Grade 3) including all 'very severe reactions requiring prolonged treatment, e.g. anaphylactic shock, usually, but not always, involving two or more organ systems'. Mertes and colleagues³⁷ in 2003 included in Grade 3 life-threatening events 'cardiovascular collapse, tachycardia or bradycardia, arrhythmias, severe bronchospasm' and in Grade 4 'circulatory inefficacy, cardiac and/or respiratory'. In 2007, Krøigaard and colleagues³⁸ introduced Grade 5: fatal anaphylaxis. Consensus diagnostic criteria for definition of anaphylaxis were reported in 2006 but have significant limitations if applied to perioperative anaphylaxis.³⁹ In 2010, yet another classification was published—classifying all hypotension as Grade 4.⁴⁰

Despite this apparent surfeit of grading systems, we found none entirely clear or satisfactory and developed the classification shown in Table 1. This classification aimed specifically to accommodate the normal variations in vital signs and physiology that can be seen in the perioperative setting, particularly in elderly, frail, or co-morbid patients. The NAP6 classification of perioperative (hypersensitivity and) anaphylaxis uses the pragmatic terms 'unexpected' and 'severe' in the belief that anaesthetists can distinguish the usual from the unusual, and a reaction requiring rescue treatment from one which does not. We used a clear cut off for Grade 4 (i.e. if indications for initiating CPR are fulfilled). During the NAP6 project another group published a new classification and this publication also usefully reviews many of the existing classifications and their limitations in respect to perioperative anaphylaxis.⁴¹ This used three Grades A–C: Grade A is not life-threatening and therefore does not meet the accepted definition of anaphylaxis, and Grade B includes some Grade 2–3 characteristics of other definitions, with Grade C being similar to Krøigaard's Grade 4.

During early case reviews it became apparent that 'indication for CPR' might not be as clear-cut as we had thought. The case report form asked both for the lowest BP recorded (though not its duration) and whether CPR was started. In a large number of cases, the lowest BP was very low, often being <60 mmHg, <50 mmHg, or even unrecordable, but CPR was not performed. This was discussed at length in the panel. We took external advice, from experts in resuscitation, anaphylaxis, and their guidelines, and concluded that it was logical to set a lowest systolic BP at which it was reasonable that CPR should start in adult patients. In the awake patient it is now routine to start CPR when 'there are no signs of life/signs of responsiveness'. As perioperative anaphylaxis most commonly takes place after induction of anaesthesia, these signs are absent. In invasively monitored patients, a BP of <50 mmHg is predictive of central and peripheral pulselessness⁴² which should trigger CPR. As non-invasive BP monitors tend to over-estimate the BP

in severe hypotension, a non-invasive BP recording of <50 mmHg implies the true BP is even lower. We therefore judged that when the lowest systolic BP was <50 mmHg, CPR was indicated. This rule was then applied to all adult cases. These cases were recorded as Grade 4, and if CPR was not started it was recorded as 'CPR not started when indicated'. We also judged this a deviation from (resuscitation) guidelines and recorded whether this was the only such deviation. This group of patients (lowest systolic BP and no CPR) was examined as a separate cohort to explore whether their outcomes differed from other patient groups. The NAP6 classification of grade of anaphylaxis was therefore updated to include this critical BP cut-off ([Supplementary Table S2](#)).

In the analysis of investigation of anaphylaxis, the allergists and immunologists on the panel required a clear way to classify the type of immunological event and devised that shown in [Table 3](#). The presence of a dynamic tryptase increase was determined using an accepted consensus method,²⁷ which has (since NAP6 started) been confirmed to have high specificity (78%), positive predictive value (98%), and a moderate negative predictive value (44%) in perioperative anaphylaxis.⁴³ Where there was no dynamic increase in tryptase we used a value of >99th centile as indicating elevation: this has been shown to improve sensitivity of the above test.²⁸ This adds a level of diagnostic rigour which is unlikely to be present where classification is judged only on signs of hypersensitivity and results of SPTs. Assessing utility and quality of allergy clinic investigation was further aided by including the consensus view that the NAP6 panel of NMBAs¹² should be used and that allergy to both chlorhexidine and latex should be tested routinely because of their widespread (and often hidden) presence in healthcare settings.^{12,22,38,44,45} Finally, we used a structured method to define the degree of certainty with which culprit agents were identified and only included those that were definite or probable culprits in reporting our findings.

The published guidelines selected for providing standards against which the quality of practice was assessed^{19–23} were chosen to encompass immediate resuscitation (including of cardiac arrest), secondary clinical management, referral to an allergy clinic, primary and specialist allergy investigation, record keeping, and communication with patients and healthcare professionals. UK guidelines were selected, being the most relevant to the patient population being studied.

There are several limitations to the study methodology. First, in the survey phase, we may have missed cases, but we made significant efforts to capture all cases from every UK NHS hospital and we accounted for missed cases and uninterpretable data in all estimations of activity and drug exposure. Second, in the registry phase, we chose not to include mild (Grades 1–2 reactions). This was decided before the study started. The aim of the study was to explore only life-threatening reactions. Pragmatically it is less likely that all anaesthetists in all UK hospitals would report all Grade 1–2 events and these cases are also more likely to have diagnostic uncertainty or to be missed clinically. Third, it is possible not all cases of suspected Grade 3–5 anaphylaxis have been reported, but we made considerable efforts to capture all cases through widespread publicity of the project, establishing a Local Coordinator in each hospital and requiring monthly returns from each hospital to track case activity. Fourth, we relied on anaesthetists to report cases of 'suspected anaphylaxis', and the reporting of cases was therefore dependent on clinical diagnostic skills. However, as anaphylaxis is a clinical diagnosis before investigation, this limitation would likely

exist for any such prospective or retrospective study. Finally, not all cases underwent 'full review' by the review panel. All cases were screened and cases that clearly did not meet inclusion criteria were excluded. Of the 266 cases meeting inclusion criteria, 184 were reviewed by the full panel to extract detailed data on process and quality of care. The other 82 cases had a shorter multidisciplinary panel review to extract key data (grade of reaction, type of reaction, putative culprit agent, and level of certainty). These cases were all further reviewed by the multidisciplinary team as part of the numerical and sub-analyses performed in analysing the full dataset. Whilst the interrogation of these cases was less in-depth than that of the other 184 cases, it was still considerable. Using this method, we received >500 reports of perioperative anaphylaxis. We were able to analyse 266 cases and identify 199 culprit agents in 192 cases. Detailed results are presented and discussed in the accompanying papers^{31–33} and in the full report.

As with previous NAPs, NAP6 is the product of a concerted national effort by all departments of anaesthesia in the UK and, through its various phases, the vast majority of UK anaesthetists. This project has also involved considerable multidisciplinary working with both allergists and clinical immunologists. The project could not take place without the generous voluntary efforts of many people and we acknowledge that here and offer them our thanks. The projects require anaesthetists to report cases where a significant critical incident has occurred, and harm may have come to the patient. We rely on anaesthetist's openness and honesty. The NAP6 panel, including the Clinical Lead, had no access to any information regarding the geographical source of the report, the identity of the reporter, or any patient, hospital or clinician identifiable details. This anonymity, embedded within the project design, remains central to its success.

Authors' contributions

Co-designed methodology of the study: T.M.C., N.H.

Analysed results: T.M.C., N.H.

Wrote all drafts of the paper and the final draft: T.M.C.

Reviewed and revised early drafts of the paper and the final draft: N.H.

Contributed to design and methodology of the study. Administered study. Took part in review of draft manuscript leading to finalisation: L.F.

Contributed to the design and methodology of the study, reviewed the results and took part in review of draft manuscripts leading to finalisation: all other panel members.

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East, Former National Coordinator of the Anaphylaxis Campaign (Anaphylaxis Campaign). We thank Prof J. Nolan (Bath), and Dr J. Soar (Bristol) for advice on indications for starting cardiopulmonary resuscitation.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.bja.2018.04.001>

Declarations of interest

T.M.C. is an associate editor of the *British Journal of Anaesthesia*. He is not aware of any financial conflicts. N.H., L.F., T.G., K.Fl., S.M., H.T., A.W., N.McG., K.Fe., J.H., W.E., H.K., M.T., D.N.L., S.N., S.K., K.-L.K., S.F., M.B., and A.McG. all declare they have no conflicts of interest. S.R.M. is the Director of the NIAA Health Services Research Centre which commissioned this study.

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6th National Audit Project (Part A)

Inclusion criteria

Please note: If all these inclusion criteria apply, you will be able to report the details of the case. If not, then it is unlikely to be suitable to be reported to NAP6. If you are in doubt, please contact the NAP6 Moderator at nap6moderator@rcoa.ac.uk

1.1 Did the event occur between 5 Nov 2015 00:00 to 4 Nov 2016 23:59? ☐ Yes ☐ No

1.2 Did the event occur during the perioperative period?

i.e. the period between the first administration of a drug

(including pre-med) and the post-procedure transfer to the ward, ICU or HDU?

☐ Yes ☐ No

1.3 Did the anaesthetist suspect that the event was caused by anaphylaxis? ☐ Yes ☐ No

1.4 Did the event occur in a patient undergoing a procedure requiring general or regional anaesthesia or sedation or managed anaesthesia care (anaesthetist monitoring only) under the care of an anaesthetist?

☐ Yes ☐ No

1.5 If the event occurred in HDU/ICU/ED, was the patient undergoing an interventional procedure (not resuscitation) under general anaesthesia, administered by an anaesthetist?

☐ Yes ☐ No ☐ N/A

1.6 Are you reporting a case of suspected anaphylaxis grades 3-5?

For details on the grades please click the link on the right.

☐ Yes ☐ No

1.7 Did the event occur in an NHS hospital? ☐ Yes ☐ No

Please enter your five digit case ID number:

(This is the number supplied to you by the NAP6 team when you notified the case by email. It is not possible to progress with the case report unless the unique five digit case number has been entered. If you don't have a five digit case ID number, please email the NAP6 team at nap6@rcoa.ac.uk)

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Demographics

2.1 Patient Age

☐ <1	☐ 1-5	☐ 6-15	☐ 16-25	☐ 26-35
☐ 36-45	☐ 46-55	☐ 56-65	☐ 66-75	☐ 76-85
☐ 86-95	☐ >95	☐ Unknown		

2.2 Patient Sex

☐ Male ☐ Female ☐ Unknown

[Please enter height and weight, BMI will be calculated automatically.
\(Click here to populate\)](#)

2.3 Height

 cm

2.4 Weight

 kg · Kg/m²

2.6 Body habitus

☐ Underweight - Estimated/calculated BMI less than 18.5	☐ Normal weight - Estimated/calculated BMI 18.5-24.9
☐ Overweight - Estimated/calculated BMI 25-29.9	☐ Obese - Estimated/calculated BMI 30-34.9
☐ Morbidly obese - Estimated/calculated BMI 35 or greater	

2.7 Ethnicity (NHS Classification)

☐ British (White)	☐ Irish (White)	☐ Any other White Background
☐ White and Black Caribbean (Mixed)	☐ White and Black African (Mixed)	☐ White and Asian (Mixed)
☐ Any other Mixed Background	☐ Indian (Asian or Asian British)	☐ Pakistani (Asian or Asian British)
☐ Bangladeshi (Asian or Asian British)	☐ Any Other Asian Background	☐ Caribbean (Black or Black British)
☐ African (Black or Black British)	☐ Any other Black Background	☐ Chinese (Other Ethnic Group)
☐ Any Other Ethnic Group	☐ Not Known	

2.8 What is the patient's ASA physical status?

☐ ASA 1 ☐ ASA 2 ☐ ASA 3 ☐ ASA 4 ☐ ASA 5 ☐ ASA 6

2.9 What was the type of admission?

☐ Day case ☐ Elective inpatient ☐ Emergency ☐ Other

2.10 What was the intended conscious level?

☐ General anaesthesia ☐ Deep sedation ☐ Moderate sedation
☐ Minimal sedation ☐ Managed anaesthesia care

INTENDED CONSCIOUS LEVEL - Select the most appropriate category:

General anaesthesia - GA, WITH or WITHOUT regional or local anaesthesia.

Deep sedation - cannot be roused easily but will respond purposefully to repeated or painful stimuli

Moderate sedation - responds purposefully to verbal stimulus (known in dentistry as conscious sedation) or tactile stimulation.

Minimal sedation - equates to anxiolysis and has no appreciable effect on vital reflexes.

Managed care - anaesthetist in attendance for monitoring purposes but no sedation of anaesthesia administered.

Intervention Status

3.1 Grade of Index Anaesthetist (or PA(A)) responsible for administering the anaesthetic drugs

- ☐ Consultant
 ☐ Other career grade doctor
 ☐ ST4-7
 ☐ ST3/CT3
☐ CT1/CT2
 ☐ PA(A)
 ☐ Other (e.g. research fellow)
 ☐ Unknown

Please specify:

3.2 Grade of most senior anaesthetist (or PA(A)) present at the onset of suspected anaphylaxis

- ☐ Consultant
 ☐ Other career grade doctor
 ☐ ST4-7
 ☐ ST3/CT3
☐ CT1/CT2
 ☐ PA(A)
 ☐ Other (e.g. research fellow)
 ☐ Unknown

Please specify:

3.3 Grade of most senior anaesthetist present during resuscitation

- ☐ Consultant
 ☐ Other career grade doctor
 ☐ ST4-7
 ☐ ST3/CT3
☐ CT1/CT2
 ☐ PA(A)
 ☐ Other (e.g. research fellow)
 ☐ Unknown

Please specify:

3.4 Planned type of operation

- | | | | |
|--|--|---|--|
| ☐ Cardiac | ☐ Cardiology | ☐ Dental | ☐ Maxillo-facial |
| ☐ ENT | ☐ Gastroenterology | ☐ General surgery | ☐ Gynaecology |
| ☐ Neurosurgery | ☐ Obstetrics | ☐ Ophthalmology | ☐ Elective Orthopaedics |
| ☐ Trauma | ☐ Pain | ☐ Plastics | ☐ Psychiatry |
| ☐ Radiology | ☐ Thoracic | ☐ Urology | ☐ Vascular |
| ☐ Other minor procedure | ☐ Other major procedure | ☐ Other intermediate procedure | ☐ Renal transplant |
| ☐ Other transplant | ☐ Unknown | | |

Please specify details:

3.5 Caesarean Category

- ☐ Caesarean Category 1
 ☐ Caesarean Category 2
 ☐ Caesarean Category 3
☐ Caesarean Category 4
 ☐ Unknown

3.6 Degree of urgency of the case

- ☐ NCEPOD Priority - Immediate
 ☐ NCEPOD Priority - Urgent
 ☐ NCEPOD Priority - Expedited
☐ NCEPOD Priority - Elective
 ☐ NCEPOD Priority - Unknown

3.7 Was the intervention/procedure significantly modified, abandoned or postponed as a result of the suspected anaphylactic reaction?

- ☐ Yes, abandoned before intervention/procedure started
 ☐ Yes, abandoned after intervention/procedure started
☐ Yes, intervention/procedure modified
 ☐ No

☐ Unknown

Details:

3.8 Was the intervention/procedure rescheduled because of the anaphylaxis?

- ☐ Yes
 ☐ No, intervention/procedure completed
☐ Intervention/procedure was not completed and it was decided not to re-schedule
 ☐ Unknown

DRAFT

Medical History & Drugs (prior to this episode)

4.1 Angioedema

- ☐ Yes
☐ No
☐ Unknown

4.2 Urticaria

- ☐ Yes
☐ No
☐ Unknown

4.3 Eczema

- ☐ Yes
☐ No
☐ Unknown

4.4 Hay fever

- ☐ Yes
☐ No
☐ Unknown

4.5 Food Allergy

- ☐ Yes
☐ No
☐ Unknown

4.6 Asthma

- ☐ Yes, controlled
☐ Yes, poorly controlled
☐ No
☐ Unknown

4.7 Symptoms, or other evidence of coronary artery disease

- ☐ Yes
☐ No
☐ Unknown

4.8 Angiotensin Converting Enzyme Inhibitor

- ☐ Yes
☐ No
☐ Unknown

4.9 Beta blocker

- ☐ Yes
☐ No
☐ Unknown

Please list food allergies:

4.10 Allergy history recorded on anaesthetic record

- ☐ Penicillin ☐ Cephalosporin ☐ Other antibiotic (please specify)
☐ Latex ☐ Muscle Relaxant ☐ Chlorhexidine
☐ Iodine ☐ NSAID ☐ Opioid
☐ Other (please specify) ☐ No allergy ☐ Not recorded

Other:

4.11 Which Muscle Relaxant?

4.12 Which Opioid?

☐ 4.13 Other Opioid

4.14 Allergy history recorded on drug chart

- ☐ Penicillin ☐ Cephalosporin ☐ Other antibiotic (please specify)
☐ Latex ☐ Muscle Relaxant ☐ Chlorhexidine
☐ Iodine ☐ NSAID ☐ Opioid
☐ Other (please specify) ☐ No allergy ☐ Not recorded

Other:

4.15 Which Muscle Relaxant?

4.16 Which Opioid?

☐ 4.17 Other Opioid

4.18 Has this patient experienced perioperative anaphylaxis on a previous occasion confirmed by investigations?

- ☐ Yes (please give more details) ☐ No ☐ Unknown

4.19 Severity

- ☐ 1 ☐ 2
☐ 3 ☐ 4
☐ Unknown

4.20 How long ago was the previous reaction in years and months?

Y Y : M M

4.21 Did the Index Anaesthetist know about this previous reaction before the event currently being reported?

- ☐ N/A ☐ Yes ☐ No ☐ Unknown

4.22 What were the details of the previous reaction, including cause?

- ☐ Click here to give details
☐ Unknown

Details:

5.1 Has this patient experienced suspected perioperative anaphylaxis on a previous occasion **NOT confirmed by investigations?**

- ☐ Yes
- ☐ No
- ☐ Unknown

5.2 Was this known about before the event currently being reported?

- ☐ Yes
- ☐ No
- ☐ Unknown

5.3 How long ago was the previous (not investigated) reaction?

Y	Y	:	M	M
---	---	---	---	---

5.4 What were the details of the previous (not-investigated) reaction, including the suspected cause?

- ☐ [Click here to give details](#)
- ☐ Unknown

Details

Details of the Event

6.1 Where was the patient at the time when anaphylaxis was suspected?

- | | | |
|---|---|--|
| ☐ Preoperative ward (as part of pre-op pathway only) | ☐ Anaesthetic room | ☐ Operating theatre |
| ☐ Recovery room | ☐ Radiology | ☐ Cardiac Cath lab |
| ☐ Endoscopy | ☐ Delivery Suite | ☐ During transfer |
| ☐ HDU/ICU | ☐ Emergency Department | ☐ Other (please give details) |

Other:

6.2 On which day of the week did the event take place?

- | | |
|------------------------------------|-----------------------------------|
| ☐ Monday | ☐ Tuesday |
| ☐ Wednesday | ☐ Thursday |
| ☐ Friday | ☐ Saturday |
| ☐ Sunday | |

6.3 Time of the suspected anaphylactic event:

Please identify the time as accurately as possible because it is critical for subsequent data analysis (please use 24 hour clock)

H	H	:	M	M
---	---	---	---	---

6.4 Suspected culprit drug/substance (only one permitted)

6.5 Grade of Reaction (remember mild (grade 1-2) reactions are not admissible)

- | | |
|----------------------------------|----------------------------------|
| ☐ Grade 3 | ☐ Grade 4 |
| ☐ Grade 5 | ☐ Unknown |

6.6 What was the FIRST clinical feature of the reaction noticed by the anaesthetist (pick one)?

- | | | |
|--|---|--|
| ☐ Cardiac Arrest | ☐ Hypotension | ☐ Bronchospasm/High airway pressure |
| ☐ Other Respiratory Distress | ☐ Cyanosis/Oxygen Desaturation | ☐ Reduced/Absent CO2 Trace |
| ☐ Flushing/Non-urticarial Rash | ☐ Urticaria | ☐ Laryngeal Oedema/Stridor |
| ☐ Swelling/Oedema (non-laryngeal) | ☐ Tachycardia | ☐ Bradycardia |
| ☐ Patient Feeling Unwell | ☐ Itching | ☐ Nausea/Vomiting |
| ☐ Abdominal Pain | ☐ Diarrhoea | ☐ Unexplained Loss of Consciousness |
| ☐ Other (please specify) | | |

Drugs administered during the 120 minutes prior to the first clinical feature of anaphylaxis

Please select all relevant drugs and make sure you indicate the route, total dose/volume and, when applicable, the time started

7.1 Pre-med:

Time given:

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

Route:

Total Dose Administered Before Anaphylactic Event:

Other:

--

H	H	:	M	M
---	---	---	---	---

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7.2 Did the patient have a gas induction?

☐ Yes ☐ No ☐ Unknown

7.3 Induction agent/ sedative drug:

Time started:

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

Route:

Total Dose Administered Before Anaphylactic Event:

Other:

--

H	H	:	M	M
---	---	---	---	---

--

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Drugs administered during the 120 minutes prior to the first clinical feature of anaphylaxis ctd

Please select all relevant drugs and make sure you indicate the route, total dose/volume and, when applicable, the time started

8.1 Analgesic drug:

	Time started:	Route:	Total Dose Administered Before Anaphylactic Event:
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		
Paracetamol	H H : M M		

Other:

	H H : M M		
	H H : M M		
	H H : M M		
	H H : M M		

8.2 Muscle relaxant drug:

	Time started:	Route:	Total Dose Administered Before Anaphylactic Event:
	H H : M M	IV	mg
	H H : M M	IV	mg
	H H : M M	IV	mg
	H H : M M	IV	mg
	H H : M M	IV	mg
	H H : M M	IV	mg
Suxamethonium	H H : M M		mg

Drugs administered during the 120 minutes prior to the first clinical feature of anaphylaxis ctd

Please select all relevant drugs and make sure you indicate the route, total dose/volume and, when applicable, the time started

9.1 Anti-emetic:

Time started:

Route:

Total Dose Administered
Before Anaphylactic Event:

	H H : M M				mg
	H H : M M				mg
	H H : M M				mg
	H H : M M				mg
	H H : M M				mg
	H H : M M				mg
	H H : M M				mg
	H H : M M				mg

Other:

	H H : M M				mg
--	-----------	--	--	--	----

9.2 Antibiotic/ Antimicrobial:

Time started:

Route:

Total Dose Administered
Before Anaphylactic Event:

	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg

Other:

	H H : M M					mg
	H H : M M					mg
	H H : M M					mg
	H H : M M					mg

Drugs administered during the 120 minutes prior to the first clinical feature of anaphylaxis ctd

Please select all relevant drugs and make sure you indicate the route, total dose/volume and, when applicable, the time started

	10.2 Antibiotic(s) Test Dose(s):	Time:	Total Dose:
10.1 Did the patient receive an IV test-dose of antibiotic?		H H : M M	mg
		H H : M M	mg
	Other: 	H H : M M	mg
	☐ Yes		
☐ No			
☐ Unknown			

10.3 IV Colloid:	Time started:	Route:	Total Volume Administered Before Anaphylactic Event:
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
	H H : M M	IV	ml
Other: 	H H : M M	IV	ml

10.4 Local anaesthetic:	Time started:	Route:	Total Dose Administered Before Anaphylactic Event:
	H H : M M		mg
	H H : M M		mg
	H H : M M		mg
	H H : M M		mg
	H H : M M		mg
Other: 	H H : M M		mg

Drugs administered during the 120 minutes prior to the first clinical feature of anaphylaxis ctd

Please select all relevant drugs and make sure you indicate the route, total dose/volume and, when applicable, the time started

11.1 Reversal drug:

Time started:

Route:

Total Dose Administered
Before Anaphylactic Event:

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

IV
IV
IV

11.2 Drug affecting blood coagulation:

Time started:

Route:

Total Dose Administered
Before Anaphylactic Event:

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

Other:

	H	H	:	M	M
--	---	---	---	---	---

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Other substances administered during the 120 minutes prior to the first clinical feature of anaphylaxis

Please select all relevant drugs/substances and make sure you indicate the route, total dose/volume and, when applicable, the time started

☐ 12.1 Chlorhexidine

Route:

☐ Skin prep before cannulation

Time started:

H	H	:	M	M
---	---	---	---	---

☐ Skin prep before surgery

H	H	:	M	M
---	---	---	---	---

☐ Coated/impregnated central line

H	H	:	M	M
---	---	---	---	---

☐ In medical lubricant gel

H	H	:	M	M
---	---	---	---	---

☐ Other

H	H	:	M	M
---	---	---	---	---

☐ 12.2 Methylene blue dye

Route:

☐ Tissue infiltration

Time started:

H	H	:	M	M
---	---	---	---	---

☐ Tubal (gynae)

H	H	:	M	M
---	---	---	---	---

☐ IV (e.g. parathyroid surgery)

H	H	:	M	M
---	---	---	---	---

☐ Other

H	H	:	M	M
---	---	---	---	---

☐ 12.3 Patent blue dye

Route:

☐ Tissue infiltration

Time started:

H	H	:	M	M
---	---	---	---	---

☐ Other

H	H	:	M	M
---	---	---	---	---

12.4 Other drugs/ substances:

Time started:

Route:

Total Dose/Volume Administered
Before Anaphylactic Event:

Other route:

H	H	:	M	M
---	---	---	---	---

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

--	--	--	--	--

12.5 Blood products:

Time started:

Route:

Total Dose/Volume Administered
Before Anaphylactic Event:

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

Other:

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

Other:

H	H	:	M	M
---	---	---	---	---

IV

--	--	--	--	--

13.1 What was the time interval between exposure to the suspected culprit drug/substance and appearance of the first clinical feature?

- ☐ 0 - 5 mins
 ☐ 6 - 10 mins
 ☐ 11 - 15 mins
 ☐ 16 - 30 mins
☐ 31 - 60 mins
 ☐ 61 - 120 mins
 ☐ Greater than 120 mins

13.2 What was the time interval between exposure to the suspected culprit drug/substance and identification of the event as a Clinical Incident by the anaesthetist?

- ☐ 0 - 5 mins
 ☐ 6 - 10 mins
 ☐ 11 - 15 mins
 ☐ 16 - 30 mins
☐ 31 - 60 mins
 ☐ 61 - 120 mins
 ☐ Greater than 120 mins

13.3 What was the time interval between exposure to the suspected culprit drug/substance and the anaesthetist suspecting anaphylaxis?

- ☐ 0 - 5 mins
 ☐ 6 - 10 mins
 ☐ 11 - 15 mins
 ☐ 16 - 30 mins
☐ 31 - 60 mins
 ☐ 61 - 120 mins
 ☐ Greater than 120 mins

13.4 Was there a new arrhythmia (not requiring CPR) during the event?

- ☐ Yes
 ☐ No
 ☐ Unknown

☐ Atrial Fibrillation
 ☐ Other Supraventricular Tachycardia
 ☐ VT (with pulse)

☐ Bradycardia
 ☐ Other

13.5 If the anaphylaxis was Grade 4 or Grade 5, what was the type of cardiac arrest when this first occurred?

- ☐ Asystole
 ☐ VF/Pulseless VT
☐ PEA (Pulseless Electrical Activity)
 ☐ Bradycardia Requiring CPR
☐ Unknown
 ☐ N/A

13.6 Was the cardiac arrest preceded by? (select as many as apply):

- ☐ Prolonged hypotension
 ☐ Prolonged hypoxia
 ☐ Prolonged arrhythmia

13.7 Where cardiac arrest occurred, was this?

- ☐ Despite prompt treatment of anaphylaxis
☐ With possible contribution by delayed treatment of anaphylaxis
☐ With probable or certain contribution by delayed treatment of anaphylaxis
☐ As a complication of management of anaphylaxis
☐ As a complication of the primary procedure
☐ Other

Please enter details:

13.8 What was the time interval between exposure to the suspected culprit drug/substance and (first) cardiac arrest?

- ☐ 0 - 5 mins
 ☐ 6 - 15 mins
☐ 16 - 30 mins
 ☐ 31 - 60 mins
☐ 61 - 120 mins
 ☐ Greater than 120 mins

14.1 Please indicate which clinical features were present at any time during the anaphylactic episode (select as many as needed)

- | | | |
|--|--|---|
| ☐ Cardiac Arrest | ☐ Hypotension | ☐ Bronchospasm/High airway pressure |
| ☐ Other Respiratory Distress | ☐ Cyanosis/Oxygen Desaturation | ☐ Reduced CO2 Trace |
| ☐ Absent CO2 Trace | ☐ Flushing/Non-urticarial Rash | ☐ Urticaria |
| ☐ Laryngeal Oedema/Stridor | ☐ Swelling/Oedema (non-laryngeal) | ☐ Tachycardia |
| ☐ Bradycardia | ☐ Patient Feeling Unwell | ☐ Itching |
| ☐ Nausea/Vomiting | ☐ Abdominal Pain | ☐ Diarrhoea |
| ☐ Unexplained Loss of Consciousness | ☐ Other (please give details) | ☐ New Coagulopathy (please specify features) |

Please give details:

Please specify features:

14.2 What was the lowest recorded blood pressure during the hour after the event?

 /

☐ Unrecordably low

14.3 What was the lowest recorded oxygen saturation during the hour after the event?

☐ Unrecordably low

14.4 Did the patient die as a result of the anaphylactic episode? - i.e. the patient would have survived if it were not for anaphylaxis?

☐ Yes ☐ No ☐ Uncertain

Please give details:

14.5 If the patient died as a result of the incident, how long after the incident was it? Please indicate the exact number of days if less than 30

☐ Less than 30 days ☐ Greater than 30 days ☐ Time interval before death not known

Number of days:

14.6 Relevant autopsy findings:

14.7 Was (initial) tracheal intubation difficult due to airway swelling?

☐ Yes ☐ No ☐ N/A ☐ Unknown

Please give details:

14.8 Was an unplanned change of airway needed during the anaphylactic episode?

☐ Intubation ☐ Re-intubation ☐ Unknown
☐ Front of neck airway ☐ Other ☐ No

Please give details:

14.9 Was it necessary to re-intubate the patient after elective extubation or airway removal at the end of primary procedure?

☐ Yes ☐ No ☐ N/A

Please give details:

14.10 Was tracheal re-intubation difficult due to airway swelling?

☐ Yes ☐ No ☐ N/A ☐ Unknown

Please give details:

14.11 Please give a brief narrative description of the event if not covered by the preceding questions:

With reference to the drug/substance you suspect caused the reaction: Prior to the perioperative anaphylactic event, did the patient have a history of symptoms suggestive of allergy to:

15.1 The same drug/substance that you suspect caused the perioperative anaphylaxis?

☐ Yes ☐ No ☐ Unknown

Please give details:

15.2 A cross-reacting substance of the same class - e.g. a penicillin and a different penicillin?

☐ Yes ☐ No ☐ Unknown

Please give details:

15.3 A cross-reacting drug/substance of a different class - e.g. a history of cephalosporin allergy, when the anaphylactic event was thought to be due to a penicillin (or vice versa)?

☐ Yes ☐ No ☐ Unknown

Please give details:

15.4 What were the circumstances surrounding administration of the suspected drug/substance?

- ☐ There was an active decision to administer the drug after consideration of the previous allergy history
- ☐ The person administering the drug/substance was not aware of the previous allergy history
- ☐ The drug/substance was administered in error

Please give details:

15.5 This is because:

- ☐ No allergy history was taken
- ☐ There were difficulties in communicating with the patient
- ☐ There were communication difficulties within the clinical team
- ☐ The patient didn't declare the allergy
- ☐ The information about the allergy was not clearly visible to the person administering the drug/substance

15.6 Why was no allergy history taken?

- ☐ Because of the urgency of the procedure
- ☐ Because of omission
- ☐ Other

Please give details:

15.7 For drug/substance administration errors, which of the following contributing factors were involved:

Immediate clinical management of the event (DURING THE 6 HOUR PERIOD AFTER THE ONSET OF THE EVENT)

16.1 What was the time interval from onset of first clinical feature to the start of clinical treatment specifically for anaphylaxis?

- ☐ 0 - 5 mins
 ☐ 6 - 10 mins
 ☐ 11 - 15 mins
 ☐ 16 - 30 mins
 ☐ 31 - 60 mins
 ☐ 61 - 120 mins
 ☐ Greater than 120 mins

16.2 Was a consultant anaesthetist involved in the care of the patient during the anaphylactic episode?

- ☐ Yes directly
 ☐ Yes at a distance
 ☐ No
 ☐ Unknown

16.3 Was there a need to ask for assistance during the anaphylactic episode?

- ☐ Yes
 ☐ No
 ☐ Unknown

16.4 Was there a delay in the treatment of suspected anaphylaxis?

- ☐ Yes
 ☐ No

16.5 Please give reason for delay

- ☐ Slow to diagnose
 ☐ Drugs not available
 ☐ Appropriate assistance not available
 ☐ Other (please specify)

Please give details of the assistance:

16.6 Was a specific anaphylaxis pack used in treatment (do not include a general cardiac arrest pack)?

- ☐ Yes
 ☐ No
 ☐ Unknown

16.7 To what extent did the theatre team contribute to the management of the event?

- ☐ Effective contribution
 ☐ Partially effective
 ☐ Non-contributory
 ☐ Contributions were counter-productive
 ☐ Unknown

16.8 Please comment on the contribution of theatre team during the event

16.9 Did theatre team contribute effectively to the management of the incident?

- ☐ Yes, all
 ☐ Yes, some
 ☐ No
 ☐ Unknown

16.10 Was a specific guideline used to guide management?

- ☐ AAGBI anaphylaxis guideline
 ☐ Resuscitation Council anaphylaxis guideline
 ☐ ALS cardiac arrest protocol
 ☐ Other (please specify)
 ☐ Unknown
 ☐ No

16.11 Did you have immediate access to an anaphylaxis guideline during this event?

- ☐ Yes
 ☐ No
 ☐ Unknown

16.12 Did you have immediate access to an anaphylaxis algorithm?

- ☐ Yes
 ☐ No
 ☐ Unknown

16.13 How did you access the anaphylaxis algorithm?

- ☐ Laminate
 ☐ Smartphone
 ☐ Anaphylaxis pack
 ☐ Memory
 ☐ Other

Drugs Administered During Resuscitation

Please pay special attention to the dose units (mg, mcg, etc.)

17.1 IV bolus(es) of adrenaline administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

		.		
--	--	---	--	--

mg

17.3 IM bolus(es) of adrenaline administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

		.	
--	--	---	--

mg

17.5 Metaraminol IV bolus(es) administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

		.	
--	--	---	--

mg

17.2 IV infusion of adrenaline started up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

		.	
--	--	---	--

mg

17.4 Ephedrine IV bolus(es) administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--

mg

17.6 Metaraminol IV infusion started up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

		.	
--	--	---	--

mg

18.1 Noradrenaline IV infusion started up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--

mg
18.2 Phenylephrine IV bolus(es) administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--	--

mg
18.3 Phenylephrine IV infusion started up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--	--

mg
18.4 Vasopressin IV bolus(es) administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--

units
18.5 Vasopressin IV infusion started up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--

units
18.6 Glucagon IV bolus(es) administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--

mg

19.1 Glucagon IV infusion started up to 6 hours after the onset of the event
☐ Yes
 ☐ No
 ☐ Unknown
Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--

 mg
19.2 Atropine IV administered up to 6 hours after the onset of the event
☐ Yes
 ☐ No
 ☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

--	--

 mg
19.3 Glycopyrrolate IV administered up to 6 hours after the onset of the event to treat bradycardia
☐ Yes
 ☐ No
 ☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

--	--

 mg
19.4 Salbutamol IV bolus(es) administered up to 6 hours after the onset of the event
☐ Yes
 ☐ No
 ☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--

 .

--	--

 mg
19.5 Salbutamol IV infusion started up to 6 hours after the onset of the event
☐ Yes
 ☐ No
 ☐ Unknown
Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--

 .

--	--

 mg
19.6 Inhaled/nebulised salbutamol administered up to 6 hours after the onset of the event
☐ Yes
 ☐ No
 ☐ Unknown
Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered up to 6 hours after the onset of the event

--	--

 .

--	--

 mg

20.1 Magnesium Sulphate IV bolus(es) administered up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--	--	--	--

mg
20.2 Magnesium Sulphate IV infusion started up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--	--	--	--

mg
20.3 Aminophylline IV bolus(es) administered up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered by bolus up to 6 hours after the onset of the event

--	--	--	--	--

mg
20.4 Aminophylline IV infusion started up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time Started

H	H	:	M	M
---	---	---	---	---

Time Finished, if infusion completed during the 6 hour period following the event

H	H	:	M	M
---	---	---	---	---

TOTAL dose (mg) administered by infusion up to 6 hours after the onset of the event

--	--	--	--	--

mg
20.5 Chlorphenamine IV administered up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

--	--	--

mg
20.6 Ranitidine IV administered up to 6 hours after the onset of the event
☐ Yes
☐ No
☐ Unknown
Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

--	--	--	--

mg

21.1 Hydrocortisone IV administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

				mg
--	--	--	--	----

21.3 Sugammadex IV administered up to 6 hours after the onset of the event to treat the anaphylactic reaction

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

					mg
--	--	--	--	--	----

21.2 Dexamethasone IV administered up to 6 hours after the onset of the event

☐ Yes ☐ No ☐ Unknown

Time of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

				mg
--	--	--	--	----

21.4 Other Drug 1:

☐ Yes ☐ No

Time Started/of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

					mg
--	--	--	--	--	----

Route

☐ IV Bolus(es) ☐ IV Infusion ☐ IM ☐ Inhaled
☐ SC ☐ Intraosseous ☐ Other

Please specify:

21.5 Other Drug 2:

☐ Yes ☐ No

Time Started/of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

					mg
--	--	--	--	--	----

Route

☐ IV Bolus(es) ☐ IV Infusion ☐ IM ☐ Inhaled
☐ SC ☐ Intraosseous ☐ Other

Please specify:

21.6 Other Drug 3:

☐ Yes ☐ No

Time Started/of First Dose

H	H	:	M	M
---	---	---	---	---

No. of Doses

--	--

TOTAL dose (mg) administered up to 6 hours after the onset of the event

					mg
--	--	--	--	--	----

Route

☐ IV Bolus(es) ☐ IV Infusion ☐ IM ☐ Inhaled
☐ SC ☐ Intraosseous ☐ Other

Please specify:

22.1 IV colloid administered during the 1st hour after the event

	Volume in litres (to the nearest 0.5litre)
Gelofusine	.
Haemaccel	.
Gelaspan	.
Volplex	.
Isoplex	.
Albumin 4.5%	.
Albumin 20%	.
Starch	.
Dextran	.
Other:	.

22.3 IV colloid administered during the subsequent 2 hours (i.e. between 3 hours after the event and 5 hours after the event)

	Volume in litres (to the nearest 0.5litre)
Gelofusine	.
Haemaccel	.
Gelaspan	.
Volplex	.
Isoplex	.
Albumin 4.5%	.
Albumin 20%	.
Starch	.
Dextran	.
Other:	.

22.2 IV colloid administered during the subsequent 2 hours (i.e. between 1 hour after the event and 3 hours after the event)

	Volume in litres (to the nearest 0.5litre)
Gelofusine	.
Haemaccel	.
Gelaspan	.
Volplex	.
Isoplex	.
Albumin 4.5%	.
Albumin 20%	.
Starch	.
Dextran	.
Other:	.

22.4 Volume of IV crystalloid administered in 1st hour after suspecting anaphylaxis (to the nearest 0.5 litre)
 .
22.5 Volume of IV crystalloid administered during the subsequent 2 hours (i.e. between 1 to 3 hours after the event) to the nearest 0.5 litre
 .
22.6 Volume of IV crystalloid administered during the subsequent 2 hours (i.e. between 3 to 5 hours after the event) to the nearest 0.5 litre
 .
22.7 Did the patient require cardiac compressions?
☐ Yes ☐ No ☐ Unknown
22.8 Time of starting cardiac compressions
 H H : M M
22.9 Duration of cardiac compressions in minutes

23.1 Where was the patient first transferred after resuscitation?

☐ Operating Theatre ☐ Recovery Room ☐ ICU/HDU
☐ Ward ☐ Other (please give details)

23.2 Time between anaphylactic event and patient being transferred to HDU/ICU:

H	H	:	M	M
---	---	---	---	---

23.3 Was transfer to a different hospital required for ICU/HDU care?

☐ Yes ☐ No ☐ Unknown

23.4 Why was it necessary to transfer to a different hospital for ICU/HDU care?

☐ The hospital where the event occurred has no HDU/ICU
☐ The ICU/HDU was full in the hospital where the event occurred
☐ A higher level of HDU/ICU care was required than could be provided in the hospital's own HDU/ICU
☐ Unknown

23.5 What was the reason for transferring the patient to ICU/HDU?

☐ As a result of anaphylaxis (patient would not have been admitted otherwise)
☐ Planned transfer, NOT related to anaphylaxis
☐ Unplanned transfer, NOT related to anaphylaxis
☐ Other (please give details)

23.6 What was the initial level of support in ICU/HDU?

☐ Level 2 ☐ Level 3
☐ Unknown

23.7 What was Highest level of support in ICU/HDU?

☐ Level 2 ☐ Level 3
☐ Unknown

23.8 Unplanned duration of level 3 support for treatment of anaphylaxis

--	--	--

 Days
23.9 Unplanned duration of level 2 support for treatment of anaphylaxis

--	--	--

 Days
23.10 Unplanned TOTAL length of stay in hospital as a result of treatment of anaphylaxis

--	--	--

 Days
23.11 If transferred to ICU/HDU as a result of anaphylaxis, were vasopressors or inotropes needed in ICU/HDU?

☐ Yes ☐ No ☐ Unknown

23.12 If transferred to ICU/HDU as a result of anaphylaxis, were bronchodilators needed in ICU/HDU?

☐ Yes ☐ No ☐ Unknown

Please give details:

--

Please give details:

--

23.13 Outcome of Hospital episode

☐ Normal, expected outcome ☐ Delayed discharge but no harm
☐ Delayed discharge and harm ☐ Harm, but not delayed discharge

23.14 If patient suffered harm, please classify (see table for classifications)

☐ Low ☐ Moderate ☐ Severe
☐ Death ☐ Unknown

23.15 During ICU/HDU stay was there an evidence of any recurrence of anaphylaxis?

☐ Yes ☐ No ☐ Unknown

Please give details:

--

Initial Investigations

24.1 Was blood taken for Mast cell tryptase? ☐ Yes ☐ No ☐ Unknown

***IMPORTANT: If the Mast Cell Tryptase results are not known at the time of reporting and completing Part A, they can be entered into Part B when the results are known. It is extremely important that all the available results are entered.**

24.2 Mast cell tryptase timing and results (including baseline levels).

Please enter the time interval between the event and the blood samples being taken

Time after first clinical feature HH:MM				Result
				ng/ml or mcg/L
H	H	:	M M	.
H	H	:	M M	.
H	H	:	M M	.
H	H	:	M M	.
H	H	:	M M	.
H	H	:	M M	.

24.3 Were the blood samples taken as requested by the anaesthetist?

☐ Yes ☐ No ☐ Unknown

If no, please give details of discrepancies:

24.4 At the time of completing Part A, has the laboratory provided a result for each of the mast cell tryptase blood samples that were taken?

☐ Yes ☐ No ☐ Unknown

24.5 If the laboratory did not provide a result for each of the mast cell tryptase blood samples that were taken: please give details of discrepancies

Events between reaction and allergy clinic investigations

25.1 Has it been decided not to refer the patient to an allergy clinic?

☐ Yes ☐ No

25.2 What was the reason for not referring the patient to an allergy clinic?

25.3 Was the patient given written or oral advice about which drugs/substances to avoid, before they were seen in an allergy clinic?

☐ Yes, written ☐ Yes, oral ☐ Yes, both written and oral
☐ No ☐ Unknown

25.4 Was anaesthesia or sedation required before the patient was seen in the allergy clinic?

☐ Yes ☐ No ☐ Unknown

25.5 Was this anaesthetic/sedation uneventful?

☐ Yes ☐ No ☐ Unknown

25.6 If there was a further reaction during this period, please provide details, including severity

25.7 Has the further reaction been reported to NAP6?

☐ Yes ☐ No ☐ Unknown

Adverse sequelae as judged by the patient and/or their family member or carer: e.g. memory impairment - Only if on balance of probabilities this is attributable to the anaphylactic event. This is important, please provide as much detail as possible in the comment section.

26.1 Change in mood

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.2 Impaired memory

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.3 Impaired coordination

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.4 Impaired mobility

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.5 Anxiety about future anaesthesia/sedation

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.6 Myocardial Infarction

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.7 Cardiac Failure

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.8 Stroke

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.9 Evidence suggestive of a new psychological disorder including PTSD; for example, flashbacks, nightmares, repetitive and distressing images or sensations, or physical sensations such as related pain, nausea, sweating or trembling

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

26.10 Impaired renal function:

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

☐ **26.11 Other**

Please give details:

DRAFT

Referral to Allergy Clinic

27.1 Who referred the patient to the allergy clinic?

- | | |
|---|---|
| ☐ Anaesthetist present at the time of the reaction | ☐ Different anaesthetist |
| ☐ Surgeon | ☐ GP |
| ☐ N/A | ☐ Other (Please specify) |

27.2 What information was sent to the allergy clinic at the time of referral for further investigation?

- | | |
|---|---|
| ☐ Copy of the anaesthetic chart | ☐ Copy of the drug chart |
| ☐ Copy of contemporaneous notes made by the anaesthetist | ☐ AAGBI referral proforma |
| ☐ Other referral proforma providing the same information as the AAGBI proforma | ☐ Other referral proforma providing less information than the AAGBI proforma |
| ☐ Mast cell tryptase results | ☐ Other |
| ☐ N/A | ☐ Unknown |

Adverse Event Documentation and Reporting

27.3 Has a hazard warning (e.g. Medic Alert) been issued to the patient? ☐ Yes ☐ No ☐ Unknown

27.4 Who issued the hazard warning?

- ☐ Index Anaesthetist ☐ Local Coordinator ☐ Allergy Clinic ☐ Other (please specify)

27.5 Was the case reported through the MHRA yellow card process? ☐ Yes ☐ No ☐ Unknown

27.6 Who reported the case to MHRA?

- ☐ Index Anaesthetist ☐ Local Coordinator ☐ Allergy Clinic ☐ Other (please specify)

27.7 Has the event been reported through the Trust incident reporting system? ☐ Yes ☐ No

27.8 Who reported the event through the Trust incident reporting system?

- ☐ Index Anaesthetist ☐ Another Anaesthetist ☐ Other (please specify)

27.9 Was the patient's clinical management altered as a result of waiting for a clinic appointment?

- | | | |
|---|--|---|
| ☐ Cancer surgery was delayed | ☐ Urgent non-cancer surgery was delayed | ☐ Non-urgent surgery was delayed |
| ☐ Other treatment was delayed (please specify) | ☐ No alteration | ☐ Unknown |

- ☐ 1. To avoid possible errors please review your entries, **ESPECIALLY NUMERIC DATA**, before submitting the completed form
2. **YOU MUST MAKE NOTE** of the unique case ID number assigned to you by the NAP6 Administrator as you will require this for Part B of the webform
3. Tick the box to the left to confirm that Part A of the webform is complete and accurate
4. When you have checked your entries, select 'SUBMIT' at the bottom of the page. Once submitted you **CANNOT** re-access or edit this form
5. Once you have selected 'SUBMIT' please save a PDF copy of your report by clicking on the 'SAVE PDF' button on the following page. This is important if there are queries about any of your answers

6th National Audit Project - Part B

Please enter your five digit case ID number: This is the number supplied to you by the NAP6 team when you notified the case by email and that was also entered in Part A of the webtool.

It is absolutely imperative that the same ID number is entered in both parts of the webtool so as to be able to link the two sets of data.

1				
---	--	--	--	--

Intervention Status

1.1 Was procedure completed between the time of completing PART A and the time of completing PART B?

- ☐ Yes
 ☐ No, the procedure was completed before submitting PART A
☐ No, it was decided that the procedure was not required/indicated
 ☐ No, the patient is still waiting for the procedure
☐ Unknown

1.2 Did the patient take pholcodine cough medicine prior to the event? (this information may be contained in the allergy clinic letter)

- ☐ Yes, less than 3 months prior to the event
 ☐ Yes, 3-6 prior to the event
 ☐ Yes, 6-12 months prior to the event
☐ Yes, more than 12 months prior to the event
 ☐ No
 ☐ Unknown

Medical History & Drugs (prior to this episode)

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

Angioedema ☐ Yes ☐ No ☐ Unknown Urticaria ☐ Yes ☐ No ☐ Unknown Eczema ☐ Yes ☐ No ☐ Unknown Hay fever ☐ Yes ☐ No ☐ Unknown Food Allergy ☒ Yes ☐ No ☐ Unknown Asthma ☐ Yes, controlled ☐ Yes, poorly controlled ☐ No ☐ Unknown Please list food allergies: Angiotensin Converting Enzyme Inhibitor ☐ Yes ☒ No ☐ Unknown Beta blocker ☒ Yes ☐ No ☐ Unknown Details of the previous (not-investigated) reaction:	1.3 Angioedema ☐ Yes ☐ No ☐ Unknown 1.4 Urticaria ☐ Yes ☐ No ☐ Unknown 1.5 Eczema ☐ Yes ☐ No ☐ Unknown 1.6 Hay fever ☐ Yes ☐ No ☐ Unknown 1.7 Food Allergy ☐ Yes ☐ No ☐ Unknown 1.8 Asthma ☐ Yes, controlled ☐ Yes, poorly controlled ☐ No ☐ Unknown Please list food allergies: 1.9 Angiotensin Converting Enzyme Inhibitor ☐ Yes ☐ No ☐ Unknown 1.10 Beta blocker ☐ Yes ☐ No ☐ Unknown 1.11 What were the details of the previous (not-investigated) reaction? ☐ N/A ☐ Click here to give details ☐ Unknown
--	--

DRAFT

Initial Investigations

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

2.1 Mast cell tryptase timing and results (including baseline levels)

Please enter the **time interval** between the event and the blood samples being taken

If certain results were not known at the time of reporting and completing Part A, please enter the updated results onto the table on the right.

Time after first
clinical feature HH:MM

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

Result
ng/ml or mcg/L

			.	
			.	
			.	
			.	
			.	
			.	

Were the blood samples taken
as requested by the anaesthetist?

☐ Yes ☐ No ☐ Unknown

If no; please give details of discrepancies:

Did the laboratory provide a result for each of the
mast cell tryptase blood samples that were taken?

☐ Yes ☐ No ☐ Unknown

If the laboratory did not provide a result for each
of the mast cell tryptase blood samples that were
taken please provide details of discrepancies:

Time after first clinical
feature HH:MM

H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M
H	H	:	M	M

Result
ng/ml or mcg/L

			.	
			.	
			.	
			.	
			.	
			.	

2.2 Were the blood samples taken
as requested by the anaesthetist?

☐ Yes ☐ No ☐ Unknown

If no; please give details of discrepancies:

2.3 Did the laboratory provide a result for each of the
mast cell tryptase blood samples that were taken?

☐ Yes ☐ No ☐ Unknown

2.4 If the laboratory did not provide a result for each
of the mast cell tryptase blood samples that were
taken please provide details of discrepancies:

DRAFT

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

Was anaesthesia or sedation required before the patient was seen in the allergy clinic?

☐ Yes ☐ No ☐ Unknown

Was this anaesthetic/sedation uneventful?

☐ Yes ☐ No ☐ Unknown

If there was a further reaction during this period, please provide details, including severity

Has the further reaction been reported to NAP6?

☐ Yes ☐ No
☐ Unknown ☐ N/A

3.1 Was anaesthesia or sedation required before the patient was seen in the allergy clinic?

☐ Yes ☐ No ☐ Unknown

3.2 Was this anaesthetic/sedation uneventful?

☐ Yes ☐ No ☐ Unknown

3.3 If there was a further reaction during this period, please provide details, including severity

[View Table](#)

3.4 Has the further reaction been reported to NAP6?

☐ Yes ☐ No
☐ Unknown ☐ N/A

Adverse sequelae as judged by the patient and/or their family member or carer: e.g. memory impairment - Only if on balance of probabilities this is attributable to the anaphylactic event

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

Change in mood

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Impaired memory

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Impaired coordination

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Impaired mobility

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Anxiety about future anaesthesia/sedation

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

4.1 Change in mood

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

4.2 Impaired memory

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

4.3 Impaired coordination

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

4.4 Impaired mobility

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

4.5 Anxiety about future anaesthesia/sedation

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

Myocardial Infarction

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Cardiac Failure

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Stroke

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Evidence suggestive of a new psychological disorder including PTSD; for example, flashbacks, nightmares, repetitive and distressing images or sensations, or physical sensations such as related pain, nausea, sweating or trembling

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

Impaired renal function

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

☐ Other

Please give details:

5.1 Myocardial Infarction

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

5.2 Cardiac Failure

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

5.3 Stroke

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

5.4 Evidence suggestive of a new psychological disorder including PTSD; for example, flashbacks, nightmares, repetitive and distressing images or sensations, or physical sensations such as related pain, nausea, sweating or trembling

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

5.5 Impaired renal function

☐ None ☐ Mild ☐ Moderate
☐ Severe ☐ Unknown

Comment:

☐ 5.6 Other

Please give details:

Events between reaction and allergy clinic investigations

6.1 What was the interval between the event and the date seen in allergy clinic? (first clinic appointment). Please enter whole number of days.

☐ N/A

number of days after event

6.2 What was the interval between the event and the date seen in allergy clinic? (second clinic appointment) Please enter whole number of days.

☐ N/A

number of days after event

6.3 What was the interval between the event and the date seen in allergy clinic? (third clinic appointment) Please enter whole number of days.

☐ N/A

number of days after event

6.4 Did the allergy clinic request further information from the anaesthetist before the patient was seen in clinic?

☐ Yes ☐ No ☐ Unknown

6.5 Is there evidence of a response to that request?

☐ Yes ☐ No ☐ Unknown

6.6 Did the allergy clinic request further information from the anaesthetist after the patient had been seen in clinic?

☐ Yes ☐ No ☐ Unknown

6.7 Is there evidence of a response to that request?

☐ Yes ☐ No ☐ Unknown

Allergy history recorded by allergy clinic

6.8 Allergy history recorded by allergy clinic. Please select all that apply.

- ☐ Penicillin
 ☐ Cephalosporin
 ☐ Other antibiotic (please specify)
- ☐ Latex
 ☐ Muscle Relaxant
 ☐ Chlorhexidine
- ☐ Iodine
 ☐ NSAID
 ☐ Opioid
- ☐ Other (please specify)
 ☐ No Allergy
 ☐ Not Recorded

Other:

6.9 Which Muscle Relaxant?

6.10 Which Opioid?

☐ 6.11 Other Opioid

Skin tests performed in the allergy clinic -

please note that Skin Prick tests are on a separate page from Intradermal tests

7.1 Results of SKIN PRICK tests performed in the allergy clinic. Please input all the information provided in the allergy clinic letter.

[illegible]

8.1 Results of INTRADERMAL tests performed in the allergy clinic. Please input all the information provided in the allergy clinic letter.

	Concentration	Units of concentration	Positive;	Negative;	Equivocal
Saline control	.		☐	☐	☐
Histamine control	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐
	.		☐	☐	☐

Other investigations performed in the allergy clinic

9.1 Results of specific-IgE tests. Please input Total IgE as well as all other available results.

	Result		
Total IgE	.		
Allergen	Result	Positive;	Negative;
Penicilloyl V	.	☐	☐
Penicilloyl G	.	☐	☐
Amoxicilloyl	.	☐	☐
Ampicilloyl	.	☐	☐
Cefaclor	.	☐	☐
Suxamethonium	.	☐	☐
Latex	.	☐	☐
Chlorhexidine	.	☐	☐
Ethylene Oxide	.	☐	☐
Pholcodine	.	☐	☐
Morphine	.	☐	☐
Gelatin	.	☐	☐
Lignocaine	.	☐	☐
Protamine	.	☐	☐
	.	☐	☐
	.	☐	☐
	.	☐	☐

10.1 Other investigations performed in the allergy clinic

Investigation	Positive	Negative	Equivocal
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

10.2 Results of CHALLENGE TESTS performed by the allergy clinic

Drug/Substance	Final Dose	Units	Positive	Negative	Equivocal
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐
	·		☐	☐	☐

11.1 Culprit drug(s)/agent(s)/substance(s) (identified in allergy clinic)

PLEASE SCROLL DOWN MENU

11.2 Other culprit drug(s)/agent(s)/substance(s) (identified in allergy clinic) not included in above list

11.3 What level of confidence in their diagnosis did the allergy clinic express?
☐ High

 ☐ Intermediate

 ☐ Low

 ☐ Not specified

☐ Other (please specify)

11.4 What was the diagnostic class expressed by the allergy clinic?
☐ Allergic anaphylaxis

 ☐ Non-allergic anaphylaxis

 ☐ Anaphylaxis, not classified as allergic or non-allergic

☐ Not anaphylaxis

 ☐ Indeterminate

 ☐ Not specified

☐ Other (please specify)

11.5 What specific advice was given to the patient by the allergy clinic regarding future avoidance? ☐ None
11.6 What specific advice given by the clinic to the patient regarding safe alternatives? ☐ None
11.7 Did the clinic send the GP a copy of their letter?
☐ Yes

 ☐ No

 ☐ Unknown
11.8 Did the clinic send the patient (or patient representative/carer) a copy of their letter?
☐ Yes

 ☐ No

 ☐ Unknown
11.9 Did the allergy clinic provide the patient (or patient representative/carer) with written information on which drugs/substances to avoid?
☐ Yes

 ☐ No

 ☐ Unknown
Please list the drugs/substances:

11.10 Was the patient provided with written information on which drugs/substances are safe alternatives?
☐ Yes

 ☐ No

 ☐ Unknown
Please list the drugs/substances:

Using the information provided to you by the allergy clinic, in particular the culprit drug/substance identified by the clinic AND any additional allergy history elicited by the allergy clinic, did the patient have a history of symptoms suggestive of allergy to:

12.1 The same drug/substance that you suspect caused the perioperative anaphylaxis?

☐ Yes ☐ No ☐ Unknown

Please give details:

12.2 A cross-reacting substance of the same class - e.g. a penicillin and a different penicillin?

☐ Yes ☐ No ☐ Unknown

Please give details:

12.3 A cross-reacting drug/substance of a different class - e.g. a history of cephalosporin allergy, when the anaphylactic event was thought to be due to a penicillin (or vice versa)?

☐ Yes ☐ No ☐ Unknown

Please give details:

12.4 What were the circumstances surrounding administration of the suspected drug/substance?

☐ There was an active decision to administer the drug after consideration of the previous allergy history

☐ The person administering the drug/substance was not aware of the previous allergy history

☐ The drug/substance was administered in error

12.5 This is because:

☐ No allergy history was taken

☐ There were difficulties in communicating with the patient

☐ There were communication difficulties within the clinical team

☐ The patient didn't declare the allergy

☐ The information about the allergy was not clearly visible to the person administering the drug/substance

Please give details:

12.6 Why was no allergy history taken?

☐ Because of the urgency of the procedure

☐ Because of omission

☐ Other

Please give details:

12.7 For drug/substance administration errors, which of the following contributing factors were involved: [View Factors](#)

The questions on this page were previously asked in Part A. You now have the opportunity to update your report with any new formation that has become available since you completed Part A. The information you gave in Part A is displayed on the left of the page for reference. Please enter any new information in the accompanying blank boxes on the right of the page.

Has a hazard warning (e.g. Medic Alert) been issued to the patient?

☐ Yes ☐ No ☐ Unknown

Who issued the hazard warning?

☐ Index Anaesthetist ☐ Local Coordinator
☐ Allergy Clinic ☐ Other (please specify)

Was the case reported through the MHRA yellow card process?

☐ Yes ☐ No ☐ Unknown

Who reported the case to MHRA?

☐ Index Anaesthetist ☐ Local Coordinator
☐ Allergy Clinic ☐ Other (please specify)

Has the event been reported through the Trust incident reporting system?

☐ Yes ☐ No

Who reported the event through the Trust incident reporting system?

☐ Index Anaesthetist
☐ Another Anaesthetist
☐ Other (please specify)

13.1 Has a hazard warning (e.g. Medic Alert) been issued to the patient?

☐ Yes ☐ No ☐ Unknown

13.2 Who issued the hazard warning?

☐ Index Anaesthetist ☐ Local Coordinator
☐ Allergy Clinic ☐ Other (please specify)

13.3 Was the case reported through the MHRA yellow card process?

☐ Yes ☐ No ☐ Unknown

13.4 Who reported the case to MHRA?

☐ Index Anaesthetist ☐ Local Coordinator
☐ Allergy Clinic ☐ Other (please specify)

13.5 Has the event been reported through the Trust incident reporting system?

☐ Yes ☐ No

13.6 Who reported the event through the Trust incident reporting system?

☐ Index Anaesthetist
☐ Another Anaesthetist
☐ Other (please specify)

14.1 (First) allergy clinic letter received by the index anaesthetist or the supervising anaesthetist?

☐ Yes ☐ No ☐ N/A ☐ Unknown

14.2 (Second) allergy clinic letter received by the index anaesthetist or the supervising anaesthetist?

☐ Yes ☐ No ☐ N/A ☐ Unknown

14.3 (Third) allergy clinic letter received by the index anaesthetist or the supervising anaesthetist?

☐ Yes ☐ No ☐ N/A ☐ Unknown

14.4 What was the time interval in weeks between referring the patient to the allergy clinic and the anaesthetist receiving a diagnosis from the clinic?

☐ N/A

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whole number of weeks

14.5 Was the patient's clinical management altered as a result of waiting for a clinic appointment?

☐ Cancer surgery was delayed ☐ Urgent non-cancer surgery was delayed ☐ Non-urgent surgery was delayed
☐ Other treatment was delayed (please specify) ☐ No alteration ☐ Unknown

14.6 How much confidence does the Index Anaesthetist or Supervising Anaesthetist have in the diagnosis made by the allergy clinic?

☐ High ☐ Intermediate ☐ Low ☐ Unknown

Reason for less than high confidence:

14.7 Does the Index Anaesthetist or Supervising Anaesthetist feel that the allergy clinic letter accurately summarises the clinical event?

☐ Yes ☐ No ☐ N/A

What are the discrepancies?

14.8 Does the Index Anaesthetist or Supervising Anaesthetist feel that the allergy clinic provided enough information to enable the planning of a safe future anaesthetic?

☐ Yes ☐ No ☐ Unknown

What is the reason?

Anaesthesia/sedation subsequent to the allergy clinic appointment

15.1 Has the patient received anaesthesia/sedation subsequent to the allergy clinic appointment?

☐ Yes ☐ No ☐ Unknown

15.2 If yes; was this uneventful?

☐ Yes ☐ No ☐ Unknown

If there was a further reaction during this period please provide details, including Severity:

15.3 Has the further reaction been reported to NAP6?

☐ N/A ☐ Yes ☐ No ☐ Unknown

☐ 1. To avoid possible errors please review your entries, **ESPECIALLY NUMBERCAL DATA**, before submitting the completed form

2. Tick the box to the left to confirm that Part B of the webform is complete and accurate

3. When you have checked your entries, select 'SUBMIT' at the bottom of the page. Once submitted you **CANNOT** re-access or edit this form

4. Once you have selected 'SUBMIT' please save a PDF copy of your report by clicking on the 'SAVE PDF' button on the following page. This is important if there are queries about any of your answers

Appendix A

NAP6 papers explained

Previously published 'baseline' papers

Kemp H, Thomas M, Cook TM, Harper NJ. NAP6 baseline survey: UK anaesthetists' perspectives and experiences of severe perioperative anaphylaxis. *Br J Anaesth* 2017; 119: 132-9

- A survey of ≈11,000 UK anaesthetists exploring experience of anaphylaxis in the previous 12 months, in their career and their attitudes to anaphylaxis in terms of concerns and avoidance behaviour with certain drugs.

Egner W, Cook TM, Harper NJ, et al. Specialist Peri-Operative Allergy Clinic Services in the UK 2016: Results from the Royal College of Anaesthetists Sixth National Audit Project. *Clin Exp Allergy* 2017;47: 1318-30

- A survey of all UK adult and paediatric specialist drug allergy services that investigate perioperative anaphylaxis. The survey explores self-reported activity and processes and compared this with published guidelines.

Papers presenting the main NAP6 results

Paper 1

Anaesthesia, Surgery and Life-Threatening Allergic Reactions: Protocol and methods of the 6th National Audit Project (NAP6) of the Royal College of Anaesthetists. Cook TM et al.

- A paper describing in detail how the NAP6 project was performed.

Paper 2

A cross-sectional study of anaesthetic workload in the United Kingdom in 2016: The NAP6 Activity Survey. Kemp H et al.

- A survey of all UK hospitals identifying anaesthetic activity by day of week, by specialty and establishing patient demographics. Providing denominator data for the NAP6 registry to enable calculation of incidences.

Paper 3

Use of anaesthetic drugs in United Kingdom practice. A cross-sectional study within the 6th National Audit Project of the Royal College of Anaesthetists. Marinho Set al.

- A survey of all UK hospitals identifying drug exposures relevant to NAP6. Providing denominator data for the NAP6 registry to enable calculation of incidences.

Paper 4

Anaesthesia, surgery and life threatening allergic reactions. Epidemiology and clinical features of perioperative anaphylaxis: The 6th National Audit Project. Harper NJN et al.

- Main results of NAP6 part 1, describing the epidemiology and clinical features (presenting and through the reaction) of anaphylaxis.

Paper 5

Anaesthesia, Surgery and Life-Threatening Allergic Reactions: Management, outcomes and recommendations in the 6th National Audit Project (NAP6) of the Royal College of Anaesthetists.

Harper NJN et al.

- Main results of NAP6 part 2, describing how anaphylaxis was treated, the outcomes and providing an in depth analysis of deaths. The paper also reports sub-specialty results and presents the project recommendations.

A further paper submitted to Clinical and experimental allergy reports the nature of laboratory investigation of cases reported to NAP6.

Specialist perioperative allergy clinic services in the UK 2018: Results from the Royal College of Anaesthetists Sixth National Audit Project (NAP6) Investigation of Perioperative Anaphylaxis. Egner W et al

- A description of the methods used for investigating suspected cases of anaphylaxis reported to NAP6 and benchmarking this against current standards.

Supplementary Table 1. Definitions of clinical features.

The following text accompanied the table 'Some of the clinical features are subjective. The anaesthetist should use their own judgement when interpreting these definitions. If unsure whether to report a particular clinical feature, the general guidance is to include rather than exclude. NAP6 includes only severity grades 3, 4 and 5, i.e. severe anaphylaxis. Some non life-threatening clinical features may be additionally present and these should be recorded.'

Cardiac arrest	Absence of effective cardiac output.
Hypotension	Fall in blood pressure greater than could be explained by coexisting comorbidities, neuraxial blockade or daily medication
Bronchospasm	Wheeze and/or raised ventilatory pressure greater than could be readily explained by coexisting comorbidities
Cyanosis/oxygen desaturation	Subjective appearance of cyanosis or unexpected fall in SpO ₂
Reduced/absent capnography trace	Unexpected low amplitude of capnography trace, or absent trace
Flushing/non-urticarial rash	Erythema or non-raised rash
Urticaria	Raised wheals
Laryngeal oedema	Glottic swelling seen at laryngoscopy or stridor suggestive of glottic swelling
Swelling/oedema (non-laryngeal):	Any other swelling:
Tachycardia:	Rise in heart rate not readily explicable by coexisting co-morbidities or a light plane of anaesthesia
Bradycardia:	Fall in heart rate not readily explicable by coexisting comorbidities, concomitant drug administration, co-existing beta adrenergic blockade, or vagal reflex
Patient feeling unwell	The awake patient complains of acutely feeling unwell
Itching:	The awake patient complains of itching

Supplementary table 2. Grading of perioperative hypersensitivity/anaphylaxis used for analysis in the NAP6 project. Note this differs from Table 1 in the paper only by inclusion of a nadir blood pressure of less 50 mmHg as a criterion for Grade 4. This is highlighted in red.

Grade	Features	NAP6
1 <i>Not life-threatening</i>	Rash, erythema and/ or swelling	Hypersensitivity - Excluded
2 <i>Not life-threatening</i>	Unexpected hypotension – not severe e.g. not requiring treatment and/or bronchospasm – not severe e.g. not requiring treatment +/- Grade 1 features	Hypersensitivity - Excluded
3 <i>Life-threatening</i>	Unexpected severe hypotension and/or severe bronchospasm and/ or swelling with actual or potential airway compromise +/- Grade 1 features	Included if perioperative anaphylaxis suspected.
4 <i>Life-threatening</i>	Fulfilling indications for CPR +/- systolic blood pressure <50mmHg	Included if perioperative anaphylaxis suspected.
5 Fatal	Fatal	Included if perioperative anaphylaxis suspected.

Appendix 1. Panel review form.

DATE OF REVIEW:

CASE ID:

Does the report meet the inclusion criteria? ☐ Yes ☐ No

If no, why:

Might it be a duplicate? ☐ Yes ☐ No

If yes, action taken:

Is the report interpretable? ☐ Yes ☐ No

If no, action taken:

Timing of event ("induction" refers to first drug/substance administered by the anaesthetist)

- ☐ Pre-induction ☐ After induction and before surgery/intervention
☐ During surgery/intervention ☐ After completion of surgery/intervention

Class of event (as determined by review panel)

- ☐ Allergic anaphylaxis ☐ Non-Allergic anaphylaxis ☐ Anaphylaxis, mechanism uncertain
☐ Not anaphylaxis ☐ Uncertain ☐ Not stated

Class of event (as determined by allergy clinic)

- ☐ Allergic anaphylaxis ☐ Non-Allergic anaphylaxis ☐ Anaphylaxis, mechanism uncertain
☐ Not anaphylaxis ☐ Uncertain ☐ Not stated

Grade of event as determined by review panel: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Uncertain

Immediate care (tick)

	Yes	No	Unclear	N/A
Resuscitation by anaesthetist of appropriate grade				
Prompt recognition of critical event				
Prompt recognition of anaphylaxis				
Appropriate airway management				
Prompt pharmacological treatment for anaphylaxis				
Comprehensive pharmacological treatment for anaphylaxis				
Prompt initiation of cardiac compressions				
Administration of adrenaline when indicated				
Appropriate iv fluid management				
Suspected culprit agent discontinued promptly				
Actual culprit agent discontinued promptly				

Intervention abandoned appropriately				
--------------------------------------	--	--	--	--

Clinical management by the anaesthetist:

☐ Good ☐ Poor ☐ Good and poor elements ☐ Un-assessable

Subsequent care (tick)

	Yes	No	Unclear	N/A
Transfer to different hospital for HDU/ICU				
Written information given to patient prior to clinic appointment				
Appropriate MCT samples requested				
Appropriate MCT results available				
Investigation impacted by un-actioned MCT sample request(s)?				
Was the patient referred to an allergy clinic if appropriate?				
Was adequate information provided to the allergy clinic at referral?				
Was the clinic waiting time significantly detrimental to the patient?				
Patient given written information by anaesthetist prior to clinic appointment				
Patient given hazard warning e.g., Medic Alert by anaesthetist				
Case reported to MHRA by anaesthetist				

Referral to allergy clinic:

☐ Good ☐ Poor ☐ Good and poor elements ☐ Un-assessable

Allergy clinic investigation (tick)

	Yes	No	Unclear	N/A	if no specify
All potential culprits investigated					
Sufficient panel of muscle relaxants*					
Chlorhexidine investigated*					
Latex investigated*					
Appropriate SPTs*					
Appropriate IDTs*					
Appropriate blood tests					
Was it necessary to measure baseline MCT in clinic					
Appropriate challenge tests					
Appropriate advice on future avoidance					
Written information to patient e.g. copy of clinic letter					
Clinic letter to anaesthetist					
Clinic letter to GP					
Patient given Hazard Warning e.g. Medic Alert by clinic					
Case reported to MHRA by clinic					

* see crib sheet

Allergy clinic investigation:

☐ Good ☐ Poor ☐ Good and poor elements ☐ Un-assessable

Culprit agent(s)

Identity of drugs/substance suspected by:	Drug/substance 1	Certainty H/I/L/Not stated	Drug/substance 2	Certainty H/I/L/Not stated	Unable to identify (tick)	Not recorded (tick)
Anaesthetist						
Allergy clinic						
Review panel						

CONTRIBUTORY AND CASUAL FACTORS

Specific (tick those that apply)

	Yes	No	Unclear	N/A
Incomplete pre-intervention allergy history				
Pre-intervention allergy history not heeded				
Possibility of cross-sensitivity not heeded				
A previous reaction was not appropriately investigated				

Was the index event preventable? ☐ Yes ☐ No ☐ Uncertain

If yes, how might it have been prevented?

--

If there was a further reaction, could it have been prevented?

☐ Yes ☐ No ☐ Uncertain ☐ N/A

If yes, how might it have been prevented?

--

SEVERITY OF PHYSICAL HARM (NPSA)

This is the harm occasioned by the whole episode (see crib sheet)

Severity grade	Description (tick against the most severe feature)	Tick
Uncertain	Insufficient information	
None	No harm (whether lack of harm was due to prevention or not)	
Low	Minimal harm necessitating extra observation or minor treatment	
Moderate	Significant, but not permanent harm, or moderate increase in treatment	
Severe	Permanent harm due to the incident	
Death	Death due to incident	

DEPARTURE FROM GUIDELINES

Significant departure from:	Unclear	N/A	Yes	No	If yes specify
AAGBI Safety Guidelines					
RCUK Guideline					
BSACI Guideline on investigation					

Lessons to be learned:

Any possible recommendations arising:

Amend Summary Narrative (i.e. modify draft prepared by NH) ☐ Yes ☐ No

Action taken:

Consider: Any further information needed. If yes, action taken:

Is this case suitable for a vignette? ☐ Yes ☐ No. If yes, why?