NAP6 LOCAL CO-ORDINATOR GUIDE FOR INDEPENDENT HOSPITALS

21st January 2016

Summary of amendments

The inclusion criteria have been revised in the light of queries from Local Coordinators (LCs) – thank you.

1. The inclusion criteria have been expanded to incorporate patients undergoing interventional procedures under regional anaesthesia, local anaesthesia and managed anaesthesia care (monitoring by the anaesthetist), as well as sedation and general anaesthesia. This change applies across NAP6 and affects both the Core Project (case reports) and the Activity/Allergen Survey. Please see pages 2 and 3. Patients should be included only if they are under the care of an anaesthetist.

2. We have clarified which cases from HDU/ICU/ED should be included. Please see page 3.

3. We have amended the table to emphasise that only Grade 3, 4 and 5 cases in which anaphylaxis is suspected should be reported. Please see page 3.

We hope this makes things clearer for all.

First and foremost, we wish to thank you for agreeing to take on the role of Local Co-ordinator (LC) for NAP6: a role crucial to the success of this important national project. This is the first National Audit Project (NAP) from the Royal College of Anaesthetists to take reports from the Independent Sector. Your work will be instrumental in this being a feature in future NAPs.

Many LCs who have volunteered for this role also served as local reporters/co-ordinators for previous NAPs projects, so are familiar with many activities such as uploading of information onto a secure website. There are some procedural differences between NAP6 and previous NAPs, and of course some of you will be new to the role of LC. This document is a guide to the role of NAP6 Local Co-ordinator, so that you can understand and plan what will be needed to perform the role successfully.

One of the key differences between previous NAPs and NAP6 is the cross-specialty collaboration with allergists and immunologists. In addition to reporting details of the anaphylactic reaction, LCs will be asked to input information they receive from the allergy clinic about the outcome of allergy testing. By "closing the loop" in this way, we will be able to record the final diagnosis and the clinic's recommendations for future anaesthesia. Another reason for working closely with allergy clinics is so that we can build up a picture of specialist perioperative allergy clinics across the UK, with a view to improving the provision of these services to the anaesthetic community.

For each activity, there may be further information that we send, as not all the protocols are finalised. For general information, there will be articles in the Royal College of Anaesthetists' *Bulletin*, and also online at the National Institute of Academic Anaesthesia (NIAA)/ Health Services Research Centre (HSRC) website (http://www.niaa.org.uk/HSRC_home under 'Projects') and the NAP6 website (http://www.nationalauditprojects.org.uk/NAP6home).

Project outline

NAP6 is in 3 parts:

- **Baseline Survey (NHS hospitals only)**
- **Core Project**
- **Activity/Allergen Survey**

We can reassure you that additional phases will not be added to NAP6, so what we currently plan in terms of phases is all that we will ask you to help with.

Baseline Survey

There will be no Baseline Survey for the Independent Sector. However, Local Coordinators in independent hospitals as well as NHS hospitals will be asked to complete a brief, on-line Organisational Survey about the hospital's policies for perioperative anaphylaxis.

Core Project (Case reports)

This will run with a similar process to that of NAP4 and NAP5.

The Core Project will begin in independent hospitals on 5 February 2016 and last for nine months. From 5 February 2016 and on a monthly basis until 4 November 2016, LCs will be asked to check and report whether there have been any cases of severe perioperative anaphylaxis in the independent hospital(s) they are reporting for. The method of reporting cases is described below.

Activity/Allergen Survey

This survey will be carried out in Spring 2016. Its purpose is to obtain quantitative information on patient exposure to a wide range of potential allergens such as anaesthetic drugs, antibiotics etc.

One survey form (paper) will be completed by the anaesthetist for all interventional procedures (GA, RA, sedation or managed anaesthesia care). Each hospital will be asked to carry out the survey on two specified consecutive days. These two days will be randomly allocated to hospitals (with the exception of specialist hospitals which will have a different allocation process). LCs will be asked to co-ordinate this survey in their hospital to ensure that all anaesthetists are aware of the survey and to check that a survey form is completed for every patient. Survey forms will be returned by LCs to NAP6 for collating and processing. This information will be used with the results of NAP6 case reports to enable the NAP6 team draw inferences about the relative risks of severe anaphylaxis arising from exposure to potential perioperative allergens.

Inclusion and exclusion criteria

NAP6 will collect reports of severe (i.e. life-threatening) perioperative anaphylaxis in adults and children.

Perioperative anaphylaxis: Anaphylaxis which 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-med) and the post-procedure transfer to the ward, HDU or ICU.

Cases should be reported only if anaphylaxis is suspected and the severity of the reaction is Grade 3, 4 or 5 (see table, below).

<u>Grades of anaphylaxis</u>. A suspected anaphylactic reaction characterised by the following:

Grade	Features	NAP6
1 *Not life-threatening*	Rash, erythema and/ or swelling	Excluded
2 *Not life-threatening*	Unexpected hypotension – not severe e.g. not requiring treatment and/or bronchospasm – not severe e.g. not requiring treatment +/- Grade 1 features	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 IS SUSPECTED
4 *Life-threatening*	Fulfilling indications for CPR	INCLUDED IF PERIOPERATIVE ANAPHYLAXIS IS SUSPECTED
5 Fatal	Fatal	INCLUDED IF PERIOPERATIVE ANAPHYLAXIS IS SUSPECTED

Anaphylaxis is a severe, life-threatening, generalized or systemic hypersensitivity reaction. Although it might be interesting to include the common minor perioperative reactions in NAP6, the number would be overwhelming and this information is unlikely to benefit patients to the same degree. Therefore, NAP6 includes only severe anaphylaxis (grades 3-5).

Patient location

All hospital locations are included. For practical reasons we include patients from HDU/ICU/ED only if a general anaesthetic is administered by an anaesthetist for an interventional (not resuscitation) procedure.

LCs in independent hospitals should report all cases of suspected anaphylaxis that occur in their hospital(s) regardless of how the patient's care is funded – i.e. insured, self-pay and NHS-funded.

Monthly reporting

LCs will be asked formally to check with the following sites for any such cases:

- The anaesthetic department, if appropriate (e.g., by monthly email shot, or formally raising the question at any departmental or staff meetings)
- ICU/HDU
- Elsewhere in the hospital as necessary

During NAP6, as for NAP5, **each month the LC will be asked to report the number of cases of severe perioperative anaphylaxis in their hospital, including when this is zero**.

Reporting cases
Cases should be reported as soon as possible after the suspected anaphylactic event has occurred. Please do not wait until the cause has been investigated in an allergy clinic before reporting the case. There will be an opportunity to add the allergy clinic information to your report.

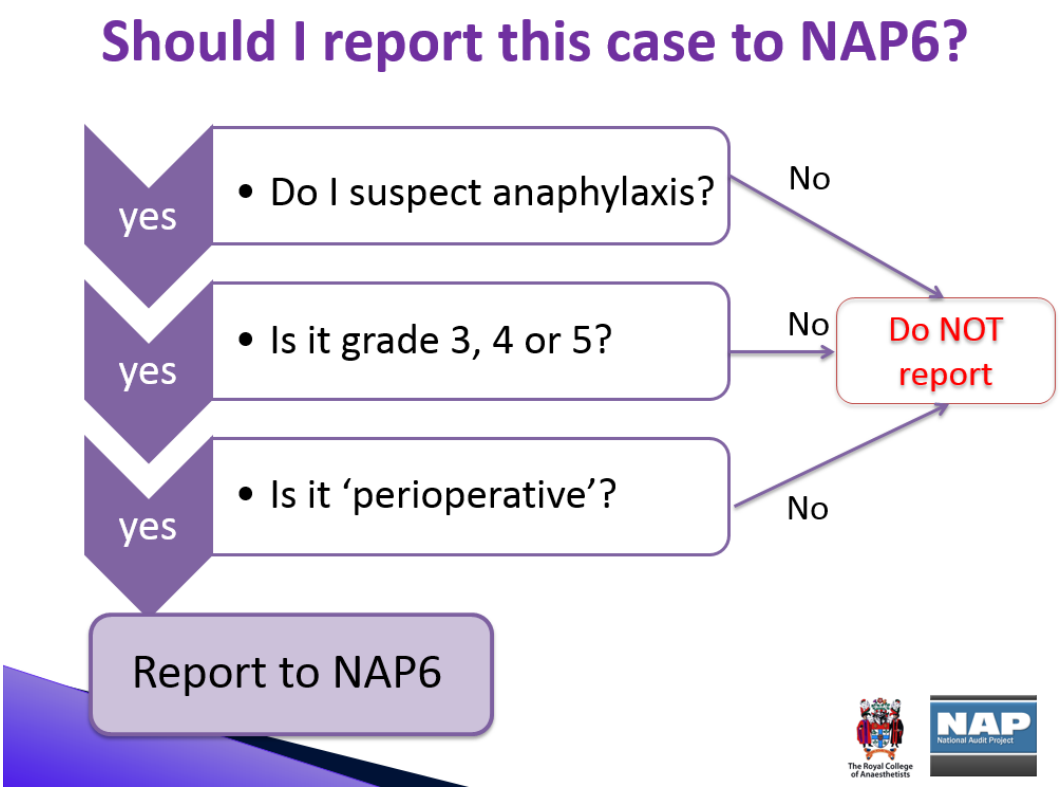
All cases of perioperative anaphylaxis fulfilling the inclusion criteria should be reported to NAP6 if the suspected anaphylactic event occurs between 00.00 hrs on 5th February 2016 and 23.59.59 hrs on 4th November 2016. Some of these patients will inevitably be investigated in and allergy clinic after 4th November 2016 and the information from the allergy clinic will be entered after the clinic letter has been received by the referring anaesthetist. The cut-off date for entering allergy clinic information will be 4th May 2017.

If the LC becomes aware of a case of suspected severe perioperative anaphylaxis in their hospital(s), the following steps will be necessary:

1. Liaise with the anaesthetist(s) involved if they have not already contacted you.
2. Contact NAP6 (NAP6@rcoa.ac.uk) where we will issue you with separate Case ID and Password for each case.
3. Retrieve anaesthetic and other relevant case notes
4. Extract the key information. Data will include: age range, weight, surgery type, induction agents and doses, maintenance drugs, resuscitation, patient outcome etc. A PDF of the information required is available on the NAP6 website and you may wish to use this a guide before reporting the case via the NAP6 on-line webtool. It is expected that you will need to discuss the case in detail with the anaesthetist(s) involved.
5. Use the provided Case ID and Password to access the secure webtool and upload the information. **Data entry will be a two-step process:**
    - Part A will record patient details and the details of the event
    - Part B will allow LCs to enter information provided by the allergy clinic when the cause of the reaction has been investigated.

        No patient-identifiable information will be entered.

An aide memoire for reporting



Which hospitals are taking part?
All NHS hospitals will take part in NAP6, plus a number of Independent Sector hospitals that have committed to the data capture terms and conditions.

NAP6 report
All cases and the two surveys will be analysed by a review panel including appropriate stakeholders. Analysis and writing/publishing takes approximately 15 months. We anticipate the NAP6 report will be published in Spring 2018.

SPAs and support for LCs
It is our view that all activity related to the NAP6 Local Co-ordinator role in the Independent Sector is performed by local agreement or as "pro bono". The College will provide evidence in support of relevant activity. In recognition of the role played by the NAP Local Co-ordinators we will send you a certificate confirming the role, which you may include in your personal portfolio.

NAP6 Queries – FAQs v.1
Last updated 29 January 2016.

Clinical queries

1. **Can I just check that local/regional procedures are excluded (unless done under sedation or if GA is co-administered)?**

   The inclusion criteria have been widened and all cases attended by an anaesthetist are now included. **Please see the updated LC information pack which is available to download on our website:** (http://www.nationalauditprojects.org.uk/NAP6-Resources).

2. **Where will bone cement implantation reactions fit into NAP6, mimicking as they do anaphylactoid reactions?**

If the timing of the reaction strongly suggests Bone Cement Implantation Syndrome such that anaphylaxis is not suspected, it is not necessary to report the case to NAP6. However, if anaphylaxis is suspected (or indeed part of a differential diagnosis) the case should be reported.

3. **Do we include cases that have been done under local anaesthetic or regional block with no sedation for example Caesarean section under spinal anaesthesia? These patients will still be receiving a variety of drugs including in most cases antibiotics.**

   Yes these are now included. **Please see updated inclusion criteria below** (this is contained on p2. of the LC info pack).

4. **Are children included?**

   Yes, NAP6 will collect reports of severe (i.e. life-threatening) anaphylaxis in adults and children.

5. **What is the definition of "perioperative anaphylaxis"?**

NAP6 definition of perioperative anaphylaxis

Anaphylaxis which occurs:

- in a patient undergoing a procedure requiring general or regional anaesthesia or sedation or managed anaesthesia care (anaesthetist monitoring only)

AND

- under the care of an anaesthetist

AND

- between the period of first administration of a drug (including pre-med) and the post-procedure transfer to the ward, HDU or ICU

6. **Grade 2 anaphylaxis states hypotension / bronchospasm not requiring treatment. I just want to clarify, if a patient receives simple treatment like any vasopressor (ephedrine/metaraminol/phenylephrine) or salbutamol nebs for bronchospasm – are they excluded?**

The definitions in the table (below) are pragmatic. Remember that all the definitions start with 'suspected anaphylaxis'. If anaphylaxis is not suspected, there is no need to report the case to NAP6. There is an element of judgement in deciding whether hypotension (or bronchospasm) was mild or severe and hence whether the case was Grade 2 or 3. To aid judgement we have described grade 2 as 'e.g. not requiring treatment'. However it may be that someone with relatively mild hypotension and suspected anaphylaxis receives modest doses of a vasopressor or fluid. This might still be consistent with 'mild hypotension'. Hypotension that is profound, sustained, resistant to treatment or requires extensive treatment is 'severe' and thus the case is grade 3.

Grades of anaphylaxis. A suspected anaphylactic reaction characterised by the following:		
Grade	**Features**	**NAP6**
1 *Not life-threatening*	Rash, erythema and/ or swelling	Excluded
2 *Not life-threatening*	Unexpected hypotension – not severe e.g. not requiring treatment and/or bronchospasm – not severe e.g. not requiring treatment +/- Grade 1 features	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 IS SUSPECTED**
4 ***Life-threatening***	**Fulfilling indications for CPR**	**INCLUDED IF PERIOPERATIVE ANAPHYLAXIS IS SUSPECTED**
5 Fatal	**Fatal**	**INCLUDED IF PERIOPERATIVE ANAPHYLAXIS IS SUSPECTED**

7. **Cross speciality - Are the immunologists also going to enter the data, have they been informed separately already?**

   Data will not be entered by Immunologists and allergists. The reporting form will be in two parts. In part A, the case details will be reported. In part B, the LC/reporting-anaesthetist will enter the information provided by the allergy clinic in their clinic letter after the patient has undergone investigation. Allergists and immunologists will be aware of NAP6 because a survey of allergy clinics will take place, but they will not be asked to enter any information about specific cases.

8. **Are HDU, ICU and the Emergency Department included?**

   Yes, but only if the patient received a general anaesthetic for an interventional procedure (not resuscitation) administered by an anaesthetist.

9. **In some areas like endoscopy – the surgeons and endoscopist provide sedation to the patients. Any allergic reaction noted or occurring in that setup is not included in our audit – is that right?**

   Yes, we are only including cases under the care of an anaesthetist at the time of the reaction.

10. **I am registering this audit and would appreciate it if you could let me have some details of the protocol with details of the methodology, data collection items etc.**

    If your audit department needs a full list of questions to be asked in the baseline and registry phases these will be placed on the NAP6 website at (link tbc). We can also send a copy of the data forms when completed upon request.

11. **What time commitment is required from LCs?**

    As the arrangements between hospitals vary it is difficult to ascertain a set amount of time required. However, a feedback survey from the last NAP confirmed that LCs took, on average, an hour per week to perform the required data collection. Please refer to the LC information pack for key information containing the timelines.

12. **When is NAP6 expected to start and finish?**

    NAP6 in the Independent Sector runs 5 Feb 2016 – 4 Nov 2016.

Yours sincerely,

Nigel Harper

Professor Nigel Harper
Consultant Anaesthetist, Manchester
& NAP6 Lead

Dr Tim Cook
Consultant Anaesthetist, Bath
& Director of NAPs

If you have any further queries relating to your role as LC, please do not hesitate to contact Professor Nigel Harper, NAP6 Clinical Lead, via NAP6@rcoa.ac.uk