EXTERNAL REVIEW OF NATIONAL AUDIT PROJECTS 3&4

EXECUTIVE SUMMARY

1. The National Audit Projects are internationally important reports with the potential significant impact on patient outcome and experience during and after anaesthesia and surgery.

2. The chosen topics are relevant to patients, anaesthetists and the wider health service.

3. The NAPs are of generally very high quality in terms of process, data collection and analysis.

4. The NAPs represent good value for money for the Royal College of Anaesthetists and the anaesthesia profession as a whole.

5. There could be greater clarity over the precise purpose of the projects in the future.

6. The dissemination process should be an integral part of the project from the start.

7. Consideration should be given to the role of repeating / closing the loop of NAPs 3 & 4 at an appropriate interval.

8. Consideration should be given to a defined parallel process for producing recommendations for practice.

9. HSRC should consider formal succession planning for the time when Dr Tim Cook demits his official and unofficial roles to ensure that organisational memory is not lost.

10. Future NAPs should consider whether formal sub-studies to investigate specific questions / generate hypotheses would add value to the overall NAP process.

11. The NAP process could usefully be extended to include independent practice.

12. The possibility of exporting the NAP ‘brand’ to other countries should be considered.

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TERMS OF REFERENCE

To conduct formal external review of the National Audit Projects (NAP 3 and NAP 4) run by the Royal College of Anaesthetists.

CONFLICTS OF INTEREST

- I am a Fellow of the Royal College of Anaesthetists and member of the Association of Anaesthetists of Great Britain & Ireland.
- I am not a member of any of any of the specialist societies directly linked to either of the NAPs.
- I am a member of the BJA editorial board and sit on the NIAA research council.
- I am on the advisory board of, and am an author for, EIDOhealthcare, a company which produces medical information leaflets. I have not discussed this review with them; to the best of my knowledge, there is nothing written in this report, or that I have heard during my review, which would be of any benefit to EIDO beyond that which is already in the public domain.
- I have no pecuniary interest in any other organisations which might benefit from anything in this report.

BACKGROUND AND CONTEXT

The National Audit Projects for anaesthesia have developed over time from surveys of anaesthetic process (NAP1 and 2) to intricate surveys of outcome related to anaesthetic practice (NAP 3 -5). The Royal College of Anaesthetists allocated approximately £150,000 to this project in 2001.

- NAP1 : Supervisory Role of Consultant Anaesthetists
- NAP2 : Place of Mortality and Morbidity Review Meetings
- NAP3 : Major Complications of Central Neuraxial Block in the United Kingdom (joint with National Confidential Acute Pain Critical Incident Audit)
- NAP4 : Major Complications of Airway Management in the UK (joint with Difficult Airway Society)
- NAP5 : Accidental Awareness during general anaesthesia (joint with AAGBI)

The underlying purpose of the current NAPs is implicit:

To improve **outcomes** and **safety** for patients following anaesthesia or anaesthetic interventions with a focus on topics that are:

- Potentially serious for patients
- Of interest to anaesthetists
- Of interest to patients
- Uncommon enough that only a national approach will provide adequate information.

Secondary aims of the NAPs include:

Raising awareness of anaesthesia, pain and critical care in

- the wider medical community
- the media

- national bodies
- local hospitals and Trusts

Embedding quality improvement within anaesthetic departmental practice

PROCESS OF REVIEW

Opinion on the NAPs was requested by letter / email from various stakeholders. Some of these replied by email, others were interviewed in person by the author.

- Association of Anaesthetists: President
- Royal College of Anaesthetists: President; Deputy Chief Executive and Director of Professional Standards; Patient Liaison Group
- Intensive Care Society
- Obstetric Anaesthetists Association
- British Pain Society
- Difficult Airway Society
- International review was sought from the US and Australia

Complete Review of literature and reports

Extensive discussion with Tim Cook

Informal discussion with 'on the ground' anaesthetists

FINDINGS

The findings are all grounded in the implicit outcomes of the NAPs listed above. For brevity, these will not be repeated unnecessarily.

TOPICS

The choice of topics was in part serendipitous, due to co-incidence of the desires of the specialist societies (Pain and Difficult Airway) and the College.

The topics for NAP 3, NAP 4 (and NAP 5) are of relevance to every anaesthetist both in the UK and internationally. They also have relevance to patients, non-anaesthesia healthcare professionals, and the media.

Although there is an argument for including peripheral regional anaesthesia within NAP 3, this author believes that would have been inappropriate; partly due to the relative inexperience of the team and process and because it would have created a far more complicated study where messages would have been lost.

The process of topic choice has become more transparent with each NAP.

There needs to remain an element of cabinet decision making on the final choice of topic, to avoid the NAP process being asked to answer unanswerable questions.

The decision process could benefit from a clear separation of choice of topic, which derives from the wider anaesthesia / patient community, and the partner organisations (specialist societies) that help deliver the projects.

This would help protect against (unfounded) suggestions that partner organisations were in any way misusing the NAP machinery.

TEAM

The success of the NAPs is dependent on all aspects of the NAP team.

NAP LEADERSHIP

In the perception of anaesthetists, and to large extent in practice, the success of the NAPs is a product of the drive, organisation and skills of Dr Tim Cook. This is currently a huge strength for the NAP process. It is crucial that HSRC commits to succession planning for the time when Tim Cook demits from official and unofficial roles in NAP. There are many other individuals who have made immense contributions to the projects (named in the reports) who should not be forgotten.

NAP SUPPORT

The administrative support within the College is good. There are lessons to be learnt around planning for dissemination. (vide infra)

One almost whole-time administrator was allocated to NAP3 and NAP4; her co-ordination and administration were fundamental to the success of the projects. The Royal College has provided most of the support and infrastructure for both NAP3 and NAP 4. There has been some financial support from the partner organisations directly: NPSA paid some of NAP3 costs; the Difficult Airway Society DAS paid around £10K of NAP4 costs. The considerable time given by David Counsell (NAP3) and officers of the Difficult Airway Society (NAP4) should not be under-estimated.

NAP REVIEW

The clinical review groups were composed of 'representatives' from relevant parties, selected by the partner organisations, presumably based on availability, interest and ability. The final outcome of the review process was good; whether it could have been better with formal selection of review panels based on ability, knowledge and experience is not known. Future NAPs might consider whether an appointments process would add value.

NAP LOCAL REPORTERS

The engagement of local reporters has been key to the whole NAP process. That every department could find an individual to take on this moderately burdensome role is a testament to the professionalism of anaesthetic departments throughout the UK. The local reporters are not directly paid, but it can be argued that such a role justifies at least part of their SPA time and is therefore funded by their NHS employer.

If NAPs are to continue successfully, it is imperative that HSRC / NAP leads have a national strategy for maintaining both individual LR engagement and support from Trust CEOs in straitened financial circumstances.

METHODS

The methods have matured from NAP3 to NAP4. Most of the criticisms which could be levelled at NAP3 were addressed by the NAP team in NAP4. This is evidence of a team that is adaptable and learns from past experience.

ENGAGEMENT

A clear strength of NAP3 and NAP4 was the depth and spread of engagement in the projects by relevant partners:

- All four Chief Medical Officers of the UK
- The relevant specialist societies
- The Medical Protection Organisations

- NPSA
- 100% of relevant NHS trusts.
- >80% of individual anaesthetists in the census phases

This level of engagement may easily be taken for granted, but future NAPs must ensure that they have at least this degree of engagement. As discussed below, there is scope for active engagement of the private sector.

Quantitative

Denominator

Considerable effort was put into quantifying the denominator (number of people / procedures at risk). The two week snapshot used in both NAP3 and NAP 4 was a reasonable balance between precision and reliability of data capture. Purists could argue that greater precision would be obtained with longer periods of collection. Cross validation of the results reported by NAP, HES data (performed informally by the NAP team), and data obtained by the author of this report, would suggest that the denominator is precise enough for its purposes.

There are two caveats.

First, is the lack of independent sector work. At the time of the NAP 4 report, 10% of surgical activity was estimated to occur in the private sector. There is no evidence to suggest that care provided in the independent sector is notably better or worse than in the NHS. It would be reasonable to assume that, at the least, the major players in the independent sector would be willing to engage with the NAP process. Although the numbers involved are relatively small, inclusion of the private practice might improve the penetration of the NAPs into countries, notably the US, where there are philosophical objections to socially provided healthcare.

Second is the lack of a denominator for non-theatre and ICU work. This author believes that the data on the numerator for non-theatre (mainly ED) and ICU complications of airway management speak for themselves. However, the lack of an incidence estimate, in a report which makes potentially uncomfortable recommendations, provides opportunities for criticism by some parties.

Numerator

Two linked questions had to be answered by the NAP team. How to define a complication and how to capture all the complications.

NAP3:

Definition of complication: There is no single definition of complications of central neuraxial block which answers every question. In general, this author believes that the definitions used by NAP3 were appropriate: major complications which caused, or had the potential to cause permanent harm (including drug errors). There are nuances within this definition – permanent harm can be very minor, and temporary harm may have had significant impact on the patient. Given the numbers involved, the author does not feel that finessing the quantitative data to that extent would have added to the reports. The qualitative information is provided in the reports.

Capturing complications: there were several strengths of the NAP approach, which should be embedded in future NAPs: local reporters in 100% of Trusts; multidisciplinary reporting (11 / 67 identifiable reporters were non-anaesthetists in NAP3); cross-checking with NHSLA, NRLS and media reports. The NAP team acknowledge that it is unlikely that every event was captured but, outside of a formal prospective cohort study, it is difficult to envisage significantly better capture at present. Fully integrated electronic records might provide another cross-validation tool, but this is not a realistic prospect in the foreseeable future.

There was a complete separation between details of the reporters and the NAP administrative and / or review teams making it impossible to link cases with originating organisations or individuals. This is highly commendable. Not only did this provide a robust ethical and governance framework for the project but also helped promote the voluntary reporting of incidents.

NAP4:

Definition of complication: There is no single definition of complications of airway management which answers every question. In general, this author believes that the definitions used by NAP4 were appropriate: complications that led to: death; brain damage; need for an emergency surgical airway; unanticipated ICU admission or prolongation of ICU stay.

These definitions have the advantage of being relatively clear. However, the exclusion of events which lead to less serious complications, or which were successfully managed before such serious complications ensued does possibly reduce the power of the qualitative analysis. To widen the definition would inevitably have increased the NAP workload for local reporters and the analysis team if undertaken a national level. A sub-study could perhaps be included a part of future NAPs to address these types of question.

Capturing complications: The process of capture was similar to that for NAP3. The NAP team acknowledged that there significant under-reporting of incidents was possible. This makes estimates of the incidence of major airway complications less precise, but as discussed below, the true value of the NAP process is in the qualitative review; this is unlikely to be heavily influenced by additional cases.

Qualitative review

Anaesthetists, politicians, patients and the media all respond most deeply to stories, anecdotes and vignettes. The detailed review of every case report followed by publication of details of many of these in the final reports is perhaps the most important aspect of the NAPs.

The NAP reports used a robust review process. NAP4 involved a double expert review, which built on the single group expert review of NAP3. The NAP reports, and the process, rightly highlighted the risks of bias in any retrospective review of case management where the outcome is known. It is not possible to say how well these biases were overcome. This is a potential weakness, particularly when recommendations to change practice are made. The assumption that 'poor practice' is associated with outcome is weakened by a lack of evidence of how often good outcome occurs with 'poor practice.'

Within the constraints of practicality, future NAPs might consider the use of good outcome controls, or review of sampled 'rescued' bad outcomes to provide some reference points.

The expert reviewers for NAP3 made a sensible decision to acknowledge uncertainty about causation for neuraxial complications. With hindsight, the use of the terms optimistic and pessimistic, whilst absolutely clear in meaning in the text of the reports, may have lacked clarity for 'headline' reading.

Results

Validity of Quantitative analysis

NAP3: Notwithstanding the relatively minor caveats above, the quantitative analysis is generally robust. The methods are robust enough that estimates of complication incidences are unlikely to be wrong by any clinically important degree. The subgroup analysis of increasingly small numerators and denominators is treated with appropriate caution in the reports.

Although the process of NAP3 was different from, and more robust than previous studies, the results have face validity. The incidences are not wildly different from previous pooled estimates, though probably more reassuring. Due to the absence of non-neuraxial controls, only absolute risk estimates can be provided. Although there are data

from other studies on the risks associated with non-neuraxial analgesia they have different methodologies and lack the comprehensive nature of NAP3.

NAP4: The tables of incidences are based solely on the reported cases. However, the report also, rightly, estimates that it is possible that only 1/3 – 1/4 complications were captured. The headline figure of 1 in 22,000 major airway complications is perhaps reassuring; a figure of 1 in 7,000 probably rather less so.

The NAP report is cautious in its analysis of ICU and ED airway complications simply describing the number and context of the events. The relatively small number of reported events makes conclusions from these more open to criticism. However, the onus is for detractors to demonstrate that complications in these areas are less frequent and better managed following NAP4.

Validity of Qualitative Analysis

NAP3: Considerable thought was clearly given to the possible contributory factors in each of the cases. Ultimately, the narrative reflects the (expert) opinion of the review panel. Other individuals may legitimately disagree with individual conclusions. However, it the opinion of the author that there are no major structural deficiencies in the analysis. There is one major caveat to this opinion. NAP3 only collected cases; no controls were included. Ascribing causation or contribution of process and practice to outcome following neuraxial blockade is therefore problematic. Inevitably, most of the comments in the report are based on expert opinion and when read alone can come across as more dogmatic than perhaps intended. The learning points at the end of each chapter are more nuanced. Consideration could be given in future NAPs to providing explicit details of the evidence (and its strength) used as the basis of the expert opinions.

NAP4: As with NAP3, the review of individual cases is very thorough. The interpretation of the events surrounding the cases is more nuanced than in NAP4 reflecting the multi-individual and evolving nature of airway management. As with NAP3 the lack of controls means that there are theoretical issues with ascribing behaviour or practice as true risk factors. However, the analysis has been done with reference to well recognised frameworks of safety practice and learning.

Recommendations

NAP3 did not include recommendations. However, the learning points which conclude each section are in effect recommendations. With hindsight, the report could have been more explicit about this. These learning points are generally expert opinion, but given the novelty of NAP3 there was little evidence on which to base these points anyway.

NAP4 was much more explicit about recommendations – there are over 160 in total. Most of the recommendations are reassertions of accepted good practice. Some, particularly the recommendation for capnography in critical care units, are more controversial. Very few of the recommendations have direct research evidence to back them up, but are based on an expert review of the reported cases, understanding of airway management and common sense. This is not unreasonable given the nature of NAP4.

With future NAPs, dependent on their topic and findings, there may be a role for a more formal recommendation / guidelines development akin to the practice advisories from the US or AAGBI glossies.

Dissemination

The results of the NAPs have been disseminated in a variety of formats, appropriate for a variety of audiences.

Journal articles:

NAP3:

- Full report - British Journal of Anaesthesia, 2009 (cited 172 times by end 2012);

- Census phase – Anaesthesia, 2008 (cited 25 times by end 2012).
- Follow up - British Journal of Anaesthesia, 2011

NAP4:

- Full report: Part 1: (Anaesthesia) - British Journal of Anaesthesia, 2011 (cited 81 times by end 2012)
- Full report: Part 2 (Intensive care and Emergency Departments) - British Journal of Anaesthesia, 2011 (cited 54 times by end 2012)
- Census phase - British Journal of Anaesthesia, 2011 (cited 12 times by end 2012)

Full report

NAP 3: sent to each UK NHS hospital anaesthetic department (paper and electronic formats), to all persons reporting cases and to heads of all supporting organizations.

NAP 4: paper report sent as for NAP3 and to all hospital chief executives.

Website

The NAPs have a dedicated web presence within HSRC where the reports can be downloaded along with podcasts and webinars.

Lectures: Tim Cook has spoken at around 45 meetings about both NAP 3 and NAP4. The NAP4 team had spoken at more than 100 meetings by the end of 2012.

http://www.bbc.co.uk/news/health-12892141

http://news.bbc.co.uk/1/hi/health/7821056.stm

Media

A press agency was used to facilitate penetration into the non-medical media. This was only moderately successful, though both NAPs were picked up by the BBC, and NAP3 made it into Marie-Claire. The NAP3 press release was picked up by media in 56 countries, and NAP4 in 25, in the initial days following release. There has been a steady flow of requests for information from a variety of media organisations since publication.

Overall dissemination and penetration

Within the academic anaesthesia community, the NAP articles are highly cited, suggesting good penetration. A follow-up survey of reporters found that they had had some interaction with NAP 3 information an average of 2.7 times each. The penetration into individual anaesthetists is hard to gauge. An informal survey of trainees and consultants at the author's institution suggested that all anaesthetists had heard of NAP3 and 4; many had changed their practice on the basis of the reports; very few had read the full reports; final FRCA was cited as a driver to read the reports or papers. The discussion of NAP4 at central / regional teaching meetings such as Core Topics was highlighted. The podcasts have been widely accessed.

The paper reports are quite different in feel between NAP3 and NAP4. NAP3 is relatively brief and an 'easy' read. There are a few aspects of the numerical analysis which are difficult to disentangle between the different tables. NAP4 is a dense, long book covering every aspect of airway management failure from numerous different angles. It is not an easy read, and it is unlikely that many people have read it from cover to cover. The authors took great care to provide accessible information, with an executive summary and a separate list of the recommendations, but there is a risk that the richness and quality of the information has not been fully appreciated.

The penetration of the reports into wider consciousness could have been better. In comparison with the wide attention which reports from other Colleges receive, the NAPs are making ripples rather than waves.

The current website is comprehensive but could perhaps improve its focus and presentation. For instance, the landing pages for NAP – both on the RCOA website and at http://www.nationalauditprojects.org.uk/NAP_home have no explicit information on the purpose of the projects or the potential benefit to patients and anaesthesia.

Future NAPs may benefit from explicit mechanisms to ensure and audit penetration and uptake. These are skills which may not necessarily lie with those of a clinical lead. Such an audit process should attempt to capture the various strands of quality measures: process; training and education; and outcomes. Some of these could be effectively driven by the College, and Association and Specialist Societies. For example, the RCoA accreditation standards could be explicit about specific recommendations; NAPs could be included as core material for training; departments could be encouraged to record and report specific complications or surrogate markers (e.g. time to MRI following 'red flag' symptom onset following epidural analgesia; number of emergency surgical airways). There may be a role for concerted education campaigns around specific themes. These are simply suggestions from the author, there may be other, and better ways.

OVERSEAS

The NAPs have been well received overseas in Europe and Australasia. The papers have been cited by journals across the world, including the USA. Commentary on the reports from two overseas reviewers for this report was positive. Anecdotally, there may be more limited penetration into the US than other countries though this is relatively speculative. Some European countries have expressed a desire to develop local versions of the NAP methodology.

OUTCOMES

Improved patient outcomes have not yet been demonstrated from either NAP, not least because neither has been repeated. However, subsidiary / surrogate outcomes have been investigated to an extent.

NAP3:

Penetration of the reports has been discussed above. Anaesthetists have changed some of the information they give to patients about risk and written information has changed. Without formally repeating the census it is not possible to say whether the impression of a move away from CSE and thoracic epidurals is real, or even related to the NAP 3 report.

NAP4:

Again, it is too early to draw many conclusions about changes. There is some evidence that the report has given impetus towards introduction of capnography in non-theatre areas, and development of better equipped and more standardised airway trollies. This recommendation is in four new / updated guidelines from RCoA, AAGB&I, ICS and European Board of Anaesthesiology. There is an impression that NAP4 has lead anaesthetists to more ready use of large bore rather than narrow bore cricothyroidotomy, but again this would need some element of a formal census to confirm this.

VALUE FOR MONEY

It is not possible to truly cost the NAPs. The College provided a near whole-time administrator for NAP3 and 4. Approximately £50K was spent by the College on NAP3 and £60K on NAP4. This excluded the time for the administrator, other College officers and facilities used to support the projects. There was considerable time given by the key players in addition to the time of the local reporters. The local reporter time is mostly subsumed into supporting professional activities (SPA) time and is therefore essentially funded by the NHS.

CONCLUSIONS

Overall the NAPs were very well run, and well received by anaesthetists in the UK and the various specialist societies. Although this report makes some recommendations for improvement these should not detract from the general extremely high standard of the projects.

The engagement of the anaesthesia (100% of NHS departments) and wider community (CMOs, NPSA, Medical Defence societies), particularly for NAP4 is exemplary and although it appears as only one or two lines in the reports the importance of this, nor the effort to achieve it, should not be understated.

The choice of topics for NAP3 and 4 was good even though the process was a little opaque. Choice of topics for future NAPs will be harder with a need to balance engagement of the anaesthesia community with relevance to the 'outside world'. Repeating NAP 3 and 4 should be considered along with introducing more in depth sub-studies to answer some of the questions about causation and prevention of adverse outcomes. It may also have a role in generating hypotheses for future research.

The methods of data collection and analysis are generally robust. Although it is possible to criticise most aspects to a degree, the NAPs achieved a pragmatic balance of scientific purity and realistic data collection.

The qualitative analysis of the reports improved from NAP 3 to NAP4. These qualitative reports probably provide more useful information for anaesthetists (and therefore patients) than the quantitative data. The quantitative data are still fundamental however, both to provide context to the qualitative data, and to allow future comparison.

The dissemination process could be improved both with regard to the 'outside world' and the anaesthesia community. There has been only a limited assessment of the impact of the NAPs so far, (though future work is planned). This process could be better embedded into the NAP process as a whole.

The NAPs represent excellent value for money to the RCOA, specialist societies and the wider NHS, regardless of how the costs are estimated.

RECOMMENDATIONS

1. There needs to be greater clarity over the precise purpose of the NAPs in the outward facing material – particularly the website.
2. The decision process could benefit from a clear separation of choice of topic, which derives from the wider anaesthesia / patient community, and the partner organisations (specialist societies) that help deliver the projects.
3. There needs to remain an element of cabinet decision making on the final choice of topic, to avoid the NAP process being asked to answer unanswerable questions.
4. It is crucial that HSRC commits to succession planning for the time when Tim Cook demits from official and unofficial roles in NAP.
5. Future NAPs might consider whether an appointments process for the review panels would add value.
6. It is imperative that HSRC / NAP leads have a national strategy for maintaining both individual LR engagement and support from Trust CEOs in straitened financial circumstances.
7. Future NAPs must ensure that they have at least the degree of engagement of NAP 3 and 4 (All four Chief Medical Officers of the UK; The relevant specialist societies; The Medical Protection Organisations; NPSA (Commissioning Board or equivalent); 100% of relevant NHS trusts.
8. Future NAPs could consider the involvement of the independent sector.
9. The complete separation between details of the reporters and the NAP administrative and review teams is highly commendable and should be retained.
10. Sub-studies with more prolonged data collection, more specific / targeted data, with appropriate expert statistical advice at the planning stage could be considered in future NAPs.
11. Within the constraints of practicality, future NAPs might consider the use of good outcome controls, or review of sampled 'rescued' bad outcomes to provide some reference points.
12. Consideration could be given in future NAPs to providing explicit evidentiary tables for basis of the expert opinions.
13. There may be a role for a more formal recommendation / guidelines development akin to the practice advisories from the US or AAGBI glossies.
14. The dissemination of the projects should be explicitly planned for and costed at the start of the NAP process.
15. The website could improve its focus and presentation.
16. Plans to measure the penetration and impact of the projects should be included at the planning stage of future NAPs.
17. Repeating NAP 3 and 4 should be considered along with introducing more in depth sub-studies to answer some of the questions about causation and prevention of adverse outcomes.