



Tim Cook



Alan McGlennan

Key findings

- The care of a substantial proportion of patients undergoing surgery and anaesthesia in independent hospitals is funded by the NHS.
- Only 13% of the 304 independent hospitals contacted by NAP6 agreed to take part. The reasons cited by those unable to take part included the difficulties associated with communicating with the large number of consultant anaesthetists with practising privileges and the lack of an 'anaesthetic department'.
- The NHS and other organisations funding the care of patients in independent sector hospitals should work with regulators and inspectors to ensure that all independent hospitals are included in national audits and registries.
- As very few independent sector hospitals reported to NAP6, the data are unlikely to be representative of the sector, so we excluded the data from formal numerical analysis.
- We are unable to comment either on the frequency of perioperative anaphylaxis in independent hospitals, or on the adequacy of its management or investigation.
- Those cases that were reported to NAP6 showed that life-threatening perioperative anaphylaxis may occur in independent hospitals.
- Solo anaesthetists, isolated locations, the lack of critical care facilities, the potential need to transfer patients to another hospital, and the lack of integrated allergy clinics all present unique challenges to those managing these events in independent sector hospitals.

Introduction

Independent sector hospitals provide a parallel healthcare service to NHS hospitals in the UK. Traditionally, these hospitals provided care for fee-paying and insured patients. More recently, increasing numbers of NHS-funded patients have had surgery in independent sector hospitals, based initially on the 'any willing provider' scheme introduced in 2009, which became 'any qualified provider' in 2011.

Since 2015, NHS patients undergoing surgery have a choice of providers through NHS Choices (<https://www.nhs.uk/pages/home.aspx>) and the NHS e-Referral Service. This system replaced 'Choose and Book', which was established in 2005. In 2016, the UK government committed to extending choice for patients (Department of Health 2017).

In 2017, it was reported that 45% of in patients in independent sector hospitals are NHS-funded, and that in a quarter of private hospitals this number exceeds 50% (CHPI 2017). NHS-funded patients receiving care in independent sector hospitals should receive the same quality of routine and emergency care as NHS patients in NHS hospitals and, of course, these standards should also apply to privately-funded patients. It is also logical that the care provided in independent sector hospitals, particularly when NHS-funded, should be subject to the same degree of audit and quality assurance as NHS hospital care. Engagement by independent sector hospitals with national clinical audits has previously been recommended (Leys 2014).

Most independent sector hospitals are relatively small, and few have High Dependency or Intensive Care facilities (Leys 2014). For this reason, the nature and extent of surgery conducted there and the patients who undergo surgery tends to be of lower risk than in many NHS hospitals (CHPI 2017). With a lower-risk surgical population in these hospitals, it can be anticipated that major complications will arise less frequently. When complications do arise during or after surgery, there may be a need to transfer patients to other hospitals for specialist care. Unlike many such complications, perioperative anaphylaxis is an unpredictable, and therefore largely unavoidable, complication.

Anaesthetists and surgeons may work as individuals in independent sector hospitals, or they may be formed into groups, partnerships or 'chambers'.

For logistical reasons, independent sector hospitals have not been included in previous National Audit Projects. At the inception of NAP6, it was decided that there should be an intention to include independent sector hospitals.

Engaging with the independent sector

In 2015, we began attempts to include all independent sector hospitals in NAP6 in the same manner as NHS hospitals.

In May 2015, the President of the Royal College of Anaesthetists wrote to all independent hospital chief executives highlighting the recommendations made in the 4th National Audit Project (Cook 2011) and seeking their engagement in NAP6. This correspondence was followed by further letters to all hospitals in June 2015. In September 2015 a letter was sent describing the process of NAP6 to those hospitals who had registered an interest.

The independent sector

Also in September 2015, a further letter was sent by the President of the Royal College of Anaesthetists to independent sector hospital chief executives to remind them that 30 October 2015 was the deadline for registering interest in NAP6. As few positive responses were received by this deadline, an email was sent in December 2015 to all independent hospital leads with information about the project and a list of those hospitals participating. Hospitals were contacted using a list provided by the Association of Independent Healthcare Organisations based on Lang & Buisson data.

Many hospitals did not reply to our correspondence. Of those that did, some gave reasons why the hospital could not take part in the project, including:

- The absence of an anaesthetic department to coordinate the project
- The absence of an anaesthetist who could act as Local Coordinator
- The large number of anaesthetists with practicing privileges to the hospital (in one case more than 200) and the variability of their presence at the hospital, meaning that dissemination of relevant information and tracing responses was impractical
- The rarity of anaphylaxis at that hospital
- That the data would be 'confidential' or of a 'competitive nature'.

In view of the practical difficulties, we allowed non-anaesthetist hospital employees to be Local Coordinators, provided they were willing to accept the responsibilities that the role required. By January 2016 41 hospitals had agreed to take part. The NAP6 steering panel met to consider whether the independent sector should be included at all in the project in view of the low rate of engagement. Some of those hospitals and individuals that had engaged had clearly made considerable efforts to do so, and were keen to be part of the project. Conversely, the panel took the view that, with approximately 10% of the sector engaged, the data would not be representative of the sector as a whole and that there was a danger of its inclusion leading to biased results. After much discussion, it was agreed that those hospitals that had volunteered to take part in NAP6 would be included. However, in view of the small number of independent sector hospitals that had agreed to participate, it was agreed 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, ie. a thematic analysis, and not for numerical analysis.

Local Coordinators in the independent sector were sent an information pack designed specifically for the independent sector. We did not perform the anaesthetic baseline survey (see Chapter 7) in the independent sector, as most anaesthetists working in those hospitals would also be employed in NHS hospitals and would have completed the survey at their NHS post. We did not perform an Activity/Allergen Survey (see Chapter 8 and 9) in the independent sector because too few independent sector hospitals were engaged in NAP6 to make any results meaningful. Local Coordinators were asked to complete the Brief Organisational Survey describing local services at their hospitals and to send monthly returns of cases reported including 'nil returns'.

The main registry phase of NAP6 started on 5 November 2015, but because of limited responses it was decided to delay the independent sector part of this until early 2016. Reports from the independent sector were accepted from 5 February 2016 for a period of nine months.

Numerical analysis

Brief Organisational Survey

Twenty-six responses were received covering 33 hospitals (range of hospitals covered by each response 1–4), a response rate of 80% of those who agreed to participate and 11% of all independent sector hospitals. These included both traditional 'private hospitals' and Independent Sector Treatment Centres. Anaesthetic services provided at the location included general anaesthesia in 33 (100%), regional anaesthesia in 32 (97%), sedation in 33 (100%) and managed anaesthesia care in 26 (82%). Thirteen (39%) hospitals had a High Dependency or Intensive Care Unit and two (6%) an emergency department.

The number of consultant anaesthetists on the hospital staff varied widely from 10 to more than 200 (mean 50, median 30).

Eleven (33%) hospitals had an anaphylaxis lead anaesthetist. Guidelines for the management of anaphylaxis were immediately available in the majority of theatres in 28 (85%) hospitals: predominantly the AAGBI guidelines (54% of those with guidelines) or the guidelines of the Resuscitation Council UK (RCUK) (39%), though it was not certain the latter were anaphylaxis-specific rather than Advanced Life Support (ALS) guidelines. Sixteen (49%) hospitals reported having a guideline for immediate investigation of anaphylaxis, and three (9%) a guideline for referral for investigation. Twenty-six (79%) hospitals reported immediate availability of an anaphylaxis pack. Fifteen (45%) hospitals were able to provide details of locations where patients would be referred for specialist investigation; 15 of these were NHS hospitals and one a clinician in the independent sector. Four (12%) commented that referral would be to the patient's general practitioner, and four (12%) described management as 'consultant dependent'. The largest hospital (in terms of consultants with practising privileges) provided a full range of anaesthetic services. It had no anaphylaxis lead, no access to guidelines in theatres, no anaphylaxis pack, and no guidelines or pathways for investigation or referral of cases of perioperative anaphylaxis.

Table 1 compares the responses to the Brief Organisational Survey from NHS and independent sector hospitals.

Table 1. Brief Organisational Survey: NHS and independent sector hospitals

	NHS	Independent sector
Responses		
Number	323	33
% of relevant UK hospitals in that sector	91%	11%
Response rate of hospitals that agreed to take part in NAP6	91%	80%
Staffing		
Consultants (median, range)	32 (1-150)	10-220
Overall size of department	77 (1-228)	-
Services provided		
General anaesthesia	98.1%	100%
Regional anaesthesia	99.4%	97%
Sedation	96%	100%
Managed anaesthesia care	84.8%	82%
ICU or HDU	72.1%	39%
Emergency department	63.5%	6%
Local preparedness		
Anaphylaxis lead	47.1%	33%
Guidelines immediately available	95%	85%
AAGBI guidelines	88%	54%
RCUK guidelines	13%	39%
Anaphylaxis pack	50%	79%
Guidelines for investigation	42.1%	49%
Referral for investigation		
Pathway for referral	13.3%	9%
Known referral location	94.8%	45%
Refer to GP or undefined	0.3%	24%

Main NAP6 case reporting phase

Reporting involved completion of two parts of a case report form: Part A describing the patient details and clinical event, Part B describing allergy clinic investigation (see Chapter 5, Methods). Eligibility required both parts to be submitted.

There were seven requests from independent hospitals to report cases, and each was issued with log-in details. In two cases Part A and Part B of the report form were received and in five only Part A was received.

We do not have data to enable us to calculate incidences of perioperative anaphylaxis in independent sector hospitals. We also have insufficient data to make judgements or comments about the quality of care delivered to patients.

A full analysis of these seven cases is not appropriate, but a few pertinent findings are:

- Four of the patients were aged 66–75 years
- Five patients were undergoing orthopaedic surgery
- All were undergoing elective surgery
- All patients were ASA 2 or 3
- Five patients received antibiotics (nine in total) and four patients received neuromuscular blocking agents (NMBAs)

- Anaphylaxis was reported as Grade 3 in four cases, Grade 4 in two, and the grade was not recorded in one. However, as several cases had a lowest systolic blood pressure below 50 mmHg, the panel would classify three cases as Grade 3 and four as Grade 4
- An anaphylaxis pack was used in three cases, and an algorithm to guide management in six cases
- In five cases the anaesthetist managed the event without assistance; in one case assistance was called for from nursing staff and in one case from another anaesthetist
- CPR was not performed in any of the four cases where systolic blood pressure fell below 50 mmHg
- In four cases the surgery was abandoned, in one it was modified and in two it was completed
- Transfer to critical care was required in three cases
- In two cases the patient was transferred to another hospital for further care
- All seven patients were referred to an allergy clinic for further investigation by the index anaesthetist
- Six of the events were reported to hospital incident reporting systems and none was reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

Discussion**Organisation**

This is the first time there has been an attempt to engage the independent sector in a National Audit Project by the RCoA.

We were unable to recruit the vast majority of independent sector hospitals to the NAP6 project. This was despite considerable effort. We are particularly grateful to those individuals and hospitals that did engage with the NAP6 project, and this has provided some exploratory data.

The organisation of consultant services within independent sector hospitals was judged by some hospitals to be a barrier to engagement in and delivery of such a project. The Care Quality Commission (CQC) has previously highlighted the large number of consultants with practising privileges in private hospitals as a risk to patient safety due to infrequent attendance and unfamiliarity with hospital equipment, procedures and policies (CQC 2016). The fact that hospitals considered their large consultant base a barrier to engagement with NAP6 suggests that this may also impact on information dissemination and engagement in safety-related audit, quality assurance and governance.

It is possible that independent sector hospitals that have anaesthetic groups might be better able to manage projects such as NAP6, but we were not able to explore this directly.

Several independent sector respondents noted that they had concerns about reporting data that might be considered 'competitive'. It is difficult to understand why the sharing of information about adverse incidents in a national audit such

The independent sector

as NAP6 can be deemed to be commercially or competitively sensitive, and it is possible that better prior communication might have allayed these concerns.

The Private Healthcare Information Network (PHIN <https://www.phin.org.uk/>) is an independent, not-for-profit organisation mandated by the government to improve data quality and transparency in the independent hospital sector. PHIN and regulators and inspectors, such as the CQC and the Healthcare Inspectorate Wales, should cooperate, to support or mandate improved engagement in safety-related national audits in the independent hospital sector.

Clinical issues

There is no reason to think that unpredictable severe complications such as perioperative anaphylaxis might not occur in independent sector hospitals. The cases reported to NAP6 confirm this to be the case. Each of these events was unpredictable, potentially life-threatening, and time-critical.

The mainstay of independent sector surgical work is elective orthopaedics, which accounts for a quarter of surgical workload in that sector (Competition and Markets Authority 2014). In 2012, almost 1 in 5 NHS-funded knee and hip arthroplasties were performed in a private hospital (Arora 2014). It is therefore likely that many patients will be relatively elderly, and that many will receive antibiotics (the commonest cause of perioperative anaphylaxis). Our exploratory data support this supposition and also showed that patients may well receive an NMBA. As antibiotics and NMBAs are together the cause of 80% of life-threatening perioperative anaphylaxis events, it is predictable that these events will occur from time to time in independent sector hospitals. It therefore behoves organisations and individuals working in independent sector hospitals to be prepared for the management of these cases.

The Brief Organisational Survey shows that among those hospitals responding from the independent sector there was a degree of preparedness for perioperative anaphylaxis. In some matters preparation appeared less than in NHS hospitals and in others greater. The AAGBI anaphylaxis guidelines were less likely to be available in the independent sector, and it is possible that some respondents were referring to the Resuscitation Council UK ALS guidelines when indicating that the RCUK anaphylaxis guidelines were immediately available. The provision of anaphylaxis packs appears higher in responding independent sector hospitals than in NHS hospitals, but policies and plans for referral for investigation of anaphylaxis appeared unsatisfactory in a substantial number of cases. The data should be interpreted with caution as, although the NHS data is from 91% of hospitals, the 33 responding hospitals from the independent sector represent only 11% of hospitals in this sector. Consequently, there may be inaccuracy or bias in the results. The organisational survey which we used has the potential to identify both good and poor preparedness and this, or a similar set of questions, might be of value to regulators and inspectors in assessing safety of independent hospitals.

In contrast to NHS hospitals, where an anaesthetist in training may join a consultant and where many theatres are generally active simultaneously, this is less likely to be the case in independent sector hospitals, particularly in small units. In most cases anaesthetists will work individually and there may or may not be other anaesthetists present. If they are present, they may or may not be known to each other. When life-threatening anaphylaxis occurs, resuscitation may require more than one person, and sometimes more than one anaesthetist may be necessary. This is particularly so if there are airway complications or cardiac arrest during perioperative anaphylaxis. Ensuring the rapid availability of additional anaesthetists who can assist in these circumstances may be a practical challenge in the independent healthcare sector. This issue has been highlighted before (Leys 2014). Where anaesthetists work together collaboratively, this may be easier to achieve.

Resuscitation from life-threatening perioperative anaphylaxis may require establishment of intensive (Level 3) care. This may be outwith some anaesthetists' normal practice. Where this is the case it can present a significant challenge, and prompt involvement of a specialist intensivist or anaesthetist with the requisite skills may not be easy in an independent sector setting. Again, where anaesthetists work together collaboratively in the independent sector this may be easier to achieve.

After, or sometimes during, resuscitation from life-threatening perioperative anaphylaxis, patients may need transfer to critical care. As most independent sector hospitals do not have critical care facilities, this again poses both organisational, logistical and patient-safety challenges. Not all anaesthetists are skilled in managing transport of critically ill patients. Independent hospitals should consider agreed arrangements for the transfer of patients to nearby hospitals with appropriate facilities.

In NHS hospitals, clinical governance meetings, including Morbidity and Mortality meetings, are a routine part of all anaesthetic departments' practice. These arrangements rarely exist in independent sector hospitals, and the potential to present, discuss, reflect and learn from relevant cases is therefore absent.

Finally, as most independent sector hospitals do not have an in-house specialist allergy clinic, the management of the referral process, ensuring that this is completed, the patient is fully informed and that important drug reactions are reported to regulatory authorities is yet another challenge that should be met by agreed and documented referral and reporting procedures.

In summary, all hospitals, whether NHS or independent sector, must be prepared to treat patients with life-threatening anaphylaxis and manage their onward care. When this occurs in an independent sector hospital, and particularly in small units, there are unique challenges over and above those found when managing patients in large NHS hospitals.

Recommendations

National

- The results and recommendations of NAP6 are relevant to independent sector hospitals and should be disseminated to independent sector hospitals, their governance leads and anaesthetists working there
- For reasons of patient safety and quality assurance, commissioners of services in independent sector hospitals, and both regulators and inspectors, should ensure that these hospitals, and the patients undergoing care in them, are included in national audits and registries.

Institutional

- Independent sector organisations should work to improve engagement with national audits and registries that focus on quality and safety of patient care
- Independent sector hospitals should have the same levels of preparedness for managing life-threatening perioperative anaphylaxis as NHS hospitals. This includes, but is not limited to, an anaphylaxis lead, a resuscitation team, anaesthetic anaphylaxis treatment and investigation packs in all theatres, appropriate training of all theatre staff, immediate availability of first line anaphylaxis drugs (adrenaline and corticosteroids),

prompt availability of second line drugs (glucagon and vasopressin), standard operating procedures for management of anaphylaxis, escalation to provision of intensive care before transfer, ongoing care and transfer to another hospital where necessary, and referral for specialist investigation

- Independent sector hospitals should have systems to ensure safety-relevant matters can be discussed, disseminated and acted on by all anaesthetists who work there. Collaborative working between anaesthetists in independent sector hospitals should be encouraged to increase governance and safety. An 'independent department of anaesthesia' is one solution to this, and this may provide benefits equivalent to those of departments of anaesthesia in the NHS.

Individual

- Anaesthetists working in independent sector organisations should be trained and prepared to manage life-threatening anaphylaxis
- Anaesthetists working in independent sector organisations should participate in national audits and registries
- Anaesthetists working in independent sector organisations should be trained in and prepared to transfer a critically ill patient to another hospital for further care. Where they do not possess these skills, another clinician with these competences should be enrolled in the patient's care.

References

CHPI 2017: No safety without liability: reforming private hospitals in England after the Ian Paterson scandal. Centre for Health and the Public Interest. November 2017. <https://chpi.org.uk/wp-content/uploads/2017/10/CHPI-PatientSafetyPaterson-Nov29.pdf> (Accessed 18 April 2018).

Competition and Markets Authority 2014: Private healthcare market investigation. Final report 2014. Competition and Markets Authority 2014. https://assets.publishing.service.gov.uk/media/533af065e5274a5660000023/Private_healthcare_main_report.pdf (Accessed 18 April 2018).

Cook 2011: Cook TM, Woodall N, Frerk C. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1 Anaesthesia. *Br J Anaesth* 2011; 106: 617-31.

CQC 2016: Kent Institute of Medicine and Surgery: Quality Report. Care Quality Commission 2016. http://www.cqc.org.uk/sites/default/files/new_reports/AAAD9203.pdf (Accessed 18 April 2018).

Department of Health 2017: The Government's mandate to NHS England for 2016-17. Department of Health 2017. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/600604/NHSE_Mandate_2016-17.pdf (Accessed 18 April 2018).

Leys 2014: Leys C, Toft B. Patient safety in private hospitals, the known and unknown risks. Centre for Health and the Public Interest 2014. <https://chpi.org.uk/papers/reports/patient-safety-private-hospitals-known-unknown-risks/> (Accessed 18 April 2018).

Arora 2014: Arora S, Charlesworth A, Kelly A, Stoye G. Public payment and private provision: the changing landscape of health care in the 2000s. Nuffield Trust 2014. <https://www.nuffieldtrust.org.uk/research/public-payment-and-private-provision-the-changing-landscape-of-health-care-in-the-2000s> (Accessed 18 April 2018).