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Lessons for pediatric anesthesia from audit and incident reporting

This review will attempt to put the various systems that allow clinicians to assess errors, omissions or avoidable incidents into context and where possible, look for areas that deserve more or less attention and resource specifically for those of us who practice paediatric anaesthesia. Different approaches will be contrasted with respect to their outputs in terms of positive impact on the practice of anaesthesia. These approaches include audits by governmental organisations, national representative bodies, specialist societies, commissioned boards of inquiry, medico legal sources and police force investigations. Implementation strategies are considered alongside the reports as the reports cannot be considered end points themselves. Specific areas where paediatric anaesthetics has failed to address recurring risk through any currently available tools will be highlighted.

National large scale audit

It has been 10 years since the National Confidential Enquiry into Perioperative Death (NCEPOD) report 'Then and Now'[1] itself a 10 year retrospective which concluded that shortcomings in the provision of high dependency care persisted and the local systems for reviewing perioperative deaths were not fully effective, this was particularly the case for anaesthesia where the majority (72%) of deaths were not discussed formally within the department. If we are to learn the lessons from our most challenging cases there must be suitable platform to analyze the cases. The NCEPOD reporters took care to distinguish between multidisciplinary review and

departmental morbidity/mortality review, re-stating the importance of both. The benefits of multidisciplinary audit are echoed throughout almost all the NCEPOD reports, and this seems to be backed up by other recommendations which have driven changes in our practice: For example the reduction in occasional practice in paediatric surgery and anaesthesia that has occurred within the lifetime of the NCEPOD reports, has been driven by departmental review against accepted standards of care as laid down by NCEPOD. Such reviews are required by the department of health and the General Medical Council in the UK [2]. Adequately funded national large scale audit recommendations will be implemented to a reasonable extent if departments continue to function with their existing levels of resource.

Police/criminal investigations regarding pediatric anesthesia

So should all large reports have their implementation policed? Paediatric anaesthesia has experience of the legal systems involvement in the management of specific incidents: Operation Orcadian involved several police forces in England mounting an extremely thorough investigation on the suspicion that patients were being deliberately harmed by the insertion of pieces of plastic into the anaesthetic breathing system. The operation was highlighted and gained national prominence after the death of a 9 year old boy. The police operation was relatively long, and expensive, it concluded that there was no evidence of criminal offence in the 13 cases it considered. It gave rise to the Expert Group on Blocked Anaesthetic Tubing (EGBAT) [3] under the guidance of the chief medical officer along with the National Patient Safety Agency (NPSA) who took a broader view of patient breathing tube

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blockage concluding that most were not due to foreign bodies. EGBAT also issued guidance for some sensible, minor changes in equipment manufacture.

Police involvement lead to a specific report on 13 cases, it definitely highlighted a specific problem, but was expensive and required the convening of a medical group to carry the principle through to practice. The police force is of course just one part of the legal infrastructure; the legal system has many expert analysts in the field of medical error:

Closed claims projects

The closed claims project [4] has, as its raw data, summaries of closed medico legal insurance claims. These are interpreted by a group of experienced clinicians who have produced an impressive array of reports for the profession. One of the project's inescapabable findings is that even when an anaesthesiologist provides appropriate care (as judged by his/her peers), there is a 40% chance that a malpractice payment will be made [5]. The closed claims study includes over 60% of settled claims, presumably a representative sample, but cannot estimate the incidence of the complications as the denominator is unknown. Although this study is laboured with a protracted legal timeframe and as a consequence reflects practice about 5 years previous to it own reporting, it has been instrumental in influencing practice such as difficult airway management and improved monitoring guidelines.

Both police investigations and the closed claims study have a legal starting point, this usually means that the analysis will focus on individuals' actions. These are important, however much of what we now understand about the genesis of common errors or failures in practice is that there are deficiencies in the system. This may simply constitute awkwardness in achieving best practice: Adequate hand hygiene requires time, availability of appropriate cleaning materials, well stocked at the point of patient care. An education and monitoring system is also necessary and finally an enforcement policy. If any of these is missing an imperfect system exists and this may explain the continued poor compliance and prevalence of MRSA [6]. More complex processes are even more vulnerable to system errors, but remain amenable to change once best practice has been defined. Better methods of prescribing opiates to children by well motivated, well lead and adequately resourced groups of clinicians were able to reduce opiate related adverse drug events by 67% [7].

Subspecialty registry of adverse events

The closed claims study pointed to differences in the aetiology of adult and paediatric cardiac arrest, there was a recognition that this was an important area for further study, and also that the closed claim methodology alone would be insufficient for such a detailed purpose. The Pediatric Perioperative Cardiac Arrest (POCA) Registry [8] was formed as a result; it used a system of voluntary participation, specific institutional reporting officers and anonymisation. Somewhat surprisingly, the POCA registry findings of predominantly cardiac aetiology of cardiac arrest under anaesthesia did not mirror the closed claims study findings of predominantly respiratory aetiology. The causes of these differences were perhaps under-reporting of respiratory events, under-reporting of very sensitive cases (this may also be rephrased as extreme caution in spite of the anonymisation), different time frames of

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study and participation bias – larger institutions were more likely to subscribe to the registry however prosecutors of malpractice claims show no institutional favouritism.

Reports from the POCA registry continue to provide valuable data and practical advice for clinicians concerning the highest risk groups, associated procedures and optimum management strategies for management [9]. It is the largest study of its kind and certainly one of the most valuable. Even the best designed self report audits are likely to suffer from bias and under-reporting but do have the potential to collect specific and clinically relevant information which would be difficult to obtain otherwise. As the Pediatric Sedation Research Consortium reported, the participants in such audits tend to be organised, well motivated departments and thus the findings may reflect best practice [10]. This group found that only 2 patients out of 50000 required CPR during propofol sedation.

Quantification of risk is important in allowing us to allocate resources and in communicating with patients and their parents. Putting a figure onto the frequency of a particular adverse event elevates the information from soft to hard evidence, thus strengthening the information and allowing strategies for the avoidance of the event to be measured.

The Australian Incident Monitoring System (AIMS) [11] is perhaps the best established structured incident review process. Now running for over 20 years it has evolved, expanded and informed. Has this process ensured that the health service learns lessons and alter practice? Staff impressions are that patient outcomes have improved on account of the AIMS process, however many of these are difficult to quantify. Some improvements have been measured and once more, the more specific the information is, the more appropriate clinical data can be produced. The specialty AIMS found that in the lifetime of the project there were very encouraging improvements in problem areas that AIMS had specifically highlighted; breathing system disconnection associated with hypoxic brain injury, recognition of endobronchial intubation and improved monitoring of anaesthetic agents. Although AIMS cannot claim absolute responsibility for these quality improvements it would be churlish not to admit that the introduction of the AIMS system was a hugely significant factor in the safety culture that engendered these changes. *Well administered national reporting systems can play a major role in enhancing a safety culture and establishing best practice. Evidence supports the leadership of such projects being translated into clinical actions [12].*

In contrast to the British and the North American system that have generally focussed on projects of limited lifetimes, or changed focus to specific areas as specific concerns arise, the AIMS has remained more consistent in its methodology. This raises the possibility of using the data collected to monitor effectiveness over time. The administrators of the AIMS system realise that this may introduce a disincentive to reporting, which would be unwelcome in the context of low reporting rates by medical staff [12]. The lesson for implementation here is not that medical staff does not wish to have their case reviewed but that they may wish only to use one system and national systems with a strictly formatted data entry system may generate less appropriate analysis than local review? This view would seem to be supported by the infrequency with which units attempted to benchmark their data to the national dataset. *Longer term audits must address concerns about ease of entering an appropriate dataset and work to ensure those contributing feel a degree*

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of 'ownership' of the system [12]. This includes maintaining a focus on safety improvements, not monitoring directives [13].

The Australian patient safety foundation has upgraded their data input, now called the Advanced Incident Monitoring Study. They have also produced an evidence based crisis management manual for acute healthcare workers which sets emergency algorithms in context.

Specialty society audits

The Royal College of Anaesthetists in the UK has led a series of large audits, the two most recent having been very successful in engaging the profession. National Audit Project 3 (NAP3) concerning complications of neuraxial block [14], obtained an impressive 100% return from anaesthetic departments in the UK for its census phase, thus enabling the authors to publish data with denominators and estimate risks with accuracy and confidence intervals. No self report audit could ever claim a 100% numerator but the methodology allowed for easy reporting before a review stage at which an expert panel adjudicated on the causation of the adverse affect reported. Despite having 21 500 children in the denominator the confidence intervals for risks of complications were very wide and paediatric anaesthetists are left to extrapolate from the findings based on adult patients. NAP4 concerning complications of airway management will report in the first half of 2011. The college has followed up their audits with widespread dissemination of the findings in multiple formats, and is studying how these have been presented and discussed at the departmental level; initial analysis shows 98% of anaesthetists were aware of the results and 2/3 had changed their practice as a result [15]. When published in full

this should give all auditors valuable information as to the most efficacious methods of result feedback. *It is possible to obtain risk estimation data for serious complications through large scale audits.*

The process of obtaining information from private institutions was more difficult than from the NHS and this conclusion potentially applies to systems where the major health provider is the government.

Multicentred audits

An interesting comparison is possible between NAP3 and the national paediatric epidural audit [16] as these two projects concern a similar subject matter with the same population over a comparable period in time. They did not set out to achieve the same end points as a consequence of their design with NAP3 looking for major complications only whereas the paediatric audit through a network of voluntary reporting centres was able to capture minor complications as well. Caution must be exercised when interpreting reported minor complication rates from multicentre audits: The national paediatric opiate audit in the UK [17] studied major and minor incidents with opiate infusions, one of the subsidiary findings was that a high percentage of pump programming errors were reported from one centre. This seems to be a reporting difference rather than an actual complication rate difference. The moral is that whilst we can easily agree on whether a patient has nerve damage present 6 months after an intervention, we find it harder to consistently agree what pump programming errors present a real risk to the patient. The easier an event is to define for an audit reporter, the more reliably it will be recorded and thus the strength of conclusion will be greatest for unmistakable events.

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The recently formed Wake up Safe group [18], a body of the Society for Pediatric Anesthesia in the USA aims to provide a high level peer review for serious incidents and use this information as the building blocks for quality improvement programmes, their initial findings regarding wrong sided procedures and drug errors will be familiar to most experienced practitioners. Whether the multicentre peer review they use can effect greater changes in practice than departmental critical incident analysis or national programmes remains to be seen.

Implementation of findings

Implementation of the findings of national audit is often a more difficult task than the completion of the audit itself. There is no specific funding for implementation. Most units will have clinical governance frameworks and many will have senior clinicians responsible for leading audit processes within the department. An ideal implementation strategy will begin with presentation of the audit findings and provision of supporting educational material – for instance local service audit and local case numbers appropriate to the national audit findings presented. Strategies for improved diagnosis of problems will help to raise awareness at all levels, for acute pain service problems this may take the form of clearer pain monitoring charts, or prompts on the charts regarding when ward staff should seek advice from pain team specialists. These changes will have to be underpinned by education of all staff groups involved with the patients care. Lessons for the individual are less important than those for the team or the organisation [19]. Industry has learned how to bridge the gap between ideal systems and normal day to day practice, this transition needs to happen in medical care as well. Doctors are good at accumulating knowledge and

much less accomplished at translating this knowledge into practice, behavioural change is the key and by that we must understand behaviour of the whole medical team, once again the actions of the individual are less important [20]. Do all our hospitals have incident meetings engaging all staff groups – or do they tend to revolve around groups of senior clinicians with little other input? Some of the issues with implementation of quality improvement (QI) are historical – it is a new science but one which anesthetists should be keen to adopt as targeted QI packages seem to have more effect in acute than chronic care settings [21]. A collaboration of NICUs using structured QI methodology [22] was able to greatly improve their 'on-time' administration of surfactant compared to units using traditional feedback through audit programmes [21].

Institution of practice guidelines sometimes seems like a blunt instrument and guidelines need to be locally appropriate, but sometimes being pedantic and stating the obvious is all that is required; a good example would be the NPSA guidance to prevent the retention of throat packs following surgery [23]; use at least one visual and one written procedure to indicate a throat pack is in place, know who the responsible person is and educate all staff about standard operating procedures (SOPs). This raises the question, why does it help us to re-state something we already know? The reason is that knowledge failure is less common than implementation failure [24]. Evaluation systems for the kind of non-technical skills that lead to these implementation failures exist but even with expert leadership it can be difficult to implement their use in the clinical environment [25]. Some notable progress has been made in guideline implementation recently; the programme of care 'bundles' by the Institute for Healthcare Improvement has very practical advice and up to date audit data which provides clear information exchange on proven

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effective interventions for those wishing to reduce the incidence of ventilatorassociated pneumonia in PICU for example [26].

Audits and guidelines

Audits are one of the principal tools for learning about resuscitation. Resuscitation is perhaps the most obvious of protocol directed management in anaesthesia. Conventional study design presents practical difficulties that are extremely difficult to overcome and large retrospective cohort studies yield valuable information concerning cardiopulmonary resuscitation. What does analysis of this area tell us about implementation of findings of audit? Little in isolation is the first point to make, there have been changes in practice such as more widespread teaching of advanced life support courses and simplification / convergence of resuscitation algorithms that have served well to improve outcome [27, 28]. But these changes would not have occurred without the audits that raised concerns and pointed towards the best route forwards. SOPs are the way in which the military ensure that predictable tasks are completed efficiently and thoroughly. SOPs fit hand in hand with military culture. SOPs are readily established by pre-deployment training for military clinicians and this approach has measured positive outputs [29]. Healthcare providers are not as easily able to send teams of clinicians on intensive training courses but the principle of focussing on reliable stepwise completion of important procedures remains sound, even if the implementation is by coercion not compulsion. The WHO surgical safety checklist is an example of team behaviour change driven by repeated serious incidents, an immense amount of effort was necessary for this to be established but the demonstrated improvements should enshrine this process into routine medical

care [30]. Individual behavioural change in healthcare workers is possible by identifying and removing the many barriers that may make adherence to good practice difficult - hand hygiene is an obvious example again [22]. Continually audited small incremental change may engender better behavioural change than one fell swoop, according to the Breakthrough Series curricula [31].

Departmental audits

Local audits generally do not reach the pages of widely read medical journals, Editors must be increasingly cogent of their impact factor in an age where medical publishing competes with internet based sources of information and only the highest quality paper publications will survive. The benchmark for publication of audits seems to be very high indeed, departments who keep internal databases including morbidity can produce important findings that would be extremely difficult to obtain using other audit methodologies. The Boston children's hospital was able to determine that although the incidence of cardiac arrest was higher in children undergoing cardiac procedures, the mortality was not [32]. The Neurosurgical centre in Belgrade were able to highlight the sitting position and operative time >2hours but not age - were associated complications [33]. If as a profession we believe in the dissemination of findings and good practice could the bulletins and supplements that accompany our scientific journals carry an audit of the month page? Local audits have the benefits of specific design for the area being studied and consistency of data collection. Perhaps most importantly, the findings will be relevant to the working environment. This is why local audits can be a powerful force for change. All readers will be aware that this change does not always follow well intentioned

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recommendations. Lack of implementation is often a resource issue, the other main barrier is one professional group recommending changes that affect the work of another group. A well designed project will form a team at the start that can represent all parties to whom recommendations may apply. Whilst we require a large denominator when studying complications, consistency of recording is the most important factor in audit design when examining efficacy; only local audits have been able to detailed efficacy e.g. pain scores. No large scale audit has been able to achieve this which serves to emphasize the requirement of local *and* national audits to guide the provision of appropriate services.

The future of audit self educating and steering the profession can in no way be taken for granted. The president of the Royal College of anaesthetists in the UK has recently appealed for greater participation in the ongoing NCEPOD study examining perioperative death in children [34]. Under-reporting appears to be common in local audits as well as national projects, simple apathy that reporting will do no good is one reason, concerns regarding the confidentiality centrally held databases reduce reporting rates in addition to possible disciplinary consequences must also be considered. In the UK the privileged status of anonymised audit records from legal scrutiny has yet to be tested in the courts[35] The Australian legal system has taken a pragmatic approach and protected the anonymity of databases held for quality improvement

Challenges for audit in paediatric anaesthesia

When audit goes wrong; the ramifications of the Kennedy report into cardiac surgical services from children at Bristol [36] continue to affect the way that medical care is

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delivered. Problems came to light after an audit by an anaesthetist found a high mortality, the data was inadequately scrutinised prior to wide reporting and created huge amounts of bad feeling between groups of doctors and between doctors and patients. This led to an inglorious mud slinging match between several parties in the medical and national press [37]. The report by Ian Kennedy, Professor of Health Law, Ethics and Policy was a detailed retrospective examination geared to produce a set of recommendations for future practice, it espoused the principles of patient centred care, openness, competence, accountability and quality improvement. To its credit is one of the few large reports on the fundamental causes of adverse incidents that has sustainable funding to ensure there is continuing audit and appropriate risk management processes in place. It is incumbent on those who administer audits and incident management programmes to feed back adequately to those who provide the input. Kennedy realised that bad systems would perpetuate bad decisions, these systems may be physical, procedural or administrative in which clinicians are apt to fail unless they are either very good or very lucky. Unfortunately, systems are harder to test than individuals and the tools used for appraisal and revalidation are largely blind to the context in which the clinician works.

We continue to fail on the implementation as well as the process of incident reporting in some areas as well; Cases of administration of epidural medicines into intravenous lines continue to be reported albeit rarely, but with disastrous consequences. These are not new complications – their solution may involve the profession acting with equipment manufacturers . Manufacturers continue to produce more sophisticated devices, smart infusion pumps for example may have the capacity to reduce medication errors – one of our most common type of error in pediartic practice, but this potential frequently is not realised [38]. The type of errors

may change, but behavioural aspects and basic programming errors e.g. decimal point errors still persist.

Changing practice on the result of local or national incident reports is not as important as a unit adopting a process of quality improvement involving evaluation of changes within the workplace.

Another example of failure to progress a relatively common problem is the lack of consistent labelling and administration system for medications. Other articles have explored the reasons why these errors continue to happen [39]. But one common factor in our professions inability to implement working solutions here seems to be that these issues demand partnership with industry, the FDA or its equivalent.

Our representative bodies do engage with these industries, but whereas ASA guidelines will be adopted by the profession, no such degree of influence can be brought to bear on other industries – or the problems mentioned would have been resolved. A higher level of control is required and this will require our professional bodies continuing to lobby government.

Table 1. Incident and error report types and outcomes

Type of report	Examples	Lessons learned concern these areas	Caveats	Chances of Implementation
Nationally funded mortality audit	NCEPOD [1]	Organisation of healthcare. Local mortality review	Implementation not well funded and administered	Reasonable chances but slow
National incident database. (Long-term)	AIMS[12]	Wide range of common errors and problems	Lack of denominator, report rates fall over time	Good
Sub-specialty specific prospective database	POCA registry.[8] National pediatric epidural and opiate audits.[9]	Detailed clinical patterns and outcomes	Lacks incidence data	Extremely good (and inexpensive)
National focussed prospective audit	NAP audits (RCoA, UK) [14]	Specific Incidence data of major complications	Despite size of audit, paediatric figures less specific	Good
Boards of Inquiry	Kennedy report (Bristol Children's Cardiac) [36]	Governance of medical care, culture within systems and monitoring of outcomes	Lessons from one system must be extrapolated to others	Very good due to high profile and funding
Police investigation	Operation Orcadian [3]	Criminal responsibility	Expensive, very limited scope	Poor, unless professional bodies engaged
Medico legal (analysis by	Closed claims	Patterns of significant	Long timeframe and	Reasonable, if

clinicians)	study[4]	incidents	lack of specificity	slow
Local audits	[32,33]	Specific areas of practice. Able to examine efficacy accurately	Variable reporting and quality	Excellent potential but variable in practice

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