Comparative effectiveness and safety of physician and nurse anaesthetists: a narrative systematic review

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Background. Despite widespread debate on the merits of different models of anaesthesia care delivery, there are few published data on the relative safety and effectiveness of different anaesthesia providers.

Method. We conducted a systematic search for, and critical appraisal of, primary research comparing safety and effectiveness of different anaesthetic providers.

Results. Our search of Medline, EMBASE, CINAHL, and HMIC for material published between 1990 and April 2003 yielded four articles of relevance to the question. The studies used a variety of methodologies and all had potential confounding factors limiting the validity of the results.

Conclusions. In view of the paucity of high-level primary evidence in this area, it is not possible to draw a conclusion regarding differences in patient safety as a function of provider type. There are difficulties in collecting events as ‘anaesthesia-related’, and also in the variable definitions of ‘supervision’ and ‘anaesthesia care team’. We suggest that existing attempts to show differences in outcome might usefully be complemented by studies examining measures of anaesthetic process.


Keywords: anaesthesia, audit; anaesthesia, personnel; organizations, health care; safety, anaesthesia providers

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In the UK, anaesthesia has traditionally been administered only by physicians. A projected manpower shortage in anaesthesia has led to suggestions that non-physicians be trained to give anaesthetics. Anaesthesia is administered with apparent success throughout the world by providers from a number of different professional groups, working either alone or together. However, this is a controversial subject in the UK, and it is important to investigate the facts behind the debate. There has been, to our knowledge, no systematic attempt to gather evidence in this area.

We set out to perform a systematic review of primary studies of the relative safety of different provider models.

(iii) Outcomes: effectiveness, safety and perceptions of users and other stakeholders.
(iv) Preferred study design: comparative quantitative studies (effectiveness and safety), whether randomized controlled trial or observational. Qualitative studies for other aspects.

We searched for material from three principal sources:

(i) A computerized literature search was performed in Medline, CINAHL, EMBASE, Health Management Information Consortium (a UK ‘grey literature’ database), and the

Methods

Our inclusion criteria for material to answer the study question were:

(i) Population: patients undergoing surgery or other procedures.
(ii) Intervention: anaesthesia delivered by different professional groups.

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Cochrane Library, using the appropriate search terms for each database. The full search strategy is available from the authors on request. We searched for material published during the period 1990 to April 2003, as we felt that anaesthetic practice before 1990 (in terms of training, drugs, equipment, monitoring, and organization) was too dissimilar from current practice to be of relevance to modern-day policy.

In addition, we searched for reports of studies into patients’ views on different anaesthesia providers. Although our inclusion criteria for material to answer the review question were quite specific, we set our search strategy deliberately broad, limiting it neither by publication type nor study design. Existing systematic reviews were also sought.

(ii) Scrutiny of reference lists of articles retrieved in the database search.
(iii) Personal knowledge of the members of the Expert Advisory Group convened for the project. This comprised academic anaesthetists with an interest in professional boundaries and/or clinical epidemiology, public health specialists, managers, a patient advocate, and representatives from UK nursing and theatre staff organizations.

Retrieved abstracts were screened for relevance and the full text of promising material was obtained. The articles of different types were appraised using standard principles for each study type.3

Results and appraisal of studies
The process of screening and selection is summarized in the QUOROM type diagram (Fig. 1).4 Initial database searching identified 1073 abstracts. Two researchers (M.K. and A.S.) working independently screened the abstracts and the results were compared. Initial disagreement on relevance occurred over only 25 abstracts. 966 were excluded at this stage. Reasons are given in Figure 1. Further material was located from reference lists and from the Expert Group. We obtained the full text of the remaining articles. These were read by the two researchers and a consensus reached on inclusion. Again, reasons for exclusion are listed in Figure 1.

We found four primary articles on safety,5–8 from a variety of settings, and using various methodological approaches (Table 1). No studies dealt primarily with effectiveness. We also found no reports of patients’ views on different anaesthesia providers. The studies we identified are too dissimilar to be subject to formal statistical meta-analysis, and are described fully below.

Silber and colleagues (2000)5
This study aimed to compare outcomes of surgical patients whose anaesthetic care was either personally provided, or directed by, an anesthesiologist, with outcomes when care was neither performed nor directed by an anesthesiologist. Data were obtained from the Medicare billing records of 217 440 patients who underwent general surgical or orthopaedic procedures in Pennsylvania between 1991 and 1994. The three principal outcome measures were: death within 30 days of admission, in-hospital complication rate, and ‘failure-to-rescue’ rate. This last mentioned measure had been developed previously by Silber’s team,9 and is defined as the 30-day death rate in those patients in whom either a complication developed or who died without a recorded complication. It is calculated by dividing the number of patients who died from complications by the sum of the number of patients who experienced a complication and the numbers of patients who died without experiencing a complication. The concept has (in our opinion) an intuitive appeal in that it assumes that complications are likely to affect all practitioners equally but that more skilled practitioners are more likely to be able to treat complications effectively when they occur. Medical direction is as defined by the Medicare program in 1983 (Table 2).

The unadjusted death rate was 3.41% in directed patients and 4.53% for undirected patients (these are both higher than for routine anaesthesia and probably reflect the high proportion of emergency cases). After adjustment for previously identified confounding factors, three factors showed independent effects on death and failure-to-rescue rates: hospital size, nurse-to-bed ratio, and direction by an anesthesiologist. The adjusted odds ratios when care was not directed by an anesthesiologist were greater for death (odds ratio 1.08, 95% CI 1.00–1.15), and failure-to-rescue (odds ratio 1.10, 95% CI 1.01–1.18). Complication rates were not influenced by medical direction.

There are a number of difficulties with this study.10 The undirected group (23 010) was considerably smaller than the directed group; 14 317 of these were assumed to be undirected as no bill was submitted for anaesthesia services. Some (1287 at most) were residents’ cases, but the rest are assumed to have been supervised either by a physician or a staff nurse anesthetist. The remaining 8873 patients were supervised, but not directed, by an anesthesiologist or directed by a non-anesthesiologist physician. One correspondent suggested that ‘supervision’ by surgeons could have contributed to the negative outcome in ‘undirected’ cases, rather than the nurse anesthetist (CRNA) being supervised.11 In addition, cases were designated ‘undirected’ even if patients had undergone a previous directed anaesthetic during the same hospital stay. Further, the Medicare claims data used do not allow the investigators to judge the cause of death. The 41 ‘failure-to-rescue’ complications are diverse and vary in how closely the anesthesiologist is responsible for causation or management. Thus, there are two anaesthesia-specific complications (‘anaesthesia event’ and ‘malignant hyperthermia’); eight cardiovascular problems ranging from serious arrhythmia to hypotension...
and congestive heart failure; and six respiratory problems including aspiration pneumonia and bronchospasm. Twelve of the complications are more surgical, for example peritonitis, gangrene of extremity, etc., and another group are within the remit of the whole perioperative team (decubitus ulcer, renal dysfunction, and sepsis). Another correspondent pointed out that, with the odds ratios given above, ‘the influence of absence of medical direction seems very small, at least for an unselected patient population’. 12

Hoffmann and colleagues (2002) 6
Hoffmann and colleagues produced an analysis of a more circumscribed clinical issue. In this prospective,
uncontrolled, non-randomized observational study, data on complications were collected on 1000 children who underwent bilateral myringotomy with tympanostomy tube placement from 1998 to 2000. The authors noted adverse events, both major (laryngospasm, bradycardia, stridor, dysrhythmia and 10% decrease in oxygen saturation from baseline) and minor (upper airway obstruction, recovery longer than 30 min, emesis, and persistent agitation). It is not clear from the paper whether these outcomes were pre-specified. ASA physical status, age, concurrent medical conditions, and type of anaesthetic provider were recorded. Major adverse events are said to have occurred in 1.9% of cases (although only 17 patients are accounted for in the relevant table of results). The type of anaesthesia provider was not a significant pre-dicator of an adverse event (\( P = 0.06 \)), there being no difference between nurse anaesthetists, attending anesthesiologists, or residents for major events. No data are provided on the proportions of cases anaesthetized by nurses and specialist anesthesiologists. The authors make no further comment on provider type.

The main limitations of this study are the use of outcomes that have in themselves no permanent effect on the patient, the small sample size, and the fact that the data were collected not by an independent observer but by the providers themselves.

Maaløe (2000)\textsuperscript{\textcopyright}

This unpublished doctoral thesis reported a year-long, multicentre study of untoward incidents in anaesthesia. Six hospitals were purposively selected to represent a spectrum of hospitals in Denmark, ranging from university hospitals to smaller general hospitals. In all, 58 incidents were pre-specified and these included those with more potential for longer-term effects on the patient than those listed in Hoffman’s work. Incidents were classified by aetiology as ‘physiological’ or ‘procedural’. ‘Physiological’ were defined as incidents related to predefined adverse physiological reactions to anaesthesia, for example hypotension (a 50% decrease of systolic arterial pressure), suspected aspiration of gastric contents, and cardiac arrest. ‘Procedural’ incidents were defined as anaesthetic procedures where more than two attempts were required, or where the procedure failed altogether. This included events such as oesophageal intubation, dental damage, inadvertent i.v. injection of local anaesthetic, and residual muscle relaxation. A two-part reporting form was assigned to each patient. The first part described basic patient data and was completed by the nurse anaesthetist/anaesthesiologist. The second was used to describe incidents, and was filled out only if an incident occurred, by the person who observed the incident (nurse anaesthetist, assistant, recovery nurse). Data were obtained from 64 401 anaesthetics, administered between May 1996 and April 1997, during which 7764 incidents were recorded (12.1%). Nurses maintained 88.3% of the anaesthetics, and doctors 11% (provider not specified in 0.7%). Inexperienced doctors had the highest incident rate, and fully trained specialists, the lowest. Trained nurses had an incident rate very similar to specialists, at about 11% for both groups.

Pine and colleagues (2003)\textsuperscript{\textcopyright}

Pine and colleagues analysed risk-adjusted mortality rates for a large group of Medicare patients from 22 American states. Patients were excluded from the analysis if billing

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**Table 1** Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Setting</th>
<th>Number of patients</th>
<th>Outcome measure(s)</th>
<th>Potential limiting factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoffmann (2002)\textsuperscript{\textcopyright}</td>
<td>Observational clinical study in simple paediatric ENT surgery</td>
<td>US tertiary care childrens’ hospital</td>
<td>1 000</td>
<td>Adverse events during anaesthesia and recovery</td>
<td>Small study. No outcome measures of long-term significance. Self-reporting bias possible</td>
</tr>
<tr>
<td>Maaløe (2000)\textsuperscript{\textcopyright}</td>
<td>Prospective observational clinical study</td>
<td>Six Danish hospitals of various types and sizes</td>
<td>64 401</td>
<td>Critical incidents during anaesthesia</td>
<td>Self-reporting bias possible</td>
</tr>
<tr>
<td>Pine (2003)\textsuperscript{\textcopyright}</td>
<td>Analysis of administrative (billing) information</td>
<td>22 states in USA, 1995–7</td>
<td>404 194</td>
<td>Overall perioperative mortality</td>
<td>Some potential cases excluded (incomplete data). No information on contribution of anaesthetic provider to deaths</td>
</tr>
</tbody>
</table>

**Table 2** TEFRA conditions of payment for ‘medical direction’

The anesthesiologist billing for the medical direction of a CRNA (nurse anesthe-
tist) must:
1. Perform the preoperative assessment
2. Prescribe the anaesthesia plan
3. Participate in the demanding parts of the anaesthetic (including induction and emergence)
4. Make frequent checks during the course of the anaesthetic
5. Remain physically available
6. Not personally administer concurrent anaesthetics
7. Provide indicated postoperative care

Established by the US Tax Equity and Fiscal Responsibility Act (TEFRA), 1982. Cited in Silber and colleagues\textsuperscript{\textcopyright}.

\[ P = 0.06 \]
data were incomplete or ambiguous. Data for 404 194 patients who underwent one of eight elective procedures in 1995, 1996, or 1997 were included. In-hospital mortality rates were compared for solo anesthesiologists (who provided anaesthesia in 33.2% of cases), CRNAs (nurse anesthetists) working alone (8.2%), and ‘anaesthesia care teams’ (58.6%). By far the commonest type of anaesthesia practice in an individual hospital (over 260 000 cases) was where both team care and solo care by anesthesiologists was practised. The death rates were generally low—ranging from 0.11% after mastectomy to 1.2% after cholecystectomy. The authors found no evidence of significant differences in risk-adjusted surgical mortality rates by type of anaesthesia provider or by type of anaesthesia practice within the hospital. However, the data sources did not allow them to identify whether the death was related to anaesthesia or not.

Discussion
We have found no recent, high-level evidence that there are significant differences in safety between different anaesthesia providers. We found no studies addressing the question of relative effectiveness of providers, nor any work aimed at eliciting patients’ views.

While we have found no consistent, high-level evidence of a difference in safety of anaesthetic care between different providers, this is not necessarily evidence of absence of a difference. None of the studies presented here is without methodological flaws or questionable assumptions. In fairness to the authors, however, much of the material could not be expected to provide a definitive answer to this question. Retrospective analyses of administrative datasets predominate and although complex analyses have been used to correct for known confounders, this approach is inherently inferior to the analysis of prospective, purpose-collected data. As Fleisher and Anderson point out in an editorial comment13 on a later paper of Silber’s,14 analysis of administrative datasets is designed to generate hypotheses, not to test them. Medicare claims data do not contain all relevant information. For instance, it is not possible to reach definitive conclusions about causes of death or other outcomes. Hoffmann’s context-specific clinical study was small and used outcomes which, though important to anesthetists, are usually transient, self-limiting or successfully managed by the provider, and of no permanent consequence to the patient.6 Maaløe’s much more extensive, quality-assured data collection has, in our opinion, greater likelihood of conveying an accurate picture of anaesthetic practice,7 although it too was not a randomized investigation and relied on reporting of anaesthetics by providers themselves.

We found no material dealing with effectiveness but did not find this surprising. Our impression is that the anaesthetic community takes the efficacy of drugs used for granted, and tends to focus more on risk and safety.15 16 This influences the research agenda. Likewise, whilst the patient’s perspective on healthcare is increasingly being sought, this is less relevant in a context where the patient is unconscious for much of the time when they are in contact with the practitioner.

It is perhaps unusual for systematic reviews to begin with such a large number of articles and yet include so few in the finished work (Fig. 1). Our search was intentionally broad, as scoping searches had suggested a paucity of material. We accepted that this was likely to yield some irrelevant material but preferred to perform an optimally sensitive search. In fact, the many comments, letters, and other studies revealed by our search not only helped provide invaluable contextual material to further our understanding of this issue, but also allowed us to capture criticisms of some of the primary studies included.

Our work is the first systematic review designed to address this question. An article published in 1996 reviewed previously published work and set it in a professional and policy context.17 It contained no new primary data yet, being the first publication in a peer-reviewed journal on the subject for some years, has been frequently cited since. An accompanying editorial (acknowledging that the article was subjective and clearly partisan18), and subsequent correspondence in the journal19–21 are, in contrast, seldom referred to. The article provoked vociferous responses from nurse anesthetists in the US, correcting some errors of fact as well as arguing over points of opinion.22 The suggestion it makes—that anaesthesia care teams are the safest model of provision—is the authors’ interpretation of the work of Bechtoldt,23 Forrest,24 and Silber.9

Caution is needed when the phrase ‘anaesthesia care team’ is being referred to. This may mean different things and it is necessary to establish just what is being debated. For instance, although anesthesiologists and nurse anesthetists (CRNAs) may work within the same department, the manner of that co-existence may vary considerably. Perhaps the commonest arrangement is where anesthesiologists ‘medically direct’ or ‘supervise’ one or more CRNAs. However, there may be a more ‘consultative’ relationship where CRNAs involve anesthesiologists only on request. Alternatively, anesthesiologists and CRNAs may work alone at all times, without interacting at all. Sometimes the composition of the ‘anaesthesia team’ is not specified; alternatively, studies such as those of Silber and colleagues,5 14 compare results at the level of individual hospitals rather than individual care teams.

Another difficulty inherent in work in this field is defining the extent to which adverse events can be thought of as ‘anaesthesia-related’. Anaesthesia is in the unusual position within clinical medicine in that it is not therapeutic in itself, but rather enables other interventions. As it is not administered in isolation, many patient outcomes depend on the net effect of a number of different influences throughout the perioperative period. The various reports summarized in this review use differing definitions of ‘anaesthesia related’
and, because the ‘control event rate’ is higher if a more inclusive definition is used, this could have a greater effect on study findings than differences in risk between providers. However, based on the limited data available, it is clear that it is impossible to draw a conclusion regarding patient safety as a function of provider type given these data.

Our review has allowed us to identify many possible pitfalls, which could be avoided in future studies in this area. Should a definitive answer to this question be sought, it is well recognized that the ‘ideal’ study (usually a huge randomized controlled trial of mortality with different provider types is mooted) is unfeasibly large. The alternatives would include the use of commoner outcomes (such as ‘failure to rescue’ from complications more directly within the control arm) and making explicit the assumption we make implicitly in our everyday practice of the anesthetists). Alternatively, making explicit the assumption can be avoided in future studies in this area. It is clear that it is impossible to draw a conclusion regarding patient safety as a function of provider type given these data.

This would be one way of addressing Fleisher and Anderson’s goal of identifying ‘additional actions or training within the domain of the anesthesiologists that ensures that our patients receive the best quality of care’. Our own work in defining professional knowledge in action in anaesthesia, offers one possible approach, and Klemola and Norros and Larson and colleagues have also explored the different ways anaesthetists conceptualize the anaesthetic process.

However, one must also question the wisdom of pursuing the production of ‘definitive’ evidence to address this question. Writing on evidence-based medicine and anaesthesia, Goodman noted that, as there is no evidence that evidence-based medicine leads to better medical care, ‘the debate will continue as most human debates do, on emotional and rhetorical grounds’. We believe that this will be true of non-physician anaesthesia both in countries where it is well established and also where it is still experimental, as in the UK.

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