# Major incidents and complications in otherwise healthy patients undergoing elective procedures: results based on 1.37 million anaesthetic procedures

J. H. Schiff<sup>1,2\*</sup>, A. Welker<sup>3</sup>, B. Fohr<sup>4</sup>, A. Henn-Beilharz<sup>1</sup>, U. Bothner<sup>5</sup>, H. Van Aken<sup>6</sup>, A. Schleppers<sup>7</sup>, H. J. Baldering<sup>8</sup> and W. Heinrichs<sup>8</sup>

<sup>1</sup> Department of Anaesthesia and Intensive Care, Katharinenkrankenhaus, Klinikum Stuttgart, Stuttgart, Germany

<sup>2</sup> James Cook University, Queensland, Australia

<sup>3</sup> Department of Anaesthesia, Dr-Horst-Schmidt-Kliniken, Wiesbaden, Germany

<sup>4</sup> Department of Anaesthesia, University of Heidelberg, Heidelberg, Germany

<sup>5</sup> Department of Anaesthesia, Ulm University, Ulm, Germany

<sup>6</sup> Department of Anaesthesia and Intensive Care, University Hospital Muenster, Muenster, Germany

<sup>7</sup> DGAI (German Society of Anaesthesia and Intensive Care Medicine), Nuremberg, Germany

<sup>8</sup> AQAI (Applied Quality Assurance in Anaesthesia and Intensive-Care Medicine/Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin, AQAI Ltd), Mainz, Germany

\* Corresponding author: Klinik für Anästhesiologie u. operative Intensivmedizin, Katharinenhospital, Kriegsbergstrasse 60, D-70174 Stuttgart, Germany. E-mail: janschiff@hotmail.com

## **Editor's key points**

- Death and other serious complications occurring in otherwise healthy surgical patients may indicate a failure of anaesthesia safety.
- This study evaluated severe adverse incidents, events, and complications reported to a national anaesthesia database.
- For healthy patients, the risk of death or other serious complication from anaesthesia was about 10 per million anaesthetics.
- Large-scale electronic registries provide a vehicle for improving patient care.

**Background.** Improved anaesthesia safety has made severe anaesthesia-related incidents, complications, and deaths rare events, but concern about morbidity and mortality in anaesthesia continues. This study examines possible severe adverse outcomes or death recorded in a large national surveillance system based on a core data set (CDS).

**Methods.** Cases from 1999 to 2010 were filtered from the CDS database. Cases were defined as elective patients classified as ASA physical status grades I and II (without relevant risk factors) resulting in death or serious complication. Four experts reviewed the cases to determine anaesthetic involvement.

**Results.** Of 1 374 678 otherwise healthy, ASA I and II patients in the CDS database, 36 met the study inclusion criteria resulting in a death or serious complication rate of 26.2 per million [95% confidence interval (CI), 19.4–34.6] procedures, and for those with possible direct anaesthetic involvement, <u>7.3 per million cases</u> (95% CI, 3.9–12.3).

**Conclusions.** This is the first study assessing severe incidents and complications from a national outcome-tracking database. Annual identification and review of cases, perhaps with standardized database queries in the respective departments, might provide more detailed information about the cascades that lead to unfortunate outcomes.

**Keywords:** complications; computerized anaesthesia; medical records systems; mortality; outcome assessment

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The mortality rate in patients undergoing non-cardiac surgery can be substantial,<sup>1</sup> with between 0.5% and 1% at 48 h,<sup>2 3</sup> and up to 4% at 7 days after surgery.<sup>4</sup> However, the mortality rate after major surgical procedures has decreased dramatically;<sup>5 6</sup> in addition, improvements in anaesthesia safety have made anaesthesia-related deaths and severe outcomes rare events.<sup>7-9</sup>

The ASA physical status (PS) classification, when compared with individual comorbidities, may have the strongest statistical association with complications.<sup>10-12</sup> With longer survey periods, other factors also appear to come into effect, such as underlying disease, particularly malignancies.<sup>1 13</sup> With an estimated 230 million anaesthetic procedures taking place worldwide annually<sup>14</sup> and about 10 million in Germany alone (in 2009) (www.gbe-bund.de), perioperative mortality and major complications represent a small but relevant proportion of cases.

Mortality is considered a vital estimate of risk associated with anaesthesia with an apparently clear definition. However, even a mortality rate must often be regarded as a rather crude risk estimate because of its relative rarity. The comparison of death rates is feasible only when using the same criteria for the numerator, the follow-up period, and the denominator.

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Estimates of the incidence of mortality, even if based on the best available data, differ widely across studies, possibly as a result of differences in the definitions used and sources studied.<sup>15</sup> A spectrum of time limits has been used for studies, ranging from perioperative<sup>16</sup> <sup>17</sup> to 1 yr,<sup>7</sup> <sup>8</sup> the lack of defined populations as a denominator for the number of deceased and different ranges of procedures, and severity of co-existing illness and the urgency of the operations often impedes exact calculations, even when the numerator is quite accurate. Together with varying definitions of the anaesthetic contribution, this obviously impacts heavily on results, rendering direct comparisons between studies difficult.

The clear definition of mortality generally stands in contrast to the more debatable definitions of morbidity.

Even if the event of death due to an unexpected difficult or failed tracheal intubation is well defined, the reported incidence varies widely. The reported proportions of problems with managing the airways (i.e. problems relating to oxygenating the patients, difficult or failed intubation of the trachea, etc.) in all anaesthesia-related deaths cover a wide range between  $8\%^{18}$ <sup>19</sup> and 100%.<sup>20</sup><sup>21</sup>

The observed differences between the reported rates should therefore come as little surprise and has caused the continuation of debate over complications in patients undergoing surgery and anaesthesia.

After legislation on quality assurance and cost-containment regulations in Germany, the German Society of Anaesthesia and Intensive Care Medicine (*Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin*, DGAI) has guided the establishment of a national surveillance system on the basis of a minimal set of data (the core data set, CDS) in conjunction with a standardized reporting system for anaesthesia-related incidents, events, and complications (IECs).<sup>22–27</sup>

Growth in private practice anaesthesia, increasing numbers of elderly and multimorbid patients, and high-risk procedures and also the lack of population-based, prospective data collection fuel debate over complications in patients undergoing surgery and anaesthesia.

Analysis of mortality and serious morbidity in relatively healthy patients could control for the influences of patients' disease and to help gain insight into the contribution of anaesthesia to perioperative mortality.

Our objectives were to:

- (i) determine the incidence of severe perioperative outcomes in healthy patients classified as ASA PS grades I and II undergoing elective procedures in the CDS, filtered for severe adverse IECs in the period from 1999 to 2010; and
- (ii) identify cases where the underlying problem (IEC) codes suggest direct anaesthetic involvement.

## **Methods**

In this cohort study, patients with ASA PS grades I and II that displayed anaesthesia-related IECs (coded as grade 5) were filtered from the CDS collated between 1999 and 2010. Cases were analysed for the maximum of eight underlying problem (IEC) codes and rates of severe perioperative outcomes were calculated.

### **CDS database**

The German Society of Anaesthesia and Intensive Care Medicine (DGAI) has introduced the standardized reporting of anaesthesia-related IECs in 1993. In its second version (Supplementary Appendix), the CDS used in this study was designed to reflect several key factors and includes patient characteristic and administrative data, risk factors, pre-existing disease, information about the admitting surgical department, and the type and duration of anaesthesia.

It is important to keep the system simple enough to be practical, yet detailed enough to be informative for the purposes of education, quality assurance, research, and administration.<sup>28</sup> The CDS was developed jointly by the European Society for Computing in Anaesthesia and Intensive Care and the Society for Computing and Technology in Anaesthesia and is designed to capture a range of information about the anaesthetic encounter that can be pooled and shared among many institutions in order to facilitate the analysis of large patient populations.<sup>24 25</sup>

In addition to patient characteristic data and anaesthetic risk factors, anaesthetic characteristics such as duration of anaesthesia, induction time, etc. are stored, the CDS falls short in the documentation of details of vital signs and of the type, route, and dosage of anaesthetics and other drugs, as these are not stored in the database, but have to be part of anaesthetic record-keeping. The DGAI proposed the CDS as a single uniform data set in combination with the documentation of anaesthetic details to form a single, multipage record, which represents the legal documentation of the course of anaesthesia that can be tailored to suit institutional anaesthetic record criteria in order to achieve comparable documentation across all participating providers and to minimize workload and inconsistencies.

Of the 116 fields in the data set, 24 are dedicated to the description of a maximum of eight incidents and complications (Supplementary Appendix). The definitions of IECs are based on the model of anaesthetic mishaps or near-incidents.<sup>29</sup>

The incidents and complications can be selected from a list of predefined IECs and is documented in five ascending grades (Supplementary Appendix).

### Data source

Data were collected for a benchmark project. Anaesthetic departments in hospitals or in private practice can take part in the project on a voluntary basis. Participation in this external quality-assurance project is free for departments inside the state of Baden-Württemberg, sponsored by the Medical Board; departments from other federal states take part for a small fee.

The emphasis is on routine documentation of incidents and complications in relation to the level of care and patient characteristic data. Data are generated at the site of the anaesthetic procedure. Anaesthetic departments choose either paper-based but computer-readable documents (CRDs), which are scanned, or to generate data directly with automated anaesthesia records, or anaesthesia information management systems to create a file. The data have to be uniform with the CDS for processing in the multicentre national database (Supplementary Appendix). Participating departments submit annual CDS data for all anaesthetic procedures carried out during each 12 month period.

A check programme is used to screen for conflicting or false data entries, such as patients aged <0 or >110 yr, ASA status >V, Caesarean sections in men, etc. Once the data have passed the check, they are submitted to the Medical Board, which recodes each hospital's identity to ensure anonymity. The data are then forwarded for processing to the AQAI Institute (Applied Quality Assurance in Anaesthesia and Intensive-Care Medicine/Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin, AQAI Ltd, Mainz, Germany). Plausibility checks are carried out for extreme values (induction time >2 h, operating time >18 h, resolution of anaesthesia >1 h), and each set of data is manually checked for other implausibilities.

After ethics committee approval (No. 089-05-f, Ethical Committee of the Medical Board, federal state of Baden-Württemberg), the present study used checked but otherwise unprocessed CDS (version 2.0) data collected between 1999 and 2010 from the database. Data based on the CDS version 1.0 were excluded.

#### Inclusion criteria, cases, and case classification

The cases in the current study were defined as patients in ASA PS I or II that feature at least one severe (grade 5) incident code, in order to detect severe incidents and complications in otherwise healthy individuals. To increase the likelihood of inclusion of only true ASA PS I and II patients, those in which there were relevant comorbidities—coded as risk factors and classified as being pathological (and therefore relevant)were excluded. In a preliminary study (unpublished data), we found coding errors frequently to affect the ASA PS grade with approximately the same percentage displaying relevant (pathological) comorbidities, suggesting false low ASA PS classification. Furthermore, emergency and urgent procedures, procedures that did not take place during normal working hours, and cardiac surgery procedures were excluded (as the incident coding could be difficult in these cases) in order to limit systematic error. While it was necessary for cases to feature at least one severe (grade 5) incident code, it was expected that other incidents would also be coded (complex incidents),<sup>30</sup> so that at least one problem code, or a combination of codes, would suggest a severe outcome or death of the patient.

Each identified case was independently reviewed for the underlying problem codes by each of four anaesthetists. The anaesthetists had to be experienced in investigating errors, near-misses, or crisis simulations and all had longstanding experience in the development, analysis, or both of the CDS. The cases were discussed using a modified nominal group technique.<sup>31–33</sup> This process consisted first of a classification of cases as certain (one problem code or combination suggesting a severe outcome or death of the patient); indeterminate (no certainty that the events coded led to a severe outcome);

or not relevant (with no problem code or combination suggesting a severe outcome) by each expert. Secondly, all of the cases were discussed during a telephone conference. Cases were subject to further discussion if one of the four anaesthetists classified the case as not relevant when the other three had classified it as certain, or vice versa; or when there were two or more divergent classifications of the case. After the latter cases had then been reviewed individually, the reviewers met again in phone conferences to reflect on each case and reach a decision. A case was considered to have been classified if three of the four reviewing anaesthetists agreed on one classification and if the fourth opinion was not contradictory. When the reviewers could not agree, the classification was changed to indeterminate. The reviewers were then asked to comment on the likelihood of each case showing specific anaesthesia-related features in a similar process. Codes that suggested direct anaesthetic involvement were analysed using a modified Edwards classification and were considered to be anaesthesia-related if they met the criteria for category 1 or 2 (Table 1).9 34

It was assumed that it would be possible to identify all cases in which death was coded as one of the discharge options (which are independent of the incident codes), from the operating theatre or post-anaesthesia care unit using this classification system. This method also served as a check on whether it would be possible to classify severe cases identifying mortality.

### Statistical analysis

The same selection criteria as described above were used to determine the common denominator for calculating the rates of complications—that is, the total of ASA I and II patients. The SPSS (version 19.0; SPSS Inc., Chicago, IL, USA) and Microsoft Excel programs were used for statistical analysis. The 95% confidence intervals (95% CIs) were calculated using the Excel function BETAINV.

## Results

Between 1999 and 2010, a total of 101 anaesthetic departments, mostly in the southern part of Germany, took part in the DGAI benchmark project. The majority of records were documented in secondary care institutions (43%) (Table 2).

Among the 4 594 110 anaesthetic procedures recorded, 622 949 data sets were excluded as they were based on CDS version 1.0; mostly acquired during 1999 (Fig. 1). A total of 3 971 161 anaesthesia records based on CDS version 2.0 were therefore available for the years 2000–2010 (Figs 1 and 2), with a total of 642 077 grade 1–5 incidents documented. For the years 2009 and 2010, data from the federal state of Bavaria could not be included, as they had to remain with the regional Medical Board for processing and were therefore unavailable for the study (Fig. 2).

In the accumulated data, 2 817 551 records represented all ASA PS I and II patients (Table 2), with a total of 285 incidents grade 5 cases (ASA PS I, n=67, 62.5 per million cases; and ASA PS II, n=218, 124.8 per million cases).

The inclusion criteria were met in a total of 84 incidents grade 5 cases among 1374678 elective and non-urgent

and colleagues <sup>34</sup>	
Incidents/compli	ications attributable to anaesthesia
Category 1	Where it is reasonably certain that the incident/complication was caused by the anaesthesia or other factors under the control of the anaesthetist
Category 2	Where there is some doubt whether the incident/complication was entirely attributable to the anaesthesia or other factors under the control of the anaesthetist
Category 3	Where the incident/complication was caused by both surgical and anaesthesia factors
	Explanatory notes
	<ul> <li>The intention of the classification is not to apportion blame in individual cases, but to establish the contribution of the anaesthesia factors to the incident/complication</li> </ul>
	• The above classification is applied regardless of the patient's condition before the procedure. However, if it is considered that the medical condition makes a substantial contribution to the anaesthesia-related incident/complication, subcategory H should also be applied
	• If no factor under the control of the anaesthetist is identified that could or should have been done better, subcategory G should also be applied
Incidents/compli	ications in which anaesthesia played no part
Category 4	Incident/complication in which the administration of the anaesthesia is not contributory and surgical or other factors are implicated
Category 5	Inevitable incident/complication, which would have occurred irrespective of anaesthesia or surgical procedures
Category 6	Incidental incident/complication, which could not reasonably be expected to have been foreseen by those looking after the patient, were not related to the indication for surgery, and were not due to factors under the control of the anaesthetist or surgeon
Unassessable ind	cidents/complications
Category 7	Those that cannot be assessed despite considerable data but where the information is conflicting or key data are missing
Category 8	Cases that cannot be assessed because of inadequate data

Table 1 Classification of incidents and complications. Categories for incidents, events, and complications adapted from Gibbs<sup>9</sup> and Edwards

 Table 2
 Patient characteristic details of the analysed database.

 PS, physical status
 PS

	Cases (n)
Level of care	
Specialized hospital	208 492
Primary care institution	901 541
Secondary care institution	1 698 988
Tertiary care institution, referral centre	1 147 979
Day surgery, outpatient care	14 161
Sex	
Male	1 905 813
Female	2 065 105
Intersex	243
Status	
Day surgery cases	553 215
Admitted patients	3 385 104
Short stay	32 842
ASA PS grade	
I	1 070 370
II	1 747 181
III	986 377
IV	147 920
V	18 929
Data lacking	384

procedures recorded during normal working hours (with the exclusion of cardiac surgery procedures) in ASA I and II patients (Fig. 1) (ASA I, n=30, 44.9 per million cases; ASA II,

n=54, 76.3 per million cases). All eight cases that had the discharge code 'death' were among the grade 5 incidents identified.

After the 84 cases had been reviewed, 48 were excluded as it was found that the codes did not represent severe outcomes (e.g. damage to the teeth, nerve damage with regional anaesthesia, etc.).

Thirty-six cases with a certain or inconclusive severe outcome remained for further analysis; the rate of complications in the low-risk group was therefore 26.2 per million (95% CI, 19.4–34.6). This included nine in the ASA PS I group and 27 in the ASA PS II group (13.5, 95% CI, 7–23.5; and 38.2, 95% CI 27–52.7 per million cases). Only one case was found to have occurred on postoperative day 1 (Case no. 80). Of these cases, three in the ASA PS I group and 20 in the ASA PS II group had complex incidents. Although they were not complex, the remaining 13 cases were found to represent major morbidity or mortality by at least three of the four reviewers (Tables 3 and 4) and were considered for analysis.

Cases in which at least three of the reviewers were certain that the coding was equivalent to a severe outcome amounted to five in the ASA PS I group (7.5; 95% CI, 2.9–15.7 per million cases) and 21 in the ASA PS II group (29.7; 95% CI, 19.9–41.1 per million cases). All cases in which there was a discharge option of 'death' were still among those identified (Table 3). Discharge options other than death were not taken into account. Many data sets from the hospitals showed either no coding or a single uniform code (such as 'normal ward') for the particular field. The remaining ten cases were classified as intermediate (Table 4).



Fig 1 Filtering process of available data 1999–2010. CDS, core data set.



**Fig 2** Numbers of patients per year during the study period. For the years 2009 and 2010, data from the federal state of Bavaria could not be included, as they had to remain with the regional Medical Board for processing and were unavailable for the study.

In the group with definite severe outcomes, the rate of possible anaesthesia-related events was 7.3 per million cases (95% CI, 3.9–12.3; i.e. 10 cases) during the immediate perioperative period. Of these, two cases in the ASA PS I group (3; 95% CI, 0.5–9.4) and eight in the ASA PS II group (11.3; 95% CI, 5.6–20.4 per million cases) were considered to be anaesthesia-related (Table 3). When comparing the rates of difficult intubation in the identified certain cases, rates were 2/5 (40%) for ASA PS I and 8/21 (38%) for ASA PS II, respectively, with a total of nine cases coded as unexpected difficult intubation. Analysis of the intermediate cases yielded six cases with problems pertaining to airway management, but only one

**Table 3** Certain cases identified from the database, ASA PS I and II patients who suffered a severe incident/complication undergoing elective procedures. Bold rows indicate anaesthesia-related events identified by the reviewers after multiple rounds of a nominal group technique. Only the first three incidents/complications are displayed. Only case two had two additional incidents/ complications (shock, grade 5 and cardiac arrest, grade 5) and case three (ischaemia, grade 5 and anaemia, grade 2). Level of care: 1, primary care; 2, secondary care; 3, tertiary care; spec, specialized hospital; ENT, ear-nose-throat; D/C, discharge to; ICP, intracranial pressure; TIVA, total i.v. anaesthesia

Case no.	Level of care	Age (yr)	Sex	Dept	ASA	Type of anaesthesia	Intubation of trachea	Incident 1	Grade	Incident 2	Grade	Incident 3	Grade	Duration of anaesthesia (min)	D/C
1	2	50	М	General surgery	II	TIVA	Yes	Unexpected difficult intubation	5					140	
2	2	90	М	General surgery	II	Missing	Yes	Pulmonary embolus	5	Cardiac arrest	5			83	Death
3	3	50	F	Urology	Π	Combination general and regional anaesthesia	Yes	Hypotension	5	Hypovolaemia	5	Shock/ alterations in microcirculation	5	577	Death
4	3	65	М	Neurosurgery	II	I.V. induction, inhalation maintenance	Yes	Hypovolaemia	5	Tachycardia	3	Hypotension	3	395	
14	2	47	М	Neurosurgery	Π	Balanced anaesthesia	Yes	Cardiac arrest	5					65	Death
17	2	54	М	Thoracic surgery	Π	Combination general and regional anaesthesia	Yes	Hypotension	1	Bradycardia	1	Cardiac arrest	5	480	Death
19	spec	44	F	General surgery	II	I.V. induction, inhalation maintenance	Yes	Bronchospasm	1	Unexpected difficult intubation	5			60	
21	spec	54	М	General surgery	II	I.V. induction, inhalation maintenance	Yes	Myocardial infarction	5					95	
22	2	76	F	Obstetrics/ gynaecology	II	I.V. induction, inhalation maintenance	Yes	Myocardial infarction	5	Cardiac arrest	5			185	
31	3	65	F	Urology	II	Balanced anaesthesia	Yes	Hypotension	3	Tachycardia	3	Hypovolaemia	5	282	
34	1	76	М	Urology	II	TIVA	No	Bronchospasm	5	Hypotension	5	Impaired right cardiac function	5	85	
37	1	46	F	General surgery	II	Balanced anaesthesia	No	Intubation impossible	5	Hypoxaemia	5	Cardiac arrest	5	140	Death
38	1	53	м	Orthopaedic surgery	II	Balanced anaesthesia	Yes	Intubation, not classified	5	Unexpected difficult intubation	5			68	

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44	1	33	F	ENT surgery	ΙΙ	I.V. induction, inhalation maintenance	Yes	Hypotension	4	Cardiac arrest	5			75	
46	2	53	М	ENT surgery	Π	I.V. induction, inhalation maintenance	Yes	Unexpected difficult intubation	5					160	
48	3	44	М	General surgery	II	TIVA	Yes	Hypoxaemia	3	Pneumonia	5			180	
49	3	27	F	Obstetrics/ gynaecology	II	I.V. induction, inhalation maintenance	Yes	Unexpected difficult intubation	4	Oesophageal intubation	5	Reintubation	4	50	
50	3	66	F	Neurosurgery	II	Balanced anaesthesia	Yes	Hypovolaemia	5	Cardiac arrest	5	Ventilator	1	165	Death
51	3	47	F	Obstetrics/ gynaecology	II	Balanced anaesthesia	Yes	Clotting disorders	5	Unplanned admittance to ICU	5	Acidosis	3	440	
53	3	25	М	Trauma surgery	II	Balanced anaesthesia	Νο	Unexpected difficult intubation	5					125	
54	3	32	М	Trauma surgery	II	Balanced anaesthesia	Yes	Intubation impossible	5					120	
58	2	50	F	Obstetrics/ gynaecology	I	Missing	Yes	Unexpected difficult intubation	5					82	
59	2	44	м	General surgery	I	Combination general and regional anaesthesia	No	Unexpected difficult intubation	5					65	
68	2	58	F	Trauma surgery	Ι	I.V. induction, inhalation maintenance	Yes	Myocardial infarction	3	Hypovolaemia	5	Anaemia	3	285	Death
69	1	5	М	ENT surgery	Ι	I.V. induction, inhalation maintenance	Yes	Cardiac arrest	5					45	Death
80	3	45	М	Neurosurgery	Ι	I.V. induction, inhalation maintenance	Yes	Increased ICP	5	Other central nervous problems	5			429	

BJA

Case no.	Level of care	Age (yr)	Sex	Dept	ASA	Type of anaesthesia	Intubation of trachea	Incident 1	Grade	Incident 2	Grade	Incident 3	Grade	Duration of anaesthesia (min)
6	3	67	F	Neuro surgery	II	Balanced anaesthesia	Yes	Obstruction of the airway	5					335
12	3	3 months	М	Maxillo-facial surgery	II	I.V. induction, inhalation maintenance	Yes	Multiple or missed punction (blood vessels)	1	Obstruction of the airway	5			245
13	2	50	М	General surgery	II	Balanced anaesthesia	Yes	Hypotension	1	Pneumothorax	5			240
20	spec	33	F	General surgery	II	I.V. induction, inhalation maintenance	Yes	Bradycardia	2	Hypotension	5			53
35	2	35	М	Orthopaedic surgery	II	TIVA	Yes	Tracheal tube kinking	5	Tube defect	5	Reintubation	1	110
43	2	62	М	ENT surgery	II	Local anaesthesia	Yes	Reintubation	5	Hypotension	3			605
56	1	58	М	Medical procedure	Ι	Spinal anaesthesia	No	Airway, not classified	5					30
57	1	62	F	Urology	Ι	Balanced anaesthesia	Yes	Unexpected difficult intubation	1	Reintubation	5			220
60	2	45	М	General surgery	Ι	I.V. induction, inhalation maintenance	Yes	Pneumothorax	5					135
70	3	39	F	Neurosurgery	Ι	Balanced anaesthesia	Yes	General reactions, not classified	5					149

Table 4 Intermediate cases identified from the database, ASA PS I and II patients who suffered a severe incident/complication undergoing elective procedures. See Table 3 for abbreviations

being defined as an unexpected difficult intubation. Thus, problems managing the airways in our patients leading to a severe outcome were found with a frequency of 11.6 (95% CI, 7.3–16.8) per million cases, while events with the definition of an unexpected difficult intubation as coded in the database were less frequent with 7.3 (95% CI, 3.9–11.4).

A total of four telephone conferences were held to classify all cases with the nominal group technique (Fig. 3).

## Discussion

To the best of our knowledge, this is the first study that has assessed severe incidents on the basis of data from a national outcome-tracking database. Our study included data from a large European country, with a rate of major complications for healthy patients undergoing elective surgery of about 3 per 100 000 and those identifiable as associated with anaesthesia (such as difficulties in airway management), about 10 per million. The lack of an established national surveillance system has been found to hinder a systematic approach to anaesthesiarelated IECs.<sup>35</sup> The present study analysed data from a national database, the anaesthetic procedures recorded in which were prospectively documented for a quality assurance benchmark analysis. No specific briefing or training was given to the anaesthetists who documented the anaesthetic procedures other than the preparation needed to document the CDS in the departments concerned. The study should therefore be regarded as an observational analysis of prospective data.

## **Incidence comparisons**

The overall incidence of incidents observed when the CDS database was analysed was 16.2%. Other studies have reported rates of 18–32%, all using similar definitions of incidents but with longer survey intervals.<sup>36–40</sup> A single-centre study with a long history of participation in quality assurance projects, using the same definitions, reported a general incident



Fig 3 Nominal group technique.

rate of 22%.<sup>25</sup> As the present study reflects real-life routine reporting of incidents, the general incident rate observed can be regarded as confirming the feasibility of the approach used. A previous study identified three main situations that led to a fatal outcome: coronary artery disease and perioperative is-chaemia, triggered by anaemia; hypovolaemia; and aspiration of gastric contents. In cases related solely to anaesthesia, the authors noted deviations from standard practice in 98% of the cases, such as inadequate management of hypotension in 39%.<sup>7</sup> It is therefore not surprising that 11 of the 36 cases in the present study involved hypovolaemia.

By comparison, a retrospective analysis reported rates of cardiac arrest, critical incidents, and subsequent death of 98.6, 594.1, and 31.2, respectively, per million anaesthesia cases in the group of ASA PS I and II patients. The rates of cardiac arrest and death entirely attributable to anaesthetic management were 18.7 and 1.4, respectively.<sup>41</sup> While these figures look similar to those in the present study, the study concerned was analysing cardiac arrest and deaths, not severe incidents, had a longer survey period, and also included emergency cases.

Two other large studies used death certificates to identify cases retrospectively and analysed deaths on the basis of ICD-9 and -10 codes. An anaesthesia-related death rate of 1.1 per million population per year was found for the USA. Subgroups were analysed for age, but not for ASA PS.<sup>8</sup> A French study analysed a sample of death certificates, and the physicians and anaesthetists involved were also asked about the cases identified. The estimated rate of deaths related to anaesthesia was 54 in 1 million anaesthetic procedures. The risk was reported to be 4 and 54 per million for those with ASA PS I and II.<sup>7</sup> Both studies had substantially longer survey intervals, but also included emergencies and the number of anaesthetic procedures used as the denominator was an estimate on the basis of samples of anaesthetic procedures.<sup>8</sup>

In Australia, all deaths that occur within 24 (to 48) h of anaesthesia, or deaths in which an anaesthetic is thought to have been a contributing factor, have to be reported in accordance with local state legislation. The cases are reviewed, and standardized reports are used. Among 112 deaths considered to be anaesthesia-related, 18 patients were classified as ASA PS I or II. Again, the numbers of anaesthetic procedures are calculated estimates and the proportion of the study population in ASA PS I and II was not assessed.<sup>9</sup>

Arbous and colleagues prospectively identified the incidence of 24 h postoperative mortality and the estimated incidence of coma to be 880 and 50 per million anaesthetic procedures. ASA PS I or II patients accounted for 8.4% of the cases (n=67). Only 21.5% of the procedures were elective, and proportions of ASA PS I or II patients were not stated.<sup>19</sup>

A recent meta-analysis described a decrease in anaesthetic sole mortality in developed countries with an actual rate of 25 per million anaesthetics, the crude surgical mortality for ASA PS I and II patients to be 557 and 1408 per million operations.<sup>2</sup>

In general, comparisons of rates of severe adverse events are hampered by different study intervals, sampling techniques, grading systems for severe outcomes, and by the criteria used for inclusion in studies. It is important to emphasize again that the numbers given in the present study include both outcomes—death and severe health impairment—in the immediate perioperative period.

# General aspects of incident reporting, limitations of the study, and bias

Cases were filtered from the database on the basis of experience in previous studies and were controlled for variables that might have led to a higher ASA PS classification. While filters were used to increase the likelihood of the inclusion of true ASA PS I and II patients, we may have also excluded a proportion of true ASA PS I or II patients among the 1 442 873 patient records (Fig. 1).

We are aware that there might have been more cases that were anaesthesia-related which remained undetected by the approach used. Details of vital signs, anaesthetics, and other drugs administered are not stored in the database; thus, the analyses had to rely solely on the IEC problem codes. In order to focus on anaesthetic involvement, realistic approach was to analyse events using anaesthesia-specific codes. Data generation at the site of the anaesthetic procedure also might yield a problem, because it may not include cases in which mortality due to the anaesthetic procedure occurred at a later point in time.

Ideally, an analytical adjustment should be conducted to remove the influencing factors when estimating anaesthesiarelated or attributable deaths. Therefore, urgent and emergency procedures and cardiac surgery where serious problems are more frequently encountered but where determination of causation might be unclear were excluded, to control for the influences of patients' disease and other factors, in order to limit systematic error, thus restricting the reporting of mortality and serious morbidity to relatively healthy patients, that is, ASA PS I and II. However, we were able to review a quite large population, and a considerable number of, in this group, quite rare events of patients suffering severe harm or dying under an anaesthetic procedure was captured in the study presented.

Maybe even more important than the crude numbers of deaths or the mortality rates attributable to anaesthesia is the thorough analysis of the causation. Medication-related events include, for example, overdose, medication error, and unwanted side-effects. The proportions of medication-related events on overall anaesthesia-associated mortality are reported in a range between around  $20\%^{17}$  <sup>35</sup> <sup>42</sup> up to about 50%.<sup>8</sup> <sup>16</sup> <sup>43</sup> Li and colleagues<sup>8</sup> report that of the 241 anaesthesia-related deaths in their study, 79.7% had adverse effects of anaesthetics in therapeutic use. Biboulet and colleagues<sup>44</sup> reported that four out of eight cases with anaesthesia-related cardiac arrest were in association with anaesthetic overdose.

The rates of anaesthesia-related death due to airway management problems cover a wide range; Biboulet and colleagues<sup>44</sup> reported 25%, Braz and colleagues<sup>16</sup> 55.5%, Charuluxananan and colleagues<sup>42</sup> 21.3%, Gibbs<sup>45</sup> 15%, Kawashima and colleagues<sup>35</sup> 7.9%, Newland and colleagues<sup>43</sup> 20%, and

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Sprung and colleagues<sup>17</sup> 80%. In one small study, assessing anaesthetic mortality in ASA PS I and II patients, two patients out of 56 153 died, the one where anaesthesia was considered the major contributing cause was a difficult intubation. The numbers presented in our study being around 40% for airway problems.

In the absence of codes suggesting other common anaesthesia factors such as malignant hyperpyrexia, anaphylaxis, allergic reactions, problems with regional anaesthesia, etc., these cases all had codes involving the airways (e.g. tube and airway problems) and were therefore identifiable as anaesthesiarelated. Lacking further details, other codes such as hypotension or non-specific reactions could not be classified, nor could the underlying causes, and the cases had to be classified as indeterminate. We considered extrapolating the number of anaesthesia-related severe IECs using details from the observation that only 15% of anaesthesia-related deaths arose from problems involving the airways. These numbers may not be used since patients of all ASA PS were included in the study mentioned, while the medical condition of the patient was considered a significant factor in the fatalities.<sup>9</sup> It has also to be assumed that the relatively healthy patient group in our study might be less susceptible to drug selection and dosage problems, less likely to be resuscitated and would present in better medical condition than ASA III-V patients, in which the majority of deaths occur.<sup>9</sup>

Multiple aspects influence incident reporting-starting with the level of motivation for documenting anaesthetic activities beyond the normal anaesthesia recording. Nevertheless, in contrast to self-reporting systems (critical incident reporting systems), there is an element of routine documentation in the reporting of IECs, it is also important to emphasize that this record in conjunction with details on vital signs, drugs administered, etc. represents the legal documentation in many departments. It can be assumed that acceptance was increased through the use of ergonomic principles,<sup>46</sup> with duplicate documentation being avoided.<sup>24 25</sup> Bias may arise from the fact that contribution to this project is on a voluntary basis. Refusal, or inability to participate, and the level of incidents for these departments remain unknown. With the current design, we have no way of excluding a non-participation bias, which is common in similar studies. While participation in the incident and complication benchmark analysis project is free, or at minimal charge, providing the data requires considerable resources. The availability of equipment (e.g. scanners, or computer interfaces), training, and motivation of personnel may prove obstacles even for departments that are willing to participate. Thus, most of the reported cases came from  ${\sim}100$  different anaesthetic departments, mainly in the federal state of Baden-Württemberg. Furthermore, there might be missing records for single institutions if not all are scanned and critical incidents could therefore be unavailable.

Bias in documenting incidents can also arise from anaesthetists' fear of attracting blame. This can only be overcome by ensuring strict policies of confidentiality in the participating departments. Although data processing for this project is the responsibility of the Medical Board, in which data are kept strictly confidential, departmental policies are not under the Board's direct control. It can only be assumed that departmental participation in the project reflects an attitude in which the cultural environment needed to maintain confidentiality policies is established and sustained.

At the time when CRDs are introduced, many records require correction.<sup>47</sup> Only data from CDS version 2, in use since 1999, were used in the present study—some time after the use of CRD had become routine in many departments. With the routine use of CRDs, documentation discipline becomes more stable. False readings with CRDs still occur, however,<sup>47</sup> and cannot be excluded with the present study design.

While frequent low severity incidents are prone to influence by systematic causes (i.e. documentation discipline), severe incidents with narrow definitions were found to be more stable.<sup>24 48</sup>

General problems include the lack of agreement on how to appraise adverse outcomes and events in anaesthesia, along with anaesthetists' individual opinions about what is worth documenting. Many problems are not technically measurable (e.g. difficult intubation) and threshold measures may prove vague in this extremely complex clinical context. For example, despite the potential importance of arterial pressure measurement limits to determine IECs, no universally acceptable definition of intraoperative hypotension exists.<sup>49–51</sup>

While definitions for normal reference ranges may be established, the impact of deviations will always depend on many co-variables and be finally determined by the clinician, as incidents include the examination of many more variables in the individual clinical context. The emphasis in the CDS is therefore on the anaesthetist's judgement, who may better take account of the individual clinical context and patient situation to detect incidents than any automated system.<sup>52</sup>

The CDS has also been used successfully to create a large outcome-tracking database.  $^{\rm 25\ 27}$ 

The nominal group technique provided scope for discussion and a strategy for solving disagreements between the reviewers in assessing cases. Problem codes for all cases were analysed by each reviewer. Incidents grade 5 were defined as 'permanent damage or death' and was changed in 2003 by the DGAI to 'death'. Before (and even afterwards in some cases), the definition incorrectly included, for example, damage to the teeth, thus cases with codes representing minor problems were excluded.

There is therefore strong evidence that the group of patients identified suffered (unexpectedly) disastrous outcomes or died. However, it remains uncertain whether more patients might have died than the eight for whom the records showed the discharge code 'death'. The introduction of a certain element of bias is always possible with a discussion technique. The possible effects on numerator data are important only in relative and may not be so important in absolute terms.

In view of the differences between studies, the present investigation provides a unique approach to morbidity and mortality for a study population in central Europe. The study combines a large data set of prospectively recorded routine data with a reliable number of anaesthetic procedures. Annual identification of cases and carrying out standardized surveys of the respective departments and anaesthetists as described<sup>7</sup> could provide more detailed information about the cascades that lead to unfortunate outcomes. In addition, analysis of other ASA PS groups will display risk factors for incidents of different grades using the CDS database in the near future.

## **Supplementary material**

Supplementary material is available at *British Journal of Anaesthesia* online.

# **Authors' contributions**

J.H.S.: study design, data (modified nominal group technique) and statistical analysis, manuscript draft, manuscript revision, and member of the quality assurance group of the Medical Council of Baden-Württemberg since 2002, for which he was appointed chair in December 2012. The group is evaluating the data of the CDS for the benchmark project.

A.W.: data analysis (modified nominal group technique) and manuscript revision. B.F.: data analysis. A.H.-B.: data analysis (modified nominal group technique). U.B.: study design and manuscript draft. H.V.A.: study design and manuscript draft. A.S.: study design and manuscript correction. H.J.B.: data and statistical analysis. W.H.: data analysis (modified nominal group technique), study design, co-authoring ethical approval, and manuscript reediting.

## **Declaration of interest**

U.B. is now working for Boehringer-Ingelheim GmbH, Ingelheim, Germany. W.H. is the owner of AQAI GmbH (Applied Quality Assurance in Anaesthesia and Intensive-Care Medicine/Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin, AQAI Ltd, Mainz, Germany). AQAI provides commercial analysis of data sets for various hospitals. AQAI is also holding the database on its servers. The work was supported by AQAI by giving free access to the database and by generating some special results out of the database. AQAI did not influence any results of this paper in view of any commercial interests that AQAI may have.

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