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JAMES COOK
UNIVERSITY
AUSTRALIA

DOCTOR OF PHILOSOPHY

PERIOPERATIVE PATIENT OUTCOME IN ANAESTHESIA

Thesis submitted by

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For the degree of Doctor of Philosophy in

The School of Public Health, Tropical Medicine and

Rehabilitation Sciences at James Cook University

November 2013

STATEMENT OF ACCESS

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I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

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STATEMENT OF THE CONTRIBUTION
OF OTHERS

I wish to acknowledge the contribution of my co-authors to a number of manuscripts included as part of this thesis:

Chapter 2   The Heidelberg Perianaesthetic Questionnaire – development of a new refined psychometric Questionnaire

I developed the study protocol, did the statistical analysis and drafted the manuscript. Professor Johann Motsch is head of clinical research at Heidelberg University. He introduced me to research methods in clinical practice and has guided me in the development of my own research projects. He has been my teacher and mentor since I started my specialist training in 1999. Sebastian A. Fornaschon and Susanne Frankenhauser helped recruit patients and recorded and transcribed the interviews. My brother Maximilian Schiff, Martin Bauer and Stephanie A. Snyder-Ramos provided expertise with the psychometric design and helped with the testing. Eike O. Martin provided infrastructure and means for the study and made sure that I got time off for the research project, while Bernd W. Böttiger helped with the statistical analysis. Stefan Knapp helped recruiting patients at his institution.

Chapter 3   Development of a questionnaire to assess patients experiences with anaesthesia ("EFA"), for the Workgroup: Quality management of the German Society of Anaesthesiology (DGAI)

This paper was completed in collaboration with Leopold L. Eberhart, *3* Deputy Director, Department of Anaesthesiology and Postoperative Intensive Care Medicine, University Giessen-Marburg, Campus Marburg, Germany, and Michael Hüppe, Universität zu Lübeck, Department of Anaesthesiology, Lübeck, Germany. Both of them provided their expertise and results with their own questionnaire to form the new "EFA". The project was chaired and funded by the DGAI (German Society of Anesthesia and Intensive Care Medicine, Deutsche Gesellschaft für Anaesthesie und

Intensivmedizin) by Alexander Schleppers, Director of the DGAI, Nürnberg, Germany. Angela Möllemann, Georg Pützhofen, and Jörg Martin contributed to the study design and helped recruit patients at their institutions, while Ulrich Bothner helped with performing the statistical tests and edited the manuscript. I developed the study protocol, did the statistical analysis and composed the manuscript.

Chapter 4 Establishing a perianaesthetic patient satisfaction questionnaire by cross validation of three questionnaires - a quality control study

This paper was prepared in collaboration with the Department of Anaesthesiology and Postoperative Intensive Care Medicine, University Giessen-Marburg, Campus Marburg, Germany. Leo Eberhart co-developed the study protocol and helped with patient recruitment. Susanne Frankenhauser and Sebastian A Fornaschon helped with patient recruitment and entered data into the database. Bernd Böttiger and Johann Motsch provided expertise with study design and statistical tests. Prof Martin provided resources needed for the study. I developed the study protocol, did the statistical analysis and wrote the manuscript.

Chapter 5 The Anaesthesia Preoperative Evaluation Clinic (APEC): A prospective randomised controlled trial assessing impact on consultation time, direct costs, patient education and satisfaction with anaesthesia care

Susanne Frankenhauser and Sebastian A. Fornaschon helped with patient recruitment and follow up and entered data into the database. Stephanie Snyder-Ramos and Karin Schmidt participated in the actual patient care. Bernd Böttiger and Johann Motsch provided expertise with study design, Maria Pritsch helped with the statistical tests. Prof Martin provided resources needed for the study. I developed the study protocol, did the statistical analysis and wrote the manuscript. Clare Heal helped with the manuscript draft and did the proof corrections.

Chapter 6   Paediatric Peri-anaesthesia Questionnaire: development and data from eight hospitals across Germany

This paper was prepared by the two main authors, Nicolai Russ and myself. Together we developed the study design in collaboration with Andreas Walther, who also helped with the manuscript draft. Katja Ihringer recruited patients, helped with the initial interviews and entered data into the database. Clare Heal helped with the manuscript, while I did the statistical analysis. Eike Martin helped recruiting other hospitals and provided his expertise for the study design.

Chapter 7   Paediatric patients with disabilities – assessment of satisfaction with anaesthesia

This study and publication was achieved with the same contributions detailed for the research in Chapter 6.

Chapter 8   Case analysis of unexpected critical incidents in ASA I and II patients derived from a benchmarking project in anaesthesiology

This study was completed in collaboration with the Medical board of the Federal Country Baden-Württemberg, Germany. Matthias Felsenstein and Arne Pullwitt were responsible for the recruiting of hospitals, the mailing, and collection of information from the hospitals. Ulrich Bothner and I developed the study protocol and did the statistical analysis, while Albrecht Henn-Beilharz and Jörg Martin helped with the evaluation of the answers received from the hospitals.

Chapter 9   Major Incidents, Events and Complications (IECs) in ASA PS 1 and 2 Patients Undergoing Elective Procedures — Results Based on 1.36 Million Anaesthetic Procedures

This study was completed in collaboration with the Medical board of the Federal Country Baden-Wuerttemberg, Germany and AQAI (AQAI GmbH, Applied Quality Assurance in Anesthesia and Intensive-Care Medicine/*Angewandte Qualitäts-sicherung in Anästhesie und Intensivmedizin*, AQAI Ltd., Mainz, Germany). AQAI is

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I would like to thank Prof Dr Johann Motsch for helping me to set up the first of the studies and Prof Dr Eike Martin for granting me study leave. Without the experiences and knowledge gained during the first studies I would not have been able to set up the further studies that constitute this thesis. I would like to thank Samantha Talbot for proofreading and help with editing the thesis.

Finally, I would like to thank my family and friends for their patience.

23.11.2013

Date

Signature

LIST OF ABBREVIATIONS

AAI	Atlantoaxial Instability
AEs	Anaesthetic Events
ANP	Anaesthesiological Questionnaire (Anästhesiologischer Nachbefragungsbogen für Patienten)
ANP-KA	Anaesthesiological Questionnaire Cardiosurgery (Anästhesiologischer Nachbefragungsbogen für Patienten, Kardiochirurgie)
ANZCA	Australian and New Zealand College of Anaesthetists
APAIS	Amsterdam Pre-operative Anxiety and Information Scale
APEC	Anaesthesia Pre-operative Evaluation Clinic
AQAI	Applied Quality Assurance in Anesthesia and Intensive Care Medicine/*Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin*, AQAI Ltd., Mainz, Germany
ASA PS	American Society of Anaesthesiologists Physical Status
CDS	Core Data Set
CFA	Confirmatory Factor (Component) Analysis
CI	Confidence Intervall
DGAI	German Society of Anaesthesia and Intensive Care Medicine
DSG	Down Syndrome Group
EFA	Exploratory Factor Analysis
"EFA"	Questionnaire to assess patients experiences with anaesthesia ("Evaluierter Fragebogen Anästhesie")
ENT	Ear, Nose, Throat
EVAN-G	Evaluation du Vécu de l'Anesthésie Générale
F	Female
GA	General Anaesthesia with/without Regional Anaesthesia
HPQ	Heidelberg Perianaesthetic Questionnaire
Hrs	Hours
IC	Institutional Consent/Approval
ICD	International Classification of Disease
IDC	Item Dimension Correlation

IDV	Item Discriminant Validity
IEC	Incidents, Events, and Complications
IIC	Item Internal (Interitem) Correlation
IOM	The Institute of Medicine
ISAS	Iowa Satisfaction with Anesthesia Scale
LPPSq	Leiden Perioperative care Patient Satisfaction questionnaire
M	Male
MAC	Monitored Anaesthesia Care
MANOVA	Multivariate Analysis Of Variance
MBI	Maslach Burnout Inventory
MC	Multiple Choice
MGPq	McGill Pain questionnaire
NRS	Numeric Rating Scale
OR	Operating Room (Theatre)
PACU	Post-operative Anaesthesia Care Unit (Recovery Room)
PCA	Principal Component Analysis
POD	Post-operative Day
PONV	Post-operative Nausea and/or Vomiting
POQOLS	Paediatric Oncology Quality of Life Scale
PPIA	Parental Presence during Induction of Anaesthesia
PPP33	Perioperative Patient Questionnaire (Fragebogen zur Patientenbeurteilung der Perioperativen Phase)
PPQ	Paediatric Peri-anaesthesia Questionnaire
PSI-S	Parenting Stress Index Short Form
PSPACq	Patient Satisfaction with Perioperative Anaesthetic Care Questionnaire
QA	Quality Assurance
RA	Regional Anaesthesia
SD	Standard Deviation
SOPPCAS	Scale of Patients' Perceptions of Cardiac Anaesthesia
STAI	Spielberger Stait-Trait Anxiety Inventory
UK	United Kingdom
USA	United States of America
VRS	Visual Rating Scale

WCCS   The Wascana Client-centered Care Survey

WOM   Word of mouth

ABSTRACT

Background

Patient satisfaction with anaesthesia is an important but complex measure. However, there are only a few appropriate psychometrically designed instruments that contain items on all important factors. Psychometric instruments providing information about satisfaction in children are completely missing. Thus, a need for sound psychometrical instruments to assess satisfaction with anaesthesia care in the German adult and paediatric patient population exists.

Anaesthesia is a high risk medical profession and it is important to evaluate severe incident, events and complications (IEC) including deaths that occur. Details about the anaesthetic risks are an important part of the anaesthetic consult. There is no standardised worldwide registry system and a lack of thorough reported data on critical IEC or deaths, hence, debate over the incidence of anaesthesia-related mortality in the different countries continues and rates for anaesthesia-related severe IEC in Germany need to be evaluated.

The aims of my studies were to develop measures for **perianaesthetic satisfaction in adult and paediatric patients, as well as to determine the rate of severe IEC attributable to anaesthesia in Germany**.

Specific aims of the studies presented in this thesis:

Satisfaction

- **To develop perianaesthetic <u>questionnaires for adult and paediatric patients</u> that adhere to a strict psychometric design**

- **To compare satisfaction with anaesthesia between participating hospitals,**

in paediatric patients with/without disabilities and existing questionnaires

- **To analyse the anaesthesia pre-operative evaluation clinic (APEC) and the ward with regard to time (costs), information gain and patient satisfaction**

IEC (incidents, events and complications)

- **To evaluate the general quality of the collected (core) data (set) (CDS), the frequency of coding errors in** American Society of Anaesthesiologists Physical Status (**ASA PS**) **1 and 2 Patients and to identify filtering methods that could be used in future studies**

- **To elucidate the underlying mechanisms of the severe IEC**

- **To assess the frequency of severe IEC in healthy patients in the whole dataset and the anaesthetic contributions**

Methods

The thesis comprises the results of eight dedicated studies. One regional, one national, and one paediatric questionnaire were developed based on a sound psychometric design to assess patient satisfaction with anaesthesia. This included patients' involvement, cognitive and pilot testing, validation for validity and reliability, and the adjustment for confounding variables. The basis of this thesis is the multicentre development of the Heidelberg Perianaesthetic Questionnaire (HPQ). Five of the studies presented are directly linked to or are using the findings and experiences made in this study.

The questionnaires were used to test the performance of an APEC, to benchmark hospitals, as well as to test satisfaction between different patient groups. IEC were assessed in the CDS, which is in use as a national surveillance system. A first study

identified rather healthy patients displaying severe IEC. The frequency of coding errors in the dataset between 2002 and 2004 was determined by matching the cases to more detailed reports received by mail from the participating anaesthetic departments, and the nature of IEC were analysed. Filtering methods to analyse a large set of data with more than 4 million anaesthetic records were employed. In this second study, the incidence of severe IECs in healthy patients was determined. Cases where the underlying (IEC) codes suggested direct anaesthetic involvement were identified and analysed through normative discussion groups.

Overall results and conclusions of the studies presented in this thesis

My psychometric questionnaires were used to evaluate satisfied and dissatisfied groups and to benchmark satisfaction with anaesthesia care at different hospitals. The main areas where satisfaction may be improved include patient information, preparation for anaesthesia, as well as discomfort and its treatment. Satisfaction with anaesthesia was lower in the groups of children with disabilities as compared to non-disabled. Negative comments related to the anaesthetists' behaviour, the anaesthetic consultation, and anxiety.

Another study that co- and cross-validated a translated French questionnaire found that instruments should best be constructed and validated within the same socio-cultural background. Assessment of the anaesthetic consult found favourable results in terms of time spent for the consult with the patient and amount of information passed on to the patients for the APEC compared to the ward.

The studies using the CDS provide detailed data on the topic of severe IEC including death. Coding errors were encountered with a frequency of nearly 50%. Most reported events (IEC) were related to patient, surgical or procedural risks, 15% were noticeable or conspicuous events. The rate of major morbidity/mortality was about 3 per 100,000, the anaesthetic contribution was about 1 per 100,000 cases in healthy patients.

Overall relevance of the studies presented in this thesis

My studies presented here constitute a sound psychometric approach to the development of instruments for the measurement of patients' satisfaction with anaesthesia and the first worldwide for paediatric patients. The questionnaires presented are valid and reliable tools and thus hold the key to essential feedback data from patients for the identification of specific areas where improvement in patient care can be achieved. The relevance of the developed tools presented in this thesis is highlighted by the fact that all questionnaires have already found entry to routine clinical use at various hospitals worldwide.

My studies also provided sound evidence that an APEC substantially improves the cost efficiency and the delivery of comprehensive information to the patients during the anaesthetic consult. In the light of cost containment discussions with time restraints in patient care, this is an important finding.

The studies using the CDS provide the first reliable data on the frequency of severe anaesthesia-related IEC and death for Germany, holding the key for national monitoring and international comparison of rates. While they indicate low rates of anaesthesia-related IEC, measures to improve the quality of the CDS data need to be adopted, facts that have been presented at various national and international conferences.

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THESIS INTRODUCTION AND OVERVIEW

Introduction

Annually, an estimated 230 million anaesthetic procedures are being conducted worldwide[1], in Germany alone about 10 million occurred in 2009 (www.gbe-bund.de). In general, anaesthesia means 'loss of sensation'. General anaesthesia induces deep hypnosis to allow tests or procedures (e.g. colonoscopy etc.) and surgical operations on patients. Anaesthesia aims to prevent pain and discomfort. With the induction of general anaesthesia, the anaesthetist deliberately aims to alter physiological functions. Unconsciousness, muscle paralysis and pain control enable a wide range of medical procedures to be performed.

The state of anaesthesia is considered intrinsically unsafe. According to Aitkenhead[2] the induced unconsciousness carries with it risks of airway obstruction, soiling of the lungs, and inability to detect peripheral injury. The drugs administered may have side effects, particularly on the cardiovascular and respiratory systems. The induced muscle paralysis necessitates the use of artificial ventilation, making the patient dependent on the anaesthetist and his equipment for the fundamental functions of oxygenation and excretion of carbon dioxide. The anaesthetist therefore not only plays a role in ensuring that the patient is asleep, or, to be more precise, hypnotised or anaesthetised, but he/she also plays a fundamental role in securing the physiological functions of the patient once the patient is "under" anaesthesia for the surgical procedure. As a result, anaesthesia generally puts the patient at risk of complications resulting from the actions (or inactions) of the anaesthetist, the actions of the surgeon, and from failure or malfunction of anaesthetic equipment.

In the immediate recovery period, the patient will still be under the supervision of the anaesthetic team, while physiological functions slowly return to normal, following pharmacological rules of half-live times and organ function. At this stage, pain and side effects of the drugs administered may take effect and be perceived by the patient once the patient starts regaining consciousness.

Patients' satisfaction with anaesthesia is generally a quite intricate issue. Patients want to be informed about the course and the risks of the procedure. However, often the risks associated with the course of anaesthesia are not readily available and existing information on specific courses or from certain areas may not be generalisable. Apart from other, more objective outcomes such as anaesthetic sequelae, satisfaction also includes patient expectations and perceptions.[3] Thus patients' satisfaction with anaesthesia is complex, consists of different aspects and entities and also involves parts of anaesthetic care such as pre-anaesthetic consultations.

Background

Patient surveys provide valuable data for utilisation of services rendered in patient care and supply care providers with information about patient preferences. In addition, they may improve and intensify the anaesthetist-to-patient relationship[4], but may also be seen as tools in marketing strategies.

Patient satisfaction is fundamentally based on *patient-centered care* and *shared decision making*—two new and often still foreign concepts to many clinicians.[5] Investigating patient satisfaction with anaesthesia is especially complicated because of several reasons:

Satisfaction as an entity comprises many different aspects such as physical, emotional, mental, social and cultural factors. Satisfaction is further influenced by the triangular relationship of the patient-clinician-organisation and the patient's judgment may be strongly affected by the final result, which depends on factors other than the anaesthesia (i.e. surgery) as well as other known (i.e. age, gender etc,) or unknown variables.[6, 7] Satisfaction is defined as the result of the comparison between patients expectations and perceived outcome.[8] Patient satisfaction depends on objective as well as subjective patient values. Both elements are absolutely personal, that is, each patient has expectations that result from his or her own beliefs and previous experiences. The experience of the treatment are individual perceptions by the patient and may be independent of its objective measurement (for example pain, nausea etc.).[9]

Most of the scientific literature claiming to accurately assess patient satisfaction with anaesthesia focus on the assessment and management of purely objective outcomes, such as pain, nausea, and vomiting.[9-13] This is an alarming finding especially when compared to other industries where the emphasis is on the 'customers' and where whole organisations are being built around the customer.

Even to date, many studies are using non-validated instruments or poorly developed tools, which may lead to bias and inaccurate results.[14] The existing instruments are also developed in countries with unique cultures and are therefore difficult to compare or transfer.[15] A problem arises when instruments are applied to patients in different cultures, speaking different languages, since there is no 'gold standard instrument' for measuring satisfaction.

Therefore, instruments devoted to measure patient satisfaction need to follow a step-wise psychometric process and subsequent validation in practice. This will result in a multidimensional questionnaire using multiple items to investigate specific events.[6, 14]

Assessing children's experiences with anaesthesia care is even more complex than in adults. Answering a questionnaire requires explicit recall, which in turn, requires explicit memory which children begin to develop at around 3 years of age.[16] Opinions about satisfaction with care are rarely sought from children. Parental opinions of satisfaction with care have previously been used as a substitute. The simplicity[17] or the focus on certain[18] or general aspects[19, 20] of the anaesthetic experience pose limitations in the assessment of children's satisfaction with anaesthesia. In addition, there are no data on satisfaction with anaesthesia in the group of disabled children.

There is clearly a need for thorough, developed multi-item psychometric instruments that measure specifically adults and children's satisfaction with anaesthesia. Moreover, there is a need to compare developed instruments to existing instruments of the aimed socio-cultural background.

The patient has the right to be informed about the course and the risks of the (anaesthetic) procedure. This is part of the pre-anaesthetic assessment, which also involves a review of the medical records, patient's history, a physical examination with appropriate investigations[21-23] and obtaining consent. The assessment process can take up to 30% of the total anaesthesia time and/or account for up to 9% of the total

anaesthesia cost.[24] Studies have shown patient satisfaction correlates strongly with the time spent at the outpatient clinic.[25, 26] However, Anaesthesia Preoperative Evaluation Clinics (APECs) have not been evaluated for any of these outcomes.

Anaesthesia is perceived to be a particularly risky area of medicine[27] but the risks are not readily listed anywhere and existing data may not be generalisable from the specific region/area of their origin.[2] Mortality is literally a vital estimate of risk with a clear definition, in contrast to the more debatable definitions of morbidity. Because of the rarity of this complication, mortality is also a somewhat crude estimate of risk. The main problem that renders comparisons between studies on anaesthesia-related or anaesthesia solely caused mortality difficult is that different criteria to define anaesthetic death are used (based on differing time periods, i.e. starting from deaths in the Operating Room (Theatre) (OR) during anaesthesia to up to one year after the procedure), and variations are encountered in definitions separating anaesthetic and surgical factors. In addition, some studies have to rely on estimates only of the total number of anaesthetic procedures as the denominator, increasing the variation even further. Thus, a wide range of estimates on perioperative anaesthetic mortality exists.[2, 27]

Unfortunately, no standardised worldwide registry system exists that would allow the thorough reporting of information surrounding these deaths, including outcomes by surgical subtypes, by anaesthetic subtype, and by patient risk groups.

Specific aims

Satisfaction

The impetus behind the development of questionnaires to assess patient satisfaction with anaesthesia was the intention to install an Anaesthesia Preoperative Evaluation Clinic (APEC) at the Department of Anaesthesiology at Heidelberg University, as well as a growing interest in patient experiences with the process of anaesthesia. A colleague, Martin Bauer, had developed a brief patient satisfaction questionnaire for our department.[4] This brief instrument includes some psychometric features, but lacks refinement in details of patient concern and was not developed in conjunction with

patients and carers. It was found not suitable to evaluate the complete anaesthetic process. Nevertheless, I was able to use the corresponding research infrastructure in our department. As the APEC was also to be open for paediatric patients undergoing a wide range of anaesthetic procedures, this patient group was also of particular interest in terms of patient satisfaction.

Poor information about the anaesthetic procedure carries potential problems. If the anaesthetic procedure and its risks are poorly understood, informed consent is of questionable value and may lead to fears and adverse outcome. There was considerable scientific, clinical and economic interest to evaluate experiences of the different patient groups with anaesthesia, the pre-anaesthetic consult, as well as the APEC in terms of its efficiency.

This triggered the following **specific aims for my PhD studies on anaesthesia satisfaction**:

- **to develop perianaesthetic <u>questionnaires for adult and paediatric patients</u> that adhere to a strict psychometric design (Chapters 2, 3, 6)**

- **to compare scores of participating hospitals (Chapters 2, 3, 6)**

- **to compare existing questionnaires (Chapter 4)**

- **to compare the APEC and the ward with regard to time (and as secondary, outcome costs), information gain and patient satisfaction (Chapter 5)**

- **to compare satisfaction with anaesthesia in paediatric patients with and without disabilities (Chapter 7)**

<u>IEC (incidents, events and complications)</u>

Realistic estimates of the incidence of mortality, even if based on the best available data, show a wide variation between different studies, being influenced by the type

and the origin of the study. Therefore, risks of anaesthesia (i.e. results of IEC), and specific estimates vary for each country, and are not readily listed anywhere, but are a central part of the anaesthetic consult. Anaesthesia-related IECs not only impact on the patient's wellbeing, they can also impact on today's cost-conscious clinical healthcare environment.[28]

In Germany, a national surveillance system on the basis of a minimal set of data (the core dataset, CDS) in conjunction with a standardised reporting system for anaesthesia-related IEC was established nearly two decades ago.[29] The data collected in the federal state of Baden-Wuerttemberg has never undergone scientific analysation but was made available to me. There has been a strong interest to evaluate this CDS to get a realistic image of severe morbidity and mortality in the state, which has prompted me to formulate and subsequently address the following **specific aims for the analysis of severe IEC and mortality in healthy patients and the anaesthetic contribution (Chapter 8, 9)**:

- **to evaluate the general quality of the collected (core) data (set) (CDS) (Chapter 8)**

- **to assess the frequency of coding errors in ASA PS 1 and 2 Patients (Chapter 8)**

- **to elucidate the underlying mechanisms that led to the severe IEC (Chapter 8)**

- **to identify filtering methods that could be used in future studies (Chapter 8)**

- **to assess the frequency of severe IEC in healthy patients in the whole dataset and the anaesthetic contributions (Chapter 9)**

Setting

The clinical studies took place in Germany. Heidelberg University is a major tertiary referral center, with a total capacity of 2000 beds. It is one of the largest university hospitals across Germany and Europe. The recruitment of patients started at Heidelberg University hospital with the first study on patient satisfaction being the development of the HPQ (Heidelberg Perianaesthetic Questionnaire) (Chapter 2). Subsequently, I was able to involve up to eight departments from across Germany to include patients at other institutions for the multicentre studies on satisfaction with anaesthesia in adult and pediatric patients that followed (Chapters 2, 3, 4, 6, 7). The study presented in Chapter 5 is the only study presented in the thesis that included patients from a single institution. Further collaboration was established with specialists to collect information for a national questionnaire (Chapter 3). Other institutions were contacted to receive input from psychologists (Chapter 2) and epidemiologists (all Chapters) in the course of the studies. One of the studies was triggered by the DGAI (German Society of Anaesthesia and Intensive Care Medicine; Chapter 3). The DGAI was also involved in another study (Chapter 9), when part of the national surveillance system was to be evaluated by myself and members of a working group on quality assurance in anaesthesia, which is situated at the medical board of the federal state of Baden-Wuerttemberg (Chapters 8, 9). For Chapter 9, AQAI (Applied Quality Assurance in Anesthesia and Intensive Care Medicine/*Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin*, AQAI Ltd., Mainz, Germany), which usually provides commercial analysis of data sets for the medical board, provided free access to the database and also assisted in generating some special results from the database.

The core dataset on anaesthesia IECs consists of patients from a total of 101 German institutions (Chapters 8, 9).

Approval by the Research Ethics Committee given for each of the studies (see Chapters) and Ethical oversight was provided by JCU, Approval Notice H3805.

Studies involved in this thesis

Figure 1.1 depicts an overview of all studies involved in the thesis and details how each contributes to answering the 'Specific Aims' listed above.

There was considerable scientific, clinical and economic interest to evaluate experiences of the different patient groups with anaesthesia, the pre-anaesthetic consult, as well as the APEC in terms of efficiency. This forms the first major branch (satisfaction) of my thesis. The other branch answers the need and strong interest to evaluate the CDS to achieve a precise picture of severe morbidity and mortality in patients undergoing anaesthesia in Germany (IEC).
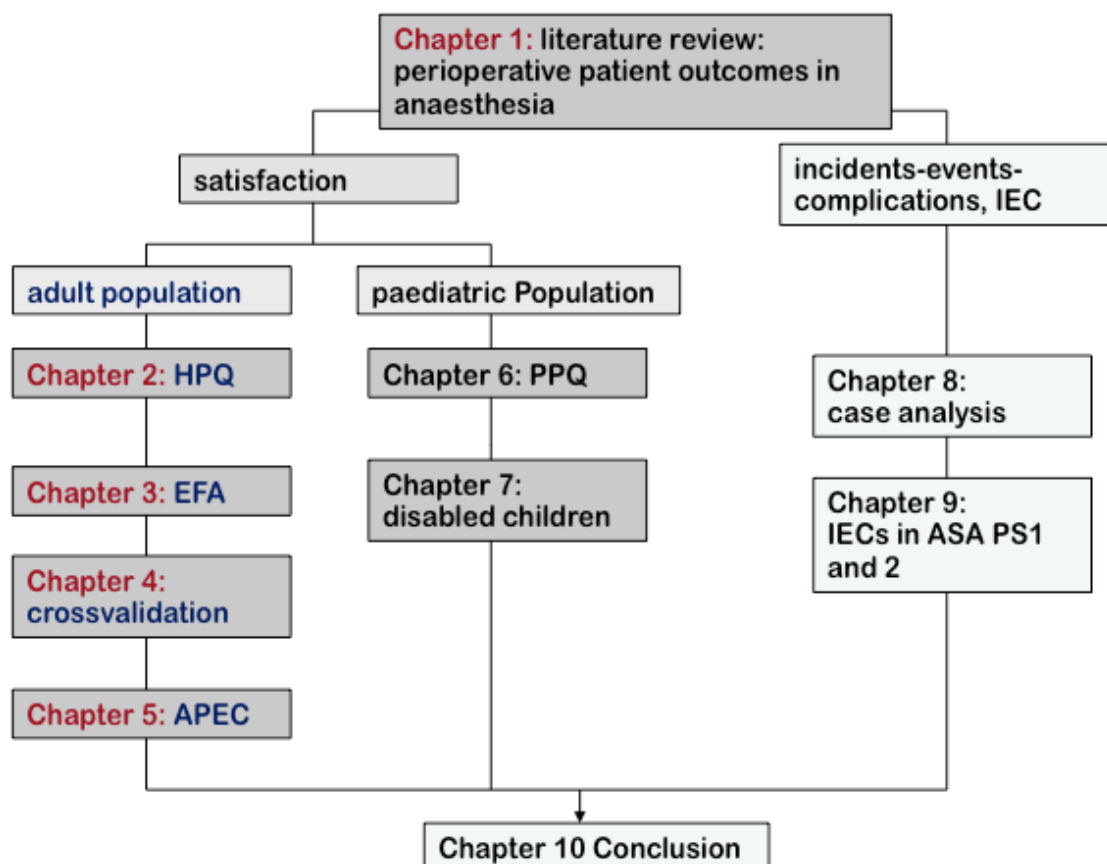
Figure 1.1: Thesis flow chart

First Branch – Satisfaction: The first study in Chapter 2 provides the basis and foundation of my satisfaction studies. Results and experiences gathered during this study influenced all subsequent studies on adults (adult population) and children (paediatric population). The resulting questionnaire, involving 1398 patients and 59 health care professionals, is based on maximum rigour of psychometric development and is suitable to be administered to all adult patients undergoing general anaesthesia (GA), a fact, that has been confirmed in a recent, independent study.[14] This first multicentre study, '**The Heidelberg Perianaesthetic Questionnaire (HPQ) – development of a new refined psychometric Questionnaire**' covered a regional area of anaesthetic supply within the vicinity of Heidelberg University. The second study aimed at developing a national questionnaire, where results and experiences of three regional questionnaires were merged into a single, national questionnaire (Chapter 3 '**Development of a questionnaire to assess patients experiences with anaesthesia ("EFA")**') to allow a broader (in terms of area of distribution and patients' population), that is, a nationwide patient spectrum to be represented. Again, a maximum of psychometric rigour was applied in this multicentre study for which a total of 1048 patients were analysed.

In Chapter 4, my own instrument, the HPQ as developed and discussed in Chapter 2, was compared with two other instruments. One, the PPP33, had already been used in Chapter 3, the other had been established in a different socio-cultural background. With 219 patients recruited and 184 patients analysed, this study **established a perianaesthetic patient satisfaction questionnaire** (the French EVAN-G) **by cross validation of three questionnaires as a quality control study.**

The APEC – one trigger of the first study (Chapter 2) – was evaluated in the following study '**The Anaesthesia Preoperative Evaluation Clinic (APEC): A prospective randomised controlled trial assessing impact on consultation time, direct costs, patient education and satisfaction with anaesthesia care**' (Chapter 5), in comparison with the anaesthetic consult on the wards. The outcomes measured were the length of time for each consultation, the amount of information passed on to patients and the level of patient satisfaction, with a subset of questions used to address the pre-anaesthetic consultation on a total of 174 patients.

As our department caters for patients of all age groups, we were also interested in satisfaction of our paediatric patients. The two studies involving paediatric patients are presented in a separate arm of Figure 1.1 (paediatric population) and in Chapters 6 and 7. The instrument that is presented in Chapter 7 '**Paediatric Perianesthesia Questionnaire: development and data from eight hospitals across Germany**' can be considered a benchmark study for investigating paediatric patients satisfaction with anaesthesia. By comparison to other available instruments that display hardly any psychometric features, it was constructed using the same methods and psychometric rigour as in the studies on adults (Chapter 2–4). It was not designed to be specifically answered by the children alone in order to reduce the number of missing questionnaires, but some questionnaires were directly answered by children. This multicentre study analysed questionnaires completed by 1052 children and their families at eight anaesthesia departments.

Following the interest of one of my co-authors, Nicolai Russ, whose son has trisomy 21, the 'Down syndrome', I set up a study aiming to evaluate satisfaction with anaesthesia care on a large number of children with different disabilities: '**Paediatric patients with disabilities – assessment of satisfaction with anaesthesia',** (Chapter 7). Two groups were considered, a group of children with disabilities and a group of children with Down syndrome (215 disabled children; 125 answers from Down syndrome journals, 90 from the hospitals). The results were compared to matching controls drawn from patients included in the study presented in Chapter 6.

Second Branch – Incidents, events and complications (IEC): Studies in the second major branch were based on the availability of the CDS and the need to assess severe IEC and mortality, in an effort to generate reliable estimates for the risks of dying under anaesthesia in Germany. Providing the risks may also be a part of the anaesthetic consult as presented in Chapter 5. The first study '**Case analysis of unexpected critical incidents in ASA PS 1 and 2 patients derived from a Benchmarking Project in anaesthesiology'** (Chapter 8) evaluated the quality of the collected CDS of 366,334 ASA PS 1 and 2 patients. Data in the CDS for which severe IEC were found were compared to 317 anaesthetic reports received by mail and the

frequency of coding errors in ASA PS 1 and 2 patients, as well as the underlying mechanisms that had led to the severe IEC were analysed.

The results of the study presented in Chapter 8 were used to employ filtering methods for the analysis of the CDS between 1999 and 2010 (Chapter 9). This study '**Major Incidents, Events and Complications (IECs) in ASA PS 1 and 2 Patients Undergoing Elective Procedures — Results Based on 1.36 Million Anaesthetic Procedures**' determined the incidence of severe perioperative outcomes in healthy patients in ASA PS 1 and 2 undergoing elective procedures. Nominal group techniques were used to determine overall severe outcomes as well as direct anaesthetic involvement in the 84 cases identified in the CDS where the underlying problem (IEC) codes suggested such an involvement.

Collaborations and research support

Available funding

CHAPTER 1:
LITERATURE REVIEW

Overview

An ever-increasing competition in the health care marketplace has fuelled the drive toward increased use of consumer surveys to assess health care experiences. In general, patient surveys provide valuable data for utilisation of services rendered in patient care and supply care providers with information about patient preferences. It is important to realise that instruments upon which decisions may be made have to be valid, reliable and multidimensional.[30] Unfortunately, many of the available instruments do not take into account the complexity of satisfaction, which includes components such as physical, emotional, mental, social and cultural factors, the strong emotional context and the influence of specific drugs on cognition especially if the desired outcome is satisfaction with anaesthesia. In addition, anaesthesia is deemed a high risk area among the medical professions, and part of the anaesthetic process might not even be consciously accessible to the patient (i.e. general anaesthesia). In general, the anaesthesia-related risk has been significantly reduced within the last decade. Nevertheless the risk and the possibility of dying or suffering permanent damage still exists.[28, 31-41] It therefore remains important to report of anaesthesia-related incidents, events, and complications (IEC). IEC not only impact on the patient's wellbeing, they can also impact on today's cost-conscious clinical healthcare environment.[28]

While I was working as a registrar I was given the opportunity to start my own research project and I embarked on the development of a perioperative anaesthetic questionnaire that strictly adheres to a psychometric protocol in order to be valid and reliable. While doing so, I was nominated as a member of the quality assurance working group at the medical board of Baden-Wuerttemberg, one of Germany's largest states, to evaluate anaesthetic data on sever morbidity and mortality. Consequently, and from a public health point of view, I have put focus on the

assessment of patient outcome in anaesthesia, with emphasis on the development of valid and reliable tools to assess satisfaction in adults and children/parents/carers, as well as on the incidence and the impact of severe IECs – important and timely research topics.

This review of published literature constitutes the foundation for my doctoral studies. It aims to give a critical overview of the current published knowledge on the topics of perioperative patient satisfaction with anaesthesia and severe perioperative IECs and mortality (the most severe IEC) as patient outcomes.

By reviewing the literature, I sought to provide an evidence base for the conduct of the studies, which I now present in this thesis. It also helps to put my own studies into context with contemporary published literature. The literature review is structured in four main parts:

1. Historical perspective

2. Epidemiology and public health impact of patient outcomes with a focus on patient satisfaction and severe IECs

3. Measuring patient satisfaction in anaesthesia

3a. Methodological aspects

Validity

Reliability

Feasibility/Acceptability

Method and timing of administration

Bias and confounding variables

3b. Satisfaction in anaesthesia in adult patients

3c. Satisfaction in anaesthesia in paediatric patients and/or parents

4. Measuring mortality and severe IECs in anaesthesia

4a. Introduction

4b. Mortality and severe IECs in anaesthesia

Search strategies

Satisfaction in anaesthesia in paediatric or adult patients

The search was conducted using Medline, the Cochrane Data Base, and Google Scholar for studies published between January 1995 and March 2013. The search was restricted to German and English publications. The search also included tangential electronic exploration of related articles (i.e. 'snowballing': using links to related references to search for additional articles).

In recent years the annual output of papers indexed as satisfaction-related has reached several hundred. Thus, the first step of the literature review was to identify relevant literature. The search strategy employed was developed to identify literature representing 'good quality' reports that were addressing satisfaction with anaesthesia using a questionnaire, or an equivalent type of interview. As poorly constructed survey instruments are prone to bias and thus misleading outcomes, the definition of a 'patient-satisfaction questionnaire' included that it was an instrument that was developed using at least elements of psychometric techniques. Only those papers that met these criteria were scrutinised in detail. The studies with low methodological rigour were screened and a sample will be presented only for comparison.

Thus, included in the review were only articles where the published report included the results of an explicit assessment of anaesthesia related patient satisfaction, i.e. the investigators assessed satisfaction as a dependent variable.[42, 43] Studies using the same instrument were only included if the following study added information for validity, reliability or the psychometric construction of the questionnaire.

Moreover, the literature review was exclusively concerned with patient satisfaction with anesthesia care in adults or paediatric patients for general anaesthesia. Thus, questionnaires devoted to measure certain (related) aspects or only parts of the anaesthesia treatment, such as sedation, 'quality of recovery' or satisfaction solely with pain management or the pre-anaesthetic visit etc. were excluded.

Excluded also were papers that did not report an assessment of user satisfaction: editorials, letters, discussion papers, comments, critiques, non-patient assessments of

satisfaction, and non-satisfaction assessments of care quality.

Measuring patient satisfaction in anaesthesia

The search was conducted using the following key words to retrieve articles:

anesthesia (including anaesthesia), AND patient satisfaction AND questionnaire(s).

Only review articles or original articles that reviewed or evaluated methodology were chosen. The searches were restricted to the time period from January 1995 to March 2013 as the first psychometric instruments assessing patient satisfaction with anaesthesia are found in the late 1990s.[30]

Satisfaction in anaesthesia in adult patients

The search was conducted using the following key words to retrieve articles:

anesthesia (including anaesthesia) AND patient satisfaction AND/OR questionnaire(s) AND adults.

Satisfaction in anaesthesia in paediatric patients

The search was conducted using the following key words to retrieve articles:

anesthesia (including anaesthesia) AND patient satisfaction AND/OR questionnaire(s) AND pediatric (including paediatric) patients.

Mortality and severe IECs in anaesthesia

The search period was from January 2000 to April 2013, only studies in German and English were included if they reported on a population of at least 3000 patients who underwent general anaesthesia for surgery in a hospital setting and for which a full text version was available. The studies had to report on a period starting in 1995 or thereafter, or reporting of events including the year 1995. Older studies were not considered relevant since the anaesthetic related mortality has declined over recent decades, thus older information would not be comparable to my own studies.

In concordance to the study by Bainbridge et al.[43], a minimum sample size of 3000 was chosen to reasonably estimate adverse events that occur at a rate of one in 1000 or less. This also should exert control for small studies that otherwise would skew the event rate estimates since occurrence of death and severe outcomes (for example cardiac arrest) were expected to be far lower than one in 1000. Because the aim was to assess outcomes in unselected patients who underwent surgery, studies reporting exclusively on regional or local anaesthesia or those done in a non-hospital setting were excluded. Studies focusing on specific endpoints (for example myocardial ischemia) were also excluded as were studies relating to populations in developing countries. Studies had to report a number of anaesthetic procedures as a denominator to determine the rate of anaesthesia-related deaths. The search also included tangential electronic exploration of related articles (i.e. 'snowballing': using links to related references to search for additional articles).

A MEDLINE, Google Scholar and Cochrane library search was performed to search for evaluating mortality and severe morbidity. Searched terms were mortality AND death AND severe incidents AND general anaesthesia OR severe morbidity AND general anaesthesia.

1. Historical perspective

Systematic satisfaction study reports have appeared in the health literature for at least 40 years.[44] Satisfaction has gained widespread use among the patient reported outcomes. These measurements report not only on symptoms but also on combinations of physical, mental and social health, cognitive capacity, general perceptions of wellbeing, and patient satisfaction.[6, 44] Reported outcome measures are used for several purposes. They may serve as an aid in clinicians' decision-making processes. The results of the outcome measures may also be seen as marketing tools in terms of customer orientation and might therefore even help to direct patient flow.[45, 46] Anaesthesia and the perioperative period increase the complexity of evaluating patient based measures. The perioperative period is a short time interval, combined with high emotional tension and confusing drugs effects. These difficulties may explain weaknesses with some existing tools. In addition, they often rely on expert instead of patient views, are not metrically sound, or make no distinction between different types of anaesthesia.[6, 47] Satisfaction cannot be considered as an objective indicator of the quality of anaesthesia care, but constitutes the best way to assess the outcome from the point of view of the patient. Anaesthetists have tried to develop objective measures of patient satisfaction with anaesthesia care.[6, 47]

The state of anaesthesia is considered to be an intrinsically unsafe condition. The anaesthetised patient is being put at risk of complications from anaesthetic drugs, the actions of the surgeon and from failure or malfunction of anaesthetic equipment. The patient will also be dependent on the actions, or inactions, of the anaesthetic team. Drugs with potential side effects, particularly on the cardiovascular and respiratory systems, are being administered. During the course of anaesthesia, the anaesthetist deliberately alters physiological functions: the loss of consciousness as part of sedation and general anaesthesia carries with it risks of airway obstruction, aspiration of contents into the lungs, and inability to detect peripheral injury. Pharmacological muscle paralysis is often induced, which necessitates the use of artificial ventilation. During this time, the patient will be dependent on the anaesthetist's actions and his/her equipment for the fundamental functions of oxygenation and excretion of carbon dioxide.[2] It is often stated that the first reported death under anaesthesia dates back to 1848, but Declan J. Warde[48] writes in a correspondence letter that it is

incorrect to state the first documented fatality associated with anesthesia was that of Hannah Greener in January 1848. However, the girl's unfortunate demise was almost certainly the first in England. It might therefor also be the first reported death due to chloroform. But there seems to exist compelling evidence that anaesthetic ether was responsible for a number of deaths during the preceding year. Two deaths that were believed to be related to ether anaesthesia had been reported to the Academy of Medicine in Paris, France as early as February 1847.

It was not until 1954, when the first comprehensive study of anaesthesia-related mortality was published, that reliable data on anaesthetic mortality were made available. This landmark study involved 10 academic medical centers and 599,500 surgical patients in the United States during 1948–1952. The authors of the study found that the anesthesia-related death rate was 64 deaths per 100,000 procedures, varying by anaesthetic agents, types of providers, and patient characteristics. Based on their study results, Beecher and Todd[49, 50] estimated that the annual number of anaesthesia related deaths in the United States of America (USA) was more than twice the mortality attributable to poliomyelitis at that time, a total of 5,100 anaesthesia-related deaths, or 3.3 deaths per 100,000 population.

Anaesthesia is still regarded as a high risk activity, although many experts acknowledge that 'very impressive' safety improvements have been made in this field. This statement was asserted by the Committee on Quality of Health Care for the Institute of Medicine (IOM), issued in the USA. The Committee stated that anaesthesia mortality rates have decreased from 2 deaths per 10,000 anaesthetics administered in the 1980s to about 1 death per 200,000 to 300,000 anaesthetics administered today. Unfortunately, they fail to provide reference for the 'impressive' gains in safety that has led the IOM to this conclusion.[51] The scientific basis supporting this opinion has also been questioned because of a wide range of differing methodologies and operational definitions used to evaluate the trends in mortality cited.[51, 52] In general, improvements in anaesthesia safety have made anesthesia-related deaths rare events, and studying rare events usually requires large sample sizes and considerable resources.[50]

The rise in the use of anaesthesia in private practice, the increasing number of elderly and multimorbid patients, and the number of high-risk procedures as well as the lack of population-based, prospective data has caused the continuation of debate over major morbidity and mortality in patients undergoing surgery and anaesthesia.

2. Epidemiology and public health impact of patient outcomes with a focus on patient satisfaction and severe IECs

Patient safety and quality of care, including patient satisfaction, are now clearly on the health policy agenda. Added to the real personal costs of adverse events are the financial costs. Previous Australian studies have estimated that direct hospital costs of adverse events in Australia range between $483 million[53] and $900 million per annum.[54] International rates for adverse events (variously defined) range between 3.7% and 45.8% of all admissions[55], with the Australian rate found to be 16%.[54] In this study, patients with adverse events stayed about 10 days longer and had a seven times higher risk of in-hospital death than those without complications. After adjusting for age and comorbidity, the presence of an adverse event adds $6826 to the cost of each admitted episode.

Still, the level of anaesthetic contribution is far from clear. Reported rates of IEC from all causes during or shortly after an operation range from 18–32%, all using similar definitions of IECs but are often based on different survey intervals.[35-37, 56, 57] A single centre study from a centre with a long history of participation in quality assurance projects, reported a general perioperative IEC rate of 22% in a noncardiac surgery population.[32, 58]

One study dating back nearly two decades evaluated a retrospective case series to assess whether hypothetical improvements in the quality of perioperative care can decrease hospital costs for elective surgical operations in high risk patients. The study found that eliminating **a**dverse anaesthetic **e**vents (AEs) entirely (identified by chart review) would decrease total hospital costs (i.e. for all patients in that group) by less than 0.5% (95% confidence bound <1.2%). The authors concluded that for low- and moderate-risk procedures, hypothetical improvements in the quality of anaesthetic

care would not reduce costs, but followed on to state that improving the quality of perioperative care may be cost efficient for high risk operations.[59] In contrast, other studies investigating AEs in anaesthesia and costs linked even minor IEC occurrence to increased PACU (post anaesthesia care unit) utilisation, while severe IEC are being treated in ICU and the linkage is therefore obvious. The mean difference of PACU length of stay for patients with minor IECs was prolonged by a range of 6%–26% when adjusted for coexisting severity features and the authors concluded that even minor but frequently occurring IECs have an impact on PACU utilisation and are thus important to measure.[28, 60]

How is value created in health care?

To the providers of medical and anaesthesia care the answers to this question seem evident. Value is determined by the outcomes of health care. This can be seen in relation to its costs, while the value of individual health care services is best determined from the perspective of the individual patient.[61]

This perspective has made patient-reported outcomes a key basis of comparison for services delivered and includes patient satisfaction as one important outcome. Patient satisfaction has become one of the standard indicators of the value of received health care, including anaesthesia-related care. Future health care reforms may link payment to 'pay-for-performance' and 'value-based purchasing' models, including the reporting of patient-reported outcomes.[5] Thus patient satisfaction will exert influence on patient flow, and directly impact on the economic success of the caregivers. It will therefore be of paramount importance to assess patient satisfaction in the most objective way possible.

3. Measuring patient satisfaction in anaesthesia

<u>Definition of patient satisfaction</u>

A frequently cited definition of patient satisfaction was formulated by Pascoe.[8, 14] It defines patient satisfaction as healthcare recipients' reactions to their care, composed of both a cognitive evaluation and an emotional response. The model is derived from concepts from psychology and those from theories of consumer satisfaction. Following these concepts, patients compare the care they receive to an intrinsic ideal, a minimal expectation, an average of past experiences, or a sense of what one deserves. The degree of satisfaction is the difference between actual and expected care and is expressed as the degree of satisfaction or dissatisfaction. A patient may start out with a very low expectation of the standard of care. Patient satisfaction, to put it simply, depends on the congruence between what is expected by the patient and what occurs to the patient.[8, 44] Expectations in this context are said to be beliefs that are created by a cognitive process and may be classified into ideal, predicted-practical, normative (what should happen), or unformed expectations.[46, 62]

The theory of a simple equation (Satisfaction = Perception - Expectation), although appealingly simple, has shortcomings in remaining rather vague and speculative. However, all reviews agree that patient expectations play a significant role in the formulation of patient satisfaction. Wu et al.[46] explains that there are different theories of patient satisfaction:

<u>Intrapatient comparison theories</u> – where patient expectations are matched with perceptions of medical care. Patient satisfaction or dissatisfaction arises from differences between what is expected and what is perceived to occur.

<u>The disconfirmation theory</u> – where consumers compare their perceptions of a service (or product) against prior expectations and the resultant size and direction (negative or positive) of the disconfirmation results in satisfaction or dissatisfaction. This is the dominant model of nonmedical, customer satisfaction, which however may not reflect patient satisfaction with medical care.[46, 63]

Equity theories – where patients compare their balance of inputs (e.g., time and money) and outputs (e.g., medical care and the results of such care) with those of other patients. Equity theories are based on the premise that patient satisfaction relates to whether patients believe that they have been treated fairly. Equity and patient satisfaction occurs when people perceive they are treated fairly and may possibly increase when patients ascribed more favorable outcomes to themselves when compared with others.[46, 62]

The authors Fung and Cohen[44] speculate whether satisfaction in general is a cognitively based attitude, an emotion, an intrinsic psychological trait (e.g., a tendency to be grateful), a cultural attitude about health and healthcare, or some combination of all of these elements. Again, in a first review of methodology used to assess patient satisfaction, the authors stated that much of the theory used to assess patient satisfaction is speculative and incomplete and poses more questions than answers.

The uncertain psychological foundation and multidimensional complexity has hampered the development of reliable and valid instruments because of these reasons.[9] The analysis is further complicated by the triangular relationship of the patient-clinician-organisation where patients' satisfaction will be affected by factors other than anesthesia, for example the results and care delivered by the surgical department.[9] In addition, in some studies, satisfaction appears to be independent from other, more quantifiable measurements of clinical outcomes (i.e. incidence of a sore throat).[64] Finally, patient satisfaction is confounded and influenced by many known and unknown variables, making its measurement even more difficult.

While it might appear to be a difficult task to measure and improve patient satisfaction with anesthesia, it is not an impossible task. Patients are perfectly able to express their opinion on the quality of the interaction with their anaesthesiologist, the anaesthetic encounter, as well as on the morbidity experienced after anaesthesia. Provided the appropriate methodology is used, patients' experience with anaesthesia can be appraised just as well as their experience with other medical services where several surveys to determine their experience have successfully been developed.[47, 65]

There are mainly two general approaches to evaluate patients' experiences and attitudes towards medical care in general and anaesthesia in particular as briefly outlined below:

Interviews: Face to Face, Focus Groups, Telephone (questionnaires) interviews

Interviews have been widely used to report patient satisfaction.[4, 66-68] However, the resource and cost implications of interviews rule out this method as a means of recording patient satisfaction as a means of routine evaluation of patient satisfaction.

Questionnaires

The instruments most widely used are questionnaires, commonly self-administered and completed by the patients themselves. This approach has some clear advantages. It allows surveys with high volumes, requires a lower budget than face-to-face or other personal interview methods and controls for interviewer and selection bias, as all patients coming to a specific department over a specific period can be included.[6]

Questionnaires that do rely exclusively on single-item ratings of patients' global satisfaction with their entire experience show uniformly high ratings. However, the reliability of single-item global satisfaction ratings is poor and inadequate to address the complexity of satisfaction.[69, 70] Other questionnaires that are set up intuitively do not take into account the complexity of the nature of satisfaction.[47] Thus, measuring patient satisfaction requires a more complex, psychometric instrument that will be discussed in detail in the following Section.

3a. Methodological aspects

This Section focuses on the methodological aspects of measuring patient satisfaction. It will serve as the basis to evaluate the satisfaction questionnaires identified by the literature review.

Patient-reported satisfaction with anaesthesia is generally high, both in studies and clinical practice. However, often a single question or visual analog scale is the likely cause for this result, providing only limited information to enable service evaluation or quality improvement.[44] In addition, patients may have limited knowledge regarding anaesthesia and the role of the anaesthetist and answers may reflect on the 'perioperative experience' and not the specific anaesthetic care.

Reviews agree that the instrument to investigate patient satisfaction should be multidimensional.[6, 9, 44, 47, 69, 71] In 1999, Sitzia[42] assessed the psychometric properties of instruments to measure satisfaction and demonstrated that less than 10% of the studies fulfilled the requirements of psychometric construction. In a more recent review, Heidegger and colleagues[6] stated that a psychometric questionnaire uses multiple items to probe specific events or concerns that occurred in that experience, events that together determine patients' satisfaction with their care. They also concluded that the involvement of patients in the development of an instrument to measure satisfaction is very important. All reviews state that the patient's involvement must form an integral part of the development of the questionnaire. Satisfaction measures need to take account of the socio-demographic, cultural, and cognitive influences and attitudes of the socio-cultural background of their use.[6, 9, 30, 44, 47, 69, 71] Instruments that do not consider these aspects are of questionable value. The authors agree that only psychometric instruments of high-quality, i.e. instruments that have been constructed following a rigourous psychometrical process, will be able to generate high-quality data.[6, 42, 44]

Thus, a formal methodology of questionnaire construction is essential to allow measurement of complex psychological phenomena such as intelligence or, in this instance, satisfaction. The development of a patient-satisfaction tool requires a step-wise psychometric process with subsequent validation in practice, and the following

steps to constitute a questionnaire on patient satisfaction have been proposed:

Item generation and generation of dimensions

- Constructing Pilot Questionnaire and Pilot Testing
- Revision and Retest
- Final Questionnaire[6, 44, 69]

The initial testing of a scale is not sufficient to verify all of the attributes of both the reliability and validity of the scale. Results obtained with a new scale must therefore be interpreted with caution.

A key factor is the quality of the assessment instrument in terms of validity and reliability.[42, 72, 73] Validity and reliability are concepts concerned with the questionnaire being a valid (conform) and reliable (consistent) measure of patients experiences. Validity refers to the absence of systematic error of a measure, whereas reliability judges random error (scatter). Validity concerns the ability of an instrument to measure what it is intended to measure. Reliability judges the consistency of (repeated) measurements.

Both, overall validity and overall reliability are composed of different logical aspects. Table 1.1, derived from Capruzzo and Alvisi[9], presents the core aspects involved in the evaluation process of an instrument to measure patient satisfaction (along with the comments of other reviewers on the topic).

Table 1.1: Requirements for evaluation of any instrument to measure patient satisfaction

	Author							
	Capuzzo and Alvisi[9]	Bell[71]	Chantong[69]	Fung[44]	Heidegger[6]	Sitzia[42]	LeMay[47]	Wu[46]
Requirement	**Definition**							
Validity	**Multifaceted concept to measure conformity:**	√	√	√	√	√	√	√
Content validity	Ability of the instrument to reflect the domains of interest for the patients, all important components regarding satisfaction are included.				√	√	√	
Face validity	Being meaningful and easy to understand, items measure what they are intended to.		√	√				
Criterion validity	Ability of the instrument to show the same findings as the gold standard.		√		√ predictive validity or concurrent validity	√		
Construct validity	Ability of the instrument to confirm any logical hypotheses previously created.		√	√	√	√ Three step approach		
Convergent validity	Ability of the instrument to correlate with other measures of patient satisfaction (external validity) or related to it, may also include discriminant validity.		√			√	√	
Reliability	**Multifaceted concept to measure consistency:**	√	√	√	√	√	√	√
Internal consistency	Ability of the individual items in a domain to measure the same underlying concept.		√	√	√ (Scale reliability)	√	√	
Test-retest reliability	Ability of the instrument to give the same results when repeated in the same conditions.		√ plus interrater relaibility	√	√ (difficult in real hospital setting)	√	√(considered irrelevant)	
Feasibility/ Acceptability	Evaluated by the response rate and the time to complete a questionnaire (Chantong)				√ (Practicability)			

Validity

Content validity and Face validity

First, the instrument must contain items on all factors deemed important to the trait under study, and appropriate formats must be used. This is referred to as content validity. While content validity may often be difficult (if not impossible) to demonstrate, the researcher has at least to try to come as close as possible to a complete list of relevant aspects.[6]

The development of a questionnaire should therefore include the following:

The patient's view

Patients must be included in the collection of items to assure content validity. If they are not, the questionnaire may omit relevant parts of patient perception of anaesthesia care. One possibility is to conduct focus groups with patients who have already undergone anaesthesia, while face-to-face interviews are another possibility. In general, there seems to be no clear-cut advantage of one method over the other; however interviews are often more likely to extract individual experiences, while focus groups may also focus on capturing group dynamics. Of importance is to sample relevant cases purposely until no new ideas emerge from the interviews rather than to interview a representative sample.[74-77]

The evaluation of the current literature

Important aspects from other studies measuring the same or neighbouring constructs have to be considered and incorporated, where appropriate. This may be achieved by systematic review of relevant literature.

The expert's view

Experts in the field (in our case, the hospital setting) should contribute to what they perceive as relevant factors to the construct intended to be measured.

The incorporation of these different viewpoints are critical as it was found that differences between patients' and health care professionals' views exist. For example doctors tend to underestimate the relevance of communication and information.[44]

Content validity is usually judged by a panel of experts following literature review, patient interviews (focus groups etc.) and interviews with health care professionals. This is also called face validity and is a subjective assessment by investigators as to how far their items appear to measure the outcomes they intended to measure.[69] Note that other authors describe face validity as referring to being meaningful and easy to understand.[9]

The inclusion of open ended questions, most often placed at the very end of a questionnaire, will allow respondents to give comments on content, missing items, wording, response choice etc. This inclusion should be considered essential to take into account potential changes in patient population, environment etc.

Criterion Validity

Criterion validity is the correlation of the new scale with an existing validated 'gold standard'. In the empirical concept of criterion validity, any new scale must show a correlation with an accepted scale in the field. Sometimes criterion validity is referred to as 'predictive validity' or 'concurrent validity', depending on how the relationship is interpreted, either in a causal or a temporal manner.[6] However, in light of the absence of a gold standard for patient satisfaction in anaesthesia, the use of alternative approaches is suggested:

Construct validity (discriminative ability)

For construct validity, the instrument is being tested to verify whether it is able to confirm one or more logical hypotheses that are created from the underlying theoretical construct. While not all authors regard a stepwise approach to construct validity as essential, Sitzia[42] proposes the following approach:

> (i) first, research evidence is used as far as possible to build a hypothetical relationship between the construct and the observable, for example, a relationship between satisfaction with waiting time at a clinic (the construct)

and 'walk-outs' from the clinic (the observable);

(ii) second, statistical analysis is employed to identify items that relate to the construct. For example, a correlation between the items measuring satisfaction and waiting times might be measured;

(iii) third, studies are conducted to determine the extent to which the measures of the concept can produce predicted results.

Included in this concept is the testing of the instrument to verify whether it is able to confirm one or more logical hypotheses. These hypotheses are created from the underlying theoretical construct, which often includes analysis for age and gender, as these factors have been found to alter satisfaction scores. Different tests may be used, such as tests that identify extreme groups, who in theory are likely to produce differing results such as older people, males, patients after short surgery or patients with good perceived health status.[9, 46] While correlations with the observable are desirable, the scale should not correlate with dissimilar, unrelated variables; the demonstration of this is referred to as discriminant validity (for example item discriminant validity (IDV)).

Debate continues over advantages and disadvantages of the type of rating scales and the number of the rating categories for items used to construct the scales. An uneven point answer scale is often likely to result in medium values for satisfaction, as patients tend to avoid using extreme response categories (central tendency bias), but an even point scale is more helpful when the dichotomous separation of patients satisfaction (satisfied/dissatisfied) is the main focus. Similar accounts have been made for the grading of the answer scales used, which should be proportionate and match the question.

Construct validity can be used for subjective outcomes such as satisfaction and happiness where definitive standards do not exist. These may be expressed as hypotheses indicating correlation between patient satisfaction, and other measurements. Subscales or dimensions may be correlated with other measures such as the Spielberger Stait-Trait Anxiety Inventory (STAI)[78] or the McGill pain

questionnaire (MGPq)[79] as well as others. This is also referred to as convergent validity or external validity.

Analysing construct validity also includes strategies that test for the multidimensional structure of the questionnaire. Analysis of the resulting different domains (often also referred to as dimensions), which are reflecting on different topics should be included to capture different themes with any number of items. The classic approach is to generate such scales following an exploratory or confirmatory approach (i.e., factor analysis, such as principal component analysis (PCA)). Alternatively, scales are built according to themes to which questions are assigned (qualitative content analysis) (see also Reliability).

Convergent validity

Some authors include convergent validity into the concept of construct validity.[9, 42, 46, 69] Heidegger et al.[6] describe the measures taken as external or concurrent validity. In general, convergent validity is the correlation of the new measure with other measures of patient satisfaction, or aspects of the new measure with other measures such as anxiety etc.

Reliability

For an instrument on patient satisfaction to be a reliable tool, two attributes are essential. The first is the internal consistency, usually measured by the Cronbachs alpha. Cronbachs alpha is a measure of homogeneity and reflects the correlation between items of a scale and the correlation between the items and the total score.[72, 80] Internal consistency measures the extent to which individual items in a scale/dimension measure the same underlying concept. Population based data are used to calculate Cronbachs alpha.[42, 72] To prove internal consistency, a Cronbachs alpha of 0.7–0.9 should be achieved, indicating that 30% or less of the variability is due to measurement error (i.e., inaccuracy in the measurement), whereas a value above 0.9 is said to indicate that the questionnaire is too narrow in the scope or has a redundancy of items.[80]

The sample size suggested for testing reliability is around 10 respondents per question; an inappropriate small developmental sample to evaluate internal consistency (Cronbachs alpha) can produce inappropriately favourable results.[6, 47, 80]

The building of scales offers the advantage to integrate responses of many single items into one score. The classic approach is to generate such scales by using an exploratory factor analysis (EFA)[6], often referred to as principal component analysis (PCA). One of the primary objectives of confirmatory component analysis (CFA) is its ability to assess the construct validity of a proposed measurement model. The term *construct* is defined in a broader way, as a characteristic or concept that a test or other measurement procedure is intended to measure.[81, 82] There are many other techniques for assessing reliability in special situations.[83] It is of paramount importance that researchers demonstrate an adequate procedure of developing and testing their constructs.[6]

Other measures of reliability include item internal consistency or item internal correlations (IIC)), that can be assessed by correlating each item with its scale, correlations with r > 0.4 are suggested to support item internal consistency. IDV can be assessed by determining the extent to which items correlate more with the dimensions they are hypothesised to represent than with the others.[72, 84]

Test-retest Reliability

Also known as stability, test-retest reliability refers to the reproducibility of an instrument in terms of administration by different raters or by the same rater on different occasions. In terms of self-administered instruments, these are usually observations on the patient on two occasions separated by some interval of time. The minimum value of the correlation coefficient should be 0.7.[69] In the hospital setting, having the instrument for time-dependent constructs completed by the same person in the same situation at least twice seems unrealistic, since at least the time since the procedure/discharge will differ between the two surveys. In general, it is argued that it is too much to expect a patient to fill in the same questionnaire multiple times[6], and that responses may vary with time as the concept of satisfaction is influenced by the effects of memory, among other reasons.[47]

<u>Inter- and intra-rater agreements</u>

Inter- and intra-rater agreements assess how accurately different observers agree with each other, and how accurately the same observer agrees over time, respectively.[14]

Feasibility/Acceptability

The acceptability of a questionnaire may be evaluated by the response rate and the time to complete a questionnaire.[85] While the response rate is also dependent on other variables such as the mode of distribution, timing of administering of the questionnaire or the patient group under survey etc., the time needed for completion is more easily determined. Feasibility might also mean that the questions are easy to understand, increasing the rate of compete and returned questionnaires.

<u>Wording questions – tests for understandability and readability</u>

Questions should be worded to contain only a single idea/concept, although some items may be phrased into several questions. The writing intricacy should not be too difficult and reading level can be adjusted using computed indices such as the 'fog index' (Microsoft, Redmond, WA, USA). Cognitive surveys are specifically designed to recognise the cognitive processes and assess whether the meaning and subject of the questions are understood. This identifies patients who poorly understand the intended meaning ('nonattitudes').[73, 86, 87]

Method and timing of administration

Most instruments have been developed for self-administration as this approach is inexpensive and feasible. Typically, the questionnaires are distributed, collected or sent back (by internal mail) during the hospital stay or mailed after a certain time of discharge. The postal distribution of the questionnaires sometime after discharge may negatively impact on the number of responses received.[88] Alternatively, questions are administered by telephone or by face-to-face interviews. In the latter situation, other forms of questioning (open or semi-structured interviews) may be used alternatively. Combinations are also possible (interviewer assisted interviews etc.). Each method

may introduce a certain element of bias that must be considered (see below). In particular, interviews are resourceful and costly, implications that often rule out this method as a means of standard recording of patient satisfaction outside the research setting.

Patient satisfaction may vary with time and may be influenced by recall of the events. In a study comparing satisfaction over time fewer problems were reported after nine weeks.[88, 89] Patient satisfaction should not be assessed too early, when it may still be dominated by the relief that the procedure is over and was completed safely[90], but also not too late. The ideal time of administration of the instrument to assess patient satisfaction has not been defined. Some authors collected answers within two days[30, 66, 91, 92] or after hospital discharge, others not before two weeks (see below).

Bias and confounding variables

Bias should be considered whenever possible and minimised by the research strategy. Heidegger et al.[6] list the most important types of bias in patient surveys as follows:

<u>Selection bias:</u> is the systematic inclusion or exclusion of patients with certain criteria. It can be minimised if all patients in a certain setting (hospital and specific time period) are included ('all-comers').

<u>Interviewer bias:</u> is a bias introduced by the behaviour of the interviewers. As LeMay et al.[47] put it: "…patients may have been influenced by either the presence of the anesthesiologist or the suspicion that the anesthesiologist could identify them. For instance, if the anesthesiologist remains nearby while the patient is completing the questionnaire, the patients' right to anonymity and confidentiality is not protected. Patients cannot be expected to express their comments, suggestions or grievances if they have even the slightest doubt that their right to confidentiality and anonymity is not being respected." The interviewer bias plays an important role in interview settings, but may not be as relevant in self-administered surveys if strict rules for anonymity and confidentiality are followed.

<u>Non-responder bias:</u> is a bias introduced by the differences between persons participating in the study and those not participating/declining to participate.[93] The response rate is important and missing data from non-responders may affect the validity of the results as their level of satisfaction remains unknown and may differ from those who participate. However, indirect assessment might be possible when structural data on non-responders are available. The patient mix of responders can be compared to the patient mix of non-responders, and non-responder bias may be estimated based on knowledge of the satisfaction levels according to patient mix parameters in the responders.

<u>Social desirability:</u> The bias of social desirability describes a tendency to answer questions as expected or in a way that the society or the interviewer may regard as positive. This is a more relevant factor if the survey is conducted as an interview but may also play a role in surveys conducted while the patient is still in hospital.[7, 47, 83]

<u>Confounding bias:</u> Confounding bias means that a found relationship (e.g. between study factor and outcome) does not reflect a true association but is disturbed by the effect of one or more other variables (confounders or covariates; outside the study factor and outcome). In the context of patient satisfaction studies, or benchmarking wards, units or hospitals, variables such as those discussed below in '<u>Factors associated with patients' satisfaction with anaesthesia</u>', which are factors of the 'patient mix', must be considered as potential confounding variables. A probable solution is to check the selected parameters for effects on the outcomes (dimensions of satisfaction and general satisfaction) and, in a second step, to adjust the crude outcome values for these confounding parameters.[6, 94]

<u>Factors associated with patients' satisfaction with anaesthesia</u>
Sitizia and colleagues[42] argue that ratings may be influenced by respondents' characteristics, such as age or educational attainment[95], by the patient's expectations[62] and by socio-psychological phenomena, such as self-interest, the Hawthorne effect, or gratitude. Wu et al.[46] state that the main variables that are said to be determinants of patient satisfaction are patient related determinants, provider related determinants and process related determinants. These groups summarise endogenous, exogenous and contextual factors that have been found to exert influence on patient satisfaction.

Capuzzo and Alvisi[9] add that satisfaction is not only influenced by many factors that have been shown to exert influence, but probably also by others that remain unknown. Table 1.2 lists factors known to influence patient satisfaction, collated from the studies identified in this literature review.[9, 46]

Table 1.2: Factors found to influence patient satisfaction (direction that increases patient satisfaction with anaesthesia stated if known)

Patient related factors	Socio-demographic factors Age (older age) Gender (male gender) Education (lower education level) Income (lower income) Marital status (married) Occupation Race Social class Physical and psychological health/comorbidities (good health as perceived by the patient) Anxiety and Depression (low level of anxiety, no depression) Expectations (low expectations)
Surgery anaesthesia related factors	Type (specialised procedures) Extent (minor procedures) Duration (short lasting procedures) Setting (ambulatory vs inpatient) Adverse outcomes (no/absence)
Health care–related factors: centre-specific	Information (information given by the anaesthetist, anaesthesia information leaflet provided, two or more postoperative anaesthetic visits, anaesthesia summary given at discharge) Provider verbal/nonverbal interactions Socio-emotional behavior Empathy Perceived competence Perioperative nurses dedicated to anaesthesia
Health care related factors: general	Provider-related Provider competence (reputation v observation) Process-related Accessibility and convenience Ancillary services Bureaucratic factors Cost Environmental factors Organisation of health care

Patient related determinants are mainly factors such as age, gender, race, education, income, marital status, social class, occupation, physical–psychological health, anxiety and depression[91, 96, 97], perceived health[3, 46, 89], and comorbidities[67, 91], along with the expectations as previously discussed. With regard to socio-demographic factors, young age is associated with lower satisfaction[3, 66, 89, 91, 92, 98, 99], as is female gender[89, 92, 100] and higher level of education.[6] Wu and colleagues[9, 46] state in contrast that female gender was associated with higher satisfaction, citing from studies of the 1970s and early 1990s. [46, 101, 102]

While clinical outcomes and care have a relevant relationship to patient satisfaction[67, 99, 103], the most relevant factors influencing patient satisfaction, in any phase of anaesthesia, are probably staff related.[9] Positive communication that reinforces a partnership-building relationship with the patient will most likely result in greater patient satisfaction.[104, 105] In addition, the level of patient satisfaction increases with a greater amount of information provided.[6]

In any case, any instrument will have to show how it measures and controls for these potentially confounding variables. Another universal problem is the use of instruments in different socio-cultural environments. While problems in translating questionnaires are obvious, differences in expectations (for example in countries with a tax based national health care system) might be more subtle and difficult to measure.

Pilot Testing

Pilot testing is considered an important phase of construction. It allows to generate experiences with the new instrument in 'the field', that is, under real circumstances. The process of pretest and pilot testing is for revision of the first version(s) of a questionnaire. It allows to adjust items with ambiguous meanings, which can be subsequently reworded or eliminated using the response from the pilot test, but also to maximise the reliability and validity of the questionnaire. This process will often result in a shorter, validated final version of the questionnaire.[69] During the process of questionnaire construction, one might have to 'sacrifice' at least one sample (for example the pilot test) for the sake of the psychometric construction of a questionnaire.[47]

Preamble to

3b. Satisfaction in anaesthesia in adult patients and

3c. Satisfaction in anaesthesia in paediatric patients and/or parents

In the following, the literature on the appropriateness of different methodologies to measure patient satisfaction is discussed and a critical review is presented of the rigour of the original psychometric development – the foundation of any satisfaction measure as outlined in Section 3a.

To the best of the author's knowledge, there is no published system for comparing the quality of the psychometric development processes for questionnaires in a structured and objective manner. Thus, in the following, a rating scale is proposed (and then applied to the identified literature on questionnaire development) for the evaluation process (Table 1.3). It will assess how authors report the questionnaire development process, the pilot testing, and the testing for validity, reliability, and acceptability of each instrument. The results will be compared to the criteria mentioned before in Section 3a.

The points of the proposed scale are not evenly distributed over the items but reflect the importance of each of the criteria for the development and construction process of a psychometric questionnaire. The scale results in an overall score reflecting the depth of psychometric development and validity and reliability testing behind each questionnaire. The maximum achievable score totals 10 Points, which indicates the highest accuracy of psychometric development and testing behind the questionnaire. Each instrument will be evaluated as follows:

Rating Scale: Validity testing (6 Points total)

Most validation studies begin with content validity and face validity. Proper assessment of content and face validity must give consideration to the views of the parties involved, that is, the patient, the health care professionals, and the relatives. Items that emerge directly from input from patients represent what patients truly value, and opinions from providers can ensure that significant elements of care have not been missed (1 Point).[69] A systematic literature review provides a good foundation for the item construction, while the point of view from the carer's side

offers another perspective (each 0.5 Points). There is a need to review the content of items in the questionnaire, in order to reduce the number of questions and to include only items deemed important and unambiguous. Open-ended questions at the end of questionnaires can be useful for content validation. The rating of items and the pilot testing should be comprehensive.[6, 69] The resulting questions should be meaningful, easy to understand and should be asked in more than two (ordinal) categories (2 Points total). For external, concurrent validity or convergent validity, the new measure is correlated to other measures measuring at least aspects of the new measure such as anxiety etc. 'Extreme groups' are likely to produce differing results (e.g. older versus younger people, males versus females etc.) providing the means for assessing the new scale (2 Points).

Rating Scale: Subscales and Statistical Analysis (2 Points total)

Creation of subscales allows for measuring certain aspects of care, the creation of which may be conducted by a content analytical approach or statistical approaches using PCA or CFA (2 Points).[6, 81, 82]

Rating Scale: Reliability (2 Points total)

The aspects of reliability, namely i) internal consistency (1 Point); ii) test-retest reliability (0.5 Points as this is a debatable test in measuring patient satisfaction, see above); and iii) Feasibility/Acceptability (i.e. time needed for completion: 0.5 Points) are tested separately. Points for reliability are only allocated if the criteria for the sample size requirement (power) to test reliability (10 respondents per question) is met.

Unfortunately, there are no statistical measures to formally test for content validity, therefore the following paragraphs have to rely on the process of the item generation as proposed above to assess content and face validity of the studies identified for the review.

Table 1.3: Proposed rating scale of the depth of psychometric development

Assessment		Points
Content & Construct validity	The patient's view: Involvement of patients (interviews, focus groups)	1
	The evaluation of the 'state of the art': literature review	0.5
	The expert's view: Interviews, focus groups with health care professionals	0.5
	Question design: questions address only one subject and 3 or more point scales	0.5
	Rating of items by patients	0.5
	Pilot testing/writing intricacy/comprehension probing	1
Convergent validity	External or concurrent validity (correlation with other measures investigating aspects of the new measure as anxiety)	1
	Assessment of 'extreme groups' and/or correlation to a global satisfaction question	1
Creation of subscales or dimensions		1
Using statistical methods (PCA/CFA)		1
Reliability	Internal consistency	1
	Test-retest reliability	0.5
Feasibility/Acceptability		0.5

3b. Satisfaction in anaesthesia in adult patients

From a list of more than 700 articles, 23 matched the desired criteria (Appendix I: Tables 1.4 and 1.5; and Figure 1.2). Eleven authors published studies that described the development of questionnaires to assess satisfaction with anaesthesia[3, 4, 7, 66, 81, 82, 89, 91, 99, 106-111] while others used existing or modified existing instruments.[15, 112, 113] Published studies also aimed at answering questions other than general satisfaction, such as different modes of application (i.e. interview vs. questionnaire)[4], the assessment of factors predictive of satisfaction[3, 66], the effect of Anesthesiology Consultant Reports (ACR)[114] or repeated visits[68] and investigate satisfaction often only as secondary outcomes.

Thierbach et al.[115] focused on the inquiry of subjective patient impressions to help to identify and avoid psycho-vegetative stressing situations and to improve patient satisfaction with anaesthesia. This study encompasses the whole process of anaesthesia treatment and was therefore included in the review. Three studies used single questions for the assessment of satisfaction along with other perioperative outcomes.[45, 64, 67] Myles et al.[67] identified potentially modifiable factors associated with dissatisfaction, for which the postoperative recovery period and anaesthetic intraoperative events and complications (IEC) were also analysed.[67] The studies by Bothner et al.[64] and Tong et al.[45] also did not exactly meet the criteria as they assess satisfaction by one single question only, but both link intraoperative events with patient satisfaction, similar to the study by Myles et al.[67], the main subjects of this PhD thesis, and were thus kept included. Brown et al.[116] also investigated intraoperative events and patient satisfaction, but used an instrument drafted by the researchers with four questions assessing anaesthesia care.

In the following Section, the literature found will be evaluated in detail. Despite the depth of psychometric development, other formal criteria for the conduct of studies will be considered, followed by a critical appraisal of the satisfaction results reported by the studies. Tables 1.4 and 1.5 in the Appendix section provide an overview on the assessed questionnaires.
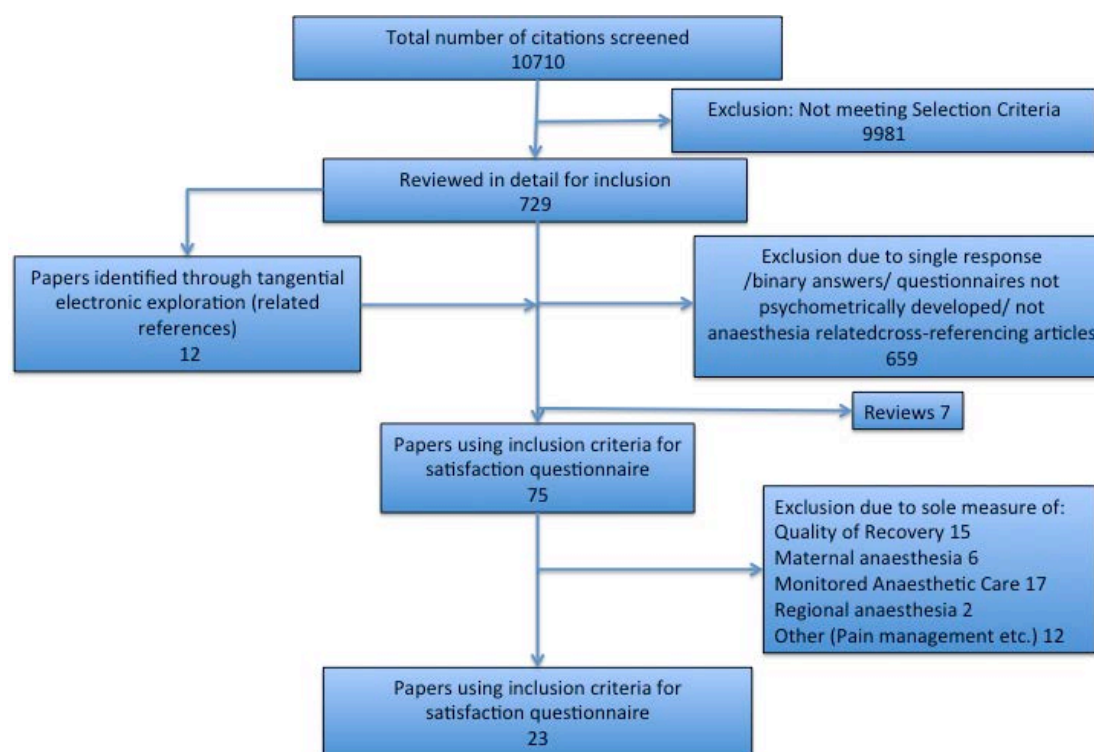
Figure 1.2: Flow chart: literature search – Adult patient satisfaction

Ethical oversight

Using patient data for research purposes requires informed consent as an absolute minimum. Usually, ethical oversight is recommended and the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study can start.

In most of the studies discussed here, ethical oversight was provided, though two studies had informed consent only.[64, 115] In the studies by Whitty et al.[99] and Myles et al.[67], it was stated that ethic approval was sought only for the use of obtaining patient medical data, while for their interviews Whitty and colleagues did not provide evidence of informed consent or ethical oversight. Jlala et al.[112] reported that the local research ethics committee was informed and consent was deemed unnecessary. Evidence of informed consent or ethical oversight was completely missing in the studies reported by Brown et al.[116] and Hadjistavropoulos et al.[113]. In the latter study it was mentioned that data were acquired for routine quality assurance, nevertheless ethic approval was neither mentioned or sought, nor waived.

<u>Content and face validity</u>

<u>Item generation (see also Section 3a)</u>

A comprehensive literature review was conducted and described in eight of the studies.[4, 7, 66, 81, 82, 89, 91, 99, 111] Details of the search strategies used were reported by two authors.[7, 81, 82] Other authors relied on previously published instruments: Caljouw et al.[15] used the Evaluation du Vécu de l'Anesthésie Générale (EVAN-G) and Jlala et al.[112] employed an English adaption of the LPPSq, following modifications Caljouw et al. had made on the EVAN-G.[15, 112] Kouki et al.[110] relied on the results of the questionnaires from Auquir et al.[91], Capuzzo et al.[66] and Heidegger et al.[89] but failed to state which items he used from the different questionnaires. Hüppe et al.[107-109, 117, 118] followed recommendations from the DGAI and combined the simple DGAI instrument with a multidimensional symptom list published previously.[117, 118] Thierbach et al.[115] relied on results of the STAI, the 'Mainzer Angstinventar' (Mainz anxiety inventory), and the 'Basler- Befindlichkeits-Skala'.[78, 119, 120] Most of the studies reported no additional literature search.[15, 108, 110, 112, 115] Bother et al.[64] used the DGAI instrument as proposed and published in 1992[118], with no underlying literature research. Tong and colleagues[45, 121] relied on a study dating back to 1987.[121] Hadjistavropoulos et al.[113] used the WCCS (Appendix I: Table 1.5).[122]

The authors Brown et al.[116], Fleisher et al.[114], Gaszynski et al.[106], Myles et al.[67] and Zvara et al.[68] did not report a literature search nor reported the use of former questionnaires.

It was found that experts in the field can contribute to identify relevant factors/items for the construct of the questionnaire[6] but only five of the authors explicitly report interviews with health care experts (doctors, nurses etc.).[4, 7, 66, 81, 82, 89]

As already pointed out in the previous Section (3a), patients involvement should form an integral part of the questionnaire development and should also be considered if an instrument is to be referred from a different socio-cultural background, particularly because there are socio-demographic and cultural influences on satisfaction.[6]

Seven authors described having sought patient advice in the development process:

Face-to-face interviews were held in five studies[7, 66, 81, 82, 91, 111] (Caljouw et al. used results of EVAN-G, Jlala relied on results of the study by Caljouw et al.)[15, 112], while Heidegger et al.[89] and Whitty et al.[99] held interviews in focus groups to gain insight into the patients perspective and to generate items.

Rating (see also Section 3a)

As part of the validity analysis, rating (or ranking) of items for subjective importance by patients and/or caregivers can be used. This might help to assess the importance of items to patients, especially during the phase of item generation. Two authors describe the use of item ranking[15, 66]. Additionally, Sindhvananda et al. [111] describe item ranking by experts only. Mui et al.[81, 82] used a new, more sophisticated approach; they statistically evaluated reliability and validity based on the content validity coefficient (V value) and the homogeneity reliability coefficient (H value).[81, 82] Naturally, the studies using single questions did not employ item ratings.[45, 64, 67]

Wording questions – Tests for understandability and readability (see also Section 3a)

Ten authors describe the use of open ended questions to allow comments on content, missing items, wording, response choice etc.[7, 15, 45, 66, 81, 82, 89, 91, 99, 110, 115] Heidegger et al.[89] and Mui et al.[81, 82] reported the use of ope -ended questions for their pilot questionnaires only. Only Whitty describes the use of an instrument to analyse for the writing intricacy such as the 'fog index' (Microsoft, Redmond, WA, USA), which is used to adjust the reading level of the questions.[99] Cognitive surveys are specifically designed to recognise the cognitive processes and assess whether the meaning and subject of the questions are understood. This identifies patients who poorly understand the intended meaning ('nonattitudes'). Unfortunately, not a single study analysed included a cognitive survey.

Pilot test (see also Section 3a)

Of the studies analysed, twelve authors reported having done a pilot test.[4, 7, 15, 66, 81, 82, 89, 91, 99, 107, 108, 110-112] Hüppe et al.[107-109] published three studies developing the Anaesthesiological Questionnaire (Anästhesiologischer Nachbefragungsbogen für Patienten; ANP). The first study may be considered a pilot test as validation was commenced in a second, larger study. Similar occurred for the studies published by

Capuzzo et al.[3, 66]; even though the authors mentioned a pilot test with 100 patients for the first study, the second was done with a larger number of respondents.

Criterion validity (see also Section 3a)

To assess criterion validity, scores or contents of the instrument are correlated with a 'gold standard'. Since there is no accepted definitive standard of satisfaction, criterion validity cannot be used to assess questionnaires measuring patient satisfaction.[6, 9]

Construct validity (see also Section 3a)

Construct validity can be used for subjective outcomes such as satisfaction and happiness where definitive standards do not exist. Subscales or dimensions may be correlated with other measures and hypotheses that can be created from the underlying theoretical construct are being tested. In addition, the questionnaire may be analysed for their multidimensional structure to generate scales (which may be as well part of reliability). This will also allow item internal consistency or item internal correlations (IIC) to be assessed. Most studies used correlations of the dimensions to assess construct validity. The use of IIC and/or Item Dimension Correlation (IDC) and/or IDV was reported by five authors.[15, 91, 110-112]

Construct validity was also evaluated in nine studies assessing the effect of known influencing variables, most commonly age, gender as well as others.[7, 15, 66, 81, 82, 89, 91, 107, 108, 112, 113] Hadjistavropoulos et al.[113] analysed only the type of anaesthesia, site of service, nature of service and surgical service but not age or gender, while Whitty et al.[99] states the importance of age and gender, but fall short in reporting any details.

External validity assessments utilising other measures was found in only one study by Auquir et al.[91] The authors investigated the relationships of specific dimensions of their EVAN-G (e.g., pain, anxiety) and the McGill Pain Questionnaire (MGPq), as well as the STAI.[78, 79, 91]

Reliability (see also Section 3a)

Dimensions were given in a total of 15 studies and scale determination by using an EFA, also referred to as PCA, was conducted in eight studies.[7, 15, 81, 82, 89, 91, 110, 111] Mui et al were the only group to simultaneously employ CFA.[81, 82] In the study by

Caljouw et al.[15], the authors used PCA from only the best loading factors and omitted the analysis of a total of 18 questions for validity and reliability. Six studies reported the use of either content analysis or simply used the chronological order of the overall care to determine the scales.[4, 64, 66, 99, 108, 116] Capuzzo et al.[66] reported three domains of satisfaction, distinguishing between physical, emotional, and relational factors. While it was not stated how they assessed their domains, it seems logical that content analysis was involved to some extent. Three authors distinguished between physical discomfort and satisfaction[4, 64, 107, 108], while Hüppe et al.[107-109] subdivided satisfaction further into three dimensions. Hadjistavropoulos et al.[113] used the WCCS (Wascana client centered care survey)[122] by modification, and Jlala et al.[112] adapted the LPPSq by translation and modification. However, both authors failed to report the tests used to determine the modified questionnaires' structure.

Cronbachs alpha was stated by eleven authors[3, 4, 7, 15, 66, 81, 82, 89, 91, 107-109, 111-114], although only the minority reported on both correlation of items in the scale and correlations between the items and the total score. Hadjistavropoulos et al.[113] reported internal consistency on the basis of the original questionnaires only (Appendix I: Table 1.5).

Test-retest Reliability (see also Section 3a)

Five authors reported having assessed test-retest reliability.[4, 7, 66, 91, 107, 108] In general, it is argued that it is too much to expect a patient to fill in the same questionnaire multiple times, and that responses may vary with time as the concept of satisfaction is influenced by the effects of memory, which is an undesirable effect.[6, 47]

Intra-rater and Inter-rater Agreements (see also Section 3a)

Two studies tested inter-observer reliability, to demonstrate that patients demonstrate consistent results on repeated administration and to assess to what extent different interviewers affect the results.[45, 66] Naturally, this evaluation is not feasible for all studies, as it requires an information collection technique involving 'raters', such as interviewers etc.

Feasibility/Acceptability

Time for completion of the questionnaire or the interview was given by only four of

the authors.[7, 66, 81, 82, 91] There is no 'ideal' timeframe during which completion should be accomplished. Acceptability is also dependent on multiple factors such as the mode of administration (questionnaire vs. interview, mail or mail back questionnaires etc.), the questionnaires length as well as its format.[123]

General remarks

Caljoouw et al.[15] and Jlala et al.[112] used results of previously published instruments originating from a country with a different language and a different socio-cultural background. While translation should follow a back-to-back process and 'revision committee and pre-testing',[124] the generalisability of questionnaires across different settings is far from clear, and it is not necessarily correct to assume that a questionnaire is valid outside its country of origin as there may be disparities in health care and patient expectations between nations and healthcare systems. Both authors report a pilot study to assess for understandability, Caljouw et al. also sought expert opinions but falls short in describing the translation process. Jlala et al. acknowledge that the English translation of the LPPSq did not utilise the ideal translation process.[15, 112]

Method and timing of administration

The optimal timing for completing a satisfaction questionnaire for patients undergoing anaesthesia is not clear. The longer the interval since the procedure, the more other effects will come into effect, together with the effect of memory, meaning that satisfaction results might be blurred. Restriction of the period of questionnaire administration to the first 48–72 hours (hrs) after surgery is found in a number of studies exploring anaesthesia care management.[4, 15, 45, 64, 66, 67, 81, 82, 91, 107-112, 115] The assessment of satisfaction at a later point could mainly reflect perceptions related to surgery.[91]

While all questionnaires that were returned by mail had a time interval >72 hrs, the vast majority of interviews were held <= 72 hrs.[3, 4, 66, 67, 91] Interviews have also been linked to high ratings of patient satisfaction.[44] Le May state that "patients cannot be expected to express their opinion when there are doubts about confidentiality and anonymity".[47] However, Bauer et al.[4] found that their standardised interview

identified more patients reporting lower degrees of satisfaction compared to the questionnaire and was, therefore, superior in detection of anaesthetic quality.

Satisfaction results

From the patient's perspective, one can imagine that the simple fact of having passed the perioperative period without any major adverse event would overestimate patient satisfaction. This is probably true and may explain the very high levels of satisfaction when the question is simply whether a patient is 'satisfied', 'somewhat dissatisfied', or 'dissatisfied'.[67] The studies where single questions (often in combination with other questions) were addressing overall satisfaction with anaesthesia provided uniformly high ratings, despite the provision of different rating categories (from dichotomous to five point scales).[4, 45, 64, 67, 106-110, 114-116] Indeed, in the study by Myles et al.[67], the variable 'patient satisfaction' is considered as a major outcome, however it was measured only by one question with answer categories and the results were even dichotomised (satisfied vs somewhat dissatisfied/dissatisfied). Such strategy is regarded poor as it does not generate enough variance in the distribution of the results.[47] Moreover, if the results are apparently quite favourable, there is not much incentive to improve the quality of services provided. If measured only very simplistically, the apparent high satisfaction ratings should give the anaesthetist little cause for self-congratulation. It rather should raise suspicion since it may simply reflect the poor quality of the measurement tool. Valuable insights can be gained from less satisfied patients. Interestingly, even among patients who identified themselves as satisfied, comments suggesting further improvements can be found.[116] The reporting of high overall satisfaction in the light of significant medical problems with care has been addressed as 'hidden' discontent.[125] When more detailed scores were used to determine global satisfaction, dissatisfaction or problems, ratings were generally lower than those achieved by simplistic assessments, thus providing more room for improvement.

Potential confounding variables (see Section 3a) were analysed in some studies. But only one study provided adjusted satisfaction scores for these variables.[89]

The information relating to the studies discussed above can also be found in Appendix I: Tables 1.4 and 1.5.

Appraisal of psychometric questionnaires

Psychometrically developed questionnaires are important for care for a number of reasons. Patient-reported satisfaction with anaesthesia is generally high, both in studies and clinical practice; a single question or visual analogue scale is likely to lead to this result. In addition, the measure of satisfaction will need to cover all aspects of care, which are deemed important by patients, health professionals and relatives. In addition, it needs to be designed to analyse areas of care, i.e. dimensions, for which improvement strategies might be developed following the satisfaction assessment process.

Seven questionnaires (excluding my own) displayed a psychometrically sound development and reached scores equal to or above 6.5 points. In the following paragraph, questionnaires with equal or above 3.5 points on my scale are discussed in some detail to allow insight into the psychometric properties of the questionnaire construction as well as the satisfaction results obtained (see also Table 1.6).

With respect to the level of rigour of psychometric construction, the SOPPCAS (scale of patients' perceptions of cardiac anaesthesia) constitutes the benchmark with the maximum score of 10 Points. Le May and coworkers[7] present an instrument to measure patients' perceptions of the quality of cardiac anaesthesia services (administered by interview or as a mail back questionnaire) with seventeen items in four dimensions. The restriction to cardiac anaesthesia services only is a major drawback; its validation for this group only impedes inclusion of 'allcomers' i.e. to assess general perception with anaesthesia. They also included a measure for social desirability, for which a score of 14/20 was obtained, indicating moderate levels of social desirability. Remarkably, the SOPPCAS itself appeared to be unaffected by social desirability. Global mean satisfaction with anaesthesia services was 4.45 ± 0.64 out of a maximum of 6.0, men and women were equally satisfied. Interestingly, older patients seemed less satisfied with respect to their interactions with anaesthesiologists. This was interpreted as an effect of the interviews, where it was assumed that older patients do not verbalise their dissatisfaction. Unfortunately the study was conducted in Canada in a single institution only.

9 Points: Auquir and coworkers[91] published the EVAN-G in 2005. It includes twenty six items, six specific scores and one global index score. The development of the EVAN-G questionnaire comprised a phase of item generation and a phase of psychometric validation. In addition, the patient sample was generated to be proportionally matched to the population of patients undergoing general anaesthesia in France. Concurrent validity was supported not only by the STAI but also by the MGPQ. With this valid, and reliable tool, global mean satisfaction was reported to be 75% (SD 14%), with the information score being the lowest (64%, SD 22%), and discomfort the highest. Influencing factors for global satisfaction were type of surgery, type of anaesthesia, patients' age, and whether they belonged to the laryngeal mask group.

8.5 Points: Mui et al.[81, 82] report the construction, pre-testing, and practical application of their valid and reliable questionnaire, the Patient Satisfaction with Perioperative Anesthetic Care questionnaire (PSPACq), in two separate studies. They followed a rigourous protocol of psychometric construction of their 30-item questionnaire and also performed pre-test and determination of the content validity coefficient (V value) and homogeneity reliability coefficient (H value), of each item and the overall questionnaire to develop the final version of the pilot questionnaire. In addition to EFA, they also utilised CFA. In the clinical application of the developed questionnaire they obtained a total satisfaction score of 69.8% (SD 10.2%). Their score was significantly associated with age, gender, and educational level. The authors claim to have tested the nomological validity of the PSPACq by analysing for the effects of confounding variables, but also by comparing the satisfaction results to patient loyalty as a secondary outcome. The correlations of patient loyalty to the PSPACq were moderate and ranged from 0.203 to 0.461 for the seven dimensions; and 0.548 for the total satisfaction score. This is also interpreted by the authors as supporting nomological validity.[82]

7.5 Points: Maurizia Capuzzo and coworkers[3, 66] published two studies on the assessment of satisfaction with anaesthesia. Their first study[66] is the pilot study, including not only expert and patient interviews but also a ranking of items. The resulting 10 item final instrument was subsequently administered to 219 consecutive inpatients by interview. To assess reliability, the authors used measures of internal

consistency and of interobserver reproducibility. In the study that followed[3], the patients were given the questionnaire and were offered assistance for filling it in when required. The mean global satisfaction score was 8.7 (95% CI: 8.7– 8.8), being highest for the relational domain (8.9 (95% CI: 8.8–8.9)) and lowest for the emotional domain with 8.6 (95% CI: 8.6–8.7) points. Multivariate regression analysis identified five variables as significant predictors of mean global satisfaction: patients satisfaction were higher when they 1) had been treated in a service with perioperative nurses specifically dedicated only to anaesthesia; 2) had been treated where anaesthesia related information leaflets were provided preoperatively; 3) had received more than two anaesthesiologist visits after surgery; 4) had a good perceived health; and 5) were older than 70 yrs. While gender did not exert any influence, all domains were significantly different when the patients were grouped according to the other variables such as age, education, perceived health, extent of surgery, etc. Notably, the study tried to link results of the Maslach Burnout Inventory (MBI) to satisfaction, allowing the three components of burnout (emotional exhaustion, depersonalisation, and personal accomplishment) to be measured; but no relationship was found between staff burnout and patient satisfaction.[3, 66]

7.5 Points: Heidegger et al.[89] report a rigourous protocol: generation of items, construction of the pilot questionnaire, pilot study, statistical analysis (construct validity, factor analysis, reliability analysis), compilation of the final questionnaire, main study, repeated analysis of construct validity and reliability for their questionnaire. In contrast to other studies, they put emphasis on problems with perioperative anaesthetic treatment. The average problem score from all (six) hospitals was 18.6%. Most problems were mentioned in the dimensions 'Information/Involvement in decision-making' (mean problem score: 30.9%) and 'Continuity of personal care by anaesthetist' (mean problem score: 32.2%). The overall assessment of the quality of anaesthesia care was good to excellent in 98.7% of cases. The authors conclude that individual dimensions are superior to a global satisfaction score. Amongst the confounding variables considered, age, sex, subjective state of health, type of anaesthesia and level of education had an influence on the total problem score. Similar to our own study, the authors adjusted the scores for confounding variables to allow comparison between the participating hospitals. The questionnaire is commercially available only.

6.5 Points: The Leiden Perioperative care Patient Satisfaction questionnaire (LPPSq) was developed by Caljouw and coworkers.[15] Based on the results of the EVAN-G by Auquir et al.[91], this instrument was modified by adding questions about information given about the operation and operating theatre, and satisfaction about the amount of information given. While the authors fail to explain the translations process, it is debatable as to whether it is sufficient to rely on the results of item generation, in this case the face-to-face semistructured interviews, accomplished in a different socio-cultural background. At least an open-ended question at the end of the questionnaire, where patients were asked to give their supplementary comments or mention the important issues missed in the questionnaire, was used. Nevertheless, the rest of the psychometric construction and testing followed a strict protocol. Global mean satisfaction was 92.1%, influenced by gender, age, and surgical specialty. The lowest patient satisfaction score was for information (85.6%) and the highest for staff–patient relationship (93.4%). The study tried to link satisfaction to the occurrence of undesirable outcomes of anaesthesia care, but no correlation to the LPPSq was found.

6.5 Points: Sindhvananda et al.[111] reviewed the medical literature and performed patient interviews to generate the dimensions of satisfaction. Items were generated according to customer satisfaction surveys and a pilot questionnaire was developed and verified for content validity. The developed questionnaire did take some of the complexity of patient satisfaction with anaesthesia care into account. Global satisfaction was 86.4% (4.699/5 Points). In contrast to other studies on patient satisfaction, items were rated by experts but not patients. No confounding variables were analysed or accounted for.

5 Points: Jlala et al.[112] used the multidimensional LPPSq. While psychometric construction for the original LLPSq has been reported[15], the modification of the instrument as reported by Jlala et al. lack a literature research or patients' interviews of any kind that could serve as a basis of the reported modifications. Jlala et al. used a simple adaption, and the translation process of the LPPSq was generated by only one bilingual researcher translating the Dutch version of the questionnaire into English. To be put into a different socio-cultural background, an instrument not only needs to be tested for validity and reliability, but also be checked for construct validity.

5 Points: Kouki et al.[110] published three separate questionnaires to assess adult Greek patients admitted for elective surgery in an academic hospital: Q1 (patients who underwent general anaesthesia alone or combined with epidural) and Q2 (patients who received regional anaesthesia alone) covered perioperative anaesthetic care; Q3 covered postoperative analgesia services in the ward (patient-controlled analgesia or epidural analgesia). The authors used results of previous studies[3, 66, 89, 91] for the construction but did not report further details. They also fail to report the Cronbachs alpha as the main measure of reliability. In addition, they give only vague information about validity of the questionnaires, although PCA was used separately for each questionnaire. The satisfaction results were: Q1: 98.6% perceived the anaesthesia procedure as good or excellent; Q2: 98.4% the regional anaesthesia procedure as good or excellent and Q3: 96.3% the pain management as good or excellent. No significant differences in overall patient satisfaction regarding sex, age, ASA PS, or educational level was found. The communication dimension score in Q1 and Q2, sense of shivering in Q2, and pain management and anaesthesiologist behaviour dimension scores in Q3 were significantly associated with patient satisfaction in a multiple logistic regression analysis.

4.5 Points: Bauer et al.[4] developed a questionnaire to quantify the degree of patient satisfaction with anaesthesia and to compare the questionnaire technique with standardised face-to-face interviewing as a secondary aim. 589 patients were studied on the second postoperative day, either receiving the questionnaire for self-administration or were interviewed. The authors did not report patient involvement, rating or the use of open ended questions in the development process. Furthermore, questions relating to medical staff or their behavior were completely missing. Internal consistency was 0.84, analysis for a structure of the questionnaire was not reported, but two dimensions of care were given: anaesthesia-related discomfort and satisfaction with anaesthesia. The data on patient satisfaction showed a high degree of satisfaction (>90%), however, the questions on satisfaction with anaesthesia were answered consistently in a more critical manner during the interview. Of the questionnaire patients, 74% were 'very satisfied', while 24% were 'satisfied', while in the interview group, only 43% of patients were 'very satisfied' and 55% were 'satisfied' with the anaesthetic department. However, satisfaction was generally high. 'Drowsiness' (75%), 'pain at the surgical site' (55%), and 'thirst' (50%) were the

most frequent problems relating to anaesthesia-related discomfort.

4.5 to 4 Points: Hüppe et al.[107-109] published three studies on questionnaires. The first and second study describe the development[108] and validation for reliability and validity of the ANP.[107] The third study used the modified questionnaire to assess cardiac surgery patients.[109] In general, their questionnaire consists of two parts. Part 1 assesses the intensity of symptoms related to the postoperative periods 'recovery room', 'first hours on ward' and the 'current state'. Part 2 measures patients' satisfaction with anaesthesiological care, unspecific perioperative care and postoperative convalescence. The authors did not report a comprehensive literature review nor were patient opinions included in the construction process. They found influences on satisfaction for age, but not gender. The dimensions of care allegedly follow a content analytical approach, but the process of finding the dimensions is not reported. The difference found between the remembered complaints in the 'recovery room' and the 'first hours on ward' is of only a small degree. Global satisfaction was high with 94.7% (very satisfied 61.1%, satisfied 33.6%); the most commonly reported postoperative symptoms were: thirst/dry mouth (77.25%) and pain at the site of the operation (67.6%).

3.5 Points: Hadjistavropoulos and coworkers[113] used a former questionnaire, which was modified by rewording and adding questions. The WCCS was developed and published in 1986. The authors fall short of the description of the underlying changes. Nor were they reporting any assessment towards reliability, while they were able to demonstrate face validity and some features of construct validity. Six different dimensions were reported, of which information (Mean 2, SD 0.92) and involvement (Mean 2, SD 0.83) score best, while physical comfort had the lowest scores (1.79, SD 0.8) on a 1 (strongly agree) to 5 (strongly disagree) scale. Their study is the only study that reports on characteristics of respondents and non-respondents, which were found to be comparable.

Conclusion:

The appraisal of the tools used in this review focused on previous publications that describe the development or use of questionnaires on perioperative satisfaction with anaesthesia. Of more than 700 articles using patient satisfaction as an outcome measure in this review, only seven used patient-satisfaction measures that were multidimensional and had undergone a sound psychometric development process – paramount in the development of a reliable measurement tool for patients' satisfaction with anaesthesia.

Of the 22 questionnaires analysed, three used single questions only to measure satisfaction, which are likely to produce very high satisfaction ratings (Tables 1.4–1.6).[45, 64, 67] The overall problem of the seven studies presenting a sound psychometrically construction is that all studies presented have been accomplished in different socio-cultural backgrounds. The use of instruments from a different socio-cultural environment is a universal problem. Differences in expectations and how questions are being interpreted by the patients might be subtle, but will certainly exert influence. Thus, a validation and analysis for reliability needs to be done after translation, testing for understandability and comprehensibility, before a questionnaire can be considered for use. One of the seven instruments with good psychometric rigour used a questionnaire after translation.[15] The authors fail to explain the translation process, while the rest of the psychometric construction and testing followed a strict protocol. But it remains debatable as to whether it is sufficient to rely on the results of item generation, accomplished in a different socio-cultural background. Restricting the validation and analysis of a patients satisfaction questionnaire to a certain group of patients (i.e., cardiac surgery) is another problem, found in one of the top seven studies[7], as an instrument is best validated for the inclusion of 'allcomers' i.e. to assess the general group of patients receiving anaesthesia care. It is important that researchers show that the meaning of the questions are well understood by the recipients. Open ended questions were used in most of the studies, but will be insufficient to determine the cognitive process behind the answers. None of the studies presented used cognitive surveys to recognise the cognitive processes and to assess whether the meaning and subject of the questions are understood, that is, to identify patients who poorly understand the intended meaning ('nonattitudes').[73, 86, 87]

The analysis of confounding variables comprises exogenous, contextual and endogenous factors that have been found to exert influence on patient satisfaction. In any case, the instrument will have to show how it measures and controls for these potential confounding variables. While all of the seven studies reported the assessment for common confounding variables, only Heidegger et al.[89] made adjustments of the scores to take account for the confounding variables. This approach is of particular importance when a comparison comparing between different departments or hospitals is the focus. Unfortunately, the instrument by Heidegger and coworkers is only commercially available, distributed by the Picker-Institute, Switzerland.

Thus, there is clearly a need for a sound psychometrical instrument to assess satisfaction with anaesthesia care in the German patient population. This instrument will need to prove a maximum of psychometric rigour, a maximum of patient orientation, including tests for understandability, as well as testing and the consecutive adaption for confounding variables to be of use also as a benchmark tool.

Table 1.6: Studies on adult patient satisfaction; Rating of psychometric development

		Points	Auquir et al.[91]	Bauer et al.[4]	Bothner et al.[64]	Brown et al.[116]	Caljouw et al.[15]	Capuzzo et al.[3,66]	Fleisher et al.[114]	Gaszynsky et al.[106]	Hadjista-vropoulos et al.[113]	Heidegger et al.[89]
Content & Construct validity	The patient's view: involvement of patients (Interviews, Focus Groups etc.)	1	1				1	1				1
	The evaluation of the 'state of the art': Literature review	0.5	0.5	0.5			0.5	0.5				0.5
	The expert's view: Interviews, Focus Groups with health care professionals	0.5		0.5			0.5	0.5				0.5
	Question design: questions address only one subject and 3 or more point scales	0.5	0.5	0.5		0.5	0.5	0.5			0.5	0.5
	Rating of Items by Patients	0.5						0.5				
	Pilot Testing (or writing intricacy and comprehension probing)	1	1	0.5			0.5	0.5				1
Convergent validity	External or concurrent validity (correlation with other measures investigating aspects of the new measure)	1	1									
	Discriminance or 'extreme groups' and/or correlation to a global satisfaction question	1	1				1	1			0.5	1
Creation of subscales or dimensions		1	1	1		1	1	1			1	1
Use of statistical methods (PCA/CFA)		1	1				0.5				0.5	1
Reliability												
	Internal consistency	1	1	1			1	1	1		1	1
	Test-retest reliability	0.5	0.5	0.5				0.5				
Feasibility/Acceptability		0.5	0.5					0.5				
	Total	10	9	4.5	0	1.5	6.5	7.5	1	0	3.5	7.5

		Points	Hüppe et al.[107, 108]	Hüppe et al.[109]	Jlala et al.[112]	Kouki et al.[110]	Le May et al.[7]	Mui et al.[81, 82]	Myles et al.[67]	Schiff et al.[126]	Schiff et al.[127]	Sindhvananda et al.[111]
Content & Construct validity	The patient's view: involvement of patients (Interviews, Focus Groups etc.)	1					1	1		1	1	1
	The evaluation of the 'state of the art': Literature review	0.5	0.5	0.5	0.5	0.5	0.5	0.5		0.5	0.5	0.5
	The expert's view: Interviews, Focus Groups with health care professionals	0.5					0.5	0.5		0.5	0.5	
	Question design: questions address only one subject and 3 or more point scales	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Rating of Items by Patients	0.5								0.5		0.5 (Rating by Experts)
	Pilot Testing (or writing intricacy and comprehension probing)	1	1	1	1	1	1	1		1	1	1
Convergent validity	External or concurrent validity (correlation with other measures investigating aspects of the new measure)	1					1	0.5		1		
	Discriminance or 'extreme groups' and/or correlation to a global satisfaction question	1	0.5	0.5	1	1	1	1		1		
Creation of subscales or dimensions		1	0.5	0.5	1	1	1	1		1	1	1
Use of statistical methods (PCA/CFA)		1			0.5	1	1	1				1
Reliability												
	Internal consistency	1	1	1	1		1	1		1	1	1
	Test-retest reliability	0.5	0.5				0.5					
Feasibility/Acceptability		0.5					0.5	0.5		0.5		
	Total	10	4.5	4	5	5	10	8.5	0.5	9.5	5.5	6.5

		Points	Thierbach et al.[115]	Tong et al.[45]	Whitty et al.[99]	Zvara et al.[68]
Content & Construct validity:	The patient's view: involvement of patients (Interviews, Focus Groups etc.)	1			1	
	The evaluation of the 'state of the art': Literature review	0.5	0.5	0.5	0.5	
	The expert's view: Interviews, Focus Groups with health care professionals	0.5				
	Question design: questions address only one subject and 3 or more point scales	0.5	0.5	0.5	0.5	0.5
	Rating of Items by Patients	0.5				
	Pilot Testing (or writing intricacy and comprehension probing)	1			1	
Convergent validity	External or concurrent validity (correlation with other measures investigating aspects of the new measure)	1				
	Discriminance or 'extreme groups' and/or correlation to a global satisfaction question	1			0.5	
Creation of subscales or dimensions		1			1	
Use of statistical methods (PCA/CFA)		1				
Reliability						
	Internal consistency	1				
	Test-retest reliability	0.5		0.5		
Feasibility/Acceptability		0.5				
	Total	10	1	1.5	4.5	0.5

3c. Satisfaction in anaesthesia in paediatric patients and/or parents

The search identified a total of 120 studies, of which six (excluding my own study) were included in this review (Appendix II: Table 1.7; Figure 1.3).

Introduction

Opinions about satisfaction with care are rarely sought from children, despite the increasing awareness and growing discussion in research and public policy literature regarding the rights of children and adolescents to participate in research and make decisions about their own health care.[128, 129]

The approach to assess children's experiences with anaesthesia care is very complex: answering a questionnaire requires explicit recall, which in turn, requires explicit memory which children begin to develop at around 3 years of age.[16] Parental opinions of satisfaction with care have previously been used as a substitute for opinions from children and adolescents. When proxies, i.e. parents/ guardians/ relatives are used to determine experiences with anaesthesia, in particular if the survey includes aspects of the immediate perioperative period (i.e., induction of anaesthesia, waking up or 'coming around', PACU), one will have to realise that only a fraction of the proxies will have been present at the time. To take account of this fact, it is important to understand that the statements given are:

    i)   either estimates given by parents/ guardians/ relatives, or

    ii)   derived from the child's memory by the parents/ guardians/ relatives, or

    iii)   direct memories of the child.

The use of proxies has been considered controversial, yet, research is lacking to answer the question as to whether parents truly capture and accurately represent children's and teens' satisfaction with health care.

Answering a questionnaire not only requires explicit recall and memory, but children are also highly suggestive, especially at younger ages. Careful questioning is required[16] and questions have to be designed to match the cognitive and emotional level of the child. Social desirability and observer bias might also distort results.[47, 130] Families desire health care that reduces children's physical stressors such as pain or discomfort, psychological stressors such as inadequate information or lack of control,

and environmental stressors such as unfamiliar surroundings or people.[18, 131, 132] Being included in decisions about care is valued highly by patients.[133, 134] In general, research investigating children's satisfaction with anaesthesia care is scarce, a finding that is conveyed with the very few instruments identified by this literature search.

Of the six studies found, two studies were dedicated exclusively to the development and testing of satisfaction questionnaires for paediatric patients.[17, 135] Other studies were carried out to investigate not only satisfaction, but satisfaction along with other outcomes, such as the effect of parental presence during induction of anaesthesia,[136, 137] the effect of introducing education programs for parents[138] or preferences in decision making with regard to the child's anaesthetic care.[139] In these studies, satisfaction was a mere secondary outcome, nevertheless, satisfaction questions and/or questionnaires were used and the studies therefore were included in this analysis.

Similar to the approach used in Section 3b, the following Section will evaluate the literature found. The depth of the psychometric development as well as other formal criteria for the conduct of studies will be considered. This is followed by a critical appraisal of the satisfaction results reported by the studies.
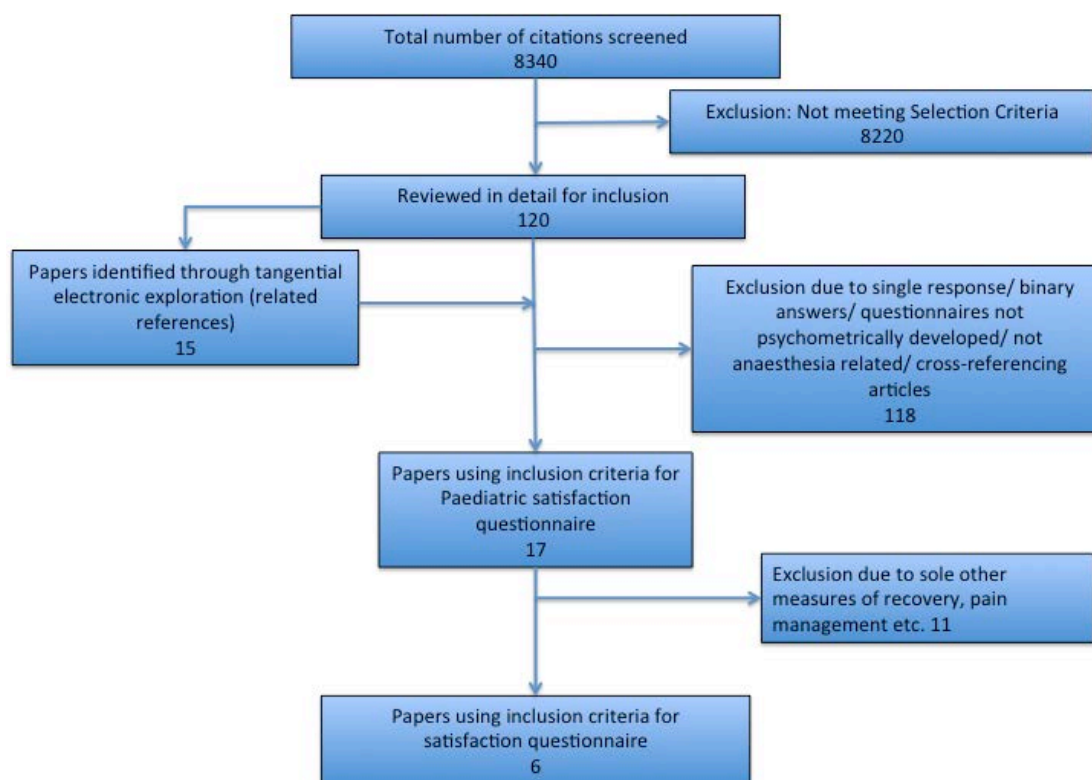
Figure 1.3: Flow chart: literature search – Paediatric patient satisfaction

Ethical oversight

A prerequisite for using patient data for research purposes is the provision of informed consent and ethical oversight. In studies involving children, written informed consent is usually obtained from parents before questionnaires are handed to the child. All studies eligible for this review met these criteria and provided evidence of informed consent and ethical oversight.

Content and face validity

Item generation

A comprehensive literature review was only conducted in the study by Iacobucci et al.[17] Chan et al[138] cited some literature on which their satisfaction questions were based, while the study by Palermo and co-workers reported that their questions were based on a previous study for which an 'empirical' literature search had been used to identify items.[137, 140] Search strategies were not given in any of the studies analysed.

The inclusion of expert opinion to identify relevant factors/ items for the construct of the questionnaire[6] was reported explicitly in one study.[136] While the study by Iacobucci et al.[17] suggests expert involvement, the study cited by Palermo and co-workers[137] had previously included expert opinion.[140]

Patient's involvement should form an integral part of development; in this case proxies (parent/ guardians/ relatives) and children capable of participating. Again, instruments were subject to assessment for patient involvement in the construction, as well as the use of open questions to allow for comments on content, missing items, wording, response choice, etc., allowing parent/ guardians/ relatives and children to add their individual perspectives.

For the item generation, not a single of the analysed studies described having asked children and/or their proxies in the development process, neither in face-to-face interviews with older children nor in family (or group) interviews.

Rating
As part of the validity analysis, rating (or ranking) items for subjective importance by patients and/or caregivers might be used to emphasise the importance of the single items to the patient group under survey. Again, no study put emphasis on the importance of items as per opinion of the evaluated population.

Wording questions – Tests for understandability and readability
Including questions with more than one subject addressed is particularly likely to lead to confusion in children. The questions need to be put into a context to have contextual meaning or importance to allow children to encode and retrieve memories that have meaning to them.[141] The writing intricacy should not be too difficult and reading level should be adjusted to meet the reading levels of the children.

None of the studies reported adjustment of reading levels for the writing intricacy nor a cognitive survey (designed to recognise the cognitive processes and to assess whether the meaning and subject of the questions were understood). Only one study stated that items were explained during the telephone interview.[139] Only Iaccoucci et

al.[17] describe the use of open ended questions to allow comments on content, missing items, wording, response choice etc.

Pilot test

As explained above, a pilot test allows generating experiences with the new instrument in 'the field': A pilot test was described only by Chan and coworkers.[138]

Criterion validity

For criterion validity scores or contents of the instrument are correlated with a 'gold standard', however, there is no accepted criterion that can serve as a definitive standard of satisfaction and construct validity may be used instead.

Construct validity

In the studies identified in this literature review, satisfaction was often reported as a secondary outcome, used to determine differences between groups of intervention. While these are implicit in the sense of the study, they may not be used to determine known hypothesis, as the study serves to reject or prove another hypothesis given by the intervention. Commonly, age and gender, education levels etc. are utilised as these factors have been found to alter satisfaction scores (see above).

None of the studies analysed used correlations of the dimensions to confirm construct validity, furthermore the use of IIC and/or IDC and/or IDV was not reported in any of the studies.

Construct validity was tested in one of the studies assessing the effect of known influencing variables such as age, gender, education level and others.[138] Tait et al.[139] described differences between different levels of education. Iacobucci et al.[17] reported the 'testing of several hypotheses', that is, an association between some of the children's responses (e.g. anxiety, with regard to nursing care) and the degree of satisfaction as reported by their parents.

External validity testing employing other measures was indirectly reported by only one author: Palermo et al.[137] described his questionnaire as having adapted items from a previous instrument; the Perception of Procedures Questionnaire, which had been

used to measure parental satisfaction with the infant's anaesthesia and surgery care (e.g. communication with staff, attention to concerns, emotional support).[140]

The Perception of Procedures Questionnaire was shown to correlate well with the Pediatric Oncology Quality of Live Scale (POQOLS), the Parenting Stress-Index Short Form (PSI-S), to child distress and parent and nurse observations of distress. This does not, however, prove external validity for the dimension of satisfaction as used in a modified version in the study by Palermo et al.

Reliability

It is important that researchers demonstrate an adequate procedure for developing and testing their constructs before presenting them as scales, and multiple techniques for assessing reliability are available for different situations.[6, 83]

Scale determination by using an EFA or PCA was reported by only one author,[136] while Tait and co-workers[139] used qualitative content analysis for determination of the three scales. The study by Palermo et al.[137] used seven items to determine satisfaction; however six of these had formed a single dimension in a previous study, while one question was added by the authors for the purpose of the study. Although it is debatable whether a scale generally needs testing to prove reliability when used in the same context and the same socio-cultural background, the study mentioned used a part of an instrument that had been constructed to assess child and parent distress related to lumbar puncture, that is, for a completely different purpose and also in a different setting.[140]

Finally, values for the Cronbachs alpha were given for four of the studies, excluding the one by Palermo et al. (Appendix II: Table 1.8).[17, 136, 138, 139]

Test-retest Reliability

One study reported having tested for test -retest reliability,[17] while it is argued that it is too much to expect a patient to fill in the same questionnaire multiple times,[6] and that responses may vary with time as the concept of satisfaction is influenced by time-dependent memory effects.[47] These problems are likely to be aggravated when children are involved.

Intra-rater and Inter-rater Agreements

The testing of the association between some of the children's responses (e.g. anxiety, with regard to nursing care) and the degree of satisfaction as reported by their parents may include an element of inter-rater agreement,[17] also in this case it may be interpreted more in the sense of measurement and outcome than as a testing tool.

Feasibility/Acceptabillity

Interestingly, time for completion of the questionnaire or the interview was not stated in any of the studies.

General remarks

Palermo and co-workers[137] used results of a previous published instrument.[140] While the instrument addresses important aspects of satisfaction, it was not designed to measure experiences with the anaesthetic procedure and the reported results thus remain rather questionable.

The assessment of children's' experiences and satisfaction with anaesthesia care is even more complex than in adults. While numerous studies used parental opinions of satisfaction as a substitute, opinions from children and adolescents themselves were only investigated in the study by Iacobucci et al.[17], where children were directly addressed to answer at least part of the questionnaire.

As previously discussed (Section 3a), the optimal timing for administration of a satisfaction questionnaire remains generally unclear. In anaesthesia care management in the paediatric population, restriction of the period of questionnaire administration to the first 48–72 hrs after surgery is found in a number of studies.[17, 135, 137-139] In the study by Boonmak et al.[135], parents were called at home on POD (post-operative day) one for the telephone interview. The only mailed questionnaire was intended to be returned within two weeks, and, if not returned, a reminder telephone call was initiated.[136]

<u>Satisfaction results</u>

Interviews have been linked to high rating of patient satisfaction.[44] In this review, the study by Boonmak et al.[135] used telephone interviews, which proved to provide high satisfaction ratings in all aspects measured. Other studies also reported high satisfaction ratings: Kain et al.[136] reported parental satisfaction as a secondary endpoint. Parental satisfaction with the overall care provided was significantly higher among the sedative and Parental Presence during Induction of Anaesthesia (PPIA) group compared with the sedative group. In the study by Iacobucci et al.[17], parents generally expressed a high degree of satisfaction (9/10 points) and satisfaction correlated significantly with environmental comfort and post-operative observations performed by anaesthetists and nursing staff. In the children, lack of fear at the moment of being anaesthetised and lack of anxiety on the day preceding surgery, were attributed to the serenity transmitted by the anaesthetist and nurses.

Palermo et al.[137] designed their study to assess differences between parental presence and absence during anaesthesia induction in infants on the child's behavioural distress of the procedure. (Parental) satisfaction reflects one dimension derived from a former questionnaire and was high and at comparable levels between the two groups (presence 6.5 (SD 0.3) and absence 6.7 (SD 0.4) of a maximum of 7 points).

In the study by Tait et al.[139], overall parental satisfaction was high (Visual Analogue Scale (VAS) 8.9 (SD 1.3) on a 10-point analogue scale) with parents of children who experienced Post-operative Nausea and/or Vomiting (PONV) being less satisfied (8.5 (SD1.6) vs. 9.1 (SD1.1) without PONV), as were those who wanted more participation than experienced.

In general, analysis of satisfaction should be conducted to elicit any possible effects and appropriate adjustments should be made[6], to take into account variables relating to the composition of the patient sample and other confounding variables, which then will allow direct comparison between different providers etc. In the study by Chan et al.[138], parents who received an education program were less anxious and reported increased satisfaction compared to those not receiving the program; while overall satisfaction was generally low (76% (SD 6.6%) vs. 69% (SD 5.3%)).

Appraisal of psychometric questionnaires

Psychometrically developed questionnaires are important for care for a number of reasons. Patient-reported satisfaction questionnaires need to be designed to analyse areas of care, i.e. dimensions, for which improvement strategies might be developed following the satisfaction assessment process.

None of the reported questionnaires for paediatric patients investigating anaesthetic care (excluding my own) displayed a psychometrically sound development or reached scores equal to or above 6.5 points on the scale that I have proposed at the end of Section 3a. In the following paragraph, questionnaires with equal or above 3.5 points on my scale are discussed in some detail to allow insight into the psychometric properties of the questionnaire construction as well as the satisfaction results obtained (see also Table 1.9).

The study by Kain et al.[136] reached 5.5 points. The child's and the parental anxiety throughout the perioperative period were the primary endpoints of this study. Parental satisfaction was the secondary endpoint. A satisfaction questionnaire was developed using a rational empiric approach that involved three steps: (1) conceptual grouping of items with input from anaesthesiologists, nurses, child-life specialists, psychologists, and surgeons; (2) factor analysis; and (3) examination of internal consistency. The result is a 21-item questionnaire with two dimensions. The weakness of the study lies in the area of item construction and convergent validity.

4 Points: The study by Chan et al.[138] was designed to evaluate effects of an educational program on anxiety and satisfaction in parents being present for anaesthesia induction of their child. A quasi-experimental pre-test and post-test design was employed. The Chinese version of the STAI and the Parental Satisfaction with Care Questionnaire were used to address parents' anxiety and satisfaction with care. A parental satisfaction with care questionnaire was developed, based on previous work of different authors assessing patient satisfaction. This questionnaire assesses parents' opinion about the practice of parental presence during induction of anaesthesia (PPIA) and the visitation by the anaesthetist in the PACU. The performance of the operating theatre staff was also included, covering areas such as adequacy. While the authors include a pilot test, assessment for extreme groups, and some reliability testing, they

fail to provide many other features of psychometric framework for their instrument.

<u>4 Points: Iacobucci et al.</u>[17] aimed to develop a rapidly interpretable questionnaire to measure the level of parental satisfaction when their children undergo surgery and to provide information on factors triggering anxiety in children. The questionnaire was constructed using a literature review, but the authors fail to report details. In addition, children or parents were not included in the phase of the questionnaire construction. The authors report tests for construct validity, reliability (Cronbachs alpha) as well as for test-retest reliability. A pilot phase is missing, so are tests for writing intricacy and understandability, although open ended questions were included. Even though the questionnaire was divided into two sections, test to define dimensions of care have not been accomplished. The first section of the questionnaire is dedicated to the parents and the second to the children investigating emotional/behavioral spheres as well as the comfort provided.

179 parents of children were included in the analysis, and authors received answers from 112 children (of these parents) for section two of their questionnaire. Parents generally expressed a high degree of satisfaction (9/10 points). Satisfaction correlated significantly with environmental comfort and post-operative observations performed by anaesthetists and nursing staff. In children, lack of fear at the moment of being anaesthetised and lack of anxiety on the day preceding surgery, were attributed to the serenity transmitted by the anaesthetist and nurses. Significant anxiety resulted from the fear of an unpleasant impact with the operating room.

The other studies lack important aspects of content and convergent validity[139], aspects of convergent validity and reliability[137] or any psychometric feature altogether.[135]

Conclusion

The appraisal of the tools used in the identified literature of this review focused on previous publications that describe the development or use of perioperative satisfaction with anaesthesia. Only a small proportion of paediatric patient-satisfaction measures could be identified that were multidimensional and had undergone at least some sort of psychometric development process – paramount to the reliable and valid measurement of paediatric patient satisfaction with anaesthesia. Psychometrically developed questionnaires are important for care for a number of reasons as are discussed in Section 3a.

Of the six questionnaires analysed, not a single study can be considered to provide a valid and reliable psychometric tool. Most of the instruments show at least some psychometric features,[17, 136, 138, 139] but one study failed entirely to report any psychometric properties (Tables 1.7-1.9).[135]

Children are intelligent, capable people and should be allowed to participate in health care decision where possible i.e. to the level of their development.[128] Research investigating children's satisfaction with anaesthesia care however remains scarce, despite the increasing awareness and growing discussion regarding the rights of children to participate in research and make decisions about their own health care.[129] This finding is supported by the literature review for this PhD thesis, where only one study could be identified that evaluated satisfaction by asking the children themselves[17] – most of the studies addressed parental satisfaction. Interestingly, none of the studies were psychometrically sound constructions; accordingly, their results remain of uncertain value.

Thus, there is clearly the need for sound psychometric questionnaires that allow assessment of children's and parent's satisfaction with anaesthesia care.

Table 1.9: Studies on paediatric patient satisfaction; Rating of psychometric development

		Points	Boonmak et al.[135]	Chan et al.[138]	Iacobucci et al.[17]	Kain et al.[136]	Palermo et al.[137]	Schiff et al.[142]	Tait et al.[139]
Content & Construct validity:	The patient's view: involvement of patients (Interviews, Focus Groups)	1						1	
	The evaluation of the 'state of the art': Literature review	0.5		0.5	0.5		0.5	0.5	
	The expert's view: Interviews, Focus Groups with health care professionals	0.5			0.5	0.5	0.5	0.5	
	Question design: questions address only one subject and 3 ore more point scales	0.5		0.5	0.5	0.5		0.5	Q not given
	Rating of Items by Patients	0.5						0.5	
	Pilot Testing (or writing intricacy and comprehension probing)	1		1		1		1	
Convergent validity	External or concurrent validity (correlation with other measures investigating aspects of the new measure as anxiety)	1					0.5	1	
	Discriminance or 'extreme groups' and/or correlation to a global satisfaction question	1		1	1	0.5 as per study design		1	1
Creation of subscales or dimensions		1				1		1	1
Using statistical methods (PCA/CFA)		1				1		1	
Reliability	Internal consistency	1		1	1	1		1	1
	Test-retest reliability	0.5			0.5				
Feasibility/Acceptability		0.5							
	Total	10	0	4	4	5.5	1.5	9	3

4. Measuring mortality and severe IECs relating to anaesthesia

A MEDLINE and Cochrane library search were performed to search for studies evaluating mortality and severe morbidity. The search identified a total of 59 studies, of which 37 were rejected, 9 were review articles, while 13 matched the set criteria (see Section: Search criteria) and were included in this review (Appendix III: Tables 1.10 and 1.11; Figure 1.4).
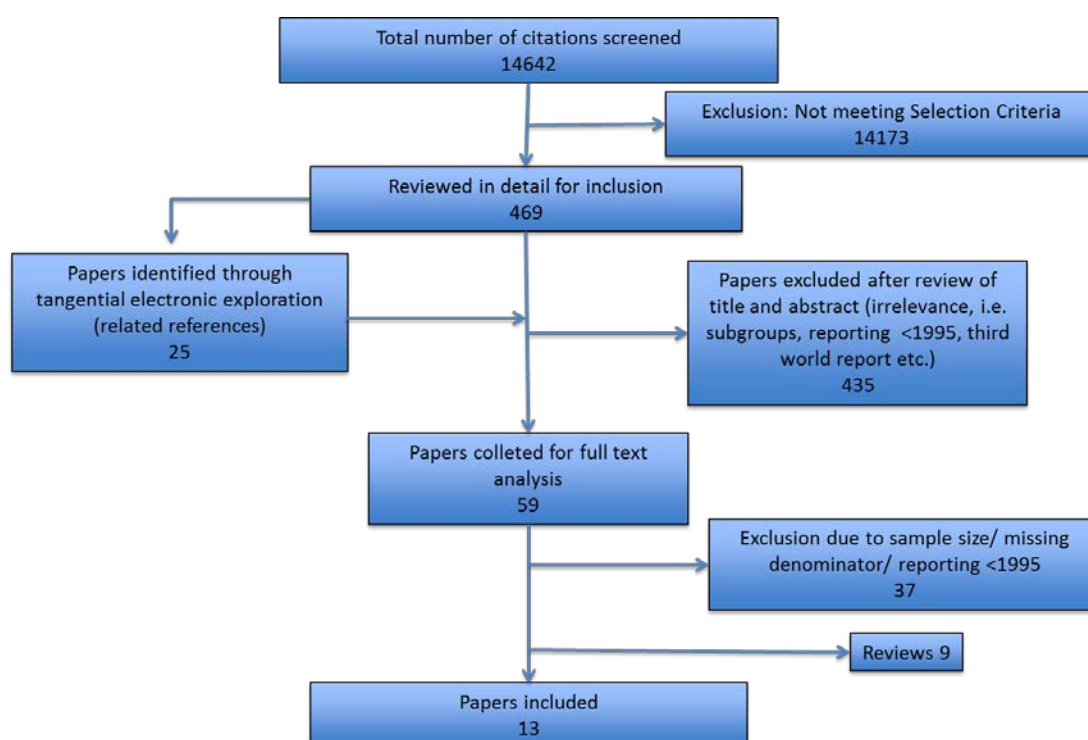
Figure 1.4: Flow chart: literature search – Major morbidity and mortality in anaesthesia

Introduction

Death is per se a clearly defined endpoint. The use of mortality as a primary outcome may help in improving the quality of data. This might carry the chance of complete data acquisition and will help to minimise the chance of a confounded relationship between risk factors and outcome.[2] In order to obtain an accurate numerator for anaesthetic mortality, it is necessary to first identify deaths during or within a specified period relating to an anaesthetic. In a second step, the circumstances of the death need to be scrutinised to elucidate a potential anaesthesia related cause or contribution to the death.[143]

Definitions for morbidity associated with anaesthesia are even more complex. This Section includes studies that reported on perioperative anaesthesia related mortality, and with or without anaesthesia related (severe) morbidity. Available studies are examined and discussed with respect to study period, data source, denominator, primary outcome, anaesthesia related morbidity, perioperative mortality rate, anaesthesia-related mortality rate, mortality rate for which anaesthesia was solely responsible, and preventable anaesthetic mortality rate as defined by each study.

4b. Mortality and cevere IECs relating to anaesthesia

Reporting

Mortality is a vital estimate of risk associated with anaesthesia with an apparently clear definition. This generally stands in contrast to the more debatable definitions of morbidity. However, even a mortality rate must often be regarded as a rather crude risk estimate because of its relative rarity and the differing methods employed to record death. One of the first caveats in terms of accuracy of the numerator refers to the period of reporting an anaesthetic death, that is the time frame between the first anaesthetic contact and possible anaesthesia related death, ranging from the anaesthetic encounter during an operation to hours, days, weeks, months or even years post procedure.[2] In terms of the reporting, different methods are being employed.

In a number of studies, reporting was voluntary (both prospectively[31, 51, 144-148] and retrospectively[149]), which coincides with a high probability of information bias in the sense of underreporting.[31, 51, 144-147, 149] These drawbacks can be minimised by using specific reporting systems to cross-check results in order to obtain a complete picture and reduce the rate of missed events. This approach was chosen in five studies where some employed even monthly survey of hospital deaths.[31, 51, 52, 144, 148, 150]

In the Australian study by Gibbs[143], reporting of death under anaesthesia or deaths where anaesthesia is thought to be a contributing factor, is mandatory according to state regulations in three states: Western Australia (WA); New South Wales (NSW) and Queensland (QLD) (partly via the coroner). In Tasmania reporting is a condition of employment, where the reporting of death under anaesthesia is mandatory by contract, while for the remaining states and territories reporting is on a voluntary basis.

Newland et al.[151] states in his study that reporting of adverse events by faculty, residents, and nurse anaesthetists was mandatory for each case in his study. A number of other authors used

databases with prospectively coded data ([151, 152](audit data), [150, 153]), or International Classification of Disease (ICD) codes 9[52] or ICD 10[50] to identify cases from death certificates as further discussed below. Biboulet and co-authors[148] fall short to comment on the exact nature of reporting in their study.

One of the most important points with respect to the reporting is to ensure that the process of reporting and investigating the incident is non-punitive and/or even confidential. Studies have shown that anaesthesiologists will comply with a system of self-reporting if the process is non-punitive and likely to result in tangible improvements in patient care.[51, 154] Lagasse et al.[155] and Lienhardt et al.[52] discussed the importance of the non-punitive nature of the review. In Australia, reports to the committees are confidential and legally protected; there is no disincentive to the naming of the anaesthetist(s) involved or any risk of litigation. Gibbs[143] follows to explain that in all states, the reports received and all details pertaining to the deaths (including personnel and hospital) were de-identified before being brought in front of the committees. Newland and co-authors[150] state there was no identification of the patient or healthcare provider(s), and the abstracts used to describe the events leading to the cardiac arrest during anaesthesia were prepared without assigning responsibility. During their study, the abstracts could only be identified by a three-digit number, assigned by one of the authors and submitted anonymously to the Anesthesia Study Commission, recruited for the project.

In the study by Kawashima et al.[149], questionnaires were collected by mail in a double envelope to protect the confidential data of the hospitals and to encourage precise responses, while Arbous and coworkers[31, 144] collected anonymous anaesthetic and recovery forms. Furthermore, the authors explain that the anaesthesiologists communicated to the research committee via a 'correspondent', thus preserving the anonymity of both the patient and anaesthesiologist involved.

In terms of trust and confidentiality, Charaluxananan and co-workers[146] aimed at designing their study forms to meet the requirements of the investigator, the attending anaesthesiologists, as well as nurse anaesthetists. They also succeeded in getting all hospitals to use an identical form. In addition, they organised workshops and internal audits at all sites and the process was piloted by staff of six university hospitals before it was employed, thus reducing the problem of compliance and reliability of anaesthesia personnel, as well as concerns regarding possible medico-legal problems and difficulties with definitions.

Review process, peer review

In addition to its effect on self-reporting rates, peer review can also affect published anaesthesia-related mortality rates through the accuracy of their judgments.[51] A peer review process will allow to define perioperative death to which human error by the anaesthesia provider has contributed, as well as to identify the factors that have led to the fatal outcome. Although the accuracy of judgments by a peer group can never be absolutely assured, measures can be taken to improve the reliability of the peer review process: for instance use of multiple reviewers who meet to discuss the case has been shown to markedly increase consensus among reviewers.[156-159] However, discrepancies are not a problem of definition but more one of the degrees of subjective interpretation. In the study by Arbous et al.[144] for example, out of 119 actually anaesthesia related cases, only 36% (n=43) were judged by all of the three classifiers as having a relationship with anaesthesia, all other cases, only one or two reviewers agreed on the relationship with anaesthesia.

It therefore seems prudent to involve more than two reviewers to analyse the cases. While two studies involved a large team of classifiers (Arbous et al.[144]: Morbidity and Mortality Committee (n=5) as well as other anaesthetists (n=13); and Lagasse et al.[51]: peer review staff (n=25), residents (15)), the study commission in the study by Newland et al.[150] was composed of five reviewers (three nationally recognised chairpersons of academic anaesthesia departments, a surgeon who is chair of a department of surgery, and a senior faculty internist and pulmonologist, certified in critical care medicine). Four studies[52, 146, 147, 151] reported to have employed three reviewers each. In two other studies[148, 152], the authors did not follow the more stringent methods involving specific study-related review committees, with only two authors assessing the cases, while one of the studies assessed inter-rater reliability of three individual reviewers for the first 10 charts to confirm uniformity of data extraction.[153] Two authors simply mention that review committees had been employed but fall short to report the composition of these: Gibbs[143] states that Australian state anaesthetic mortality committees consist of members from the anaesthesia community and other health professionals, while Kawashima et al.[149] simply employ committees ('data were sorted and analysed each year by members of the JSA Committee on Operating Room Safety'(n= not given)).

Definitions of anaesthetic contribution to mortality

A medical 'error' might either human or system related. Nominal definitions for subcategorising these two types of errors may increase the objectivity of the process.[155-157] Lagasse et al.[51] define error based on the IOM definition as 'Failure of a planned action to be completed as intended' or 'use of a wrong plan to achieve an aim; the accumulation of errors results in accidents'. To make the peer review process less threatening, these definitions allow reviewers to look at the system critically. It seems that death during anaesthesia or within a defined time period is objective. However, determining whether an anaesthetic factor has caused or contributed to the death remains an opinion only and therefore is always subjective (at least to some extent). It is therefore imperative that authors explain the system they have used to evaluate contributions from anaesthesia.

A number of authors described definitions to determine the role of anaesthesia in the fatal outcomes.[31, 50-52, 143-145, 147-151, 153] Arbous et al.[31, 144] used three steps: the first to determine the main related factor; the second to determine a contributing factor; and the third to determine the main related factor. For steps one and two, the factors involved could be anaesthesia (A), surgery (S), the patient (P), or a combination of these (M). The third step follows the approach proposed by Edwards et al.[160]. After being discussed by the committee, the cases are further subclassified using a Study Subclassification System to determine the nature of the event. [144, 161]

The use of the modified criteria published by Edwards et al.[160] (Appendix IV) were also promoted by Gibbs[143], where deaths in categories 1–3 of this classification can be considered 'anaesthesia-related', while only deaths in category 1 are considered to be 'anaesthesia-caused'. Deaths classified in categories 4–6 (surgical, inevitable and incidental deaths) are considered 'not anaesthesia-related'.

In six studies, authors used similar definitions, however, they neither directly referenced the criteria promoted by Edwards nor sufficiently explained the system used (by giving examples).[52, 146-148, 150, 151] In the study by Newland et al.[150], commission members were asked to rate the anaesthetic contribution (for cardiac arrests) on a five point scale ranging from 1 (certain, that anaesthesia was the primary cause (certainty > 90%)) to 5 (anaesthesia was neither the primary nor an important contributing cause of the adverse event). Lienhardt and co-workers[52] determined the causal role of anaesthesia in the process leading to death using a

three-point scale, which seems related to the Edwards criteria, but providing more details of the cause of death as being 'not anaesthesia related', 'partially related to anaesthesia' and 'totally related' to anaesthetic care. Furthermore, they promote an additional dichotomous (high–low) classification to describe how reliable the conclusions are deemed to be.

In the study by Lagasse et al.[51] anaesthesia-related mortality was defined as perioperative death to which human error by the anaesthesia provider, as defined by the peer review process, had contributed. If the departmental peer review committee determined that human error had contributed to an adverse outcome, they judged the degree to which the anaesthesia care provider had contributed to that outcome. The contribution was graded on a three-point Likert scale ranging from minor to major. Analysing ICD-10 codes used to identify anaesthesia-related deaths from the USA multiple-cause-of-death data files, Li and coworkers[50] analysed the role anaesthesia played in the deaths based on the causal chain of events leading to death as identified by the order on the death certificate and ICD coding guidelines. Here, anaesthesia related deaths were operationally defined as deaths that included one of the anaesthesia-related codes as the underlying cause of death or included at least one anaesthesia-related code as a listed cause among the multiple causes of death. It is debatable as to whether this allows judgment of the chain of events.

In the study by Kawashima et al.[149] the data requested from the hospitals included the principal cause of each incident selected from a list of 44 items provided on the questionnaire. Unfortunately, the authors do not state which factors or combinations of factors were sought to determine the contribution of anaesthesia.

Another definition is given in the study reported by Sprung et al.[153] where any cardiac arrest that occurred after an anaesthetic drug was given to a stable patient (e.g., narcotic, muscle relaxant, induction agent) who had either an immediate arrest or depression of ventilation leading to hypoxemic cardiac arrest was considered as primarily attributable to anaesthesia. All obvious mishaps in airway management (e.g., inability to intubate the trachea, unrecognised accidental extubation, and lost airway during tracheotomy) were also considered as primarily attributable to anaesthesia. While this approach seems straight forward, it remains debatable why unstable patients (e.g., those with bleeding aortic aneurysm), whose arrest occurred after an anaesthetic induction agent was given, were not considered as having had an anaesthesia-attributable cardiac arrest.[153]

Finally, Khan et Khan[152] did not give any indication on how they judged a potential anaesthesia involvement, although the cases they present show features of the classification promoted by Edwards.

Definition of perioperative death: a function of time

A spectrum of time limits has been used for studies, ranging from perioperative (induction to discharge PACU or admission ICU)[151, 153] to one year[50, 52] (Appendix III: Table 1.11) rendering direct comparisons between the studies difficult. The most frequent used timeframe was between 24 to 48 hrs within the procedure.[31, 51, 143-148, 150, 152] However, some patients who suffer anaesthesia-related complications may not die for weeks, months or even years after the anaesthetic. These deaths would not be captured in studies using such limits.[2] On the other hand, with longer survey periods, other factors may increasingly play a role such as underlying diseases, particularly malignancies.[162]

Denominator data

The lack of defined populations as a denominator for the number of deceased often impedes exact calculations of outcome rates for death with anaesthetic contribution or death exclusively attributable to anaesthesia, even when the numerator is quite accurate. The imprecise denominator obviously impacts heavily on results. Exact data on denominators were delivered by nine of the authors (Appendix III: Table 1.11).[51, 145-153] Arbous et al.[31, 144] estimated the total number of anaesthetics administered during the study by means of a Hospital Characteristics Questionnaire with characteristics of the anaesthetic practice, giving number of anaesthetic procedures performed for a total participation of 46 practices (90%) in 58 locations. Gibbs states that the method of determining the total number of anaesthetic procedures varied between the reports included in the study. The numbers of anaesthetics administered per annum were approximations (and therefore also estimates) for the reports between 1994 and 1998 that were based on the total number of separations from hospitals in the states involved (based on ICD-9 codes). From 2000 onwards, the number of anaesthetic procedures was based on anaesthetic codes using ICD-10 codes.[143]

Li and coworkers[50] calculated their estimates of hospital anaesthesia-related mortality based on national estimates of hospital surgical discharges for the study period generated from the National Hospital Discharge Survey (using the defined surgical procedural codes). The

National Hospital Discharge Survey data used were a proxy measure of exposure to anaesthesia among hospital inpatients as they were based on a multistage random sampling scheme, and the national estimate of the annual number of hospital discharges. This estimation approach assumes that each hospital discharge would have involved one single anaesthetic course only. On the other hand, not all patients will have undergone an anaesthetic procedure.

Another complex method to determine the denominator of anaesthetic procedures is given by Lienhardt et al.[52] The denominator of anaesthetic procedures was estimated based on a national survey conducted three years earlier from a sample of 62,000 anaesthetic procedures performed in all French hospitals and clinics.

The estimation processes in the two latter studies include multiple steps, with each step increasing the inaccuracy of the total denominator and rendering the final estimate increasingly imprecise.

Perioperative mortality partially or totally attributable to anaesthesia and causation

The comparison of death rates is complicated by many factors as mentioned above. A direct comparison is feasible only when using the same criteria for the numerator, the time period, and the denominator. In the assessed studies, a 24 hours perioperative time period was most frequently encountered.[31, 144, 145, 147, 150] The results report a total rate of perioperative death (due to all aetiologies) of between 8.8[144] to 28.3[145] per 10,000 anaesthetics in 'allcommers', patients undergoing elective and emergency procedures. The rate of anaesthesia-related deaths (corresponding to Edwards classification 1–3) ranges between around one[144, 150] to 5.75[145] per 10,000 anaesthetic procedures.

Anaesthesia-related death rates in the immediate perioperative period and during the first 12 hours ranged from 0.6[148] to 1.12 [151] per 10,000 anaesthetic procedures. It is interesting to note that the studies investigating a 48 hours post procedure time period found even lower rates ranging from 0.19[143] to 0.75[51] per 10,000 anaesthetic procedures, while the two studies analysing death certificates without any time restriction, found the lowest rates of only 0.082[50] to 0.54[52] per 10,000 anaesthetic procedures.

It is important to stress that both of the last mentioned studies primarily used death certificates from which procedures were selected by using ICD codes.[50, 52] Lienhardt et al.[52] included an

analysis of questionnaires sent to each medical certifier to explain the reason, type, and date of the (anaesthetic) procedure and to provide a chronological description of events and complications that had led to the unfortunate demise of the patient. However, basing the numerator on ICD coding as was done in the two latter studies is likely to be less sensitive than scrutiny of anaesthesia records and/or the prospective recording of events, and, together with the uncertain denominator using ICD coding is probably likely to underestimate anaesthesia related mortality.

Reported death rates where anaesthesia factors were considered solely responsible for the death of the patients in the first 24 hours range between 0.03[143] and 1.71[145] per 10,000 anaesthetics.

However, not only the above mentioned deviations in denominators and definitions, periods etc, but also different compositions in patient populations, different ranges of procedures and severity of co-existing illness as well as the urgency of the operations impact on the estimates of mortality rates. The observed differences between the reported rates should therefore come as little surprise.

Ideally, an analytical adjustment should be conducted to remove the influencing factors when estimating anaesthesia related or attributable deaths. A good starting point is when the reporting of mortality and serious morbidity is restricted to relatively healthy patients, i.e. ASA PS 1 and 2. Furthermore, urgent and emergency procedures as well as cardiac surgery where serious problems are more frequently encountered but where determination of causation might be unclear, should all be excluded. This will control for the influences of patients' disease and other factors and will help gain insight into the contribution of anaesthesia to perioperative mortality. However, in the above described resulting group, a quite large population will have to be reviewed to capture a considerable number of, in this group, quite rare events of patients dying under an anaesthetic procedure.

Only three studies allow the comparison of rates of rather healthy patients, i.e. ASA PS 1 and 2, stating rates of anaesthesia related mortality of between 0.12[148] and 0.29[51] per 10,000 anaesthetics for the studies with a more direct approach, i.e. analysing a definite number of anaesthetic procedures pro- or retrospectively, while Lienhardt et al.[52] give calculated numbers of 0.04 and 0.5 for ASA PS 1 and 2 patients respectively.

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%[145, 149, 153] up to about 50% [50, 150, 151]. Li and coworkers[50] report that of the 241 anaesthesia related deaths in their study, 79.7% had adverse effects of anaesthetics in therapeutic use. Biboulet et al.[148] reported that four out of eight cases with anaesthesia related cardiac arrest were related to anaesthetic overdose.

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%[31, 144] and 100%.[147, 152] In more detail: Biboulet et al.[148] reported 25%(2/8), Braz et al.[151] 55.5%, Charuluxananan et al.[145] 21.3%, Gibbs[143] 15%, Kawashima et al.[149] 7.9%, Newland et al.[150] 20%, and Sprung et al.[153] 80%.

While discrepancies between members of a committee of what event is factually anaesthesia related may be understandable, problems involving the airways (e.g. tube and airway problems) should be quite easily identifiable as anaesthesia-related.

Evolution of anaesthesia related mortality

The mortality rate in patients undergoing noncardiac surgery can be substantial[162] and ranges between 0.5% and 1% within 48 hours[43, 163], up to 4% within 7 days.[164] However, mortality rates after major surgical procedures have fallen substantially over the last decade.[165, 166] In addition, improvements in anaesthesia safety in particular have rendered anaesthesia-related deaths and severe outcomes rare events.[50, 52, 167] Many authors state that anaesthetic mortality, too, has decreased substantially over the last few decades, a statement that has however been questioned by Lagasse[51] about 10 years ago. He states that anaesthesia-related mortality measured worldwide is not a stable system and that an unstable system does not have a definable capability. In other words, the volume of anaesthetics given and the number for the denominator are neither stable nor clearly defined. One cannot detect trends in anaesthesia safety until the causes of variation have been removed. These causes of variation may represent real differences in anaesthesia safety between the various samples, or just differences in the tools used to measure anaesthesia-related mortality (e.g., definitions, sampling methods). Lagasse[51] not only presented original data on perioperative mortality, but

also a review of literature between 1966 to 2000, using the keywords 'anesthesia AND mortality'. He plotted the anaesthesia-related mortality rates found in the literature in a control chart (attribute P chart) and did not detect any time trends in anaesthesia-related mortality, with the majority of the data points more than three standard deviations from the mean anaesthesia-related death rate. This wide variation in anaesthesia-related mortality rates may be due to differences in operational definitions, varying in the studies analysed from intraoperative deaths to deaths occurring within 30 days or prior to discharge from the hospital - even generally including patients who failed to regain consciousness to the definition of perioperative 'death'.[51]

Also a lack of appropriate risk stratification renders the identification of trends in anaesthesia safety difficult since study populations often differ, both regionally and historically, with respect to perioperative risk. In addition, regional differences often coincide with differing practice standards, technological resources, and reporting mechanisms. Those variations may be quite substantial especially when different countries are considered.[51] It therefore seems prudent to analyse data within the same country or even within the same institutions and to control for potential influences when different settings are compared.

Unfortunately, very few data from within the same country are available to show a trend in anaesthesia-related mortality. Of the studies analysed in this literature review, three studies investigated time trends of anaesthesia-related mortality.[52, 143, 153] Neville Gibbs reported for the Australian and New Zealand College of Anaesthetists (ANZCA) Mortality Working Group analysing triennial reports from 1985 to 2008. This study found that the reported anaesthetic-related mortality rate (Edwards class 1–3) ranged from about 0.28 per 10,000 anaesthetic procedures for the 1985–1987 triennium to about 0.12 for the 1997–1999 triennium; with the latest figure currently being at about 0.18. At the same time, the rates of deaths where anaesthesia was the major contributing factor fell from about 0.13 to 0.028 for the last triennium 2006–2008 per 10,000 anaesthetic procedures.[143]

In terms of the accuracy of the numerator and denominator, Gibbs[143] reported that the denominator data for the earlier reports were indirect estimates, in particular the reports between 1991 and 1999 were based on the number of surgical separations and were very likely to have overestimated the number of anaesthetic procedures performed, which would have led to an underestimation of the respective rates of anaesthesia mortality. The most

recent reports used anaesthesia-related codes collected at each hospital by the Australian Institute of Health and Welfare, which is likely to be more accurate. In terms of the numerator, the composition of participating states differed over the time periods, casting some doubt on the stability of this measure as the regional differences may also imply differences in practice.

Lienhart et al.[52] surveyed anaesthetists involved in the care of a proportion of cases recorded in the French national mortality database and made a comparison with the nationwide 1978–1982 survey[168], which suggested a 10-fold decrease in anaesthesia mortality rate over the 20-year time period of the study. This trend however may be confounded by a change in the characteristics of the population anaesthetised, with the proportion of ASA PS 3 and 4 patients having increased several fold in their study. Moreover, differing time frames of analysis (the first survey including 24 hrs, the latest report including deaths occurring long after the anaesthetic procedure) are likely to lead to a relative underestimation of the anaesthesia-related deaths in 1978–1982, which reinforces the notion of a reduction of anaesthesia related death rates.

Although Sprung et al.[153] did not report on a decline of anaesthesia-related deaths, they observed the incidence of cardiac arrest to have decreased over the duration of the study period from 7.8 per 10,000 in 1990–1992 to an annual incidence of 2.5 per 10,000 in 2000. However, such trends should be interpreted with caution since likely changes in the patient population together with anaesthesia/surgery related factors may also exert substantial influence.

Conclusion

This literature review identified a wide range of estimates for anaesthesia related mortality. In particular the wide range of perioperative mortality rates may be caused by differences in operational definitions and reporting sources. This is well illustrated by Pedersen[51, 169], who described markedly different perioperative mortality rates in the same population depending on the timing of the patients' deaths.

Although death is a clearly definable end point, a number of problems render comparison between studies difficult, starting with the reporting of cases, which may be compulsory or voluntary. Studies where the investigators used existing databases (of varying reliability) have to be distinguished from those that relied solely on voluntary reports. Voluntary reports can provide reliable information, but are often subject to under-reporting and selective reporting. These can sometimes be minimised by using other reporting systems to crosscheck results. Mandatory reporting regulated by law, or reporting as a condition of employment contracts can substantially improve reporting rates. The use of databases may be recommended, some more recent studies successfully used death ICD codes on death certificates to identify anaesthesia-related deaths. However this approach is likely to be less sensitive than a thorough assessment of anaesthesia records and/or prospective recording. Another problem is the long prevailing bias that anaesthetic deaths are by definition preventable may have precluded identification of human or system-related risk factors whose prevention could probably have contributed to an improvement in anaesthetic care.

Maybe even more important in reporting anaesthesia-related deaths is that reporting needs to be nonpunitive or confidential to reach high reporting rates. Sharing knowledge on the cascades leading to the unfortunate demise of the patients among the anaesthesia community may add to the acceptance of the extra work to be put into reporting once patients have died in the course of anaesthesia.

The multi-faceted causes of medical complications and their complexity are factors that limit the use of simple descriptive tools and are the reason why expert opinions are used instead – commonly in expert committees of various compositions.

There still remains a considerable amount of uncertainty about what exactly should be defined as anaesthesia-related death, or were anaesthesia is considered solely responsible for the

decease of a patient. Although a classification exists since 1956[160], this classification is only rarely used in research studies for various reasons.

A wide spectrum of time limits has been used in the published literature, starting with all deaths occurring before the time of transfer of the patient from the operating theatre or from the recovery room, over a time limit of deaths occurring within 24–48 hrs after anaesthesia, up to a period of 7–10 days in some other studies or even with no limitation. In general, studies have differing objectives, coinciding with varying study designs, populations, definitions and time spans, which all render direct comparisons of studies quite difficult if not impossible.

While denominator data are often generally unreliable estimates, the numerator will often be under-reported, particularly in situations with potential medico legal implications. Therefore, perioperative mortality in which anaesthetic factors are involved maybe not as low as the estimate suggests.

Finally, not all anaesthetic accidents are preventable despite the optimal use of currently available techniques and thus are also not necessarily error related (for example anaphylaxis).

This acknowledges the limitations of currently available agents and techniques, and provides justification for further research and development in these areas. Quite generally, purely observed trends should be interpreted with caution due to possible changes in patient populations and procedure related factors. Although studies suggest that the patients are progressively older and sicker, a trend towards a decreasing rate of anaesthesia related/caused deaths is being found. A problem in this instance is that comparison without information of patients' coexisting diseases, for example as expressed by the ASA PS, will not allow factors responsible for the trends to be detected. The current studies do not identify the data needed to clearly detect or calculate such trends.

One promising strategy for future studies is the analysis of mortality and serious morbidity in relatively healthy patients removed of the influence of patients co-morbidities, together with the exclusion of urgent and emergency procedures as well as cardiac surgery where serious problems are encountered frequently but where determination of causation might be unclear.

CHAPTER 2:

THE HEIDELBERG PERIANAESTHETIC QUESTIONNAIRE – DEVELOPMENT OF A NEW REFINED PSYCHOMETRIC QUESTIONNAIRE

Introduction

Patient satisfaction is a useful indicator of the quality of anaesthesia. This Chapter reports the multicentre development of the Heidelberg Perianaesthetic Questionnaire (HPQ) to assess patient's contentment. The development of this questionnaire was motivated by the intention to install an Anaesthesia Preoperative Evaluation Clinic (APEC) at the Department of Anaesthesiology at Heidelberg University, as well as by a growing interest in patient experiences with the process of anaesthesia.

In contrast to many of the earlier studies, I aimed at including a large sample size through using a multicentre approach. This meant capturing a patient population representing a wide geographic area of anaesthesia care. In order to improve on the methods used in earlier studies, I have included a rating for the relevant items to be put in the questionnaire for patients' and health-care professionals' preferences. In addition, the resulting questions underwent a cognitive survey and a pilot-testing to assure that the meaning and subject of the questions were correctly understood. Overall, a rigourous protocol was developed allowing the development of a psychometrically sound instrument to assess patient satisfaction.

Chapter 2 forms the basis of this PhD thesis. The subsequent studies presented in the thesis (Chapters 3 to 7) were directly based on the findings, experiences and clinical observations made during this first study.

The specific research aims for the study presented in Chapter 2 were:

- to develop perianaesthetic questionnaires for adult and paediatric patients that adhere to a strict psychometric design
- to compare a variety of participating hospitals
- to compare satisfied with dissatisfied patients

The Heidelberg Peri-anaesthetic Questionnaire – development of a new refined psychometric questionnaire[*]

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Summary

We have developed a questionnaire to assess patients' peri-anaesthetic satisfaction. We recruited 1398 patients and 59 health care professionals for construction and validation. Relevant items were rated for preferences. The resulting questions underwent a cognitive and a standard pretest. The resultant Heidelberg Peri-anaesthetic Questionnaire consists of 38 questions about five identified themes: trust and atmosphere; fear; discomfort; treatment by personnel; and information and waiting. Internal consistency was demonstrated for the sum score (Cronbach's $\alpha = 0.79$) and the five factors (Cronbach's $\alpha = 0.42$–0.79). Multivariate analysis found significant influences of age, school education, marital status and duration of anaesthesia. Dissatisfied patients had a median (IQR [range]) of 73% (66–76% [35–83]), and satisfied patients 92% (90–94% [88–100]) of the sum score. The Heidelberg Peri-anaesthetic Questionnaire offers a valid and reliable way to identify dissatisfied patients and generate quality improvement and also has use as a benchmark tool.

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Summary

The development, construction and validation of the questionnaire comprised a total of 1561 patients and 59 health care professionals. For the development of the HPQ (Heidelberg Perianaesthetic Questionnaire) I followed a strict psychometric protocol, starting with the identification of relevant items, followed by a rating of the items by the patient involved for preferences. Subsequently, the resulting questions underwent a standard pretest and a cognitive survey to test for comprehensibility. The latter is a unique feature of this study.

The final questionnaire achieved a response rate of 84%. A large sample size of 912 patients was analysed; a sample size that compares favorably to previous studies.

The resultant HPQ consists of 38 questions around five identified themes. Two VAS measure global satisfaction with anaesthesia and surgical treatment and a global index score is also included. The HPQ proved to be highly correlated to other instruments to support convergent validity. A multivariate analysis was applied to capture influences of potential confounding variables. Scores among patient groups were normalised to allow comparison between different hospitals and/or different patient groups. The HPQ achieved non-overlapping ranges of the sum scores between dissatisfied (median (range)) of 73% (35–83%), and satisfied patients (92% (88–100%)).

As for the rigour of psychometric development, our own developed HPQ scored 9.5 points on the scale explained in Chapter 1 (Table 1.6). Only the study by LeMay et al.[7] had reached the maximum of 10 points on that score, indicating a maximum of psychometric rigour. The difference is explained by the inclusion of a test -retest in the latter study, which is not considered to be of major importance. While the LeMay study included only patients after cardiac surgery from a single institution to measure patients' perceptions of the quality of cardiac anaesthesia services, the HPQ has undergone validation at three different hospitals with a wide spectrum of patients covering a broad spectrum of risks. Unlike most other instruments on patient satisfaction, the HPQ places emphasis on the patients' concerns to detect dissatisfaction, a fact that is strongly corroborated by the non-overlapping ranges between dissatisfied patients and satisfied patients resulting in a distinct separation between the groups for comparison.

The HPQ is the first perianaesthetic questionnaire tested by both a standard pretest and a

cognitive method. After passing through several phases the HPQ can now be considered to be psychometrically sound, although the task is ongoing as terminologies may become old-fashioned, and values and practice patterns are subject to changes. The limitations of the HPQ are to be found in different patient groups, for example paediatric patients or patients undergoing regional anaesthesia. While the latter are able to answer the questionnaire it was not specifically designed for this situation and may have to be amended. For evaluation of a larger paediatric patient population, it was sought to develop a separate questionnaire to take the different complexities of this population as well as the problems with children answering a questionnaire into account. These further research projects are presented in Chapters 6 and 7. The original German version of the HPQ is presented in Appendix V.

CHAPTER 3:

DEVELOPMENT OF A QUESTIONNAIRE TO ASSESS PATIENTS EXPERIENCES WITH ANAESTHESIA ("EFA")

The results from my previous study detailed in Chapter 2 covered a regional area of anaesthetic supply. With the described study I aimed at introducing a questionnaire for the assessment of the quality of anaesthesia from the point of view of the patient, using the experiences of three former studies. These three studies dealt with previously established German questionnaires, including the HPQ. These questionnaires were to be merged into a single, national questionnaire to allow an even broader, nationwide, patient spectrum to be represented. The methods were derived from the previous study (Chapter 2) and aimed at applying the same psychometric rigour. The previous questionnaires included were the PPP33 (Perioperative Patient Questionnaire; Fragebogens zur Patientenbeurteilung der perioperativen Phase)[170] and the ANP (Anaesthesiological Questionnaire; Anästhesiologische Nachbefragungsbogen für Patienten)[107, 108]. While the latter has been discussed extensively in Chapter 1, the PPP33 is not exclusively focused to capture anaesthetic treatment and the aim of the authors had been to design a simple patient-oriented tool for multidisciplinary application. This instrument constitutes a broader measure of patient experiences in hospital, including treatment by surgery and areas of hospitality, including quality of the room service, food etc. and was therefore not analysed in Chapter 1. Nevertheless, its development process has followed a psychometric protocol, it captures a broad patient spectrum, and it was developed in Germany and available for the analysis.

The main aim of our study, as discussed in this Chapter, is to develop a nationwide questionnaire to assess patients experiences with anaesthesia ("EFA") (therefore extending the 'range' of the other questionnaires). This was supported by the Working group 'Quality management' of the German Society of Anaesthesiology and Intensive Care Medicine (DGAI).

Evaluierter Fragebogen Anästhesie[1,*]

Entwicklung eines Fragebogens zur Erfassung der spezifisch vom Patienten empfundenen Anästhesiequalität

Evaluated Anaesthesia Questionnaire: Developement of a questionnaire to assess patients' experiences with anaesthesia

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▸**Zusammenfassung:** Die vorliegende Arbeit stellt die Entwicklung eines Fragebogens zur Erfassung der spezifisch vom Patienten empfundenen Anästhesiequalität durch das Forum Qualitätsmanagement und Ökonomie BDA/DGAI vor.
Methodik: Interviews mit Patienten, Ärzten und Pflegepersonal sowie die bereits vorhandenen Fragebögen aus drei vorangegangen Studien wurden ausgewertet, mit den Ergebnissen einer Literaturrecherche verglichen und durch ein Expertenteam bezüglich anästhesierelevater Items ausgewertet. Der Pilotfragebogen mit 53 Fragen wurde an fünf Standorten getestet und 580 Fragebögen analysiert. Die auf 33 Fragen reduzierte finale Version des EFA wurde im nächsten Schritt mit 468 Patienten validiert.
Ergebnisse: Die Fragen des EFA werden auf einer 4-stufigen Likert-Skala beantwortet und können acht Dimensionen zugeordnet werden. Einige Fragen weisen eine erhöhte Rate an fehlenden Werten auf, die angesprochenen Probleme gelten allerdings definitionsgemäß als relevant und wurden beibehalten. Ein Cronbach´s α von 0,86 für den Gesamtbogen sowie 0,48 bis 0,85 für die Dimensionen zeigt eine gute interne Testreliabilität an, während die Dimensionen als weitgehend unabhängig betrachtet werden können. Die Patienten erreichten 71.9±13,6 [27,3–97] % der Punkte, in den Dimensionen teilweise deutlich niedriger, hierbei zeigt sich Raum für Verbesserung im klinischen Alltag.
Schlussfolgerung: Neben dem umfassenden Ansatz und der Einbeziehung der Erfahrungen mehrerer vorangegangener Instrumente zeichnet sich der EFA vor allem durch seine Patientenorientierung aus. Er erfasst neben somatischen Befindlichkeitsstörungen die Informationsweitergabe sowie den Umgang mit Problemen aus der Sicht der Patienten.
Weitere Evaluationen müssen zeigen, inwieweit die Ergebnisse auf ein breiteres Patientenspektrum übertragbar sind. Eine Anpassung soll im Verlauf bei Teilnahme weiterer Einrichtungen durch erneute Analyse und Bestimmung von Einflussfaktoren stattfinden.

▸**Schlüsselwörter:** Anästhesie – Postoperativer Fragebogen – Qualitätsmanagement – Patientenzufriedenheit.

▸**Summary:** With this study we introduce a questionnaire for the assessment of the quality of anaesthesia from the point of view of the patient, using the experiences of former studies.
Methods: Interviews with more than 480 patients, health professionals as well as all questionnaires of the former studies were considered, compared to a systematic literature research and analysed for relevant items by an expert team.
The pilot questionnaire including 53 questions was distributed at five hospitals and 580 questionnaires were analysed. The final version consisted of 33 questions and was answered by 468 patients for further validation.

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Summary

For the study, all previous information resulting from three instruments, the PPP33; my own, the HPQ; and the ANP were revisited. More than 480 interviews with patients, health professionals and relatives were re-evaluated and compared to a systematic literature search. Relevant items were identified by an expert team, consisting of the authors of the studies and other experienced researchers from the DGAI.

A pilot questionnaire consisting of 53 questions was distributed in five hospitals, 580 were analysed. The modified final version consisted of 33 questions to be answered on a 4-point-Likert scale and was answered by 468 patients for further validation. The questions were assigned to eight dimensions by content analysis, although some questions still had a high rate of missing values. Since the problems they address are considered to be relevant by definition, they were not deleted.

The calculated Cronbachs alpha for internal consistency was 0.86 for the questionnaire and ranged between 0.48 and 0.85 for the single dimensions. PCA or CFA were not utilised at that stage, as it was aimed to collect even more questionnaires to analyse a larger sample. The dimensions were considered being independent of each other with high values for item dimension correlation (IDC) and low dimension inter correlations. Most important, patients displayed overall scores of (mean±standard deviation) 71.9%±13.6% (range 27.3 – 97%) with even lower scores for some of the dimensions, thus leaving room for further improvement.

The "EFA" reached a total of 5.5 points on the rating scale of questionnaires (see Chapter 1), which is merely an indication of its validation not being completed at this stage, which is one of the weaknesses. That is, results were obtained on a relatively small patient population, given the aim to be representative of a nation with 80 million people and an estimated number of 10 million anaesthetic procedures per year. Assessment for influencing or confounding variables will follow once a larger sample has been collected.

The new instrument, the "EFA" is distinguished by being patient-orientated. It captures aspects deemed import by patients and carers, for example somatic disturbance, information transfer as well as the patient's perspective as to how well the staff deals with patient's problems.
The "EFA" is presented in Appendix VI in its original Version.

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CHAPTER 4:

ESTABLISHING A PERIANAESTHETIC PATIENT SATISFACTION QUESTIONNAIRE BY CROSS VALIDATION OF THREE QUESTIONNAIRES – A QUALITY CONTROL STUDY

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As already discussed in Chapter 1, of the recently developed instruments, many originate from different countries with unique cultures and traditions, values and health care systems. For these reasons, results are difficult to compare, as they are likely to emphasise differences in aspects of patient satisfaction.

In the study described in this Chapter, I aimed at comparing our instrument, the HPQ as developed and discussed in Chapter 2, to other instruments, especially one arising from a different socio-cultural background, the EVAN-G.

A validated instrument available in several languages is important for international multicentre studies involving different cultural groups. In particular, problems arise if any instrument is to be applied to patients in different cultures, speaking different languages, since there is no 'gold standard instrument' for measuring satisfaction for control. Not only will the instrument need to be translated to be understood, but also comprehensibility, feasibility, validity and reliability will have to be examined. Even then, results will still be difficult to compare across different social and cultural backgrounds. Moreover, results obtained might be hard to interpret since there is no direct reference. To obtain results from a bilingual patient population to validate a questionnaire as recently suggested will prove a difficult option to many clinicians and researchers. At the time of our study as presented in this Chapter, and even up to date, no study has investigated changes in performance, validity and reliability after having translated a complex instrument measuring satisfaction.

The purpose of this study was to develop a German version of the EVAN-G (Evaluation du Vécu de l`Anesthésie Générale, France) originating from France. By using a novel cross validation approach, we aimed at validating the German version of the EVAN-G after due

translation and to test this version for validity, reliability, and feasibility. We also aimed at assessing its underlying structure of dimensions and to compare its performance with two German instruments as references, the PPP33 and our own instrument the HPQ as discussed in Chapter 2.

The following study is presented as a manuscript draft.

Establishing a perianaesthetic patient satisfaction questionnaire by cross validation of three questionnaires – a quality control study

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Running Title: Cross validation of three questionnaires

Background and objective: Questionnaires measuring patient satisfaction with anaesthesia have become popular. Using a novel approach we validated and evaluated the German translation of the EVAN-G (**E**valuation du **V**écu de l`**An**esthésie **G**énérale) in comparison it with two other questionnaires assessing patient satisfaction.

Methods: The German translation of the EVAN-G was developed by a panel of linguistic experts using a series of forward and backward translations. Patients were assigned to receive a random set of two of three questionnaires: the HPQ (**H**eidelberg **P**erianaesthetic **Q**uestionnaire), the PPP33 (**P**atientenbeurteilung in der **p**erioperativen **P**hase), and the EVAN-G. For all questionnaires, a principal component analysis was made and instruments were compared for time taken to answer, degree of completion and reliability. Scores were assessed for confounding factors and compared.

Results: 184 Patients returned their questionnaires. The PPP33 took shortest to answer ((mean (SD) 8.5 (3.1) min, $p \leq 0.001$). The EVAN-G had the lowest total score (64.6 ± 10.2, $p < 0.001$), indicating a greater ability to measure dis-satisfaction but substantially more missing items assessing pain and discomfort, where it also scored higher ($p \leq 0.01$). Reliability was good and correlations were moderate between the total scores and most of the sub scores. Only the HPQ correlated to general satisfaction with anaesthesia. All Sum scores were influenced by age and preoperative pain.

Conclusions: Our findings indicate that instruments constructed and validated within the same socio cultural background and language are more likely to be valid and reliable. Even if a questionnaire is examined for validity, comprehensibility and feasibility, it may not perform as proposed in a new environment.

Keywords: anaesthesia, audit, patient satisfaction, measurement techniques, outcome, surgery

Introduction:

The evaluation of quality of medical care has put a focus on patient's satisfaction. Patients should be engaged in the process of quality management [171]. Questionnaires offer advantages over other qualitative tools such as lower costs and less bias [7, 46, 172]. The quality of the results depends on construction and validation. Results of patient surveys may direct patient flow or influence remuneration so it is important that instruments are valid, reliable and multidimensional [30, 44]. Furthermore, health service delivery is multifaceted, and the patient's experience can be influenced by physical, emotional, mental, social and cultural factors, as well as the influence of specific drugs on cognition. Recent questionnaires have been developed following psychometric protocols to take some of the complexity into account. Instruments developed in countries with unique cultures are difficult to compare because of differences in aspects of patient satisfaction measured [15]. A validated instrument available in several languages is important for multicenter studies involving different cultural groups. A problem arises when instruments are applied to patients in different cultures, speaking different languages, since there is no 'gold standard instrument' for measuring satisfaction. The Instruments will need to be translated but results are difficult to compare if an instrument is being used in different social and cultural backgrounds and comprehensibility, feasibility, validity and reliability will need to be examined. Even then, results might be difficult to be interpreted as there is no direct reference. To obtain results from a bilingual patient population to validate a questionnaire as recently suggested will prove a difficult option to many clinicians and researchers. The purpose of this study was to develop a german version of the EVAN-G (Evaluation du Vécu de l`Anesthésie Générale, France) [91]. Using a novel cross validation approach, we aimed to validate the german translation of the EVAN-G in the light of two german instruments as refenrences, the HPQ (Heidelberg perianaesthetic Questionnaire, Heidelberg, Germany) [126] and the PPP33 (Patientenbewertung der perioperativen Phase, Marburg, Germany) [170] in a given setting. To ensure that valid results are produced for the german EVAN-G, we aimed to test its validity and reliability and analyse for potential confounding variables in comparison to the other questionnaires [3, 66, 67, 91]

Methods

After approval by the Research Ethics Committee (N° 077/2006, Medical Faculty of Heidelberg on April 27th 2006; Chairperson Prof. Dr. med Thomas Strowitzki), patients were randomly assigned to receive a set of two questionnaires (using computer generated random number tables) at our university hospital (1650 beds).

Patient inclusion criteria were: written informed consent to participate in the study, age over 16 years, absence of dyslexia, ability to speak, read, write and understand German, no ICU stay (but high dependency unit (HDU) up to 24 hrs) and only elective procedures under general anaesthesia. Eligible patients were identified by the clinic information system (ISH-med, SAP, Walldorf, Germany) during a four-week period in October 2007 and enrolled by a study nurse; informed consent was obtained by the study physician.

The EVAN-G was used in its German translation. Each patient was approached by the same person, who introduced herself as independent from the investigator team, questionnaires were collected in a sealed opaque envelope. All patients received a random combination of two of the three questionnaires, which were given in a fixed order in an envelope within 36 hours after the operation by a research assistant. By giving two questionnaires to the patient at a time we assumed that the results would be less vulnerable to bias such as surgical outcomes and differences in patient characteristics. It has been found that some patient characteristics influence satisfaction (e.g. gender, age [91, 92, 107, 126]) and only the HPQ had been adjusted for these confounding variables [126].

Questionnaires

All questionnaires had been designed psychometrically: items were identified by a literature review and interviews with patients, relatives and health care professionals, and had been assessed for reliability and validity. Analysis had been made to ensure that the questionnaires used were valid and reliable measure of patients experiences. Validity evaluates the systematic error of a measure (drift) whereas reliability evaluates the random error of a measure (scatter). The HPQ consists of 38 questions to be answered on a uniform four-point Likert-scale (3 = strongly agree, 2 = agree, 1 =disagree, 0 = strongly disagree). It assesses five identified dimensions (trust and atmosphere (questions 2, 18-20, 37-38), fear (questions 7-9, 11, 13-14), discomfort (questions 15-17, 22-23, 26-33), treatment by personnel (questions 21, 24-25 34-36), information and waiting (questions 1, 3-6, 10, 12) with demonstrated internal consistency (Cronbach's α=0.79 for the sum score and Cronbach's α= 0.42-0.79 for the

dimensions). The HPQ has been validated in three different hospitals in Germany and adapted to different confounding variables (Appendix V PhD Thesis).

The PPP33 has 33 questions that are answered on a four point Likert scale (0=applies not at all, never to 3= applies completely, always). It consists of eight dimensions: information (questions 1-6, 12), autonomy (questions 9-11, 18, 19, 25), communication (questions 26-31), discomfort (questions 16, 17, 20-22), pain (questions 13-15), regeneration (questions 23-24) and anxiety (questions 7-8) with a Cronbach's $\alpha=0.8$ for the sum score and 0.23 to 0.79 for the dimensions. It covers the total of patients' hospital stay but some questions are anaesthesia-specific. It has been validated in three hospitals in Germany.

Auquier et al. validated their EVAN-G questionnaire in eight anaesthesia departments in France. It consists of 26 questions in six dimensions: attention (questions 6, 10, 15, 21-22), information (questions 1-5), privacy (questions 7, 9, 20, 23-24), pain (questions 13-14, 18-19), discomfort (questions 8, 11-12, 16-17) and waiting (questions 26-27) with Cronbach's between 0.73 and 0.91. The EVAN-G is answered on a five point Likert scale with answers tailored to the questions. The original questionnaire from P. Auquir was independently translated by three professional translators, who were native German speakers into written German [173]. Drafts were critically reviewed by a panel consisting of the translators and three bilingual medical professionals before a revised draft was agreed upon.

Each version was back-translated to French separately by another two linguistic experts, who had no prior knowledge about the EVAN-G. The German version was modified until the final text was accepted by the panel and the back translated version match the French original.

The EVAN-G was pretested on a sample of 20 patients for comprehensibility and feasibility of the questionnaire using a cognitive survey [87, 126]. The EVAN-G questions were in a different order in the actual questionnaire from that suggested by the publication. All questionnaires were used in their original formats and two global Visual Analogue Scales were added (VAS 0= completely dissatisfied to 10= completely satisfied) to measure the general perception of treatment with anaesthesia and surgery. All patients were asked to record starting and finishing times for each of the questionnaires. Before analysis, negative items were reversed, and scores were transformed to a 0-100 scale, with high scores indicating high level of satisfaction or approval. Questionnaires with more than 20% answers missed were excluded, for the remainder, missing values were replaced by mean values [72, 174].

Statistical analysis

For statistical analysis SPSS (SPSS 14.0, SPSS Inc. Chicago, Illinois) and Excel (Microsoft® Excel XP, Microsoft Corp. Redmond, Washington) were utilised. For ordinal data and scores, nonparametric tests were applied. Continuous and ordinal data were compared between groups using Wilcoxon's ranked sum test and the Kruscal-Wallis test respectively. Categorical data were tested between groups using Fisher's exact test. Satisfaction sum scores were compared to patient characteristics (gender, age, work situation, pre operative pain, smoking, diabetes, daily alcohol intake, airway disease, allergies, fatigue and patients' feelings (feeling relaxed, exhausted etc.)) and clinical features (surgical procedure, specialty, and type of anaesthesia) using independent sample t-tests or ANOVA as appropriate. Correlations were made by correlation coefficients (Pearson r or the Spearman correlation for the scores [175]). A $p < 0.05$ was considered statistically significant.

Exploratory principal component analysis (PCA) with varimax rotation was used to assess the underlying factor structure of the questionnaires after obtaining the Kaiser-Meyer-Olkin (KMO) measure, a value above 0.5 indicates that distinct and reliable factors are produced by factor analysis. The measure of sampling adequacy (MSA) was obtained for each individual item within a questionnaire which had to exceed a minimum of 0.5 to ensure that the variables sufficiently correlated with one another [176, 177].

Reliability was assessed by Cronbach`s α, values a from 0.61 to 0.80 represents a substantial, from 0.81 to 0.9 a good correlation. Higher values can be suspicious of redundancy. Item-discriminant validity (IDV) was assessed by the extent to which items correlated with themes they were not hypothesised to represent. Items should have a higher correlation with their own dimension (inter-item correlation (IIC)) than with other dimensions and should be above 0.40. External validity was tested by correlations between scores and the visual analogue scales (VAS) (convergent validity).

Using the information given in the original publications we calculated 70 questionnaires in each group to find significant differences between groups with an α=0.05 and a β=0.1, but for the factor analysis three to four questionnaires have to be answered per question to be reliable [72, 175]. We therefore aimed for 120 patients to answer each questionnaire.

Results

Translation

Eight preliminary drafts were prepared before the final text of the EVAN-G was approved by the panel. The major difficulties and disagreements arose from the questions dealing with privacy.

Completed questionnaires

A total of 219 patients were approached and 184 returned their questionnaires (Patient flow chart and Table 4.1)

More than 5% missing answers were found only for one of the PPP33 questions (question 6) and eight of the EVAN-G questions (questions 6, 8, 9, 10-13, 15, 24).

Time for completion

The EVAN-G took longest to be answered (10.6±8.1 min) compared to the HPQ (10.5±3.6 min, p=0.03, CI95% of the difference 0.2-3.9) and the PPP33 (8.5±3.1 min, p<0.001, CI95% of the difference 1.2-3.6), while the PPP33 was also answered in a significant shorter time than the HPQ (p=0.001, CI95% 1.4-1.9).

Dimensions and Reliability

Kaiser-Meyer-Olkin Measure of Sampling Adequacy was 0.6, 0.61and 0.69 for HPQ, PPP33 and EVAN-G, the Bartlett's Test of Sphericity <0.001 for all the questionnaires, indicating that the factor model is appropriate. PCA showed that most of the questions loaded for the factors as expected. The five factor model for the HPQ found questions 6 and 21, the six factors for the EVAN-G questions 17 and 19 and the eight factors for the PPP33 questions 10 and 13 not loading for the factors they were supposed to contribute. Explained variance was 45%, 61% and 60% respectively.

The Cronbach`s α was calculated for the three questionnaires and their dimensions (Table 4.2). For all questions of the questionnaires, IIC were well above 0.4, apart from one HPQ question (question 38). IDV was below 0.4 for all but two EVAN-G (question 11, 27), 35 of the 38 HPQ questions (question 4, 20, 36) and for 26 of the PPP33 questions (question 5, 19, 25, 27, 28, 32, 33).

Scores and correlations between questionnaires

Comparing the sum scores the EVAN-G scored significantly lower than the PPP33 (p<0.001, CI95% 10-16) and the HPQ (p<0.001, CI95% 11.6-16.6). This applied for most dimension scores as well apart from discomfort, where the EVAN-G scored significantly higher then the other two instruments (HPQ p<0.001, CI95% 3.3-11.3 and PPP33 p=0.016, CI95% 1.2-11.5, Table 4.3).

Correlations were calculated between the questionnaires sum scores for the patients receiving one set of two questionnaires sum scores: HPQ and PPP33 correlated (r=0.5, p<0.01) as did the HPQ with the EVAN-G (r=0.6, both p<0.01), between PPP33 and EVAN-G there was a less strong correlation (r=0.3, p=0.05).

Influencing factors / Confounding variables

Older patients scored significantly higher then the younger patients in the questionnaires sum and some of the sub-scores. Patients who reported every day pain before operation (58 of 180 patients (32%), distribution not significant between questionnaires), scored significantly lower in all sum scores and in some of the sub scores dealing with pain and its treatment (Table 4.4)

Other variables that affected the scores were the magnitude of the operation (PPP33 "autonomy" (inverse relationship) and EVAN-G "privacy") and ASA-preoperative status (EVAN -G "attention" and "information"). Moreover, the PPP33 sum and the sub scores "autonomy" and "anxiety" were substantially lower (p<0.05) if the patients judged their own health state as being "not very good" or "poor".

Discussion

To the best of our knowledge this is the first study that used a cross validation approach to institute a translated instrument and to compare different psychometric peri-anaesthetic questionnaires. We firstly developed a german version of EVAN-G, and then validated the translated EVAN-G questionnaire parallel to two german instruments which had been validated in Germany. Furthermore we compared the instruments performance in measuring patient satisfaction. We did not have a bilingual patient population and instead chose to analyse the EVAN-G in the context of the other questionnaires [173] which represents a novel approach.

Questionnaires should be easy to apply; return rates should be high and the frequency of missing items low [123].

After translation and pretesting, no problems with the translated EVAN-G version were found. Random sets of two questionnaires were given to each individual; therefore differences between groups were small. The PPP33 took shortest, the EVAN-G longest to answer despite the least number of items, the latter was also returned with highest number of missing values. Auquir et al. had to exclude more than 10% of the returned EVAN-G while we excluded only 4% but found most of the missing items to be related to arrival in theatre and recovery, addressing discomfort and pain. Our patients all received pre-medication drugs and their memory might have been impaired, but the corresponding PPP33 and HPQ questions were answered.

The items within a questionnaire are related to concepts behind the questionnaires, the so-called scales, factors or dimensions. With a measure of the sampling adequacy (KMO) of greater than 0.5 [176] we were able to reproduce the dimensions for all questionnaires. Item loadings [91, 126, 170] were comparable to the publications for all questionnaires, supported by good inter-item correlations (IIC). The Cronbachs alpha was substantial for the sum and most of the sub scores, values of 0.4-0.5 do not necessarily confirm that relationships between items do not exist, but indicate that the scales are less homogeneous [175].

Topics which share similar items correlated to a certain extent between questionnaires, in particular pain and discomfort. This HPQ dimension also correlated to the PPP33 dimension 'autonomy', covering similar items, while the correlation between "trust and atmosphere" (HPQ) and "accommodation" (PPP33) might be random, the latter comprising two questions of more general nature. Correlations were only moderate, maybe because of differences in aspects of satisfaction measured.

While there was a moderate correlation between the sum scores, the EVAN scored markedly lower than the other two and lower than previously published. Generating a low sum score is generally favourable because it provides more room for improving quality. While the primary EVAN-G study found the discomfort dimension to score high in relation to its sum score, this EVAN-G dimension also scored higher in comparison to the other instruments in our study.

The PPP33 assesses some non anaesthesia related factors making a correlation to the surgical VAS more likely and only about half of the EVAN-G questions are anaesthesia related, while the HPQ features mainly anaesthesia-related subjects. This may gives an explanation as to why neither the PPP33 nor the EVAN-G showed a correlation to the overall VAS assessing for anaesthesia care and that the PPP33 correlated moderately to the VAS with surgical care. Correlation to the overall assessment would be expected with context effects likely in this study [123], but it could be argued that a general question describes patient satisfaction poorly [7].

The questionnaires information scores were low and correlated well to the sum scores, underscoring the importance of issues representing information and communication [30, 89, 172].

Analysis for confounding variables found that the sum as well as most of the sub scores were substantially influenced by age [178, 179] in our study, but not by gender [3, 89, 107]. We found that pre-operative pain influenced all the instruments, which has not been reported during any of the validation processes. Our results highlight suggestions that pre operative pain may be linked to postoperative pain and satisfaction [179, 180]. Other factors either had no influence or group samples were too small (for example, our sample had only 8% diabetic patients) to allow sufficient power for analysis.

This study has certain limitations. Patients are selected from a single centre. A high percentage of intermediate cases was chosen to limit distortion of results by prolonged ICU stay and may also have led to the low percentage of excluded questionnaires. There is no 'gold standard instrument' to measure patient satisfaction to which all instruments could be compared to. Other available instruments were not included as they either had substantially less items [66], were commercial instruments [89] or were unpublished at the time [15]. All of them were also published in social-cultural circumstances different from ours. A larger sample would allow a more detailed analysis, a multivariate approach to the confounding variables and a more accurate principal compound analysis [72, 175].

The German EVAN-G has been translated thoroughly, has undergone a quantitative analysis and reproduced reliability and PCA results which were similar to the French version, parallel the results of the two other instruments were also substantially comparable with results from the relevant publications.

Hence we believe our version is conceptually, semantically, and operationally equivalent to the French version. It is therefore appropriate to compare the German EVAN-G. The EVAN-G presents its items in a more complex manner (landscape format, the answer formats differ between the questions) and questions are composed of two parts which could to lead to potential conflict within the individual when answering [123]. These points were criticised by some of the patients in the open question section and may reflect the fact that the EVAN-G has been constructed in different socio-cultural background and language. Considering the overall performance results for validity and reliability, all questionnaires should allow a detailed analysis of satisfaction. However, in this setting, performance in certain areas of interest was different from published results where the EVAN-G had more missing items in measuring discomfort and pain and scored higher for discomfort, the overall score was lower than published previously while both other instruments scored as expected. Our instrument (the HPQ) performed effectively in this particular environment; however it will have to prove its performance in a different socio-cultural background.

For the clinician faced with the choice of instruments to measure patient satisfaction with anaesthesia, our findings indicate that a psychometric tool must be used with caution in a new socio-cultural environment. Instruments will need to be translated and comprehensibility, feasibility, validity and reliability need to be examined. Instruments constructed and validated within the same cultural background and language, here the PPP33 seemed more likely to provide a valid and reliable measure with less testing [73, 87]. However, at least a pilot study on a small sample seems advisable.

Table 4.1: Patient characteristics for each of the cross validated questionnaires. Values are
       number (proportion) or mean (±SD).

	HPQ	PPP33	EVAN-G
Sex; M / F	53 / 67	53 / 67	53 / 66
Age: years	53.6±14.4	53.4±14.3	55.3±14.2
ASA physical status			
1 and 2	87 (78.4%)	75 (75.9%)	86 (79%)
3 and 4	24 (21.6%)	27 (24.1%)	25 (21%)
Surgical speciality			
Gynaecological	45 (37.5%)	35 (29.2%)	42 (35%)
Ear Nose Throat	29 (24.2%)	34 (28.3%)	29 (24.2%)
Neurosurgery	6 (5%)	9 (7.5%)	9 (7.5%)
Visceral	8 (6.7%)	9 (7.5%)	5 (4.2%)
Vascular	11 (9.2%)	11 (9.2%)	13 (11.7%)
Urological	13 (10.8%)	14 (11.7%)	13 (10.8%)
Orthopaedic	8 (6.7%)	8 (6.7%)	8 (6.7%)
Extent of surgery			
Minor	9 (8%)	10 (8%)	7 (6%)
Intermediate	84 (70%)	84 (70%)	83 (70%)
Major	18 (15%)	18 (13%)	17 (14%)
Major plus	9 (8%)	11 (9%)	12 (10%)

HPQ (Heidelberg perianaesthetic Questionnaire, Heidelberg, Germany), PPP33
(Patientenbewertung der perioperativen Phase, Marburg, Germany), EVAN-G (Evaluation du
Vécu de l`Anesthésie Générale, France), ASA=American Society of Anaesthesiologists

Table 4.2: Results of scores and correlations for each questionnaire

	Mean ± SD (95% CI)	Cronbachs alpha	Factor Loadings	Correlation to VAS anaesthesia	Correlation to VAS surgery	Correlation to sum score
HPQ						
Sum score	78.6 ± 9.6 (76.9-80.4)	0.8		0.43**	0.31**	
Trust and atmosphere	88 ±14.2 (85.4-90.5)	0.7	0.4-0.7	0.35**	0.16	0.4**
Fear	76.7 ±28.2 (71.6-81.8)	0.7	0.3-0.9	0.00	0.07	0.58**
Discomfort	75.9± 14.6 (73.2-78.5)	0.6	0.3-0.7	0.11	0.21*	0.75**
Treatment by personnel	90.8± 11.6 (88.7-92.9)	0.7	0.3-0.7	042**	0.29**	0.55**
Information and waiting	78.1± 15.5 (75.3-80.9)	0.4	0.2-0.5	0.35**	0.29**	0.67**
PPP33						
Sum score	77.6± 13.2 (74.5-79.2)	0.8		0.18	0.32*	
Information	77.4± 21.7 (73.5-81.3)	0.8	0.3-0.8	0.30*	0.38**	0.64**
Autonomy	71.2± 21.3 (67.3-75)	0.7	0.1-0.7	0.04	0.18	0.75**
Communication	86.3± 15.1 (83.6-89)	0.8	0.1-0.8	0.22	0.45**	0.67**
Discomfort	76.9± 23.1 (72.7-81)	0.6	0.4-0.7	0.04	0.01	0.62**
Pain	80.8± 22.1 (76.8-84.7)	0.5	0.3 and 0.5	0.03	0.16	0.53**
Regeneration	69.0± 30.3 (63.5-74.6)	0.6	0.4 and 0.7	0.01	0.16	0.56**
Fear	72.8± 29.7 (67.4-78.2)	0.5	0.7 and 0.8	0.03	0.11	0.3**
Accommodation	82.1± 24.4 (77.6-86.5)	0.8	0.15	0.13	0.05	0.49**
EVAN-G						
Sum score	64.6± 10.2 (62.8-66.5)	0.8		0.08	0.16	
Attention	60.1± 15.9 (57.2-63)	0.8	0.6-0.78	0.2	0.41**	0.72**
Information	54.1± 14.2 (51.5-56.7)	0.8	0.66-0.78	0.01	0.01	0.67**
Privacy	57.3± 11 (55.3-59.3)	0.7	0.4-0.7	0.18	0.06	0.5**
Pain	70.4± 17.9 (67.2-73.7)	0.7	0.25-0.42	0.38*	0.27	0.65**
Discomfort	83.2± 16.7 (80.1-86.2)	0.7	0.2-0.8	0.02	0.17	0.65**
Waiting	62.4± 30.4 (56.9-67.9)	0.9	0.9	0.17	0.01	0.5**

HPQ (Heidelberg perianaesthetic Questionnaire, Heidelberg, Germany), PPP33 (Patientenbewertung der perioperativen Phase, Marburg, Germany), EVAN-G (Evaluation du Vécu de l`Anesthésie Générale, France), SD=standard deviation, Correlation is significant at the ** 0.01 level (2-tailed), * 0.05 level

Table 4.3: Cross-valida-tion	HPQ					EVAN-G					
	Dimensions	Trust, atmospher	Fear	Discomfort	Treatment by personnel	Information, waiting	Attention	Information	Privacy	Pain	Discomfort	Waiting
PPP33	Information	0.2	0.16	0.18	0.4**	0.43**	0.29*	0.33**	0	0.1	0.12	0.28*
	Autonomie	0.13	0.13	0.47***	0.24*	0.03	0.06	0.01	0.1	0.13	0.1	0.07
	Communication	0.2*	0.01	0.15	0.13	0.3*	0.4**	0.03	0.05	0.3*	0.45***	0.1
	Discomfort	0.04	0	0.43***	0.14	0.01	0.01	0.02	0.2	0.14	0.4**	0.2
	Pain	0.15	0.03	0.54***	0.15	0.26*	0.18	0.03	0.15	0.2	0.21	0.2
	Recovery	0.1	0.1	0.33*	0.1	0.001	0	0.06	0.2	0.2	0.21	0.03
	Anxiety	0.03	0.54***	0.32**	0.1	0. 1	0.31*	0.27*	0.06	0.27*	0.29*	0.05
	Accommodation	0.52***	0.26*	0.07	0.19	0.26*	0.1	0.1	0.05	0.2	0.2 0.2	0.03
EVAN-G	Attention	0.37**	0.18	0.22*	0.2	0.46***						
	Information	0.38**	0.04	0.2	0.17	0.31*						
	Privacy	0.04	0.02	0.02	0.27*	0.1						
	Pain	0.32*	0.1	0.4**	0.5**	0.33*						
	Discomfort	0.01	0.1	0.54***	0.3*	0.36**						
	Waiting	0.03	0.2	0.31*	0.2	0.4**						

Table 4.4: Influence of everyday pain on the sum and the dimension scores. Mean (sd) and 95% confidence interval (CI) of the mean difference between the group with and without everyday pain.

	no pain	pain	95% CI	p
HPQ				
Trust and atmosphere	89 (1.4)	85.4 (1.6)	-2 - 9.3	
Fear	77 (2.3)	76 (2.5)	-10.2 -12.2	
Discomfort	77.8 (1.3)	71.2 (1.7)	0.9- 12.3	0.02
Treatment by personnel	92.3 (1.1)	87.3 (1.2)	0.5 - 9.5	0.03
Information and waiting	79.3 (1.6)	75.4 (1.4)	-2.2 - 10.3	
Sumscore	80 (9.1)	75.5 (10)	0.7 8.2	0.02
PPP33				
Information	79.4 (19)	73.1 (26.8)	-2 - 14.8	
Autonomie	73.9 (18.3)	65.4 (26)	0.3 - 16.7	0.042
Communication	88.4 (12)	81.9 (19.7)	0.7 - 12.3	0.028
Discomfort	79.7 (18.3)	70.9 (30.4)	-0.1 - 17.7	
Pain	86.3 (15.2)	69 (29)	9.2 - 25.3	<0.001
Regeneration	68.7 (29.7)	69.7 (32)	-12.9 - 10.8	
Fear	74.5 (27)	69.3 (34.7)	-6.4 – 16.7	
Accommodation	82.3 (22.7)	81.6 (27.9)	-8.8 - 10.3	
Sumscore	79.9 (10.7)	72.6 (16.5)	2.3 - 12.3	0.005
EVAN-G				
Attention	61.7 (16.1)	57.2 (15.2)	1.4 - 10.6	
Information	54.4 (14.6)	53.6 (13.5)	- 4.5 - 6.1	
Privacy	57.7 (11.4)	56.6(10.4)	-3 - 5.3	
Pain	72.1 (16.9)	67.4 (19.4)	-2 - 11.5	
Discomfort	85.2 (15.5)	79.7 (18.3)	-0.7 - 11.7	
Waiting	62 (30)	63 (31.5)	-12.6 – 10.5	
Sumscore	62.7 (9.6)	65.5 (10.9)	0.2 - 6.7	0.04

Summary

This study indicates that instruments constructed and validated within the same socio-cultural background and language are more likely to be easily applied. Despite the back-to-back German translation of the EVAN-G developed by a panel of linguistic experts and a pre-test on a sample of 20 patients for comprehensibility and feasibility of the questionnaire using a cognitive survey, the EVAN-G had the highest rate of missing answers, in particular for items assessing pain and discomfort, where it also scored higher than the other instruments. The EVAN-G took longest to answer despite having the least number of items, reflecting the complexity of some question-answer combinations. Using a five-point-Likert scale (HPQ and PPP33 are based on four-point-Likert scales) it showed the lowest total score.

All questionnaires had been designed psychometrically as outlined in Chapter 1 and reliability for each of the instruments was good and correlations were moderate between the total scores and most of the sub scores. All sum scores were influenced by age and preoperative pain.

The use of instruments in different socio-cultural environments is a universal problem. Differences in expectations and how questions are being interpreted by the patients might be subtle, but will certainly exert influence. Our study is the first to co- and cross-validate instruments that were from different socio-cultural backgrounds using instruments originating from the background in question as controls. The most relevant recommendation from this study is that prior to its use in clinical practice, thorough testing and validation is essential before an existing questionnaire can be transferred cross-culturally or across languages.

CHAPTER 5:

THE ANAESTHESIA PREOPERATIVE EVALUATION CLINIC (APEC): A PROSPECTIVE RANDOMISED CONTROLLED TRIAL ASSESSING IMPACT ON CONSULTATION TIME, DIRECT COSTS, PATIENT EDUCATION AND SATISFACTION WITH ANAESTHESIA CARE

Anaesthesia preoperative evaluation clinics (APECs) are relatively new institutions. The APEC at the surgical clinic of Heidelberg University was established in the year 2002. It is staffed by one supervising staff anaesthetist, one or more anaesthesia residents and a secretary/registered nurse. About 90% of all patients admitted for surgery (including general surgery, trauma and orthopaedic surgery, urology, vascular surgery) in the surgical clinic are seen within this service. While they have been proven to be cost effective in many areas, APECs have not been universally adopted in Europe. Also many questions remain with respect to the patients' satisfaction of an APEC. Previous studies have at least shown that patient satisfaction is strongly correlated with the time spent at the outpatient clinic. One of the aims of the trial described in this Chapter was therefore to assess whether there are any differences in patients' satisfaction between the two locations (ward and APEC) of the pre-anaesthetic consultations, using the HPQ as constructed in Chapter 2.

One of the main problems of APECs is that its introduction comes at a considerable cost in terms of personnel (i.e. nurse-secretary, the anaesthetist working 'off- theatre' during that time) and overheads. On the other hand, in institutions without an APEC, part of the time devoted to the pre-anaesthetic consult will certainly be overtime, adding to the case costs. Other potential savings such as the elimination of unnecessary or extensive laboratory testing may not be realised. APECs were also found to reduce last-minute delays and cancellations as well as the total length of hospital stay. Previous studies have fallen short in addressing the costs related to personnel and/or savings when establishing APECs. So far, no studies have

compared the pre-operative visit times between an APEC and the ward. Nor have any other studies compared patient satisfaction and gain in information between APEC and ward consultations.

In the study described here, I set out to investigate whether an APEC provides a difference in pre-operative visit time, to quantify this time difference and assess any contributing circumstances. Naturally, my own instrument, the HPQ (Chapter 2), was used to evaluate patient satisfaction with anaesthesia. A subset of questions was used to address the pre-anaesthetic consultation, addressing the consultation environment, friendliness of staff, time constraints, the content and understandability of the information provided by the anaesthetist. During the consult, the core tasks to be addressed are the fitness of the patients for the anaesthetic and surgical procedure and the discussion of anaesthesia and its related risks before written informed consent (if possible) is to be obtained. Poor information about the anaesthetic procedure carries potential problems. If the anaesthetic procedure and its risks are poorly understood, informed consent is of questionable value and may lead to fears and adverse outcome. I also set out to investigate the amount of information taken up by the patient when seen in the APEC or the ward.

Therefore, a prospective randomised controlled trial was designed and conducted with the specific aims to compare pre-operative anaesthetic consultations between ward and APEC with respect to:

- anaesthetist consultation time and costs involved,
- amount of information conveyed to the patient, and
- patient satisfaction with anaesthetic care.

ORIGINAL ARTICLE

The Anesthesia Preoperative Evaluation Clinic (APEC): a prospective randomized controlled trial assessing impact on consultation time, direct costs, patient education and satisfaction with anesthesia care

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ABSTRACT

Aim. Anesthetic preoperative evaluation clinics (APECs) are relatively new institutions. Although cost effective, APECs have not been universally adopted in Europe. The aim of this study was to compare preoperative anesthetic assessment in wards with an APEC, assessing time, information gain, patient satisfaction and secondary costs.
Methods. Two hundred and seven inpatients were randomized to be assessed at the APEC or on the ward by the same two senior anesthetists. The outcomes measured were the length of time for each consultation, the amount of information passed on to patients and the level of patient satisfaction. The consultation time was used to calculate impact on direct costs. A multivariate analysis was conducted to detect confounding variables.
Results. Ninety-four patients were seen in the APEC, and 78 were seen on the ward. The total time for the consultation was shorter for the APEC (mean 8.4 minutes [P<0.01]), and we calculated savings of 6.4 € per patient. More information was passed on to the patients seen in the APEC (P<0.01). The general satisfaction scores were comparable between groups. A multivariate analysis found that the consultation time was significantly influenced by the type of anesthesia, the magnitude of the operation and the location of the consultation. Gain in information was significantly influenced by age, education and the location of the visit.
Conclusions. The APEC reduced consultation times and costs and had a positive impact on patient education. The cost savings are related to personnel costs and, therefore, are independent of other potential savings of an APEC, whereas global patient satisfaction remains unaltered. *(Minerva Anestesiol 2010;76:491-9)*

Key words: Anesthesia - Pre-anesthetic - Cost analysis - Patient satisfaction - Information.

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Summary

The main results of this study were that a) the total consultation time by the anaesthetist to complete a pre-anaesthetic visit was significantly shorter and more effective, i.e. more information was gained by patients, when the consultation was conducted in the APEC than in the ward; and b) the general satisfaction was comparable between the two settings. This study revealed new aspects of cost utility through the establishment of an APEC. The consultation time was also used to calculate impact on direct costs revealing that savings of 6.47 € (9.33 AU$) per patient were achieved by an APEC. It is also of importance to note that the savings by the APEC calculated in this study are related to personnel costs and therefore independent of other potential savings in the downstream process.

Multivariate analysis identified influencing factors on consultation time (type of anaesthesia, the magnitude of the operation and the location of the consultation) and on the gain in information (age, education and the location of the visit).

A detailed analysis of the reasons for the differences in pre-operative visit times between an APEC and the ward revealed that, as expected, transition times between patients and wards contributed to delays, but it was predominantly the non-availability of patients, or the incompleteness of charts that mainly accounted for the significantly longer visiting time in the wards. The identified issues are thus clearly of an organisational nature and many of these are overcome in the APEC by a nurse-secretary.

CHAPTER 6:

PAEDIATRIC PERIANESTHESIA QUESTIONNAIRE: DEVELOPMENT AND DATA FROM EIGHT HOSPITALS ACROSS GERMANY

Opinions about satisfaction with care are rarely sought from children, despite the increasing awareness and growing discussion in research and public policy literature regarding the rights of children and adolescents to participate in research and make decisions about their own health care.

Asking children about their experiences with anaesthesia care is a complex task. Explicit recall with explicit memory can be expected in children aged 3 or older. Alternatively, proxies (i.e. parents or carers) have been used to determine experiences with anaesthesia. However, if the survey includes aspects of the immediate perioperative period these proxies may not even have been present. In general, it remains unknown to what extent the proxies are able to capture and accurately represent children's and teen's experiences with health care. This complexity has hindered the construction of valid and reliable tools to assess paediatric patients satisfaction with anaesthesia.

Based on my experience gained from studies described in previous Chapters (Chapter 2 to 4) I tried to address the complex task of constructing and evaluating a questionnaire to assess satisfaction with anaesthesia in children. The resulting study described in this Chapter was designed to add to the available knowledge by implementing a variety of specific design features. First, it was designed as a large, multicentre study; second, its construction involved not only experts and parents but also children; third, it was designed for and finally answered by children or their carers; fourth, it was assessed and adapted for confounding variables; and fifth, it was used as a benchmark tool to compare paediatric patient satisfaction with anaesthesia between participating hospitals.

The specific aims of the study described here were:

- to construct a self-administered questionnaire to measure paediatric patient satisfaction in conjunction with all stakeholders that can be answered by older children, or parents in conjunction with younger children that adheres to a rigourous psychometric protocol, and

- to compare results obtained by the questionnaire between different hospitals.

BJA

Paediatric Perianesthesia Questionnaire: development and data from eight hospitals across Germany

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Key points

- Patient satisfaction, as a quality indicator, is becoming a popular subject for the study.
- Authors developed a questionnaire, which was completed by >1000 children, or parents.
- 'Privacy and waiting', 'information giving', and 'discomfort' were the most important determinants of satisfaction/ dissatisfaction.
- This novel method can be used for further research on interventions to improve patient satisfaction.

Background. Opinions about satisfaction with care are rarely obtained from children and few studies of this type exist in the area of paediatric anaesthesia. In this study, we developed a comprehensive self-administered questionnaire to measure the level of paediatric and, as a substitute in younger children, parental satisfaction with anaesthesia. In addition, we aimed to identify factors influencing satisfaction and compare results between hospitals.

Methods. We followed a rigorous protocol including construction of a pilot questionnaire and qualitative and quantitative analysis. The questionnaire was adapted for confounding variables. We analysed satisfied and dissatisfied groups and compared satisfaction scores between participating hospitals.

Results. A questionnaire was developed which comprised 37 questions assessed on a five-point Likert scale. With a response rate of 71%, a total of 1052 patients completed the questionnaire. In the final analysis, 760 questionnaires (72%) were included. Most questionnaires were answered by the parents [705 (92.8%)]. The mean age of children was 6.7 (4.97) yr. Multivariate analysis found a history of previous anaesthetic problems and the identity of the person answering the questionnaire as influencing factors on the sum score. The most important differences between satisfied and dissatisfied children were found for the dimensions 'privacy and waiting', 'information giving', and 'discomfort'. Scores differed between hospitals.

Conclusions. Our psychometric questionnaire provides a novel approach to paediatric patient satisfaction with anaesthesia care and covers areas deemed important by children, parents, and carers. Significant differences between satisfied and dissatisfied groups and between participating hospitals were found.

Keywords: audit; measurement techniques; outcome; paediatric anaesthesia; patient satisfaction; surgery

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Summary

This study can be considered a benchmark study for investigating paediatric patients' satisfaction with anaesthesia. In the scoring system used in Chapter 1, the PPQ (Paediatric Perianesthesia Questionnaire) I developed achieved high scores (Table 1.9). The sound psychometrical development included a pilot phase of the questionnaire, followed by qualitative and quantitative analysis and reached overall the maximum score of nine points. The developed psychometric questionnaire provides a novel approach to paediatric patient satisfaction with anaesthesia care and covers novel areas deemed important by children, parents and carers.

The final PPQ comprises 37 questions assessed on a five-point-Likert scale, forming five dimensions, to be answered either by the child or by parents/carers, if possible in conjunction with the child. The instrument was not designed to be specifically answered by the children alone. While children reached scores similar to the parent group, this gives no indication if children judge their treatment in the same way as adults do. Multivariate analysis found a history of previous anaesthetic problems and the identity of the person answering the questionnaire as influencing factors on the sum score and the questionnaire was adapted for these confounding variables, another feature that is unique to our PPQ in comparison to other instruments mentioned in Chapter 1. Compared to the studies mentioned in Chapter 1 the total sum score of satisfaction was lower in our study, thus leaving enough room for improvement.

Significant differences between satisfied and dissatisfied groups as well as between participating hospitals were found. The study was a multicentre study and results can therefore be utilised in different settings and as a benchmark-tool.

The original version of the PPQ can be found in Appendix VII, the English translation in Chapter 7.

CHAPTER 7:

PAEDIATRIC PATIENTS WITH DISABILITIES – ASSESSMENT OF SATISFACTION WITH ANAESTHESIA

As already mentioned in Chapter 6, opinions about satisfaction with care are rarely sought from children, and even less so from specific subgroups like children with disabilities. While I was working on the study presented in Chapter 6, one of the co-authors initiated a discussion about satisfaction with anaesthesia in children with disabilities (his son has trisomy 21, the 'Down syndrome') who certainly have special needs. The 'Down syndrome' represents the most common chromosomal abnormality as a chronic disabling condition that cannot be cured and these children and their families learn to function in the most effective way. Patients with Down syndrome and their families may have different expectations and attitudes toward medical treatment and anaesthesia than children without disabilities, as may have families with children with other forms of disabling conditions. This is how the idea for the study presented in Chapter 7 emerged.

The presented study aimed at adding knowledge concerning anaesthetic treatment of children with various disabling conditions and reflects on their experiences of the pre-anaesthetic consult as already discussed in Chapter 5, as well as on the other areas of anaesthetic treatment, using our newly developed instrument, the PPQ as introduced in Chapter 6.

In this study, we sought to evaluate a large number of children with different disabilities with the specific aims:

- to assess satisfaction with anaesthesia care in a group of parents of children with disabilities and in a group with Down syndrome (DSG); and where possible in the children themselves, and
- to employ matched controls to compare satisfaction with anaesthesia care between children with and without disabilities.

ORIGINAL ARTICLE

Pediatric patients with disabilities – assessment of satisfaction with anesthesia

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Summary

Background: Opinions about satisfaction with care are rarely obtained from disabled children and their carers, and few studies of this type exist in the area of pediatric anesthesia. We specifically aimed to assess groups of children with disabilities and Down syndrome and aimed to identify factors influencing satisfaction in these groups.

Methods: We assessed two groups of children using the Paediatric Perianesthesia Questionnaire (PPQ). Families with Down syndrome children (Down syndrome group, DSG) were approached via a Down syndrome family support magazine, and families with disabled children were enrolled in hospitals. Two hundred and fifteen disabled children (125 from the journal, 90 from the hospitals) were compared to matching controls without disabilities. Controls were drawn randomly using computer-generated tables of random numbers using data from the PPQ validation, to match cases for confounding variables.

Results: Satisfaction was lower in both groups with disabilities ($P < 0.05$) (lowest in the DSG), fewer would choose the hospital or anesthetic department again. In both of the disabled groups, negative comments were related to the anesthetists' behavior during the consultation, the content of the consultation, and how anxiety was dealt with. Ninety five percent in the DSG reported that the anesthetist had not mentioned or enquired about atlantoaxial instability. Satisfaction was lower than the rest of the respective group if memories of the disclosure of the disabling condition were negative ($P = 0.006$) or if potential offensive terms had been used during the consultation ($P < 0.001$).

Conclusions: This is the first study to assess families with disabled children for satisfaction with anesthesia. Our findings suggest that parents of children with disabilities are less satisfied with their anesthetic care than parents of children without disabilities. Potential bias comes from the self-selection of the DSG and the recall period in this group.

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Summary

The study revealed that the satisfaction with anaesthesia care was lower in both groups with disabilities when compared to children without disabilities, with DSG patients scoring the lowest.

In both of the disabled patient groups, fewer would choose the hospital or anaesthetic department again. In both disabled groups, negative comments were related to the anaesthetists' behaviour during the consultation, the content of the consultation, and how anxiety was dealt with.

In addition, over ninety percent in the DSG reported that the anaesthetist had not mentioned or enquired about atlantoaxial instability (AAI) and over 80% stated that problems with thyroid functions had not been discussed. The AAI and chronic hypothyroidism were used in the study as common abnormalities that are relevant to the anaesthetic procedure, but may not be obvious. There are many other abnormalities of Down syndrome which include cardiac complications, tracheal stenosis, a predisposition to respiratory complications, microgenia, and (relative) macroglossia.

As for influencing factors, satisfaction was lower when memories of the disclosure of the disabling condition were negative or when potentially offensive terms to address the children or their condition had been used during the anaesthetic consultation.

It is concerning to find that patients/carers perceived that the common abnormalities that are relevant to the anaesthetic procedure were not at all, or at least not sufficiently, discussed during the consultation. These facts should be basic knowledge of any anaesthetist. Please note that these findings do not necessarily imply that the anaesthetist had not asked the questions. Moreover, the results may also be subject to the parent's recall bias. However, the common perception (>80%) of insufficient discussions specific to the disabilities represents an alarming figure.

As a consequence, I initiated a review article focusing on the common abnormalities and their relevance to the anaesthetic treatment encountered in patients with Down syndrome. This review article titled 'Anaesthesiological considerations for patients with trisomy 21 (Down syndrome)' was published while I was composing this PhD thesis and can be found as Appendix VIII of this thesis.

CHAPTER 8:

CASE ANALYSIS OF UNEXPECTED CRITICAL INCIDENTS IN ASA I AND II PATIENTS DERIVED FROM A BENCHMARKING PROJECT IN ANAESTHESIOLOGY

Perioperative outcome in anaesthesia comprises many areas. Patient surveys (Chapter 1) provide valuable data for utilisation of services rendered in patient care and supply care providers with information about patient preferences as discussed in Chapters 1-7. While it seems that anaesthesia has become safer over the last decades, it still is deemed a high risk area among the medical professions and the risk and the possibility of dying or suffering permanent damage still exists.

As outlined in Chapter 1, estimates of the incidence of mortality, even if based on the best available data, differ widely between different studies and are clearly influenced by the type and the origin of the study. Therefore, risks of anaesthesia of specific procedures (and in different countries) are not easily available. This information, however, is necessary to validly inform the patient about the anaesthetic risk, and thus constitutes a vital part of the anaesthetic consultation (Chapter 5).

It therefore remains important to report on anaesthesia-related incidents, events, and complications (IEC). IEC not only impact on patient's wellbeing, but also on today's cost-conscious clinical healthcare environment.

In Germany, a national surveillance system on the basis of a minimal set of data (the core dataset, CDS) in conjunction with a standardised reporting system for anaesthesia-related IEC was established nearly two decades ago. In addition to patient demographic data and anaesthetic risk factors, anaesthetic characteristics such as duration of anaesthesia, induction time etc. are stored (coded). 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 dataset 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 minimise workload and inconsistencies.

The data of the CDS have been made available to me for scientific evaluation due to my participation in –- and since 2013 as the chair of – the working group 'Quality assurance in anaesthesia' situated at the medical board of the federal country Baden-Wuerttemberg, Germany.

The evaluation of the CDS data presented here in Chapter 8 was conducted with the specific aims to assess:
• the quality of the collected (core) data (set) (CDS)
• the frequency of coding errors in ASA PS 1 and 2 Patients
• the underlying mechanisms that let to severe IECs

The following study is presented as a manuscript draft.

Case analysis of unexpected critical incidents in ASA 1 and 2 patients derived from a Benchmarking Project in anaesthesiology

Results from the project "quality assurance in anaesthesiology" of the General Medical Council of the Federal Country Baden-Wuerttemberg in Germany

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Summary

Aim: The German Society of Anaesthesiology and Intensive Care Medicine advised standardised reporting of anaesthesia-related incidents, events, and complications (IEC). We analysed severe IEC for specific groups and elective procedures.

Methods: Cases with ASA PC 1 or 2 and IEC 4 or 5 were derived from a database on routine anaesthesia data (Kerndatensatz 2.0) between 2002 and 2004 and sent to the respective hospitals to study the course of events as primary endpoints and for coding errors as secondary endpoints of the study.

Results: Out of 366,334 anaesthetics during the study period, 516 cases were identified. 60% of the hospitals responded. Coding errors were found in 157 (49%). Cases were classified: 56 (35%) to category i (system immanent Risk), 80 (50%) to ii (organisational matters, safety issues), and 24 (15 %) to iii (noticeable or conspicuous events). A rate for IEC 5 (death) of 0.62 per 100,000 (95% CI 0.03 – 1.89) and an IEC4-Rate of 99.2 per 100,000 (95% CI 86.6 – 112.5) was calculated.

Conclusions: Cases analysis may serve as a starting point for further analysis of errors in the respective hospitals. Considering the good return rate, this has been the case. The calculated rates provide a starting point for further analysis of the CDS. Coding errors seem frequent.

Background

The mortality rate in patients undergoing noncardiac surgery can be substantial,[162] and ranges between 0.5 and 1% (48 hours),[43, 163] up to 4% (7 days).[164] However, the mortality rate after major surgical procedures has fallen dramatically[165, 166] with improvements in anaesthesia safety having made anaesthesia-related deaths and severe outcomes rare events.[50, 52, 167]

Researchers have shown that the American Society of Anesthesiologists (ASA) physical status when compared to individual comorbidities may have the strongest statistical association with major morbidity and mortality.[181-183] With longer survey periods, other factors also appear to come into effect, such as underlying disease, particularly malignancies.[162, 184] With an estimated 230 million anaesthetic procedures taking place worldwide annually[1] 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.

While some authors state that anaesthetic mortality, too, has decreased substantially over the last few decades, this was also put into question about 10 years ago. Anaesthesia-related mortality measured worldwide is not a stable system and this unstable system does not have a definable capacity, hence the volume of anaesthetics given and the number for the denominator are neither stable nor clearly defined. One cannot detect trends in anaesthesia safety until the causes of variation have been removed.[51] The incidence of perioperative mortality directly attributable to anaesthesia has a wide range, possibly as a result of differences in the definitions used and sources studied.[51] In addition, the rise in the use of anaesthesia in private practice, the increasing number of elderly and multimorbid patients, and number of high-risk procedures as well as the lack of population-based, prospective data has caused the continuation of debate over major morbidity and mortality in patients undergoing surgery and anaesthesia.

Following legislation on quality assurance and cost-containment regulations in Germany, the German Society of Anesthesiology 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 dataset, CDS) in

conjunction with a standardised reporting system for anaesthesia-related incidents, events, and complications (IEC).[32, 58, 185-188]

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.

Therefore, the aims of the present study were to evaluate the quality of the collected data in the core dataset (CDS) for coding errors in ASA PS 1 and 2 patients with unexpected severe outcomes (IECs). It was further sought to establish filtering procedures, which would be used to analyse the whole of the collected data in the CDS in another study to follow. By doing so, we were going to analyse the nature and the underlying mechanism of severe IECs in the rather healthy ASA PS 1 and 2 patients.

Materials and Methods

   This study used the CDS in its second version, which has been designed to reflect several key factors apart from IECs. It includes substantial demographic and administrative data, risk factors, preexisting disease, information about the admitting surgical department, and the type and duration of anaesthesia. The CDS was developed jointly by the European Society for Computing in Anesthesia and Intensive Care and the Society for Computing and Technology in Anesthesia and can be pooled and shared among many institutions in order to facilitate the analysis of large patient populations.[32, 58] This uniform dataset can be tailored to suit institutional anaesthetic record criteria in order to achieve comparable documentation across all participating providers and minimise workload and inconsistencies. In addition, the CDS and its evaluation meet the following criteria:

- One record set for each individual patient.
- Standing definitions for IECs and routine documentation.
- Automated tools for screening of systematic and coding errors.

   Of the 116 fields in the dataset, 24 are dedicated to the description of up to eight IECs. The DGAI recommends the following definitions of IECs, based on the model by Cooper et al. of anaesthetic mishaps or near-incidents,[38] and all three of the following conditions have to be fulfilled:

- The IECs occur during the anaesthetist's responsibility — i.e. from the time when the anaesthetist is first present at the induction of anaesthesia until the patient's discharge to the ward or intensive care unit (ICU) from either the operating room/procedure suite or postoperative care unit (PACU) or recovery room.
- The IECs lead to an intervention by the anaesthetist.
- The IECs caused or could have caused morbidity or mortality if the anaesthetist had not intervened.

The IEC can be selected from a list of predefined IECs (Appendix IX) and is documented in five ascending grades:

1   IECs with no impact on postoperative care — no additional post-operative care is necessary (including near-incidents).
2   IECs clinically important only for care in the PACU — no impact on transfer to the ward.

3   IECs clinically relevant for post-operative care — a prolonged stay in the PACU or special observation on the ward is clearly necessary.

4   IECs clinically important for post-operative care — the problem cannot be solved satisfactorily in the PACU and transfer to an intermediate care unit or ICU is necessary.

5   IEC = death.

Data Source

Data of the CDS 2.0 were collected during a benchmark project that has been initiated by the Medical Board of Baden-Wuerttemberg, one of Germany's federal states, since 1999. Here, anaesthetic departments in hospitals or in private practice can take part in the benchmark project on a voluntary basis. Participation in this external quality-assurance system is free of charge for departments inside the state of Baden-Wuerttemberg, where the Medical Board paid for the main costs up to 2010. Departments from other federal states are also able to take part for a small fee.

The emphasis in this benchmark project is on routine documentation of IECs in relation to the level of care and patient demographic data. Data are generated at the site where the anaesthetic procedure takes place. Anaesthetic departments can choose either to keep paper-based yet computer-readable records that are scanned or to generate data directly via interfaces to create a file. The data have to be uniform for processing in the multicentre national database. Participating departments annually submit data for all anaesthetic procedures carried out during each one-year period.

A check program is used to screen for conflicting or false data entries, such as patients aged < 0 or > 110 years, American Society of Anesthesiology Physical Status (ASA PS) > 5, 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 Anesthesia 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. IEC rates are then calculated and compared with data from scientific studies. In addition, all data are entered into a benchmarking file in which IEC rates are compared between participants using results from multivariate regression models. A working group in the Medical Board, consisting of eight

anaesthetists and one medical computing specialist, reviews and comments on the results before they are decoded by the Medical Board and the results are sent by post to the hospitals.

The present study used checked but otherwise unprocessed CDS (version 2.0) data from the database. Data that were collected between January 2002 and December 2004 were analysed after ethics committee approval. Data based on version 1.0 of the CDS were excluded. Primary end points were coding errors; a secondary end point was the analysis and categorisation of the events; and a tertiary end point was comparison of the number of cases with coding errors to the number of records in the CDS with potential coding errors as detected by filtering methods.

All records with ASA PS 1 or 2 and IEC grades 4 or 5 were detected in the database, emergency and urgent procedures, procedures that did not take place during normal working hours, and cardiac surgery procedures were excluded (as the IEC coding might be difficult in these cases).

The CDS has deficiencies 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 nevertheless have to be part of anaesthetic record-keeping. Thus, for identification of coding errors and to gain insight into the events, records identified in the CDS were decoded by the Medical Board to allow the hospitals where the event had taken place to be identified by the Medical Board. The latter send queries to the respective hospitals. A query included time and date as well as patient characteristics of the records from the database to allow the case to be identified by the hospitals. The hospitals were then asked to return details on the course of events or to indicate that a case was falsely coded. For the answers, no specific form was used. False coding implied that the record had the combination ASA PS 1 or 2 and IEC 4 or 5 in the database, but the hospital identified the case (hospital record including vital signs and of the type, route, and dosage of anaesthetics and other drugs) showing the ASA PS to be higher or the IEC to be lower.

The answers from the queries were received by the Medical Board. If the answers were not anonymous regarding sender and contents, the Medical Board deleted names and decoded the reports to ensure anonymity, which were then sent to members of the working group for the cases to be analysed.

Each identified case was independently reviewed and then classified by three members of the working group, anaesthetists experienced in investigating errors, near-misses, or crisis simulations. Firstly, reports with coding errors were separated into three groups: ASA PS coding error, IEC coding error, other coding errors.

All other cases without coding errors were classified into the following categories:

i)   system immanent risk (bleeding, aspiration in a well fasted patient, anaphylaxis etc.) – where a risk that is inherited in the operating or anaesthetic procedure is unveiled

ii)   organisational matters (hypothermia, prolonged procedures, substitution of large amounts of blood components etc.) – situations where it seems safer or where there are no other options than to monitor the patient in HDU/ICU, this includes near misses

iii)   noticeable or conspicuous events – anaesthetic or procedural events where there is some evidence that a different treatment regime could have prevented the IEC (neglect to follow protocols, etc.).

The events were further classified using a modified classification system,[143] (Table 8.3)

All cases where the reviewers could not agree, the next lower classification was used, all cases where the cascades were not identifiable were classified as i).

The relative frequency and the nature of coding errors (i.e. false high ASA PS or IEC) as indicated by the hospitals was used to employ filtering strategies to identify a similar number of records in the database that would most likely match the falsely coded cases. First, we assumed that ASA PS 1 and 2 patient records, indicating healthy individuals, should/would not display many risk factors classified as pathological and therefore relevant for anaesthesia. These were risk factors considered to indicate a higher ASA PS status than coded in the records. The nineteen items of the pre-operative risks were pooled into four groups of risk factors (cardio-vascular, pulmonary, neurologic, metabolic). For example coronary artery status, myocardial function, large and small vessel disease, ECG and blood pressure were pooled into cardio-vascular risk factors. Second, to determine the common denominator for the rate of IEC 4 and 5, all the records from the database belonging to known clinics who had

sent answers were added as identified by the clinic codes, for the remainder of the cases where departments had answered the query anonymously the mean number of the remainder of anaesthetic records in the database was used.

The SPSS (version 14.0; SPSS Inc., Chicago, Illinois) and Microsoft Excel programs were used for statistical analyses. The 95% confidence intervals (95% CI) were calculated using the Excel function BETAINV.

Results

Between 2002 and 2004, a total of 577,163 records were available in the database, with 366,334 records of ASA PS 1 und 2 patients. The data had been collected from 38 anaesthetic departments. Of these, 483 records displayed a combination with IEC 4 and 33 with IEC 5. In the database, 364 (70%) of the analysed records showed no or just one relevant risk factor, (154 (30%) two or more), with cardio-vascular and pulmonary risks being most frequent. In addition, 55 (11%) records presented IEC that were most likely not severe (i.e. damage to the teeth, multiple attempts for regional anaesthesia).

For the year 2002, 50% (7 of 14) departments answered the query, for the following year 62% (16 of 26), and for 2004 63% (19 of 30). The Medical Board received a total of 317 (100%) descriptions of events until 2010 relating to the period between 2002 and 2004. The majority of coding errors were ASA PS related (n=102 (32%)), in another 48 (15%) of the cases the IEC code was incorrect, and 7 (2%) were not elective procedures. For the remainder of 160 (51%) cases, the reports were subject to further analysis. Table 8.1 displays demographic data of theses cases, Table 8.2 displays the characteristics of the identified records in the database. The hospitals that had sent the reports had contributed a total of 160,267 ASA PS 1 and 2 patient records in the database during 2002 to 2004. This number was used as the denominator for the calculations. Of the 160 reports, 159 displayed IEC 4 and one case IEC 5 (death). This resulted in an IEC 5 rate of 0.62 per 100,000 (95% CI 0.03 – 1.89) and an IEC 4 rate of 99.2 per 100,000 (95% CI 86.6 – 112.5) (Flowchart Caseanalysis).

These cases were classified as follows:
i) system immanent risk (aspiration in a well fasted patient, anaphylactic reactions etc.); n=56 (35%)
ii) organisational matters (hypothermia, prolonged procedures, etc.); n=80 (50%)
iii) noticeable or conspicuous events; n = 24 (15%), (Table 8.3)

Examples:
Category i) A 28-year-old male patient scheduled for an elective operation of the maxillary sinuses. The patient has been seen in the APEC several days ahead of the procedure. On the day of the operation, the patient has been checked in uneventfully and anaesthesia is induced. On induction, the patient regurgitates gastric contents despite having fasted. Following an

internal SOP (standard operating procedure) algorithm, the liquid in the patient's pharynx is sucked, the trachea is immediately intubated, followed by blind tracheal suction. This is followed by a bronchoscopy, which revealed no aspiration of gastric contents in trachea and bronchi. No other signs of aspiration occur and the patient is operated on, at the end, the trachea is extubated and the patient is admitted to HDU for monitoring. On post-operative day (POD) 1, the patient is discharged to the normal ward.

Category ii) A 57-year-old male is scheduled for dorsal stabilisation after an older fracture of the vertebral body of the seventh thoracic segment. During the three hours of operation, he loses a larger amount (approx. 2.5 litres) of blood and receives 3 packs of red cells, 3 fresh frozen plasma and 1 l of processed antologous blood collected from a surgical site. After stabilisation, the patient's trachea is extubated and the patient is being brought to ICU for post-operative observation as it was felt that the post-operative care unit (PACU) would not be sufficient to care for the patient.

Category iii) A 89-year-old patient is scheduled for a hernia operation. Being anxious in the induction room, the anaesthetist wants to administer 2 mg of Midazolam. Instead of a concentration of 1 mg per ml, he opens an ampoule containing 5 mg per ml and the patient receives 10 mg of Midazolam. The anaesthesia is immediately induced, after the procedure the patient is being brought to ICU were the trachea is extubated 2 hours after the procedure under Flumazenil infusion.

Discussion

The lack of an established national surveillance system has been found to hinder a systematic approach to anaesthesia-related IECs.[149] The present study analysed data from a national database, the anaesthetic procedures in the CDS had been documented prospectively for a quality assurance benchmark analysis. While there is another federal country where documentation of IEC are mandatory, the scientific evaluation was accomplished only for a smaller fraction of cases for CDS version 1. The project is run by the Association for Quality Assurance (EQS), data based on the CDS version 2 are not available.[189-191]

Multiple aspects influence documentation - starting with the level of motivation for documenting anaesthetic activities beyond the normal anaesthesia record. In the present study, it can be assumed that acceptance was increased through the use of ergonomic principles,[192] with duplicate documentation being avoided as recommended by the DGAI.[32, 58] Participation in the benchmark analysis project is free of charge, but providing the data comes at considerable resources. In addition, particularly at the time of induction, many computer-readable documents (CRDs) require correction,[193] with the routine use of CRDs documentation discipline becomes more stable. False readings with CRDs still occur, [193] Moreover, if codings are false, i.e. a patients of ASA PS 1 or 2 that experienced an IEC Grade 4 or 5 is falsely coded on the record with a higher ASA PS or lower grade of IEC, this cannot be excluded with the study design used.

For the analysis of coding errors and the cascades that have led to the unfortunate outcomes, we firstly analysed records that were identified in the database, and secondly, a query was sent to the respective departments. With a return rate of about 60%, we were able to analyse a large fraction of the cases, the return rate can be considered high in comparison to other studies. [149, 194] This positive rate of returned queries might be a result of keeping anonymity, and should be interpreted in the light of an ongoing quality assurance project, with a high willingness to participate on the side of the departments. While some departments sent simple statements indicating that the ASA PS or IEC code was wrong, others sent more detailed information on the cascade leading to the event of IEC 4 or 5. Whether all of these statements were correct is beyond the control of our study.

The present study analysed the codes that were most likely representing severe IEC in relatively healthy patients. First, we have analysed the identified records from the database for codes that could result in a higher ASA PS. While we found at least one relevant risk factor in a total of 322 (62%) records, 30% of the identified records in the CDS displayed two or more risk factors. This corresponded favorably to the 32% of cases identified by the answers of the hospitals where ASA PS codes were found to be wrong. Previous studies showed that the ASA PS classification depends on multiple parameters and is not well defined; a high inter-rater variability has been described.[195-197] It is therefore not surprising that the majority of coding errors concerned the ASA PS.

In another 15% of the reported cases by the hospitals, the IEC code was incorrect, and in 2% procedures were urgent. By comparison, 11% of the records in the database were found by the reviewers to display incorrect IEC codes. One of the problems is the imprecise definition of IEC severity grade 5 until 2003, which was defined as 'permanent damage or death'. This definition 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.

The remainder percentage of cases that remained undetected by our approach may be considered as coding problems that cannot be controlled by filtering mechanisms. By keeping anonymity, we were unable to match the answers of the hospitals directly to the records from the database. We were left to believe that filtering cases in the database with the exclusion of two or more risk factors would leave true ASA PS 1 and 2 patients and that analysing the IEC for codes suggesting low severity would allow us to at least approximate the real number of severe IEC.

The mere analysis of the records in the CDS seems to slightly overestimate the number of cases as compared to the answers of the hospital. However, a common phenomenon is true underreporting of cases.[58, 198] To detect the true number of cases (i.e. ASA 1 and 2 patients with true ICE 4 or 5) using our study design, this would mean scrutinising all available records at the hospitals in order to detect the degree of real underreporting. Reasons for underreporting are multifaceted: a general problem is the lack of agreement on how to appraise adverse outcomes and events in anaesthesia, along with anaesthetists' individual opinions about what is worth documenting. In addition, the anaesthetists' fear of attracting

blame may also result in cases not being reported. Simply forgetting to mark the boxes indicating a severe event may also pose a problem in the turbulent situation of a crisis. With the current study design, we were unable to assess the degree of underreporting.

In general, the definitions of IECs and the grading system used in the CDS allow documentation of everyday anaesthesia problems and their clinical impact with emphasis on the clinician's judgment, who may better take account of the individual clinical context and patient situation to detect IECs than any automated system.[199] The fear of attracting blame may be overcome by ensuring strict policies of confidentiality in the participating departments. Although data processing for the project described here is the responsibility of the Medical Board, in which data are kept strictly confidential, departmental policies are not under the Board's direct control.

In the current study, the rates of IEC 4 and 5 have to be interpreted with caution. In general, severe IEC (especially IEC 5 = death) are rare and our sample was too small for reliable conclusions to be drawn. In addition, the timeframe of the IEC documentation with the CDS is 24 hours post procedure. For the majority of departments, documentation using the CDS ends with the recovery period. For this timeframe, we have found a mortality rate of 0.062 per 10,000 anaesthetics. By comparison, the 24 hours perioperative time period is most frequently encountered in studies investigating severe morbidity or death.[31, 144, 145, 147, 150] The studies report a total rate of perioperative death (due to all aetiologies) of between 8.8[144] and 28.3[145] per 10,000 anaesthetics in 'allcommers', patients undergoing elective and emergency procedures. The rate of anaesthesia related deaths (corresponding to Edwards classification 1-3) ranges between around 1[144, 150] and 5.75[145] per 10,000 anaesthetic procedures. Anaesthesia related death rates in the immediate perioperative period and during the first 12 hours ranges from 0.6[148] to 1.12[151] per 10,000 anaesthetic procedures. The studies that allow the comparison of rates of rather healthy patients, i.e. ASA PS 1 and 2, state rates of anaesthesia related mortality of between 0.13[148] and 0.29[51] per 10,000 anaesthetics for the studies with a more direct approach, i.e. analysing a definite number of anaesthetic procedures pro- or retrospectively, while Lienhardt et al.[52] give calculated numbers of 0.04 and 0.5 for ASA PS 1 and 2.

While we were able to use hospital codes for some departments, others were sent completely anonymous. Therefore, the common denominator in our study was calculated using true numbers of anaesthetic procedures from those identified (by code) and a mean

number of the remainder of hospital anaesthetic procedures. While our calculations can be considered as being quite exact, calculating or estimating denominators to determine the rate is a frequent phenomenon, mainly because large prospective observations would be needed to determine exact denominators for the scarce events of severe events or death especially in ASA 1 or 2 patients.[31, 50, 52, 143, 144]

The secondary outcome of the study was the classification of cases. While details of vital signs and of the type, route, and dosage of anaesthetics and other drugs are not stored in the database records, our investigations relied on the answers received. The query did not use a specific format and the amount and the way information was given was at the discretion of the departments. This did not pose a problem for cases where coding errors were obvious, but some of the answers lacked detailed information for the cases to be classified (n= 8).

Among the cases reviewed, those of category i) were clearly defined as inherent problems, which were solved by using standard operating procedures (SOPs) and algorithms. Cases in category ii) were mainly unplanned post-operative ICU admissions. Prolonged operations, hypothermia or simply the structure of the hospital where the PACU or the normal ward was unable to take adequate care of the respective patients (after the PACU had closed) led to the ICU/HDU admissions (safety thinking). In the category iii) were cases where the reviews found noticeable or conspicuous anaesthetic or procedural events. This represents a very heterogeneous group of cases. Frequently, the reviewers noticed communication errors, but medication related errors and deviations from standard practice were also found in the surgical and anaesthetic care.

The proportions of medication related events on overall anaesthesia associated mortality are reported in a range between around 20%[145, 149, 153] up to about 50%[50, 150, 151]. Authors state that about 80% of the incidents were adverse effects of anaesthetics in therapeutic use[50], or that four out of eight cases with anaesthesia related cardiac arrest were related to anaesthetic overdose.[148] 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 also cover a wide range of between 8% [31, 144] and 100%. [147, 152]

However, there seems to be a large proportion of preventable problems, exceeding the 15%

of conspicuous events found in our study. A French study found that only in 2% of the cases partially or totally related to anaesthesia, no deviation of standard practice was identified; in 56% more than four deviations were recorded.[52] Preventability ranges from all (cardiac arrests and the consecutive deaths) [148] to 17.5% of the deaths being preventable (maybe preventable 18.2%))[145]. Gibbs reports that the proportion of deaths with no correctable factor increased from <5% in the 1991–1993 triennium to about 50% in the 2006–2008 triennium. [143]

With this study, we were able to identify the proportion of coding errors, the analysis of these errors were used to employ filtering strategies to be used in future studies to analyse the CDS. In addition, we identified a proportion of suspicious events, the analysis of which has been distributed at various national conferences for quality assurance purposes.

Table 8.1: Demographic data of the analysed cases

		n	*%*
ASA PS	1	59	36.9
	2	98	61.3
	1 or 2	3	1.9
Sex	m	70	43.8
	f	69	43.1
	missing	21	13.1
Age group	<= 14 years	19	11.9
	<= 40 years	23	14.4
	<= 80 years	78	48.8
	> 80 years	8	5.0
	missing	32	20.0
Type of	General anaesthesia	100	62.5
Anaesthesia	Regional anaesthesia	5	3.1
	Combination, general and regional	15	9.4
	missing	40	25.0

Table 8.2: Hospital characteristics of the identified records in the database

Hospital Level of Care		
	n	*%*
Specialised Hospital	24	4.6
Primary	184	35.7
Secondary	184	35.7
Tertiary	124	24
Total	516	100

Table 8.3: Categorisation oft the conspicious cases: (according to [200])

A	Preoperative	n
i	assessment	4
ii	management	2
B	**Anaesthesia Technique**	
i	choice or application	4
ii	airway maintenance	3
iii	ventilation	
iv	circulatory support	
C	**Anaesthesia Drugs**	
i	selection	
ii	dosage	1
iii	adverse event	
iv	incomplete reversal	
v	inadequate recovery	
D	**Anaesthesia Management**	
i	crisis management	
ii	inadequate monitoring	2
iii	equipment failure	
iv	inadequate resuscitation	
v	hypothermia	1
E	**Postoperative**	
i	management	3
ii	supervision	
iii	inadequate resuscitation	
F	**Organisational**	
i	inadequate supervision	
ii	poor organisation and communication	3
iii	poor planning	
G	**Other** (surgical factors not directly related to anaesthesia care)	1
H	**Medical Condition**	

Figure 8.1: Flow Chart: Case analysis
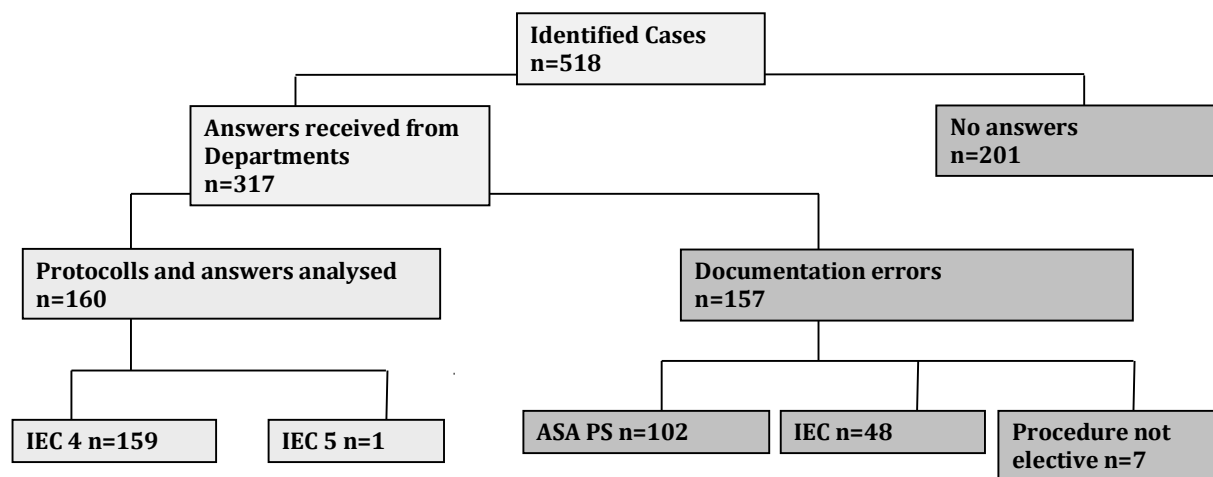
Summary

The presented study was able to identify the frequency and nature of severe IECs in rather healthy ASA PS 1 and 2 patients as well as the frequency of coding errors in the database. In order to determine the frequency of coding errors and the frequency of severe IECs, potential cases were identified by retrieving all ASA PC 1or 2 patients who had an IEC 4 or 5 event from the database between 2002 and 2004.

The cases were re-identified by the medical board to identify the hospitals where the event had taken place and queries were sent to the respective hospitals. The hospitals were asked to return details on the course of events or to indicate that a case was falsely coded. False coding implied that the case had the combination ASA PS 1 or 2 and IEC 4 or 5 in the database, but the hospital record identified the ASA PS as higher or the IEC as lower. The relative frequency and the nature of coding errors (i.e. false high ASA PS or IEC) was used to employ filtering strategies to identify a similar number of cases in the database that would most likely match the falsely coded cases.

In addition, the event reports as received by the hospitals were classified either as known (system immanent) risk, i.e. aspiration in a well fasted patient, anaphylactic reactions etc.; organisational matters (hypothermia, prolonged procedures, etc.); situations where it seems safer or where there are no other options than to monitor the patient in HDU/ICU; and noticeable or conspicuous events (anaesthetic or procedural events where there is some evidence that a different treatment regime could have prevented the IEC (drug errors, communication matters, deviations from standard practice, neglect to follow protocols, etc.).

The results are based on data between 2002 and 2004, therefore the frequency found will give only an indication and the entire database will need to be explored to achieve the full information. It should also be noted that the frequency of coding errors was analysed for rather healthy individuals and consequently the results do not indicate that the problems occur with the same frequency in patients' subgroups at higher risks.

For the CDS, the DGAI did not define any criteria for determining the cause of an event (e.g., surgical or anaesthetic factors). In critical situations, it is often hard to

determine responsibility, because interactions are abundant and complex. While the study was able to analyse some of the cascades leading to the event, we did not specify the degree of anaesthetic contribution. 505 cases with combinations of ASA PS 1 or 2 and IEC 4 or 5 were identified in the CDS and the queries were sent to the hospitals.

A total of 317 detailed reports were received from the hospitals of which 157 (49%) identified coding errors. The majority of coding errors were ASA PS related (n=102; absolute %: 32), in another 48 (15%) of the records the IEC code was incorrect, and 7 (2%) were not elective procedures. For the remaining 160 (51%) cases, the reports were analysed. The hospitals that had sent the reports contributed a total population of 160,267 ASA PS 1 and 2 patient records to the database, which was used as the denominator for the calculations. Of the 160 reports, 159 displayed IEC 4 and one case IEC 5. This results in an IEC 5 rate of 0.62 per 100,000 (95% CI 0.03 – 1.89) and an IEC 4 rate of 99.2 per 100,000 (95% CI 86.61 – 112.5). The majority of IECs were attributable to organisational matters such as patients been admitted to ICU for safety issues. A proportion of 15% was found to show features of noticeable or conspicuous events.

The data from the database were checked for codes that could reflect these coding problems as reported by the hospitals

This is the first study to analyse a large, national database on routine anaesthetic data. The main result was that coding errors occurred relatively frequently. The rate of severe IEC was determined and a proportion of cases with noticeable events were detected, while in all other cases common problems relating to the procedure or anaesthesia had caused the incorrect IEC. Based on the coding errors found, specific filtering methods were developed to be used in future studies, as will be outlined in more detail in Chapter 9.

CHAPTER 9:

MAJOR INCIDENTS, EVENTS AND COMPLICATIONS (IECS) IN ASA PS1 AND 2 PATIENTS UNDERGOING ELECTIVE PROCEDURES – RESULTS BASED ON 1.36 MILLION ANAESTHETIC PROCEDURES

In 2011, the CDS data collated between 1999 and 2010 in 101 anaesthetic departments, mostly in the southern part of Germany, for a benchmark project were made available to me. With the expertise acquired in the study in Chapter 8, I planned to analyse the data of this large dataset, comprising a total of 4,594,110 raw anaesthetic procedures stored in the database. A subset of 3,971,161 anaesthetic records were based on CDS version 2.0, and were therefore available for the planned analysis. The aim was to analyse data on healthy ASA PS 1 and 2 patients undergoing non-emergency procedures during normal working hours. This setting was chosen to account for and eliminate common confounding variables, such as co-morbitities, and to unveil the anaesthetic impact on major morbidity and mortality in these cases.

The specific aims of the study presented in this Chapter were to:

1) determine the incidence of severe perioperative outcomes in healthy patients in ASA PS 1 and 2 undergoing elective procedures from a large dataset based on CDS data that were filtered for severe outcomes (IECs) in the period from 1999 to 2010; and

2) identify cases where the underlying problem (IEC) codes suggest direct anaesthetic involvement.

The following study is presented as a manuscript draft and has been submitted for review to the British Journal of Anaesthesia.

Major Incidents, Events and Complications (IECs) in ASA PS1 and 2 Patients Undergoing Elective Procedures – Results Based on 1.37 Million Anaesthetic Procedures

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Background: Improved safety in anaesthesia has made severe anaesthesia-related incidents, events, and complications (IECs) and deaths rare events. The lack of population-based, prospective data has caused the debate over morbidity and mortality in anaesthesia to continue. This study examines possible severe outcomes or deaths recorded in a large national surveillance system based on a core dataset (CDS).

Methods: The authors filtered cases from the CDS database collated between 1999 and 2010. Cases were defined as patients in American Society of Anaesthesiologists (ASA) Phyisical Status grades 1 and 2 displaying IECs Grade 5, scheduled for elective surgery without relevant risk factors. Cases were reviewed for the maximum of eight problem (IEC) codes by four experts. Combinations of problem codes were discussed in multiple rounds with a modified Delphi technique before cases were classified as certain, indeterminate, or not relevant. Cases classified as certain were analyzed for codes suggesting direct anaesthetic involvement.

Results: Of the 1,364,678 ASA 1 and 2 patients in the CDS database, inclusion criteria were met in 84 cases. In 48 cases, the problem codes did not represent major outcomes (classified as not relevant). The rate of major morbidity and mortality in the ASA physical status 1 and 2 patients was calculated to be 2.62 per 100,000 (95% CI, 1.94 to 3.46; i.e. 36 cases), and the rate of cases with possible direct anaesthetic involvement was 0.73 per 100,000 cases (95% CI, 0.39 to 1.23; i.e. 10 cases).

Conclusions: This is the first study assessing severe IECs on the basis of prospective data from a national outcome-tracking database. Other studies have reported comparable figures, but used different study designs. Annual identification of cases using similar data-filtering methods and standardized queries in the respective departments might provide more detailed information about the cascades that lead to unfortunate outcomes.

Keywords: outcome, records, anaesthesia, complications, mortality

The mortality rate in patients undergoing noncardiac surgery can be substantial;[162] and ranges between 0.5 and 1% (48 hours);[43, 163] up to 4% (7 days).[164] However, the mortality rate after major surgical procedures has fallen dramatically,[165, 166] in addition, improvements in anaesthesia safety have made anaesthesia-related deaths and severe outcomes rare events.[50, 52, 167]

Researchers have shown that American Society of Anaesthesiologists (ASA) physical status when compared to individual comorbidities may have the strongest statistical association with major morbidity and mortality.[181-183] With longer survey periods, other factors also appear to come into effect, such as underlying disease, particularly malignancies.[162, 184] With an estimated 230 million anaesthetic procedures taking place worldwide annually[1] and about 10 million in Germany alone (in 2009) (www.gbe-bund.de), peri-operative mortality and major complications represent a small but relevant proportion of cases.

The incidence of peri-operative mortality directly attributable to anaesthesia also has a wide range, possibly as a result of differences in the definitions used and sources studied.[51]

Following legislation on quality assurance and cost-containment regulations in Germany, the German Society of Anaesthesiology 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 dataset, CDS) in conjunction with a standardized reporting system for anaesthesia-related incidents, events, and complications (IEC).[32, 58, 185-188]

The rise in the use of anaesthesia in private practice, the increasing number of elderly and multimorbid patients, and number of high-risk procedures as well as the lack of population-based, prospective data has caused the continuation of debate over major morbidity and mortality 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:

1) determine the incidence of severe perioperative outcomes in healthy patients in ASA PS grades 1 and 2 undergoing elective procedures from a large dataset based on CDS data that were filtered for severe outcomes (IECs) in the period from 1999 to 2010; and

2) identify cases where the underlying problem (IEC) codes suggest direct anaesthetic involvement.

Materials and Methods

In this cohort study, patients in ASA PS grades 1 and 2 that displayed anaesthesia-related incidents, events, and complications (IECs), Grade 5 cases were filtered from a core dataset (CDS) database collated between 1999 and 2010. Cases were analyzed for the maximum of eight underlying problem (IEC) codes and rates of severe perioperative outcomes were calculated.

Core Dataset (CDS) Database

The German Society of Anaesthesiology and Intensive Care Medicine (DGAI) has introduced the standardized reporting of anaesthesia-related incidents, events, and complications (IECs) in 1993. In its second version, the CDS used in this study was designed to reflect several key factors and includes demographic 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. [201] 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.[32, 58]

In addition to patient demographic 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 dataset in combination with the documentation of anaesthetic details to form a single, multipage record, which represents the legal documentation of the course of anaesthethesia 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 dataset, 24 are dedicated to the description of a maximum of eight IECs (Appendix IX). The definitions of IECs are based on the model of anaesthetic mishaps or near-incidents.[38]

The IEC can be selected from a list of predefined IECs and is documented in five ascending grades.

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-Wuerttemberg, sponsored by the Medical Board; departments from other federal states take part for a small fee.

The emphasis is on routine documentation of IECs in relation to the level of care and patient demographic data. Data are generated at the site of the anaesthetic procedure. Anaesthetic departments choose either paper-based but computer-readable documents (CRD), which are scanned, or to generate data directly with automated anaesthesia records (AAR), or anaesthesia information management systems (AIMS) to create a file. The data have to be uniform with the CDS for processing in the multicenter CDS data for all anaesthetic procedures carried out during each twelve-month period.

A check program is used to screen for conflicting or false data entries, such as patients aged < 0 or > 110 years, ASA Status > 5, cesarean 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 Country of Baden-Wuerttemberg), 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 1 or 2 that feature at least one severe (grade 5) IEC code, in order to detect severe IECs in otherwise healthy individuals. To increase the likelihood of inclusion of only true ASA PS 1 and 2 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 IEC 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) IEC code, it was expected that other IECs would also be coded (complex IECs),[202] 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 and/or analysis of the CDS. The cases were discussed using a modified Delphi technique.[203] This process consisted firstly 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 (Appendix IV PhD Thesis).[160, 167]

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 IEC codes), from the operating room or PACU 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 major morbidity and mortality — i.e. the total of ASA 1 and 2 patients. The SPSS (version 19.0; SPSS Inc., Chicago, Illinois) and Microsoft Excel programs were used for statistical analysis. The 95% confidence intervals (95% CI) 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 9.1).

Among the 4,594,110 anaesthetic procedures recorded, 622,949 datasets were excluded as they were based on CDS version 1.0; mostly acquired during 1999. A total of 3,971,161 anaesthetic records based on CDS version 2.0 was therefore available for the years 2000 to 2010 (Figure 9.1), with a total of 642,077 grade 1–5 IECs 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 processing and were therefore unavailable for the study Figure 9.2).

In the accumulated data, 2,817,551 records represented all ASA PS 1 and 2 patients (Table 9.1), with a total of 285 IEC grade 5 cases (ASA PS 1, n = 67, 6.25 per 100,000 cases; and ASA PS 2, n = 218, 12.48 per 100,000 cases).

The inclusion criteria were met in a total of 84 IEC grade 5 cases among 1,374,678 elective and non-urgent procedures recorded during normal working hours (with the exclusion of cardiac surgery procedures) in ASA 1 and 2 patients (Figure 9.1) (ASA 1, n = 30, 4.49 per 100,000 cases; ASA 2, n = 54, 7.63 per 100,000 cases). All eight cases that had the discharge code "death" were among the grade 5 IECs 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 major morbidity and mortality in the low-risk group was therefore 2.62 per 100,000 (95% CI, 1.94 to 3.46). This included nine in the ASA PS 1 group and 27 in the ASA PS 2 group (1.35, 95% CI, 0.7 to 2.35; and 3.82, 95% CI 2.7 to 5.27 per 100,000 cases). Only one case was found to have occurred on postoperative day 1 (case No 80). Of these cases, three in the ASA PS 1 group and 20 in the ASA PS 2 group had complex IECs. 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 (Table 9.2 and Table 9.3) 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 1 group (0.75; 95% CI, 0.29 to 1.57 per 100,000 cases) and 20 in the ASA PS 2 group (2.83; 95% CI, 1.88 to 4.11 per 100,000 cases). All cases in which there was a discharge option of "death" were still among those identified (Table 9.2). Discharge options other than death were not taken into account. Many datasets from the hospitals showed either no coding or a single uniform code (such as "normal ward") for the particular field. The remaining 11 cases were classified as intermediate (Table 9.3).

In the group with definite severe outcomes, the rate of possible anaesthesia-related events was 0.73 per 100,000 cases (95% CI, 0.39 to 1.23 — i.e., 10 cases) during the immediate perioperative period. Of these, two cases in the ASA PS 1 group (0.3; 95% CI, 0.05 to 0.94) and eight in the ASA PS 2 group (1.13; 95% CI, 0.56 to 2.04 per 100,000 cases) were considered to be anaesthesia-related. A total of four telephone conferences were held to classify all cases.

Discussion

The lack of an established national surveillance system has been found to hinder a systematic approach to anaesthesia-related incidents, events, and complications (IECs).[149] 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 core dataset in the departments concerned. The study should therefore be regarded as an observational analysis of prospective data. 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 1 per 100,000.

To the best of our knowledge, this is the first study that has assessed severe IECs on the basis of data from a national outcome tracking database.

Incidence Comparisons

The overall incidence of IECs observed when the CDS database was analyzed was 16.17%. Other studies have reported rates of 18–32%, all using similar definitions of IECs but with longer survey intervals.[35-37, 56, 57] A single-center study with a long history of participation in quality assurance projects, using the same definitions, reported a general IEC rate of 22%.[32] In another study using results of CDS version 1 of the federal country of Hamburg, where the documentation of IECs are mandatory, a total of 14.1% of IEC was found.[190, 191] As the present study reflects real-life routine reporting of IECs, the general IEC rates 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 ischemia, triggered by anemia; hypovolemia; 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%.[52] It is therefore not surprising that 11 of the 36 cases in the present study involved hypovolemia.

By comparison, a retrospective analysis reported rates of cardiac arrest, critical incidents and subsequent death of 9.86, 59.41, and 3.12 respectively per 100,000

anaesthesia cases in the group of ASA 1 and 2 patients. The rates of cardiac arrest and death entirely attributable to anaesthetic management were 1.87 and 0.14, respectively.[194] While these figures look similar to those in the present study, the study concerned was analyzing cardiac arrest and deaths, not IECs, 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 aneasthesia-related death rate of 1.1 per million population per year was found for the United States. Subgroups were analysed for age, but not for ASA PS.[50] 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 5.4 in 100,000 anaesthetic procedures. The risk was reported to be 0.4 and 5.4 per 100,000 for those with ASA PS 1 and 2.[52] 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[52] or surgical discharges.[50]

In Australia all deaths that occur within 24 (to 48) hours 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 1 or 2. Again, the numbers of anaesthetic procedures are calculated estimates and the proportion of the study population in ASA PS 1 and 2 was not assessed. [167]

Arbous et al prospectively identified the incidence of 24-hour postoperative mortality and the estimated incidence of coma to be 8.8 and 0.5 per 10,000 anaesthetic procedures. ASA PS 1 or 2 patients accounted for 8.4% of the cases (n = 67). Only 21.5% of the procedures were elective, and proportions of ASA PS 1 or 2 patients were not stated.[31] A recent meta analysis described a decrease in anaesthetic sole mortality in developed countries with a actual rate of 2.5 per 100.000 anaesthetics, the crude surgical mortality for ASA PS 1 and 2 patients to be 55.7 and 140.8 per 100.000 operations.[43]

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 1 and 2 patients, we may have also excluded a proportion of true ASA PS 1 or 2 patients among the 1,442,873 filtered patient records (Figure 9.1).

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. 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 anaesthesia-related. Lacking further details, other codes such as hypotension or nonspecific 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.[167] 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 3-5 patients, in which the majority of deaths occur.[167]

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, CIRS), 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 dapartments. It can be assumed that acceptance was increased through the use of ergonomic principles,[192] with duplicate documentation being avoided.[32, 58] 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 IEC 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 IEC 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 approximately 100 different anaesthetic departments, mainly in the federal state of Baden-Wuerttemberg. Furthermore, there might be missing records for single institutions if not all are scanned and critical incidents could therefore be unavailable.

Bias in documenting IECs 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 computer-readable documents (CRDs) are introduced, many records require correction.[193] 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,[193] and cannot be excluded with the present study design.

The focus was on severe cases, while frequent low severity IECs are prone to influence by systematic causes (i.e. documentation discipline), severe IECs with narrow definitions were found to be more stable.[58, 204]

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 blood pressure measurement limits to determine IECs, no universally acceptable definition of intra-operative hypotension exists.[205][206, 207]

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 IECs include the examination of many more variables in the individual clinical context. The emphasis in the CDS is therefore on the anaesthetists judgment, who may better take account of the individual clinical context and patient situation to detect IECs than any automated system.[199]

The CDS has also been used successfully to create a large outcome-tracking database.[32, 188]

The Delphi techniques 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. IEC Grade 5 was 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 dataset 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 anaesthesiologists as described[52] could provide more detailed information about the cascades that lead to unfortunate outcomes. In addition, analysis of other ASA physical status groups will display risk factors for IECs of different grades using the CDS database in the near future.

Table 9.1: Demographic details of the analysed database

	Cases (n)
Level of care	
Specialized hospital	208492
Primary care institution	901541
Secondary care institution	1698988
Tertiary care institution, referral center	1147979
Day surgery, outpatient care	14161
Sex	
Male	1905813
Female	2065105
Intersex	244
Status	
Day surgery cases	553215
Admitted patients	3385104
Short stay	32842
ASA PS grade	
1	1070370
2	1747181
3	986377
4	147920
5	18929
Data missing	384

ASA PS= American Society of Anesthesiologists Physical Status

Table 9.2: Certain cases identified from the database, ASA PS 1 and 2 patients who suffered a severe IEC undergoing elective procedures. Dark shadowed fields indicate anesthesia-related events identified by the reviewers after multiple rounds of a normative group technique.

Case No.	Level of Care	Age (years)	Sex	Dept.	ASA	Type of anaesthesia	Intubation of trachea	IEC 1	Grade	IEC 2	Grade	IEC 3	Grade	Duration of Anaesthesia	Duration of Proc./OP	D/C
1	2	50	m	general surgery	2	TIVA	yes	Unexpected difficult Intubation	5					140	105	
2	2	90	m	general surgery	2	missing	yes	Pulmonary embolus	5	Cardiac arrest	5			83	67	death
3	3	50	f	urology	2	combination general and regional anaesthesia	yes	Hypotension	5	Hypovolaemia	5	Schock/alterations in Microcirculation	5	577	527	death
4	3	65	m	neuro surgery	2	i.v. induction, inhalational maintanance	yes	Hypovolaemia	5	Tachycardia	3	Hypotension	3	395	221	
14	2	47	m	neuro surgery	2	balanced anaesthesia	yes	Cardiac arrest	5					65	30	death
17	2	54	m	thoracic surgery	2	kombination general and regional anaesthesia	yes	Hypotension	1	Bradycardia	1	Cardiac arrest	5	480	255	death
19	spec	44	f	general surgery	2	i.v. induction, inhalational maintanance	yes	Bronchospasm	1	Unexpected difficult Intubation	5			60	20	
21	spec	54	m	general surgery	2	i.v. induction, inhalational maintanance	yes	Myocardial Infarction	5					95	75	
22	2	76	f	obestetrics/gynaecology	2	i.v. induction, inhalational maintanance	yes	Myocardial Infarction	5	Cardiac arrest	5			185	160	

Case No.	Level of Care	Age (years)	Sex	Dept.	ASA	Type of anaesthesia	Intubation of trachea	IEC 1	Grade	IEC 2	Grade	IEC 3	Grade	Duration of Anaesthesia	Duration of Proc./OP	D/C
31	3	65	f	urology	2	balanced anaesthesia	yes	Hypotension	3	Tachycardia	3	Hypovolaemia	5	282	230	
34	1	76	m	urology	2	TIVA	no	Bronchospasm	5	Hypotension	5	Impaired right cardac function	5	85	55	
37	1	46	f	general surgery	2	balanced anaesthesia	no	Intubation impossible	5	Hypoxaemia	5	Cardiac arrest	5	140	15	death
38	1	53	m	orthopaedic surgery	2	balanced anaesthesia	yes	Intubation, not classified	5	Unexpected difficult Intubation	5			68	30	
44	1	33	f	ENT surgery	2	i.v. induction, inhalational maintanance	yes	Hypotension	4	Cardiac arrest	5			75	50	
46	2	53	m	ENT surgery	2	i.v. induction, inhalational maintanance	yes	Unexpected difficult Intubation	5					160	95	
48	3	44	m	general surgery	2	TIVA	yes	Hypoxaemia	3	Pneumonia	5			180	125	
49	3	27	f	obestetrics/gynaecology	2	i.v. induction, inhalational maintanance	yes	Unexpected difficult Intubation	4	Esophageal Intubation	5	Reintubation	4	50	35	
50	3	66	f	neuro surgery	2	balanced anaesthesia	yes	Hypovolaemia	5	Cardiac arrest	5	Ventilator	1	165	75	death
51	3	47	f	obestetrics/gynaecology	2	balanced anaesthesia	yes	Clotting Disorders	5	Unplanned admittance to ICU	5	Acidosis	3	440	415	
53	3	25	m	trauma surgery	2	balanced anaesthesia	no	Unexpected difficult Intubation	5					125	80	
54	3	32	m	trauma surgery	2	balanced anaesthesia	yes	Intubation impossible	5					120	70	
58	2	50	f	obestetrics/gynaecology	1	missing	yes	Unexpected difficult Intubation	5					82	55	

Case No.	Level of Care	Age (years)	Sex	Dept.	ASA	Type of anaesthesia	Intubation of trachea	IEC 1	Grade	IEC 2	Grade	IEC 3	Grade	Duration of Anaesthesia	Duration of Proc./OP	D/C
59	2	44	m	general surgery	1	mbination neral and gional aesthesia	no	Unexpected difficult Intubation	5					65	25	
68	2	58	f	trauma surgery	1	i.v. induction, inhalational maintanance	yes	Myocardial Infarction	3	Hypovolaemia	5	Anaemia	3	285	230	death
69	1	5	m	ENT surgery	1	i.v. induction, inhalational maintanance	yes	Cardiac arrest	5					45	25	death
80	3	45	m	neuro surgery	1	i.v. induction, inhalational maintanance	yes	Increased ICP	5	Other Central Nervous Problems	5			429	371	

Level of Care: 1= primary Care, 2= secondary care, 3= tertiary care, spec= specialized hospital, ENT= Ear-Nose-Throat, D/C= discharge option

Table 9.3 Intermediate cases identified from the database, ASA PS 1 and 2 patients who suffered a severe IEC undergoing elective procedures.

Case	Level of Care	Age (years)	Sex	Dept.	Type of anaesthesia	Tracheal Intubation	IEC 1	Grade	IEC 2	Grade	IEC 3	Grade	Duration of Anaesthesia	Duration of Proc./OP
6	3	67	f	neuro surgery	balanced anaesthesia	yes	Obstruction of the Airway	5					335	261
12	3	0,25	m	maxillo-facial surgery	i.v. induction, inhalational maintanance	yes	Multiple or Missed Punction (Bloodvessels)	1	Obstruction of the Airway	5			245	150
13	2	50	m	general surgery	balanced anaesthesia	yes	Hypotension	1	Pneumothorax	5			240	165
20	spec	33	f	general surgery	i.v. induction, inhalational maintanance	yes	Bradycardia	2	Hypotension	5			53	0
35	2	35	m	orthopaedic surgery	TIVA	yes	ET-Tube kinking	5	Tube defect	5	Reintubation	1	110	45
43	2	62	m	ENT surgery	local anaesthesia	yes	Reintubation	5	Hypotension	3			605	515
56	1	58	m	medical procedure	spinal anaesthsia	no	Airway, not classified	5					30	1
57	1	62	f	urology	balanced anaesthesia	yes	Unexpected difficult Intubation	1	Reintubation	5			220	163
60	2	45	m	general surgery	i.v. induction, inhalational maintanance	yes	Pneumothorax	5					135	105
70	3	39	f	neuro surgery	balanced anaesthesia	yes	General reactions, not classified	5					149	79

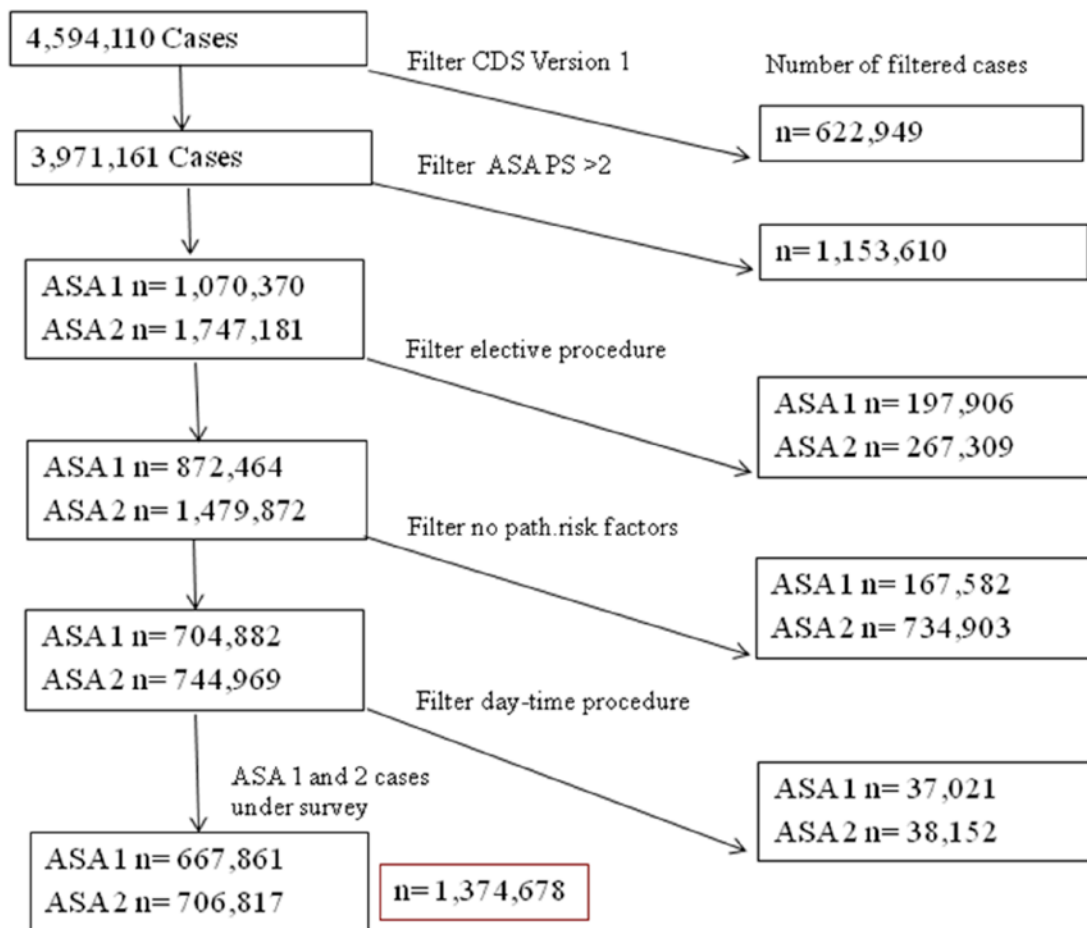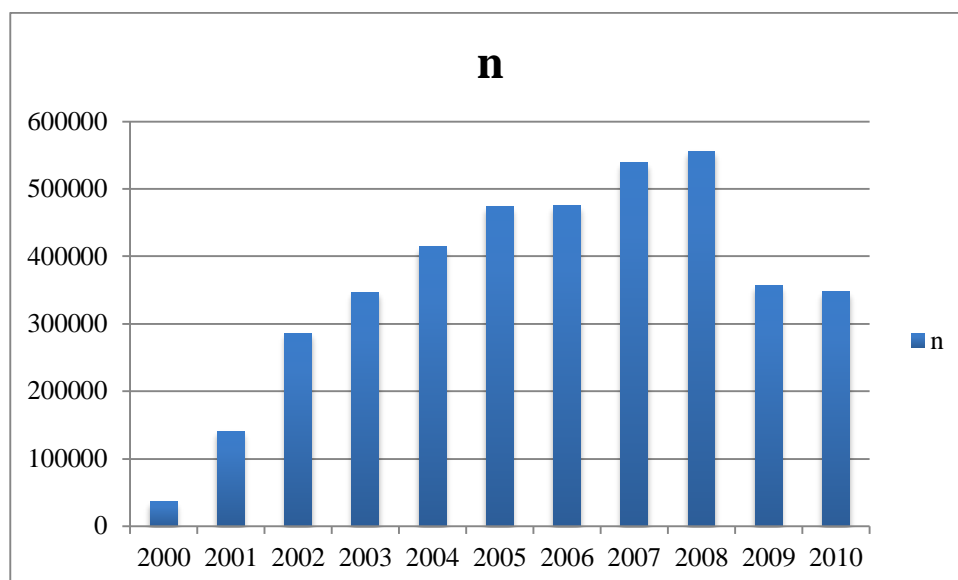Figure 9.1: Filtering process of available Data 1999-2010

Figure 9.2: Number of datasets collected per year during the study period

Summary

The described study represents data from Germany, a large European country, with a total of about 10 million anaesthetic procedures (in 2009) per year. We found a rate of major complications in healthy patients undergoing elective surgery of about 3 per 100,000 and a rate of about 1 per 100,000 for incidents associated with anaesthesia (such as difficulties in airway management). In the database, 1,364,678 ASA PS grade 1 and 2 patients met the criteria of being rather healthy and undergoing a non-emergency procedure during normal working hours. As found in Chapter 8, many cases had to be excluded as they did not meet the inclusion criteria. For instance, out of 84 cases displaying relevant IECs, 48 cases had to be excluded because the problem codes did not represent major outcomes (for example damage to the teeth).

The rates found are generally comparable to other studies that assessed mortality and severe morbidity (see Chapter 1) but have to be interpreted with caution as comparisons of rates of severe adverse events are often hampered by different study intervals, sampling techniques, grading systems for severe outcomes, and by the specific inclusion criteria applied. It is therefore important to emphasise that the numbers given in the present study include both outcomes — death and severe health impairment — in the immediate perioperative period and focus only on rather healthy individuals undergoing elective procedures.

Additional anaesthesia-related incidents may have remained undetected by the approach used that focused exclusively on anaesthetic involvement by analysing anaesthesia-specific codes, in the absence of details of vital signs, anaesthetics, and other drugs administered.

Selection bias arising from the voluntary contribution to this database, as well as information bias in documenting IECs at the site (department) with possible underreporting cannot be excluded. The normative group discussion as used for this study to determine the degree of severity of IEC and the anaesthetic involvement provided scope for discussion and a strategy for solving disagreements between the reviewers in assessing cases.

The present investigation provides a unique approach to morbidity and mortality for a large study population in central Europe. This is the first study based on a nationally

used dataset analysing routine data and also provides a reliable number of anaesthetic procedures conducted as the denominator.

This study is currently under review at the British Journal of Anaesthesia.

CHAPTER 10:

LITERATURE UPDATE, OVERALL CONCLUSIONS, RELEVANCE AND RECOMMENDATIONS

In Chapter 10 a literature update is presented followed by an outline of the overall conclusions and recommendations of the studies presented in this thesis. Subsequently, the contributions of the thesis to the discipline are detailed. The Chapter concludes with an outline of future research.

1. Literature update

2. Overall conclusions, relevance and recommendations on:

> **2a. Construction and use of perianaesthetic <u>questionnaires for adult and paediatric patients</u> that adhere to a psychometric design and evaluation of the APEC (Chapters 2 to 7); and**

> **2b. Severe IEC and mortality in healthy patients and anaesthetic contribution (Chapter 8, 9).**

3. Open questions and future research plans

1. Literature update

The literature review of this PhD thesis included studies up to April 2013. Between April and September 2013 when this thesis was written up, only one notable study was published on satisfaction, summarising results from different questionnaires in a review fashion. No other new instruments or studies on patient satisfaction were found. Another study, already published in 2012, did not exactly meet criteria to be included in the literature review, but does provide insight into the available studies and anaesthesia-related mortality over the time and will therefore also be discussed in this literature update. For the subject of anaesthesia-related mortality, no new, recently published studies were found.

Barnett and co-authors published a systematic review on patient satisfaction measures in anaesthesia in August 2013.[14] Similar to the literature search that was conducted for the purpose of the main literature review for the thesis, the authors conducted a systematic review to identify all tools used to measure patient satisfaction with anaesthesia, which have undergone a psychometric development and validation process. They also appraised the quality of these processes, and made recommendations of tools that may be suitable for use in different clinical and academic settings. Among numerous studies using non-validated instruments or poorly developed tools claiming to accurately assess satisfaction with anaesthesia, they state to have found a number of robustly developed and subsequently validated instruments. Their final analysis consists of 71 articles describing a total of 34 patient-satisfaction scores, developed and evaluated using psychometric testing for different areas of anaesthesia. The authors discuss three studies developed to measure maternal satisfaction with obstetric care; one French article, measuring satisfaction with regional anaesthesia in a non-obstetric setting[208]; as well as the most referenced instrument assessing satisfaction with Monitored Anaesthesia Care, the Iowa Satisfaction with Anesthesia Scale (ISAS) together with a further 17 studies using the ISAS to assess satisfaction.[30] Among the six tools used in paediatric anaesthesia, my own instrument, the PPQ is also discussed. For the PPQ, they state 'The Pediatric Perianesthesia Questionnaire, which is answered by the patient and parent together, was the most robustly developed measure in this field'. The second questionnaire I developed during my PhD studies, the HPQ (Chapter 2), is found in the review among the nineteen questionnaires measuring patient satisfaction with perioperative care. The authors state that 'for the perioperative assessment of satisfaction, …. the more lengthy questionnaires, such as ……the Heidelberg perianesthetic questionnaire are also acceptable to patients, and therefore, may be suitable for research purposes'. The EFA (Chapter 3) is also mentioned as an 'additional article' as its validation in still in process.

Barnett and coauthors used a rating system similar to the one used for this thesis, indicating the depth of psychometric development and testing behind each questionnaire, totaling 6 points. Both of my instruments developed during my PhD studies, the HPQ and the PPQ, scored highest marks in their categories. Interestingly, the authors, too, identified a number of the questionnaires that were used in other

socio-cultural backgrounds than they were validated in, with their validity and reliability not being established after translation. They also conclude that perhaps the most significant finding is that the vast majority of anaesthesia-related studies do not use validated tools, which may lead to biased and misleading results.

Another important study was published by Daniel Bainbridge and co-workers[43]. They identified studies published up to February 2011 (in any language, with a sample size of over 3000) that reported perioperative mortality across a mixed surgical population who had undergone general anaesthesia. While aiming to synthesise the available global data on anaesthetic and surgery-related deaths in high-income versus low-income settings, they also assessed the risk of perioperative and anaesthesia-related mortality for temporal trends through a meta-regression. 87 studies met the inclusion criteria. They observed a decline in mortality solely attributable to anaesthesia, a decrease in total perioperative mortality, as well as in the incidence of cardiac arrest over time. Interestingly, the baseline risk of patients who presented for surgery as expressed by the ASA score increased over the decades. For the developed countries, they observed a fall in anaesthetic contributory mortality from 2.34 (95% Confidence Intervall (CI) 2–2.75) in the 1970s–80s to 0.85 (95% CI 0.75–0.96) in the 1990s–2000s, with the anaesthetic sole mortality falling from 0.52 (95% CI 0.42–0.64) to 0.25 (95% CI 0.21–0.3) per 10,000 anaesthetic procedures respectively.

The results need to be interpreted in light of the limitations of the data available. As in other studies, the denominator is often blurred and most studies reported events intraoperative and within the first 24–48 hrs postoperatively, whereas only four studies reported 30-day anaesthesia mortality, but were excluded. Crude death rates were used without adjustment for specific comorbidities or type of surgical procedure. Therefore, bias and confounders that may differ over time might have affected the results. The authors conclude that despite an increase in patient baseline risk, perioperative and anaesthetic-related mortality rates have steadily declined over the past 50 years, and this might be an indicator of the cumulative effect of efforts to improve patient safety in the perioperative setting over the decades.

2. Overall conclusions, relevance and recommendations

This thesis comprises a literature review and eight original studies, five of which have been published in scientific peer-reviewed journals, one is currently in review for publication (Chapter 9), and in two cases, manuscript drafts are presented (Chapter 4, 8). In addition, and as a consequence of the study presented in Chapter 7, one own review article is presented in Appendix VIII. Approval by the Research Ethics Committee given for each of the studies (see Chapters) and Ethical oversight was provided by JCU, Approval Notice H3805, Appendix X.

Triggered by the intention to install an Anaesthesia Preoperative Evaluation Clinic (APEC) at the Department of Anaesthesiology at Heidelberg University, as well as by a growing interest in patient experiences with the process of anaesthesia, the observations from the initial original clinical studies on patient satisfaction led to further exploration of the results in adult patients. Experiences made in the development of questionnaires in adults were then to be transferred into the research in children.

Satisfaction is a complex entity, which comprises many different aspects such as physical, emotional, mental, social and cultural factors. Satisfaction is further influenced by many known (i.e. age, gender etc,) and also unknown variables[6, 7], by the triangular relationship of the patient-clinician-organisation as well as factors other than anaesthesia (i.e. surgery). Satisfaction is defined as the result of the internal and individual comparison between patient's expectations and perceived outcomes.[8] Most of the scientific literature claiming to accurately assess patient satisfaction with anaesthesia focuses on the assessment and management of purely objective outcomes.[9-13] Other studies are using non-validated instruments or poorly developed tools, which may lead to bias and inaccurate results.[14]

The basic research on adult and paediatric patient satisfaction and the knowledge gained during the development of the instruments provided the basis for subsequent studies. Thus, I was able to compare different instruments (Chapter 4), satisfaction with the APEC (Chapter 5) and different patient groups (Chapter 7). The considerable

scientific, clinical and economic interest to evaluate experiences of the different patient groups with anaesthesia, the pre-anaesthetic consult, as well as the APEC in terms of efficiency forms the first major branch (satisfaction) of my thesis (Figure 1.1).

The second branch (IEC) answers the need and strong interest to evaluate the core data set (CDS) to achieve a precise picture of severe morbidity and mortality in patients undergoing anaesthesia in Germany (IEC). One of the main problems in comparing and analysing major morbidity and mortality and its anaesthetic contribution is that most of the published incidences vary considerably, mainly as a result of the different sources, study designs and methods used. The studies in this branch investigated and clarified the related aspects of perioperative patients outcome, namely severe (IECs (Chapter 8, 9), reflecting severe morbidity and mortality in rather healthy patients.

Anaesthesia is deemed a high risk area among the medical professions, and part of the anaesthetic process might not be consciously accessible to the patient (i.e. general anaesthesia). The anaesthesia-related risk has been significantly reduced within the last decade but the risk and the possibility of dying or suffering permanent damage is still very real.[43] The incidence of perioperative mortality directly attributable to anaesthesia also has a wide range, possibly as a result of differences in the definitions used and sources studied.[51] The actual risks of anaesthesia are not readily listed anywhere, nor are there any country or health care system specific data available and those complications recorded often differ widely between different studies.[2, 209] It therefore remains important to report anaesthesia-related IEC. IEC not only impact on patients' wellbeing, but are likely to also impact on today's cost-conscious clinical healthcare environment.[28]

In general, my studies have been performed in collaboration with other Departments of Anaesthesiology as well as the DGAI (German Society of Anesthesia and Intensive Care Medicine), Nuernberg, Germany, and the AQAI (Applied Quality Assurance in Anesthesia and Intensive-Care Medicine/Angewandte Qualitätssicherung in Anästhesie und Intensivmedizin, AQAI Ltd.), Mainz, Germany, and the Medical

Board Baden-Wuerttemberg, among others with smaller contributions (see also Collaborations and research support).

Between November 2007 and August 2010 I have been working as a specialist in anaesthesia and intensive care medicine at the Mackay Base Hospital in Northern Queensland. As a result of my clinical academic interests, I was affiliated with James Cook University School of Medicine and Dentistry as Associate Professor between 2008 and 2011. This position involved teaching clinical aspects of anaesthesia to medical students and residents. Returning to Germany, I'm working as a senior consultant in anaesthesia at the Klinikum Stuttgart, Katharinenhospital, and was appointment as chair of the working group 'Quality assurance in anaesthesia' at the medical board of Baden-Wuerttemberg in 2013.

This Section of Chapter 10 also outlines the knowledge available prior to my doctoral studies, and summarises overall results and conclusions of my studies and the contribution these studies have made to the existing knowledge on perioperative patient outcome in anaesthesia. First, the findings of each Chapter are presented together with their relevance. This is followed by overall recommendations for each branch (Figure 1.1) respectively.

Studies belonging to the first major branch (Figure 1.1) were based on the following specific research aims:

2a. The construction and practical use of perianaesthetic questionnaires for adult and paediatric patients that adhere to a psychometric design and evaluation of the APEC (Chapters 2 to 7), with the specific aims:

- **to develop perianaesthetic <u>questionnaires for adult and paediatric patients</u> that adhere to a strict psychometric design (Chapters 2, 3, 6)**

- **to compare scores of participating hospitals (Chapter 2, 3, 6)**

- **to compare existing questionnaires (Chapter 4)**

- **to compare APEC and the ward with regard to time (and as secondary outcome costs), information gain and patient satisfaction (Chapter 5)**

- **to compare satisfaction with anaesthesia in paediatric patients with and without disabilities (Chapter 7)**

The first study that is part of the main body of the thesis is presented in <u>Chapter 2:</u>
<u>The Heidelberg Perianaesthetic Questionnaire – development of a new refined psychometric questionnaire</u>
At the time of the start of the study on the first questionnaire, three psychometrically designed questionnaires had recently been published. While these surveys have important strengths and weaknesses, each of them was established and validated in social contexts different from our own, none was checked by different test strategies

or cognitive measures and only one instrument included an item rating. One of the instruments was only available commercially. Many studies also fail to make adjustments for confounding variables.[66, 89, 91, 126]

The study presented in Chapter 2 reports the psychometric and multicentre development of a new instrument, the Heidelberg Perianaesthetic Questionnaire (HPQ) to assess patient's satisfaction. For construction and validation I was able to recruit a total of 1398 patients and 59 health care professionals. Relevant items were rated for preferences; the resulting questions underwent a cognitive and a pre-test. Among 38 questions, five factors/dimensions of care could be identified and good to excellent internal consistency was demonstrated. The scores were adjusted for confounding variables by multivariate analysis.

After passing through several phases, the HPQ can now be considered:

- a psychometric, reliable and valid tool to assess satisfaction with anaesthesia care;
- allows the distinction between satisfied and dissatisfied patients with non-overlapping satisfaction ranges; and
- implies a structure that enables a detailed view of the relevant domains involved.

The HPQ was also used as a benchmark tool in this study to evaluate differences in patients' satisfaction between hospitals.

The relevance of the HPQ as a psychometrically sound instrument is recognised in a recent review[14] and it has already been used in different scientific studies.[210, 211] In addition, it has been put into clinical routine use at various hospitals in Germany, Brazil, Great Britain and Ireland, were it was verified that the questionnaire is easily administered and understood by the patients. At my own institution, it is used on about 500 patients per year for quality assurance. This questionnaire holds the key to meaningful feedback data from our patients and the data identify and address areas that require improvement. In addition to the original publication of the study, I also presented the findings (including abstract) at an international conference.

Chapter 3: Development of a questionnaire to assess patients experiences with anaesthesia ("EFA")

My second major study aimed at developing a national questionnaire, where results and experiences of three regional questionnaires were merged into a single, national questionnaire to allow a broader (in terms of area of distribution and patients' population), nationwide patient spectrum to be represented. Again, a maximum of psychometric rigour was applied in this multicentre study where a total of 1048 patients were included and analysed in detail.

The methods were derived from the previous study (Chapter 2) and the study merged three German questionnaires, including the HPQ into a novel, single, national psychometric designed questionnaire, applying the same psychometric rigour. The final version consists of 33 questions in eight dimensions (by content analysis) with good to excellent internal consistency. Of importance, patients overall scored 71.9%±13.6% (range 27.3% – 97%) on the scale, with even lower scores for some of the dimensions. It thus can be stated that there is still ample room for further improvement.

This instrument has been published and subsequently found its way into practice by having been officially endorsed by the DGAI to be used for the CDS (core data set) nationwide for quality assurance.

Chapter 4: Establishing a perianaesthetic patient satisfaction questionnaire by cross validation of three questionnaires - a quality control study

In this Chapter, my own instrument, the HPQ as developed and discussed in Chapter 2, was compared with two other instruments. One, the PPP33 had already been used in Chapter 3, the third, the EVAN-G had been established in a different socio-cultural background. The EVAN-G was used after back-to-back translation and all questionnaires underwent parallel validation. With 219 patients recruited and 184 patients analysed, the study presented in Chapter 4 compared three psychometric questionnaires on patient satisfaction with anaesthesia. All instruments were of good reliability while only moderate correlations between the total scores of the questionnaires was found. The PPP33 took the shortest time to answer, the EVAN-G had the lowest total score, indicating a greater ability to measure dissatisfaction but

had substantially more missing items assessing pain and discomfort. This indicates that the instrument that has been constructed and validated within a different socio-cultural background and language is less easily applied.

This is of particular interest as other authors have also identified a number of questionnaires that were used in other socio-cultural backgrounds than they were validated for, together with their questionable validity and reliability after translation.[14] My study is the first to co- and cross-validate instruments from different socio-cultural backgrounds using instruments originating from the background in question as controls.

Chapter 5: The Anaesthesia Preoperative Evaluation Clinic (APEC): A prospective randomised controlled trial assessing impact on consultation time, direct costs, patient education and satisfaction with anaesthesia care

The APEC – one of the stimuli for the first study (Chapter 2) – was evaluated in this study for the length of time for each consultation, the amount of information that is passed on to patients and the level of patient satisfaction. The study included 174 patients. The time for the consultation in the APEC was shorter compared to the ward, more information was passed to the patients seen in the APEC, while general satisfaction scores were comparable. I was able to show in this study that the APEC reduced consultation times and costs by 6.47 € (9.33 AU$) per patient and that the APEC consultation had a positive impact on patient education. The cost savings are related to personnel costs and therefore independent of other potential savings of an APEC. APECs have not been universally adopted in Europe and this study aimed to create the evidence base for the establishment of further APECs as effective and efficient clinics.

In addition to the publication of this study, the editors of Minerva Anesthesiologica have published an invited editorial on the topic, underlining the magnitude of my findings.[212]

Chapter 6: Paediatric Perianesthesia Questionnaire: development and data from eight hospitals across Germany

As our department caters for patients of all age groups, we were also interested in satisfaction of our paediatric patients. By comparison to other available instruments, that display hardly any psychometric features, it was constructed using the same methods and psychometric rigour as the prior discussed studies on adults (Chapter 2-4). Assessing children's satisfaction with anaesthesia care is especially complex as children are suggestive and explicit memory is not developed before around 3 years of age.[16] Thus, opinions about satisfaction with care are rarely sought from children but have previously been substituted by parental opinions of satisfaction with care. Furthermore, the simplicity[17] or the focus on certain[18] or some general aspects[19, 20] of the anaesthetic experience pose further limitations on the assessment of children's satisfaction with anaesthesia using the previously available instruments.

For the construction and validation of the PPQ, 1085 children and families participated in the process of construction and validation. The final PPQ comprised 37 questions forming five dimensions, to be answered either by the child or by parents/carers, if possible in conjunction with the child. A history of previous anaesthetic problems and the identity of the person answering the questionnaire were also included and found to be relevant influencing factors on the sum score. I could show that the most important differences between satisfied and dissatisfied children were found for the dimensions 'privacy and waiting', 'information' and 'discomfort' and that the scores differed between hospitals.

The study resulted in a sound psychometric questionnaire that constitutes a novel approach to paediatric patient satisfaction with anaesthesia care and especially covers areas perceived as important by children, parents and carers. It can be considered a benchmark study for investigating paediatric patients' satisfaction with anaesthesia.[14] It has already been put into clinical practice at our institution as well as various other hospitals not only in Germany but also worldwide (Colorado, United States of America (USA); Brazil; Great Britain and Ireland). It constitutes a relevant aide to clinicians in the identification of areas in their routine clinical work that require improvement. In addition to the publication of the study, the results were presented (including abstracts) at two national conferences.

Chapter 7: Paediatric patients with disabilities – assessment of satisfaction with anaesthesia

This study constitutes the first ever study to evaluate satisfaction with anaesthesia in children with disabilities and their families. One of my co-authors, Nicolai Russ, whose son has trisomy 21, 'Down syndrome', was especially interested in this area.

The study comprised two groups, a group of children with disabilities and a group of children with Down syndrome (215 disabled children; 125 answers from Down syndrome journals, 90 from the hospitals). The results were compared to matching controls drawn from patients included in the study presented in Chapter 6. Satisfaction was lower in both groups with disabilities, with the group of Down syndrome patients scoring the lowest. In both of the disabled patient groups, fewer would choose the hospital or anaesthetic department again. In addition, negative comments were related to the anaesthetists' behaviour during the consultation, the content of the consultation, and how anxiety was dealt with. A special concern identified in this study was that it was perceived that the anaesthetist did not discuss the common abnormalities that are relevant to the anaesthetic procedure during the consult. This has prompted me to author a review article focusing on the common abnormalities and their relevance to the anaesthetic treatment encountered in patients with Down syndrome, which is presented in Appendix VIII.

<u>General remarks and recommendations on the construction and use of perianaesthetic questionnaires for adult and paediatric patients that adhere to a psychometric design and evaluation of the APEC (Chapters 2 to 7)</u>

Based on the evidence found by my studies, it can be recommended that clinicians and researchers incorporate validated measures into everyday practice and in clinical studies. Patient satisfaction should be measured and reported fairly and accurately, using psychometric questionnaires that take the complexity of patient satisfaction into account. Only a psychometric questionnaire comprises the multiple items necessary to probe specific aspects to determine patients' satisfaction with their care. Unfortunately, the vast majority of questionnaires are set up intuitively and do not adhere to psychometric protocols.[6, 14, 47]

In the development of such an instrument, patient's involvement is of paramount importance and thus has to form an integral part of the development. Only with the application of cognitive measures and the inclusion of confounding variables, will accurate analysis of patient's level of contentment be possible. Practicable test strategies need to be defined for routine application. Finally, the validated psychometric questionnaire may be used to benchmark different hospitals for satisfaction with anaesthetic treatment.

It is important to realise that a person answering the questionnaire other than the patient will distort results. It is thus recommended that when proxies are used to collect information on behalf of the patients in the treatment process, to include this fact as a potential confounder (Chapter 5).

Based on the evidence found by my studies, it is also recommended that questionnaires, which are to be used from different socio-cultural backgrounds, first have to be tested for validity, reliability and comprehensibility. This will minimise potential problems that are part of the differences in patient's expectations and of the different settings (health care systems etc.) where the questionnaire originates from.

As result of my studies, areas where anaesthetic treatment may be improved were found in the discomfort dimension, e.g., to thirst, pain, drowsiness, and problems with waking following anaesthesia for adults. Further differences were found in other

dimensions, such as fear of the procedure and anaesthesia, bad quality of sleep prior to the procedure, and anxiety about long waiting periods, and being left alone. In children, the evidence of my studies points to the areas where satisfaction could be improved: pain and its treatment, the immediate recovery period following anaesthesia, the waiting period, privacy, the response to the needs/wants of parents/children in the recovery room, reassurance by the anaesthetist and, as found in other studies, the information given during the consult (Chapter 6). Areas of concern in families with disabled children relate especially to the way information was given and the amount of information received (Chapter 7).

Taking into account my findings of satisfaction among the paediatric patient population given in Chapter 6 and 7, as well as the information given in Chapter 4 (the evaluation of the APEC), the establishment of APECs is strongly recommended where they have not been adopted as yet. The APEC allows the anaesthetists to review the patient's records and general health questionnaires, see and examine the patients and give the information needed to explain the perioperative course of the planned anaesthesia procedure(s) with less time restraints and in a more professional environment. This will address some of the concerns encountered and will allow to specifically teach young registrars to put emphasis on children's and families' needs. In addition, my studies delivered evidence that the APEC improves the cost-efficiency of the hospital, not only by decreasing costs for routine laboratory tests, patient cancellations and their hospital stay, but also for savings that are related to personnel costs and are therefore independent of other potential savings in the downstream process (Chapter 5). Additional to the publications mentioned so far, my studies also resulted in invitations to numerous conferences as invited speaker on the topics presented in this thesis.

Studies in the second major branch of Figure 1.1 were based on the availability of the CDS and the need to assess severe IEC and mortality in an effort to generate reliable estimates for anaesthesia-related mortality in Germany. The studies belonging to the second major branch (Figure 1.1) were based on the following specific research aims:

2b. Analysis of severe IEC and mortality in healthy patients and the anaesthetic contribution (Chapters 8, 9), to:

- **evaluate the general quality of the collected (core) data (set) (CDS) (Chapter 8)**

- **assess the frequency of coding errors in ASA PS 1 and 2 Patients (Chapter 8)**

- **elucidate the underlying mechanisms that led to the severe IEC (Chapter 8)**

- **identify filtering methods that could be used in future studies (Chapter 8)**

- **assess the frequency of severe IEC in healthy patients in the whole dataset and the anaesthetic contributions (Chapter 9)**

CHAPTER 8: Case analysis of unexpected critical incidents in ASA PS 1 and 2 patients derived from a benchmarking project in anaesthesiology

Giving details about all risks for critical events involved in an anaesthetic procedure form an important part of the anaesthetic consult as presented in Chapter 5. Unfortunately, no standardised worldwide registry system exists that would allow the thorough estimation and reporting of critical incidents, including incidences by surgical subtypes, by anaesthetic subtype, or for specific patient groups.

My first study in the second branch (Figure 1.1) evaluated first the quality of the collected CDS, the data of which were collected mainly in the federal state of Baden-Wuerttemberg. Second, it was aimed to analyse the events behind the IECs coded by analysing reports received by mail from the hospitals. The data of 366,334 ASA PS 1and II patients were available for the years 2002 to 2004. Data entries of 516 rather healthy ASA PS 1 and 2 patients for which severe IEC had been coded in the CDS were found. Queries for all of these 516 cases were sent by the Medical Board by mail to the respective departments between 2002 and 2010, and 317 anaesthetic reports were received. I was able to analyse a total of 160 cases with correct codes of IEC and ASA PS based on the answers from the anaesthetic departments, while the remainder

represented false codings. The number of participating hospitals represented a total of 176,535 records from ASA PS 1and 2 patients as denominators in the dataset. Using the reports received from the hospitals, the 160 cases were classified into groups indicating that the majority of IECs with severity grade 4 (problem cannot be solved in the PACU and patient has to be transferred to ICU) were due to organisational problems, where patients had been admitted to ICU (for example) for safety issues. Only a small fraction, 15% of the 160 cases were noticeable or conspicuous events. To specify filtering methods to be used in future studies, I also analysed the 516 cases in the CDS for codes that could result in higher ASA PS of the patients. As a result I have found that about 30% had two or more relevant risk factors coded, indicating coding errors. Comparing this finding to the answers received from the hospitals, this was about the same percentage of coding errors, indicating that for futures studies, risk factors may be used as a filter to reduce case with false ASA PS 1 and 2 codes.

This is the first study to analyse a large, national database on routine anaesthetic data and resulted in invitations to one international and two national conferences as invited speaker, with a total of two published abstracts.

Chapter 9: Major Incidents, Events and Complications (IECs) in ASA PS 1 and 2 Patients Undergoing Elective Procedures – Results Based on 1.36 Million Anaesthetic Procedures

Mortality is a risk with a clear definition, in contrast to the more debatable definitions of morbidity. Mortality is a rare complication of anaesthesia, and comparisons between studies on anaesthesia-related or anaesthesia-solely caused mortality are difficult to interpret since often different criteria are used to define anaesthetic death and varying definitions separating anaesthetic and surgical factors are used. Consequently, a wide range of estimates on perioperative anaesthetic mortality can be encountered in the literature.[2, 27]

In this Chapter, the incidence of severe perioperative outcomes in healthy patients in ASA PS 1 and 2 undergoing elective procedures was determined using all data entries in the CDS between 1999 and 2010. The study represents data from Germany, using a national database with 3,971,161 anaesthetic records, based on the core dataset (CDS). Nominal group techniques were used to determine overall severe outcomes as

well as direct anaesthetic involvement in the 84 cases identified in the CDS where the underlying problem (IEC) codes suggested such an involvement. The study used filters as determined in Chapter 8 and found a rate of major complications for healthy patients undergoing elective surgery in the CDS of about 3 per 100,000 and about 1 per 100,000 for events identifiable as being anaesthesia related (such as difficulties in airway management). In the database, 1,364,678 ASA PS 1 and 2 patients met criteria of being rather healthy and undergoing non-emergency procedures during normal working hours.

This is the first study analysing severe IEC in rather healthy patients using routine data of a nationally employed dataset. It resulted in evidence-based incidences of severe anaesthesia-related morbidity and mortality. This evidence was predominantly achieved by a reliable number of anaesthetic procedures as denominator – in contrast to the most published studies that had to rely on debatable estimates of the total number of conducted anaesthetic procedures only.

This study resulted in invitations to two international conferences as invited speaker, with a total of two abstracts and full article published in the conference proceedings.

<u>General remarks and recommendations on the analysis of severe IEC and mortality in</u>
<u>healthy patients and the anaesthetic contribution (Chapters 8, 9)</u>

Mortality *per se* has a clear definition in contrast to the more debatable definitions of morbidity. In anaesthesia, however, mortality is a very rare complication and different criteria are used to define anaesthetic death. Moreover, varying definitions are employed to separate anaesthetic from surgical factors. Thus a wide range of estimates on anaesthesia-related mortality is encountered in the published literature. Based on the results of my literature review, I would recommend the establishment of a worldwide registry system to allow reporting of reliable information, including outcomes by surgical subtypes, by anaesthetic subtype, and by patient risk groups. Furthermore, anaesthetic-related mortality should be reported, using a consistent timeframe and standard definitions to class mortality and the relation to anaesthesia in order to achieve comparable and reproducible results.

As a result of my study in Chapter 8, I found that up to 50% of the cases had coding errors. Thus, measures to improve the quality of the data collected with the CDS need to be taken. I recommend the following approaches to improve data quality:

- A mandatory reporting of all deaths or severe IECs under anaesthesia or where anaesthesia is sought to be a contributing factor. This could be achieved for instance by state regulations and would certainly increase the accuracy of the numerator.
- At the same time, a system to collect reliable information about the number of all anaesthetic procedures - i.e. the denominator – has to be put in place. While the CDS could be used for the hospitals participating in the project, for Germany the quality assurance report could be utilised. This report has already been issued annually by every institution across Germany (by law), and includes the total number of anaesthetics administered by each hospital.

While these goals are hard to achieve, the distribution of knowledge about the frequency of coding errors as found in my studies could in turn lead to education programs that may reduce the number of coding errors in the CDS. In fact, I have presented these numbers at various national conferences and have received some

feedback concerning necessary action to be taken. In addition, we have issued a letter by the Medical Board addressing the issue of coding problems.

The analysis of the rather healthy population of ASA PS 1 and 2 patients as used in Chapter 8 and 9 circumvents the problem of the influencing factors of co-existing disease and will allow comparison of the contribution of anaesthesia to severe morbidity and death.

3. Open questions and future research plans

Regional anaesthesia is gaining increasing popularity, partly due to improvements in safety and success attributed to ultrasound guided techniques.[168] Numerous studies concerned with satisfaction with anaesthetics can be found in the published literature. However, a recent review on patient satisfaction by Barnett et al. identified only one single tool, which used a psychometric development and evaluation process to construct a questionnaire measuring satisfaction with regional anaesthesia in the non-obstetric setting.[14, 208] Despite growing interest in evaluating the efficacy and outcomes of regional anaesthesia, this lack of validated tools for measuring satisfaction with regional anaesthesia has also been observed by other authors[46]. Thus, there is an urgent need to develop a sound psychometric instrument to have this growing part of anaesthesia properly assessed for patient satisfaction. Based on the findings of the studies on satisfaction, I plan to develop a revised version of our HPQ devoted to patient satisfaction with regional anaesthesia. This study is currently being planned.

The other instrument**, the questionnaire to assess patients experiences with anaesthesia ("EFA", Evaluierter Fragebogen Anästhesie)**, as presented in Chapter 3 is planned for further validation and refinement. Subsequently, data will be collected for a nationwide benchmark analysis as planned by the DGAI.

For the general assessment of patient satisfaction with anaesthesia, a number of questionnaires have been psychometrically developed in a variety of clinical specialties and settings. Some of the questions frequently found in satisfaction surveys are whether patients would choose the same hospital or anaesthetic department again, and whether they would recommend the hospital or department to their families and friends. This can be considered an ultimate question, similar to the promoted 'net promoter system', which reflects the building of customer relationships worthy of loyalty by treating customers so well so that they become loyal promoters of the business. This is a statement from the world of business and economics.[213] One of the analysed studies considered patient loyalty as an external criterion to evaluate the nomological/convergent validity of the PSPACq. Hence they analysed a group of

100 patients who completed the PSPACq and a 5-item patient loyalty scale within 48 hrs and found that the correlations between patient satisfaction and loyalty items were all statistically significant.[82] While there is substantial evidence from research that patient satisfaction could significantly predict patient loyalty, there is little mention of what this prediction really means in terms of patient (customer) behaviour.[214-217] The medical literature is almost silent about this phenomenon – that is, the proportion of dissatisfied patients who do complain and will tell their families, friends etc., or the fraction of patients who are really satisfied and hence become loyal customers telling their friends about their positive perceptions of the hospital and its facilities. Word of mouth (WOM) is one way of communicating, while there are multiple other canals of communication. WOM is said to be one of the most influential canals of communication and is received from 'people like me' in contrast to marketer initiated communications, and therefore given high credibility.[218] Having assessed patient satisfaction in Chapters 2 to 7, the natural questions that arise are: 'What follows after (hospital/anaesthetic) discharge? How will satisfied and dissatisfied patients behave in terms of the WOM 'propaganda'?' The medical literature does not give much information about how dissatisfied and satisfied patients 'behave'. It remains practically unknown if and how they communicate good and bad experiences and what factors influence their behaviour. To shed some light on these issues, I am currently conducting a study to assess WOM behaviour in satisfied and dissatisfied patients. Based on the findings of the studies presented in this PhD thesis and on the literature review, I will aim:

- to assess the communication channels that were important to the patients when choosing a hospital;
- to evaluate which channels patients are using to distribute their experiences;
- to show what influences patient's satisfaction after hospital discharge (i.e. perceived health problems, prolonged sick leave, unplanned doctors consultations etc.); and
- to evaluate how often satisfied patients communicate their good experiences and how often dissatisfied patients communicate their bad experiences.

This study was approved by the ethical committee of the federal country Baden-Wuerttemberg (No F-2012-o14) and is already recruiting patients.

I will also be involved in future evaluations of the CDS where some novel work just started. The current projects will aim at assessing the database:

- to build a cross validated multifactorial index of perioperative risks for adults undergoing anaesthesia;

- to assess the possible economic impact of different preoperative anaesthesia-related incidents, events, and complications on post-anaesthesia care/ICU utilisation; and

- to assess patient sub-groups for the incidence of IEC (i.e. smokers, malnourished etc.)

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LIST OF APPENDICES

APPENDIX I: ADDITIONAL TABLES - ADULT PATIENT SATISFACTION

Table 1.4: Studies on adult patient satisfaction; Conception of questionnaires

Author	Year	No of Hospitals/ Institutions/Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No of Items	No. of dimensions (no. of questions)	Response Format
Auquir et al.[91]	2005	eight (four university hospitals)/France	977/874 (89.4%)	GA; elective surgery (except obstetric), or endoscopic procedures requiring GA (excluding: MAC, RA)	4-48hrs post procedure	26 items	six by PCA: attention (5), privacy (4), information (5), pain (5), discomfort (5), and waiting times (2)	self-administered, questionnaire: EVAN-G; 5-point-Likert scale; scores transformed into 0–100 scale for satisfaction
Bauer et al.[4]	2001	single institution (university hospital)/ Germany	700/589 (84%)	GA; elective general, vascular, trauma, urological, ENT, gynaecological surgery	2nd post-operative day (POD)	15 items	two: anaesthesia-related discomfort (10) and satisfaction with anaesthesia (5)	interview and self-administered questionnaire, anaesthesia-related discomfort 3 point-, satisfaction with anaesthesia 4-point-Likert scale
Bothner et al.[64]	1996	single institution (university hospital)/ Germany	282/249 (88%)	orthopaedic surgery	<= 4th POD	10 items	satisfaction (2), physical symptoms (8)	self-administered questionnaire; dichotomus y/n
Brown et al.[116]	1997	single institution (university hospital)/ USA	315/239 (75.9%)	GA (83%)	middle of the month after procedure	10 items	four: overall care (1), scheduling (2), anaesthetic care (4), results (3)	mail back, self-administered questionnaire; 4-point-Likert scale
Caljouw et al.[15]	2008	single institution (university hospital)/ Netherlands	382/307 (80.4%)	GA 83.5%; general, gynaecological, orthopaedic, urological, obstetrical, plastic surgery	in hospital, <48hrs post procedure	39 items	three by PCA: information (4), fear and concern (7), staff–patient relationship (14), additional questions: discomfort and needs (7), professional competence with problems (4) and service (3)	self-administered questionnaire: LPPSq; 5-point-Likert scale, scores range between 21- 105 points
Capuzzo et al.[66]	2005	single institution (university hospital)/ Italy	279/219 (75%)	GA (93.6%); general surgery (abdominal, thoracic, surface)	morning of 2nd POD	10 items	three domains: physical (2), emotional (4), relational (4)	face-to-face interview, NRS 0-10

Author	Year	No of Hospitals/ Institutions/Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No of Items	No. of dimensions (no. of questions)	Response Format
Capuzzo et al.[3]	2007	four (three teaching, one nonteaching hospital)/ Italy	1506/1290 (86%)	GA (67%); orthopedic, urological, abdominal, endocrine, vascular, gynecological, thoracic surgery and other	1-2 days post procedure	10 items	three domains: physical (2), emotional (4), relational (4)	self-administered with assistance, NRS 0-10
Fleisher et al.[114]	1999	single institution (university hospital)/ USA	372/229 (60.4%)	GA (65%), MAC (35%)	outpatients	6 items (incl. one global satisfaction)	no specific dimensions	mail-back: pre-paid envelope, self-administered or interview if questionnaire not returned >2 weeks, satisfaction 5-point- Likert scale
Gaszynsky et al.[106]	2011	single institution (university hospital)/ Poland	42	general surgery		11 satisfaction items (18 total)	no specific dimensions	self-administered, dichotomous y/n
Hadjistavro-poulos et al.[113]	2001	single institution (university hospital)/ Canada	1018/268 (26%)	GA (76%); general medicine, general, neurosurgery, obstetrics/ gynecology, ophthalmology, orthopaedic surgery, paediatric, plastic surgery, psychiatry, urology, vascular surgery	sent to patient 2-3 month post procedure	35 items	PCA in the original study, six subscales: information provision, involvement in care, respect, community transition, physical comfort, and emotional	mail back, self-administered 5-point-Likert scale
Heidegger et al.[89]	2002	six hospitals, multicentre study/ Switzerland	3785/2348 (62%)	GA (74.5%), RA	1-2 weeks post procedure	29 items	six by PCA: information/ involvement in decision making (9), respect/ confidence (6), delays (4), nursing care in recovery room (2), continuity of personal care by anaesthetist (4), pain management (4)	mailed questionnaire, including reminder letters after 2 weeks, 3-point-Likert Scale

Author	Year	No of Hospitals/ Institutions/Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No of Items	No. of dimensions (no. of questions)	Response Format
Hüppe et al.[107, 108]	2000 and 2003	single institution (university hospital)/ Germany	1490/1112 (74.6%)	GA (91.2%); general, trauma/orthopaedic, plastic surgery, other	first (41.6%) second (18%), third (14.5%) POD	part I (19 items post OP, 17 items for > 1 POD); Part II 10 items	part I physical problems (19 items post OP, 17 items if > 1 POD); Part II satisfaction: three dimensions: perioperative anaesthetic care (4), unspecific perioperative care (4), postoperative reconvalescence (2)	self-administered, 4-pointLikert-scale
Hüppe et al.[109]	2005	22 institutions with cardiosurgery, mulicentre study/ Germany	2120/1688 (79.6%)	GA for cardiosurgery	1-4 POD (39%) and 5-8 POD (61%)	part I (19 items post OP, 17 items for > 1 POD); Part II 10 items	see above	self-administered with assistance, 4-point Likert-scale
Jlala H et al.[112]	2010	single institution/ United Kingdom (UK)	157/100 (74%)	GA (50%), RA (50%)	<= 3 POD (return to box on wards)	39 items (24 items) (dimension discomfort and needs excluded, due to low reliability)	english adaption of the LPPSq, with information provision (6), discomfort and needs (9), fear and concern (4), professional competence (3), patient-staff relationship (14) and service (3)	self-administered, questionnaire: LPPSq, 5-point-Likert scale
Kouki et al.[110]	2012	single institution (university hospital)/ Greece	370/345 (93.2%)	GA (82%), RA (18%)	1 POD	Q1 general (GA+-RA) (8), Q2 (RA) (7), Q3 (post OP analg. service) (10)	by PCA four Q1: communication with the anesthesiologist (3), sense of cold/ shivering (2), pain and perception of noise (2), and sense of nausea (1); three Q2: communication with the anesthesiologist (3), sense of cold/ shivering(2), and nausea and anxiety (2); five Q3: anesthesiologist intervention upon symptoms (3), pain (1), care by the anesthesiologist/ physical activity (3), nausea/ vomiting (2), and anesthesiologist behaviour (1)	4-point-Likert scale, with a few in a binary/ dichotomous (yes/no) format

Author	Year	No of Hospitals/ Institutions/Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No of Items	No. of dimensions (no. of questions)	Response Format
Le May et al.[7]	2001	single institution (university hospital)/ Canada	T1 179/170 (94.9%) and T2 170/ 133 (78.3%)	GA: cardiosurgery	T1 4-5 POD, T2 15 d post discharge	17 items	four by PCA: patient/ anaesthesiologist interaction (7), preoccupations related to anaesthesia (4), experience with anaesthesia (4), pain management (2)	6-point-Likert scale, T1 interview, T2 self-administered mail-back questionnaire
Mui et al.[81, 82]	2009/ 2011	single institution (university hospital)/ Taiwan	1300/1110 (85.4%)	GA (20%), RA (80%)	6-48 hrs post procedure	30 items	seven by PCA and CFA: provider-patient relationship (7), information (5), anaesthesia related sequelae (4), fear (3), concern (3), discomfort and needs (4), waiting period (4)	self-administered, 5-point-Likert scale
Myles et al [67]	2000	single institution/ Australia	17106/10811 (63%)	General, orthopedic, cardiothoracic, neuro, vascular, urology, gynecology, ENT, ophthalmologic, burns, plastic surgery and others	24 hrs post procedure	one global question on satisfaction with anaesthesia	see above	interview, VAS three point scale
Schiff et al.[126]	2008	three hospitals, multicentre study/ Germany	1265/912 (84%)	GA (93%); trauma, gastrointestinal, vascular, urology, gynecology, neurosurgical, ENT, ophthalmology, thoracic surgery	32 hrs (6–48 hrs)	38 items	five by PCA: trust and atmosphere (6), fear (6), discomfort (13), treatment by personnel (6), information and waiting (7)	self-administered, 4-point-Likert scale,

Author	Year	No of Hospitals/ Institutions/Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No of Items	No. of dimensions (no. of questions)	Response Format
Schiff et al.[127]	2008	five (multicentre, including four university hospitals)/ Germany	580	GA	6-48 hrs postprecudure	33 items	eight (content analysis); information (3), trust (4), treatment and appraisal (2), atmosphere (4), recovery (4), autonomy (4), analgetic treatment (5), treatment of postoperative problems (5)	4-point Likert-scale
Sindhvanan-da et al.[111]	2003	two hospitals (one university hospital)/ Thailand	380/272 (71.6%)	GA, obstetric-gynaecology, orthopaedic, general, ENT, eye surgery	24-48 hrs post procedure	10 items	three by PCA: pre-anaesthetic visit (2), anaesthesia service in OR (3), post-operative anaesthesia care (4), one question for general satisfaction	self-administered 5-point-Likert scale
Thierbach et al.[115]	2003	single institution (university hospital)/ Germany	519	GA (76.3%), RA (23.7%); trauma/orthopaedic, general surgery	first and third POD	9 items	no specific dimensions	self-administered, five point VRS
Tong et al.[45]	1997	single institution (university hospital)/ Canada	5228/2730 (52%)	GA (59%), MAC (39%)	24 hrs post procedure	one global question on satisfaction with anaesthesia	NA	telephone interview, 3-point scale (poor, good, excellent)
Whitty et al.[99]	1996	single institution/ UK	172/126 (73%)	GA	at home	44	eight (chronological & themes): before hospital (3), before the operation (14), the operation (8), after the operation (5), at home (1), looking back (8), about yourself (4), open question (1)	mail-back, self-administered, 5-point-Likert scale
Zvara et al.[68]	1996	single institution (university hospital)/ USA	151/144 (95.3%)	general, thoracic, vascular, urologic, gynecologic, and orthopaedic surgery	2 day after last post op visit	10 items	overall satisfaction with care (2), patients' perception of and satisfaction with anaesthesia and the anaesthesiologist	interview, either face-to-face or by telephone, 5-point-Likert scale

Table 1.5: Studies on adult patient satisfaction; Validity and reliability

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Auquir et al.[91]	y	patients (face-to-face-interviews, recorded & transcribed), literature review, open ended questions	29 and 171 Patients/ no: some items contain more than one idea/ not stated	content validity, face validity, construct validity (IIC, IDC, IDV), convergent validity (external validity: MGPQ, STAI; discriminant validity (correlation of scores between groups:age, sex, ASA etc.)): global score correlated poorly with age (only >65) ASA PS,	0.73 - 0.91	intraclass correlation coefficient 0.72 - 0.81	9 (SD 7) min	no rating
Bauer et al.[4]	y	expert opinion (nurses and anaesthetists), literature search	yes, 40 patients/ y/ not stated	content validity, face validity, no test for gender or age	0.84	re-test (McNemar, no difference) after 3 days		no interviews, incomplete validity testing, no PCA, no open questions, no staff related questions (behavior/treatment), no rating
Bothner et al.[64]	IC	not stated, use of questionnaire as recommended by the DGAI[118]	no/ y/ not stated	no	no	no		single satisfaction question
Brown et al.[116]	n	no	no/ y/ not stated	no	no	no		instrument drafted by researchers, no testing whatsoever, despite patients being very satisfied or satisfied and none dissatisfied, the researchers found a lot of negative comments!

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Caljouw et al.[15]	y	using results from Auquir et al., open-ended questions, rating	yes, 50 patients/ y/ not stated	content validity, face validity, construct validity (IIC, IDC, IDV), convergent validity (discriminant validity (correlation of global score between groups: gender, age, and work situation; and clinical features: surgical procedure, specialty, earlier operated, and type of anaesthesia); satisfaction: women<men, younger age (<50 yrs)< older; patients with employment < household duties and retired	0.69 to 0.94 (0.9) (21 questions)			PCA from only the best loading factors, omittance of analysis of a total of 18 questions for validity and reliability, face and content validity only by expert opinion and pilot study, no rating
Capuzzo et al.[66]	y	expert opinion (nurses, doctors, experts in communication science), literature search, face-to-face-interviews, rating for relevance and importance, open ended questions	yes, 100 patients/ y/ not stated	construct validity, face validity, convergent validity (discriminant validity (correlation of global score between groups: age))	0.84	Inter-observer and test-retest reliability (combined), >0.75	9 min (ICR 8-10 min)	use of rating, short, serves as pilot study
Capuzzo et al.[3]	y	see Cappuzzo et al. 2005	yes, 100 patients/ y/ not stated	see above plus: discriminant validity (correlation: gender differences not observable, sign differences: age, education, perceived health, extent of surgery, type of anaesthesia, post OP analgesia managed, no of post OP visits, nurses dedicated to anaest., anaesthesia leaflet info)	0.84	see above	see above	
Fleisher et al. [114]	y	no	no/ y/ not stated	no	0.62			simple instrument, no testing, authors report having developed the questionnaire previously as part of the outpatient ophthalmologic clinical follow-up

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Gaszynsky et al.[106]	y	no particular description	no/ y/ not stated	no				instrument drafted by researchers, no testing whatsoever
Hadjistavro-poulos et al. [113]	no	no particular description [122]	no/ y/ not stated	face validity only, and only for initial study, not for the modified version used in this study, construct validity (MANOVA used for type of anaesthesia, site of service, nature of service, surgical service, NOT for age or gender)	0.86-0.94			modified instrument, despite rewording and adding of items not tested for validity except face-validity:
Heidegger et al.[89]	y	focus groups, expert opinion (recorded & transcribed), lit. review, open ended questions in pilot version	yes, 122 Patients/ ?: questionnaire & questions not printed/ y on lay members of staff	content validity, face validity, construct validity, convergent validity (influencing factors by mult. linear regression mode); mean total problem influenced by the factors age, sex, subjective state of health, type of anaesthesia and level of education	0.43 - 0.77			no retest, adjustment for confounding variables
Hüppe et al.[107, 108]	IC, y	some literature (no search criteria given), satisfaction assessed according to recommendations of the DGAI	431 (yr 2000)/ y/ not stated	construct validity (testing for effects of age (found for both) and gender (found for physical problems but not satisfaction))	0.76 - 0.91 (0.82)	only for direct post-operative (recovery) physical symptoms (state)		no lit search, no patient involvement, hardly any validity testing. First study 2000 included construction and pilot testing, second study a larger population and testing for reliability and validity
Hüppe et al.[109]			see above	construct validity tested for ANP-KA (testing for effects of age (found for both) and gender (found for physical problems but not satisfaction))	0.86 - 0.88	not separate for ANP-KA		

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Jlala H et al.[112]	(Y) waived	s. Caljouw et al.	yes, 50 patients/ y/ not stated	construct validity (age, gender IIC, IDV)	0.65 - 0.98 (0.94) (discomfort and needs 0.21)			no own lit research, no focus groups or interviews, simple adaption, poor translation process: the English adaptation generated by one bilingual researcher, then compared to the published translated version
Kouki et al.[110]	y	used results of three studies (Capuzzo, Heidegger, Auquir), open ended question	yes: Q1, 30 patients; Q2 30 patients; Q3 45 Patients/ y/ not stated	construct validity (IIC, IDC), maybe face validity (by use of former studies), influence tested for sex, age, ASA status, educational level, anaesthetists behaviour; multivariate analysis: age and anaesthetist-behaviour for GA exert sign. Influence on satisfaction	no	no	no	no focus groups or interviews, simple adaption, translation process not described, no reliability, no converged validity, maybe face validity
Le May et al.[7]	y	expert opinion, literature review,, face-to-face-interviews, pre-test, open ended questions	yes, 17 patients/ y/ not stated	content validity, face validity, construct validity, convergent validity (Marlow-Crone social desirability scale and psychological distress abbreviated form), satisfaction m>f, young>old	0.47 - 0.78 (0.58)	T1 vs. T2 comparable	15 min for interview	first study with respect to social desirability, complete psychometric design with re-test
Mui et al.[81, 82]	y	expert opinion, literature review, face-to-face-interviews, pre-test (recorded & transcribed), open ended questions	yes, 64 patients/ no, some contain more than one idea/ y	content validity (content validity coefficient (V value) and homogeneity reliability coefficient (H value)), face validity, construct validity, convergent validity, global score correlated with age, sex, educational level, types of anesthesia, and different surgical procedures	0.58 - 0.9		3-8 min	first study to use CFA as well as statistical methods (Aikens methods v- and h- value) instead of rating
Myles et al.[67]	y	not stated	no/ y/ not stated	no				single satisfaction question, embedded in QA interview.

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Schiff et al.[126]	y	literature review, patient focus groups and one-on-one interviews with relatives and health care professionals (recorded & transcribed), open-ended questions, rating questionnaire	yes, 139 patients/ y/ y fog index	content validity, face validity, construct validity (IIC, IDC), convergent validity, and external validity (STAI & APAIS); discriminant validity, global satisfaction affected by age, education, marital status	0.42 - 0.79 (0.79)		12 min (SD 7)	
Schiff et al.[127]	y	literature review, interviews with patients, relatives, health professionals (results from[107, 108, 126, 170]), open question	yes, 580/ y/ y fog index	construct, IDC, IIC, face validity, validation ongoing	0.5 - 0.9 (0.86)	no		Instrument awaits testing for validity and reliability once adequate amount of data have been generated
Sindhvananda et al.[111]	y	literature review and patient interviews (face-to-face), rating by experts	yes, 135 patients/ questionnaire in Thai/ not stated	content validity (IIC, expert ratings and correlation to items), face validity	0.88			the questionnaire has taken some of the complexity into account and proves some validity and reliability
Thierbach et al.[115]	IC	some literature used (STAI, 'Mainzer Angstinventar, 'Basler-Befindlichkeits-Skala), open questions	no/ y/ not sated	no				satisfaction aspects, more emotional satisfaction, no physical aspects (pain etc.), no global satisfaction, but indicator of satisfaction given (same anaesthetist again)
Tong et al.[45]	y	some literature used (no search criteria), cited instrument [121] validated?, open questions for dissatisfaction and satisfaction	no/ not stated/ not stated	no		inter-rater reliability for interview: 200 Patients (k>0.9)		single question, validation ?

Author	Ethic approval /oversight	Item Generation	Pilot Testing/ single ideas/ writing intricacy (understandability)	Validity tested	Internal consistency	Test-retest reliability	Time for completion	Remarks
Whitty et al.[99]	y (use of medical data)	focus groups (recorded & transcribed), some literature (no search criteria), open question	yes/y/ y fog index	content validity, face validity, no assessment for confounding variables reported (but stated in methods)				no reliability, hardly any validity testing
Zvara et al.[68]	y	none	no/ y/ not stated	no				no validation

APPENDIX II: ADDITIONAL TABLES - PAEDIATRIC PATIENT SATISFACTION

Table 1.7: Studies on paediatric patient satisfaction; Conception of questionnaires

Author	Year	No of Hospitals/Institutions/ Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No. of Items	No. of Dimensions (No. Of Questions)	Response Format
Boonmak et al.[135]	2009	single institution (tertiary care)/ Thailand	106/ 99 (93.4%)	GA/RA for ambulatory services; surgery, orthopaedic, ENT surgery, radiological investigations	telephone interview 24 hrs post discharge (1 POD)	five items (regarding: overall anaesthesia service, peri-anaesthesia care, PACU care, patient care at home)		4-point-Likert scale
Chan et al.[138]	2002	single institution (university hospital)/ China	50 parents (25 intervention and 25 control group)	GA	1 POD	18 items		5-point-Likert scale, overall satisfaction on 0-10 scale
Iacobucci et al.[17]	2005	single institution (university hospital)/ Italy	214/ 179 (84% parents, 53% children)	GA/RA for minor abdominal or genitourinary procedures	immediately after return to the ward	15 item, six for parents, nine for children		15 items, six for parents (10-point-Likert scale), nine for children (either dichotomous y/n or multiple choice (MC)
Kain et al.[136]	2000	single institution (university hospital)/ USA	111/ 103 (92%) for inclusion in study, response rate (questionnaire) 68%	GA for outpatient surgery	mail back within 2 weeks, reminder telephone call	21 items	by PCA; two dimensions: overall parental satisfaction with the function of the childrens hospital, and parental satisfaction with the separation process	VAS 5 cm
Palermo et al.[137]	2000	single institution (university hospital)/ USA	83/73 (87%)	GA for outpatient surgery (mainly general or uro-genital surgery)	in PACU	seven items (original study six items)	as single dimension derived from Kazak A et al.	7-point-Likert scale

Author	Year	No of Hospitals/Institutions/ Country	No. of Patients recruited/ analysed (response rate)	Anaesthesia and/or type of surgery	Timing	No. of Items	No. of Dimensions (No. Of Questions)	Response Format
Schiff et al.[142]	2010	eight anaesthetic departments, 2 university hospitals; 4 tertiary hospitals, 1 primary hospital; 1 secondary hospital/ Germany	1052/ 760 (71%)	GA/RA range of surgical procedures, with surgical grades: minor in 36.6%; intermediate in 51.6%; major in 8.2%; and major+ in 3.4%	4-48 h post procedure	37 items	by PCA; five dimensions: treatment of discomfort (7), privacy/waiting (10), information giving (7), discomfort (9), treatment of pain (4)	5-point-Likert scale, VAS =-10 for global satisfaction with anaesthesia and surgery, self-administered questionnaire answered by older children, or parents in conjunction with younger children
Tait et al.[139]	2001	single institution (tertiary care)/ USA	331/308 (93.1%)	GA	1 POD	30 items, eight related to satisfaction	preferences (11), concerns (11), satisfaction (8)	Telephone interview: 4-point-Likert scale, global satisfaction VAS 10 point

Table 1.8: Studies on paediatric patient satisfaction; Validity and reliability

Author	Ethic approval /oversight	Item Generation	Pilot Testing/single ideas/writing intricacy (Understandability)	Validity Tested	Internal consistency	Test-retest reliability	Time for Completion	Remarks
Boonmak et al.[135]	y		n/y/not stated					poor construction (reflects merely the researchers ideas)
Chan et al.[138]	y	some literature cited as basis of questionnaire development	y/n/n	(construct validity); test for influence of patents age, education, employment status	0.89			
Iacobucci et al.[17]	y	literature review, open ended questions	n/y/n	construct validity was examined by testing several hypotheses :for associations between the degree of satisfaction reported by the parents and some outcomes (e.g. anxiety, with regard to nursing care)	0.86	McNemar 0.79, correlation between adults and childrens answers		
Kain et al.[136]	y	empirical approach: input from anaesthetists, nurses, child-life specialists, psychologists, surgeons	y/y/n	difference between study groups, i.e. parent present vs. absent	0.93 for factor I (overall care) and 0.94 for factor I1			
Palermo et al.[137]	y	according [140]: Health care professionals involvement in group discussions, empirical literature search	n/y/n	face validity, concurrent validity with correlations to POQOLS and PSI-S, correlations to child's distress and parent and nurse observations of distress				authors added one item to original study, reassessment for validity and reliability not established

Author	Ethic approval /oversight	Item Generation	Pilot Testing/single ideas/writing intricacy (Understandability)	Validity Tested	Internal consistency	Test-retest reliability	Time for Completion	Remarks
Schiff et al.[142]	y	literature review, semi-structured interviews with patient families, one-on-one interviews with older children and healthcare professionals, rating, open ended questions	y (with probing)/y/y (fog index)	face validity, content validity, discriminant validity (IDV, IIC), convergent validity (VAS correlation), satisfaction associated with the experience of previous anaesthetic problems and the person answering the questionnaire (person other than the child's mother scored higher), no influence of gender or on the scores	0.74-0.9 (0.87)			construction and validation followed a rigourous protocol, the questionnaire was adapted for confounding variables, groups of satisfied and dissatisfied were analysed and compared between participating hospitals
Tait et al.[139]	y		n/n/Items were explained	face validity, assessment of differences between groups (education, level of participation)	preferences (0.91), concerns (0.88), satisfaction (0.9)			questions/answers not displayed for satisfaction

APPENDIX III: ADDITIONAL TABLES - MAJOR MORBIDITY AND MORTALITY

Table 1.10: Studies assessing major morbidity and mortality; Study descriptions

Author	Country	Data Source	Study Period	Denominator (No. of Anaesthetics)	Inclusion/ exclusion	primary outcome	severe morbidity (i.e. cardiac arrest etc.)	Time of Death
Arbous et al.[31, 144]	Netherlands	46 anaesthetic practices at 58 different hospitals; seven university hospitals, eight teaching hospitals; voluntary reporting system	1995-1996	calculated 869,483		death (mortality)	remained unintentionally comatose (morbidity)	24 hrs after anaesthesia
Biboulet et al. [148]	France	single institution, university hospital, voluntary reporting	1989-1995	exact 101,769	excl. ASA PS 5	perioperative cardiac arrest		during anaesthesia and the first 12 postoperative hours in the PACU or ICU
Braz et al.[151]	Brazil	single institution, tertiary teaching hospital; cases prospectively from database, forms completed by anaesthesia staff	1996-2005	exact 53718		perioperative cardiac arrest	cardiac arrest (not dead)	OR and PACU
Charuluxananan et al.[145]	Thailand	20 hospitals (7 university, 4 general, 5 tertiary or regional, and 4 district hospitals), recording in data entry form; workshop and internal audits, forms piloted by staff of 6 university hospitals to ensure compliance	2003-2004	exact 163403		perioperative Death		24 hr postoperative
Gibbs[143]	Australia	Data collected by Australian state anaesthetic mortality committees, in part voluntary reports, others mandatory as per state regulation (WA; NSW and QLD via coroner), in Tasmania reporting is condition of employment	1983-2008	indirect estimates 1991–1999, calculated (ICD-10 codes) 2000–2008		death		24-48 hrs, (Tasmania 30 days)

Author	Country	Data Source	Study Period	Denominator (No. of Anaesthetics)	Inclusion/ exclusion	primary outcome	severe morbidity (i.e. cardiac arrest etc.)	Time of Death
Kawashima et al.[149]	Japan	questionnaires sent to all JSA Certified Training Hospitals at the end of every year, data collected retrospectively, data sorted and analysed each year by members of the Committee on Operating Room Safety (n= not given)	1994- 1998	exact 2,363,038		incidence of cardiac arrest during anesthesia and surgery	other critical events during anesthesia and surgery	within 7 postoperative days
Khan and Khan [152]	Saudi Arabia	single institution, university hospital, retrospective review by two anaesthetists	1992-2006	exact 140,384 thereof (ASA1 n=29,220), ASA 2 (n=26,923)	exclusion: cardiac anaesthesia	death		within 48 hrs of anaesthesia
Kyokong et al.[147]	Thailand	single institution, university hospital, retrospective review by three anaesthetists, part of the THAI study, see Charaluxananan	2003- 2006	exact 50,409		death		within 24 hr postoperative period
Lagasse[51]	France	urban university hospital network (two institutions, one analysed period 1995-1999), multiple referral sources: the anaesthesiologists, other clinical personnel, follow-up phone call by nursing staff and concurrent chart reviewers (voluntary reporting system), standardised peer review model	1995-1999	exact 14,6548	as per peer review	death		death during operation or within two PODs
Li et al.[50]	USA	ICD-10 codes specifically related to anaesthesia/anaesthetics, codes used to identify anaesthesia-related deaths from the USA multiple-cause of-death data files	1999-2005	estimated 105.7 million surgical discharges	based on a number of ICD-10 codes, capturing the death certificates in which an anaesthesia complication or adverse event was listed among the multiple causes of death	anaesthesia related death		no limitation

Author	Country	Data Source	Study Period	Denominator (No. of Anaesthetics)	Inclusion/ exclusion	primary outcome	severe morbidity (i.e. cardiac arrest etc.)	Time of Death
Lienhardt et al.[52]	France	ICD: 9th revision manuals for codes using a variable sampling fraction, medical certifiers were sent a questionnaire, the anesthesiologist in charge was offered a peer review. Files were reviewed to determine the mechanism of each perioperative death and its relation to anesthesia.	1999	7,756,121; estimated from a national survey in 1996	list of all ICD-9 codes that might relate to anaesthesia	anaesthesia related death		no limitation
Newland et al.[150]	USA	single institution, university hospital, retrospective review by committee	1989-1999	exact 72,959		cardiac arrest		within 24 hrs of surgery
Sprung et al.[153]	USA	single institution, university hospital, retrospective review by two anaesthetists	1990-2000	exact 518,294	cardiac surgery, cardiac cathetrisation	cardiac arrest		perioperative (induction to discharge PACU or admission ICU)

Table 1.11: Studies assessing major morbidity and mortality; Results

Author	No of Procedure Deaths	Deaths per 10,000 anaesthetics			Causes of anaesthesia related deaths	(Anaesthesia) preventable deaths
		Perioperative death rate	Anaesthesia related death rate (Edwards category 1-3)	Death rate: anaesthesia solely responsible		
Arbous et al. [31, 144]	811 (769 (95%) within 24 h, 42 (5%) remained comatose (died later in hospital)	8.8 (769/869,483)	1.4 (119/869,483)		cardiovascular management 62 (52%), other anaesthetic management 57 (48%), ventilatory management 12 (10%), monitoring 12 (10%)	
Biboulet et al. [148]			0.6 (6/191,769), 0 (0/63,184) ASA 1, 0.35 (1/28,375) ASA 2, 0.12 (1/ 91,559) ASA 1 and 2		anaesthetic overdose 4 (67%), hypovolemia 2 (33%) and hypoxemia due to difficult tracheal intubation 2(33%).	all cardiac arrests (and therefore deaths) totally related to anaesthesia were classified as avoidable
Braz et al.[151]	118	21.97 (118/53,718)	1.12 (6/53718)	0,56 (3/53718)	respiratory events (55.5%) and medication-related events (44.5%)	
Charuluxanan et al.[145]	462	28.3 (462/163,403)	5.75 (94/163403)	1,71 (28/163403)	medication related events (relative overdose) 22 (23.4%), uncontrolled hemodynamic status 17 (18.1%), exangination 14 (14.9%), uncontrolled hypoxia (loss of airway, unable to ventilate) 12 (12.8%), early extubation 8 (8.5%), inappropriate post-anaesthesia care (5.3%)	Preventable death in relation to all perioperative deaths: 81 (17.5%) - may be preventable 84 (18.2%)
Gibbs[143]			1994-1996 (0.16; 1/63,000), 1997-1999 (0.12; 1/79,500), 2000-2002 (0.18; 1/56,000), 2003-2005 (0.19; 1/53,400), 2006-2008 (0.18; 1/55,500)	1994–1996 (0.07; 1:153,000), 1997–1999 (0.043; 1:220,000), 2000–2002 (0.06; 1:180,000), 2003–2005 (0.04; 1:254,000), 2006–2008 (0.03; 1:360,000)	anaesthesia technique (choice/application; airway, ventilation circulatory support), drugs (selection, dosage etc.), preoperative (assessment, management), anaesthesia management (crisis management, inadequate monitoring etc.)	deaths with no correctable factor increased from <5% in the 1991–1993 triennium to about 50% in the 2006–2008 triennium

Author	No of Procedure Deaths	Deaths per 10,000 anaesthetics				(Anaesthesia) preventable deaths
		Perioperative death rate	Anaesthesia related death rate (Edwards category 1-3)	Death rate: anaesthesia solely responsible	Causes of anaesthesia related deaths	
Kawashima et al.[149]	OR: 597; 7 days: 372	7.18 (text) (1725/2,363,038)		0.21(text) (48/2,363,038), during surgery 0.1 (text)	drug overdose or selection error (15.3%), serious arrhythmia (13.9%), myocardial infarction, ischemia, coronary spasm (8.8%), inappropriate airway-management (7.9%), inadvertent high spinal anaesthesia (7.4%), inadequate vigilance (6.9%), massive haemorrhage, hypotension (5.1%), overdose of inhaled anaesthetics (2.8%), suffocation, aspiration (2.8%), and disconnection and/or misconnection of the breathing circuit (2.3.%).	Preventable deaths totally attributable to anaesthesia: human error caused 53.2% of cardiac arrests during surgery and contributed to 22.2% of deaths in the OR, human error caused 80.0% of deaths within 7 days after surgery
Khan and Khan[152]	2	0.35 (2/56,153)	0.17 (1/56,153)	0.17 (1/56,153)	airway management (difficult intubation) 2 (100%)	
Kyokong et al.[147]	80 (25 intra-operative, 1 PACU, 54 during first 24-hours), ASA 1 0/28,283, ASA 2 8/16,541; ASA 1 and 2 1.78 (8/44,824)	15.87 (80/50,409)		0.2 (1/50,409)	airway obstruction due to tracheal granuloma	
Lagasse[51]	232; ASA 1 (4/35,025), ASA 2 (22/67,851), ASA 3 (53/34,146), ASA 4 (67/9,086), ASA 5 (86/440)	15,8 (232/146.548)	0,75 (11/146,548); ASA 1 (0/ 35,025), ASA 2 (3/ 67,851), ASA 3 (2/34,146) ASA 4 (6/9,086), ASA 5 (0 /440), ASA 1 and 2 0.29 (3/102,876)			

Author	No of Procedure Deaths	Deaths per 10,000 anaesthetics			Causes of anaesthesia related deaths	(Anaesthesia) preventable deaths
		Perioperative death rate	Anaesthesia related death rate (Edwards category 1-3)	Death rate: anaesthesia solely responsible		
Li et al.[50]	2,211anaesthesia-related deaths; 867 in hospital, 348 in ambulatory care, 46 on arrival, 258 at home, 44 in hospice, 315 at nursing homes, 327 in other places, 6 place unknown		0.21of each hospital discharge involved one anaesthetic; inpatients: 0.082 (867/ 105,700,000)	0.022 (241// 105,700,000)	anaesthesia-related deaths: overdose of anaesthetics(46.6%); adverse effects of anaesthetics in therapeutic use (42.5%); anaesthesia complications during pregnancy, labor, and puerperium (3.6%); other complications of anaesthesia (7.3%). anaesthesia as the underlying cause of death: adverse effects of anaesthetics in therapeutic use (79.7%); anaesthesia complications during pregnancy; labor, and puerperium (19.1%); wrongly placed endotracheal tubes (1.2%)	
Lienhardt et al.[52]	235 (role of anaesthesia possible or certain)		0.54 (totally and mainly related; mainly anaesthesia-related 0.47), ASA 1 0.04 and ASA2 0.5	0.069 (1/145,500)	coronary artery disease and perioperative ischemia often triggered by anemia, true hypovolemia (associated with hemorrhage), or relative hypovolemia and aspiration of gastric contents	Only in 2% of cases partially or totally related to anaesthesia, no deviation of standard practice was identified; in 56% more than four deviations were recorded
Newland et al.[150]	115 cardiac arrests		0.96 (7/72,959)	0.55 (4/72,959)	medication- related events 2 (29%), complications associated with central venous access 2 (29%), airway management 2 (29%), perioperative myocardial infarction 1 (14%))	
Sprung et al.[153]	223 cardiac arrests, 146 deaths	2.81 (146/518,294)		0.1 (5/518,294)	airway (4), neuromuscular block (inadequate reversal, 1)	

APPENDIX IV: EDWARDS CLASSIFICATION, MODIFIED

IECs attributable to anesthesia

Category 1 Where it is reasonably certain that the IEC was caused by the anesthesia or other factors under the control of the anesthetist

Category 2 Where there is some doubt whether the IEC was entirely attributable to the anesthesia or other factors under the control of the anesthetist

Category 3 Where the IEC was caused by both surgical and anesthesia factors

Explanatory notes:

- The intention of the classification is not to apportion blame in individual cases, but to establish the contribution of the anesthesia factors to the IEC

- 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 anesthesia-related IEC, subcategory H should also be applied

- If no factor under the control of the anesthetist is identified that could or should have been done better, subcategory G should also be applied

IECs in which anesthesia played no part

Category 4 IECs in which the administration of the anesthesia is not contributory and surgical or other factors are implicated

Category 5 Inevitable IECs, which would have occurred irrespective of anesthesia or surgical procedures

Category 6 Incidental IECs, 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 anesthetist or surgeon

Unassessable IECs

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

IEC= *Incidents, Events and Complications*

Categories for incidents, events and complications) adapted from Gibbs[7] and Edwards et al.[160, 167]

APPENDIX V: THE HEIDELBERG PERIANAESTHETIC QUESTIONNAIRE (HPQ)

Klinik für Anaesthesiologie
Klinische Ökonomik und
Qualitätsmanagement
in der Anaesthesiologie
Dr. med. Jan-H. Schiff
Tel.: 06221 – 56 36371
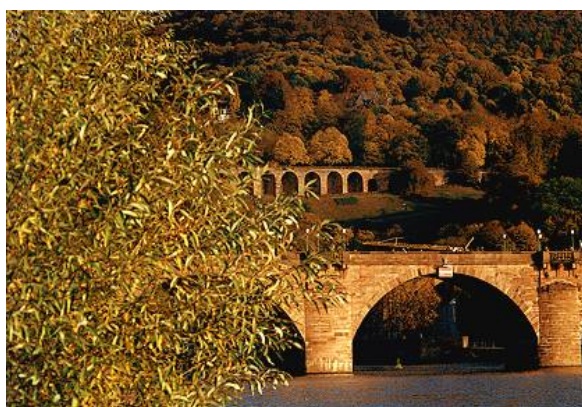
Sehr geehrte Patientin, sehr geehrter Patient,

um unsere Patienten in Zukunft besser behandeln zu können, interessieren uns Ihre **Erfahrungen mit der Narkoseabteilung**. Aus diesem Grund möchten wir Sie bitten, sich etwa 10 Minuten Zeit zu nehmen und den folgenden Fragebogen auszufüllen.

Ihre dabei gemachten Aussagen werden selbstverständlich vertraulich und anonym behandelt.

Die Teilnahme an der Untersuchung ist freiwillig. Sie kann jederzeit und ohne Angabe von Gründen durch Sie selbst widerrufen werden, ohne dass Ihnen hieraus irgendwelche Nachteile entstehen.

Es ist für uns sehr wichtig, dass Sie jede Frage mit einem Kreuz (☒) beantworten.

Bitte überprüfen Sie bei den folgenden Aussagen, in welchem Maße diese für Sie zutreffen. Kreuzen Sie das entsprechende Kästchen an. Trifft für Sie eine Aussage nicht in vollem Maße zu, benutzen Sie die Kästchen „trifft eher zu" oder „trifft eher nicht zu".

Vielen Dank im Voraus für Ihre Mitarbeit

Dr. med. Jan Schiff

Filter elective procedure

Die folgenden Fragen 1. bis 6. beziehen sich auf das Narkose-Aufklärungsgespräch

Bitte machen Sie bei <u>jeder</u> Frage <u>ein</u> Kreuz!	trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
1. Die Wartezeit vor der Narkoseaufklärung war lang.	❏	❏	❏	❏
2. Die Narkoseauklärung fand in einer an- genehmen Atmosphäre (Räumlichkeit) statt.	❏	❏	❏	❏
3. Der Narkosearzt der Narkoseaufklärung sollte freundlicher sein.	❏	❏	❏	❏
4. Der Narkosearzt stand während der Narkoseaufklärung unter Zeitdruck.	❏	❏	❏	❏
5. Der Narkosearzt informierte zu wenig über die bevorstehende Narkose.	❏	❏	❏	❏
6. Die Informationen vom Narkosearzt waren verständlich.	❏	❏	❏	❏

Die folgenden Fragen 7. bis 14. beziehen sich auf den Zeitraum von der Narkoseaufklärung bis kurz vor der Narkose

Bitte machen Sie bei <u>jeder</u> Frage <u>ein</u> Kreuz!	trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
7. Angst vor der Narkose spielte eine große Rolle.	❏	❏	❏	❏
8. Angst vor dem Eingriff spielte eine große Rolle.	❏	❏	❏	❏
9. Die Nacht vor dem Eingriff war erholsam.	❏	❏	❏	❏
10. Der Eingriff wurde auf einen anderen Tag verschoben.	❏	❏	❏	❏
11. Es gab die Angst, die Kontrolle zu verlieren.	❏	❏	❏	❏
12. Die Wartezeit am Morgen vor Beginn des Eingriffs war lang.	❏	❏	❏	❏

		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
13.	Gefühle des Alleingelassenseins belasteten sehr.	❑	❑	❑	❑
14.	Allgemein spielte Aufregung / Angst in der Zeit vor der Narkose eine wichtige Rolle.	❑	❑	❑	❑

Die folgenden Fragen 15. bis 20. beziehen sich auf die Narkose

Bitte machen Sie bei <u>jeder</u> Frage <u>ein</u> Kreuz!		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
15.	Durst war vor der Narkose ein Problem.	❑	❑	❑	❑
16.	Es kam zu frieren oder zittern im Narkoseeinleitungsraum.	❑	❑	❑	❑
17.	Schmerzen vor der Narkose waren belastend.	❑	❑	❑	❑
18.	Die Narkose war genau so, wie es mit dem Narkosearzt besprochen worden war.	❑	❑	❑	❑
19.	In der Narkoseeinleitung herrschte eine angenehme Atmosphäre.	❑	❑	❑	❑
20.	In der Narkoseeinleitung kümmerte sich das Personal und war als Ansprechpartner da.	❑	❑	❑	❑

Die folgenden Fragen 21. bis 35. beziehen sich auf den Zeitraum ab dem Aufwachen aus der Narkose <u>bis einige Stunden nach der Narkose</u>

Bitte machen Sie bei <u>jeder</u> Frage <u>ein</u> Kreuz!		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
21.	Das Aufwachen aus der Narkose war angenehm.	❑	❑	❑	❑
22.	Nach der Narkose kam es zu Schmerzen im Operationsgebiet.	❑	❑	❑	❑
23.	Schmerzen an anderen Stellen (Kopf, etc.) waren nach der Narkose wenig vorhanden.	❑	❑	❑	❑
24.	Schmerzen wurden vom Personal ernst genommen.	❑	❑	❑	❑

		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
25.	Schmerzen wurden durch das Personal rasch gelindert.	❑	❑	❑	❑
26.	Nach der Narkose kam es zu Übelkeit oder Erbrechen.	❑	❑	❑	❑
27.	Heiserkeit / Halsschmerzen waren nach der Narkose ein Problem.	❑	❑	❑	❑
28.	Nach der Narkose zeigte sich Muskelschwäche.	❑	❑	❑	❑
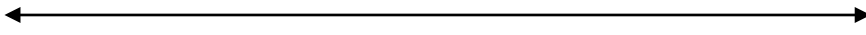
Bitte machen Sie bei **<u>jeder</u>** Frage **<u>ein</u>** Kreuz!		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
29.	Es trat nach der Narkose Durst auf.	❑	❑	❑	❑
30.	Harndrang war nach der Narkose ein Problem.	❑	❑	❑	❑
31.	Es kam nach der Narkose zu frieren oder zittern.	❑	❑	❑	❑
32.	Es kam nach der Narkose zu Schwierigkeiten beim Atmen.	❑	❑	❑	❑
33.	Schläfrigkeit / Konzentrationsstörung nach der Narkose waren belastend.	❑	❑	❑	❑
34.	Direkt nach dem Erwachen kümmerte sich das Personal und war als Ansprechpartner da.	❑	❑	❑	❑
35.	Das Narkosepersonal im Aufwachraum oder auf Intensivstation war freundlich.	❑	❑	❑	❑
36.	Die Erholung nach der Narkose verlief gut.	❑	❑	❑	❑

Außerdem interessiert uns in Bezug auf die Narkose:

Bitte machen Sie bei **<u>jeder</u>** Frage **<u>ein</u>** Kreuz!		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
37.	Dem Narkosepersonal konnte man vertrauen.	❑	❑	❑	❑

38.	Man konnte sicher sein, dass der Narkosearzt im Sinne des Patienten entscheidet.	❏	❏	❏	❏

39.	Die Behandlung durch die Narkoseabteilung war insgesamt: (bitte auf der Linie ankreuzen) ← ────────────────────────────── → sehr gut ☐ ☐ sehr schlecht

Abschließend interessiert uns neben der Narkose auch noch:

		trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
	Bitte machen Sie bei **jeder** Frage **ein** Kreuz!	trifft zu	trifft eher zu	trifft eher nicht zu	trifft nicht zu
40.	Die Erholung seit dem Eingriff verläuft gut.	❏	❏	❏	❏

41.	Die Behandlung durch die **chirurgische** Abteilung war insgesamt: (bitte auf der Linie ankreuzen) ← ────────────────────────────── → sehr gut sehr schlecht
42.	Der Fragebogen ist: (bitte auf der Linie ankreuzen) ← ────────────────────────────── → genau richtig zu lang ☐
43. Ich habe alle Fragen verstanden!	☐

❏ Ja

❏ Nein, folgende nicht (bitte geben Sie die Nr. der Fragen an): _____

Haben Sie bei jeder Frage ein Kreuz gemacht?

Gibt es weitere wichtige Punkte, Beschwerden, Sorgen oder Anliegen, die in diesem Fragebogen nicht enthalten sind?

_____

_____

_____

_____

Herzlichen Dank!

Ihr Narkoseteam

APPENDIX VI: "EFA"QUESTIONNAIRE TO ASSESS PATIENTS EXPERIENCE WITH ANAESTHESIA ("EVALUIERTER FRAGEBOGEN

Individuelles Kliniklogo

Klinik **Verantwortliche Person, Kontakt**

Postanschrift:
Telefon:
Telefax:
e-mail:
Internet:
Aktenzeichen: Version 3.2007
Datum:

EFA-Fragebogen
Evaluierter Fragebogen zur Anästhesiequalität

Sehr geehrte, liebe Patientin,
sehr geehrter, lieber Patient,

um die Qualität der Versorgung in unserer Einrichtung weiter zu verbessern, sind wir auf Rückmeldung durch unsere Patienten angewiesen.

Bitte nutzen Sie die Möglichkeit, mit dem nachfolgenden Fragebogen Ihre Eindrücke mitzuteilen. Sie unterstützen uns durch eine offene und ehrliche Beantwortung aller Fragen bei unserer Arbeit. Die Auswertung Ihrer Antworten erfolgt streng anonym und hat keinerlei Auswirkungen auf Ihre individuelle medizinische Behandlung.

Wir bitten Sie, zu den Aussagen Stellung zu nehmen, indem Sie die für Sie zutreffende Antwort auf der jeweiligen Skala ankreuzen.

Bitte markieren Sie, ob eine Aussage

- **nicht** für Sie zutrifft,
- **etwas** für Sie zutrifft,
- **ziemlich** für Sie zutrifft,
- **stark** für Sie zutrifft.

Es ist für uns sehr wichtig, dass Sie alle Fragen vollständig beantworten.

Vielen Dank im Voraus für Ihre hilfreiche Mitarbeit !

Geschlecht:	weiblich O	männlich O	Alter: _____	Jahre

	Beginn der Bearbeitung (bitte Datum und Uhrzeit eintragen)**:** ____ **.** ____ **. 200**___ um ____ **:** ____ **Uhr**	trifft **nicht** zu	trifft **etwas** zu	trifft **ziemlich** zu	trifft **stark** zu
1.	Es wurde zu wenig über die Risiken der bevorstehenden Narkose informiert.	O nicht	O etwas	O ziemlich	O stark
2.	Der Ablauf der Narkose sollte besser erläutert werden.	O nicht	O etwas	O ziemlich	O stark
3.	Die vorhandene Zeit für das Narkose-Aufklärungsgespräch war zu kurz.	O nicht	O etwas	O ziemlich	O stark
4.	Der Arzt der Narkoseaufklärung war einfühlsam.	O nicht	O etwas	O ziemlich	O stark
5.	Die Narkoseaufklärung verlief in ruhiger und entspannter Atmosphäre.	O nicht	O etwas	O ziemlich	O stark
6.	Man kann sich hier sicher sein, dass das Narkoseteam im Sinne des Patienten berät.	O nicht	O etwas	O ziemlich	O stark
7.	Man kann sich hier sicher sein, dass das Narkoseteam im Sinne des Patienten Empfehlungen gibt.	O nicht	O etwas	O ziemlich	O stark
8.	Die Medikamente vor dem Eingriff trugen zur Entspannung bei.	O nicht	O etwas	O ziemlich	O stark
9.	Man hatte den Eindruck, dass alle sich bemühen Wartezeiten am Tag des Eingriffs möglichst zu gehalten.	O nicht	O etwas	O ziemlich	O stark
10.	Der Patient erfährt Zuwendung durch das Narkoseteam.	O nicht	O etwas	O ziemlich	O stark
11.	Die Narkoseeinleitung verlief in ruhiger und entspannter Atmosphäre.	O nicht	O etwas	O ziemlich	O stark
12.	Man kann sich hier sicher sein, dass das Narkoseteam im Sinne des Patienten Entscheidungen fällt.	O nicht	O etwas	O ziemlich	O stark
13.	Man kann sich hier sicher sein, dass das Narkoseteam im Sinne des Patienten handelt.	O nicht	O etwas	O ziemlich	O stark
14.	Zwischen Ärzten und Pflegepersonal des Narkoseteams herrscht hier ein gutes Klima.	O nicht	O etwas	O ziemlich	O stark

		trifft **nicht** zu	trifft **etwas** zu	trifft **ziemlich** zu	trifft **stark** zu
15.	Im Aufwachraum herrschte eine unangenehm hektische Atmosphäre.	O nicht	O etwas	O ziemlich	O stark
16.	Das Aufwachen aus der Narkose war angenehm.	O nicht	O etwas	O ziemlich	O stark
17.	Schon kurz nach der Narkose konnte man sich hier wieder selbst versorgen.	O nicht	O etwas	O ziemlich	O stark
18.	Man konnte nach dem Eingriff schnell selbst wieder auf die Toilette gehen. Ggf. Alternativ: Man konnte nach der Narkose schnell selbst wieder das Bett verlassen.	O nicht	O etwas	O ziemlich	O stark
19.	Die Erholung nach der Narkose verlief gut.	O nicht	O etwas	O ziemlich	O stark
20.	Nach der Narkose bekam man schnell wieder die Umgebung mit.	O nicht	O etwas	O ziemlich	O stark
21.	Nach der Narkose kam die Kontrolle über den eigenen Körper nur sehr langsam wieder zurück.	O nicht	O etwas	O ziemlich	O stark
22.	Nach der Narkose konnte man sich schnell wieder verständlich äußern.	O nicht	O etwas	O ziemlich	O stark
23.	Nach der Narkose war die eigenständige Beweglichkeit stärker eingeschränkt als erwartet.	O nicht	O etwas	O ziemlich	O stark
24.	Nach der Narkose wurden Schmerzen im Operationsgebiet gut behandelt.	O nicht	O etwas	O ziemlich	O stark
25.	Nach der Narkose waren Schmerzen außerhalb des Operationsgebietes (z.B. Kopf, Hals, Rücken) belastend.	O nicht	O etwas	O ziemlich	O stark
26.	Die auftretenden Schmerzen nach dem Eingriff wurden umgehend behandelt.	O nicht	O etwas	O ziemlich	O stark
27.	Nach der Narkose waren die Schmerzen zeitweise außer Kontrolle.	O nicht	O etwas	O ziemlich	O stark
28.	Durch die Schmerzen wurde der Schlaf beeinträchtigt.	O nicht	O etwas	O ziemlich	O stark
29.	Übelkeit oder Erbrechen wurden gut behandelt.	O nicht	O etwas	O ziemlich	O stark
30.	Heiserkeit oder Halsschmerzen wurden gut behandelt.	O nicht	O etwas	O ziemlich	O stark
31.	Beschwerden durch Schläuche, Katheter oder Infusionen wurden gut behandelt.	O nicht	O etwas	O ziemlich	O stark

| 32. | Das Durstgefühl wurde gut behandelt. | O nicht | O etwas | O ziemlich | O stark |
| 33. | Die Probleme beim Wasserlassen wurden gut behandelt. | O nicht | O etwas | O ziemlich | O stark |

Gibt es weitere wichtige Anliegen, Beschwerden, Sorgen, die Sie uns mitteilen möchten und die in diesem Fragebogen nicht enthalten sind? Wenn ja, bitte hier eintragen:

| |
| |
| |
| |

Alles ausgefüllt? ☺ Dann nochmals vielen Dank !

APPENDIX VII: PAEDIATRIC PERIANESTHESIA QUESTIONNAIRE (PPQ)

UniversitätsKlinikum Heidelberg

Fragebogen für Kinder, Jugendliche und deren Eltern zur Messung der Zufriedenheit mit der Narkoseabteilung

Pädiatrischer Perianästhesiologischer Fragebogen (Paediatric Perianesthesia Questionnaire (PPQ))

Liebe Kinder, sehr geehrte Eltern,

bei Ihrem Kind ist ein Eingriff mit Narkose geplant. Vielleicht ist es die erste Narkose, möglicherweise hatte Ihr Kind aber auch schon in der Vergangenheit eine oder mehrere Narkosen.

Die Bedürfnisse der Patientengruppe Kinder und deren Eltern werden bislang häufig in den meisten Krankenhäusern in Deutschland ungenügend berücksichtigt. Die Ergebnisse aus Befragungen von erwachsenen Patienten sind nicht einfach auf Kinder und deren Eltern übertragbar.

Wir haben daher an der Klinik für Anaesthesiologie am Universitätsklinikum Heidelberg einen Fragebogen entwickelt, der speziell für Kinder, Jugendliche und deren Eltern ausgelegt wurde. Dieser Fragebogen zielt darauf ab, die Bedürfnisse, Sorgen und Ängste der Kinder und Eltern sowie die Erfahrungen mit der Narkose zu erfassen. Die Entwicklung wurde mit Hilfe von Kindern und deren Eltern (bzw. Bezugspersonen) durchgeführt. Der Fragebogen geht neben Aspekten der allgemeinen Behandlung auch auf Fragen zum gesundheitlichen Zustand des operierten Kindes sowie auf die Lebenssituation der Familie ein.

Mit Ihrer Mithilfe soll es in Zukunft möglich sein, Kinder und Jugendliche im Rahmen einer Narkose besser behandeln und Eltern besser betreuen zu können.

Wir freuen uns sehr, wenn Sie sich die Zeit nehmen, diesen Fragebogen zu beantworten. Für das Ausfüllen werden Sie nur wenige Minuten benötigen. Bitte lassen sie sich Zeit beim Ausfüllen. Kann das Kind die Fragen selbst beantworten, so helfen Sie bitte beim Ausfüllen des allgemeinen Teils.

Sollte das Kind **nicht** in der Lage sein, die Fragen eigenständig zu beantworten so lesen Sie bitte dem Kind die Fragen in einem ruhigen Ton vor; vermeiden Sie Wiederholungen und versuchen Sie so wenig wie möglich zu erklären. Tragen sie bitte die Antworten des Kindes in die entsprechenden Felder ein.

Bei der Bearbeitung des Fragebogens ist es wichtig, dass Sie **keine Frage unbeantwortet** lassen. An den Stellen, an denen die Fragen nur für einen speziellen Teil der Kinder und Eltern gilt, werden Sie direkt darauf hingewiesen.

Wir versichern Ihnen, dass aus den persönlichen Daten, die wir erheben, keine Rückschlüsse auf Ihre Person oder ihr Kind möglich ist. Ihre Angaben werden entsprechend den Vorgaben des Datenschutzes streng vertraulich behandelt und anonym ausgewertet. Darüber hinaus möchten wir Ihnen noch mitteilen, dass der Fragebogen von der Ethikkommission der Universität Heidelberg genehmigt wurde. Die Ergebnisse der Untersuchung werden wir Ihnen als Dank für Ihre Mitarbeit über die Homepage unserer Klinik präsentieren, oder auf Wunsch per Post zuschicken (siehe Seite 10). Diese angegebenen persönlichen Daten werden <u>nicht</u> in die Auswertung miteinbezogen.

Wir danken Ihnen ganz herzlich für Ihre Mitarbeit und wünschen Ihnen und Ihrem Kind allzeit alles Gute.

Dr. med. Jan Schiff, MPH   Dr. med. Nicolai Russ

Katja Ihringer
Walther

Priv.-Doz. Dr. med. Andreas

Die folgenden Fragen beziehen sich auf allgemeine Angaben zur Lebenssituation:
Bei den folgenden Fragen sind mit Mutter und Vater die Erziehungspersonen
gemeint, bei denen das Kind derzeit überwiegend lebt.

Die Familie besteht aus ___ Erwachsenen und ___Kindern
Wann ist die leibliche Mutter geboren? _____ Monat ____ Jahr
Wann ist der leibliche Vater geboren? _____ Monat ____ Jahr
Was ist der Beruf der Mutter? _____
Was ist der Beruf des Vaters? _____
Wurden die Geschwister bereits auch operiert? Wenn ja, wie oft insgesamt? _____mal
Sind die Eltern getrennt lebend? ❑ ja   ❑ nein
Was ist der höchste Schulabschluss der Eltern? ❑ (noch) kein Abschluss ❑ Hauptschulabschluss ❑ Realschulabschluss ❑ Abitur ❑ Berufs-/Fachschulabschluss ❑ Fachhoch-/Hochschulabschluss ❑ sonstiger Abschluss

Die folgenden Fragen beziehen sich ausschließlich auf das Kind, das jetzt operiert wird/ gerade operiert wurde und für das dieser Fragebogen beantwortet wird

Wie ist das Kind krankenversichert? ❑ gesetzlich ❑ privat   ❑ gar nicht ❑ gesetzlich mit privater Zusatzversicherung
Geburtsdatum des Kindes: _____ Monat ____ Jahr
Geschlecht des Kindes: ❑ weiblich   ❑ männlich
Wurde das Kind schon einmal operiert? ❑ nein ❑ ja   wenn ja, wie sind Ihre Erinnerungen an die letzte Operation   ❑ positiv   ❑ eher positiv   ❑ neutral   ❑ eher negativ   ❑ negativ
Wie lange liegt die letzte Operation zurück? ____Monate bzw. ____ Jahre
Was wurde bei Ihrem Kind bei der **letzten** Operation operiert? _____
Was wird bei Ihrem Kind **jetzt** operiert? _____
Nach Ihrer Einschätzung war die **letzte** Operation ❑ klein   ❑ mittel   ❑ groß
Nach Ihrer Einschätzung ist die **jetzige** Operation ❑ klein   ❑ mittel   ❑ groß
Gab es bei den bisher durchgeführten Narkosen aus Ihrer Sicht Probleme? ❑ nein ❑ ja, und zwar _____
Das Kind ist, abgesehen von dem Grund für die letzte Operation (Mehrfachnennung mgl.) ❑ gesund, ❑ hat weitere organische Erkrankungen, wenn ja, welche?   _____ ❑ ist geistig behindert, wenn ja, welche Behinderung?   _____ ❑ ist körperlich behindert, wenn ja, welche Behinderung?   _____ ❑ ist geistig und körperlich behindert, wenn ja, welche Behinderung? _____
Wenn das Kind chronisch organisch erkrankt oder geistig/körperlich behindert ist, wie sind Ihre

Erinnerungen an die Diagnoseübermittlung dieser Erkrankung/Behinderung und der anschließenden Betreuung Ihrer Sorgen, Ängste und Trauer? ❑ positiv   ❑ eher positiv   ❑ neutral   ❑ eher negativ   ❑ negativ

Das Kind, um das es bei dieser Operation geht, wird jetzt /wurde ❑ ambulant ❑ stationär operiert.

Die Behandlung durch die <u>chirurgische Abteilung</u> war bisher insgesamt (bitte auf der Linie markieren):

◆━━━━━━━━━━━━━━━━━━━━━━━━◆
sehr gut   sehr schlecht

Die folgenden Fragen beziehen sich auf das Narkoseaufklärungsgespräch

Frage		Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
1	Die Wartezeit auf das Narkosegespräch war zu lang.					
2	Die Atmosphäre während des Narkoseauf-klärungsgesprächs war angenehm.					
3	Der Ablauf der Narkose wurde verständlich erklärt.					
4	Der Ablauf der Narkose wurde ausführlich erklärt.					
5	Die Fragen zur Narkose wurden ausführlich beantwortet.					
6	Der Narkosearzt stand während des Gesprächs unter Zeitdruck.					
7	Nach dem Narkoseaufklärungsgespräch war ich/waren wir beruhigter als vorher.					
8	Der Narkosearzt, der das Aufklärungsgespräch durchgeführt hat, sollte nach unserer Meinung auch die Narkose durchführen.					
Die folgenden drei Fragen bitte nur von Eltern beantworten, deren Kind Down-Syndrom hat, alle anderen gehen bitte direkt zur Frage 12.						
9	Der Narkosearzt hat uns auf die Probleme mit der Halswirbelsäule bei Down-Syndrom Kindern angesprochen.					
10	Der Narkosearzt hat uns auf die Schild-drüsenfunktion des Kindes angesprochen.					
11	Der Narkosearzt hat über das Down-Syndrom mit den Begriffen...(mehrere Antworten möglich) ❑ Down-Syndrom ❑ Trisomie 21 ❑ Mongolismus ❑ ...solche Kinder gesprochen.					
12	Das Narkoseaufklärungsgespräch fand... ❑ im Krankenzimmer ❑ in der Anästhesieambulanz ❑ auf dem Gang oder ❑ _____ statt.					
13	Was ist Dir (Ihnen) während des Narkoseaufklärungsgesprächs besonders negativ aufgefallen?					

	_____	
14	Was ist Dir (Ihnen) während des Narkoseaufklärungsgesprächs besonders positiv aufgefallen? _____	
15	Was sollte im Zusammenhang mit dem Narkoseaufklärungsgespräch dringend verbessert werden? _____	

Die folgenden Fragen beziehen sich auf die Zeit am Operationstag bis zum Beginn der Narkose:

Frage		Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
16	Die Wartezeit auf den Beginn des Eingriffs war zu lang.					
17	Das Beruhigungsmedikament hat gut gewirkt.					
18	Der erste Kontakt mit dem Narkosearzt am Operationstag schaffte ein Gefühl des Vertrauens.					
19	Der erste Kontakt mit der Anästhesiepflegekraft schaffte ein Gefühl des Vertrauens.					
20	Die Eltern durften lange genug vor dem Beginn der Narkose beim Kind bleiben.					
21	Wo mussten sich die Eltern von dem Kind verabschieden? ❑ auf der Station ❑ vor dem Operationsbereich ❑ im Narkoseeinleitungsraum					
22	Wenn die Eltern bis in den Narkoseeinleitungsraum bei dem Kind bleiben durften, mussten Sie ❑ vor oder ❑ nach dem Einschlafen des Kindes den Raum verlassen?					
23	Nach der Operation kam das Kind ❑ auf die Intensivstation ❑ in den Aufwachraum ❑ direkt auf die Normalstation.					

Frage		Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
24	Nach dem Eingriff hat der Narkosearzt die Eltern über den Verlauf der Narkose informiert.					
26	Das Kind wurde in … ❑ Allgemeinanästhesie (=Vollnarkose) ❑ Teilnarkose ❑ Kombination aus Teilnarkose und Allgemeinanästhesie ❑ örtlicher Betäubung operiert.					

 Die folgenden Fragen 27 bis 44 sollten bitte nur von den Eltern beantwortet werden, deren Kind nach der Narkose entweder noch im Aufwachraum überwacht wurde, bevor es auf die Normalstation durfte, oder deren Kind nach der Narkose auf die Intensivstation verlegt wurde.

Die Eltern, deren Kind nach der Narkose direkt auf die Normalstation gebracht wurde, gehen bitte direkt zur Frage 45 (ab Seite 7).

Frage	Im Aufwachraum/auf der Intensivstation	Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
27	Die Eltern durften zu ihrem Kind in den Aufwachraum/ auf die Intensivstation.					
28	Nach dem Aufwachen durften die Eltern schnell genug zu ihrem Kind.					
29	Ich (das Kind) hatte im Aufwachraum/ auf der Intensivstation Schmerzen.					
30	Gegen die Schmerzen wurde im Aufwachraum/ auf der Intensivstation schnell genug Medikamente gegeben.					
31	Gegen die Schmerzen wurde im Aufwachraum/ auf der Intensivstation ausreichend Medikamente gegeben.					
32	Ich (das Kind) hatte im Aufwachraum/ auf der Intensivstation Übelkeit und Brechreiz.					
33	Gegen Übelkeit und Brechreiz wurden im Aufwachraum/ auf der Intensivstation schnell genug Medikamente gegeben					
34	Gegen Übelkeit und Brechreiz wurden im Aufwachraum/ auf der Intensivstation ausreichend Medikamente gegeben.					
35	Ich (das Kind) hat im Aufwachraum/ auf der Intensivstation gefroren.					
36	Gegen das Frieren im Aufwachraum/ auf der Intensivstation wurde schnell genug etwas unternommen.					
37	Ich (das Kind) hatte im Aufwachraum/ auf der Intensivstation Schwierigkeiten beim Atmen.					
38	Gegen die Schwierigkeiten beim Atmen im Aufwachraum/ auf der Intensivstation wurde schnell genug etwas unternommen.					
39	Meine Probleme (die Anliegen des <u>Kindes)</u> <u>wurden</u> im Aufwachraum/ auf der Intensivstation ernst genommen.					
40	Die Anliegen der <u>Eltern</u> im Aufwachraum/ auf der Intensivstation wurden ernst genommen.					
41	Meine Privatsphäre (die des Kindes) und die der Eltern wurde im Aufwachraum/ auf der Intensivstation respektiert.					
42	Was ist Dir (Ihnen) im Aufwachraum/ auf der Intensivstation besonders negativ aufgefallen? _____					

| 43 | Was ist Dir (Ihnen) im Aufwachraum/ auf der Intensivstation besonders positiv aufgefallen? _____ |
| 44 | Was sollte im Aufwachraum/ auf der Intensivstation dringend verbessert werden? _____ |

Die folgenden Fragen beziehen sich auf die Zeit auf der Normalstation. <u>Ab hier bitte wieder von allen Eltern beantworten</u>.

Frage	Zurück auf der Station	Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
45	Zurück auf der Station hatte ich (das Kind) Schmerzen.					
46	Gegen die Schmerzen wurden auf der Station schnell genug Medikamente gegeben.					
47	Gegen die Schmerzen wurden auf der Station ausreichend Medikamente gegeben.					
48	Zurück auf der Station hatte ich (das Kind) Übelkeit und Brechreiz.					
49	Gegen Übelkeit und Brechreiz wurden auf der Station schnell genug Medikamente gegeben.					
50	Gegen Übelkeit und Brechreiz wurden auf der Station ausreichend Medikamente gegeben.					
51	Zurück auf der Station habe ich (hat das Kind) gefroren.					
52	Gegen das Frieren auf der Station wurde schnell genug etwas unternommen.					
53	Der Ablauf im Zusammenhang mit der Narkose war so, wie es mit dem Narkosearzt besprochen war.					
54	Ich habe mich (das Kind hat sich) schnell genug wieder so bewegen können, wie es wollte.					
55	Ich bin (das Kind ist) schnell genug nach der Narkose wieder fit gewesen.					

Allgemeine Fragen zur Operation und Narkose

56	Was ist Dir (Ihnen) im Zusammenhang mit der Narkose besonders negativ aufgefallen? _____
57	Was ist Dir (Ihnen) im Zusammenhang mit der Narkose besonders positiv aufgefallen? _____
58	Was müsste im Zusammenhang mit der Narkose dringend verbessert werden? _____

59	Die Behandlung durch die <u>Narkoseabteilung</u> war insgesamt (bitte auf der Linie markieren):
	◆————————————————————————◆
	sehr gut sehr schlecht

Frage		Trifft überhaupt nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft voll und ganz zu
60	Am Tag nach der Operation möchte(n) ich/wir gerne noch einmal mit dem Narkosearzt über den Verlauf der Narkose sprechen.					
61	Wenn ich/wir die Wahl hätte(n), würde(n) ich/wir dieses Krankenhaus für diese Operation wieder wählen.					
62	Wenn ich/wir die Wahl hätte(n), würde(n) ich/wir diese Narkoseabteilung wieder wählen.					
63	Der Fragebogen ist (bitte auf der Linie markieren): ◆————————————————◆ viel zu kurz genau richtig viel zu lang					

64	Die Behandlung durch das <u>ärztliche Personal</u> war insgesamt (bitte auf der Linie markieren): ◆————————————————◆ sehr gut sehr schlecht

65	Die Behandlung durch das <u>Pflegepersonal</u> war insgesamt (bitte auf der Linie markieren): ◆————————————————◆ sehr gut sehr schlecht

66	Ich habe alle Fragen verstanden. ❑ Ja ❑ Nein, folgende nicht (bitte geben Sie die Nr. der Fragen an):_____

Wer hat den überwiegenden Teil der Antworten gegeben?
❑ Mutter   ❑ Vater   ❑ das betroffene Kind   ❑ andere Person

Tragen Sie bitte hier noch die Buchstaben ein:

   Erster Buchstabe des Vornamen des Kindes   _____

   die beiden ersten Buchstaben des Nachnamen des Kindes_____

Haben Sie bei jeder Frage, die für Sie in Betracht kommt, ein Kreuz gemacht?

Gibt es weitere wichtige Punkte, Beschwerden, Sorgen, Probleme oder Anliegen, die in diesem Fragebogen nicht enthalten sind?

_____

Herzlichen Dank!
Wenn Sie möchten, dass wir Ihnen die Ergebnisse der Gesamtstudie zuschicken (❑ per Post, oder ❑ per e-mail), tragen Sie bitte hier Ihre Adresse ein.

Name:_____   Strasse:_____

Postleitzahl:_____   Wohnort: _____
e-mail Adresse: _____

APPENDIX VIII: REVIEW ARTICLE: ANAESTHEIC CONSIDERATIONS IN DOWN SYNDROME PATIENTS

CME Zertifizierte Fortbildung

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Anästhesiologische Besonderheiten der Trisomie 21 (Down-Syndrom)

Zusammenfassung
Die Trisomie 21, auch als Down-Syndrom bezeichnet, gehört mit einer Prävalenz von etwa 1:800 Schwangerschaften zu den häufigsten angeborenen chromosomalen Veränderungen. Die meisten der resultierenden chronischen Behinderungen gelten als nichtheilbar und be-treffen Menschen verschiedenen Alters, Bildungsstands und verschiedener Volkszugehörig-keit. Die Lebenserwartung dieser Patienten steigt – wie auch bei dem Rest der Bevölkerung – mit zunehmendem medizinischem Fortschritt. Aufgabe der Gesundheitsdienstleister ist es, Familien und Betroffenen zu helfen, die Folgen dieser Behinderungen zu mildern sowie mit den Einschränkungen möglichst gut zurechtzukommen. Symptomvariabilität und Expres-sivität des Down-Syndroms erscheinen äußerst vielfältig, basierend auf dem typischen Phä-notyp mit der häufigen Trias aus mentaler Retardierung, Handanomalien und angeborenen Herzfehlern. Auch andere Veränderungen sind mitunter wichtig für die anästhesiologische Versorgung, wie eine atlantoaxiale Instabilität (AAI), Trachealstenose, Neigung zu respirato-rischen Infektionen, Hypothyreoidismus, Mikrogenie und relative Makroglossie. Weiterhin haben Patienten bzw. Familien mit Kindern mit Down-Syndrom spezifische Erwartungen an die medizinische und anästhesiologische Versorgung.

Schlüsselwörter
Atlantoaxialgelenk · Gelenkinstabilität · Herzkrankheiten · Respirationsstörungen · Trachealstenose

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APPENDIX IX: CODING OF INCIDENTS, EVENTS, AND COMPLICATIONS (IECS) IN THE CORE DATASET (CDS), VERSION 2.0

General Codes
At least one general code from the following is mandatory for coding of an IEC.

0000   No IEC, not classified

1000   Respiratory system, not classified

2000   Cardiovascular system, not classified

3000   General reactions, not classified

4000   Laboratory tests, not classified

5000   Central nervous system, not classified

6000   Regional anesthesia, not classified

7000   Apparatus, not classified

8000   Lesions, not classified

Problem-Based IECs, Frequently Used; Usage Advised
1102   Bronchospasm

1204   Hypoventilation

1301   Unexpected difficult intubation

2101   Hypotension

2102   Hypertension

2201   Tachycardia

2202   Bradycardia

2203   Arrhythmia

2305   Hypovolemia

3101   Nausea

3102   Vomiting

3103   Shivering

3108   Allergic reaction

IEC Subgroups
1000   Respiratory system, not classified

1100   Airway, not classified

1101   Laryngospasm

1102   Bronchospasm

1103   Lesions of the airway

1104   Stridor (glottis area)

1105   Aspiration

1106   Obstruction of the airway

1200   Respiratory control/gas exchange, not classified

1201   Hypoxemia

1202   Pulmonary edema

1203   Hyperventilation

1204   Hypoventilation

1300   Intubation, not classified
    1301   Unexpected difficult intubation
    1302   Secondary fiberoptic intubation
    1303   Intubation not possible
    1304   Esophageal intubation
    1305   Unilateral intubation
    1306   Re-intubation
    1307   Rapid sequence induction (RSI) failed
    1308   Fiberoptic intubation failed
1400   Endotracheal tube problems, not classified
    1401   Disconnection
    1402   Endotracheal tube kinking
    1403   Tube defect
    1404   Unplanned extubation
1900   Other respiratory problems, not classified
    1901   Pneumothorax
    1902   Hemothorax
    1903   Pneumonia
    1904   Planned extubation not possible
    1905   Unplanned postprocedural respirator therapy
    1999   Other respiratory problems
2000   Cardiovascular system, not classified
    2100   Blood pressure, not classified
        2101   Hypotension
        2102   Hypertension
    2200   Heart rate, not classified
        2201   Tachycardia
        2202   Bradycardia
        2203   Arrhythmia
    2300   Perfusion, not classified
        2301   Myocardial infarction
        2302   Angina
        2303   ST segment changes (asymptomatic)
        2304   Pulmonary embolus
        2305   Hypovolemia
        2306   Shock/alterations in microcirculation
        2307   Cardiac arrest
    2400   Myocardial function, not classified
        2401   Impaired left cardiac function
        2402   Impaired right cardiac function
        2403   Decompensated cardiac function/pulmonary edema
    2900   Other cardiovascular, not classified
        2901   No venous return (autologous blood donation)
        2999   Other cardiovascular problems

3000   General reactions, not classified
    3100   General reactions, not classified
        3101   Nausea
        3102   Vomiting
        3103   Shivering
        3104   Hypothermia
        3105   Hyperthermia
        3106   Malignant hyperpyrexia
        3107   Anaphylaxis
        3108   Allergic reaction
    3200   Organ-specific general reactions, not classified
        3201   Oliguria/anuria/acute renal failure
        3202   Transfusion reaction
        3203   Icterus
    3300   Pain, not classified
        3301   Sore throat (after endotracheal intubation)
        3302   Mandibular joint (after general anesthesia)
        3303   Muscular pain
        3304   Wound pain
        3305   Headache (general)
        3306   Postspinal headache
        3307   Back pain
        3309   Other pain
    3400   Discharge, not classified
        3401   Unplanned recovery time > 3 h
        3402   Unplanned admittance to intensive-care unit
        3403   Unplanned return (operating room, recovery)
    3500   Procedure/operation, not classified
        3501   Unplanned expansion of procedure/operation
        3502   Unplanned shortening of procedure/operation
        3503   Procedure/operation not done
4000   Laboratory values, not classified
    4100   Blood count, not classified
        4101   Anemia
    4200   Metabolism, not classified
        4201   Hyperglycemia
        4202   Hypoglycemia
    4300   Acid–base balance, not classified
        4301   Acidosis
        4302   Alkalosis
    4400   Water electrolytes, not classified
        4401   Hyperkalemia
        4402   Hypokalemia
        4403   Hypernatremia

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          4404   Hyponatremia
4900   Other laboratory tests, not classified
          4901   Hypoproteinemia
          4902   Bacteremia (autologous blood)
          4903   Clotting disorders
          4999   Other laboratory tests

5000   Central nervous system, not classified
     5100   General neurological problems, not classified
          5101   Delayed emergence from anesthesia
          5102   Agitation
          5103   Neuromuscular block (residual)
          5104   Confusion
          5105   Awareness (general anesthesia)
          5106   Residual opiate effect
     5200   Central neurological problems, not classified
          5201   Central anticholinergic syndrome
          5202   Ischemia
          5203   Seizures
          5204   Increased intracranial pressure
          5205   Cerebral venous hypoxemia
     5900   Other central nervous problems, not classified
          5901   Vertigo
          5999   Other central nervous problems

6000   Regional anesthesia (RA), not classified
     6100   Puncture, not classified
          6101   Multiple or missed puncture
          6102   Positive blood aspiration
          6103   Accidental dural perforation
          6104   Unplanned paresthesia
          6105   Failed RA/change of anesthesia
     6200   Application, not classified
          6201   Pain on injection
          6202   Intravascular Injection
          6203   Neurological symptoms during/after RA injection
     6300   RA catheter, not classified
          6301   Catheter detachment
          6302   Cannula defect
          6303   Inflammation
          6304   Wrong Positioning
          6305   Hematoma
          6306   Catheter detachment without advice by anesthetic department
     6400   Effect, not classified
          6401 High/total neuraxial anesthesia
          6402   Partial effect

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6403   Inadequate effect
6404   Arrested labor/ uterine inertia
7000   Apparatus, not classified
    7100   Equipment/standard monitoring, not classified
        7101   Ventilator
        7102   Electrocardiography
        7103   Blood pressure
        7104   Pulse oximetry
        7105   Intubation equipment
        7106   Warming devices
    7200   Additional equipment/expanded monitoring, not classified
        7201   External pacemaker
        7202   Defibrillator
        7203   Fiberoptic
        7204   Extracorporeal circulation (unintentional stoppage)
    7300   Intravascular administration, not classified
        7301   Infusion system
        7302   Infusion pump
        7303   Drugs (errors, etc.)
    7400   Autologous blood, not classified
        7401   Plasmapheresis equipment
        7402   Blood donation equipment
        7403   Blood centrifuge/separator
        7404   Donated volume smaller than planned
        7405   Abortion of autologous blood donation
        7409   Other (autologous blood)
8000   Lesions, not classified
    8100   Punctures, not classified
        8101   Missed/multiple vascular punctures
        8102   Accidental arterial puncture
    8200   Nonspecific lesions, not classified
        8201   Skin
        8202   Muscle/soft tissue
        8203   Nerves
    8300   Specific lesions, not classified
        8301   Upper airway
        8302   Teeth/lips/gums
        8303   Eyes
        8304   Epistaxis
        8305   Hoarseness
    8400   Reactions after peripheral venous puncture, not classified
        8401   Infection
        8402   Malpositioning
        8403   Hematoma

8500   Reactions after central venous puncture, not classified
    8501   Infection
    8502   Malpositioning
    8503   Hematoma
    8504   Failed central venous catheter puncture/insertion
8600   Reactions after arterial puncture, not classified
    8601   Infection
    8602   Ischemia
    8603   Malpositioning
    8604   Hematoma
    8605   Accidental injection into arterial cannula

= recommended by the DGAI

APPENDIX X: HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

> This administrative form
> has been removed

Townsville Cairns Mackay