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Routine based recording of adverse events during anaesthesia

Application in quality
improvement and safety.

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LIST OF PAPERS

This thesis is based on the following original papers, which will be referred to by Roman numerals:

- I. *Fasting S, Gisvold SE.* Data recording of problems during anaesthesia: presentation of a well-functioning and simple system.
Acta Anaesthesiol Scand 1996;40:1173-83.
- II. *Mellin Olsen J, Fasting S, Gisvold SE.* Routine preoperative gastric emptying is seldom indicated. A study of 85,594 anaesthetics with special focus on aspiration pneumonia.
Acta Anaesthesiol Scand 1996;40:1184-8.
- III. *Fasting S, Gisvold SE.* Adverse drug errors in anesthesia, and the impact of coloured syringe labels.
Can J Anaesth 2000;47:1060-7.
- IV. *Fasting S, Gisvold SE.* Equipment problems during anaesthesia--are they a quality problem?
Br J Anaesth 2002;89:825-31.
- V. *Fasting S, Gisvold SE.* Serious problems during anesthesia - a five year review of 83,844 anesthetics.
Can J Anaesth 2002;49:545-53.
- VI. *Fasting S, Gisvold SE.* Statistical process control methods allow the analysis and improvement of anesthesia care.
Can J Anaesth 2003;50:767-77

INTRODUCTION

Anaesthetic complications causing major morbidity and death are rare occurrences. The anaesthesia related mortality rate is not agreed upon,^{1,2} but the rate was recently estimated at 0.6/10,000³ and 1.4/10,000.⁴

Serious anaesthetic complications do not occur spontaneously, but are the outcomes of evolutionary processes. Through the interaction of multiple factors, a simple incident may evolve into a serious incident which may further evolve to an accident.⁵ However, because of recovery processes such as error detection and correction, minor incidents occur more commonly than serious ones, which in turn are more common than accidents. Thus, most accidents are avoided, although some still occur.

The comparative rarity of fatal accidents after anaesthesia permits few opportunities to study their evolution or to develop strategies to prevent their recurrence in other patients.⁶⁻⁹ The higher frequency of incidents or 'near misses' affords more opportunities for analysis leading to accident prevention. This approach is well demonstrated in aviation, nuclear power technologies and other high-risk industries.⁹⁻¹¹ This 'aviation approach' to analysis and reporting of 'near-misses' has also been recommended as a basis for risk reduction in medicine.⁹⁻¹¹

Adverse events - as outcome measures:

Anaesthesia is not a 'therapeutic' speciality like medicine or surgery, where 'successful treatment' is a useful outcome. As anaesthesia primarily facilitates treatment of patients, the range by which to compare outcomes is usually limited to the presence or absence of adverse outcomes.^{8,12}

When serious outcomes are rare, however, investigators often adopt 'intermediate or surrogate' outcomes as endpoints for true morbidity.¹³⁻¹⁵ In anaesthesia,

transient hypoxaemia can be regarded as a 'surrogate outcome' for hypoxic brain damage, which is a 'real outcome' with implications for the patient's current and future health status.

We therefore argue that because of the rarity of serious 'real' outcomes such as hypoxic brain damage, it is relevant to study the causes and prevention of 'surrogate outcomes', such as severe transient hypoxaemia, as some of these have the potential for developing into serious 'real' outcomes. However, the relevance of recording minor adverse events in anaesthesia has been questioned, as their impact on the patient's subsequent postoperative course is uncertain. Some studies have shown that even minor adverse events influence the patient's clinical course. Bothner et al. found in their study that minor perioperative anaesthesia-related incidents did influence post-anaesthesia care unit utilisation.¹⁶ Niskanen et al. found a similar association between intraoperative incidents and length of stay in the post-anaesthesia care unit and hospital, also when ASA-class was corrected for.¹⁷ Boëlle et al. found that undesirable events were associated with progression into critical events with an odds ratio of 3.4-4.8, indicating the potential of even minor events for leading to serious morbidity.¹⁸ Sanborn et al. found a highly significant association between the occurrence of electronically detected intraoperative incidents and in-hospital mortality.¹⁹

Thus a central principle in our project is that minor adverse events have a potential for developing into serious accidents, and that analysing the occurrence and causes of these events may facilitate accident prevention.

Adverse events – reporting compliance:

The informative value of adverse event reporting is dependent on the data provider's level of compliance with the recording system.

Voluntary reporting has been associated with a low level of compliance when based on anonymous written reports, which are submitted only when an incident occurs.¹⁹⁻²³ There are many possible reasons for this. It is important that the intention with the recording is to improve quality and learning, and that there is a non-punitive attitude around the reporting of adverse events.^{24,25} Lagasse et.al found good compliance with voluntary reporting in a system where only serious events were reported.²⁶ In a follow up study, the factors contributing to good compliance were thought to be the learning potential, the severity of the outcome, and the non-punitive departmental attitude.²⁷

Elements of human error are involved in 60-80 % of adverse events.²⁸⁻³² Traditionally this has resulted in a tendency to blame the individual when an incident occurred, with consequent reluctance from the individual to report errors.

However, there has been an increasing focus on the 'system contribution' to adverse events, which means that the system the individual works in is important both for the occurrence and the detection and reversal of human errors.³³⁻³⁷ This is a consequence of human psychology research, where mechanisms of 'human errors' have been clarified. Making errors are an inherent part of human psychology and activity – not a result of negligence, which has been the traditional approach in error management in medicine.³⁴ The same approach is also focussed in an extensive report from Institute of Medicine: 'To Err is Human' (www.books.nap.edu).³⁸ The consequence of this knowledge is that the working environment must be designed in a way to keep humans from making errors, and limit their consequences when they occur. This approach will also possibly help to change the objective of reporting from 'blame and hide' towards 'learn and improve'.²⁵

In addition, motivation for voluntary reporting can be ensured by relevant feedback to the data providers. The definitions of events, and severity should be as precise as possible and the recording should represent little added workload for the anaesthesiologist.¹⁹⁻²²

Adverse events - Systems for recording:

Several methods for obtaining data about adverse events during anaesthesia are available. These include anecdotal reports, mortality studies, morbidity studies, 'closed claim' studies, and incident monitoring studies.

Incident monitoring was first described by Flanagan in 1954 as the 'critical incident technique'.³⁹ This technique was developed to reduce loss of military pilots under training. Here the focus was to learn from the 'near miss', 'incident', or 'adverse event'. The technique was modified and introduced in anaesthesia by Cooper in 1978,⁴⁰ where retrospective examination of the characteristics of human error and equipment failure uncovered patterns of frequently occurring incidents. Later, numerous publications based on analysis of 'critical incidents' or 'adverse events' were published, the best known being the 'Australian Incident Monitoring Study' (AIMS).⁴¹ Here, incidents were collected using a standard form, and later analysed by a study group.

A major disadvantage with this approach is that the incidence of a specific adverse event cannot be calculated, as the denominator (the total number of anaesthetics) is unknown; there are few publications based on data recording from all cases of anaesthesia, where adverse event incidence can be calculated:

Cooper and co-workers recorded operating room adverse events in a study concerning feedback about complications and use of pulse oximetry. Adverse events pertinent to recovery room care were recorded as 'recovery room impact events' (RRIE).⁴² The study was designed to include all recovery room admissions, but in fact data was collected from only 71% of cases.

A study by Cohen et.al describes the methodology for studying anaesthetic outcome for parallel use in four different hospitals.⁷ All patients receiving an anaesthetic in any of the four hospitals were included in the study, which was

project based, and went on for two years, with one to two project nurses employed in each hospital.

Several studies have been published from a project launched by the German Society of Anaesthesiology and Intensive Care Medicine (Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin (DGA)) following regulations imposed by German health-care law. Data were collected from all anaesthetics, and the project is planned to record continuously from all hospitals. Perioperative events were defined, and recorded similarly across institutions. However, they were not separated into operating theatre and recovery room occurrences, or categorised by type of anaesthesia.⁴³⁻⁴⁹

The basis for our study is a routine based recording system, in which information is recorded from every anaesthetic procedure. The recording of adverse events is an integral part of this system, and can be separated in intra- and post-operative events and stratified according to various risk factors. The main objective of this thesis was to evaluate the feasibility of the system, and to demonstrate possible applications of recorded adverse event data in quality improvement and risk reduction.

AIMS OF THE THESIS

The main objectives of this thesis were to evaluate the feasibility of a routine based system for recording of adverse events during anaesthesia, and to demonstrate possible applications of these data in quality improvement and safety:

- To describe the recording system in terms of database structure, methods for implementation in daily routines, quality control of data, and possible applications (Paper I).
- To analyse the severity and occurrence of gastric aspiration, and evaluate the safety of our routines for preoperative gastric emptying (Paper II).
- To analyse the severity and occurrence of medication errors, and the effect of introducing colour coded syringe labels as a quality improvement effort (Paper III).
- To analyse the severity and occurrence of equipment problems, and evaluate whether our routines for checking and maintenance are adequate (Paper IV).
- To analyse the pattern and causes of the most serious problems, and use this information to improve preventive strategies (Paper V).
- To analyse the quality of the anesthetic process by applying statistical process control methods to adverse events relevant to anaesthetic safety or quality (Paper VI).

PATIENTS AND METHODS

From 1985, this department developed a system for routine based data recording of information from all anaesthetic cases. The system has remained basically unchanged over the years, but has been adjusted according to changes in medical practice and increased focus on safety and quality.

Hospital and department:

St. Olavs Hospital, University Hospital of Trondheim has 960 beds and admitted 43.000 patients (60 % emergencies) in 2001. All types of surgery are performed, except transplantation and paediatric cardiac surgery. The anaesthesiologists always work in co-operation with a qualified nurse anaesthetist with 18 months post-graduate education and training in anaesthesiology.

Recorded information:

The anaesthetic chart normally documents drugs and fluids administered during the anaesthetic, and physiological variables. In addition, as a part of our standard anaesthetic chart we have included specific data fields – with information about the ‘intraoperative’ (Figure I, page 12) and ‘postoperative’ part of the anaesthetic (Figure II, page 13).

The ‘intraoperative’ fields contain information about the patient, the operation, timing of events, the anaesthetic and problems encountered. The information recorded in these fields is listed in Table I (page 14). Variables 1-7 concern patient related information, including ASA Physical Status Classification. Variables 8-12 concern the procedure. Variables 13-16 describe the duration of the anaesthetic and procedure. Variables 17-20 concern the anaesthetic technique, anaesthetic drugs, breathing circuit (airway from 1993), and any supplemental anaesthetic techniques. Variable 21 describes intraoperative problems or adverse events.

Figure I
Intraoperative anaesthetic chart

ANESTESIJOURNAL St. Olavs Hospital HF										Rom nr.	Født:	Pers.nr.
Preop. diagnose										Avrd.	Navn:	Adr.:
Planlagt op.												
BT	Vekt	Høyde	Hgb.	Kreat.	Na.	K	Alb.	Dato		Blod bestilt	Tr.k.:	
Andre prøveresultater												
<div> <div> <div>A</div> <div>Uten anm.</div> </div> <div> <div>B</div> <div>Chokersyktd</div> </div> <div> <div>C</div> <div>Intest</div> </div> <div> <div>D</div> <div>Hjertelst</div> </div> <div> <div>E</div> <div>Arrytmi</div> </div> <div> <div>F</div> <div>Hjertelst</div> </div> <div> <div>G</div> <div>Arteriosklerose</div> </div> <div> <div>H</div> <div>Hypertoni</div> </div> <div> <div>I</div> <div>Lungesykt</div> </div> </div> <div> <div>J</div> <div>Hyperkali</div> </div> <div> <div>K</div> <div>Allergi</div> </div> <div> <div>L</div> <div>Alkohol</div> </div> <div> <div>M</div> <div>Adipositas</div> </div> <div> <div>N</div> <div>Diabetes</div> </div> <div> <div>O</div> <div>Endokrin syktd</div> </div> <div> <div>P</div> <div>RWimmusyktd</div> </div> <div> <div>Q</div> <div>Dr. luftv. int.</div> </div> <div> <div>R</div> <div>Neus/Nep. lene</div> </div>												

S

Malignitet

T

Bledd. tend./antst.

U

Undersmersting

V

Vaskul. lene

W

Infisert plat

X

Hepatitt/N/V.

Y

Andre syktd

Z

Akutt skade

Ø

Pågående bleed.

Premedikasjon:

+

Morgenmedisin

Ja / Nei

Sign.

ASA-gruppe

Fields for data information are shaded on the chart.

Postoperative anaesthetic chart

POSTOPERATIV JOURNAL

Diagnose: _____

Utført operasjon: _____

Operatør: _____

Type anestesi: _____

Beskjed til postop, avd. _____ O2 ☐ Ja ☐ Nei

Smerlestilende: _____

I.v. væske postop: _____

Dren: _____

Medikamenter: _____

Prøver: _____ Blod i reserve enh.

Andre beskjeder: _____

Status ved ankomst postop, avd.	Respirasjon	god	middele	dårlig	Tube
Anestesi/pålegg	Bevissthet	god	middele	dårlig	Respirator
			Rec. apl.		

Innløst p.o. dato: _____

Item klokken: _____

LP klokken: _____

Operasjonsdøgn nr. 06.00 - 06.00

Væskeoversikt	Før og under	Etter op.	I alt	Total tilførsel
Blod				
Ringer				
Glucose				
Blodtap				
Dren				
Bandasje				
Aspirert				
Diurese				
Peristaltik				

Totalt tap: _____

Balanse: _____

HVOR OVERVÅKET

1. Sentral - P.O. pas.	A. Uten anm.	O. Lungestørning
2. Sentral - Rec. pas.	B. Kvalme/opkast	P. Oliguri
3. Recovery 3 - P.O. pas.	C. Sen oppvåkning	Q. Urinretensjon
4. Recovery 3 - Rec. pas.	D. Uroforvring	R. Omsorgsproblem
5. Ratt til hovedintensiv	E. Hypotermi < 35.5°C	S. Smerteproblem
6. Ratt på post	F. Resp. depresjon	T. Stens/GPP/MORS
7. Andre reolint avd.	G. Luftveisproblem	U. Feilmedisinering
	H. Hypoksi	X. Utstyrsteknisk problem
	I. Hypovolem	Y. Temp. > 38°C
	J. Pagående blødn.	Z. Annet
	K. Azymer/EKG forandr.	
	L. Systemer	
	M. Hypotensjon > 20%	
	N. Hypertensjon > 30%	

☐ NEMS (kan P.O. pas.)

☐ Alvort grad (1-4)

☐ Postop. respirator

☐ Overl. intensiv

HUSK DATAFELT

Klokken

SAT

TEMP

Oksygen

Resp.-frakv.

Time/durese

Diurese

Blødning

Dren

Tap

Tilførsel

Medisin

BESKJED TIL SENGAVD.

Ved smerte: _____

Andre med.: _____

Væske/ernæring: _____

Rapport

Rapport mottatt av: _____

Rapport gitt av: _____

Fields for data information are shaded on the chart.

Table I
Structure of database (Ref. Paper I)

No	Variable recorded in database	Recorded on Chart
1	Last name	Text
2	First name	Text
3	Birth date	Date
4	Person identity number	Text
5	Sex (M/F)	Check-box
6	Preoperative illnesses	Check-box
7	ASA-class	Text
8	Emergency case (Y/N)	Check-box
9	Ward department	Text
10	Procedure department	Text
11	Type of procedure	Text
12	Date of procedure	Date
13	Start of anaesthetic	Numeric
14	Start of procedure	Numeric
15	End of procedure	Numeric
16	End of anaesthetic	Numeric
17	Anaesthetic technique	Text
18	Anaesthetic drugs	Text
19	Breathing circuit / Airway	Text
20	Supplemental anaesthesiological technique	Text
21	Intraoperative problems	Check-list
22	Problem severity	Numeric
23	Doctor / Nurse Identity	Text

The table shows the variables, the variable content, and format of information in database.

Fields for doctor and nurse identity are also included. These are not mandatory, and are mostly used by trainees who want personal reports regarding number of procedures or specific anaesthetic techniques performed.

Additionally, we have recorded information concerning resource utilisation in the recovery and postoperative unit, as well as any problems occurring postoperatively. These fields have not been analysed as a part of this study.

Intraoperative problems:

One variable concerns 'intra-operative problems'. We defined an intra-operative problem as an event that requires one or more measures either to prevent further complications, or to treat a situation that is currently or potentially serious, and does not routinely occur during the conduct of anaesthesia. The 'problem checkbox' as it is printed on the anaesthetic chart is presented in Figure III (page 16), where a difficult emergence problem with a severity of Grade 3 is recorded as an example.

In the 'problem checkbox' we have included problems commonly encountered in anaesthetic practice, but anaesthesia, as a primary causative factor is not a necessity. Thus, the causative factor for an event recorded as a 'hypotension problem' is not necessarily anaesthesiological, but may be due to the patient's medical condition or to uncontrolled surgical bleeding.

Events are also graded according to severity on a scale from one to four. 'Grade 1' events are trivial, easily dealt with and not affecting the patient's condition. 'Grade 2' events are moderately difficult, with some effect on the patient, but of low severity. 'Grade 3' situations are either very difficult to manage, or cause a serious deterioration in the patient's state, and may have consequences for the patient postoperatively. 'Grade 4' implies a fatal outcome.

Some of the problems are more precisely defined on the reverse side of the anaesthetic chart (Table II, page 17).

Figure III

'Problem Checkbox' as printed on anaesthesia chart

<input type="checkbox"/>	Uneventful
<input type="checkbox"/>	Laryngeal spasm
<input type="checkbox"/>	Bronchospasm
<input type="checkbox"/>	Aspiration
<input type="checkbox"/>	Hypertension > 30%
<input type="checkbox"/>	Hypotension > 30%
<input type="checkbox"/>	Arrhythmia / ECG change
<input type="checkbox"/>	Intubation difficulties
<input type="checkbox"/>	Perforation of the dura
<input type="checkbox"/>	Convulsions
<input type="checkbox"/>	Tooth injury
<input type="checkbox"/>	Allergic reaction
<input type="checkbox"/>	Hypothermia < 35.5 °C
<input type="checkbox"/>	Hyperthermia > 39.0 °C
<input type="checkbox"/>	Bleeding > 20%
<input checked="" type="checkbox"/>	Difficult emergence
<input type="checkbox"/>	Inadequate anaesthesia/analgesia
<input type="checkbox"/>	Equipment/Technical problem
<input type="checkbox"/>	Cardiac arrest / CPR
<input type="checkbox"/>	Oxygenation problems / Hypoxaemia
<input type="checkbox"/>	Hypercapnia
<input type="checkbox"/>	Drug error / Syringe swap
<input type="checkbox"/>	Other
Severity of problem	
3	

A problem during emergence from general anaesthesia is recorded, judged to be of severity 3. A short description of the adverse event is written on the anaesthesia chart.

Table II**Recorded problems, with added supplementary definitions:****Circulatory**

Hypotension - 30 % fall for > 5 minutes or > 50 % fall in blood pressure (BP)

Hypertension – More than 30 % increase in BP for 5 minutes or more

Arrhythmia / ECG changes – Occasional extrasystoles not included

Bleeding – Loss of more than 20 % of estimated blood volume

Cardiac Arrest / Cardiopulmonary resuscitation

Respiratory

Difficult emergence from general anaesthesia

Oxygenation problems/Hypoxaemia – saturation < 90 % for > 5 minutes, or < 75%

Laryngeal spasm

Bronchospasm

Hypercapnia – $p\text{CO}_2 > 7.5 \text{ kPa}$

Procedure related

Inadequate analgesia/anaesthesia—insufficient regional anaesthesia or awareness

Intubation difficulties – trained intubator using more than 1 minute

Equipment problems

Drug errors

Dural perforation

Pulmonary aspiration

Dental injury

Other

Hypothermia - Temperature < 35.5 °C.

Hyperthermia - Temperature > 39 °C.

Allergic reactions

Convulsions

Other adverse events

Method of recording:

Completion of the chart, including documentation of the anaesthetic work as well as the information in the data fields, is mandatory for every anaesthetic procedure.

Consequently, the data field for intraoperative problems is addressed at the end of every anaesthetic. If the case went uneventfully, this is indicated by 'Uneventful' in the check-list. If there has been a problem, the coding is agreed upon between the anaesthesiologist and the anaesthesia nurse, and marked accordingly in the appropriate check box with level of severity.

The recording is kept simple, and most codes are printed on the reverse side of the anaesthetic chart to minimise extra work associated with completion of the data fields. Only the codes for operative procedures are separate, also kept simple with about 250 separate codes, available in every operating theatre.

The data are stored in a database on the hospital server, accessible only to key personnel in the department, and not directly by hospital management. This ensures confidentiality for the individual anaesthesiologist, and departmental control with reports based on the database.

Additionally, the department has attempted to create an atmosphere of 'confidence and openness' regarding problems. Department meetings are held, both for doctors and nurses, where selected cases are discussed. The focus is on the learning potential of the problem, and rather than on the individual anaesthesiologist or nurse.

Quality Control:

A consultant reviews all charts before department secretaries enter the data. If any data fields on the charts are incomplete, they either are supplemented based on information on the chart, or returned to the anaesthesiologist responsible.

During data entry, a program checks the information continuously for logical inconsistencies (for example that the surgery does not start before the anaesthetic).

After data entry, the database is quality checked by a consultant. Another data program checks the database for incorrect values, missing data and logical inconsistencies. In addition, possible errors in coding of anaesthetic techniques, airway, ASA, regional anaesthetic, are checked with reference to the copy of the anaesthetic chart.

Resource use:

Data from about 20,000 charts are entered each year, i.e. about 100 charts per working day. Since each chart requires about two minutes, this occupies a secretary for 3-4 hours each day. Two consultants use totally approximately one hour per day for checking the charts and for quality control of the database.

Analysis of data – retrieval of charts :

Variable case selection criteria are used in the papers in this thesis; for details, refer to the individual papers. When needed for analysis, the database information was supplemented by retrieval of the patient's anaesthetic chart. Copies of the charts from the last ten years are stored in the department.

Statistical methods:

For comparison of categorical data between groups, a chi-square or Fischer's exact test was used, while a T-test was used for continuous data. A 'chi-square test for trend' was used for testing trends in binomial proportions.⁵⁰ P-values are two-sided, and $P < 0.05$ is considered statistically significant.

Statistical process control:

Statistical process control methods were used for statistical evaluation of the anaesthetic process.⁵¹⁻⁶⁰

The occurrence of adverse events during a defined time interval (bi-monthly or tri-monthly) was charted, the rate being number of adverse events per hundred anaesthetics (percent). This rate is expected to vary between periods, a 'natural' variation caused by the random combination of many different causes, e.g. time of day, the patient's physical condition, methods used, and working routines (common causes). This natural variation is inherent as a regular part of the process performance and characterises a 'stable' process.

'Unnatural' variations, on the other hand are observations that are very unlikely to occur within a 'stable' process. They characterise the 'unstable' process, and are usually presumed to represent special events or deviations from the regular process (special causes).

The frequency of adverse events during the defined time intervals were plotted in a 'p-chart', where each data point expresses the percent of cases with adverse events in a given interval.^{51,52} The p-chart also includes probability limits for 'natural' process variation. These are calculated from the binomial-based standard deviation of proportions [$SD = \sqrt{p(1-p)/n}$], where 'p' is the long-time average proportion of events, and 'n' the number of cases in the interval. The 'Upper/lower control limits' for natural variability are set to ± 3 SD's from the

long-time average, in accordance with recommendations from the literature.⁵² The normal distribution was taken as an approximation to the binomial-probability distribution, which is acceptable when 'n' is large and 'P' is low.⁶¹ Consequently the likelihood for data values, which represent natural variability, to be between these 3 SD limits is high ($P=0.9973$).

Observations beyond the 3 SD 'control limits' are unlikely to occur within an unchanged process ($P=0.0027$), and probably represent 'unnatural variation' due to a special cause. Supplementary 'within limit' tests for process stability have been suggested, for example eight or more consecutive points on the same side of the average, 12 of 14 consecutive points at the same side of the average, or a trend of six points in a row steadily increasing or decreasing.^{52, 59}

Whether the process is in statistical control (stable) or not in control (unstable) determines what kind of action is appropriate to improve the process. To improve 'stable processes', the regular underlying factors of the process must be changed. In 'unstable processes' the new 'special' causes must be identified and removed from the regular process. Interventions to improve quality become 'special' cause that will cause the original stable process to change, and be re-established as a new stable process, but with the process average moved in the desired direction.⁵⁹

SUMMARY OF RESULTS:

Paper I: Data recording of problems during anaesthesia – presentation of a well-functioning and simple system

This paper is primarily a method and feasibility paper describing the data recording system, and giving examples of possible applications.

The data recording system is kept simple, both in database design and in recording, in order to reduce extra workload for the data providers. All data information is entered directly on the anaesthetic chart, and all necessary codes are printed on the reverse side of the chart. The department has created an atmosphere with focus on 'confidence and learning potential' regarding problem recording. These elements, together with relevant feedback to the data providers, should improve compliance with the system.

Information was recorded about the patient, the anaesthetic, timing of events, and intraoperative problems. The latter was used as a basis for applications in quality improvement and safety.

There was an increase in recorded problems from 3.6 % of cases in 1985 to 14.5 % of cases in 1995, but the increase was mainly in minor problems. In 1995, we recorded a problem of minor severity in 10.3 % of anaesthetics, a problem of moderate severity in 3.5 % of cases, and a serious problem in 0.6 % of cases.

This methodology article also gives examples of data application; quality improvement (equipment problems, further examined in Paper IV), evaluation of current practices (aspiration pneumonia, further examined in Paper II), application in education (departmental meetings with nurses and doctors), and research (fatigue as a cause of reduced patient safety, manifested as increased problem rates during night-time anaesthesia).

Comparing problems between day-time and night-time surgery, there was an increased rate of problems at night. However, the day and night case-mixes were different, as patients in ASA-class 3-5, older than 70 years, emergencies, and general anaesthesia, were more common during at night. These differences might explain the difference in problem rates if stratified analysis were to be done, but this question is not pursued further in this study.

Paper II: Routine preoperative gastric emptying is seldom indicated. A study of 85,594 anaesthetics with special focus on aspiration pneumonia.

Pulmonary aspiration of gastric contents remains an important cause of anaesthetic morbidity. Gastric emptying with a gastric tube preoperatively has been extensively used as prophylaxis. We wanted to evaluate the frequency and severity of aspiration in our hospital, and whether our routines for gastric emptying could be considered safe.

During the four-year study period (1989 to 1993), 85,594 anaesthetic procedures were recorded. Twenty-five cases were recorded with 'Pulmonary aspiration', and retrieved for closer analysis. All cases occurred during general anaesthesia (incidence 1: 2,106). No cases were recorded among regional anaesthetics or sedation. Thirteen cases occurred in 'elective' procedures (incidence 1: 3,303) and twelve during 'emergency' procedures (incidence 1: 809). One half of the cases occurred during induction, predominantly gastrointestinal and gynaecological surgery.

Outcomes were as presented in Table III (Page 24). Three patients were seriously affected initially, with severe and prolonged oxygen desaturation. Two patients developed severe aspiration pneumonia, and needed prolonged postoperative respirator treatment. There were no mortality or lasting morbidity.

Table III**Outcome of pulmonary aspiration – number of cases**

	<i>Immediate morbidity</i>	<i>Long-term morbidity</i>
	n	n
None	11	19
Slight	11	4
Serious	3	2

Long-term morbidity means that there are symptoms or signs of pulmonary aspiration lasting beyond 24 hours.

Routine preoperative gastric emptying is performed only in cases of suspected intestinal obstruction (ileus), and not in other cases for emergency surgery. The safety of this routine was evaluated by the analysis of the aspiration cases. Only one case could possibly have been prevented by stricter routines for preoperative gastric emptying. We conclude that pulmonary aspiration is rare, and that our current routines are safe.

Paper III: Adverse drug errors in anaesthesia, and the impact of coloured syringe labels.

Drug errors are common in hospitalised patients, but the incidence of this problem in anaesthesia is unknown. Coloured syringe labels have been suggested for minimising 'syringe swaps',⁶²⁻⁶⁵ but their effects have not been evaluated.

We studied cases with adverse drug events or drug errors. The study period was thirty-six months (Sept. 1996 – Oct. 1999), eighteen months before and eighteen months after an intervention to reduce the frequency of errors (departmental education and introduction of colour coded syringe labels).

Sixty-three cases of 55,426 anaesthetics were recorded as having a drug error (0.11%, incidence 1:880). Fifty-six occurred during general anaesthesia (incidence 1:660), and seven during regional anaesthesia (incidence 1:2560). The type and severity of errors were as presented in Table IV.

Table IV

Distribution of type and severity of drug errors:

Drug Errors	Period 1 n	Period 2 n	Total n
All	40	23	63
Syringe swaps	16	12	28
Ampoule swap	8*	1*	9
Other wrong drug	4	4	8
Wrong dose	12	6	18
Drug errors Severity 1	22	11	33
Drug errors Severity 2	16	11	27
Drug errors Severity 3	2	1	3

Period 1 is the first eighteen months of the study period, Period 2 is the last eighteen months of the study period, after the quality intervention. Number of cases = n.

No statistically significant difference was found between periods using Fisher's exact test, except for a reduction in rate of ampoule swap* (P=0.04).

Syringe swaps were most common (44% of events), and muscle relaxants were the drug most commonly given in error. All but one syringe swap were between syringes of equal size. No significant reduction in drug errors was detected from period one to period two, except for a reduction in ampoule swaps.

No contributing factors other than similarity of syringe size and colour could be identified for syringe swaps. In 'wrong dose' errors, single examples of contributing factors were recently introduced drugs, new staff, and paediatric patients.

Three problems were judged serious (Severity Grade 3); they caused severe oxygen desaturation. The cause was ventilation with 100% N₂O instead of oxygen in two cases, and in one case succinylcholine was mistaken for saline and used to flush the i.v. cannula in an awake patient. Twenty-seven events were judged as of moderate severity (Grade 2). Of these, twelve patients received muscle relaxant when awake, and six of these had noticeable paralysis before general anaesthesia was induced.

We conclude that drug errors are uncommon, but have a potential for serious morbidity. Colour coded labels did not eliminate the problem of syringe swaps.

*Paper IV: Equipment problems during anaesthesia
– are they a quality problem?*

Equipment problems are known to contribute to anaesthetic morbidity and mortality.⁶⁶⁻⁶⁹ The magnitude and pattern of these problems are not established. We wanted to analyse the magnitude of this problem in our department, and if quality improvement efforts were needed.

Cases with equipment problems during a five-year study period (1996-2000) were studied; we performed 83,154 general and regional anaesthetics in the period.

Equipment problems were recorded in 157 cases (0.19%), more during general anaesthesia (0.25%) than during regional anaesthesia (0.05%).

Most equipment problems were trivial, as presented in Table V. Four problems were judged as serious, but no patient suffered any lasting morbidity, or needed prolonged postoperative care. All the serious problems involved elements of human error.

Table V:

Type of Equipment Involved, and severity of problem:

Equipment involved	Severity Grade 1 n	Severity Grade 2 n	Severity Grade 3 n	All equipment Problems n
Anaesthesia Machine	26	22	1	49
Invasive arterial pressure	14	4	-	18
Non-invasive arterial pressure	14	1	1	16
Gas analyser	12	-	-	12
Other Monitor	8	2	-	10
ECG	10	-	-	10
Heart Lung Machine	-	5	2	7
Pulseoximeter	7	-	-	7
Endotracheal tube	4	1	-	5
Infusion pump	4	1	-	5
Temperature measurement	4	-	-	4
Capnograph	3	1	-	4
IV access	1	1	-	2
Central Venous Pressure	2	-	-	2
Defibrillator	1	1	-	2
Blood Warmer	1	-	-	1
Thorax drain	-	1	-	1
Laryngoscope	1	-	-	1
Diuresis set	-	1	-	1
Total	112	41	4	157

Number of cases = n

One third of the problems occurred with the anaesthesia machine, with the most common being leakage from, or wrong connection of, the breathing system. The majority of other problems occurred with invasive and non-invasive blood pressure monitoring.

A quarter of problems involved elements of human error. The equipment involved was mostly the anaesthetic machine, and the errors were inadequate pre-use checks.

No trends were noted in the rate of equipment problems, while there were an increased occurrence of other problems in the study period.

With our current routines for checking and maintenance, we found equipment problems to be a small quality problem in the department.

Paper V: Serious intraoperative problems – a five-year review of 83,144 anaesthetics.

Serious intraoperative problems represent 'near misses' from major anaesthetic morbidity and mortality. We wished to study the pattern and occurrence of these problems in order to improve preventive strategies. We also wanted to investigate the clinical consequences of the most serious problems, as the accident potential of the 'near misses' is a fundamental assumption of our project.

We studied cases with serious problems (severity Grade 3) or death (Grade 4) intraoperatively. During the five-year study period (1996-2000), we performed 83,844 cases of general anaesthesia, regional anaesthesia, and sedation (anaesthesia for cardiac surgery was not included).

There were 315 cases (0.4%) recorded with serious problems, and 42 (0.05%) with intraoperative death.

Among the 315 serious problems there were more problems during general anaesthesia, than during regional anaesthesia or sedation. Anaesthesia was considered the major causative factor in 111 cases, surgery in 23, and the patient's medical condition in 181 cases. Anaesthesia was also a contributory factor in 78 cases in which the patient's medical condition was considered the major factor. (Table VI)

Table VI: Serious problems occurring during anaesthesia analysed for major causative factors:

Problem	Major factor			Total
	Anaesthesia	Surgery	Medical condition	
	n	n	n	
Hypotension	13	18	93(27)	124
Intub. Difficulties	25	-	57(41)	82
Arrhythmia	14	1	12 (3)	27
Difficult emergence	23	2	2 (2)	27
Allergy	14	-	-	14
Oxygenation problems	-	-	8	8
Aspiration	4	-	1 (1)	5
Laryngeal spasm	4	-	-	4
Drug error	4	-	-	4
Respiratory arrest	3	-	-	3
Myocardial ischemia	-	-	3 (1)	3
Bronchospasm	1	-	2 (2)	3
Equipment problem	2	-	-	2
Other	4	2	3 (1)	9
Total number	111	23	181 (78)	315

Numbers in parenthesis are cases where anaesthesia was considered a contributory factor.

When anaesthesia was considered the major causative factor, the most common problems were with intubation, difficult emergence, allergy, arrhythmia and hypotension. Eighty-two of these (73%) were considered preventable.

In 85 of the 315 cases (27%) the problem resulted in a change in the patient's expected postoperative course, sixty-one had an unplanned ICU admission, three underwent tracheotomy, and in twenty-one, surgery was postponed because of intubation difficulties. In twenty-six of the 111 cases (23%) in which anaesthesia was considered the major factor, the problem caused a change in postoperative course. Eighteen were admitted to ICU, one had a tracheotomy, and in seven cases surgery was postponed. One patient later died in the ICU.

Forty-two patients died intraoperatively. All were ASA-class IV or V, except three with uncontrollable bleeding during surgery. There were no anaesthesia-related intraoperative deaths.

Possible preventive measures for hypotension problems included improved preoperative evaluation and stabilisation, and better choice of induction doses. Prevention of intubation problems included better preoperative prediction of problems, and the use of an algorithm for choosing the correct technique when difficulties were anticipated. Preventive measures for serious arrhythmia included improved preoperative evaluation, and better routines for monitoring during all phases of anaesthetic care. To prevent problems during emergence, critical appraisal of extubation criteria, including residual effect of drugs should be considered.

Paper VI: Statistical process control methods allow the analysis and improvement of anaesthesia care.

The occurrence of adverse events during anaesthesia partly reflects the quality of the anaesthesia process. Special statistical methods should be applied for analysis of process performance. We have exemplified the use of statistical process control methods with our data.

For this study, all cases during the five-year period (1997-2001), were included, except cardiac anaesthesia and children (age < 16 years). This totalled 65,170 anaesthetics, of which 38.8 % were regional, and 69.2 % general. For the statistical process control analysis, we charted the bi-monthly rate of adverse events. Because of their relevance to anaesthesia quality or safety, four types of adverse events were selected for analysis: inadequate analgesia during brachial plexus blockade, difficulties during emergence from general anaesthesia, intubation problems, and medication errors.

Of 2,228 brachial plexus blocks, 358 (16,1%) were recorded as inadequate. The failure rate varied between bimonthly periods from 8% to 26%. The process was statistically stable evaluated by a p-chart, as no points fell outside the calculated control limits, and no trends were detected.

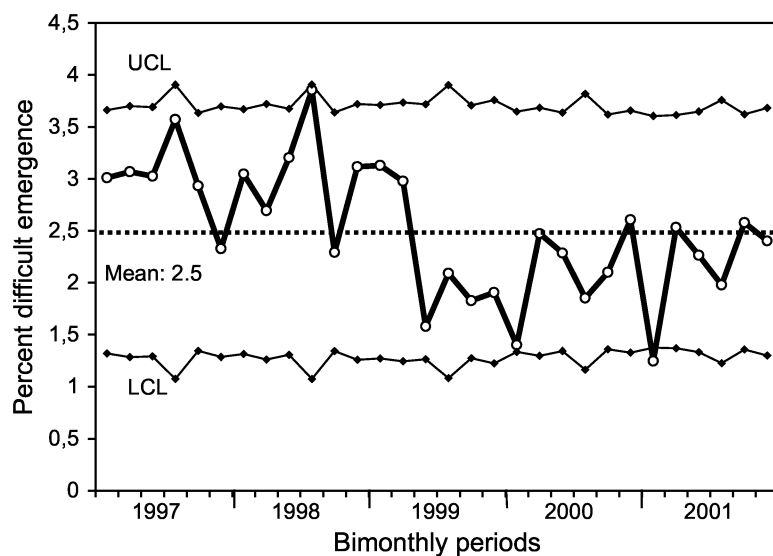
Among 45,087 general anaesthetics, there were 1,123 cases (2.5%) with difficulties during emergence from general anaesthesia, and variability from 3.85% to 1.25%. The process from 1997 to 2001 was statistically unstable, with points outside the control limits (Figure IV, page 33). However, if the data series are regarded as two different processes, before and after the intervention in 1999 (educational focus on the problem, including preventive strategies and the use of opioids and neuromuscular blocking drugs), the processes presents as two different statistically stable processes (Figure V, page 33). The mean rate of problems was reduced after the intervention (3,0 % vs. 2,1%) ($P < 0.001$).

There were 429 cases with difficult intubation (severity Grade 2 & 3) among 28,081 intubations (1.5%), with variability between 0.52% and 2.20%. The process was statistically stable.

The occurrence of medication errors was 81 in 65,170 anaesthetics (0.12%), with variability between 0.03% and 0.25%, representing a stable process. The lower control limit was not applicable, as the calculation returns negative rates.

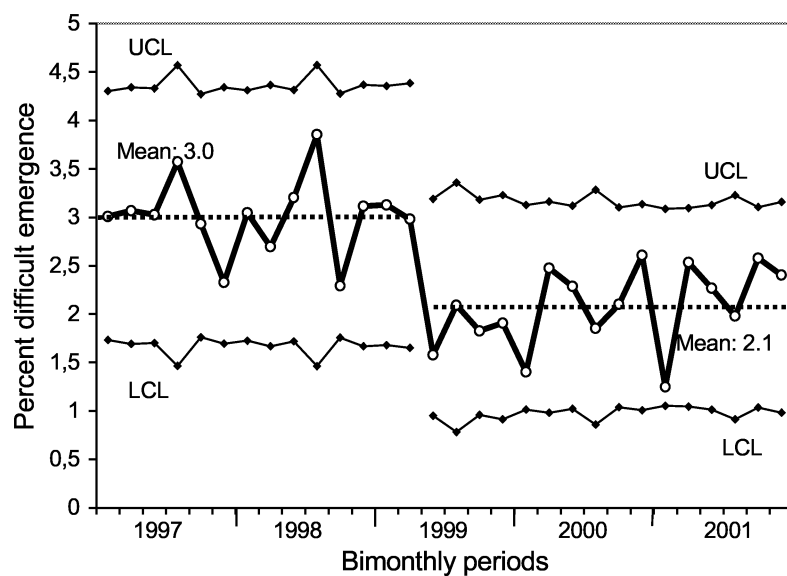
In this study we exemplified the application of statistical process control methods to rates of adverse events, and demonstrated how p-charts can be used for monitoring and improvement of quality.

Figure IV



Control chart showing the rate of difficult emergence from general anesthesia. UCL = Upper Control Limit . LCL= Lower Control Limit. Data points (O) are bimonthly percentages. Data points (♦) are UCL / LCL .

Figure V:



Control chart showing the rate of difficult emergence from general anaesthesia separated in two processes; before and after intervention. UCL = Upper Control Limit . LCL= Lower Control Limit. Data points (O) are bimonthly percentages. Data points (♦) are UCL / LCL.

DISCUSSION:

Most important findings – general conclusions

The aims of this study were to establish a routine-based system for recording adverse events during anaesthesia, and to evaluate the use of these data as basis for improvement of quality and safety in anaesthesia.

Paper I describes the recording system; the recorded information, how the system is implemented in the daily routine, how the quality of the data is ensured, and possible applications of such data. The main focus of this paper was on feasibility and compliance.

Paper II analyses the occurrence and severity of gastric aspiration, and concludes that it is a rare complication, which seldom causes serious morbidity. A restrictive policy toward gastric emptying preoperatively did not result in more cases of gastric aspiration.

Paper III analyses the occurrence of drug errors during anaesthesia and the possible effect of introducing coloured syringe labels on the frequency of errors. Drug errors were uncommon, mostly of low severity, but clearly with a potential for disaster. The introduction of coloured labels did not eliminate the syringe swap errors.

Paper IV analyses equipment-related problems, and the need for additional quality improvement. Such events were found to be rare, and of low severity. The anaesthetic machine was most often involved. No specific strategies for problem reduction could be suggested apart from better preoperative checks. Our levels of maintenance and internal education seem adequate.

Paper V analyses the most serious adverse events, which are presumed to have a considerable potential for evolving into accidents. The most common events were intubation problems, difficult emergence, allergy, arrhythmia, and hypotension. In cases where anaesthesia was a main contributory factor, two thirds were considered preventable with simple strategies.

Paper VI illustrates how statistical process control methods can be used to analyse the rate of adverse events, and to assess the quality of the anaesthetic process. We selected four quality-related events, and assessed the variability of their underlying processes. We were able to determine whether changes in problem rate only represented natural variations, or were real deviations in process performance.

The general conclusion from the study is that it is possible to record the occurrence of adverse events in a simple routine based system. A simple recording system and a non-punitive recording culture are important prerequisites. Analysis of adverse events enables us to evaluate aspects of anaesthetic safety, which is an important part of anaesthetic quality. The application of statistical process control methods separates natural variations in problem rates from real changes in process performance, important for planning quality improvement strategies.

Quality in anaesthesia:

It is difficult to formulate a concise, meaningful and generally applicable definition of the quality of health care, as it includes different aspects as patient safety, patient satisfaction, patient outcomes, economical aspects, and resource use.⁷⁰⁻⁷² Eagle and Davies subdivided quality of care in anaesthesia into seven different attributes.⁷³ These attributes were safety, provider competence, acceptability, accessibility, efficiency, appropriateness, and effectiveness - each concerning different aspects of quality.

Most of these quality attributes can be addressed with our simple perioperative database, which includes both administrative and medical information (Paper I).

However, as our chief interests were the safety and morbidity aspects of quality, we have focussed on the analysis of intraoperative adverse events, as in other studies concerning quality and safety in anaesthesia.^{7,16,30,74,75}

Quality measurement:

There is an increased interest in performance measurement and ranking of performance in medical care. However, it has proven difficult to define practical and useful quality indicators for medical care, including anaesthesiology.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (www.jcaho.org) includes performance measures in their accreditation of hospitals in the United States. They list their most important attributes for performance measures, which also are applicable to quality indicators:

- A: Relevant - improvement is likely to have clinically significant impact
- B: Precise definition and specification
- C: Reliability – consistently reproducible results across organisations
- D: Validity – are we measuring what we intended to measure
- E: Easy interpreted – understandable by users of data
- F: Risk adjustment or stratification possible
- G: Resource utilisation evaluated
- H: Useful in the accreditation process
- I: Processes or outcomes measured are under provider control

These attributes are to be included when performance measures are elaborated for use in the accreditation process. The same attributes have been basis for the Norwegian recommendation for quality indicators in somatic hospitals (www.odinsok.dep.no). Other, 'Non-Core' measures have been adapted for perioperative care, but are only available for hospitals accredited by JACHO.

Traditionally measures for quality of care have been evaluated based on structure, process, and outcome.^{73,76} Structure measures refer to characteristics of the department, like administration, physical environment, personnel, and equipment. Process measures refer to how the system operates. Outcome measures refer to the patient's subsequent health status.

If quality of care criteria are based on structural or process measures, it should be demonstrated that variations in the attribute they measure lead to differences in outcome. Similarly, if outcome measures are to be credible it must be demonstrated that changes in the processes of care will produce differences in outcome.⁷⁶

Quality measures can be separated in administrative (e.g. delays) and clinical measures (e.g. patient harm). From our system, we have exemplified quality indicators relevant for the quality and safety of clinical practice, some of which are applicable as rate-based departmental quality indicators.

In short, a good quality indicator should represent an important quality issue, be relatively easy to define precisely, and must occur with a frequency that makes it a suitable rate based indicator. However, information for improving quality may also be acquired from sentinel events, which are serious events occurring too rare to be suitable as rate-based indicators. These can be reviewed as separate events, or in groups, for quality purposes when they occur (Paper III, IV, V).

Closing the 'quality circle':

Using rate-based events as quality indicators to improve clinical practice is an application of the classical 'quality circle'. The 'quality circle' consists of the elements of planning (plan), intervention (do), data collection, data evaluation (study), change process based on results (act), and eventually new data evaluation to check if the rate of events has changed as a reflection of improved

quality. To calculate rates, both the number of adverse events (nominator), and the number of procedures where an event could occur (denominator) are needed. When the departmental rates of specified adverse events are known, these can be compared to department performance standards. When applying this principle to patient logistics in a department, the 'first patient start time' and 'turnaround time between patients' were significantly reduced in a study by Vitez and Macario.⁷⁷ We also found a reduction in the rate of 'difficult emergencies' after a quality intervention in our department, illustrating the same principle (Paper VI).

Recording of adverse events

Definitions:

We defined intraoperative adverse events as 'an event that requires one or more measures, either to prevent further complications, or to treat a situation that is currently or potentially serious, - and which does not routinely occur during the conduct of anaesthesia'. This definition is similar to that of Cooper, who introduced the concept of critical incidents into anaesthesia in 1978,⁴⁰ and to later definitions.^{41,49,78} The common characteristic is that lasting morbidity is not necessarily assumed; it is the potential evolution into a serious accident that is the focus of interest.

We have deliberately used the terms 'problem' or 'event' for our recording system, as terms such as 'error' or 'complication' have more negative implications. 'Problems' are encountered by every anaesthetist; they are part and parcel of the practice of anaesthesia. In choosing the words 'problem' or 'event' we believe that compliance and consistency in reporting may be improved.

Reporting compliance - underreporting:

Our system is based on 'mandatory' reporting of data on every anaesthetic given. Included in this is the recording of adverse events during the anaesthetic; the problem check-box must be marked in all cases. If nothing untoward occurs during the anaesthetic, this is indicated in the 'uneventful' check-box (Figure III, page 16).

We have created a non-punitive reporting culture, where the objective of the recording is to learn and prevent re-occurrence. We also emphasise feed-back to the data providers, and have minimised the extra workload connected to the data recording. The system is an integral part of departmental routines, and the definitions, and practice of the system is well embedded in our routines. The anaesthetic and its documentation on the chart are the joint responsibility of the anaesthesiologist and anaesthesia nurse, which also may improve compliance. Based on these efforts and the quality control of the charts, our opinion is that the compliance in our system of problem recording is good.

Quality of data:

We have a constant focus on data quality. Review of the charts before data entry detects incomplete data, and incorrect data can be corrected. Data are also checked for logical inconsistencies during data entry, and for medical inconsistencies by a consultant after data entry. An alternative approach is to let the anaesthesia providers enter the data themselves, as this increases the possibilities for interactive data validation during entry.

In a nation-wide German quality improvement project, an automatic readable anaesthetic data record was used,⁴³ reducing the need for secretarial data entry, and possibly reducing errors. However, there still was a need for pre-entry chart control, as well as human and computer checks to maintain data quality.⁴⁷

Thus, to ensure adequate quality of data it is necessary with close follow up of the quality of the information, both before and after the data are entered into the database.

Reliability – internal and external comparison

One of the important attributes of a quality indicator is reliability; the ability to consistently identify the events it was designed to over time, and - if comparisons between institutions are planned - across health care organisations.

Reliability will depend on a clear definition and understanding of the events, which the indicators are meant to capture. Such consistency is probably easier to obtain within a single institution, as factors other than sampling variability should change little between measurement periods.⁷ We have not specifically tested the internal reliability in our system, by checking inter-rater consistency etc. However, the definitions are relatively simple, and have been virtually unchanged for several years. Additionally - as the problem definitions are well known in the department, the case-mix is stable, and practice changes are gradual, the stability of the adverse event rates may be interpreted as reliability.

Between institutions however, varying degrees of reporting compliance among staff, differences in case-mix, interpretation differences, and differences in practice patterns may influence the reliability.⁷ Even when risk factors are corrected for, inter-institutional comparison of 'near-miss' data have proven difficult.^{7,79} Different publications from the German Quality Improvement Project, using identical methodology, also showed large variation in problem rate between institutions.⁴³⁻⁴⁹ The Norwegian Association of Anaesthetists designed an data application (NAFREG) in 1988, for recording of an agreed upon minimal basis data-set.⁸⁰ The registration system was evaluated in six hospitals, and was apparently working well for administrative purposes, but the discrepancy in problem occurrence was found to be too great for inter-institutional comparisons.⁸¹

Health administrators and the public, however, ask for quality 'measurements' and comparisons between institutions and departments. Most comparisons have been on managerial performance, such as waiting times or time from admission to surgery, and such indicators also dominate suggestions for indicators by Sosial og Helsedepartementet in 2003 (www.helsetilsynet.no). More clinically directed indicators have been difficult to define, and are not yet used for comparison between institutions. Indeed, the value of comparisons between institutions has been questioned, and statistical process control methods have been recommended as an alternative to traditional performance league tables.⁸²

Project Results

Paper I: Data recording of problems during anaesthesia – presentation of a well-functioning and simple system

There are few publications based on mandatory reporting from all cases, and they are either more than ten years old,^{7,42} or group intraoperative and postoperative problems together.⁴³⁻⁴⁹

Cooper and co-workers reported a frequency of 13.8% 'recovery room impact events' (RRIE) in the operating room.⁴² The most frequent intraoperative problems in their study were hypotension, arrhythmia, hypertension, and intubation difficulties. However, the type of anaesthesia and the severity of events were not stated.

In Cohen's study, data on patients from four teaching hospitals were collected. The rate of operating room adverse events varied from 14.9% to 27.8% between the four hospitals.⁷

Several studies have been published from a German Quality Assurance project, where data were collected from all anaesthetics, and 63 types of perioperative

events were defined, with five levels of severity.⁴³⁻⁴⁹ The frequency of events varied from 14.1% to 27.9%, but operating theatre and recovery room events were not separated, and neither were types of anaesthesia.

In our study, the frequency of adverse events among all cases increased from the year 1985 (3.6%) to 1995 (14.5%) (Paper I), in 2002 the overall frequency of adverse events was 14.9%. The initial increase in problem occurrence probably reflected a learning process and the establishment of a reporting culture in the department. The average incidence of adverse events during regional and general anaesthesia in adults was 18.3% in the period 1997-2001.

It is not possible to compare the frequency of events between studies, as definitions, compliance, case-mix, anaesthetic practice, are variable. However, the rate of intraoperative adverse events is of the same magnitude between studies using similar methods, indicating a level of adverse events detected with this methodology.

The definitions of severity of problems are also variable between studies. Our definitions are in accordance with national recommendations in Norway, where the definition relates to the difficulty of the situation, and the effect on the patient, without presupposing any lasting morbidity or changed outcome.⁸⁰ Other studies have graded severity after impact on need for postoperative room care.^{42,47} In our study, serious events occurred in 0.4% of anaesthetics (Paper V), while the rate was between 0.2% and 2.1% in the German studies.⁴³⁻⁴⁹

The present study has demonstrated that a simple anaesthetic database allowed anaesthesiologists to learn from past experience, and to strive to improve patient care. Important aspects with the system are the creation of a reporting 'culture', the departmental ownership of the data, relevance of problem analysis, and the need for continued attention to problem occurrence.⁸³

Paper II: Intraoperative pulmonary aspiration - routines for preoperative gastric emptying:

Pulmonary aspiration of gastric contents has been,⁸⁴ and still is a feared complication of anaesthesia.⁸⁵⁻⁸⁷ However, a low occurrence of pulmonary aspiration has been found in various groups of patients.⁸⁸⁻⁹⁶

The frequency of pulmonary aspiration in our department (3.0 : 10,000 elective general anaesthetics) is similar to the frequency in two large prospective studies from the United States (2.2 and 2.6 per 10,000 elective general anaesthetics respectively).^{85,94} One retrospective study in children showed a higher incidence of 10.2 per 10,000.⁹⁶

Even if the current mortality from gastric aspiration is low, there is a potential for serious morbidity (Paper II) and death.⁹⁷⁻¹⁰⁵ Preventive measures are therefore important, and involve control of gastric contents by preoperative fasting, pharmacotherapy to reduce gastric pH, and methods to minimise regurgitation.^{87,106} Reducing the amount of gastric contents includes evacuation of gastric contents via a nasogastric tube. In a Norwegian survey, 76% of the departments would use preoperative mechanical gastric emptying in emergency gynaecological laparotomy,¹⁰⁷ while only 18% of the respondents would perform this procedure in a recent survey from New Zealand.¹⁰⁴ The procedure is uncomfortable and stressful,¹⁰⁸ and does not guarantee an empty stomach.¹⁰⁹

Our practice was more restrictive, in that we used preoperative mechanical gastric emptying only in cases of suspected intestinal obstruction. This practice did not contribute to our cases of gastric aspiration, and appears to be safe, provided that other anaesthetic techniques for prevention of pulmonary aspiration are performed.

Paper III: Adverse drug errors, and the impact of coloured syringe labels

Drug errors are among the most frequent adverse events in hospitalised patients.¹¹⁰⁻¹¹³ The magnitude and severity of the problem in anaesthesia has not been established, as most studies have not classified the type of drug errors,⁷ or have been based on reports on incident cases only.^{28,102,114,115}

We found a total problem incidence of 15% and a drug error incidence of 0.11% in the population studied. With similar methodology to ours, Cohen et al.⁹¹ found a 10.6% incidence of intraoperative problems, and 0.18% drug complications, but no classification of drug errors was provided. In a study by Spittal et al.,⁶⁸ which was based on forms filled in only when a problem had occurred, a problem rate of 6.7% was recorded, of which 0.16% were 'wrong drug or dose' incidents. In a recent study by Webster et al.,¹¹⁶ anaesthetists were asked to return a study form recording drug errors for every anaesthetic. From 10,806 anaesthetics, 81 errors were reported, giving an incidence of 0.75%.

If the drug errors are compared to the total problem occurrence, the drug errors represented 0.8% of all problems recorded in our study. This is comparable to 1.5% by Cohen,⁹¹ and 2.4% by Spittal.⁶⁸ However, other studies based on voluntary reporting of incidents, but without knowledge of the total number of cases, have found greater representation of drug errors, from 7.2% to 22%.^{28,102,114}

Even if the rate of drug errors is low, the potential for serious morbidity exists. Fifty percent of the events in our study were of intermediate or serious severity. Seven patients who received muscle relaxants when awake were partly or completely paralysed before induction of general anaesthesia, which predisposes to problems with anxiety postoperatively.^{117,118} In the study by Webster et al, no serious morbidity occurred, but in seven of 81 cases 'major physiological changes' were reported.¹¹⁶ In Orser et al.'s survey of anaesthetic practice in Canada, 1.4% of adverse events resulted in major morbidity, and four deaths were reported.¹¹⁵

Thus, although drug errors constitute a relatively small problem in anaesthesia, both in absolute terms and in relation to other problems, there have potential for major morbidity.

Our intervention with colour coded labels and general educational sessions, did not significantly reduce the occurrence of drug errors. Short et al. reported similar findings; no change in drug errors after a quality improvement intervention.³⁰ It is however, problematic to apply statistical process control methods to these results, as such low frequencies impairs p-chart analysis (Paper VI). Therefore, a qualitative approach for analysis may more applicable.^{119,120}

'Syringe swap' was the most common error in our study, as in that of Orser et al.¹¹⁵, and was second to 'wrong dose' only in the report by Webster et al.¹¹⁶. The introduction of coloured labels, thought to provide 'visual and mental cues',⁶²⁻⁶⁵ is clearly not strong enough to prevent error. Indeed, the value of the concept of colour coding has been questioned.¹²¹

In anaesthesia, as in hospitals, most drug errors are totally or partially attributed to human error.^{111,114-116,122} Examples of psychological factors which increases the possibility of a human error are 'inattention', 'haste', 'communication problems', and 'fatigue'.^{34,123,124} Preventative strategies should not only aim to reduce these psychological factors, but must also aim at reducing the possibility for error caused by non-psychological factors. Thus the environment, or 'system', in which the anaesthesiologist works must also be the target for corrective strategies. These strategies should search to reduce both the occurrence and the consequences of medication errors.³⁴

Standardisation is an important example of a 'system based' approach.^{114,122,125} It can be achieved by the selection of drugs in the department, by defining drug preparation routines, and by the layout of drug trolleys. National standardisation of drug labels would be ideal, but difficult to implement.¹²⁶ Ampoules and syringe

labels should also have large letters. Almost no swaps occurred between drugs in syringes of different sizes in our study and the AIMS study.¹¹⁴ Thus if one size of syringes was used for only one group of drugs, this might be a strong enough visual cue to reduce syringe swaps.

It has been recommended that the medical profession place less reliance on short-term memory and vigilance, and instead should address the potential for reducing errors through the use of checklists and computerised decision aids.³⁴ Double-checking of ampoules as the drug is drawn up into the syringe, and checking the label on the syringe as the last procedure before giving the drug to the patient, should be standard.

Since the introduction of colour coded drug labels did not eliminate the problem of syringe swap, other system improvements, such as better visual cues, and better checking procedures are needed in the line of defences against drug errors.¹²⁷

*Paper IV: Equipment problems during anaesthesia
– are they a quality problem?*

Equipment malfunction contributes to anaesthetic morbidity and mortality , and the anaesthesia machine is most often involved.^{28,66-69}

We found 0.19% equipment problems in our study. Previous studies have shown the frequency of equipment problems to vary between 0.2-2.1%, but study design, reporting methods, problem classification and preoperative checking routines have varied or not been specified.^{7,31,49,68}

Four studies using mandatory data recording from all anaesthetics have reported incidence of equipment problems. Our frequency is of the same magnitude as those of Cohen and coworkers who found 0.1 – 0.4% equipment problems in 27,184 anaesthetics in four different hospitals.⁷ A check-off form was completed

for every patient, and eighteen types of intraoperative problems were included, but severity was not assessed. The incidence of total problems varied from 14.9% to 27.8% among the four hospitals.

In three studies from the German Quality Assurance project the frequency of equipment problems was 0.7%,⁴³ 0.9%,⁴⁶ and 1.2%⁴⁹ the frequency of all problems was 23.2%, 27.9% and 22% respectively. We found fewer equipment problems and fewer total problems than in those studies, but these included the whole perioperative period and definitions and classifications were different. There is of course a possibility of differences in problem occurrence, and/or reporting compliance.

The general conclusions from these studies and our own are similar; equipment problems are rare and of low severity. A few had untoward effect on patients, but there was no lasting morbidity. Nevertheless, equipment problems do carry a potential for serious outcome, and preventive measures are important.^{16,43,67,90}

Other studies have collected data by voluntary reporting only of problem cases. The overall problem figures are generally lower, as underreporting is well recognised.^{20,21} Short and co-workers reported a frequency of 0.23% equipment/breathing system problems in 16,379 anaesthetics, but an overall problem rate of only 0.76%.³¹ Spittal and co-workers reported 2% equipment related problems in 5,056 cases, with an overall problem rate of 6.68%.⁶⁸ The case mix, routines for preoperative checking of the anaesthesia machine, and level of maintenance of other equipment, were not specified in these studies.

The anaesthesia machine was the most common cause of equipment problems in our study (31%), as in the German ones (22-30%).^{43,46,49} Also in other studies, where the denominator is not known, problems related to the anaesthesia machine were most common (52-73%).^{28,31,68,69}

'Human error' was the main contributing factor in our study, as in others.^{31,67} The main cause is insufficient checking of the anaesthesia machine before use, and especially between cases. (Paper III)³⁰

To reduce the possibility of equipment problems caused by human errors it is important to modify the working environment so that the possibility of human error is minimised, and so that the possible injury caused by such errors also is minimised. This is an example of a 'system' approach to error management, where the working environment of the anaesthesiologist is optimised to avoid errors.^{34,128,129}

We found no change in occurrence of equipment problems, but the low rate of equipment problems limits statistical appraisal. Ideally, follow up of problems as part of continuous quality improvement efforts should lead to a decreased problem frequency. Short and co-workers found no change in problem occurrence from a critical incident reporting program,³⁰ but the program was considered effective in detecting latent system errors.

The usefulness of equipment problem rate as a continuous numerical quality indicator is limited because of the low rate, as changes in occurrence caused by quality efforts are difficult to separate from natural variation. Therefore, the most suitable further analysis of these data may be as 'sentinel events', where problems are analysed individually, or in groups, to elucidate causative factors and preventive measures, rather than through a numeric approach.

Paper V: Serious intraoperative problems – a five-year review of 83,144 anaesthetics.

Since anaesthetic mortality and serious morbidity are rare, their analysis is of limited value for quality improvement efforts.⁶⁻⁹ In our study, all the intraoperative deaths were caused by life-threatening medical conditions or surgical factors,

rather than anaesthetic complications. Study of the 'near miss' - the serious non-fatal problem - is therefore a more valuable starting point for preventive strategies,^{6,36} a philosophy used in aviation and other complex non-medical industries.^{9,11}

Intubation, difficult emergence, arrhythmia, anaphylaxis and hypotension were the commonest serious problems. Four studies, all representing mandatory reporting, are partially comparable to ours.^{42,43,46,49} These report both the occurrence and severity of incidents, but all have included incidents in the operating and recovery rooms together.

Cooper and co-workers reported incidents in the operating room or the recovery room as 'recovery room impact events' (RRIE).⁴² A RRIE occurred in the operating room in 13,8% of the anaesthetics, and the four most frequent intraoperative problems were hypotension, arrhythmia, hypertension and difficult intubation.

Three studies were published from a large German Quality Assurance project.^{43,46,49} Sixty-three types of incidents were defined, and five levels of severity according to their impact on postoperative care. Serious problems (Severity class 4-5) occurred in 1.2% in 18,350 cases,⁴³ 0,9% in 26,907 cases,⁴⁶ and 1.0% in 96,000 cases.⁴⁹ The overall problem frequencies were 23.2%, 27.9% and 22% respectively. The most common serious problems were respiratory, arrhythmia, and hypotension.

We did not use 'recovery room impact' as a criterion for severity, as it may not always be adequate. For example, most airway problems are treated without sequel, but still have the potential for catastrophic outcome.¹³⁰ It is important to evaluate the potential for disaster as well as the actual morbidity.

Hypotension was the most common serious problem in our study, as elsewhere,^{43,46,49} but its exact definition is difficult. Serious hypotension was most

often related to serious medical conditions or surgical bleeding, rather than anaesthesia. The most important anaesthetic preventive measures were to improve preoperative evaluation, preoperative stabilisation, and choice of induction drug dosage.

Airway problems are still among the most important cause of death and serious morbidity in anaesthesia.^{3,4,90,131,132} Our incidence of serious intubation problems of 0.2% is comparable to 0.4% in Rose and Cohen's study.¹³³ However, again the frequency of problems will vary according to the definition used.¹³⁴

Methods for preoperative airway evaluation have been tested with different predictive values.^{133,135-137} Nearly half of our patients with unexpected intubation problems had anatomical signs predicting intubation difficulties when reassessed afterwards. Better routines for preoperative evaluation, and early discontinuation of repeated intubation attempts may help reduce the risk.^{135,138}

Difficult emergence from general anaesthesia represented an important cause of serious problems in our study, but is seldom mentioned explicitly elsewhere. The main problems were related to airways and hypoventilation, and the causes were either misjudgement of residual drug effects, or of the patient's respiratory status before extubation. Increased use of neuromuscular blockade monitoring, and possibly delayed extubation should be considered as preventive measures.

Bradycardia and asystole were the most common serious arrhythmias. Their low frequency probably reflects prompt diagnosis and treatment of bradycardia and hypotension during central neuraxial blockade, necessary to avoid life-threatening circulatory collapse.^{139,140}

The frequency of serious allergic reactions was 1: 6,000 in our study, while in the German studies the frequency was from 1:4,500 to 1:6,400.^{43,46,49} In a French study by Laxenaire and co-workers the frequency of anaphylactic and anaphylactoid reactions during anaesthesia was 1:4,850.¹⁴¹ When neuromuscular

blocking drugs were used, the frequency of serologically confirmed anaphylactic reactions was 1:6,500. However, if anaphylactoid reactions were included as well, the frequency was around 1:3,250, comparable to our study (1: 3,000 cases when neuromuscular blocking drugs were used).

In the Laxenaire study anaphylactic shock had a 1% incidence of mortality or severe neurological sequelae.¹⁴² The only patient to die in our study was a man, ASA class II, in whom circulatory collapse dominated the symptoms and the diagnosis of anaphylaxis was delayed. Circulatory collapse is the sole predominant symptom in about 10% anaesthetic anaphylactic reactions,¹⁴² and it is important to bear this in mind when a patient develops severe hypotension after drug injection.

We had no cases of 'classic' aspiration, i.e. patients with a suspected full stomach or peritonitis who aspirated during induction. We follow the Norwegian 'National Fasting Guidelines',¹⁴³ which recommend preoperative gastric emptying only before induction of general anaesthesia where intestinal blockage is suspected. However, it is important to evaluate aspiration risk also in patients outside the 'classic full stomach' group, as gastric retention can be secondary to other serious conditions. (Paper II)

In twenty-three percent of the cases with serious problems caused by anaesthesia, the problem proved relevant for the patient's subsequent postoperative course, and did affect outcome. These 'near misses' have an inherent accident potential, and are relevant for the development of adverse events into accidents with major morbidity or mortality.

Even if rates between hospitals are difficult to compare, the patterns and possible preventive strategies of our study may be transferable to other institutions. Such data have proven suitable for accumulation in a central database, as in the Australian AIMS project,⁴¹ in parallel to systems for reporting 'near misses' in aviation.⁹⁻¹¹

Paper VI: Statistical process control methods allow the analysis and improvement of anaesthesia care.

The quality of the anaesthetic process can in part be evaluated by the occurrence of adverse events during anaesthesia. However, conclusions drawn from simple 'snap-shot' measurements of frequency of adverse events are not useful unless the characteristics of the underlying process is understood.^{58,144} Statistical tools, such as process control methods, may be applied to make inferences about process performance.⁵¹⁻⁵⁹

Statistical process control methods, first proposed by Walter Shewhart,¹⁴⁵ have been used for many years for process improvement in industry. They have also been applied in health care for describing and analysing processes that affect quality of care in healthcare organizations,^{56,144,146,147} as well as in anaesthesia.^{18,26,77,148}

Variation is expected in any process. Different conditions, patients, staff, and methods all combine randomly and contribute to variation in performance, even when the process itself remain unchanged. Under such conditions, isolated observations provide insufficient information on which to base decision-making, as they may be the result of chance, rather than real deviation in process performance. Decision-making requires a series of observations, so that recognisable and predictable patterns can be appreciated. Statistical process control methods, and 'Control Charts' can be used to accomplish this.^{54,149,150}

If a new data point on a p-chart has a higher value than the previous one, but both are within the 'control limits' of the chart, this reflects natural variation within a stable process. If this apparent 'increase' was acted upon as if the process had fundamentally changed, the analysis and action taken could be wrong, as the process probably is unchanged. The 3 SD control limits includes 99.73% of all

natural process variability. Consequently, the probability of measurement points occurring outside control limits, within an unchanged process is very small when using 3 SD limits. Such wide limits prevent too many 'false alarms', but may also conceal significant trends, as too few 'true alarms' may go off.⁵⁵

In summary, the control chart shows whether a process is stable or subject to special cause variation. This determines if valid comparisons can be made, and indicates the correct approach to improve the process. It will also show if a quality improvement initiative has been effective. However, the control chart says little, by itself, about quality, as a process can be 'stable' with minimal natural variation, and still reflect poor quality if the frequency of a quality associated adverse event is too high.

We analysed the department's ability to supply well functioning brachial plexus blocks. The process was statistically stable, but the average failure rate is high compared to published studies.¹⁵¹ Clearly the department must take corrective action, but we have not solved this problem, as can be seen from the persisting high failure rate. The analysis illustrates that even if the process is stable it still may reflect poor quality.

Figure IV (page 33) presents the rate of difficulties during emergence from general anaesthesia. The process is statistically unstable. A quality improvement intervention in 1999, results in a decreased frequency, and can be seen as a special cause in the chart, with nine consecutive points below the long time mean. In Figure V (page 33) the data-points are treated as two different processes, before and after the intervention. There are clearly two different stable processes; the lower mean value in the second time period indicates a successful intervention. The current rate of emergence problems must now be re-evaluated for acceptability from a quality and safety viewpoint, thus closing the quality circle.

The analysis of the process representing intubation difficulties shows a stable process, with an average rate of 1,5%. This is comparable to 1.8% difficult

intubations in a study by Rose and Cohen,¹³³ and such comparisons with international literature will determine if our frequency is acceptable.

We found a low rate of drug errors. As a consequence of this, the lower control limit calculation return values below zero, and therefore only 'within limits' tests for special causes are available, reducing the informative value of the chart. There are alternative statistical process control methods for charting infrequent events,^{52,60} or alternatively qualitative analysis may form a basis for preventive strategies.^{119,120}

We recorded intraoperative adverse events in 18.3% of anaesthetics, using a routine based recording system, and have analysed the frequency of selected adverse events, as a reflection of the quality of the anaesthetic process. The variability of the process was analysed by the statistical process control method of 'control p-charts'. This analysis can be used as a basis for monitoring and improving quality. It remains an important challenge to define and record those adverse events that are best suited as indicators of the quality of the anaesthesia process.

CONCLUSIONS

The aims of this study were to establish a routine based system for recording of adverse events during anaesthesia, and to evaluate the use of the data as basis for improvement of quality and safety in anaesthesia.

We have reached the following conclusions:

- Gastric aspiration is a rare complication, and seldom causes serious morbidity in our department. A restrictive policy toward gastric emptying preoperatively did not result in more cases of gastric aspiration.
- Even if drug errors were uncommon, they often were of more than minor severity, and with a potential for disaster. The introduction of coloured labels as a quality improvement intervention did not eliminate the syringe swap errors.
- Equipment problems were rare, and of low severity. The anaesthetic machine was most often involved, and better preoperative checks were needed. Our levels of maintenance and internal education seemed adequate.
- The most common serious adverse events were intubation problems, difficulties during emergence, allergy, arrhythmia, and hypotension. In cases where anaesthesia was the main contributory factor, two thirds were considered preventable with simple strategies.
- Statistical process control methods, applied to four quality-related events, were used to analyse the quality of the work process. This enabled us to conclude whether changes in problem rate represented natural variations, or were real deviations in process performance.

- It is possible to record the occurrence of adverse events as a part of departmental routine. A simple recording system and a non-punitive recording culture are important prerequisites for adequate reporting compliance, but the possibility of underreporting of adverse events is not solved.
- Analysis of adverse events enables us to evaluate aspects of anaesthetic safety and quality, and both qualitative methods and statistical process control methods may be applied to evaluate the effects of quality improvement efforts. However, reliable and valid indicators of anaesthetic quality are not established, and should be a focus for further research.

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Correction:

Paper V, Table I (Corrected: figures for Types of surgery)

Table I: Demographic data and occurrence of problems – according to type of anesthesia:

	<i>General anesthetics</i>	<i>Regional anesthetics</i>	<i>Sedation</i>
All cases (n)	59,185	20,564	4,095
Cases with problems (Grade 1-4) (n)	9,451 (16,0%)*	3,541 (17,2%)	199 (4,9%)*†
Cases with serious problems (Grade 3)(n)	270 (0,5%)	39 (0,2%)*†	6 (0,1%)*†
General surgery (%)	25	23	40
Orthopedic surgery (%)	23	64	8
Gyn/Obst surgery (%)	22	10	3
Neurosurgery (%)	7	-	3
Other (%)	24	3	45
Age ± S.D.	35.7 ± 23.5	58.3 ± 20.1	55.3 ± 21.2

* = P < 0.01 compared to regional anesthetics; † = P < 0.01 compared to general anesthetics. SD= standard deviation.

Paper VI, Table I (Corrected: figures for Types of surgery)

Table I: Patient characteristics – 65,170 anesthetics

	<i>Regional anesthesia</i>		<i>General anesthesia</i>		<i>Total</i>	
Anesthetics (n)	20,083		45,087		65,170	
Age (years, mean +/- S.D.)	59.3 ± 19.9 *		45.7 ± 18.8		49.9 ± 20.2	
Sex (Male/Female, %)	48 / 52		39 / 61		42 / 58	
	n	%	n	%	n	%
Types of surgery						
General surgery	4,490	22.4	12,175	27.0	16,665	25.6
Orthopedic surgery	12,902	64.2	10,867	24.1	23,769	36.5
Neurosurgery	17	0.1	3,564	7.9	3,581	5.5
Gyn/Obst surgery	1,973	9.8	12,284	27.2	14,257	21.9
Other	701	3.5	6,197	13.7	6,898	10.6
ASA physical status *						
ASA 1	4,783	23.8	12,967	28.8	17,750	27.2
ASA 2	9,079	45.2	22,836	50.6	31,915	49.0
ASA 3	5,434	27.1	7,237	16.1	12,671	19.4
ASA 4	778	3.9	1,906	4.2	2,684	4.1
ASA 5	9	0.0	141	0.3	150	0.2

Age and American Society of Anesthesiologists (ASA) status was higher in regional than general anesthesia (* P<0.001). SD= standard deviation.