



Protective Ventilation in the OR

Human error in anaesthesia:

whose fault is it anyway?

Part I

This whitepaper addressing relevant issues regarding human error in anaesthesia has two main aims: One, we want to provide anaesthetists with an extensive overview of the topic, and two, to offer information that could be used as background material for further discussions in hospitals on why it would be important to take a closer look at this matter and how to potentially improve the situation.

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CHAPTER I: INTRODUCTION

“To err is human”: This phrase coined in the 17th century by English poet Alexander Pope was also the title of a study published in 1999 by the US Institute of Medicine Committee on Quality of Health Care in America. The aim of that paper was to “break the silence that has surrounded medical errors and their consequence – but not by pointing fingers at caring health care professionals who make honest mistakes.”¹ Since then, numerous studies have tried to raise the awareness of the issue of medical errors, to analyse its scale and to indicate possible ways forward.

So what scale are we talking about here? The experts we spoke to are well aware that errors do of course happen, but the extent of the problem seems much harder to pinpoint. And that is not surprising, given that even the available literature has thrown up hugely varying results which differ not only from country to country, but even within countries.

For instance, one study that is quoted most often by other authors is the seminal US-American report “To err is human: Building a Safer Health System”.¹ Here, preventable adverse events were shown to be a leading cause of death in the United States: Between 44,000 and 98,000 people die each year as a result of medical errors; two percent of admitted patients experience a preventable adverse drug event, resulting in average increased hospital costs of US\$ 4,700 per admission (about 2.8 million US\$ per year for a 700-bed teaching hospital), and the increased hospital costs of preventable adverse drug events affecting inpatients are about 2 billion US\$ per year. But according to a 2013 study by Johns Hopkins University School of Medicine, medical error was the 3rd leading cause of mortality in the United States (after cardiovascular disease and cancer), responsible for a horrendous 251,000 cases of death – significantly higher than in the Kohn report.²

And the numbers do not seem to decline: In a study published in 2010, adverse events were reported in 30 percent of hospital admissions – up to ten times higher than previously estimated –, while another review of studies from 2008-2011 estimated that

more than 400,000 deaths per year could be attributed to preventable adverse events.³

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It is the longest, most encompassing paper we have published so far, but in our view the volume is in line with the importance of the topic. Therefore we have decided to divide the paper into 2 parts: In the first part (chapter I-III), the focus is on errors in anaesthesia, starting with the status quo – currently available data on frequency and consequences of errors –, and followed by an analysis of probable causes (structural or otherwise). The second part of the whitepaper (chapter IV) will evaluate possible approaches to improve the situation, such as better organization or optimization of the perioperative setting.

As the experts reviewing this paper will state, medical mistakes still tend to get swept under the carpet, meaning missed opportunities to implement urgently needed changes, or to learn from previous errors. However, the tide seems to be turning: More and more professionals working in health care systems are beginning to realize that investing in quality management – and that includes how to positively deal with medical errors – will not only result in better medical outcomes for the patient, but also protect the staff's mental wellbeing as well as improve the financial results of a hospital.

CHAPTER II: STATUS QUO IN ANAESTHESIA

The numbers are impressive: An anaesthesiologist may inject up to half a million different drugs during his or her professional life. Therefore, “the chance of making an inadvertent error is easily fathomable” – or, to put it differently, it is statistically likely that some form of error will occur sooner or later, say the authors of a current Indian-US American study.⁴

Medication Errors

Say “errors in medicine” and most likely the first association will be “drug errors” – it is, after all, the most researched topic of all errors in medicine, with an abundance of studies worldwide. One paper from New Zealand found a frequency of drug administration error per anaesthetic case of 0,75 % or 1 per 133 anaesthetics, mostly due to incorrect doses and substitutions.⁵ According to a Japanese study, the drugs most commonly administered in a faulty way were opioids, cardiac stimulants and vasopressors; in general, syringe swap was the leading cause of errors. And: the responsible anaesthesiologists were most likely doctors with little experience.⁶ By contrast, a South African report found that neither the experience of the anaesthetist nor the nature of surgery influenced the incidence, and that nearly 40 percent of all errors were due to misidentification of drug ampoules.⁷

Critical Incidents & Mortality in Anaesthesia:

Figures vary significantly

The authors of the Kohn report mentioned in the introduction quote studies from the UK, Australia and other countries showing that anaesthesia mortality rates are around 1 death per 200,000-300,000 anaesthetics administered. This is significantly better than the rate of 2 deaths per 10,000 anaesthetics observed in the early 1980s, which were due to “very impressive” gains made during recent decades, say the authors.

However, the fact that the situation may be less bad than in previous years is no reason to get complacent. Another paper reports a rate of anaesthesia-related mortality in Taiwan of 11.9 deaths / 100.000 cases and classifies more than half of all anaesthesia-related complications as “preventable”, conceding that these mortality rates were about tenfold higher than in the US, Japan and the UK.⁸

For Germany, a recent analysis of a large national database identified a risk of ten per one million anaesthetics for death or other serious complications.⁹ Another interesting aspect was seen in an analysis of large national US databases: Here, the authors identified increasing trends of major in-hospital complications despite decreasing in-hospital mortality. The assumption is that a certain proportion of mortality might fall through the cracks due to short hospital stays and early discharge to intermediate care facilities;

and most types of these adverse events could be influenced by anaesthetic and perioperative care.¹⁰ A European surgical outcomes study reported an unexpectedly high mortality rate of four percent before discharge, but with pronounced differences between the 28 participating European countries.¹¹

And the risks of children and newborns in particular were recently confirmed in the APRICOT study, which analysed a total of 31,000 anaesthetic procedures in around 30,000 children treated in 261 centres across 33 European countries.¹² In this study, the incidence of perioperative severe critical events was 5.2 percent, with an incidence of respiratory critical events of 3.1 percent.

Incidents involving medical technology

While medication errors are most extensively studied, other areas are also affected by human errors, and one of them is technology. For instance, data from the Australian Incident Monitoring Study suggest that medical technology contributed to 26 percent of analysed¹³; a Swiss-Austrian review in turn reports that in many cases of human error, well proven technology (bronchoscopy, capnography) had been disregarded, leading to perioperative respiratory and airway-related complications.¹⁴ Another Australian study found that a suboptimal design of equipment such as monitors (size and legibility of display), anaesthesia machines, infusion pumps or interchangeable pipeline connectors could constrain the anaesthesiologist and result in errors.¹⁵ Taken together, these findings are a clear indication that with respect to medical errors, some of the focus should be on medical technology.

Device training

The ‘German Coalition for Patient Safety’ (APS) for users and operators of anaesthesia equipment point to another factor particularly interesting in light of the context mentioned in the paragraph above. In their literature review, they found that instruction and training in anaesthesia machines are perceived to be “sometimes of minor importance”, and that failure to perform functional testing seems to be a “common cause” of critical incidents in anaesthesia.¹⁶ In particular, the authors quote studies on the interaction between device-related user knowledge and adverse events in anaesthesia, which showed that the majority of these events are down to a deficient use of the device.

Numbers still underestimated?

However, it should be pointed out that all the numbers quoted above might represent a gross underestimation, as it is highly unlikely that they include those cases of death occurring days after anaesthesia; the discussion surrounding protective ventilation is one indication that not all post-operative complications that might have been caused in the perioperative phase are correctly assigned.

The conclusion can only be that it will be very difficult to really comprehensively collect reliable data regarding anaesthesia-related morbidity and mortality.

The human factor in the genesis of critical incidents

According to one study of 2002, most of the preventable errors of 359 investigated incidents involved human error, namely 82%.²⁰ The most frequent problems ranged from breathing circuit disconnection, inadvertent gas flow change to syringe swap (syringes confused or interchanged and the wrong drug nearly or actually given) to hypovolaemia (fluid replacement not properly managed). Here, equipment failures were only responsible for 14% of preventable incidents, but the authors point out that equipment design played an important role here, as did inadequate experience and insufficient familiarity with equipment or with the specific surgical procedure. Other factors frequently associated with incidents were inadequate communication among personnel, haste or lack of precaution, and distraction.

In addition, reporting mistakes is deeply biased due to the “blame game” played by so many institutions, which creates a work atmosphere of fear and shame and makes reporting mistakes a real career risk. Dr. Brian Goldman gave a superb talk on the influence of the “blame game” on health care providers at TEDx Toronto ([click here to watch](#)).

Errors: the financial implications

Errors also imply the threat of malpractice claims, which physicians in the United States face with a likelihood of between 75 % (for low-risk specialities) and up to 99 % (for the highest-risk specialities), say two experts from the University of California.¹⁶ According to this paper, the cost of medical liability in the U.S. approaches \$60 billion a year.

A UK study conducted by researchers at the Royal Bournemouth Hospital analysed 93 claims (with a total cost £4,915,450) filed under “anaesthesia” in the NHS Litigation Authority database between 1995 and 2007.¹⁹ Here, patients alleged being harmed directly by a drug administration error or by an allergic reaction.

- 62 claims involved alleged drug administration errors (total cost £4,283,677) and 15 resulted in severe harm or death.
- Half alleged the administration of the wrong drug, in most cases a neuromuscular blocker.
- Of the claims alleging the wrong dose had been given, nine alleged opioid overdose including by neuroaxial routes.
- The most frequently recorded adverse outcomes were
 - ‘Awake-paralysis’ with 19 claims and a total cost £182,347 and
 - Respiratory depression requiring intensive care treatment (13 claims; £2,752,853).
 - 31 claims involved allergic reactions (total cost £631,773).
 - In 20 claims, the patient allegedly received a drug to which they were known to be allergic (total cost £130,794).
- All claims in which it was possible to categorize the nature of the error involved ‘human error’.

Fewer than half the claims appeared likely to have been preventable by an “ideal double checking process”, say the authors.

According to the above mentioned paper by Kohn et al, preventable adverse events as a leading cause of death in the US resulted in increased hospital costs of on average US\$ 4,700 per admission (about 2.8 million US\$ per year for a 700-bed teaching hospital), while the increased hospital costs of preventable adverse drug events affecting inpatients were about 2 billion US\$ per year.

Summing it up

Errors in anaesthesia may happen less frequently than in earlier times, but they are still common and can have devastating consequences for the patients as well as severe financial implications for the hospitals. So is all this solely the fault of the anaesthetist? In the next chapter, we will look at the most likely causes behind these mistakes.

CHAPTER III: ERRORS IN ANAESTHESIA AND THEIR CAUSES

This chapter will explore the main factors most probably associated with errors in a comprehensive overview.

Human error

Just how common are human errors in anaesthesia? A report by psychologist Dr. James Reason rates the involvement of human error at 70 to 80 % of anaesthetic incidents and accidents.²⁰ Based on the 'Australian Incident Monitoring Study' published in 1993, the most common contributing factors identified here include misjudgement (16 %), failure to check equipment (13 %), fault of technique, equipment problems, inattention, haste, inexperience and communication problem.²¹

These reports seem to suggest that it is mainly the anaesthetist himself/herself who is solely responsible for errors. However, the last decade has thrown up a wealth of data showing that in many, if not most cases, the culpability lies in the anaesthetist's environment, such as the suboptimal organisation of the workplace or technical devices of suboptimal design, to name but two important factors. In addition, there is arguably a tendency from hospitals to identify individual people as source of an error, rather than go through the trouble of analysing the actually root causes, which are often systemic and therefore much harder to address and change.²⁰

Organisation and framework

However, it is not only a poor organisation of the workplace or technical devices of suboptimal design that play a part in the framework of the daily life of every anaesthesiologist. In fact, most pressure is arguably exerted from the top, as health care systems worldwide are forced to adapt to ever-tighter budgets, squeezing more and more surgeries into the same hours of a working day and potentially leading to an "assembly-line" type of work place.

This point of view is shared by Dr. Gerd Albuszies, MD, PhD, MBA, Chief Physician of the Clinic for Anaesthesiology at the Health and Care Centre in Russelsheim, Germany: "The most encompassing factor is the organisation or framework of the anaesthesiologist's

work place." Technically, the devices anaesthesiologists work with offer all relevant functionalities, explains the expert. "However, there are factors related to this framework that we also have to deal with. This includes understaffing – which inevitably leads to an increased workload –, staff lacking sufficient practice due to not having used a certain technical device or technique for a significant period of time, frequently updated standards set by professional bodies but not yet fully reflected by practitioners or the need for offering service 24 hours a day, which also has to be viable in terms of medical and economical dimensions. Take all these things together and you can begin to appreciate how it might be difficult for an anaesthesiologist in this setting to always do the right thing".

In addition, the organisational framework may also have implications that go beyond the actual anaesthesia during surgery: "For instance, some postoperative anaesthesia-associated pulmonary or cardiac complications may only arise days after the actual surgery. But in many cases, we are not informed about these complications, because these days we only see the patient during the actual perioperative period – we no longer do the rounds on the wards like we used to. And therefore we no longer have the opportunity to identify and consequently learn from possible mistakes."

Anaesthesia workplace and environment

So let's take a closer look at the workplace of anaesthetists in the OR. To start, there may be long phases of calm, but when something does happen, the situation can get very serious very quickly. Hence, the anaesthesiologist has to keep up a high vigilance at all times, and at certain times, he or she will be need to perform several demanding tasks simultaneously and under high time pressure. The workplace is extremely complex, and anaesthetists are required to keep an overview over multiple data streams. Technical equipment is of course supposed to aid and support the anaesthetist, but in many cases the machines display data in a non-intuitive way and therefore make the decision-making process more difficult and hence more prone to errors.

For instance, the above-mentioned paper by James Reason states that equipment-related problems seem to be top of the list of the causes of anaesthesia-related errors, and this problem may be exacerbated by the user, as two (older) papers seemed to

indicate: One study found that 48 % of anaesthetists use new equipment “without reading the manual”, and 60 % do not follow the manufacturer’s check procedure, while the other investigation stated that 30 to 41 % of anaesthetists perform no checks at all.^{22,23}

Another possible source of error that should be mentioned is the lack of communication between anaesthetist and surgeon, adds Dr. Steffen Seemann, anaesthesiologist at the Russelsheim Clinic. “In our experience, operating surgeons often fail to immediately recognise problems that might arise for an anaesthesiologist, and vice versa. Thus, each group is solely occupied with dealing with its own problems, thereby missing the chance to jointly approach a problem such as a haemorrhage or circulatory failure.”

Distractions galore

Directly connected to this complex workplace is an environment with a multitude of distractions, as British researchers report.²⁴ During the observation of 32 surgical operations, they noted 3,557 potentially distracting events, a third of which were deemed to cause actual distraction. 1,227 events involved the anaesthetist, and interestingly, the second commonest initiators of distraction were other anaesthetists (the most common one was the circulating nurse). The authors point out that even though most of these events had no externally visible effect, it should be noted that “anaesthetists need to address themselves as causes of distractions and the potential impact on patient safety.”

Another British study found an average overall frequency of around one distracting event every four minutes. In detail: During induction and transfer into theatre, one event was observed every three minutes, during emergence one every two minutes and during maintenance one every 6.5 minutes.²⁵ 22 % of events were judged to have negative patient consequences, including deterioration in physiological variables, delays in procedure or prevention of smooth induction of anaesthesia, and 3.3 % were seen as positive. In this study, the authors make the point that “anaesthetists should also bear in mind that the potential for distraction is mutual and reciprocal and their actions can also threaten safety by interrupting other theatre staff”.

In light of the complexity of the anaesthetist’s workplace and environment it is self-evident that distractions can impact patient safety.

Alarm fatigue

The constantly beeping alarms on devices are another important potential source of distraction. According to an analysis at Johns Hopkins Hospital (Baltimore, USA), there are on average 350 alerts per hospital bed per day; on an intensive care unit there are on average 771 alerts per bed per day. 85 to 90 percent are false alarms or unnecessary alerts requiring no clinical intervention.²⁶ In the operating room, a high number of false alarms can lead to a “crying wolf” phenomenon, otherwise known as “alarm fatigue”: After a while, physicians do not take alarms seriously anymore, even in cases of true emergencies, warn researchers at the University Medical Center Hamburg-Eppendorf (Germany).²⁷ In this prospective study on 25 cardiac surgery patients, the authors digitally recorded alarms 8,975 from the patient monitor and the anaesthetic workstation; the mean density of alarms was 1.2/minute. The most notable result was that about 80 percent of alarms had no therapeutic consequences whatsoever.

Unanticipated problems and exertion

Another factor is the rate of unanticipated problems during surgery that require intervention by the anaesthetist. According to the report mentioned above by James Reason, this occurs in 18 % of surgeries; in 3 to 5 %, the unplanned event will be serious. 45 % of events occur during the maintenance phase of anaesthesia, implying that “patient monitoring problems, along with very high workload in the event of an emergency, can make excessively high demands upon the attentional resources of the anaesthetist”. The suboptimal dealing with unanticipated problems during surgery is also known as “failure to rescue”. A study by the European Society of Anaesthesiology (ESA) in 63 hospitals with close to 6,000 patients reported a markedly decreased mortality of hospital patients when all patients were routinely assessed for pulmonary complications on the first postoperative day: 0.9 % vs. 2-4 % in other studies.²⁸ This, say the authors, “adds to the hypothesis that some degree of postoperative mortality might have been avoided by earlier detection of postoperative complications.”

Sleep deprivation

Another huge problem area of physicians working in hospitals and potentially leading to human error is sleep deprivation. A randomized controlled study evaluated the performance of 48 residents in anaesthesia in a sleep-deprived state (after a night shift) and after a night of sleep in two crisis scenarios:

1. Oesophageal intubation followed by anaphylactic shock and
2. Anaesthesia-related bronchospasm followed by ventricular tachycardia.²⁹

The resident's crisis management performance was associated with sleep deprivation: well-rested residents showed significantly better reactions than their sleep-deprived colleagues. The main errors occurred regarding drug administration and dose, delay in identification of hypotension, and missing communication with the surgical team about situation.

Unsurprisingly, sleep deprivation also leads to higher daytime sleepiness, poorer attention and concentration, longer response latency and more errors, as an investigation of 18 young doctors demonstrated.³⁰

Australian researchers put sleep deprivation into perspective by comparing tired participants with participants under the influence of alcohol.³¹ They found that after 17-19 hours without sleep, performance test results were equivalent or worse than those seen under a blood alcohol concentration (BAC) of 0.05 %; response speeds were up to 50 % slower and accuracy measures were significantly poorer than at this level of alcohol.

And: Sleep deprivation decreases confidence in anaesthesia skill and significantly impairs 'non-technical' skills such as team working, decision-making and "situation awareness", report French researchers who assessed 20 residents after a night shift.³²

Situational awareness

Situational awareness (SA) is defined as "the perception of elements of the environment within a volume of time and space, the comprehension of their meaning and the projection of their status in the near future", or, to put it more snappily, "being aware of your surroundings". SA was also in the focus of a study by the

team at the University of Munich, Germany. The authors state that accurate SA is the "indispensable precursor for correct decision-making and action" and that by consequence errors are frequently the result of incorrect SA.³³

The two researchers reviewed 200 cases from the German Anaesthesia CIRS ('Critical Incident Reporting System'). SA errors were identified in 81.5 % of 103 cases attributable to anaesthesia. The causes were that individuals had not perceived relevant information and consequently did not comprehend important aspects, leading to wrong decisions. In other cases, the information was complete, but it was processed incorrectly, or there was a failure to search for additional information or a failure to continuously re-evaluate the situation.

One could argue that a reduced SA is in fact the result of a long line of preceding influences addressed in this chapter: The organisational framework that increases the workload, leading to sleep deprivation, the workplace that is (over)burdened with information and distractions such as alarms, the patient that may show unanticipated problems: all these factors may reduce the ability of "being aware" of the surrounding and responding in an adequate and timely fashion.

A very interesting video on this topic, which we would urge any interested party to watch, examines the role of human factors and situational awareness that played a part in the death of Elaine Bromiley ([click here to watch the video](#)). Elaine Bromiley's husband, the pilot Martin Bromiley, founded the Clinical Human Factors Group in 2007, in the aftermath of the incident and subsequent investigation.

Ventilation and equipment

In light of the stressful environment, the complexity of the workplace and the perhaps suboptimal knowledge regarding the technical devices, it is not surprising that ventilation during anaesthesia is another area prone to be affected by human error.

In adverse respiratory events, three mechanisms of injury account for three-fourths of cases: inadequate ventilation (196; 38 %), oesophageal intubation (94; 18 %), and difficult tracheal intubation (87; 17 %), reported a US-American claims study.³⁴

“Inadequate ventilation” was used to describe claims in which it was evident that insufficient gas exchange had produced the adverse outcome, but it was not possible to identify the exact cause; this group had the highest proportion of cases in which care was considered substandard (90 %).

In another (older) closed-claims report, the authors analysed approximately 9,800 patient injuries related to gas delivery equipment and found that the majority of claims (85 %) involved provider error with or without equipment failure.³⁵ “Provider error contributed to severe injury, especially with inadequate alarms, improvised oxygen delivery systems, and misdiagnosis or treatment of breathing circuit events”, summarise the authors.

The role of anaesthesia gas delivery equipment as potentially important source of patient injury was the focus of a closed claims analysis by the University of Washington School of Medicine (USA).³⁶ Here, the authors found that while claims associated with gas delivery equipment are infrequent, they are often severe. According to reviewers, the majority of claims could have been prevented by pulse oximetry, capnography or a combination of these two monitors; overall, 78 % of cases were deemed preventable with the use or better use of monitors.

These insights into the role of the technical equipment in ventilation also include a lesson for manufacturers: namely that equipment should be developed with more than just one eye on the factors influencing human errors, leading to more intuitive, user-friendly interfaces and presentation of data. Such devices might help to improve patient outcomes.

The impact on health care providers: the 2nd victim

In this article, the main focus of human error has been on the outcome for the patient, but the impact that errors can have on the health care providers themselves should not be overlooked either, warn researchers at the Emory University School of Medicine in Atlanta (USA) in a topical report.³⁷ The authors state that while physicians might feel guilt, anxiety and depression after medical errors, it is also worth noting that the “pervasive culture of perfectionism and individual blame in medicine plays a considerable role toward these negative effects.” In addition, many physicians feel there is a lack of personal and administrative support, which may “further contribute to poor emotional well-being.”



How the present “name, blame and shame” culture in medicine with its absolute intolerance of errors actually compounds the currently unsatisfactory situation and what can be done to improve it – from structural, organisational and technical points of view – will be the subject of part two of this whitepaper.

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