FACTORS INFLUENCING ADVERSE EVENT AND ERROR REPORTING IN ANAESTHESIOLOGY

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DECLARATION

I, Steven Robert Nel, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signed

On this day of 2017

ABSTRACT

Background

Adverse events and errors are a widespread cause of morbidity and mortality in the health care environment. Adverse event and error reporting systems have been shown to potentially reduce the occurrence of these events, however there is still significant under-reporting. Little is known regarding the barriers to reporting of adverse events and errors in the context of South Africa, or what emotional and attitudinal barriers may be present regarding a formal reporting system amongst anaesthetists in the Department of Anaesthesiology at the University of the Witwatersrand.

Methods

A prospective, descriptive, contextual study design utilizing an anonymous self-administered questionnaire was distributed to 133 anaesthetists who attended academic anaesthetic meetings.

Results

One hundred and eighteen questionnaires met the criteria for analysis, giving a response rate of 92%. Barriers to reporting included a “code of silence” in medicine and blame from colleagues. If a specified error as opposed to an adverse event had occurred, participants were more likely to agree with barriers regarding fear of litigation, disciplinary action, getting into trouble, as well as colleagues that may be unsupportive. Strategies to promote reporting of adverse events and errors include senior role models who encourage reporting and individualised feedback regarding reports made.

Conclusions

Most anaesthetists in our study disagreed with barriers to reporting an unspecified adverse event. However, if an error has occurred, reporting behaviour may be inhibited by barriers regarding fears of litigation, disciplinary action and lack of support. Senior role models that openly support reporting along with individualised feedback may increase reporting rates.

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LIST OF ABBREVIATIONS

ANZCA – Australian and New Zealand College of Anaesthetists

MeSH – Medical Subject Headings

NASA – National Aeronautics and Space Administration

NRLS – National Reporting and Learning System

SASA – South African Society of Anaesthesiologists

UK – United Kingdom

URL – Uniform Resource Locator

US – United States (of America)

WHO – World Health Organisation

WITS – University of the Witwatersrand

SECTION 1: Literature Review

This section aims to review the current literature regarding adverse event and error reporting in general medical practice, as well as in the speciality of anaesthesia. Initially, the safety of anaesthesia as a speciality will be explored. The review will then analyse the historical context in which adverse events and errors were reported, whilst reviewing problems with definitions and taxonomy of adverse event and error reporting systems. The review will then contrast the incidence of adverse events and errors in general medical practice as compared to anaesthesia. Current reporting structures will be reviewed, followed by analysis of the literature with regards to limitations of these reporting structures. Lastly, the factors that may influence the reporting of adverse events and errors will be reviewed.

1.1 The safety of anaesthesia as a specialty

"Health care in the United States is not as safe as it should be – and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented…" states an excerpt from the report "To err is human: Building a safer health system" released in 1999 by the Institute of Medicine. (1)

The report highlighted how there was an "epidemic of medical errors" occurring in health care, and advocated for the delivery of safer care for patients. This led to a strong political response from the United States (US) Congress who allotted $50 million to the agency for Healthcare Research and Quality with the main focus of reducing medical errors. (1)

Even though there is renewed emphasis on safe health care as a result of the report from the Institute of Medicine, anaesthesia decades previously had implemented measures to reduce harm to patients in the operating room. Anaesthesia is well known for advancements in patient safety, and is described as one of the leaders with regards to reducing mortality, having some of the lowest death rates. (2) However, this was not always the case.

The landmark study by Beecher and Todd in 1954 (3) described the rate of anaesthetic related deaths and complications in nearly 600 000 anaesthetics given over a five year period, and was one of the first recorded scientific studies aimed at reducing the risks associated with anaesthesia. The study found primary anaesthetic related mortality rates of 1 in 1560 patients. This resulted in various changes in practice, most notably the suggestion for the removal of curare, a muscle relaxant that was associated with a higher mortality. This

study replaced previous anecdotal evidence that was the basis for clinical decision-making in anaesthesia (3).

Haller (4) cites evidence from the literature detailing the decline in the anaesthesia related mortality rate. He states that at the end of the 19th century 1 in 900 patients died subsequent to anaesthesia. He contrasted this with a substantial reduction in the current mortality rate of between 1 in 100 000 to 1 in 200 000. He does however caution that the above statistics should be interpreted with care, as there is still not currently a clearly defined taxonomy of "anaesthesia related death", and thus the figures could potentially be different to what is described.

Gaba (2), an anaesthesiologist and a pioneer in human factors related to anaesthesia, explored reasons for improved safety in anaesthesia. With anaesthesia becoming a more complex specialty, and the fact that it extended to include intensive care, he proposed that it attracted a "higher calibre of staff". He also stated that due to the fact that anaesthesia has no actual therapeutic benefits for patients and is a relatively high-risk specialty, that anaesthetists tend to be reluctant to take risks and are more inclined to focus on safety of patients. He further proposed that as the field of anaesthesia attracted individuals with a background in biomedical engineering, safety models were imported from other "hazardous technological pursuits, including aviation". Lastly, he observed that in the 1970's to 1980's the cost of medical malpractice insurance climbed dramatically, and "was at risk of becoming unavailable", possibly promoting a shift towards safer anaesthetic practices. (2)

As safe as anaesthesia is purported to have become, there is still a risk of morbidity and occasionally mortality (4-6). Botney et al (7) described some of the potentially avoidable complications that could occur in anaesthetic practice, and detailed the risk of occurrence. Morbidities like dental injury (1 in 4500) and intra-operative awareness (1 in 500) were still reasonably common occurrences, whereas morbidities like neurological injury and airway injuries were rare (1 in 5000-10 000).

1.2 The historical context for reporting of adverse events and errors

The various methods by which patient safety has been advanced in anaesthesia were reviewed by Runciman and Merry (8) in their book titled "The Wondrous Story of Anesthesia".

The authors highlighted how:

- in the 1960's Ross Holland in Australia and Gai Harrison in South Africa researched mortality due to anaesthesia, showing a trend towards mortality reduction over the next few decades.
- in 1974 Cooper initiated the critical incident reporting system in anaesthesia, and also described his 1978 essay on preventable anaesthetic mishaps.
- in the 1980's the medical indemnity crisis resulted in the creation of the Anesthetic Patient Safety Foundation in 1985, which formed as a result of the 1984 International Committee for the Prevention of Anaesthesia Mortality and Morbidity meeting in Boston.
- in 1988 the National Confidential Enquiry into Perioperative deaths in the United Kingdom (UK) and Australian Patient Safety Foundation formed.
- in 1991 the retrospective medical record reviews in the Harvard Medical Practice study led to the development of a "comprehensive classification of things that can go wrong", creating the foundation for the modern incident reporting systems of today.

The preliminary work of Flanagan (9), in 1954, was where the term "The critical incident technique" was first introduced into the literature. It arose from his observations of the Aviation Psychology Program of the United States Army Air Forces in World War II. He described how the aviation industry used studies to analyse various mishaps in fighter pilots, and fully discussed the method by which a critical incident may be detailed. He further described a critical incident as "any observable human activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act".

Cooper et al (10) in 1978 and Williamson et al (11) in 1985 were the first discernible role players in the anaesthetic environment to review undesirable anaesthetic outcomes as "critical incidents", and were the first to consider a framework from which other anaesthetists may learn from these incidents. The first notable critical incident monitoring system was set up in 1988 in Australia when Runciman (8) spearheaded the movement to create the Australian Incident Monitoring Study in Anaesthesia.

This system was the catalyst for the formation of the Australian Patient Safety Foundation in 1989, which took a broader focus on patient safety in Australia (12). It was seven years later that the foundation created the Australian Incident Monitoring System as an “initiative to look at options for reducing risk in South Australian health care units”. (12)

Since then, there has been international progress in the formation of other national incident reporting systems, examples being the National Reporting and Learning System (NRLS) in the UK, created in 2003 (13), and the Critical Incident Reporting System that has been utilized in Switzerland since 1997 (14).

A discussion of other incident reporting systems will follow later in the chapter.

Definitions of adverse events and errors

There is currently no known universal taxonomy for anaesthetic terms in incident reporting systems (15), and definitions of adverse events and errors are numerous and variable (4, 5, 15-18). Staender (17) argues that defining “critical incidents” or “adverse effects” can be difficult due to the variability of outcomes from each incident. Smith et al (5) state that without agreement on definitions, incident reporting systems in healthcare are unlikely to reach the same potential as in other industries.

The World Health Organization (WHO) draft guidelines for adverse events and reporting systems (19) define adverse events as: “an injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable”.

The WHO draft guidelines (19) further describe an error as: “the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care”.

Smith et al (5) state that the UK Royal College of Anaesthetists official definition of a critical incident was well known in their study population, yet staff interviewed created their own working definitions based on perceived seriousness of the event, as well as eventual outcome, with good outcomes less likely to be reported. They suggest that the experience of the anaesthetist determines their “definitional power”, where a more experienced anaesthetist may judge an adverse event as routine practice, whereas a less experienced

anaesthetist may judge the same adverse event as an incident worth reporting. The example given being the disconnection of a circuit while a patient was under general anaesthesia.

Tamuz et al (16) focused on the impact definitions may have on error reporting rates in their 2004 study titled “Defining and classifying medical error: lessons for patient safety reporting systems”. The authors showed how without clear definitions of errors or adverse events being available, incidents were “defined away” and not reported, as they did not meet the “working definition of an error”.

1.3 Incidence of adverse events and errors in clinical practice

General incidence of adverse events and errors

Landmark research by Brennan et al (20) had appraised the medical records of 30 121 patients admitted to 51 acute care hospitals in New York in 1984. They reported an adverse event rate of 3.7% of all admissions. There was further research done on the same data used by Brennan et al (20), which found that the nearly 70% of the reported adverse events were due to medical error (21).

In 1995, Wilson et al (22) reviewed medical records of 14 179 patients admitted to 28 hospitals, in order to understand the quality of health care in Australia. They found that the rate of adverse events was 16.6 per 100 admissions, with “permanent disability in 13.7%” and “death in 4.9%”. They also determined that at least 50% of the adverse events were preventable.

Using computerised models to detect adverse drug events at a hospital in Utah, United States in 1991, Classen et al (23) found rates of adverse drug events to be 1.7%. This contrasts with Bates et al (24) in 1995 who found substantially higher rates of adverse drug events, totalling 6.5% of all admissions. This was achieved by using chart reviews and self-reports from health care professionals.

Andrews et al (25) used ethnographers to observe daily activities in 10 surgical units throughout three academic hospitals over a period of two months in the US. They found that adverse event rates were 45.8% (480 of 1047 patients), of which 17.7% (185 patients) of adverse events were of a serious nature.

Starmer et al (26) performed a prospective intervention study at a Boston Children’s Hospital in 2013, where they implemented a resident handoff bundle with standardised communication and handoff training. They had 1255 admissions over the period of the

study, of which 642 were in the pre-intervention group and 613 in the post-intervention group.

They found initially that there were error rates of 33.8% in the pre-intervention group of patients, with preventable adverse event rates of 3.3%. Their post–intervention results showed a 50% decline in both rates. (26)

Anaesthetic related incidence of adverse events and errors

Cooper et al (10) studied preventable anaesthesia mishaps in 1978 in the US, and found that 18% of anaesthetics would develop “an unexpected problem requiring intervention” during the anaesthesia, and “3 to 5% of those anaesthetics will involve a serious unplanned event”.

Catchpole et al (27) analysed 12 606 anaesthetic related incidents over a two year period in UK based hospitals, and found that 75% of the incidents resulted in no harm, 22.5% in little or moderate harm, and 2.1% in severe harm or death.

These results contrast with a 2009 study by Gupta et al (28) in India, which was a prospective internal audit into critical incident reporting in anaesthesia. The study was performed over a one-year period with a total of 14 134 anaesthetics being delivered to patients. The results of the study show that 112 (0.79%) critical incidents were reported, with complete recovery in 80 (72%) patients and death in 32 (28%) patients. They also found that incidents were highest amongst paediatric, American Society of Anesthetists physical class grade 1, general surgery patients undergoing emergency surgery.

Gupta et al (28) further showed that the incidence of mortality was found to be 22.6 per 10 000 anaesthetics. With anaesthesia as the only cause of death, the rate was 5.6 per 10 000 anaesthetics. The main reason stated for the death rate was human error (75%), which was predominantly ascribed to poor judgment (67.5%).

Lundgren (29) in 2011 analysed the perioperative death rates in two major academic hospitals in Johannesburg. The author found that anaesthetic contributory death rate was approximately 0.4 per 10 000 anaesthetics delivered, which was described as being comparable to the rates in the UK. This contrasts with Gupta et al (28), where their described mortality rate in a tertiary hospital was more than ten times that shown by Lundgren (29).

Madzimbamuto and Chiware (30) described the implementation of a critical incident reporting system in anaesthesia in two teaching hospitals in Zimbabwe. They had 62 completed critical incident forms submitted between May and October in 2000, with a total of 14 165 anaesthetics delivered. They described 130 critical incidents, giving a rate of 0.92. Of these 40 were emergency cases and 22 were elective cases. Incidents reported were "hypotension, hypoxia, bradycardia, electrocardiogram changes, aspiration, laryngospasm, high spinal and cardiac arrest. They reported that human error was responsible for 50% of critical incidents, and equipment failure a further 50%. Patient outcomes showed that 15% died, and 23% required unplanned admission to an intensive care unit setting. The mortality rate was comparable to that described by Gupta et al (28).

Gordon et al (6) published a survey in 2006 by South African anaesthetists with regards to drug administration errors. They sent confidential surveys to 720 anaesthetists nationally, and had 133 returned surveys. The authors found that 94% of anaesthetists in the sample had inadvertently administered an incorrect drug to a patient, with five deaths and three non-fatal cardiac arrests noted following incorrect drug administration.

Labuschagne et al (31) performed a similar survey in 2011 in the Free State. They found that 39.3% (n=84) of participants had at least one drug administration error in their careers.

1.4 Current reporting structures

Various systems for reporting of adverse events and errors have been employed within the health care industry, each having an impact on a professional's likelihood of reporting an adverse event or error (32).

Pham et al (33) in 2013 published a review article identifying different structures and functions of incident reporting systems. The following examples were given:

- national reporting systems (Australia Incident Monitoring System and the NRLS in the UK)
- local systems (Patient Safety Network and the Pennsylvania Safety Reporting System)
- speciality specific, an example given being an Intensive Care Unit Reporting System
- incident specific, such as the MedMARx system which focuses on medication incidents.

Suresh et al (34) in 2004 suggested that amassing errors that are speciality specific might be more likely to show a trend of errors, than if the errors were diluted in a general error reporting system, with the consequent possibility of being overlooked.

Leape (35) argues that many of the current error reporting systems are inadequate, as they are not meeting the main objective of improving patient safety. The author analysed the success of the NASA Aviation Safety Reporting System as portrayed by Billings (36), and suggested three factors why medical incident reporting systems were inadequate. Firstly, reporting needed to be safe, for example, pilots are "immune from disciplinary action if they report promptly". The second factor was that they needed to be simple, indicating that a one-page report was ideal. Lastly, that incident reporting systems needed to be made worthwhile, citing an example of how in aviation, experts scrutinised the confidential report and then distributed recommendations to pilots and the Federal Aviation Administration. (35)

Leape (35) further gave examples of successful voluntary reporting medical error systems, namely the Medication Error Reporting Program, MedMARx and the National Nosocomial Infection Survey, describing how these systems shared similar features with the NASA Aviation Safety Reporting System.

Leape (35) contrasted the success of voluntary reporting systems to those that are mandatory, and stated that mandatory systems are "seldom simple, safe, or worthwhile". This is in opposition to the views of Kohn et al (1) whose report suggested that mandatory reporting was an important part of patient safety culture, as it ensured that health care practitioners and institutions were held responsible for their actions.

Holden et al (32) reviewed anonymity and confidentiality in designing an incident reporting system. They described factors that might allow for a more effective reporting system, with a suggestion that a system that embraces anonymity would allow for better reporting of incidents, as they will be non-punitive. Runciman (37) concurs than anonymous reporting would be beneficial as health care staff would be more likely to report adverse events or errors, even though he conceded that ethically it was contentious.

1.5 Benefits associated with reporting of adverse events and errors

"The belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries is a powerful element of the vision behind the WHO World Alliance for Patient Safety." – Sir Liam Donaldson, chair for the World Alliance for Patient Safety. (19)

There are many reports and studies on the benefits associated with incident reporting systems available in the literature (17, 33, 38-45), many of which echo the hopes described by Donaldson.

Smith and Forster (38) proposed that there would be “improved professional learning and better patient outcomes from higher quality care”. They also described the potential for improved trust between staff and patients, fewer chances of litigation, and a “more realistic view by patients of staff and medicine’s limitations”

Wood and Nash (40) analysed mandatory state-based error reporting systems in the United States in 2005, and found that a collection of data on adverse incidents would allow for analysis regarding trends and similarities. This allowed for identification of common incidents, and focused attention for system improvements to occur.

Williams and Osborn (41) in 2006 suggested the opportunity to share the analysis of adverse events globally, thus allowing for cross border learning, and potentially reducing adverse event occurrence.

According to Staender (17) there are meaningful lessons that can be learnt from incident reporting systems. He described four advantages to incident reporting. These were quantity, recoveries, root cause information, and learning.

With regards to quantity he argued that incidents are much more common than severe events, and thus there will be many more incidents to analyse for any given period of time. He also described how recoveries could be analysed by looking for preventative processes whereby the serious events were avoided, rather than analysing what had actually happened in the case of a severe event. He further described how incidents could be analysed from their root causes, thus forming “the basis of very strong quality-improvement actions”. Lastly, he theorized that by passing on personal experiences on critical events, others might learn valuable lessons, thus possibly avoiding similar events.

Smith et al (5) echoed Staender’s (17) proposed advantage of learning through reporting. Their study was of a qualitative design, and explored adverse events in anaesthetic practice, based on focus group interviews with medical professionals. They depicted a scenario in a focus group, where they asked practitioners how they had gained their anaesthetic knowledge. They reported that this prompted many anaesthetists to focus on cases that “had not gone according to plan”. They described how this “triggered a lively discussion” of

learning from events that had occurred in an anaesthetist's career, and concluded that reporting was beneficial for continuing education within the anaesthetic community.

Staender's (17) opinions also support those of Vincent (45), who described how the analysis of incidents could provide a framework on which to base decisions regarding policy and practice changes that could ultimately lead to reduced occurrences of adverse events.

A review by Pham et al (33) further elaborated on Staender's (17) idea that global learning can occur from incident reporting systems. They described how incident-reporting systems could benefit multiple organisations, through sharing of information at "local, regional, national and international levels". They use the example of the Canadian Global Patient Safety Alerts, which is a collection of adverse events with full case details. These safety alerts describe the processes involved through which the failure occurred, and discuss the interventions implemented to prevent a further occurrence of the same error. The Chief Executive Officer of the Canadian Patient Safety Institute cites these safety alerts have "more than 684 alerts and 3400 recommendations from 23 contributing organizations around the world" (42). This information has been used worldwide to alter safety practices in medicine.

Pham et al (33) also observed that incident reporting systems tend to alter the patient safety culture of the organization, especially if the incidents were reported back to the health care professionals, as it communicated how important the organization felt patient safety was.

Kaplan and Barach (44) considered the evaluation of "near misses" rather than adverse events. In doing so they proposed that analysis of near misses had many benefits such as:

- "near misses occur 300-400 times more frequently [than adverse events], enabling quantitative analysis
- there are fewer barriers to data collection, allowing analysis of interrelationships of small failures
- recovery strategies can be studied to enhance proactive interventions
- hindsight bias is more effectively reduced".

As echoed by Pham et al (33), Kaplan and Barach (44) also stated "perhaps the least appreciated and most unique attribute is the potential for incident reporting to engage the staff in safety activities. This involvement may bring about mindfulness and a change in safety culture".

Furthermore, there are also benefits to society with incident reporting systems. In 2000 Barach and Small (43) described societal incentives to reporting. They argued that from a legal perspective, reporting would ensure accountability and enforce reporting statutes amongst health care professionals. From a regulatory perspective they claimed there could be enhanced regulatory trust, greater transparency and more public accountability.

1.6 Limitations associated with reporting of adverse events and errors

As beneficial as incident reporting systems could potentially be, they are also associated with several limitations.

Catchpole et al (27) analysed 12 606 reported anaesthesia incidents from the UK NRLS. They endeavoured to understand how a large database like the NRLS might contribute to identifying incidents and system based problems. As part of their analysis they discussed some of the limitations such a database may have. The authors concluded that the "lack of detail inherent to large data fields prohibit translation of these results into robust arguments for immediate change in clinical practice". (27)

Catchpole et al (27) also found that medication error or treatment failure may be difficult to tell apart, especially in anaesthesia with the amount of medications given to any one patient. They referred to one example where an extravasation injury was classified as a medication error, showing problems with hierarchy in the taxonomy of medical error reporting. (27)

Henriksen and Kaplan (46) discussed issues regarding hindsight bias in their 2003 review. They described hindsight bias as "the exaggerated extent to which individuals indicate they would have predicted the event beforehand". They gave evidence regarding hindsight bias and its effects on medicine and health services research. They discussed that the retrospective analysis of medical errors, as is done with incident reporting systems, is particularly prone to hindsight bias, and describe how this might have a negative influence on the analysis of the error.

Another limitation to incident reporting systems is the high prevalence of under-reporting amongst health care professionals. According to Taylor et al (47) in 2004, only one in five incidents are reported. They also showed that nurses are 80% more likely to report errors than physicians (OR = 2.8, 95% CI: 1.3 – 6.0). Under-reporting of incidents can make the overall analysis less meaningful (27).

A further limitation can be found in the study by Braithwaite et al (48), in Australia, in 2008. They analysed attitudes towards the implementation of an incident reporting system. The

survey took the form of an online anonymous questionnaire completed by 2185 health practitioners, which found that nurses tended to report more adverse events than physicians. The authors argued that this disproportional reporting might lead to bias and the potential for prioritisation of certain incidents over others.

Catchpole et al (27) also described the potential for data inaccuracies when incidents were reported by healthcare professionals who were not directly involved in the events that occurred. An example given was the reporting of epidural related complications to the NRLS, where it was found that the higher levels of harm reported for epidurals might "reflect a bias away from reporting no-harm events". These errors may have been reported by nurses, who may not have understood the hierarchical classification of errors related to epidurals. Thus, many incidents were reported as "other" and as "treatment/procedure" errors. These errors may have been correctly classified had the physicians directly involved reported them.

Catchpole et al (27) concluded that for data from an incident reporting system to be meaningful, there needs to be a "sufficiently validated reporting and analysis framework", without which "substantial classification inconsistencies" must be assumed.

Tamuz et al (16) reported similar concerns in their study on defining and classifying medical error, where they analysed how medication errors were reported in a hospital complex. They found an important source of underreporting was due to potential medication incidents being "defined away" or "classification bias". They described "defined away" as the respondent's definition of what the error was not meeting the didactic definition of the pharmacy's error reporting system. This confusion around definitions thus resulted in the staff being less likely to report it, as the incident did not classify as an "error".

Woolf et al (49) studied the effect "cascade analysis" had on analysis and prevention of medical errors. They found that there was difficulty with assigning a single classification when a "cascade" of errors had occurred. This also led to similar classification limitations as discussed by Tamuz et al (16).

These and other problems with classification were summarised in a review of medical error reporting systems by Holden and Karsh (32) in 2007. They emphasised the importance of developing "mature taxonomies in health care". This would allow for conforming standards on what to report, the format the report should take, and, ultimately will facilitate "meaningful analysis and control steps in the safety process".

Pham et al (33), in 2013, describe various limitations to incident reporting systems. Firstly, they state that incident reporting systems are non-random samples encompassing all potential reports, and thus cannot be used to measure patient safety rates. Reasons stated in their review included the fact that events or errors were under-reported, citing reporting rates as low as 7% of all incidents, as well as the fact that different methods are used to detect errors resulting in varying conclusions about safety. The authors also stated that incident reporting systems could not be used to compare organisations, as institutions that report more errors did not necessarily have higher error rates.

According to Pham et al (33) incident reporting systems could not be used to measure changes over time with regards to safety practices. The reason for this is that "valid error rates are required to make inferences in safety over time", which cannot be ascertained with incident reporting systems. The authors suggested that incident reporting systems can generate too many reports, citing an example of how Johns Hopkins Hospital generates approximately 500 reports per month. They state that it may not be possible for an organisation to analyse such a high number of reports, and even less likely to create actionable responses. (33)

Lastly, Pham et al (33) indicate that "incident reporting systems often do not generate in-depth analysis or result in strong interventions to reduce risk". Reasons described were that with limited resources, error investigations were often superficial, and that staff have "limited or no training in adverse event investigation or human factors". Furthermore, meaningful system changes are rare, with most interventions being "informing staff involved and education/training". (33)

1.7 Factors influencing adverse event and error reporting

Factors which may impede reporting

As discussed previously, the rate of under-reporting of adverse events and errors is inadequate (16, 33, 47). Some of the reasons for this will be explored.

Holden and Karsh (32) compiled a review of medical error reporting system design considerations in 2007, and described various barriers to reporting.

They discussed how busyness and fatigue play an important role, as health care practitioners could have high work burdens. Suresh et al (34) described the leading self-reported barriers to reporting to be "time involved in documenting an error" and "extra work involved in reporting".

Holden and Karsh (32) also described how lack of knowledge about the reporting system acted as a barrier to reporting. They stated that medical staff might be unaware that reporting structures exist in their institutions, or not know their purpose. Jeffe et al (50) used focus groups to explore physicians' and nurses' perspectives on error reporting in hospitals. They found that there was some confusion over whether or not less serious errors and near misses needed reporting, and whose responsibility it was to report these.

Heard et al (51), in 2012, surveyed 443 anaesthesiologists and anaesthesiology residents in Australia and New Zealand with an anonymous questionnaire. The authors analysed the effect of the "perfectibility model" on the likelihood of reporting. They described the "perfectibility model" as being "based on beliefs that physicians are capable of and should provide error-free practice, with anything less being unacceptable". They hypothesised that this model would have a negative impact on the anaesthesiologist's likelihood to report medical errors. However, they found that 79% of respondents disagreed or strongly disagreed with the statement: "If a doctor is careful enough, he or she will not make an error". This contrasts with a systematic review by Kaldjian (52) who showed that medical perfectionism is a reason for reduced reporting of errors.

Even though 79% of respondents disagreed with the statement in Heard et al's (51) study regarding the perfectibility model, nearly 30% agreed or strongly agreed that: "If I admit to an error I will feel like a failure", and "It would affect my self-esteem to admit to an error". These statements contextualise what many other authors have found regarding reasons for not reporting (32, 43, 52, 53). They have found that blame and shame are serious disincentives to reporting adverse events and errors. This may explain why in the study by Heard et al (51) 5% of respondents agreed or strongly agreed that they would "protect their self-interests ahead of a patient's; for example, by hiding or denying an error". Additionally, 10% of respondents agreed or strongly agreed that "they would cover up an error if they could".

The authors stated that the results may be influenced by "social desirability bias", and thus respondents answered the questions "as a good person should" rather than answering what they would actually do in a scenario with a bad outcome. To account for this, Heard et al (51) included a second section to their questionnaire where they analysed how respondents would react to an adverse event with or without an error. The respondents were given a scenario where anaphylaxis occurred due to the giving of an antibiotic intra-operatively. In half the respondents the questionnaire indicated that the anaphylaxis occurred even though the patient had no history of allergy to any antibiotics, and in the other half the questionnaire indicated that the doctor knew that the patient had an allergy to the specific antibiotic, and

inadvertently had given it. The authors found that anaesthesiologists in the “error” group were more likely to agree with barriers regarding “litigation, disciplinary action, trouble, blame, lack of support from colleagues, and not wanting the case discussed in meetings”, than those in the non-error group. (51)

Leape (35) also supported the finding that doctors and nurses are fearful of litigation and disciplinary action, and are thus less likely to report adverse events and errors. The author also reported that among physicians “shame and fear of liability, loss of reputation, and peer disapproval” were especially prevalent reasons why adverse events and errors were not reported.

Kaldjian et al (53), in 2006, developed an “empirically derived, comprehensive taxonomy of factors that affect voluntary disclosure of errors by physicians”. They reviewed 316 articles, and identified 91 impeding or facilitating factors to the willingness of physicians to disclose errors. They also conducted focus group studies and found a further 27 factors that were pertinent. These factors were collated together into domains, four domains being facilitating factors and four domains being factors that impeded reporting of errors. (53) The four domains that impede reporting are shown in Table 1, which was transcribed directly from Kaldjian et al (53).

The main theme present in the first domain of “attitudinal barriers” was that of perfectionism and the competitive nature of doctors, which was a potential cause of reduced reporting. A persistent theme that was present in the second domain of “helplessness” was that respondents wanted to know what was going to happen to their report, as they were fearful that it would jeopardise them at a later stage in their careers with detrimental effects. The third domain addressed feelings of uncertainty, and the fourth domain focused on “fears and anxieties”. This last domain explored feelings of shame and guilt, as well as fears of disclosing the error. (53) This last domain echoes similar findings by Wu. (54) The author was of the opinion that medical errors have a second victim, namely the health care professional involved, and commented that some physicians “are deeply wounded, loose their nerve, burn out, or seek solace in drugs and alcohol”. Similar findings were also described by Leape (35) and Heard et al (51).

Heard et al (51) uncovered similar themes. They found that the statement “doctors who make errors are blamed by their colleagues” to be significant, where 46% of respondent agreed/strongly agreed with the statement. They also stated that after reporting a serious error, physicians reported high levels of “emotional distress, shame, guilt, self-reproach, self-perceptions as failures, fear of blame and criticism…”

Legal concerns of reporting and financial liabilities were also profound barriers to reporting, as shown in the fourth domain (53), a concern supported by Leape (35).

Kaldjian et al (53) conclude that by taking into account factors that could impede reporting adverse events and errors, implementation of reporting structures may be more likely to succeed.

Table 1: Factors that impede physician disclosure of medical errors (53)

Attitudinal Barriers	Helplessness
• Perpetuating perfectionism, and blaming and humiliating those involved with errors • Perpetuating silence about errors, denying errors, or believing others don't need to know about one's errors • Being arrogant and proud • Placing self-interests before patient-interests • Allowing competition with peers to inhibit disclosure • Believing disclosure is an optional act of heroism • Doubting the benefits of disclosure	• Lacking control of what happened to information once it is disclosed • Lacking confidentiality or immunity after disclosure • Lacking institutional and collegial support after disclosure or a professional forum for discussion • Believing error reporting systems penalise those who are honest • Lacking feedback after reporting errors • Lacking time to disclose errors • Feeling helpless about errors because one cannot control enough of the system of care
Uncertainties	**Fears and Anxieties**
• Being uncertain about how to disclose • Being uncertain about which errors should be disclosed • Being uncertain about the cause of an adverse event • Disagreeing with a supervisor or trainee about whether an error occurred	• Fearing legal or financial liability • Fearing professional discipline, loss of reputation, loss of position, or loss of advancement • Fearing patient's or family's anger, anxiety, loss of confidence, or termination of physician-patient relationship • Fearing the need to admit actual negligence • Fearing the need to disclose an error that cannot be corrected • Fearing the possibility of looking foolish in front of junior colleagues and trainees • Fearing negative publicity • Fearing the possibility of 'fallout' on colleagues • Feeling a sense of personal failure and loss of self esteem

Factors which may facilitate reporting

There is less evidence in the literature regarding factors that may facilitate the reporting of adverse events and errors than there is regarding the barriers to reporting (55). The four domains from Kaldjian et al (53) that facilitate reporting of errors are shown in Table 2, which was transcribed directly from Kaldjian et al (53).

Table 2: Factors that facilitate physician disclosure of medical errors (53)

Responsibility to Patient	Responsibility to Profession
• Desire to communicate honestly with patients or explain the circumstances of an error • Desire to show respect for patients or treat patients fairly • Desire to facilitate further medical care for harmed patients	• Desire to share lessons from learned errors • Desire to serve as a role model in disclosing errors or breaking bad news • Desire to strengthen inter-professional relationships and build inter-professional trust • Desire to change professional culture by accepting medicine's imperfections and lessen the focus on managing malpractice risks
Responsibility to Self	**Responsibility to Community**
• Desire to account for one's actions • Sense of duty as a physician • Desire to maintain one's integrity • Desire to treat others as one would like to be treated • Desire to empathise and apologise • Desire to alleviate guilt or pursue forgiveness • Willingness to accept one's fallibility and limitations, and to be vulnerable • Desire to follow one's conscience or 'do the right thing' • Desire to follow one's religious/spiritual beliefs	• Desire to enhance the health of future patients • Desire to sustain patients' trust in the medical profession • Desire to foster physician-patient relationships that can absorb the shock of error • Desire to help patients to be more realistic about medicine's imperfections • Desire to help patients understand the complex causes of errors

The "responsibility to patient" domain centres on the respect that a physician should have for a patient as a fellow human, and suggests that free and honest communication is central to

continuing a respectful physician-patient relationship. The second domain focuses on the responsibility the physician has towards him/herself, and explores “professional and personal values” derived from the physician’s character principles. The main theme present was that the physician needs to have the courage and conviction to admit to making an error, and be prepared for the associated consequences. In the domain of “responsibility to profession”, the physician may feel that a duty is present to allow others to learn from their error, potentially encouraging and environment where errors can be disclosed without fear of reprisal from colleagues. The last domain explores the responsibility the physician has to the community, and emphasises the formation of relationships centred around trust.

Heard et al (51) in their study explored 17 factors that may encourage anaesthetists to report errors. The statement with the highest agreement was found to be “generalised de-identified feedback about reports received from the anaesthetic community”, with nearly 95% of the respondents in agreement. This response was echoed in studies by other authors (33, 55, 56). A second factor that predominated was that of senior members of staff encouraging reporting, with 91% of respondents agreeing or strongly agreeing.

Flin and Yule (57) conducted a review of the effects of leadership on safety in health care. The authors found that senior managers have “a prime influence on the organisation’s safety culture”. Heard at al (51) further described how in a “free-text” section that was present in the questionnaire, respondents eagerly wrote how support from department heads who were not judgemental, and senior anaesthesiologists discussing their own errors with junior staff, promoted reporting of adverse events in their environment.

Heard et al (51) also found that nearly 90% of respondents agreed with the statement that legislated protection of information provided from use in litigation was important. Other factors in agreement were the ability to report anonymously (84%), clear guidelines about which adverse events to report (82.8%), how confidentiality would be kept if the report supplied their details (79.5%), and individualised feedback regarding the reports submitted (79%).

Factors that found less support when analysed by Heard et al (51) were continuing professional development points for reporting (66.2%), the ability to report at home by computer (65%), education about the purpose of reporting (58,7%), computer based reporting systems (52.3%), and training on how to fill in forms (approx. 50%). The statement that had the least support was that of payment received for time taken to report, with only 20% of respondents agreeing.

In summary, even though there are well established adverse event and error reporting systems that have been instituted, evidence shows that there are still significant rates of under-reporting. Some studies have attempted to understand the barriers to reporting of adverse events and errors, but none have done so in the context of a developing nation such as South Africa, with its own unique health care challenges

"The currency of patient safety can only be measured in terms of harm prevented and lives saved. It is the vision of the World Alliance that effective patient safety reporting systems will help to make this a reality for future patients worldwide." (19)

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SECTION 2 – Journal guidelines to authors

This section highlight's the guidelines which the author has followed with regards to the length and formatting of the research article.

The guidelines followed in creating the draft article were those of the Southern African Journal of Anaesthesia and Analgesia, which is the intended journal of publication.

Southern African Journal of Anaesthesia and Analgesia guidelines to authors

Article sections and length

The following contributions are accepted (word counts exclude abstracts, tables and references):

Original research (2800 – 3200 words/ 4-5 pages)

FULL AUTHOR GUIDELINES

Title page
All articles must have a title page with the following information and in this particular order: Title of the article; surname, initials, qualifications and affiliation of each author; The name, postal address, e-mail address and telephonic contact details of the corresponding author and at least 5 keywords.

Abstract
All articles should include an abstract. The structured abstract for an Original Research article should be between 200 and 230 words and should consist of four paragraphs labeled Background, Methods, Results, and Conclusions. It should briefly describe the problem or issue being addressed in the study, how the study was performed, the major results, and what the authors conclude from these results. The abstracts for other types of articles should be no longer than 230 words and need not follow the structured abstract format.

Keywords
All articles should include keywords. Up to five words or short phrases should be used. Use terms from the Medical Subject Headings (MeSH) of Index Medicus when available and appropriate. Key words are used to index the article and may be published with the abstract.

Acknowledgements
In a separate section, acknowledge any financial support received or possible conflict of interest. This section may also be used to acknowledge substantial contributions to the research or preparation of the manuscript made by persons other than the authors.

References
Cite references in numerical order in the text, in superscript format (Format> Font> Click superscript). Please do not use brackets or do not use the foot note function of MS Word.

In the References section, references must be typed double-spaced and numbered consecutively in the order in which they are cited, not alphabetically.

The style for references should follow the format set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org) prepared by the International Committee of Medical Journal Editors. Abbreviations for journal titles should follow Index *Medicus* format. Authors are responsible for the accuracy of all references. Personal communications and unpublished data should not be referenced. If essential, such material should be incorporated in the appropriate place in the text.

List all authors when there are six or fewer; when there are seven or more, list the first three, then ";et al."; When citing URLs to web documents, place in the reference list, and use the following format: Authors of document (if available). Title of document (if available). URL. (Accessed [date]).

The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.
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More sample references can be found at: http://www.nlm.nih.gov/bsd/uniform_requirements.html"

Tables

Tables should be self-explanatory, clearly organised, and supplemental to the text of the manuscript. Each table should include a clear descriptive title on top and numbered in Roman numerals (I, II, etc) in order of its appearance as called out in text. Tables must be inserted in the correct position in the text. Authors should place explanatory matter in footnotes, not in the heading. Explain in footnotes all non-standard abbreviations.

For footnotes use the following symbols, in sequence: *, †, ‡, §, ||, **, ††, ‡‡

Figures

All figures must be inserted in the appropriate position of the electronic document. Symbols, lettering, and numbering (in Arabic numerals e.g. 1, 2, etc. in order of appearance in the text) should be placed below the figure, clear and large enough to remain legible after the figure has been reduced. Figures must have clear descriptive titles.

Photographs and images

If photographs of patients are used, either the subject should not be identifiable or use of the picture should be authorised by an enclosed written permission from the subject. The position of photographs and images should be clearly indicated in the text. Electronic images should be saved as either jpeg or gif files. All photographs should be scanned at a high resolution (300dpi, print optimised). Please number the images appropriately.

Permission

Permission should be obtained from the author and publisher for the use of quotes, illustrations, tables, and other materials taken from previously published works, which are not in the public domain. The author is responsible for the payment of any copyright fee(s) if these have not been waived. The letters of permission should accompany the manuscript. The original source(s) should be mentioned in the figure legend or as a footnote to a table.

Review and action

Manuscripts are initially examined by the editorial staff and are usually sent to independent reviewers who are not informed of the identity of the author(s). When publication in its original form is not recommended, the reviewers' comments (without the identity of the reviewer being disclosed) may be passed to the first author and may include suggested revisions. Manuscripts not approved for publication will not be returned.

Ethical considerations

Papers based on original research must adhere to the Declaration of Helsinki on ";Ethical Principles for Medical Research Involving Human Subjects"; and must specify from which recognised ethics committee approval for the research was obtained.

Conflict of interest

Authors must declare all financial contributions to their work or other forms of conflict of interest, which may prevent them from executing and publishing unbiased research. [Conflict of interest exists when an author (or the author's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her opinions or actions.]* *Modified from: Davidoff F, et al. Sponsorship, Authorship, and

Accountability. (Editorial) JAMA 2001: 286(10) The following declaration may be used if appropriate: "I declare that I have no financial or personal relationship(s) which may have inappropriately influenced me in writing this paper."

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All submissions must be made online at www.sajaa.co.za and correspondence regarding manuscripts should be addressed to:

The Editor, SAJAA, E-mail: toc@sajaa.co.za

Note: Ensure that the article ID [reference] number is included in the subject of your email correspondence.

Electronic submissions by post or via email

Authors with no e-mail or internet connection can mail their submissions on a CD to: SAJAA, PO Box 14804, Lyttelton Manor, 0140, Gauteng, South Africa.

All manuscripts will be processed online. Submissions by post or by e-mail must be accompanied by a signed copy of the following indemnity and copyright form. CLICK HERE to download and save it to your computer.

Tips on Preparing your manuscript

1. Please consult the “Uniform requirements for manuscripts submitted to biomedical journals” at www.icmje.org
2. Please consult the guide on Vancouver referencing methods at: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=citmed.TOC&depth=2
3. The submission must be in UK English, typed in Microsoft Word or RTF with no double spaces after the full stops, double paragraph spacing, font size 10 and font type: Times New Roman.
4. All author details (Full names, Qualifications and affiliation) must be provided.
5. The full contact details of corresponding author (Tel, fax, e-mail, postal address) must be on the manuscript.
6. There must be an abstract and keywords.
7. References must strictly be in Vancouver format. (Reference numbers must be strictly numerical and be typed in superscript, not be in brackets and must be placed AFTER the full stop or comma.)
8. It must be clear where every figure and table should be placed in the text. If possible, tables and figures must be placed in the text where appropriate. If too large or impractical, they may be featured at the end of the manuscript or uploaded as separate supplementary files.
9. All photographs must be at 300dpi and clearly marked according to the figure numbers in the text. (Figure 1, Table II, etc.)
10. All numbers below ten, without percentages or units, must be written in words.
11. Figure numbers: Arabic, table numbers: Roman

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SECTION 3 – Draft Article

Factors influencing adverse event and error reporting in Anaesthesiology

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Keywords:

Anaesthesia, critical incident, adverse event, reporting systems, patient safety.

Abstract

Background

Adverse events and errors are a widespread cause of morbidity and mortality in the health care environment. Adverse event and error reporting systems have been shown to potentially reduce the occurrence of these events, however there is still significant under-reporting. Little is known regarding the barriers to reporting of adverse events and errors in the context of South Africa, or what emotional and attitudinal barriers may be present regarding a formal reporting system amongst anaesthetists in the Department of Anaesthesiology at the University of the Witwatersrand.

Methods

A prospective, descriptive, contextual study design utilizing an anonymous self-administered questionnaire was distributed to 133 anaesthetists who attended academic anaesthetic meetings.

Results

One hundred and eighteen questionnaires met the criteria for analysis, giving a response rate of 92%. Barriers to reporting included a "code of silence" in medicine and blame from colleagues. If a specified error as opposed to an adverse event had occurred, participants were more likely to agree with barriers regarding fear of litigation, disciplinary action, getting into trouble, as well as colleagues that may be unsupportive. Strategies to promote reporting of adverse events and errors include senior role models who encourage reporting and individualised feedback regarding reports made.

Conclusions

Most anaesthetists in our study disagreed with barriers to reporting an unspecified adverse event. However, if an error has occurred, reporting behaviour may be inhibited by barriers regarding fears of litigation, disciplinary action and lack of support. Senior role models that openly support reporting along with individualised feedback may increase reporting rates.

Introduction

Adverse events and errors are still a widespread cause of morbidity and mortality in the health care environment,[1-5] with ample literature indicating that many of these errors are often preventable.[5-9] Adverse events and errors have been increasingly recognised and focused upon since the report released in 1999 by the Institute of Medicine titled "To Err is Human: Building a safer health system". The report highlighted that there was an "epidemic of medical errors" occurring in health care, and advocated for the provision of safer care for patients. It showed that between 44,000 to 98,000 patients die in hospitals in the United States annually due to medical errors that were potentially preventable.[10] Rates of adverse events or errors vary in the literature, but range from approximately 16% to almost 46% of patients admitted. Serious adverse event rates were found to be as high as 17% of admissions.[2, 11]

A key trend within the medical community currently is to maximise patient safety and reduce medical errors or harm to patients.[10] The field of anaesthesia is known to be a leader in good safety practices, having initially pioneered adverse event reporting in the medical domain, using lessons learnt from the aviation industry[12] as well as having shown a considerable decline in mortality rates over the last 50 years.[13-17] In an effort to reduce adverse events, there has been research into improving patient safety by exploring any factors that may potentially lead to harm. Evidence supports the fact that a large percentage of adverse events are from "system failures" and "organisational factors", which are potentially avoidable.[18] As a result of the high rate of preventable errors, many medical institutions and societies have instituted formal adverse event and error reporting systems as a way to improve patient safety.[19]

Benefits of such systems are that analyses can be performed on various incidents or adverse events, which can be used for further learning, and to facilitate the framework for robust prevention strategies, possibly leading to reduced adverse events in the future. It also creates a societal culture of reporting, which is currently lacking within the health care field when compared with other critical environments or industries.[16, 20, 21]

Even though there are institutions that have adverse event reporting systems in place, there is still a significant problem with under-reporting of adverse events and errors.[16, 22] Reasons for this include factors such as time available to report, lack of anonymity, lack of clarity of definitions of adverse events, and perceived seriousness of the event itself. Some observational studies have shown that up to 90% of adverse events and errors are not being reported.[20, 23]

Heard et al,[23] in 2012, identified barriers to adverse event and error reporting amongst anaesthetists in Australia and New Zealand, and described factors which may improve reporting. The authors found that a significant barrier to reporting was fear of blame by colleagues. They also described further barriers to reporting when doctors had made an error that lead to an adverse event as compared to doctors who had not made an error even though an adverse event had occurred. There is little research describing barriers to reporting of adverse events and errors in the context of a developing nation such as South Africa, especially where adverse event reporting systems are not well established and seldom used. This study aimed to describe perceived barriers to the reporting of adverse events and errors amongst anaesthetists in the Department of Anaesthesiology at the University of the Witwatersrand, as well as to propose factors that may promote or encourage the reporting of adverse events and errors.

Method

Approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, and other relevant authorities. This was a prospective, contextual, descriptive study where anaesthetists in the Department of Anaesthesiology were asked to voluntarily complete an anonymous self-administered questionnaire at departmental academic meetings. Consent was implied on completion of the questionnaire, which was placed in a sealed box. One author (SN) was available to answer questions.

The questionnaire used was modified slightly from that published by Heard et al,[23] who derived their questionnaire through an extensive review of the available literature. The conduct and content of this questionnaire varied from that by Heard et al[23] in the following aspects, namely, questionnaires were completed by anaesthetists at departmental academic meetings rather than by mailed surveys, and the statement "ANZCA Continuing Professional Development points for reports" was modified to "SASA Continuing Professional Development points for reports" to make it appropriate for a South African context. The research design also varied, as Heard et al[23] used a randomised between-groups design, whereas this study utilised a single-subject design for the scenario questions. The questionnaire consisted of five sections, with three sections listing statements to be rated using a 5-point Likert Scale. Possible selections ranged from "strongly agree" to "strongly disagree". The layout of the questionnaire is shown in Table I.

Table I: Summary of questionnaire structure

Section	Intention	Description
Section 1	Demographic characteristics	Single answer selection from a range of variables
	Knowledge of existing adverse event and error reporting systems	
Section 2	Explore attitudinal and emotional factors regarding the reporting of adverse events	13 statements on a 5-point Likert scale. 10 statements focused on attitudinal barriers, and 3 statement focused on fears and anxiety barriers
Section 3	Determine barriers to the reporting of an adverse event (section 3A)	17 statements on a 5-point Likert scale, with a case scenario where a patient has an anaphylactic reaction to an antibiotic administered, with no pre-operative history of any allergy (an adverse event)
	Determine barriers to the reporting of an error (section 3B)	17 statements on a 5-point Likert scale, with a case scenario where a patient has an anaphylactic reaction to an antibiotic administered, with the anaesthetist recalling a pre-operative history of an allergy to that specific antibiotic (an error)
Section 4	Strategies that may promote or improve the reporting of adverse events and errors	17 statements on a 5-point Likert scale
Section 5	Further comments on current reporting structures, further barriers to reporting, and factors that may facilitate reporting of events	Free text paragraph

Of the 208 anaesthetists eligible to participate, it was estimated that 166 (80%) would be available at academic meetings, with the remainder involved with other commitments such as annual leave and emergency calls. Of the potential 166 participants, a response rate of 80% was targeted (n = 133). Interns rotating through anaesthesia were excluded from participating. Returned questionnaires that were less than 50% complete were used to calculate the response rate, but not included in data analysis.

Data were captured onto spreadsheets using Microsoft Excel® 2011. GraphPad Prism® v5.02 was used to analyse data, in consultation with a biostatistician. Categorical variables were presented using frequencies and percentages. For section 3 the Likert scale data were treated as interval scale data, with a score of 1 assigned to strongly agree, successively to a score of 5 for strongly disagree, thus a higher score showing higher levels of disagreement. Wilcoxon matched pairs were then used to compare the responses between the two groups. A *P* value of <0.05 was considered to be statistically significant. As per Heard et al,[23] the Likert scales used in sections 2, 3 and 4 were converted from 5-point to 3-point Likert scales, i.e. agree and strongly agree to agree, neutral remained the same, and disagree and strongly disagree to disagree. This was presented as ordinal scale data. Percentages were rounded off one decimal point.

Results

One hundred and thirty-three questionnaires were distributed at four consecutive departmental academic meetings, with a total of 123 returned, yielding a response rate of 74%. Five questionnaires were excluded as they were less than 50% complete (n = 118). Twenty-four questionnaires had some data missing, however they were all included in the data analysis. Of these, two participants did not complete section 3B at all, and were thus excluded from the Wilcoxon matched pairs analysis (n = 116). Table II details participants' demographic data.

Table II: Participant's demographic data

Characteristic	Frequency (n)	Percentage (%)
Gender		
Male	49	41.5
Female	68	57.6
Unknown	1	0.9
Age (years)		
21 - 30	26	22.1
31 - 40	64	54.2
41 - 50	8	6.8
51 - 60	15	12.7
61 - 70	3	2.5
Unknown	2	1.7
Professional designation		
Medical officer	25	21.2
Registrar	47	39.8
Consultant	36	30.5
Unknown	10	8.5
Years of experience		
Less than 5	53	44.9
5 - 10	40	33.9
11 - 20	10	8.5
> 20	14	11.9
Unknown	1	0.8

Table III shows participants knowledge of current reporting structures available at their workplace, with 105 (89%) participants aware of a reporting system at their workplace, and 94 (90%) participants indicating that the reporting system available was a formal system that was paper or computer based.

Table III: Current reporting structures available

Characteristic	Frequency (n)	Percentage (%)
Adverse event or error reporting system at workplace?		
Yes	105	89.0
No	3	2.5
Do not know	10	8.5
If yes, formal or Informal system?		
Formal system	94	89.5
Informal system	11	10.5
If yes, who instituted it?		
Anaesthesiology department	88	83.8
Hospital	2	1.9
Provincial government	1	1
National government	0	0
Do not know	14	13.3

Figure 1 shows the results from Section 2 of the questionnaire, which explored participants' attitudes and emotional factors regarding the reporting of adverse events and errors. For 11 out of 13 statements most participants were in disagreement. The only statement with which more participants agreed than disagreed was "Medicine has a culture of silence where errors are not talked about", with only 32% disagreeing. A second statement "Doctors who make errors are blamed by their colleagues" had the same levels of agreement versus disagreement (34%). The two statements with the highest levels of disagreement were "Competition with my peers would prevent me from disclosing an error" and "I would cover up an error if I could".

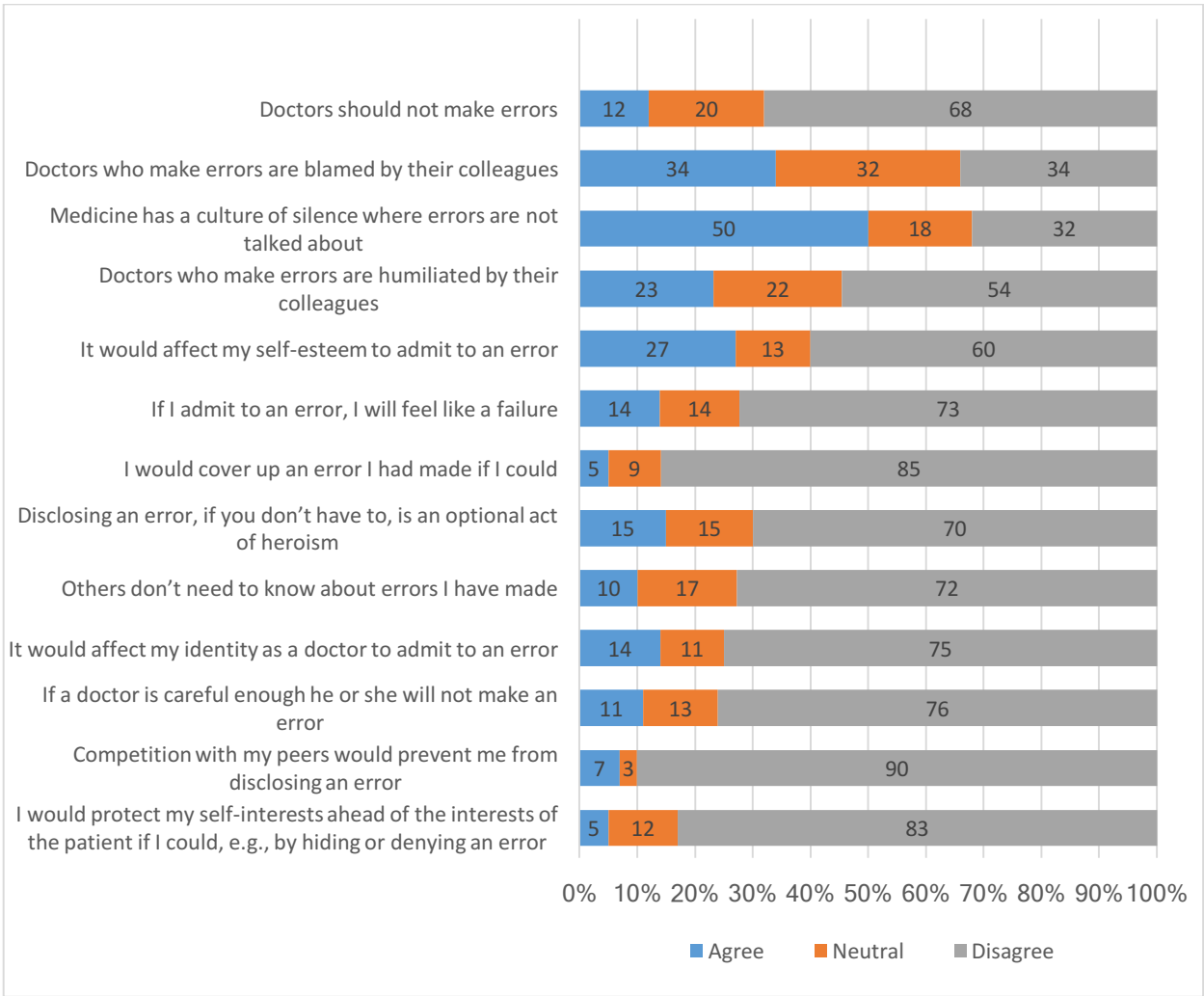

Figure 1: Attitudinal and emotional factors regarding the reporting of adverse events

Section 3 explored potential barriers to the reporting of an adverse event or error with a given clinical scenario. When comparing participant's responses for section 3A where no error had occurred as opposed to section 3B where an error had occurred, participants were more likely to agree with four statements when an error had been made, all with p-values of < 0.0001 (Table IV). These statements were:

- "I am worried about litigation" (76% vs 31%)
- "I don't want to get into trouble" (63% vs 45%)
- "My colleagues may be unsupportive" (47% vs 13%)
- "I am worried about disciplinary action" (59% vs 13%)

For the above statements, if an adverse event had occurred rather than an error, participants were more likely to disagree with those statements as potential barriers. With regards to the other 13 potential barriers to reporting, participants were more likely to disagree with the statements, regardless of whether the scenario was associated with an adverse event or an error. Of these 13 statements, only seven found statistical significance.

Where the median values and interquartile ranges were the same in a given question, the sum of ranks showed where the difference occurred. A lower sum of rank indicated a greater level of agreement and a higher sum of rank indicated a greater level of disagreement.

Table IV: Potential barriers to reporting an adverse event or error when anaphylaxis occurred in a given clinical scenario*

Statement	Group	Sum of Rank	Median (Interquartile Range)	P value
1. I am worried about litigation.	NE	391	4 (2-4)	<0.0001
	E	257	2 (2-2)	
2. I don't want to get into trouble.	NE	359	3 (2-4)	<0.0001
	E	299	2 (2-3)	
3. My colleagues may be unsupportive.	NE	444	4 (3-4)	<0.0001
	E	331	3 (2-4)	
4. I am worried about disciplinary action.	NE	447	4 (3-4)	<0.0001
	E	307	2 (2-4)	
5. I may be blamed unfairly for the event.	NE	423	4 (3-4)	0.001
	E	376	4 (2-4)	
6. I do not want the case discussed at meetings.	NE	457	4 (4-5)	<0.0001
	E	386	4 (2-4)	
7. Adverse event reporting makes little contribution to quality of care.	NE	513	5 (4-5)	0.0029
	E	489	4 (4-5)	
8. I don't know whose responsibility it is to make a report.	NE	476	4 (4-5)	0.2061
	E	485	4 (4-5)	
9. A good outcome of the case makes reporting unnecessary	NE	481	4 (4-5)	0.2061
	E	490	4 (4-5)	
10. I don't know which adverse events should be reported.	NE	420	4 (3-4)	0.0117
	E	441	4 (3-4)	
11. Even if I don't give details I am worried they will track me down.	NE	463	4 (4-5)	0.0081
	E	440	4 (3-4)	
12. The forms take too long to fill in and I just don't have time.	NE	402	4 (3-4)	0.0079
	E	419	4 (3-4)	
13. When I am busy at work I forget to make a report.	NE	368	3 (2-4)	0.0167
	E	383	4 (2-4)	
14. I don't feel confident the information will be kept confidential.	NE	402	4 (3-4)	0.2691
	E	393	4 (3-4)	
15. I never get any feedback after I report an adverse event.	NE	362	3 (2-4)	0.3216
	E	357	3 (2-4)	
16. I wonder about who else will have access to the information.	NE	369	3 (2-4)	0.0837
	E	358	3 (2-4)	
17. As long as the staff involved learn from incidents it is unnecessary to discuss any further.	NE	469	4 (4-5)	0.9723
	E	469	4 (4-5)	

* In the clinical scenario in section 3A there was an adverse event but no error, whereas in section 3B there was an adverse event as a result of an error in giving an antibiotic to a patient with a known allergy to that antibiotic, causing anaphylaxis. NE = No-error, E = Error

In Section 4 strategies that may promote or improve reporting of adverse events and errors were investigated (Figure 2). The statement with the most agreement (98%) was "Role models, e.g. senior colleagues who openly encourage reporting". There were high levels of agreement for most statements. The statement that had the highest level of disagreement was "payment taken for time to report" with 62% disagreeing. The statement "SASA Continuing Professional Development points for reports" also had less support with 55% agreeing.

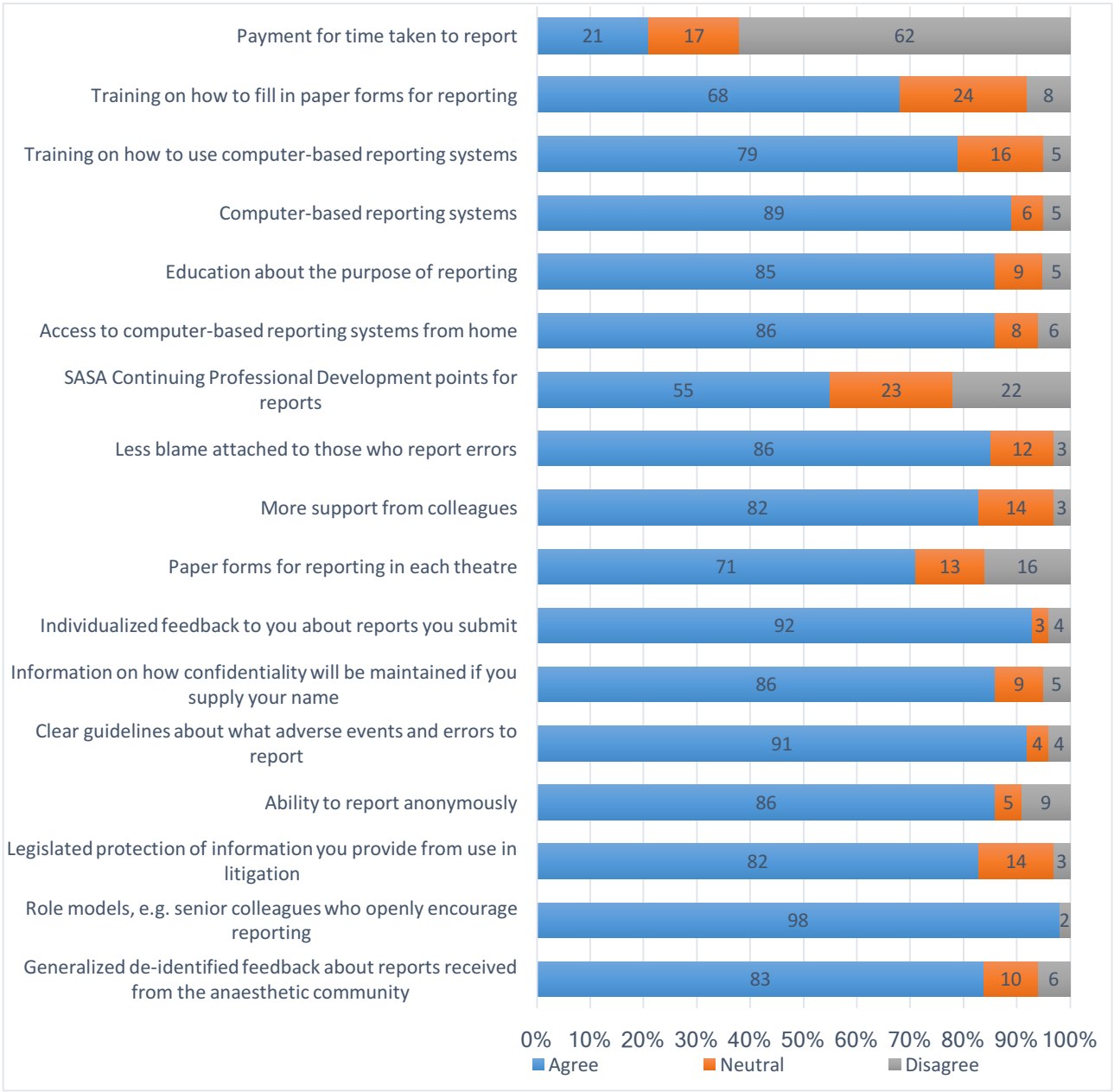

Figure 2: Strategies that may promote or improve the reporting of adverse events and errors

Section 5 was for participant's free text, and allowed for any comments regarding adverse event and error reporting structures, as well as any further factors that may influence reporting. Only 37 (31%) participants completed the comments section. Common themes with regards to barriers to reporting included fear of litigation, discrimination and blame from colleagues. Other barriers included not knowing what or when to report, and forgetting to report. Factors suggested that may promote or enhance reporting included support from senior colleagues, individualised feedback and debriefing, making reporting easier with shorter forms and electronic submissions, and having a clear reporting structure in place. Many participants felt it should be compulsory to report, with some stating it should be a legal requirement.

Discussion

Of the 118 participants in our study, there was a female predominance (58%), with 76% of participants falling between the ages of 21 to 40 years. Most participants (89%) were aware of some form of adverse event or error reporting system at their workplace, with 84% stating that the anaesthetics department at their workplace had instituted the reporting system.

Section 2 explored anaesthetist's attitudes to the reporting of adverse events and errors. The statement that had the most agreement amongst participants (50%) was "Medicine has a culture of silence where errors are not talked about". This contrasted with the 37% who agreed with the same statement by Heard et al's study[23] This confirms that a "code of silence" is an important factor that may inhibit the reporting of adverse events, a concern also expressed by other authors.[24, 25] A second barrier to reporting that was prevalent was that of "blame", with 34% of participants agreeing that colleagues will blame them for errors made, which is lower than the 46% who agree in Heard et al's study[23] This belief is strongly supported in the literature, and is associated with serious consequences such as anxiety, depression and suicide.[21, 24, 26-28] If analysis of adverse events and errors only focuses on the individual involved, and directs blame, then deeper and more meaningful analysis of system error and root cause analysis will not be possible, seriously limiting the usefulness of reporting systems as a learning and patient safety tool.[27, 29-32] Excluding the barriers of blame and a culture of silence, participants in our study generally disagreed with most of the proposed barriers to reporting. Importantly, between 68 to 76% of participants disagreed with the statements "Doctors should not make errors" and "If a doctor is careful he or she will not make an error". This showed a trend away from the traditional thinking of the "medical perfectibility model" where doctors have unrealistic expectations of providing error-free medical care, towards more realistic expectations that errors can and will happen.[24] Only 5% of participants

agreed that they would cover up an error if they could, compared with 10% agreement in Heard et al's study.[23] Only 5% of participants in both studies agreed that they would protect their self-interests ahead of those of a patient's. Such low levels of agreement may be accurate, or may represent a socially acceptable response of what "should be answered". Of concern was that 23% of participants in our study felt that they would be humiliated by their colleagues when making errors, as compared to 18% by Heard et al,[23] signifying a potentially serious disincentive towards reporting adverse events or errors.

With the given clinical scenario, if participants had made an error as opposed to an adverse event, they were significantly more likely to agree with barriers concerning fear of litigation (76 vs 31%), not wanting to get into trouble (63 vs 45%), unsupportive colleagues (47 vs 13%), fear of disciplinary action (59 vs 13%), fear of being blamed unfairly (30 vs 24%), and not wanting the case to be discussed in meetings (26 vs 8%), with comparable findings by Heard et al.[23] The similar findings between both studies may indicate that these fears or concerns are universal and legitimate.

Participants' most significant concern was fear of litigation, with 76% of participants fearing litigation if they had made an error as opposed to Heard et al[23] where there was 58% agreement regarding the same barrier. If participants had an adverse event as opposed to an error, then only 31% agreed with fear of litigation as a barrier to reporting. This concern may be explained by an increasing trend towards litigation in South Africa, with high value claims of greater than R5 million increasing by more than 900% over the last five years.[33] This may be compounded by the fact that adverse event and error reports may be subject to "legal discovery, with very damaging materials that were intended for safety rather than legal use" being subpoenaed for civil lawsuits.[34]

Most participants regardless of whether associated with an error or no error scenario disagreed with statements regarding not knowing which adverse event to report (67-73%), being too busy at work and forgetting to report (44-53%), forms taking too long to fill and not having the time (55-64%), and that "adverse event reporting makes little contribution to quality of care" (91-93%). This latter finding is in keeping with those by Heard et al's study,[23] where approximately 2% agreed that "Adverse events make little contribution to care". Disagreement with these statements also showed that time and busyness are not important barriers to reporting, a finding corroborated by Heard et al's study,[23] but in contrast with findings by other authors.[20, 27] The statement "Even if I don't give my details I am worried they will track me down" had 73 to 79% disagreement as compared to the same statement by Heard et al[23] which had 62 to 68% disagreement. This differs with other authors who have found that anonymity influences willingness to report. [26, 35]

This study found that the most important factor that may facilitate the reporting of adverse events and errors to be senior colleagues who openly encourage reporting, with 98% of participants agreeing, and none disagreeing. A similar proportion in agreement of 91% was found by Heard et al.[23] This demonstrated how important leadership can be in creating a successful reporting system. The statement "Individualised feedback to you about reports you submit" was the second most accepted statement, with 92% agreeing. These statements differ from Heard et al[23] who identified generalised de-identified feedback (94%) rather than individualised feedback (79%) as the most prevalent statement. With generalised feedback there is potential to learn from previous errors or adverse events,[29, 30, 36] however individualised feedback may allow for debriefing of the event, and gives closure to the individual involved.[37] A third statement where 90% of participants agreed was "clear guidelines about what adverse events or errors to report", with 83% of participants in the research by Heard et al[23] also agreeing. Without clear guidelines, errors "can be defined away" by misinterpreting ambiguous definitions, leading to under-reporting.[38] The lack of a universal taxonomy for adverse event and error reporting systems also makes clear guidelines on what to report important.[30, 38-40]

The statements with the lowest level of agreement was payment in return for time taken to report (21%), with similar findings from Heard et al.[23] Other statements that had lower levels of agreement were those regarding continuing professional development points for reporting (55%), which may represent a bias towards registrars in training who do not need to gain professional development points, and a preference in our study towards computer based rather than paper based reporting systems (89% vs. 70%). This contrasted with research by Heard et al,[23] where 73% of participants agreed or strongly agreed to paper based reporting, as compared with only 52% agreement towards computer-based reporting systems.

An important finding from participants' free text was that many felt that reporting of adverse events and errors should be compulsory, with some feeling it should even be a legal requirement to report.

Limitations

This study is contextual to the Department of Anaesthesiology at the University of the Witwatersrand, and thus the results may not be generalisable to other anaesthetic departments or medical departments in South Africa or other countries. However, an advantage is that results from this study compare closely to those by Heard et al,[23] indicating that the findings may be universal to countries with similar medical and legal systems. Responder bias is a further potential limitation, as participants who completed the questionnaire may be more willing to fill in adverse event and error forms than those who did not fill in questionnaires.

The order of statements and the clinical scenarios utilised may have influenced participants' responses and could vary if other scenarios or statements were used, however, this questionnaire was based on that by Heard et al,[23] and strengthens the findings of our study, as our results are comparable to those of Heard et al[23]. The way in which participants completed the questionnaire could have been affected by "social desirability bias", where participants may have completed the questionnaire in a socially acceptable manner rather than with direct honesty.

Conclusion

The majority of anaesthetists in our study disagreed with barriers to reporting an unspecified adverse event, however, if an error has occurred, there is a greater likelihood that reporting behaviour may be inhibited by barriers regarding fears of litigation, disciplinary action and lack of support. Senior role models that openly support reporting along with individualised feedback may increase reporting and the associated benefits thereof.

Acknowledgements

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Conflict of Interest

I declare that I have no financial or personal relationship(s) which may have inappropriately influenced me in writing this paper.

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SECTION 4 – Appendices

Appendix 1 – Postgraduate Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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12 January 2016
Person No: 0204336Y
PAG

Dr SR Nel
Po Box 79057
Senderwood
Bedfordview
1401
South Africa

Dear Dr Nel

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Factors influencing adverse event and error reporting in anaesthesiology* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 2 – Ethics Approval

R14/49 Dr Steven Robert Nel

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150102

NAME: (Principal Investigator)	Dr Steven Robert Nel
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Factors Influencing Adverse Event and Error Reporting in Anaesthesiology
DATE CONSIDERED:	30/01/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Juan Scribante
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	13/07/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

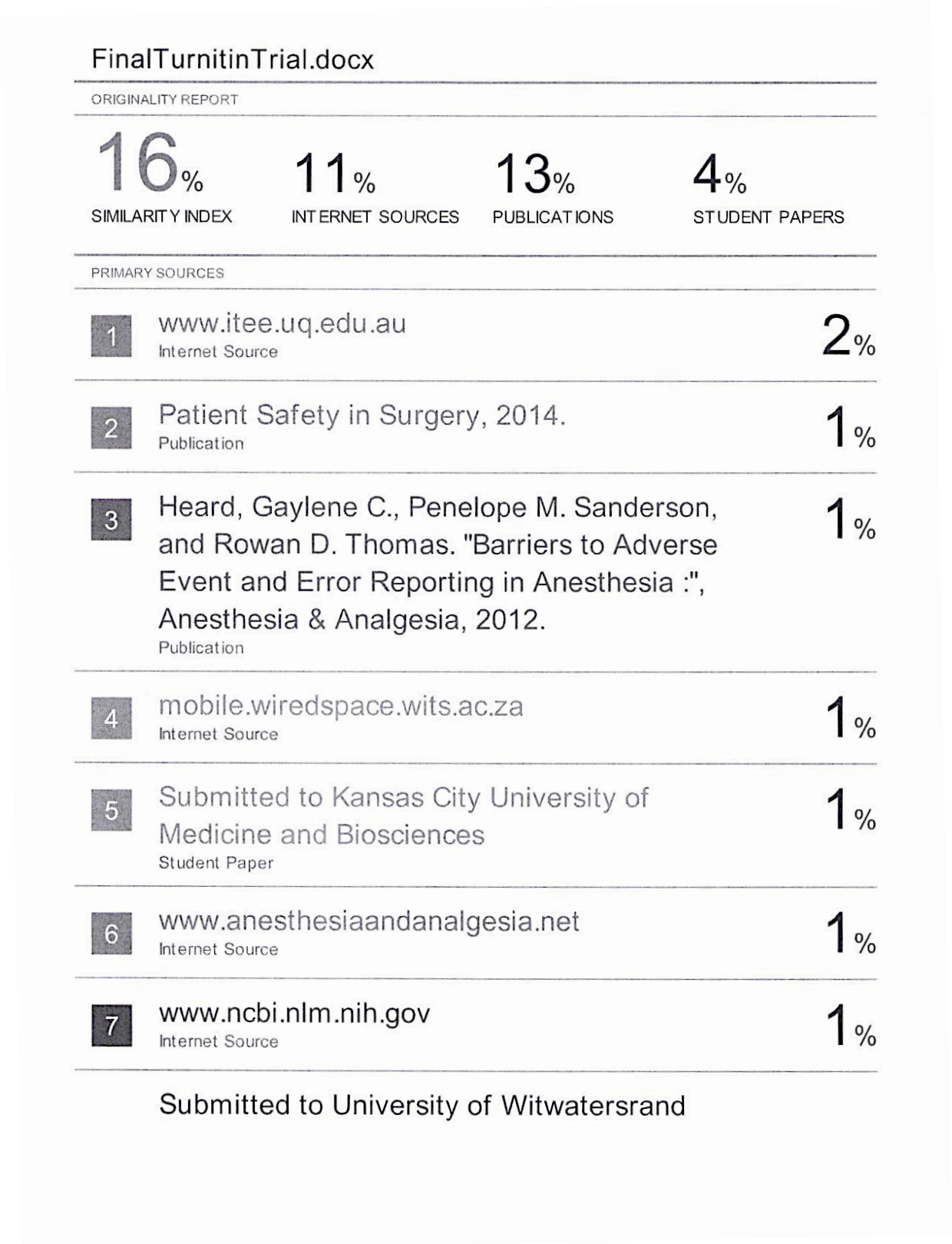
DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in January and will therefore be due in the month of January each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3 – Turnitin Report



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ORIGINALITY REPORT

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PRIMARY SOURCES

1	www.itee.uq.edu.au Internet Source	2%
2	Patient Safety in Surgery, 2014. Publication	1%
3	Heard, Gaylene C., Penelope M. Sanderson, and Rowan D. Thomas. "Barriers to Adverse Event and Error Reporting in Anesthesia :", Anesthesia & Analgesia, 2012. Publication	1%
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Submitted to University of Witwatersrand

SECTION 5 - Proposal

Factors influencing adverse event and error reporting in Anaesthesiology

Steven Nel

0204336Y

Supervisor: Juan Scribante

Department of Anaesthesiology

Co-supervisor: Helen Perrie

Department of Anaesthesiology

Co-supervisor: Professor Christina Lundgren

Department of Anaesthesiology

5.1 Introduction

Adverse events and errors are still a widespread cause of morbidity and mortality in the health care environment (1-5), with ample literature detailing that many of these errors are often preventable (5-9).

Adverse events and errors have been increasingly recognised and focused upon since the report released in 1999 by the Institute of Medicine titled “To Err is Human: Building a safer health system”. The report highlighted that there was an “epidemic of medical errors” occurring in health care, and advocated for the provision of safer care for patients. The report showed that between 44,000 to 98,000 patients die in hospitals in the United States yearly due to medical errors that were potentially preventable (10).

Rates of adverse events or errors vary in the literature, but range from approximately 16% (2) to as high as nearly 46% of patients admitted (11). Serious adverse events were found to be as high as 13 to 17% of admissions (2, 11).

A current trend within the medical community is to maximise patient safety and reduce medical errors or harm to patients (10). The field of anaesthesia is known to be a leader in good safety practices, having initially pioneered adverse event reporting in the medical domain using lessons learnt from the aviation industry (12), as well as having shown a considerable decline in mortality rates over the last 50 years (13-17).

In an effort to reduce adverse events, there has been research into improving patient safety by exploring any factors that may potentially lead to harm. Evidence supports the fact that a large percentage of adverse events are from “system failures” and “organisational factors”, which are potentially avoidable. (18)

As a result of the high rate of preventable errors, many medical institutions and societies have instituted formal adverse event and error reporting systems, as a way to improve patient safety by allowing for learning from “near misses” and “adverse events” (19).

Benefits of such systems are that analyses can be done on various incidents or adverse events, which can be used for further learning, and to facilitate the framework for robust prevention strategies, possibly leading to reduced adverse events in the future. It also creates a societal culture of reporting, which is currently lacking within the medical field when compared to other environments or industries where errors can have serious consequences. (16, 20, 21)

Even though many institutions have adverse event reporting systems in place, there is still a significant problem with under-reporting of adverse events and errors (16, 22). Reasons for this have been noted to include factors such as time available to report, lack of anonymity, lack of clarity of definitions of adverse events, and perceived seriousness of the event itself. Some observational studies have shown that up to 90% of adverse events and errors are not being reported. (20, 23)

Heard et al (23) in 2012 researched the barriers to adverse event and error reporting within the Australian and New Zealand context, as well as describing factors which would improve reporting. The authors found that a significant barrier to reporting was fear of blame by colleagues. They also described further barriers to reporting when doctors had made an error that led to an adverse event as compared to doctors who had not made an error even though an adverse event had occurred.

There is paucity of information available regarding adverse event and error reporting systems implemented currently in South Africa. The Nelson R Mandela School of Medicine and the University of KwaZulu-Natal have published guidelines regarding the reporting of adverse events and errors (24), and The Council for Health Service Accreditation of Southern Africa have instituted a pilot project to run in 45 public institutions in the Free State which started in 2007. This pilot project is modelled on Australian Incident Management System that was initiated in 1996 (25). These pilot projects are however on a small scale, and there is no information regarding their success

5.2 Problem statement

It has been shown that adverse event and error-reporting systems are an integral part of a health care safety culture, and have the potential to reduce harm to patients, yet formal adverse event and error reporting systems are not widely available in South Africa. There is also no evidence that the barriers to reporting of adverse events and errors as described in the literature would be applicable to developing countries such as South Africa, who face their own unique health system challenges, nor whether they would be applicable to the Department of Anaesthesiology at Wits.

5.3 Aim

The aim of this study is to describe anaesthetists perceived barriers to the reporting of adverse events and errors, and factors that may promote or encourage this reporting in the Department of Anaesthesiology at Wits.

5.4 Objectives

The objectives of this study will be to:

- describe knowledge of existing adverse event or error reporting systems that are utilised in daily practice
- describe the perceived barriers to the reporting of adverse events and errors
- describe the perceived barriers to the reporting of an adverse event in a theoretical clinical scenario where an error was made by the anaesthetist, compared to a theoretical clinical scenario where an adverse event was present but no error made by the anaesthetist
- describe the factors that may promote or encourage reporting of an adverse event or error.

5.5 Research assumptions

The following definitions will be used in the study

Anaesthetist: is any qualified doctor working in the Department of Anaesthesiology including medical officers, registrars and consultants**.**

Medical officer: is a qualified doctor practising in the Department of Anaesthesiology under specialist supervision**.** Medical officers with more than 10 years of experience are career medical officers and are regarded as consultants.

Registrar: is a qualified doctor that is registered with the Health Professions Council of South Africa as a trainee anaesthetist**.**

Consultant: is an anaesthesiologist who has completed all criteria and passed the required South African College of Medicine examinations, or equivalent. They are regarded as specialists in the field. Career medical officers are included in this definition.

Error: “the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care”. (26)

Adverse event: “an injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care.

Adverse events may be preventable or non-preventable". (26)

Preventable adverse event: "an adverse event caused by an error or other type of systems or equipment failure" (26).

Near-miss or close call: "serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event." (26)

Adverse drug event: "a medication-related adverse event" (26).

5.6 Demarcation of study field

The study will be conducted in the Department of Anaesthesiology, affiliated to the Faculty of Health Sciences of the University of the Witwatersrand. The staff complement of the department is 22 medical officers, 112 registrars and 74 consultants. The following hospitals are affiliated to the university.

- Charlotte Maxeke Johannesburg Academic Hospital, a 1200 bed central hospital.
- Chris Hani Baragwanath Academic Hospital, a 2888 bed central hospital.
- Helen Joseph Hospital, a 500 bed tertiary hospital.
- Rahima Moosa Mother and Child Hospital, a 338 bed regional hospital.

5.7 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Post Graduate Committee of the University of the Witwatersrand.

This study uses an anonymous self-administered questionnaire (Appendix 1). The questionnaire will be voluntary and consent is implied on completion of the questionnaire. The researcher will approach participants at departmental academic meetings, explain the study and invite them to take part. If they agree the researcher will give them a participant's information letter (Appendix 2) with the questionnaire.

Data will be collected without identifying information, and will be assigned a study number, thus maintaining anonymity. Completed questionnaires will be placed in sealed boxes. Confidentiality will be ensured, as only the researcher and supervisors will have access to the raw data.

Data will be stored securely for six years after completion of the study. Study will be conducted according to the principles of the Declaration of Helsinki (27) and the South African Guidelines for Good Clinical Practice (28).

5.8 Methodology

5.8.1 Research design

Burns and Grove (29) describe a research design as the framework for a study. According to Brink (30), a research design determines the methods by which the researcher obtains subjects, collects data and interprets results.

A prospective, contextual, descriptive research design will be followed in this study.

A prospective study is one that measures variables that occur during the course of the study (30). This is a prospective study, as data will be collected at the time the study takes place.

A contextual study is one which refers to a specific group or population, defined by De Vos et al (31) as a “small-scale world”. The “small-scale world” can be for example a ward, intensive care unit or a clinic. This study is contextual because research will be done with anaesthetists working at hospitals affiliated to the University of the Witwatersrand.

According to Brink (30), a descriptive study is one in which a population’s characteristics are being described, so as to answer a specific question about the population, without attempting to establish a causal link. The factors influencing adverse event and error reporting in anaesthesia will be described.

5.8.2 Study population

The study population consists of all anaesthetists working in the Department of Anaesthesiology.

5.8.3 Study sample

Sample method

In this study a convenience sampling method will be used, as is suitable for a descriptive design (29). Convenience sampling involves the sampling of respondents who are readily available to the researcher (30). This study will sample participants who attend departmental academic meetings in the Department of Anaesthesiology.

Sample size

The sample size will be realised by the response rate. At the time of the study will take place there should be 208 eligible anaesthetists for the study. Questionnaires will be administrated to the entire accessible population who are present at academic meetings. At the time of data collection, it is estimated that 42 (20%) anaesthetists will be inaccessible due to leave, out of town rotations, etc. A response rate of 60% (100 questionnaires) is considered as acceptable, but a response rate of 80% (132 questionnaires) will be targeted.

Inclusion and exclusion criteria

The inclusion criterion for this study is all anaesthetists working in the Department of Anaesthesiology who are willing to partake in the study.

The exclusion criteria for this study are:

- interns
- anaesthetists on annual or sick leave.

5.9 Collection of data

5.9.1 Development of questionnaire

Based on an extensive literature review a questionnaire was identified from a study published in 2012 by Heard et al (23) in Australia. The questionnaire was modified to contextualise it to the South African environment. The questionnaire was then reviewed by three senior anaesthesiologists to achieve face and content validity. Following consultation, minor corrections were made.

The self-administered questionnaire (23) (Appendix 1) consists of five sections. Questions in section 2, 3 and 4 are statements listed with a 5-point Likert scale ranging from “strongly agree” to “strongly disagree”.

Section 1 will focus on the demographics characteristics of the respondents and will include:

- gender
- age group
- professional designation
- years of anaesthetic experience

- knowledge of existing adverse event or error reporting systems that are utilised in participants' daily practice.

Section 2 will specifically explore attitudinal and emotional factors that could influence whether an unspecified adverse event caused by an error would be reported. It contains 13 statements; 10 statements centred around the theme of attitudinal barriers and 3 statements based on fear and anxiety barriers.

Section 3 will focus on reporting an adverse event of anaphylaxis, with or without an error as its cause. It will contain two case scenarios with two different endings. The first case scenario will describe an anaphylaxis due to antibiotic administration for a patient who gave no history of any drug allergy. The second case scenario will be similar to the first case scenario, but will state that the anaesthetist will realise afterwards that he/she have given a particular antibiotic in error, after noting that the patient had an allergy to that particular antibiotic. There will be 17 statements for each scenario to rate as barriers to reporting the adverse event of anaphylaxis.

Section 4 will focus on strategies that may improve the reporting of adverse events and errors. There will be 17 statements on factors that may promote the reporting of adverse events and errors amongst anaesthetists.

Section 5 will be for participant's free text, allowing for general comments regarding the questionnaire, as well as any further factors that may influence the reporting of adverse events and errors.

5.9.2 Data collection

The researcher will approach the convenor at the department academic meetings, and ask to address the meeting. Information will be provided to the meeting attendees regarding the research, and the researcher will invite them to take part in the study. Those who are interested will receive an information letter (Appendix 2) and the questionnaire (Appendix 1). The researcher will be available to answer any questions, and the completed questionnaires will be returned in a sealed box.

Blank questionnaires that are returned will be assigned a number and used for response rate calculation but not for data analysis.

5.9.3 Data analysis

Data will be captured onto spreadsheets using Microsoft Excel 2011.

The statistical program Graphpad Prism v5.02 will be used to analyse data, in consultation with a biostatistician. Descriptive statistics will be used. Categorical variables will be summarised using frequencies and percentages. The Likert scale will be treated as ordinal data and Wilcoxon matched pairs will be used to compare variables. A *P* value of <0.05 will be considered to be statistically significant.

5.10 Significance of the study

There is considerable evidence within the literature demonstrating that the introduction of an adverse event and error reporting system is associated with the potential for reduced harm, a view that is supported by the World Health Organisation (26) and the Institute of Medicine (10) in the United States.

There is also evidence from studies by Heard et al (23) and other authors (32-37) that define some of the barriers to adverse event and error reporting. However, there is wide variability between the various authors' findings. It is also important to note that the research from these authors has been done in developed countries. South Africa as a developing country potentially has different health care challenges, and thus research from Heard et al (23) and other authors may not translate to the effective implementation of an adverse event and error reporting system in South Africa.

This study seeks to describe the barriers to adverse event and error reporting that are applicable in the Department of Anaesthesiology at Wits. This study also seeks to describe which factors would facilitate a greater likelihood of reporting adverse events. The results of this study may direct further research aimed at creating a framework for the implementation of a formal adverse event and error reporting system in South Africa, or allow for the strengthening of adverse event and error reporting systems that may already be present.

5.11 Validity and reliability of the study

Validity is defined as the accuracy of an instrument to perform an intended measurement. Reliability refers to the consistency with which an instrument yields the same results (30).

The validity and reliability of this study will be maintained by:

- using a validated questionnaire with content and face validity
- placing completed questionnaires into a sealed box, thus facilitating a non-threatening environment and anonymity
- checking 10% of the data entered to ensure quality of data entry
- consulting with a biostatistician for data analysis.

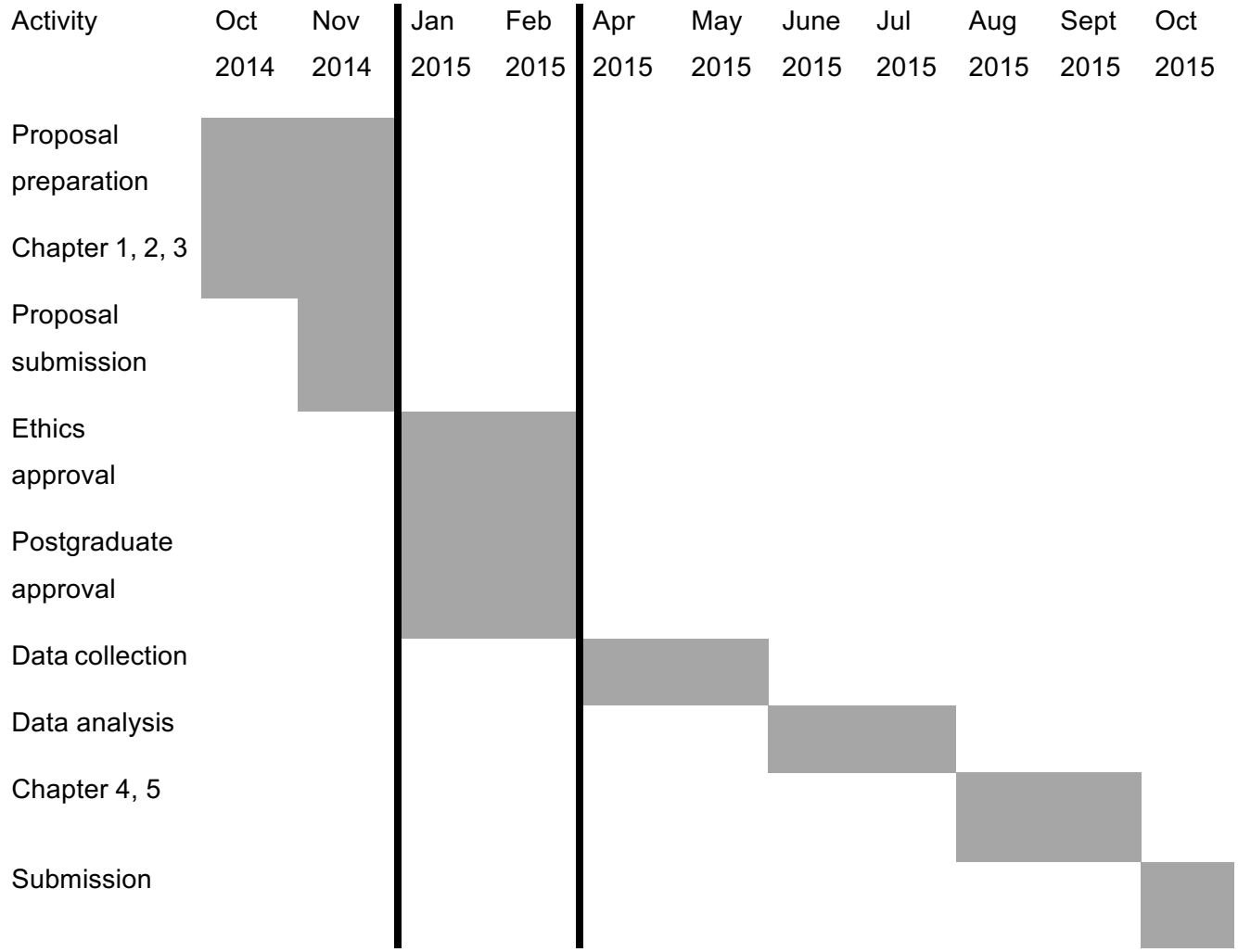
5.12 Potential limitations of the study

Limitations are defined as restrictions or problems that may decrease the application of the findings to the general population (29).

The potential limitations of this study are that:

- the study is contextual to the Department of Anaesthesiology at Wits, and thus may not be able to be generalised to other anaesthesiology departments
- a convenience sample will be used in this study. This may not adequately represent the perceptions of all anaesthetists in the department.

5.13 Project outline



5.14 Financial plan

Budget

Item	Number	Cost	Total
Printing	1200	R1/page	R1 200
Binding	3	R150	R 450
Total			R1 650

The Department of Anaesthesiology will bear the cost of printing and paper for the proposal, ethics and postgraduate approvals.

5.15 References

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Appendix 1: Questionnaire (23)

Section 1

1. Gender: Female ☐ Male ☐

2. Age (years): 21 – 30 ☐ 31 – 40 ☐ 41 – 50 ☐ 51 – 60 ☐ 61 – 70 ☐ > 70 ☐

3. Practice type:

Mostly private ☐
Mostly public ☐
Public and private ☐
Other ☐ _____

_____

4. Professional designation:

Medical officer ☐
Registrar ☐
Consultant ☐
Other ☐

5. Years of experience:

<5 ☐ 5 – 10 ☐ 11 – 20 ☐ >20 ☐

6. Adverse event and error reporting systems:

Do you have any form of adverse event or error reporting system at your work place? Yes ☐
No ☐ Don't Know ☐

If yes, is it a formal system of reporting (Paper or computer based), or informal system (verbal discussions, copied charts etc.)?

Formal system ☐ Informal system ☐

If yes, who instituted it?

Anaesthetics department ☐ Hospital ☐ Provincial government ☐ National government ☐ Don't Know ☐

In this section, please mark with a ☒ the option you feel is most appropriate with regards to the reporting of an adverse events or errors. Please make a selection for each question.

	SECTION 2	STRONGLY AGREE	AGREE	NEUTRL	DISAGREE	STRONGLY DISAGREE
1.	I would protect my self-interests ahead of the interests of the patient if I could, e.g., by hiding or denying an error.	☐	☐	☐	☐	☐
2.	Competition with my peers would prevent me from disclosing an error.	☐	☐	☐	☐	☐
3.	If a doctor is careful enough he or she will not make an error.	☐	☐	☐	☐	☐
4.	It would affect my identity as a doctor to admit to an error.	☐	☐	☐	☐	☐
5.	Others don't need to know about errors I have made.	☐	☐	☐	☐	☐
6.	Disclosing an error, if you don't have to, is an optional act of heroism.	☐	☐	☐	☐	☐
7.	I would cover up an error I had made if I could	☐	☐	☐	☐	☐
8.	If I admit to an error I will feel like a failure.	☐	☐	☐	☐	☐
9.	It would affect my self-esteem to admit to an error.	☐	☐	☐	☐	☐
10.	Doctors who make errors are humiliated by their colleagues.	☐	☐	☐	☐	☐
11.	Medicine has a culture of silence where errors are not talked about.	☐	☐	☐	☐	☐
12.	Doctors who make errors are blamed by their colleagues.	☐	☐	☐	☐	☐
13.	Doctors should not make errors.	☐	☐	☐	☐	☐

Please read the following clinical scenario:

You have placed a patient under general anaesthesia in theatre and given a prophylactic antibiotic as per departmental guidelines. The patient has no known history of allergies. The patient subsequently develops an anaphylaxis suspected to be due to the antibiotic given. You manage the anaphylaxis appropriately and the patient has an uneventful recovery.

In this section, please mark with a ☒ the option you feel is most appropriate with regards to the reporting of an adverse event or error for the clinical scenario

	SECTION 3 A	STRONGLY AGREE	AGREE	NEUTRL	DISAGREE	STRONGLY DISAGREE
1.	I am worried about litigation.	☐	☐	☐	☐	☐
2.	I don't want to get into trouble.	☐	☐	☐	☐	☐
3.	My colleagues may be unsupportive.	☐	☐	☐	☐	☐
4.	I am worried about disciplinary action.	☐	☐	☐	☐	☐
5.	I may be blamed unfairly for the event.	☐	☐	☐	☐	☐
6.	I do not want the case discussed at meetings.	☐	☐	☐	☐	☐
7.	Adverse event reporting makes little contribution to quality of care.	☐	☐	☐	☐	☐
8.	I don't know whose responsibility it is to make a report.	☐	☐	☐	☐	☐
9.	A good outcome of the case makes reporting unnecessary.	☐	☐	☐	☐	☐
10	I don't know which adverse events should be reported.	☐	☐	☐	☐	☐
11	Even if I don't give my details I am worried they will track me down.	☐	☐	☐	☐	☐
12	The forms take too long to fill in and I just don't have time.	☐	☐	☐	☐	☐
13	When I am busy at work I forget to make a report.	☐	☐	☐	☐	☐
14	I don't feel confident the information provided will be kept confidential.	☐	☐	☐	☐	☐
15	I never get any feedback after I report an adverse event.	☐	☐	☐	☐	☐
16	I wonder about who else will have access to the information I disclose.	☐	☐	☐	☐	☐
17	As long as the staff involved learn from incidents it is unnecessary to discuss them any further.	☐	☐	☐	☐	☐

Please read the following clinical scenario:

You have placed a patient under general anaesthesia in theatre and given a prophylactic antibiotic as per departmental guidelines. The patient subsequently develops an anaphylaxis suspected to be due to the antibiotic given. **You recall that on your pre-operative examination the patient gave a history of allergy to that specific antibiotic.** You manage the anaphylaxis appropriately and the patient has an uneventful recovery.

In this section, please mark with a ☒ the option you feel is most appropriate with regards to the reporting of an adverse event or error for the clinical scenario

	SECTION 3 B	STRONGLY AGREE	AGREE	NEUTRL	DISAGREE	STRONGLY DISAGREE
1.	I am worried about litigation.	☐	☐	☐	☐	☐
2.	I don't want to get into trouble.	☐	☐	☐	☐	☐
3.	My colleagues may be unsupportive.	☐	☐	☐	☐	☐
4.	I am worried about disciplinary action.	☐	☐	☐	☐	☐
5.	I may be blamed unfairly for the event.	☐	☐	☐	☐	☐
6.	I do not want the case discussed at meetings.	☐	☐	☐	☐	☐
7.	Adverse event reporting makes little contribution to quality of care.	☐	☐	☐	☐	☐
8.	I don't know whose responsibility it is to make a report.	☐	☐	☐	☐	☐
9.	A good outcome of the case makes reporting unnecessary.	☐	☐	☐	☐	☐
10	I don't know which adverse events should be reported.	☐	☐	☐	☐	☐
11	Even if I don't give my details I am worried they will track me down.	☐	☐	☐	☐	☐
12	The forms take too long to fill in and I just don't have time.	☐	☐	☐	☐	☐
13	When I am busy at work I forget to make a report.	☐	☐	☐	☐	☐
14	I don't feel confident the information provided will be kept confidential.	☐	☐	☐	☐	☐
15	I never get any feedback after I report an adverse event.	☐	☐	☐	☐	☐
16	I wonder about who else will have access to the information I disclose.	☐	☐	☐	☐	☐
17	As long as the staff involved learn from incidents it is unnecessary to discuss them any further.	☐	☐	☐	☐	☐

In this section, please mark with a ☒ the option you feel is most appropriate with regards to the factors that may promote or encourage the reporting of adverse events and errors:

	SECTION 4	STRONGLY AGREE	AGREE	NEUTRL	DISAGREE	STRONGLY DISAGREE
1	Generalized de-identified feedback about reports received from the anaesthetic community.	☐	☐	☐	☐	☐
2	Role models, e.g. senior colleagues who openly encourage reporting.	☐	☐	☐	☐	☐
3	Legislated protection of information you provide from use in litigation.	☐	☐	☐	☐	☐
4	Ability to report anonymously.	☐	☐	☐	☐	☐
5	Clear guidelines about what adverse events and errors to report.	☐	☐	☐	☐	☐
6	Information on how confidentiality will be maintained if you supply your name.	☐	☐	☐	☐	☐
7	Individualized feedback to you about reports you submit.	☐	☐	☐	☐	☐
8	Paper forms for reporting in each theatre.	☐	☐	☐	☐	☐
9	More support from colleagues.	☐	☐	☐	☐	☐
10	Less blame attached to those who report errors.	☐	☐	☐	☐	☐
11	SASA Continuing Professional Development points for reports.	☐	☐	☐	☐	☐
12	Access to computer-based reporting systems from home.	☐	☐	☐	☐	☐
13	Education about the purpose of reporting.	☐	☐	☐	☐	☐
14	Computer-based reporting systems.	☐	☐	☐	☐	☐
15	Training on how to use computer-based reporting systems.	☐	☐	☐	☐	☐
16	Training on how to fill in paper forms for reporting.	☐	☐	☐	☐	☐
17	Payment for time taken to report.	☐	☐	☐	☐	☐

Section 5:

This section is for free text. Please give any further information on reasons you would NOT report adverse events or errors, factors that you feel might facilitate better implementation of an adverse event and error reporting system, or notes about any reporting structure you are aware of or utilizing currently:

Any Feedback on this questionnaire/study?

Thank you for your time, it is much appreciated.

Appendix 2: Information sheet

Dear Colleague,

Hello, my name is Steven Nel, and I am an anaesthesiology registrar in the Wits Department of Anaesthesiology. I would like to invite you to participate in my MMed research study titled “Factors influencing adverse event and error reporting in Anaesthesiology”. This study was approved by the Human Research Committee (Medical) (M150102)

The study aims to describe the perceived barriers to the reporting of adverse events and errors amongst South African anaesthetists, as well as to determine which factors might facilitate enhanced reporting practices amongst anaesthetists.

Participation is on a voluntary basis and consent is implied on completion of a questionnaire. All information given will remain strictly confidential and anonymous, as no personal details will need to be provided to compete the questionnaire. There will be no penalty for not participating in this study.

All questionnaires, whether completed or not, should please be given back to the researcher. All questionnaires will be given a unique number once back with the researcher, that can in no way identify the participant. Only my supervisors and I will view the completed surveys, thereby ensuring confidentiality. The questionnaire should not take longer than 10 minutes to complete.

No incentives will be provided for the completion of the questionnaire. Completion of this questionnaire will however assist in identifying barriers to adverse event and error reporting, and could help implement a system of reporting in the future, to the benefit of all anaesthetists.

Before completion of the survey, please ensure that you understand the above information.

Your time is greatly appreciated. Any questions regarding this study can be directed to the following people:

- Professor Cleaton-Jones (chairperson of the HREC): (011) 717-1234
- Steven Nel (researcher): 084 239 8007

Sincerely,

Steven Nel