ANAESTHETISTS' KNOWLEDGE OF THE MEDICOLEGAL PROCESS FOLLOWING AN ANAESTHETIC RELATED INCIDENT

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

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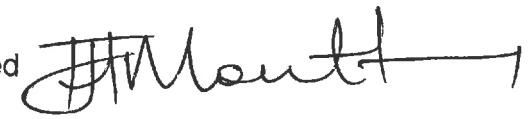
DECLARATION

I, Hlamatsi Jacob Moutlana, 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 22 day of AUGUST 2017

ABSTRACT

Background

Anaesthetic practice is associated with a variety of complications, which could result in medicolegal consequences. There is minimum exposure to medicolegal teaching during medical training and therefore a potential knowledge gap among anaesthetists may exist. Therefore the aim of the study is to describe the knowledge of anaesthetists in the Department of Anaesthesiology at the University of the Witwatersrand (Wits) regarding the medicolegal process following an anaesthetic related incident.

Methods

A prospective, descriptive, contextual study design utilising an anonymous self-administered questionnaire was distributed to 174 anaesthetists during academic meetings and convenient sampling was used.

Results

One hundred and seventy questionnaires met the criteria for analysis, giving a response rate of 98%. The overall median score was 42.5% (IQR 35.1-49.3%), showing the overall knowledge was poor. The median score for the knowledge regarding preparation of anticipated medicolegal action was 52.1% (IQR 42.7-57.3%) whereas for the possible legal consequences it was 34.3% (IQR 25.9-43.0%), showing poor knowledge in the subsections too. Senior anaesthetists performed better than their junior counterparts, however none of the groups' knowledge was adequate.

Conclusions

Anaesthetists employed in the Department of Anaesthesiology at Wits did not have adequate knowledge of the medicolegal process following an anaesthetic related incident.

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LIST OF ABBREVIATIONS

AAGBI	The Association of Anaesthetists of Great Britain and Ireland
GMC	General Medical Council
HCP	Health Care Provider
HPCSA	Health Professions Council of South Africa
MPS	Medical Protection Society
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
SA	South Africa
UK	United Kingdom
USA	United States of America
Wits	University of the Witwatersrand

SECTION 1: Literature Review

This section aims to review the current literature regarding the medicolegal processes following anaesthetic related incidents. Firstly the anaesthetic related incidents will be explored. The legislation governing the practice of anaesthesia in South Africa will then be reviewed. The review will then analyse both the international and South African legal processes. Lastly, the knowledge of the processes among anaesthetists will be reviewed.

1.1 Anaesthetic related incidents

Anaesthetists provide care to more than 60% of acute hospital admissions (1). Anaesthetised patients are at risk of complications from anaesthetic related incidents, which in turn may be as a result of actions or inactions of anaesthetists (2). These incidents are a source of morbidity or mortality (3) and may lead to medicolegal claims against doctors and or hospitals (1).

Human decisions and actions may contribute to an incident, both of which may be due to active failures, latent failure or both. Active failures are unsafe acts or omissions performed by health care workers such as anaesthetists or surgeons and include errors for example wrong syringe labeling, cognitive failure or deviations from safe practice and standard of care. Latent failures include decisions by management, which impact on patient care, for instance: inappropriate staffing, heavy workload and poor supervision. (4)

1.1.1 Anaesthetic related morbidity

Anaesthetic morbidity encompasses any complication that occurs during the perioperative period, with the exception of death. It can be categorised according to severity into three categories namely: minor, intermediate and major. The minor group includes moderate distress without permanent sequelae for example postoperative nausea and vomiting; serious distress without permanent sequelae for example dental injury constitutes intermediate morbidity, whereas permanent disability and sequelae, for instance spinal cord injury is classified as major morbidity. (5)

Minor anaesthetic related incidents have an overall incidence of between 18% and 22% (5-7). The prevalence of major morbidity for example cardiac arrest is between 0.8 and 3.3 per 10 000 anaesthetics administered, whereas that of anaesthesia related brain injuries is between 0.15 and 0.9 per 10 000 (5).

1.1.2 Anaesthetic related mortality

Anaesthetic related mortality refers to death occurring under or subsequent to, the care of an anaesthetist (5). Trends in the incidence of anaesthesia related mortality remain contentious. This may be due to inconstant definitions and reporting sources. The definitions and time frames for the perioperative period considered vary widely among studies. Studies conducted in different countries indicate that anaesthesia related mortality rates are lower than two decades ago. (8) A case control study of patients undergoing anaesthesia between 1995 and 1997 by Arbous et al, showed a 24 hour postoperative death rate of 8.8 per 10 000 anaesthetics (9). However, during the last three decades the incidence of anaesthesia related mortality is reported to be 0.04 – 7 per 10000 anaesthetics (5, 10).

1.1.3 Anaesthesia related medicolegal incidents

The four principles of contemporary medical ethics: beneficence, nonmaleficence, autonomy and justice guide the practice of medicine (11). Breach of any of the ethical principles may lead to medicolegal claims against doctors and institutions (1).

In the United Kingdom (UK), anaesthesia contributed one in 40 claims reported to the National Health Service Litigation Authority (NHSLA) between 1995 and 2007. Regional anaesthesia contributed to most of those claims. Other contributors to negligence claims included obstetric anaesthesia, inadequate anaesthesia, dental damage, airway complications, drug associated complications, positioning and consent. (1)

The most common reason for legal proceedings in medical practice is negligence (12, 13). Negligence is defined as a conduct that is short of a standard of care. The so-called “reasonable person” is the most commonly used standard. (14) The reasonable person as described by Strauss, refers to a person of average intelligence, knowledge and wisdom (15). Failure to abide by standards of care may subject anaesthetists to possible legal consequences (16).

In order to be successful in a negligence suit, the complainant has to prove the following four elements:

- duty,
- breach of duty,
- causation and,
- damages (13, 16).

The complainant will need to prove that the anaesthetist owed him/her a duty (13, 16). The principle of legal duty arises from the idea that in a civilised society, each person owes a duty of reasonable care to others. This duty exists only when a doctor-patient relationship is established and the exception to the duty of care exists when the doctor sees the patient as a nonprofessional, for example in social settings. (14)

To prove the breach of professional duty, the concept of standard of care comes into play, where the care will be compared to that which a reasonable professional in a similar situation would have provided to the patient. The reasonable person being the one defined above. (14)

The patient will have to prove that the anaesthetist's acts resulted in actual damage (13, 16). A direct relationship between the alleged misconduct and subsequent injury must be shown. The fourth element is called damages, where the calculation of damages concludes a medical malpractice claim. (14)

1.2 Legislation

Numerous statutory legislations regulate the practice of the medical profession in South Africa (17). There is minimum exposure to acts and regulations governing the medical profession during undergraduate training, as a result very few doctors know or understand them (18). In South Africa (SA) the following statutes govern the practice of medicine: the Health Professions Act 56 of 1974 (19), the Births and deaths Registration Act 51 of 1992 (20), the Inquest Act 58 of 1959 (21), the National Health Act 61 of 2003 (18), and the Health Professions Amendment Act 29 of 2007 (17).

1.2.1 The Health Professions Act 56 of 1974

The Health Professions Act 56 of 1974 (19) allows for the establishment of the statutory regulatory body, the Health Professions Council of South Africa (HPCSA). The aims and objectives of the council are among others, to:

- "protect the public in matters involving the rendering of heath services by persons practicing a health profession,
- uphold and maintain professional and ethical standards within the health professions
- investigate complaints concerning persons registered with the council and ensure appropriate disciplinary action, and
- to ensure that health service users are treated with respects and dignity" (19).

The Act also allows for the HPCSA to recommend to the Minister of Health to establish "a professional board with regard to any health profession in respect of which a register is kept in terms of this Act (19)." Every person desiring to practice as a medical practitioner within South Africa is required to register in terms of the Health Professions Act. The professional board has powers to remove names from the register under certain circumstances, for example: request for removal, failure to pay the professional board and being found guilty of unprofessional conduct. (17, 19)

According to the Act: "unprofessional conduct means improper or disgraceful or unworthy conduct (19)." A professional board may institute an inquiry into claims of unprofessional conduct. Health practitioners found guilty of unprofessional conduct may be liable to the following penalties:

- a caution or a reprimand or both,
- suspension,
- removal from the register,
- a prescribed fine,
- compulsory period of service, or
- the payment of proceedings cost (17, 19).

Health practitioners have the right to appeal against decisions of the council, a professional board or appeal committee. Such appeals may be forwarded to the relevant High Court and a one-month notice from the date of decision must be given. (19)

Section 56 of the Act also previously defined anaesthetic related death as: “the death of a person whilst under the influence of a general anaesthetic or local anaesthetic, or of which the administration of an anaesthetic has been a contributory cause, shall not be deemed a death from natural causes” (19). This section was substituted by section 48 of the Health Professions Amendment Act 29 of 2007 (17), which will be discussed later.

1.2.2 The Births and Deaths Registration Act 51 of 1992

The practice of medicine is unfortunately associated with death. Death can either result during or subsequent to the administration of anaesthesia. The Births and Death Registration Act 51 of 1992 (20) govern the process of dealing with such deaths. It is advisable for anaesthetists to have thorough knowledge and understanding of the Act governing anaesthesia and procedure-related deaths (18).

The Act requires that the medical practitioner decides whether a death was due to natural or unnatural causes. A medical practitioner fills Form BI 1663 stating the cause of death if satisfied that a death was due to natural causes and a prescribed certificate stating the cause of death is issued. Deaths due to unnatural causes are reported to the police. (20)

1.2.3 The Inquests Act 58 of 1959

According to the Inquests Act 58 of 1959 (21), any person who has reason to believe that a death is due to unnatural causes should report such a death to the police (18, 21). Failure to do so may render a person guilty of an offence and liable to a fine. Section 3 of the Act provides for investigation of the circumstances of the death. If the body is available, the district surgeon, if necessary, shall examine it. The report of the investigation is then submitted to the public prosecutor. (21)

The public prosecutor may then submit all relevant information to the magistrate of the district concerned, if criminal proceedings are not instituted concerning the death. If upon reviewing the information, it appears that such death was due to other than natural causes, the magistrate may if necessary ensure that an inquest into such a death is held. (21)

The inquest is defined as a judicial inquiry to ascertain the facts relating to an incident (22). It may be a formal hearing that includes interviewing of relevant witnesses or the inquest magistrate may only examine documents, in case of a paper inquest. The magistrate determines whether there is merit for prosecution concerning a specific case. (18)

The presiding judge or magistrate will hear the case in court, where depending on the judgement the accused can be sentenced according to criminal law if guilty or a civil lawsuit instituted for damages. The HPCSA may also subject the physician involved to a disciplinary hearing. (18)

1.2.4 The National Health Act 61 of 2003

Another act of importance is the National Health Act (Act 61 of 2003) (18), which defines deaths due to unnatural causes. In the regulations to the Act, one of the definitions describes unnatural death as any due to physical or chemical influence. Anaesthetic and procedure related deaths are also included in the definition of unnatural deaths (18, 23).

1.2.5 The Health Professions Amendment Act 29 of 2007

The Health Professions Amendment Act 29 of 2007 (17) provides definitions for deaths during or following a surgical procedure. Anaesthetic related deaths were defined by section 56 of the Health Professions Act (Act 56 of 1974) until 2007, when section 56 of 1974 was replaced by section 48 of the Health Professions Amendment Act (Act 29 of 2007). This amendment substituted anaesthesia related deaths with procedure related deaths, which broaden the act to include procedures not requiring anaesthesia (18, 24).

According to the Act, “the death of a person whilst under the influence of a general or local anaesthetic, or as a result of, a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes” (24).

1.3 Legal process

Anaesthesia practice, as with many fields of medical care, is associated with patient harm and iatrogenic injury. The resulting harm may lead to medicolegal claims against doctors and institutions (1). Although the chance of facing a medicolegal claim in any anaesthetist’s career is small, the process if it happens may be stressful and complex (25).

Litigation against the anaesthetist can be in the form of a criminal or a civil case. In the former the complainant files a complaint with the police and the concerned anaesthetist is prosecuted according to criminal law. While in the latter the aggrieved seek compensation for harm caused by the anaesthetist's actions. (13)

1.3.1 International legal processes

1.3.1.1 Legal processes in the United Kingdom

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) have published guidelines to guide anaesthetists on how to deal with the aftermath of catastrophes in anaesthetic practice. A guide on how to record the incident, the debriefing process and medicolegal issues are outlined. (26)

The possible course of events following an unexpected mortality or morbidity is as follows:

- "internal inquiry,
- Coroner's inquest (England and Wales) or Procurator Fiscal's (Scotland) Investigation,
- Criminal prosecution,
- General Medical Council (GMC) investigation,
- Civil litigation (26)."

In the UK, the NHSLA handles both clinical and non-clinical negligence cases on behalf of the National Health Service (NHS). It administers those claims under various schemes, including: the Clinical Negligence Scheme for Trusts and the Existing Liability Schemes (27). The NHSLA is a special health authority that was established in 1995 (28).

According to the NHS Indemnity Arrangements, the NHS bodies, which include: Health Authorities, Special Health authorities and NHS Trusts, are liable for their employees' negligent acts and omissions (29). For clinical negligence claims happening while employed by the NHS Trust, the employer covers for civil litigation. Such claims are brought through the NHSLA (26). Where negligent harm took place under circumstances covered by the indemnity, NHS bodies accept full financial liability and costs are not recovered from the health care professional involved (29).

The NHS employer does not cover incidents involving private patients or where there is a possibility of criminal charges being instituted. In those circumstances personal legal cover is required. However, legal cover from one of the medical defence organisations is advisable, even for doctors employed by the NHS. It is also recommended that the respective organisations should be notified should there be a claim against the doctor. (26)

A protocol for the resolution of clinical disputes exists. It provides patients, healthcare providers and advisers with timed steps to follow when a dispute arises. It assists in facilitating and accelerating relevant information exchange, and sometimes help to resolve disputes without legal action. (30)

As illustrated in Figure 1.1, the steps of the protocol are kept simple. The one side outlines steps to be followed by the patient while the other guides the health care provider. The patients and their advisers inform the healthcare provider of any grievances, so that the provider can offer clinical advice, and also advise the patient if anything has gone wrong and take appropriate action. A full range of options available should be considered, including a written explanation of the adverse outcome and appropriate dispute resolution methods. Litigation is not the only option at this stage; mediation and negotiation may also take place. (30)

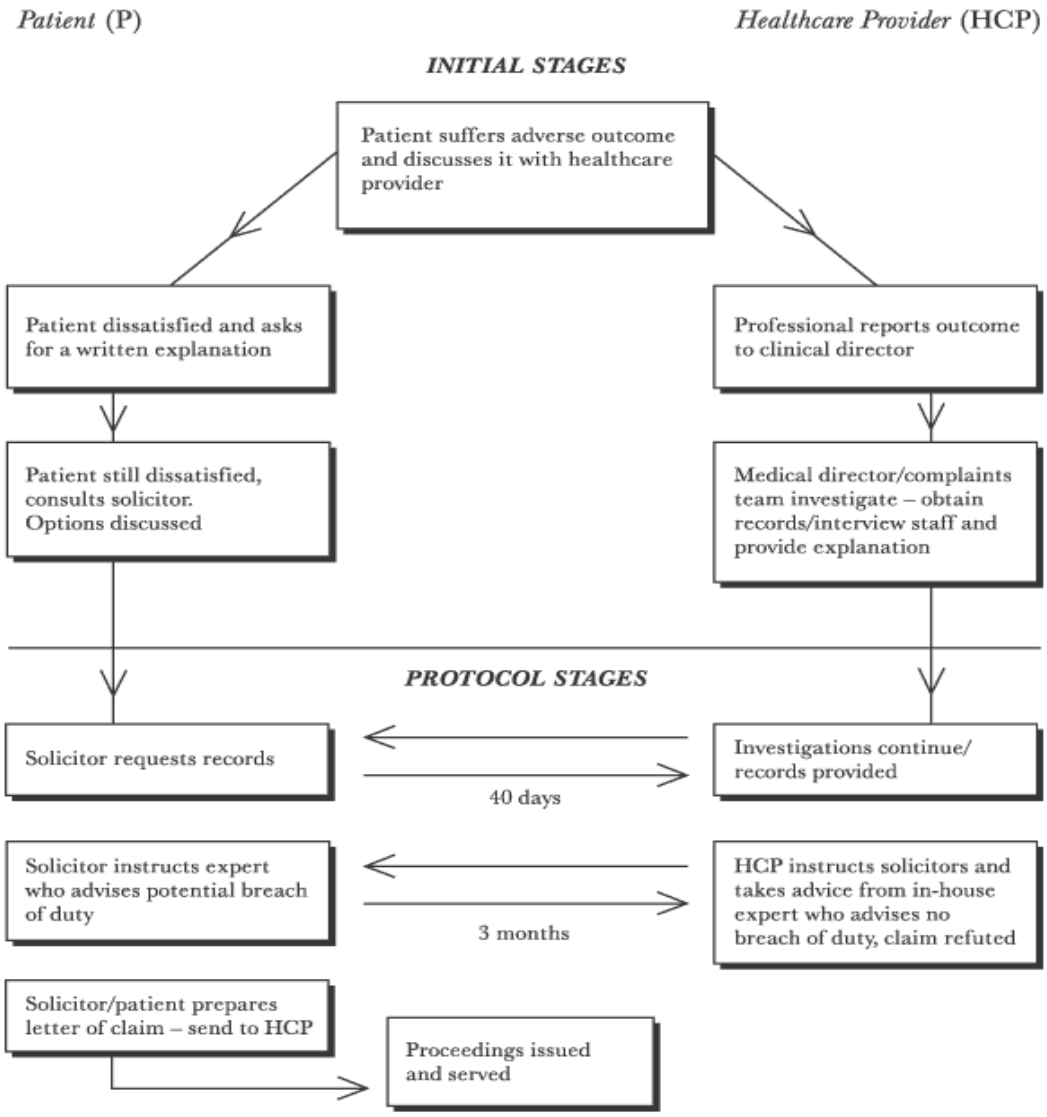

Figure 1.1: An illustration of the likely sequence of events in a number of health care situations (30)

1.3.1.2 Legal processes in the United States of America and other countries

In the United States of America (USA) the legal system governing medical negligence is based on adversarial advocacy. In this system attorneys from both parties find and present evidence for their case to an impartial party, such as a judge or jury. This system is designed to promote efficient self-resolution of civil disputes. The aggrieved patient (plaintiff) files a lawsuit and seeks legal reparation from the court. If successful, the court delivers a judgement for the plaintiff and a court order for damages is issued. (14)

A medical negligence lawsuit is initiated by filing a summons, claim form or complaint; all called pleadings. In these pleadings the alleged wrongs committed by the defendant and a demand for relief are set forth. A number of legal tools are available. The first legal tool in a dispute is the process of discovery, which involves sharing of information and understanding of facts between parties involved. It takes place between filing the suit and the trial, and is facilitated by requests for documents, interrogatories and depositions. (14)

The process of discovery is essentially an extensive pretrial and an out of court litigation process between parties. Following the filing of the case, an interrogatory form is submitted to the opposing party, to gather preliminary and demographic information about the party. The formal proceeding in which a litigant is questioned under oath by a counsel then follows. These are called depositions, a record of which is made for use later in court. The rationale behind these is for both parties to exchange facts and reach a mutual understanding and settle the case. (14)

In the USA, the aggrieved patient hires his or her own lawyers on a contingency-fee basis, where the lawyer collects money only if a monetary damage is awarded. A lawyer appointed by their medical malpractice insurance company on the other hand, represents the defendant (doctor). Once the court has assessed the damages, the losing party can appeal the judgement to the next higher level of court. (14)

A system similar to that used in the USA is used in Canada. But the Canadian Medical Protective Association insures most physicians in Canada. Alternatively informal judicial forums are used to address patient concerns. In Japan on the other hand, the professional liability program offers an out-of-court claim review system that is faster than a court review, but patients can also sue in court. A collective insurance pool covers the physicians and most belong to the Japanese Medical Association. (14)

In the French system, patients bring claims before a regional government appointed review board, in a so-called out-of-court no fault system. Patients are then compensated from a national fund that is funded by general fund revenues and insurance premiums placed on doctors and hospitals. A similar system is used in Sweden, Finland, Denmark and Norway. (14)

1.3.2 The South African medicolegal process

Unlike in the UK, where guidelines published by the AAGBI and the Australian and New Zealand College of Anaesthetists on how to deal with anaesthetic incidents (26, 31), similar South African guidelines could not be identified. However after personal communication with the Head of Department of Anaesthesiology at Wits (32), the process of how the situation may unfold was formulated. Figure 1.2 depicts a summary of personal communication with the Head of Department of Anaesthesiology at Wits (32).

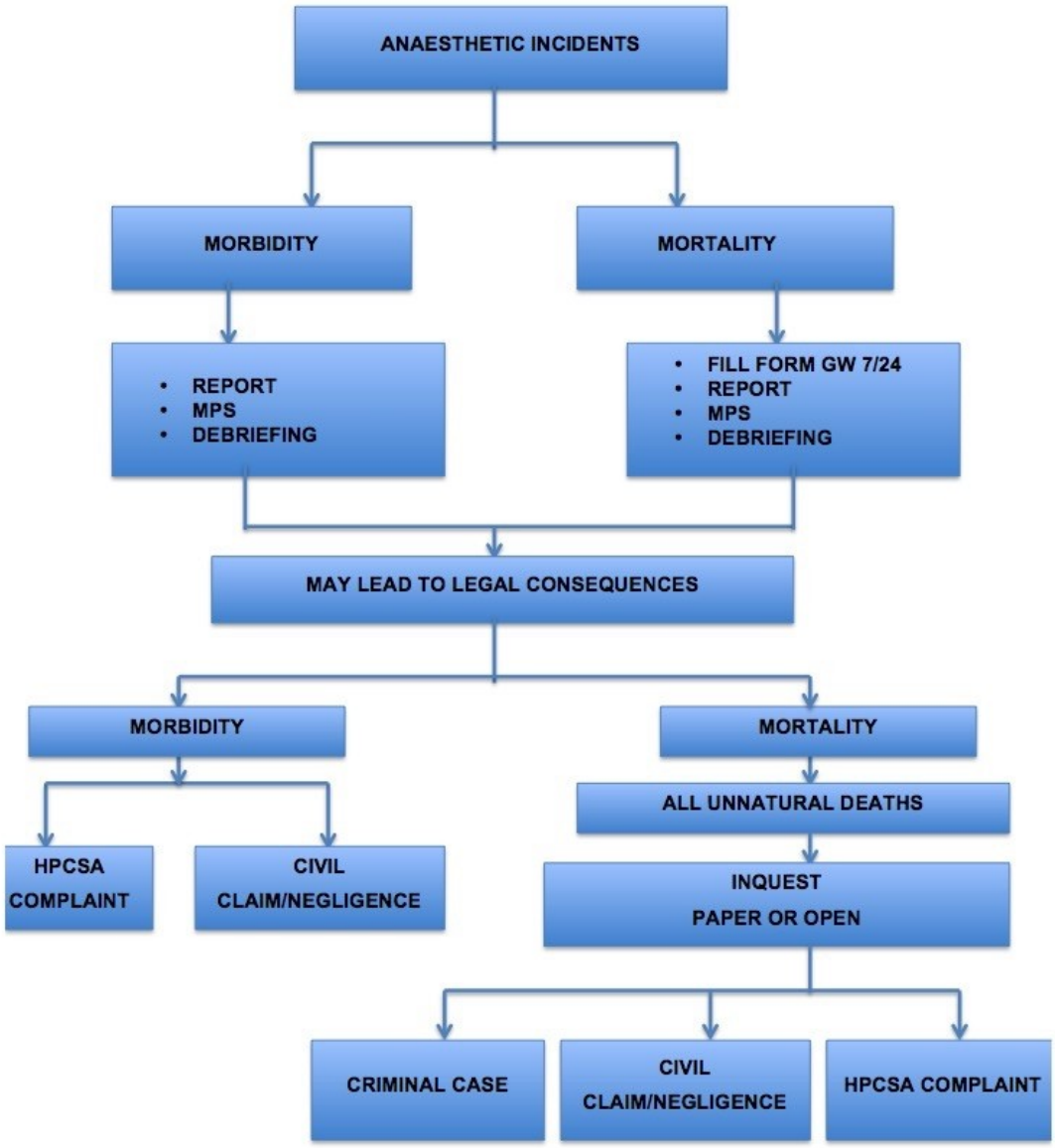

Figure 1.2: Possible sequence of events following an anaesthetic related incident (32)

1.3.2.1 Anticipation of legal action

In anticipation of legal action various steps must be taken as shown in Figure 1.2. These steps include writing of a report, Medical Protection Society (MPS) notification, the debriefing process, and in case of mortality, filling of the Form GW 7/24.

Report

An accurate, clear, objective and detailed record of the anaesthetic and the event must be written (33). The records should be in a legible handwriting, timed, dated and signed (31). If unable to immediately write notes, a retrospective account must be made as soon as possible (26). The report should include personal details (qualifications, relevant clinical experience); details of other health professionals involved; patient details; presentation and history; examination findings and subsequent management. The report should follow chronologically stating the writer's involvement and be factual. The report should be signed and dated; then a copy must be made and kept. (33)

MPS notification

The MPS will need to be notified at the earliest opportunity following a mishap (34). Notification can be done via telephone, email or filling of a medicolegal query contact form on the MPS website. Details to be provided include demographic information, date and details of the incident whether employed in the private or public sector. Should a legal action arise, the following documents need to be attached: the HPCSA's letter informing the doctor of the complaint and the letter of complaint, letters from the lawyers informing the doctor of the claim and particulars of the claim. (35)

Debriefing process

After an incident or a mishap the anaesthetist involved may experience shock, anger, fear and guilt (26). The anaesthetist need to take part in a debriefing process (26, 36). The main aims are to learn from the experience and also to reduce immediate distress and identify individuals likely to develop long-term psychological problems (26). The process involves professional and psychological debriefing and on-going psychological counselling (26).

Form GW 7/24

According to the Health Professions Amendment Act 29 of 2007 “death of a person whilst under the influence of a general anaesthetic or local anaesthetic, or as a result of a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause” shall be deemed unnatural (24). In case of the incident arising under conditions in the above-mentioned Act, the doctors involved shall complete Form GW 7/24 (an example of the form is attached as Appendix 3 in section 4). The form contains a section for patient details, section to be filled by the surgeon and the anaesthetist. The form is filled at the earliest possible time after the incident and needs to accompany the body to the forensic department for medicolegal autopsy.

1.3.2.2 Legal consequences

HPCSA complaint

An anaesthetic related incident either resulting in morbidity or mortality may lead to a complaint being filed with the HPCSA. According to the HPCSA, healthcare professionals registered with them are required to uphold prescribed standards of professional and ethical behavior. A complaint could therefore be lodged against the healthcare professional if such standards are

breached. (37) Upon receipt of the complaint the HPCSA will forward it to the healthcare practitioner within seven days and request a written explanation. The practitioner could be suspended pending a formal inquiry if he/she poses an imminent threat to the public. The letter of complaint and the practitioner's explanation is then referred to a Committee of Preliminary Inquiry (or Professional Board concerned) for consideration. (37)

Should there be grounds for a complaint, a Professional Conduct Committee will hold an inquiry. Oral evidence is presented and expert witness is often required. Should the healthcare practitioner be found guilty, the Committee's decision is final unless an appeal is lodged. Penalties may include: a caution, reprimand or both; a fine; suspension; removal from the relevant register; a compulsory period of professional service and/or payment of proceeding costs. (37)

Civil claim or negligence

The law of contract and of tort (wrongful act) governs the relationship between a patient, and doctor and or hospital. By consulting a doctor or health institution, the patient enters into a contractual relationship with any of those parties. The contract exists by a mere agreement and no legal formalities are required for its conclusion. In practice patients are required to give written consent for treatment, but the contract may be concluded tacitly or may be verbal. Failure to perform or deviation from the terms of contract constitutes a breach of contract. Such a breach may lead to a negligence claim. The law of delict comes into play where no contract is formed between the two parties. The law expects doctors and hospitals to exercise reasonable care to prevent harm. Failure to do so may result in liability for negligence. (17)

The MPS in South Africa published step-by-step guidelines that guide doctors on what to expect should a clinical negligence claim be brought against them. Figure 1.3 shows the steps of the ensuing claim. The first step to a claim is the issuing of a letter of demand, which sets out demands from the claimant and a time frame to satisfy such. The MPS will need to be notified upon receipt of the letter, if not done already. Failure to comply within the said time frame will lead to issuing of a summons. (34)

A summons is a document obtained by the claimant from the court, with details of the claim. It is usually accompanied by the particulars of the claim, which contains allegations against the doctor. There is a tight time frame with the summons and the claimant may apply for a default judgement if the doctor fails to respond. If the court grants a default judgement, a warrant of execution may be granted as a result, where the court may attach some of the doctor's possessions to pay the claimant. (34)

As shown in Figure 1.3, a response to the summons may be a settlement out of court or defend to trial. A decision is taken after investigating the claim fully and ascertaining the facts. An expert opinion on whether the case is defensible or not may be sought. If represented by MPS, they will contact the claimant's legal team to agree on a settlement figure should a decision to settle be taken. (34)

If a decision to defend the case is made, the Notice of Intention to Defend Form is completed and submitted to the claimant's lawyer. Pleadings between the two parties then take place, where documentary exchange takes place and legal documents are prepared. A settlement out of court is still possible at this stage. If the case is to proceed to court, the MPS will seek an independent expert's opinion. The expert will provide a reflective opinion on the specifics of the case. (34)

Before the trial a meeting is held, where all experts involved are brought together. A final offer can also be made to the claimant at this stage. At the trial both parties present their case. Cross-examination of witnesses takes place and all evidence is presented. Judgement is given and it may be followed by an appeal. The claimant will need to prove negligence of the defendant and if successful the quantum of the claim must be decided upon, where the compensation amount is decided. (34)

In South Africa there is no social insurance system for medical malpractice or criminally caused injuries. Claims against private doctors or institutions are done in the court of law. Those against a state institution are done in terms of the State Liability Act (17). Any claim brought against the state has to be cognisable in any competent court. The claim can either arising out of contract entered lawfully on behalf of the state or wrong doings committed by civil servants within their scope of authority. (38)

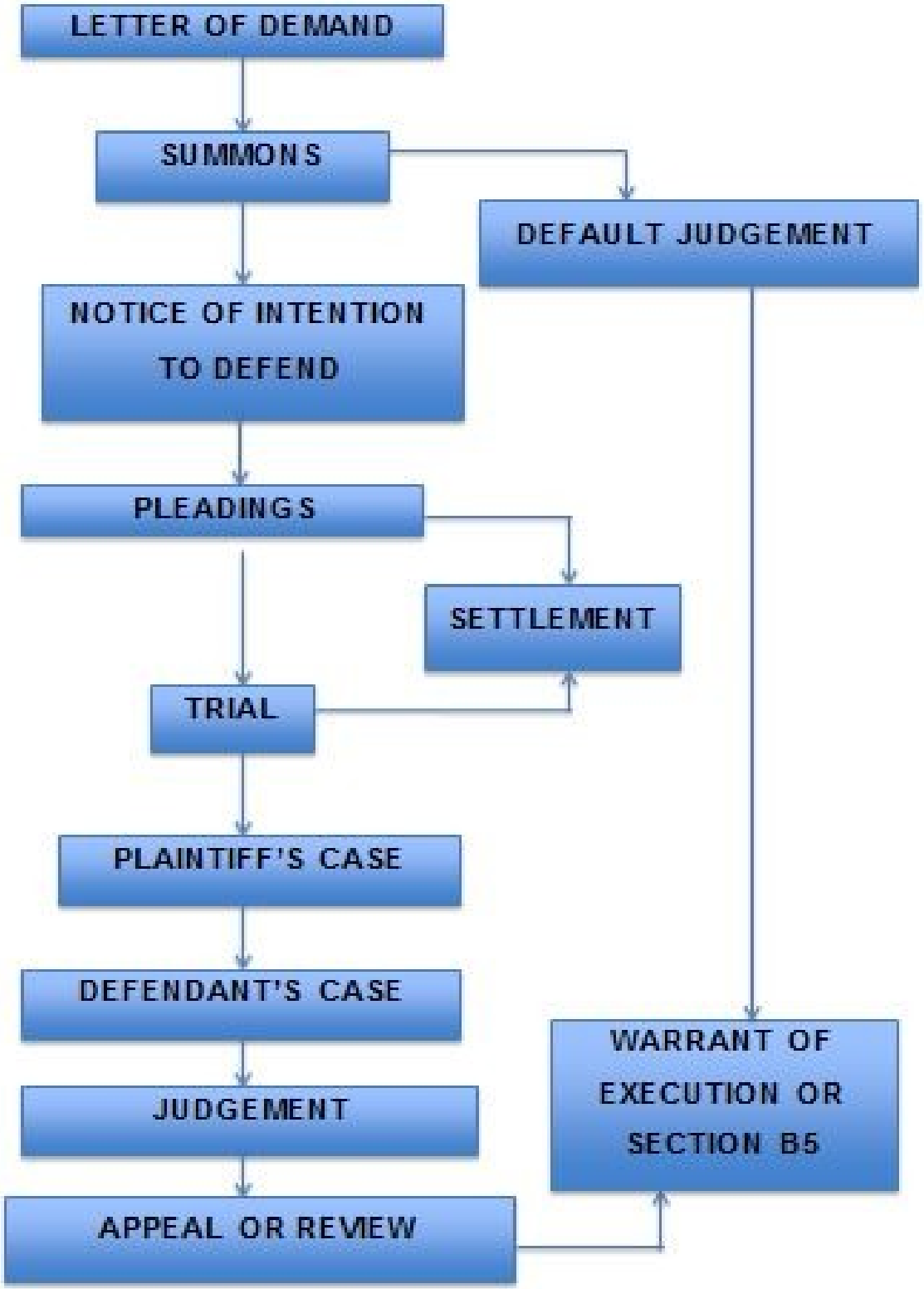

Figure 1.3: Civil claim process flowchart (34)

Inquest

An inquest is defined in the Oxford dictionary as “a judicial inquiry to ascertain facts relating to an incident (22).” Deaths related to anaesthesia are regarded as unnatural according to the Health Professions Act 29 of 2007 (24). According to the Inquest Act 58 of 1959, such deaths require a medicolegal investigation and must be reported to the police (21). Form GW 7/24 as described above will need to be filled. A postmortem will need to be conducted; the police will need to investigate the circumstances of the death and report the death to the inquest magistrate (21).

An inquest shall be held in public (open inquest) unless it appears to the inquest magistrate that it will be in the best interest of the witness’s safety, then it will be held behind closed doors (closed inquest) (21). A paper inquest can be conducted where information supplied to the magistrate is reviewed and there is no need to examine witnesses. Following an inquest the following may ensue: a criminal case can be opened, a civil claim or HPCSA complaint (32).

Criminal case

The doctor-patient relationship is not directly governed by criminal law. However, the doctor may possibly commit various common-law crimes in the course of medical practice. These may include murder, assault, culpable homicide, defamation and contempt of court (17). Such cases will be dealt with according to the Criminal Procedure Act 51 of 1977 (39).

Anaesthetists may be summoned to court to give evidence in criminal proceedings. The MPS has published guidelines for doctors to follow when giving evidence in court. In preparation for going to court, doctors are advised to read through their report, review medical records and make sure these records will be available. The evidence should be factual, accurate and relevant. While in the witness box doctors are advised to take their time after taking the oath, carefully listen to questions, answer truthfully, keeping answers short and simple. (40)

1.4 Knowledge of the medicolegal process

Studies assessing the knowledge of medicolegal aspects among doctors in SA could not be identified. A study done at 12 private hospitals in SA, assessing the critical care nurses' knowledge of legal liability issues in the critical care environment, showed a below standard level of knowledge. The study showed a total average of 38.45%, which was 21.55% below the set standard of 60%. (41) In the UK, a study assessing the knowledge and training pertaining to medical law among trainees in anaesthesia showed that knowledge of the law relevant to anaesthesia was poor. It also showed that trainees had received limited training in decreasing exposure to litigation. (42)

A survey done in Canada at the University of Ottawa, assessing the knowledge of medicolegal issues by family medicine residents showed that residents were confused about medicolegal issues (43). A study done in Vadodara, India assessing the knowledge and awareness among interns and residents regarding medical law and negligence showed that participants lacked knowledge on medical negligence (44). A study done in New Zealand to assess healthcare providers' knowledge of laws relating to consent indicated poor overall knowledge of some key areas (45).

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SECTION 2 – Journal guidelines to authors

This section highlights the guidelines that 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 footnote 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, suchmaterial 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 infootnotes, 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."

Submissions and correspondence

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 size10 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

This section presents the draft article in the format according to the authors' guidelines. The format of the draft article is presented according to the Southern African Journal of Anaesthesia and Analgesia, which is the intended journal of publication.

Anaesthetists' knowledge of the medicolegal process following an anaesthetic related incident

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Keywords:

Anaesthetic incidents, medicolegal process, anaesthetists' knowledge, legal consequences, medicolegal action.

Abstract

Background

Anaesthetic practice may be associated with a variety of complications, which could result in medicolegal consequences. There is minimum exposure to medicolegal teaching during medical training and therefore a potential knowledge gap among anaesthetists may exist. Therefore the aim of the study is to describe the knowledge of anaesthetists in the Department of Anaesthesiology at the University of the Witwatersrand (Wits) regarding the medicolegal process following an anaesthetic related incident.

Methods

A prospective, descriptive, contextual study design utilising an anonymous self-administered questionnaire was distributed to 174 anaesthetists during academic meetings and convenient sampling was used.

Results

One hundred and seventy questionnaires met the criteria for analysis, giving a response rate of 98%. The overall median score was 42.5% (IQR 35.1- 49.3%), showing the overall knowledge was poor.The median score for the knowledge regarding preparation of anticipated medicolegal action was 52.1% (IQR 42.7-57.3%) whereas for the possible legal consequences it was 34.3% (IQR 25.9 - 43.0%), showing poor knowledge in the subsections too. Senior anaesthetists performed better than their junior counterparts, however none of the groups' knowledge was adequate.

Conclusions

Anaesthetists employed in the Department of Anaesthesiology at Wits did not have adequate knowledge of the medicolegal process following an anaesthetic related incident.

Introduction

Anaesthetists are involved in caring for more than 60% of acute hospital admissions. Anaesthetised patients are at risk of complications from anaesthetic related incidents. [1] These incidents are a source of morbidity or mortality [2] and may lead to medicolegal claims against doctors/hospitals.[3] Major morbidity for example cardiac arrest, has a prevalence of between 0.8 and 3.3 per 10 000 anaesthetics administered, whereas brain injuries related to anaesthesia contributes 0.15 to 0.9 per 10 000. [4]Minor anaesthetic related incidents contribute to the overall incidence of 18 to 22%. [4,5,6]

Trends associated with the incidence of anaesthetic mortalities remain contentious. This may be due to inconsistencies in definitions and reporting sources. The definitions and time frames for the considered perioperative period vary widely among studies. [7]During the last three decades the incidence of anaesthesia related mortality is reported to be 0.04 to 7 per 10 000 anaesthetics. [4, 8]

The four principles of contemporary medical ethics: beneficence, nonmaleficence, autonomy and justice guide the practice of medicine. [9] Breach of any of the ethical principles may lead to medicolegal claims against doctors and institutions. [3]The most common reason for legal proceedings in medical practice is negligence.[10, 11] A conduct that is less than a standard of care is considered negligence and the term "reasonable person" is the most commonly used standard. [12]

The practice of medicine is regulated by numerous statutory legislations. In South Africa (SA) the following statutes govern the practice of medicine: the Health Professions Act 56 of 1974, [13] the Births and deaths Registration Act 51 of 1992, [14]the Inquest Act 58 of 1959, [15] the National Health Act 61 of 2003, [16] and the Health Professions Amendment Act 29 of 2007. [17] These acts allow for the establishment of the regulatory body, the Health Professions Council of South Africa (HPCSA), [13] governing of deaths both natural and unnatural, [14] investigation of the circumstances of each unnatural death, [15, 16] definition of anaesthetic related deaths, [16, 18] and definitions for deaths during or following a procedure, [16, 19] respectively.

Anaesthesia practice as with many other fields of medical care is associated with patient harm and iatrogenic injury. The resulting harm or injury may lead to medicolegal claims against doctors. [3] Although the chance of facing a medicolegal claim in any anaesthetist's career is small, the process may be stressful and complex. [20] The processes to follow after an anaesthetic related incident differs per countries and institutions.

In the United Kingdom (UK), the Association of Anaesthetists of Great Britain and Ireland (AAGBI) have produced guidelines for dealing with the aftermath of catastrophes in anaesthetic practice. A guide on how to record the incident, the debriefing process and medicolegal issues are outlined. The possible course of events following an unexpected mortality or morbidity is as follows: "internal inquiry, Coroner's inquest (England and Wales) or Procurator Fiscal's (Scotland) Investigation, criminal prosecution, General Medical Council (GMC) investigation or civil litigation." [21]

In South Africa (SA) guidelines similar to the AAGBI guidelines could not be identified. However after personal communication with the Head of Department in Anaesthesiology at Wits, the process of how the situation may unfold is shown in Figure 1.

Studies assessing the knowledge of medicolegal aspects among doctors and especially anaesthetists in the international literature are limited. No studies of knowledge of medicolegal aspects among anaesthetists in SA could be identified. Medicolegal education for anaesthetists at various times during their training can improve anaesthetists' knowledge base regarding medicolegal interactions. [22] The knowledge of the medicolegal process following an anaesthetic related incident amongst anaesthetists at Wits is not known; therefore this study aims to describe that knowledge.

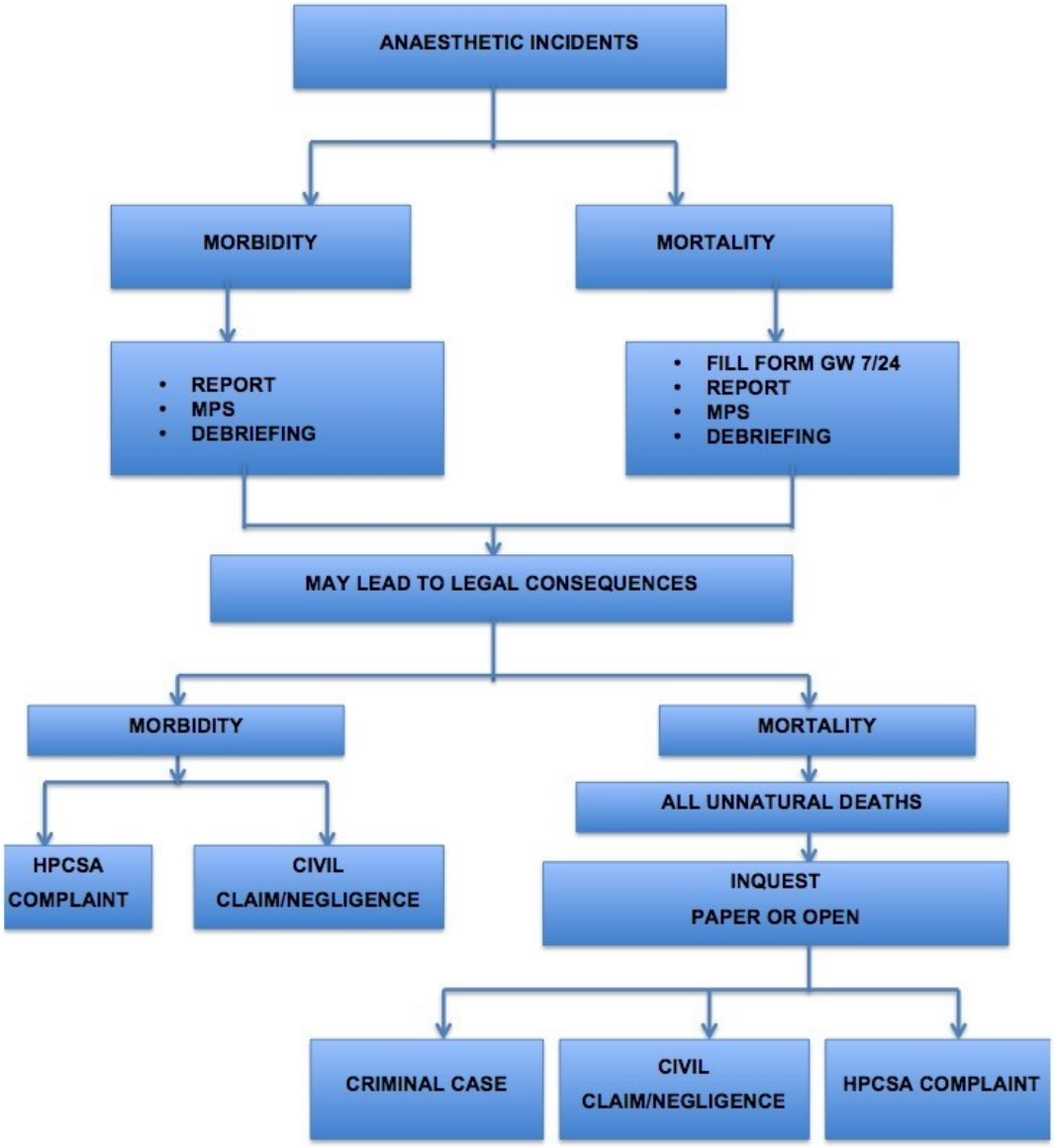

Figure 1: Possible sequence of events following an anaesthetic related incident

Method

Approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) of (Wits) and other relevant authorities. This was a prospective, contextual, descriptive study using an anonymous self-administered questionnaire distributed at departmental academic meetings.

The questionnaire was developed following literature review ensuring content validity, and in consultation with two medicolegal experts in the department to ensure face and content validity. The questionnaire included anaesthetists' knowledge of the preparation for anticipated medicolegal action with regard to writing a report of the incident, reporting the incident to the Medical Protection Society (MPS), the debriefing process and completion of Form GW 7/24. It also included the knowledge of possible legal consequences following incidents with regard to the: inquest process, civil process, criminal process and the HPCSA process.

Convenient sampling was used and anaesthetists employed in the Department of Anaesthesiology at Wits were invited to participate and were given a study information leaflet. Interns, anaesthetists on leave at the time of data collection, and part-time anaesthetists who do not attend academic meetings were excluded from the study.

Of the 206 anaesthetists eligible to participate, a response rate of 60% would be considered acceptable, however a response rate of 80% was targeted. Questionnaires were distributed to all accessible anaesthetists at departmental academic meetings during May and June 2015. Agreement to complete the questionnaire implied consent. A total of 174 questionnaires were handed out and 171 were returned, giving a response rate of 98%. The study included 85% of anaesthetists in the Department of Anaesthesiology at Wits.

Data were captured onto spreadsheets using Microsoft® Excel 2011, and analysed using SAS® version 9.4 for Windows in consultation with a biostatistician.

Table I: Questionnaire sections and questions addressing each section

Sections	Questions
1. Writing a report of the incident	2.2, 6 and 7
2. Reporting the incident to MPS	2.2 and 2.5
3. The debriefing process	2.3; 2.4; 8 and 9
4. Completion of form GW 7/24	3; 4 and 5
5. Inquest process	10; 11; 12; 13 and 14
6. Civil process	10; 15 and 16
7. Criminal process	10 and18
8. HPCSA process	10; 19 and 20

Scores for each question in the eight sections (Table I) were reported in tables as the number and percentage of participants who answered correctly. The average scores for the first four sections, as shown in Table I was used to create the overall score for the knowledge of the preparation for anticipated medicolegal action. Similarly, the average score for section five to eight was used to create the overall score for the knowledge of possible legal consequences. The average score of the eight sections was then used to create the overall knowledge score, and each section contributed equally to the overall score. Scores were analysed as continuous variables, and also categorised as a percentage of participants who achieved ≥75%. Scores were summarised by the mean and interquartile range.

The acceptable score to determine overall knowledge was 75% according to the agreement with medicolegal experts in the Department of Anaesthesiology at Wits. Senior anaesthetists included career medical officers and anaesthesiologists, whereas junior anaesthetists were comprised of registrars, junior medical officers and community service medical officers. Comparison of the overall and section scores between junior and senior anaesthetists was carried out using the Wilcoxon rank sum test.

Results

Of the 171 questionnaires returned, one was not completed; therefore (n = 170). The demographics of participants are shown in Table II. The median years of experience were 4.5 (IQR 3 - 8).

Table II: Demographic data of participants

Demographic	Frequency (n)	Percentage (%)
Gender		
Female	114	67.1
Male	56	32.9
Employment status		
Juniors	98	57.6
Seniors	71	41.8
No answer	1	0.6
Indemnity cover		
MPS	164	96.5
Others	1	0.6
None	5	2.9
Civil claim		
No	167	98.2
Yes	2	1.2
No answer	1	0.6

At the beginning of the questionnaire a scenario was presented and 162 (95.3%) participants identified the death to be due to unnatural death. The overall scores for the entire study, the knowledge of the preparation for anticipated medicolegal action (section 1 – 4) and the knowledge of possible legal consequences following incidents (section 5 – 8) are presented in Table III.

Table III: Overall scores for the 2 subsections and entire study

Score	Median	Interquartile range		Participants ≥75%
Section 1 – 4 overall score	52.1	42.7	57.3	1.2
Section 5 – 8 overall score	34.3	25.9	43.0	0.0
Entire study overall score	42.5	35.1	49.3	0.0

The summary of questions, answers, the number and percentage of participants who answered correctly for the preparation of anticipated medicolegal action are presented in Table IV.

Table IV: Section 1 – 4 scores (please refer to Table 1 for numbering legend)

Question, description and answer	**Correct**	
Writing report of the incident	**N**	**(%)**
2.2. Action immediately after an adverse outcome • **Write detailed, clear and objective report**	153	90.0
6. What needs to be in the report? • **Detailed, clear and objective information** • **Information based on medical records** • **Own recollection** • **Usual practice**	 112 88 74 19	 65.9 51.8 43.5 11.2
7. Who should the report be addressed to? • **Head of department** • **Quality control department**	 26 8	 15.3 4.7
Reporting the incident 2.2. Action immediately after an adverse outcome • **Notify MPS**	 132	 77.6
2.5. Consultation if summoned to give evidence • **Your indemnity insurance**	151	88.8
Debriefing process 2.3. What to do when reporter asks for information • **No comment**	 155	 91.2
2.4. Would you meet with the family? • **Yes** What would you tell the family? • **The truth** • **Full details**	 163 161 152	 95.9 94.7 89.4
8. Debriefing process in your department? • **Yes**	 117	 68.8
9. Expectations of debriefing process • **Psychological counselling** • **Departmental debriefing**	 61 90	 35.9 52.9
The completion of Form GW 7/24 3. When do you fill in the form • **Following unnatural deaths** • **Following procedure related deaths**	 15 22	 8.8 12.9
4. What is the form called? • **Form GW 7/24**	 10	 5.9
5. Which laws govern completion of the form? • **Births and Deaths Registration Act 51 of 1992** • **The National Health Act 61 of 2003** • **Health Professions Act 56 of 1974** • **Health Professions Amendment Act 29 of 2007**	 2 3 5 4	 1.2 1.8 2.9 2.4

The summary of questions, answers, the number and percentage of participants who got the right answers for the knowledge of possible legal consequences are presented in Table V.

Table V: Section 5 to 8 scores (please refer to Table 1 for numbering legend)

Question, description and answer	**Correct**	
The inquest process	**N**	**%**
10. What legal consequences may follow an incident?		
• **Inquest process**	61	35.9
11. What is an inquest?		
• **Judicial inquiry to ascertain facts relating to a patient's death**	50	29.4
12. Is an inquest always necessary following anaesthetic related death?		
• **Yes**	37	21.8
13. What should the magistrate decide upon completion of inquest?		
• **Identity of the deceased**	4	2.4
• **Date of death**	7	4.1
• **Likely cause of death**	15	8.8
• **Any act or omission on the part of an individual**	33	19.4
14. Possible consequences following results of an inquest		
• **Criminal charges**	40	23.5
• **Civil claim**	52	30.6
• **HPCSA complaint**	41	24.1
The civil process		
10. What legal consequences may follow an incident?		
• **Civil claim**	66	38.8
15. Grounds to be sued for negligence		
• **Duty owed to the patient**	18	10.6
• **Breach of duty**	50	29.4
• **Acts resulting in actual damage**	12	7.1
• **Calculation of resulting damages**	3	1.8
16. What to do upon receiving a letter of demand		
• **Inform your indemnity insurance**	129	75.9
The criminal process		
10. What legal consequences may follow an incident?		
• **Criminal proceedings**	48	28.2
18. Can criminal proceedings be instituted against you professionally?		
• **Yes**	151	88.8
The HPCSA process		
10. What legal consequences may follow an incident?		
• **HPCSA complaint**	36	21.2
19. Circumstances under which a complaint against an anaesthetist can be lodged with the HPCSA		
• **Improper conduct**	49	28.8
• **Charging excessive fees**	16	9.4
• **Incompetence in treating patients**	77	45.3
• **Disclosing patient information without permission**	6	3.5
• **Improper relationships**	4	2.4
• **Unauthorised advertising**	1	0.6
• **Over-servicing patients**	1	0.6
• **Criminal convictions**	2	0.6
• **Performing surgical procedures without consent**	3	1.2
• **Rude behavior towards patients**	4	2.4
• **Racial discrimination**	0	0.0
20. What penalties can the HPCSA subject to those found guilty of misconduct?		
• **A caution/reprimand or both**	15	8.8
• **A fine**	77	45.3
• **Suspension**	74	43.5
• **Removal from relevant register**	88	51.8
• **A compulsory period of professional service**	5	2.9
• **Payment of the costs of the proceedings or restitution**	2	1.2

Table VI represents the overall scores for knowledge regarding the preparation for anticipated medicolegal action.

Table VI: Overall scores for Section 1 – 4 (please refer to Table 1 for numbering legend)

Score	Median	Interquartile range		Participants ≥75%
Writing a report of the incident	33.3	25.0	41.7	4.1
Reporting the incident to MPS	100.0	50.0	100.0	73.5
Debriefing process	75.0	62.5	87.5	64.1
Completion of form GW 7/24	0.0	0.0	0.0	0.0
Section 1- 4 overall score	52.1	42.7	57.3	1.2

The overall knowledge of possible legal consequences is presented in Table VII.

Table VII: Overall scores for Section 5 – 8 (please refer to Table 1 for numbering legend)

Score	Median	Interquartile range		Participants ≥75%
Inquest process	20.0	6.7	38.3	1.8
Civil process	31.3	25.0	56.3	5.3
Criminal process	50.0	50.0	50.0	24.7
HPCSA process	11.6	8.6	22.7	0.0
Section 5 – 8 overall score	34.3	25.9	43.0	0.0

The comparison between junior and senior anaesthetists' overall section, as wells as entire study scores, is presented in Table VIII.

Table VIII: Overall score comparison between senior and junior anaesthetists

Score	Anaesthetist status	N	Median	Interquartile range		Participants ≥ 75%	P values
Section 1 - 4 overall score	**Jnr**	98	47.9	37.5	54.2	0.0	
	Snr	71	55.2	49.0	59.4	2.8	<0.0001
Section 5 - 8 overall score	**Jnr**	98	31.6	21.7	41.0	0.0	
	Snr	71	39.6	32.6	47.9	0.0	<0.0001
Entire study score	**Jnr**	98	38.9	30.1	46.0	0.0	
	Snr	71	47.0	41.4	53.8	0.0	<0.0001

The comparison of knowledge of the preparation of anticipated medicolegal action between the two groups is presented in Table IX.

Table IX: Section 1 – 4 Comparison between junior and senior anaesthetists

Score	Anaesthetist status	N	Median	Interquartile range		Participants ≥ 75%	P values
Writing a report of the incident	**Jnr**	98	25.0	16.7	41.7	1.0	
	Snr	71	33.3	25.0	41.7	8.5	0.031
Reporting the incident to MPS	**Jnr**	98	100.0	50,0	100.0	65.3	
	Snr	71	100,0	100.0	100.0	85.9	0.0015
Debriefing process	**Jnr**	98	75.0	62.5	87.5	58.2	
	Snr	71	87.5	62.5	87.5	71.8	0.0005
Completion of form GW 7/24	**Jnr**	98	0.0	0.0	0.0	0,0	
	Snr	71	0.0	0.0	16.7	0.0	0.085
Section 1-4 score	**Jnr**	98	47.9	37.5	54.2	0.0	
	Snr	71	55.2	49.0	59.4	2.8	<0.0001

Table X presents the comparison of knowledge of possible legal consequences between the groups.

Table X: Section 5 – 8 comparison between junior and senior anaesthetists

Score	Anaesthetist status	N	Median	Interquartile range		Participants ≥ 75%	P value
Inquest process	**Jnr**	98	19.2	0.0	26.7	1.0	
	Snr	71	31.7	13.3	51.7	2.8	<0.0001
Civil process	**Jnr**	98	28.1	25.0	56.3	5.1	
	Snr	71	50.0	25.0	56.3	5.6	<0.021
Criminal process	**Jnr**	98	50.0	50.0	50.0	19.4	
	Snr	71	50.0	50.0	100.0	32.4	<0.028
HPCSA process	**Jnr**	98	9.8	8.6	16.7	0.0	
	Snr	71	16.7	8.6	38.9	0.0	<0.0083
Section 5 - 8 overall score	**Jnr**	98	31.6	21.7	41.0	0.0	
	Snr	71	39.6	32.6	47.9	0.0	<0.0001

Discussion

The study included 98 (57.6%) junior anaesthetists and 71 (41.8%) senior anaesthetists. Five (2.9%) participants had no indemnity cover. Two (1.2%) participants had a civil claim brought against them at some point in their career.

One hundred and sixty two (95.3%) participants could identify an unnatural death as described in the scenario. This is important because all unnatural deaths need to be reported according to the Inquest Act 58 of 1959. [15] This study shows that anaesthetists' overall knowledge of the medicolegal process following an anaesthetic related incident is poor. The overall median score was 42.5% (IQR 35.1-49.3%). No respondents scored ≥75%. This could be attributable to the lack of standard published guidelines in SA, as compared to other countries like the UK where the AAGBI has guidelines published. [21]

The knowledge in different sections of the medicolegal processes was variable. In the section assessing the knowledge of anticipation for possible medicolegal action, the median score was 52.1% (IQR 42.7 – 57.3%) and only 1.2% of the participants achieved an overall score of ≥75%. This showed that the overall knowledge in this section was poor. The median score for reporting the incident to MPS was 100% (IQR 50 – 100%) and 73.5% of participants achieving ≥75%. This could be attributable to the fact that in this study, 97.1% of the participants had indemnity insurance and could be getting regular information regarding the reporting of incidents. The worst performance for this section was regarding the completion of Form GW 7/24, with a median of 0% (IQR 0.0 – 0%) and none of the participants achieving ≥75%.

The knowledge regarding the completion of Form GW 7/24 and the laws that govern it was very poor. Less than 15% of participants could answer questions in that particular section. This could be attributable to the poor knowledge of the correct name for the form, which could have led to the poor performance in the subsequent questions. The form needs to be filled for all unnatural deaths and procedure related anaesthetic deaths. [19, 23] The poor knowledge regarding laws governing the

completion of Form GW 7/24 could be attributable to the lack of medicolegal teaching at various stages of the medical career. [16]

More than 90% of participants knew the correct procedure of dealing with the media and the patient's family after adverse events. Participants did not seem to have adequate knowledge regarding the debriefing process and what to expect from the process. This could be attributable to lack of written departmental guidelines to deal with incidents.

The overall median score for the section assessing possible legal consequences following incidents was 34.3% (IQR 25.9 – 43.0%) and none of the participants achieved ≥75%. In this section participants knew more about the criminal process, with the mean of 50% (IQR 50 – 50%) and 242.7% of participants achieving ≥75%. Participants knew less about the HPCSA process.

The anaesthetists' knowledge of possible legal consequences following anaesthetic was very poor. Less than 40% of participants knew that an inquest is a possible legal consequence that may follow anaesthetic related incidents. A majority of participants were not aware of the importance of an inquest. The knowledge regarding the civil process was also poor, however 75.9% of participants knew they had to inform their indemnity insurance upon receiving a letter of demand. 88.8% of candidates were aware that criminal proceedings may be instituted against an anaesthetist professionally. Only 21.2% of candidates knew that an HPCSA complaint may follow anaesthetic related incidents. The specific circumstances that could result in an HPCSA complaint are listed on their website and available for all doctors to familiarise themselves. [24]

The median overall scores for senior anaesthetists were higher than junior anaesthetists, regarding the entire study and for both sections. The effect sizes for the differences are all weak, reflecting that the difference between the two groups is small, however both groups had poor knowledge. Both groups performed the worst in the completion of Form GW 7/24, with the means of 0.0% (IQR 0.0 – 0.0%) for juniors and 0.0% (IQR 0 – 16.7%) for senior anaesthetists. The slight difference in knowledge could be attributable to the experience of seniors in dealing with incidents.

Similar studies or surveys looking at the knowledge of medicolegal aspects by medical practitioners in particular anaesthetists in SA could not be identified for comparison. A study done at 12 private hospitals in SA, assessing the critical care nurses' knowledge of legal liability issues in the critical care environment, showed a below standard level of knowledge. The study showed a total average of 38.45%, which was 21.55% below the set standard of 60%. [25] In the UK, a study assessing the knowledge and training pertaining to medical law among trainees in anaesthesia showed that knowledge of the law relevant to anaesthesia was poor. It also showed that trainees had received limited training in decreasing exposure to litigation. [26]

A survey done in Canada at the University of Ottawa, assessing the knowledge of medicolegal issues by family medicine residents showed that residents were confused about medicolegal issues. [27] A study done in Vadodara, India assessing the knowledge and awareness among interns and residents regarding medical law and negligence showed that participants lacked knowledge on medical negligence. [28]
A study done in New Zealand to assess healthcare providers' knowledge of laws relating to consent indicated poor overall knowledge of some key areas. [29] The studies highlighted also showed poor knowledge amongst participants.

Limitations

This study was done contextually in the Department of Anaesthesiology at the Wits, and consequently may not be generalisable to other departments in South Africa and other countries.

Conclusion

Anaesthetists employed in the Department of Anaesthesiology at Wits did not have the adequate knowledge of medicolegal processes following anaesthetic related incidents. The overall knowledge as well as knowledge in the subsections was poor. The knowledge amongst senior anaesthetists is better than their junior counterparts, however the difference is small.

The importance of knowledge of medicolegal aspects relating to anaesthesia cannot be over emphasised. The possibility of receiving a clinical negligence claim remains despite the fact that most doctors will avoid it during their careers. The receipt of a negligence claim is a stressful and frustrating situation for any doctor. The authors suggest the extension of this survey to the wider South African anaesthetic community. Due to the importance of the anaesthetists having adequate medicolegal knowledge, the authors further recommend continuous education programs on this subject by the South African Society of Anaesthesiologists and MPS, for example through a webpage or electronic communications.

Acknowledgements

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Conflict of Interest

The authors declare that they had no financial or personal relationship(s), which may have inappropriately influenced the writing of this paper.

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SECTION 4 – Appendices

Appendix 1 - Postgraduate Approval

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

03 February 2015
Person No: 700588
PAG

Dr HJ Moutlana
P O Box 31747
Superbia
Polokwane
0759
South Africa

Dear Dr Moutlana

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Anaesthetists' knowledge of the medicolegal process following an anaesthetic related incident* 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 HJ Moutlana and Prof Lundgren

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140325

NAME: (Principal Investigator)	Dr HJ Moutlana and Prof Lundgren
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Anaesthetists' Knowledge of Medicolegal Process Following an Anaesthetic Related Incident
DATE CONSIDERED:	28/03/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Juan Scribante
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	14/01/2015

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 Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized 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 the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3: Form GW 7/24

GW 7/24

DEPARTMENT OF HEALTH AND WELFARE

REPORT ON PERSON WHOSE DEATH IS ASSOCIATED WITH THE ADMINISTRATION OF AN ANAESTHETIC OR A DIAGNOSTIC OR THERAPEUTIC PROCEDURE

INSTRUCTION

1. This form may be used as evidence in case of a legal inquiry. The person completing it is warned that he need not answer any question, without prejudice to himself, should he not desire to do so.
2. To be completed as follows:
   - Parts A and B—by the medical practitioner in charge of the patient.
   - Part C—by the medical practitioner other that the anaesthetist who carried out the procedure.
   - Part D—by the medical practitioner who administered the anaesthetic.
   - Part E—by any other person (e.g. nursing sister).
3. Use additional sheets if space provided is inadequate.
4. It is advisable to keep a copy on the patient's file.

PART A.—GENERAL INFORMATION (IN BLOCK LETTERS)

1. Hospital or institution ..... Ward .....
2. Hospital No. ..... Date of admission .....
3. Name of patient .....
4. Age ..... Sex ..... Race .....
5. Occupation .....
6. Patient's home address .....
7. Medical practitioner(s):
   - In charge .....
   - Others .....
   - Anaesthetist .....
   - Theatre and/or ward sister(s) .....
8. Date and time of death .....

PART B.—MEDICAL PARTICULARS OF PATIENT

Name of patient.....

1. History.....

Drug or alcohol addiction.....

Previous anaesthetics.....

Treatment: (a) before admission.....

(b) after admission.....

2. Pre-operative examination:

General (physique, nutrition).....Mass.....

Temperature.....°C. Septic Foci.....

Cardio-vascular system: Pulse.....B.P.: Syst.....Diast.....

Hb.....Other.....

Respiratory system.....

(mention specially any evidence of excessive mucus).....Resp. rate.....

Uro-genital system.....

.....Urine.....

Other systems.....

3. Diagnosis.....

4. Patient's general condition:

Good	Fair	Poor	Serious	Grave

5. Time and nature of last meal.....

6. Pre-operative preparation if any prescribed or carried out personally by medical practitioner completing Part B (e.g. I.V. fluids, electrolytes, oxygen, etc.).....

7. Stomach tube (if used): When.....

Size.....Make.....Result.....

Signed.....

Date.....Qualifications.....

GW 7/24

PART C.—PARTICULARS OF THE PROCEDURES UNDERTAKEN (e.g. Surgery)

Name of patient.....

(This excludes the anaesthetic administration)

1. Were all relevant particulars in Part B and any other relevant feature(s) noted before the procedure was undertaken?.....

2. Nature of procedure.....

3. Time commenced..... Terminated.....

4. Details of condition(s) affecting the course of the procedure (e.g. shock, haemorrhage, unconsciousness including pre-operative treatment if prescribed or carried out by medical practitioner).....

5. Therapy prescribed during the procedure: (e.g. blood transfusion, drugs).....

6. Account of events leading to patient's death (including resuscitative measures).....

7. Opinion regarding cause of death.....

Date.....

Signed.....

Qualifications.....

GW 7/24

DEPARTMENT OF HEALTH AND WELFARE

REPORT ON PERSON WHOSE DEATH IS ASSOCIATED WITH THE ADMINISTRATION OF AN ANAESTHETIC OR A DIAGNOSTIC OR THERAPEUTIC PROCEDURE

INSTRUCTION

1. This form may be used as evidence in case of a legal inquiry. The person completing it is warned that he need not answer any question, without prejudice to himself, should he not desire to do so.
2. To be completed as follows:

   Parts A and B—by the medical practitioner in charge of the patient.

   Part C—by the medical practitioner other that the anaesthetist who carried out the procedure.

   Part D—by the medical practitioner who administered the anaesthetic.

   Part E—by any other person (e.g. nursing sister).

3. Use additional sheets if space provided is inadequate.
4. It is advisable to keep a copy on the patient's file.

PART A.—GENERAL INFORMATION (IN BLOCK LETTERS)

1. Hospital or institution ..... Ward .....
2. Hospital No. ..... Date of admission .....
3. Name of patient .....
4. Age ..... Sex ..... Race .....
5. Occupation .....
6. Patient's home address .....
7. Medical practitioner(s):

   In charge .....

   Others .....

   Anaesthetist .....

   Theatre and/or ward sister(s) .....

8. Date and time of death .....

PART D.—THE ANAESTHETIC

GW 7/24

Name of patient.....

1. Were all particulars in Part B and any other relevant feature(s) noted before the administration of the anaesthetic?.....

2. Premedication prescribed.....

Was premedication satisfactory.....

3. Duration of induction..... Duration of anaesthetic.....

4. Agents used:

(a) Intravenous, including muscle relaxants (give amounts and antidotes and state whether used for *induction only* or *fractionally throughout* administration).....

(b) Inhalation (indicate where possible whether used as main anaesthetic agent or in supplementary capacity; also whether required in large, small or moderate amounts. In case of semi-closed nitrous oxide, give approximate flow of gases maintained and approximate average oxygen).....

(c) Rectal (amounts).....

(d) Regional or spinal (amounts and concentrations).....

Expiry date of any drugs, if known.....

Method of administration (indicate type of apparatus used and mention any specific technique with special reference to controlled or assisted respiration if muscle relaxants used).....

Complications.....

What was the first alarming sign?

Exact time of respiratory arrest ..... Cardiac arrest .....

If cardiac massage performed, state interval from cardiac arrest to cardiac massage

Method of cardiac massage and/or defibrillation

Result

Resuscitative measures

5. Details of drugs used and general condition:

Exact time	Drug	Dosage	Injection site	Result	B.P.	Pulse	Respir.

6. Account of death and events leading thereto

7. Opinion with regard to cause of death

Signed .....

Date ..... Qualifications .....

GW 7/24

PART E.—OTHER ACCOUNTS OF THE DEATH

Name of patient.....

1. .....

Signed.....

Date..... Qualifications.....

2. .....

Signed.....

Date..... Qualifications.....

SECTION 5 - Proposal

Anaesthetists' knowledge of the medicolegal process following an anaesthetic related incident

Hlamatsi Jacob Moutlana

Student no: 700588

Supervisor: Juan Scribante
Department of Anaesthesiology

Co supervisor: Professor Christina Lundgren
Department of Anaesthesiology

5.1 Introduction

Anaesthetists provide care to more than 60% of acute hospital admissions (1). The practice of anaesthesia can be associated with a variety of complications, which may be a result of anaesthetist's actions or inactions (2). Some of these incidents can be costly, with major consequences (3). These incidents are a source of morbidity or mortality (4) and may lead to medicolegal claims against doctors (1).

Negligence and failure to abide by standards of care subject physicians to negligence claims (5). For a successful negligence suit, the following needs to be proven: duty, breach of duty, damages and causation (5, 6).

In England the National Health Service Litigation Authority (NHSLA) handles negligence cases on behalf of the National Health Service (NHS). The NHSLA consists of various schemes where claims in different categories can be lodged. (7) Over the last decade, in England approximately one in 40 claims reported to the NHSLA were related to anaesthesia (1).

The American Society of Anaesthesiologists Closed Claims database retrieves data about adverse outcomes from medical liability insurance carriers. The data indicate huge financial implications to the anaesthetists as a result of liability claims. (8)

Literature indicating data relating to closed claims in South Africa could not be identified. But according to the Medical Protection Society (MPS), there has been a rise in the number of large claims, with an increase of 250% in reported claims in excess of R2.5 million since 2008. (9)

The practice of medicine is regulated by numerous statutory legislations. In South Africa (SA) the following statutes govern the practice of medicine: the Health Professions Act 56 of 1974 (10), the Births and deaths Registration Act 51 of 1992 (11), the Inquest Act 58 of 1959 (12), the National Health Act 61 of 2003 (13), and the Health Professions Amendment Act 29 of 2007 (14). The acts allows for the establishment of the regulatory body, the Health Professions Council of South Africa (HPCSA) (10), governing of deaths both natural and unnatural (11),investigation of the circumstances of each unnatural death (12, 13), definition of anaesthetic related deaths (13, 15), and definitions for deaths during or following a procedure (13, 16), respectively.

The legal process following negligence differs among different countries. In England if the incident occurred while employed by the NHS Trust, the employer covers the claim (17). Practitioners need liability insurance coverage for their specific specialty and role (18). Personal representation by one of the medical defence organisations is important if the incident involves a private patient or if there is a possibility of criminal charges being pressed, both of which are not covered by the NHS employer (17).

In the United States of America, the system of law governing civil dispute resolutions is referred to as the adversarial system. It involves skillful presentation of arguments by attorneys from both sides before the judge. In contrast to the British system, doctors practicing in the USA generally take medical malpractice insurance, to protect them should they face a case of medical negligence or unintentional injury. (19)

The MPS published in one of its casebook articles, a step-by-step account of how a civil claim progresses. Doctors are guided through each step of the process. (9) In contrast to the British system, South Africa has no social insurance system. Claims against private practitioners or institutions are instituted via proceedings in a court of law. Those against a state institution are done in terms of the State Liability Act. (14)

The processes to follow after an anaesthetic related incident differs per countries and institutions. In the United Kingdom (UK), the Association of Anaesthetists of Great Britain and Ireland (AAGBI) have produced guidelines for dealing with the aftermath of catastrophes in anaesthetic practice. A guide on how to record the incident, the debriefing process and medicolegal issues are outlined. The possible course of events following an unexpected mortality or morbidity is as follows: “internal inquiry, Coroner’s inquest (England and Wales) or Procurator Fiscal’s (Scotland) Investigation, criminal prosecution, General Medical Council investigation or civil litigation.” (17)

In South Africa guidelines similar to the AAGBI guidelines could not be identified. However after personal communication with the Head of Department in Anaesthesiology at the University of Witwatersrand (Wits), the process of how the situation may unfold is outlined. The process includes: writing of a report, the MPS notification as the situation dictates, debriefing process and in case of mortality, completion of Form GW 7/24. An anaesthetic related incident might lead to legal consequences, which may include: the HPCSA complaint, civil claim, criminal case, or an inquest. (20)

Studies or surveys looking at knowledge of medicolegal aspects by medical practitioners in particular anaesthetists in South Africa could not be identified. A study done at 12 private hospitals in SA, assessing the critical care nurses’ knowledge of legal liability issues in the critical care environment, showed a below standard level of knowledge. The study showed a total average of 38.45%, which was 21.55% below the set standard of 60%. (21)

In the UK, a study assessing the knowledge and training pertaining to medical law among trainees in anaesthesia showed that knowledge of the law relevant to anaesthesia was poor. It also showed that trainees had received limited training in decreasing exposure to litigation. (22)

A survey of Ontario family medicine residents' knowledge of medicolegal issues and attitudes towards medicolegal training concluded that residents are confused about medicolegal issues. (23)

The legal process following anaesthetic related incidents could be very complex. Medicolegal education for anaesthetists at various times during their training can improve anaesthetists' knowledge base regarding medicolegal interactions (24). The identified knowledge gaps in this regard could be filled by educational sessions from various experts in the field.

5.2 Problem statement

The importance of knowledge of medicolegal aspects relating to anaesthesia cannot be over emphasised. The possibility of receiving a clinical negligence claim remains despite the fact that most doctors will avoid it during their careers. The receipt of a negligence claim is a stressful and frustrating situation for any doctor (9). Knowledge of the medicolegal process relating to those claims is imperative.

There is minimum exposure to acts and regulations governing the medical profession during undergraduate training, as a result very few doctors know or understand them (13). There is a possibility of a potential knowledge gap with regards to this issue among anaesthetists in South Africa, although studies to substantiate this could not be identified.

The question therefore arises whether anaesthetists in the Department of Anaesthesiology at Wits are knowledgeable regarding the medicolegal process following an anaesthetic related incident.

5.3 Aim

The aim of this study is to describe the knowledge of anaesthetists in the Department of Anaesthesiology at Wits regarding the medicolegal process following an anaesthetic related incident.

5.4 Objectives

The first objective of this study will be to describe anaesthetists' knowledge of the preparation for anticipated medicolegal action with regard to:

1. writing a report of the incident
2. reporting the incident to MPS
3. the debriefing process
4. completion of Form GW 7/24.

The second objective of this study will be to describe anaesthetists' knowledge of the possible legal consequences following anaesthetic related incidents with regard to the:

5. inquest process
6. civil process
7. criminal process
8. HPCSA process.

The third objective of this study will be to compare the knowledge of the senior and junior anaesthetists, regarding the overall knowledge and each of the two subsections.

5.5 Research assumptions

The following definitions will be used in the study.

Anaesthetists: will be all doctors working in the Department of Anaesthesiology at Wits excluding interns. Anaesthetists will be divided into senior and junior anaesthetists.

Senior anaesthetists: will include anaesthesiologists and career medical officers.

Junior anaesthetists: will include registrars, junior medical officers and community service medical officers.

Anaesthetic related incident: an anaesthetic incident, which has a potential to produce harm to the patient (25).

Debriefing process: a set of procedures, which includes stress debriefing following an incident and ongoing psychological counselling (17).

Form GW 7/24: a form that is completed following unnatural deaths (also known as the “white form or DOT form”)

Inquest process: the process of a judicial inquiry to ascertain facts relating to an incident (26).

Civil process: the process where a doctor is sued for damages.

Criminal process: the process where criminal proceedings are instituted.

HPCSA process: the process where a complaint is lodged with the HPCSA and disciplinary proceedings.

Adequate knowledge: a score of ≥75% for each section

5.6 Demarcation of study field

The study will be conducted in the Department of Anaesthesiology at Wits. The following hospitals are affiliated to the department:

- Chris Hani Baragwanath Academic Hospital
- Charlotte Maxeke Johannesburg Academic Hospital
- Helen Joseph Hospital
- Klerksdorp Hospital
- Rahima Moosa Mother and Child Hospital
- Wits Donald Gordon Medical Centre

The staff complement for the department includes: 65 anaesthesiologists, 13 career medical officers, 19 medical officers and 109 registrars.

5.7 Ethical considerations

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

Once the study is approved, at academic meetings anaesthetists will be invited to participate. Those who agree to participate will receive an information letter (Appendix 1) and a self-administered questionnaire (Appendix 2). The agreement to complete the questionnaire will imply consent for the participation in the study, which is voluntary.

Anaesthetists will complete the questionnaire anonymously. Upon completion, questionnaires will be placed in an unmarked envelope, sealed and placed in a collection box. The only people to have access to the raw data will be the researcher and supervisors to ensure confidentiality. The collected data will be stored securely for six years following completion of the study.

If the results show a lack of knowledge regarding medicolegal processes is found the researcher will organise a departmental workshop involving medicolegal experts in the department and MPS.

The study will be conducted in adherence to the principles of the Declaration of Helsinki 2013 (27) and the South African Good Clinical Practice Guidelines (28).

5.8 Research methodology

5.8.1 Research design

A prospective, contextual and descriptive research design will be used.In a prospective study a population is selected and followed over time to determine outcomes (29). This study will identify a group of anaesthetists, collect data from them during the course of the study, and determine an outcome.

A contextual study is a study that takes place in a specific environment (30). This study is contextual, as it will be conducted in the Department of Anaesthesiology at Wits.

A descriptive study aims to describe a phenomenon. There is no manipulation of any variables and no effort to determine variable relationships. Variables of interest are defined and can be classified as facts, needs, opinions or attitudes. They are then described to provide a picture of the phenomenon as it occurs. (29) This study will describe anaesthetists' knowledge of the medicolegal process following anaesthetic related incidents.

5.8.2 Study population

Anaesthetists working in the Department of Anaesthesiology at Wits will form the study population.

5.8.3 Study sample

Sample size

The study sample will be realised by the response rate. The Department of Anaesthesiology at Wits consists of 65 anaesthesiologists, 13 career medical officers, 109 registrars and 19 medical officers. Questionnaires will be distributed to all eligible anaesthetists. A response rate of 60% is considered acceptable, however a response rate of 80% will be targeted.

Sampling method

Convenient sampling will be used in this study. Convenient sampling is a process by which data that is conveniently accessible is gathered by the researcher (30). All eligible anaesthetists will be invited to take part in the study.

Inclusion and exclusion criteria

The inclusion criteria in this study will be:

- senior and junior anaesthetists employed in the Department of Anaesthesiology at Wits
- anaesthetists consenting to take part.

The exclusion criteria in this study will be:

- interns working in the department
- anaesthetists on leave at the time of data collection
- part-time anaesthesiologists who do not attend academic meetings.

5.9 Data collection

5.9.1 Questionnaire development

The questionnaire was developed following an extensive review of the literature to ensure content validity. Two medicolegal experts in the Department of Anaesthesiology were consulted to ensure face and content validity.

5.9.2 Questionnaire distribution

The number of anaesthetists working in the Department of Anaesthesiology at Wits was obtained from the heads of departments to determine a response rate. The questionnaire will be distributed over a two-month period at academic departmental meetings. The researcher will ask the convenor of the meetings if the anaesthetists could have 10 to 15 minutes to complete the questionnaire. The researcher will give a brief overview to all those present and invite them to participate. Those agreeing to participate will be given an information letter (Appendix 1) and a self-administered questionnaire (Appendix 2). The questionnaires will be allocated a study number to monitor the number of questionnaires returned. The researcher will be present when the questionnaires are completed to prevent data contamination and to answer questions. The anaesthetists will put the completed questionnaire in the unmarked envelope, seal it and place it in a sealed data collection box at the end of the meeting.

5.9.3 Data analysis

Data will be entered into a Microsoft®Excel 2011 and analysed in consultation with a biostatistician. Microsoft® Excel and SAS® version 9.4 for Windows will be used for data analysis. Descriptive and inferential statistics will be used. Categorical data will be summarised using frequencies and percentages and continuous variables will be summarised using means and standard deviations for normally distributed data and medians and ranges will be used for data not normally distributed. Comparisons between groups will be done using the independent t test or Mann-Whitney test depending on the distribution of the data. A p value of <0.05 will be considered statistically significant.

5.10 Significance of the study

The possibility of receiving a clinical negligence claim remains despite the fact that most doctors will avoid it during their careers. The receipt of a negligence claim is a stressful and frustrating situation for any doctor. (9)

There is minimum exposure to acts and regulations governing the medical profession during undergraduate training and as a result very few doctors know or understand them (13). If knowledge is found to be lacking this can be addressed, as knowledge of the medicolegal process relating to claims is imperative.

5.11 Validity and reliability

The validity of a study is the extent to which it reflects the characteristics being measured (30). The reliability of a study refers to the consistence of the measures implemented in the study (29).

Validity and reliability of the study will be ensured by:

- using an appropriate study design
- using a representative study sample
- data analysis being done in consultation with a biostatistician.

Validity and reliability of the questionnaire will be ensured by:

- conducting an extensive literature review prior to developing the questionnaire ensuring content validity
- expert anaesthetists assessing the questionnaire ensuring face and content validity.

5.12 Potential study limitations

This study will be done contextually in the Department of Anaesthesiology at Wits and the results of the study may not be generalisable to other institutions. However, the study may identify knowledge gaps that can be addressed. Convenient sampling could be a limitation but will target a representative number of anaesthetists.

5.13 Project timeline

Activity	Jan 2014	Feb 2014	March 2014	June 2014	July 2014	Aug 2014	Sept 2014	Oct 2014	Nov 2014
Protocol preparation									
Writing Chapters 1-3									
Ethics and postgrad submission									
Data Collection									
Data Capturing									
Analysis of results									
Writing chapters 4-5									
Submission of MMED									

5.14 Financial plan

Description	Price per item	Number of items	Total
Proposal	60c/page	400	R240
Questionnaire and information letter	60c/page	600	R360
Envelopes	R1/envelope	200	R200
Research report	60c/page	1000	R600
Binding	R200/copy	3	R600
Total			R2000

The cost of the paper and printing will be incurred by the Department of Anaesthesiology.

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Appendix 1: Information letter

Dear colleague

Hello, my name is Jacob Moutlana and I am an anaesthesiology registrar. I would like to invite you to participate in my M Med research study entitled: **Anaesthetists' knowledge of the medicolegal process following an anaesthetic related incident.**

There is minimum exposure to acts and regulations governing the medical profession during undergraduate training and as a result very few doctors know or understand them. The possibility of receiving a clinical negligence claim remains; despite the fact that most doctors will avoid it during their careers. The receipt of a negligence claim is a stressful and frustrating situation for any doctor. Knowledge of the medicolegal process relating to those claims is imperative. Therefore, I would like to ascertain the knowledge of anaesthetists in the department with regard to the medicolegal process following an anesthetic related incident.

Agreement to complete the questionnaire will imply consent and participation is voluntary. You are free to withdraw from the study at any time without having to provide a reason. Withdrawal or refraining from participation carries no penalty or repercussion of any sort.

Questionnaires are completely anonymous and should take approximately 10 - 15 minutes to complete. Once completed, questionnaires should be placed into an unmarked envelope, sealed and placed in the sealed data collection box. Confidentiality will be ensured as only my supervisors and I will have access to the raw data.

If the results show a lack of knowledge of the medicolegal process, a workshop addressing the problem will be organised in the department. However, if you have concerns with regard to the medicolegal processes you can contact the Head of the Department: Prof Lundgren on 0119339560 or MPS www.medicalprotection.org/southafrica

The Human Research Ethics Committee (HREC) (Medical) (Number M140325) and the Graduate Studies Committee of Wits have approved the Study.

If you have any questions or concerns with regard to the study, you may contact me on 0828318164 or the chairperson of the HREC Prof Cleaton-Jones on 0117171234.

Thank you for taking the time to read this letter

Yours sincerely
Jacob Moutlana

Appendix 2: Questionnaire

Please tick the boxes where appropriate and complete the open-ended questions.

1. Demographics

1.1 What is your current employment status?

Community service medical officer	
Junior medical officer	
Registrar	
Career medical officer	
Anaesthesiologist	

1.2 How many years of experience do you have in anaesthesia?

1.3 What is your gender?

Male	
Female	

1.4 Do you have professional indemnity cover (e.g. MPS)?

MPS	
Other	
None	

1.5 Have you ever had a civil claim brought against you?

Yes	
No	

2. A doctor anaesthetises a 10 year old boy for adenotonsillectomy. Towards the end of the procedure the child has a bradycardia followed by cardiac arrest. Resuscitation is successful. The child is taken to ICU for ventilation. The child does not regain consciousness and dies nine months later from aspiration pneumonia.

2.1. Is this a death due to:

Natural causes	
Unnatural causes	
I do not know	

2.2. What should be done immediately after the anaesthetic?

2.3. When the child dies in ICU, a reporter from YOU magazine phones you. What do you do?

2.4. Would you meet with the family?

Yes	
No	

If your answer is yes, what do you tell them?

2.5. Who would you consult if you are summoned to give evidence in court?

3. When do you fill in the “White form”?

4. Do you know what it is called?

5. Do you know which laws govern the completion of the “white form”?

6. If you are required to write a report on an adverse outcome, what needs to be in the report?

7. Who should the report be addressed to?

8. Do you have a debriefing process in your department?

Yes	
No	
I do not know	

9. What do you expect from a debriefing process?

10. What legal consequences may follow an anaesthetic related incident?

11. What is an inquest?

12. Is an inquest always necessary following an anaestheticrelated death?

Yes	
No	
I do not know	

13. What should the magistrate decide upon completion of an inquest?

14. What consequences may follow the results of an inquest?

15. On which grounds may an anaesthetist be sued for negligence?

16. What should you do upon receiving a letter of demand to institute a civil claim?

17. What happens if you do not respond to the letter of demand?

18. Can criminal proceedings be instituted against you professionally?

Yes	
No	
I do not know	

19. **Under which circumstances can a complaint against an anaesthetist be lodged with the HPCSA?**

20. **What penalties can the HPCSA subject to those found guilty of misconduct?**

Thank you for completing the questionnaire

Appendix 3: Questionnaire memorandum

2. A doctor anaesthetises a 10 year old boy for adenotonsillectomy. Towards the end of the procedure the child has a bradycardia followed by cardiac arrest. Resuscitation is successful. The child is taken to ICU for ventilation. The child does not regain consciousness and dies nine months later from aspiration pneumonia.

2.1. Is this a death due to:

Natural causes	
Unnatural causes	**X**
I do not know	

2.2. What should be done immediately after the anaesthetic?

Completion of the GW 7/24 form
Write a detailed and clear report of the incident
Notify MPS

2.3. Wen the child dies in ICU, a reporter from YOU magazine phones you. What do you do?

No comment

2.4. Would you meet with the family?

Yes	**X**
No	

If your answer is yes, what do you tell them?

The truth about the incident
The full details of the incident

2.5. Who would you consult if you are summoned to give evidence in court?

Your indemnity insurance, e.g. MPS

3. When do you fill in the "White form"?

Following unnatural deaths and,
Procedure-related deaths

4. Do you know what it is called?

Form GW 7/24

5. **Do you know which laws govern the completion of the "white form"?**

The Births and Deaths Registration Act 51 of 1992
The National Health Act 61 of 2003
The Health Professions Act 56 of 1974
The Health Professions Amendment Act 29 of 2007

6. **If you are required to write a report on an adverse outcome, what needs to be in the report?**

Detailed, clear and objective information
Report based on medical records,
Own recollection,
Usual practice

7. **Who should the report be addressed to?**

Head of the department
Quality control department

8. **Do you have a debriefing process in your department?**

Yes	**X**
No	
I do not know	

9. What do you expect from a debriefing process?

Psychological counselling
Departmental debriefing

10. What legal consequences may follow an anaesthetic related incident?

Civil claim
Criminal proceedings
Inquest
HPCSA complaint

11. What is an inquest?

A judicial inquiry to ascertain facts relating to a patient's death

12. Is an inquest always necessary following an anaestheticrelated death?

Yes	**X**
No	
I do not know	

13. What should the magistrate decide upon completion of an inquest?

Identity of the deceased
The date of death
The cause or likely cause of death
Whether the death was brought about by any act or omission on the part of an individual

14. What consequences may follow the results of an inquest?

Criminal charges
Civil claim
HPCSA complaint

15. On which grounds may an anaesthetist be sued for negligence?

If there was duty owed to the patient
Breach of duty
Causation: anaesthetist's acts resulted in actual damage
Damages: calculation of resulting damages

16. What should you do upon receiving a letter of demand to institute a civil claim?

Inform your indemnity insurance e.g. MPS

17. What happens if you do not respond to the letter of demand?

Summons are issued

18. Can criminal proceedings be instituted against you professionally?

Yes	**X**
No	
I do not know	

19. Under which circumstances can a complaint against an anaesthetist be lodged with the HPCSA?

Improper conduct
Charging excessive fees
Incompetence in treating patients
Disclosing patient information without their permission
Improper relationships
Unauthorised advertising
Over-servicing patients
Criminal convictions
Performing surgical procedures without the patient's informed consent
Rude behaviour towards patients
Racial discrimination

20. What penalties can the HPCSA subject to those found guilty of misconduct?

A caution or a reprimand or both
A fine
Suspension for a specified period from practicing his/her profession
Removal from the relevant register
A compulsory period of professional service
Payment of the costs of the proceedings or restitution

Appendix 4: Form GW 7/24

GW 7/24

DEPARTMENT OF HEALTH AND WELFARE

REPORT ON PERSON WHOSE DEATH IS ASSOCIATED WITH THE ADMINISTRATION OF AN ANAESTHETIC OR A DIAGNOSTIC OR THERAPEUTIC PROCEDURE

INSTRUCTION

1. This form may be used as evidence in case of a legal inquiry. The person completing it is warned that he need not answer any question, without prejudice to himself, should he not desire to do so.
2. To be completed as follows:
   - Parts A and B—by the medical practitioner in charge of the patient.
   - Part C—by the medical practitioner other that the anaesthetist who carried out the procedure.
   - Part D—by the medical practitioner who administered the anaesthetic.
   - Part E—by any other person (e.g. nursing sister).
3. Use additional sheets if space provided is inadequate.
4. It is advisable to keep a copy on the patient's file.

PART A.—GENERAL INFORMATION (IN BLOCK LETTERS)

1. Hospital or institution ..... Ward .....
2. Hospital No. ..... Date of admission .....
3. Name of patient .....
4. Age ..... Sex ..... Race .....
5. Occupation .....
6. Patient's home address .....
7. Medical practitioner(s):
   - In charge .....
   - Others .....
   - Anaesthetist .....
   - Theatre and/or ward sister(s) .....
8. Date and time of death .....

PART B.—MEDICAL PARTICULARS OF PATIENT

Name of patient.....

1. History.....

Drug or alcohol addiction.....

Previous anaesthetics.....

Treatment: (a) before admission.....

(b) after admission.....

2. Pre-operative examination:

General (physique, nutrition).....Mass.....

Temperature.....°C. Septic Foci.....

Cardio-vascular system: Pulse.....B.P.: Syst.....Diast.....

Hb.....Other.....

Respiratory system.....

.....Resp. rate.....

(mention specially any evidence of excessive mucus).

Uro-genital system.....

.....Urine.....

Other systems.....

3. Diagnosis.....

4. Patient's general condition:

Good	Fair	Poor	Serious	Grave

5. Time and nature of last meal.....

6. Pre-operative preparation if any prescribed or carried out personally by medical practitioner completing Part B (e.g. I.V. fluids, electrolites, oxygen, etc.).....

7. Stomach tube (if used): When.....

Size.....Make.....Result.....

Signed.....

Date.....Qualifications.....

PART C.—PARTICULARS OF THE PROCEDURES UNDERTAKEN (e.g. Surgery)

GW 7/24

Name of patient.....

(This excludes the anaesthetic administration)

1. Were all relevant particulars in Part B and any other relevant feature(s) noted before the procedure was undertaken?.....
2. Nature of procedure.....
3. Time commenced..... Terminated.....
4. Details of condition(s) affecting the course of the procedure (e.g. shock, haemorrhage, unconsciousness including pre-operative treatment if prescribed or carried out by medical practitioner).....
5. Therapy prescribed during the procedure: (e.g. blood transfusion, drugs).....
6. Account of events leading to patient's death (including resuscitative measures).....
7. Opinion regarding cause of death.....

Signed.....

Date..... Qualifications.....

PART D.—THE ANAESTHETIC

GW 7/24

Name of patient.....

1. Were all particulars in Part B and any other relevant feature(s) noted before the administration of the anaesthetic?.....

2. Premedication prescribed.....

Was premedication satisfactory.....

3. Duration of induction..... Duration of anaesthetic.....

4. Agents used:

(a) Intravenous, including muscle relaxants (give amounts and antidotes and state whether used for *induction only* or *fractionally throughout* administration).....

(b) Inhalation (indicate where possible whether used as main anaesthetic agent or in supplementary capacity; also whether required in large, small or moderate amounts. In case of semi-closed nitrous oxide, give approximate flow of gases maintained and approximate average oxygen).....

(c) Rectal (amounts).....

(d) Regional or spinal (amounts and concentrations).....

Expiry date of any drugs, if known.....

Method of administration (indicate type of apparatus used and mention any specific technique with special reference to controlled or assisted respiration if muscle relaxants used).....

Complications.....

What was the first alarming sign?

Exact time of respiratory arrest ..... Cardiac arrest .....

If cardiac massage performed, state interval from cardiac arrest to cardiac massage

Method of cardiac massage and/or defibrillation

Result

Resuscitative measures

5. Details of drugs used and general condition:

Exact time	Drug	Dosage	Injection site	Result	B.P.	Pulse	Respir.

6. Account of death and events leading thereto

7. Opinion with regard to cause of death

Signed .....

Date ..... Qualifications .....

GW 7/24

PART E.—OTHER ACCOUNTS OF THE DEATH

Name of patient.....

1. .....

Signed.....

Date..... Qualifications.....

2. .....

Signed.....

Date..... Qualifications.....