

AN ANALYSIS OF EVIDENCE-BASED MEDICINE IN CONTEXT OF MEDICAL NEGLIGENCE LITIGATION

(a practical study)

by

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SUMMARY

A medical negligence case presented to the court is based on averments of neglected duty of care of the defending doctor, a duty owed in accordance with the law of delict, and alternatively and/or accumulatively averments that the contractual agreement between the complainant and the defending doctor was not honoured.

In order to prove failure of duty of care and/or breach of agreement, the complainant bears the onus of proof to present to the court reliable medical evidence that would enable the court to reach a decision. The courts have ruled for and against many plaintiffs throughout the years, setting the standards and yardsticks for the requirements of medical negligence.

The value or lack thereof of the medical evidence presented came under the magnifying glass in the case of *Michael vs Linksfield Park Clinic (Pty) Ltd 2001 (3) SA 1188 SCA* and the court indicated the necessity for a “collective mind” from the medical profession. Brilliant legal writers published on this topic and the search and need created this dissertation.

The study sets as goal to scrutinize the quality of medical evidence in general, and more specific the Michael-case. From a wide perspective medical evidence was researched, and the term evidence-based medicine led the study to an existing “collective mind” of the medical profession. The study investigated the history and development of evidence-based medicine in order to evaluate whether it can be seen as the “collective mind” of the medical profession. Satisfied that the “collective mind” was found the study tested the available medical evidence, randomly searched, against specific medical issues in the Michael-case and the study compiled substantial medical evidence to work with. An independent expert was consulted and the medical evidence was scrutinized with commentary, explanation and the basis formulated for negligence. The Michael-case was deconstructed and subsequently reconstructed, and the outcome predictably different, based on sound medical evidence.

The study explained and warned against exploitation of the statistical data and incorrect interpretation of results.

The study concluded that the court as the ultimate trier of the facts should determine whether the medical evidence presented to the court forms part of the “collective mind”, and whether it complied with logical principles and reasoning prior to reaching a decision.

General notes:

1. Wikipedia and e-medicine was used as first search and easy reference and not for court purposes or proper reference;
2. Note that the dissertation has a legal component and medical component and the references in the Bibliography is split under legal and medical references;
3. Note all the chapter regarding the Michael-case reference to:
epinephrine=adrenaline; nor-epinephrine=nor-adrenaline; propranolol=propranolol
(American spelling versus the English spelling, both accepted in South Africa);
4. The spelling of nomenclature like anaesthetist versus anesthetist, gynaecologist versus gynecologist; paediatrist versus pediatricist etc are used inconsistently as it is once again the American spelling versus the British spelling, which are accepted in South Africa.

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CHAPTER 1

PURPOSE AND REASON FOR STUDY

1. Introduction

This chapter serves to give an overview of the purpose and reason of the dissertation. It analyzes expert evidence presented in court, in medical negligence matters, and hopes to set a standard of evidence-based medicine as opposed to the opinion-based evidence of the past.

Three themes can be identified throughout the study, the first is a comparative study of the role of the medical expert in court and how it developed over the years in the United States of America and the Commonwealth Countries, which includes South Africa. It is to be noted that this comparison is not a detailed comparison but merely an illustrative comparison in order to show the impact of opinion-based evidence on the legal systems.¹ The second theme is a scrutiny of the medical evidence presented to court in conjunction with an argument to show that the “collective mind” of the medical expert that seemed to have evaded the courts for so long should be found in scientific arguments based on evidence-based medicine. The last theme is an attempt to prepare the courts against incorrect use of statistical-data obtained from evidence-based medicine, and to refrain from confusing probable cause with the sterile statistical arguments of probability in mathematics.

Medical negligence matters have always been a challenge for lawyers due to the intricate aspects of the anatomy and physiology only known to the medically qualified. The courts have to rely on medical experts to explain the field of medicine in order for the court to come to a decision.

¹ Carstens PA & Pearmain DL *Foundational Principles of South African Medical Law* (2007) p 604 for a detailed summary of the relevant source referencing in context of professional negligence worth mentioning. Giesen D, *International Medical Malpractice Law* (1988) is a study displaying a thorough and comprehensive work comparing medical malpractice between countries but also between the common law and civil law systems

To adjudicate issues not clearly understood by judges have lead to unexpected rulings and a feeling of injustice in the medico-legal environment specifically the claimant or Plaintiff's side, and amongst the general public. Uncomplicated surgical procedures resulting in severe adverse outcomes but ruled in favour of the doctor attracted criticism towards the judiciary and cynicism amongst the public, reflecting a perception of injustice, or maybe justice not correctly understood.

This study attempts to explain medical negligence as seen against the formal legal principles, how the aspects of medical negligence have developed and what the general test for negligence is as described and used in courts. It will explain the role of the medical expert in the test for negligence and how the courts see the medical experts as a yardstick to provide a standard of care. The study ultimately will show the adverse outcomes as a result of opinion based medicine in the place of science based medicine.

In summary the core of the study is that *the ultimate decision-making lies with the court*. Every medical expert should guard against subjective opinion. Their ultimate role is to assist the court to come to a fair and just decision even if that is contrary to medical opinion. The hypothesis used by the courts and the consequential opinion of the expert should be based on trusted scientific resources that can be tested in court. The court is not bound by expert opinion.

1.1 Implications of decisions of courts

The *stare decisis* principle, the way that common law developed, is an accumulation of precedents binding outcomes, future outcomes and all decisions.

Carstens and Pearmain² reiterate that “[i]t is settled law that a Court can only depart from the previous decisions of a Court of equivalent status in the same area of jurisdiction where it is satisfied that that the previous decision is ‘clearly wrong’”. This

² Carstens and Pearmain p 567

principle was re-affirmed by the honourable Judge Cloete in *Shabalala v Attorney-General, Transvaal, Gumede v Attorney-General, Transvaal*³

These precedents, set by higher courts are followed by the lower courts and courts of similar status and an “unfair” decision taken in 1924⁴, *Van Wyk v Lewis*, can literary cascade into future standards for medical negligence and malpractice matters, impacting severely onto lives of the injured and trusting public.

In the *Van Wyk v Lewis* matter, mentioned above, a physician and surgeon had to perform an emergency operation for an acute appendicitis. After opening the abdomen they discovered that the gall bladder was also affected with signs of necrosis on the surface of the gall bladder.⁵ The widespread sepsis resulted into a complicated surgical process with the surgeon attempting to drain the gallbladder.⁶ When the incision was made to insert the tube there was a rush of septic matter and the friability of the gallbladder made it difficult for the surgeon to close the gallbladder.⁷ The surgeon had to pack the different areas⁸ to create a clear field for the operation. The swabs were counted to the satisfaction of the sister and abdomen closed. Apparently some time later the patient evacuated a small piece of muslin (swab) and refused to pay the surgeon. An action for damages entered into between the patient and the surgeon turned out in favour of the doctor, as the court was of the opinion that the doctor delegated the task of swab-counting to the sister, and she failed to do so.⁹ The courts however set the standard of care for negligence.¹⁰

³ Carstens and Pearmain p 567 and *Shabalala v Attorney General Transvaal* 1995(1) SA 608

⁴ *Van Wyk v Lewis* (1924) AD, and for a detailed discussion of this matter see Carstens and Pearmain p 796

⁵ It is suggested that the patient already had a perforated appendix at this stage with peritonitis (inflammation of the intestines) spread throughout the abdominal cavity.

⁶ Note that during 1924 it was not yet well known that the gallbladder can be excised, and maybe the reason why the surgeon only drained it. The first removal of the gallbladder was performed in Europe during 1882 by a certain Johan August Langenbuch. Turner Gray *History of gall-bladder surgery* (1939) The British Medical Journal p 464-465

⁷ The duct from the liver, *ductus hepaticus* connects with the duct from the gall-bladder called the *ductus cysticus* and forms a common bile duct that enters the duodenum. Meyer BJ, *Die Fisiologiese Basis van Geneeskunde* (1976) p 54.10

⁸ It is suggested that the surgeon blocked the duct with a swab to have a clear operating field and failed to remove it afterwards, thereby putting the swab into the duct that feeds the duodenum.

⁹ Why the patient's legal team did not join the sister to the action is not known. Why the anatomy and physiology was not explained to the court is also not known.

¹⁰ See Chapter 2 paragraph 2.2 for the test

1.2 The medical expert as the yardstick against which negligence is measured

Medical evidence presented in court is the yardstick or test against which the court would measure the level of care, skill and diligence of the defendant medical practitioner. If the Court finds the defendant doctor to fail the test¹¹ set by his/her peers the defendant would be liable for damages.

Over the years, certain tests were set, followed, changed, defined and re-defined by the courts as to what constitutes “negligence”. Standards were defined to create legal certainty and the scene was set for what is “reasonable”, in other words, the standard of care¹².

1.3 Medical bias

It is well described and known amongst scientists in the medical field to guard against being subjective and selective in their findings and conclusions. The value that any medical scientist puts to experiments depends heavily on the way the clinical trials were controlled and run¹³. It is well documented that aspects that might interfere with the objectivity of the readings and conclusions of the medical scientist should be documented in sufficient detail in order for the peers to rely on the outcomes of these scientific trials, knowing and appreciating that there might have been additional variants that could have influenced the study. They would then be in a position to judge for themselves the reliability and value of the conclusions in the research.¹⁴ Thus medical scientific principles take care of medical bias, why not apply the same principles in law? Medico-legal expert-opinions based on biased conclusions have the effect that the tested aspects become worthless as it only reflects the subjective opinion of the expert or scientists who favour a specific outcome.

¹¹ Chapter 2 paragraph 2.2

¹² Chapters 2, 3 and 4 provides a detailed overview of the standard of care

¹³ Chapter 5 explains medical scientific studies

¹⁴ This is effectively testing scientific studies that are to be used in court

1.4 Is the yardstick reliable?

As mentioned above, an opinion-based report of the medical expert which favour a specific outcome, does no justice to either medicine or the law. In this regard the question arises: Is the definition of the role of the expert, the boundaries and limitations of the expert's testimony, and the truthful place of the own opinion of the expert enough to assist the court? How can the court test the testimony of the medical expert and put a value to each testimony, in order for the court to be in a position to jealously guard against the medical expert usurping the role of the court?¹⁵ These questions challenged the judiciary in several countries and these questions were addressed by the different courts as the presiding officers became more and more concerned about the unreliable medical expert, who sings the tune of the person paying for his services.¹⁶

It will be shown that the above challenges, more specifically addressed in common law countries like the United States of America, Canada and England are the research base for this study. The study will suggest several solutions, as the concerns raised throughout are a real threat to the independence of the judiciary.

The study will discuss the British Broadcasting Corporation in England, more specifically Professor Meadow's saga, reported by Claire Herald, who wrote that "a General Medical Council hearing has struck Professor Sir Roy Meadow off the register after finding him guilty of giving erroneous and misleading evidence in the Sally Clark case. So what does the future hold for expert witnesses? Why did the court not guide against bias? Why was the evidence not verified?"¹⁷

The study will discuss how the United States of America warns that the courts seemed to fail when guarding against bias and when the scientific basis for any expert's opinion

¹⁵ *R v Stockwell* (1993) 9 CAR 260 **and** for a detailed comparative study of the exclusionary rules also see Meintjies van der Walt L A few plain rules? A comparative perspective on exclusionary rules of expert evidence in *South Africa* (2001) (64) THRHR p 236-256

¹⁶ See Chapters 2,3 and 4 how this problem developed and was addressed

¹⁷ Chapter 2 deals with the developments to contain medical bias in England

is scrutinized. The study will look at the *Frye v United States*¹⁸ matter where a rule was established that state that “the subject matter of expert testimony be of a type generally accepted within its recognized professional sphere, and it especially applies to scientific evidence.”

The study will look at Rossi¹⁹, in the United States of America, who maintains that traditional evidence doctrine comes in four parts. First the doctor should state his/her qualifications. Secondly the doctor should give a foundation for his/her opinion, namely why he/she is relying on the X-ray evaluation, EEG results, history of unconsciousness, seizures, and other facts that support the opinion. The third and most important requirement would be that all the facts underlying the opinion actually be in evidence. The court would understand what data the expert was relying on and, since the data was before the court, it could assess its value, and evaluate the expert’s conclusion. After the facts supporting the expert’s opinion was proved, then comes the fourth step, namely the opinion, expressed in words of reasonable probability or certainty.²⁰

It will be shown, that this study supports the viewpoint of Rossi²¹ as it seemed that he stumbled on the solution and aimed to bring science to the court for the judiciary to understand the basis of and the reasoning behind any expert opinion in order to decide the matter.

The study will show that the English courts influenced South African courts with the dicta of Lord Browne-Wilkinson in the *Bolitho v City and Hackney Health Authority*²² saying that “[T]he court is not bound to absolve a defendant from liability for allegedly negligent medical treatment or diagnosis just because evidence of expert opinion, albeit genuinely held, is that the treatment or diagnosis in issue accorded with sound medical practice.” If the court found that the basis of and the reasoning behind the expert evidence provided, is not based on sound scientific principles then the court can take cognizance of expert opinion, however, and decide what is fair and just in accordance with common law

¹⁸ *Frye v United States* 293 F.1013 (D.C.Cir.1923) **and** see Faust F Rossi *Expert witnesses* (1991) p 27 for a discussion

¹⁹ Faust F Rossi p 5

²⁰ Faust F Rossi p 27-30

²¹ Faust F Rossi p 28-30

²² *Bolitho v City and Hackney Health Authority* (1998) AC 232 (HL) **and** Carstens and Pearmain p 788

principles. It will be shown that it is for the court to determine the “soundness” of medical evidence in practice as that should be based on sound scientific principles and above all in accordance with the Constitution²³ of South Africa. Patient rights like the right to dignity and bodily integrity is a basic right based on sound principles which should be of a high standard of professional ethics, accountability and responsiveness to the needs of the public, and should be impartial, fair and just.²⁴

1.5 Basis for expert opinion

The basis for the expert opinion is the scientific background, research and all published studies on which the medical expert has to rely in order to get to the conclusion in his expert opinion. During the presentation of the scientific basis the court should play an active role and should participate. If the principles of physiology and anatomy and even the cause of the disease and/or injury and/or illness do not support the medical opinion of the expert, then the opinion is irrelevant individualistic and not an opinion based on a collective sound scientific medical principles. The science basis should be gathered from medical research studies and scientific data, namely evidence based medicine, and should be challenged by the court, if it is not based on logical principles. From this background the thesis statement was derived.

2. The thesis and thesis statement

Does evidence based medicine banish *ipse dixit* and reclaim the power of the legal decision-makers in medical negligence matters?

2.1 The purpose of the study

The purpose of the study is to show that science, as basis for a medical expert’s testimony, should only be used to advise the court regarding the scientific intricacies of

²³ Act 108, 1996.

²⁴ *Van Huyssteen and Others NNO v Minister of Environmental Affairs and Tourism and Others* 1996(1) SA 283(C) at 305D (SA)

the medical question at hand. In other words, the medical expert must explain and illustrate the level and the research done in a specific field. The expert should point out to the court the value that can be attached to the tested research material done in that field, the reliability of the research material and whether these studies were tested amongst the scientific peer group by way of publishing it in reliable recognized medical journals open for comments. The expert should show to the court what trusted methods of reporting were used as well as indicate the different international medical viewpoints and schools of thought. Finally, the expert who decides to base his/her opinion on statistical data should show to the court that the statistical data and principles relied upon, was taken from a study/target group of people similar to the issue at hand in court.²⁵

Once the experts have discussed these and put all the above material before the court, only then would the court be inclined to request an expert to express his personal opinion regarding the best available evidence in a specific field. Through these tested methods, there would be little room for opinion-based evidence that might mislead the court, and the courts will be in a position to decide on matters without allowing its role being overruled by the medical expert.

The above method of requesting from the experts to use evidence based medicine as suggested, would also put the courts in a better position to criticize/assess medical practice that seems *contra bonos mores*, and does not serve the public.

2.2 The test for the study

This study stands to test the reliability of the medical expert witness in the current legal system and more specifically medical negligence cases in South Africa, as to whether the medical expert is truthfully assisting the court to come to an unbiased, fair and just conclusion.

²⁵ Chapter 10 deals in great detail with the population for the study and the target group and how the inappropriate quotation of statistical data confuses the interpretation of medical action.

2.3 Limitations of the study

The focus of the study is limited to civil matters that are medical negligence cases, where the facts in dispute are in broad terms based on general medical practice, medical standards, medical protocols and medical principles based on scientific research. The study in context takes issue with the incorrect logic and reasoning of the criminal matter of the Sally Clarke-case to illustrate the fallacies derived at, based on incorrect reasoning in evidence presented to the court.

The study excludes criminal matters by reason of the decision by the honourable Judge Rumpff A, in the matter of *S v Mngomezulu*²⁶. The court found with regard to the mitigation circumstances, that evidence lead by a psychiatrist should have a basis or foundation for the opinion, and if such an opinion cannot be linked with facts before the court, the opinion became abstract with no value to the court. It should be noted that even if the basis or foundation for the opinion was done on known psychiatric or psychological principles, the science of human behavior is not exact, cannot be tested and seen as the norm, as even normal behavior is defined within a culture group or religious group, to note only a few.

Although the behavioral aspects of human nature is a science in its own right and the influence of psychological aspects on human behavior a major aspect that forms part of all criminal proceedings in the concept of "intent", these psychiatric and psychological aspects fall outside the scope of this study, and are therefore excluded.

It is further suggested that criminal matters that turned on scientific medical data, should be put before the court with a sound basis of evidence based medicine and logic and incorrect assumptions and probabilities should be treated with caution and should be tested based on sound reason and logic.

²⁶ 1972(1) SA 797 A: 798H-799A .In this matter the Judge had two Assessors and the accused was found guilty on a murder charge, and the death sentence was passed, the case was taken on appeal. The judge said "wanneer psigiatriese getuienis in verband staan met feite wat deur die Hof aanvaar is, volg dit nie noodwendig dat die Hof die psigiatriese opinie moet aanvaar nie. In die lig van getuienis in geheel is dit nog die taak van die Hof om te beoordeel of die psigiatriese of psigologiese getuienis self aanvaarbaar is of nie, maar sonder skakeling met feite wat voor die Hof gelê word, is psigiatriese en psigologiese opinie abstrakte teorie."

2.4 Brief chapter overviews

1. Chapter one, gives an overview of the dissertation, namely the reliance of the courts on medical experts, the problem with unreliable expert testimony, the influence on the public should this problem continue and the suggested solution, tested against a decision of the Court of Appeal.
2. Chapter two explains the South African approach of medical negligence, it explains the test for negligence and the standard of care provided by the medical experts, but ultimately sets the standard used by the courts to come to a fair and just decision.
3. Chapter three gives a brief overview of the position in a common law country namely the United States of America and gives an idea how they established expert rules to deal with similar unreliable expert witnesses.
4. Chapter four shows, in a brief overview, similar problems in English courts and another common law countries, Australia, and shows different rules of evidence and legal principles which are appreciated and followed in South Africa to obtain proper and reliable expert testimony.
5. Chapter five explains in two parts the broader principles of evidence based medicine and shows how it was tested amongst the medical scientific world, and the methodology followed by medical researchers, to arrive at a reliably trustworthy source document.
6. Chapter six addresses the aspects of medical and legal causation in order to determine the manner in which medical experts arrive at a conclusion and to show the manner the law brings cause and effect together.
7. Chapter seven reports the facts and the decision of the controversial matter of *Michael vs Linksfild Park Clinic (Pty) Ltd*.²⁷
8. Chapter eight takes a re-look at the facts in the *Michael vs Linksfild Park Clinic (Pty) Ltd* case and the medical information that should have been presented to the court and that was omitted.

²⁷ *Michael v Linksfild Park Clinic (Pty) Ltd* 2001 (3) SA 1188 SCA

9. Chapter nine shows the reconstruction of the *Michael vs Linksfield Park Clinic (Pty) Ltd* claim based on proper medical evidence and shows that had this information been put before the court with the proper allegations based on sound scientific medical evidence, the outcome should have been in favour of the plaintiffs.
10. Chapter ten appraises statistical data principles and explains by way of examples how the use of incorrect quotations of statistical data by the medical expert departing from sound interpretation principles can arrive at bizarre decisions that are not sound in law, and not serving the public.
11. Chapter eleven is a summary of the recommendations and conclusions arrived at throughout the study.

CHAPTER 2

OVERVIEW OF THE DEVELOPMENT OF MEDICAL NEGLIGENCE IN SOUTH AFRICA

1. Introduction

This chapter does not serve to address the detailed requirements needed in medical negligence cases, however only intends to look at how the criteria developed over the years, and what criteria the courts apply regarding the test for negligence against the evidence presented. It should be noted that the development took place across the spectrum of civil and criminal matters. The purpose of this chapter is not to be comprehensive, merely to illustrate the development. The emphasis is on the *evidence presented* and what is expected from the medical expert to satisfy the court that the defendant-doctor acted not in accordance with his duty to care and therefore in a negligent manner. The ensuing paragraphs will show a slow developing standard of care as expected from the medical profession and applied by the courts. It will also show a need for a “collective mind” from the medical profession, a united approach, that can assist the court in order for the court to determine whether the act or omission of the offending doctor falls within the parameters of the set standard or not.

The study’s ultimate goal is to illustrate, with the background of medical negligence principles obtained from a rich history²⁸ from across the globe, that a court can be misled with incorrect medical evidence presented. The detailed analysis and practical study of the Michael-case²⁹ will demonstrate the evidence that needed for the court to understand the intricate workings of medicine in action.

This study demonstrates the need for an overview of other jurisdictions due to the fact that in the Michael-case,³⁰ the assessment of the evidence in the medical negligence case, in the Supreme Court of Appeal’s decision relied exclusively on analogous English

²⁸ Chapter 2,3,4 address the common law development throughout the world

²⁹ *Michael v Linkfield Park Clinic (Pty) Ltd* 2001(3)SA1188(SCA) a detailed analysis follows in chapter 7,8,9

³⁰ See footnote 29 *infra*

authority in the decision of the House of Lords in *Balitho v City and Hackney Health Authority*.³¹

The study will discuss certain cases and legislation regarding medical negligence aspects in the United States of America and England.

2. Background

The statement that the South African legal system is under strong influence of English Law³², is most probably an understatement,³³ however a statement useful to describe the influence of the English courts on the different tests that can be noted in the following paragraphs. Bear in mind that English law together with Roman law and later Roman-Dutch law forms the root of South African common law.³⁴

2.1 The reasonable man-test

In the South African Courts, in a criminal matter, *R v Meiring*³⁵, it was found that “[the] standard of care and skill which would be observed by the reasonable man”, that standard was the test for ordinary negligence. It was confirmed in the *S v Van As*³⁶ case where it was established that an amount of foreseeability was also required. The foreseeability aspect was also conformed in private law,³⁷ and further requirement was needed, the offender had to foresee the general possibility of damages and ought to have omitted or neglected to take steps to prevent any harm or injury, prior to finding another liable for damages.

³¹ 1998 AC 232 (HL) [E], Carstens PA and Pearmain DL, *Foundational Principles of South African medical law* (2007) p 669 footnote 309 on p 699

³² Izette Knoetze 'n Regsvergelykende studie van deskundige getuienis in straf- en siviele verhoore (2007) LLD verhandeling Universiteit Oranje Vrystaat, P7

³³ Giesen D, *International Medical Malpractice Law* (1988) is a study displaying a thorough and comprehensive work comparing medical malpractice between countries but also between the common law and civil law systems; Carstens & Pearman p 605 for a detailed summary of the relevant source referencing in context of professional negligence that is worth mentioning.

³⁴ See Chapter 4 for more on English common law.

³⁵ 1927 AD 41 46; Claassen NJB and Verschoor T, *Medical Negligence in South Africa*(1992) p 6

³⁶ *Van As* 1976 (2) SA 921 A 929

³⁷ Claassen and Verschoor p 6

In *Kruger v Coetzee*³⁸, the Appeal Court narrowed the test for negligence to a simple line of thought, that a diligent *paterfamilias* would foresee that his actions might cause harm to another and would take steps to avoid that, and if he failed to do so when, the reasonable man would have done so, he would be liable.³⁹

The next step for the Court was to describe a diligent *paterfamilias*. As the diversity of a population would influence the test of the “reasonable” man, Holmes A J in *S v Burger*⁴⁰ describes the reasonable man as follows: “One does not expect of a *diligens paterfamilias* any extremes such as Solomonic wisdom, prophetic foresight, chameleonic caution, headlong haste, nervous timidity, or the trained reflexes of a racing driver. In short, a *diligens paterfamilias* treads life’s pathway with moderation and prudent common sense.”

2.2 The reasonable doctor-test

In civil law the test for medical negligence was described in 1924, with the leading case of *Van Wyk v Lewis*⁴¹ where the Court decided that a medical practitioner does not need to have “ the highest possible degree of professional skill, but he is bound to employ reasonable skill and care,” and Wessels AJ re-affirmed that “We must place ourselves as nearly as possible in the exact position in which the surgeon found himself when he conducted the particular operation, and we must then determine from all the circumstances, whether he acted with reasonable care or negligence.”⁴²

2.3 Reasonable skill of a specific field determined by peers

Claassen and Verschoor showed the reasonable skill expected by the patient from the doctor was narrowed to indicate that “the physician will reasonably acquaint himself with developments in medicine.”⁴³ They went as far as to say “If a physician fails to employ a

³⁸ 1966 (2) SA 428 (A) 430

³⁹ Claassen and Verschoor p 7

⁴⁰ 1975(4)SA 877 (A); Claassen and Verschoor p 7

⁴¹ 1924 AD 438 444; Claassen and Verschoor p 9

⁴² 1924 AD 461; Claassen and Verschoor p 14

⁴³ Claassen and Verschoor p 16; Straus SA & Strydom MJ, *Die Suid-Afrikaanse geneeskundige reg* (1967)

recently developed but widely acknowledged method of treatment and his patient is prejudiced by the outdated method used by him then the physician can be held liable for the consequences.”⁴⁴

2.4 The Court determines the standard of care based on a potential collective agreement of the experts (peers)

The situation arose where the Court, having no expertise in medicine still has to assess medical matters. Expert evidence submitted, had to be weighed and assessed for its correctness, in order to find the facts. However, the conclusion that followed had to be an independent decision arrived at by the Courts, without undue influence by the medical experts.

The practical application thereof was to find a way to allow the medical experts not “to lead” or direct the Court so to speak, but to assist the Court to decide on the matter. Information should be presented to the Court by medical experts in such a manner for the Court to understand the principles and reasoning behind the opinion of the medical expert.

Carstens and Pearmain⁴⁵ explain that this difficult situation is even more problematic “where medical experts who are called upon to testify on behalf of a plaintiff or the defendant medical practitioner in a medical negligence action have conflicting opinions or represent different but acceptable schools of thought in medical malpractice.” The Courts are the ultimate decision-maker and should be put in a position to test the actions of the offending medical practitioner against the standard of care set by its

p 267 where the authors point out that the meaning of “reasonable “ will depend mainly on prevailing views in the medical profession at the time in question

⁴⁴ Claassen and Verschoor p 16; Giesen D & Fahrenhorst I, *Civil liability arising from medical care - Principles and trends - International Legal Practitioner* (1984) 9 (3):82; Shartel B & Plant ML, *The law of medical malpractice* (1959) Charles C Thomas p 117

⁴⁵ Carstens and Pearmain p 861; listed by Carstens and Pearmain in *Webb v Isaac* p 273; *Coppen v Impey* p 309; *Pringle v Administrator Tvl* p 379; *Castell v De Greef* (1994) 4091; Barlow 1948 THRHR p 178; Carstens PA, *Nalatigheid en verskillende gedagterigtings binne die mediese praktyk* (1991) THRHR p 673; Strauss SA, *Doctor, Patient and the Law: A selection of Practical Issues* (1991) p 122; Claassen en Verschoor p 26; Van Oosten FFW, *Medical Law-South Africa in International Encyclopedia* (1996) para 89; Strauss SA, *Medical Law-South Africa in International Encyclopedia of Laws* (2006) para 79

previous decisions, and influenced by the standard set down by the medical practitioners' peers, and teachers.

According to Martin⁴⁶ “[Evidence of] accepted practices or customs cannot be used for the creation of a legal standard as this would mean that a profession compiles its own standards of reasonable care.” It would be admissible only to assist the Court to test whether the offending medical practitioner acted as a reasonable careful man in similar circumstances and whether reasonable care had been exercised.

Accepted practice or custom is only relevant in ascertaining the standard of care as it reflects the existing state of knowledge [of the peers] as well as what is regarded as proper, but there are limitations to the Court's acceptance thereof. The Court may judge certain practices as unreasonable and may find that precautions exist which are so essential that even their universal disregard would not excuse their omission.”⁴⁷

In South Africa, in 1924 the Court of Appeal, in *Van Wyk v Lewis*,⁴⁸ Chief Justice Innes explicitly states that: “The testimony of experienced members of the profession is of the greatest value in questions of this kind. But the decision of what is reasonable under the circumstances is for the Court; it will pay high regard to the views of the profession, but it is not bound to adopt them.”

Carstens and Pearmain⁴⁹ are of the opinion that “[T]he primary function of the medical expert is to guide the Court to a correct decision on questions falling within the expert's specialised field”.

⁴⁶ Martin CRA, *Law relating to medical practice* (1979) p 366; Claassen and Verschoor p 27

⁴⁷ See footnote 40 and Martin p 366

⁴⁸ Claassen and Verschoor p 27; *Van Wyk v Lewis* 1924 AD: 447-448

⁴⁹ Carstens & Pearmain p 860, 861; and quote also Hoffman LH and Zeffert DT, *The South African Law of evidence* (1992) p 97; Schmidt CWH and Rademeyer H, *Bewysreg* (2000) p 463; *S v Gouws* 1967 (4) SA 527 (E)

2.5 The Court sets boundaries for medical experts

The Supreme Court of Appeal, “in *Michael vs. Linksfield Park Clinic (Pty) Ltd*⁵⁰ had the opportunity to authoritatively enunciate the general applicable considerations in assessing expert medical evidence.”

Carstens and Pearmain⁵¹ summarized it as follows:

1. the Court itself would determine whether the defendant’s conduct was reasonable or negligent on the basis of expert evidence presented to the Court, and that is not an opinion of the expert
2. the credibility of the expert would not form part of the considerations of the Court, rather an examination of the opinions of the experts, and an analysis of the essential reasoning, preparatory to the Court reaching its own conclusion
3. with professional negligence the governing test is the standard of conduct of the reasonable practitioner, in a particular field, however not always helpful to the Court
4. of importance is to find out the logical reasoning behind the expert’s opinions during the evaluation of the expert evidence
5. the Court is not bound by the evidence presented by the experts, albeit genuinely held, but looks whether the conduct in issue was in accordance with sound practice
6. the Court should satisfy itself that such an opinion had a logical basis, that the expert considered comparative risks and benefits, and should it be found that a body of experts overlooked a considerable risk, that could have been guarded against, that would be seen as not reasonable even if the universal conclusion did not reflect this opinion
7. a defendant can be held liable despite the support of a body of experts’ opinions to the contrary, if that opinion cannot withstand logical analysis and reasoning
8. assessment of medical risks and benefits is a matter of clinical judgment which the Court would normally make with the assistance of a medical expert, but it would be

⁵⁰ Carstens and Pearmain p 861,862; *Michael v Linksfield Pty Ltd* 2001 (3) SA1188 (SCA) p 784

⁵¹ Carstens and Pearmain p 862; *Michael v Linksfield-* case

wrong to decide a case on simple preference, where conflicting views exist, both with logical reasoning

9. only where expert opinion cannot be logically supported, would the experts have failed to provide a yardstick to measure the conduct of the defendant against
10. finally, it must be remembered that the medical expert, as scientist, is used to assess the likelihood of the events against a scientific certainty, and not weighing the balance of probability of the most likely cause of events.

The Court set this standard, based on a “decision of the House of Lords” in the medical negligence case of *Bolitho v City and Hackney Health Authority*,⁵² where it was held, that a Court is not bound to accept medical expert opinion just because evidence is led by an expert in the field, if that treatment or diagnosis, in issue, is not in accordance with sound medical practice. “The Court must be satisfied that such opinion has a logical basis, in other words that the expert has considered comparative risks and benefits and has reached a ‘defensible conclusion’.”⁵³

2.6 The boundaries are not without problems

In the “*Scientific Method: The Crucible for reliable and valid expert evidence?*”,⁵⁴ Meintjes-van der Walt expresses her concern by saying that “[L]ack of special tutoring in different fields of expert evidence may lead to judges placing undue reliance on the mere ‘*ipse dixit*’⁵⁵ of the expert or to judges relying unrealistically on the qualifications or experience of the expert or inadvertently overestimating either the value of cross-examination or the lack thereof.” Meintjes-van der Walt⁵⁶ succeeds in describing an analytical method to assess and evaluate scientific evidence. Meintjes-van der Walt⁵⁷ proposes Whitney’s summary of guidelines as a general guide relevant to the evaluation

⁵² *Bolitho v City and Hackney Health Authority* [1998] AC 232 (HL); Carstens and Pearmain p 788

⁵³ *Bolitho v City and Hackney Health Authority* 1998 AC 232 (HCL); Carstens and Pearmain p 862

⁵⁴ Van der Walt LM *Scientific Method: The Crucible for reliable and valid expert evidence?* (2006) (2) *Speculum Iuris* p 177

⁵⁵ Van der Walt p 177, she quotes Saks M, *Banishing Ipse Dixit: The effect of Kumho Tire on Forensic Identification Science* (2000) Washington and Lee LR 879

⁵⁶ Van der Walt p 201

⁵⁷ Van der Walt p 201; Whitney R A *Practical Lawyer’s Guide to the application of Daubert and Kumho* American Journal of Trial Advocacy (1999) 252-253.

of expert evidence. Whitney mentioned the following should be put to the expert:

- that a precise explanation of each step in the expert's reasoning, methodology, or application of principles leading up to each conclusion be given,
- the factual basis and assumptions used by the expert,
- the sources of fact basis or assumptions,
- the reasoning that lead to the conclusion and opinion.

3. Conclusion

It should be noted that there is a difference between the onus of proof, to establish liability in a civil matter as opposed to the onus of proof that the public prosecutor has to discharge in a criminal matter. In a civil case the weight of evidence that the court must assess in order to determine liability is balanced on a 50/50 scale and the preponderance of the probabilities sways the court to its decision. In a criminal matter the weight of the evidence before the court should allow the court to come to a conclusion beyond reasonable doubt.⁵⁸

In this study and additional to the development throughout the years, the plea is for strict scrutiny of the expert evidence by the Courts. The legal boundaries are in place but the boundaries to evaluate medical expert opinion *per se* might become individualistic and with a unilateral approach that is lacking in the necessary scientific principles.

It is submitted, as can be seen in the chapters to follow that the aim of any evidence before the court should always be to assist the court to come to a proper conclusion, in its function as the ultimate ruling body. The evidence should be critically evaluated by the court for adequacy and should be relevant to the underlying scientific foundation and medical question before the Court. A careful explanation and understanding of the reasoning process behind the foundation established by the expert should be requested by the court. The reasoning process used by the expert should be weighed against common law principles, and finally, the conclusion should be justified, taking all aspects

⁵⁸ Carstens & Pearmain p 855 offer a thorough explanation with a comprehensive list of references regarding the development of this concept in medical negligence.

into consideration. An assessment should be undertaken by the Court to evaluate the medical data for scientific accuracy, the accuracy of the expert opinion in light of the existing scientific literature and the process. After the process of scrutinizing the evidence presented by the expert, had been done, only then will the legal process be initiated with the criteria discussed in this chapter.

With the medical evidence clarified, the court would be in a position to progress through the different tests for negligence, and will apply it in order to determine liability and negligence.

The following chapters will address in broader terms and for the sake of clarity only the different approaches in the United States of America and England to illustrate how far from the scientific principles a court can wander if the role of the expert is not defined.

CHAPTER 3

DEVELOPMENTS IN THE UNITED STATES OF AMERICA REGARDING EXPERT EVIDENCE

1. Introduction

In an attempt to understand expert evidence and in an attempt to prevent expert bias this chapter analyzes the difficulties experienced in the American jurisdictions, and why these courts prescribed rules to guard against expert bias. It should be borne in mind that this study does not intend to be a comprehensive study⁵⁹ or detailed comparison between American and South African law but merely to provide background regarding similar difficulties experienced in courts.

2. Background

The United States of America is a common law country, as their traditional law is based on the British statutes and the unwritten law (common law) of England which were used before the United States of America was founded. In all states except Louisiana (which is based on the French civil code) the common law of England was adopted as the general law of the state.⁶⁰

During the 1800's, a deep rooted suspicion surrounding the reliability of the medical experts was the underlying force for the enactment of the Federal Evidence Rules 702 to 705⁶¹ in the United States of America. This was called for as lay jury members were exposed to experts that sounded good, looked good and acted well on the witness-stand, in extremely complicated matters, and then "voted" for or against the plaintiff or accused, for all the wrong reasons. It was obvious that the personality of the expert

⁵⁹ Giesen D, *International Medical Malpractice Law* and footnote 2 under chapter 2 *supra*, for a comprehensive study

⁶⁰ See discussion about common law in Chapter 3 footnote 1

⁶¹ Faust F Rossi *Expert witnesses* (1991) p 10

played a substantial role in convincing the jury. It seemed an unhealthy situation that was not based on sound legal principles or scientific principles.

Rossi⁶² stated: “How can they be expected to resolve a dispute on complicated issues among experts who take conflicting positions? How much screening should the judge do to keep unreliable expertise from the jury?”

3.1 Unreliable experts

In the United States of America, the Federal Evidence Rule 702 states: “If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.” So it is clear that the evidence presented to the court should be assisting the court to understand the complicated intricacies of the evidence presented in a specific field of interest, in order for the court to come to a conclusion based on sound factual or scientific principles.

In the Frye-case⁶³, the court sets certain standards in the United States of America by rejecting evidence of a lie detector test on the basis that it is novel scientific evidence brought before court and not seen as the “general accepted standard.”⁶⁴ The court set the limitation and inferred that scientific evidence is inadmissible unless “its underlying theory or methodology had achieved general acceptance in the appropriate scientific community.”⁶⁵ It seems that despite these cautionary measures and specific rules put in place by the court in order to reduce the interference with the judiciary, the medical experts were still in a powerful position to influence the jury.

This study supports the initial methodology suggested by Faust F Rossi, namely, to have the court understand and appreciate the underlying scientific basis and principles of medical evidence presented to court prior to forming a legal conclusion. However to

⁶² Faust F Rossi p 10

⁶³ *Frye v United States* 293 F 1013 (D.C. Cir.1923) also see Chapter 1

⁶⁴ Faust F Rossi p 27

⁶⁵ Faust F Rossi p 28

determine the true depth of this statement, this study has to take an in-depth look into the original rules known.

These rules were summarized as being:

- 1) the common knowledge rule, where no expert should testify on issues known as common knowledge, or known to the ordinary person;
- 2) the field of expertise rule where the expert testifies in the field of which their expertise falls, and in the field where they acquired a degree of expertise;
- 3) the ultimate issue rule, where it is commonly stated that the witness may not be asked to testify about a matter which is an ultimate issue, i.e. whether the accused is to be found guilty or the defendant is to be seen as negligent;
- 4) the basis rule where the basis for the expert testimony should be shown to the court and made clear to the court.

The ultimate issue rule was abolished by statute in some jurisdictions of the United States and Canada, but partially introduced for certain kinds of testimony by mental health professionals.^{66 67} These jurisdictions have decided on a method where the more sensible approach is to determine what is fact and science, and what is opinion and theory, and instead of protecting the jurors from biased experts, establish the nature of the disagreements between the medical experts and assist the jurors to understand the impact of this.⁶⁸

During October 1984, Congress⁶⁹ of the United States of America amended Rule 704 with the Insanity Defense Reform Act by saying that no expert shall testify whether a defendant did or did not have the mental state or condition or any element of the crime charged as such ultimate issues are matters for the trier of fact alone.

It seems that the reason for this amendment was to eliminate competing witnesses, and to clear the courts of quasi-scientific experts that are good performers, who sway the

⁶⁶ Rule 704(a) United States Federal Rules of Evidence and section 69 of the Canadian Evidence Code.

⁶⁷Rule 704 (b) of the United States Federal Rules of Evidence

⁶⁸ Freckelton IR, *The trial of the expert: a study of expert evidence and forensic experts* (1987) p 77

⁶⁹ In Public Law 98-473, 98 Stat.2067

courts to their personal opinion, without supporting that opinion with sound factual or scientific principles.

3.2 Introduction of the scientific method as standard for expert evidence

The United States Supreme Court decision in *Daubert v Merrell Dow Pharmaceuticals Inc*⁷⁰, introduced the scientific methodology as the standard for evaluating the expert evidence. The court directed the trial courts to consider the following factors:

1. whether the scientific theory or technique has been empirically tested;
2. whether the scientific theory or technique has been subjected to peer review and publication;
3. whether the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation have been established and
4. whether a technique has gained general acceptance within the scientific community.

Meintjes-van der Walt⁷¹ assesses the *Daubert* criteria as follows and makes out an argument for the acceptance in South African law:

- (a) Testability: One of the fundamental principles of a scientific theory is that it must be possible to prove that a proposition is wrong if indeed it is not true. Testing entails the recording of data. All concepts should be meaningful and capable of measurement, which requires objective standards. An additional advantage is that it helps to overcome the effects of confirmation bias, a phenomenon whereby scientists tend to settle on a theory on the outset and thereafter tend to look for

⁷⁰ *Daubert v Merrell Dow Pharmaceuticals Inc* 509 US 579 113 Ct 2786 and 2795 (1993); Van der Walt LM, *Scientific method: the crucible for reliable and valid expert evidence* (2006) Vol 20 Issue 2 *Speculum Iurisi* p 186

⁷¹ Van der Walt, *Scientific Method* p 191, quotes Mahoney MJ, *Scientist as subject: the Psychological Imperative* (1976) p 155

data to confirm the theory, rather than trying to discredit or refute it. Any testimony that is not researched-based should clearly state the basis of the testimony⁷².

(b) Peer review and publication

Whether a theory or technique has been subject to peer review and publication is consideration in the *Daubert*-case⁷³ by the court as a ‘relevant, though not dispositive consideration in assessing the scientific validity’.⁷⁴ Meintjes-van der Walt, with reference to Relman and Angel⁷⁵ recognizes that “peer review is not and cannot be an objective scientific process, nor can it be relied on to guarantee the validity or honesty of scientific research, despite much uninformed opinion to the contrary”

(c) Rate of error and controlling standards

Meintjes-van der Walt with reference to Foster and Huber⁷⁶ indicates that an error effects the reliability of measurement and or validity, that leads to incorrect interpretation of the data. Results of a survey done in the USA showed that judges did not fully understand the meaning of “error rate” and often were unsure how to use the concept to assess the admissibility of proffered evidence⁷⁷. They omit to test the basis of the evidence for relevancy.

(d) General acceptance

Based on the *Daubert*-case,⁷⁸ the courts indicated that those most qualified to assess the general validity of a scientific method will have a determinative voice. The test is a two-step analysis, to identify the field in which the underlying principle falls; and to determine whether that principle has been generally accepted by

⁷² Ibid p 193

⁷³ *Daubert*- case p 594 also footnote 10

⁷⁴ Van der Walt, *Scientific Method* p 194

⁷⁵ Vander Walt, *Scientific Method* p 194, quotes Relman AS and Angel M, *How Good is Peer Review* (1989) New England Journal of Medicine p 827

⁷⁶ Van der Walt *Scientific Method* p194, quotes Foster and Huber *Judging Science* p 215

⁷⁷ Dobbin SA, *Applying Daubert: How Well do Judges Understand Science and Scientific Method*(2002) *Judicature* 244-247; See also Van der Walt, *Scientific Method* p 195

⁷⁸ *Daubert* – case p 3010

members of the identified field. The recognition and acceptance of a scientific technique or claim by the scientific community is an important indicator of its reliability. It was said that expert testimony based on “legitimate, pre- existing research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were derived by scientific method.”⁷⁹

3.3 Doubts

Faust F Rossi⁸⁰ (in American context) explains that there were doubts whether the adversarial system and its procedures are suitable for the task of handling expert witnesses, but more so of the trial judge’s discretion in handling issues of expert testimony. It is the function of the trial judge to deal with the issues whether the expert is suitably qualified, and whether the evidence lead will be “helpful” in terms of the rules of court. Faust F Rossi stated and quoted Prof Wigmore: “The trial judge’s discretion is necessarily broad for he sits in the arena of litigation. He knows from the pleadings the contentions of the parties, the direction which the case will take, and from his experience can predict, as the evidence unfolds before him, the problems with which the jury must wrestle. From his exposure to the peculiar circumstances of a particular case, he is best suited to answer Professor Wigmore’s determinative question: ‘On *this subject* can a jury from *this person* receive appreciable help?’”⁸¹

3.4 Requirements for expert evidence

It seems that besides an attempt to control the basis and content of the evidence presented in court, the American system stumbled across another problem. What evidence is needed for the jury to arrive at a sound, fair and just conclusion? Faust F Rossi attempted to formulate a list to define when evidence would assist the jury? The list was summarized as follows by Faust F Rossi⁸²:

⁷⁹ Van der Walt *Scientific Method* p 199

⁸⁰ Faust F Rossi p 97 quotes Wigmore HJ *Evidence* (1940) p 21 and Wigmore HJ *A treatise on the Anglo-American System of evidence in trials at Common Law* (1940) revised (1961)

⁸¹ Faust F Rossi p 97

⁸² Faust F Rossi p 97

- The subject matter put to the court had to be scientifically complex material “beyond the ken” of ordinary people.
- The subject matter had to have a reliable scientific basis, and the trial judge can determine whether that is so and declare it admissible evidence or not.
- The subject matter must assist the trier of fact. “If the expert’s opinion ‘will assist the trier of fact to understand the evidence or to determine a fact in issue,’ the subject matter is appropriate.”
- The subject matter must be “generally accepted within its recognized professional sphere, and it especially applies to scientific evidence.” This rule was created to shield jurors from the “undue influence of scientific evidence that has not achieved legitimacy.” It is not enough that a qualified expert, or several experts, testify on a subject that a specific technique is valid, it must be generally accepted within the scientific community.
- Testimony of an expert founded “entirely on personal observation is likely to be especially credible and persuasive. The treating physician, for example may take the stand and give an opinion based on facts that the doctor learned from personally examining the patient.”
- A hypothetical question is used as a common technique to ask the expert to assume the truth of certain aspects and then to give his opinion based on these assumptions.
- A further test of “reasonable reliance exists” where an expert is relying on certain facts that is non-evidence data, the court must determine whether the reliance was reasonable. This decision is for the trial judge to make and not the expert. However, it must be made on sufficient factual data, and not on hearsay evidence even if expressed in the specific field by another expert.

-The test for “evaluating the expert’s testimony [is seen] as one of legal sufficiency (“more likely than not”) rather than scientific sufficiency – a standard that approaches certainty.”

-The ultimate issue limitation where it is common “to prohibit the expert from testifying directly about the ultimate issue to be decided on the now discredited ground that such testimony would invade the province of the jury.”

The American courts were now ready to assist the jury by sifting the evidence presented and by ensuring that it deals with a complicated matter that is not known to the person in the street: it is based on a reliable source and generally accepted; it is relevant, reasonable and appropriate to the facts before the court; it distinguishes between a treating doctor and expert testimony; and any hypothetical question is used for technical reasons and not to draw a conclusion from the expert.

3.5 Alternative process

An alternative process used in medical malpractice matters in America to be mentioned is the Motion for Summary Judgment.⁸³ This American process is used as a pre-trial procedure. Rossi⁸⁴ explains the process by saying that “S[s]ummary judgment is proper when the moving party is able to show that there is no genuine issue of fact or, as is sometimes said, when the motion clearly shows that the movant would be entitled to a directed verdict if the case proceeded to trial. Federal Rule of Civil Procedure 56(e) provides further that affidavits ‘shall be made on personal knowledge [and] shall set forth such facts as would be admissible in evidence.’ It [sic] goes on to say that when a motion for summary judgment is made and supported under the Rule, an adverse party may not defeat summary judgment by mere allegations or denials but ‘must set forth specific facts showing that there is a genuine issue for trial.’”⁸⁵

⁸³ This process should be considered in South Africa as an option especially with *res ipsa loquitur* cases.

⁸⁴ Faust F Rossi p 129

⁸⁵ A process similar to that of our summary judgment applications that needs to be rebutted with a Notice of Opposition and a proper affidavit setting out the defense of the Respondent in such terms to satisfy the court that a *bona fide* defense exists.

The above process can be seen as a formal process allowing the pre-trial judge another opportunity to protect the jurors from biased experts, as the Motion for Summary Judgment is dealt with by the presiding judicial officer whose only duty is to determine whether the Respondent showed that he has a valid defense, and whether he has satisfied the court that he has a valid defense.

If the Respondent satisfied the court, the Motion would be denied and the case would proceed to trial. If the court sees the opposition of the motion as frivolous, and with no prospects of success on the papers of the Respondent, the Motion will succeed. This has the effect that the Respondent would have to seriously reconsider the fact whether he wants to proceed to trial, as the pre-trial process indicates that his chances of success is small and would be insufficient to convince the pre-trial judge.

3.6 Conclusion to alternative process

The pre-trial judge controls the process with little room for expert bias other than that allowed by the judicial officer. At trial, the trial judge scrutinizes the basis or foundation of all expert evidence, and with the assistance of the processes of courts and the Rules, guards against the jurors being influenced with unreliable expert evidence.

4. The precautionary rules against unreliable expert evidence did not extend as far as Federal Government

Despite the strict court rules to protect the public and to keep the courts independent, some serious malpractice incidents slipped through the watchful eye of the US Food and Drug Administration Center for Devices and Radiological Health, Division Small Manufacturers (FDA). The strict principles developed in law seemed not maintained in the health industry with insufficient protection for the public.

The following story⁸⁶ is about a medical device registered in the United States of America, as far back as 1998. Eight surgeons were sent to Switzerland to be trained by a Swedish doctor, a certain Dr Ulmsten, who originally developed the procedure. He would do the operation three times and that would constitute proper and sufficient training for a surgeon.

The product, Gynacare PROLIFT, total pelvic repair system PFRT01 Ethicon Deutschland, was recalled from the market by the US Food and Drug Administration Center for Devices and Radiological Health, Division Small Manufacturers (FDA) on 20 April 2007.

According to the documents submitted to the FDA, Johnson and Johnson claimed that a substantial equivalence existed between the Gynacare Prolift TVT sling and an existing Protegen Sling manufactured by BOSTON Scientific, which was not correct and seen as understated and misleading.

It was shown that these two sling materials are vastly different from each other in every respect, including composition, fabric construction, mechanical properties, porosity and morphology. The ONLY feature that made these two tapes similar to each other is that both are textile materials. So Johnson and Johnson did not comply with section a-6 of CFR807.92 of the FDA for determining the basis of substantial equivalence and pushed the device through the registration process claiming the same technological characteristics, as the Protegen sling.

Additionally, knowing that the edges of the fabric of the PROLIFT are cut and raw (with cut loops and protruding filaments) and that tissue erosion or extrusion, was a major adverse reaction of the product, it would have been prudent and responsible had Johnson and Johnson conducted proper clinical trials. The submissions by Johnson and Johnson were not correct and the FDA should have requested proper preclinical and clinical studies especially with the numerous complications reported at the time for the Protegen Sling from Boston Scientific, which was referenced by Johnson and

⁸⁶ <http://www.topix.net/forum/com/jnj/TTE0RAIRMP5EFC052> (accessed 5.7.2010) and miamiblog@bellsouth.net

Johnson in their submission to the FDA as a predicate device. Also, well known to Johnson and Johnson at the time, should have been the research in the field and publications like “*Complications and untoward effects of the Tension-free Vaginal Tape Procedure*”⁸⁷ and the publication “*Bleeding complications with tension-free vaginal tape operation*”⁸⁸, stating clearly that the device is not safe, and has serious irreversible complications.

The question remains unanswered: Why did the American Food and Drug Administration Center for Devices (FDA) ONLY order the recalling of the device in 2007, after a court case⁸⁹ compelled them to do so, and not during the first retrospective review of the medical peers in the field, published 2003?⁹⁰

5. Questionable actions

Bearing in mind all the precautions to protect the public against biased expert evidence in court, it seemed inexcusable why biased expert reports, most probably submitted for substantial pharmaceutical gain, were not scrutinized, but accepted. Why do the rules to guard against unscientific medical evidence not extend as far as the pharmaceutical companies? It is clear that the regulatory authority of the pharmaceutical industry and the judicial authority are not addressing the same issue and are not using the same scientific principles to root out biased medical expert evidence. Maybe it is simply a question of financial gain? It is disconcerting that in this regulated field of scientific medicine many people still suffer from serious adverse reactions and mutilations from a medical device, that allegedly was properly registered, but where the source documents were not tested against sound medical, scientific principles and evidence.

⁸⁷ Karam M M, Segal J L, Vassallo B J and Kleeman S D, *Complications and untoward effects of the tension-free vaginal tape procedure* (2003) American Journal of Obstetrics & Gynecology 2003; 101:929-932 . This is a retrospective review of patients undergoing the TVT procedure over a 4 year period to report intra-operative complications (like bladder perforation, excessive bleeding, voiding dysfunction, erosion, nerve injury, urinary retention, and the incidence of re-operation).

⁸⁸ Flock F, Reich A, Mueche R, Kreienberg R and Reister F, *Hemorrhagic complications associated with tension-free vaginal tape* (2004) American Journal of Obstetrics and Gynecology 2004; 104: 989-994.

⁸⁹ Case No: 06-21116-CIV-UNGARO-BENAGES United States District Court for Florida , *Lana C Keeton vs Ethicon Inc a New Jersey corporation JOHNSON &JOHNSON* Docket 03/16/2007

⁹⁰ Why is the same device registered in South Africa and not been deregistered as Johnson and Johnson lost their legal battle in America? Why are the source documents, the basis for the research material not challenged with the Medicines Control Council South Africa?

6. Conclusion

Most likely the answers for the ineffective control of the above adverse reactions are not found in the interpretation and application of the law, but rather in the inefficient functioning and control of the regulatory body which has as objectives the registration of medical devices. It is highly probable that the scientific medical principles and the literature quoted above⁹¹ were presented in court as evidence against the pharmaceutical company responsible for the registration of the device, and it is likely that the court found that the evidence presented by the pharmaceutical company was not based on a reliable source and not generally accepted. Most probably that was the reason why the case was decided in favour of the plaintiff/complainant.

⁹¹ See footnotes 87 and 88

CHAPTER 4

OVERVIEW OF THE ENGLISH COURTS AND INFLUENCE ON COMMON LAW

1. Introduction

The English legal system of common law is the basis of many countries' legal systems throughout the world. South Africa forms part of the common law countries, as well as major countries like the United States of America, New Zealand, Canada and Australia. In this chapter this study intends to assess the way that expert evidence was addressed in England, originally and later on, as English law together with Roman law forms the basis of several common law principles and as such has a substantial influence throughout common law countries, and also South Africa.

2. Background of the English System

The English legal system of common law is the basis of many countries' legal systems throughout the world. South Africa as well as the United States of America form part of the common law countries.

The Law Society of the United Kingdom described common law as the essence of law which is derived and has its force and authority from the practice of the people. The system of jurisprudence that originated from England and which was later adopted in the United States of America is based on precedent instead of statutory laws. Case law is the law created by judges when deciding individual disputes and cases and is called the doctrine of judicial precedents (*stare decisis*).⁹² Common law changes constantly and each state or country progressively developed its own common law over time.

It seemed that in Old England there were two types of courts, namely the law courts where the judge applied statutes and the equity courts where the judges 'created' law as certain aspects had to be 'interpreted' that was not prescribed by the statutes, and these

⁹² <http://international.lawsociety.org.uk> p 2 (accessed 5.7.2010)

laws were called 'common law'. England and Wales are constituencies of the United Kingdom. English law is one of the major European legal systems, and the other based on Roman Law.⁹³

3. First appearance of expert evidence in English courts

Expert evidence forms part of English courts since the 14th Century.⁹⁴ During this time the courts made use of a *Special Jury* to assist the court, they consisted of important skilled and qualified people. The special function of the *Special Jury* was to advise the court in certain fields of expertise.⁹⁵

Several courts existed in England during the 16th to 18th Century, and different courts had different jurisdictions. Dwyer⁹⁶ explains that the main jurisdictions were common law (*King's Bench, Common Pleas, and Exchequer*) equity (the *Court of Chancery*, and some of the work of the *Court of Exchequer*), and the *Ecclesiastical and Admiralty Courts*.

For purposes of this discussion it is not intended to address the functions of the different courts merely to point out that the jurors had the main task to appraise the information before them in order to come to a conclusion based on reliable factual information and sound legal principles.

To review the role of the medical expert proved to be exceptionally difficult due to the fact that prior to engaging in a discussion regarding substandard treatment or procedures of the medical profession, the jurors or trier of facts, had to understand and appreciate the scientific principles underlying the medical treatment or procedures that caused liability. This study intends to assess the development of medical expert evidence in English courts and the standards underwriting the medical evidence as prescribed by the profession. It is not the intention to enter into a comprehensive

⁹³ <http://international.lawsociety.org.uk> p 2 (accessed 5.7.2010)

⁹⁴ Izette Knoetze, 'n Regsvergelykende studie van deskundige getuienis in straf- en siviele verhoore (2007). LLD verhandeling Universiteit Oranje Vrystaat Erasmus 1991: 267 p 13

⁹⁵ Ibid p14

⁹⁶ Knoetze p 15 and she quotes Dwyer D, *The Judicial Assessment of Expert Evidence* (2007) ;97-98

overview of English law *per se* but merely to give background to the reader to understand the analysis of the practical study that follows later in this study.⁹⁷

4. Medical expert evidence

Knoetze opines that it seemed that one of the first physicians asked to present evidence to court was during 1730 in England. The physician was used in court to testify regarding mental capacity, of an accused.⁹⁸ The multiplicity of all courts was finally reorganized and rationalized by the Supreme Court of Judicature Acts of 1873 and 1875,⁹⁹ and the *Court of Chancery* and the *Courts of Common Law* were now seen as one. During 1858 with the decision *R v Esdaile and Others*,¹⁰⁰ the witness was referred to as expert and asked for an opinion by honourable Lord Campbell CJ. Lord Campbell, however, stated that the courts are not bound to follow the opinion of the expert.

Even as far back as 1858¹⁰¹ the judges were fully aware of their lack of skill and expertise in certain intricate matters, like medical malpractice and negligence, however, were cautious and wary of the fact that the decision should stay the prerogative of the decision-maker and never be that of the expert.

4.1 Unreliable experts limited the role of the expert

Towards the middle of the 19th century the inconsistent and unreliable experts' testimony, lead to several studies and several detailed analysis of the role of the expert as well as defining the role of the expert.¹⁰²

In England and Wales, under the Civil Procedure Rules 1998, an expert is required to be independent and address his report to the court.

⁹⁷ Chapter 7,8,9

⁹⁸ Knoetze p 18 quotes Dwyer p102 and *Ex parte Ferrars* (1730) Mosely 332 ER 423

⁹⁹ Knoetze p 15

¹⁰⁰ Knoetze p 13 and *R v Esdaile and Others* (1858) 1F.&F.213:230,175ER 696:705

¹⁰¹ Knoetze p 13

¹⁰² Knoetze p 13

Baker and Lavers states that the Civil Procedure Rules do not have all the answers and quotes Rule 35.3 that applies to expert evidence in courts:¹⁰³

“(1) *It is the duty of an expert to help the court on the matters within his expertise.*

(2) *This duty overrides any obligation to the person from whom he has received instructions or by whom he is paid.*”

The Civil Procedure Rule 35.4 allows for a process in which application should be made to court to request permission prior to instructing an expert to testify in court.¹⁰⁴

Baker and Lavers¹⁰⁵ summarized the role of the expert as described in the *Anglo Group PLC v Winther Brown & Co* as follows¹⁰⁶:

- An expert witness should at all stages in the procedure, on the basis of the evidence as he understands it, provide independent assistance to the court and the parties by way of objective unbiased opinion in relation to matters within his expertise. An expert should never assume the role of an advocate.
- The expert’s evidence should normally be confined to technical matters on which the court will be assisted by receiving an explanation, or to evidence of common professional practice. The expert witness should not give evidence or opinions as to what the expert himself would have done in similar circumstances or otherwise seek to usurp the role of the judge.

4.2 The role of the expert prescribed by case law

Medical law in England is the cornerstone of South African medical law. This study does not purport to be a comprehensive study on medical law in England¹⁰⁷ and intends to

¹⁰³ Knoetze p 69 quotes Baker E, Lavers AP, *Expert Witness (Case in Point)* (2005) p 92

¹⁰⁴ http://www.justice.gov.uk/civil/procrules/fin/contents/parts/part35.htm#rule35_4 (accessed 5.7.2010)

¹⁰⁵ Knoetze p 72 **and** Bakers and Lavers p 4-5

¹⁰⁶ Knoetze p 72-73 she quotes *Anglo Group PLC v Winther Brown & Co* (2002) 72 Con LR 118, T&CC

¹⁰⁷ For an overview on medical law in England refer to Kennedy IM and Grubb A *medical Law, Text and Materials* (2000) and Jackson RM and Powell JL, *Professional Negligence* (1987) and (2000)

refer to English case law to illustrate aspects thereof in the detailed analysis of the Michael-case¹⁰⁸ later in this study.

The British courts have not examined the status and admissibility of expert testimony as the United States courts¹⁰⁹ have, as seen in Chapter Three, previously, with the summary of the role of the expert in *Daubert v Merrell Dow Pharmaceuticals, Inc*¹¹⁰.

They do however, set out the duties of the expert in *Anglo Group PLC v Winther Brown & Co Ltd*¹¹¹. The expert should be able to provide evidence that is not clear to the ordinary person. (*R v Turner*¹¹²) The test of the status of the medical evidence would probably mirror the test for negligence; it should reflect a reasonable body of medical opinion (*Bolam v Friern Hospital Management Committee*)¹¹³, which does not mean there are no opposing opinions (*Maynard v West Midlands Regional Health Authority*)¹¹⁴ and it should be logical (*Bolitho (deceased) v City and Hackney HA*)¹¹⁵. On the Bolitho view, the type of retrospective inference offered by some pediatric experts would fail on the grounds of logic.¹¹⁶ A discussion of the case of Sir Meadow can be seen later in this chapter.

McNair J in the 1957 case of *Bolam*¹¹⁷ stated that "a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art."

¹⁰⁸ Michael v Linkfield Park Clinic (Pty) Ltd 2001 (3)SA1188(SCA) and Chapters 7,8,9

¹⁰⁹ See chapter 3 on *Daubert*-case

¹¹⁰ *Daubert v Merrel Dow Pharmaceuticals Inc* 509 U.s. 579 (1993)

¹¹¹ 72 Con LR 118 (2000)

¹¹² 1 All ER 70 (1975)

¹¹³ 2 All ER 118 (1975)

¹¹⁴ 1 All ER 635 (1985)

¹¹⁵ AC 232 (1998)

¹¹⁶ Knoetze p 72

¹¹⁷ *Bolam v Friern Hospital Management Committee* 2All ER 118, Kennedy and Grubb p 215, Carstens and Pearmain p 704

4.3 *Bolam* principles gain popularity

The *Bolam* principles had been accepted in England (and South Africa¹¹⁸) and seen as applying to treatment as well as diagnosis, together with the doctrine of informed consent.

In *Whitehouse v Jordan*¹¹⁹ Lord Edmund Davies referred to the *Bolam* test and said that the standard cannot be the standard of the ordinary man in the street as he does not have the special skill the standard must be “the ordinary skilled man exercising and professing to have that skill”. (This test was also applied in South Africa¹²⁰)

In another landmark decision of the House of Lords in *Sideway v Bethlehem Royal Hospital Governors*¹²¹ in which the appellant patient’s appeal was dismissed, Bridge LJ commenting on the issue of non-disclosure said that it was an issue to be decided primarily on the basis of expert medical evidence, applying the *Bolam* test. Scarman LJ in his judgment addressed the patient’s right of self determination. In an interesting observation on whether or not English law should recognize the rule of informed consent, he stated: “the common law is adaptable: it would not otherwise have survived over the centuries of its existence.” He went on to say: “unless statute has intervened to restrict the range of judge made law, the common law enables the judges, when faced with the situation where a right recognized by law is not adequately protected, either to extend existing principles to cover the situation or to apply an existing remedy to redress the injustice. There is here no novelty: but merely the application of the principle ‘ubi jus ubi remedium’.” Scarman LJ considered the American and Canadian cases of *Canterbury v Spence*¹²² and *Reibl v Hughes*¹²³, which explored the parameters of the

¹¹⁸ Carstens and Pearmain p 679 for detailed discussion of Bolam principle

¹¹⁹ [1981] 1 All ER 267(HL), Kennedy and Grubb p 366, Jackson and Powell p 308, Carstens and Pearmain p 704

¹²⁰ *Pringle v Administrator Transvaal* 1990 (2) SA 379 (W)

¹²¹ (1985) 1 All ER p 643

¹²² (1972) p 464 F2d772, Claassen and Verschoor p 69

¹²³ (1980) 114 DLR (3d)1, Claassen and Verschoor p 69-71, Carstens and Pearmain p 891, 992

“prudent patient” test. (South Africa applied this doctrine in the classical case of *Castell v De Greeff*)¹²⁴

4.4 *Bolitho*-case: Courts not bound by expert opinion

The law of medical negligence and disclosure of risk in England was developed further in the 1997 case of *Bolitho v City and Hackney Health Authority*¹²⁵, In this case the appellant’s appeal was dismissed. Browne-Wilkinson LJ said that the fact that distinguished experts expressed an opinion demonstrates the reasonableness of the opinion. “But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.”

The ultimate decision-making should rest with the courts.

4.5 *But for*-test no longer enough

There has been some further development in English law in this area in the case of *Chester v Afshar*.¹²⁶ Hope LJ addressed the issue of causation in consent. He appeared to move from the “but for” test of causation by accepting that an injury is within the scope of the doctor’s duty to inform and therefore by not informing the patient of such injury, it could be said to have caused the injury. The last mentioned case contributed to taking medical law forward in England and has made it clear that a doctor has a duty to inform a patient of significant adverse outcome, or risks or complications, from a medical procedure.

Van den Heever¹²⁷ is of the opinion that the *Fairchild v Glenhaven Funeral Services Ltd*¹²⁸ had established that the “but for“- test of causation is no longer sufficient to attribute liability to a defendant in breach of his duty of care to a claimant.

¹²⁴ (1994) (4) SA 408 (C), Carstens and Pearmain p 891

¹²⁵ (1997) 3 WLR 1151, Carstens and Pearmain p 788

¹²⁶ [2004] All ER (HL), Carstens and Pearmain p 835

¹²⁷ Van den Heever *Doctrine of a loss of chance*(2007) p 29-30, Carstens and Pearmain p 837

¹²⁸ [200]LLR 361 (HL), Carstens and Pearmain p 837

4.6 Australia shifts the emphasis to the patient-expectation

Bearing in mind that Australia is also a common law country it is prudent to assess influence of case law that might have an influence on other common law countries in view of the fact that South African courts not only take cognizance of foreign case law, but also apply certain foreign case law principles,¹²⁹ as directed by our Constitution.

The Australian case of *Rogers v Whitaker*¹³⁰ had greatly influenced the medical jurisprudence in disclosure of risks throughout the common law world. Mason J considered *Bolam* and *Sideway* in the United Kingdom and the case of *Reibl* in Canada and said that the issue under consideration is not whether the doctor carried out his professional activities in accordance with his professional standards, but what is considered here is “the patient’s right to know what risks are involved”. In a very pertinent observation in his judgment he said “the duty of a medical practitioner to exercise reasonable care and skill in the provision of professional advice and treatment is a single comprehensive duty. However, the factors according to which a Court determines whether a medical practitioner is in breach if the requisite standard of care will vary according to whether it is a case involving diagnosis, treatment or the provision of information or advice; the different cases raise varying difficulties which requires consideration of different factors.” In this case the doctor lost his appeal, as evidently the patient made it clear that no harm should befall her one good eye, and the judges confirmed that it is reasonable for a patient with one good eye to be so concerned about the possibility of injury to that eye especially from a procedure that is elective.

In essence, the law moved from *what was expected from a reasonable doctor* to what the *expectations of a reasonable patient* is. It moved from doctor-centered to patient-self-determination and patient-centered.

¹²⁹ Chapter 2 footnote 4

¹³⁰ (1992) 175 CLR 479, Carstens and Pearmain p 885 and 891

4.7 Common law countries not in agreement

Not all common law countries are seen to have moved away from the *Bolam* principles as can be seen in the Singapore matter¹³¹ where the judge, Yong Pung How CJ considered the *Bolam* test. He said that “[I]n determining whether a doctor has breached the duty of care owed to his patient, a judge will not find him negligent as long as there is a respectable body of medical opinion, logically held, that supports his action.” The reference to the phrase “logically held” should be noted and the judgment said that the *Bolitho* case added a necessary addendum to the *Bolam* matter. Their Lordships, however humbly admitted that “at the heart of the *Bolam* test is the recognition that judicial wisdom has its limits.”

4.8 The basis for expert opinion should be reliable

For completeness, brief mention is to be made to the Ireland case of *Dunne v the National Maternity Hospital and Jackson*.¹³² Finley CJ stated that “if a medical practitioner charged with negligence defends his conduct by establishing that he followed a practice which was general, and which was approved of by his colleagues of similar specialization and skill, he cannot escape liability if in reply the plaintiff establishes that such practice has inherent defects which ought to be obvious to any person giving the matter due consideration.” Judge Kearns confirmed this situation in the *Geoghegan v Harris*¹³³ matter where he quoted a renowned Irish academic jurist, Mr John Healy “the Courts have recognized the institutional reality that they retain at the very least a residual power to override expert opinion, even where that opinion unanimously supports the defendant[‘s] (sic) propositions. The Irish Courts considerably more pragmatic in this regard, have repeatedly acknowledged this to be so.”

¹³¹ *Dr Khoo James and Anor v Gunapathy d/o Munandy* (2002) 2SLR 414

¹³² (1989) IR 91

¹³³ (2000) 3 IR 536

5. The reality is diverse

The standard is set clear and the courts guard jealously against anyone who tries to interfere with the set principles, but despite all that strict measurement put in place the courts are still wide open to influence from experienced, skilled men of position as can be seen in the recent case of *Sally Clark*¹³⁴ discussed hereunder. It will be seen that often medical experts base their opinion on statistical data, arriving at statistical conclusions which seems far removed from reality.

The purpose for the following discussion of the *Sally Clark-matter* is double fold. First to demonstrate that in developed countries that had been seen to set the legal standards for medical negligence over many centuries for other common law countries, the courts are nevertheless influenced by bias in expert evidence, and secondly to illustrate the fallacy of statistical data quoted out of context.¹³⁵

5.1 A 'conviction' on statistical data

This is a discussion of Munchausen Syndrome by Proxy and Cot Death¹³⁶, an article by Dr Gwen Adshead,¹³⁷ a Consultant Psychotherapist.

She analyzes the matters where "one or two pediatricians who have given expert testimony have been the subject of personal vilification and professional investigation. These cases [where a doctor testified against a mother with regard to child abuse like shaken baby syndrome and the like,] raise[d] questions about the use of medical expert testimony when there is real uncertainty in the scientific community and the emotional stakes are high."¹³⁸

¹³⁴ *R v Clark* [2003] EWCA Crim 1020

¹³⁵ See chapter 10 for a detailed discussion of the fallacy.

¹³⁶ Munchausen is where the mother of a child deceives the doctor that the child is suffering from certain ailments for other purposes like to draw attention to herself in showing how good mother she is or merely to attract attention to herself for selfish pathological reasons, see discussion later in this chapter.

¹³⁷ Adshead G, *Evidence-Based Medicine and Medicine-Based Evidence: The expert witness in cases of factitious Disorder by Proxy* (2005) American Academy of Psychiatry and the Law Online 33:1: 99-105

¹³⁸ *Ibid* p 99-105

Adshead¹³⁹ continues that in 1977, Prof Roy Meadow described the syndrome of Munchausen by proxy as follows: the mothers deceive the health care professionals into believing that their children are ill by giving false signs and symptoms of the children to the health care providers.

Professor Meadow¹⁴⁰ suspected that the mothers were doing this to draw attention to themselves. Meadow apparently said that when mothers actively deceive the doctors, the role of the doctors becomes that of an investigator, protecting the child against possible abusive behavior of the parent. *“This adversarial attitude extends into research as well as normal clinical practice,”* and the researchers made a study of apnea attacks (stopped breathing) in infants and the causes. The researchers found 14 cases where the problems with breathing that the children experienced, were the results of their parents’ attempt to smother them.¹⁴¹ A further study was done, this time in 39 children, in which there was suspicion of child abuse. Police investigations showed that they were correct in 33 out of the 39 children (84.16%).¹⁴²

Adshead continues that Professor Meadow himself had knowledge of 81 children¹⁴³ who had been found by the criminal courts to have been killed by their parents. Said Meadow: *“Most of these deaths had originally been categorized as sudden infant death syndrome (SIDS). There are several theories about why infants might suddenly die (genetically acquired thermoregulation problems, sleeping posture, toxic mattress content, or heart or respiratory problems) and some limited evidence for all of them¹⁴⁴”*. And another cause of SIDS is smothering of the child by the parent, according to Meadow.

¹³⁹ Ibid p 99-105

¹⁴⁰ Meadow R, *Unnatural sudden infant death* (1999) (Arch Dis Child 80:7-14 [Abstract/ Free Full Text]

¹⁴¹ Adshead, p 101; Samuels M, Mc Cloughlin W, Jacobson R, *Fourteen cases of imposed upper airway obstruction* (1992) Arch Dis Child 67:162-70

¹⁴² Adshead, p 101; Southall D, Plunkitt M, Banks MW, Falkov AF, Samuels MP, *Covert video recordings of life-threatening child abuse: lessons for child protection* (1997) Pediatrics 100:735-60

¹⁴³ Adshead, p 99-105 **and** Meadow R, *Unnatural sudden infant death* p 7-14,

¹⁴⁴ Adshead, p 99-105; Ward PM, Blair PS, Fleming P, *et al* and the CESDI SUDI Research Group: *A clinical comparison of SIDS and explained sudden infant deaths: how healthy and how normal?* (2000) Arch Dis 82:98-106

Professor Meadow frequently testified in court for the Crown, because of his research and experience. In the *Sally Clark*-case, it was alleged that the mother had caused the death of her two children. Several pediatricians were called for both sides, post-mortem results were made available. Apparently, the experts agreed that the cause of death was not SIDS, however they did not agree as to what caused the infants' death. Adshead explains that *"At the trial, Professor Meadow cited a published statistic in his testimony, indicating that the chance of a second cot death happening in a middle class home was 1 in 73 million.¹⁴⁵ This figure has come back to haunt him. The mother was eventually convicted and went to prison."* Her second appeal was successful, on the grounds *'that a prosecution medical expert (not Professor Meadow) had failed to disclose evidence that might support a medical cause for her children's death.'* Adshead says that *"The accusation is that the Professor identified too much with the prosecution and molds his interpretation of the data to fit the prosecution's case. This identification with the cause, and not the facts of his opinion, could mean that he either consciously or unconsciously gave misleading evidence to the court, which would be unprofessional behaviour.¹⁴⁶"* *"A General Medical Council hearing has struck Professor Sir Meadow off the medical register after finding him guilty of giving erroneous and misleading evidence in the Sally Clark case.¹⁴⁷"*

Adshead concludes that the murder convictions of Sally Clark and Angela Cannings were overturned after failures in expert witness testimony. A review of 300 infant death convictions follows and the Court of Appeal is hearing the cases of four people convicted of killing or harming babies. If they are cleared, 90 other cases could be challenged.¹⁴⁸

The obvious question is: How is it that a country that has such influence in the rest of the common law world can get it so wrong with expert bias? Why was the basis of the expert evidence not tested?

¹⁴⁵ Adshead, p 99-105; Fleming P, Blair PS, Bacon C, Berry J eds *Sudden unexpected deaths in infancy* (2000) London: Her Majesty's Stationery Office p 91-2

¹⁴⁶ Adshead, p 99-105; Gutheil T, Hauser M, White M, et al: *The whole truth versus the admissible truth: as ethical dilemma for expert witnesses* (2003) *J Am Acad Psychiatry Law* 31:422-7

¹⁴⁷ <http://news.bbc.co.uk/1/hi/uk/4637687.stm> p1 (accessed 5.7.2010)

¹⁴⁸ *Ibid* p1

Later in the study ¹⁴⁹ an attempt will be made to explain the fallacies behind the reasoning of the above statistical data and interpretation thereof. An attempt will also be made to explain that the role of the court is to guard against the wrong interpretation of statistical data. The study will show the questions the court should ask in order to appreciate the statistical evidence put before the court in order to arrive at a proper understanding of the purpose behind the statistical analysis and the data presented. The court should ask whether the reason behind the analysis of the statistical data and subsequent conclusion arrived at, is logical and based on sound arguments.

6. Conclusion

In conclusion it can be seen that throughout the common law countries the courts retained their wide discretion to not accept the standard presented by the medical profession, although genuinely held, but to entertain the principle that if that standard falls short of the reasonable standard of care expected by the patient, it will be seen as negligent action. The courts can be misdirected but if the rules and guidelines that were developed, throughout the centuries, in all common law countries are followed, unfortunate misguided decisions and adverse outcomes will be limited.

¹⁴⁹ See chapter 10 for more detail about wrong interpretation of statistical data.

CHAPTER 5

Part one - EVIDENCE BASED MEDICINE - overview

1. Introduction

The first four chapters have shown that despite very clear rules and guidelines in the different jurisdictions of the courts in common law countries, the courts are commonly misguided in respect of the quality of medical evidence presented. A thorough study should guide the courts regarding the quality of the medical evidence of the medical experts. The courts should claim back its judiciary role and be the ultimate decision-maker and trier of facts. The courts should not be influenced by the opinion of the medical expert unless based on sound, logical scientific evidence as voiced by the medical profession. This study is of the opinion that such medical evidence is found in the principles of evidence-based medicine.

This chapter introduces the medical part of this dissertation and gives a brief medical overview about what evidence-based medicine is, where evidence-based medicine had its origin, and why we need evidence-based medicine, specifically in medical negligence cases.

Evidence based medicine has not developed a new concept of evidence, says Hurwitz,¹⁵⁰ the major contribution is in the emphasis it places on a hierarchy of evidential reliability in which medical conclusions related to medical evidence from controlled scientific experiments are given greater credibility than conclusions grounded in other evidence. Hurwitz explains that evidence based guidelines are authoritative in that it embodies a combination of the best medical evidence and judgments, designed to ensure that medical recommendations regarding e.g. diagnosis, are valid and reliable.¹⁵¹ Hurwitz alerts clinicians to the fact that medical guidelines combined with evidence based medicine might have the effect that civil litigators increasingly will possibly plead

¹⁵⁰ Hurwitz B *How does evidence based guidance influence determinations of medical negligence* School of Humanities, King's College, London WC2R 2LS brian.hurwitz@kcl.ac.uk

¹⁵¹ *Ibid*

just one particular form of negligence: failing to follow guidelines.^{152 153}

Before embarking on a plea for all medical evidence presented to the court to be based on evidence-based principles one should first determine how stable and thus reliable such medical evidence is. Studies made to determine how quickly “medical evidence” can change in clinical medicine, showed that certain medical data, research and treatment can be outdated within one year.¹⁵⁴

It is evident that no general rule regarding medical evidence can be cast in stone and each individual case should be guided by the merits of the matter, namely the medical facts that gave rise to the medical negligence allegations, and the scientific information supporting those medical facts.

One could not agree more with Mayer¹⁵⁵ when he quoted Santayana¹⁵⁶ who said: *“History is a pack of lies about events that never happened told by people who weren’t there. Those who cannot remember the past are condemned to repeat it.”* In other words, adequate research leads to publications that are read and scrutinized by the peers and criticism thereof leads to better research and better medicine. In a simpler form, learn from research as to not repeat mistakes.

2. Background leading to evidence-based medicine

In order to provide an understanding of the history of evidence-based medicine this study listed some of the highlights in medical history as summarized by Mayer, who compiled a comprehensive study in his book, *Essential Evidence-Based Medicine*.¹⁵⁷ Although testing medical interventions for efficacy has existed since the time of

¹⁵² Mayer D *Essential Evidence-Based Medicine* (2004) p 3

¹⁵³ See also conclusion of Chapter 5- part two

¹⁵⁴ Kaveh G, Shojania M D, et al *How quickly do systematic reviews go out of date? A survival analysis* (2007) American College of Physicians. *Ann Intern Med*, 147: P224-233 - discussion follows later in this chapter

¹⁵⁵ Ibid p 8

¹⁵⁶ Santayana G (1863-1952) Mayer p1

¹⁵⁷ Mayer p 3

Avicenna's *The Canon of Medicine* in the 11th 158 century it only gained momentum in the 20th century and impacted on almost all fields of health care.

Mayer¹⁵⁹ explains that the Greeks began to systematize medicine approximately the same time as the *Nei Ching* appeared in China. Although Hippocratic medical principles are considered archaic, his principles of the doctor-patient relationship are still very relevant today. In the Middle Ages the practice of Greek and Roman medicine continued.

Mayer is of the opinion that the first medical school was started during the 13th century in Italy¹⁶⁰, but it was only the 18th century that saw the development of modern medicine “with the isolation of foxglove (digitalis) [for abnormalities in heart rhythm] by Whithering, the use of inoculation (against smallpox) by Jenner, and the postulation of the existence of vitamins (vitamin C, antiscorbutic factor) by Lind.”¹⁶¹

Mayer further states that during 1545 with the book on games of chance, *Liber de Ludo aleae*, written by Giralamo Cardano, an attempt was made to use mathematics to describe statistics and probability, and he accurately describe the probability of throwing various numbers with a dice.¹⁶²

He includes some of the statistical points that developed, as medicine relies on statistics to determine whether medication or treatment has a desired effect or positive outcome.¹⁶³ He states that some of the statistical foundational aspects were based on these ground rules. According to Mayer the statistical thinking had Jacob Bernoulli devising the law of large numbers, which stated that as the number of observations increased the actual frequency of an event would approach its theoretical probability. In other words the larger the number of the sample group/ study group /target group the

¹⁵⁸ Brater DC and Daly WJ *Clinical Pharmacology in the Middle Ages: Principles that presage the 21st century* (2000) *Clinical Pharmacology & Therapeutics* 67(5), p447-450(449)

¹⁵⁹ Mayer p 3

¹⁶⁰, Mayer p 3

¹⁶¹ Mayer p 3

¹⁶² Mayer p 4

¹⁶³ The true use of statistics is very valuable however the misunderstanding of statistical evidence and misquoting thereof is discussed in chapter 11.

more probable, the probability. He opines that this is the basis of all modern statistical inference.¹⁶⁴

Mayer indicates that the studies of physiology and other basic science research began to appear in large numbers in the 19th century, and by the 20th century medicine moved from the empirical observation of cases, to the scientific application of basic sciences in determining the best therapies and to catalog the diagnoses.^{165 166}

He maintains that a 200-year gap existed before the controlled clinical trial became the standard study for new medical innovations, and it was only in the 1950's that the randomized clinical trial became the standard for excellent research.¹⁶⁷

2.1 Cochrane Collaboration

Evidence-based medicine cannot be mentioned without reference to Professor Archie Cochrane, a Scottish epidemiologist, who¹⁶⁸ has advocated for the principles of evidence-based medicine to be widely accepted in clinical medicine. Cochrane centers became an international organization, the Cochrane Collaboration.

Mayer explains that subsequently several groups working on systematic reviews spread through the United Kingdom and today they have formed a network in cyberspace throughout the world.¹⁶⁹ He concludes that Cochrane was particularly important in the development of the current movement to perform systematic reviews of medical topics.¹⁷⁰

¹⁶⁴ Mayer p 6

¹⁶⁵ Mayer p 7

¹⁶⁶ This study supports the opinion that the medical profession needs sound scientific evidence to move away from opinion based evidence.

¹⁶⁷ Mayer p 7

¹⁶⁸ Cochrane A through his book *Effectiveness and Efficiency: Random Reflections on Health Services* (1972) and Cochrane Collaboration: The reliable source for evidence in healthcare(<http://www.cochrane.org/> accessed 5.7.2010)

¹⁶⁹ Mayer p 8

¹⁷⁰ Mayer p 8

Methodologies to determine “current best medical evidence available” were put in place by the Mc Master University research group led by David Sackett and Gordon Guyatt.¹⁷¹

3. A definition of evidence-based medicine

Evidence-based medicine has been defined widely by different authors, however has been defined in more modern times by Sackett *et al*, as **“the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”**¹⁷²

4. The value of evidence-based medicine

The value of evidence based medicine in clinical medical practice and the effect of this on the patient seems obvious: although the individual clinical experience during examination by a clinician (doctor) is critical, the current best available medical evidence in a field (clinically relevant research), is of utmost importance, for a holistic diagnosis. The efficacy of any diagnosis and plan of treatment is strengthened with evidence from systematic research as the latest research of external clinical medicine can invalidate previously accepted techniques, treatment and diagnostic tests¹⁷³.

Evidence-based medicine is “the integration of clinical expertise, patient values, and the best evidence into the decision making process for patient care.”¹⁷⁴ Clinical expertise is the clinician’s cumulated experience, to wit training and clinical skills. The patients have their concerns and expectations, informed the doctor in this regard, who then searches for the best evidence available from proper clinical research that can be trusted.

¹⁷¹ Guyatt G, Cairns J, Churchill D, *et al*. [Evidence-Based Working group] *Evidence-based medicine. A new approach to teaching the practice of medicine* (1992) JAMA 268:2420-5

¹⁷² Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS, *Evidence based-medicine: what it is and what it isn't* (1996 BMJ 312 (7023):71-2 (<http://www.bmj.com/cgi/content/full/312/7023/71> accessed 5.7.2010)

¹⁷³ Sackett *et al* p 71-2 and <http://www.hsl.unc.edu/services/tutorials/ebm/what.is.htm>

¹⁷⁴ Sackett *et al* p 71

5. Empowerment through medical evidence

Whilst we all would like to believe that “good doctors have perhaps always based their decisions on good evidence,”¹⁷⁵ studies done by the South African Medical Research Council showed that clinicians are of the opinion that they do not have the time to scan the research the relevant medical question, and sometimes lack the research skills.

Gething,¹⁷⁶ who reported on these studies by the South African Medical Research Council mentions in her overview that the principle function of evidence-based medicine is to exploit new developments in information technology and so identify the clinical question and then to identify information relevant to the clinical question. In other words evidence-based medicine “teach[es] you the skills to appraise that article for quality”

In this way harmful practice that has been tested will be eliminated, and effective care is accessible to all, and the “best treatment based on [the] best evidence” as indicated by a Dr Volmink, Cochrane Centre South Africa.¹⁷⁷

Volmink explained that the Cochrane Centers strive to gather medical information “to facilitate systematic reviews of randomized controlled trials across all areas of healthcare.”¹⁷⁸ Scientific research based on ‘randomized controlled trials’¹⁷⁹ is the better standard whereby groups of people are given the treatment to be tested or the quasi-treatment (a placebo) without being informed who has been given the active ingredient (blinded), and then be scientifically tested and analyzed.

Cochrane Reviews look at “all the evidence pertaining to a particular clinical question, have appraised that evidence for quality, and presented and synthesized that information in a way that minimizes bias.”¹⁸⁰ Volmink explains how the Cochrane Centers assess medical evidence. “There are now very clear guidelines for what

¹⁷⁵ Gething L, *Empowerment through medical evidence* (2000) Vol 31 (6) Dec South African Medical Research Council p 4-7

¹⁷⁶ Gething p 4

¹⁷⁷ Gething p 5 and Cochrane A, *Cochrane’s legacy of EBM* [evidence-based medicine] *strive to empower doctors* and abstracts and synopses of the Cochrane reviews <http://www.cochrane.org>

¹⁷⁸ Ibid

¹⁷⁹ See Chapter 5- part two

¹⁸⁰ See footnote 177

constitutes good evidence [medical] for various types of clinical questions- questions about diagnosis, treatment, prognosis, whether treatment does harm or not.”¹⁸¹ Volmink informs that these guidelines are used to read and assess the medical literature published and weigh the value of such an article. All the abstracts from the Cochrane reviews are available and can be read to determine how the article was classified. Volmink regards the reluctance of medical schools to offer formal instruction on evidence-based medicine due to the fact that it challenges “authoritarianism in medicine”¹⁸² whereby the student now becomes empowered and challenges the professor.¹⁸³

With medical malpractice suits increasing, it is clear that the public are becoming more aware of their rights as patients and are interested to read medical publications and challenge their doctors with information obtained from the internet.

6. Evidence-based medicine is effectively the third person in the consultation room

The Internet serves in healthcare and services as a guide for patients to help them find high- quality health information. It can assist doctors to communicate effectively with their patients as foreseen by Peter Yellowlees,¹⁸⁴ however also serves to assist the physician to update his knowledge in a certain field, keeping up with new research and incorporate it into the decision-making-process.

6.1 What does the doctor say about evidence-based medicine?

“In a survey of 625 office-based primary care physicians and 100 physician opinion leaders in the United States, nearly two-thirds reported that the current volume of

¹⁸¹ Ibid p 5

¹⁸² Ibid p 5

¹⁸³ It should be noted that several emails were sent and although confirmation of the emails were received the accessibility of information from the Cochrane Centers seems limited to few

¹⁸⁴ Yellowlees P, The Internet: a third Person in our Consulting Rooms (MBBS MD)
<http://www.medscape.com/viewarticle/589642>

scientific information was unmanageable.”¹⁸⁵

A further survey by the above authors ¹⁸⁶ reported that Australian physicians identified that limited time, search skills and access to evidence were seen as impediments to make use of research data. It showed that in order for the full potential of evidence-based medicine to improve the physician’s need to be educated in the use of evidence-based medicine and access to systems with high-quality evidence are needed at the point of clinical decision making.

6.2 Putting evidence-based medicine into context

Mayer ¹⁸⁷ is of the opinion that all physicians believe they practice evidence-based medicine, but “the observed variation in practice suggests otherwise.” He suggests that evidence-based medicine may be seen as an attempt to standardize the practice of medicine. However even if evidence-based medicine is the best approach to a clinical problem, the physician has to determine “whether the individual patient will benefit from that approach.”¹⁸⁸ Mayer sees the art of medicine in the assessment of the patient and the medical information available; the decision as to which approach to take in the diagnosis and the treatment; the interpretation of the relevant information in context with the clinical findings and evidence-based medicine information available; and the application of medicine in practice with the follow-up of the outcomes.

It is clear from the stance by Mayer that the scientific basis for each diagnosis needs to be determined by the medical professional, and for that he/she needs knowledge and appreciation of the medical condition. In addition to that the physician needs his own clinical examination and findings to determine whether the medical evidence available is indeed the information relevant to his patient. The same principles would apply regarding the differential diagnosis, in a case where the physician is uncertain of the

¹⁸⁵ Craig CJ, Irving L M and Stockle MR *Evidence-based medicine: useful tools for decision making* (2001) MJA174;248-25 and <http://www.mja.com.au/public/issues/174-05-050301/craig/craig.html> p 2

¹⁸⁶ See above footnote and Scott I, Heyworth R, Fairweather P, *The use of evidence-based medicine in the practice of consultant physicians. Results of a questionnaire survey* (2000) Aust NZJMed 30:319-326

¹⁸⁷ Mayer p 14

¹⁸⁸ Mayer p 15

diagnosis, and the physician follows each line of thought of the alternative diagnosis on a scientific basis.

In particular, Mayer states that the science is contained in the literature and in the ability of the clinician to interpret that literature for its scientific basis and soundness.¹⁸⁹ Mayer summarizes that “[T]he art is in determining to which patient the literature will apply and then communicating the results to the patients. You learn scientific facts during the first two years of medical school that will be the building blocks for caring for your future patients. The clinical and basic sciences are the foundation of the science of medicine. Having a critical understanding of new advances in medicine through reading the medical literature is an important part of this science. You will also learn the art of medicine. This includes the ability to perform an adequate history and physical examination of your patient so that you can extract the maximum amount of evidence to use for good medical decision-making. You will also need to give information to your patient about their illness and be able to empower them to act appropriately to affect a cure or control and moderate the illness. Finally, you must be able to know when to apply the results of the most current literature to your patient. When is the patient close enough in characteristics to the population group studied and when should other approaches to the patient’s illness be used?”¹⁹⁰

6.3 Limitations of evidence-based medicine that are of concern to clinicians

In the initial stages of the development of evidence-based medicine the originators of the concept were of the opinion that the principles of medicine may be codified and put into guidelines that should be treated as set rules. Hurwitz¹⁹¹ quotes Grimly and states that of concern, is the fact that in the absence of evidence clearly applicable to the case in hand, a clinician might be forced by guidelines, to make use of evidence which is only doubtfully relevant, and that was generated most likely in a different grouping of patients that might use similar but not identical treatment. He compares this by saying that to use

¹⁸⁹ Mayer p 15

¹⁹⁰ Mayer p15

¹⁹¹ Hurwitz B *How does evidence based guidance influence determinations of medical negligence* School of Humanities, he quotes Grimley EJ *Evidence-based medicine and evidence-biased medicine* *Age Ageing* (1995)24:461-3 brian.hurwitz@kcl.ac.uk

medical evidence in this manner would be like the fabled drunkard who searched under the street lamp for his door key because that is where the light was, even though he had dropped the key somewhere else.

6.4 On a lighter note: possible suggestion of existing alternatives to evidence-based medicine

The medical profession realized that opinion-based evidence is not sound in scientific reasoning, logic and appreciation and showed this by their following humoristic approach to opinion-based evidence or described as *ipse dixit* in law.

The following is an article that appeared in the *British Medical Journal* which is described as a humorous look at alternatives to evidence-based medicine¹⁹² and that was originally written by two physicians, Messrs Isaacs and Fitzgerald poking fun at their colleagues.

Isaacs and Fitzgerald said that clinical decisions should as far as possible, be evidence based and this is seen from the so-called clinical dogma.¹⁹³ Physicians are urged to lump all the relevant randomized controlled trials into one giant meta-analysis and come out with a combined odds ratio for all decisions. “Physicians, surgeons, nurses are doing it;¹⁹⁴ soon even the lawyers will be using evidence based practice.¹⁹⁵ But what if there is no evidence on which to base a clinical decision?”

Isaacs and Fitzgerald¹⁹⁶ in amused play said: “We, two humble clinicians ever ready for advice and guidance, asked our colleagues what they would do if faced with a clinical

¹⁹² Mayer p 15 **and** Isaacs D, Fitzgerald D, *Seven alternatives to evidence-based medicine* (1999)BMJ 319: 1618 Professor Isaacs is a clinical professor and Professor Fitzgerald a staff physician at the Department of Education and Medicine, New Children’s Hospital, Westmead, NSW, Australia

¹⁹³ Mayer p 16 **and** Evidence-based medicine working Group. *Evidence-based medicine: a new approach to teaching the practice of medicine* (1992) JAMA 268: 2420-5 **and** Rosenberg W, Donald A, *Evidence-based medicine: An approach to clinical problem solving* (1995) BMJ 310: 1122-6

¹⁹⁴ Mayer p 16 **and** Sackett DL, Rosenberg WM, Gray JAM, Haynes RB, Richardson WS, *Evidence based medicine what it is and what it isn’t* (1996) BMJ 312: 71-2 **and** Solomon M J, McLeod R S, *Surgery and the randomized control led trial: past, present and future* (1998) Med J Aust 169: 380-5 **and** Mc Clarey M, *Implementing clinical effectiveness* (1998) Nursing management 5: 16-9

¹⁹⁵ Mayer p 16 **and** EBM and IMF. *J Exponential Salaries* (1999) 99:1-9

¹⁹⁶ Mayer p 16

problem for which there are no randomized controlled trials and no good evidence. We found ourselves faced with several personality based opinions, as would be expected in a teaching hospital. The personalities transcend the disciplines, with the exception of surgery, in which discipline transcends personality.”

The categories of the replies received from the colleagues of the esteemed physicians were as follows:

6.4.1 Eminence based medicine- this is found with the more senior colleagues. The more senior, the less importance he/she placed on the need for anything as “mundane” as evidence. Experience seems to outweigh any amount of evidence. The senior colleagues of the esteemed writers allegedly had a dedicated and touching faith in clinical experience and defined it as ‘making the same mistakes with increasing confidence over an impressive number of years.’¹⁹⁷ The senior colleagues as eminent physicians, apparently have white hair and balding pate, often called the ‘halo’ effect.

6.4.2 Vehemence based medicine- this is where huge voluminous amounts of evidence is presented and seen as a substitution of volume for evidence. It is an effective technique for brow beating the more junior or timorous colleagues and for convincing the physician’s relatives of his/her ability.

6.4.3 Eloquence based medicine- this is based on physical appearance. The year round suntan, carnation in the buttonhole, silk tie, Armani suit, and tongue should all be equally smooth. Sartorial elegance and verbal eloquence are seen as powerful substitutes for evidence.

6.4.4 Providence based medicine- this is found when the caring practitioner has no idea of what to do next and decides that the decision may be best left in the hands of the Almighty. The opinions of the esteemed writers are that ‘too many clinicians are unable to resist giving God a hand with the decision making’.

¹⁹⁷ Mayer p 16 and Solomon MJ, McLeod RS, *Surgery and the randomized control led trial: past, present and future* (1998) Med J Aust 169: 380-5 **and** O'Donnell M, *A skeptic's medical dictionary* (1997) BMJ Books

6.4.5 Diffidence based medicine- this situation occurs with finding solutions. Some physicians see problems. Others look for answers. The diffident physician refrains from taking any action from a sense of despair, which for obvious reasons is seen as better than doing something merely because it hurts his/her pride to do nothing.

6.4.6 Nervousness based medicine- this is where a fear of litigation is a powerful stimulus to over investigate and over treat a patient. In an atmosphere where litigation-phobia exists, the only bad test is the test the physician did not think of ordering.

6.4.7 Confidence based medicine- This is restricted to the surgeons table.

7. Comments

Mayer is of the opinion that there are plenty of alternatives for the practicing physician in the absence of evidence. This is what makes medicine an art as well as a science.¹⁹⁸

The above was a summary of the background of evidence-based medicine and the different feelings and concerns in the industry about it. Some see this as a miracle tool that will solve all the problems of diagnostic testing, interpretation thereof, different treatment suggestions, different treatment outcomes and suggestions towards risk management and outcomes.

Hurwitz opines that “[R]igid, uncritical adherence to guidelines is therefore not the formal, administrative or managerial expectation of clinicians working in the NHS [National Health System in UK]. In the United States, tensions surfacing between treatment protocols and doctors’ clinical judgment have led the courts to rule that clinicians may not use as a defense to negligence that their clinical judgment has been corrupted by guidelines.”¹⁹⁹

¹⁹⁸ Mayer p 16

¹⁹⁹ Hurwitz, B *How does evidence based guidance influence determinations of medical negligence* School of Humanities, King’s College, London WC2R 2LS brian.hurwitz@kcl.ac.uk (accessed 5.7.2010) and see *Wickline vs California* California Reported (1986) 228; 661-67

They maintained that no guideline can cover the full extent of the disease, illness or treatment, as people and illnesses vary, it is for the doctor or other health professional to interpret the information and then to decide when the guideline is no longer applicable.

8. How quickly do systematic reviews go out of date?

Systematic reviews are the assessment of the information of a specific topic in order to determine whether the stance of the medical fraternity in that discipline has changed in view of the different studies done by the peers and the summary or these reviews then indicate the current viewpoint based on the historical data. The above question was researched as a study by Kaveh *et al.*²⁰⁰ It is a systematic review of 100 quantitative systematic reviews, published from 1995-2005. A signal for updating was posted when any changes in statistical significance occurred or relative changes in effect occurred that magnitude at least 50% and that involved at least one of the primary outcomes of the original systematic review or any mortality outcome.

It was noted that signals occurred within two years for 23% of reviews and within one year for 15%; It was further noted that only 4% of reviews had a signal within one year of the end of the reported search period; 11% had a signal within two years of the search. Shorter survival was associated with cardiovascular topics and heterogeneity in the original review.²⁰¹

This study concludes with Kaveh *et al* that in a cohort of high-quality systematic reviews directly relevant to clinical practice, signals for updating occurred frequently and within a relatively short time. Once the search date is older than even one year, the users should determine whether more recent trials on the same topic exists in order to see whether new evidence has altered the findings of a given systematic review.²⁰²

²⁰⁰ Kaveh G, Shojania MD, et al *How quickly do systematic reviews go out of date? A survival analysis* (2007) American College of Physicians. *Ann Intern Med*, 147: P224-233

²⁰¹ Kaveh *et al* p 224

²⁰² Kaveh *et al* p 232

9. Clinical Predicament

In the past, a physician faced with a “clinical predicament” would turn to a senior physician, says Mayer, to have a definitive answer to his problem. This would take the form of an informal discussion on rounds with the senior attending physician or he would refer the patient to a more senior colleague, seen as the specialist. The decision would come from the more experienced (and usually older) physician, and would be accepted at face value by the more inexperienced physician. It was usually based upon many years of experience of the older physician, but was not necessarily ever tested empirically.²⁰³ In this light it is obvious as to how quickly “evidence” can change in clinical medicine, the above way of finding information is unscientific and risky. Hence the plea: Learn from research not to repeat mistakes.

10. Does evidence-based medicine care to improve outcomes to patients?

Before answering that question, one should wonder whether this question should be answered by physicians (who have their own opinion, little time and constraints to access information) or by patients?

Observational studies by Krumholtz *et al* and Soumerai *et al* showed “that treatments proven in randomized trials and systematic reviews seem to work equally well in routine clinical practice.”^{204 205} It remains unclear what interventions are most effective in helping clinicians use research data more effectively in decision making²⁰⁶. Guidelines, computer-generated reminders, opinion leaders, and outreach visits or combinations thereof have been shown to improve care and patient outcomes, but passive

²⁰³ Mayer p 10

²⁰⁴ Krumholtz H M, Radford M J, Ellerbeck E F *et al*, *Aspirin for secondary prevention after acute myocardial infarction in the elderly: prescribed use and outcomes* (1996) *Ann Intern Med* 124: 292-298

²⁰⁵ Soumerai S B, McLaughlin T J, Spiegelman D, *et al*, *Adverse outcomes of under use of beta-blockers in elderly survivors of acute myocardial infarction* (1997) *JAMA* 277: 115-121

²⁰⁶ Oxman A D, Thomson M A, Davis D A, Haynes R B, *No magic bullets: a systemic review of 102 trials of interventions to improve professional practice* (1995) *CMAJ* 153: 1423-1431 and Walton R, Dovey S, Harvey E, Freemantle N, *Computer support for determining drug dose: systemic review and meta-analysis* (1999) *BMJ* 318: 984-990

dissemination strategies e.g. conferences and printed educational materials, have not.

On the other hand, Coomarasamy²⁰⁷ is of the opinion that individual evidenced-based medicine has no improvement on health care.

11. Another side to health care (Managed Care)

In order to understand another face of evidence-based medicine, one should note that evidence-based medicine has a non-clinical, profit-based side where managed health care at organizational or institutional levels have attempted to produce guidelines, policies and regulations to health professionals to regulate the cost of health care.

Yealy *et al* opines that although highly effective for the profit margin of the institution, this may lower rather than raise the standard of care to the patient and was criticized as being there to serve cost cutters and suppress clinical freedom. There is evidence of improvement in the efficacy of health care when evidence-based medicine is practiced at the organizational level, as an overall functioning of a hospital or health care organization can be measured against the best of currently available medicine.²⁰⁸

It seems that evidence-based medical evidence is used to set up protocols for the medical insurance companies to determine basic prescriptions for specific conditions, effectively allowing the medical professional to make the diagnosis, but withholding the right to prescribe a specific medication for a specific patient. The diagnosis triggers a pro-forma prescription that was pre-arranged and bought in bulk and patient individuality and doctor's preference flew out the window. Three areas of evidence-based medicine can be identified in the industry in this regard, namely, patients with acute or chronic pathologies and a clinician panel will select treatment options based on the best research for each patient; a systematic review of medical literature gets turned into large practical guidelines; or a medical panel of professionals work to popularize the method

²⁰⁷ Coomarasamy A, Khan K S, *What is the evidence that post-graduate teaching in evidence based medicine changes anything? A systematic review* (2004) *BMJ* 329 (7473): 1017.

doi:10.1136/bmj.329.7473.1017 (<http://www.ncbi.nlm.nih.gov/pubmed/15514348> accessed 5.7.2010)

²⁰⁸ Yealy D M, Auble T E, Stone R A, *et al*, *Effect of increasing the intensity of implementing pneumonia guidelines: a randomized controlled trial* (2005) *Ann Intern Med.* 1434 (12): 881-94.

and usefulness of the practice in the public, patient communities, educational institutions and continuing education for practicing professionals.

Seen in this light, what is important to the patients and their rights are the fact that *“Evidence-based medicine has demoted ex cathedra statements of the ‘medical expert’ to the least valid form of evidence. All ‘experts’ are now expected to reference their pronouncements to scientific studies.”*²⁰⁹

Invaluable is Professor David Grahame-Smith’s²¹⁰ reaction to this by word of the eloquent Socrates and his pupil *Enthusiasticus*:

“Enthusiasticus: Those who manage our medical practice ...are particularly anxious to get value for money and wish to be sure that doctors’ actions are effective...

Socrates: So there must be a large number of doctors practicing cost ineffective medicine for such a grand scheme.... They see evidence based medicine as a means to shackle the doctors....

Beware, Enthusiasticus that you are not used as a dupe in a political game of health economics.”

12. Evidence-based medicine influenced the Canadian Courts

Although reference previously was made to the United States of America, the United Kingdom and Australia as common law countries the Canadian experiences is particularly instructive as standard therapy known and used for years suddenly was questioned.

Antman *et al* described evidence-based medicine is a child of the nineties. Western medicine was traditionally based on the scientific method and much conventional and standard therapy that has been perpetuated by textbooks written by acknowledged

²⁰⁹ See Chapter 6 where the Supreme Court of Appeal supported this view in the Michael-case

²¹⁰ Graham S, *Enthusiasticus and Socrates* (1995) BMJ 310:1126-1127 (29 April) or (<http://www.bmj.com/cgi/content/full/310/6987/1126> accessed 5.7.2010)

authorities, however, sometimes without empirical proof of effectiveness.²¹¹ They opine that for about thirty years, authorities recommended calcium-channel blockers and anti-arrhythmic medications to prevent heart attacks, even though there was no proof that it worked, and there was evidence that it was most likely harmful. The same experts failed to advise thrombolytic therapy (to prevent thrombosis) and aspirin, even though research had shown this therapy to be effective treatments.²¹² They claim further that since the early 1990's, *Authoritarian Medicine* was challenged by evidence-based medicine to provide proof of effectiveness. They conclude that where the necessarily limited professional experience of a clinical authority is challenged through the wisdom of proper and adequate accumulated medical research, the courts will progressively favour the research and global findings.²¹³

13. Comments

It would be unfair to the doctors if mention is not made of *financial based evidence*, the absolute core business of the pharmaceutical companies, and touched on in paragraph 11 *supra*.

Bear in mind the busy practice of the doctor, where valuable time is slotted in order to meet with the representatives from the different pharmaceutical companies; would it be so wrong to trust the information provided by the pharmaceutical companies' representative believing that this indeed was based on sound scientific principles?

Elliot²¹⁴ conveys a disconcerting message that over the last twenty-five years medicine and consumerism have been on an unchecked collision course. He explains how shifty characters work the production line in Big Pharma from the professional guinea pigs who test-pilot new drugs, and the ghost writers who pen so-called "scientific" articles for drug manufacturers to the PR specialists who manufacture "new" bulletins. He explains

²¹¹ Antman E M, Lau J, Kupelnick B, Mosteller F, Chalmers T C, *A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. Treatment for myocardial infarction* (1992) JAMA Jul 8 VOL: 268 (2), p 240-8, comment in JAMA 1993 Jan 13, 269 (2): 214 Department of Medicine, Brigham and Woman's hospital , Boston
(<http://www.medlit.info/guests/mmpcanadian/medlit.htm> accessed 5.7.2010)

²¹² Antman et al p 9

²¹³ Antman et al p 10

²¹⁴ Elliot C, *White Coat Black Hat* (2010) p 51-59

that drug reps will do practically anything to meet quota, and gift-giving became a super specialized field of very subtle bribery, and finally he explains that the “independent” ethicists who oversee all that commercial medicine has to offer from their *pharmaceutical funded* chairs. Elliot discovers a medical plot of deep deception (that became almost institutionalized) that indicates a sad day for the medical scientific culture when no information can be trusted.

Retrospectively seen, the ultimate decision to match the patient with the medication is determined by the physician, and as such, the liability of these consequences should lie with him/her. Thus, the medical professional should not rely on medical information provided through pharmaceutical presentations but should read the package insert to determine whether the scientific information is reliable and valuable.

14. Conclusion

Part one of this chapter, dealt with the origin of evidence-based medicine, the concept of evidence-based medicine in broader terms, the value of evidence-based medicine, what doctors think of evidence based medicine, how evidence-based medicine in practice depicted problem areas in authority-based unscientific medicine, and how evidence-based medicine empowers the medical profession, seen as the collective mind of the profession.

In part two of this chapter, the emphasis shifted to a finer and detailed analysis of the methods and workings of evidence-based medicine, how the research material was obtained and what value should be given to certain clinical trials, and in certain instances, how to interpret clinical trials. The conclusions derived from these studies should ultimately be of value to the court as the court would be in a position to test the basis of any opinion as the basis should have been resourced from research material.

Effectively the court would be able to analyze the source of the research-basis of all medical evidence presented, for validity and reliability, and ultimately for logical reasoning, as conclusions made by the medical experts relying on medical literature presented, can be flawed.

CHAPTER 5

Part two- EVIDENCE BASED MEDICINE - The methodology

1. Introduction

The purpose of this chapter is to delve into the research methodology on which evidence-based medicine is based in order to understand the logic and reasoning behind research results and outcomes. What sample group was used, on what basis was the group selected, are the similarities of the sample group comparable with the facts before the doctor in order for him/her to use the research done on the sample group and the sample group outcomes for his/her patient? If the clinician finds that his/her patient has the exact symptoms of the patients used in the sample group, then it is most likely that the clinician's patient will get the same results. However this conclusion can be drawn had the research study been based on proper, logical, scientific methods. An analysis of this method in a research study forms the basis for this chapter.

Evidence-based medicine is not only research studies that are published, it goes further, utilizing specialist groups to analyze the medical evidence and categorize it in systematic review articles and complete overviews of articles in order that the physician can determine immediately whether it is a reliable study that can be trusted.

It should be noted that as explained in the previous chapter, the Cochrane Centers and other working groups were put up across the globe and the evidence-based medicine published and graded lost its national identity and became part of a huge evidence-based machine stating the authoritative voice of the global profession, by grading evidence.

2. An overview of the method of evidence-based medicine

Del Mar and Glasziou explain that research material are assessed and graded by panels of experts in a specific field called work groups to assist the medical professional to determine the reliability of the medical evidence in the field. Evidence based medicine therefore requires new skills including efficient literature searching and the application of formal rules of evidence in evaluating the clinical literature.²¹⁵ The users of the literature and research material available need to be able to determine how much confidence they can place in the recommendations.

The British Medical Journal published grading done by a Grade Working Group²¹⁶ who explained that “[J]udgments about the strength of a recommendation require consideration of the balance between benefits and harms, the quality of the evidence, translation of the evidence into specific circumstances, and the certainty of the baseline risk.” The need for simplicity has to be balanced with the need for full and transparent consideration of all important issues.

3. Education in the use of evidence-based medicine and identifying high-quality evidence available

Many publications appear in many medical journals, medical newsletters and other newspapers. Bearing in mind what was explained in the previous chapter, one can understand that even if a paper was written by an esteemed medical professional, one must guard against opinion based evidence as opposed to evidence-based medicine, based on proper scientific research.

Schardt from the Duke University Medical Center²¹⁷ advises the user of evidence-based medicine to use the following steps to scrutinize the literature:

²¹⁵ Del Mar C, Glasziou P and Mayer D *Teaching evidence based medicine* (2004) BMJ Volume 329; 990-1 (<http://bmj.com/cgi/content/full/329/7473/989> accessed 27.6.2010)

²¹⁶ Grade Working Group *Grading quality of evidence and strength of recommendations* (2004)BMJ Volume 328; 1-8

²¹⁷ <http://mcclibrary.duke.edu/subject/ebm/overview/ebmkeitz.html> accessed 27.6.2010

After the clinician has assessed and made an initial diagnosis, the clinician should

- formulate the clinical question
- select resources (Medline, ACP Journal, Cochrane Database etc.,) and conduct a search that would filter out irrelevant information
- critically appraise evidence for validity (closeness to the truth) and applicability (usefulness, relevancy)
- integrate evidence with clinical expertise and clinical findings in the patient and apply to the practice
- evaluate the performance in conjunction with the patient.

Evident from the steps suggested by the Duke University Medical Center is a thorough analysis of the patient's condition after the clinician has taken a history from the patient, examined the patient, done clinical tests to confirm the diagnosis. Once the clinician has formulated a diagnosis together with differential diagnosis (should he be incorrect with his initial diagnosis) then the clinician would access a trustworthy data base like Cochrane Centers, where he/she would conduct a search for the relevant clinical condition. From these trustworthy sources the clinician would receive several literature articles that has been graded by the Center as being best available evidence with support from other medical centers or information informing the clinician that this information was not monitored by the peers and therefore not supported and graded as best available evidence. In such instance the clinician will know that he has to scrutinize the study and critically appraise the evidence in the literature for flaws in reasoning before deciding to use the information on his/her patient. The clinician would then use the information in addition to his medical knowledge, expertise and clinical findings in the patient and apply it whilst evaluating the performance of his/her patient continuously.

Duke ²¹⁸ further indicates that a study by Crowley in 2003, reported that the CAR study showed that of 520 clinical questions for which answers were sought in the medical literature. In 53% of these cases the literature confirmed the management decision, but in 47% of these cases the literature changed the medication, diagnostic test, or prognostic information given to the patient, dramatically.

Accordingly Duke indicates that Michaud ²¹⁹ is of the opinion that, “Most primary therapeutic clinical decisions in 3 general medicine services are supported by evidence from randomized controlled trials.” Michaud continues that this should be reassuring to those who are concerned about the extent to which clinical medicine are based on empirical evidence. Also reassuring is the fact that this finding has the potential for quality assurance, as it was discovered that literature search could have potentially improved these decisions in some cases.

3.1 Formulate the clinical question and the diagnosis

Seen above was the analysis of the process from clinical evaluation to decision-making and treatment. Most importantly the initial diagnosis needs to be scrutinized as this is the source from where all other assumptions will be made. In other words if the initial diagnosis is not done properly based on sound principles, the clinician will be going nowhere with any evidence-based medicine albeit fully supported and underwritten by the profession.

Keitz, Edelman and Greenblatt,²²⁰ start out by stating that the clinical tasks should contain the following information:

- The clinical examination of the medical practitioner would have an interpretation of the findings from the history and physical examination of the patient;
- The etiology would consist of identifying causes for disease;

²¹⁸ http://www.mclibrary.duke.edu/subject/ebm/overview/ebm_keitz.html p2 accessed 27.6.2010 and Crowley (2003)

²¹⁹ http://www.mclibrary.duke.edu/subject/ebm/overview/ebm_keitz.html accessed 27.6.2010 and Michaud G, (1998)

²²⁰ http://www.mclibrary.duke.edu/subject/ebm/overview/ebm_keitz.html p2 accessed 27.6.2010

- Diagnostic testing would consist of the interpretation of the diagnostic tests in order to confirm or exclude diagnosis;
- Prognosis would consist of the likely clinical course over time;
- Therapy would consist of how to select treatments to offer patients that which does more good than harm, and all options available;
- Prevention would consist of how to reduce the chance of the disease by identifying and modifying risk factors;
- Self-improvement would be how to keep up to date, improve your clinical skills and run a better, more efficient clinical practice.

3.2 Select resources and critical appraisal

Keitz, Edelman and Greenblatt, from Duke University explain that in order to obtain the best available evidence in the field, the clinician should analyze previous scientific studies such as:

3.2.1 Randomized Controlled Clinical Trials and Controlled Clinical Trials

These trials involve one or more test treatments, one control treatment, specified outcome measures for evaluation and a bias free method of assigning patients to the test treatment. Drugs, devices or procedures are studied for diagnostic, therapeutic and prophylactic effectiveness and control measures include placebos, active medicine, no treatment, dosage forms and historical comparisons. When using random number tables to assign patients to a test or control treatment, the trial is characterized as a **RANDOMIZED CONTROLLED TRIAL**.²²¹ When using coin flips, odd-even numbers, patient numbers or days of the week or other pseudo- random processes are known as **CONTROLLED CLINICAL TRIALS**.²²² Advantages of a randomized controlled trial would be unbiased, blind trials that facilitate the statistical analysis. Disadvantages would be that these trials are expensive, volunteer bias (selection of volunteers are

²²¹ http://www.mcclibrary.duke.edu/subject/ebm/overview/ebm_keitz.html (accessed 27.6.2010)

²²² Ibid p3

done according to pre-diagnosis of the patient) and ethically problematic²²³, as the patient receiving placebos are in effect, “fooled”.

Blinding can be single blinding or double blinding. When neither the investigator nor the patient is aware of whether the patient is in the active group or in the control group (placebo), the effects the patient is experiencing may be attributed to either the treatment they are receiving or not. This is referred to as a double blind study. Single blinding is when the investigator is aware of the active group but not the patient. Double blinding is done to ensure that the investigator does not over interpret outcomes.

3.2.2 Cohort Study (large groups of people)

Defined populations, as a whole, are followed in an attempt to determine distinguishing subgroup characteristics.²²⁴ The advantages of these trials are that it is ethically safe,²²⁵ subjects can be matched, timing of events can be established, eligibility criteria and outcome assessments can be standardized and it is administratively easier and cheaper than the randomized controlled trials. The disadvantages are that the control subjects might be difficult to identify, blinding is difficult, no randomization present and for rare diseases large sample sizes and long follow-up are necessary.²²⁶

3.2.3 Case Control Study²²⁷

These studies identify persons with a certain disease of interest and a control group without the disease. The study compares diseased and non- diseased persons regarding the frequency or levels in each group. Some would have the disease of interest and their characteristics are compared with the unaffected persons.²²⁸ The advantages of the studies are that it is inexpensive, quick and the only feasible method

²²³ Ibid p4

²²⁴http://www.mcclibrary.duke.edu/subject/ebm/overview/ebm_keitz.html p 3 (accessed 27.6.2010)

²²⁵ An expert consulted indicated that this is not invariably true as he made reference to the infamous Tusagee syphilis study which was a cohort study

²²⁶ See footnote 224

²²⁷ An example of such a study would be Cattran DC, Appel GB, Hebert LA, et al, A randomized trial of cyclosporine in patients with steroid-resistant focal segmental glomerulosclerosis (1999) North America Nephrotic Syndrome Study Group. *Kidney Int* 56: 2220-2226

²²⁸ See footnote 224

for very rare disorders, or those with long lag between exposure and outcome. The disadvantages are one has to rely on recall or records to determine exposure, the selection of the control group is difficult, and there is potential for bias in the recall and records selection.

3.2.4 Cross-Sectional Study

This is the observation of a defined population in a single point in time. Exposure and outcome are determined simultaneously. The advantages are that it is cheap and simple and ethically safe. The disadvantages are that it establishes association and not causality, the recall can be biased and group sizes may be unequal.²²⁹

3.2.5 Review²³⁰

This is the examination of already published material, published in a review format. It can be broad or narrow however the most desired reviews are those of current literature. These reviews must be differentiated from historical reviews on similar subjects. Specific headings for specific types of reviews are known like academic reviews, literature, multi-case reviews, reported cases and tutorial reviews.²³¹

3.2.6 Systematic Review

These reviews focus on specific topics and answer a specific question. An extensive review of the evidence is given after the methodology was presented.²³²

²²⁹ Ibid

²³⁰ An example would be Early Breast Cancer trialists' Collaborative Group. *Tamoxifen for early breast cancer: an overview of the randomized trials* (1998) *Lancet* 351:1451-1467

²³¹ See footnote 224

²³² An example would be Oxman AD, Thomson MA, Davis DA, Haynes RB, *No magic bullets: a systemic review of 102 trials of interventions to improve professional practice* (1995) *CMAJ* 153: 1423-1431

3.2.7 Meta Analysis (overview of clinical trials) ²³³

Combination of results of independent studies, obtained from published material, and the summaries of the conclusions to evaluate the therapeutic effectiveness and to plan new studies where it was ascertained that the information is inefficient.²³⁴ It was only natural that Meta Analysis (or the analysis of analyzed studies) be introduced as it was clear that the size of sample group in a study influences the variability of the resulting calculation: the smaller the sample the wider the Confidence Interval (CI),²³⁵ the Standard Deviation or Standard Error. Naturally the question arose: what if similar studies be grouped together and then statistically analyzed as if the study subjects were part of a much larger study? In this way a number of studies that did not show an effect could by increasing the sample size in combination show an effective outcome. So although each study individually does not present evidence for effective treatment combined (in a group) they do.²³⁶

4. Evaluation of statistical data in literature ²³⁷

Sackett *et al* and the publishing group of the British Medical Journal show that the research studies accumulated data regarding a population group and a study group, which was a clearly defined group of patients similar in all important ways other than the exposure to treatment, diagnostic test or therapy. This data would be published after certain calculations were made in order to determine the risk or harm or such result that

²³³ An example would be Walton R, Dovey S, Harvey E, Freemantle N Computer support for determining drug dose: systemic review and meta-analysis (1999) BMJ 318: 984-990

²³⁴ The above information is taken from the Evidence-Based Medicine Glossary at Oxford University and the National Library of Medicine as seen on the website of Duke University
<http://www.mcilibrary.duke.edu/subject/ebm/overview/ebmkeitz.html>(accessed 27.6.2010)

²³⁵ See Chapter 5-part two- paragraph 4.2

²³⁶ An expert explained that one of the problems of meta-analysis is that it is difficult to find studies in the literature that contain sufficient detail that indicate that it can logically be combined, and the decision which studies to reject from the meta analysis must be a judgement call. When interpreting meta-analysis the methodology should be scrutinized for possible selection bias. If correctly performed the evidence provided by meta-analysis is usually classified as the most dependable type in the hierarchy.

²³⁷ Sackett DL *et al* Evidence-based medicine: How to practice and teach EBM (2000) p 233-243 and BMJ Publishing Group Clinical Evidence: The International source of best available "evidence" for effective healthcare (2006) BMJ Publishing Group

was foreseen in the hypothesis. Scientists used these statistical data to express the different results after the evidence had been evaluated.

4.1 Terminology used to express results ²³⁸

- **Absolute risk:** is the probability that the individual will experience the outcome;
- **Absolute risk reduction (ARR):** the absolute arithmetic difference in rates of bad outcomes between experimental and control participants in a trial calculated as Experimental event rate minus Control event rate (EER- CER) and accompanied by a 95% CI (confidence interval);
- **Baseline risk:** the risk of the event occurring without the active treatment;
- **Bias:** systematic deviation from study results from true results;
- **Blinding/blinded:** a trial is fully blinded if all the people involved are unaware of the treatment group receiving the active treatment until after the results are known;
- **Confidence interval (CI):** Quantifies the uncertainty in measurement. It is usually reported as 95% CI, which is the range of values within which we can be 95% sure that the true value for the whole population lies. E.g. for a NNT of 10 with a CI of 5-15 we would have 95% confidence that the true NNT value was between 5 and 15.
- **Controls:** refers to the participants in the comparison group;
- **Heterogeneity:** refers to the dissimilarity between studies in a meta-analysis group;
- **Homogeneity:** refers to the similarity between groups or studies;

²³⁸ See footnote 234

- **Morbidity:** rate of illness but not death;
- **Mortality:** rate of death;
- **Non-systematic review:** a review or meta-analysis that either did not perform a comprehensive search of the literature, and contains only a selection of the studies, or did not state its methods for searching and appraising the studies;
- **NNT (number needed to treat):** the number of patients who need to be treated to achieve one additional favourable outcome, calculated as $1/ARR$ and accompanied by a 95% CI (confidence interval);
- **Treatment effects:** after the use of intensive insulin therapy it was shown that a reduction in retinopathy (a complication of diabetes) occurred in diabetic patients, to 13%(EER-experimental event rate) from 38%(CER-control event rate). The Confidence interval (CI) was 95%. Relative risk reduction (RRR) = $EER-CER/CER=66\%$ and Absolute risk reduction (ARR) = $EER-CER= 25\%$ Number needed to treat: $1/25\%=4$. Four people need to be treated in order to have one successful one-
- **Risk increase (harm):** (Relative risk increase (RRI) same as above the difference is that the effect was the other way round and had increased, Absolute risk increase (ARI) and number needed to harm (NNH) are similarly defined
- **Validity:** the soundness or rigour of a study, the study is internally valid if the way it is designed means that the results are unbiased, and gives an accurate estimate of the effect.²³⁹

4.2. The larger the group in the study the smaller the CI and the more reliable

Sackett *et al* explain that the confidence interval (CI) gives a measure of the precision (or uncertainty) of study results for making inferences about the population of all such patients, and 95% of such intervals will contain the true population value. The CI gives

²³⁹ Sackett *et al* p 233

the strength of evidence regarding quantities of direct interest such as treatment benefit. Often it is a range of values that falls between the confidence limits. The uncertainty showed by the CI is proportional to the square root of the sample size. Smaller samples provide less information than larger samples, and the CI would be correspondingly wider in a smaller sample than a larger sample. e.g a “paper comparing three tests to diagnose *H.pylori* reported the sensitivity of the C urea breath test as 95.8% (95%CI, 75-100%). While the figure of 95.8% is impressive, the small sample of 24 adults with *H.pylori* means that there is considerable uncertainty in that estimate as shown by the wide CI. If the same sensitivity had been observed in a sample of 240, the 95% CI would have been from 92.5 to 98.0%.²⁴⁰ Sackett *et al* state that “The most appropriate methods of statistical analysis and presentation must be largely a matter for personal judgment although increasingly journals are requesting or requiring authors to use CIs when presenting their key findings. It seems clear that the wide adoption of CIs in medical research papers over the last decade has been of great benefit to a more correct understanding of the external evidence used in the practice of evidence-based medicine.”²⁴¹

There are other statistics that were previously used to report on the variability on statistical data demonstrated in treatment effect studies and are almost exclusively reported in older studies. These statistics are based on the variability of the data obtained in the study and say nothing about the population the clinician is interested in. The most commonly used are the standard deviation (SD) and the standard error of the mean (SEM). Using these parameters and trying to answer the clinicians’ question “what do these numbers mean for other patients in the population, such as mine” is a common mistake not only in interpreting studies but in presenting evidence to the courts. It is recommended that any data reported as a Mean (+-SD) should be recalculated by a statistician and interpreted by such an expert. Studies, that report data as a Mean+- a second number without specifying SEM, SD or CI should be treated with doubt and

²⁴⁰Sackett *et al* p 233-243

²⁴¹ *Ibid* p 242

rejected for purposes of evidence.²⁴²

5. Grading the quality of evidence

It is important to know that the grading of evidence-based medicine can be done in several different manners of which only one is described hereunder. It is not practical for individual clinicians to make complex decisions without evidence-based medicine assistance as it can do more harm than good.

The Grade Working Group²⁴³ assists in that their recommendations show how much confidence users of evidence-based medicine can place in systematically developed guidelines. They are of the opinion that their recommendations facilitate critical appraisal of these judgments and help to improve communication of this information.

They maintain that “[R]eviewers should consider four key elements: study design, study quality, consistency and directness” when appraising medical research studies.

The study design is the basic study design that can be based on observational studies or randomized trials. An observational study result, with the same objective, can differ vastly from randomized trials, which have the effect that observational studies are seen to be of lower value than randomized trials. “On the other hand randomized trials are not always feasible and, in some instances observational studies may provide better evidence, as is generally the case for rare adverse events.”²⁴⁴ The Grade Working Group concludes that it is “essential to consider study quality, the consistency of results across studies, and the directness of the evidence, as well as the appropriateness of the study design”²⁴⁵ in determining the value of the research. They continue that the study

²⁴² This remark was obtained from an expert (and statistician) who recommended that the formulas for calculating these numbers be obtained from Sackett or other introductory textbook for formulas.

²⁴³ Grade Working Group Grading quality of evidence and strength of recommendations (2004) BMJ Volume 328;

²⁴⁴ See footnote 239

²⁴⁵ Ibid p 2

quality is the detailed study methods and execution.²⁴⁶ The reviewers should take into consideration the criteria of adequacy of allocation concealment, blinding, and follow-up.

With regard to consistency, the Grade Working Group warns that there should be similarity of estimates of effect across the study.²⁴⁷ There should be explanations for important inconsistencies so that the reviewer can decide whether the results can be trusted or not, was the inconsistency significant or not. The working group states that the “Directness refers to the extent to which the people, interventions, and outcome measures are similar to those of interest. For example, there may be uncertainty about the directness of the evidence if the people of interest are older, sicker, or have more co-morbidity than those in the studies. To determine whether important uncertainty exists, we can ask whether there is a compelling reason to expect important differences in the size of the effect.”²⁴⁸

In 2005 Sackett *et al* published Evidence-based medicine guidelines²⁴⁹ after “a need for a handbook on the wide range of diseases and conditions encountered by the general physician” emerged. In many instances high-quality evidence is not available but some evidence is available, and the guidelines then indicate that information per grading system is done as follows:

- A (high): Further research is very unlikely to change our confidence in the estimate of effect
 - Several high-quality studies with consistent results
 - In special cases: one large, high-quality multi-centre study
- B (moderate): Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
 - One high-quality study

²⁴⁶ Grade Working Group *Grading quality of evidence and strength of recommendations* (2004) BMJ Volume 328;

²⁴⁷ *Ibid* p 3

²⁴⁸ *Ibid* p 3

²⁴⁹ Sackett *et al*, p 233-243 **and** Kunnamo I, *et al Evidence-based guidelines* (2005) p xxvii

- Several studies with some limitations
- C (low): Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- One or more studies with severe limitations
- D (very low): any estimate of effect is very uncertain
- Expert opinion
- No direct research evidence
- One or more studies with very severe limitations²⁵⁰

6. Recommendations

The Grade Working Group published their recommendations made during the grading of the evidence that involved a trading off between benefits and harms.²⁵¹ They maintain that making the trade-off inevitably involves placing, implicitly or explicitly, a relative value on each outcome, and all these involve opinions of panel members. They explain that it is therefore not strange to find a panel “developing guidelines” and elect not to make a recommendation for clinical practice however make a specific recommendation regarding the research that is needed to reduce uncertainty and/or clarify the trade-offs.

7. Imprecise or sparse data

There seems to be no defined basis for dealing with sparse data, however a Grade Working Group²⁵² concludes that two possible definitions would be:

²⁵⁰ Kunnami *et al* p xxvii

²⁵¹ Grade Working Group *Grading quality of evidence and strength of recommendations* (2004) BMJ 2004 Volume 328; p5

²⁵² Grade Working Group *Grading quality of evidence and strength of recommendations* (2004) BMJ 2004 Volume 328; p5

- Data is sparse if the results include just a few events or observations and they are uninformative.
- Data is imprecise if the confidence intervals are sufficiently wide that an estimate is consistent with either important harms or important benefits.

These different definitions can result in different judgments. The Working Group suggest that the right approach to a single study with a small sample size yielding a wide confidence interval should be considered as imprecise or sparse data. They emphasize that confidence intervals that are sufficiently wide, irrespective of other outcomes would be consistent with conflicting recommendations and should be treated as being imprecise or sparse data.

8. Doctors should understand the analysis of the scientific data and be able to interpret it

Evidence-based medicine provides guidance to clinicians in formulating answers to a variety of circumstances. These include how to interpret a test for diagnostic purposes, how to decide on effectiveness on a particular form of treatment, to test the applicability of the prognosis or outcome, to determine the clinical importance of the planned therapy, to determine the evidence about the causation of harm (some clinicians choose to interpret the finer points of statistical data in an attempt to justify their decisions or draw unwarranted conclusions from difficult to interpret data)²⁵³

Straus *et al*²⁵⁴ say that some practitioners are concerned about the legal implications that evidence-based medicine poses, and ask whether clinicians can be considered negligent by the courts for not applying evidence based guidance in decision making. They express the concern that the fear that medical treatment and actions taken and weighed against evidence-based medicine could result in the inappropriate, broad brush application of guidelines for every patient intervention whereby “the art of practicing medicine is replaced purely with science- a soul destroying prospect for any clinician.”

²⁵³ See chapter 10 for a detailed discussion in this regard

²⁵⁴ Strauss SE and Jones G, *What has evidence based medicine done for us* (2004) BMJ Volume 329; 987-8

Respectfully a very narrow viewpoint as the art of medicine lies in the determining in the diagnosis and integrating that with the best evidence in the field and not in the prescription of a guided-step-by-step performance.

9. Conclusion:

The World Health Organization uses systematic reviews in forming new guidelines. Care should be taken with any reviews as secondary opinions can influence decisions and the decision-making process. Any changes or alternatives to a treatment need a logical, consistent, scientific-based approach to ensuring best practice. Best available medical evidence should be found regarding the different patients' needs. Research studies are done for different reasons but mainly concentrate on different diseases and treatments, and different medication and its effectiveness. A challenge for the clinician is always to determine the purpose of the study before him in order to use the information contained in the research study for his/her patient. Clinicians need not fear stepping away from guidelines of evidence based medicine if proper grounds exist to motivate alternative treatment.

This study will show in the chapters to follow how incorrect, insufficient and misconstrued information put before the court in the Michael-case²⁵⁵, resulted in justice not served. Reliable evidence-based medicine, based on the principles laid out in the previous chapters would have resulted in a judiciary, that understood the medical information before them, appreciated the medical information for its scientific basis and value and appreciated the evidence before the court as being detrimental to the case of the offending doctor and would have appreciated that, based on evidence-based medicine, the court could come to no other conclusion but to rule in favour of the plaintiff, and justice would have prevailed.

²⁵⁵ *Michael v Linksfeld Park (Pty) Ltd 2001(3)SA1188(SCA)*, A detailed analysis follows in chapter 7,8,9

CHAPTER 6

CAUSATION

1. Introduction

The purpose of this chapter is to illustrate the difference between medical causation and legal causation. It is an attempt to differentiate between the two yet it is not a simple matter and each individual matter should be analyzed in context. Several examples will be used in illustration and although it will be from the common law countries, it should not be seen as a comparative study merely an example to illustrate the different viewpoints between the two professions. Bear in mind the ultimate goal of this study is to analyze the Michael- case²⁵⁶ that was overturned by the Supreme Court of Appeal. By using practical medical evidence available, this study will demonstrate that had logical and practical medical evidence, based on scientific principles been presented to the court, the result would have been different. All the previous chapters gave background to the development of expert evidence in the different common law courts, and also the reasoning of the courts before arriving at a decision. It is in this context that the inclusion of the principles of causation must be seen, and not as an attempt to make an in-depth or comprehensive study of legal causation. It is the reasoning behind causation and the workings of causation in medical negligence matters that need to be emphasized and discussed in order to appreciate the legal cause of action.

2. Medical causation

Mayer defines medical causation as follows: “The ultimate goal of medical research is to increase our knowledge about the interaction of a particular agent (cause) with our health or disease (effect). Causation is the relationship between an exposure and an outcome such that the exposure resulted in the outcome. However the strength of an association may not be equivalent to proving a cause-and-effect relationship.”²⁵⁷

²⁵⁶ *Michael v Linksfeld Park (Pty) Ltd 2001 (3)SA1188(SCA)*, A detailed analysis follows in chapter 7,8,9

²⁵⁷ Mayer D, *Essential evidence-based medicine* (2004) p17

He continues that most biometrical studies attempt to show a relationship between a certain cause and outcome. “The cause may be a risk factor resulting in a disease, or a treatment helping to alleviate suffering. The effect is a particular outcome that we want to measure. Not all study designs are capable of proving a cause-and-effect relationship.”²⁵⁸

The cause can also be the independent variable (set by the environment or the researcher) like a risk factor or diagnostic test or specific treatment. The effect is the dependent variable. The effect depends on the cause or is influenced by the cause.²⁵⁹

3. Does medical causation differ from legal causation?

Different schools of thought, an apparent controversy within the medical profession, create confusion with the onus of proof for the Plaintiff in medical negligence cases and should be clarified. Legal commentators point out that it should not be a problem of medical proof or sufficiency, but rather the difference between medical causation and legal causation.²⁶⁰

Berman²⁶¹ *et al* are of the opinion that the medical doctor “is solely interested in causation from the standpoint of scientific medicine. That is to say, to him the cause of a given condition is thought of in terms of some intrinsic pathological, chemical, or medical factor which result in, affects or produces a particular condition. He seeks to isolate the precise force of nature which has caused the condition, and where several such inherent, intrinsic factors combine to produce a given result and if the physician can identify one but not all of these factors, he is justified from a medical standpoint in holding that he does not know the cause.”

Berman *et al* continue and said that legal causation [discussed in detail hereunder] on the other hand, is where it can be found that a “significant external factor or extrinsic event which alters in some way the then existing state of health of the accident victim.

²⁵⁸ Mayer p17

²⁵⁹ Mayer p17

²⁶⁰Berman E Z *et al Examination of medical experts*(1968) by Mathew Bender New York p 316

²⁶¹ Ibid p 316

To the lawyer, where a traumatic event is a substantial factor in bringing about an injury or condition, it is the legal cause of the injury or condition even though underlying bodily processes or forces of nature may combine with the trauma to produce the given result.”²⁶²

The difference in the above principles is well illustrated by a certain Professor Small, who cited a bizarre but excellent example: “Following an explosion, an Indiana coal miner was taken to the hospital with two perforations in his skull, a severe scalp wound, severe burns and fractures of both legs.” He was admitted to hospital in shock, very low blood pressure and pulse. Initially he was unable to eat but had little mouths-full of soup, slowly over a period of time, with no bowel movements. On the fifteenth day he began vomiting convulsively, and on the next day he died.²⁶³

It seems that physiological principles like shock and the low blood pressure would have had an impact on the alimentary functions in the body and the patient should have been treated with intravenous fluids until such time that normal bowel function was restored. Intake and output should have been monitored in a severely ill patient, and therefore insufficient medical management played a significant role in the outcome of the above scenario.

In the case *Miami Coal Co vs Luce*,²⁶⁴ with a workman’s compensation claim by the widow for her and her children, the different viewpoints became clear. The doctors were of the opinion that the cause of death was blocked bowels. However the court was of the opinion that had in not been for the mine accident, the *sequelae* would not have happened and the miner would not have died. Two of the three doctors “soberly assigned the cause to obstructive bowels and opined further that the explosion injuries were not the cause”.²⁶⁵

²⁶² Berman *et al* p 316-317

²⁶³ Berman *et al* p 317

²⁶⁴ *Miami Coal Co v Luce*, 76 Ind App 245,249,131 NE 824 (1921)

²⁶⁵ Berman *et al* *Ibid* p 317

The court went as far as to say: “Indeed, if it was not for the saving grace of what we call common sense, justice would be defeated in almost every case where opinion evidence is admitted.”²⁶⁶

Berman *et al* are of the opinion that medical causation had difficulty in separating cause from etiology.²⁶⁷

3.1. Death certificates should state the cause of death

In South Africa medical causation and legal causation created confusion in courts. A doctor indicated on the death certificate of a deceased patient that the patient died of respiratory failure (the breathing of the patient ceased). The legal profession would perceive the cause of death to be “the overdose of sleeping tablets” and would see the ensuing respiratory failure as a consequence of the overdose. (The overdose caused the muscles to relax to such an extent that normal breathing cannot take place and the patient died). Furthermore, the legal profession would argue that *we all will eventually die of respiratory failure* as the failure to breathe is part of the dying process that is the reason why the cause of death was the tablets.

A Bloemfontein (South Africa) pathologist was criticized when he indicated on the death certificate of a patient, the cause of death was *complicated retroviral disease stage IV and pulmonary tuberculosis*, instead of respiratory failure.²⁶⁸

3.2. Etiology in medicine

Before we attempt to bridge the gap between the two professions perception of causation, it might be useful to understand medical causation and the etiology behind it. The medical dictionary²⁶⁹ describes the etiology as a word derived from the Greek,

²⁶⁶ Berman *et al* Ibid p 317 **and** *Miami Coal Co v Luce*, 76 Ind App 245,249,131 NE 824 (1921)

²⁶⁷ Berman *et al* Ibid p 317

²⁶⁸ www.news24.com/News/pathologist-face-the-music-24.11.2006 (accessed 17.6.2010)

²⁶⁹ Stedman's medical dictionary (1976), p 489

meaning “[G. *aitia*, cause, + *logos*, treatise, discourse]. Causation: the doctrine of causes, the study of causes; specifically the cause of the disease.”

The medical dictionary²⁷⁰ further describes the word “cause” in finer detail. The cause is seen as “that which produces an effect or condition; that by which a morbid change or disease is brought about”. A difference is made between: Constitutional cause is seen as “acting from within or through some systemic processor inborn error”; Predisposing cause is “anything that produces a susceptibility or disposition to a disease without itself causing the disease”; Proximate cause is “the immediate actual cause”; Specific cause is “the action of which produces only one definite cause; e.g. the specific micro-organism that produces diphtheria, tuberculosis or tetanus”.

It is most likely that the different causal aspects, described above, not always understood by the legal profession, are the cause of the confusion. A person not eating well and wasting, such a person would be predisposed to infection (the predisposing cause), now such a person falls ill with cholera (a bacteria found in contaminated water causing severe gastro-enteritis) the specific cause of the illness is the specific bacteria. Should this person die, the medical person will describe the actual cause of death, the dehydration and loss of electrolytes, as a result of the gastro-enteritis and the inability to cure the infection timely.

The legal cause of action would be the contaminated water and the liability will rest with the responsible party for the contaminated water and the spread of the illness. The drinking of the contaminated water would be seen as the direct cause of the illness.

3.3 Cause and effect

Medical research may show medical cause-and-effect that can be very valuable for the legal process, however the purpose of the study should be scrutinized as this is not always the case:

²⁷⁰ Ibid p 239

In the following resuscitation ²⁷¹ article, “Doppler measurement of cardiac output during cardiopulmonary resuscitation” by Fodden *et al* ²⁷² the cause and effect aspect is clear. It is a research study where the output of the heart (amount of blood leaving the heart at a given period in time) was measured with an instrument called a Doppler instrument. This was done scientifically in Sheffield, England, in the accident and emergency unit of the hospital. The article was published in 8 May 1996 in the Journal for Accident and Emergency Medicine. The abstract was described as “to estimate the cardiac output produced by external cardiac compression during standard cardiopulmonary resuscitation performed by two groups of operators with different levels of experience and training.” The results showed that the less experienced group produced an output of 1.2L/min, significantly less than the experienced group, fully trained in the technique who produced 3.2L/min. The conclusion which they arrived at was: Differences in cardiac output during external cardiac compression are related to experience with the technique.

The above study is a prospective study where the result showed the cause-and-effect in medicine. In other words, better pulmonary resuscitation produces a better cardiac output which results in better blood flow to all the organs and effective life support. Poor resuscitation leads to poor results and ultimate death.

The above study could have been used very effectively in the Michael-case ²⁷³ in favour of the claimant as the case turned on effective resuscitation management, ²⁷⁴ and the requisites for effective resuscitation are described in this scientific based controlled study.

4. Legal causation

In law a *causal nexus* is required between conduct (an act or omission) and damage (harm/injury), which form the basis for a claim and delictual liability. No one can be

²⁷¹ This study is discussed in chapter 8 in detail

²⁷² Fodden DI, Crosby AC, Channer KS *Doppler measurement of cardiac output during cardiopulmonary resuscitation* (1996) Journal: Accident Emergency Med Vol:13: 379-382

²⁷³ 2001(3)SA1188(SCA),

²⁷⁴ See chapters 7,8,9 later in this study

found liable if he or she did not cause the damage. Neethling *et al* formulates is as follows: “The question whether there is a causal nexus in a particular case, is a *question of fact* which must always be answered in light of the available evidence”.²⁷⁵

Several theories were developed to assist the court with finding the factual nexus.²⁷⁶ In other words the onus of proof lies with the Plaintiff, to find a link (nexus) between the harmful occurrence (event), and the damage (harm). The most important theory in this regard is the *conditio sine qua non*- theory (better known as the “but for” theory).²⁷⁷ The Plaintiff must show that had it not been for the action or omission of the defendant doctor, the Plaintiff would not have suffered harm/injury/damages.

Neethling *et al*²⁷⁸ distinguish between the theories in a clear manner, “all the theories use the *condition sine qua non* theory as their point of departure in order to determine initially whether a *factual* causal nexus between the act and the harmful consequence exists; if it does exist, so-called *factual causation* is present. Such a factual causal nexus may, however, extend very far- in fact *ad infinitum*- because a single act can in principle give rise to an endless chain of harmful events. Because no legal system can, on the grounds of fairness, allow unlimited liability merely based on causation, the next question that arises is for which of these harmful events flowing from this conduct, should a defendant be held liable. All the abovementioned causation theories, with the exception of the *condition sine qua non*, attempt to solve this problem.”

He continues that the *conditio sine qua non* test for factual causation is largely criticized for the flexibility of its application in courts, and that its application “compels one in certain circumstances to follow a particularly clumsy and indirect approach which

²⁷⁵ Neethling, *et al* *Law of delict* (1994) See also revised editions 1999 and 2001. In 1994 edition p 159 Often expert evidence is decisive as in the case of *Ocean Accident and Guarantee Corporation Ltd v Koch* 1963 4 SA 147 (A)- this is a motor vehicle accident where the court had to decide whether the collusion and the anxiety caused by it had resulted in the thrombosis after a neck injury. On appeal it was held that it is impossible to say that the thrombosis was the result of the accident.

²⁷⁶ Carstens PA & Pearmain DL, *Foundational principles of South African medical law* (2007) p 509-512, the writers gave a comprehensive description of how the reasoning of the courts developed, with discussed cases, finding the factual nexus.

²⁷⁷ Neethling *et al* p 161

²⁷⁸ Neethling *et al* p 159

ultimately does not provide a solution.”²⁷⁹

Neethling²⁸⁰ *et al* explains that the law approaches factual causation differently from the medical profession. If a person was stabbed in the chest by a knife, and a negligent nurse allowed him to fall from his bed and he sustained a skull fracture and died, the medical profession will possibly see the skull fracture as the cause of death, whilst the legal profession will view the initial stabbing as well as the negligent conduct of the nurse as causes of death.

It should be noted that the *conditio sine qua non* theory brings the following reasoning about: had it not been for the stab wound in the chest he would not have been admitted to hospital, would not have fallen from his bed and would not have died. The factual causal link is therefore established in law, with obvious contributory negligence aspects, that need to form part of the case, however the further legal causality should still be addressed.

Neethling *et al* offers that the legal causation can be described in general terms as “determining for which harmful consequences actually caused by the wrongdoer’s wrongful, culpable act he should be held liable.”²⁸¹

The question must be answered opines Neethling *et al* whether the link between the act (omission) and the harm is sufficiently close or direct for legal liability, or whether the harm is too remote²⁸². “Normally legal causation is only problematic where a whole chain of consecutive or remote consequences results from the wrongdoer’s conduct, and where it is alleged that he should not be held legally responsible for *all* the consequences.”²⁸³

They continue that theories used by the courts are: adequate causation theory (the damage must be adequately connected to the conduct); the direct consequence theory

²⁷⁹ Neethling *et al* p 163

²⁸⁰ *Ibid* p 168

²⁸¹ Neethling *et al* p 169 **and** their footnote 51 “factual and legal causation must be clearly distinguished”

²⁸² Neethling *et al* p 169 **and** their footnote 51

²⁸³ Neethling *et al* p 170 **and** their footnote 54

(an actor is liable for the direct consequences of his act); the theory of fault (an actor is only liable for those consequences of which he had fault) and the reasonable foreseeability theory (an actor is liable for those consequences covered by his intent and which he should have foreseen).²⁸⁴

Farlam AJ states in *Smit v Abrahams*²⁸⁵ that as long as the kind of damage is foreseeable the extent and the precise manner need not be foreseeable. He stated that the reasonable foresight test is combined with the direct consequences test in that a defendant will be held liable if he could reasonably foresee certain consequences of his culpable conduct, and any direct consequences arising from the conduct even if not foreseen.

Carstens and Pearmain²⁸⁶ state that this view was accepted.

Legal causation principles are sometimes complex and only arrived at by substituting a hypothetical lawful conduct with the unlawful conduct of the defendant. In *Silver v Premier, Gauteng Provincial Government*²⁸⁷, the minority judgment of Corbett JA in *Simon & Co (Pty) Ltd v Barclays National Bank Ltd*²⁸⁸ was quoted by the court and indicated that to arrive at a factual cause the court must sometimes find it necessary to substitute the unlawful conduct of the defendant with a lawful conduct more so if the unlawful conduct of the defendant takes the form of an omission. The court uses the example of a driver driving at an excessive speed and causing injury to someone else after a collision occurred. The hypothetical question, would the collision have been avoided and the injury to the driver, had the driver been driving at a reasonable accepted speed, would be a positive course of conduct replacing the negative action or omission, and thereby establish factual causation.

²⁸⁴ Neethling *et al* p 169-195

²⁸⁵ 1992(3)SA 158 (C) also see Carsten and Pearmain p 509

²⁸⁶ Carsten and Pearmain p 510 quoting *Gibson v Berkowitz 1996 (4) SA 1029 (W)* and *S v Mokgethi 1990 (1) SA 32 (A)*

²⁸⁷ 1998(4)SA569(W) quoted and discussed in detail by Carstens and Pearmain p 510

²⁸⁸ 914C- 918A quoted and discussed by Carstens and Pearmain p 510

The legal causation aspects discussed above should not be seen as a complete summary other than background information to understand the reasoning of the courts in deciding medical negligence matters.²⁸⁹

5. Back to expert evidence

5.1 Proposed guidelines regarding expert evidence by the medical profession

Even the medical expert is looking for guidance to better the role of the expert. Seen in the light of the above inherent differences (most probably misunderstanding of causation in medicine) between causality in medicine and in the law, it is not surprising that medical experts are severely being criticized as being biased and called “jukebox experts... who sing the tune they are paid for.”²⁹⁰ Grobler opines that a need exists for expert guidelines, standards, training and accreditation of expert witnesses.²⁹¹

From the medical profession a need was identified to describe the roll of the medical expert and Grobler²⁹² in an attempt to set the medical standards for the medical experts, looked towards the list of the UK Civil Procedure Rules, where it encapsulates the responsibilities of the medical expert as a possible solution for this need. Grobler summarizes of the UK procedure rules as follows:

- Expert evidence presented to the court should be, and should be seen to be, the independent product of the expert uninfluenced by the exigencies of litigation
- An expert witness should provide independent assistance to the court by way of objective and unbiased opinion to matters within his expertise. (Under the Civil Procedure Rules, it is an express requirement that the expert’s duty to the court over-rides any obligation to the person from whom he has received his instructions or by whom he is paid).

²⁸⁹ See footnote 271 *supra*

²⁹⁰ Grobler S, *The role of the expert witness* (2007) *The South African Gastroenterology Review* p 11.

²⁹¹ Grobler p11

²⁹² Grobler p12

- An expert witness should never assume the role of an advocate.
- An expert witness should state the fact or assumptions on which his opinion is based (Under the Civil Procedure Rules, it is an express requirement that an expert's report states the substance of all material instructions on the basis of which the report was written).
- An expert witness should not omit to consider material facts which could detract from his concluded opinion.
- An expert witness should make it clear when a particular question or issue falls outside his expertise.
- If an expert's opinion is not properly researched because he considers that insufficient data is available, then this must be stated.
- If, after exchange of reports, an expert changes his view on a material matter, having read the other side's expert's report or for any other reason, such change of view should be communicated to the other side without delay, and when appropriate to the court.

Grobler²⁹³ maintains that "In Australia, there are legislated requirements that all expert witnesses need to agree to before giving their opinion and the expert is considered to be the court's expert."

5.2 The need to overcome expert bias

As described in Chapter two, previously, several authors addressed the aspects of medical bias and offered solutions to this challenge, one of whom can be found in the "*Scientific Method: The Crucible for reliable and valid expert evidence?*"²⁹⁴ of Meintjes-van der Walt. She expresses her concern by saying that if special tutoring would take

²⁹³ Grobler p12 **and** Federal Courts of Australia. Guideline's for expert witnesses in proceedings in the federal court of Australia. http://www.fedcourt.gov.au/how/prac_direction.html Sept 2006 (accessed 5.7.2010)

²⁹⁴ Van der Walt LM, *Scientific Method: The Crucible for reliable and valid expert evidence?* (2006) (2) *Speculum Iuris* p 177

place in different fields of expert evidence, this may lead to judges placing undue reliance on the mere ‘*ipse dixit*’ of the expert or relying unrealistically on the qualifications or experience of the expert and thereby allowing the medical expert to enter the arena of the judiciary. Meintjes-van der Walt²⁹⁵ succeeds in describing an analytical method to assess and evaluate scientific evidence.

5.3 The roll of the expert determined by the Supreme Court of South Africa

Carstens²⁹⁶ shows how the boundaries were set in an Appeal Court decision, *Michael vs Linksfeld Park Clinic*²⁹⁷ when the court was confronted with facts, medical information and legal aspects that were insufficiently analyzed. The court investigated previous court decisions and came up with a thorough list regarding the requirements from the medical experts and the approach of the court. The court summarized the approach of the courts to medical evidence as follows:

- The issue of reasonableness or negligence is for the court to decide – on the basis of often conflicting expert opinion (1200D-E)
- the determination will not involve credibility but rather an examination of the opinions, the analysis of the essential reasoning, and based on that the court will reach its own conclusions (1200 D-E)
- the standard is the conduct of the reasonable practitioner in the particular professional field, not always a helpful guide (1200 F-G)
- a determination whether the opinion is founded on logical reasoning (1200I-J)
- the court is not bound to find a defendant liable for negligence just because evidence of expert opinion are led to that effect, as such evidence should in issue accord with sound practice (1201A-B)

²⁹⁵ Van der Walt p 201

²⁹⁶ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* (2002) (65) THRHR Vonnisse P431-436

²⁹⁷ 2001(3) SA 1188 (SCA)

- the court must be satisfied that such an opinion had a logical basis- even a body of professional opinion can overlook an obvious risk, even universally held (1201 A-B)
- A defendant can be held liable despite the support of a body of professional opinion sanctioning the conduct in issue (1201C-E)
- The assessment of medical risks and benefits is a matter of clinical judgment, which a court will not normally make without expert evidence, however it should be supported by reason (1201 D-E)
- Only where expert opinion cannot be logically supported at all will it fail to provide the benchmark by reference to which the defendant's conduct fails to be assessed (1201 E)
- It must be borne in mind that expert scientific witnesses tend to assess likelihood in terms of scientific certainty and not in terms of which the balance of probabilities lies on a review of the whole of the evidence (1201 E-F)

6. Conclusion

Legal causation is crucial to link the incident with the offender and with the harm/injury suffered. If the occurrence is too remote then a claim for damages cannot succeed, as the legal nexus does not exist which had to fault the offender. In the Michael-case,²⁹⁸ the courts had a chance to look at the roll of the expert in great depth and despite the unsuccessful outcome for the injured Plaintiff the decision was fair and just, given the information before the court. The court had been presented with insufficient medical information (evidence) as the medical experts did not assist the court. One of the medical doctors was biased simply because he was the treating doctor. He was involved in the matter in every material and practical aspect, indicating no room for an independent view. He should have been heard as a witness or cited as a defendant, and should not have acted as an independent expert witnesses.

Seen from the summary of the role of the expert as determined by the Supreme Court of

²⁹⁸ Michael v Linksfeld Park Clinic 2001 (3) SA 1188 (SCA) See chapter 7 and 8 for discussion

Appeal in South Africa, above, the court was looking for a “collective mind”²⁹⁹ of the expert. The court looked for a generalization amongst experts in the Michael-case,³⁰⁰ experts who are in an agreement. The court described it as its search for a “collective mind” amongst the experts which the court could not find.

In the light of the information contained in all the previous chapters and arguments, what better “collective mind” of the medical industry to present to the court, than the collaboration of medical evidence in the form of evidence-based medicine.

In the chapters to follow, the Michael-case³⁰¹ will be re-assessed with sufficient medical information from the “collective mind” of the medical profession and industry to test the impact on the outcome of a case, and the Michael-case will be used as an example.

²⁹⁹ See Chapter 2 paragraph 2.4 supra

³⁰⁰ 2001(3) SA 1188 (SCA)

³⁰¹ 2001(3) SA 1188 (SCA)

CHAPTER 7

MICHAEL-CASE: THE FACTS

1. Introduction

In the previous chapters the role of the expert in various common law countries³⁰² and what is expected from the medical evidence before the courts, have been discussed. Chapter 5 introduced the medical part of the dissertation and took us through the resources of the medical evidence and the principles of evidence based medicine. It was illustrated that the basis of medical research is founded on scientific evidence, with due regard to all aspects that can influence research recommendations. It was noted that the management of evidence-based medicine in the hands of groups like the grade working groups and centers like the Cochrane Centers aim to provide a global consensus regarding certain medical research conclusions which might well tie in with what the court had in mind in its search for a “collective mind.”³⁰³

The importance of this chapter is to show how a case presented to a court based on inadequate and incorrect medical information leaves the judiciary with no other decision but to rule against the Plaintiff. The study starts with a mere summary of the facts of the reported case, *Michael v Linksfeld Park Clinic*³⁰⁴ and the averments contained in the particulars of claim of the Plaintiff (parents on behalf of Michael) as well as a summary of the reasoning used by the court in order to arrive at the final conclusion.

The following chapter³⁰⁵ will endeavour to use the principles as explained by evidence-based medicine to place the correct information before the court and thereafter to assess whether the correct medical evidence would have changed the outcome of the *Michael-case*.

³⁰² Chapters 1-4

³⁰³ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA) and Chapter 2 paragraph 2.4 for collective mind

³⁰⁴ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

³⁰⁵ Chapter 8

2. The *Michael*-case - the facts

In the *Michael*-case the following facts were before the court: The Plaintiffs were the mother and father of the injured young man. The Plaintiff's 17-year-old-son sustained a sports injury to his nose. They consulted a plastic and reconstructive surgeon, a certain Dr Fayman, who suggested a rhinoplasty, to repair the nose, by removing a hump from the dorsal aspect of the nose, to its normal state. The operation to be performed had to correct the deviated septum of the nose (in the middle). The plastic surgeon was assisted by another doctor, Dr Rubin, and by an anaesthetist, the Second Defendant in the matter. The First Defendant was the Linksfield Hospital, in Johannesburg, in its capacity as the employer of the two registered nurses who were employed as qualified nursing personnel in the operating theatre.³⁰⁶

2.1 The operation

The patient was anaesthetized (09h45) (given an inhalant and *propranolol*) and the surgeon injected a local anesthetic (*lignocaine and adrenaline*) into the nose of the patient and inserted at the back of each nostril a ribbon-gauze soaked in *cocaine* solution. The *cocaine* was administered to constrict the blood vessels (vasoconstriction effect) in order for the surgeon to have a bloodless field during the operation. (An overdose of *cocaine* has cardio-toxic effects that can lead to cardiac arrest).³⁰⁷

Surgery commenced at 10h00. During surgery (10h15) bleeding suddenly occurred in the right nostril, obscuring the operative field, and bringing the operation to a stop. The anaesthetist noticed a dramatic increase in the patient's heart rate and blood pressure (10h15) (hypertensive crisis).³⁰⁸ The Second Defendant diagnosed the reason for this as too light anaesthesia, and he deepened the degree of anaesthesia, in an attempt to bring down the heart rate and the elevated blood pressure. He injected a further 1mg of *Propranolol* into the drip line, the blood pressure declined as anticipated but fell

³⁰⁶ Carstens PA & Pearmain DL, *Foundational principles of South African medical law* (2007) p 784-793

³⁰⁷ Carstens and Pearmain p 784-793

³⁰⁸ Ibid

alarmingly below normal and the heart rate slowed down to an alarming pace (bradycardia) (10h20-10h28). The QRS complex widened, and the patient went into cardiac arrest and asystole (flat line) (10h28) (see 1193G-1194B).³⁰⁹ Cardio-pulmonary resuscitation (external heart massage) (10h28) was performed, with *ephedrine*, *isoprenaline* and *adrenaline*, as the Second Defendant considered that there was an over-action by the *propranolol*, and he attempted to raise the heart rate and the blood pressure by trying to remove the beta- blocker effect. This was not successful.³¹⁰ A defibrillator was acquired and an attempt was made to defibrillate the heart (by shocking the heart into any heart action) in order to restore normal heart beats. (It was recorded as 200joules, CPR and *adrenaline*, 200 joules, CPR and *adrenaline*, 360 joules, CPR and *adrenaline* and *bretyliumtosylate* and *sodium bicarbonate* and *calcium gluconate*).³¹¹ The defibrillator appeared to malfunction and another was employed to defibrillate the heart. A second defibrillator was used and they applied 360 joules and 360 joules. After a period of about 20 minutes, ventricular tachycardia was seen and later sinus tachycardia. The heart function was restored (10h44) and the patient taken to ICU. An echocardiogram showed an enlarged heart with left ventricular contractility significantly reduced. The report read “*marked global myocardial dysfunction, probably acute*”, possibly the result of prolonged hypoxia. Obviously prolonged hypoxia did occur and although it is in dispute precisely by what mechanism the myocardial damage came to be caused, what is not in issue is that hypoxia caused injury to the brain. The patient had sustained major brain damage as a result of cerebral anoxia. He was left to be in a permanent vegetative state, brain dead.³¹²

2.2 The allegations of medical negligence

Negligence was alleged against the anesthetist (Second Defendant) and the clinic (First Defendant).

³⁰⁹ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* (2002) (65) THRHR Vonnisse P431-436

³¹⁰ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 435

³¹¹ Carstens and Pearmain p 784-793

³¹² Carstens and Pearmain p 784-793

The Second Defendant:

- It was alleged that he failed to take adequate account of the effect the *cocaine* would have in conjunction with what he himself administered and to guide Dr Fayman as to the upper dose limits of *cocaine*
- He failed to dilute the *propranolol* which was given to combat the hypertensive crisis
- The use of *propranolol* in conjunction with *cocaine* created the risk of sudden heart failure
- He failed to recognize the risk or to prevent life-threatening bradycardia and cardiac arrest³¹³

First and Second Defendant:

- First and Second Defendant failed to ensure that a functional defibrillator was available, and that he was reasonably acquainted with its workings
- First and Second Defendant failed to order a defibrillation at the earliest opportunity, alternatively attempted defibrillating an asystolic heart worsening the outcome³¹⁴

The Plaintiffs alleged that the Second Defendant acted in a negligent manner during the cardiac arrest, and joint negligence was averred against both the Defendants in respect of the resuscitation process. (see 1196H-1197G)³¹⁵

By agreement between the parties the trial judge was asked to determine only the question of liability. Having found that none of the alleged negligence was proved the Plaintiffs lost their claim for damages,³¹⁶ but leave was granted to take the matter on appeal.

³¹³ Carstens and Pearmain p 787

³¹⁴ Carstens and Pearmain p 787-788

³¹⁵ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 431-436

³¹⁶ Carstens P *Setting the boundaries for expert evidence in support or defense of medical negligence* p 432

2.3 The Supreme Court of Appeal determined certain grounds for negligence

2.3.1 The cardiac arrest

What was the cause of the cardiac arrest? It was confirmed that the cause of the cardiac arrest was in all probability *cocaine* toxicity (1198I).³¹⁷ Carstens and Pearmain reiterated that the “plaintiffs contended that it was *propranolol* and that the hypertensive crisis was occasioned by too light anesthesia. For the second defendant it was maintained that the cause of both the hypertensive crisis and the arrest was *cocaine* toxicity.”³¹⁸

The real question was whether the cardiac arrest ought to have been foreseen (foreseeability), as a reasonable possibility, and that he would have guarded against (avoided) (1197I)?³¹⁹

It was found by the Supreme Court that the Second Defendant’s consideration that the hypertensive crisis was due to too light an anesthetic was reasonable, as well as that the over-action of *propranolol* and of the heart’s arrested state as asystole, were reasonable.(1199H)³²⁰

2.3.2 The resuscitation of the patient

Whether the “defective defibrillator” caused an unreasonable delay in the resuscitative process, and whether the ignorance of the Second Defendant and the theatre sister regarding the workings of the defibrillator caused unreasonable delay? The court held that the answer to that enquiry entailed examination of what resuscitation measures were taken during the first defibrillation and whether that was effective and whether the picture would have been different in the absence of their ignorance.

The court confirmed that the measures taken to combat the diagnosed asystole were

³¹⁷ Ibid p 432

³¹⁸ Carstens and Pearmain p 788

³¹⁹ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 431-436

³²⁰ Ibid p 432

appropriate and that it had been reasonable to resort to and persist with defibrillation. (1199I-J) The trial court made no finding whether the first defibrillator was in working order, or whether further defibrillation initially would have restored the patient's heartbeat and whether such restoration would have occurred any earlier than was in fact the case (1200A-C) ³²¹

The Supreme Court of Appeal also noted in its judgment “that in the trial court, none of the experts was asked, or purported to express a collective or representative view ³²² of, what was or was not accepted as reasonable in South African specialist anaesthetic practice in 1994. It stated that although it has often been said in South African cases that the governing test for professional negligence is the standard of conduct of the reasonable practitioner in the particular professional field, that criterion is not always itself a helping guide to finding the answer. The present case, it said, showed, why.

Carstens and Pearmain summarize the judgment and indicate from the judgment that “[A]part from the absence of evidence of what practice prevailed it was not a question of simply the standard, for example of the reasonable attorney or advocate, where the court would be able to decide for itself what was reasonable conduct. The court asked how the conduct and views of the notional reasonable anesthetist could be established without a collective or representative opinion especially in view of the fact that the primary function of the experts called was to teach, with the opportunity only of part-time practice. In these circumstances, said the court, counsel were probably left with little option but to elicit individual views of what the respective witnesses considered reasonable.” ³²³

2.3.3 The expert evidence

The above case had five medical experts testifying in court either on behalf of the Plaintiffs or the Defendants.

³²¹ Ibid p 432

³²² See Chapter 6- conclusion and Chapter 2 paragraph 2.4 for collective mind

³²³ Carstens and Pearmain p 788

The plastic surgeon (Dr Fayman), testified on behalf of the Plaintiffs (as the treating doctor and the independent expert witness).

Carstens³²⁴ also observes that the court highlighted the essential difference between the scientific and judicial measure of proof with reliance on another decision of the House of Lords in the Scottish case of *Dingley v The Chief Constable, Strathclyde Police*³²⁵ where it was said that: “One cannot entirely discount the risk that by immersing himself in every detail and by looking deeply into the minds of the experts, a judge may be seduced into a position where he applies to the expert evidence the standards which the expert himself will apply to the question whether a particular thesis has been proved or disproved...instead of assessing as a judge must do, where the balance of probabilities lies on a review of the whole evidence.”

Carstens says “that the court correctly ruled that it must be satisfied that the tendered medical opinion based on logic is not necessarily indicative of reasonableness or unreasonableness within the realm of accepted medical practice. Logic refers to a process of reasoning /rationality based on scientific or deductive cause and effect.”³²⁶

3. Conclusion

It is inexplicable how almost all the medical information was before the court in some sort of form, however without proper scientific basis or guidelines or even explanation and without guiding the court through the intricacies of pharmacological principles. The aspects in dispute were the different drug interactions and physiological impact on the heart of the Plaintiff, and whether the resuscitation efforts were significant and how that impacted on the condition of the Plaintiff. One can only wonder why the services of a clinical pharmacologist were not obtained to address the different drug interactions, and/or a trauma specialist to place before the court all the aspects of significant and

³²⁴ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 431-436 **and** Carstens and Pearmain p 790 **and** footnote 618 of the latter

³²⁵ Carstens P, *Setting the boundaries for expert evidence in support of defense of medical negligence* p 431-436 foot note 21 and he quotes *Dingley v The Chief Constable, Strathclyde Police* 2000 SC 77 (HL)

³²⁶ Carstens and Pearmain p 790 **and** Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 431-436

effective resuscitation methods and principles. Had that been done the outcome of this adverse decision of the court might have been different.

The next chapter will indicate the qualifying information that can be obtained by means of a simple search on the internet, which should have formed part of the information before the court and with this information, the different legal approach of the *Michael*-case based on logic medical evidence. The next chapter will indicate, that had reliable and proper scientific literature been used, and had it been placed in the hands of qualified medical experts to explain to the court the intricate medical anatomical and physiology workings, as well as the scientific drug interactions, based on evidence-based medicine, the outcome would have been sound in medicine and sound in law.

CHAPTER 8

THE *MICHAEL*-CASE: THE MEDICAL EVIDENCE (deconstruction)

1. Introduction

The objective of this chapter is to demonstrate the accessibility of evidence-based medicine information from the internet by entering the individual medication and its use, and by entering phrases like “*propranolol* side effects”, “*propranolol* interaction with *lidocaine*”, “cardiovascular toxicity”, “*lidocaine* and *adrenaline*”, “*lidocaine*, *adrenaline* and *propranolol*”. All the information obtained was summarized yet some proof to be of lesser value and relevance after consultation with an expert. These remarks are shown in the footnotes.

The literature is summarized and the medical information explained in a simplistic manner to make the general principles of anatomy and physiology easy to understand. The information that follows is an explanation of the side effects of the drug *propranolol*, the adverse interaction of *propranolol* with *lidocaine*, the cardiotoxicity or toxic effect that the combination of the two medications had on the heart, the interaction of *lidocaine* and *adrenaline*, and the combined effect that all three drugs, *lidocaine*, *adrenaline* and *propranolol*, had on the cardiovascular system of the patient. The latter was the information that should have been presented to the court, and is the ultimate reason why this case was not successful. The court had no alternative but to rule in favour of the defendant as the medical evidence put before the court did not discharge the onus of proof for the plaintiff. The literature in respect of the abovementioned drug interactions has been analyzed and will be applied to the *Michael*³²⁷-case and discussed in detail.

It is important to note that the medical evidence used in this chapter was not research obtained from medical experts, but extracts easily obtainable from package inserts and websites like e-medicine, in order to illustrate the easy access to information. An expert

³²⁷ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

would have made the task of the legal professional easier but the legal professional should update him/herself with the available information prior to consulting the medical expert.

2. The administration of medication

For ease of reference a summary of the time of administration and medication used in the Michael-case³²⁸ is set out hereunder:

09h40:	IV and ECG
09h45:	anesthetic induction (inhalant and <i>propanolol</i>)
09h50:	local anesthetic (<i>lignocaine and adrenaline</i>) plus <i>cocaine</i> soaked nose plug
10h00:	onset of operation
10h15-28	bleeding and tachycardia (supra-ventricular tachy-dyshythmia) and hypertension (hypertensive crisis) deepened anesthesia plus <i>propanolol</i> bradycardia QRS complex widened CPR and <i>ephedrine and isoprenaline and adrenaline</i>
10h28	cardiac arrest and asystole CPR attempted
1 defib	200 joules CPR and <i>adrenaline</i> 200 joules CPR and <i>adrenaline</i> 360 joules CPR <i>adrenaline, bretyliumtosylate, sodium bicarbonate, calcium gluconate</i>
2 defib	360 joules 360 joules
10h44	ventricular tachycardia and sinus tachycardia

³²⁸ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

	ICU
19h00	echocardiogram (heart enlarged and L ventricular contractility reduced significantly) Severe hypoxia and brain damage

It should be noted that most of the medication toxicity effects have an influence on the central nervous system and the cardiovascular system of the patient. As the above patient was mechanically ventilated, there was no risk of respiratory failure and the central nervous system effect is therefore not discussed.

*Note that: epinephrine = adrenaline
norepinephrine = noradrenaline
propranolol = propranolol (American vs British use)*

3. Different medication, certain aspects of it and the adverse effects in the event of overdose or inadvertent intravascular injection

3.1 Propranolol (beta-adrenergic blocking agent)

From the Michael-case the facts are reported that “*propranolol* is a beta blocker which lowers excessive heart rates by blocking the beta adrenergic receptors in the heart which govern heart rate stimulation...The package insert published in November 1993...stated that intravenous administration was for the emergency treatment of cardiac dysrhythmias especially including supraventricular tachydysrhythmias.”³²⁹

Kinney *et al* describe *propranolol* as a non-selective beta blocker mainly used in the treatment of hypertension. It is also indicated for tachyarrhythmias, myocardial infarction, angina pectoris and other. It blocks the action of *epinephrine*³³⁰ and *norepinephrine* on both β_1 - and β_2 - adrenergic receptors.³³¹ They maintain that

³²⁹ Carstens PA & Pearmain DL, *Foundational principles of South African medical law* (2007) p 785

³³⁰ also known as adrenaline

³³¹ Kinney WW, Kambam JR, Wright W *Propranolol pretreatment reduces cardio-respiratory toxicity due to plain, but not epinephrine-containing, intravenous bupivacaine in rats* (1991) *CAN J Anaesth* 38;4:533-6

propranolol as beta blocker interacts with *lidocaine*, thereby decreasing blood pressure and/or decreasing cardiac contractility. They are of the opinion that *propranolol* is completely absorbed quickly and peaks with plasma levels being approximately 1-3 hours after ingestion.³³² Kinney *et al* with their scientific study at the Vanderbilt University, Nashville, tested the effects of *propranolol* on the cardio-respiratory toxicity of *bupivacaine* either with *epinephrine* and without (plain), and found that “addition of *epinephrine* to the *bupivacaine* eliminated the protective effect of *propranolol*.”³³³ The study confirms that “drug interactions are more common than usually appreciated, and may be either manipulated to the patient’s benefit, or may be potentially life-threatening if not anticipated and managed safely.³³⁴ They state that “[M]yocardial depression due to *propranolol* is known to be additive to that caused by *halothane*³³⁵, *enflurane* and *isoflurane*.”^{336 337}

Kinney³³⁸ *et al*, infers that “rats receiving plain *bupivacaine* did not exhibit the bizarre, markedly widened QRS complexes seen in rats receiving *bupivacaine* with *epinephrine*. Furthermore, the only instances of ventricular fibrillation occurred in pretreated rats receiving *bupivacaine* with *epinephrine*, consistent with the arrhythmogenic properties of *epinephrine*. *Propranolol* may protect against plain *bupivacaine* toxicity due to its antiarrhythmic properties. Since the addition of *epinephrine* completely eliminated the

and this study used the reference to Wikipedia (see hereunder) in order to show how easy access to information was prior to consulting with the experts. **Please note that an expert consulted, criticized this information of Kinney and opines that epinephrine is a mixed alpha and beta agonist and nor epinephrine is a beta agonist without alpha effects- this is material to the interaction between propranolol and epinephrine later in the Michael averments.**

Categories: Otologicals / Antiarrhythmic agents/Local Anesthetics/Sodium channel blockers/ World Health Organization essential medicines/Acetamides <http://en.wikipedia.org/wiki/propranolol> p3(accessed 5.7.2010)

³³² Kinney *et al* p 533-6 **An expert consulted opines that this statement indicates the time period after ingestion but in the Michael-case the drug was administered intravenously, and the effect thereof, immediately.**

³³³ Kinney *et al* p 533-6

³³⁴ Kinney *et al* p 534 and Stanley TH Foreword, *Drug Interactions in Anesthesia* (1986);vii-viii

³³⁵ Kinney *et al* p 534 and Roberts JG, Foex P, C larke JNS, Bennet MJ, Haemodynamic interactions of high dose propranolol pretreatment and anaesthesia in the dog. *Halothane dose-response studies* (1976) *Br J Anaesth* 48: 315-25

³³⁶ Kinney *et al* p 534 and Kopriva CJ, Brown ACD, Pappas G, Haemodynamics during general anesthesia in patients receiving propranolol (1978) *Anesthesiology* 48:28-33

³³⁷ Kinney *et al* p 534 and Philbin DM, Lowenstein E, Lack of beta adrenergic activity in the dog: a comparison of circulatory effects of halothane and isoflurane after propranolol administration (1976) *Br J Anaesth* 48:1165-70

³³⁸ Kinney *et al* p 533-6

protective effect of *propranolol* pretreatment, evidently any expected beneficial effect due to *epinephrine*'s positive inotropy is more than overcome by the potential additive arrhythmogenicity of *epinephrine* with that of *bupivacaine*.”³³⁹ Kinney *et al* conclude that the mechanisms of *bupivacaine* is not clear but, “[B]y blocking fast sodium channels, *bupivacaine* exerts its local anaesthetic action. *Bupivacaine* also blocks “fast reponse” cardiac structures, specifically the maximum upstroke velocity of the myocardial action potential (V_{max}) of phase 0 of the action potential, thus depressing myocardial contractility. It also blocks “slow response” cardiac structures, thus exerting calcium channel blocking properties, specifically on specialized cardiac conduction tissue, thus depressing AV [atrio-ventricular] conduction.”³⁴⁰

They propose that “Perhaps *propranolol*'s negative chronotropic effect increases tolerance for *bupivacaine*-induced coronary vasoconstriction, because of reduced compromise of coronary perfusion due to less relative shortening of diastolic time than would occur at a higher heart rate in the absence of *propranolol* pretreatment.”³⁴¹

3.2 Local anesthetics (*lignocaine* and *adrenaline*)

From the Michael-case, the facts are: “Dr Fayman injected a local anesthetic (*lignocaine* and *adrenaline*) into the nose and inserted at the back of each nostril a plug of ribbon gauze soaked in a *cocaine* solution. The use of *cocaine* has a two-fold purpose. It is a local anesthetic and a vasoconstrictor. The blood vessels of the nasal lining bleed very readily and it was necessary to constrict them to ensure a clear [bloodless] view for the surgeon. *Cocaine* is widely used for this purpose in ear, nose and throat surgery.”³⁴²

³³⁹ Kinney *et al* p 535 and Moore DC, Systemic toxicity of local anesthetic drugs (1983) *Seminars in Anaesthesia* 2: 62-74

³⁴⁰ Kinney *et al* p 535 **and** Clarkson CW, Hondeghem LM, *Mechanism for bupivacaine depression of cardiac conduction: fast block of sodium channels during the action potential with slow recovery from block during diastole* (1985) *Anesthesiology* 62:396-405

³⁴¹ Kinney *et al* p 535 **The expert consulted opines that this statement is not relevant to the case.**

³⁴² Carstens and Pearmain p 785

3.2.1 Interaction of lidocaine and adrenaline

The package insert of *lignocaine* describes *lidocaine* (*xylocaine* or *lignocaine*) as a local anesthetic and antiarrhythmic drug.”³⁴³ It explains that lidocaine as local anesthetic is characterized by a rapid onset of action and “intermediate duration of efficacy.”³⁴⁴

Longer acting substances are sometimes needed like bupivacaine but lidocaine has the advantage of the rapid onset of action. With the use of *adrenaline* (also called *epinephrine*) the vasoconstricting effect on the arteries delays the re-absorption of *lidocaine* with the effect that the anesthetic time is almost doubled.³⁴⁵ *Lidocaine* as antiarrhythmic drug is used intravenously for the treatment of ventricular arrhythmias.³⁴⁶

3.2.2 Lidocaine and cardio toxicity

According to the package insert *Lidocaine* is contraindicated in any heart block, hypotension, bradycardia and other not relevant for this discussion, and although “additional cardiovascular effects present at higher concentrations, though cardiovascular collapse may also occur with low concentrations.”³⁴⁷ The cardiovascular effects may include hypotension, bradycardia, arrhythmias, and/or cardiac arrest- some of which may be due to hypoxia secondary to respiratory depression. The elimination half-life of *Lidocaine* is approximately 90-120 minutes, which may be prolonged with hepatic impairment or drug interaction.³⁴⁸

Zamanian prepared an article on “Toxicity, Local Aesthetics “and explains that the need to perform painless procedures lead to the development of local and infiltration anesthetics. These anesthetic agents are generally safe but when used in an

³⁴³ Lignocaine package insert and see Wikipedia (referred to hereunder) not as a primary source however as an easy reference to quickly understand the workings of the drugs

Categories: Otologicals/Antiarrhythmic agents/Local Anesthetics/Sodium channel blockers/ World Health Organization essential medicines/Acetamides <http://en.wikipedia.org/wiki/lidocaine> (accessed 5.7.2010)

³⁴⁴ See footnote 338 *supra*

³⁴⁵ See also package insert of bupivacaine and footnote 338 *supra* and <http://www.drugs.com/pro/bupivacaine> (accessed 5.7.2010)

³⁴⁶ *Ibid*

³⁴⁷ See package insert and footnote 338 *supra*

³⁴⁸ *Ibid*

inappropriate route or dose it can be toxic.³⁴⁹ They observe that the “addition of epinephrine to some local anesthetic solutions prolongs duration of action by causing vasoconstriction and decreasing systematic absorption.”³⁵⁰ The duration of the combined action of *lidocaine* and *epinephrine* can be as long as 120-360 minutes. They are of the opinion that “The search for less toxic long-acting local anesthetic was prompted after the occurrence of numerous fatalities associated with the cardiovascular toxicity of *bupivacaine*.”³⁵¹ They describe the pathophysiology of local anesthetic agents and opine that it can be classified as local and systemic levels of manifestations. The systematic effect is what is relevant to the above matter. “Systemic toxicity of anesthetics involves the central nervous system (CNS) the cardiovascular system, and the immune system....Cardiovascular effects are primarily those of direct myocardial depression and bradycardia, which may lead to cardiovascular collapse.”³⁵²

Zamanian adds that the toxicity may be potentiated in patients with preexisting heart block or heart conditions. “However inadvertent intravascular injection is the most common cause of local anesthetic toxicity” even³⁵³ administered with the recommended dose. They list the signs of direct cardiac effects as: myocardial depression and cardiac dysrhythmias. *Bupivacaine* is especially cardiotoxic.³⁵⁴ They warn that “*Epinephrine*-containing local anesthetics may cause hypertension, tachycardia and myocardial ischemia,”³⁵⁵ and “serious toxic effects (e.g. Seizures, cardiac death) have been described after topical cocaine application, particularly in infants and children. Because of this, *cocaine* is no longer recommended for topical anesthesia due to increased toxicity, expense, and federal regulatory use.”³⁵⁶

³⁴⁹ This study used the website of e-medicine by choice in order to show easy access for medical laypeople to medical information prior to consulting with an expert and Zamanian RT, Instructor of Medicine, Pulmonary hypertension clinical service. Division of pulmonary and critical care Medicine. Vera Moulton Wall Center for pulmonary vascular disease. Stanford University Medical Center <http://emedicine.medscape.com/article/819628-overview> p1 (accessed 27.6.2010)

³⁵⁰ <http://emedicine.medscape.com/article/819628-overviewp1> (accessed 27.6.2010)

³⁵¹ <http://emedicine.medscape.com/article/819628-overview> p 2 (accessed 27.6.2010) and see footnote 344 *supra*

³⁵² *Ibid*

³⁵³ Zamanian study of e-medicine p 2 and see footnote 344 *supra* and package insert

³⁵⁴ *Ibid* p 3 and see footnote 344 *supra* and see package insert

³⁵⁵ Zamanian study of e-medicine p 8 and see footnote 344 *supra*

³⁵⁶ *Ibid* p 5 and see footnote 344 *supra*

3.2.3 Interaction of Lidocaine and epinephrine

The package insert of *lidocaine with epinephrine*, in respect of the hemodynamic effect indicates that the “direct effects of local anesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.”³⁵⁷ It warns that according to pharmacokinetic principles, it is indicated that the absorption rate of the *lidocaine* to be “considerably slowed by the addition of epinephrine, although it also depends on the site of the injection.”³⁵⁸ “*Lidocaine* is completely absorbed following parenteral administration. The rate of absorption depends on the dose, route of administration, and vascularity of the injection site.”³⁵⁹

3.2.4 Vasoconstriction

The *bupivacaine* package insert³⁶⁰ warns that “[L] local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully restricted quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply such as digits, nose, external ear, or penis.”

3.2.5 Systemic toxicity

Chan *et al* from the Department of Anaesthesia and Intensive Care, The Chinese University of Hong Kong and the Prince of Wales Hospital, Shatin, Hong Kong published a review article on “Local anaesthesia outside the operating room.”³⁶¹ They investigate the “serious adverse effects and even fatalities that may result from the use of local anesthetic agents, arising from a variety of causes such as systemic toxicity, allergy vasovagal syncope, and reaction to additives present in the local anesthetic.”³⁶² They set themselves out to formulate a document so that “a good understanding of LA (local

³⁵⁷ package insert of lidocaine hydrochloride with epinephrine p 22

³⁵⁸ Ibid p 22

³⁵⁹ Package insert of lidocaine hydrochloride and epinephrine p22

³⁶⁰ <http://www.drugs.com/pro/bupivacaine.htm> p5 (accessed 27.6.2010)

³⁶¹ Chan SK, Karmakar MK, Chui PT, Local anaesthesia outside the operating room (2002) HKMJ Vol 8:106-13

³⁶² Chan et al p 106

anesthetics) pharmacology is the key to safe use of these agents. This article reviews the pharmacology, toxicity, and clinical aspects of LA s applicable to settings outside the operating room.”³⁶³ They reiterate all the known signs of cardiovascular system toxicity as “myocardial depression, severe ventricular arrhythmias, ventricular fibrillation and asystole.”³⁶⁴ They observe that “*Cocaine*, which causes vasoconstriction and inhibits the reuptake of catecholamines, can cause hypertension, tachycardia, arrhythmia, myocardial ischemia, and sudden death. Although the maximum recommended dose of *cocaine* in adults is 1-3mg/kg fatalities have been reported following the use of less than 200mg.”^{365 366}

3.2.6 Effects of a beta-blocker

Chan *et al* warned that “Although *propranolol* has been used successfully to treat cocaine-induced cardiac effects³⁶⁷, β -blockers should be used with caution because of the unopposed α -receptor-mediated effects.³⁶⁸ Alternatively a short-acting beta-blocker like *esmolol* may be considered.”³⁶⁹

3.2.7 The physiology and etiology of drug interaction

Chan *et al* describe the management of systemic toxicity in detail. They indicate³⁷⁰ that relative overdose will present with arrhythmias and nervous system irritability together with convulsions, and the recommended treatment is cardiopulmonary resuscitation, the administration of *benzodiazepines* and that *bretylium* should be considered for refractory ventricular fibrillation. They explain that a reaction to vasoconstrictor will present with

³⁶³ Chan *et al* p 106

³⁶⁴ Chan *et al* p 108

³⁶⁵ Chan *et al* p109 and Barash PG, *Cocaine in clinical medicine* (1977) NIDA Res Monogr 13:193-200

³⁶⁶ Chan *et al* p109 and Johns ME, Hendersohn RL, *Cocaine use by the otolaryngologist; a survey* (1977) *Trans Am Acad Ophthalmol Otolaryngol* 84: 969-73

³⁶⁷ Chan *et al* p109 and Rappolt RT, Gay GR, Inaba DS. *Propranolol: a specific antagonist to cocaine* (1977) *Clin Toxicol* 10:265-71

³⁶⁸ Chan *et al* p109 and Ellenhorn MJ, Schonwald S, Ordog G, Wasserberg J, Ellenhorn's medical toxicology: *diagnosis and treatment of human poisoning* (1997):356-86 **The expert opines that this is the nexus between the medication and adverse effect and outcome**

³⁶⁹ Chan *et al* p109 and Polan S, Tadjiechy M, *Esmolol in the management of epinephrine- and cocaine-induced cardiovascular toxicity* (1989) *Anesth Analg* 69:663-4

³⁷⁰ Chan *et al* table 2

tachycardia, hypertension, headache, apprehension and the recommended treatment is to administer a short acting beta-blocker like *esmolol* if tachycardia and hypertension persists. They warn that a vasovagal reaction will present with bradycardia, hypotension, pallor, faintness and should be treated with *atropine* and the patient's legs should be elevated. They warned further that an anaphylaxis will present with hypotension bronchospasm, urticaria and oedema and should be treated with subcutaneous *adrenaline* injection. Chan *et al* are of the opinion that "the prevention of hypoxia and acidosis are of the utmost importance during treatment."³⁷¹

They maintain that cardiopulmonary resuscitation should be initiated when profound CVS [cardio vascular system] depression is present. Ventricular tachycardia or fibrillation should be treated with cardioversion (higher energy may be required). As *bupivacaine* dissociates from sodium channels slowly, CPR [cardiopulmonary resuscitation] should be continued for at least 60 minutes or more in patients with *bupivacaine*-induced VF [ventricular fibrillation]. The medical treatment for *bupivacaine*-induced ventricular arrhythmias remains controversial. *Lignocaine*, paradoxically, has been used.³⁷² *Bretylium* may facilitate cardioversion in refractory VF [ventricular fibrillation].³⁷³ They warn of drug interactions with patient with concurrent medications. "Serious hypertension-bradycardia has been reported in a patient on a β -blocker because of interaction with *adrenaline*."³⁷⁴

David Pescod³⁷⁵ is of the view that the cardiovascular system is more resistant than the central nervous system and cardiac toxicity "can occur through cardiac conduction, reduced force of contraction of the ventricles and peripheral vascular smooth muscle relaxation." He explains that *lignocaine* is used to treat ventricular arrhythmias, however that "higher doses of local anaesthetics will cause cardiac arrest. The cardiovascular toxicity of *bupivacaine* appears to differ from *lignocaine* and the cardiac resuscitation is

³⁷¹ Chan *et al* p111

³⁷² Chan *et al* p111 **and** Davis NL, de Jong RH, *Successful resuscitation following massive bupivacaine overdose* (1982) *Anesth Analg* 61:62-4

³⁷³ Chan *et al* p111 **and** Kasten GW, Martin ST, *Bupivacaine cardiovascular toxicity: comparison of treatment with bretylium and lidocaine* (1985) *Aesth Analg* 64:911-6

³⁷⁴ Chan *et al* p111 **and** Dzubow LM, *The interaction between propranolol and epinephrine as observed in patients undergoing Moh's surgery* (1986) *J Am Acad Dermatol* 15:71-5

³⁷⁵ Chapter 38: Local anaesthetic toxicity and

http://www.developinganaesthesia.org/index.php?option=com_content&task=view p2(accessed27.6.2010)

more difficult with bupivacaine toxicity, and acidosis and hypoxia potentiate the cardiotoxicity of bupivacaine.³⁷⁶

3.3 Cocaine (cocaine hydrochloride)

Wiedeman,³⁷⁷ illustrates that *cocaine hydrochloride* is widely used as a topical anesthetic for otolaryngologic surgery. He maintains that cardiovascular complications, and specifically myocardial injury, are well documented side effects of illicit cocaine use. He describes a 23-year-old woman without coronary artery disease who had an acute non-Q-wave myocardial infarction and stunned myocardium after receiving topical *phenylephrine hydrochloride* and *cocaine* anesthesia for elective nasal septoplasty. He explains that these cases are rare and that they hope to heighten awareness of the potential lethal complications of using *cocaine*, *phenylephrine*, or the combination of both as topical anesthetics in otolaryngologic practice. He warns that *cocaine* may inhibit the therapeutic effects of beta adrenergic blocking agents.

It should be noted that the above description of the incident that happened with the 23-year-old woman is similar to the facts of the Michael-case³⁷⁸.

The package insert of *propranolol hydrochloride* clarifies and warns that although beta-adrenergic blocking agents are recommended to reduce tachycardia and myocardial ischaemia, the use of a beta-adrenergic blocking agent with *cocaine* may increase the risk of hypertension and excessive bradycardia,³⁷⁹ and the adrenergic blockade may leave *cocaine's* alpha-adrenergic activity unopposed.

David Pescod opines that different local anesthetics are more likely to cause systemic toxicity. He is of the opinion that the safest local anesthetics are the *esters*, *chlorprocaine* and *procaine*. From least toxic to most toxic the local anesthetics can be ranked: *chlorprocaine*, *procaine*, *prilocaine*, *lignocaine*, *mepivacaine (carbocaine)*,

³⁷⁶ Ibid p2

³⁷⁷ Wiedeman HP, James KB. Cardiac complication from use of cocaine and phenylephrine in nasal septoplasty (1995) Archives of otolaryngology Vol 131;6: 681-684

³⁷⁸ Michael v Linksfeld Park Clinic 2001 (3) SA 1188 (SCA)

³⁷⁹ <http://www.drugs.com/mmx/propranolol-hydrochloride.html> p16 (accessed 27.6.2010)

etidocaine, bupivacaine, tetracaine (amethocaine), dibucaine (cinchocaine) and cocaine."³⁸⁰

3.4 Deepened the anesthesia

This is done by increasing the concentration of *halothane* (3% and above) or concentrations of other halogenated hydrocarbon anesthetic agents are used to produce controlled hypotension during anesthesia because of the risk of excessive hypotension.³⁸¹

4. Resuscitation

Hampton from the University of Nottingham, addresses the complex principles of the ECG in an easy explanation. He explains that an ECG results from electrical changes associated with contraction first of the atria and then of the ventricles. Atrial contractions are associated with the P wave. He describes the QRS complex by saying that a ventricular contraction is associated with the QRS complex. If the first deflection is down it is a Q. If the first deflection is up it is an R. A downwards deflection after an R is an S.³⁸² He explains that the broadening of the QRS complex indicates abnormal intra ventricular conduction, which can be noted in abnormalities like bundle branch blocks and in complexes of stimuli that originated in the ventricular muscles.³⁸³

Schreiber explains the process of resuscitation and says that in an emergency situation the "respiration may cease due to respiratory arrest" and the patient will stop breathing. She explains that cardiac arrest is the sudden stopping of the effective pumping activity of the heart, causing the blood pressure to drop to zero. The patient immediately becomes unconscious, the pupils start dilating, breathing fails after approximately 30 seconds of gasping respiration and the pulse is absent in all the major arteries, including

³⁸⁰ Chapter 38 : Local anaesthetic toxicity and

http://www.developinganaesthesia.org/index.php?option=com_content&task=view&ip(accessed5.7.2010)

³⁸¹ <http://www.drugs.com/mmx/propranolol-hydrochloride.html> p15(accessed27.6.2010) **The expert consulted opines that the deepened anaesthetic increases the toxic affects of halothane which induces myocardial depression and rhythm disturbances.**

³⁸² Hampton JR, *The ECG made easy* (1973) Nottingham University p 6

³⁸³ *Ibid* p 66

the brachial, carotid and femoral. The patient is virtually dead but can, in some cases, be revived if immediate action is taken to ensure oxygenation of the body.³⁸⁴ She observes that the cause of cardiac arrest may be impaired conduction due to anoxia or myocardial malfunction due to hypoxia, certain drugs and anesthetic agents.³⁸⁵ If the patient is ventilated, and adequate breathing is established and the patient is in asystole (absence of pulse), external cardiac massage must be commenced immediately.³⁸⁶ She continues that external cardiac massage is done by placing the lower eminences of the palm of one hand over the lower third of the body of the sternum. The other hand is placed over the top of the first. The fingers must not touch the chest. The position of the hand is midline of the chest and about the fourth intercostals space, or nipple line in the male. She explains that the operator should kneel at the side of the patient on the floor, or bed. Keeping the elbows straight, the hands are pressed sharply, vertically downwards towards the spine, rhythmically, at the rate of 60 to 80 times per minute. With each compression, the sternum should be compressed 3-5 cm towards the spine. Approximately 35 to 45 kg of pressure must be exerted on the chest of an adult patient in order to message the heart. If the rescuer's arms are kept straight he may simply lean forward with each compression so transferring his body mass to the patient's chest. Cardiac compressions should never be interrupted for more than 5 seconds for any reason.³⁸⁷ The compressions are done in an attempt to mechanically compress the heart to maintain a cardiac output. Schreiber confirms that it is possible to maintain an arterial blood pressure of 100mmHg/13,3kPa by this method.³⁸⁸ She holds that CPR must be continued until successful or until the patient is declared dead.³⁸⁹

A study done by Fodden *et al*³⁹⁰ illustrates that when the output of the heart (amount of blood leaving the heart at a given period in time) was measured with the Doppler instrument³⁹¹, it showed that less experienced operators produced an output of

³⁸⁴ Schreiber LA, *Manual of advanced Nursing* (1973) p 361

³⁸⁵ *Ibid* p 361

³⁸⁶ Schreiber p 363

³⁸⁷ Schreiber p 363

³⁸⁸ Schreiber p 363

³⁸⁹ Schreiber p 364

³⁹⁰ Fodden DI, Crosby AC, Channer KS, *Doppler measurement of cardiac output during cardiopulmonary resuscitation* (1996) *J Accident Emergency Medicine* 13:379-382

³⁹¹ discussed in chapter 7

1.2L/min, significantly less than the experienced group, who produced 3.2L/min. The conclusion made was that differences in cardiac output during external cardiac compression are related to experience with the technique. The two groups that formed part of the study was different in the following aspects, the one group contained personnel, each of whom had exceeded the criteria for a pass result of the Resuscitation Examination for Members of the Royal College of General Practitioners. The less experienced group, were student nurses who had been trained in basic life support and were familiar with the technique, having used mannequins previously but were not greatly experienced with cardiac message technique on humans.³⁹² The study shows that there are no differences in cause of death from those cases whose cardiac message was performed entirely by more skilled personnel, and the skill of the operator maximizes cardiac output without increasing injury to the chest wall or to the thoracic or abdominal contents.³⁹³ The study states that the normal resting cardiac index is 2.6 to 3.6L/min and we have shown that the cardiac output produced by cardiopulmonary resuscitation can be equivalent to that measured in life.³⁹⁴

Fitzgerald *et al* remark that the outcome of resuscitation efforts depends upon several factors including the cause of the arrest, the time delay to the onset of basic life support, and the distribution of blood flow during resuscitation. The effort of cardiopulmonary resuscitation is to maintain adequate cerebral and cardiac oxygenation until spontaneous cardiac output returns; the long term outcome is therefore dependent upon cerebral and cardiac flow.³⁹⁵

It is clear from the above that if resuscitation is done effectively it can maintain life. The more effective the resuscitation effort the better the quality of life preserved. If adequate blood reaches the brain, life will be preserved with normal brain function.

³⁹² Fodden *et al* p 379

³⁹³ *Ibid* p 381

³⁹⁴ Fodden *et al* p 381 **and** Fitzgerald KR, Babbs CF, Frissoria HA, Davis RW, Silver DI, *Cardiac output during cardio pulmonary resuscitation at various compression rates and durations* (1981) *Anesthesia Journal Physiology* 241:H442-8

³⁹⁵ Fodden *et al* p 381

5. Discussion

The above medical information is freely available on the internet, and should have formed part of the practice of any surgeon or anesthetist specializing in otolaryngological procedures. The Second Defendant and Dr Fayman should have been aware of all the published literature mentioned above or similar. All the medical experts in the above matter had a duty to inform the court in respect of the medical evidence available and this information should have been brought to the attention of the court.

5.1 Pharmacological chaos created by the anesthetist and surgeon ³⁹⁶

At 09h45 *propranolol* was administered to slow the heart rate that was increased due to the anesthetic agents.

At 09h50 local *lignocaine* with *adrenaline* was administered with a plug at the back of each nostril soaked in *cocaine*.

The purpose of the *adrenaline* was to constrict blood vessels to create a “bloodless” field for the operation. As seen from the literature above it is known that *adrenaline* can be absorbed systemically via the blood vessels and mucous membranes, specifically in blood rich areas supplied by end arteries or have otherwise compromised blood supply like the nose.

It is also well known from the literature that inadvertent injection into the blood vessels will have the effect that an unknown amount of *adrenaline* with *lignocaine* and *cocaine* are being absorbed systematically.

Adrenaline has an effect on alpha- and beta-receptors. The effects on the alpha receptors cause vasoconstriction, which also cause a reflex slowing of the heart rate by inhibiting sympathetic stimulation. The effects on the beta-receptors cause vasodilatation (blood vessels to open) and heart rate to increase. The combined effect

³⁹⁶The following discussion was done after consultation with the expert

on the alpha- and beta- receptors, leave a balanced effect of slight increase in systemic blood pressure due to systemic vasoconstriction.

When the *adrenaline* was effectively administered right after the *propranolol* (beta-blocker), the following effect is seen: The beta effect is blocked and the alpha effect remains. The pharmacology of *adrenaline* (alpha- and beta-) is changed by the beta-blocker into an almost pure alpha stimulant, which leads to systemic vasoconstriction and cause an increase in blood pressure that is severe, depending on the amount absorbed.

The increase in blood pressure would not be expected to be accompanied by a very rapid heart rate as the beta-stimulating effect of the *adrenaline* is now blocked by the *propranolol*.

The nasal plug soaked with *cocaine* was inserted into each nostril. *Cocaine* also has a local anesthetic effect like *lignocaine*. As can be seen from literature above, one of the main uses for *lignocaine* is for its antiarrhythmic effects. Thus *lignocaine* has the effect on the heart of slowing conduction, and *propranolol* has the same effect. The three drugs in combination (*propranolol*, *lignocaine* and *cocaine*) create severe slow conduction (depressing cardiac conduction) that can present with a widened QRS complex leading to asystole.

In the early phases of cocaine absorption the blood pressure and heart rate may increase, as was found at 10h15 when the excessive bleeding started and sinus ventricular tachydysrhythmia was seen with hypertension.

The above reaction was expected as explained above, however, misinterpreted and incorrectly seen as too light an anesthesia, by the second defendant. The second defendant should have been aware that *propranolol* was already administered at 09h45 and has a half life of 120min; that by administering *lignocaine* and *adrenaline*, the workings of *propranolol* will be changed in certain aspects and enhanced in aspects of cardiac depressive effect; that *cocaine* has extreme toxic effects and in combination with *lignocaine* and *adrenaline* effectively increased the dosage of *lignocaine* to induce a

systemic effect; that *lignocaine* has an effect for up to 3 hours, which can be more in combination with other drugs; that to administer another ampoule of *propranolol* in the above circumstances was incorrect.

By administering the second dose of *propranolol* (beta-blocker), the second defendant created a further slowing of an already slowing conduction in the heart tissue which leads to cardiac arrest and cardiac asystole.

The reasoning found behind the deepening of the anesthesia can in certain aspects be faulted, as the increase in *halothane* would have had the result of lowering the blood pressure, but also have the effect of myocardial depression, which was already compromised at this time. Had the second defendant found it necessary to counteract the hypertensive crisis (due to the unopposed *adrenaline* alpha-effect and exacerbated by the *cocaine* effect) caused by Dr Fayman and himself, he should have used an alpha-blocker, which would have dilated the systemic blood vessels and so safely reduced the blood pressure without causing an interference with conduction in the heart.

In the light of the above, the initial *propranolol* injection is questionable, and the second injection of *propranolol*, contra-indicated.

5.2 Management of cardiac arrest

As can be seen from the literature above, the essence of heart massage or cardiopulmonary resuscitation (CPR) is to artificially support the circulation by means of external cardiac massage. This prevents further cardiac damage and eventual brain damage.

Most important, is to maintain the circulation of blood flow by compressing on the chest effectively enough, to create a cardiac output, i.e. to cause blood to flow from the right side of the heart into the body. The negative pressure in the heart, after compression, will cause blood from the body to flow to the left side of the heart. External heart massage is an attempt to effectively take-over the pump function of the heart.

The patient (Plaintiffs' son) in the Michael-case, under discussion,³⁹⁷ was on a ventilator and additional ventilation needed during the resuscitation process would have been to increase the oxygen level of the ventilator to a higher setting in order to assist the body to try to maintain oxygenation during CPR.

The management of the arrest should have been treated in the following manner:

Asystole (flat line on the monitor) is an indication that there is no heart conduction that can be depicted on the monitor. A beta-stimulant (like *isoprenaline* or *adrenaline*) administered intravenously followed immediately by cardiac compressions (CPR) would lead to accelerate conduction in the heart, which can lead to the restoration of normal heart rhythm or fibrillation (ventricular).

Ventricular fibrillation is an asynchronous conduction in the heart, and is when the ventricular muscle fibers contract independently, and no QRS complex can be identified.³⁹⁸ When the rhythm is identified as being a ventricular fibrillation, it is clear that there can be no cardiac output as the ventricles are not in synchronization meaning it cannot produce a contraction that can empty the heart effectively. In this case cardiac output and circulation of oxygenated blood flow must be maintained by means of CPR, only occasionally to be interrupted by applying the defibrillator.

In the unlikely event that the heart rhythm is not restored, or the fibrillation of the heart is not terminated, or the heart remained without any conduction tracings (asystole), CPR must be applied without interruption with the application of the defibrillator. This should continue until such time that the experienced cardiopulmonary expert is satisfied that they have a dead heart, like in the event of ante mortem hemorrhage, or where pulmonary thrombo-embolism was present or if there was any evidence of aortic valve stenosis or incompetence or severe myocardial damage due to pulmonary illnesses,³⁹⁹ or myocardial infarction.

³⁹⁷ *Michael v Linkfield Park Clinic* 2001 (3) SA 1188 (SCA)

³⁹⁸ Hampton p 40

³⁹⁹ Fodden *et al* p 380

The above pre-existing illnesses were not present in the Michael-case as the 17-year-old-man was young, healthy, fit and had no previous illnesses or pre-existing conditions.

The Second Defendant and Dr Fayman were experts in their fields and ought to have been aware that the medication administered had caused the asystolic effect. The cardiopulmonary resuscitation should have been initiated without delay and continued without interruption, and only briefly interrupted with the defibrillation attempts.

Effective CPR should have been administered until successful or until the patient was declared dead.

The cardiac conduction of the heart was restored eventually but the residual myocardial damage showed that the circulation was not maintained in the heart (ineffective heart massage and cardiac output) and therefore not in the brain, and lead to the consequent brain damage.

6. Conclusion

There can be no doubt that the correct medical information from the medical experts would have changed the outcome of this case. The inadequate information provided, had not allowed the court to arrive at an informed decision. The case was deemed to fail on the lack of medical evidence to prove the plaintiff's case. It can be argued that the legal team of the plaintiff were not experienced enough to present an intricate medical case like this to the court, nevertheless, the crucial medical facts were omitted and not disclosed. It should be noted that no legal conclusion can be made on aspects involving medical principles if a lack of medical evidence and medical conclusions are absent. The court suspected that the essential medical information was lacking hence its revisiting the boundaries of the expert ⁴⁰⁰ and its request for a "collective mind" from the medical profession. In the previous chapters ⁴⁰¹ this was discussed in detail.

⁴⁰⁰ Carstens P, *Setting the boundaries for expert evidence in support or defense of medical negligence* p 431-436

⁴⁰¹ See Chapter 6 and 7

In the next chapter certain recommendations are made regarding the averments required to form the basis for the particulars of claim in the Michael-case. These averments were obtained from the medical facts contained in this chapter ⁴⁰², and summarized for purposes of the claim.

⁴⁰² 2001 (3) SA 1188 (SCA)

CHAPTER 9

MICHAEL-CASE: THE RECONSTRUCTION

1. Introduction

The function of Chapter 7 was to summarize the facts that were presented to the court in the *Michael-case*⁴⁰³, and investigated the evidence-based medical facts that were presented to the court. The aim of Chapter 8 was to endeavour to find additional medical evidence based on evidence-based research material in an attempt to appreciate where the medical experts were misguided or misdirected and in order to understand the reasoning behind the findings of the court. It was established that insufficient medical evidence was presented to the court and it was concluded that had the correct evidence been presented to court the outcome would have been different. Proper evidence-based medicine literature were found and disclosed in the previous chapter and it is based on this medical information that Chapter 9 will prepare all the particulars contained in a claim document for the court. The objective of this chapter is to make recommendations regarding the averments that should have formed part of the Plaintiff's 'particulars of claim' in the pleadings of the *Michael-case*⁴⁰⁴ in order to establish the defendant's liability. This chapter is effectively reconstructing the *Michael-case*.⁴⁰⁵

2. Citations

It is recommended that the plastic surgeon (Dr Fayman) should have been cited as the First Defendant, his assistant (Dr Rubin) should have been cited as the Second Defendant, and the anesthetist, should have been cited as the Third Defendant. The hospital was not at fault as the defibrillator was not defective and would not have been as crucial in the resuscitation process had the resuscitation been managed properly. In

⁴⁰³ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

⁴⁰⁴ *Ibid*

⁴⁰⁵ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

the Michael⁴⁰⁶-case, the doctors failed to manage a hypertensive crisis created by the anesthetist, and failed to adequately resuscitate the patient out of this crisis and their failure caused them to deflect their liability by blaming the hospital.

3. Allegations

The following paragraphs will be listing the allegations depicted from the agreements between the parties. It will show the duty of care of the doctors, the information that should have formed part of the knowledge of a reasonable surgeon and reasonable anesthetist, under similar circumstances, and the information that should have formed part of what they ought to have known, and thus what they should have foreseen might happen under these circumstances. It will show their failure to act in accordance with their knowledge and duty of care. These allegations will form part of the framework of the particulars of the claim of the plaintiff.

3.1 The agreement between the Michaels and the plastic surgeon

It is recommended that the allegations in the particulars of claim should have stated that an agreement between Mr and Mrs Michael (the Plaintiffs) on behalf of their son, regarding the treatment of their 17-year-old son and the plastic surgeon (Dr Fayman)⁴⁰⁷ were that:

At all material times, Dr Fayman and the Plaintiffs entered into an oral agreement in terms of which the Dr Fayman undertook:

- to perform a rhinoplasty operation on the Plaintiff's son; and
- to do or cause to be done and to further furnish medical treatment and follow-up medical treatment, care and supervision to Plaintiff's son;
in exchange for remuneration.

⁴⁰⁶ Ibid

⁴⁰⁷ Dr Fayman was not cited as a Defendant and acted as expert witness before the court. All involved should have guarded against expert bias.

It is recommended that at all material times, a further material term of the agreement was that an expressive, alternatively implied, alternatively tacit term of the agreement, with Dr Fayman, should have been that:

- Dr Fayman would furnish the required and necessary medical care, treatment and supervision; and/or
- That such medical care, treatment and supervision would be administered and performed with due professional skill, care and diligence as can be reasonably expected of a plastic surgeon for the health, comfort and well-being of the Plaintiff's son; and /or
- That the medical care would include *inter alia* to take a complete medical history, to perform proper examinations, to do possible tests and investigations, to consider a probable diagnoses with possible differential diagnoses, to treat and/or refer or consult another specialist, and to obtain informed consent from the Plaintiffs, regarding material risks and complications by disclosing all information pertaining to the medical condition of the Plaintiff's son, to adequately follow-up on the medical condition of the Plaintiff's son when needed; and/or
- That should the medical condition of the Plaintiff's son change in whatever way possible he would re-examine, re-diagnose, re-consider differential diagnoses, and alter the management plans or treatment plans in accordance with the changed condition and/or refer them to a specialist in the field; and/or
- That any change in the medical condition of the Plaintiff's son could occur unexpectedly more specifically that they be alerted to any surgical or anesthetic crisis should that occur.

It is recommended that it should be alleged that it was within the contemplation and knowledge of Plaintiffs and Dr Fayman in concluding such an agreement that in the event of Dr Fayman being in breach of the agreement as set out above, the Plaintiff's son would suffer damages.

3.2 Duty of care of the plastic surgeon

It is recommended that accumulatively and/or alternatively Dr Fayman owed a duty of care to Plaintiff's son *inter alia*

- to perform the operation; and/or
- to further treat or cause to treat any follow-up medical conditions that might rise with the necessary skill, care and expertise and with due professional skill, care and diligence as can be reasonably expected of a plastic surgeon; and/or
- that in managing the medical intervention as well as follow-up medical intervention of the Plaintiff's son, will take such reasonable and necessary steps to ensure that no further harm will come to the Plaintiff's son other than that can be reasonably expected in similar circumstances; and/or
- to inform them properly of the nature, scope, administration, importance, consequences, material risks, dangers, disadvantages of, prognosis and the alternatives to any proposed treatment or operation that was to be performed; and/or
- to inform them properly of the nature, scope, administration, importance, consequences, material risks, dangers, disadvantages of, prognosis and the alternatives to any proposed follow-up treatment or operations that was to be performed.

It is recommended that an allegation should be made that it was within the contemplation and knowledge of Plaintiffs and Dr Fayman in the event that Dr Fayman failed to act in accordance with his duty of care, the Plaintiff's son would suffer damages.

3.3 Agreement and duty of care owed by the assistant Dr Rubin

It is recommended that it should be alleged that a similar agreement and duty of care was owed to the Plaintiff's son by Dr Rubin, the assistant of Dr Fayman as it is not clear who administered the *cocaine* or who injected the *lignocain and adrenaline* injection. It is recommended that in actual fact there is no difference in duty of care between Dr

Fayman and Dr Rubin. By merely accepting to act as an assistant to the surgeon, tacitly attracts a duty of care.

3.4 Agreement between the Michaels and the anesthetist (Second Defendant)

It is recommended that the allegations regarding the agreement between Mr and Mrs Michael (the Plaintiffs) on behalf of their son, regarding the treatment of their 17-year-old son and the anesthetist (Second Defendant) were that:

At all material times, Second Defendant and the Plaintiffs entered into an oral agreement in terms of which the Second Defendant undertook:

- to administer anesthetic during the rhinoplasty operation on the Plaintiff's son; and
- to do or cause to be done and to further furnish medical treatment and follow-up medical treatment, care and supervision to Plaintiff's son, in exchange for remuneration.

It is recommended that a further material term of the agreement that was at all material times an expressive alternatively implied alternatively tacit term of the agreement, with Second Defendant was that:

- he would furnish the required and necessary medical care, treatment and supervision; and/or
- such medical care, treatment and supervision would be administered and performed with due professional skill, care and diligence as can be reasonably expected of an anesthetist for the health, comfort and well-being of the Plaintiff's son; and /or
- the medical care would include *inter alia* to take a complete medical history, to perform proper examinations, to do possible tests and investigations, to consider a probable diagnoses with possible differential diagnoses, to treat and/or refer or consult another specialist, and to obtain informed consent from the Plaintiffs, regarding material risks and complications by disclosing all information pertaining

to the medical condition of the Plaintiff's son, to adequately follow-up on the medical condition of the Plaintiff's son when needed; and/or

- should the medical condition of the Plaintiff's son change in whatever way possible he would re-examine, re-diagnose, re-consider differential diagnoses, and alter the management plans or treatment plans in accordance with the changed condition and/or refer them to a specialist in the field; and/or
- any change in the medical condition of the Plaintiff's son could occur unexpectedly more specifically that they be alerted to any surgical or anesthetic crisis should that occur.

It is recommended that it should be alleged that it was within the contemplation and knowledge of Plaintiffs and Second Defendant in concluding such an agreement that in the event of Second Defendant being in breach of the agreement as set out above, the Plaintiff's son would suffer damages.

3.5 Duty of care of the anesthetist

It is recommended that it should be alleged that an accumulatively and/or alternatively Second Defendant owed a duty of care to Plaintiff's son *inter alia*

- to administer the anesthetic during the operation; and/or
- to further treat or cause to treat any follow-up medical conditions that might rise with the necessary skill, care and expertise and with due professional skill, care and diligence as can be reasonably expected of a plastic surgeon; and/or
- that in managing the medical intervention as well as follow-up medical intervention of the Plaintiff's son, will take such reasonable and necessary steps to ensure that no further harm will come to the Plaintiff's son other than that can be reasonably expected in similar circumstances; and/or
- to inform them properly of the nature, scope, administration, importance, consequences, material risks, dangers, disadvantages of, prognosis and the

alternatives to any proposed treatment or operation that was to be performed;
and/or

- to inform them properly of the nature, scope, administration, importance, consequences, material risks, dangers, disadvantages of, prognosis and the alternatives to any proposed follow-up treatment or operations that was to be performed.

It is recommended that it should be alleged that it was within the contemplation and knowledge of Plaintiffs and Second Defendant in the event that Second Defendant failed to act in accordance with his duty of care as set out above, the Plaintiff's son would suffer damages.

3.6 Breach

3.6.1 It is recommended that it should be alleged that in breach of the agreement and duty of care between the parties, Dr Fayman and his assistant (Dr Rubin) and the Second Defendant (the anesthetist) failed to furnish such medical care treatment and supervision with due professional skill and care and diligence as can be reasonably expected of a plastic surgeon, assistant and anesthetist.

3.6.2 It is recommended that it should be alleged that in breach of their duties of care Dr Fayman and Dr Rubin (assistant) and Second Defendant (the anesthetist) acted negligently, wrongfully and unlawfully in one or more of the following ways, in that they should have been aware of or ought to have known regarding otolaryngological procedures one or more of the following:

3.6.3 It is recommended that with regard to the creation of a hypertensive crisis with the medication⁴⁰⁸ it should be alleged:

- that medication interaction is a material risk that can lead to severe complications;

⁴⁰⁸ Explained in detail in chapter 8

- that local anesthetics like (*lignocaine and adrenaline*) are used for local anesthetic purposes as well as for antiarrhythmia in the treatment of life threatening ventricular arrhythmias;⁴⁰⁹
- that local anesthesia is contra-indicated in patients with heart blocks, hypotension and bradycardia as this can lead to cardiovascular collapse;⁴¹⁰
- that to administer *adrenaline (epinephrine)* after the *propranolol* changed the *adrenaline* into a pure alpha stimulant due to the beta blocking effect of the *propranolol* which will increase the blood pressure (hypertensive crisis)⁴¹¹;
- that local anesthesia can inadvertently be administered into a vein, and that it is the most common cause of local anesthetic toxicity that leads to systemic toxicity;
- that systemic toxicity has *inter alia* cardiovascular effects that are primarily those of direct myocardial depression, severe bradycardia that ultimately lead to cardiovascular collapse;
- that toxicity may be potentiated in patients with pre-existing heart block or heart conditions;
- that *epinephrine*-containing local anesthetics (like *lignocaine* and *adrenaline*) may cause hypertension, tachycardia and myocardial ischemia and serious toxic effects and that because of this *cocaine* is no longer recommended for topical anesthesia due to increased toxicity;
- that the absorption rate of *lignocaine*⁴¹² is slowed by the addition of *epinephrine/adrenaline* depending on the site of the injection;
- that the nose has a vast amount of blood vessels and unintentional administration of the local anesthetic into a vein is common and should be guarded against;
- that *propranolol*⁴¹³ should be used with caution because of its unopposed alpha-receptor mediated effects and a short acting beta blocker like *esmolol* should have been the medication of choice;

⁴⁰⁹ It has a local anaesthetic effect and when administered intravenously for ventricular arrhythmias it has a "calming" effect on the heart as it affects the nerve conduction of the heart by slowing it down

⁴¹⁰ Where a pre-existing condition is present and a patient has nerve conduction problems- in the above scenario a pre-existing condition was created with the beta-blocker (*propranolol*) that blocked receptors to decrease heart rate

⁴¹¹ See discussion at the end of chapter 8

⁴¹² Local anaesthetic

- that *propranolol* blocks the the beta adrenergic receptors that govern heart rate stimulation;
- that a long acting beta blocker (like *propranolol*) is used in treatment of hypertension, and blocks the action of *epinephrine/adrenaline*⁴¹⁴;
- that *propranolol* interacts with *lignocain*⁴¹⁵ and creates slow conduction of the heart that can present with a widened QRS complex in the ECG rhythm of the heart;
- that sufficient medical literature warns against the interaction of *propranolol* *epinephrine/adrenaline* and *lignocaine* causing a depressing action on the heart, and severe slow conduction;
- that *propranolol* administered at 09h45 has a half life of 120min and *lignocaine* had an effect of up to 3 hours and by administering another ampoule of *propranolol* and thus created an already slow conduction into cardiac arrest and asystole;
- that proper interaction was needed between the surgeon, the assistant and the anesthetist regarding the choice and administration of medication;

3.6.4 It is recommended that regarding the resuscitation⁴¹⁶ the following allegations should be made:

- that broadening of the QRS complex on the ECG is an indication of abnormal intra ventricular conduction^{417 418}
- cardiac arrest has no effective cardiac output causing no blood flow to go to the vital organs of the body and the brain;
- that with proper resuscitation the cardiac output can effectively be maintained until such time that the cardiac function is restored;

⁴¹³ Beta-blocker that blocks beta receptors to slow down heart rate

⁴¹⁴ See chapter 8 for detailed discussion how the interaction of these drugs affect one another

⁴¹⁵ Ibid

⁴¹⁶ See full detailed explanation in chapter 8

⁴¹⁷ Caused by the medication that worked on the conduction of the nerves of the heart

⁴¹⁸ Necessary to notice when re-diagnosing the emergency condition of systemic toxicity

- that with adequate resuscitation the resuscitation team had time to sort the issues with the defibrillator, as manual rhythmic pressing down on the heart⁴¹⁹ can create an efficient cardiac output which is seen as successful resuscitation that can continue for long periods of time as necessary;
- that the medication interaction caused the crisis and cardiac arrest and by proper cardiac massage⁴²⁰ would have allowed enough time for the emergency medication (like *adrenaline*) to take effect and to allow some sort of the heart function to return;
- that a heart in fibrillation or a still heart is non functional with no blood flow and needs to be assisted with cardiac massage of the resuscitation process to maintain the cardiac output;
- the defibrillator assists to either restore a fibrillating heart to normal or a dead heart to life (even if it means into fibrillation) without stopping the effective cardiac massage;
- that seen in the light of the above there was ample time for the doctors to manage the defibrillator if effective cardiac massage had been maintained.

3.6.5 It is recommended that it should be alleged that the Defendants failed in their agreements and duties of care to the Plaintiffs in one or more of the following ways:

- failed to maintain a professional standard of competence in self-improvement (as prescribed by the regulations of the code of conduct of the Health Profession Council of South Africa); and/or
- failed to endeavour to maintain the highest level of knowledge and skill required within the Defendants' area of practice by not adhering to the standards set down by his peers alternatively failed to practice evidence based medicine alternatively failed to inform the Plaintiffs of the standard of skill that the Defendants were practicing; and/or

⁴¹⁹ Cardiac massage

⁴²⁰ depressing on the heart and thus causing proper cardiac output

- failed to obtain informed consent from the Plaintiffs regarding the risks and complications; and/or
- failed to honour the Plaintiffs' right to self-determination by not presenting to and discussing with them the reasonable different management options, risks and complications; and/or
- failed to take the risks and complications of the medication and the medication interaction into consideration alternatively failed to properly appreciate the risks and complications of the interaction between *propranolol*, *lignocaine*, *adrenaline* and *cocaine* and practised in orolaryngologic surgery and anaesthesia in an unsafe manner; and/or
- failed to recognize that they had created a hypertensive crisis by administering the *adrenaline* right after the *propranolol*; and/or
- failed to recognize that the *cocaine* toxicity created a systemic toxicity and the combined effect of the three drugs *propranolol*, *lignocaine* and *cocaine* created a severe slow conduction in the heart; and/or
- failed to recognize that by administering another ampoule of *propranolol* created the asystole of the heart, as an already slowing conduction in the heart tissue was now blocked completely with a long acting beta blocking agent; and/or
- failed to properly manage the hypertensive crisis caused by the Defendants; and/or
- failed to properly resuscitate⁴²¹ the Plaintiffs' son after causing the asystole.

4. Conclusion

The above is a detailed outline of what averments are recommended to form part of the particulars of the claim to discharge the onus of proof. It does not serve as a *pro forma*-particulars of claim, however it should be helpful to guide any plaintiff through most of the averments that are needed to get past exception, and to stop prescription. There is far more information contained in the above to explain the medical intricacies than is necessary for pleadings, however, experience showed that once the medical expert has

⁴²¹ See chapter 8 for detailed description of proper resuscitation

ascertained the aspects of negligence, the detail regarding the exact negligent act or omission becomes part of the pleadings.

It should be noted that Chapter 8 compiled the medical evidence for the reconstruction of the Michael-case and Chapter 9 reconstructed the case with evidence-based medical evidence. The above application of evidence-based medicine in the law is of great value to the legal professional as the medical information becomes part of his knowledge about the matter and can be tested by him, his client, and most importantly the court.

In order to introduce the next and final chapter, it is necessary to note that evidence-based medicine, the objective of the research and more specifically the statistical aspects of the research should be tested and tested again, to avoid peculiar and irrational results.

CHAPTER 10

THE CRITICAL APPRAISAL OF STATISTICAL EVIDENCE AND THE PITFALLS

1. Introduction

This chapter serves to analyze statistical data that was presented to court and to determine the accuracy of the reasoning and interpretation thereof. In the previous chapters⁴²² evidence based medicine was investigated and analyzed and in summary the value of evidence based medicine became clearer in its role to provide the court with quality, trustworthy, scientific material, on which to base its legal decision. The court as the ultimate decision-maker, is put in a position to decide whether the logic behind the expert's reasoning is based on sound scientific evidence. The court is even in a position to question the scientific basis of the literature presented, before accepting the logical reasoning and opinion of the expert. Notwithstanding the above, medical evidence is allowed to be presented to court based on the unilateral opinion of an esteemed expert, and accepted by the court as law, without ascertaining the basis for the medical evidence. One would think that the rules of the different courts had cleared the bias of the medical experts from the courtroom, and through the development of the role of the expert in all the common law countries, that all the judicial officers would be weary of the evidence presented as an opinion instead of literature based on medical evidence, yet it is not the case. In this chapter it will be shown that the power of the unilateral expert remained untouched in certain instances and to this day the court is misdirected as a result of the unfounded evidence that is presented to the courts.

2. Test the test results

The doctor conducts a clinical examination of the patient, which includes the history and physical examination of the patient and that provides all the data to formulate a diagnosis and certain differential diagnosis. Causes of the diseases would be found in research material, and articles published. The clinician uses the literature on diagnostic

⁴²² Chapter 5,7,8,9

testing to assist with the confirmation of the diagnosis if the tests results are valid and reliable. In order to test the test results an understanding of the research process is needed.⁴²³ The test results testing “the prognosis” or outcome of the disease consists of research data showing the likely clinical course over time and taking into consideration all the variants. The test results testing “the therapy” consists of how to select treatments to offer patients that which does more good than harm, and other options available. The test results testing “the prevention” of illness or disease consists of how to reduce the incidence of the disease by identifying and lowering risk factors.

Evidence-based medicine provides guidance to clinicians in formulating answers to a variety of circumstances as mentioned above. To interpret and understand the finer detail or research, an understanding of the tests and an explanation of the statistical data is needed in order not to draw unwarranted conclusions from research data.

3. Diagnostic tests

Sackett ⁴²⁴ *et al* maintains that one way or another a diagnostic test will turn out with an opinion from a researcher as being “normal” or “abnormal” in patients with certain medical conditions. It is necessary to take into consideration all the data that the reporter used to arrive at this conclusion. A normal range should be developed for the test. This means that the test result should be compared to the value found in normal people (i.e. people without the disease being tested for). Should the value fall outside this range it should be clear that the result is deemed to be “abnormal”. What the abnormality means is dependent on the medical condition present and informs the clinician as to the need for further testing or to support or exclude a diagnosis.

Sackett ⁴²⁵ *et al* explains that, suppose one works with a patient with anemia. The probability that the patient has iron deficiency anemia is 50:50. Is it useful to do a serum ferritin test to detect whether it is iron deficiency anemia? Suppose one found a

⁴²³ The basic information used to describe test results were discussed previously in chapter 5 with concepts like (ABR) absolute risk reduction and (NNT) number needed to treat, etc.

⁴²⁴ Sackett D L, Sharon E Strauss, W Scott Richardson, William Rosenberg, R Brian Haynes, *Evidence-based medicines How to practice and teach EBM* (2000) p 69

⁴²⁵ *Ibid* p 72

systematic review of several studies that performed this diagnostic test. The test results showed that 90% of patients with iron deficiency have serum ferritins in the level of the patient. The proportion of patients with the target disorder who have positive test results on this test is called “sensitivity”. And 15% of patients with other causes of their anemia have results in the same range of the patient. Meaning that the patient’s result would be about six times as likely (90% out of 15%) to be seen in someone with iron deficiency anemia than in someone without the condition; the “likelihood ratio” for a positive test result. Could the results move us to some threshold that would cause us to stop all further testing?⁴²⁶ There are two thresholds that should be borne in mind. If the diagnostic test was negative or created a likelihood ratio of near 0.1, the post test probability might become so low that we would abandon the diagnosis and turn to other diagnostic possibilities. The negative test result moved us from above the “test threshold” to below the test threshold, and we are not doing any more tests for that diagnostic possibility.⁴²⁷

Sackett⁴²⁸ *et al* explain that if the diagnostic test came back positive or generated a high likelihood ratio, the post-test probability might become so high that one would also abandon further testing because one had made one’s diagnosis and would now move to choosing the most appropriate therapy.” One crossed from below the “treatment threshold” to above the treatment threshold. If one’s diagnostic test result leaves one stranded between the “test threshold” and “treatment threshold” then one would continue to pursue that initial diagnosis by performing other tests.⁴²⁹ Sackett concludes that diagnosis is not about finding absolute truth but about limiting uncertainty and establishes both the necessity and the logical base for introducing probabilities, pragmatic test – treatment thresholds and the like.⁴³⁰

⁴²⁶ Sackett *et al* p 84

⁴²⁷ Sackett *et al* p 84

⁴²⁸ Sackett *et al* p 84

⁴²⁹ *Ibid* p 85-86

⁴³⁰ Sackett *et al* p 92

4. Questions to answer in applying a valid diagnostic test to an individual patient⁴³¹

Sackett *et al* explain that the clinician needs to determine whether the sample group that was used in the study had similar complaints and symptoms than that of his/her patient, prior to using the study material as guidance for his patient. The questions will assist the doctor with determining this.

1. Is the diagnostic test available, affordable, accurate and precise in the setting?
2. Are the study patients similar to the individual patient?
3. Will the test result move us across a possible threshold?
4. Would the test result help the patient reach his goal?

5. Legal implications

It is recommended that in the event that the doctor decides against further tests based on the likelihood ratio for a positive test result of about six times as likely (as can be seen from the above scenario) and started treatment on the assumption that that diagnosis is correct, and this decision leads to further harm/injury, then certain legal implications will follow such action. The doctor did not discuss the likelihood of accurate diagnosis and treatment with the patient and made a decision on statistical data to take a risk with the diagnosis without informing the patient. It is suggested that the doctor, by keeping this information from the patient is liable and responsibility for an adverse outcome or wrong diagnosis.

It is suggested that should the doctor embark on this decision he is effectively and actively removing the patient's chances to further diagnostic tests and early treatment and in this respect should be held responsible for the consequences resulting from his decision even if based on sound statistical principles.

⁴³¹ Sackett *et al* p 81

6. Prognosis

The diagnosis of the patient had the consequence that treatment is recommended based on research studies and outcome results, or in certain instances part of research.

Sackett ⁴³² *et al* maintains that in an ideal world the prognosis study would be representative of the entire population who ever lived and who developed the disease. Obviously this is impossible and one has to make do with the few studies performed. Follow-up studies need to be done in order to determine the prognosis of the patient on treatment or even after treatment was completed.

Sackett *et al* questions how long should patients be followed-up in a study? Or at least what is an indication of “sufficient” follow-up? Sackett *et al* ⁴³³ suggests that a simple rule should be followed. If the loss [not accounted for] is fewer than 5% than this should be an indication of little bias. If the loss is more than 20% then it is an indication that the loss seriously threatens validity.

Sackett *et al* explains that if a study was done on 100 patients, 4 died and 16 was lost, the deaths would be seen as 4 out of 84 (4.8%). A “crude” case fatality rate would count the 4 deaths among the 84 (as it is known what happened to them and is reported). What about the lost 16? In a worst case scenario those could be counted as deaths (making it 4+16) =20 out of (84 followed- including the four deaths- and 16 lost- now seen as dead) - $20/100 = 20\%$ that is four times the rate reported in the study. Best case scenario only 4 out of 100 died (counting the 16 as lost but not dead) = 4% Worst case scenario being 20% and this study would probably be judged by saying that the follow-up was not sufficiently completed.⁴³⁴

⁴³² Sackett *et al* p 96

⁴³³ Sackett *et al* p 97

⁴³⁴ Sackett *et al* p 97

7. Is this evidence about prognosis valid? ⁴³⁵

Sackett *et al* maintains that in order to determine whether the evidence compiled in the study has any value it is sensible to question the following aspects:

1. Was a defined representative sample of patients assembled at a common (usually early) point in the course of their disease?
2. Was patient follow-up sufficiently long and complete?
3. Were objective outcome criteria applied in “blind” fashion?
4. If subgroups with different prognosis are identified:
 - Was there adjustment for important prognostic factors?
 - Was there validation in an independent group of test-set patients?

The answers to these questions are indicative of whether the test results can be trusted, and whether the answers provided by the test are reliable without interference.

8. Therapy

Studies done to test therapy need to be scrutinized by the clinician for several aspects to determine validity and reliability. As discussed in detail in Chapter 5 the control groups for medication commonly are monitored as double blind studies in order to be more reliable.

Sackett ⁴³⁶ *et al* shows further that therapy studies are done with a medication or treatment program and the control group of people given the placebo. The test results should be tested to show clinical importance (meaning that if the evidence does not show a clinical importance the validity of the test has no meaning). The magnitude of the treatment effect is shown by showing that the experimental treatment increases the risk of a good event, and this is calculated as relative risk reduction (RRR) where the risk is

⁴³⁵ Ibid p 95

⁴³⁶ Sackett *et al* p 105

reduced (harm prevented) from the control group that showed progression in illness to treatment group that showed reduction in disease.^{437 438}

The Sackett group continues to make calculations to get to an ARR (absolute risk reduction) and from there to NNT (number needed to treat). These calculations can summarize the situation by saying that e.g. from an ARR (absolute risk reduction) of 11% it can be derived that the NNT (number needed to treat) is $1/10\%$ ⁴³⁹ = 9. This means that you have to treat 9 people for a certain period (33 months) to prevent one additional person from suffering a progression of their illness.⁴⁴⁰

9. Questions to validate the studies⁴⁴¹

Sackett *et al* opine that again the clinician is in a position to question the study presented to him for reliability and validity, by ensuring that the way the study was planned and set-up was indeed testing the relevant aspects that is claimed and that variables that can influence results are minimized.

1. Was the assignment of patients to treatment randomized? And was the randomization list concealed? (In other words the list was not planned)
2. Was follow-up of patients sufficiently long and complete?
3. Were all patients analyzed in the groups to which they were randomized?
4. Were patients and clinicians kept blind to treatment?
5. Were groups treated equally, apart from the experimental therapy?
6. Were the groups similar at the start of the trial?
7. Is our patient so different from those in the study that its results cannot apply?
8. Is the treatment feasible in our setting?
9. What are our patient's potential benefits and harms from the therapy?
10. What are our patient's expectations for both the outcome we are trying to prevent and the treatment we are offering?

⁴³⁷ Shown in chapter 5 as relative risk reduction (RRR)

⁴³⁸ Sackett *et al* p 111

⁴³⁹ It is suggested that it is 1/11 (NNT=1/ARR) which is 9,09 and that 1/10% is a typing error

⁴⁴⁰ *Ibid* p 113

⁴⁴¹ Sackett *et al* p 106

The answers to the above questions will satisfy the clinician as to whether he/she can trust the test, that the test sample is similar to his patient's condition and that should he rely on this information in treating his/her client, the same outcome can be expected.

10. Legal implication

It is recommended that the study should be screened to compare well with the condition of the individual patient, and even then the clinician should be careful not to rely on statistical data to motivate treatment. Statistical data is based on assumptions and hypothesis and is notoriously known for being inaccurate as it is done for projections and speculation and not relevant to the specific condition of the individual patient. It is recommended that the clinician should use the mathematical inferences done by statistical data with caution as it can divert the attention from the individual patient, yet the individual patient is the one with the adverse effect that will approach his legal representative and instigate litigation.

Statistical data is impersonal and unemotional and it ignores norms and values and preferences. More specific, the Sackett⁴⁴² group attempts to give the decision-making-power, better known as informed consent, back to the patient by asking "how can we convert these into a form that permits our patient to make his own treatment decision?" They maintain that one should first elicit the patient's preferences? Then inform the patient about the bad outcomes that the clinician hopes to prevent and the adverse reaction that might be caused, with therapy. The patient needs to be put in a position where he/she can weigh the consequences of the good of the therapy (treatment) against the bad of the treatment (side effects) and the progression of the disease. The statistical data will provide amounts to explain this e.g. if the patient puts a value to the bad effect of the progression of the disease, 0.05 (almost as bad as being dead) and the adverse effect of the treatment (side effects) as being 0.95, then it can be said that the

⁴⁴² Sackett *et al* p 123

patient believes that disease progression is 19 times worse than the adverse events from the therapy (0.95/0.05).⁴⁴³

This study suggests that in the light of the abovementioned individual's medical situation the clinician can explain to the patient about the likelihood of the success of the treatment, as the patient had chosen to continue with treatment despite the bad side effects. Bear in mind that weighing the outcomes play an intrinsic part of the decision making in therapy and side effects can have a deterring effect on the decision making process. A patient making his own decisions in a responsible informed way would be reluctant to blame the physician for an adverse outcome.

11. Interpretation of Statistical Evidence: The Prosecutors Fallacy and the Defense Attorney's Fallacy⁴⁴⁴

11.1 Probabilities in context

Peirce⁴⁴⁵ indicates that probabilities are strictly objective and at the same time very great, but they can never be absolutely conclusive. In English, the "likelihood" concept appears in many writings by Peirce.⁴⁴⁶ It is where model-based inference is distinguished from statistical procedures based on objective randomization. Peirce explains that probabilities that are strictly objective and at the same time very great, although they can never be absolutely conclusive, ought nevertheless not to influence our preference for one hypothesis over another; but slight probabilities, even if objective, are not worthy of any consideration.⁴⁴⁷ On the other hand, mere subjective likelihoods should be disregarded altogether, for they are "merely expressions of our preconceived notions."⁴⁴⁸

⁴⁴³ Ibid p123

⁴⁴⁴ Thompson W C and Schumann E L, *Interpretation of Statistical Evidence in Criminal Trials: The Prosecutor's Fallacy and the Defense Attorney's Fallacy* (1987) Law and Human Behaviour Vol 11 No3 -the terms are a product of Thompson and Schuman

⁴⁴⁵ Peirce C S *Collected Papers* 7.227; also *Essential Peirce* Vol 2 p 102-3; *Illustrations of the Logic of Science* p 1877-78

⁴⁴⁶ Ibid

⁴⁴⁷ See paragraph 11.4 and 11.5 *infra*

⁴⁴⁸ Peirce, *Essential Peirce* Vol 2 p 102-3

It should be noted that probabilities in all likelihood would never be anything other than probabilities, and should only influence a patient's decision (or for that matter a physician's decision) in the event where two similar situations are weighed against another.

The decision would be: which situation has more side-effects or which situation is more harmful to my condition (as patient). On the other hand, if a probability is less likely to happen under specific circumstances, the decision should be: is the influence of the situation or side-effects worth considering? And then lastly, if the likelihood of side-effects is subjective and based on a person's opinion, and not based on research principles it should be ignored until proof is found to alter any decision⁴⁴⁹.

11.2 It's all about interpretation

Peirce⁴⁵⁰ continues and says that experience must be one's chart in economical navigation; and experience shows that likelihoods are treacherous guides. He is of the opinion that nothing has caused so much waste of time and means, in all sorts of researchers, as inquirers becoming so wedded to certain likelihoods as to forget all the other factors of the economy of research. He maintains that unless very solidly grounded, likelihood is far better disregarded. He says that even when likelihood seems solidly grounded, it should be proceeded upon with a cautious tread, with an eye to other considerations, and recollection of the disasters caused.⁴⁵¹

11.3 The fallacy of the reasoning

Thompson and Schumann⁴⁵² say that "prosecutor's fallacy"⁴⁵³ is a fallacy of statistical reasoning made in law where *the context in which the accused has been brought to the court* is falsely assumed to be irrelevant to judging how confident to be in *evidence*

⁴⁴⁹ See paragraph 11.4 and 11.5 *infra*

⁴⁵⁰ See paragraph 11.4 and 11.5 *infra*

⁴⁵¹ Peirce, *Essential Peirce* Vol 2 p 102-3

⁴⁵² Thompson *et al* Vol 11 No 3

⁴⁵³ Vickers A, *What is a p-value anyway?* 34 *Stories to help you actually understand statistics* p 122

against them with a statistical measure of doubt. They ⁴⁵⁴ continue by saying that in criminal cases where the evidence shows a match between the defendant and the perpetrator on some characteristics, the jury often receives statistical evidence on the incidence rate of the 'matching' characteristics. They further opine that two experiments were done testing undergraduate's ability to use such evidence appropriately when judging the probable guilt of a criminal suspect based on written description of evidence. In experiment one it varied whether incidence rate statistics were presented as conditional probabilities or as percentages and found that the former [conditional probability] promoted inferential errors favouring the prosecution while the latter [percentages] produced more errors favouring the defense. Experiment two exposed the subjects to two fallacious arguments on how to interpret the statistical evidence. The majority of subjects failed to detect the error in one or both of the arguments and made judgments consistent with fallacious reasoning. In both experiments a comparison of subject's judgments to Bayesian⁴⁵⁵ norms revealed a general tendency to underutilize the statistical evidence.

11.4 The P Value

Vickers ⁴⁵⁶ maintains that when doing a study or research problem and when trying to find if some finding is significant, statisticians are using the method called the "P Value". P is short for probability of getting something more extreme than your result when there is no effect in the population. When physicians try to determine whether or not a particular study is of any true value, they would consider the P value. Evidence based studies are promoted, with findings that are statistically significant. It might be applied to treatment, or diagnosis or disease.

Vickers writes entertainingly about statistics to explain the P value. He explains that when going home each night he had the choice to cycle home between a busy road or a road winding through the backstreets. Being statistically obsessed he spent 2 years

⁴⁵⁴ Vickers p 122

⁴⁵⁵ Base rate is the essence of Bayesian method (conditional probability: same as "given A what is probability of B") see paragraph 11.5 *infra*

⁴⁵⁶ Vickers p 122

recording how long each route takes on a number of occasions and he calculated means and standard deviations. He looked for the quickest route and analyzed his times. It turned out that travel time on the busiest route is shorter, but the difference between the two routes is not statistically significant (P value = .4). Nonetheless it seemed sensible to take what is most likely the quicker route even though it hasn't been proved that it will get him there faster. He decides to get more information and spends another period, this time randomly select a route home and record the times. After analyzing the data there is strong evidence that going home via the busy road is faster (P value = .0001), not by much as it saved him 57.3 seconds on average). He decided that the longer road is more enjoyable as it is a more pleasant journey.

Vickers argues that if it is true that P values determine our actions, for instance in the case of clinical trials done on drugs, where it is said that if $P < .05$ treatment is effective and $P \geq .05$ treatment is not effective, then the bicycle trip home proved the opposite. He chose the busy road when the P value was .4 but not when P value was .0001. Vickers opines that this information suggests that one has to re-look at what P -values are. He states that the most important thing about P values is the fact that it is only used to test hypotheses. He says it is widespread practice to cite P values for baseline differences between groups in a randomized trial. However one must bear in mind that the only hypothesis being tested is whether there are real differences between groups. Yet it is known that the groups are randomly selected so any differences in characteristics such as age or gender, must be due to chance alone.

Vickers explains when one does decide to test ideas the conclusion is often an insufficient reason for action, as proved with the bicycle test. It was proved that using the busy road was quicker yet he chose a different road based on considerations like pleasure and quality of life. It should be noted that these considerations formed no part of the hypothesis test. He humorously quotes a certain Dr Omar Sanchez who indicated that "statistics are like a bikini. What it reveals is suggestive but what it conceals is vital".

11.5 The base rate fallacy

Bar-Hillel⁴⁵⁷ says that base rate fallacy in probability judgments is people's tendency to ignore base rates in favour of e.g. individual information (when available) rather than integrating the two. The tendency has important implications for understanding judgment phenomena in many clinical, legal and socio-psychological settings. Specificity is achieved either by providing information on a smaller set than the overall population, of which the target case is a member of. The base rate fallacy is the result of pitting what seemed merely coincidental therefore low relevance base rates against more specific or causal information. A series of probabilistic inference problems is presented in which relevance was manipulated and the empirical results confirm the fallacy. In particular, base rates will be combined with other information when the two kinds of information are perceived as being equally relevant to the judged case.

Jaynes is of the opinion that if a defendant was selected from a large group because of the evidence that needs to be considered then this should be included in weighing how incriminating that evidence is, and not doing so is a base rate fallacy.⁴⁵⁸ Jaynes explains this by way of an example: "The base rate fallacy is also called base rate neglect and it is an error that occurs when the conditional probability of some hypothesis H given some evidence E is assessed without taking into account the base rate of prior probability of H and the total probability of evidence. For example is a city of 1 million inhabitants there are 100 known terrorists and 999 900 non-terrorists. The base rate probability of 1 random inhabitant of the city being a terrorist is 0.0001 and the base rate probability of 1 random inhabitant being a non-terrorist 0.9999. In an attempt to catch the terrorists, the city installs a surveillance camera with automatic facial recognition software. If one of the known terrorists is seen by the camera, the system has a 99% probability of detecting the terrorist and ringing an alarm bell. If the camera sees a non-terrorist, it will only incorrectly trigger the alarm 1% of the time. So the failure rate of the camera is always 1%. Suppose somebody triggers the alarm. What is the chance

⁴⁵⁷ Bar-Hillel M, *The base-rate fallacy in probability judgments* (1980) (2002) *Acta Psychologica*, 44, p 211-233
Hebrew University Jerusalem Israel

⁴⁵⁸ Jaynes ET, *Prior Probabilities* (1968) *IEEE transactions on Systems Science and Cybernetics* 4 (3):227-241
and see also Vickers p122-6

he/she is really a terrorist? Someone making the base rate fallacy would incorrectly claim that the false-alarm rate must be 1 in 100, because the failure rate of the device is 1 in 100, so if the alarm rings, there's a 99% probability that the camera has detected a real terrorist. The fallacy arises from the assumption that the device-failure rate and the false-alarm rate are equal. This assumption is incorrect, because if the camera sees a random sampling of the population—or even some less-random sample, like the people entering an airport—it is far more likely to see non-terrorists than terrorists. The higher frequency of non-terrorists increases the false-alarm rate. Imagine that the city's entire population of one million people passes in front of the camera. About 99 of the 100 terrorists will trigger the alarm—and so will about 9,999 of the 999,900 non-terrorists. Therefore about 10,098 people will trigger the alarm, and only about 99 of them will be terrorists. So the probability that a person who triggers the alarm is actually a terrorist is only about 99 in 10,098, or $1/102$ (so false alarm rate is 101 in 102!).⁴⁵⁹

11.6 Typical occurrences of the fallacy⁴⁶⁰

The first form is when conditional probability is misunderstood, says Papoulis. For example, the prior odds of whether the defendant being guilty *before* the evidence was introduced are neglected. When a prosecutor found some evidence (DNA match) and the expert testified that the probability of finding this evidence if the accused were innocent is tiny, the fallacy occurs if it is observed that the probability of the accused being innocent must be comparably tiny. The probability of innocence would only be the same small value if the prior odds of guilt were exactly 1:1. If the accused is otherwise totally unconnected to the case, and is only in the court room due to that DNA evidence then we should consider a much lower prior probability of guilt, such as the overall rate of offenders in the populace. The fallacy can rise from multiple testing, when evidence is compared against a large data basis. The size of the database elevates the likelihood of finding a match by chance. DNA is soundest if a match is found after a single directed

⁴⁵⁹ Jaynes p 227-241

⁴⁶⁰ Papoulis A, *Conditional Probabilities and Independent Sets* (1984) Vol 2-3 Probability Random Variables and Stochastic Processes p 33-45

comparison because the existence of matches against a large database where the test sample is of poor quality is very likely by mere chance.

Consider the following argument ⁴⁶¹ state Rossmo *et al*, where a lottery winner is accused of cheating based on the improbability of winning. At trial the prosecutor calculates the (very small) probability of *winning the lottery without cheating*, and argues that this is the chance of innocence. The flaw: he failed to account for the low prior probability of winning in the first place. Mistaking conditional probability for unconditional led to several wrongful convictions of British mothers, ⁴⁶² one accused of murdering two of her children where the primary evidence was the statistical improbability of two children dying accidentally in the same household (under Meadow's law.) ⁴⁶³ Though multiple accidental deaths (in this case cot deaths) are rare, so are multiple murders. With only the facts of the death as evidence it is the ratio of these (prior) improbabilities that gives the correct posterior probability of murder. ⁴⁶⁴ Rossmo *et al* indicate in another scenario a crime scene DNA is compared against a database of 20 000 men. A match is found, that man is accused and at his trial it is testified that the probability that two DNA profiles match is only 1 in 10 000. This does *not* mean that the probability that the suspect is innocent is 1 in 10 000. Since 20 000 men were tested there were 20 000 opportunities to find a match by chance. Even if none of the men in the database left the crime-scene DNA, a match by chance to an innocent is more likely than not, the chance of getting at least one match amongst the database. So evidence like this alone is non compelling data results. If the culprit was in the database then he or more other men would probably be matched in either case, it would be a fallacy to ignore the number of records searched when weighing the evidence. Cold hits like this on DNA databanks are now understood to require careful presentation as evidence at trials.

⁴⁶¹ Rossmo DK, *Failures in Criminal Investigation: Errors of Thinking* The Police Chief LXXVI (10) "The prosecutor's fallacy is more insidious because it typically happens by mistake" **and** Rossmo DK, *DNA Identification in the Criminal Justice System* Australian Institute of Criminology **and** Thompson EL Schuman *Interpretation of Statistical Evidence in Criminal Trials Law and Human Behaviour* (Springer)II (3) :167

⁴⁶² See Chapter 4 previously

⁴⁶³ Chapter 4 paragraph 5.1

⁴⁶⁴ Goldacre B, *Prosecuting and defending by numbers* (2006) The Guardian <http://www.guardian.co.uk/science/2006/oct/28/uknews> (accessed 27.6.2010) rarity is irrelevant, because double murder is rare too. An entire court process failed to spot the nuance of how the figure should be used. Twice" **and** footnote 36 *supra*

Vickers ⁴⁶⁵ explains that conditional probability depends on both the prior probability (condition before the test) and the value of the information after the test (the accuracy) and if this is not accurately addressed the fallacy is created. ⁴⁶⁶

12. Discussion of the fallacies and its influence in courts

In the adversarial system the legal professional is free to produce evidence as best suits their case, prosecutor's fallacy can be costly if retrials are the result (Professor Meadow's testimony in the Sally Clark case) ⁴⁶⁷ or in the judges summation of the evidence.

Hill ⁴⁶⁸ states that to test evidence against probabilities, all alternative probabilities should also be taken into consideration. In the Sally Clark-case the only probability that was considered was that of the prosecution (double homicide) and the probability of the mother's case, namely two successive deaths in the family as a result of sudden infant death syndrome (SIDS), was not even proposed in court. There is even good reason to argue that the likelihood of a second death in a household with a previous death of SIDS would be significantly greater should you wish to go into that argument. Hill⁴⁶⁹ attempts to accurately compare the chances of these two possible explanations. He concluded that successive accidents are between 4.5 and 9 times more likely than successive murders so that the *a priori* odds of Clark's guilt were between 4.5 to 1 and 9 to 1 *against*. No doubt useless information although her case was re-investigated and turned around, she never recovered and later died from alcohol poisoning.⁴⁷⁰

⁴⁶⁵ Vickers, p122-6 has more explanations and examples and calls it "prior probability"

⁴⁶⁶ The underlying principles of Bayesian method

⁴⁶⁷ *R v Clark* [2003] EWCA Crim 1020 **and** See Chapter 4 for a detailed discussion. It was argued at the trial by Professor Meadow and he cited published statistic in his testimony, indicating that the chance of a second cot death happening in a middle class home was 1 in 73 million.

⁴⁶⁸ Vickers A p 122, 196-8

⁴⁶⁹ Hill R, *Multiple sudden infant deaths- coincidence or beyond coincidence* (2004) Paediatric and Perinatal Epidemiology 18:322-323- Mathematic Professor at Salford

⁴⁷⁰ Shaikh T, *Sally Clark, mother wrongly convicted of killing her son, found dead at home* London, The Guardian (March 17, 2007)

13. Remarks on statistical evidence

It should be noted that it is of great importance that the legal nexus should at all times run like a gold thread through all the legal arguments and if this link cannot be maintained, then such a case before a court should fail. Scurich supports this by saying that the idea is that each piece of evidence need not conclusively establish a proposition, but that “all the evidence can be used as a mosaic to establish the proposition.”⁴⁷¹

After the confusion created by the Clark-case the Royal Statistic Society showed their concerns about the statistical fallacies presented to court by stating that “Society does not tolerate doctors making serious clinical errors because it is widely understood that such errors could mean the difference between life and death. The case of *R v Clark*⁴⁷² is one example of a medical expert witness making a serious statistical error, one which may have had a profound effect on the outcome of the case.”⁴⁷³

13.1 The basic legal principles omitted behind the *Clark*-case

As stated by Vickers and Bar-Hillel in paragraph 11.4. and 11.5 *supra* it is clear that the court in the Sally Clark-case was misguided, regarding the facts that the overall global trend had influence on the specific case (relevance) and the considerations of the P values or probabilities was not even considered on Meadow’s version. Additional to that, Schwikkard and Van der Merwe⁴⁷⁴ state that similar fact evidence is generally inadmissible because of the fact that it is irrelevant (relevance). The argument for the inadmissibility is due to the prejudicial effect that outweighs its probative value. For example Schwikkard *et al* used the situation where a jury that is made aware of the past bad conduct of the accused, may decide that he deserves the punishment irrespective

⁴⁷¹ Scurich N, *Interpretive arguments of Forensic Match Evidence: An Evidentiary Analysis* (2010) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1539107 (accessed 27.6.2010)

⁴⁷² *R v Clark* [2003] EWCA Crim 1020

⁴⁷³ <http://www.rss.org.uk/PDF/RSS%20> (accessed 5.7.2010) Statements regarding statistical issues

⁴⁷⁴ Schwikkard PJ, Van der Merwe S, *Principles of Evidence* (2002) p 66-67

of whether he is guilty of the offence charged. It will only be admissible when it is both logically and legally relevant.⁴⁷⁵

It should be noted that if one considers the above legal principles which is trite law and accepted standards in common law countries, how is it possible that the English courts allowed the sterile, unemotional, irrelevant evidence of statistical data to influence a decision to convict? There was no legal nexus, similar evidence should not be allowed under general conditions, how can speculative evidence be allowed that speculates about a guilty or innocent verdict even if it is labeled a sophisticated statistical term like probability or likelihood? Additional to that, as discussed above, with statistical data not applied correctly?

13.2 Misdirection of the court in the *Clark*-case regarding expert evidence

It can only be presumed that the court was confused with the legal principle of preponderance of probability and the statistical data regarding probability that was presented. A party bringing an action to court carries the onus of proof and once this onus is discharged, that party is successful. A court of law weighs the evidence put before it and based its decision on whether the onus of proof was met, and whether the court was satisfied that the party proved its case. The evidence should tip the scale of justice 51% in favour of the successful party. The evidentiary rules have been established to determine how the court should decide which evidence should be considered and what weight to put to it. It can be amongst others, of a factual nature or plain circumstantial evidence. However, the interpretation thereof is extremely subjective. In other words whether the evidence presented has swayed the judge to rule in its favour. It is for this reason that a court of Appeal was established with extra and independent judges, to eliminate or reduce the element of subjectivity.

If the courts allow any party in the action or proceedings to add weight to the scales of justice (the subjective mind of the court and the exclusive duty of the court) with statistical data that is not relevant or that is incorrectly interpreted, the court is seriously

⁴⁷⁵ *R v Pharanque* 1927AD 57; *R v Zawels* 1937AD 342; *Laubscher v National Food Ltd* 1986 SA 553 (ZS)

misdirected, as the weight of these evidence, if allowed, should be seen as informative and not probative. This was not seen in the Sally Clark case.⁴⁷⁶

The court should treat the statistical data with caution, but more so, the legal representative should argue that the court should not be influenced incorrectly and that the weight of the evidence should be seen in context, and interpreted separately, however, only once the logic is clear can it be added to the scales of justice.

14. More examples of errors in statistics and failure of logical reasoning

This study intends to use the two scenarios *infra* where the medical professionals were summonsed in a claim for compensation in a medical negligence action. The medical experts used statistical data incorrectly to justify the actions of the negligent doctor.

14.1 Scenario one⁴⁷⁷

Dr A was the Defendant physician of a 75-year-old woman, who suffered from a 6-month history of recurrent syncope. This is an episode of a short period of dizziness that occurs in the upright position followed by loss of consciousness and a fall. Consciousness is regained spontaneously after a few minutes. An abnormal ECG showed a 1st degree AV block⁴⁷⁸ and QT prolongation. A further 24-hour ECG recording showed sinus bradycardia⁴⁷⁹ and extrasystoles⁴⁸⁰, interpreted as supraventricular⁴⁸¹ and two unsustained episodes interpreted as supraventricular. A diagnosis was considered of drug-induced sinus node dysfunction possibly due to a beta-blocking medication. A further syncope attack showed that the patient's blood pressure fell alarmingly low to levels of serious concern. An expert explains that what is evident is an elderly woman with a classic history of Stokes Adams attacks. Characteristic of Stokes Adams attacks

⁴⁷⁶ See paragraph 11.4 and 11.5 and Chapter 4 for a detailed discussion of the Clark-case

⁴⁷⁷ The information is obtained from a case settled out of court subject to a confidentiality clause and which was unreported. The patient and expert agree to the use of the information on condition that they remain anonymous.

⁴⁷⁸ When the nerve conduction of the heart is blocked partially

⁴⁷⁹ Slow heart rate

⁴⁸⁰ Irritating heart shows the ventricles discharging off beat

⁴⁸¹ Originating from the atria and not the ventricles

is loss of consciousness with pallor that may be followed by a flush when regaining consciousness. The expert continues that the condition known as the “tachycardia-bradycardia⁴⁸²” syndrome is also known to be problematic. The condition is commonly progressive and commonly leads to syncope or sudden death. In reality, each episode of syncope is an episode of sudden death that the patient recovers from by good fortune rather than medical wisdom. Use of medication suppresses the tachy-arrhythmia, but often worsens the brady-arrhythmia. The expert offers that most physicians and cardiologists, when faced with this problem would seriously consider the implantation of a permanent pacemaker as a first resort. Another differential diagnosis viz., the likelihood of a cardiac diagnosis for syncope, ought to have been considered, said the expert. This is determined with a 24-hour ambulatory blood pressure monitor, which may have shown either low pressure readings in the upright position, or alternatively no significant drop in reading over 24 hours.

14.1.1 Medical discussion

The expert explains that the use of a specific beta-blocker is known to cause brady-arrhythmia and syncope. It is also a known cause of QT-interval prolongation, which most likely can progress to a bizarre heart rhythm known as “*torsade de pointes*”⁴⁸³ (also known as polymorphic ventricular tachycardia) and commonly resultant cardiac syncope (loss of cardiac output to the point of starvation of the brain).

Comment: In other words Dr A was the direct cause of the old lady’s symptoms by way of the prescribed beta-blocker.

The expert offers that Dr A made unwarranted conclusions based on the ambulatory blood pressure monitor. Dr A was of the opinion that there was no immediate danger to life from the recurrent episodes of loss of consciousness of the old lady and omitted to admit her to hospital, in fact gave instructions to not admit her and send her home. At home, the old lady, as expected, continue to experience further episodes of “sudden

⁴⁸² Rapid pulse interrupted by episodes of slow beats

⁴⁸³ A bizarre rhythm well known and identified as *torsade de pointes*

death” and did not recover from the second. The expert explains that hypotensive⁴⁸⁴ episodes rarely cause true syncope with loss of consciousness, and that the differential diagnosis, especially in the presence of long QT syndrome, and with a beta-blocking agent known to cause long QT syndrome and to predispose to malignant ventricular arrhythmia, most likely lead to cardiac syncope and sudden cardiac death. The single ambulatory blood pressure study was unlikely to pick up an episode of “sudden death” in the absence of symptoms during the period of being monitored. The family who accompanied the old lady to the hospital and to the Defendant’s rooms was extremely unhappy with the management of her medical condition.

14.1.2 The statistics

An explanation by the Defendant doctor was based on statistical data. He indicated that in-hospital resuscitation is successful in only a third of cases (30%) and that admission would in any case have made no difference. This explanation is offered based on statistical evidence of the “*torsade de pointes*” (also known as polymorphic ventricular tachycardia). A further percentage is quoted namely that at-home resuscitation attempts have a likelihood of 10% success rate. Clearly the Defendant physician wishes for the interpretation of the statistics, that only 3 out of 10 people with that disease can be saved in hospital, and 1 out of 10 at home. The odds to save the patient were against her and even if she was admitted to hospital the sequelae would have been the same.

14.1.3 Legal discussion and interpretation

It is recommended that the statistical data should be qualified and explained in accordance with some questions and answers. The statistical data relied on by the Defendant doctor should be analyzed in detail to test the relevancy of the figures quoted in comparison with the situation of the old lady, which is the one before the court. The studies quoted were based on observations made by emergency team specialists

⁴⁸⁴ Low blood pressure

involved in in-hospital resuscitations, and para-medical teams called out in emergency situations.

The following aspects are questioned and should not pass the test for relevancy:

1. The study sample is too diverse and large to qualify the statistical data. The figure of 30% for the in-hospital success rate of resuscitation for cardiac arrest includes many causes that can be seen as unexpected as well as the results of attempts to resuscitate the unresuscitateable – i.e. patients terminal from other systemic or morphological cardiac disease.
2. The expert is of the opinion that the chances of resuscitating a “torsade” due to drug treatment with no other cardiac or systemic disease is likely to be well above 75%, bringing the sample group to a much smaller group with better outcome ratios .
3. The statistics used as explanation by the physician was done for one reason only, that is to justify his actions or omission to act, and should be treated as misconduct and a deliberate intention to use the prosecutor’s fallacy to mislead the presiding officer.
4. What were the potential benefits and harms from the lack of treatment, both in hospital and by sending her home? The Defendant sent the old lady home and effectively withheld treatment from her. To quote a chance of survival of resuscitation at home of 1 out of 10 is an argument against him and not justification for his actions. With proper treatment of her condition in hospital her expectations for a good outcome was feasible and reasonable.
5. Was the treatment of the patient feasible? In the light of the expert’s explanation the treatment was insufficient and the diagnosis was incorrect not expected from a specialist cardiologist physician. When given a second chance to correct his diagnosis, he stubbornly persisted with the wrong treatment and diagnosis, despite questions from his colleagues.

14.2 Scenario Two⁴⁸⁵

The patient was 40 years old in her third pregnancy. She visited the antenatal clinic regularly. She had two previous successful pregnancies, both delivered normally, and each baby weighed more than 4 kg. She had no relevant medical history but both her parents were known to be diabetic. The uterine size correlated with the dates. She weighed 103 kg. Her blood pressure was normal. Ultrasound scan showed a normal foetus and correlated with the calculated dates. At her next visit at about 26 weeks, she weighed 107 kg, and a little glucose was found in her urine. Blood glucose was measured at 7.6 mmol/l. At 36 weeks she went to a different gynecologist/obstetrician for the further management of her pregnancy. The patient was seen twice more by the private gynecologist, during which he did not perform any ultrasound fetal tests to determine the baby's size. She started spontaneous labour and was admitted to the Labour Ward. The admitting midwife noted that it was a big baby. At about 2 ½ hours after admission, the private gynecologist considered performing a Caesarean section because of slow progress and a big baby. He gave medication to hasten delivery. The cervix was fully dilated and he undertook delivery with the vacuum extractor. He indicated this was for deep transverse arrest of the fetal head (DTA). The fetal head was delivered easily with one pull. However, great difficulty was experienced in delivering the shoulders. The exact procedure is not described but the left humerus was fractured in delivering the posterior shoulder. The male baby weighed 5050gm and was in an excellent condition. Great difficulty was experienced in delivering the shoulders and subsequently the presence of an Erb's palsy was diagnosed.

14.2.1 Discussion of macrosomia

An expert explains that there is no dispute that this foetus was macrosomic. Macrosomia is a risk factor for traumatic delivery which may result in injury to both mother and fetus. Macrosomia is certainly associated with diabetes, but it also occurs

⁴⁸⁵The information is obtained from a case settled out of court subject to a confidentiality clause and which was unreported. The patient and expert agree to the use of the information on condition that they remain anonymous.

with lesser degrees of abnormal maternal glucose metabolism not amounting to established diabetes. An increased body weight without diabetes is another risk for macrosomia.

14.2.2 Discussion of the labour process

The notional expert A says that in modern obstetric practice it is not possible to determine fetal size with any degree of confidence. This means that deciding on elective caesarian section is not recommended. This means that a patient is left to go into labour and the progress of labour is monitored. If there is fetal head dystocia a caesarian section is performed. If the head progresses labour continues and in the majority of cases continue without further events. In some cases the shoulders are not delivered spontaneously. A variety of maneuvers are then performed which may include caesarian section at this late stage in order to deliver the shoulders. In these cases a small percentage of babies are left with Erbs paralysis. On the basis of this low risk of Erbs paralysis the expert concludes that the management of labour in this case was not negligent.

14.2.3 Statistical data quoted

Expert A presented medical evidence that lead him to this conclusion. He claimed that in a population of patients who delivered babies of over 4,5 kg, 86% deliver safely vaginally, and of the remaining 14% needed caesarian section, due to the large head and that of these patients 7% had shoulder dystocia (e.g the head passed but the shoulder impacted) quoting that of the population of babies' whose shoulders impacted 25% resulted in Erbs. He argued that 0.25 (25% of 7%) resulted in Erb's palsy. He continued to argue that this means that 400 caesarian sections would need to be performed to in order to prevent 1 case of Erbs palsy. From this he concluded that the labour process could not be criticized. There is a high likelihood that this statistical argument can be accepted by a court based on the expert's use of the literature, to support his conclusion.

14.2.4 Legal discussion of the statistical data presented

It is submitted that the reasoning of the expert under 14.2.3 is flawed. The statistical data should be qualified and explained in accordance with some questions and answers. The statistical data relied on by the expert and the Defendant doctor should be analyzed in detail to test the relevancy of the figures quoted in comparison with the situation of the macrosomic baby, which is the one before the court. The percentages quoted were based on observational studies, however the circumstances under which these were done should be determined.

It is recommended to analyze the following:

1. Was a representative sample used for comparison?

Incorrect evidence was presented as the population in the reference study needed a caesarian section after the head was impacted or the shoulder was impacted during a vaginal delivery. It showed that the risk for the baby of getting shoulder dystocia under these circumstances was significantly low. However that was not the correct scenario to compare with the case in point. The true study needed to compare the abovementioned macrosomian baby with, would be a study showing what percentage of babies get shoulder dystocia if the head is forced through with a vacuum extractor. It is submitted that the incorrect study sample was quoted. The true study sample should have been a mother with a larger than normal baby, attempting normal labour, progressing slowly, a caesarian section was considered yet not opted for vacuum extraction was used to force the baby's head through, resulting in a baby with shoulder dystocia. What percentage of babies resulted in shoulder dystocia and Erb's palsy based on the given study? It is suggested that there would be no statistical data to quote from as a similar scenario would never be attempted as a research study because of the very high risk involved. Having made the decision to force the large baby's head through with the vacuum extraction, the true representative example needed to compare this case with would be: a large baby with slow progress

during labour and with a forced vacuum extraction to release the head, what is the harm/risk of shoulder dystocia? The harm/ risk increased and no study sample exists which will classify this example under imprecise or sparse data ⁴⁸⁶ for reasons that it would be unethical to allow this situation to occur.

2. With each incorrect decision that the doctor makes the representative sample for comparison would change, as explained above, and the further away one moves from a set scenario the higher the chances that no research scenario would exist based on the high risk, or irrelevance of the study.
 - On the Defendant's version, the ultrasound is not accurate in establishing fetal weight, and quotes an error range of 25% to 30%. Thus, on the worst case scenario the baby's weight could have been between 3687gm and 6415gm. The representative example needed for a true comparison was found in literature as can be seen that the overall incidence of shoulder dystocia varies based on fetal weight, occurring in 0.6 to 1.4 percent of all infants with a birth weight of 2,500 g (5 lb, 8 oz) to 4,000 g (8 lb, 13 oz), increasing to a rate of 5 to 9 percent among fetuses weighing 4,000 to 4,500 g (9 lb, 14 oz) born to mothers without diabetes.^{487 488 489}
 - Shoulder dystocia occurs with equal frequency in primigravid and multigravid women, although it is more common in infants born to women with diabetes.⁴⁹⁰
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 - Several additional prenatal and intrapartum factors have been associated with an increased incidence of shoulder dystocia. The single most common risk factor for shoulder dystocia is the use of a vacuum extractor or forceps during delivery.⁴⁹²

⁴⁸⁶ See Chapter 5-part two

⁴⁸⁷ Sokol R J, Blackwell S C, for the American College of Obstetricians and Gynecologists. Committee on Practice Bulletins–Gynecology. ACOG practice bulletin no. 40: *shoulder dystocia* November 2002 (replaces practice pattern no. 7, October 1997). *Int J Gynaecol Obstet.* 2003; 80: 87–92.

⁴⁸⁸ Nesbitt T S, Gilbert W M, Herrchen B, *Shoulder dystocia and associated risk factors with macrosomic infants born in California* (1998) *Am J Obstet Gynecol.* 179: 476–80.

⁴⁸⁹ Acker D B, Sachs B P, Friedman E A, *Risk factors for shoulder dystocia* (1985) *Obstet Gynecol.* 66: 762–8.

⁴⁹⁰ Sokol R J, Blackwell S C *ibid*

⁴⁹¹ Mocanu E V, Greene R A, Byrne B M, Turner M J, *Obstetric and neonatal outcomes of babies weighing more than 4.5 kg: an analysis by parity* (2000) *Eur J Obstet Gynecol Reprod Biol.* 92: 229–33

⁴⁹² Sokol R J *et al* p 87-92

- Among the most common fetal complications are brachial plexus palsies (Erb's palsy), occurring in 4 to 15 percent of infants.^{493 494 495}
- Nearly all palsies resolve within six to 12 months, with fewer than 10 percent resulting in permanent injury.^{496 497 498}

3. What are the patient's potential benefits and harms from the decision making? And was the treatment feasible?

The gynaecologist acted negligently as he failed to take all reasonable steps to reduce the risk of shoulder dystocia and consequent Erb's palsy and in fact increased the risk of shoulder dystocia by forcing the baby's head through by means of a vacuum extraction procedure at a time when it was clearly contraindicated. He failed to properly and adequately manage the delivery of the baby and failed to prevent further harm/ injury to the baby. He knew or ought to have known that the baby was at high risk of developing impacted shoulders he failed to use safe standards and techniques and failed to exercise the degree of skill and care reasonably to be expected of a specialist obstetrician and gynaecologist in the above circumstances.

14.2.5. Right data for wrong reason

It is recommended that the motive for the statistical data should be analyzed prior to accept any reasoning that fell out of the norm. It should be noted that the study accessed research material that had considerations as starting blocks other than medical research and which was based on financial gain only. It was called: "Prophylactic cesarean delivery is not recommended as a means of preventing morbidity

⁴⁹³ Acker D B, Sachs B P, Friedman E A, *Risk factors for shoulder dystocia* (1985) *Obstet Gynecol.* 66:762–8

⁴⁹⁴ Gherman R B, Goodwin T M, Souter I, Neumann K, Ouzounian J G, Paul R H, *The McRoberts' maneuver for the alleviation of shoulder dystocia: how successful is it?* (1997) *Am J Obstet Gynecol.* 176:656–61

⁴⁹⁵ Gherman R B, Ouzounian J G, Goodwin T M, *Obstetric maneuvers for shoulder dystocia and associated fetal morbidity* (1998) *Am J Obstet Gynecol.* 178:1126–30

⁴⁹⁶ Gherman et al p 1126-30

⁴⁹⁷ Rouse D J, Owen J, Goldenberg R L, Cliver S P, *The effectiveness and costs of elective cesarean delivery for fetal macrosomia diagnosed by ultrasound* (1996) *JAMA* 276:1480–6

⁴⁹⁸ Gherman R B, Ouzounian J G, Miller D A, Kwok L, Goodwin T M *Spontaneous vaginal delivery: a risk factor for Erb's palsy?* (1998) *Am J Obstet Gynecol.* 178:423–7

in pregnancies in which fetal macrosomia is suspected.”⁴⁹⁹ [SOR evidence level C, expert opinion based on cost-effectiveness analysis]. Analytic decision models have estimated that 2,345 cesarean deliveries, at a cost of nearly \$5 million annually, would be needed to prevent one permanent brachial plexus injury in a patient without diabetes who had a fetus suspected of weighing more than 4,000 g. In the subgroup of women with diabetes, the frequency of shoulder dystocia, brachial plexus palsy, and cesarean delivery was higher, leading the authors to conclude that a policy of elective cesarean delivery in this group potentially may have greater merit.⁵⁰⁰ [SOR evidence level C, expert opinion based on cost-effectiveness analysis]. It is recommended that the above research should be seen in context, namely that of financial information only and can never be seen as the norm by clinicians to base decisions on as this will lead to bizarre reasoning and decision-making.

It is submitted that the above research was done for financial reasons for cost effectiveness and the outcome was to save on caesarian-section-operation-cost. In the previous paragraph it was shown how extremely far removed from reality one becomes if one tries to verify non caesarian section decisions in a scenario where the odds went all wrong. There is no doubt that the gynecologist had the opportunity to determine how big the baby was, and even with the known error of the sonar, would have discovered that it was a baby weighing more than 4,5 kg. Having known that it is contraindicated to force a baby's head through the birth channel if there was slow progress and the baby was more than 4,5 kg, the action of the medical professional can be nothing other than negligent, and the statistical data quoted seen as irrelevant to the incident, and a clear attempt to mislead the court.

15. Conclusion

Evidence presented to the Court should be scrutinized, tested and questioned prior to arriving at any legal conclusion.

⁴⁹⁹ Rouse *et al* p 1480–6

⁵⁰⁰ Rouse *et al* p 1480-6

Ultimately the legal reasoning and decision-making should be logical and satisfy the needs of the people and should protect every individual's constitutional rights in a fair and just manner, and should not be misleading and seen as arriving to conclusions that are ludicrous and unreliable. The following comical example shows the power of irrelevant misguided statistics used at worst:

PS:

An irrelevant ill-thought through after thought:⁵⁰¹

(A) *The number of physicians in the United States is 700,000.*

(B) *Accidental deaths caused by Physicians per year are 120,000.*

(C) *Accidental deaths per physician is 0.171*

Statistics courtesy of United States Department of Health and Human Services.

(A) *The number of gun owners in the United States is 80,000,000 (80 million)*

(B) *The number of accidental gun deaths per year, all age groups is 1,500.*

(C) *The number of accidental deaths per gun owner is .0000188*

Statistics courtesy of FBI

Statistically, doctors are approximately 9,000 times more dangerous than gun owners.

Remember, 'Guns don't kill people, doctors do.'

However not everyone has a gun and almost everyone has at least one doctor. This means you are over 9,000 times more likely to be killed by a doctor than by a gun owner!!!

Out of concern for the public at large, the statistics on lawyers are withheld for fear the shock would cause people to panic and seek medical attention!

⁵⁰¹ chain mail- anonymous

CHAPTER 11

CONCLUSION

1. Introduction

Throughout the previous ten chapters the study developed and demonstrated many aspects around several difficulties related to medical negligence litigation. As the intricacies of medicine have to be determined prior to any legal action can take place, the study shifted to the legal and medical information required to discharge the onus of proof in a medical negligence case and focused on the role of the expert in court. The study investigated the medical basis of the information provided by the experts, and discovered that medical experts should show the “collective mind” of the profession to the court based on principles of evidence-based medicine, which in its turn is based on reliable research ideologies. Ultimately the study concentrated on the application of reliable evidence-based medicine and the influence thereof on an existing court case. The study cautioned the use of statistical data as inaccurate use of data without a sound rationale can lead to peculiar unreliable conclusions and should be avoided. Considering the broad overview of the study as summarized, one should have a closer look at whether the study met the goals set out to achieve.

2. Purpose of the study

The purpose of the study was to analyze medical evidence presented to court *in totum*, from the legal aspects that are required to win the case, to the medical basis of the medical evidence presented by the medical expert. The study has focused on the role of the expert in court and showed that the role of the expert is in essence fourfold and can be summarized as the honourable judge Sopinka has shown in the Canadian case *R v Mohan*⁵⁰², namely:

- to furnish the court with information that is relevant to the matter;

⁵⁰² *R v Mohan* [1994] 2 SCR 9 at 21

- to assist the court with evidence which is likely to be outside the experience and knowledge of the court, however guarding against experts contesting each other with the court being the referee;
- to consider any exclusionary rules prior to deciding the facts;
- to ensure that the expert is indeed qualified to assist the court with the relevant aspects before the court.

The study confirmed that the contention developed from the above role of the expert, that expert evidence should only be admitted if there are grounds for believing that the evidence presented is reliable, should be maintained. The study showed that a standard to stamp out unreliable expert evidence from the court process and to concentrate on the probative values of the evidence presented will contribute to more legitimate outcomes. The study looked to ways to incorporate evidence that corroborate and support liability as this should be another way to test the evidence before the court, and for the court to religiously guard against role-players trying to usurp its function. This study showed that it seemed to have found corroborating evidence in the principles of evidence-based medicine.

This study progressed to investigate evidence-based medicine as a sound basis for the medical expert, analyzed it and tested it for deficiencies. It was noted that notwithstanding the above medical evidence, based on reliable scientific experiments and based on methods tested for bias and approved as being free from bias, by the scientists, it has been shown that additional limitations surfaced from the research literature. It showed in the Michael-case⁵⁰³, a lack of medical information resulted in an unfair decision and an administrative injustice. It showed further that statistical interpretation errors, for instance the Sally Clark-case⁵⁰⁴, lead to misguided and bizarre outcomes of a court case, not based on sound scientific and medical principles, and presiding officers relying too much on an expert. It showed that adequate prepared medical evidence and reliable analytical statistical data used correctly could prevent

⁵⁰³ *Michael v Linksfeld Park Clinic* 2001 (3) SA 1188 (SCA)

⁵⁰⁴ *R v Clark* (2003) EWCA Crim 1020 and *R v Cannings* (2004) 1 All ER 725

bizarre outcomes. It showed that the reasons for peer reviews and peer reviews should be scrutinized for flaws, as peer reviews can be done prior to publication or post publication, and that if it was done post publication it should be seen as being in its weakest sense as it was not evaluated by the peers at all. It suggested that opposing medical reviews should be considered and analyzed to determine the correct reason for the objections and should not be discarded, but valued for its input. It was shown that several aspects of peer reviews should be scrutinized, for instance a question that should be answered should be whether the intended outcome had bearing on any financial interest of any party.

It is in this regard that the study had to agree with Albury,⁵⁰⁵ as he refers to matters where the scientific experts are in disagreement and where there are rival concepts of objectivity, i.e. two different ways of assigning relevance to the available data and interpreting their meaning. Albury states that the question of objectivity relates to the problem of conflicting advice between scientific experts on matters of social importance, and that this is not a question of deciding in the abstract which expert is more objective, but, it should be a concrete question of which expert's version of objectivity is to be preferred.

Throughout assessing expert evidence this study showed that even published literature should be tested for its reliability as sometimes the only objective of reviews done by the peers is to evaluate manuscripts for acceptance or rejection for publication purposes and not to determine the authenticity. The study warned that the medical evidence in research material should be tested by the court itself, as journals often have obligations to scientists and physicians but unfortunately also to security investors and venture capitalists. The study showed that pharmaceutical companies or Managed Health Care organizations with an obligation to stay solvent will publish data reflecting the financial outcome of a proposed medical procedure, and in doing so will be seen to mistakenly support the effectiveness of the procedure, and as such supports incorrect and unreliable information.

⁵⁰⁵ Albury, R *The Politics of Objectivity* (1983) p 42

In the light of the above the study moved to embrace the argument that reliability, as a component of evidence, is probably the most important element of admissibility. This study found support for this statement in the Ontario Court of Appeal matter *R v Terceira*⁵⁰⁶, which was re-affirmed by the *R v Trochym*⁵⁰⁷ case, by the Supreme Court. The majority decision in the latter affirmed the *Terceira* decision that the function of the trial judge is limited to an overview of the evidence proffered in order to be satisfied that it reflects a scientific theory or technique that has either gained acceptance in the scientific community or if not accepted is considered otherwise reliable in accordance with the methodology validating it. The judge continues that the threshold test of reliability is met when the trial judge after reviewing evidence presented is of the viewpoint that the evidence presented is sufficiently reliable. The court confirmed the fact that certain types of evidence admitted in the past and accepted in the past might support a presumption in favour of the admissibility of this kind of evidence in future yet it cannot guarantee prospective admissions.⁵⁰⁸ Edmond⁵⁰⁹ supports the theme of the study as he is of the opinion that expert evidence based on intuition, speculation and experience- the so-called *ipse dixit*- should be approached with considerable apprehension in judges and prosecutors.

The study addressed the aspects of testing literature for reliability, and gave a detailed discussion to the different aspects of testing the information in the scientific literature. The study noted that potential difficulties exist around the meaning of testing, and suggested that techniques and theories should be tested for reliability and logical reasoning as the basis of the evidence. This study warned that absence of testing should ring alarm bells regarding validity aspects, and that statistical rates regarding error rates and the levels of confidence and individual competence might show that the research material was unreliable in total.

⁵⁰⁶ 1998 (1998) 123 CCC (3d) 1 at [64] see also [24]-[26]; *R. v. Johnston* (1992) 69 CCC (3d) 395 and *R. v. B.(K.G.)* (1993) 79 CCC (3d) 257.

⁵⁰⁷ [2007] 1 SCR 239 at [27]

⁵⁰⁸ *R. v. A.K. & N.K.* (1999) 137 CCC (3d) 225 at [84]

⁵⁰⁹ Edmond G, *Pathological Science? Demonstrable reliability and Expert Forensic Pathological Evidence* p 15 www.law.unsw.edu.au/staff/edmondg/docs/Goudge.pdf

3. Recommendations

Finally the study moved to make certain recommendations in order to avoid incorrect evidence been placed before the court. Prior to these recommendations it should be noted that some of the aspects that required mentioning yet do not qualify for an in depth analysis, namely, the language used by scientific experts in court when faced with a hypothetical question. This study recommends that the level of confidence expressed by certain experts should be qualified and not left to chance. If it is not qualified it would be alarming that a simple phrase like “it is possible” shows a confidence level of under 50%, that a phrase like, “it is probable” will make a case turn in the party’s favour and show a confidence level of more than 50%. It is not recommended that medical outcomes be described as “it is a medical certainty” and that this should be avoided, as well as a phrase like, “it cannot be excluded from a relevant group” or that a sample group represents a “match”. Phrases like “consistent with” or “inconsistent with” should be used by experts and the legal decision that a sample is a “match”, should be left to the court.

It is recommended that expressions of over confidence, incongruently used by experts, will contaminate the evidence and allow for contamination upon contamination in an intricate medical matter, and should be avoided. Medical experts should be informed that the medical evidence should be presented with little emotion if any, as a relation and explanation of the medical facts are what is expected from them and not an interpretation of the consequential outcome or adverse effects. Medical experts are often medically involved in a matter and are as such privy to sensitive, intimate information, and maybe unavoidably, they become part of the preliminary investigations, and as such become emotionally involved in the matter, rendering their medical evidence biased and unreliable. Medical experts should guard against bias and undue influence.

This study recommends that the judiciary should look at the evidence presented by the experts to ascertain sufficient reliability and objectivity, and should look for the collective

mind of the profession, expressed in the authoritative literature, and guard against contaminated evidence or contaminated experts.

3.1 Impartiality

The study looked at other options considered by the Canadian courts regarding the impartiality of the expert, and the possibility of how the process of court can assist the court to have an impartial expert before court. It is noted that Edmond⁵¹⁰ discusses the option of appointing court-appointed experts. He explains that questions like who picks the expert? Should the relevant professional body provide a list? What if the expert is not the expert relevant to the case material? Who determines that? Do they choose experts that are involved in professional debates or a generalist? All these questions address concerns regarding bias. Ward⁵¹¹ publishes an article discussing several reasons why the use of joint experts would seem to be ill-suited for the adversarial system. He concludes that it would result in expert evidence be criticized for not supporting the relevant case instead of being criticized for the scientific contents of the scientific material.

Edmond⁵¹² challenges the wisdom of court-appointed experts and questions whether they will make the outcome of litigation less predictable as additional experts introduce new opinions after much of the preparatory work, pleadings and pleas have been finalized. He is of the opinion that the use of court-appointed experts may actually complicate settlement negotiations and may even stimulate pre-trial activity and litigation. Edmond questions whether the selection of safe and eminent experts would raise standards of admissibility and reliability and proof and alter the legal doctrines. He asks whether it will be even more difficult to challenge the opinions of esteemed and eminent distinguished experts- such as Professor Sir Roy Meadow,⁵¹³ who was once the doyen of British paediatrics- and Edmond states that that was the kind of expert that

⁵¹⁰ Edmond G p 55

⁵¹¹ Ward T *Experts, juries and witch-hunts: From Fitzjames Stephen to Angela Cannings* (2004) *Journal of Law & Society* 369,382; Abbott A *The System of Professions: An Essay on the Division of Expert Labor* (1988) p 56

⁵¹² Edmond G and Mercer D, *Litigation Life: Law-Science Knowledge Construction in (Bendectin) Mass Toxic Tort Litigation* (2000) 30 *Social Studies of Science* 265–316.

⁵¹³ See the treatment of Meadow in *R. v. Clark* [2003] EWCA Crim 1020 and *R. v. Cannings* [2004] 1 All ER 725

judges are likely to select and trust! Edmond ⁵¹⁴ opines that efforts to protect or guarantee the credibility of a court-appointed expert may (appear to) compromise the judicial independence, and usurp the role of the trier of fact i.e. the court. He relates situations where the court appointed a panel of experts and during the trial, because the panel was continuously challenging the panel, had to request independent representation to defend the increasingly anxious experts' reputations and interests. Edmond is concerned and speculates what would happen if court appointed experts individually or as a group disagreed or reached inconsistent conclusions? What would happen to public confidence in courts and judges when the credibility of an expert, who is repeatedly appointed by the court, is compromised? He opines that what apparently seems to be a simple solution might actually become more complex and disruptive of the adversarial legal institutions, the practice of judging and the independence of the judiciary.

The study investigated with Edmond ⁵¹⁵ the system of pre-trial procedures widely used in England ⁵¹⁶ and Australia. The aim of a pre-trial conference is to try and reach an agreement, to narrow the extent of the disagreement between parties, and in some jurisdictions to produce a joint report. The study found that the value of pre-trial conferences is unclear. It should be of assistance to have the experts meet and discuss empirical testing, the significance of the absence of evidence, and whether techniques, theories and opinions have supporting specialist communities and literature. It is suggested that pre-trial meetings between experts especially where lawyers are excluded may have a likelihood to reach consensus guided by shared commitment to universal methods and scientific conventions. It is suggested that the adversarial minds of the lawyers cloud the issues and therein prevent settlement negotiations whilst true experts with integrity would agree on medical aspects free from bias.

⁵¹⁴ Edmond *et al* *Litigation Life*: p 265–316.

⁵¹⁵ Edmond G, *Judicial Representations of Scientific Evidence* 242–249. For a discussion of pretrial expert meetings associated with the use of *concurrent evidence* procedures drawn from an ongoing empirical study sponsored by the Australian Research Council, see Edmond G, *Merton and the Hot-Tub: Expert Witnesses, Concurrent Evidence and Judge-Led Law Reform in Australia* (2008) 27 *Civil Justice Quarterly*

⁵¹⁶ *Civil Procedure Rules* 1998 (England) and *Uniform Civil Procedure Rules* 2005 (NSW)

The study agrees with Edmond⁵¹⁷ that forensic scientific medical evidence, and meeting with medical experts for the defense may lead to more resilient evidence that may make it harder for the defense to identify limitations or persuade the trier of fact about weaknesses. It may be difficult for state experts to make concessions in pre-trial meetings, one might doubt the good judgment of allowing forensic experts to broker consensus with defense experts removed from the scrutiny of lawyers and the supervision of the courts. The study supports this concern as the role of the courts will once again be disrupted by the medical experts.

The study is of the opinion that admissibility determinations and assessments of reliability, and conclusions should be legal decisions rather than technical (or scientific, or medical) decisions, and the manner in which it is presented should be transparent. It should be prudent to address the concept of expert accountability and integrity by way of a guideline for experts or even a code of conduct for experts.

Freckelton⁵¹⁸ states that codes of conduct for the experts may help to reiterate the paramount duty owed by the expert witness to the courts. However, he cautions that the guidelines do not seem to discipline the experts and that the Australian codes seemed to contribute to changes in the form of expert reports and testimony rather than to substance and reliability of expert evidence.

3.2 Sanctions against experts

Edmond⁵¹⁹ raises the obvious question, namely, on what grounds are judges to apply sanctions against experts who breach their obligation to the court? How would judges determine legitimate professional differences or obduracy driven by a party's desire for a trial? What in the process divulges this? Could experts be punished by contempt of court proceedings, for attempting to pervert the course of justice, or even perjury?

⁵¹⁷ Edmond, *Judicial representations* p 248

⁵¹⁸ Freckelton I et al., *Australian Judicial Perspectives* (Melbourne: AIJA, 1999). Contrast Edmond G *Judging Surveys: Experts, Empirical Evidence and Law Reform* (2005) 33 *Federal Law Review* 95–139.

⁵¹⁹ Edmond G, *After Objectivity: Expert Evidence and Procedural Reform* (2003) 25 *Sydney Law Review* 131–64, 156–157.

This study supports Edmond's viewpoint that flagrant misconduct will be fairly obvious and remedial with or without a code of conduct, but more subtle forms of exaggeration, misrepresentation and omissions will prove more difficult to combat and will not be readily identified through guidelines.

It is recommended that experts know their duty to the court and should they fail their duty they should face legal liability. One might speculate whether strict codes of conduct might enable sanctions against experts, although professional liability should be considered. One should expect that if lawyers can be found liable if a case prescribes whilst under the lawyers control, so can an expert be found liable if cause is shown that the plaintiff lost his/her case as a result of the misconduct of the expert, or that the expert breached his obligation to the court.

4. Conclusion

Throughout this study the plea for reliable evidence-based medicine as a sound basis for expert evidence was developed in order to limit the scope of disagreement between experts and the scope of cross-examination in court as well as to attempt to reduce the number of rebuttal experts used at trial. Reliable evidence-based medical evidence has been advanced as a standard or yardstick to the court, the "collective mind" that the courts were searching for, for the court to test the medical evidence presented for its reliability, relevance and ultimately for its admissibility.

This study is of the opinion that should the court request reliable evidence-based medical literature at pre-trial, to enhance fairness and accuracy it would compel medical experts to reform their approaches to submitted evidence and proof. It is also recommended that experts' liability should be emphasized by the courts in a proper formulated code of conduct for experts, and sanctions should be followed through if experts transgress their duty to the court.

A much needed paradigm shift is called for and should be encouraged, both for the legal profession and the medical profession. The legal profession should move away from their passive role of requesting a medico-legal reports and relying on that report without

questioning the information contained in the report. The report should be accompanied by reliable evidence-based medicine literature in support of the opinion of the expert. Should there be no medical evidence available supporting the medical opinion the expert should clarify and justify the reason for the absence of supporting literature and made that available to the legal profession. No expert report worthy of its opinion should be made available without the relevant supporting documents.

The paradigm shift of the medical profession is to move away from the perception of being a paid hand of the defendant or the plaintiff and should fulfill their function and duty to assist the court with dignity and honour. The court should treat transgression or circumvention of these duties of the expert in a serious light and take action against the profession through the statutory bodies regulating the profession, as well as charge the offender with obstruction of justice.

Ultimately it should be made clear that the legal conclusion based on medical conclusions has been and always will be and remain the duty of the courts.

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