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Lungren, Aina Christina

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PERI-OPERATIVE DEATHS IN TWO MAJOR ACADEMIC HOSPITALS IN JOHANNESBURG, SOUTH AFRICA

Aina Christina Lundgren

A Thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfillment of the requirements for the degree of

Doctor of Philosophy

Johannesburg, 2011

I, Aina Christina Lundgren, declare that this thesis is my own work. It is submitted for the degree of Doctor of Philosophy in the University of the Witwatersrand, Johannesburg; it has not been submitted before for any degree or examination at this or any other University.

……. Aina Christina Lundgren

……1st……day of …October…… 2011

In memory of my father

Sixten Konrad Evert Lundgren

1920-1991

Presentations and publications arising from this study

Presentations:

University of the Witwatersrand, Guest Seminar for Application for Chief Specialist post at the Johannesburg Hospital, 31st October 2000.

Lundgren AC. The Safety of Anaesthesia in Johannesburg in the 21st Century.

University of the Witwatersrand 21st Biennial Surgical Symposium, 14th -16th June 2008.

Lundgren AC. How has anaesthesia improved?

Anaesthetic Foundation, August 2005

Lundgren AC. Informed Consent in 2005.

South African Society of Anaesthesiologists National Congress, Bloemfontein, 21st to 24th March 2010.

Lundgren AC. Are we ethical in approaching our patient's death?

Northwest Anaesthesia Refresher Course, Roodepoort, 15th May 2010.

Lundgren AC. Informed Consent in 2010.

Paediatric Anaesthesia Congress of South Africa (PACSA), Sandton, 7th November 2010.

Lundgren AC. Paediatric Consent Issues.

Publications:

Lundgren, AC. *Has Anaesthesia Improved?* Southern African Journal of Anaesthesia and Analgesia 2008; 14: 5

Lundgren, AC. *Informed Consent for the Anaesthetist*. Anaesthetic Foundation course proceedings.

Lundgren AC. *Informed Consent in 2010*. Northwest Anaesthesia course proceedings.

Lundgren AC. *Paediatric Consent Issues.* Paediatric Anaesthesia Congress of South Africa course proceedings.

ABSTRACT

Background to and purpose of the study

An adverse outcome during the administration of an anaesthetic may result in morbidity or mortality, the latter providing us with the most fundamental measure of the safety of anaesthesia for our patients. Peri-operative deaths due to anaesthesia have not been documented in the province of Gauteng, South Africa, since 1955. The purpose of this study was to document these deaths and compare the findings with previous South African studies, as well as some studies performed overseas.

Aims and objectives

This study aimed to investigate and determine the prevalence of anaesthesia associated deaths, particularly those that occurred as a direct result of anaesthesia (ACD), both general and regional in two major academic hospitals in the Johannesburg area. These were the Charlotte Maxeke Johannesburg Academic Hospital and the Chris Hani Baragwanath Maternity Hospital.

The objectives included examining current legislation and the interpretation thereof with recommendations, as well as the causes or possible risk factors involved in the peri-operative deaths that were studied.

Research methods and procedures

This was a retrospective longitudinal descriptive study, in the form of a clinical audit. All peri-operative deaths during the period 2000 to 2004 were studied at both sites. Numerous data were collected from each death, and descriptive and analytical statistics performed using SAS for Windows to provide frequencies for all of the variables recorded, with subsequent categorical analysis.

Results

The Anaesthetic Contributory Death (ACD) rate at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) was 0.4 per 10,000, which is an improvement from the pilot study that was conducted in that hospital during 1999, but it is still higher per 10,000 than the figures from the United Kingdom.

The Anaesthetic Contributory Maternal Death (ACD_M) rate at the Chris Hani Baragwanath Hospital was similar to the ACD rate at the CMJAH, and similar to the rate in the United Kingdom.

Conclusions

The ACD rate in these two hospitals is low, and may well not improve any further, as human error cannot totally be eliminated from anaesthetic practice.

The South African law does not specify a time period from the start of the anaesthetic during which a peri-operative death is classified as an ACD. This is poorly understood by the medical fraternity and general public.

Recommendations

An improved reporting system has been described and recommended, with education at all levels. Debriefing and structured peer review needs to occur after all ACDs. A correlation between the clinical and post mortem causes of death should be documented.

ACKNOWLEDGEMENTS

My husband, William Robert Steele, for inspiration and encouragement;

My supervisor, Prof Peter Cleaton-Jones, for believing in me, and for endless encouragement and infinite patience, especially on statistical matters;

The Department of Anaesthesia, Chris Hani Baragwanath Hospital for allowing me the time to complete this;

Prof Eckhart Buchmann for assistance with access to maternal data and Dr Celeste Quan, for assistance with capture of this data;

Prof Paul Fatti, Emeritus Professor of Statistics, University of the Witwatersrand for statistical advice;

Drs Michael Eliastam and Susan Tager for encouragement;

Dr Arthur Manning for encouragement and for allowing me time to collect data;

The South African Society of Anaesthesiologists and the Jan Pretorius Fund for funding;

Dr Aithne Rowse and Mrs Muriel Ndlovu, for help with acquiring references.

TABLE OF CONTENTS **Page**

Title page i

Declaration ii

Dedication iii

Presentations and publications iv

Abstract vi

Acknowledgements ix

Table of Contents x

List of Figures xix

List of Tables xx

CHAPTER 1 – INTRODUCTION **1**

Preface 1

1.1 General remarks 1

1.2 Problem statement 2

1.3 Definitions 2

1.3.1 Risks and consequences of anaesthesia 2

1.3.2 Morbidity 3

1.3.2.1 Morbidity from general anaesthesia 4

1.3.2.2 Morbidity from regional anaesthesia 6

1.3.3 Mortality 8

1.3.3.1 Anaesthetic Associated Deaths (AAD) and Anaesthesia Contributory Deaths (ACD) 13

1.3.3.2 Edwards classification 14

1.4 **Importance of this study** 15

1.5 **Aims of this study** 16

1.6 Objectives 17

1.6.1 Primary objectives 17

1.6.2 Secondary objectives 18

1.7 Study design 18

1.8 **Thesis outline** 18

CHAPTER 2 – LITERATURE REVIEW 21

2.1 International studies 21

2.1.1 Studies from the United States of America 22

2.1.2 Studies from Australia and New Zealand 24

2.1.3 Studies from Europe 26

2.2 Southern African studies 32

2.2.1 The Orenstein Report 32

2.2.2 Preventable mortality and morbidity in anaesthesia in South Africa 34

2.2.3 “Whither Anaesthesia” 35

2.2.4 The Anaesthetics Death Research Unit 36

2.2.5 Harrison’s legacy 39

2.2.6 Anaesthetic mortality at Tygerberg Hospital 41

2.2.7 Southern Africa – Zambia 45

2.2.8 Southern Africa – Zimbabwe 45

2.2.9 Comment on the Zimbabwe study 47

2.3 Conclusions 48

CHAPTER 3 – PILOT STUDY **50**

3.1 Introduction 50

3.1.1 Definitions 50

3.2 Methodology 51

3.2.1 Ethical considerations 51

3.2.1.1 Ethics approval 51

3.2.1.2 Postgraduate committee approval 51

3.2.1.3 Declaration of Helsinki 52

3.2.1.4 Hospital approval 52

3.2.2 Study sites 52

3.2.2.1 Johannesburg Hospital 52

3.2.2.2 Wits Donald Gordon Medical Centre 52

3.2.3 Study periods 53

3.2.4 Sample population 53

3.2.5 Inclusion criteria 53

3.2.6 Data collection 54

3.2.7 Data analysis 59

3.3 Results 59

3.3.1 Charlotte Maxeke Johannesburg Academic Hospital 59

3.3.2 Wits Donald Gordon Medical Centre 66

3.4 Discussion 67

3.4.1 Charlotte Maxeke Johannesburg Academic Hospital 67

3.4.2 Wits Donald Gordon Medical Centre 71

3.5 Conclusions 72

CHAPTER 4 – METHODOLOGY **74**

4.1 Study design 74

4.2 Ethical considerations 74

4.2.1 Ethics approval 74

4.2.2 Postgraduate committee approval 74

4.2.3 Declaration of Helsinki 74

4.2.4 Hospital approval 75

4.3 Study site 75

4.4 Study population 77

4.5 Study period 77

4.6 Sample population 77

4.6.1 Charlotte Maxeke Johannesburg Academic Hospital 2000-2004 77

4.6.2 Chris Hani Baragwanath Maternity Hospital 2000-2004 78

4.7 Inclusion criteria 78

4.8 Data collection 78

4.8.1 Charlotte Maxeke Johannesburg Academic Hospital 78

4.8.2 Chris Hani Baragwanath Maternity Hospital 79

4.9 Data analysis 82

4.10 Funding 83

CHAPTER 5 - CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL 2000-2004 **84**

5.1 Additional data collection specific to this part of the definitive study 84

5.2 Results – Descriptive statistics of the whole sample 85

5.2.1 Total peri-operative deaths 85

5.2.2 Broad demographics of the whole sample of peri-operative deaths 87

5.2.3 Types of surgery in all of the peri-operative deaths 88

5.2.4 Types of anaesthetics administered for all of the peri-operative deaths 90

5.2.5 Adverse events and deaths in the whole sample of peri-operative deaths 92

5.3 Results – Analytical statistics of the whole sample 93

5.3.1 ASA 94

5.3.2 Category of doctor 97

5.3.3 Anaesthetic administered or not 100

5.3.4 Anaesthetic record availability 102

5.3.5 Adverse event – when this occurred 103

5.3.6 When the patient died 104

5.3.7 Where the patient died 105

5.4 The Trauma sub-sample of peri-operative deaths 107

5.4.1 Demographics 107

5.4.2 Analytical statistics 109

CHAPTER 6 – CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL 2000-2004 **110**

The Anaesthesia Associated Deaths and Anaesthesia Contributory Deaths

6.1 Broad demographics of the AADs and ACDs 110

6.2 The AADs and ACDs in more detail 112

6.3 Discussion 118

CHAPTER 7 – MATERNAL DEATHS **121**

7.1 Introduction 121

7.1.1 Definitions 123

7.1.2 Maternal Mortality Ratio 124

7.1.3 International statistics 125

7.1.4 South African statistics 125

7.2 Anaesthesia associated maternal deaths internationally 126

7.3 Anaesthesia associated maternal deaths in South Africa 127

7.3.1 The year 1998 127

7.3.2 The Triennium 1999-2001 127

7.3.3 The Triennium 2002-2004 128

CHAPTER 8 – MATERNAL DEATHS AT CHRIS HANI BARAGWANATH MATERNITY HOSPITAL 2000-2004 **133**

8.1 Introduction 133

8.2 Methodology 133

8.3 Results: Descriptive statistics 134

8.3.1 General CHBMH statistics for the period 2000 to 2004 135

8.3.2 HIV status of maternal deaths 135

8.3.3 Maternal deaths in patients who did not undergo a surgical procedure at Chris Hani Baragwanath Hospital 136

8.3.4 Maternal deaths in patients who underwent a surgical procedure 137

8.3.5 Types of anaesthetics given 138

8.3.6 Types of procedures performed on 59 maternal deaths 141

8.3.7 Adverse events and subsequent deaths 142

8.4 Results: Analytical statistics 143

8.4.1 ASA 143

8.4.2 Category of doctor 147

8.4.3 Where the patients died 149

8.5 Anaesthesia Associated Deaths 151

8.6 Discussion 156

CHAPTER 9 – DISCUSSION AND CONCLUSIONS **159**

9.1 Problems inherent in studying anaesthesia mortality (death) 159

9.2 Charlotte Maxeke Johannesburg Academic Hospital 161

9.3 Chris Hani Baragwanath Maternity Hospital 165

9.4 Lessons from other countries 167

9.4.1 Australia 167

9.4.2 United Kingdom 167

CHAPTER 10 – RECOMMENDATIONS **168**

10.1 Peri-operative deaths, anaesthesia associated deaths and anaesthesia contributory deaths 169

10.1.1 National (South Africa) 169

10.1.2 Charlotte Maxeke Johannesburg Academic Hospital 175

10.2 Maternal deaths 176

10.2.1 National (South Africa) 176

10.2.2 Chris Hani Baragwanath Maternity Hospital 177

10.3 International recommendations 178

10.4 Future studies 178

LIST OF REFERENCES **181**

APPENDICES

Appendix A – Ethics permission 189

Appendix B – Extension of Ethics permission 190

Appendix C - Postgraduate Committee permission 191

Appendix D – Permission for title change 192

Appendix E – Data capture form 193

Appendix F – CMJAH Anaesthetic record page 1 194

Appendix G – CMJAH Anaesthetic record page 2 195

Appendix H – Maternal Death Notification form 196

List of Figures

Figure 1.1 Flow diagram of the layout of this thesis 20

Figure 3.1 Peri-operative deaths at CMJAH in 1999 60

Figure 7.1 The trend of AAD_Ms association with spinal anaesthesia 131

Figure 8.1 Bar chart of types of anaesthetic (%) administered to the women who died 139

Figure 8.2 Bar chart of ASA grades of patients (n) and seniority of anaesthetists 140

Figure 8.3 The percentage distribution of the types of procedures in mothers who died 142

List of Tables

Table 1.1 Estimated prevalence of general anaesthesia morbidity 5

Table 1.2 Prevalence of complications after regional anaesthesia – rates are per 10,000 anaesthetics 7

Table 1.3 Some English language mortality studies 9

Table 1.4 Differences between ACD and AAD 15

Table 2.1 Death totally attributable to each component of risk in the Confidential Enquiry into Peri-operative Deaths 27

Table 2.2 Anaesthesia mortality “root causes” in France, 2006 31

Table 3.1 ASA grading system and expected peri-operative mortalities 55

Table 3.2 Data and corresponding SAS coding 57

Table 3.3 Definitions used to distinguish between ACD and AAD 59

Table 3.4 Cardiac surgery patients 61

Table 3.5 Total deaths allocated to individual categories 62

Table 3.6 Total deaths at WDGMC 67

Table 3.7 Anaesthesia contributory deaths comparison table 69

Table 4.1 Definitions used to distinguish between ACD and AAD 82

Table 5.1 Total peri-operative deaths at Charlotte Maxeke Johannesburg Hospital from 2000 to 2004 86

Table 5.2 All causes of peri-operative deaths compared with AAD and ACD 86

Table 5.3 ASA Categories 87

Table 5.4 Surgical categories and corresponding procedures of the whole sample of peri-operative deaths 88

Table 5.5 Surgical categories of the peri-operative deaths 89

Table 5.6 Surgical categories versus anaesthetic given 90

Table 5.7 Anaesthetic record availability in relation to rank of anaesthetist 92

Table 5.8 Timing of adverse event versus where the patient died 93

Table 5.9 ASA by preoperative assessment 94

Table 5.10 ASA by doctor 94

Table 5.11 ASA by anaesthetic 94

Table 5.12 ASA by type of airway 94

Table 5.13 ASA by rapid sequence induction (RSI) 95

Table 5.14 ASA by airway problems 95

Table 5.15 ASA by availability of the anaesthetic record 95

Table 5.16 ASA by when the adverse event occurred 95

Table 5.17 ASA by when the patients died 96

Table 5.18 ASA by where the patients died 96

Table 5.19 ASA by surgical category 96

Table 5.20 ASA by trauma or not 96

Table 5.21 Doctor by anaesthetic given 97

Table 5.22 Doctor by airway 97

Table 5.23 Doctor by rapid sequence induction (RSI) 98

Table 5.24 Doctor by airway problems 98

Table 5.25 Doctor by availability of the anaesthetic record 98

Table 5.26 Doctor by when the adverse event occurred 98

Table 5.27 Doctor by when the patients died 98

Table 5.28 Doctor by where the patients died 99

Table 5.29 Doctor by surgical category 99

Table 5.30 Doctor by trauma or not 99

Table 5.31 Anaesthetic by airway 100

Table 5.32 Anaesthetic by rapid sequence induction 100

Table 5.33 Anaesthetic by airway problems 100

Table 5.34 Anaesthetic by availability of the anaesthetic record 100

Table 5.35 Anaesthetic by when the adverse event occurred 100

Table 5.36 Anaesthetic by when the patients died 101

Table 5.37 Anaesthetic by where the patients died 101

Table 5.38 Anaesthetic by surgical category 101

Table 5.39 Anaesthetic by trauma or not 101

Table 5.40 Anaesthetic record by when the adverse event occurred 102

Table 5.41 Anaesthetic record by when the patients died 102

Table 5.42 Anaesthetic record by where the patients died 102

Table 5.43 Anaesthetic record by surgical category 102

Table 5.44 Anaesthetic record by trauma or not 102

Table 5.45 Adverse event by when the patients died 103

Table 5.46 Adverse event by where the patients died 103

Table 5.47 Adverse event by surgical category 103

Table 5.48 Adverse event by trauma or not 103

Table 5.49 When the patient died by where the patients died 104

Table 5.50 When the patient died by surgical category 104

Table 5.51 When the patient died by trauma or not 104

Table 5.52 Where the patient died by surgical category 105

Table 5.53 Where the patient died by trauma or not 105

Table 5.54 Analytical statistics summary table of chi-square and Fisher exact test results. (* = statistically significant) 106

Table 5.55 Trauma category by aortic cross clamp 109

Table 6.1 Definitions used to distinguish between ACD and AAD 110

Table 6.2 AAD and ACD cases and where and when they died 111

Table 6.3 The AAD and ACD patients 111

Table 6.4 Important attributes of the anaesthesia contributory deaths 117

Table 6.5 ACD rates from various studies 118

Table 7.1 ACD_M statistics from South Africa 129

Table 7.2 Deaths related to regional anaesthesia as a % of ACD_Ms for that individual year 130

Table 8.1 CHBH Maternity statistics for the period 2000 to 2004 135

Table 8.2 HIV status of maternal deaths 136

Table 8.3 Maternal deaths in patients who did not undergo a surgical procedure at Chris Hani Baragwanath Hospital 137

Table 8.4 Definitions used to distinguish between ACD and AAD 137

Table 8.5 Maternal deaths in patients who underwent a surgical procedure 138

Table 8.6 AAD_M class of death associated with surgery 141

Table 8.7 ASA by category of doctor 143

Table 8.8 ASA by type of anaesthetic 144

Table 8.9 ASA by endotracheal tube 144

Table 8.10 ASA by availability of anaesthetic record 144

Table 8.11 ASA by when the adverse event occurred 145

Table 8.12 ASA by day or night 145

Table 8.13 ASA by where the patients died 145

Table 8.14 ASA by HIV status 146

Table 8.15 ASA by elective surgery or not 146

Table 8.16 Doctor by type of anaesthetic 147

Table 8.17 Doctor by endotracheal tube 147

Table 8.18 Doctor by availability of anaesthetic record 147

Table 8.19 Doctor by when the adverse event occurred 148

Table 8.20 Doctor by day or night 148

Table 8.21 Doctor by where the patients died 148

Table 8.22 Doctor by HIV status 148

Table 8.23 Doctor by elective surgery or not 149

Table 8.24 Where the patients died by endotracheal tube 149

Table 8.25 Where the patients died by HIV status 149

Table 8.26 Where the patients died by elective surgery or not 150

Table 8.27 Analytical statistics summary table of chi-square and Fisher exact test results. (* = statistically significant) 151

Table 8.28 CHBH maternal deaths in patients who received an anaesthetic by study Year 152

Table 8.29 AAD_M rate per 10000 using caesarean sections as the denominator 152

Table 8.30 CHBH maternal deaths and when they died in relation to the anaesthetic, by study year 153

Table 8.31 Maternal deaths (%) at CHBH compared with South African national averages 157

CHAPTER 1

INTRODUCTION

Preface

This thesis is written in the first person, using the Vancouver system for referencing. Several tables of definitions have been repeated in more than one chapter to aid the flow of text.

1.1 General remarks

Since the introduction of anaesthesia by Horace Wells[1] in 1844, millions of anaesthetics have been administered throughout the world, under varying circumstances and by various “anaesthetists”. The South African Society of Anaesthesiologists has applied the following definitions to those administering anaesthesia[2]:

- Anaesthetist: a person who administers anaesthesia; this may be a doctor, a nurse or a technician
- Anaesthesiologist: a medical doctor who is a specialist anaesthetist

The WHO has numerous projects and programmes running, one of which is the “Safe Surgery” project[3]. A fundamental requirement for this project is safe anaesthesia, “while protecting the patient from pain.” In conjunction with this, the World Federation of Societies of Anaesthesiologists (WFSA) has published international standards for the safe practice of anaesthesia [4].

Clinical anaesthesia has been described as a state of "physiological trespass"[5] and "an indispensable adjunct to the surgical management of disease"[6]. "The more injury and disease have encroached on the body's physiological milieu, the less can anaesthetic encroachment *per se* be tolerated, and the more does the clinical anaesthetist's margin of error accordingly shrink"[5]. At times, this poses important risk to our patients.

1.2 Problem statement

An adverse outcome during the administration of an anaesthetic may result in morbidity or mortality, the latter providing us with the most fundamental measure of the safety of anaesthesia for our patients. It is essential that this is documented consistently and accurately.

1.3 Definitions

1.3.1 The "risks" and "consequences" of Anaesthesia

With the promulgation of the National Health Act of 2003[7], legislation in South Africa now mandates that patients (health care users) be informed of the following:

- The user's health status, unless there is evidence that it is not in the best interests of the user;
- The range of diagnostic procedures and treatment options available;
- The benefits, risks, costs and consequences associated with each option;
- The user's right to refuse health services AND one must explain the implications, risks and obligations of such refusal.

It also states that the information must be communicated in a language that the user understands and in a manner that takes into account the literacy of the user (patient).

Thus, anaesthetic risk needs to be discussed with each patient who receives an anaesthetic.

In order to determine the risks and consequences of anaesthesia, there are multiple factors that need to be considered. There are those risks due to the anaesthetic itself, the risks of the surgery, and then the patient's co-morbid diseases, which may pose serious risks in their own right. Ultimately, these risks may combine into major or minor morbidity (complications) or mortality (death).

1.3.2 Morbidity

Anaesthetic morbidity ranges from major permanent disability to minor adverse events causing distress to the patient, but with no long-term sequelae. As with studies of mortality, there is a lack of uniformity in reporting peri-operative adverse events between institutions and countries.

In keeping with accepted norms, I have classified morbidity as falling into one of three groups:

- Minor morbidity: this causes moderate distress but without prolongation of hospital stay or permanent sequelae.
- Intermediate morbidity: this causes serious distress or prolongation of hospital stay, or both, but no permanent sequelae.
- Major morbidity: this causes permanent disability or disfigurement.

1.3.2.1 Morbidity from GENERAL ANAESTHESIA can be considered under the following headings:

Major morbidity:

- Cardiac arrest;
- Respiratory complications, including major airway complications;
- Cardiovascular complications (other than cardiac arrest);
- Postoperative neurological dysfunction;
- Awareness;
- Anaphylaxis;
- Ocular complications;
- Deafness;
- Peripheral nerve injuries.

Minor morbidity:

- Postoperative pain;
- Postoperative nausea and vomiting (PONV);
- Sore throat;
- Headache;
- Drowsiness and dizziness;
- Dental damage.

Reported estimated prevalence of General Anaesthesia Morbidity[8] is listed in Table 1.1

Table 1.1 Estimated prevalence of general anaesthesia morbidity [8].

MORBIDITY **Major**	RATE PER 10,000 ANAESTHETICS
Cardiac arrest	0.5 to 1.0
Respiratory complications (including airway)	2-200
Cardiovascular complications	Varies, depending on history
Postoperative neurological dysfunction	1,400-5,000 (1:2 to 1:7 immediate)
Awareness	3-30
Anaphylaxis	1
Ocular complications	0.08 – 100 (1:100 cardiac surgery)
Deafness	1 (1:1,000 cardiac surgery)
Peripheral nerve injuries	10 - 30
Minor	
Postoperative pain	Varies 1,000 – 5,000 (1:2)
Post Operative Nausea & Vomiting	2500 (1:4)
Sore throat	1,000 – 5,000 (1:2 ETT; 1:5 LMA)
Headache	2,000 (1:5)
Drowsiness and dizziness	2,000 – 5,000 (1:2 to 1:5)
Dental damage	100 (1:100)

1.3.2.2 Morbidity from REGIONAL ANAESTHESIA has been extensively studied [8]

Major risks include:

- Neurological injury of various types, including paralysis and sphincter dysfunction;
- Cardiac arrest;
- Local anaesthetic toxicity;
- Infection.

Minor morbidity is:

- Headache;
- Backache.

Reported estimated prevalence of **regional anaesthesia morbidity** (and mortality) varies.

Lienhart et al [8] looked at serious complications related to regional anaesthesia in a prospective survey in France. Their results showed that the prevalence of cardiac arrest and neurological injury associated with regional anaesthesia were very low, but both were more than three standard deviations greater after spinal anaesthesia than after other regional procedures. Two-thirds of the patients with neurological deficits had either a paraesthesia during needle placement or pain on injection. Seventy-five percent of the neurological deficits after non-traumatic spinal anaesthesia occurred in patients who had received 5% hyperbaric lignocaine**.** Their results are tabulated in Table 1.2

Table 1.2 Prevalence of complications after regional anaesthesia – rates are per 10,000 anaesthetics [8]

CRITICAL EVENT	SPINAL	EPIDURAL	PERIPHERAL NERVE BLOCKS
Cardiac arrest	6.4	1.0	1.4
Death	1.5	0	0.5
Seizures	0	1.3	7.5
Neurological injury	5.9	2.0	1.9
Radiculopathy	4.7	1.6	1.9
Cauda equina	1.2	0	0
Paraplegia	0	0.3	0
Abscess*		0.7to5.0	
Haematoma*	0.05	0.07	

*These prevalences are general figures as given in the anaesthetic literature[9].

The other important morbidity is **post-dural puncture headache**, the prevalence of which is estimated to be 1:10 to 1:100[9]. **Backache** after neuraxial blockade is estimated to be 20 to 50%.

In South Africa we do not have adequate reporting structures to quantify anaesthetic associated mortality, let alone anaesthesia-associated morbidity, despite the latter's importance, particularly from the patient's perspective. It is also becoming increasingly important to include outcomes that affect economic issues, quality of life and patient satisfaction. This thesis, however, is limited to issues pertaining to anaesthetic mortality in South Africa.

1.3.3 Mortality

Rates of death due solely to anaesthesia are sometimes difficult to ascertain, and studies reporting rates use varying definitions of deaths due to anaesthesia. What is clear is that anaesthetic related mortality is rare. In previous studies in South Africa [6 8 10-12] mortality is estimated to have ranged from 1 per 2 (these were deaths in which anaesthesia played a "role")[12] to 1.1 per 10,000 anaesthetics [13], where anaesthesia was considered solely responsible for the patient's death. If one looks at maternal deaths, then anaesthesia in South Africa is currently responsible for approximately 5% of all maternal deaths[14].

Looking world-wide, the first documented western world "anaesthetic associated death" or death directly attributable to anaesthesia was reported in 1848[15], in the United States of America, when Hannah Greener died due to aspiration on induction with chloroform. The anaesthetic was given to her by the surgeon, Mr. Meggison, who was going to "remove the nail from the great toe of her right foot" [15]. An inquest was held, in which the jury decided that she died from "congestion of the lungs from the effects of chloroform" [15].

Since then, numerous studies have been published internationally on anaesthesia mortality rates. These studies are often very difficult to compare for many of the following reasons[16]:

- There are no agreed definitions of what constitutes anaesthesia mortality;
- There is no agreement over how much of the peri-operative period to include (studies vary from 24 hours to 2 years);
- The number of years to be covered by a particular study is frequently not clear.

Thus, one cannot compare mortality rates to assess whether mortality from anaesthesia is improving. Each study needs to be looked at individually. To illustrate this I have listed many of the English language mortality studies over a period of 48 years in Table 1.3, arranged in ascending order of study (not publication). As can be seen, there is no consistency in recording the prevalence of anaesthesia associated death (AAD), or anaesthesia contributory death (ACD).

Table 1.3 Some English language mortality studies

Author/s	Year of publication	Time perspective	Country	Deaths/10,000 AAD or ACD
Beecher and Todd[17]	1954	Deaths at 10 university hospitals (1948-1952)	USA	1:2,680 AAD (3.7:10,000)
Edwards et al[18]	1956	Deaths over 5,5 years in UK (n= 1000)	UK	5,980:10,000 AAD (83% human error)
Dornette and Orth[19]	1956	Deaths in OT or in the ward (1943-1954)	USA	3.8:10,000 ACD
Clifton and Hotten[20]	1963	Death under anaesthesia, or remained unconscious;(1952-1962)	Australia	1:3,955 ACD (65% human error)
Gebbie[21]	1966	Deaths (within 10 days) over 7 years	Canada	1:6,158 AAD (1.6:10,000)
Marx et al[22]	1973	Post anaesthetic deaths within 7 days (1965-69)	USA	1:1,265 ACD
Bodlander[23]	1975	10 years (1963-1972)	Australia	0.7:10,000 ACD
Harrison[6 10]	1990	Death within 24 hours (1977-1987)	South Africa	0.7: 10,000 ACD
Lunn and Mushin[24]	1982	Death within 6 days of surgery	United Kingdom	1: 10,000 ACD
Lunn et al[25]	1983	Death within 6 days	United Kingdom	ACD 10%
Tiret and Hatton[26]	1986	Death within 24 hours and/or coma after 24 hours	France	1.3 per 10,000 AAD
Holland[27]	1987	25 years	Australia	Figures not given

Lunn JN, Devlin HB[28]	1987	Death up to 30 days postop One year	United Kingdom	1:185,056 ACD (0.05:10,000)
Coetzee[13]	1992	Within 24 hours (1987-1990)	South Africa	1.1:10,000 ACD
Horan BF Warden JC[29]	1996	Within 24 hours of anaesthesia (1984-1990) Urgent surgery	Australia	299:10,000
Lienhart et al[8]	2006	One year (1999)	France	0.12:10,000 ACD
Newland et al[30]	2002	Anesthesia-related cardiac arrest and its mortality over 10 years	USA	1.4 cardiac arrest per 10,000; 0.55 per 10,000 death

Derrington and Smith[31] reviewed studies of anaesthetic risk, morbidity and mortality in 1987, and found numerous audits and studies on “anaesthetic deaths”. The time perspective in these studies – in other words, the time that the death occurred in relation to the start of the administration of the anaesthetic ranges from 24 hours to 30 days. For example, in 1978 Harrison looked at deaths within 24 hours of the administration of the anaesthetic [11], whilst in 1963 Clifton and Hotten [20] looked at any death under, or attributable to, or without return of consciousness after anaesthesia. This latter “time perspective” is the most accurate, in terms of South African legislation, but may be impractical from the point of view of conducting an audit. The reason for this is that a patient may not regain consciousness for days, weeks or months after an anaesthetic. This may be in the intensive care unit, or in a ward, or even in a different hospital, and is often not properly documented and thus difficult to audit. In addition, if the failure to regain consciousness is due to something like hypoxic brain damage, the

patient may need to be followed up for months or even years. During this time he or she is often transferred to different places of medical care.

In South Africa, the Medical, Dental and Supplementary Health Services Professions Act of 1974[32] states that “the death of a person whilst under the influence of a general anaesthetic or local anaesthetic, or of which the administration of an anaesthetic has been a contributory cause, shall not be deemed to be a death from natural causes, as contemplated in the Inquest Act, 1959 (Act 58 of 1959), or the Births, Marriages and Deaths Registration Act, 1963 (Act 81 of 1963).” This statement has been amended in the Health Professions Amendment Act of 2007[33] to read as follows: “the death of a person undergoing, or as a result of, a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such procedure has been a contributory cause, shall not be deemed to be a death from natural causes, as contemplated in the Inquest Act, 1959 (Act 58 of 1959), or the Births, Marriages and Deaths Registration Act, 1992 (Act No 51 of1992).” This means that in this type of death a medico-legal post-mortem and inquest (paper or formal) must be held.

What was not clear with the original act (of 1974) was when a patient is no longer “under the influence” of an anaesthetic, a matter that still needs to be defined. Likewise, the phrase “as a result of a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such procedure has been a contributory cause” needs to be clearly and specifically defined. What is clear, however, is that South African legislation does not state a time limit for recovery after the start of an anaesthetic or procedure. Thus, a patient who suffers a cardiac arrest under anaesthesia with consequent hypoxic brain damage, and

dies 2 years later, should still be classified as a death to which the anaesthetic contributed. The consequences are that the death is unnatural in such a circumstance, requiring a medico-legal post mortem and inquest. This is a fact often ignored by anaesthetic and surgical colleagues, as well as by many South African health facilities. It relies largely on the “voluntary co-operation” of anaesthetists and surgeons.

Until deaths due to anaesthesia are notifiable (as with maternal deaths[14 34-36]), and all those who administer anaesthesia are suitably educated, there will not be accurate anaesthetic mortality statistics in South Africa, and therefore audits of what we do and how we are doing at it will continue to be inaccurate.

The most recently published South African audits of anaesthetic-associated deaths were by Harrison[6 10-11] who surveyed the deaths attributable to anaesthesia from 1956 to 1987, and also by Coetzee et al [13] who looked at peri-operative deaths, from July 1987 to December 1990.

All of these audits used a definition of death occurring during or within 24 hours of anaesthesia.

Harrison [11] commented as follows: “Death associated with anaesthesia is defined as a death occurring during or within 24 hours of anaesthesia, or after the failure of a patient, conscious before, to regain consciousness after anaesthesia. The choice of a period of 24 hours after anaesthesia is arbitrary. It embraces a period adequate to permit identification of death attributed to anaesthesia without the study becoming unmanageably large. Extension of this study to a surveillance of the whole period after operation, although desirable in some respects, would have

added considerably to its difficulties and complexities. It is acknowledged that in these circumstances a very small number of deaths to which anaesthesia was a major contributory factor, such as late deaths from aspiration and pneumonia, might have been missed."

Thus, Harrison acknowledged the definition of "anaesthetic death" in its broadest sense, as well as in terms of South African law, but also acknowledged the associated shortcomings.

His sentiments in arbitrarily choosing a period of 24 hours (in the setting of our current means of voluntarily reporting of deaths due to anaesthesia), are understood, and the possibility of missing a small number of deaths is acknowledged. Nevertheless, the two anaesthesia contributory deaths in the pilot study of this thesis died after this 24-hour cut-off, and yet they were both deaths directly attributable to anaesthesia, and were patients who were fit and healthy preoperatively. Both of them never woke up after the anaesthetic, and died within 7 days of the start of the anaesthetic. In terms of Harrison's definition, they were conscious before the operation, and failed to regain consciousness postoperatively.

1.3.3.1 Anaesthesia Associated Deaths (AAD) and Anaesthesia Contributory Deaths (ACD)

Deaths directly attributable to the anaesthesia or anaesthesia contributory deaths (ACDs) can be considered under the following headings:

- Deaths due to cardio-respiratory failure. These may include failure of airway and ventilation management, and failure in blood volume management and arrhythmia control. They need to be considered in their

broadest sense, as for example, in the “high spinal” that may occur in a patient coming for caesarean section. This also includes the methods used to administer anaesthesia.

- Deaths due to adverse anaesthetic drug reactions.

Both of the above fall into the category of **“human error”.**

Deaths associated with the anaesthesia but not clearly as a direct result of the anaesthetic, may be termed anaesthesia associated deaths (AADs) and may include:

- Deaths due to fires and explosions in the operating theatre;
- Deaths due to the anaesthesia and surgical technique.

Deaths not attributable to anaesthesia can be considered as follows:

- Deaths due to the injury or disease which necessitated the anaesthetic and surgical procedure;
- Deaths due to previously diagnosed co-morbid disease;
- Deaths due to undiagnosed co-morbid disease; These are also referred to as “inevitable deaths”;
- Surgical misadventure and complications.

1.3.3.2 Edwards' classification[37]

The relationship of anaesthesia to operative morbidity and mortality explains the subtle differences in AAD and ACD (Table 1.4)

Table 1.4 Definitions used to distinguish between ACD and AAD [27]

Category	Definition
I	When it is reasonably certain that the event or death was caused by the anaesthetic agent or technique of administration or in other ways coming directly within the anaesthetist's province
II	Similar to type I cases, but ones in which there is some element of doubt about whether the agent or technique was entirely responsible for the result
III	Cases in which the patient's adverse event or death was caused by the anaesthetic and the surgical technique
IV	Events entirely referable to surgical technique

There are obviously cases where there is an element of doubt, due to many reasons, including the possibility of insufficient information being available.

For the purposes of this thesis, categories I, II and III will be called **anaesthesia associated deaths (AAD)** and of these three, only category I will be considered as **anaesthesia contributory deaths (ACD).** ACD is therefore a specific subcategory of AAD that may be considered both with AAD and on its own.

1.4 Importance of this study

The data available in published articles and official reports thus far, indicate that the risk of death attributable to anaesthesia has probably declined over the years[16 38]. The reasons for this are not entirely clear. They may include new monitoring modalities, new anaesthetic drugs and changes in the anaesthesia workforce. However, no study has shown improved outcomes with any one of

these, including the advent of pulse oximetry [16]. This limitation supports the need for ongoing audits and peer review of all of the complications relating to anaesthesia, with death being at one extreme.

As a result of the confusion over the "24-hour cut-off period", paired with ignorance about the law, the reporting of ACDs and AADs in South Africa appears to have been erratic and "voluntary" over the years [6 10-11 13]; this thesis will comment on this and make recommendations later.

As has happened with maternal deaths, legislation probably needs to be introduced to formally report AADs and ACDs in South Africa[14]. This would ultimately lead to a process similar to the NCEPOD process in the United Kingdom[39], which would allow us to document the deaths in the various levels of hospitals, both government and private. As with the South African "Saving Mothers" reports[14 34-37], we would be able to identify the shortcomings in the healthcare system that lead to some of these deaths, and thus ultimately reduce the numbers of deaths. The aim would be safer anaesthesia (as measured by mortality) for all of our patients.

1.5 Aims of this study

This study aims to investigate and determine the prevalence of anaesthesia associated deaths, particularly those that occur as a direct result of anaesthesia, both general and regional in two major academic hospitals in the Johannesburg area. These will be referred to as Anaesthesia Associated Deaths (AAD) and Anaesthesia Contributory Deaths. (ACD)

For the purposes of this study, but not in keeping with previous studies [6 10-11 13], the following definitions have been used:

- An **anaesthesia associated death** (AAD) is a death occurring after the induction of a general or regional anaesthetic, or after the failure of a patient, conscious before, to regain consciousness after anaesthesia, regardless of the time that has elapsed since the start of the anaesthetic.
- An **anaesthetic contributory death** (ACD) is a similar death, but due solely to the anaesthetic.

The ACDs will therefore form a sub-group of the AADs.

1.6 Objectives

This thesis aims to identify and conclude the following, with regard to "anaesthetic" deaths:

1.6.1 Primary objectives

1. Definitions: current legislation and the interpretation thereof with recommendations.
2. The prevalence of AAD and ACD in two of the tertiary academic hospitals affiliated to the University of the Witwatersrand.
3. The causes of these deaths if possible.
4. The identification of possible "risk" factors, such as:
    - The seniority or level of training of the practitioner involved in each death.
    - The American Society of Anaesthesiologists (ASA) status of the patients who died.

- The availability of the necessary anaesthetic equipment
- The type of anaesthetic given.

5. A comparison with the prevalence of deaths attributable to anaesthesia from previous South African studies.

1.6.2 Secondary objectives

1. The quality and quantity of records kept on the patients who died.
2. The process of peer review conducted at the time, with recommendations for the reporting of AADs and ACDs in South Africa and the appropriate peer review process – ideally a South African National Enquiry into Patient Outcome and Death (NCEPOD) process, as is conducted annually in the United Kingdom[39] ?

1.7 Study design

This is a retrospective longitudinal descriptive study, in the form of a clinical audit over 5 years in two major academic teaching hospitals incumbent within the University of the Witwatersrand teaching platform. The exact details of every patient were not studied.

1.8 Thesis outline

This thesis will comprise the following chapters (as illustrated in Figure 1.1):

Chapter One: the introduction and a brief summary of the methodology used;

Chapter Two: a review of the international and Southern African literature;

Chapter Three: the pilot study;

Chapter Four: methodology of the definitive studies;

Chapters Five and Six: Charlotte Maxeke Johannesburg Academic Hospital 2000 to 2004:

Chapter Seven: maternal deaths;

Chapter Eight: maternal deaths at Chris Hani Baragwanath Maternity Hospital;

Chapter Nine: discussion and conclusions;

Chapter Ten: recommendations.

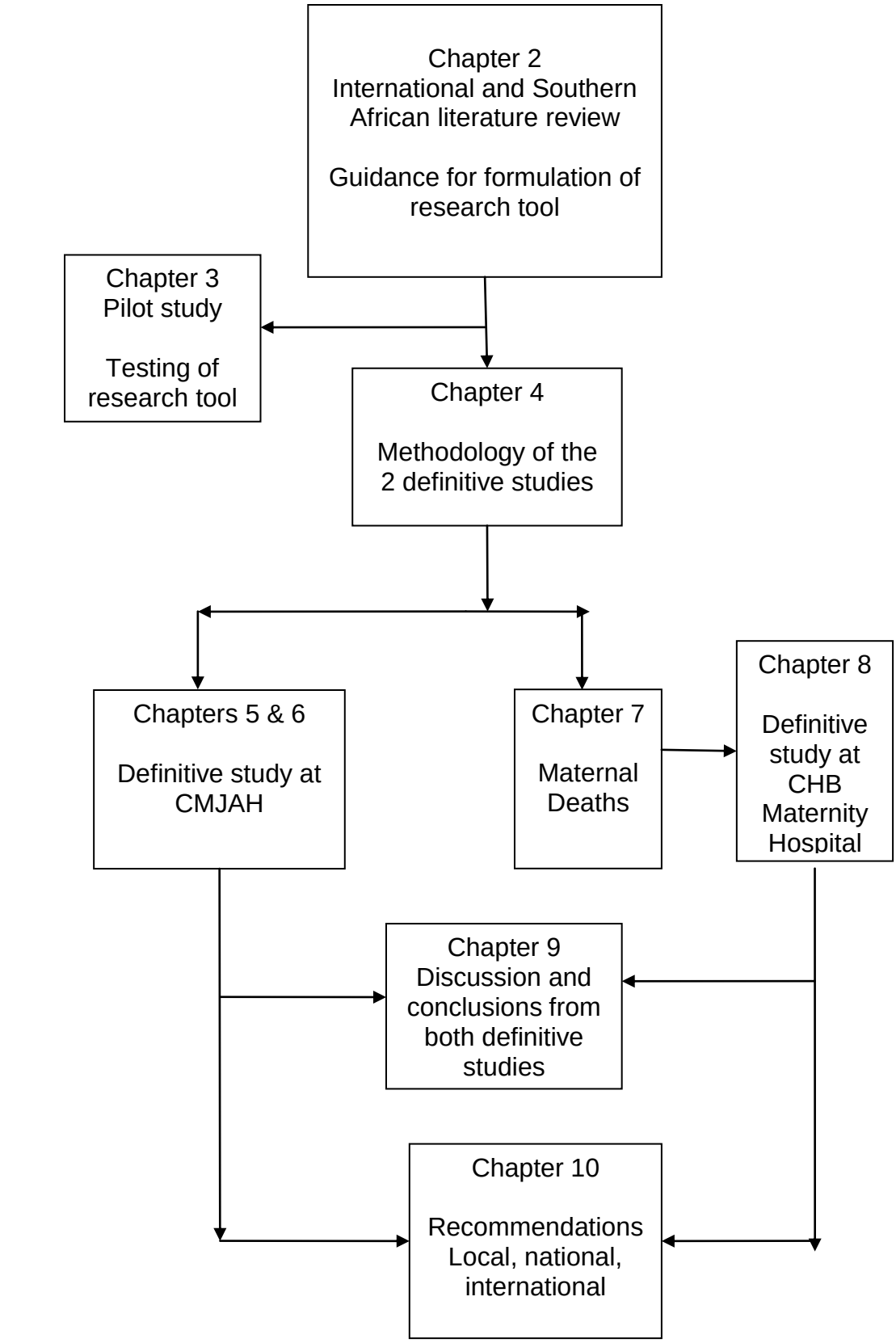


Figure 1.1 Flow diagram of the layout of this thesis

Chapter 2

LITERATURE REVIEW

A review of previous studies of deaths attributable to anaesthesia

2.1 International studies

The first formal investigation of anaesthesia-associated deaths was published in England by John Snow in 1858[40]. He documented and analyzed 50 deaths that were thought to have been caused by chloroform anaesthesia, between 1848 and 1857.

Subsequent studies performed throughout the world demonstrated steady improvements in anaesthesia-related mortality, or so it has been thought [16]. These studies have focused on identifying the causative factors for peri-operative mortality, which in many studies is a period of 30 days from the induction of anaesthesia. Several general themes have emerged since the 1940's:

- Anaesthesia represents a small but important cause of peri-operative mortality, particularly when it occurs in ASA 1 and 2 patients;
- Peri-operative respiratory complications represent a major complication;
- Elucidation of the causes of peri-operative mortality and education about these causes should lead to improved outcomes, and reduced morbidity and mortality.

Many of the studies prior to the 1980's studied patient groups from one hospital, or group of hospitals. Since the 1980's, however, many countries (United States of America, Australia and New Zealand, United Kingdom, Holland, France and others) have collected and published national anaesthetic mortality statistics[8 41-44].

2.1.1 Studies from the United States of America (USA)

Numerous studies on anaesthesia mortality have been performed over the years in the USA, starting most notably with Beecher and Todd's review of 599,548 surgical cases from ten university hospitals from 1948 to 1952 [17]. They found a prevalence of death associated with anaesthesia of 3.29:100,000.This was referred to as a "public health problem", since there were 2.4 times as many deaths attributable to anaesthesia during the five years of the study as there were deaths attributed to poliomyelitis.

Marx et al [22] looked at 34,145 consecutive surgical patients (excluding obstetrics) attended by anaesthesiologists at the Bronx Hospital Centre in the early 1970's. They studied deaths during the first seven postoperative days, and found that the two prime determinants of postoperative mortality were the physical status of the patient, and the judgment and skills of their physicians.

For the following 20 years nobody published any similar studies in the United States. In 1990 Keats[16] wrote a very thought-provoking article in the journal Anesthesia and Analgesia titled "Anaesthesia Mortality in perspective". He questioned whether anaesthesia mortality had, in fact, improved since the Beecher and Todd study [17] over 40 years earlier. He postulated the following: "Anaesthesia mortality has decreased because of our efforts toward improving anaesthesia care, and because of the efforts of others in improving medical and surgical care. Alternatively, anaesthesia mortality has not decreased because most are caused by errors, and no progress has been made in error reduction, and because we create new mechanisms of mortality at the same time as we solve them."

He stated that he thought the latter was the most likely possibility, because the risks and the benefits of what we as anaesthesiologists consider improvements in anaesthetic care are never measured in any systematic way. He looked at the risk-benefit of all commonly used monitors, and how much information was available on these in 1990. He summed his thoughts up with the following: “We have a vague estimate of the prevalence of catastrophic outcomes of anaesthesia that we describe as anaesthesia mortality. But we have no evidence that it is getting better or worse. We have not measured the results of what we believe to be the enormous progress made over the past 40 years.”
He also urged anaesthesiologists to measure the so-called improvements made in anaesthesia.

Lagasse[45] also questioned improvements in anaesthesia safety and outcomes in his review in 2002. He highlighted the statements made by the Committee on Quality of Healthcare in America that “Anaesthesia is an area in which very impressive improvements in safety have been made”. The assertions made by this committee were that anaesthesia mortality rates decreased from 2 deaths per 10,000 anaesthetics in the 1980’s, to approximately 1 death per 200,000 to 300,000 anaesthetics administered in the new millennium. The committee did not identify the studies that supported this conclusion, which is problematic, since it then went on to establish anaesthesia as a “model of safety”.
This was stated as due to improvements in outcomes because of improved monitoring techniques, the development of practice guidelines, and other systematic approaches to reducing errors. Keats [16] was highly critical of all of these areas of improvement, believing that there is no evidence for this. Lagasse [45] also pointed out numerous problems in the way in which the multiple AAD and

ACD audits have been conducted over the years, particularly the operational definitions that have been used, and he challenged the principle of comparing any one study with another. The results of his peer review process, which looked at peri-operative deaths (within 48 hours of the start of anaesthesia) during a 3-year period and a 5-year period at two different suburban university hospitals, documented an ACD of approximately 0.77:10,000.

This is very similar to Harrison's findings [6 10] at Groote Schuur Hospital (Cape Town, South Africa) in the third quinquennium of his survey. Lagasse [45] detailed the peer review process that he devised, and recommended this for documenting AADs and ACDs. He also suggested that all ACDs are due to human error of some sort, but felt that systems errors may contribute to AADs. Coetzee [13] suggested a similar peer review process in his review of peri-operative mortality at Tygerberg Hospital (Cape Town, South Africa) in 1992, as also have Australian colleagues [43-44].

2.1.2 Studies from Australia and New Zealand

In New South Wales in Australia, a Ministerial committee has had access to patients' records, and has thus investigated all deaths occurring in relation to anaesthesia since 1960 [27]. Initial studies in Australia looked at small groups of patients in single or groups of institutions. However, since the 1980's, studies have frequently been performed on a national basis, and not just on a single or small group of institutions, due to what has been considered the small sample size of the former.

This approach has developed into a national review of anaesthetic deaths throughout the country. The review of anaesthesia related mortality in Australia

2000-2002 by Gibbs and Borton [43] is a fine example of comprehensive reporting of ACDs and AADs. As with many instances in South Africa, the denominator (number of anaesthetics performed), remains “a best estimate”, although Gibbs and Borton's report [43] has the most accurate denominators thus far. Nevertheless, their report is very detailed and accurate. The total number of deaths reviewed for this triennium was 1988, of which 137 were considered to be wholly or partly influenced by anaesthetic factors, namely categories I, II and III as suggested by Holland [27]. The calculated prevalence was 0.069 deaths per 10,000 anaesthetics.

The New South Wales study of anaesthesia-related mortality [37] went one step further in evaluating the contribution of the anaesthetist to peri-operative mortality. Four groups of anaesthesia providers were identified:

- specialists, who had a specialist anaesthetic qualification;
- registrars, who were in recognized training positions;
- resident medical officers, who were junior hospital staff in non-training positions;
- non-specialists, who were “all other medical graduates acting as anaesthetists”.

The absolute number of anaesthesia-related deaths had decreased in all groups, although the denominator data are not very accurate. Trainees had increased in number, and they administered more anaesthetics, with fewer deaths. This was thought to be due to better supervision. The largest decline in absolute numbers of anaesthetics was in the non-specialist group. This was attributed to a trend to more specialization, with less general practitioner involvement in anaesthesia

administration. In addition, resident medical officers were phased out, as their role in mortality due to anaesthesia was found to occur in “good risk” patients.

This is an important aspect of ACDs and AADs that needs to be looked at in South African mortality studies, since many anaesthetics in South Africa are administered by medical officers and general practitioners.

An important concluding statement in this Australian study is: “Anaesthesia mortality studies, given adequate notification facilities, a guarantee of confidentiality and continuity of operation, can provide valuable information on standards of healthcare and contribute to an improvement in those standards[37].”

2.1.3 Studies from Europe

In the **United Kingdom** the CEPOD (Confidential Enquiry into Peri-operative Deaths) [28 38] in 1987 assessed 1 million cases of anaesthesia during a one-year period in three large regions. Unique to this study was the establishment of “crown privilege” by the government, to allow total confidentiality. CEPOD sought to establish facts about the delivery of surgery and anaesthesia, and thus facilitate improvements in the delivery of surgical care. Deaths occurring within 30days of surgery were included in the study.

The results are indicated in Table 2.1:

Table 2.1 Death totally attributable to each component of risk in the Confidential Enquiry into Peri-operative Deaths

Component	Mortality Rate Contribution
Patient	1:870
Operation	1:2,860
Anaesthetic	1:185,056

Adapted from Fleisher LA. Miller's Anaesthesia 6th Edition [38]

This gives a prevalence for ACDs of 0.05 per 10,000. The AAD prevalence was 7:10,000. This enquiry was consultant-based, and only data agreed by the consultants were accepted for analysis. All of the institutions agreed to participate, but there were negative and obstructive consultants who refused to cooperate. This caused the loss to the study of the review of a "substantial proportion of peri-operative deaths in their hospitals". One wonders if this substantial proportion would have changed this very low ACD rate.

Nevertheless, many valuable lessons have been learnt from this British enquiry:

- From the surgical perspective the death rate was inversely related to the seniority of the operating surgeon and to preoperative preparation;
- The operating surgeon was a consultant in only 19% of the orthopaedic cases, compared with 47% overall;
- When looking at anaesthetic practice, more than 80% of the cases were seen pre-operatively, but less than 50% postoperatively;
- The electrocardiogram was used in 97% of cases, but core temperature was monitored in only 7%;

- Muscle relaxants were used in more than 50% of the cases, but a nerve stimulator in only 14%.

Most important was the recommendation that "**no ASA 4 or 5 patient should ever be submitted to an operation by a trainee without direct consultation with the appropriate consultant (or senior registrar) anaesthetist and/or surgeon".**[28]

Subsequent to the 1987 CEPOD report, an annual report has been produced in the United Kingdom over the last 20 years, termed the National Enquiry into Patient Outcome and Death (NCEPOD)[39]. Deaths due to surgery and anaesthesia are not examined in detail every year, as particular surgical sub-specialties may be focused on in a particular year. Nevertheless, important recommendations made pertaining to the practice of anaesthesia are as follows:

- 1989: "Surgeons and anaesthetists should not undertake occasional paediatric practice";
- 1990: "The provision of clinical and management information about patients, including post-mortem records, needs to be improved significantly";
- 1991/1992: "Surgeons and anaesthetists must have immediate access to essential services such as recovery rooms and intensive care units if their patients are to survive";
- 1992/1993: "The skills of the anaesthetist and surgeon should always be appropriate for the physiological and pathological status of the patient";
- 1993/1994: Systems should be implemented to improve records of clinical activity, including peri-operative deaths. Clinical audit needs to be encouraged;

- 1994/1995: “Essential services (high care and intensive care) beds are still inadequate. Clinical records and data collection still needs improving”;
- 1996/1997: “Morbidity/mortality meetings should take place in all anaesthetic departments. Regular review of mortality following operations is an essential part of anaesthetic practice”;
- 1999: “There is a need for a system to assess the severity of surgical illness in children in order to gather meaningful information about outcomes. The ASA grading system is widely used by anaesthetists but, as a comparatively simple system, does have limitations for use in children. The death of any child, occurring within 30 days of an anaesthetic or surgical procedure, should be subject to peer review, irrespective of the place of death”;
- 2000: “Despite the resources that have flowed into audit activities over recent years, anaesthetists reviewed less than a third of peri-operative deaths at local meetings; this percentage has remained unchanged since 1990. It is a professional responsibility to examine one’s practice and to seek ways to improve surgical and anaesthetic management. Clinicians must strive to achieve an audit record for all deaths if professional education, credibility and public support are to be maintained”;
- 2001: “Surgeons and anaesthetists should partake in multidisciplinary audit, specialists meeting to discuss improvements in care. These meetings should concentrate less on asking “who is to blame?” and more on changing systems of practice to safeguard patients wherever possible”. Electronic patient records are also advocated, once good information systems with adequate back-up are in place.

These annual recommendations from NCEPOD are as applicable to anaesthetic practice in South Africa as they are to practice in the United Kingdom.

McFarlane et al.[46] published an audit of surgical mortality in **Scotland,** in which "areas of concern related to anaesthesia" were reviewed. They found that deaths from elective surgery declined over the 10 year period of the study. Anaesthetic areas of concern were listed as follows:

- Pre-operative assessment (in 43% of cases);
- Grade of anaesthetist (too junior) (22%);
- Technical problems (22%);
- Airway concerns (intubation and aspiration).

The authors state: "The provision of skilled anaesthetic assistance in Scotland has been recognized as a problem for many years, but the association with mortality has not been described previously." This puts a whole new perspective on the role of anaesthesia in surgical mortality.

Dutch colleagues performed a case-control study [41] of anaesthesia-related morbidity and mortality which was published in 1998. Their introduction highlights the differences between compulsory and voluntary reporting of deaths. Many of the published studies on deaths associated with or attributable to anaesthesia have relied on voluntary reporting. Their drawbacks of under-reporting, selective reporting and lack of information were emphasized. It is interesting that many of these problems are also present in other studies on deaths attributable to anaesthesia, particularly in South Africa.

Lienhart et al [8] published a survey of anaesthesia-related mortality in **France** in 2006. The study estimated the number and characteristics of anaesthesia-related deaths for the year 1999, by sampling the death certificates for that year.
They found an ACD rate of 0.12:10,000 and an AAD of 0.53:10,000. Forty-two per cent of these deaths occurred within 24 hours of the procedure and 23% of patients died later than 72 hours after the procedure. The mortality rate increased with age >45 years, and increased ASA status.
The investigators also attempted to explore some "root causes" that were associated with the deaths, as well as the contribution that each made.

These are listed in Table 2.2. In the case of some deaths there was more than one root cause.

Table 2.2 Anaesthesia mortality "root causes" in France, 2006 [8]

Institutional context – inappropriate healthcare structure, inappropriate hospital architecture, funding problems	27%
Organizational and management factors – inadequate patient orientation, inappropriate night call organization, inadequate surgical scheduling, production pressure	26%
Work environment factors – administrative and managerial support, staffing level versus skills, availability/use of equipment (point of care Hb-meter)	44%
Team factors – written and oral communication, supervision and seeking help	62%
Individual staff factors – experience/competence, judgment and analysis	51%

Task factors – availability and use of protocols, task design and clarity of structure	27%

Many investigators have attributed ACDs to human error. Lienhart et al [8] have expanded this, in an attempt to tease out the components of human error. The highest contributors were found to be team factors (involving communication, supervision and seeking help) and individual factors such as experience, competence, and judgment.

Work environment factors came a close third and the other domains involving institutional and management issues, as well as task factors played a role in a quarter of the deaths.

2.2 Southern African studies

2.2.1 The Orenstein Report

In November 1936, the first report on anaesthetic deaths was published in the South African Medical Journal by the Committee on Deaths under Anaesthesia[47]. The chair of this committee was Dr Alexander Orenstein. The terms of reference were “To investigate the causes of the high death rate in the Union from anaesthetics, and generally to make recommendations, more especially with a view to the possibility of measures being introduced which may have some practical effect in lessening the mortality.”

The committee investigated records from the principal hospitals in the Union from 1931 to 1935. These records gave information on deaths in which anaesthesia was considered to be either the primary or secondary factor (ACD and AAD respectively, in modern terminology). There were 203,159 operations, with 318

deaths that fell into this category, giving a death rate of 1.57:1,000 anaesthetics. Dr Weinbren, who was also a committee member, compared this with international figures. They were equivalent to rates at St Thomas's Hospital in London, but twice that of hospitals in Melbourne and Adelaide. The committee looked more closely at the deaths where anaesthesia was thought to have played a secondary role, and found that only 62% of these deaths could be ascribed to anaesthesia, giving a death rate of 0.93:1,000 anaesthetics. The committee also pointed out that many anaesthetics in South Africa were being given by practitioners "with relatively inadequate experience". Their recommendations included the following:

- All patients who were to have an anaesthetic were to be examined by a medical practitioner preoperatively, with the examination notes being available for the anaesthetist;
- Special care needed to be taken in the premedication of the patient (Omnopon and scopolamine were popular premedicants at the time). Specific premedicants such as morphia and barbiturates were felt to increase the risk of general anaesthesia;
- During the operation "careful watch needed to be kept on the state of the patient's breathing and the condition of the pulse". The routine use of an airway was strongly recommended;
- The use of chloroform as an anaesthetic of choice was deprecated;
- It was felt that gas (nitrous oxide) and oxygen were not safe in inexperienced hands;
- The administration of oxygen with inhalational anaesthetics was strongly recommended;

- Moot's formula was recommended to all anaesthetists:

  pulse pressure X 100 If >75 or <25, the operation was a bad risk;
  diastolic pressure

And finally

- "The importance of anaesthesia in modern medical practice is so great that the committee is of the opinion that every reasonable facility should be provided to ensure that medical students and resident medical officers have every opportunity of acquiring adequate practical experience in the administration of anaesthetics. Furthermore, the Committee considers it desirable that in hospitals, even those which are not associated with medical schools, specially trained anaesthetists should be employed and that it shall be part of their duty to impart instruction to the resident staff in the administration of anaesthetics."

In South Africa we have still not managed to achieve this last recommendation.

The committee also suggested an amendment to the Inquest Act, whereby in the case of moribund patients who died under anaesthesia, the anaesthetist may be exonerated from having to face a public inquest.

2.2.2 Preventable mortality and morbidity in Anaesthesia in South Africa

Grant-Whyte gave a fascinating overview of anaesthesia in South Africa in 1936 in the South African Medical Journal[48]. He set the scene by describing some of

the newspaper headlines at the time that sensationalized anaesthetic deaths thereby inculcating fear in the public. He made the following comments:

"The prevention of anaesthetic mortality and morbidity thus depends on three principal factors, all of which are of great importance, and no one plays a lesser or greater part than another, and all are interdependent:

1. The patient.
2. The surgeon.
3. The anaesthetist, who up to comparatively recently has been regarded as someone who comes along with rag and bottle and finds the awe-stricken patient on the operating table wide awake, looking at the theatre sister brandishing gruesome- looking instruments in the air. He arrives at the last moment and leaves the patient to his own devices as soon as the last stitch is inserted."

What is of importance in these comments is that the surgeon, patient and anaesthetist were all regarded as equally important factors in the cause of anaesthetic deaths.

2.2.3 "Whither Anaesthesia"

Muir wrote a commentary on the state of anaesthesia in South Africa in 1939[49]. At this time anaesthesia had become a recognized specialty in its own right. Oxford University had just established a Chair of Anaesthesia, and the South African Medical Council had included anaesthesia amongst the recognised specialties. Many people were documenting anaesthetic deaths worldwide.

Jarman[50] analyzed two million cases in England, and came to the following conclusions:

- The number of deaths had doubled in the previous 10 years. This was for various reasons;
- "The great majority of the fatalities occur when housemen are the anaesthetists and of this number again the majority during the early days of the new man's appointment."

If one reads Grant-Whyte's analysis [48], the anaesthetist is once again a problem when considering factors responsible for anaesthetic deaths.

Muir [49] commented as follows: "Impossible to conceive at the moment (although it is bound to come) such a department of anaesthesia as seen at Madison, The Bellevue, The Mayo Clinic and a dozen other places where a death on the table means a full-dress staff inquiry and much heart-searching, but the examples are there to aim at: they produce results and it should be our business to benefit by the experience of others and start in on the best imitation we can possibly afford".

2.2.4 The Anaesthetics Death Research Unit

In 1955 an Anaesthetic Deaths Research Unit was established in Pretoria, South Africa [12]. The purpose was to investigate and quantify the causes of death associated with anaesthesia and surgery in South Africa. Once this was ascertained, the plan was to endeavour to bring about a reduction in the mortality rate which was associated with certain surgical procedures, by means of education.

The trigger for this research unit was the Orenstein Report[47] (see 2.1.1) to the Minister of Health, in which the conclusion was "that many deaths which were not genuine anaesthetic deaths, were regarded as such in South Africa, and further that Section 86 of the Act operated unfairly to anaesthetists who are frequently

called upon to anaesthetize moribund cases with the practical certainty of having to face a public inquest. The result is to create a state of mind in the anaesthetists which tends to endanger the safety of the patient by unduly hurrying the surgeon." The Minister did not respond to this report.

The Anaesthetic Deaths Research Unit[12] looked at the anaesthetic details of one million surgical procedures, between July 1956 and March 1962. Of interest is that half of the patients received thiopentone and one third received muscle relaxants. The comment was made "One can conclude from these figures that since the introduction of the muscle relaxants, spinal analgesia has lost its popularity in South African public hospitals."

The death rate associated with anaesthesia and surgery was 1:1,062 or in modern terms 9.4:10,000. When these figures are analyzed, the following is evident:

- In only one half of the deaths did anaesthesia play a role;
- Many of the patients were not adequately resuscitated pre-operatively;
- The death rate for obstetric and gynaecology cases was unacceptably high. Many of the obstetric deaths were in women with prolonged and\or obstructed labour, and a few had already suffered ruptured uteri;
- The age group with the highest deaths was the third decade. This was thought to be due to the large number of assault patients;
- Only one quarter of the patients who died were anaesthetised by specialists. (In comparison almost half of surgeons involved with the same cases were specialists);

- Eighty per cent of the “anaesthetic” deaths were in fair or poor condition pre-operatively. (ASA status was not being used at this point in our anaesthetic history.)

From the point of view of anaesthetic technique, the following findings were made:

- A small number of deaths (14%) had received regional anaesthesia and were thought to have been overdosed;
- Muscle relaxant overdose and inadequate reversal played a small role in the anaesthetic deaths;
- Indiscriminate use of thiopentone sodium in shocked and hypotensive patients, particularly in inexperienced hands, was found to be a significant problem (10%);
- Vomiting and regurgitation with resultant aspiration pneumonia (the latter evident at post mortem) occurred in 5% of the deaths;
- Many deaths were associated with hypoventilation, resulting in hypoxia and hypercapnia. No percentage was given, and one needs to remember that this report was written prior to the advent of pulse oximetry and capnography.

The recommendation was that more anaesthetics should be given by specialists. This is in keeping with the comments made by Grant-Whyte [48] and Muir [49], as well as Jarman[50] in England.

In addition, the following measures were recommended:

- Patients need to be resuscitated adequately prior to receiving anaesthesia;

- Dosages of all drugs need to be reduced considerably in sicker and high-risk patients;
- Closer attention to detail of ventilation is required, with checking for hypoventilation, as well as the prevention of regurgitation and aspiration.

Of importance, is that many of the post-mortem results were available to Kok and Mullan [12].

2.2.5 Harrison's legacy

Harrison was the next anaesthesiologist and researcher to contribute to information on ACDs and AADs in South Africa [6 10-11]. He initially published a 10-year survey of deaths attributable to anaesthesia at Groote Schuur Hospital, from 1967 to 1976 [11]. Subsequently, he published data from a 30-year surveillance study of anaesthetic mortality, from 1956 to 1987, at Groote Schuur Hospital, commenting specifically on causes and changes in etiological patterns of these deaths [6 10]. The objectives of this surveillance study were to establish the prevalence of ACDs and also AADs, to identify the mechanisms that caused death, and to formulate strategies for prevention. Detailed records of all the ACDs were studied, including the autopsy reports.

Insofar as the definition of an ACD was concerned, Harrison [11] commented as follows: "Death associated with anaesthesia is defined as a death occurring during or within 24 hours of anaesthesia, or after the failure of a patient, conscious before, to regain consciousness after anaesthesia. The choice of a period of 24 hours after anaesthesia is arbitrary. It embraces a period adequate to permit identification of death attributed to anaesthesia without the study becoming unmanageably large. Extension of this study to a surveillance of the whole period

after operation, although desirable in some respects, would have added considerably to its difficulties and complexities. It is acknowledged that in these circumstances a very small number of deaths to which anaesthesia was a major contributory factor, such as late deaths from aspiration and pneumonia, might have been missed."

When looking at the reports arising from this survey, it was important to ascertain whether the administration of the anaesthetic or other anaesthetist-related factors caused the patient's death (an ACD), and if so, what was the cause, and was it preventable? The prevalence of ACDs during this 30-year period decreased 6-fold, from 0.43:1,000 in the first quinquennium, to 0.07:1,000 anaesthetics in the third.

The failures in clinical management that were responsible for 80% of the ACDs were:

- Failures in airway management, particularly complications with endotracheal intubations;
- Failures in pulmonary ventilation management;
- Failures in blood volume control;
- Failures in arrhythmia control.

Of interest, is that in the third quinquennium, the proportion of failures in airway management, particularly endotracheal intubations, increased with a decrease in deaths due to circulatory factors. Harrison [6] postulated that the skills, manual dexterity and clinical judgment required for airway management had not changed with time, but blood volume and arrhythmia control depended on intellectual responses to information derived from ever-improving vital function monitoring.

As with Kok and Mullan's study in 1955 [12], half of the ACDs were in American Society of Anaesthesiologists (ASA) grade 3, 4 and 5 patients. These are patients whose preoperative condition ranges from fair to critical.

2.2.6 Anaesthetic mortality at Tygerberg Hospital

Coetzee and du Toit[13] followed on from Harrison [6 10], by studying the peri-operative mortality in the anaesthetic service at Tygerberg Hospital from July 1987 for 3.5 years.

The aim of this study was to identify peri-operative deaths associated with anaesthesia, to use the information to improve patient care, and to identify problems associated with the evaluation process, thus improving peer review. This latter is an important step, as one needs a uniform process of peer review across the country, at all levels of hospitals, when documenting anaesthesia associated deaths and anaesthesia contributory deaths.

This has been implemented in Australia with great success.

Coetzee and du Toit [13] used similar definitions to Harrison [6 10]:

- A peri-operative death was defined as death occurring after the induction of general anaesthesia or the performance of a local procedure up to 24 hours after the anaesthetic was initiated;
- An anaesthesia-related death (AAD in this thesis) was defined as a death in which the anaesthetic technique could have contributed to the death, but was not the sole cause of the death;
- An anaesthetic death was defined as death caused by the anaesthetic management (ACD in this thesis).

The process that was followed after a peri-operative death was as follows:

1. The Head of Department was informed within 24 hours.
2. The data was summarized by the anaesthetist concerned.
3. Additional data was collected by the same senior anaesthetist for every case. The following questions were asked on every case:
    - Was the pre-operative evaluation and identification of essential problems correct? (good, poor, uncertain);
    - Was pre-operative resuscitation and risk management effective? (good, poor, uncertain);
    - Was the anaesthetic technique appropriate? (good, poor, uncertain);
    - Was the patient appropriately monitored? (good, poor, uncertain);
    - Did the anaesthetist recognize the problem when it initially presented? (good, poor, uncertain);
    - Did he or she then act effectively to contain or correct the risk recognized? (good, poor, uncertain);
    - Did the anaesthetist demonstrate insight into the problem? (good, poor, uncertain);
    - Did the patient die intra- or postoperatively?
    - Was the death preventable? (yes, no, uncertain);
    - Which organ (system) was the single most important leading to the patient's death?
4. This preliminary summary was drawn up by the senior anaesthetist and discussed at a quarterly post-mortem meeting, attended by all of the specialists in the department. A senior registrar represented the registrars

and medical officers. Discussions at these meetings did not identify the registrar or medical officer involved.

5. A final summary was drawn up after this meeting, and the data stored electronically.

This process of peer review and of documenting AADs and ACDs was implemented for every one of the 113 peri-operative deaths that occurred during this three and a half year study period.

Thirty-two of the 113 were AADs and of these 10 were considered to be ACDs, the latter giving a ratio of 1.1:10,000 cases.

Analysis of the 10 ACDs revealed interesting findings:

- Inadequate pre-operative evaluation and/or resuscitation in 49% of patients;
- Inappropriate anaesthetic technique in 26% of cases;
- Failure of the anaesthetist to recognize or understand the presenting problem in 62% of cases;
- Failure of the anaesthetist to take appropriate corrective action in 30% of cases.

Once again, a large number (45%) of the ACDs were classified as moribund, ASA grade 5E (emergency) pre-operatively. By definition these are patients who would have died irrespective of the surgical intervention.

What is of great importance in Coetzee and du Toit's study [13] is the **process** of review of the AADs and ACDs. The final paragraph of their paper suggests that an organized audit of anaesthesia-related incidents should take place on a regular

basis countrywide…..this process is long overdue. Muir [49], as long ago as 1939, recognized the value of this process.

One of the problems in South Africa, (as in many countries including Australia) is that there is unfortunately no central reporting system for "Deaths attributable to an anaesthetic or a diagnostic or therapeutic procedure"[51]. Reporting of the death relies solely on the surgical and anaesthesia team involved with the case, as is dictated by the Medical, Dental and Supplementary Health services Act[32-33].

There are often occasions when the practitioners concerned do not complete the GW7/24, the "Report on person whose death is associated with the administration of an anaesthetic or a diagnostic or therapeutic procedure"[51], as they feel that the patient's death was not due to the anaesthesia or the surgical procedure. Hence no medicolegal post mortem is carried out.

Thus it is currently very difficult to perform such an audit on a provincial or national basis, even prospectively, except in the case of maternal deaths, where current legislation (promulgated in 1997) dictates that all maternal deaths are notifiable [36]. As is indicated in the third report on the confidential enquiries into maternal deaths in South Africa, 2002-2004 [14], there is still significant under-reporting of deaths, even though it is now legislated that they are notifiable [36]. In addition, denominators (i.e. total number of cases done) are still problematic. Thus one can only extrapolate that it is highly likely that there is considerable under-reporting of deaths associated with anaesthesia in South Africa.

2.2.7 Southern Africa - Zambia

Heywood et al.[52] published a 7-month audit of over ten thousand operations from a Zambian teaching hospital in 1987. Anaesthetic services depended on clinical officer anaesthetists (COA's). These are non-doctors who undergo 3 years of basic training and a period of general clinical duties. Those selected receive 1 year of anaesthetic training to become qualified COA's. During the study the anaesthetic department comprised of the following: a consultant, two senior registrars, one senior house officer, three principal COA's, 12 qualified COA's and eight student COA's.

Patients who died on the day of surgery and up to and including the 6th postoperative day were included in the study. 10,592 operations were performed; 47% by general surgeons and 40% by maternity colleagues. There were 35 avoidable deaths, of which 10 were due to anaesthetic factors. This gives an ACD rate of 33: 10,000. Eighteen of the avoidable deaths were due to administrative factors such as no blood being available, poor communication, equipment failure and poor recovery facilities. 54% of all the avoidable deaths were aged less than 30 years, which is in stark contrast to European studies. In addition, the avoidable anaesthetic deaths were in major emergencies, where a COA was the anaesthetist. No consultant (*I presume a specialist, but they don't ever refer to him/her as such)* had become involved in any of these cases, which has been recognized by the authors as a deficiency.

2.2.8 Southern Africa - Zimbabwe

In 1996 McKenzie[53] published the mortality associated with anaesthesia at two Zimbabwean teaching hospitals. He reviewed all of the patients presenting for

anaesthesia and surgery during that year. His definition was similar to that used by Harrison and Coetzee [11 13], in that he selected a 24-hour cut-off. An AAD was described as death within 24 hours of anaesthesia or failure of a patient, who was previously conscious, to regain consciousness. His outcome measures were the prevalence of AAD, avoidable mortality rate (AMR), which was defined as the number of avoidable deaths per 1000 operations, and the classification of avoidable surgical, anaesthetic and administrative factors. Thus, AMR (anaesthetic) could be considered the ACD rate. Death was classified as avoidable, where mismanagement was considered to have contributed (partially or wholly) to mortality.

There were 89 AADs, giving a mortality rate of 2.58 per 1000 operations. There were avoidable factors in 45 cases, giving an AMR of 1.34 per 1000. Ten of these were maternal deaths. Of the total 45, fourteen were due to avoidable anaesthetic factors, such as respiratory (mainly ventilation and not airway) failures, as well as failures of adequate postoperative management, largely due to a lack of insight on the part of the anaesthetist. Failure to secure haemostasis was by far the most common avoidable surgical problem, particularly in urological and obstetric cases, and almost all the cases were operated on by consultants (*specialists?)* or registrars (specialist trainees). In addition, there is a category of administrative failures – 8 out of the 45. The Zambian study [52] also included this category. These encompassed a low standard of nursing care, equipment failure, and a non-functioning elevator.

From the patient perspective, 69.7% of those who died were younger than 41 years; their ASA status is not described.

Once again, as with Coetzee and du Toit's study [13], the procedure followed after the deaths is commented on. The 'required" reporting of all deaths within 24 hours of surgery yielded a large amount of data. However, as can be expected, especially in a retrospective study, there were 12 cases where a death certificate was written and autopsy therefore avoided. Post-mortem examination was also omitted in two of the three patients who failed to gain consciousness. In 24.7% of instances the case notes could not be found.

2.2.9 Comment on the Zimbabwe study

McKenzie's study [53] precipitated an editorial by James, Harrison and Morrell, in the South African Medical Journal in 1996[54]. They highlighted the fact that almost all of the avoidable anaesthetic deaths occurred with anaesthesia trainees, largely due to errors of judgment rather than failures of technical skills, and that the AAD in Harare was the same as that at Groote Schuur Hospital 35 years prior to this. They also suggested that in the absence of any anaesthesia mortality data from our non-academic hospitals in South Africa, there might be similar statistics (or worse) in these non-academic hospitals.

They further suggested better anaesthetic staffing in these non-academic hospitals, as well an improvement in anaesthetic equipment where needed. Ultimately, accurate audit and a systematic approach to this in the form of peer review is desperately needed. This, in turn, was commented on in a letter by Coetzee[55], who made the point that there was scanty evidence demonstrating that peri-operative mortality can be reduced by using capnography and pulse oximetry.

2.3 Conclusions

If one examines the ACDs and AADs that have been documented in **Europe, North America and Australia** the following important points emerge:

- There needs to be an accurate internationally agreed on definition of anaesthesia contributory death, and anaesthesia associated death, particularly the peri-operative time period involved;
- Anaesthesia represents a small but significant cause of peri-operative mortality, particularly when it occurs in ASA 1 and 2 patients;
- It is difficult to compare studies, as definitions and time periods vary. The ACD rate varies from 0.05 to 0.7:10000 anaesthetics;
- Accurate denominator figures still pose a problem in some areas;
- Specialists must be involved when ASA 4 and 5 patients are anaesthetised;
- Regular peer review must take place in all units where anaesthesia is administered;
- ACDs are most commonly due to human error; AADs may be due to human or systems errors.

In the context of studies previously conducted in **Southern Africa,** and particularly **South Africa** the following conclusions can be drawn:

- The ACD rate has improved since 1931, when the combined ACD and AAD rate was documented as being 1.57:1000 (15.7:10000). During this time period, anaesthesia has undergone major changes in many respects;
- Anaesthetics should be given by specialists in ASA 4 and 5 patients;

- Organized audit of anaesthesia-related incidents should take place on a regular basis country-wide. **We need to strive for a process similar to NCEPOD in the United Kingdom;**
- The lack of compulsory central reporting of ACDs and AADs allows for inconsistencies in reporting and probable under-reporting;
- Denominator figures are not accurate;
- The training and experience of doctors administering anaesthesia in level 1 and 2 hospitals is inadequate, in some parts of South Africa. **On closer investigation this may well be more widespread.**

The last major study of this kind in the Johannesburg area was the study by Kok and Mullin, which looked at cases done between 1956 and 1962 [12]. The conclusions drawn from this study will be considered when drawing conclusions and recommendations in this thesis, bearing in mind that anaesthesia has changed dramatically over the past 50 years.

The most recent study of AADs and ACDs in South Africa took place in the Western Cape, from 1987 to 1990 [13], where many of the South African conclusions and recommendations were made. In fact the major recent studies of anaesthesia-related deaths (AADs and ACDs) both took place in the Western Cape [6 10 13].

These will be closely examined and compared with the conclusions and recommendations that are drawn up at the end of this thesis.

CHAPTER 3

PILOT STUDY

3.1 Introduction

After reviewing the South African and international literature, it was decided to perform a pilot study in order to determine the following for planning the definitive study:

- Which variables should be recorded to investigate the prevalence of anaesthesia associated deaths (AADs), particularly those that occur as a direct result of anaesthesia, both general and regional; these are termed anaesthesia contributory deaths (ACDs)
- Whether the recording systems used at the pilot sites at the time adequately recorded the required data;
- Whether any peer review process was held at the time;
- Whether it was feasible to determine the cause of death;
- Whether it was possible to correlate post mortem findings with the deaths that were documented.

3.1.1 Definitions

In this thesis deaths are referred to as Anaesthesia Associated Deaths (AAD) and Anaesthesia Contributory Deaths (ACD), which are defined as follows:

> An **Anaesthesia Associated Death (AAD)** is a death occurring after the induction of a general or regional anaesthetic, where the anaesthetic may have contributed to the death, together with other non-anaesthetic factors.

An **Anaesthesia Contributory Death (ACD)** is a death due solely to the anaesthetic.

These definitions are based on previous studies performed in South Africa, but do not stipulate a specific time after the induction of anaesthesia, as was the case in Harrison's studies [11].

He commented as follows: "The choice of a period of 24 hours after anaesthesia is arbitrary. It embraces a period adequate to permit identification of death attributed to anaesthesia, without the study becoming unmanageably large. It is acknowledged that in these circumstances a very small number of deaths to which anaesthesia was a major contributory factor, such as late deaths from aspiration and pneumonia, might have been missed."

In this thesis all of the AADs and ACDs were documented, regardless of the time period from the start of the anaesthetic.

3.2 Methodology

3.2.1 Ethical considerations

3.2.1.1 Ethics approval

This study was approved by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand. **Appendices A and B**

3.2.1.2 Postgraduate committee approval

This study was approved by the Postgraduate Committee of the Faculty of Health Sciences of the University of the Witwatersrand. **Appendix C**

In addition the study title was changed with permission. **Appendix D**

3.2.1.3 Declaration of Helsinki

The research was conducted in keeping with the principles of the Declaration of Helsinki (2004)[56], which was the official version at the time of the study.

3.2.1.4 Hospital approval

Permission from the Chief Executive Officers of the Johannesburg Hospital and Wits Donald Gordon Medical Centre was obtained.

3.2.2 Study sites

3.2.2.1 Johannesburg Hospital (subsequently renamed the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), after the study was completed).

The Charlotte Maxeke Johannesburg Academic Hospital was selected as the pilot site, as it was believed that reasonably accurate data had been kept during the study period (1999). In addition, it was a tertiary academic hospital at the time with 1100 beds. The case mix of patients presenting for anaesthesia and surgery was good.

3.2.2.2 Wits Donald Gordon Medical Centre (WDGMC)

The second site for the pilot study was the Wits Donald Gordon Medical Centre, a University-owned private hospital, previously known as the Kenridge Hospital. This site was chosen to ascertain if it was feasible to collect similar data to that collected at a tertiary public hospital.

Wits Donald Gordon Medical Centre is a 180-bed private academic hospital. It is jointly owned by Wits University and the Medi-Clinic group. An additional reason for selecting this site was that no study had been performed to examine anaesthesia mortality at a private hospital in South Africa.

3.2.3 Study periods

The study period at the CMJAH was arbitrarily set from the 1st January to 31st December 1999.

The study period at the WDGMC was from the 1st January 2000 to 31st December 2004, a 5-year period. This was selected because fewer cases were being operated on at this hospital, and there was concern that the sample would not be adequately powered. The hospital was acquired by the University of the Witwatersrand in 2003, in the middle of the period of data collection. The hospital continued functioning without much change, and with the same surgeons and anaesthesiologists.

3.2.4 Sample population

All peri-operative deaths during the specified times at the two sites were studied.

3.2.5 Inclusion criteria

All patients who died as a result of anaesthesia and/or surgery during this time at both sites were included, unless their records were not available or inadvertently not kept.

The Department of Anaesthesia at the CMJAH kept a record of all the peri-operative deaths, in the form of a copy of the GW7/24 form[51]. These were filed in the departmental records room. Most of these forms had a copy of the anaesthetic record attached to them (**Appendices F and G**), since this was required by the department at the time. I was given access to these records, and every effort was made to obtain all of the records.

The records at the WDGMC were more difficult to access, as they had been archived. Access to the death certificates of all the patients who died during the 5-year period of this pilot study was eventually gained.

3.2.6 Data collection

Data from the hospitals were captured on the data capture form **(Appendix E).** The denominator figures were obtained from the operating theatre statistics. These are the statistics submitted from the operating theatre to the hospital administration once a month. The information is obtained from theatre registers. This was provided by the operating theatre matron.

Patient paper records were obtained from the department of anaesthesia. Permission was granted to me to take the anaesthetic department patient files home for detailed study. These records comprised the medicolegal GW7/24 forms, as well as the anaesthetic record forms. Each set of patient forms was thoroughly examined, documenting the required information required on the data collection sheet. The information on the rank of the anaesthetist was obtained from departmental rosters used during 1999.

Each death was given a number, and the month during which he or she died was documented, so that if there was information missing, it was possible to try to track this down from the various surgical departments, theatre registers and hospital records as necessary.

The data collected were:

- Demographics (excluding the patients' names) – age, sex and race;

- American Society of Anesthesiologists (ASA) grading[57] (Table 3.1).

  The ASA grading was first introduced by the American Society of Anesthetists in 1941 in order to assess the degree of a patient's "sickness" or "physical state" prior to selecting the anaesthetic, or prior to performing surgery;

Table 3.1 ASA grading system and expected peri-operative mortalities[57]

ASA physical status grading	Description	Expected peri-operative mortality rate
1	A normal healthy patient	0.06 – 0.08%
2	A patient with mild systemic disease and functional limitations	0.27 -0.4%
3	A patient with moderate to severe systemic disease that results in some functional limitation	1.8 – 4.3%
4	A patient with severe systemic disease that is a constant threat to life and functionally incapacitating	7.8 – 23%
5	A moribund patient who is not expected to survive 24 hours, with or without surgery	9.4 – 51%
E	Indicates "emergency"	

- Type and site of surgery;
- Elective or emergency surgery;
- Whether the patient was premedicated;
- Whether preoperative workup was performed on the patient (by the surgeon or the anaesthetist);

- The “level” of the anaesthetist involved in the case – registrar, specialist, senior specialist, medical officer (general practitioner);
- Whether there was any essential anaesthesia equipment unavailable for the case;
- The type of anaesthesia: local; regional; general or a combination thereof;
- Airway management: endotracheal tube, with or without rapid sequence intubation, laryngeal mask airway (LMA) or oxygen mask;
- Record keeping – whether an anaesthetic record was kept;
- Whether a recovery room record was kept;
- Whether any adverse events occurred prior to the patient’s death;
- Where the death occurred: in theatre or postoperatively in the ward or the intensive care unit;
- When the death occurred:
    - Within 24 hours after induction;
    - More than 24 hours after induction but less than 7 days;
    - Between 7 and 30 days after induction of anaesthesia.
- Whether a post-mortem was performed and whether any cause or mechanism of death was found.

In order to incorporate the data into the SAS statistical system, the data were recorded as follows in Table 3.2:

Table 3.2 Data and corresponding SAS coding

Data	SAS coding
Age	<1; Actual age; Ad (if unknown for adult)
Sex	M or F
Trauma	Y or N
ASA	1 or 2 or 3 or 4 or 5
Elective	Y or N
Category of surgery (catsurg)	Surg or Obst or Card or ENT or TSurg or Gyne or Vasc or Neur or Thor or PSur
Surgical procedure (surgproc)	Laparot or Caesar or evac or congen or laryngec or CABG or craniect or aneurysm or valve or trachres or amputate or biopsy or thoracot
Premedication (premed)	Y or N
Preoperative workup (preop)	Y or N
Doctor	Cons or Sreg or reg
Anaesthetic (anae)	GA or no or RA or LA
Airway	ETT or LMA or DLT
Rapid sequence induction (RSI)	Y or N
Airway problems (airprob)	Y or N
Anaesthetic record (anrec)	Y or N
Recovery record (recrec)	Y or N
Adverse	<24 or >24
Where the patient died (wheredead)	OT or ICU or ward
When the patient died (when died)	<24 or >24
Trauma category (trauma cat)	B or P (blunt or penetrating)
Aortic cross clamp preop (aoxclam)	Y or N

The data capture form was based on the predisposing factors and proposed “root causes” of anaesthetic deaths from the literature.

In addition, it was necessary to test my definition of ACDs from the time perspective point of view, particularly since both Harrison [6 10-11] and Coetzee [13] used the 24-hour cut-off period after the start of the anaesthetic.

The availability of anaesthetic and recovery room records is vital to all statistics of anaesthetic deaths, and the correlation with post-mortem findings would give an accurate cause of death in all of the cases.

After documenting the data on the data capture form, they were written up in an A4 quad counter book.

The data was then transferred from this book onto an Excel spreadsheet, and converted to a SAS data set for statistical analysis.

In addition, the records (forms completed after death and anaesthetic record forms) of all AADs and ACDs were photocopied and placed in a separate lever arch file. Detailed notes were made in a separate note book on each of these. Based on all of the information available, the decision was made by me as to whether the death could have been caused by the anaesthetic (AAD), and whether it was in fact solely due to the anaesthetic (ACD), based on the recommendations made by Holland[27], and listed in Table 3.3.

Table 3.3 Definitions used to distinguish between ACD and AAD[27]

Category	Definition
I	When it is reasonably certain that the event or death was caused by the anaesthetic agent or technique of administration or in other ways coming directly within the anaesthetist's province
II	Similar to type I cases, but ones in which there is some element of doubt about whether the agent or technique was entirely responsible for the result
III	Cases in which the patient's adverse event or death was caused by the anaesthetic and the surgical technique
IV	Events entirely referable to surgical technique

Thus categories I, II and III are AADs and category I is an ACD.

3.2.7 Data analysis

In this Chapter, analysis was limited to descriptive statistics using SAS for Windows (version 9.1, SAS Institute Inc, Cary NC, USA) to provide frequencies for planning the definitive study.

3.3 Results

3.3.1 Charlotte Maxeke Johannesburg Academic Hospital

There were 18,900 anaesthetic and surgical cases performed during 1999. One hundred and eleven (111) deaths were documented, of which 79% (n=88) were trauma cases who died as a result of their injuries (Figure 3.1). These deaths were either in the operating theatre or postoperatively in the intensive care unit, at varying times post-induction of anaesthesia.

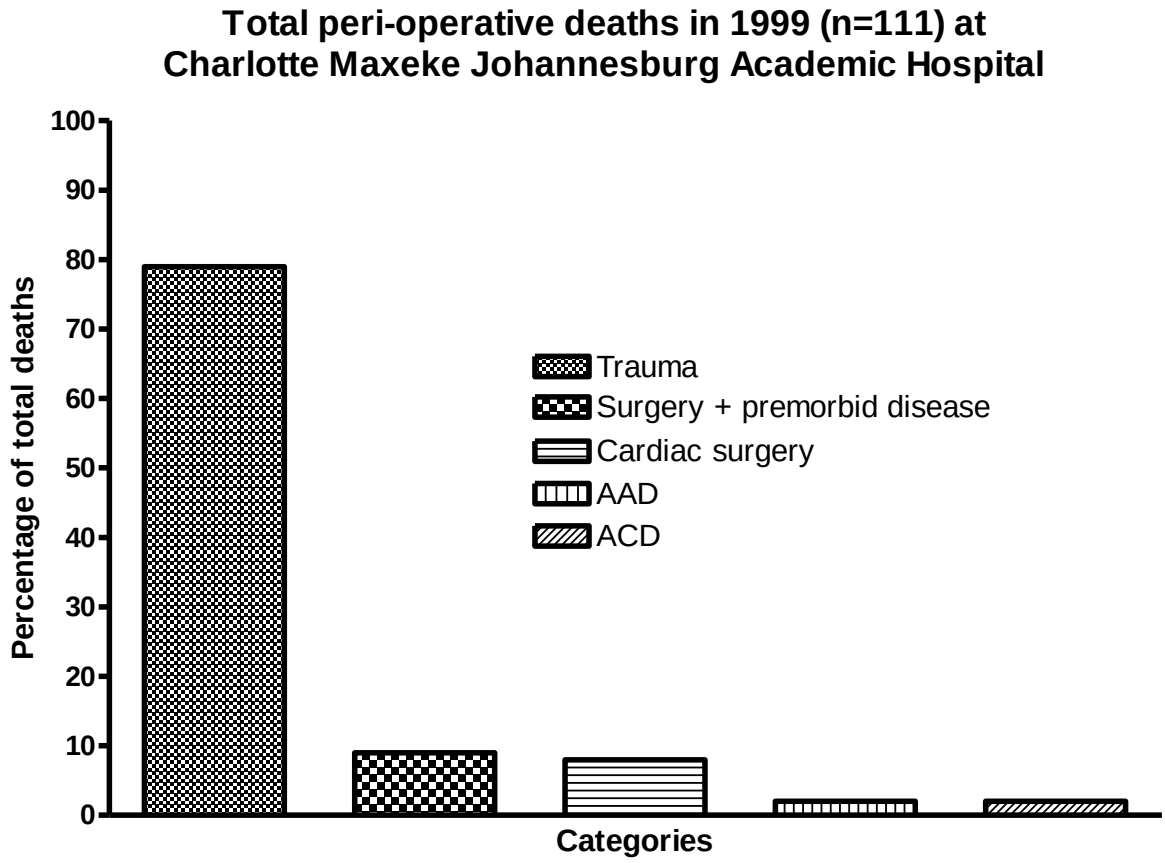


Figure 3.1 Peri-operative deaths at CMJAH in 1999

Of the 23 deaths among non-trauma patients, 8% (n=9) were patients who had cardiac surgery; all of these patients died as a direct result of their cardiac surgery (Table 3.4).

Anaesthesia was uneventful and all the necessary equipment was available.

Other features of this group included:

- Four out of the nine were paediatric patients;
- All of the patients were anaesthetised by senior specialists or specialists;
- Four out of the 9 had an ASA classification of 5E; of the remainder four were ASA grade 3 or 4; only one was an ASA grade 2.

Table 3.4 Cardiac surgery patients

Cardiac case	ASA status	Seniority of anaesthetist	Type of surgery
1 Child	3	Senior specialist	Complex congenital heart disease; prolonged cardiopulmonary bypass; died in theatre
2	4	Senior specialist	Acute aortic dissection; died postoperatively
3	3	Specialist	Tight calcific aortic stenosis; could not wean off cardiopulmonary bypass; died in theatre
4	5E	Specialist	Acute aortic dissection; cardiac arrest preoperatively; died in theatre
5 Child	3	Senior specialist	Ventriculo-septal defect with severe pulmonary hypertension; died postoperatively from a pulmonary hypertensive crisis;
6	5E	Specialist	Left ventricular rupture post myocardial infarction; died in theatre
7	2	Specialist	Elective coronary artery bypass graft; died postoperatively during first week
8 Child	5E	Senior specialist	Clotted mitral valve; died in theatre
9 Neonate	5E	Senior specialist	Critical pulmonary stenosis; catheterization; died in theatre

The other 14 cases comprised a mixture of different types of surgery and surgical complications, such as sepsis and multi-organ failure following a laparotomy.

Table 3.5 Total deaths allocated to individual categories

	Total cases	Deaths	Trauma	Cardiac	Surgery & premorbid disease	AAD
January	1,421	11	11			
February	1,525	5	5			
March	1,838	15	11	1	3	
April	1,552	14	9	2	1	2
May	1,688	6	4		1	1 (ACD)
June	1,528	7	5	2		
July	1,617	4	3		1	
August	1,590	10	9		1	
September	1,611	10	6	3	1	
October	1,564	7	7			
November	1,628	10	8	1	1	
December	1,338	12	10		1	1 (ACD)
TOTALS	**18,900**	**111 (0.6%)**	**88 (79%)**	**9 (8%)**	**10 (9%)**	**4 (3.4%)**

Ten of these fourteen patients died as a result of their surgery or their premorbid disease condition (Table 3.5). There were two patients who can be considered as having died of an anaesthesia associated cause (AAD), and two who died of anaesthesia contributory causes (ACDs).

Details of these cases are as follows:

- **AAD case 1**: This was a 7 year-old child who presented with a bowel obstruction due to Hirschsprung's disease for laparotomy. The procedure

took four hours, and was associated with large fluid shifts and a drop in body temperature. The child was taken to the intensive care unit postoperatively (for ventilation and cardiovascular support), where he died. It is not documented whether the death was within 24 hours of induction of anaesthesia.

Other relevant points are:

- This was emergency surgery;
- ASA status was a 3E
- He was not premedicated;
- It is unclear as to whether he was worked up preoperatively;
- The child was anaesthetised by a specialist, and all the required anaesthetic equipment was available;
- There were no problems with the airway;
- Record keeping was good;
- The adverse events that occurred during surgery were hypothermia and significant fluid losses, but these were corrected;
- It is not known whether a post mortem was performed and thus what the mechanism of death was.

- **AAD case 2**: This was an adult patient, age unknown, who had suffered a subarachnoid haemorrhage (SAH) and had been ventilated for 10 days. He presented with respiratory difficulties, necessitating an urgent tracheostomy. The anaesthetic proceeded carefully and uneventfully. Unfortunately the surgeon was unable to place the tracheostomy. After the

third attempt the patient vomited, suffered a bradycardia, and was unable to be resuscitated. He died in the operating theatre.

Additional points are:

- This was emergency surgery in a patient who had severe respiratory distress, and who had recently suffered a SAH. It is thus unlikely that he was worked up for the surgery;
- ASA status was a 4E
- He had been given a premedication of one mg of Midazolam intravenously in the ward;
- The anaesthetist was a senior registrar;
- Anaesthesia equipment was available in the operating theatre; it is unclear whether surgical airway equipment was not available;
- A general anaesthetic with spontaneous respiration was administered;
- Airway management was via a nasopharyngeal airway initially, as well as via the tracheostomy incision intraoperatively;
- Record keeping was adequate;
- Failure to secure a surgical airway was the catastrophic adverse event;
- It is unclear as to whether a post mortem was performed, and one can only speculate on the mechanism of death.

- **AAD case 3 (ACD case 1)**: This was a 60 year-old male, ASA grade 2, who presented for a lymph node biopsy to confirm a diagnosis of non-Hodgkins lymphoma. He was given what appears to be a straightforward

anaesthetic utilising spontaneous respiration for forty-five minutes. At the end of the procedure he was observed not to be breathing. It was then confirmed that he was pulseless. He was successfully resuscitated, and was taken to the intensive care unit, where he showed signs of cerebral irritability, as is commonly associated with hypoxic brain damage. He was found to have an ejection fraction of 20% on echocardiogram. He died during the following week, without regaining consciousness.

Points to note on this case are:

- He came for relatively minor elective surgery;
- He was assessed preoperatively and premedicated;
- A registrar anaesthetised the patient;
- Anaesthesia equipment was available;
- He received a general anaesthetic with a laryngeal mask airway;
- The anaesthetic record is not available;
- There is no indication of any sudden adverse event; at the end of surgery the patient was found to have stopped breathing, and was then found to have had a cardiac arrest;
- The patient died after the 24-hour cut-off time after induction of anaesthesia. Nevertheless, he did not regain consciousness, having been conscious before anaesthesia was commenced, and then he subsequently died;
- There is no evidence of whether a post mortem was done, thus the mechanism of death would be speculative.

- **AAD case 4 (ACD case 2)**: This was a 7 year-old child who underwent elective dental surgery. This was done under general anaesthesia with local infiltration performed by the surgeon. Anaesthesia and surgery proceeded uneventfully. The child was taken to the recovery room, and after ascertaining that all the observations were stable, the anaesthetist left the building. The child suffered a hypoxic cardiac arrest a short while later, and was eventually transferred to the paediatric intensive care unit, where he eventually died a few days later, without ever regaining consciousness.

  Of note are the following points:

  - He was an ASA 1 patient having elective surgery;
  - He was seen pre-operatively but not premedicated;
  - A specialist anaesthetised him;
  - All the necessary equipment was available;
  - Intraoperative airway management proceeded without complications;
  - Record keeping was good;
  - A chest x-ray in the intensive care unit showed a gauze swab in the lower trachea;
  - A post mortem was conducted and the cause of death found to be hypoxic brain damage.

3.3.2 Wits Donald Gordon Medical Centre

The total number of deaths at the hospital during the 5-year study period is summarized in Table 3.6.

Every avenue was explored to obtain the necessary data, but it had been lost during the changeover of ownership to the University of the Witwatersrand in 2002.

Table 3.6 Total deaths at WDGMC

Deaths	2000	2001	2002	2003	2004
Natural	Missing information	60	48	46	77
Associated with surgery	No information	4	0	1	2
AAD/ACD	N/A	0	0	0	0
TOTAL	N/A	64	48	47	79

Denominator numbers (total theatre cases) were not available, so it was not possible to calculate a prevalence rate of AADs or ACDs per 10,000 anaesthetics.

3.4 Discussion

3.4.1 Charlotte Maxeke Johannesburg Academic Hospital

The data capture form was based on the predisposing factors and proposed "root causes" of anaesthetic deaths from the literature.

In 87% of the cases the anaesthetic record was available. The possible reasons for the absence of the record in the documentation, could be that the anaesthetic record was filed elsewhere, or alternatively kept by the anaesthetist involved with the case.

The data captured in this pilot study showed that a definitive study was feasible at this site.

Anaesthesia associated deaths

On examination of the two AADs in this study, the following observations apply:

- Both were emergencies;
- ASA status was 3E and 4E, respectively;
- One patient was anaesthetised by a specialist and one by a senior registrar;
- Both patients received a general anaesthetic;
- All anaesthesia equipment was available and utilised where appropriate;
- In both cases surgery was either long or complicated;
- Anaesthetic problems were corrected during the procedure (hypothermia and fluid loss);
- There is no evidence of a post-mortem result in either case. Thus neither a cause nor a mechanism of death can be given.

There is no clear indication as to why the child died, but the surgery and anaesthesia were protracted, necessitating intensive care admission with ventilation. Therefore I have broadly categorised it as an AAD, and on more detailed examination, it can be considered an ACD.

The adult patient died from a combination of the premorbid condition and the failed surgical airway. It is not clear why the anaesthetist could not assist in securing the airway, thus it also falls into the ACD category.

Consequently, the prevalence of ACDs in this pilot study is four out of 18,900, or 1: 4,725 anaesthetics. This rate is difficult to compare with statistics from previous

studies, since in some instances the “surgical” deaths have been added to the AADs, as in the CEPOD study [38], where the prevalence of mortality from the “operation” was 1:2860. Similarly, Harrison [11] separated out the AADs from the surgical deaths, and then calculated the ACD rate.

Anaesthesia contributory deaths

The prevalence of anaesthesia contributory deaths (ACD) in this pilot study is two out of 18900. This gives a prevalence of 1: 9450 (equating to 1.06:10,000), which is much higher than the figures of 0.05 per 10,000 in the CEPOD study in the United Kingdom in 1987 [38], and higher than the 0.12:10,000 found by Lienhart et al. [8] in France in the same year as this pilot study (1999).

Table 3.7 Anaesthesia contributory deaths comparison table

Year	Author and country	ACD rate
1987	Lunn (CEPOD) ; United Kingdom [28 38]	0.05 per 10,000 (1: 185,056)
1977-1987	Harrison; South Africa [6]	0.7 per 10,000 (0.07:1,000)
1987-1990	Coetzee; South Africa [13]	1.1 per 10,000
1999	Lienhart; France [8]	0.12 per 10,000
1999	**Pilot study of this thesis**	**1.06 per 10,000**

In the South African context, if one compares these pilot study figures with those of Harrison [6 10-11], particularly in the third quinquennium of his study, they are slightly worse: 1.06:10,000 anaesthetics, as compared with those at Groote Schuur Hospital of 0.7:10,000. Coetzee’s study [13] from Tygerberg Hospital in the

Western Cape, found a prevalence of ACD of 1.1:10,000 anaesthetics, which is very similar to the results of this pilot study.

If one combines the AAD and ACD cases in this pilot study, the prevalence becomes 4:18,900, or 1:4,725, which is very high. However, both of the major previous audits of ACD and AAD in South Africa, namely Harrison [6 10-11] and Coetzee [13], did not combine their AAD and ACD figures, so for purposes of comparison, I shall also keep them separate.

The important factors that emerge in the two ACD cases are:

- Both patients died after the 24-hour cut-off as defined by Harrison, **BUT neither regained consciousness after anaesthesia, having both been fully conscious preoperatively;**
- One was ASA grade one, and the other ASA grade two; thus both fit, healthy patients preoperatively;
- One was anaesthetized by a specialist, and the other by a registrar;
- Both were seen and assessed pre-operatively;
- Both came for relatively minor surgery;
- Both received general anaesthesia;
- All the necessary anaesthesia equipment was available;
- The anaesthetic record on the adult patient is not available, but details of the anaesthetic are recorded in the GW/24 medicolegal form; the anaesthetic record for the child is available;
- Both patients appear to have suffered hypoxic events peri-operatively;

- There is information on post mortem results on the paediatric patient, simply because an open formal inquest was held. It is not known whether a post-mortem was performed on the adult patient.

3.4.2 Wits Donald Gordon Medical Centre

The records were very difficult to acquire, and as shown in Table 3.6 were incomplete.

There were no AADs or ACDs during the 5 years that was studied, which could be for the following reasons:

- Less patients in total, resulting in a very small possible sample in a definitive study;
- There were no trauma patients, because the hospital does not have a trauma unit;
- Although the patients had co-morbid diseases there were no ASA 4 or 5 patients submitted for surgery;
- All patients were anaesthetised by specialist anaesthetists.

If there had been AADs or ACDs the anaesthetic records of these patients would most probably have not been available, because the tendency amongst anaesthetists in private practice is to keep the records, and not add them to the patients' hospital records.

Taking all of the above factors into account, it was decided not to include this site in the definitive study.

3.5 Conclusions

The purpose of this pilot study was to ascertain the following:

- Which variables should be recorded to investigate the prevalence of anaesthesia associated deaths (AADs) and anaesthesia contributory deaths (ACDs);
- Whether the recording systems at the pilot sites used at the time adequately recorded the required data;
- Whether any peer review process was held at the time;
- Whether it was feasible to determine the cause of death;
- Whether it was possible to correlate post mortem findings with the deaths that were documented.

The results of this small pilot study at two totally different types of academic hospitals suggested the following:

- The variables collected at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) were appropriate for documenting the AADs and ACDs;
- The recording systems at the CMJAH adequately recorded the data required in the data collection sheet;
- The WDGMC was an unacceptable site for the pilot study due to inadequate records, low patient numbers, and also limited variety of surgery and anaesthesia. This site was therefore not included in the definitive study;
- It would appear that there was no formal structured peer review process in place at either site at the time;

- It was not possible to correlate the deaths with the post-mortem findings, simply because of the way in which the records were kept at the government mortuary at the time; likewise, it was not possible to determine the cause/s of death.

In addition the pilot study illustrated the following:

- Harrison's[6 10-11] definition incorporating the 24-hour cut off would have excluded the two ACDs in this study. Therefore all ACDs will be recorded in the definitive study, regardless of how long after the induction of anaesthesia they died;
- It is valuable to document the AAD cases, but only the ACD cases should be included in the prevalence numbers;
- A copy of the anaesthesia record should always form a part of the patient's file.

None of the pilot study data collected was included in the definitive study.

CHAPTER 4

METHODOLOGY

The results of the pilot study were encouraging, and indicated that the definitive study could continue, using similar methodology.

4.1 Study design

The definitive study was a retrospective longitudinal descriptive type, which, based on the pilot study, would be of adequate sample size for comparison with studies in South Africa and elsewhere.

4.2 Ethical considerations

4.2.1 Ethics approval

The study was approved by the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand. **Appendices A and B**

4.2.2 Postgraduate committee approval

This study was approved by the Postgraduate Committee of the Faculty of Health Sciences of the University of the Witwatersrand. **Appendix C**

In addition the study title was changed with permission. **Appendix D**

4.2.3 Declaration of Helsinki

The research was conducted in keeping with the principles of the Declaration of Helsinki (2004)[56], which was the official version at the time of the study.

4.2.4 Hospital approval

Permission from the Chief Executive Officer was obtained from each of the two sites.

4.3 Study site

The study area was located in Johannesburg, South Africa, at the following study sites:

- Academic hospital 1 – Johannesburg Hospital (subsequently renamed the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), after the study was completed): all peri-operative deaths from 2000-2004.
- Academic hospital 2 – Chris Hani Baragwanath Hospital (CHBH): maternal and peri-operative maternal deaths from 2000-2004.

The two study sites were chosen for the following reasons:

A. The Charlotte Maxeke Johannesburg Academic Hospital is a 1,100-bed quaternary academic hospital (tertiary at the time of data collection) with a good mix of patients presenting for anaesthesia and surgery. The hospital has been situated at its current location since 1979, having been previously in the middle of Hillbrow, a suburb of Johannesburg close to the inner city. It is one of the major academic teaching hospitals for the University of the Witwatersrand Faculty of Health Sciences. The pilot study indicated that this hospital was an appropriate site.

B. Chris Hani Baragwanath Hospital is a 2,800-bed tertiary academic hospital, on the doorstep of Soweto. It was built in 1942 and served as a British

Military Hospital until it was bought by the South African Government in 1948[58]. It was entered into the Guinness Book of Records in 1997 as the largest hospital in the world. The hospital performs a wide variety of surgical procedures, necessitating anaesthesia of various types, and is also one of the major academic teaching hospitals for the University of the Witwatersrand Faculty of Health Sciences.

A situational analysis was performed on the documentation pertaining to peri-operative deaths. It was discovered that during the rebuilding of the operating theatres in 1999, all of this documentation had been sent to the archives. On further investigation, I found that the records had been removed from the archives and subsequently lost. From 2000 the records were not kept systematically at all, in either the anaesthetic department or the hospital records department. This sad discovery meant that data collected would be unreliable, so the hospital as a whole was eliminated as a study site.

However, Chris Hani Baragwanath Hospital is such a large hospital, that it was decided to look into the possibility of investigating the maternal deaths, including the peri-operative maternal deaths. Unlike the CMJAH, where maternity cases are included in the overall theatre and hospital statistics, the Maternity hospital at Chris Hani Baragwanath Hospital is a stand-alone unit, and keeps separate statistics. This section of the hospital has a very busy maternity unit – one of the busiest in the country, with 70 deliveries a day in the 18-bed labour ward at the time of this study. All of the records in the Maternity Hospital, including the peri-operative records were kept under

lock and key in the Head of Obstetrics' office, and were accessible. In addition, the reporting of maternal deaths had been made compulsory by law in South Africa, since the end of 1998. This meant that complete and reliable data were available. Thus my decision was to investigate maternal deaths and peri-operative maternal deaths, as the second part of the definitive study.

4.4 Study population

The study population comprised all patients receiving anaesthetics and surgery at each study site during the specified time periods.

4.5 Study period

The study took place over the same period at both sites, namely the 1st January 2000 to 31st December 2004.

4.6 Sample population

All patient records were recorded anonymously using code numbers to preserve confidentiality.

4.6.1 Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) 2000-2004

All patients who died during or after surgery during this specified time were studied. They are referred to as peri-operative deaths. Data were obtained predominantly from the records in the records store room in the Department of Anaesthesia, supplemented by central hospital records. The process involved is described in 4.8.1.

4.6.2 Chris Hani Baragwanath Maternity Hospital (CHBMH) 2000-2004

All records of ALL the maternal deaths during this time period were examined, and the operative deaths were extracted and documented. The complete hospital records of each maternal death were kept in a locked cupboard by Professor Buchmann, the Head of Obstetrics at Chris Hani Baragwanath Hospital, in his office. All maternal deaths had been recorded in keeping with the National Policy Health Act[59], requiring the reporting of all maternal deaths as notifiable events by law. The process involved to collect the data is described in 4.8.2.

4.7 Inclusion criteria

All patients who received an anaesthetic and/or surgery at the specific hospital during the specified time period were included, unless their records were not kept. Every effort was made to obtain ALL records as described in 4.8.

4.8 Data Collection

4.8.1 Charlotte Maxeke Johannesburg Academic Hospital

Patient paper records were obtained from the Department of Anaesthesia. Permission was given to take the anaesthetic department patient files home for detailed analysis. These comprised the medicolegal GW7/24 forms, as well as the anaesthetic record forms. Each set of patient forms was examined, documenting the required information required on the data collection sheet **(Appendix E)**. The information on the rank of the anaesthetist was obtained from departmental rosters used during the study period.

Each death was given a number, and the month during which he or she died was documented. In this way, if there was information missing, it could be tracked

down from the appropriate surgical department (for example trauma and cardiothoracics), operating theatre registers and hospital records if necessary.

The denominator figures were obtained from the theatre Matron, who kept the operating theatre statistics.

4.8.2 Chris Hani Baragwanath Maternity Hospital

Access was granted to Professor Buchmann's office and the records, during working hours. I was assisted by Dr Celeste Quan, from the Department of Anaesthesia, Chris Hani Baragwanath Hospital. All of the maternal deaths were recorded, and then the peri-operative deaths extracted. The paper hospital files, GW7/24 forms and anaesthetic records were used to document the information required.

Data from the peri-operative deaths were given a specific code, and captured on the data capture form **(Appendix E)**. The information on the rank of the anaesthetist was obtained from departmental rosters used during the study period.

The denominator figures had been accurately recorded by the Department of Obstetrics and Gynaecology, and were obtained from Professor Eckhart Buchmann, the Head of the Department.

Data captured at both sites were:

- Demographics: age, sex (not for the maternity patients) and race; patients' names were excluded;

- American Society of Anesthesiologists (ASA) grading (Table 3.1);
    - Type and site of surgery;
    - Elective or emergency surgery;
    - Whether a patient was premedicated;
    - Whether preoperative workup was performed on the patient (by the surgeon or the anaesthetist); in other words whether the patient had had blood tests and other appropriate investigations, had received any necessary interventions (such as a blood transfusion), and was fit for surgery and anaesthesia;
    - The “level” of the anaesthetist involved in the case – registrar, specialist, senior registrar (a trainee with a minimum of 3 years of experience and a primary examination for the Fellowship of the College of Anaesthetists);
    - Whether there was any essential anaesthesia equipment unavailable for the case.

      This information can be obtained from the GW7/24 form and the anaesthetic record;
    - The type of anaesthesia: local; regional; general or a combination thereof;
    - Airway management: endotracheal tube, with or without rapid sequence intubation, laryngeal mask airway (LMA) or oxygen mask, in the case of a regional;
    - Record keeping: whether a contemporaneous anaesthetic record was kept and was available;

- Whether a recovery room record was kept and available; This is only valid in patients who do not go to the intensive care unit, as they do not stop off in the recovery room;
- Whether any adverse events occurred (prior to the patient's death);
- Where the death occurred: in theatre or postoperatively in the ward, or the intensive care unit;

- When the death occurred: within 24 hours after induction; more than 24 hours after induction but less than 7 days; less than 30 days after induction of anaesthesia; more than 30 days after induction of anaesthesia. This was possible for the maternal deaths at Chris Hani Baragwanath Hospital, as the notification of maternal deaths is now a legal requirement. Mothers who die up to 30 days after their procedure are properly followed up and documented.

After placing the data on the data capture form, they were collated in an A4 quad counter book. The data was then transferred from this book onto an Excel spreadsheet, and converted to a SAS data set for statistical analysis, using a similar SAS coding system as was described in Chapter 3. It took approximately 20 months on a part-time basis to collect and check the data.

In addition, the GW7/24 and anaesthetic records of all AADs and ACDs were photocopied and placed in a separate lever arch file. Detailed notes were made in a separate note book on each of these.

Based on all of the information available, it was then decided (by me) whether the death could have been caused by the anaesthetic and other factors such as the surgery (AAD), or whether it was solely due to the anaesthetic (ACD), based on the recommendations made by Holland[27], listed in Table 4.2.

Table 4.1 Definitions used to distinguish between ACD and AAD[27]

Category	Definition
I	When it is reasonably certain that the event or death was caused by the anaesthetic agent or technique of administration or in other ways coming directly within the anaesthetist's province
II	Similar to type I cases, but ones in which there is some element of doubt about whether the agent or technique was entirely responsible for the result
III	Cases in which the patient's adverse event or death was caused by the anaesthetic and the surgical technique
IV	Events entirely referable to surgical technique

Thus categories I, II and III are AADs and category I is an ACD.

4.9 Data analysis

Using SAS for Windows (version 9.1, SAS Institute Inc, Cary NC, USA) frequencies were initially listed for all of the variables recorded. These were discussed with the statistical advisor (Prof L.P. Fatti) to determine what methods were suitable for the study.

The methods recommended were:

a. Descriptive statistics, for frequencies and prevalence ratios;
b. Analytical statistics, for categorical analysis using the chi-square test and Fisher exact test, depending on the numbers per category cell. When a cell number was too low for the chi square test to be appropriate, a

combination of categories based on logic was tried. Statistical significance was accepted at $p<0.05$.

4.10 Funding

The study was funded by a research grant from the Jan Pretorius Fund, provided by the South African Society of Anaesthesiologists.

CHAPTER 5

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL 2000-2004

The whole sample of Peri-operative Deaths

5.1 Additional data collection specific to this part of the definitive study

At Charlotte Maxeke Johannesburg Academic Hospital, the following additional information was noted (in addition to **Appendix E**):

- For the trauma patients; the type of injury (blunt or penetrating) was documented, and whether a patient arrived in the operating theatre with a cross-clamped aorta. This information was annotated in the quad book, after the initial information from the data collection sheet had been entered;

- The seniority of the anaesthetist is defined as follows:

  A registrar is a trainee anaesthesiologist;
  A senior registrar is a trainee with a minimum of 2 years of experience and a primary examination for the Fellowship of the College of Anaesthetists;
  A consultant may be a specialist anaesthetist (anaesthesiologist) or a medical officer with a minimum of 10 years of anaesthetic experience;
  A specialist is a specialist anaesthetist.

- A “decade” column was added in the quad book, as many of the acutely ill adult trauma patients’ ages were not given. In these cases the decade was recorded as the 5th decade; The decades were as follows:

- 0 to 9 years = 1
- 10 to 19 years = 2
- 20 to 29 years = 3
- 30 to 39 years = 4
- 40 to 49 years = 5
- 50 to 59 years = 6
- 60 to 69 years = 7
- 70 to 79 years = 8
- 80 to 89 years = 9

5.2 Results – Descriptive statistics of the whole sample

This will be discussed under the following headings:

1. Total peri-operative deaths;
2. Broad demographics of the whole sample of peri-operative deaths;
3. Types of surgery in all of the peri-operative deaths;
4. Types of anaesthetics administered to all of the peri-operative deaths;
5. Adverse events and deaths in the whole sample of peri-operative deaths.

5.2.1 Total peri-operative deaths

The total number of peri-operative deaths during the 5-year study period is summarized in Table 5.1. The annual number ranged between 81 and 107 peri-

operative deaths. Of the 465 peri-operative deaths, 300 were associated with trauma. The “other” causes are surgery, co-morbid diseases and anaesthesia. Within the total peri-operative death numbers AAD and ACD were low.

Table 5.1 Total peri-operative deaths at Charlotte Maxeke Johannesburg Hospital from 2000 to 2004

		Peri-operative deaths			
Year	**Total cases**	**All causes**	**Trauma**	**Other**	**AAD(ACD)**
2000	19,466	97	63	31	3 (0)
2001	20,285	107	70	34	3 (2)
2002	21,462	81	58	21	2 (1)
2003	22,257	91	53	34	4 (0)
2004	21,973	89	56	30	3 (1)
Total	105,407	465	300	150	15 (4)

The prevalence rate for all causes of peri-operative deaths per 10,000 per year is calculated with the formula (death category/total cases) * 10000. The yearly rates are compared with the AAD and ACD rates in Table 5.2.

Table 5.2 All causes of peri-operative deaths compared with AAD and ACD

Year	**All Causes per 10,000**	**AAD per 10,000**	**ACD per 10,000**
2000	49.8	1.5	0
2001	52.7	1.5	1.0
2002	37.7	0.9	0.5
2003	40.9	1.8	0
2004	40.5	1.4	0.5
Total	**44.1**	**1.4**	**0.4**

As can be seen from Table 5.2 the prevalence of AAD and ACD is very low in comparison with all of the causes; the prevalence of ACDs for the entire 5 years is 0.4 per 10,000.

5.2.2 Broad demographics of the whole sample of peri-operative deaths

- Twenty-two percent of the deaths were female, and 78% male;
- Eighty-nine percent of the patients were emergencies (n= 412); forty-nine were elective procedures. An additional 4 could not be determined;
- Seventy-five percent were not worked up pre-operatively, probably because so many were emergencies, many of them ASA 5 trauma patients, who were rushed through to the operating theatre whilst being resuscitated;
- Almost half of the patients (47.8%) were anaesthetized by senior registrars; a third (34%) by specialists, and the remainder (18%) by registrars.
- The majority of cases were in the ASA 4 and 5 categories, as is illustrated in Table 5.3:

Table 5.3 ASA Categories (The data on 10 patients are missing, the information was unobtainable) Emergency cases (category E) are included in each ASA category.

ASA	Frequency	Percent
1	6	1.3
2	12	2.6
3	50	11.0
4	94	20.7
5	293	64.4

5.2.3 Types of surgery in all of the peri-operative deaths

Two thirds (66%) of the patients were trauma patients. The balance comprised cardiac surgery (10%), vascular surgery (4%), and all other types of surgery.

The following categories of surgery were identified, with their corresponding surgical procedures (operations). They are too numerous (465 peri-operative deaths) for more detailed breakdown:

Table 5.4 Surgical categories and corresponding procedures of the whole sample of peri-operative deaths

General surgery	Gastroscopy, burns surgery, sloughectomy, permcatheter insertion, laparotomy
Obstetrics	Laparotomy, caesarean section, evacuation,
Cardiac surgery	Dissection, valve replacement, laparotomy, coronary artery bypass graft, congenital heart surgery, pericardiectomy
Ear, nose and throat (ENT)	Tonsillectomy, laryngectomy, bleeding, laryngoscopy, tracheostomy
Gynaecology	Hysterectomy
Thoracics	Pneumonectomy, bronchoscopy, tracheal resection
Paediatric surgery	Biopsy, laparotomy, bronchoscopy
Vascular	Femoropopliteal bypass, abdominal aortic aneurysm repair, aortofemoral bypass, amputation, fasciotomy, aneurysm, bypass
Urology	Procedure was not specified
Orthopaedics	Hip surgery, spinal surgery
Plastic surgery	Cleft repair
Maxillofacial	Ankylosis
Trauma surgery Blunt or penetrating Aorta cross-clamp preoperatively	Sternotomy, thoracotomy, resuscitation, vascular repair, laparotomy, amputation, neck exploration

For statistical analysis the surgical categories were condensed into the following to enable a suitable number per cell for the chi-square or Fisher exact tests:

- Trauma surgery
- Cardiac surgery
- Vascular surgery
- Other surgery, which includes ENT, obstetrics, orthopaedics, paediatric surgery, plastic surgery, urology, neurosurgery, gynaecology, maxillofacial surgery, thoracic surgery

Table 5.5 Surgical categories of the peri-operative deaths and numbers of operations (The data on 4 patients are missing)

Category	Frequency	Percent
Trauma surgery	300	65.1
Cardiac surgery	45	9.8
Other surgery	99	21.4
Vascular surgery	17	3.7

As can be seen from Table 5.5 trauma surgery cases predominated.

When one looks closely at the cardiac and vascular surgery groups, the following is noted:

- Forty-three out of the 45 cardiac cases were anaesthetized by specialists (95%);
- The remaining 2 were anaesthetized by a senior registrar;

- Eleven of the 17 vascular patients (65%) were anaesthetized by specialists.

5.2.4 Types of anaesthetics administered for all of the peri-operative deaths

One third (36 %) of the patients (150 trauma and 11 from the other categories) did not receive a hypnotic agent as part of the anaesthetic. This is illustrated in Table 5.6. Many of the patients received only a muscle relaxant and a small dose of opiate, and many were apparently too sick to even tolerate an opiate. I have called this group a “no anaesthetic” group. What is unclear in this “no anaesthetic” group, is whether they received any hypnotic agents “pre-casualty” or preoperatively, as at the time that these statistics were being generated, some paramedics administered small to moderate doses of hypnotic agents such as midazolam to patients. Nevertheless, it is still important to note the high number of patients who were “analgesed” and paralysed, but not “anaesthetised” with either a volatile or intravenous hypnotic.

Table 5.6 Surgical categories versus anaesthetic given (The data on 15 patients is missing)

	Trauma n (%)	Cardiac n (%)	Other surgery n (%)	Vascular n (%)	Total n (%)
Anaesthetic	149 (33.1)	43 (9.6)	83 (18.4)	14 (3.1)	289 (64.2)
No anaesthetic	150 (33.3)	2 (0.5)	8 (1.8)	1 (0.2)	161 (35.8)

The anaesthetics given to the remaining 64% of the patients comprised the following:

- Endotracheal intubation in 98% (the others either had a tracheostomy or a laryngeal mask airway)
- Only 24% had a rapid sequence induction; this is unexpected, as 90% were emergencies, and one would have expected most of these patients to have received a rapid sequence induction. However, when one analyses the cases, it is evident that many of the ASA 4 and 5 trauma patients were intubated either in casualty, or at the trauma scene, thus obviating the need for intubation in the operating theatre. Hence the low number of rapid sequence inductions.
- There were 5 patients in whom airway problems were experienced. All of these cases are either anaesthesia contributory deaths (ACDs), or anaesthesia-associated deaths (AADs). Of interest, four out of 5 of these patients were anaesthetized by specialist anaesthetists.

Anaesthetic records

Anaesthetic records were available in only two thirds (67%) of the peri-operative deaths. Most of the 33% whose records were not available fell into the registrar and senior registrar doctor groups as can be seen from the Table 5.7. They did not attach the anaesthetic record to the GW7/24 medicolegal forms.

The prevalence of missing records was much lower in the specialist group, possibly indicating that specialists are either more thorough or meticulous, or that

they have better knowledge and insight into the keeping of medicolegal records. It could also mean that the specialists are merely more experienced.

Table 5.7 Anaesthetic record availability in relation to rank of anaesthetist (data are missing on one)

Doctor rank	No record	Record available	Totals
Registrar	49 (10.6%)	35 (7.5%)	84 (18.1%)
Senior registrar	75 (16.1%)	147 (31.8%)	222 (47.9%)
Specialist	27 (5.8%)	131 (28.2%)	158 (34.0%)
All ranks	151 (32.5)	313 (67.5%)	464 (100%)

5.2.5 Adverse events and deaths in the whole sample of peri-operative deaths

The adverse events which possibly lead to the patient's deaths occurred within the first 24 hours in 92% of cases. Furthermore, 76% of the deaths occurred within 24 hours of the induction of anaesthesia.

Sixty-two per cent (62%) of patients died in the operating theatre; 24% died in the intensive care unit, and the remainder (14%) died in the ward. These findings are illustrated in Table 5.8.

Table 5.8 Timing of adverse event by where the patient died

Adverse event timing	ICU	OT	Ward	Total
<24 hours	98 (21.1%)	287 (61.7%)	41 (8.8%)	426 (91.6%)
>24 hours	15 (3.2%)	0	24 (5.2%)	39 (8.4%)
Total	113 (24.3%)	287 (61.7%)	65 (14.0%)	465 (100%)

ICU = Intensive Care Unit; OT = Operating Theatre

5.3 Results – Analytical statistics of the whole sample

In this section eight variables were chosen as factors of clinical importance:

- ASA status;
- Doctor (registrar, senior registrar, specialist);
- Anaesthetic (yes or no);
- Anaesthetic record available (yes or no);
- Adverse event (when this occurred: <24 hours or >24 hours after the start of the anaesthetic/operation);
- When the patient died (<24 hours; >24 hours after the start of the anaesthetic/operation);
- Where the patient died (operating theatre, intensive care unit or ward);
- Whether the patients in the trauma sub-group had penetrating or blunt trauma, and whether they arrived in theatre with a cross-clamped aorta.

The cross tabulations of each of the eight variables will be shown in turn, followed by a listing of variables for which statistical significance was found or not, either by means of the chi square test or Fisher exact test. After this there will be a summary table showing the actual probability values for each testing.

5.3.1 ASA

Table 5.9 ASA by preoperative assessment (data on 18 are missing)

ASA frequency	Preop no	Preop yes	Total
1	0	6	6
2	3	9	12
3	10	39	49
4	62	30	92
5	262	26	288
Total	337	110	447

Table 5.10 ASA by doctor (data on 11 are missing)

ASA frequency	Registrar	Specialist	Senior registrar	Total
1	2	3	1	6
2	0	6	6	12
3	4	34	12	50
4	13	34	47	94
5	58	80	154	292
Total	77	157	220	454

Table 5.11 ASA by anaesthetic (data on 21 are missing)

ASA frequency	General anaesthetic	No anaesthetic	Total
1	5	0	5
2	7	0	7
3	47	1	48
4	61	11	92
5	143	149	292
Total	283	161	444

Table 5.12 ASA by type of airway (data on 16 are missing)

ASA frequency	DLT	ETT	No	Total
1	0	4	1	5
2	1	9	2	12
3	0	47	2	49
4	0	92	1	93
5	1	288	1	290
Totals	2	440	7	449

DLT = double lumen tube; ETT = endotracheal tube

Table 5.13 ASA by rapid sequence induction (RSI) (data on 12 are missing)

ASA frequency	RSI - no	RSI - yes	Total
1	5	1	6
2	9	3	12
3	37	12	49
4	53	41	94
5	238	54	292
Total	342	111	453

Table 5.14 ASA by airway problems (data on 11 are missing)

ASA frequency	Airway problems - no	Airway problems - yes	Total
1	6	0	6
2	12	0	12
3	47	3	50
4	94	0	94
5	290	2	292
Total	449	5	454

Table 5.15 ASA by availability of the anaesthetic record (data on 10 are missing)

ASA frequency	Anaesthetic record Y	Anaesthetic record No	Total
1	1	5	6
2	2	10	12
3	11	39	50
4	26	68	94
5	103	190	293
Total	143	312	455

Table 5.16 ASA by when the adverse event occurred (data on 10 are missing)

ASA frequency	< 24 hours	>24 hours	Total
1	2	4	6
2	8	4	12
3	40	10	50
4	85	9	94
5	286	7	293
Total	421	34	455

Table 5.17 ASA by when the patients died (data on 11 are missing)

ASA frequency	< 24 hours	>24 hours	Total
1	1	5	6
2	3	9	12
3	33	17	50
4	71	23	94
5	242	50	292
Total	350	104	454

Table 5.18 ASA by where the patients died (data on 10 are missing)

ASA frequency	ICU	OT	Ward	Total
1	1	1	4	6
2	2	2	8	12
3	15	18	17	50
4	33	47	14	94
5	59	217	17	293
Total	110	285	60	455

ICU = intensive care unit; OT = operating theatre.

Table 5.19 ASA by surgical category (data on 12 are missing)

ASA	Trauma	Cardiac	Surgery	Vascular	Total
1	1	0	5	0	6
2	1	0	10	1	12
3	8	18	22	2	50
4	53	15	20	5	93
5	235	11	37	9	292
Total	298	44	94	17	453

Table 5.20 ASA by trauma or not (data on 12 are missing)

ASA	No trauma	Trauma yes	Total
1	5	1	6
2	11	1	12
3	42	8	50
4	39	54	93
5	53	239	292
Total	150	303	453

Statistical significance (as indicated in Table 5.54) was achieved when ASA was compared with:

- Preoperative workup;
- The category of doctor;
- Whether an anaesthetic was given or not;
- Which airway device was used; in this case the sample other than the endotracheal tube was too small for testing;
- The use of rapid sequence induction;
- When the adverse event occurred;
- When the patients died;
- Where the patients died;
- The category of surgery;
- Whether there was trauma involved or not.

BUT not with the presence of airway problems, nor the availability of the anaesthetic record.

5.3.2 Category of Doctor

Table 5.21 Doctor by anaesthetic given (data on 11 are missing)

Doctor frequency	General anaesthetic	No anaesthetic	Total
Registrar	53	30	83
Specialist	125	29	154
Senior registrar	115	102	217
Total	293	161	454

Table 5.22 Doctor by airway (data on 8 are missing)

Doctor frequency	Double lumen	Endotracheal tube	None	Total
Registrar	0	82	1	83
Specialist	1	150	3	154
Senior registrar	1	216	3	220
Total	2	448	7	457

Table 5.23 Doctor by rapid sequence induction (RSI) (data on 5 are missing)

Doctor frequency	RSI no	RSI yes	Total
Registrar	68	15	83
Specialist	124	32	156
Senior registrar	156	65	221
Total	348	112	460

Table 5.24 Doctor by airway problems (data on 2 are missing)

Doctor frequency	Airway problems no	Airway problems yes	Total
Registrar	84	0	84
Specialist	153	4	157
Senior registrar	221	1	222
Total	458	5	463

Table 5.25 Doctor by availability of the anaesthetic record (data on 1 are missing)

Doctor frequency	Anaesthetic record Y	Anaesthetic record N	Total
Registrar	49	35	84
Specialist	27	131	158
Senior registrar	75	147	222
Total	151	313	464

Table 5.26 Doctor by when the adverse event occurred (data on 1 are missing)

Doctor frequency	< 24 hours	>24 hours	Total
Registrar	68	16	84
Specialist	145	13	158
Senior registrar	212	10	222
Total	425	39	464

Table 5.27 Doctor by when the patients died (data on 2 are missing)

Doctor frequency	< 24 hours	>24 hours	Total
Registrar	53	30	83
Specialist	125	33	158
Senior registrar	174	48	222
Total	352	111	463

Table 5.28 Doctor by where the patients died (data on 1 are missing)

Doctor frequency	Intensive Care	Operating Theatre	Ward	Total
Registrar	20	47	17	84
Specialist	48	94	16	158
Senior registrar	45	145	32	222
Total	113	286	65	464

Table 5.29 Doctor by surgical category (data on 5 are missing)

Doctor	Trauma	Cardiac	Surgery	Vascular	Total
Registrar	64	0	17	0	81
Specialist	56	43	47	11	157
Senior registrar	179	2	35	6	222
Total	299	45	99	17	460

Table 5.30 Doctor by trauma or not (data on 5 are missing)

Doctor frequency	No trauma	Trauma yes	Total
Registrar	17	65	82
Specialist	97	59	156
Senior registrar	42	180	222
Total	156	304	460

Statistical significance (as indicated in Table 5.54) was achieved when the variable Doctor was compared with:

- Whether an anaesthetic was given or not;
- The availability of an anaesthetic record;
- When the adverse event occurred;
- The category of surgery
- Whether there was trauma involved or not

BUT not with the type of airway used, whether a rapid sequence induction was used, whether there were airway problems, and when and where the patients died.

5.3.3 Anaesthetic administered or not

Table 5.31 Anaesthetic by airway (data on 18 are missing)

Anaesthetic frequency	Double lumen tube	Endotracheal tube	None	Total
General	2	282	2	286
None	0	161	0	161
Total	2	443	2	447

Table 5.32 Anaesthetic by rapid sequence induction (data on 15 are missing)

Anaesthetic frequency	No RSI	RSI	Total
General	193	96	289
None	145	16	161
Total	338	112	450

Table 5.33 Anaesthetic by airway problems (data on 12 are missing)

Anaesthetic frequency	No airway problems	Airway problems	Total
General	288	4	292
None	160	1	161
Total	448	5	453

Table 5.34 Anaesthetic by availability of the anaesthetic record (data on11are missing)

Anaesthetic frequency	No record	Record available	Total
General	97	196	293
None	53	108	161
Total	150	304	454

Table 5.35 Anaesthetic by when the adverse event occurred (data on 11 are missing)

Anaesthetic frequency	< 24 hours	>24 hours	Total
General	257	36	293
None	161	0	161
Total	418	36	454

Table 5.36 Anaesthetic by when the patients died (data on 12 are missing)

Anaesthetic frequency	< 24 hours	>24 hours	Total
General	193	99	292
None	154	7	161
Total	347	106	453

Table 5.37 Anaesthetic by where the patients died (data on 11 are missing)

Anaesthetic	Intensive care	Operating theatre	Ward	Total
General	99	138	56	293
None	13	145	3	161
Total	112	283	59	454

Table 5.38 Anaesthetic by surgical category (data on 15 are missing)

Anaesthetic	Trauma	Cardiac	Surgery	Vascular	Total
General	149	43	83	14	289
None	150	2	8	1	161
Total	299	45	91	15	450

Table 5.39 Anaesthetic by trauma or not (data on 15 are missing)

Anaesthetic frequency	No trauma	Trauma	Total
General	135	155	290
None	11	149	160
Total	146	304	450

Statistical significance (as indicated in Table 5.54) was achieved when Anaesthetic was compared with:

- Where the patients died;
- The category of surgery.

BUT not with the type of airway used, whether a rapid sequence induction was used, whether there were airway problems, the availability of an anaesthetic record, when the adverse event occurred and when the patients died, and whether trauma was involved or not.

5.3.4 Anaesthetic record availability

Table 5.40 Anaesthetic record by when the adverse event occurred

Anaesthetic record	< 24 hours	>24 hours	Total
No	134	18	152
Yes	292	21	313
Total	426	39	465

Table 5.41 Anaesthetic record by when the patients died (data on 1 are missing)

Anaesthetic record	< 24 hours	>24 hours	Total
No	102	50	152
Yes	251	61	312
Total	353	111	464

Table 5.42 Anaesthetic record by where the patients died

Anaesthetic record	Intensive care unit	Operating theatre	Ward	Total
No	40	85	27	152
Yes	73	202	38	313
Total	113	287	65	465

Table 5.43 Anaesthetic record by surgical category (data on 4 are missing)

Anaesthetic record	Trauma	Cardiac	Surgery	Vascular	Total
No	113	4	29	2	148
Yes	187	41	70	15	313
Total	300	45	99	17	461

Table 5.44 Anaesthetic record by trauma or not (data on 4 are missing)

Anaesthetic record	No trauma	Trauma	Total
No	35	114	149
Yes	121	191	312
Total	156	305	461

Statistical significance (as indicated in Table 5.54) was achieved when the Anaesthetic record was compared with:

- When the patients died;

- The category of surgery;
- Whether there was trauma involved or not.

BUT not when the adverse event occurred or where the patients died.

5.3.5 Adverse event – when this occurred

Table 5.45 Adverse event by when the patients died (data on 1 are missing)

Adverse event	< 24 hours	>24 hours	Total
<24 hours	353	72	425
>24 hours	0	39	39
Total	353	111	464

Table 5.46 Adverse event by where the patients died

Adverse event	Intensive care	Theatre	Ward	Total
<24 hours	98	287	41	426
>24 hours	15	0	24	39
Total	113	287	65	465

Table 5.47 Adverse event by surgical category (data on 4 are missing)

Adverse event	Trauma	Cardiac	Surgery	Vascular	Total
<24 hours	293	44	74	14	425
>24 hours	7	1	25	3	36
Total	300	45	99	17	461

Table 5.48 Adverse event by trauma or not (data on 4 are missing)

Adverse event	No trauma	Trauma	Total
<24 hours	127	297	424
>24 hours	29	8	37
Total	156	305	461

Statistical significance (as indicated in Table 5.54) was achieved when Adverse event was compared with:

- Where the patients died;

- The category of surgery.

BUT not when the patients died or whether there was trauma involved or not.

5.3.6 When the patient died (<24hours or >24 hours)

Table 5.49 When the patient died by where the patients died (data on 1 are missing)

When died	Intensive care	Theatre	Ward	Total
< 24 hours	46	287	20	353
>24 hours	67	0	44	111
Total	113	287	64	464

Table 5.50 When the patient died by surgical category (data on 5 are missing)

When died	Trauma	Cardiac	Surgery	Vascular	Total
< 24 hours	243	37	61	12	353
>24 hours	56	8	38	5	107
Total	299	45	99	17	460

Table 5.51 When the patient died by trauma or not (data on 5 are missing)

When died	No trauma	Trauma	Total
< 24 hours	106	245	351
>24 hours	50	59	109
Total	156	304	460

Statistical significance (as indicated in Table 5.54) was achieved when '**When** the patient died' was compared with:

- Where the patients died;
- The category of surgery;
- Whether there was trauma involved or not.

5.3.7 Where the patient died

Table 5.52 Where the patient died by surgical category (data on 4 are missing)

Where died	Trauma	Cardiac	Surgery	Vascular	Total
Intensive Care	60	20	26	5	111
Operating Theatre	216	25	38	8	287
Ward	24	0	35	4	63
Total	300	45	99	17	461

Table 5.53 Where the patient died by trauma or not (data on 4 are missing)

Where died	No trauma	Trauma	Total
Intensive care	50	63	113
Operating theatre	68	217	285
Ward	38	25	63
Total	156	305	461

Statistical significance (as indicated in Table 5.54) was achieved when **Where** the patient died was compared with:

- The category of surgery;
- Whether there was trauma involved or not.

The variables in the trauma sub-sample of patients will be discussed later in this chapter.

In the cross tabulations for analytical testing using the chi square test, low values in cells made this test inappropriate. In such instances, on the advice of the statistician, variables were grouped to use either the chi square test or Fisher exact test.

Table 5.54 Analytical statistics summary table of chi-square and Fisher exact test results. (* = statistically significant)

Variable	Chi-square P	Fisher exact test P
ASA		
Preop workup	<.0001*	
Doctor (specialist, senior registrar, registrar)	<.0001*	
Anaesthetic (yes or no)	<.0001*	
Airway (ETT, none, DLT)	Sample	too small for testing
Rapid sequence induction	<.0001*	
Airway problems	0.0127	
Anaesthetic record	0.1719	
Adverse event (<24hrs; >24hrs)	<.0001*	
When died (<24hrs; >24hrs)	<.0001*	
Where died (OT; ICU; ward)	<.0001*	
Surgical category	<.0001*	
Trauma (yes or no)	<.0001*	
Doctor (registrar, senior registrar, specialist)		
Anaesthetic (yes or no)	<.0001*	
Airway (ETT, none, DLT)	Sample	too small for testing
Rapid sequence induction	0.0474	
Airway problems	0.0860	
Anaesthetic record	<.0001*	
Adverse event (<24hrs; >24hrs)	<.0002*	
When died (<24hrs; >24 hours)	0.0162	
Where died (OT; ICU; ward)	0.0615	
Surgical category	<.0001*	
Trauma (yes or no)	<.0001*	
Anaesthetic (yes or no)		
Airway (ETT, none, DLT)	Sample	too small for testing
Rapid sequence induction		1.489
Airway problems		0.6598
Anaesthetic record		1.000
Adverse event (<24hrs; >24hrs)		7.292
When died (<24hrs; >24hrs)		1.457
Where died (OT; ICU; ward)	<.0001*	
Surgical category	<.0001*	
Trauma (yes or no)		3.248

Anaesthetic record		
Adverse event (<24 hrs; >24hrs)	.	0.0742
When died (<24hrs; >24hrs)		0.0025
Where died (OT; ICU; ward)	0.0147	
Surgical category	0.0003*	
Trauma	0.0012	0.0011
Adverse event		
When died (<24 hrs; >24hrs)		1.509
Where died (OT; ICU; ward)	<.0001*	
Surgical category	<.0001*	
Trauma (yes or no)		9.002
When died (<24hrs; >24hrs)		
Where died (OT; ICU; ward)	<.0001*	
Surgical category	0.0006*	
Trauma (yes or no)		0.0037
Where died (OT; ICU; ward)		
Surgical category	<.0001*	
Trauma (yes or no)	<.0001*	

5.4 The Trauma sub-sample of peri-operative deaths

Trauma is an overwhelming reality of life in South Africa in the 21st century. The Trauma Unit at the Charlotte Maxeke Johannesburg Academic Hospital is a level one trauma centre, handling approximately 20,000 patients per year. The Unit is one of two major referral centres in the Johannesburg area, receiving patients from throughout Gauteng, neighbouring provinces and neighbouring states. During the 5 years of this definitive study, the average number of patients treated per year was approximately 17000[60]. Two thirds (65%; n= 300) of the peri-operative deaths were trauma patients.

5.4.1 Demographics

The following data were found:

- Seventy-nine percent (79%) were in the ASA 5 category; 18% were ASA 4 patients;
- Ninety per cent (90%) were males, and 10% females;
- All cases were emergencies, and only 3% were worked up preoperatively.

Surgical procedures

- The majority of procedures (69%) were laparotomies;
- There were 168 penetrating injuries (56%); 74 blunt injuries (25%), and the remainder (19%) were not specified;
- 39 patients (13%) arrived in the operating theatre with a cross-clamped aorta, indicating a severe injury.

Anaesthesia

- Eighty per cent (80%) of the patients were anaesthetised by registrars and senior registrars;
- Half of the patients received a hypnotic as part of the anaesthetic; the other half received only a muscle relaxant, with or without analgesia; in other words they fell into the “no anaesthetic” group;
- Ninety-nine (99%) were intubated with single endotracheal tubes; only 26% of these received a rapid sequence induction; the remaining 74% arrived in theatre already intubated; none had airway problems;
- The majority (98%) had an adverse event in the first 24 hours;
- Eighty-one (81%) died within the first 24 hours, and 72% died in the operating theatre;

- As with the whole sample (trauma and non-trauma), 62% had anaesthetic records available.

5.4.2 Analytical statistics

Table 5.55 Trauma category by aortic cross clamp (data on 59 are missing)

Trauma category	No aortic cross clamp	Aortic cross clamp	Total
Blunt	74	0	74
Penetrating	131	36	167
Total	205	36	241

The Fisher exact test indicated a *p* value of <0.0001, a highly statistically significant association. Cross clamping may be associated with fewer deaths, but a more sophisticated analysis taking into account multiple factors such as the cause of the trauma and type of surgery, amongst others, would be needed to tease out the clamping effect. This is a full study in itself.

Broad discussion and **Conclusions** will follow in **Chapter 9, and Recommendations** in **Chapter 10.**

CHAPTER 6

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL 2000-2004

Anaesthesia Associated Deaths (AADs) and Anaesthesia Contributory Deaths (ACDs)

In keeping with Table 6.1 ACDs will be discussed as a subgroup of AADs.

Table 6.1 Definitions used to distinguish between ACD and AAD[27]

Category	Definition
I	When it is reasonably certain that the event or death was caused by the anaesthetic agent or technique of administration or in other ways coming directly within the anaesthetist's province
II	Similar to type I cases, but ones in which there is some element of doubt about whether the agent or technique was entirely responsible for the result
III	Cases in which the patient's adverse event or death was caused by the anaesthetic and the surgical technique
IV	Events entirely referable to surgical technique

Thus categories I, II and III are AADs and category I is an ACD.

There was an average of 3 ACD/AADs per year during the 5 year study period. Of these 15 cases, 4 may be considered ACDs, where the anaesthetic directly caused the patient's death.

6.1 Broad demographics of the AADs and ACDs

There were 15 AADs and ACDs with the following demographics:

- Thirteen out of 15 were adults (2 children);
- Seven were males and 8 females;
- Six were ASA 2; five were ASA 3 and there were four ASA 4 patients.

One third (33%) of the patients who died from an anaesthetic associated (AAD) cause, died more than 24 hours after the start of the anaesthetic, as can be seen in Table 6.2. Four of these deaths were directly attributable to the anaesthetic, (ACD) and all 4 died more than 24 hours after the start of the anaesthetic.

Table 6.2 AAD and ACD cases and where and when they died

	<24 hours	>24 hours	Totals
ICU	2	2	4
OT	6		6
Ward	2	3	5
Total	10 (66%)	5 (33%)	15

For ease of reading and in accordance with Table 6.1 I have called them all AADs, but have indicated which of these are actually ACDs.

Table 6.3 The AAD and ACD patients

AAD	**ACD or non anaesthetic factors contributing to the death**
AAD 1	Possible opiate overdose postoperatively
AAD 2	Elderly lady; cardiovascular causes
AAD 3	Pulmonary oedema post tracheal stricture repair
AAD 4	Tracheostomy complication after subarachnoid bleed
AAD 5	**ACD** – revision Ventricular Septal Defect developed arrhythmia on induction; dilated pupils; no surgery done
AAD 6	**ACD** – caesarean section for foetal distress; bleeding treated with haemacel; anaphylactic reaction requiring ICU
AAD 7	**ACD** – spinal anaesthetic; high spinal; ventilated in ward
AAD 8	Severe co-morbid diseases; amputation planned; regional blocks administered and patient stable

AAD 9	Elective intracranial surgery; became apnoeic postoperatively
AAD 10	Massive haemorrhage from airway
AAD 11	Pneumonectomy; hypoxic cardiac arrest; ligature slipped: massive haemorrhage
AAD 12	Severe vasculopath; died postoperatively from possibly a myocardial cause
AAD 13	**ACD** – Double valve replacement; over-heparinised; intra-cerebral bleed
AAD 14	Elderly man with blown pupil postoperatively; fully conscious; arrested and died after CT scan
AAD 15	Direct laryngoscopy; carinal mass; unable to ventilate

6.2 The AADs and ACDs in more detail

AAD case 1: The patient was a middle-aged woman who underwent elective gynaecological surgery. She was graded preoperatively as an ASA 2 patient. The anaesthesia and surgery were uneventful. She was stable in the recovery room, and was discharged awake. She arrived back in the ward at 11h10. At 11h20 she was given Pethidine® 100mg and Stemetil® 12,5 mg (believed to be intramuscularly). She had been given a total of 15mg morphine during her surgery.

At 12h15 the patient was apnoeic, and the sister could not record her blood pressure. She was successfully resuscitated, but suffered hypoxic brain damage. She was transferred to a level 2 hospital a week after her arrest, and died sometime later. She was also found to have metastatic cancer at the time of her procedure.

AAD case 2: This was an elderly lady who became hypotensive and hypoxic post extubation, and deteriorated as the resuscitation progressed. She had severe

underlying pulmonary disease, and was diagnosed as having “severe irreversible cardiogenic shock.”

AAD case 3: This was a 44-year old patient who had a tracheal stricture repaired. She was relatively stable intraoperatively other than initially requiring high ventilator pressures in order to ventilate her adequately. At the end of the procedure she was awake, and it was decided to extubate her, as this is usually preferred by the thoracic surgeons. The patient became restless and unco-operative, and a tracheal tug was noted, indicating respiratory difficulties. She was also found to have a profound respiratory acidosis, and severe hypoxia. She was re-intubated, and profuse amounts of pulmonary oedema fluid poured from her endotracheal tube. She suffered a cardiac arrest and was unable to be resuscitated.

AAD case 4: A 50-year old female presented with a subarachnoid haemorrhage from a giant left internal carotid artery aneurysm. She was classified as a Hunt-Hess grade 1, and declined surgery initially. After re-bleeding 10 days later, she agreed to the coiling of her aneurysm. She required prolonged intubation and ventilation as she developed pneumonia. It was decided that she required a tracheostomy, which was performed by the neurosurgeon. A large air leak was noticed after insertion of the tracheostomy, and this was found to be due to a tracheo-oesophageal fistula just above the carina (confirmed on bronchoscopy by a cardio-thoracic surgeon). Ventilation and oxygenation via the tracheostomy was inadequate. She suffered a hypoxic cardiac arrest, from which she could not be resuscitated.

AAD case 5 (ACD case 1): A 3-year old child with a ventriculo-septal defect (VSD) had developed a dehisced patch and came back to theatre for repair of this dehiscence. On induction of anaesthesia she developed a nodal bradycardia followed by a cardiac arrest, and required prolonged resuscitation for 30 minutes. Her pupils were noted to be fixed and dilated, but became smaller “over time”. Surgery was not performed, and she was taken to the intensive care unit, where she died 10 days later, after not regaining consciousness.

AAD case 6 (ACD case 2): A 23-year old pregnant woman presented for emergency caesarean section for foetal distress. She received a spinal anaesthetic and a live female baby was delivered. She started bleeding and was given a unit of haemacel®, a gelatin solution. She apparently developed an anaphylactic reaction to this, requiring resuscitation. The only intensive care unit bed that was available was at the Boksburg Benoni Hospital (now called Tambo Memorial Hospital). She was transferred there in a stable condition, and died the following day.

AAD case 7 (ACD case 3): A 23-year old woman received a spinal anaesthetic for a general surgical procedure. She developed apnoea and became unresponsive. She was successfully resuscitated and developed pulmonary oedema. Surgery was not performed, and as there were no intensive care unit beds, she was ventilated in the surgical ward, where she died.

AAD case 8: This was a 57-year old male, with significant severe co-morbid diseases – dilated cardiomyopathy, severe corpulmonale, diabetes mellitus and asbestosis. He required surgery for a septic right leg. He received a right psoas

compartment block and a right sciatic nerve block for a planned below knee amputation. Whilst being observed after the administration of the regional blocks he collapsed. Resuscitation was unsuccessful.

AAD case 9: A 68-year old woman underwent an elective intracranial procedure. She was extubated, and taken to the intensive care unit postoperatively, awake and talking. After 3 to 5 minutes she became apnoeic and suffered a cardiac arrest. She died 4 days later.

AAD case 10: A 58-year old man had previously undergone excision of a floor of mouth tumour, with hemi-mandibulectomy and pectoralis major reconstruction. Following this he had radiotherapy, and was now booked for contracture release. Prior to this elective surgery, he started bleeding orally (? haematemesis? haemoptysis) and was brought to theatre for an emergency procedure to find the source of the bleeding. He was brought to theatre gasping, and with an oxygen saturation of 40%. Oxygenation was initially via a facemask, and then via a size 6,0 endotracheal tube inserted via the cricothyroid membrane into the trachea. The patient continued to bleed profusely, and it became very difficult to ventilate and oxygenate him. Resuscitation was unsuccessful.

AAD case 11: A 54-year old male patient presented for a left pneumonectomy for a destroyed left lung due to tuberculosis. Lung isolation was attempted (and not successfully achieved) with a right endobronchial single endotracheal tube. A hypoxic cardiac arrest ensued and the patient was successfully resuscitated, with ventilation occurring via a tracheostomy. Surgery continued, and a ligature

“slipped” off the pulmonary artery, resulting in a massive haemorrhage in an already unstable patient. Resuscitation was unsuccessful.

AAD case 12: A 60-year old vasculopath presented with an acutely threatened left leg. An angioplasty was attempted, but was then converted to an aorto-bifemoral bypass graft. A combined spinal-epidural technique was used. He was haemodynamically unstable throughout the procedure, manifesting ECG signs of acute myocardial ischaemia. He died shortly after being taken to the intensive care unit postoperatively.

AAD case 13 (ACD case 4): A 30-year old male was booked for an elective double valve replacement. Whilst on cardiopulmonary bypass, his pupils were noted to be mid-dilated. The initial activated clotting time after the initial dose of heparin was very high, and it is thought that the patient may have suffered an intracerebral bleed. This was confirmed postoperatively on CT scan, which was performed as the patient showed no signs of regaining consciousness. The patient died a week after admission.

AAD case 14: A 71-year old man was found to have a “blown” pupil at the end of an uneventful general surgical procedure. He was fully conscious, but was nevertheless sent for a CT scan. He suffered a cardiac arrest immediately after the scan, and was unresuscitatable.

AAD case 15: A 3-month old infant was diagnosed with severe stridor. The child was receiving oxygen via nasal prongs preoperatively. The proposed procedure was a direct laryngoscopy to determine the cause of his stridor. Ventilation of the

infant was impossible, both via an endotracheal tube, as well as a rigid bronchoscope, due to the presence of a carinal mass which occluded both bronchi. Resuscitation was abandoned as the infant could not be oxygenated and therefore died.

On closer examination of the AADs, excluding the ACDs, The following statements can be made:

- Five AADs were as a result of surgical complications arising from the airway;
- Three (and possibly a fourth) were as a result of significant co-morbid diseases;
- Two patients became apnoeic in the ward postoperatively, one of them probably as a result of an opiate overdose.

Most of these are avoidable deaths, as are the ACDs.

Table 6.4 Important attributes of the anaesthesia contributory deaths (ACDs)

Patient	Type of surgery	ASA grade	Seniority of anaesthetist	Anaesthetic	Time after induction
ACD 1	Congenital cardiac	3	Specialist	General	10 days
ACD 2	Obstetrics	2	Senior registrar	Spinal	>24 hours < 7 days
ACD 3	General surgery	2	Senior registrar	Spinal	Uncertain
ACD 4	Cardiac surgery	3	Specialist	General	7 days

6.3 Discussion

The average rate of AADs for the 5-year period of this study was 1.4 per 10,000 patients, and the average rate of ACDs was 0.4 per 10,000 patients. This is a big improvement from the pilot study, where the ACD rate was 1.06 per 10,000.

From the South African perspective, an ACD rate of 0.4 per 10,000 compares favourably with Harrison's [6 10] and Coetzee's [13] studies in that it is marginally better. In addition, deaths due to anaesthesia in this definitive study were documented without the "24-hour after induction" cut off, that both Harrison and Coetzee used, suggesting that deaths occurring after this 24-hour period were not missed.

I have compared various ACD rates in Table 6.5.

Table 6.5 ACD rates from various studies

Year	Author and country	ACD rate
1987	Lunn; United Kingdom [28 38]	0.05 per 10,000 (1: 185,056)
1977-1987	Harrison; South Africa [6]	0.7 per 10,000 (0.07:1,000)
1987-1990	Coetzee; South Africa [13]	1.1 per 10,000
1999	Lienhart; France [8]	0.12 per 10000
1999	Pilot study of this thesis	1.06 per 10,000
2000-2004	**Present definitive study**	**0.4 per 10,000**

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In the conclusion of one of his publications [6] Harrison states the following: "in the light of observations reported here, which evidence a decrease in the prevalence

of death attributable to anaesthesia (ACD in terms of this thesis) to a level which, having regard for the human frailty is perhaps at an irreducible minimum." In other words, is it possible to eliminate human error from the causes of mortality in anaesthesia? Have we reached this "irreducible minimum", or can the ACD rate improve to that of the CEPOD study [28], which was 0.05 per 10,000 anaesthetics, an almost 10-fold decrease in prevalence on the results demonstrated in this definitive study. This is stated with reservations, as the refusal to cooperate of some of the consultants in the CEPOD study[28] may have skewed the data, rendering the findings inaccurate.

On closer examination of the four anaesthesia contributory deaths (ACDs) in this study, the following is noted:

- Two of the patients were cardiac surgery patients, and were anaesthetised by specialists;
- Two had spinals and two had general anaesthetics;
- All of them were either ASA 2 or 3;
- Three out of the 4 died > 24 hours after the start of the anaesthetic; 2 died at 7 and 10 days respectively. This clearly indicates that if one uses Harrison's definition [6 10-11] of deaths occurring within 24 hours of the induction of anaesthesia, most of these ACDs would not have been documented;
- Two patients had an adverse reaction to an intravenous drug or fluid; one to haemacel® (known to cause anaphylaxis) and the other to heparin;
- One had a known, but treatable complication from a spinal anaesthetic, namely a high spinal;

- One patient was anaesthetised for surgery, but because of the adverse response to the anaesthetic, no surgery was performed;

It is likely that “human error” played a role in some, if not all of these, and at least two of the four had well-known and treatable complications, namely anaphylaxis to haemacel® and a high spinal. In both of these cases the anaesthetic was given by a senior registrar.

As Davies and Strunin commented in 1984[61] “when the problem is due to the anesthetic, most mishaps result from the failure of the anesthetist to recognize or cope with a problem.”

The survey of anaesthesia-related mortality in France by Lienhart et al.[8] in 2006 indicated “root causes” of anaesthesia mortality. The two largest contributors were team factors (communication, supervision and seeking help) and individual staff factors (experience/competence, judgment and analysis).

All of these factors play a role in human error, and some may have played a role in the anaesthesia contributory deaths in this definitive study.

Broad discussion and **Conclusions** will follow in **Chapter 9, and Recommendations** in **Chapter 10.**

CHAPTER 7

MATERNAL DEATHS

7.1 Introduction

During the course of 1997, deaths during pregnancy, childbirth and the puerperium were made notifiable events in South Africa in terms of the National Policy Health Act (number 116 of 1990) of South Africa[59]. This was done in recognition of the need to reduce maternal mortality, which is considered a basic health indicator that reflects the adequacy of healthcare[62]. The exact maternal death rate in South Africa was not known at the time, due to a lack of accurate record-keeping. However, the World Health Organization (WHO) had estimated that almost 600,000 women were dying annually world-wide as a result of pregnancy-related conditions, particularly in the developing world[62].

In South Africa in 1998, the data collected reflected differences in the maternal mortality by population group, which was strongly suggestive of socio-economic differences and differing levels of access to healthcare [36]. The then Minister of Health appointed a National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD), tasked with "making recommendations, based on the confidential study of maternal deaths to the Department of Health, such that the implementation of the recommendations will result in a decrease in the maternal mortality."

The confidential process that occurs after a maternal death is as follows:

- "The facility in which the mother died completes a Maternal Death Notification Form (MDNF) **(Appendix H);**
- This form is sent to the provincial office within 7 days of the maternal death;

- The provincial office forwards the documentation to the Provincial Assessor, who informs the National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD) that a death has occurred;
- The NCCEMD issues a unique file number for the case;
- The Provincial Assessor is responsible for completion of the MDNF;
- The Assessor must provide information on the primary, final and contributory causes of death, and must also establish whether there were avoidable factors, missed opportunities or any other aspect of substandard care present in the maternal death;
- The Assessor must complete and return all documentation to the Province within 30 days:
- All documentation is then forwarded to the NCCEMD for collations and analysis;
- The NCCEMD uses this data to compile reports on maternal deaths in South Africa;
- Once the report is accepted, all data is destroyed, and work begins on the next report."

The confidential enquiries officially began on the 1st December, 1997, with the first report covering deaths that occurred in 1998[36].

Subsequently, there have been three further reports – 1999 to 2001[14], 2002 to 2004[34], and 2005 to 2007[35]. The latter three each cover a triennium, similar to the Confidential Enquiries into Maternal Deaths in the United Kingdom – "*Why*

Mothers Die" (now called "Saving Mothers' Lives") – a process that has been in place for over 50 years[63].

7.1.1 Definitions

The definition of a maternal death is "the death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause related to, or aggravated by, the pregnancy or its management, but not from accidental or incidental causes."[64]

It has been agreed internationally that maternal deaths are either *direct* or *indirect.*

Direct maternal deaths are those resulting from obstetric complications, from peripartum interventions (for example the administration of anaesthesia), omissions, incorrect treatment, or from a chain of events resulting from any of these.

Indirect deaths are those resulting from previous existing disease, or disease that developed during pregnancy, and which was not due to direct obstetric causes, but which was aggravated by the physiologic effects of pregnancy[64].

The WHO [64] has defined the Maternal Mortality Ratio (MMR) as the number of maternal deaths per 100,000 live births. In the United Kingdom, this definition has evolved to the number of maternal deaths per 100,000 **maternities***[65]* .

Maternities are not a measurable denominator in SA, because we do not record the number of antenatal bookings in SA. However, the Department of Home

Affairs registers live births, and the District Health Information System also gathers data on live births, thus providing our denominator.

7.1.2 Maternal Mortality Ratio

In 1952 the Maternal Mortality Ratio (MMR), excluding early pregnancy deaths, was 54/100,000 births for England and Wales[36 66]. It was noted that 49 deaths in this initial report were attributed to anaesthesia [63], and an additional 20 were identified as being "where anaesthesia was contributory". The most recent world estimate of the maternal mortality ratio is approximately 400/100,000 live births[67]. The Safe Motherhood Initiative of the WHO for developing countries has set a target of 124/100,000 live births by 2015. In addition, the United Nations has defined maternal health as one of its Millennium Development Goals. The eight goals, comprising 18 specific targets, were adopted at the United Nations as part of the Millennium Declaration in 2000 [68].

The eight goals are:

- To achieve universal primary education.
- To promote gender equality and empower women.
- To reduce child mortality.
- **To improve maternal health.**
- To eradicate extreme poverty.
- To combat HIV/Aids, malaria and other diseases.
- To ensure environmental sustainability.
- To develop a global partnership for development.

During 1998 in South Africa [36], it was estimated that the MMR was 150/100,000 live births, 12 times higher than that in the United Kingdom[69]. The difficulty with calculating the MMR in South Africa, is the absence of accurate denominator data[36 70].

As discussed in chapter 2, the serious problem with calculating mortality rates is knowing the total number of whatever one is referring to (for example anaesthetics or live births). Even in Australia, an accurate estimate of anaesthetic deaths rate could not be made in the past because total numbers of anaesthetics performed (the denominator) were not known accurately enough [37]. Likewise with calculating the MMR in South Africa, the total number of live births was not, (and is still not), accurately documented.

7.1.3 International statistics

Worldwide, 80% of maternal deaths are due to *direct* obstetric causes and 20% due to *indirect* causes [64]. Interestingly, in the United Kingdom, during the 2000 to 2002 triennium, this ratio was reversed, with *indirect* deaths being higher – psychiatric and cardiac disease topping the list [67]. During the 2003-2005 triennium, cardiac pathology and thrombo-embolism (the latter particularly in relation to obesity) topped the list of causes[71-72].

7.1.4 South African statistics

In South Africa in 1998, 63.3% of deaths were due to *direct* causes and 33.6% from *indirect* causes [36]. The “big five” causes of maternal death were as follows:

- Complications of hypertensive conditions in pregnancy;
- HIVAIDS and non-pregnancy-related infections;

- Obstetric haemorrhage;
- Pregnancy-related sepsis;
- Pre-existing medical conditions, mainly cardiac disease.

Other important causes of death were acute collapse and embolism, as well as anaesthetic complications; the latter comprised 4.8% [36].

During the triennium 1999-2001, there was a change in the pattern of maternal deaths, with AIDS-related illness becoming the leading cause [14]. Anaesthetic-related deaths are quoted as accounting for 3.1% of all the deaths. In the next period, 2002-2004, a total of 3406 maternal deaths was reported[34]. The 5 leading causes of death were listed as:

- non-pregnancy-related infections (predominantly HIV/AIDS-related);
- complications of hypertension;
- obstetric haemorrhage;
- pregnancy-related sepsis;
- pre-existing maternal disease.

2.8% were anaesthetic-related [14], which is very similar to the rate in the previous triennium.

7.2 Anaesthesia associated maternal deaths internationally (AAD_M)

Anaesthesia associated death (defined in Chapter 1 as AAD) is a leading cause of maternal mortality in the United States of America, and also in the United Kingdom, although the absolute numbers of anaesthesia contributory maternal deaths ACD_Ms are very small [66].

7.3 Anaesthesia associated maternal deaths in South Africa

The "Saving Mother" reports do not distinguish very clearly between AAD_Ms and ACD_Ms. Nevertheless, the relevant findings from the reports[14 34 36] are summarised and tabulated in Table 7.1, indicating which maternal death patients received general or regional anaesthesia.

7.3.1 The year 1998[36]

During 1998 in South Africa, there were 28 deaths reviewed in this category[36]. Postmortem revealed an undiagnosed intracardiac tumour in one patient; clearly, this cannot be considered an AAD_M or ACD_M. It would appear that the standard of reporting was poor, supported by the inadequacy of anaesthetic records. In the majority of cases, the reporting was so bad, that the cause of death was frequently ascribed on the basis of probabilities [36]. The majority of deaths occurred in level 1 and 2 "district" (peripheral) hospitals. Anaesthesia was the direct cause (ACD_M) of death in 18 cases. Thirteen out of the 18 received general anaesthesia. In one additional case anaesthetic care was described as "suboptimal". The commonest single factor responsible for death was difficult or failed intubation, resulting in severe hypoxia [36]. There were 5 ACD_Ms associated with spinal anaesthesia.

7.3.2 The triennium 1999-2001[14]

During the triennium 1999-2001, there were 76 AAD_Ms, but only 56 were felt to be ACD_Ms[14]. Of importance is that 32 of the 56 received regional anaesthesia. This is in contrast to the deaths documented in 1998, where a higher percentage of the ACD_Ms had received general anaesthesia [36]. There were 25 deaths directly arising from the complications of regional anaesthesia – all spinal anaesthetics.

The leading cause of deaths in this group was high motor blockade, which was detected late, and managed poorly in many of the cases.

7.3.3 The triennium 2002-2004[34]

During the triennium 2002-2004, there were 3406 maternal deaths, of which there were 91 AAD_MS[34]. Importantly, 72 deaths were assessed by the assessors appointed by the NCCEMD, and 62 were judged to be ACD_Ms.

General anaesthesia was administered in 33 of these ACD_M cases (53%) and spinal anaesthesia in 29 (47%). However, some of the general anaesthetics were administered following either failure of, or complications from, spinal anaesthesia. Therefore the initial method of anaesthesia chosen in this group was spinal in 35 cases (56%) and general anaesthesia in 27 (44%).

Thus, death due to anaesthesia (ACD_M) most commonly followed attempted spinal anaesthesia during this triennium. The principal cause of death in the spinal group was acute cardiovascular collapse. In the general anaesthesia group the principal cause of death was failed or difficult intubation, followed closely by postoperative collapse. Overall, catastrophic collapse following spinal anaesthesia was the single commonest cause of ACD_M, resulting in 26.4% of deaths.

Table 7.1 ACD_M statistics from South Africa[14 34 36] (GA = general anaesthesia; RA = regional anaesthesia)

PROBLEM encountered	GA/RA	1998 N = 18	1999-2001 N = 56	2002-2004 N = 62
Difficult/failed intubation	GA	6	20	18
Aspiration	GA	1	4	3
Inadequate preoperative evaluation	GA	2		
Failure to check equipment	GA	1		
Residual neuromuscular blockade	GA	1	1	
Unknown	GA	2		
Post-operative collapse	GA			5
Intra-operative collapse	GA			4
Equipment failure	GA			3
Inappropriate technique	GA		6	
TOTAL – GA		**13 (72%)**	**31 (55%)**	**33 (53%)**
High motor block	RA	3	21	5
Hypotension/high spinal	RA			15
Hypotension	RA	2	2	6
Intra-operative collapse	RA			1
Post-operative collapse	RA			2
Aspiration	RA		1	
Shock – ruptured uterus	RA		1	
TOTAL – RA		**5 (28%)**	**25 (45%)**	**29 (47%)**

Table 7.2 Deaths related to regional anaesthesia as a % of ACD_Ms for that individual year[14 34 36]

Year	Percentage regional anaesthesia
1998	33%
1999	33%
2000	35%
2001	62%
2002	20%
2003	50%
2004	63%

As can be seen from Table 7.2, in 1998, 1999 and 2000, a third of the mothers who died had been given spinal anaesthetics. This rose to almost two thirds in 2001 and 2004, was only 20% in 2002, and a half of the cases in 2003.

The trend (except for 2002), is in keeping with the anaesthetic trend to administer spinal anaesthesia to patients coming for caesarean section, rather than general anaesthesia, although we do not have denominator figures to substantiate this.

I have illustrated the trend in Figure 7.1. The secular trend from 1998 to 2004 is upwards.

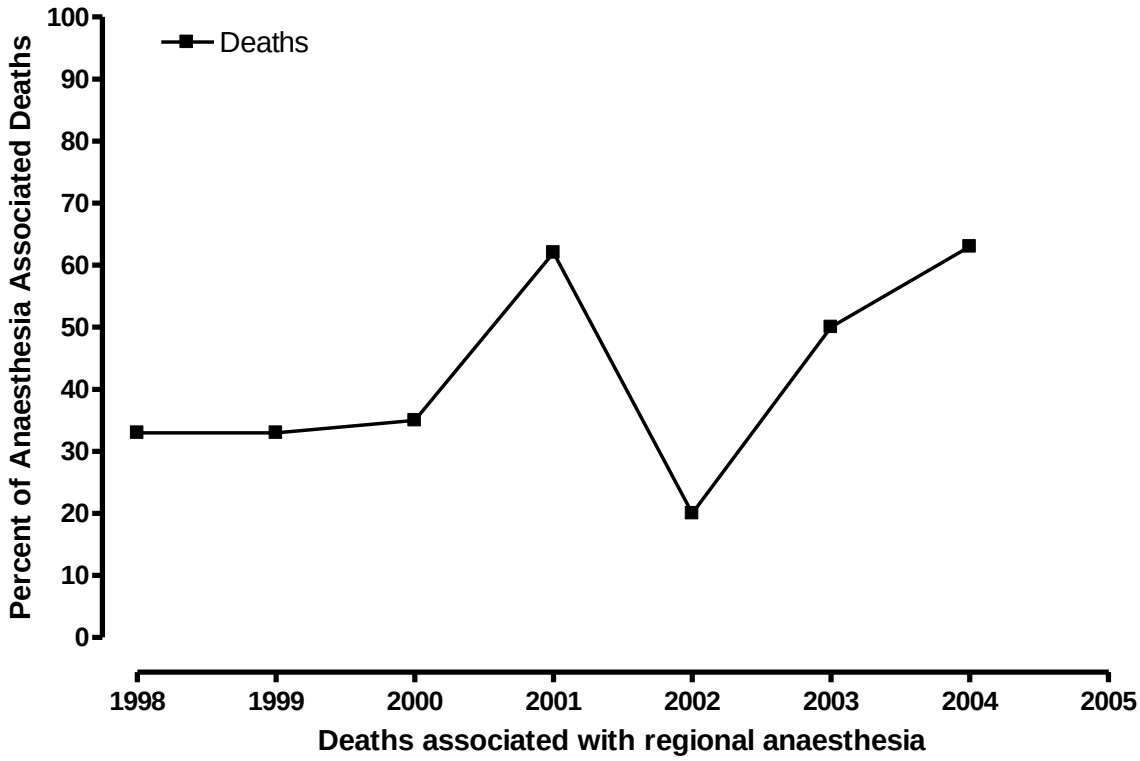


Figure 7.1 The trend of AAD_Ms association with spinal anaesthesia

Recently Lamacraft[73] performed an audit on the training and experience of doctors administering obstetric anaesthesia in level 1 and 2 hospitals in the Free State Province. This was based on the results of the third report on confidential enquiries into Maternal deaths in South Africa, 2002-2004[34], where 12.7% of all maternal deaths occurred in the Free State, and many occurred in level 1 and 2 "district-type" hospitals. Poor anaesthesia skills of practitioners administering anaesthesia at level 1 and 2 hospitals were identified. Lamacraft[73] confirmed this finding at level 1 and 2 hospitals, and identified some of the problems faced by these doctors.

These included:

- Inexperience and a lack of supervision, particularly interns;

- Lack of training and postgraduate qualifications – some of the doctors administering obstetric anaesthesia had never done so before;
- Other duties required while administering obstetric anaesthesia, such as resuscitating the baby.

The purpose of the current definitive study on maternal mortality, and particularly the contribution of anaesthesia to this, was to compare the statistics from Chris Hani Baragwanath Maternity Hospital, a major tertiary obstetric centre with those from South Africa generally during the same study period.

CHAPTER 8

MATERNAL DEATHS AT CHRIS HANI BARAGWANATH MATERNITY HOSPITAL

2000 – 2004

8.1 Introduction

Chris Hani Baragwanath Hospital (CHBH) is a 2880-bed tertiary referral academic hospital, serving Soweto in Southern Johannesburg. The Maternity Unit at CHBH manages in excess of 20,000 deliveries annually, of which approximately 30% are via caesarean section. Owing to inequalities in the district and regional hospitals in the area, the Unit manages parturients requiring all levels of care, not only tertiary care.

8.2 Methodology

All maternal deaths during this period were studied retrospectively. All patient records were recorded anonymously for confidentiality; no names of patients or doctors were documented. The data were collected as described in 4.8.2.

The following data were collected:

- Age;
- HIV status (if known);
- ASA (American Society of Anaesthesiologists) grading;
- Whether an operative procedure was performed and what the procedure was;
- Whether this procedure was an emergency or elective;
- Whether preoperative assessment was performed and whether the patient received a premedication;

- The seniority of the anaesthetist involved in doing the anaesthetic; This is defined as follows:

  A Registrar is a trainee anaesthesiologist;

  A senior registrar is a trainee with a minimum of 2 years of experience and a primary examination for the Fellowship of the College of Anaesthetists;

  A Consultant may be a specialist anaesthetist (anaesthesiologist) or a medical officer with a minimum of 10 years of anaesthetic experience.

- Whether a general or regional anaesthetic was given, and whether there were any complications, for example with the airway or the spinal anaesthetic;
- Whether the anaesthetic record was included with the documentation;
- How soon after the anaesthetic the death occurred;
- Where the patient died (operating theatre, ward, high care or intensive care unit).

The data collection sheet is included as **Appendix E.**

8.3 Results: Descriptive statistics

These will be discussed under the following headings:

1. General CHBH statistics from 2000 to 2004;
2. The HIV status of the mothers who died;
3. The maternal deaths who did not undergo a procedure;
4. The maternal deaths who had a procedure;
5. The anaesthetics that were administered;
6. Types of procedures performed;
7. Adverse events and subsequent deaths.

8.3.1 General CHBMH statistics for the period 2000 to 2004

Deliveries approximate 20,000 plus per year, with a 25-30% caesarean section rate. During this 5-year study period, there were 95,602 deliveries, 91,217 live births >1000grams, 24,718 caesarean sections, and 146 maternal deaths.

This averages out to a caesarean section rate of 27.1% if one uses the figure for live births >1000grams as the denominator. The overall maternal mortality ratio (MMR) is 160/100,000. This is in keeping with the estimated South African national ratio for all levels of hospitals[74]. The statistics for Chris Hani Baragwanath Maternity Hospital are summarised in Table 8.1.

Table 8.1 CHBH Maternity statistics for the period 2000 to 2004

Year	Deliveries (n)	Live births > 1000g (n)	Caesarean section (n)	Caesarean section (%)	Deaths (n)
2000	18,395	17,516	3,940	21.4	27
2001	18,959	17,981	4,732	25.0	29
2002	19,375	18,444	4,945	25.5	35
2003	19,671	18,814	5,370	27.3	26
2004	19,202	18,462	5,731	29.8	29
Totals	95,602	91,217	24,718	27.1	146

8.3.2 HIV status of maternal deaths

The HIV status of the mothers who are died are shown in Table 8.2.

Table 8.2 HIV status of maternal deaths

Year (deaths n)	HIV positive	HIV negative	HIV unknown
2000 (27)	8	5	14
2001 (29)	8	4	17
2002 (35)	13	12	10
2003 (26)	14	3	9
2004 (29)	18	5	6
Total (146)	61	29	56

Several interesting results emerged from this five-year period. In 2000 and 2001, slightly more patients in the maternal death group either had not had their HIV status tested, or did not know it, in comparison with those who knew their status. The year 2002 appears to be a “watershed” year, with almost identical numbers of HIV positive, negative and “unknown”, amongst the maternal deaths, with double the number of patients knowing their HIV status as compared with the “status unknown” group. In 2003 65 % had been tested, and in 2004 this figure rose to 79%. In both years, more than half of the maternal deaths were HIV positive. This period of time coincides with the National Department of Health’s drive to promote antenatal HIV testing, in order to decrease mother-to-child transmission.

8.3.3 Maternal deaths in patients who did not undergo a surgical procedure at Chris Hani Baragwanath Hospital

When the 87 maternal deaths in patients who did not have a surgical procedure at Chris Hani Baragwanath Hospital during this 5-year period were analysed, the following emerged and is tabulated in Table 8.3:

- 20 were due to direct causes, with pregnancy-induced hypertension predominating ;
- 55 were due to indirect causes, largely infective ;
- 12 were of unknown causes.

Table 8.3 Maternal deaths in patients who did not undergo a surgical procedure at Chris Hani Baragwanath Hospital

No procedure Direct	No procedure Indirect	No procedure unknown	Total
20	55	12	87

8.3.4 Maternal deaths in patients who underwent a surgical procedure

As discussed previously and in keeping with Holland's table:

Table 8.4 Definitions used to distinguish between ACD and AAD[27]

Category	Definition
I	When it is reasonably certain that the event or death was caused by the anaesthetic agent or technique of administration or in other ways coming directly within the anaesthetist's province
II	Similar to type I cases, but ones in which there is some element of doubt about whether the agent or technique was entirely responsible for the result
III	Cases in which the patient's adverse event or death was caused by the anaesthetic and the surgical technique
IV	Events entirely referable to surgical technique

Thus categories I, II and III are AADs and category I is an ACD.

The ACDs will therefore form a sub-group of the AADs, and the maternal deaths will be annotated as AAD_M and ACD_M accordingly.

Table 8.5 Maternal deaths in patients who underwent a surgical procedure

Procedure NO anaesthetic	Procedure plus anaesthetic (not AAD_M)	Procedure plus anaesthetic AAD_M	Total
4	45	10	59

8.3.5 Types of anaesthetics given

As is shown in Table 8.5 and Figure 8.1, fifty-nine (59) of the patients who died (40%) underwent a procedure (in most cases either a caesarean section, or a hysterectomy following a caesarean section), for which **55 received an anaesthetic**. Forty-two were general anaesthetics (76%); 12 were spinals (21.4%), four of which were subsequently converted to general anaesthetics. One was not specified in the record-keeping, and four perimortem caesarean sections were performed after the patients had suffered a witnessed cardiac arrest, with no anaesthesia having been administered. This was performed as part of the resuscitation in order to attempt to save the mother's life.

During the 5-year study period, there was no labour epidural analgesia service at the hospital, so there were no deaths attributable to anaesthesia, where no surgical procedure was performed.

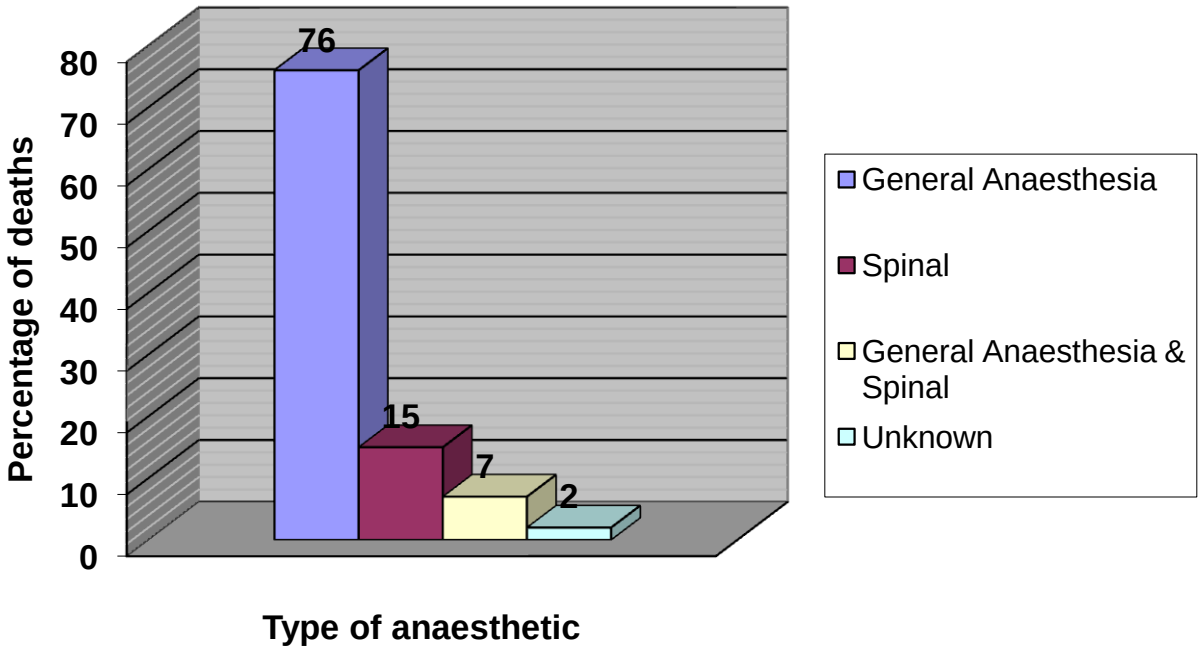


Figure 8.1 Bar chart of types of anaesthetic (%) administered to the women who died (n = 55)

Other features of the anaesthesia administered to these patients were:

- Eighty-one per cent of patients were not seen in the ward preoperatively, which is in keeping with the finding that 97% were emergencies;
- Fifty-seven percent of anaesthetics occurred during the day and the remainder at night;
- Eighty-one per cent of these patients had their tracheas intubated with an endotracheal tube, 70% utilizing the rapid sequence induction technique. There were no airway complications documented at any stage, in any of these patients;
- Anaesthetic records were available in 81% of the cases; in the remaining 19% it was not known whether records had not been kept, or whether they had been misplaced.;

- ASA grading and seniority of anaesthetist: The grading of patients, according to the American Society of Anesthesiologists Physical Status Grading, and the seniority and experience of the anaesthetists involved in these cases is illustrated, in Figure 8.2

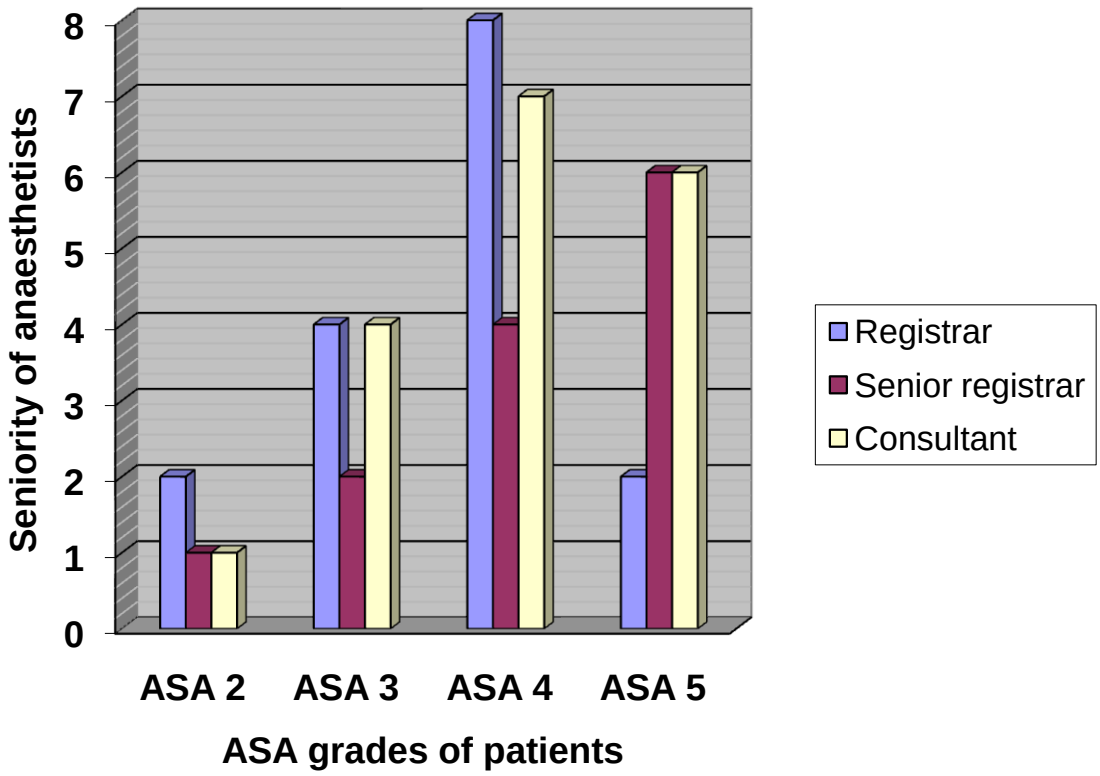


Figure 8.2 Bar chart of ASA grades of patients (n) and seniority of anaesthetists

Registrar = a trainee anaesthesiologist

Senior registrar = a trainee with a minimum of 2 years of experience and a primary examination for the Fellowship of the College of Anaesthetists

Consultant = this may be a specialist anaesthetist (anaesthesiologist) or a medical officer with a minimum of 10 years of anaesthetic experience

When the numbers shown in the bar chart are expressed as a percentage of the mothers who died, a very small percentage (7%) of these patients were ASA grade 2; 22% were ASA 3; 39% were ASA 4 and 30% ASA 5. Thus, the majority

(69%) were classified either as having severe systemic disease that is a constant threat to life and functionally incapacitating, or as moribund. (2% were ASA 1).

Previous studies of anaesthetic associated mortality in South Africa and internationally have recommended that ASA 4 and 5 patients should be anaesthetised by a specialist anaesthetist. No such recommendation has been made in the context of the Confidential Enquiries into Maternal Deaths in South Africa[14 34-36]. In this study, 38% of deaths occurred in the hands of a consultant; 28% involved a senior registrar, and 34% of deaths occurred when a registrar gave the anaesthetic. Of concern, however, is that registrars played a large role in anaesthetising ASA 4 patients, which is not in keeping with previous national and international recommendations[8 11 28]

8.3.6 Types of procedures performed on the 59 maternal deaths:

Of the 59 women whose death was associated with a surgical procedure, the majority (97%) were emergencies. The classes of AAD are illustrated in Table 8.6.

Table 8.6 AAD_M class of death associated with surgery

Class of AAD_M	Numbers of deaths associated with surgery
I, II, III	10
IV	49

The distribution of procedures is shown in Figure 8.3.

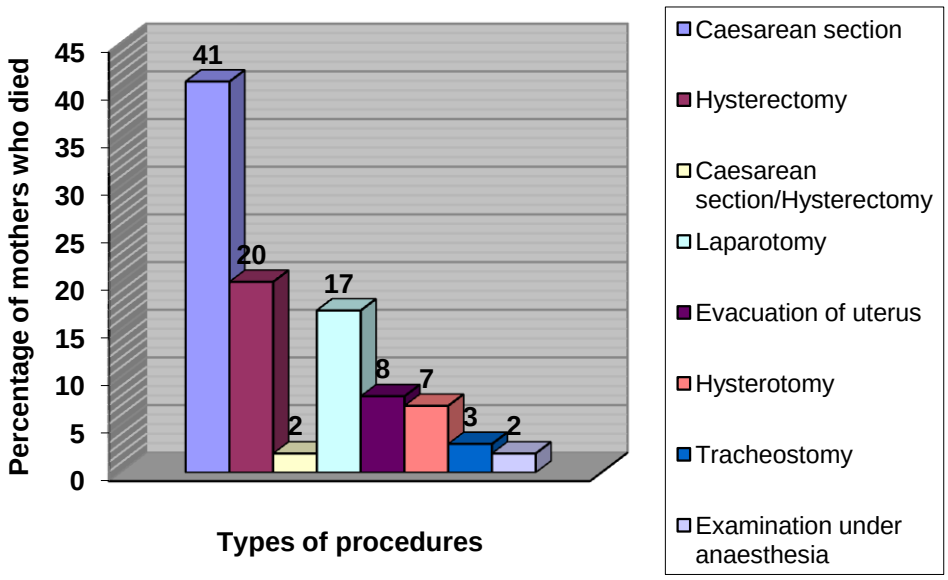


Figure 8.3 The percentage distribution of the types of procedures in mothers who died (n=59)

8.3.7 Adverse events and subsequent deaths

Almost half (48%) of the adverse events with subsequent patient death occurred within 24 hours of the anaesthetic; 39% occurred after the first 24 hours and up to 7 days after commencement of the anaesthetic; the remaining 13% died after 7 days but within 30 days of the anaesthetic.

The breakdown of where the deaths occurred for the 59 patients is as follows:

- 13% Operating theatre
- 13% Intensive care unit
- 42% High care unit
- 32% Postnatal ward

Thus 74% of deaths occurred in the high care unit and postnatal ward, which is of concern, and needs to be investigated, particularly to establish whether these two facilities have sufficient equipment and nursing.

8.4 Results – Analytical statistics

In this section three variables were chosen as factors of clinical importance regarding the 59 peri-operative deaths, namely:

- ASA status;
- Doctor (registrar, senior registrar, consultant, no anaesthetic);
- Where the patient died (operating theatre, intensive care unit, high care or ward).

The cross tabulations of each of the three variables will be shown in turn, followed by a listing of variables for which statistical significance was found or not, either by means of the chi square test or Fisher exact test. After this, there will be a summary table showing the actual probability values for each testing.

8.4.1 ASA

Table 8.7 ASA by category of doctor (data on 2 are missing)

ASA frequency	Registrar	Senior registrar	Consultant	No anaesthetic	Total
1	0	0	1	0	1
2	2	1	1	0	4
3	4	3	5	0	12
4	10	4	9	0	23
5	4	6	6	1	17
Total	20	14	22	1	57

Table 8.8 ASA by type of anaesthetic (data on 2 are missing)

ASA frequency	General anaesthetic	No anaesthetic	Spinal anaesthetic	Total
1	0	0	1	1
2	1	0	3	4
3	8	0	4	12
4	20	0	3	23
5	13	3	1	17
Total	42	3	12	57

Table 8.9 ASA by endotracheal tube (data on 2 are missing)

ASA frequency	Endotracheal tube	No endotracheal tube	Total
1	0	1	1
2	2	2	4
3	9	2	11
4	21	2	23
5	14	4	18
Total	46	11	57

Table 8.10 ASA by availability of anaesthetic record (data on 2 are missing)

ASA frequency	Anaesthetic record No	Anaesthetic record Yes	Total
1	0	1	1
2	0	4	4
3	3	10	13
4	3	20	23
5	5	11	16
Total	11	46	57

Table 8.11 ASA by when the adverse event occurred (data on 3 are missing)

ASA frequency	< 24 hours	< 7 days	< 30 days	Total
1	0	1	0	1
2	2	2	0	4
3	2	8	3	13
4	14	5	4	23
5	9	6	0	15
Total	27	22	7	56

Table 8.12 ASA by day or night (data on 19 are missing)

ASA frequency	Day	Night	Total
1	1	0	1
2	2	2	4
3	3	3	6
4	9	7	16
5	8	5	13
Total	23	17	40

Table 8.13 ASA by where the patients died (data on 4 are missing)

ASA frequency	Operating theatre	Intensive Care	High care	Ward	Total
1	0	0	0	1	1
2	1	0	0	3	4
3	1	1	4	6	12
4	2	5	7	7	21
5	3	1	12	1	17
Total	7	7	23	18	55

Table 8.14 ASA by HIV status (data on 22 are missing)

ASA Frequency	HIV negative	HIV positive	Total
1	0	1	1
2	0	2	2
3	4	5	9
4	6	8	14
5	7	4	11
Total	17	20	37

Table 8.15 ASA by elective surgery or not

ASA frequency	No	Yes	Total
1	1	0	1
2	3	1	4
3	12	1	13
4	23	0	23
5	18	0	18
Total	57	2	59

Statistical significance (as indicated in Table 8.27) was achieved when ASA was compared with:

- Type of anaesthetic administered.

BUT not with the category of doctor, the airway used, the availability of an anaesthetic record, when the adverse event occurred, whether the patient was done during the day or night, where the patient died, the HIV status, and whether the case was elective or not.

8.4.2 Category of doctor

Table 8.16 Doctor by type of anaesthetic (data on 2 are missing)

Doctor frequency	General anaesthetic	No anaesthetic	Spinal anaesthetic	Total
Registrar	16	1	3	20
Senior registrar	9	1	4	14
Consultant	17	0	5	22
No anaesthetic	0	1	0	1
Total	42	3	12	57

Table 8.17 Doctor by endotracheal tube (data on 3 are missing)

Doctor frequency	Endotracheal tube	No endotracheal tube	Total
Registrar	16	3	19
Senior registrar	10	4	14
Consultant	20	2	22
No anaesthetic	0	1	1
Total	46	10	56

Table 8.18 Doctor by availability of anaesthetic record (data are missing on 4)

Doctor frequency	Anaesthetic record No	Anaesthetic record Yes	Total
Registrar	2	18	20
Senior registrar	2	11	13
Consultant	5	17	22
No anaesthetic	1	0	1
Total	10	46	56

Table 8.19 Doctor by when the adverse event occurred (data on 4 are missing)

Doctor frequency	< 24 hours	< 7 days	< 30 days	Total
Registrar	7	11	1	19
Senior registrar	10	3	0	13
Consultant	9	7	6	22
No anaesthetic	1	0	0	1
Total	27	21	7	55

Table 8.20 Doctor by day or night (data on 19 are missing)

Doctor frequency	Day	Night	Total
Registrar	7	6	13
Senior registrar	5	7	12
Consultant	10	4	14
No anaesthetic	1	0	1
Total	23	17	40

Table 8.21 Doctor by where the patients died (data on 6 are missing)

Doctor frequency	Operating theatre	Intensive Care	High care	Ward	Total
Registrar	2	2	8	7	19
Senior registrar	1	0	6	5	12
Consultant	2	5	9	5	21
No anaesthetic	1	0	0	0	1
Total	6	7	23	17	53

Table 8.22 Doctor by HIV status (data on 24 missing)

Doctor frequency	HIV negative	HIV positive	Total
Registrar	8	7	15
Senior registrar	4	5	9
Consultant	5	5	10
No anaesthetic	0	1	1
Total	17	18	35

Table 8.23 Doctor by elective surgery or not (data on 2 are missing)

Doctor frequency	No	Yes	Total
Registrar	20	0	20
Senior registrar	13	1	14
Consultant	21	1	22
No anaesthetic	1	0	1
Total	55	2	57

Statistical significance (as indicated in Table 8.27) was achieved when the category of doctor was compared with:

- The type of anaesthetic administered.

BUT not with the airway used, the availability of an anaesthetic record, when the adverse event occurred, whether the patient was done during the day or night, where the patient died, the HIV status, and whether the case was elective or not.

8.4.3 Where the patients died

Table 8.24 Where the patients died by endotracheal tube (data on 6 are missing)

Where died	Endotracheal tube	No endotracheal tube	Total
Operating theatre	5	2	7
Intensive care	7	0	7
High care	20	2	22
Ward	10	7	17
Total	42	11	53

Table 8.25 Where the patients died by HIV status (data on 24 are missing)

Where died	HIV negative	HIV positive	Total
Operating theatre	2	2	4
Intensive care	2	0	2
High care	11	5	16
Ward	1	12	13
Total	16	19	35

Table 8.26 Where the patients died by elective surgery or not (data on 4 are missing)

Where died	No	Yes	Total
Operating theatre	7	0	7
Intensive care	7	0	7
High care	23	0	23
Ward	17	1	18
Total	54	1	55

Statistical significance (as indicated in Table 8.27) was achieved when ‘where the patients died’ was compared with:

- HIV status

BUT not when compared with the airway used, nor whether the case was elective or not.

Table 8.27 Analytical statistics summary table of chi-square and Fisher exact test results. (* = statistically significant)

Variable	Chi-square P	Fisher exact test P
ASA		
Doctor (consultant, senior registrar, registrar, none)	0.8674	
Type of anaesthetic	0.0056*	
Endotracheal tube (yes or no)	0.0789	
Anaesthetic record	0.4995	
Adverse event (<24hrs; < 7 days; < 30 days)		0.0400*
Day or night	0.8996	
Where died (OT; ICU; high care; ward)		0.0275
HIV status (positive or negative)	0.4063	
Elective or not	0.0948	
Doctor (registrar, senior registrar, consultant, none)		
Type of anaesthetic	0.0024*	
Endotracheal tube (yes or no)	0.0750	
Anaesthetic record	0.1191	
Adverse event (<24hrs; < 7 days; > 30 days)	0.0421	
Day or night	0.3687	
Where died (OT; ICU; high care; ward)	0.1851	
HIV status (positive or negative)	0.7650	
Elective or not	0.7103	
Where the patients died (OT; ICU; high care; ward)		
Endotracheal tube (yes or no)	0.0416	
HIV status (positive or negative)	0.0038*	
Elective or not	0.5532	

8.5 Anaesthesia Associated Deaths

For the purposes of the discussion of AAD_Ms and ACD_Ms at CHBH, these deaths have all been pooled.

Table 8.28 CHBH maternal deaths in patients who received an anaesthetic by study year

	2000	2001	2002	2003	2004	Total
Number of deaths (n)	15	12	12	8	8	55
AAD_M	5	3	1	1	0	10
Not AAD_M	10	9	11	7	8	45

As can be seen from Table 8.28, ten out of the 55 deaths in patients who received an anaesthetic were classified as AAD_Ms.

If one uses the total number of caesarean sections performed at CHBH per study year as the denominator, the prevalence of maternal deaths per 10,000 caesarean sections per year ranges widely over the 5-year period, but averages at 4.0 per 10,000 caesarean sections, as is shown in Table 8.29.

Table 8.29 AAD_M rate per 10000 using caesarean sections as the denominator

Year	2000	2001	2002	2003	2004	Total
AAD_M	5	3	1	1	0	10
Caesarean sections	3940	4732	4945	5370	5731	24718
AAD_M per 10,000 caesarean sections	12.7	6.3	2.0	1.7	0	4.0

Table 8.30 shows that most of these deaths (7 out of 10) occurred within 24 hours of the start of anaesthesia; 2 occurred within a week, and one within 30 days.

Table 8.30 CHBH maternal deaths and when they died in relation to the anaesthetic, by study year

Time of death after anaesthetic	2000	2001	2002	2003	2004	Total
Numbers	5	3	1	1	0	10
<24 hours	4	2	0	1	0	7
>24 hours; < 7days	0	1 **ACD_M**	1	0	0	2
>7days; <30days	1	0	0	0	0	1

After studying the anaesthetic management of these 10 patients, only one can be considered as being completely attributable to the anaesthetic (ACD). This was an anaesthetic given for a caesarean section. This equates to an "anaesthetic contributory death rate" of **0.4:10,000** (1: 24,718) caesarean sections at Chris Hani Baragwanath Hospital over this 5-year period.

In the 2000-2002 *Why Mothers Die* [74] published in the United Kingdom (UK) in 2004, the risk of a maternal death was quoted as 1:20,000 general anaesthetics. The prevalence at CHBH of 0.4:10,000 is for both general and spinal anaesthesia, but is a very similar rate to that quoted in the UK study.

Six of the 10 AAD_Ms that occurred during this 5-year period were due to bleeding. The injuries that caused the bleeding were pregnancy-induced, and not caused by the surgeon. The management of bleeding in the post partum context is not always managed very well, either by the anaesthetist or by the surgeon, thus I have termed them AAD_Ms, as it is difficult to determine whether surgery or

anaesthesia was responsible for the patients' deaths. All of these patients died within 24 hours of the start of anaesthesia.

There were 3 patients who died within 7 days of the start of anaesthesia.

- One was the ACD_M, who will be discussed in detail later.
- There was a morbidly obese parturient, who presented in labour at term for a caesarean section. She was given a spinal anaesthetic, and collapsed an hour later and was unresuscitatable. It is not clear if this was due to the spinal, or a complication such as an embolus, thus I have termed it an AAD_M.
- The other AAD_M in this group is a parturient who presented in labour at 38 weeks of gestation with foetal distress. She is documented as being a "cardiac" patient with mild mitral and aortic regurgitation previously, but had defaulted from antenatal clinic. She was given a spinal anaesthetic, which appeared to be uneventful. Two days later she collapsed and was found to have a dilated cardiomyopathy with severe left ventricular dysfunction (ejection fraction 20%). She was unresuscitatable. It is of concern that this lady's deteriorated cardiac pathology was possibly missed by the anaesthetist. I have thus also called her an AAD_M.

One AAD_M died 30 days after the start of the anaesthetic. Her death is considered an AAD_M, as there were numerous "glitches" in her management, which could attribute her death to either surgery or anaesthesia; these included an incompatible blood transfusion, accidental extubation en route to the intensive care unit and others. She died of multi-organ failure.

The ACD_M at CHBH

The single anaesthetic contributory death during this 5-year period occurred in a patient who was admitted for emergency caesarean section for macrosomia. She was graded as an ASA 3E and a specialist anaesthetist administered the anaesthetic. The patient gave a history of a previously abnormal glucose tolerance test, with a glycosylated haemoglobin level of 8,6mmol/l.

She was intravenously preloaded with 500ml of normal saline. A spinal anaesthetic was administered in the L3/4 interspace. On positioning her for the caesarean section with a left lateral tilt, she became hypotensive and distressed. Vasopressors were administered with minimal effect, and the anaesthetic was converted to a general anaesthetic. On endotracheal intubation she was found to have frank pulmonary oedema, which was treated with furosemide. She suffered a short period of asystole, which reverted to sinus rhythm after chest compressions were administered. A baby with an APGAR of 9/10 was delivered.

The patient was resuscitated and appeared to respond favourably, although she still required ventilation and inotropes. She was admitted to the intensive care unit, where she developed numerous complications over a short period of time. These included a severe metabolic acidosis, thrombocytopenia, acute respiratory distress syndrome and acute renal failure. She died two days later of multiorgan failure.

Postmortems

There was no information available on the postmortems done on any of the maternal deaths studied. Thus no accurate information can be given on the

causes of death in the 59 patients who had procedures. Nevertheless, after studying their records, the following observations can be made:

- There were more direct deaths than indirect, with hypertension (and its complications) and pregnancy-related sepsis predominating;
- There were 9 patients who died from non-pregnancy related infection, and 9 “unknowns”.

8.6 Discussion

Maternal deaths at Chris Hani Baragwanath Hospital in relation to provincial and national statistics

If one looks more closely at the South African 2002-2004 “Saving Mothers” statistics[34], 669 (19.6%) of all maternal deaths were documented in the Province of Gauteng. The majority occurred at level 1 and 2 peripheral (district-type) hospitals, but there was still a meaningful number at tertiary hospitals, such as CHBMH, where 90 deaths were recorded.

As can be seen from Table 8.31, none of these 90 deaths were anaesthesia contributory deaths.

Table 8.31 Maternal deaths (%) at CHBH compared with South African national averages

Types of deaths	RSA 1998 Saving Mothers [36]	RSA 1999-2001 Saving Mothers [14]	RSA 2002-2004 Saving Mothers [34]	CHBH 2002-2004 Present study	CHBH 2000 & 2001 Present study	CMJAH 2000/2001 Kruger's study[75]
Direct deaths (excluding ACD_M)	58.6	56.7	50.9	38.9	54.7	42.8
ACD_M	4.8	3.1	2.7	0	0.7	0
Indirect deaths	33.4	38.4	43.4	48.9	25.0	57.2 (HIV associated deaths 45.7; other 11.5)
Not classifiable	3.2	1.8	3.0	12.2	19.6	

RSA = Republic of South Africa

As has been previously mentioned, in 1998 in South Africa, there were almost twice as many direct deaths as indirect deaths (63:33) [36], with an important proportion of ACD_Ms amongst the direct deaths.

The direct: indirect ratio was maintained nationally in 1999-2001 (60:38) [14], and also at CHBH in 2000-2001 (55:25), with the ACD_M percentage decreasing. During this same time period (2000-2001),Kruger[75] found a different ratio at the Johannesburg Hospital, in that there were more indirect causes of maternal death than direct causes. (57:43).

This large increase in indirect deaths was attributable to HIV-associated illnesses. The 2002-2004 Saving Mothers report[34] showed a change in the ratio, in that the

proportion of indirect causes increased, almost approaching the same number of direct deaths.

At CHBH during this same time period (2002-2004), the number of indirect deaths also increased, and overtook the number of direct deaths, as was documented at Johannesburg Hospital in Kruger's study[75] 2 years earlier. This trend has followed nationally; the 2005-2007 Saving Mothers report[35] shows an increase in indirect deaths with a ratio to direct deaths of 48:46. Almost half of these indirect deaths are associated with HIV/AIDS.

Since 2001 the percentage of ACD_Ms has remained almost constant nationally at 3-5%, and at CHBH the prevalence was very low (0.7%) for the period of this study.

Broad discussion and **Conclusions** will follow in **Chapter 9** and **Recommendations** in **Chapter 10**.

CHAPTER 9

DISCUSSION and CONCLUSIONS

The two definitive studies that comprise this thesis generate the following discussion and conclusions.

9.1 Problems inherent in studying anaesthesia-related risk and mortality (death)

The types of studies that one can perform are:

- Prospective cohort studies, in which patients developing an outcome are studied, and in the case of death, the cause of mortality can be surmised. This is not always feasible in our environment in South Africa, mainly due to the fact that although the reporting of unnatural deaths is compulsory by law, many colleagues are still under the impression that in the case of peri-operative deaths it is voluntary. In addition, family members of the deceased are also not well informed about the law, and feel they have a right to refuse a medicolegal course. Thus the collection of data is erratic and incomplete;
- Retrospective studies, such as this current one, which involve identification of patients who have sustained an outcome, followed by defining the risk factors associated with this outcome. Problems often arise in these types of studies due to “missing” information. This is a drawback of this current study, as evidenced by the lack of anaesthetic records in one third of the study cases.

Both types of studies are subject to several biases. These may involve the patient group/s studied, measurement bias, as well as interpretation (of the AADs and ACDs in this case) bias.

The biggest problem with peri-operative mortality studies, is that the time frame varies in which a death can be attributed to the procedure and the delivery of anaesthesia. Numerous audits have been published, within which the time frames vary, from within 24 hours, to 30 days post procedure.

The law in South Africa does not state a time limit for recovery from anaesthesia, in order to consider the death of a patient as an “anaesthetic death”. Harrison’s audit[6 10-11] defined an anaesthetic death as being within the first 24 hours of an anaesthetic, and many anaesthesiologists and anaesthetists in South Africa have assumed that this is the legal definition, when in fact it is not.

Therefore, there is a high likelihood of under-reporting of anaesthesia associated and contributory deaths. To what extent this has occurred in the statistics obtained for this thesis is difficult to estimate, although I feel reassured by the fact that the morticians at the CMJAH were meticulous in following up with documentation on all unnatural deaths during the time frame of both the pilot and definitive studies in this thesis. They were essentially the “gate-keepers” of the documentation process. This attention to detail by the mortuary staff needs to be inculcated throughout the country.

9.2 Charlotte Maxeke Johannesburg Academic Hospital

The anaesthesia contributory death (ACD) rate of 0.4 per 10,000 during the definitive study is an improvement on the figures of 1.06 per 10,000 from the pilot study in this thesis, (performed in 1999) as well as previous South African studies[6] [10] [13], all of which took place at academic hospitals.

The issue of human error and the role that this played in the ACDs in this study needs to be examined in closer detail in the context of an academic hospital.

When one scrutinizes the analytical statistics (table 5.53) from CMJAH the following conclusions can be drawn from the variables documented:

- There is a statistically significant relationship between ASA and the following variables:
    - Pre-operative workup;
    - The category of doctor;
    - Whether an anaesthetic was administered or not;
    - Whether a rapid sequence induction was performed;
    - When the adverse event occurred;
    - When the patient died in relation to the start of the anaesthetic;
    - Where the patient died (operating theatre, intensive care unit or the ward);
    - The surgical category;
    - Whether there was trauma or not.

These are clinically significant EXCEPT for the rapid sequence induction, and it is surprising that the presence of an anaesthetic record was not significant.

- There is a statistically significant relationship between the category of doctor (registrar, senior registrar, specialist) and the following variables:
  - Whether an anaesthetic was administered or not;
  - The presence of an anaesthetic record;
  - When the adverse event occurred;
  - The surgical category;
  - Whether there was trauma or not.

  These are also clinically significant. When and where the patient died are not statistically significant in relation to the category of doctor; neither are they clinically significant.

- There is a statistically significant relationship between whether an anaesthetic was given or not and the following variables:
  - Where the patient died (operating theatre, intensive care unit or the ward);
  - The surgical category;

  These are also clinically significant. Surprisingly, the presence of an anaesthetic record and when the adverse event occurred are clinically significant, but not statistically so.

- With regard to the presence of an anaesthetic record, the only statistically significant variable is the surgical category. This is also clinically significant, as are when the adverse event occurred and where the patient died. The latter are not statistically significant.

- There is a statistically significant relationship between when the adverse event occurred and the following:
  - Where the patient died (operating theatre, intensive care unit or the ward);
  - The surgical category.

  These variables are also clinically significant. Of interest is the fact that when the patient died is not statistically significant in relation to the timing of the adverse event.

- There is statistical significance between when and where the patient died, which is not surprising. The surgical category is also statistically significant in relation to when the patient died, which is also clinically significant.

- There is a statistically significant relationship between where the patient died and the surgical category, including whether there was trauma or not. This is also clinically significant.

In terms of the objectives of this study, the following conclusions can be drawn:

- Recommendations are required in terms of the current legislation and the interpretation thereof. It is necessary to specify the exact procedure that

needs to be followed with a peri-operative death, as occurs with a maternal death (section 7.1). Details will be discussed in **Chapter 10.**

- It was not possible to accurately determine the causes of the ACDs in this study, as the postmortem findings could not be correlated with the complications that occurred during anaesthesia, due to the information systems in place at the time of the study.

- Identification of possible risk factors revealed the following:
  - ACDs occurred with specialists and senior registrars, so seniority did not have an impact;
  - The ACDs were ASA 2 and 3 patients, as opposed to really sick and moribund ASA 4 and 5 patients;
  - All of the necessary anaesthetic equipment was available for all cases;
  - The type of anaesthetic (neuraxial block or general anaesthetic) made no difference to the outcome.

- Anaesthetic record keeping was poor at CMJAH, and did not form part of the AAD and ACD documentation in many cases (33%). Registrars and senior registrars were the worst offenders, possibly due to ignorance, lack of insight or inexperience.

- There does not appear to have been regular, structured peer review on the cases at the time. If there was, it has not been recorded.

9.3 Chris Hani Baragwanath Maternity Hospital

- The change in the ratio of direct deaths to indirect deaths at CHBH preceded the national trend; during the second half of the 5 years studied (2002-2004), more maternal deaths at CHBH were from indirect causes than direct causes. A similar finding was made at Johannesburg Hospital (CMJAH) in 2000-2001;
- This ratio change is in keeping with a similar trend in the United Kingdom (UK), where indirect deaths were higher. The major difference is that in the UK the major indirect causes were psychiatric and cardiac disease (in 2000-2002), and cardiac pathology and thrombo-embolism in the triennium 2003-2005;
- In South Africa the major indirect cause was non-pregnancy related infections, half of which were HIV and AIDS-related;
- Similarly, at CHBH the major indirect cause was non-pregnancy-related infections.

When one scrutinizes the analytical statistics (Table 8.26) from CHBH Maternity the following conclusions can be drawn from the variables documented:

- There is a statistically significant relationship between ASA and the following variables:
    - The type of anaesthetic administered, which makes clinical sense;
    - The timing of the adverse event (<24hrs; < 7 days; < 30 days). This is also clinically significant.

- There is a statistically significant relationship between the category and presence of a doctor (registrar, senior registrar, consultant, and no doctor) and the type of anaesthetic administered. This is also clinically significant.

- There is statistical significance between where the patient died and the HIV status, which is very interesting, and clinically significant.

In term of the objectives of this study, the following conclusions can be drawn:

- The number of ACD_Ms that occurred at CHBH during the study period was much lower than the national average. Proposed reasons for this are:
  - CHBH is a tertiary teaching hospital and the department of anaesthesia runs a consultant-based anaesthetic service during the day and night;
  - All the necessary anaesthetic equipment is available in theatre;
  - Fifty-seven percent of the patients who died were operated on during the day when there are more staff on duty to help with preoperative work-up of the patient, as well as resuscitation where necessary;
  - The anaesthetic record charts indicate that patients were adequately resuscitated preoperatively, where necessary.

- The number of AAD_Ms due to bleeding is high. This is usually a joint responsibility between the surgeon and anaesthetist, and careful revision of protocols needs to be performed on a regular basis to ensure good teamwork in managing this complex problem;

- Three out of 7 AAD_Ms died after the “24-hour” cut-off, as suggested by Harrison [6 10-11]. One of them is the patient classified by as an ACD_M. This is in keeping with the findings in both the pilot study, and the definitive studies in this thesis.

9.4 Lessons from other countries

9.4.1 Australia

Various states in Australia have successfully collected and collated anaesthetic mortality statistics for over 50 years (see section **2.1.2**). Since the 1980’s this has been collected by each state, but collated on a national basis by a National Working Group on a triennial basis. *(Gibbs N, Personal Communication)*. This appears to be a similar process to the National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD) process in South Africa.

9.4.2 United Kingdom

In the United Kingdom the National Confidential Enquiries into Patient Outcomes and Deaths (NCEPOD) process has been in place since the 1980’s. This entails the confidential reporting of patient outcomes, including deaths, and including peri-operative deaths. Recommendations are made and implemented by hospital administrators responsible for clinical governance, and as can be seen from section 2.1.3 important recommendations pertaining to the practice of anaesthesia are made every year.

The Australian system of collection of data by each State, with central national collation and reporting, appears to be a system that could be adopted in South Africa, as the NCCEMD is already in place.

CHAPTER 10

RECOMMENDATIONS

I have drawn up recommendations based on the findings of the studies in this thesis, as well as my reading, and the recommendations made in other parts of the world.

Review of the ACDs and AADs that have been documented in Europe, North America and Australia previously, indicates the following:

- There needs to be an accurate internationally agreed definition of anaesthesia contributory death, and anaesthesia associated death, particularly the length of time in question, from the induction of anaesthesia;
- Anaesthesia represents a small but important cause of peri-operative mortality, particularly when it occurs in fit, healthy ASA 1 and 2 patients;
- It is difficult to compare studies, as definitions and time periods vary. The ACD rate varies from 0.05 to 0.7:10,000 anaesthetics;
- Accurate denominator figures still pose a problem in some areas;
- Specialists must be involved when ASA 4 and 5 patients are anaesthetised;
- Regular peer review must take place in all units where anaesthesia is administered.

Points that emerged from reviewing the South African literature, add the following:

- The ACD rate has improved since 1931, when the combined ACD and AAD rate was documented as being 1.57:1,000 (15.7:10,000). However, anaesthesia has changed dramatically in the past 70 plus years;
- Anaesthetics should be given by specialists in ASA 4 and 5 patients;
- Denominator figures are not accurate.

10.1 Peri-operative Deaths, Anaesthesia Associated Deaths and Anaesthesia Contributory Deaths

10.1.1 National:

The following definitions are suggested for consideration and possible adoption by the Department of Health:

- An **anaesthesia associated death** (AAD) is a death occurring after the induction of a general or regional anaesthetic, or after the failure of a patient, conscious before, to regain consciousness after anaesthesia, regardless of the time that has elapsed since the start of the anaesthetic.
- An **anaesthetic contributory death** (ACD) is a similar death, but due solely to the anaesthetic.

The ACDs will therefore form a sub-group of the AADs.

All doctors and nurses who work in operating theatres need to be made aware of the law, and that all unnatural (peri-operative) deaths **must** be reported[76], regardless of

the sentiments of the medical team and/or the next of kin. This is clearly stated in the Health Professions Act and the amendment thereof, as well as the Inquests Act[32-33 76] as follows:

"*Death of person [whilst under the influence of a general anaesthetic or local anaesthetic, or of which the administration of an anaesthetic] undergoing procedure of therapeutic, diagnostic or palliative nature or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquests Act, 1959 (Act 58 of 1959), or the Births, Marriages and Deaths Registration Act, 1963 (Act 81 of 1963)****".***

This same group of medical personnel needs to be instructed to the effect that all unnatural deaths must be reported, **regardless of the length of time that has elapsed since the administration of the anaesthetic.** As can be seen from the above excerpt from the Health Professions Amendment Act of 2007[33] and the relevant section from the Inquests Act[76] as follows: **"***any person who has reason to believe that any other person has died and that death was due to other than natural causes, shall as soon as possible report accordingly to a policeman, unless he has reason to believe that a report has been or will be made by any other person****".*** Note that no mention is made of any kind of time period.

In addition, mortuary staff need to be trained in the required processes and documentation, as this could provide a “gate-keeping” function, ensuring the reporting of cases with the correct documentation.

The process to be followed needs to be along similar lines to that involved in reporting maternal deaths (discussed in **7.1**).

Similarly, as with the process involved in the reporting of maternal deaths, it would be ideal if the Department of Health made the reporting of all AADs and ACDs compulsory, and a confidential enquiry into groups of deaths was held along similar lines as used by The National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD). Carefully selected assessors would be required to determine which deaths are AADs and ACDS. As a result of this process, recommendations along the lines of NCEPOD[39] will be made, with consequent improvement in healthcare. The necessary structures would need to be put into place by the Minister of Health.

My recommendation is as follows:

- The facility in which the patient died must complete a Peri-operative Death Notification Form (this will need to be designed)**;**
- This form should be sent to the (peri-operative deaths) provincial office within 7 days of the peri-operative death;

- This office should forward the documentation to the (peri-operative deaths) Provincial Assessor, who would then inform the National Committee on Confidential Enquiries into Peri-operative Deaths that a death has occurred;
- This Committee would then issue a unique file number for the case;
- The Provincial Assessor would be responsible for the completion of the peri-operative death notification form;
- The Assessor would provide information on the primary, final and contributory causes of death, and would also establish whether there were avoidable factors, missed opportunities or any other aspect of substandard care present in the peri-operative death;
- The Assessor should complete and return all documentation to the (peri-operative deaths) Provincial office within 30 days:
- All documentation would then be forwarded to the National Committee for Confidential Enquiries into Peri-operative Deaths for collation and analysis;
- The Committee will then use this data to compile reports on peri-operative deaths in South Africa;
- Once the report is accepted and filed at the National Department of Health, all data will be destroyed, and work would begin on the next report.

Denominator figures (the total number of theatre operations) must be regularly submitted centrally, at a provincial level.

The anaesthetic record must become part of the patient's hospital record, and not solely "owned" by the anaesthetist, or the academic anaesthetic department. In addition there should be more than one copy; possibly one in electronic format and one on paper. A hard copy needs to be filed together with the patient's file at the individual hospitals where the patient/s died.

This study investigated two groups of ACDs and AADs at two tertiary academic hospitals. We do not know the equivalent statistics at many level 2 and 3 hospitals country-wide. We know from Lamacraft's study[73] that obstetric anaesthesia at level one and two hospitals in the Free State is administered by practitioners with poor anaesthetic skills. It is likely that other similar hospitals find themselves in a similar situation country-wide.

I would recommend that until there is a reliable method of recording and reporting peri-operative deaths, and especially AADs and ACDs in South Africa, that the following recommendations from NCEPOD[39] be instituted as an interim measure:

- Surgeons and anaesthetists should not undertake occasional paediatric practice;

- Surgeons and anaesthetists must always have immediate access to essential services such as recovery rooms and intensive care units if their patients are to survive;
- The skills of the anaesthetist and surgeon should always be appropriate for the physiological and pathological status of the patient;
- Systems should be implemented to improve records of clinical activity, including peri-operative deaths. Clinical audit needs to be encouraged;
- “Morbidity/mortality meetings should take place (and be minuted) in all anaesthetic departments. Regular review of mortality following operations is an essential part of anaesthetic practice”;
- “There is a need for a system to assess the severity of surgical illness in children in order to gather meaningful information about outcomes. The ASA grading system is widely used by anaesthetists but, as a comparatively simple system, does have limitations for use in children. The death of any child, occurring within 30 days of an anaesthetic or surgical procedure, should be subject to peer review, irrespective of the place of death”;
- “It is a professional responsibility to examine one’s practice and to seek ways to improve surgical and anaesthetic management. Clinicians must strive to achieve an audit record for all deaths if professional education, credibility and public support are to be maintained”;

- No ASA 4 or 5 patient should ever be submitted to an operation by a trainee without direct consultation with the appropriate consultant (or senior registrar) anaesthetist and/or surgeon.

10.1.2 Charlotte Maxeke Johannesburg Academic Hospital

A regular process is required after every peri-operative death, incorporating debriefing and peer review. Debriefing is a widely accepted activity following the adverse outcome after an anaesthetic[77-78]. It has been proven to improve future performance, and is essential for the anaesthetist's mental and physical well-being. This was not performed, nor documented during the five-year period that was studied for this thesis.

Coetzee's study[13] followed the following peer review protocol in this regard:

1. The Head of Department was informed within 24 hours.
2. The data was summarised by the anaesthetist concerned.
3. Additional predetermined data was collected by the same senior anaesthetist on every case and a preliminary summary was drawn up.
4. The summary was discussed at a quarterly post mortem meeting, attended by all the specialists in the department. The registrars were represented, and discussions were anonymous.
5. A final summary was drawn up after this meeting.

A similar process is recommended for the Department of Anaesthesia at CMJAH.

I also recommend that debriefing[77-78] of the anaesthetist involved with the patient needs to be implemented at the same time as the anaesthetist concerned summarises the data (point 2 above). In addition, the anaesthetic record needs to be added to the documentation.

10.2 Maternal Deaths

10.2.1 National:

- Anaesthetic assessors need to be more involved in assessing all maternal deaths, as there may be anaesthetic deaths that are missed by the "screening" committee;
- My proposed definition of AAD and ACD should be adopted by the National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD);
- Maternal Mortality Rate (MMR) is still not accurate, due to incorrect denominator figures. The current definition in South Africa is per live births; this definition needs to be more specific; for example "live births > 1000gram", or "live births > 500gram". Maternities are not a measurable denominator in SA, because the number of antenatal bookings is not recorded. However, the Department of Home Affairs registers live births, and the District Health Information System also gathers data on live births, thus providing the denominator.

10.2.2 Chris Hani Baragwanath Maternity Hospital:

- In keeping with national and international recommendations, ASA 4 patients should only be anaesthetised by specialists; this study indicates that there are still many ASA 4 patients at CHBH being anaesthetised by registrars;
- Detailed examination of postoperative facilities needs to be done; 74% of deaths occurred in the High Care unit or the postnatal ward, which raises concern about the adequacy of postoperative facilities in this extremely busy tertiary referral obstetric unit;
- HIV testing antenatally needs to be encouraged. The main reason for this is to reduce the incidence of mother-to-child transmission (MTCT), which may occur antenatally or postnatally via breast milk. Once a mother knows her status, she is able to make an informed decision on issues such as breast-feeding.
- More accurate data need to be available on the post-mortem results, allowing for precise causes of death to be recorded;
- As with the recommendation at a national level, a more accurate definition of live births needs to be made, so that accurate denominator figures will allow for accurate MMR calculation;
- Regular peer review (and debriefing of the doctor/s involved) of all AADs and ACDs needs to be performed in a structured manner and on a regular basis by the Department of Anaesthesia;

- Regular reviews of protocols need to be conducted by surgeons and anaesthetists.

10.3 International recommendations

At an international level, there needs to be agreement on various aspects of AADs and ACDs, such as:

- The definitions of anaesthesia mortality;
- How much of the peri-operative period to include;
- What parameters to look for and count;
- The response rates, in keeping with the laws of the respective countries.

The Safety and Quality of Practice Committee of the World Federation of Societies of Anaesthesiologists is the organization who would be in a position to implement this *(Merry A, Personal communication).* My recommendation is that they are requested to explore and implement this.

10.4 Future studies

This thesis has demonstrated an improvement in the prevalence of ACDs at the Charlotte Maxeke Johannesburg Academic Hospital over a 5-year period. It would appear that human error played a role in these ACDs. The literature abounds with articles discussing the role of human error in preventable anaesthesia mishaps (including death)[79-82], and how important it is to identify the extent of this.

Whilst the Department of Health is implementing the compulsory reporting of all AADs and ACDs, as has been recommended in this thesis, the identification of preventable anaesthesia risks needs to be documented in South Africa. In addition, critical incidents involving anaesthesia need to be documented and analysed, as has been done in other parts of the world [79-81]. Critical incident studies have been developed from aviation, and have been successfully adapted to anaesthesia[31]. This process will begin to identify and quantify the morbidity of anaesthesia, as opposed to the mortality.

The role of human error in these critical incidents needs to be recognised, and the prevalence will probably be high, in keeping with the rest of the world [79-81]. Once the role of human error in preventable anaesthesia mishaps has been quantified, we can set up systems to manage it, as has been recommended by Reason[78]. Only then will we be able to improve the (already improved) ACD rate of 0.4 per 10,000, thus lessening the potential risk of anaesthesia for our patients even further.

The other area of study in the process of documenting AADs and ACDs is the role of the post mortem findings. The NCEPOD studies in the United Kingdom[83] have demonstrated how useful this is at times, particularly when clinically unexpected findings emerge at the time of the post mortem. In the 1999/2000 report there was a major discrepancy between the clinical diagnosis and post mortem findings in 23% of cases which had an autopsy. The pilot study in this thesis sought to obtain these records, with the aim of correlating them with the clinical information available. This

was not feasible, due to the systems that were in place at the Government Mortuary at the time of this study (*Vellema J, Personal communication*). New systems have been implemented at the Government Mortuary since then, and it is now possible to correlate the post mortem and clinical causes of death. I recommend that this be implemented on a regular basis all over South Africa.

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Appendix A Ethics Permission

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Lundgren

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M8

PROJECT An Investigation & Assessment of Procedure-Related Deaths In The Greater Johannesburg Area

INVESTIGATORS Dr AC Lundgren

DEPARTMENT Dept of Anaesethesia, Johannesburg Hospital

DATE CONSIDERED 00/28/01

DECISION OF THE COMMITTEE *

Approved unconditionally

DATE 00/01/31 **CHAIRMAN** .....(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Prof G Saayman
Dept of Dept of Forensic Pathology, University of Pretoria

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DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee.

DATE 15/2/2000 SIGNATURE .....

PROTOCOL NO.: M 8

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B Extension of Ethics permission
(poor quality was the only copy available)

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Lundgren

CLEARANCE CERTIFICATE PROTOCOL NUMBER M8

PROJECT An Investigation & Assessment of Procedure-Related Deaths In The Greater Johannesburg Area

INVESTIGATORS Dr AC Lundgren

DEPARTMENT Dept of Anaesethesia, Johannesburg Hospital

DATE CONSIDERED 00/28/01

DECISION OF THE COMMITTEE

Approved unconditionally

DATE 00/01/31 CHAIRMAN .....(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Prof G Saayman
Dept of Dept of Forensic Pathology, University of Pretoria

Works2\wim0015\HumEth97.wdb\M 8

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee.

DATE 15/2/2000 SIGNATURE .....

PROTOCOL NO.: M 8

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Approved for further 5 years

UNIVERSITY OF THE WITWATERSRAND
PROF AJ WOODIWISS
Co-Chair
2010 -12- 03
HREC (Medical)
JOHANNESBURG

Appendix C Postgraduate Committee Permission

Faculty of Health Sciences
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
7 York Road PARKTOWN Johannesburg 2193 Telegrams WITSMED Telex 4-24655.SA
FAX 643-4318 TELEPHONE 717-2075/2076
E-MAIL jmainwa@chiron.wits.ac.za

DR AC LUNDGREN
PO BOX 782874
SANDTON
2146

APPLICATION NUMBER 7959714
STATUS (DEG 77) (MD011) PZZ

2001-11-15

Dear Dr Lundgren

Approval of protocol entitled an investigation and assessment of "procedure-related" deaths in the greater johannesburg area

I should like to advise you that the protocol and title that you have submitted for the degree of Doctor Of Philosophy (Full-Time) have been approved by the Postgraduate Committee at its recent meeting. Please remember that any amendment to this title has to be endorsed by your Head of Department and formally approved by the Postgraduate Committee.

Prof PE Cleaton-Jones has/have been appointed as your supervisor/s. Please maintain regular contact with your supervisor who must be kept advised of your progress.

Please note that approval by the Postgraduate Committee is always given subject to permission from the relevant Ethics Committee, and a copy of your clearance certificate should be lodged with the Faculty Office as soon as possible, if this has not already been done.

Yours sincerely

JO Mainwaring (Mrs)
Faculty Officer
Faculty of Health Sciences

Telephone 717-2075/2076

Copies - Head of Department____Supervisor/s

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Appendix D Permission for title change

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011)717-2075/6

Reference: Ms Tania van Leeve
E-mail: tania.vanleeve@.wits.ac.za
25 January 2011
Person No: 7959714
TAA

Professor AC Lundgren
PO Box 14504
Zuurfontein
1912
Johannesburg, South Africa

Dear Professor Lundgren

Doctor of Philosophy: Change of title of research

I am pleased to inform you that the following change of title of your research report for the degree of **Doctor of Philosophy** has been approved:

FROM: Procedure-related deaths in the greater Johannesburg

TO: Peri-operative deaths in two major academic hospitals in Johannesburg, South Africa.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX E: DATA COLLECTION SHEET – DEATHS

PATIENT and SURGERY – RELATED INFORMATION

Age	
Sex	
Race	
ASA grading	
Type and Site of surgery	
Elective Y/N	
Premedication	
Preop workup	

ANAESTHESIA DOCTOR STAFFING FOR THIS CASE
EQUIPMENT AVAILABLE FOR THIS CASE

ANAESTHESIA
Local
Regional
General
Combination

AIRWAY MANAGEMENT

RECORD KEEPING
RECOVERY ROOM RECORD
PROBLEMS/ADVERSE EVENTS < 24 HOURS
PROBLEMS/ADVERSE EVENTS > 24 HOURS

DEATH
In Theatre
In recovery room
< 24 hours
> 24 hours
< 7 days
< 30 days
> 30 days

POST MORTEM Y/N
CAUSE OF DEATH
MECHANISM OF DEATH

Department of Anaesthesia - Anaesthetic Record Form

Instructions: Yes: a Bold cross [X] No: leave blank [ ] Chosen by mistake: black out box COMPLETELY [■]

Patient Details

Hospital Number

Init. Name

Birth Date 19

Sex M F Classification

ASA> 1 2 3 4 5 E
<Wt

Surgery Date 19

Start Anaesthetic h

Start Surgery h

End Anaesthetic h

Op Name:

Gen Surg.	Ortho.	Obstetric
Cardioth.	ENT	Gynae.
Plastics	Max. fac.	Neuro
Urology	Ophthal.	Other

Staff **Theatre**

Anae. 1

Anae. 2

Consult't

Surgeon

Complication **Yes** **No**

Respiratory	Equip.fail	Car. arrest
BP	Haemorrh	Death
Arrhythmia	Drug rel.	Other

Specify...

Primary Anaesthetic Technique

Induction	Spinal
Rapid Sequence	Epidural
Intravenous	Regional
Inhalational	Standby

Maintenance

Inhalational	Hypotensive
Narcotic	Hypothermia
TIVA	One Lung Vent
Other	CPB

Airway

Face Mask	Oral airway
Endotracheal tube	Venti-Mask
Laryngeal Mask	Nasopharyngeal
Tracheostomy	Other

Endotracheal Tube Insertion

Relaxant	No Relaxant
Oral	Nasal
Fibreoptic	Awake
Introducer	Double lumen
Armoured	Preformed
Size	Depth
Cuff Y	N
Pack Y	N
Air Entry R L	Check Stomach?

PREOPERATIVE ASSESSMENT

History

Examination

Airway

Medication

Allergies **Starved Y** **N**

Investigations

CXR

ECG

Hb Plates. PI PTT

Na K Urea Creat.

Problem List

Premedication

Equipment

Humidivent	Pressure pts.	Eye ointment
Humidibath	NGT	Eyes: tape
Blood Warm	Arm board	Eyes: pads
W. Blanket		

Circuit

Magill	Circle
ADE	T
Bain	Other
Jackson/R	

Ventilator Settings

RR	FiO2
Vt	IE
Vm	Pmax
PEEP	

Position

Supine	Prone
Left lateral	Trendelenb.
Right lateral	Sitting
Lithotomy	

Monitoring

ECG	O2
Oximeter	Agent
BP/NIBP	Temperature
CO2	Oes/P Steth

Ventilation

Spont.	
Control	
Assist	
Elema	
Manley	
Penlon	
Ohmeda	
Other	

Tourniquet

Site	
Time on	
Time off	
Urine cath.	
Arterial line	
CVP	
PA Catheter	
Nerve stim.	

Appendix F CMJAH Anaesthetic record page 1

Appendix G CMJAH Anaesthetic record page 2

APPENDIX H MATERNAL DEATH NOTIFICATION FORM

DEPARTMENT OF HEALTH 2008 version
CONFIDENTIAL
MATERNAL DEATH NOTIFICATION FORM
For office use only: Department of Health Office case number
NOTE:
1. This form must be completed for all deaths in pregnant women or within 42 days after
termination of pregnancy, including abortions, ectopic gestations, motor vehicle accidents,
and suicide related deaths irrespective of duration or site of pregnancy.
2. Mark with an (X) where applicable (? means unknown)
3. Attach a copy of the complete case records and anaesthetic forms to this form
4. Complete the form within 7 days of a maternal death. The completed form is sent to the
person responsible for maternal health in the province
5. All maternal deaths must be discussed at an institutional mortality meeting. Such meetings
will assist in the completion of sections 10,11 and 12 of this form
Address of contact person (Person responsible for Maternal Health in the Province)
Case discussed at Institutional mortality meeting? YES NO If YES: Date _____
1. LOCALITY WHERE DEATH OCCURRED
Province Health District
Institution Locality CHC
Clinic
Level 1
Hospital
Level 2
Hospital
Level 3
Hospital
Private
Hospital
Other -
Specify
2. DETAILS OF DECEASED
Name Inpatient No.
Address
Age (yr) Race AF = African; CO = Coloured; In = Indian; WH = White; OT=Other
Gravida Para Gestation (weeks)
(or at delivery)
Days since delivery/miscarriage
(if not applicable enter 99)

at delivery

3. ADMISSION AT INSTITUTION WHERE DEATH OCCURRED OR FROM WHERE IT WAS REPORTED

d d m m y y 24h min
Date of admission: Time of admission
d d m m y y 24h min
Date of death: Time of death
1
161
On admission: Aborting/ectopic Antenatal
Intrapartum Postpartum
Condition on admission: Stable Critcally
ill
Dead on arrival Other - specify
Diagnosis at moment of death: Abortion Ectopic pregnancy Not in labour In labour Postpartum
Reason for admission:
Referral from another centre? Y N If “Y” from

4. ANTENATAL CARE

Did she receive antenatal
care?
Y N ? If “Y”, at what
locality?
? Primary Secondary Tertiary Private Other
Antenatal
care provider
Specialist Med.Off/GP Adv. Midwife Midwife/Reg.
nurse
Other - Specify Gest. age at
booking<20wks
Y N
Total number visits.
Antenatal Risk
Factors
Risk Y N ?
Past Medical History Specify:
Hypertension
Proteinuria Other -
Glycosuria Specify
Anaemia
Abnormal lie
Previous C/Section
Comments on antenatal complications and management - List any medication
162 **5. HIV status: (Make a cross in one box only)**

Test declined Unknown HIV neg HIV pos
(not AIDS)
AIDS
(on HAART)
AIDS
(not on HAART)
(Note: AIDS =CD4<200 &/or AIDS defining illness) CD4 count = _____

6. DELIVERY, PUERPERIUM AND NEONATAL INFORMATION

Did Labour occur? Y N If “Y”, was a partogram
used
Y N ? Duration of labour ? Latent phase Active phase Second stage Third stage
(hours:min)
Delivery
(Tick appropriate box)
Undelivered Vaginal (unassisted) Vaginal
Vacuum/forceps
Caesarean section
Baby Birthweight
(g)
5 min Apgar Outcome Stillborn Neonatal
death
Alive
Comments on labour delivery and puerperium

7. INTERVENTIONS (Tick appropriate box)

Early pregnancy Antenatal Intrapartum Postpartum Other
Evacuation Transfusion Instrumental del. Evacuation Anaesthesia - GA
Laparotomy Version Symphysiotomy Laparotomy Epidural
Hysterectomy Caesarean section Hysterectomy Spinal
Transfusion Hysterectomy Transfusion Local
Transfusion Manual removal Invasive monitoring
Other - specify ICU ventilation
Comments on interventions

8. CASE SUMMARY (please supply a short summary of the events surrounding the death)

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……..……..…….....
9. AUTOPSY: Performed Not Performed
If performed: date_____, place_____, Ref. no. _____
: please report the gross findings below and send the detailed report later.
10. CAUSE OF DEATH (See Guidelines)
(Note AIDS is NOT a primary cause of death – if the woman has AIDS please give the specific cause of death e.g. TB, pneumonia,
meningitis, malaria, abortion, puerperal sepsis etc.)
164 Primary (underlying) cause of death: Specify:
Final cause of death: Specify:
Contributory (or antecedent) cause/s: Specify:
11. IN YOUR OPINION DID ANY OF THE FOLLOWING FACTORS CONTRIBUTE TO THE DEATH OF THIS PATIENT?
System Example Y N ? Specify
Personal/Family Delay in woman seeking help
Declined treatment or admission
Logistical systems Lack of transport from home to health care
facility
Lack of transport between health care facilities
Health service - Health service communication
breakdown
Facilities Lack of facilities, equipment or consumables(
drugs,infusion sets,blood,fluids etc..)
Health personnel
problems
Lack of human resources
Lack of expertise, training or education
Comments on potential avoidable factors, missed opportunities and substandard care
Please note that substandard care includes inadequate monitoring as well as substandard management.
12. WHAT HAS YOUR INSTITUTION LEARNT FROM THIS CASE AND HOW HAS IT CHANGED PRACTICE? (If applicable)
13. THIS FORM COMPLETED BY:
Name (print) Rank
Telephone Fax
Date Signature:
d d m m y y .....