Development and validation of an instrument for procedure-related death notification

Frances Kate Orr

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

Johannesburg, 2018

Declaration

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

.....

Frances Kate Orr

7th day of July, 2018

To my family

Abstract

Anaesthesia-related mortality is an important, potentially avoidable cause of perioperative mortality. A procedure-related death notification (PRDN) instrument is completed by relevant medical practitioners after an anaesthetic death and is used to audit practice and identify areas of care which need improvement. It is also used in medico-legal investigations when establishing cause of death and in the case of litigation. The current South African procedure-related death notification instrument, the GW 7/24 form, is considered to be outdated, inadequate and in need of revision.

The aim of this study was to develop and validate a new PRDN instrument using Lynn's two-stage model. During the Development stage a thorough literature review was done and items were generated to create a provisional PRDN instrument. This instrument was reviewed in a peer group discussion consisting of six local experts. Each item was debated until complete consensus was reached and experts were encouraged to make suggestions for the inclusion of additional items. During the Judgment-Quantification stage the revised PRDN instrument was emailed to 10 national experts for review. Each item was rated according to a 4-point Likert scale, with one being unimportant and four being important and succinct. The content validity of each item and of the instrument as a whole was then established by using the content validity index (CVI).

The revised PRDN instrument achieved a CVI of 0.96 making it content valid, however, it was decided to improve upon this instrument even further. The national experts made several useful comments and suggestions which were taken into consideration and incorporated into a final PRDN instrument. This instrument was then re-rated by the national experts and achieved a CVI of 1.

The final PRDN instrument is a validated, comprehensive form which could be used in place of the outdated GW 7/24 form in cases of procedure-related deaths.

Table of Contents

Declaration ii
Abstract iv
Table of Contents v
List of Figures ix
List of Tables x
List of Appendices xi
Abbreviations xii
Chapter one: Overview of the study 1
1.1 Introduction 1
1.2 Background 1
1.3 Problem statement 3
1.4 Aim 3
1.5 Objectives 4
1.6 Research assumptions 4
1.7 Ethical considerations 5
1.8 Research methodology 5
1.8.1 Research design 5
1.8.2 Study population 5
1.8.3 Study sample and sample method 6
1.8.4 Study methods 7
1.9 Significance of the study 8
1.10 Validity and reliability 9
1.11 Outline of the study 9
1.12 Summary 10
Chapter Two: Literature review 11
2.1 Introduction 11

2.2 Anaesthesia-related mortality rate 11
2.2.1 International studies 12
2.2.2 South African Studies 13
2.3 The importance of anaesthesia-related mortality audits 14
2.4 Problems with studies relating to anaesthesia-related mortality 16
2.5 Common causes of and risk factors for anaesthesia-related mortality 17
2.5.1 Preoperative factors 18
2.5.2 Intraoperative factors 18
2.5.3 Postoperative factors 19
2.5.4 Patient factors 20
2.5.5 Anaesthetist factors 20
2.6 South African legal issues surrounding anaesthesia-related deaths: 21
2.7 Critique of the GW 7/24 form 23
2.8 Lynn's Model 26
2.9 Summary 27
Chapter Three: Research Methodology 28
3.1 Introduction 28
3.2 Problem Statement 28
3.3 Aim 28
3.4 Objectives 29
3.5 Ethical considerations 29
3.6 Research methodology 30
3.6.1 Research Design 30
3.6.2 Study Population 30
3.6.3 Study sample and sample method 31
3.6.4 Study Methods 32
3.7 Data Analysis 34
3.8 Validity and reliability 34
3.9 Summary 35

Chapter Four: Results and Discussion 36
4.1 Introduction 36
4.2 Approach to data analysis 36
4.3 Results 38
4.3.1 Objective: Develop a provisional PRDN instrument from the literature using Lynn's Development stage (domain identification and item generation) 38
4.3.2 Objective: Develop a revised PRDN instrument using Lynn's Development stage (Instrument formation) 41
4.3.3 Objective: Determine content validity of the revised PRDN Instrument using Lynn's Judgment-Quantification stage 45
4.4 Discussion of results 55
4.5 Conclusion 61
Chapter Five: Summary, Limitations, Recommendations and Conclusion 62
5.1 Introduction 62
5.2 Summary of the study 62
5.2.1 Aim 62
5.2.2 Objectives 62
5.2.3 Summary of methodology and results 62
5.3 Limitations 63
5.4 Recommendations 64
5.5 Conclusion 65
References 67
Appendix 1: HREC(Medical) certificate 71
Appendix 2: Postgraduate committee approval of Mmed title 72
Appendix 3: Development stage information letter 73
Appendix 4: Judgment-Quantification stage information letter 75
Appendix 5: Provisional PRDN instrument 77
Appendix 6: Revised PRDN instrument 81
Appendix 7: Cumulative binomial distribution 86
Appendix 8: Final PRDN instrument 87

Appendix 9: GW 7/24 Form 93

List of Figures

Figure 4.1 Flow diagram demonstrating study process 37
Figure 4.2 CVI for Demographics domain 46
Figure 4.3 CVI for Hospital domain 47
Figure 4.4 CVI for Anaesthetist domain 47
Figure 4.5 CVI for Preoperative assessment domain 48
Figure 4.6 CVI for Anaesthetic technique domain 48
Figure 4.7 CVI for Airway domain 49
Figure 4.8 CVI for Ventilation domain 49
Figure 4.9 CVI for Monitoring and Equipment domain 50
Figure 4.10 CVI for Drugs domain 50
Figure 4.11 CVI for Fluids domain 51
Figure 4.12 CVI for Postoperative care domain 51
Figure 4.13 CVI for Cardiac arrest domain 52

List of Tables

Table 4.1 Provisional PRDN instrument 38
Table 4.2 Demographics of local experts 41
Table 4.3 Modified items on provisional PRDN instrument 42
Table 4.4 Demographics of national experts 45
Table 4. 5 Modified items on final PRDN instrument 53
Table 4.6 Final PRDN instrument 56

List of Appendices

Appendix 1: HREC (Medical) clearance certificate

Appendix 2: Post Graduate Committee approval of Mmed title

Appendix 3: Development stage information letter

Appendix 4: Judgement-Quantification stage information letter

Appendix 5: Provisional PRDN Instrument

Appendix 6: Revised PRDN Instrument

Appendix 7: Cumulative binomial distribution

Appendix 8: Final PRDN Instrument

Appendix 9: GW 7/24

Abbreviations

PRDN: procedure-related death notification

ASA: American Society of Anesthesiologists

NCEPOD: The National Confidential Enquiry into Patient Outcome and Death

UK: United Kingdom

CVI: Content Validity Index

SCIDUA: Special Committee Investigating Deaths Under Anaesthesia

NCCEMD: National Committee for the Confidential Enquiry into Maternal Deaths

AAGBI: The Association of Anaesthetists of Great Britain and Ireland

SASA: The South African Society of Anaesthesiologists

FiO2: fraction of inspired oxygen

Ppeak: peak inspiratory pressure

PEEP: positive end expiratory pressure

ml: millilitre

NGT: nasogastric tube

E.g.: exempli gratia(for example)

IPPV: intermittent positive pressure ventilation

ICU: intensive care unit

PACU: post anaesthesia care unit

KZN: KwaZulu-Natal

PHC: primary healthcare

CXR: chest x-ray

ECG: electrocardiogram

IVI: intravenous infusion

Chapter one: Overview of the study

1.1 Introduction

In this chapter an overview of the study is provided. This includes the background of the study, the problem statement, aim, objectives, definitions and ethical considerations. The research methodology is then looked at as well as the significance of the study; the reliability and validity; and the study outline.

1.2 Background

In 1949 Sir Robert Macintosh famously said “there should be no deaths due to anaesthesia.” (1) A death of a patient due to anaesthesia is a tragic event, both for the patient’s family and the health practitioners involved.

The mortality rate due to anaesthesia has decreased significantly over the years. In the United States in the 1950s the anaesthesia-related mortality rate was found to be 6.4 deaths per 10 000 procedures. (2) In 2009 Li et al (3) did a study which showed a 97% reduction in anaesthesia-related mortality to a rate of approximately 1 in 100 000 surgeries. Although the reason for this decrease is largely unknown, it has been attributed to improved monitoring devices.(4)

When studying anaesthesia-related mortality it is important to look at the causes and risk factors for anaesthesia-related death, as this is where interventions should be targeted. Some of the common causes of anaesthesia-related deaths found in the literature are: cardiovascular effects, caused by administration and overdose of anaesthetic drugs; airway management failure especially related to endotracheal intubation and inadequate preoperative evaluation and resuscitation. (3, 5-7) Important risk factors for mortality include: patient age (very young and old); higher ASA status;

emergency surgery; grade of anaesthetist (the more junior the higher the risk); and no assistance available during induction and emergence. (5, 8) The information relating to these risk factors is recorded on a procedure-related death notification (PRDN) instrument in order to assist forensic pathologists and other concerned parties in the formulation of a cause of death. This form is usually completed by the anaesthetist and primary practitioner.

The importance of regular and accurate audit of anaesthesia-related deaths has been highlighted in the literature. Harrison (7) describes anaesthesia-related deaths as an indicator of anaesthesia safety and the lessons learned when evaluating the cause of these deaths are essential to improving service to the patient. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in the United Kingdom (UK) regularly audit perioperative deaths and write annual reports highlighting problem areas and making recommendations. A survey done in the UK in 1997 showed that the NCEPOD reports had changed clinical practice and standards of care in over 74% of respondents. (4)

The relevant information needed to perform an anaesthesia-related mortality audit in South Africa is found on a GW7/24 form, which is considered to be a PRDN instrument, and is completed by the practitioners involved in the case. Other documents containing useful information include the anaesthetic chart and the patient's hospital file. In an audit done by Lundgren (9) in South Africa in 2011, anaesthetic records were available in only two thirds (67%) of the perioperative deaths, and the GW 7/24 form had to be relied on in the majority of cases.

In South Africa, procedure-related deaths, including deaths during anaesthesia, are governed by section 48 of the *Health Professions Amendment Act* (Act 29 of 2007):

> "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 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 and Deaths Registration Act*, 1992 (Act 51 of 1992)." (10, 11)

According to the *Inquests Act* (Act 58 of 1959) (10), all procedure-related deaths shall be reported to a police officer and a medico-legal post-mortem and inquest shall be held. During the inquest the magistrate will decide whether a case should be referred for formal prosecution of the parties involved. The clinical information required during this process is documented on the GW 7/24 form. (10)

The GW 7/24 form should therefore ideally contain all the relevant information required for anaesthesia-related mortality audits and for medico-legal purposes; however, anecdotally, local anaesthesiology and forensic pathology opinion holds that the current form does not offer a complete set of information, and is therefore an inadequate tool.

1.3 Problem statement

There has been anecdotal evidence from several South African anaesthetists and forensic pathologists that the GW 7/24 form is inadequate. The form does not contain the relevant information required in order for the pathologist to make an informed decision regarding the cause of death, nor does it contain the relevant information needed in the case of medico-legal action or for academic audit purposes. (5-8)

1.4 Aim

The aim of this study was to develop and validate a new procedure-related death notification (PRDN) instrument using Lynn's Model. (12)

1.5 Objectives

- Develop a provisional PRDN instrument from the literature using Lynn's Development Stage (Domain identification and item generation)
- Develop a revised PRDN instrument using Lynn's Development Stage (Instrument formation)
- Determine content validity of the revised PRDN instrument using Lynn's Judgment-Quantification Stage.

1.6 Research assumptions

The following definitions were used in this study:

Anaesthetist: A medical doctor who delivers an anaesthetic to a patient. For the purpose of this study, the definition encompasses medical officers, registrars and specialist anaesthesiologists.

Forensic pathologist: A medical doctor who has specialised in forensic pathology. They perform medico-legal post mortem examinations and investigate all cases of unnatural or unexplained deaths.

Procedure-related death: "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 a procedure has been a contributory cause". (11) This includes anaesthesia.

Expert: An anaesthetist or forensic pathologist in the public or private sector who is considered to be an authority on what a PRDN instrument requires.

Lynn's Model: This model describes a structured two-stage process (development and judgment- quantification) of instrument development and validation through literature review, peer group discussion and expert analysis. (12)

1.7 Ethical considerations

Approval to conduct the study was obtained from Human Research Ethics Committee (Medical) (M160684) and the Postgraduate Committee of the University of the Witwatersrand.

The study was conducted according to the principles of the Declaration of Helsinki (13) and the South African Good Clinical Practice Guidelines. (14)

1.8 Research methodology

1.8.1 Research design

A prospective, instrumental study design was followed in this study.

A prospective study is one in which the variables are measured at the time at which the study takes place. (15) In this study data was collected as the study progressed.

This study was instrumental because specific rules, as suggested by Lynn's Model (12), were applied to develop a validated instrument. (16)

Using Lynn's Model (12) this study resulted in a validated PRDN instrument which can be used for any procedure-related death in the future, for forensic or academic purposes. (17)

1.8.2 Study population

The study population included anaesthetists and forensic pathologists in South Africa who are experts in procedure-related deaths.

1.8.3 Study sample and sample method

Purposeful sampling was used in both stages of this study.

Purposeful sampling involves the researcher identifying individuals that are especially knowledgeable or experienced in the field of interest to the study. (18)

The experts in each stage were chosen by the researcher and supervisor in consultation with senior anaesthetic and forensic pathology consultants. They were chosen based on their knowledge of procedure-related deaths and the medico-legal processes surrounding these deaths in South Africa and elsewhere. They consisted of anaesthetists and forensic pathologists working in South Africa who were willing to participate in the study.

The exclusion criterion for the Judgment-Quantification stage was anyone who took part in the Development stage.

Sample size

Development stage: According to Lynn (12), the number of experts who should be used in this stage often depends on the availability of accessible and agreeable experts, but a minimum of five would provide an adequate level of control to rule out chance agreement. The maximum number of experts has not been established, but is unlikely to be more than ten. Six experts participated in the peer group discussion in this study, four anaesthetists and two forensic pathologists.

Judgment-Quantification stage: The number of experts needed in this stage follows the same principles as for the Development stage. When six or more experts are used, one expert can be in disagreement with the others and the instrument will still be assessed as content valid, however if there are five or less, all the experts must agree. In this study 10 experts were invited to participate in the study.

1.8.4 Study methods

Lynn describes a two-stage process of instrument development and validation consisting of the Development stage and the Judgment- Quantification stage. (12)

Development stage

There are three steps in the Development stage: Domain identification, item generation and instrument formation.

During the domain identification and item generation steps a thorough literature review was done by the researcher (domain identification) and a provisional PRDN instrument was produced (item generation).

During the instrument formation step the provisional PRDN instrument was reviewed and debated in a peer group discussion consisting of six experts, both anaesthetists and forensic pathologists. The experts were invited via email to join the discussion and the provisional PRDN instrument and information sheet were sent to them in advance. All six invited experts participated in the discussion which was chaired by the researcher and held at Charlotte Maxeke Johannesburg Academic Hospital.

The aim of the discussion was to refine the provisional PRDN instrument in order to improve its content validity.

During the discussion the experts were asked to grade each item according to the following Likert scale:

1. Not important
2. Of little importance
3. Important but needs alteration
4. Important and succinct

A score of 3 or 4 meant it was important and should remain on the form, a score of 1 or 2 meant it should be removed.

Each item on the provisional PRDN instrument was debated until complete consensus was reached. The experts were also encouraged to make suggestions for the inclusion of additional items.

After the peer group discussion the provisional PRDN instrument was refined to produce a revised PRDN instrument to be used in the Judgment-Quantification stage. The revised instrument was emailed to the experts to confirm that the discussed changes had been made.

Judgment- Quantification stage

During this stage the revised PRDN instrument was emailed to 10 experts around South Africa, who were not involved in the previous stage, along with an information sheet describing the study and giving instructions on how to rate the items. Eight experts responded and took part in this stage.

Lynn describes two steps to the Judgment-Quantification stage: The first is the assertion by the experts that each item on the instrument is content valid. This was done by rating each item according to the same Likert scale used in the Development stage. The content validity index (CVI) of each item and of the instrument as a whole was then calculated by the researcher. (12, 19)

1.9 Significance of the study

The significance of this study is that a new validated PRDN instrument was created which is an improvement on the current GW 7/24 form. This instrument can be used by magistrates and forensic pathologists to establish the cause of death and to determine whether parties involved need to be formally prosecuted. The data collected using the PRDN instrument can also be used in anaesthesia-related death audits to establish anaesthesia-related mortality rates and to look for causes of death and risk factors for mortality. This information can be used to educate anaesthetists and improve practice and patient care.

1.10 Validity and reliability

The use of Lynn's two-stage model ensured validity of the study.

Content validity of each item was determined by the proportion of experts who rated the item as content valid. The content validity of the instrument as a whole was calculated by the proportion of total items judged content valid.

1.11 Outline of the study

The study outline is as follows:

Chapter One: Overview of the study

Chapter Two: Literature review

Chapter Three: Research methodology

Chapter Four: Results and discussion

Chapter Five: Summary, limitations, recommendations and conclusion.

1.12 Summary

In this chapter an overview of the study was provided. The following chapter will contain the literature review.

Chapter Two: Literature review

2.1 Introduction

In this chapter the literature relating to anaesthesia-related mortality is reviewed.

Anaesthesia-related mortality rates and trends internationally and in South Africa will be reviewed, as well as the importance of doing mortality audits and the difficulties associated with establishing a true anaesthesia-related mortality rate. The common causes of and risk factors for anaesthesia-related deaths will then be reviewed.

Thereafter the laws and legal processes pertaining to anaesthesia-related deaths in South Africa will be summarised and Lynn's model of instrument development and validation will be discussed.

2.2 Anaesthesia-related mortality rate

The death of a patient due to anaesthesia is a tragic event, both for the patient's family and the health practitioners involved.

Determining the mortality rate due to anaesthesia and the causes of anaesthesia-related deaths is important as this information can be used to change practice and improve patient care in the future. (20)

There has been an apparent improvement in anaesthesia-related mortality over the years and it currently represents a minor but potentially avoidable cause of perioperative mortality. (5, 9, 21)

2.2.1 International studies

In the United States between 1948 and 1952, Beecher and Todd (2) did a study on anaesthesia-related deaths which involved 599 500 surgical patients from 10 academic medical centres. They found that the anaesthesia-related mortality rate was 6,4 per 10 000 procedures. This caused widespread alarm as there were 2.4 times as many deaths due to anaesthesia for the duration of the study as there were deaths caused by poliomyelitis. (5, 9)

In 2006 in France, Lienhart et al (22) published a survey of anaesthesia-related mortality. A sample of the death certificates for the year 1999 was analysed and an estimate of the number and characteristics of anaesthesia-related deaths was established. The rate of death related to anesthesia was 0.54/10 000 procedures, more than 10 times lower than what Beecher and Todd had found 50 years earlier. (9)

Braz et al (5) published a systematic review in 2009 of the Brazilian and worldwide literature looking at the incidence of perioperative and anaesthesia-related mortality. Thirty-three trials between 1954 and 2007 were assessed after searching Medline and Scielo. Both Brazilian and worldwide studies demonstrated a similar decline in anesthesia-related mortality rates to what was identified by Lienhart et al (22), showing an average rate of fewer than 1 death per 10 000 anaesthetic procedures in the past 20 years. It was noted by Braz (5) however, that there were significant methodological differences between the studies analysed, which made it difficult to compare anaesthesia-related mortality rates. These differences will be discussed in detail in section 2.4.

The American Society of Anesthesiologists (ASA) Closed Claims Project (23) is an initiative started in America in 1984. It analyses closed malpractice insurance claims from more than 35 professional liability companies in the United States. Each claim is

analysed and a likely cause and contributing factors for the morbidity or mortality are established. The results of the analysis of these claims are then published in scientific literature and presented at national and international meetings in the hope that peers will learn from others' mistakes and systems may be improved to avoid similar situations in the future. (23-25)

ASA Closed Claims data published in 2006 by Cheney et al (25) illustrates how anaesthesia-related mortality has decreased over time. It looked at claims where the injury occurred between 1975 and 2000. There were a total of 6,750 claims of which 2613 (39%) were for brain damage or death. The proportion of total claims for brain damage or death in 1975 was 56% and decreased steadily by about 1% per year until 2000, when brain damage or death represented 27% of total claims.

On examining professional liability premiums for anaesthetists there is a trend towards lower premiums because of an overall improvement in anaesthesia safety. In 1985 in the United States the average malpractice insurance premium was about $36 224 per year for a standard policy. By 2009 this had decreased by 40%, to $21 480. (26) Anaesthesia used to be considered a high risk specialty, in terms of professional insurance. In 1984 in the United States, 11% of the total amount paid for patient injury was caused by anaesthesia-related complications, despite anaesthetists accounting for only 3% of all medical doctors insured. (27) Anaesthetists are now ranked between medium and low risk in both the United States and in South Africa. (28)

2.2.2 South African Studies

Although anaesthesia-related mortality audits in South Africa are scarce, they have still shown a similar decreasing trend in overall mortality rate as has been seen internationally.

Between July 1956 and March 1962 The Anaesthetic Deaths Research Unit (29) found that the death rate associated with anaesthesia was approximately 5 per 10 000 cases.

(9) This was similar to what Beecher and Todd (2) found in the United States between 1948 and 1952.

30 years later, in 1987, Coetzee and Du Toit (30) studied perioperative mortality at Tygerberg Hospital in the Western Cape. They analysed the records of every death that occurred within 24 hours of the initiation of anaesthesia over a 3 and a half year period and showed that the death rate due to anaesthesia had decreased to 1,1 per 10 000 cases. Almost 20 years after that, in Johannesburg, Lundgren (9) showed that the mortality rate had decreased further, to 0.4 deaths per 10 000 cases. This trend was in keeping with the international decline in anaesthesia-related mortality rates.

The reasons for the decrease in anaesthesia-related mortality has not been definitively researched and proven. It is difficult in anaesthesia to establish a causal relationship between a specific intervention and mortality rate. Some of the possible interventions that may have contributed to the decreasing mortality rate are: better monitoring techniques, for example pulse oximetry and capnography (5, 8, 22); improved postoperative monitoring and care in the recovery room (22); better training of anaesthetists (3, 8); and the adoption of safety standards and practice guidelines. (5, 8, 22)

2.3 The importance of anaesthesia-related mortality audits

The need for anaesthesia-related mortality audits has been highlighted since 1948. This was when Sir Robert Macintosh suggested establishing a formal enquiry mechanism for determining the cause of any death as such analysis could lead to improved practice and the prevention of further deaths in the future. (20) There are several examples of mortality audit systems, both nationally and internationally, which show how a well-functioning audit system can improve patient outcomes.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) (31) is an UK organisation that has been reviewing medical, surgical and anaesthetic clinical

practice since 1987. It undertakes annual confidential surveys and research and writes reports making recommendations to improve the quality of patient care. Deaths due to anaesthesia are not examined in detail every year, but specific anaesthesia-related mortality reports and recommendations have been published over the years. (9, 31) In 1997 a survey was conducted to assess whether the NCEPOD had influenced anaesthetic clinical practice. The survey found that NCEPOD had “influenced personal clinical practice in 74% of respondents, the inception of guidelines and protocols in 75% and had helped in the improvement of essential services, staff or equipment in 80%.” (4)

The Special Committee Investigating Deaths Under Anaesthesia (SCIDUA) (6) is a committee in New South Wales, Australia, which has been reviewing anaesthesia-related deaths since 1960. Anaesthesia-related mortality data is collected and analysed and the committee then provides confidential feedback to the reporting anaesthetist. They also publish special reports in peer-reviewed journals and submit annual data to the Australian and New Zealand College of Anaesthetists for triennial reporting on anaesthesia safety. This system has encouraged reflective learning among anaesthetists and facilitates improvement in anaesthetic practice. The estimated anaesthesia-related mortality in New South Wales has declined significantly since the inception of SCIDUA, from 1 in 5 500 procedures in 1960 to 1 in 55 140 procedures in 2008.

The ASA Closed Claims Project data has resulted in several positive changes to safety standards and guidelines. In 1989 they provided evidence that many of the injuries they encountered may have been prevented by the use of pulse oximetry and capnography monitoring. The ASA Committee on Standards used these reports, amongst others, to formulate new monitoring standards in theatre and in the recovery room. The Closed Claims Project data on difficult intubation was also instrumental in the formation of the ASA practice guidelines for the management of a difficult airway. (27)

In 1997, maternal deaths were made notifiable by law in South Africa (32) and a year later the National Committee for the Confidential Enquiry into Maternal Deaths (NCCEMD) (33) was established. It is a committee which analyses each maternal death which occurs in South Africa, identifies the main cause of death, preventable factors

and areas of weakness in the health system. It publishes triennial reports on maternal mortality rates, the causes of mortality, and makes recommendations for reducing maternal mortality. It is an example of a well-functioning South African mortality reporting system. It is compulsory by law to report every maternal death. The process is confidential and it has a well-defined notification and feedback system in the form of reports whereby health practitioners can learn from previous mistakes and change practise to avoid those mistakes in the future. A similar system to report procedure-related deaths in South Africa should be established and may similarly help in reducing the anaesthesia-related mortality rate.

2.4 Problems with studies relating to anaesthesia-related mortality

Anaesthesia-related mortality statistics have often been questioned, as the true mortality rate has been difficult to establish due to several methodological challenges.

The most important of these challenges is that there is no established definition for what constitutes a death due to anaesthesia and no time frame for what is considered as the perioperative period. (20) There are two situations whereby anaesthesia can contribute to a patient's death, it can either be the sole cause of the death or the anaesthetic may have contributed in some way towards the death. There are several different names for each of these situations in the literature. Some studies do not look at the two separately and this results in a higher mortality rate than if only deaths solely attributable to the anaesthetic are looked at. This may explain the sometimes inconsistent results seen in the literature and makes mortality audits difficult to analyse and compare. (5, 9, 20)

The time frame for when a death can be classified as anaesthesia-related also differs between studies. The perioperative period has been defined variably over the years as intraoperative only; intraoperative and recovery from anesthesia; the first 12 postoperative hours; the first 24 postoperative hours; two, three, seven or thirty postoperative days. (5, 9, 20) In South Africa there is no time limit for when a death can be classified as anaesthesia-related. If a patient suffers hypoxic brain damage whilst

under anaesthesia and dies a few years later from related complications, the death will still be classified as an anaesthesia-related death. (9, 11) Many patients may be lost to follow up when this long time period is used, but many true anaesthesia-related deaths may be missed when the perioperative time period used in the definition is too short.

Other methodological challenges include the fact that the total number of anaesthesia-related deaths is low, requiring studies to have large sample sizes and resources. (20) The practice of anaesthesia has also expanded considerably, most surgical procedures are now performed in an ambulatory setting and anaesthesia is being used more regularly for minor therapeutic and diagnostic procedures making it difficult to gather accurate data. (3)

Anaesthesia-related deaths are not notifiable in most countries, including South Africa. This means mortality statistics rely largely on voluntary reporting by the medical practitioners involved and by intermittent audits. Until all anaesthesia-related deaths are notifiable and a systematic data collection and analysis system is in place, the mortality statistics may never be entirely accurate. (9)

In South Africa we have a problem of poor record keeping which makes it difficult to collect accurate mortality data. In a large audit by Lundgren (9) in 2011 it was found that anaesthetic records were lacking in one third of the study cases. This is a problem which will need to be overcome before any sustainable audit system can be achieved.

2.5 Common causes of and risk factors for anaesthesia-related mortality

The most common causes and risk factors for anaesthesia-related mortality are important to determine, as this is where interventions should be targeted. It is imperative to include the information needed to establish these causes in a procedure-related death notification (PRDN) instrument to ensure mortality data and statistics are accurate. The current South African PRDN instrument, the GW 7/24 form, does not

require medical professionals to comment on many of the causes of and risk factors for anaesthesia-related mortality. An example is that the recovery room has been shown to be a problem area in anaesthetic care and the GW 7/24 form does not require medical professionals to comment on postoperative care at all.

2.5.1 Preoperative factors

Inadequate preoperative evaluation and optimisation can lead to increased perioperative mortality. Mcfarlane et al (34) reviewed surgical and anaesthesia mortality in Scotland between 1996 and 2006. They found that the majority (43%) of anaesthesia-related mortality concerns related to preoperative assessment, both the optimisation of the patient and the decision to proceed with the surgery. They suggest patients would benefit from early referral for assessment, risk stratification and optimisation preoperatively. This sentiment was shared by Pignaton (35), who stated that intraoperative mortality may have been prevented in several patients had they received adequate primary care and preoperative assessments.

2.5.2 Intraoperative factors

Cardiovascular and respiratory incidents have been the major cause of anaesthesia-related mortality over the past 20 years. (5) In reports written by the ASA Closed Claims Project (23, 36), respiratory and cardiovascular events together made up 68% of events causing death between 1975 and 2000. Of interest, the proportion of claims for respiratory events decreased over this period, and due to this reduction the proportion of claims for cardiovascular events relatively increased so that by 2000 they occurred at the same frequency (28%). This trend seems to be associated with an increase in the use of pulse-oximetry and end-tidal carbon dioxide monitoring during this time, however this correlation is not definitively proven. It has been recommended that improvements

should focus on cardiovascular and respiratory interventions in order to reduce the number of perioperative deaths. (5, 37)

Cardiovascular events caused by both the administration of anaesthetic drugs and incorrect blood transfusion management during haemorrhage and anaemia have been particularly highlighted in the literature. (5) Lienhart et al (22) suggested that transfusion thresholds used by physicians were sometimes too low, leading to delayed or no transfusion in patients where it would have been beneficial . They found that delayed blood transfusion can cause hypotension, hypovolaemic shock, and postoperative myocardial infarction in high risk patients.

The most common respiratory-associated deaths are related to failures in airway management, particularly complications with endotracheal intubation and failures in pulmonary ventilation management. (7) The Special Committee Investigating Deaths under Anaesthesia (SCIDUA) in New South Wales, Australia, released a report in 2015 stating gastric aspiration as being one of the most common causes of patient mortality. (38) They reported the incidence of gastric aspiration during anaesthesia to be about 1 in 3200 elective cases and 1 in 900 emergency cases, with death resulting in about 5% of these cases. The Committee found that some practitioners were failing do a rapid sequence induction using suitable rapid-acting muscle relaxants in known at-risk patients.

2.5.3 Postoperative factors

Adequate and appropriate postoperative monitoring and facilities are essential in reducing anaesthesia-related mortality. This includes continued monitoring in an intensive care unit (ICU) for high-risk patients. (5, 31, 39) A survey conducted in France between 1978 and 1982 showed that half of the deaths and comas attributable to anaesthesia were from postoperative respiratory depression. This could be directly linked to a shortage of recovery rooms in the area at the time. (40)

2.5.4 Patient factors

There is a definite correlation between poor American Society of Anesthesiologists (ASA) physical status and mortality, with increased mortality seen in ASA III-V patients. (5, 41)

Age is also important, with children under one year and the elderly (over 65 years) having higher mortality rates than young adults. (5, 35)

A higher mortality rate has been noted in males. This may be due to the increased incidence of trauma and chronic cardiovascular disease in this group. The fact that emergency surgery was needed in most of these cases may play a role as emergency surgery has a higher mortality rate than elective surgery. (5)

2.5.5 Anaesthetist factors

There is a correlation between level of training of the anaesthetist and anaesthesia-related mortality. In New South Wales, Australia, there is a trend towards more specialisation with less medical officer and general practitioner involvement in anaesthesia administration. This is because it was found that medical officers played a role in mortality in “good risk” patients. Anaesthesiology trainees were involved in fewer deaths over the years likely due to better supervision by specialists. (9, 42)
In a Scottish surgical audit, McFarlane et al (34) reviewed “areas of concern related to anaesthesia” and found the grade of anaesthetist to be too junior in 22% of cases.

2.6 South African legal issues surrounding anaesthesia-related deaths:

There are several acts that relate to deaths in South Africa. Some of these acts have been amended in recent years. It is important that health practitioners become familiar with these acts and understand fully their legal responsibility in the case of mortality.

In South Africa, when a patient dies, the medical practitioner involved is required to issue a death notification form (form DHA-1663) which states the cause of death. This is governed by the Births and Deaths Registration Act (Act 51 of 1992) (43). On this form the medical practitioner states whether they feel the death was due to natural or unnatural reasons, what they feel the primary cause of death was, and any secondary or contributory factors. If the medical practitioner feels that the death was due to unnatural causes, they do not complete the certificate in the DHA-1663, but inform the police about the case and refer it to them. (10)

The Inquests Act (Act 58 of 1959) (44) governs cases where the death was thought to be due to unnatural causes. This act states that any person who believes that the cause of death was unnatural shall report the death to a policeman as soon as possible. The policeman shall investigate the circumstances surrounding the death and report the death to the district surgeon or forensic pathologist. The body of the deceased shall be examined by the district surgeon or forensic pathologist and a medico-legal inquest and autopsy will be performed in order to establish the cause of death.

The inquest may take the form of a formal hearing or a more informal “paper inquest” where there are no witnesses. The aim is not to charge the involved parties or prove guilt; it merely establishes whether the case should be referred for formal prosecution. (9, 10) In a legal court case if the medical practitioner is found to be guilty, they will be sentenced according to criminal law. If the verdict is not guilty, the practitioner can still be sentenced according to civil law or face disciplinary hearings by the HPCSA. (10)

In cases of a suspected unnatural death the medical practitioner involved in the case is obliged to provide the forensic pathologist and magistrate with the clinical details concerning the patient. These details are filled in on the GW 7/24 and D28 forms. The D28 form is completed in all medico-legal cases. The GW 7/24 form is completed when a procedure-related death occurs. This form must be completed by the medical practitioner in charge of the patient, the surgeon, anaesthetist and any other person concerned, for example a nursing sister or ancillary physician. (9, 10) The information supplied on this form should be sufficient to enable the magistrate or pathologist to decide whether a death was indeed unnatural and whether any parties involved need to be formally prosecuted. It is clearly very important that the information on this form is comprehensive and accurate.

It may be difficult for medical practitioners to decide whether a death is due to natural or unnatural causes. The National Health Act (Act 61 of 2003) (45) acts as a guide for health practitioners and states that the following deaths shall be deemed unnatural:

> "Any death due to a physical or chemical influence, direct or indirect, and/or related complications". Some examples here may be stabbing, electrocution or drug overdose.
>
> "Any death, including those deaths which would normally be considered to be a death due to natural causes, which in the opinion of the medical practitioner, has been the result of an act of commission or omission which may be criminal in nature". A patient who was not seen in the ward and not given necessary medication because of a health professionals strike would fall under this category.
> "Any death as contemplated in the Health Professions Amendment Act (Act 29 of 2007)". (11) This pertains to anaesthesia-related deaths.
>
> "Where the death is sudden and unexpected, or unexplained, or where the cause of death is not apparent."

Anaesthesia-related deaths are directly governed by the Health Professions Amendment Act (Act 29 of 2007) (11):

> “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 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 and Deaths Registration Act, 1992 (Act 51 of 1992)”.

The Health Professions Amendment Act (Act 29 of 2007) replaced the older Health Professions Act (Act 56 of 1974, Section 56) (46) in 2007. The old act stated:

> “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 Inquests Act, 1959 (Act 58 of 1959) or the Births and Deaths Registration Act, 1992 (Act 51 of 1992).”

The difference between the two acts is that the term “anaesthesia-related deaths” was replaced by the broader “procedure-related deaths”. Procedure- related deaths include anaesthesia, but also include any procedures which may not have needed an anaesthetic. There is no time limit stated in the law as to when the death can be attributed to the procedure or anaesthetic. (10) This means that even if a death occurred years after the procedure took place, it may still be deemed an unnatural death if the health professional feels that the procedure contributed to the death in some way. This ensures that no unnatural deaths are missed, but it does make it difficult to do mortality audits as long-term follow up of patients is needed. In addition it can increase the work-load of the forensic pathology service.

2.7 Critique of the GW 7/24 form

Section D of the GW 7/24 form is completed by the anaesthetist. There has been anecdotal evidence from both anaesthetists and forensic pathologists in South Africa that this section, and the form as a whole, is inadequate. Apart from poor recording of

the factors mentioned in section 2.5 above, there is also incomplete information available for forensic pathology examination and analysis. Forensic pathologists have reported difficulty in formulating the cause of death of a patient due to poorly completed and outdated GW 7/24 forms.

It has been shown in the literature that inadequate preoperative evaluation and optimisation can lead to increased perioperative mortality. (34, 35)

Question 1a of section D of the GW 7/24 form asks “Were all particulars in Part B and any other relevant feature(s) noted before the administration of the anaesthetic?” Part B is usually completed by the surgeon and contains the medical history, preoperative examination, assessment and preparation. This question denies the anaesthetist the opportunity to adequately detail their preoperative assessment and optimisation. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (47) states that the anaesthetist should assume a central role in the organisation of preoperative services. They have the necessary skills to assess and optimise patients and to decide whether to proceed with surgery and anaesthesia. The South African Society of Anaesthesiologists (SASA) also lists the preoperative risk assessment and risk management of surgical patients as one of the duties of an anaesthetist. (48) In a busy and resource-constrained country like South Africa surgeons are often expected to operate on patients whom they have not personally assessed and examined. The responsibility of the preoperative assessment often falls to the anaesthetist. It is for these reasons that it has been suggested that the preoperative assessment, which is currently completed by the surgeon in Part B of the GW 7/24 form, gets moved to Part D and gets completed by the anaesthetist.

Anaesthesia-related mortality instruments internationally focus specifically on the postoperative plan and outcome of the patient. (6, 49) The GW 7/24 form does not ask for details about the postoperative period. This is important as adequate management during the postoperative period has been shown to reduce anaesthesia-related mortality. (5, 31, 39)

The literature has shown that cardiovascular incidents, particularly the incorrect blood transfusion management during haemorrhage and anaemia, have been the major cause of anaesthesia-related mortality over the past 20 years. (5, 41) Part D of the GW 7/24 form does not make mention of blood transfusion management. In Part C, which is completed by the surgeon, Question 5 asks for “therapy prescribed during the procedure: (e.g. Blood transfusion, drugs)”. The anaesthetist is the practitioner usually responsible for blood product administration during the procedure therefore it is felt that this question should be included in Part D.

There has been a shift in focus recently from surgery and anaesthesia being seen as a specialised, tertiary service, to realising the importance of these services at a primary health care level. The World Health Assembly, which is the decision-making body for the World Health Organisation, resolved in 2015 to strengthen surgery and anaesthesia services as a component of universal health coverage. (50) This idea was reiterated at the National Forum on Surgery and Anaesthesia, held in Johannesburg, in December 2015. The discussion at the forum focused on the need for surgical and anaesthesia services at regional and district levels, and how these needs would be implemented and monitored. Several experts argued against the decentralisation of care, as maternal and anaesthetic mortality rates differ between provinces and between regional and tertiary centres. It was stated at the forum that in order for South Africa to achieve this goal, accurate data about both surgery and anaesthesia will need to be collected from all regions. (51) A procedure-related death notification form would be a useful instrument in this regard as it would highlight mortality differences across different hospital levels and different regions, and would give an indication of what interventions are required and where resources should be allocated. The current GW 7/24 form does not ask for specific details on the region or level of the hospital involved and so would not be helpful when analysing anaesthetic services across South Africa.

2.8 Lynn's Model

In 1986 Lynn developed a model to determine and quantify content validity of instruments. This model is used by researchers to collect, analyse and validate data. (17, 52, 53) It has been described as “especially influential”, particularly among nurse researchers. (54)

Validity is defined as “the extent to which that instrument measures what it is intended to measure”. Content validity is the “determination of the content representativeness or content relevance of the elements/items of an instrument by the application of a two-stage process”. (12)

The use of a two-stage process is fundamental to the validity of the instrument developed. The first stage in Lynn’s Model is the Developmental Stage.

The Development stage consists of three steps: domain identification; item generation and instrument formation. The domain identification is accomplished through a comprehensive review of the relevant literature on the subject so that all dimensions can be identified. This incorporates ideas from a variety of experts. During the item generation step items are generated for all dimensions and sub dimensions identified in step one. In the third, instrument formation step, the items generated in step two are refined and assembled into a usable form and a provisional instrument is created.

The Judgment- Quantification stage consists of two steps: The first is where a specific number of experts analyse each item on the provisional instrument, and ascertain that the items are content valid. The second step is that the entire instrument is rated as being content valid.

The number of experts needed in the Judgment –Quantification stage and the proportion of these experts that need to agree for content validity to be confirmed is decided by the application of the standard error of the proportion. A minimum number of three experts should be used and the maximum number is unlikely to exceed ten. A

table (Appendix 7) can be used to determine the proportion of experts who must be in agreement to judge an item as being content valid.

A structured procedure for the evaluation of content validity must be used by the experts. The most widely used quantification of content validity is the content validity index (CVI). A 4-point ordinal rating scale is used where one relates to an irrelevant item and four to an extremely relevant item. A rating of three or four determines content validity. The CVI for each item is determined by the proportion of experts who rate it as content valid and the CVI for the entire instrument is the proportion of total items judged as content valid.

The experts may also add any areas that they feel have been omitted from the instrument. Once the requirements of both stages of content validity are met, the instrument may then be used.

2.9 Summary

In this chapter the literature relating to anaesthesia-related mortality, the PRDN form in use in South Africa (the GW 7/24) and Lynn's Model were reviewed. In the next chapter the research methodology will be presented.

Chapter Three: Research Methodology

3.1 Introduction

In this chapter the research methodology used in the study is described. This includes the problem statement, aim, objectives and ethical considerations. The research design, study population and sampling process will be discussed, as well as the study methods, data analysis and validity of the study.

3.2 Problem Statement

There has been anecdotal evidence from several South African anaesthetists and forensic pathologists that the GW 7/24 form is inadequate. The form does not contain the relevant information required in order for the pathologist to make an informed decision regarding the cause of death, nor does it contain the relevant information needed in the case of medico-legal action or for academic audit purposes. (5-8)

3.3 Aim

The aim of this study was to develop and validate a procedure-related death notification (PRDN) instrument using Lynn's model, focusing on Section D of the current GW7/24 form. (12)

3.4 Objectives

The objectives of this study were to:

- Develop a provisional PRDN Instrument from the literature using Lynn's Development stage (domain identification and item generation)
- Develop a revised PRDN Instrument using Lynn's Development stage (instrument formation)
- Determine content validity of the revised PRDN Instrument using Lynn's Judgment-Quantification stage.

3.5 Ethical considerations

Approval to conduct the study was obtained from the Human Research Ethics Committee (Medical) (M160684)(Appendix 1) and the Postgraduate Committee of the University of the Witwatersrand (Appendix 2). The data collected in this study will be kept securely for six years.

During the Development stage of the study experts were invited to participate in a peer group discussion. An information letter was given to the participants (Appendix 3) and consent was implied by them taking part in the discussion. The experts' identity was known to the researcher, the supervisor and to the other members of the peer group discussion therefore anonymity could not be guaranteed. The participants were told about this in the information letter and were asked not to share information.

In the Judgment- Quantification stage the experts were contacted via email and once again received an information letter (Appendix 4). Consent was implied by them returning the email. The experts' identity was known only to the researcher and supervisor and no identifying information was used when the data was captured, ensuring confidentiality.

The study was conducted according to the principles of the Declaration of Helsinki (13) and the South African Good Clinical Practice Guidelines. (14)

3.6 Research methodology

3.6.1 Research Design

A prospective, instrumental study design was followed in this study.

A prospective study is one in which the variables are measured at the time at which the study takes place. (15) In this study data was collected as the study progressed.

This study was instrumental because specific rules, as per Lynn's Model (12), were applied to develop a validated instrument. (16)

Using Lynn's Model (12) this study resulted in a validated PRDN instrument which can be used for any procedure-related death in the future, for forensic or research purposes. (17)

3.6.2 Study Population

The study population included anaesthetists and forensic pathologists in South Africa who are experts in procedure-related deaths.

3.6.3 Study sample and sample method

Purposeful sampling was used in both stages of this study.

Purposeful sampling involves the researcher identifying individuals that are especially knowledgeable or experienced in the field of interest to the study. (18)

The experts in each stage were chosen by the researcher and supervisor in consultation with senior anaesthetic and forensic pathology consultants. They were chosen based on their knowledge of procedure-related deaths and the medico-legal processes surrounding these deaths in South Africa and elsewhere. They consisted of anaesthetists and forensic pathologists working in South Africa willing to participate in the study.

The exclusion criterion for the Judgment-Quantification stage was anyone who took part in the Development stage.

Sample size

Development stage: According to Lynn (12), the number of experts who should be used in this stage often depends on the availability of accessible and agreeable experts, but a minimum of five would provide an adequate level of control to rule out chance agreement. The maximum number of experts is yet to be established, but is unlikely to be more than ten. Six experts participated in the peer group discussion in this study, four anaesthetists and two forensic pathologists.

Judgment-Quantification stage: The number of experts needed in this stage follows the same principles as for the Development stage. When six or more experts are used, one expert can be in disagreement with the others and the instrument will still be assessed as content valid, however if there are five or less, all the experts must agree. In this study ten experts were invited to participate in the study.

3.6.4 Study Methods

Lynn describes a two-stage process of instrument development and validation consisting of the Development stage and the Judgment- Quantification stage. (12)

Development stage

There are three steps in the Development stage: Domain identification, item generation and instrument formation.

During the domain identification and item generation steps a thorough literature review was done by the researcher (domain identification) and a provisional PRDN instrument (Appendix 5) was produced (item generation).

During the instrument formation step the provisional PRDN instrument was reviewed and debated in a peer group discussion of six experts consisting of both anaesthetists and forensic pathologists. The experts were invited via email to join the discussion and the provisional PRDN instrument and information sheet was sent to them in advance. All six invited experts participated in the discussion which was chaired by the researcher and held at Charlotte Maxeke Johannesburg Academic Hospital.

The aim of the discussion was to refine the provisional PRDN instrument in order to improve its content validity. During the discussion the experts were asked to grade each item according to the following Likert scale:

1- Not important
2- Of little importance
3- Important but needs alteration
4- Important and succinct

A score of 3 or 4 meant the item was important and should remain on the form, a score of 1 or 2 meant it should be removed.

Each item on the provisional PRDN instrument was debated until complete consensus was reached. The experts were also encouraged to make suggestions for the inclusion of additional items.

After the peer group discussion the provisional PRDN instrument was refined into a revised PRDN instrument (Appendix 6) to be used in the Judgment-Quantification stage. The revised instrument was emailed to the experts to confirm that the discussed changes had been made.

Judgment- Quantification stage

During this stage the revised PRDN instrument was emailed to 10 experts around South Africa along with an information sheet describing the study and giving instructions on how to rate the items. Eight experts responded and took part in this stage.

Lynn describes two steps to the Judgment-Quantification stage: The first is the assertion by the experts that each item on the instrument is content valid. This was done by rating each item according to the same Likert scale used in the Development stage, with one being unimportant and four being important and succinct. The content validity index (CVI) of each item and of the instrument as a whole was then calculated by the researcher. (12, 19)

The revised PRDN instrument achieved a CVI of 0.96 making it content valid, however, it was decided to improve upon this instrument even further. The national experts made several useful comments and suggestions which were taken into consideration and incorporated into a final PRDN instrument. This instrument was then re-rated by the national experts.

3.7 Data Analysis

No data analysis was needed during the Development stage as each item was debated until complete consensus was reached.

During the Judgment-Quantification stage each item was rated by the experts according to a four-point Likert scale. This data was entered into a Microsoft Excel® spreadsheet by the researcher and then analysed.

The most widely used quantification of content validity according to Lynn is the content validity index (CVI). The CVI for each item is the proportion of experts who rated that item as content valid by giving it a score of three or four on the Likert scale. The proportion of experts who need to agree on each item in order for it to be real agreement versus chance was determined by setting the standard error of the proportion (Appendix 7). The CVI was then applied to the entire form by determining the proportion of total items judged as being content valid. (12)

3.8 Validity and reliability

Validity and reliability of the study was ensured in the following ways:

- An appropriate study design was used.
- A well-known, two-staged process was used to design the form.
- The CVI was used to validate both the items on the form and the form as a whole. This is a widely used validation tool. (12)

- Each data entry point on the Microsoft Excel ® spreadsheet was checked to ensure accuracy.

Validity in the Development stage was ensured by:

- Doing a thorough literature review to identify all dimensions and sub-dimensions relevant to the subject.
- Generating items for all domains identified and developing a provisional PRDN instrument.
- Holding a peer group discussion and debating each item on the provisional instrument until complete consensus was reached.

Validity in the Judgment-Quantification stage was ensured by:

- Eight national experts rating each item according to a 4-point Likert scale.
- Applying the CVI to each item by determining the proportion of experts who judged that item as content valid.
- Applying the CVI to the whole instrument by determining the total number of items judged content valid divided by the total number of items on the form.

3.9 Summary

In this chapter the problem statement, aim, objectives and ethical considerations were stated. The research methodology, data analysis and validity and reliability of the study were then described.

The next chapter will contain the results and discussion.

Chapter Four: Results and Discussion

4.1 Introduction

This chapter outlines the results of the study based on the study objectives. The results are then discussed.

The objectives were to:

- Develop a provisional PRDN Instrument from the literature using Lynn's Development stage (Domain identification and item generation)
- Develop a revised PRDN Instrument using Lynn's Development stage (Instrument formation)
- Determine content validity of the revised PRDN Instrument using Lynn's Judgment-Quantification stage

4.2 Approach to data analysis

An approach to data analysis is summarised in Figure 4.1 shown below.

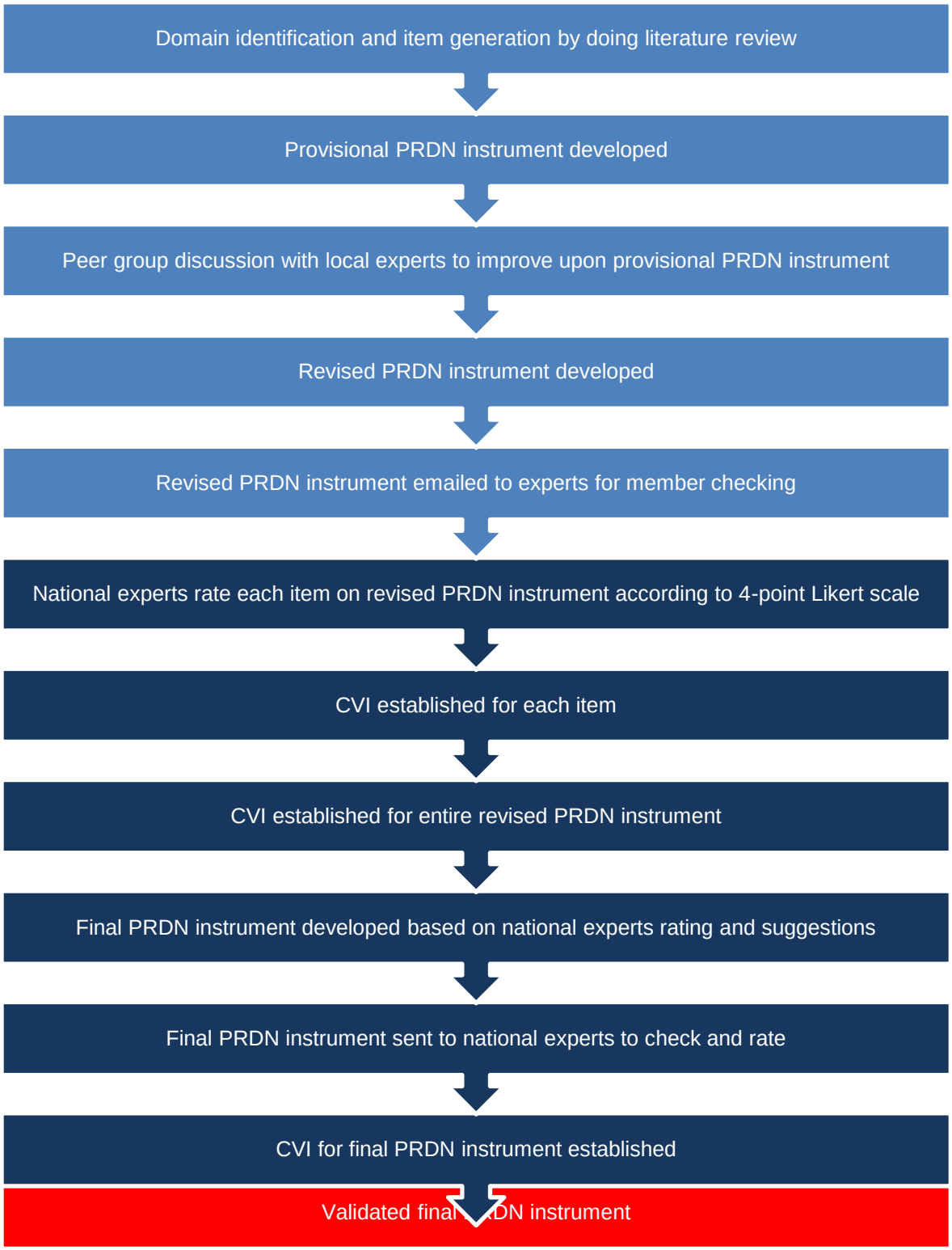

Figure 4.1 Flow diagram demonstrating study process

4.3 Results

There was no data analysis needed in the Development stage as each item was debated until complete consensus was reached.

In the Judgment-Quantification stage the content validity of each item and of the revised PRDN instrument as a whole was calculated. This revised instrument was further refined to include the suggestions made by the national experts and was then rated as content valid.

4.3.1 Objective: Develop a provisional PRDN instrument from the literature using Lynn's Development stage (domain identification and item generation)

A thorough literature review was done to determine factors related to anaesthetic mortality and morbidity, and a provisional PRDN instrument was developed which consisted of 14 domains and 66 items. This provisional instrument is shown in Table 4.1.

Table 4.1 Provisional PRDN instrument

Item and Domain	Reference
1. Demographics	
1.1 Name of patient	(55)
1.2 Age	(5)
1.3 Sex	(5)
2. Hospital	
2.1 Name of hospital	(55)
2.2 Level of hospital (PHC facility/District/Regional/Tertiary)	(56)
3. Anaesthetist	
3.1 Level of training (Intern/Community Service officer / Medical officer (state with or without Diploma in Anaesthesia/ Registrar/Consultant)	(56)
3.2 Was there an assistant (Doctor or nurse) present during induction?	(8)
3.3 Was there an assistant (Doctor or nurse) present during emergence?	(8)
3.4 Was a more senior anaesthetist available in case of emergency? (if yes please state if	(49)

telephonically or on the premises)	
4. Preoperative assessment	(57)
4.1 Elective or emergency surgery	(5)
4.2 History of presenting problem	(57)
4.3 Relevant co-morbid diseases	(57)
4.4 Previous anaesthetics	(57)
4.5 Allergies	(57)
4.6 Clinical examination	(57)
4.7 Relevant special investigations	(57)
4.8 Final clinical assessment	(57)
4.9 ASA rating	(58)
4.10 Pre-operative optimization and preparation	(57)
4.11 Pre-medication prescribed	(55)
5. Anaesthetic Technique	
5.1 General (Specify elective sequence vs rapid sequence induction)	(5)
5.2 Regional (Specify which)	(5)
5.3 Combined general and regional (specify)	(5)
5.4 Conscious sedation	(5)
6. Induction	
6.1 Please briefly describe your induction technique	(41)
6.2 Was the patient pre-oxygenated? (if applicable)	(41)
6.3 Was cricoid pressure applied? (If applicable)	(57)
6.4 Were there any problems during induction and how were they managed?	(41)
7. **Airway** (If applicable)	(7)
7.1 Type and size (Eg Endotracheal tube, supraglottic airway device, oro-pharyngeal, facemask oxygen)	(7)
7.2 Was there any difficulty with the airway and how was it managed?	(7)
8. Ventilation	(58)
8.1 Please state mode of ventilation	(39)
8.2 Fio2	(39)
8.3 Ppeak	(49)
8.3 Respiratory rate	(49)
8.4 PEEP	(49)
8.5 Tidal volume	(49)
9. Monitoring and equipment	(39, 58)

Please tick which equipment was used during the procedure	
9.1 Pulse oximetry	(58)
9.2 Capnography	(5)
9.3 ECG	(49)
9.4 Non-invasive blood pressure	(58)
9.5 Arterial line	(58)
9.6 Cardiac output monitor	(39)
9.7 Central Venous Catheter	(49)
9.8 Temperature probe	(8)
9.9 Urinary Catheter	(49)
9.10 Nerve Stimulator	(5)
9.11 Nasogastric tube	(55)
9.12 Forced air warmer	(8)
9.13 Fluid warmer	(8)
9.14 Arterial blood gas	(39)
9.15 Other	
10. Drugs	
Please state which drugs were used: (Name, dose, route , time of administration)	(55)
10.1 Induction	(41)
10.2 Maintenance	(3)
10.3 Emergence	(5)
10.4 Recovery/PACU	(5)
10.5 Drugs used for regional anaesthesia	(55)
10.6 Were there any adverse drug reactions and how were these managed?	(3)
11. Fluids	
11.1 Input: (Type, amount, route)	(5)
11.2 Were there any adverse blood product reactions? (If applicable)	(5)
11.3 Output (Type and volume of each Eg blood, urine, NGT, other)	(41)
12. Postoperative care	
12.1 Please state where patient went after the surgery: Straight to ward, PACU, ICU	(40)
12.2 If ICU was requested but denied, please state reasons for denial.	(39)
12.3 Were there any immediate post-operative complications?	(40)
13. Cardiac arrest (if applicable)	
13.1 Please describe details of the arrest	(55)
13.2 Time of arrest	(55)
13.3 Management of arrest including drugs and doses given	(55)

14. Cause of death	
In your opinion what was the likely cause of the death?	(55)

4.3.2 Objective: Develop a revised PRDN instrument using Lynn's Development stage (Instrument formation)

A peer group discussion was held on the 3 November 2016 in the Anaesthetic Department at Charlotte Maxeke Johannesburg Academic Hospital. All six of the invited local experts attended the discussion which was chaired by the researcher. Prior to the discussion the experts received an email containing the provisional PRDN instrument and information about the study. The demographics of the experts are shown in table 4.2.

Table 4.2 Demographics of local experts

Demographic	Number (%)
Gender	
• Male	1 (17)
• Female	5 (83)
Specialty	
• Anaesthetist	4 (67)
• Forensic pathologist	2 (33)
Years of experience as a specialist	
• >10	2 (33)
• <10	4 (67)

At the peer group discussion the experts were asked to rate each item according to the Likert scale shown in chapter 3. Items rated 3 or 4 were deemed important enough to remain on the form, items rated 1 or 2 were removed.

Each item was debated until complete consensus was reached. Experts were encouraged to suggest changes to current items and add any items they felt had been left off. The items which were changed during the peer group discussion are shown in table 4.3.

Table 4.3 Modified items on provisional PRDN instrument

Number	Domain and item	Modification	Notes
1	**Demographics**		
1.	Demographics	Added	Demographics to be repeated on every page
3.	**Anaesthetist**		
3.2	Was there an assistant (Doctor or nurse) present during induction?	Changed	Option added to specify who was present if applicable
3.3	Was there an assistant (Doctor or nurse) present during emergence?	Changed	Option added to specify who was present if applicable
	Was there a change-over of anaesthetist during the case?	Added	Experts felt this was important both because of the risk of complications due to inadequate handover, and when evaluating the case medico-legally.
4	**Preoperative assessment**		
4.4	Previous anaesthetics	Changed	The word “relevant” was added as it was felt this would result in more useful information.
4.7	Relevant special investigations	Changed	“Results of” was added to this item.
4.8	Final clinical assessment	Changed	Items 4.8 and 4.9 Were combined into one item.

4.9	ASA rating	Changed	The ASA scoring system was included for those not familiar with it.
	Hours since last meal: Specify: • Solids and infant formula • Breast milk • Clear fluids	Added	This is important when looking at aspiration events.
4.10	Pre-operative optimisation and preparation	Changed	"and preparation" omitted, deemed unnecessary.
6	**Induction**		
6.1	Please briefly describe your induction technique	Omitted	These 3 items were replaced by the following question: "Were there any problems during induction and how were they managed?" It was decided that any problems with the induction technique or omissions in the induction process would be covered by this answer.
6.2	Was the patient pre-oxygenated?(if applicable)	Omitted	
6.3	Was cricoid pressure applied?(if applicable)	Omitted	
8.	**Ventilation**		
8.1	Please state mode of ventilation	Changed	The following examples were added: "(eg Spontaneous, IPPV, Assist- ventilation)"
8.2	FiO2	Omitted	These 5 items were replaced by the question: "Were there any problems with ventilation of the patient and how were they managed?" It was felt that any relevant details about the ventilation would be included in this answer.
8.3	Ppeak	Omitted	
8.4	Respiratory rate	Omitted	
8.5	PEEP	Omitted	
8.6	Tidal Volume	Omitted	
9.	**Monitoring and equipment**		

9.15	Other	Added	Important, as new monitoring equipment is continually being developed.
9.16	Were there any problems with equipment and monitoring?	Added	Important to determine if faulty equipment contributed to the death.
10.	**Drugs**		
10.2	Muscle relaxants	Added	It was felt that more detailed information would be obtained if specific classes of drugs were asked for.
10.3	Analgesia	Added	
	Blood products:(Type, amount, route)	Added	Blood products may be left out unless not specifically asked for
	Estimated blood loss (ml)	Added	These three items replaced the original 11.3 "Output (Type and volume of each E.g blood, urine, NGT, other)."
	Estimated urine output (ml)	Added	
	Estimated amount (ml) of other losses (E.g NGT, Stoma). Please specify	Added	
12.	**Postoperative care**		
12.1	Please state where patient went after the surgery: Straight to ward, PACU, ICU	Changed	Changed to "Please state where and in what condition the patient went after the surgery: Straight to ward, Recovery room, High Care, Intensive care unit (ICU), other." It is important to document in what condition patient left theatre.
12.2	If ICU was requested but denied, please state reasons for denial.	Changed	Changed to "Was ICU requested?" Assume ICU was denied if it was requested but the answer "ICU" was not chosen in question 12.1.
13	**Cardiac arrest (if applicable)**	Changed	"if applicable" changed to the more specific "if present during the arrest"
	Please add any other important information	Added	There may be important information which was not covered by current items.

	relevant to the case:		
	Doctor name, signature, qualifications, contact details	Added	Doctor's demographics and contact details specifically asked for in case clarification needed.

The revised PRDN instrument was emailed to the local experts to check that all the suggested changes were made. All the experts were satisfied with the changes.

4.3.3 Objective: Determine content validity of the revised PRDN Instrument using Lynn's Judgment-Quantification stage

In the Judgment-Quantification stage ten national experts were emailed and asked to rate each item on the revised PRDN instrument. The national experts were chosen by the researcher and supervisor in consultation with senior anaesthetic and forensic pathology consultants. A total of eight experts responded to the email.

The demographics of the national experts are shown in table 4.4

Table 4.4 Demographics of national experts

Demographic	Number (%)
Gender	
• Male	3 (37.5)
• Female	5 (62.5)
Specialty	
• Anaesthetist	5 (62.5)
• Forensic pathologist	3 (37.5)
Years of experience as a specialist	
• >10	7 (87.5)

• <10	1 (12.5)
Province • Gauteng • KZN • Western Cape	 5 (62.5) 1 (12.5) 2 (25)

The national experts were sent an information letter via email outlining the study and giving instructions on how to rate the items. They were asked to rate each item according to the same four-point Likert scale used in the Development stage and shown in chapter 3. The CVI of each item was calculated by taking the number of experts who scored the item as three or four and dividing it by the total number of experts.The proportion of experts that needed to agree on each item for content validity to be established was decided by application of the standard error of the proportion. In order for the items to be regarded as content valid seven out of eight experts needed to agree (0.88). This is represented by a solid horizontal black line in the graphs below. If less than 7 out of eight of the experts scored the item with a 3 or 4 then the item was removed from the form. Figures 4.2-4.13 show the number of experts who rated each item with a 1 or 2 or a 3 or 4 on the Likert scale.

Under the “Demographics” domain, all three items scored a CVI of one.

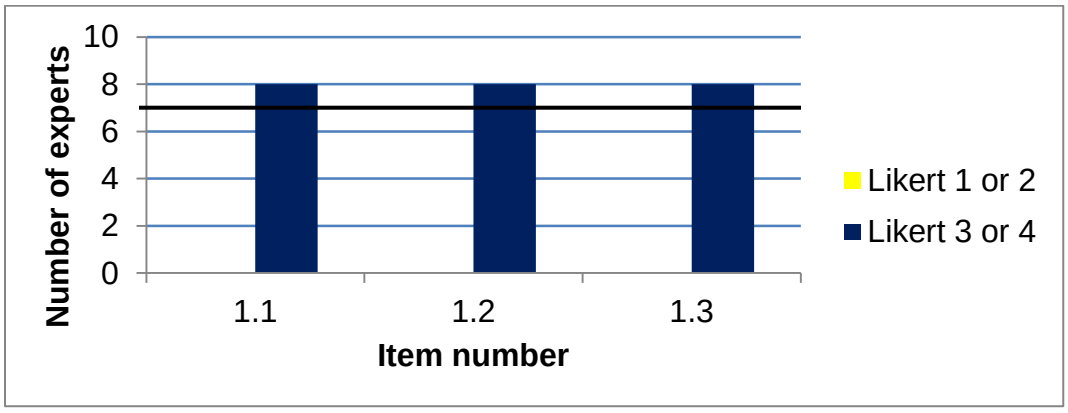

Figure 4.2 CVI for Demographics domain

Under the “Hospital” domain both items achieved the required CVI of 0.88 and were therefore deemed content valid.

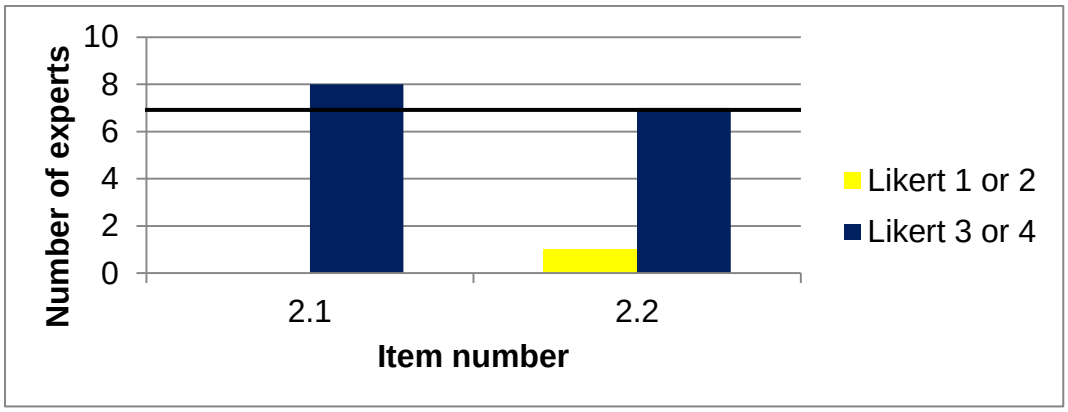

Figure 4.3 CVI for Hospital domain

Under the “Anaesthetist” domain, item 3.4 only achieved a CVI of 0.75 and was therefore removed from the final PRDN instrument. This item stated “Was a more senior anaesthetist available in case of emergency? (if yes please state if telephonically or on the premises)”.

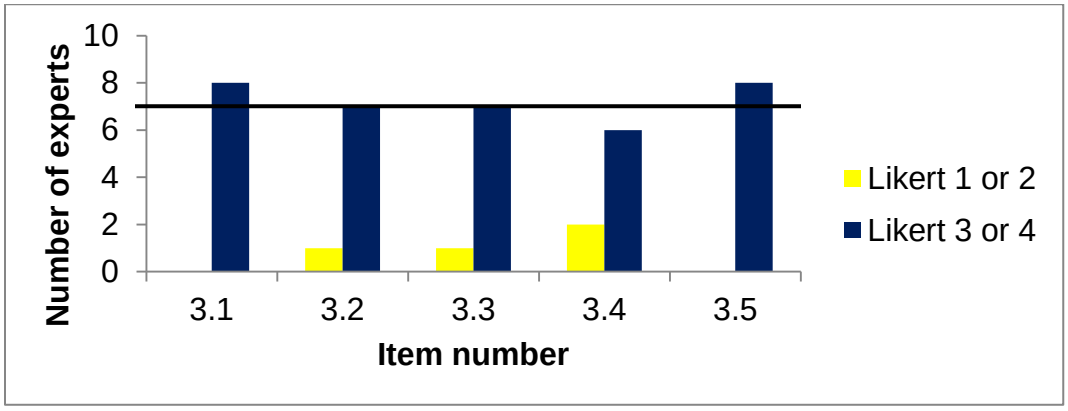

Figure 4.4 CVI for Anaesthetist domain

Under the “Preoperative assessment” domain all eleven items achieved the minimum CVI of 0.88 and were all deemed content valid.

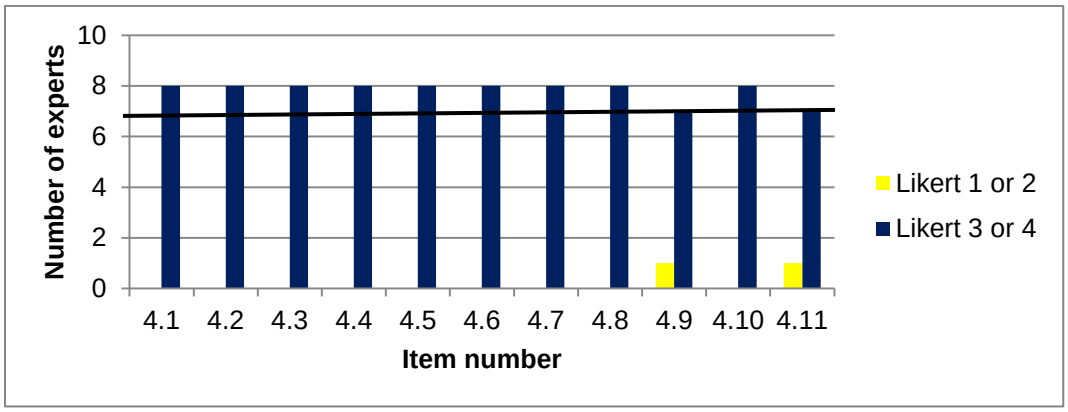

Figure 4.5 CVI for Preoperative assessment domain

All items under the domain “Anaesthestic technique” achieved a CVI of one.

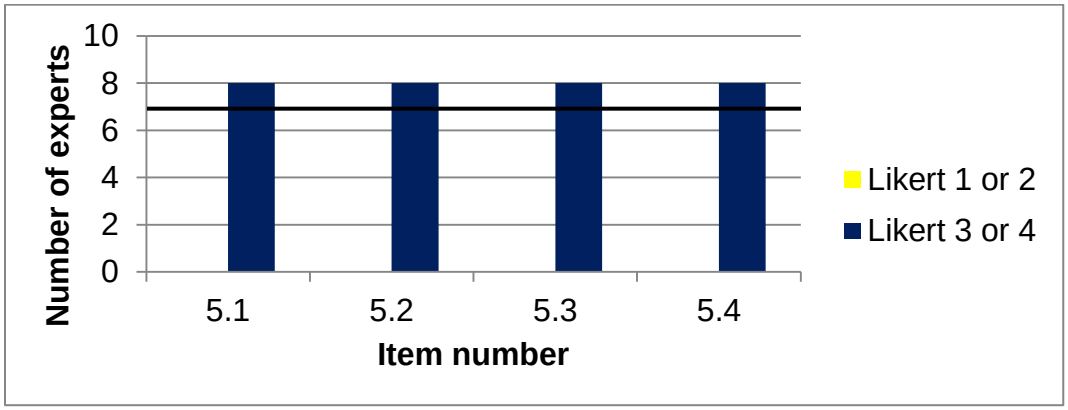

Figure 4.6 CVI for Anaesthetic technique domain

Under the “Induction” domain there was only one item. All eight experts rated this item with a Likert 3 or 4 and so it was content valid.

Under the “Airway” domain, both items achieved the minimum CVI of 0.88 for content validity.

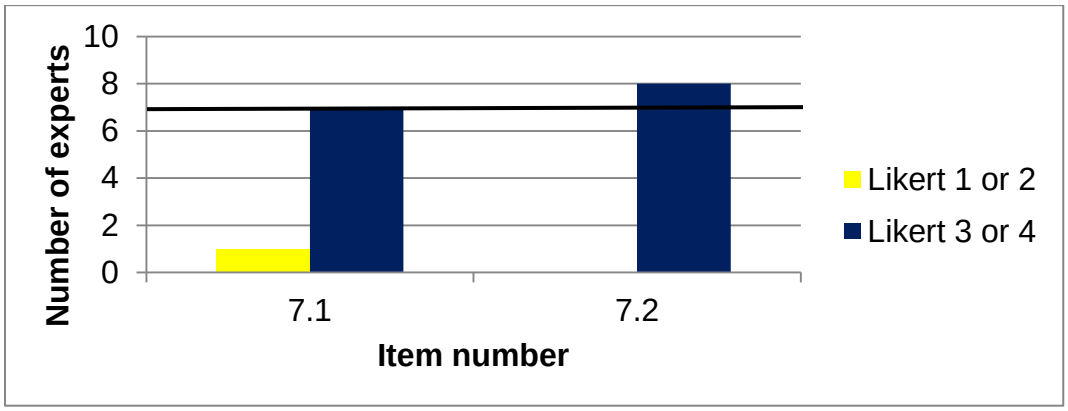

Figure 4.7 CVI for Airway domain

Both items under the “Ventilation” domain were rated as content valid.

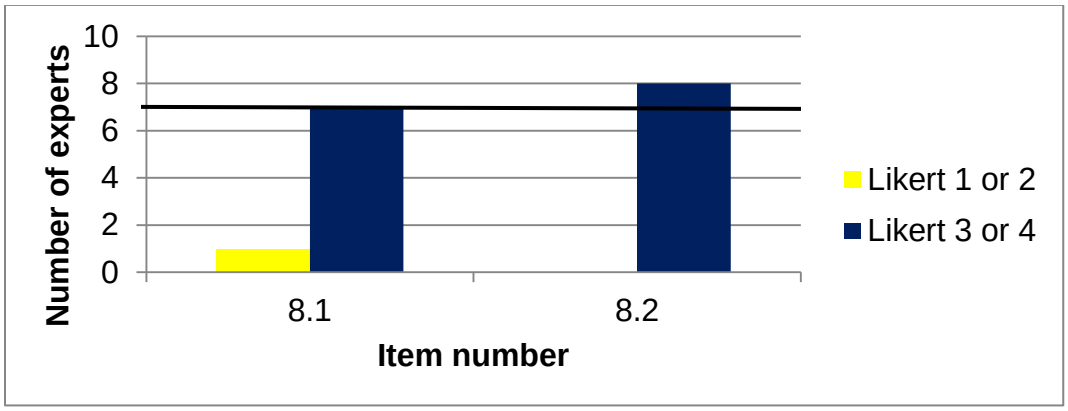

Figure 4.8 CVI for Ventilation domain

Under the domain “Monitoring and equipment”, only one item achieved less than the required CVI of 0.88 for content validity. Only six out of the eight experts rated the cardiac output monitor (item number 9.6) as important enough to specify on the PRDN

instrument. The two experts who disagreed felt it was not used regularly and could fall under item number 9.15, “Other”.

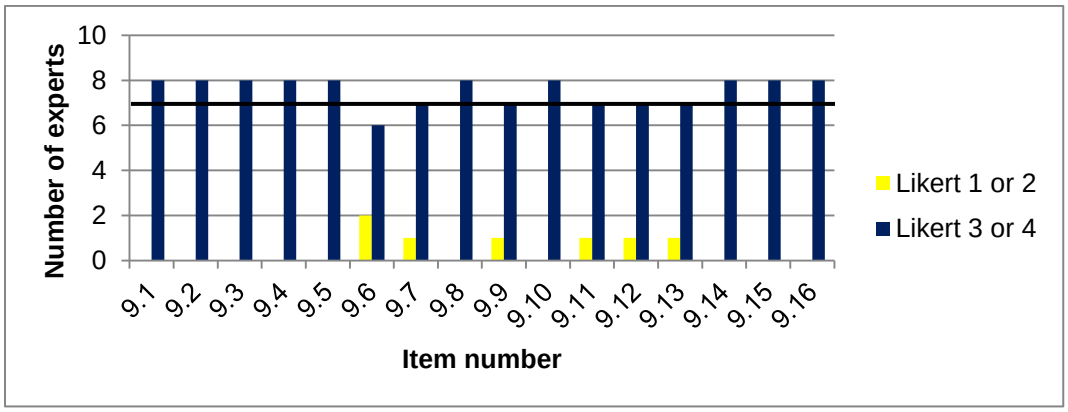

Figure 4.9 CVI for Monitoring and Equipment domain

Under the domain “Drugs”, all eight items were rated as important by the experts.

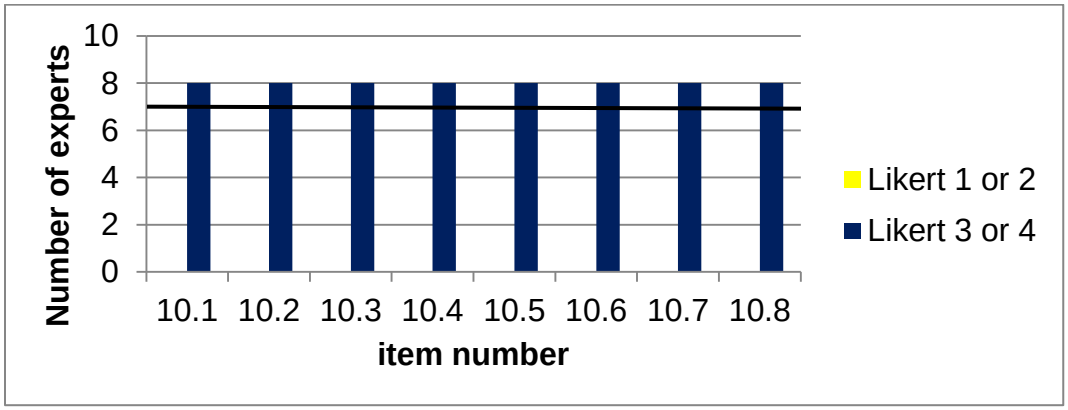

Figure 4.10 CVI for Drugs domain

Under the domain “Fluids”, five out of the six items were rated as content valid. Item 11.6 asked for the “Estimated amount (ml) of other losses (E.g. NGT, Stoma- please

specify)". Only six out of the eight experts felt this was important enough to retain on the PRDN instrument. It was therefore removed.

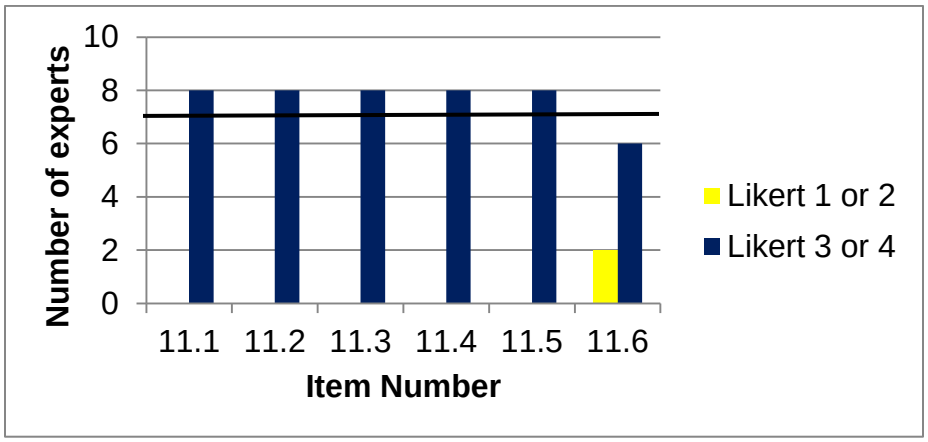

Figure 4.11 CVI for Fluids domain

Under the domain "Postoperative care", all three items were rated as content valid by the experts.

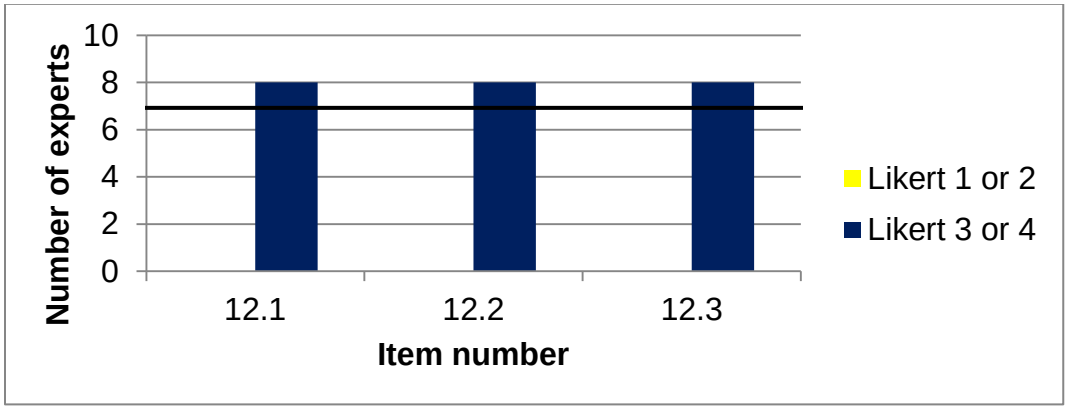

Figure 4.12 CVI for Postoperative care domain

Under the domain “Cardiac arrest”, all three items achieved the minimum CVI of 0.88. One of the experts felt that item 13.1, “Time of arrest” was not important.

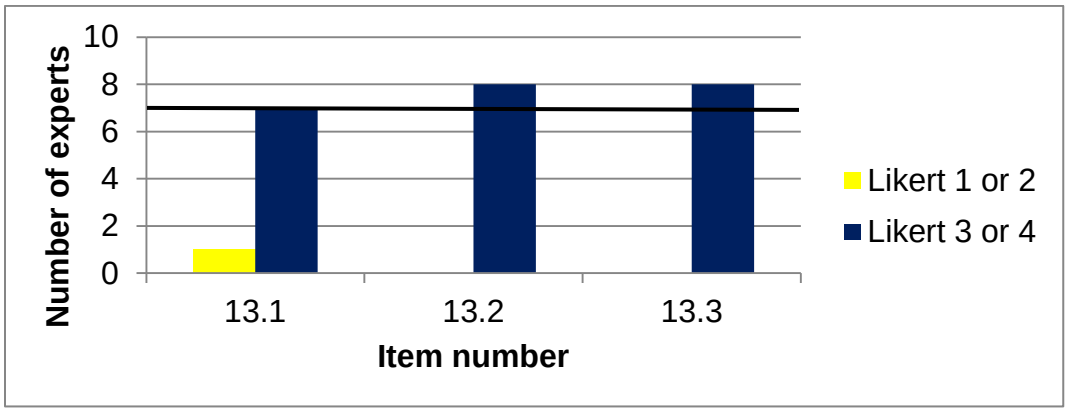

Figure 4.13 CVI for Cardiac arrest domain

The last three domains each consisted of one item. Item number 14.1 asked “In your opinion what was the likely cause of death?” Seven out of the eight experts rated this with a three or four on the Likert scale thus achieving the minimum CVI of 0.88. Items number 15.1(Other, please add any other important information relevant to the case) and 16.1 (Demographics of doctor) both achieved a CVI of 1.

After the CVI of each item was established the CVI of the entire instrument was calculated by determining the proportion of total items judged as content valid. According to the literature a newly developed instrument should have a minimum content validity index of 0.8.(19) The CVI for the revised PRDN instrument was 0.96, making it content valid.

The revised PRDN instrument achieved an adequate score to enable it to stand alone as a content valid instrument, however it was decided to improve upon this form even further. The national experts made several useful comments and suggestions which were taken into consideration and incorporated into the final PRDN instrument (Appendix 8). Table 4.6 outlines the changes to the final instrument.The final PRDN

instrument was then re-rated by the national experts and achieved a CVI of 1, every item scored a three or four by the judges.

Table 4. 5 Modified items on final PRDN instrument

Number	Domain and item	Modification	Notes
1	**Demographics**		
1.4	Hospital number	Added	Important to identify patient correctly
2	**Hospital**		
2.2	Level of hospital (PHC facility/District/Regional/Tertiary/Other-please specify)	Modified	An option for other hospital levels added. Hospital classifications may change
3	**Anaesthetist**		
3.4	Was a more senior anaesthetist available in case of emergency? (if yes please state if telephonically or on the premises)	Removed	CVI less than 0.88
4	**Preoperative assessment**		
4.4	Acute and chronic medication	Added	May be a cause of or contribute to a negative outcome
4.8	Results of relevant special investigations (e.g. CXR, ECG, blood results)	Modified	Important investigations specified
5	**Anaesthetic technique**		
5.5	Other(specify)	Added	Option for other added, for example local anaesthetic

6	**Induction**		
6.1	Date and time of induction	Added	Important to note exactly when anaesthetic started
9	**Regional anaesthesia**		
9.1	Were there any complications due to the regional technique and how were they managed?	Added	Important to ask specifically about regional anaesthesia
10	**Monitoring and equipment**		
10.6	Cardiac output monitor	Removed	CVI less than 0.88
10.15	Gas analyser	Added	Addition requested by many experts
10.16	Other (please specify)	Modified	“please specify” added
11	**IVI access**		
11.1	What IVI access was available during the case?	Added	Important to know if IVI access was appropriate for case
12	**Drugs**		
12.8	Please state any other drugs used during the procedure (Name, dose, route)	Added	Some drugs may not fall into the previous categories
13	**Fluids**		
13.6	Estimated amount (ml) of other losses (Eg NGT, Stoma- please specify)	Removed	CVI less than 0.88
14	**Postoperative care**		
14.1	Please state where patient went after surgery and in what condition they arrived at their destination: Straight to ward, Recovery room,	Modified	Wording changed to make meaning more clear

	High Care, Intensive care unit (ICU), other		
14.2	Was ICU requested? If denied please state reasons why.	Modified	If patient needed ICU but was denied it may have contributed to the death.
15	**Cardiac arrest**		
15.1	Date and time of arrest	Modified	Important to know exact details of arrest
16	**Details of death**		
16.1	Date and time of death	Added	Arrest is not synonymous with death. These details are required by law for inquest process.
16.2	Exact place of death	Added	

4.4 Discussion of results

A comprehensive PRDN instrument is an important tool for many reasons. It is used by forensic pathologists to determine the cause of death of a patient and as a medico-legal document during an inquest or investigation. It is also used by anaesthetists to audit morbidity and mortality. Audits are important as they can lead to a change in practice and better patient care. The current South African PRDN instrument, the GW 7/24 form (Appendix 9), is anecdotally described as outdated and in need of revision.

This study proposed to develop an updated PRDN instrument, using Lynn's two-stage model. Only the section relating to the anaesthetic was focused on. An extensive literature review was done to identify other PRDN instruments used locally and internationally and to investigate the common causes of and risk factors for death due to anaesthesia. In order for it to be relevant and applicable in a South African context, the

development of the new instrument used a process of stakeholder involvement by asking local and national experts to debate, revise and assess the updated instrument.

The final PRDN instrument consisted of 18 domains and 79 items. All the items were rated as content valid with a total instrument CVI of 1. There are several differences between the final PRDN instrument and the current GW 7/24 form. The final PRDN instrument is shown in Table 4.6.

Table 4.6 Final PRDN instrument

Item and Domain
1. Demographics (To be repeated on every page)
1.1 Name of patient
1.2 Age
1.3 Sex
1.4 Hospital number
2. Hospital
2.1 Name of hospital
2.2 Level of hospital (PHC facility/District/Regional/Tertiary/Other-please specify)
3. Anaesthetist
3.1 Level of training (Intern/Community Service officer/Medical officer (state with or without Diploma in Anaesthesia)/Registrar/Consultant)
3.2 Was there an assistant (Doctor or nurse) present during induction? If yes, please specify who.
3.3 Was there an assistant (Doctor or nurse) present during emergence? If yes please specify who.
3.4 Was there a change-over of anaesthetist during the case?
4. Preoperative assessment
4.1 Elective or emergency surgery
4.2 History of presenting problem
4.3 Relevant co-morbid diseases
4.4 Acute and chronic medication
4.5 Relevant previous anaesthetics
4.6 Allergies
4.7 Clinical examination
4.8 Results of relevant special investigations (eg CXR, ECG, blood results)
4.9 Final clinical assessment and ASA rating (include table of ASA scoring system for those not familiar

with it.)
4.10 Hours since last meal: Specify: Solids and infant formula Breastmilk Clear fluids
4.11 Pre-operative optimisation
4.12 Pre-medication prescribed
5. Anaesthetic Technique
5.1 General (specify elective sequence or rapid sequence induction)
5.2 Regional (specify which)
5.3 Combined general and regional (specify)
5.4 Conscious sedation
5.5 Other (specify)
6. Induction
6.1 Date and time of induction
6.2 Were there any problems during induction and how were they managed?
7. Airway (If applicable)
7.1 Type and size (Eg Endotracheal tube, supraglottic airway device, oro-pharyngeal, facemask oxygen)
7.2 Was there any difficulty with the airway and how was it managed?
8. Ventilation
8.1 Please state mode of ventilation (eg Spontaneous, IPPV, Assist- ventilation)
8.2 Were there any problems with ventilation of the patient and how were they managed?
9. Regional Anaesthesia (if applicable)
9.1 Were there any complications due to the regional technique and how were they managed?
10. Monitoring and equipment
Please tick which equipment was used during the procedure
10.1 Pulse oximetry
10.2 Capnography
10.3 ECG
10.4 Non-invasive blood pressure
10.5 Arterial line
10.6 Central Venous Catheter
10.7 Temperature probe
10.8 Urinary Catheter
10.9 Nerve Stimulator
10.10 Nasogastric tube

10.11 Forced air warmer
10.12 Fluid warmer
10.13 Arterial blood gas
10.14 Gas analyser
10.15 Other
10.16 Were there any problems with equipment and monitoring?
11. IVI Access
11.1 What IVI access was available during the case?
12. Drugs
Please state which drugs were used for: (Name, dose, route)
12.1 Induction
12.2 Muscle relaxants
12.3 Analgesia
12.4 Maintenance
12.5 Emergence
12.6 Recovery room/PACU
12.7 Drugs used for regional anaesthesia
12.8 Please state any other drugs used during the procedure (Name, dose, route)
12.9 Were there any adverse drug reactions and how were these managed?
13. Fluids
13.1 Fluid input: (Type, amount, route)
13.2 Blood products: (Type, amount, route)
13.3 Were there any adverse fluid and blood product reactions?
13.4 Estimated blood loss (ml)
13.5 Estimated urine output (ml)
14. Postoperative care
14.1 Please state where patient went after surgery and in what condition they arrived at their destination: Straight to ward, Recovery room, High Care, Intensive care unit (ICU), other
14.2 Was ICU requested? If denied please state reasons why.
14.3 Were there any immediate post-operative complications?
15. Cardiac arrest (if present during the arrest)
15.1 Date and time of arrest
15.2 Please describe details of the arrest
15.3 Management of arrest, including drugs and doses
16. Details of Death
16.1 Date and time of death

16.2 Exact place of death
16.3 In your opinion what was the likely cause of death?
17. Other
17.1 Please add any other important information relevant to the case:
18. Demographics of Doctor
18.1 Doctor name, signature, qualifications, contact details

Under the domain “Hospital”, an option was added to specify the level of hospital as PHC facility, district, regional, tertiary or other. This information is important in South Africa as there is a difference in anaesthesia-related mortality rates between different hospital levels. There is a need to collect accurate, region-specific anaesthetic information in order to identify where resources need to be allocated and how to strengthen anaesthetic services at primary, district and regional levels. (51)

The domain “Anaesthetist” included a question asking for more detail on the experience level of the anaesthetist and whether there was assistance available to them. This is also important when looking at the district and regional centres in South Africa, where community service officers, with little or no anaesthetic experience, are often expected to anaesthetise patients alone. Studies in both Australia and Scotland have shown that there is a link between inexperienced anaesthetists and anaesthesia-related mortality. (9, 34, 42) Illustrating this in South Africa would lead to better training and support of doctors working in the rural areas and therefore improve care to rural populations.

The domain “Preoperative assessment” was included in the final PRDN instrument. It has been shown in the literature that inadequate preoperative evaluation and optimisation can lead to increased perioperative mortality. (34) The preoperative assessment in the GW 7/24 form is completed by the medical practitioner in charge of the patient, usually the surgeon. It was felt by the experts, and noted in the literature, that the anaesthetist is the person who is usually responsible for the preoperative assessment and who possesses the necessary skills to assess and optimise patients for surgery. (47, 48)

The domain “Monitoring and equipment” was an addition to the final PRDN instrument. It was suggested at the peer group discussion that a tick-box format would suit this domain and would be an efficient way of collecting important information which is not included in the current GW 7/24 form. It has been shown in the literature that there is an association between the use of pulse-oximetry and end-tidal carbon dioxide monitoring and a reduction in respiratory-related damaging events. (23) Although it is not easy to prove that specific monitors reduce mortality, it is important to observe their effect on patient outcome and their safety and cost effectiveness, especially as new monitoring techniques are continually being developed. (59)

Part C of the GW7/24 form, completed by the surgeon, asks for details about conditions like shock and haemorrhage; how they affected the course of the procedure and how they were managed. It was felt by both local and national experts that the fluid and drug management of shock and haemorrhage during a procedure is usually the responsibility of the anaesthetist and should therefore be included in the anaesthetic part of a PRDN instrument. The Domains “IVI Access” and “Fluids” were added and ask for specific details on fluid and blood management. Incorrect blood management has been particularly highlighted in the international literature as a cause of anaesthesia-related morbidity and mortality, with delayed blood transfusion causing hypotension, hypovolaemic shock, and postoperative myocardial infarction in high risk patients. (5, 41)

Adequate monitoring and facilities during the postoperative period have been shown to reduce perioperative mortality rates. This includes continued monitoring in an intensive care unit (ICU) for high-risk patients. (5, 31, 39) The Royal Australasian College of Surgeons Anaesthetic Case Form (60) includes detailed questions about the recovery room management and a section on the use of intensive care and high care unit resources. The GW7/24 form does not include any questions about the postoperative period, therefore it was decided that a postoperative care domain be added to the final PRDN instrument, and that it included a question about ICU. In South Africa ICU beds are scarce resources resulting in many eligible patients being denied ICU services. The information obtained from question 4.2 in the final PRDN instrument, “Was ICU

requested? If denied please state reasons why", may help to motivate for more ICU beds in the future.

4.5 Conclusion

In chapter four, the results were presented and discussed. Chapter five will include a summary of the study, the limitations, recommendations and a conclusion.

Chapter Five: Summary, Limitations, Recommendations and Conclusion

5.1 Introduction

In this chapter a summary of the study, the limitations, recommendations and conclusion are presented.

5.2 Summary of the study

5.2.1 Aim

The aim of this study was to develop and validate a new procedure-related death notification (PRDN) instrument using Lynn's Model. (12)

5.2.2 Objectives

- Develop a provisional PRDN instrument from the literature using Lynn's Development stage (Domain identification and item generation)
- Develop a revised PRDN instrument using Lynn's Development stage (Instrument formation)
- Determine content validity of the revised PRDN instrument using Lynn's Judgment-Quantification stage.

5.2.3 Summary of methodology and results

A PRDN instrument was developed and validated using Lynn's two-stage model which consists of a Development stage and a Judgement-Quantification stage.

Development Stage

The Development stage consisted of three steps: Domain identification, item generation and instrument formation. An extensive literature review was done (domain identification) and a provisional PRDN instrument developed which consisted of 14 domains and 66 items (item generation). This instrument was debated at a peer group discussion where each item was rated and then discussed until complete consensus was reached and suggestions were made for the addition of further relevant items. This resulted in a revised PRDN instrument which consisted of 16 domains and 69 items (instrument formation).

Judgment-Quantification stage

The revised PRDN instrument was emailed to ten national experts consisting of both anaesthetists and forensic pathologists. Eight experts responded and took part in this stage. Each item on the form was rated according to a four-point Likert scale. The content validity index (CVI) of each item was calculated by the proportion of experts who rated the item with a score of three or four. The CVI of the instrument as a whole was determined by the proportion of items deemed content valid. The revised PRDN instrument, although rated as content valid, was further refined based on the experts' rating and additional comments, and a final, content valid PRDN instrument was developed which consisted of 18 domains and 79 items .

5.3 Limitations

The current GW 7/24 form consists of 4 parts. Part A and B are completed by the medical practitioner in charge of the patient, part C by the surgeon, and part D by the

anaesthetist. This study focused only on part D of the form. Ideally the other 3 parts of the form should also be updated and validated.

There is no standardised procedure-related death notification instrument internationally and in the literature. Different countries, states and hospitals all have their own forms which differ in the level of detail they require. Societies like the ASA and SASA do not have a standardised PRDN instrument template. This makes it difficult to compare our final validated PRDN instrument to a “gold standard.” A standardised PRDN instrument would make it easier and more accurate to compare anaesthesia-related mortality across hospitals, regions and countries.

The experts sampled in the study were considered to be representative of the body of expertise, however other experts may have valuable insights and opinions that were not included in this study.

5.4 Recommendations

Clinical practice

The validated final PRDN instrument should be submitted to SASA as a template for procedure-related mortality documentation. SASA can use this instrument as a society endorsed document when lobbying the Department of Health to update the current GW 7/24 form. There has been a significant increase in medical malpractice litigation in the past five years in South Africa. According to MPS the cost of claims has more than doubled over the past 2 years. In view of this there is an urgent need to update the current GW 7/24 form and ensure that comprehensive notes are kept in the event of a procedure-related death.

Research

The final PRDN instrument should be piloted at a hospital or region to assess efficacy and relevance. A qualitative study could be performed which assesses both anaesthetist and forensic pathology satisfaction with the instrument over a defined period of time. In the event of a procedure-related death, the new instrument should be completed by the anaesthetist involved together with the current GW 7/24 form. It should be used by forensic pathologists when determining the cause of death and by anaesthetists when doing morbidity and mortality audits and meetings. A questionnaire could then be completed by the relevant parties asking them for feedback and suggestions.

Part A, B and C of the GW 7/24 form should be updated. This could be done by surgical colleagues in collaboration with forensic pathology.

5.5 Conclusion

A death due to anaesthesia is a tragic event for the patient, their family and the medical practitioners involved. Although the anaesthesia-related mortality rate in South Africa has decreased there is still a lot that can be done to make anaesthesia safer. In order to identify which areas of practice need improving, and where resources need to be allocated, accurate audits of mortality and morbidity need to be carried out. To do this adequately we need proper documentation to show what happened during the procedure. One such document used is the anaesthetic chart, another is the PRDN instrument which is completed in the event of a death.

A comprehensive PRDN instrument is also needed in medico-legal situations. Forensic pathologists need the information in order to establish the cause of death and to decide whether an inquest should be held. Medical practitioners use this form when defending themselves in the case of an inquest or formal prosecution.

The current South African procedure-related death notification form, the GW 7/24, is outdated and inadequate and needs to be revised. The final PRDN instrument developed in this study is comprehensive, validated and will adequately capture all the information needed in both situations. This new instrument is a suitable replacement for Part D of the current GW7/24 form.

References

1. Macintosh R. Deaths under anaesthetics. Br J Anaesth. 1949;21(3):107-36.
2. Beecher HK, Todd DP. A Study of the deaths associated with anesthesia and surgery. Ann Surg. 1954;140(1):2-34.
3. Li G, Warner M, Lang B, Huang L, Sun L. Epidemiology of anesthesia-related mortality in the United States, 1999-2005. Anesthesiology. 2009;110(4):759-65.
4. Derrington M, Gallimore S. The effect of the National Confidential Enquiry into Perioperative Deaths on clinical practice. Anaesthesia. 1997;52:3-8.
5. Braz LG, Braz DG, da Cruz DS, Fernandes LA, Modolo NSP, Braz JRC. Mortality in Anesthesia: A Systematic Review. Clinics (Sao Paulo). 2009;64(10):999-1006.
6. Activities of the Special Committee Investigating Deaths Under Anaesthesia. Sydney: Clinical Excellence Commission; 2015 [21/6/2017]. Available from: http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0018/342720/SCIDUA-Annual-Report-2015.pdf.
7. Harrison GG. Death Attributable to Anaesthesia, A 10-year survey (1967-1876). Br J Anaesth. 1978;50:1041.
8. Gottschalk A, Van Aken H, Zenz M, Standl T. Is Anesthesia Dangerous? Dtsch Arztebl Int. 2011;108(27):469-74.
9. Lundgren A. Peri-operative Deaths in Two Major Academic Hospitals in Johannesburg, South Africa [Dissertation on the internet]. Johannesburg: University of Witwatersrand; 2011 [21/6/2017]. Available from: http://wiredspace.wits.ac.za/xmlui/bitstream/handle/10539/11663/ACL%20FINAL%20COMPLETED%20THESIS.pdf?sequence=1&isAllowed=y.
10. Jansen van Vuuren S. Acts and procedures concerning procedure-related deaths in South Africa. Afr J Prm Health Care Fam Med. 2013;5(1):453-8.
11. The Health Professions Amendment Act 29 of 2007. South Africa: Department of Justice and Constitutional Development; 2007 [26/10/2016]. Available from: http://www.gov.za/sites/www.gov.za/files/a29-07.pdf.
12. Lynn M. Determination and Quantification of Content Validity. Nurs Res. 1986;35(6):382-6.
13. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects Brazil: World Medical Association; 2013 [30/5/2016]. Available from: www.wma.net/en/30publications/10policies/b3/17c.pdf.
14. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa South Africa: Department of Health; 2006 [30/5/2016]. Available from: http://www.witshealth.co.za/Documents/South%20African%20Good%20Clinical%20Guidelines.pdf.
15. Brink H, van der Walt C, van Rensburg G. Fundamentals of Research Methodology for Healthcare Professionals. 2nd ed. Cape Town: Juta; 2006.
16. Burns N, Grove S. The Practice of Nursing Research. Sixth ed. Missouri: Saunders; 2009.
17. Vilas-Boas V, Mingotte P, Freitas M. Telephone call for post-discharge surveillance: validation and application of tool for video-assisted surgery. Rev Bras Enferm. 2015;68(5):899-905.

18. Palinkas L, Green C, Wisdom J, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. AdmPolicy Ment Health. 2016;42(5):533-44.
19. Grant S, Davis L. Selection and use of content experts for instrument development. Research in Nursing and Health. 1997;20(3):269-74.
20. Miller RD. Miller's Anesthesia. Philadelphia: Churchill Livingstone; 2010.
21. Mellin-Olsen J, Staender S, Whitaker D, Smith A. The Helsinki Declaration on Patient Safety in Anaesthesiology. Eur J of Anaesthesiol. 2010.;27(7):592-7.
22. Lienhart A, Auroy Y, Pequignot F, Benhamou D, Warszawski J, Bovet M, et al. Survey of anaesthesia-related mortality in France. Anesthesiology. 2006;105(6):1087-97.
23. Closed Claims Project and Its Registries. Seattle: Department of Anesthesiology and Pain Medicine; 2016 [13/9/2016]. Available from: http://depts.washington.edu/asaccp/projects/anesthesia-closed-claims-project.
24. Cheney FW. The American Society of Anesthesiologists Closed Claims Project The Beginning. Anesthesiology. 2010;113(4):957-60.
25. Cheney FW. The American Society of Anesthesiologists Closed Claims Project What Have We Learned, How Has It Affected Practice, and How Will It Affect Practice in the Future? Anesthesiology. 1999;91(2):552-6.
26. Do Anesthesiologists have the highest malpractice insurance rates? 2012 [22/10/2016]. Available from: www.theanesthesiaconsultant.com.
27. Lee L, Domino K. The Closed Claims Project. Has it influenced anesthetic practice and outcome? Anesthesiology Clin N Am. 2002;20:485– 501.
28. Medical Protection Society Subscription rates. South Africa: Medical Potection Society; 2015 [22/10/2016]. Available from: www.medicalprotection.org.
29. Kok O. Deaths associated with Anaesthesia and Surgery: A Statistical analysis of 1000 cases. S Afr J Surg. 1964;2:55-70.
30. Coetzee A. Peri-operative mortality in the anaesthetic service at Tygerberg Hospital. SAMJ. 1992;82:176-8.
31. National Confidential Enquiry into Patient Outcome and Death. London;2002 [26/10/2016]. Available from: http://www.ncepod.org.uk/ncepod.html.
32. National Policy Health Act 116 of 1990. South Africa: Government Gazette; 1990 [7/9/2016]. Available from: https://www.greengazette.co.za/acts/national-policy-for-health-act_1990-116.
33. Rout C, Farina Z. Anaesthesia-related maternal deaths in South Africa. South Afr J Anaesth Analg 2012;18(6):279-80.
34. McFarlane HJ, Van Der Horst N, Kerr L, McPhillips G, Burton H. The Scottish Audit of Surgical Mortality: a review of areas of concern related to anaesthesia over 10 years. Anaesthesia. 2009;64(12):1324-31.
35. Pignaton W, Braz JRC, Kusano P, Modolo M, de Carvalho L, Braz M, et al. Perioperative and Anesthesia-Related Mortality. Medicine. 2016;95(2):e2208.
36. Cheney FW, Posner KL, Lee LA, Caplan RA, Domino MK. Trends in Anesthesia-related Death and Brain Damage: A Closed Claims Analysis. Anesthesiology. 2006;105(6):1081-6.
37. Methodological Design: The Free Disctionary; [15/5/2016]. Available from: http://medical-dictionary.thefreedictionary.com/methodological+design.

38. Special Committee Investigating Deaths Under Anaesthesia, Learning from Case Reviews. Sydney: Clinical Excellence Commission; 2015 [21/6/2017]. Available from: http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0008/327509/SCIDUA-Learning-from-case-reviews-2015.pdf.
39. Arbous MS, Grobbee DE, van Kleef JW, Lange JJ, Spoormans HH, Touw P, et al. Mortality associated with anaesthesia: a qualitative analysis to identify risk factors. Anaesthesia. 2001;56(12):1141-53.
40. Tiret L, Hatton F, Desmonts JM, Vourc'h G. The implications of a national study of risk of anaesthesia. Health Policy. 1988;9(3):331-6.
41. Lienhart A, Auroy Y, Péquignot F, Benhamou D, Warszawski J, Bovet M, et al. Survey of Anesthesia-related Mortality in France. Anesthesiology. 2006;105(6):1087-97.
42. Warden J, Horan B. Deaths attributed to anaesthesia. Anaesthesia and Intensive Care. 1996;24:66-73.
43. The Births and Deaths Registration Act 51 of 1992. South Africa: Department of Justice; 1992 [26/10/2016]. Available from: http://www.info.gov.za/view/DownloadFileAction?id=122549

44. The Inquests Act 58 of 1959. South Africa: Department of Justice; 1959 [26/10/2016]. Available from: http://www.justice.gov.za/legislation/acts/1959-58.pdf.
45. National Health Act 61 of 2003. South Africa: Department of Health; 2003 [26/10/2016]. Available from: www.gov.za/sites/www.gov.za/files/a61-03.pdf.
46. The Health Professions Act 56 of 1974. South Africa;1974 [26/10/2016]. Available from: http://www.hpcsa.co.za/downloads/health_act/health_act_56_1974.pdf.
47. Pre-operative Assessment and Patient Preparation. The Role of the Anaesthetist. London: The Association of Anaesthetists of Great Britian and Ireland; 2010 [21/6/2017]. Available from: https://www.aagbi.org/sites/default/files/preop2010.pdf.
48. Bettings P, Diedericks J, Fourie P, Joubert I, Kluyts H, Lundgren C, et al. South African Society of Anaesthesiologists Practice Guidelines 2013. S Afr J Anaest Analg 2013;19(1):S1-42.
49. Lunn J, Hunter A, Scott D. Anaesthesia-related surgical mortality. Anaesthesia. 1983;38:1090-6.
50. Price R, Makasa E, Hollands M. World Health Assembly Resolution WHA68.15: ''Strengthening Emergency and Essential Surgical Care and Anesthesia as a Component of Universal Health Coverage''—Addressing the Public Health Gaps Arising from Lack of Safe, Affordable and Accessible Surgical and Anesthetic Services. World journal of surgery. 2015;39:2115-25.
51. Patel N, Peffer M, Leusink A, Singh N, Smith M. Surgery and anaesthesia in the South African context: Looking forward. SAMJ. 2016;106(2):135-6.
52. Wu S, Ho SC, Lam T-p, Woo J, Yuen PY, Qin L, et al. Development and validation of a lifetime exposure questionnaire for use among Chinese populations. Sci Rep. 2013;3:2793.
53. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. J Caring Sci. 2015;4(2):165-78.
54. Polit D, Beck C. The Content Validity Index: Are You Sure You Know What's Being Reported? Critique and Recommendations. Res Nurs Health. 2006;29:489-97.

55. Report of Person Whose Death is Associated with the Administration of an Anaesthetic or a Diagnostic or Therapeutic Procedure (GW 7/24). South Africa: Department of National Health and Population Development.
56. Gibbs N. National anaesthesia mortality reporting in Australia from 1985-2008. Anaesth Intensive Care. 2013;41(3):294-301.
57. Activities of the Special Committee Investigating Deaths Under Anaesthesia. Australia: Clinical Excellence Commission; 2014 [26/10/2016]. Available from: http://www.cec.health.nsw.gov.au/incident-management/mortality-review-committees/scidua/resource-list.
58. Case Record of Death in Association with Sedation and/or Anaesthesia Australia: Special Committee Investigating Deaths Under Anaesthesia; [30/5/2016]. Available from: http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0004/259357/scidua-questionnaire-template.pdf.
59. Chilkoti G, Wadhwa R, Saxena A. Technological advances in perioperative monitoring: Current concepts and clinical perspectives. J Anaesthesiol Clin Pharmacol. 2015;31(1).
60. Northern Territory Audit of Surgical Mortality: Royal Australasian College of Surgeons; [10/4/2017]. Available from: http://www.surgeons.org/for-health-professionals/audits-and-surgical-research/anzasm/ntasm/.

Appendix 1: HREC(Medical) certificate

R14/49 Dr Frances Orr

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160684

NAME: (Principal Investigator)	Dr Frances Orr
DEPARTMENT:	Anaesthesiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Development and Validation of an Instrument for Procedure-Related Death Notification
DATE CONSIDERED:	24/06/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ahmad Alli
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	13/07/2016

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

DECLARATION OF INVESTIGATORS

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

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Postgraduate committee approval of Mmed title

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

06 January 2017
Person No: 1321558
PAG

Dr FK Orr
206 Kent Place
Cnr North& Venus Road
Birdhaven
Johannesburg
2196
South Africa

Dear Dr Orr

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Development and validation of an instrument for procedure-related death notification* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3: Development stage information letter

Dear colleague

Hello, my name is Frances Orr and I am an anaesthetic registrar at the University of the Witwatersrand. I am conducting a research study as part of my Mmed degree. The title of the study is: Development and validation of an instrument for procedure-related death notification.

The motivation for my study is that there is anecdotal evidence that the current “Death on Table”, or GW 7/24 form is an inadequate and clumsy instrument. Procedure-related death information is important both for medico-legal purposes and for anaesthesia-related mortality audits. The latter is useful in detecting problem areas and influencing better practice and patient care.

I will be using Lynn’s model(12) to develop and validate this instrument. This is a two-stage (Development and Judgment- quantification) process that is used to determine the content validity of an instrument.

I hereby invite you as an expert in either anaesthesiology or forensic pathology to be part of the peer group that will participate in the development stage of this concept instrument. If you consent, I will send you the provisional Procedure-related Death Notification instrument prior to the peer group meeting. I have developed this provisional instrument from reviewing the relevant literature.

At the meeting I will ask that you grade each item on the form according to a 4 point scale:

1. Not important
2. Of little importance
3. Important but needs alteration
4. Important and succinct

I will also ask that you make recommendations for changes, additions or deletions to the provisional instrument.

We will debate each item on the form until 100% consensus has been reached as to whether that item should be kept or be discarded. These items will then form the revised procedure-related death notification form which will be used in the judgment-quantification stage of the study.

Participation in the peer group discussion is entirely voluntary. Participants will be requested that the contents of the discussion remain confidential, but as the researcher I cannot guarantee that confidentiality.
I appreciate that you will not directly benefit from this study but I hope that the development of a better PRDN form will help in both the medico-legal and audit processes related to anaesthesia-related deaths in the future.

This study has been approved by the Human Research Ethics Committee (HREC), (Number: M160684), and the Post Graduate Committee, University of the Witwatersrand.

My e-mail address is franceskateorr@gmail.com should you have any queries. Alternatively, contact me directly at 0836676589. Professor Cleaton-Jones, the chairman of the HREC can also be reached at 0117171234.

Thank you so much for your time.

Yours sincerely

Frances Orr

Appendix 4: Judgment-Quantification stage information letter

Dear colleague

Hello, my name is Frances Orr and I am an Anaesthetic registrar at the University of the Witwatersrand. I am conducting a research study as part of my Mmed degree. The title of the study is: Development and validation of an instrument for procedure-related death notification.

The motivation for my study is that there is anecdotal evidence that the current “Death on table”, or GW 7/24 form is an inadequate and clumsy instrument. Procedure-related death information is important both for medico-legal purposes and for anaesthesia-related mortality audits. The latter is useful in detecting problem areas and influencing better practice and patient care.

I will be using Lynn’s model to develop and validate this instrument. This is a two-stage (Development and Judgment- Quantification) process that is used to determine the content validity of an instrument. During the Development stage I reviewed the literature and developed a provisional procedure-related death notification (PRDN) form. A peer group discussion was then held and every item on this form was scored and debated until 100% consensus was reached. A revised PRDN form was then made

I hereby invite you as an expert in either Anaesthesiology or Forensic Pathology to participate in the Judgment-Quantification stage of this instrument development. If you consent, I have attached the revised PRDN form. I will ask that you grade each item on the form according to a 4 point scale:

1. Not important
2. Of little importance
3. Important but needs alteration
4. Important and succinct

Participation in this process is entirely voluntary. I, the researcher, and my supervisor will be the only people who know your identity and the data captured will not contain any identifying information thereby ensuring confidentiality.

I appreciate that you will not directly benefit from this study but I hope that the development of a better PRDN form will help in both the medico-legal and audit processes related to anaesthesia-related deaths in the future.

This study has been approved by the Human Research Ethics Committee (HREC), (Number: M160684) and the Post Graduate Committee, University of the Witwatersrand.

My e-mail address is franceskateorr@gmail.com should you have any queries. Alternatively, contact me directly at 0836676589. Professor Cleaton-Jones, the chairman of the HREC can also be reached at 0117171234.

Thank you so much for your time.

Yours sincerely

Frances Orr

Appendix 5: Provisional PRDN instrument

Item	Score
1. Demographics	
1.1Name of patient	
1.2Age	
1.3 Sex	
2. Hospital	
2.1 Name of hospital	
2.2 Level of hospital (PHC facility/District/Regional/Tertiary)	
3. Anaesthetist	
3.1 Level of training (Intern/Community Service officer / Medical officer (state with or without Diploma in Anaesthesia/ Registrar/Consultant)	
3.2 Was there an assistant (Doctor or nurse) present during induction?	
3.3 Was there an assistant (Doctor or nurse) present during emergence?	
3.4 Was a more senior anaesthetist available in case of emergency? (if yes please state if telephonically or on the premises)	
4. Preoperative assessment	
4.1 Elective or emergency surgery	
4.2 History of presenting problem	
4.3 Relevant co-morbid diseases	
4.4 Previous anaesthetics	
4.5 Allergies	
4.6 Clinical examination	
4.7 Relevant special investigations	
4.8 Final clinical assessment	

4.9 ASA rating	
4.10 Pre-operative optimization and preparation	
4.11 Pre-medication prescribed	
5. Anaesthetic Technique	
5.1 General (Specify elective sequence vs rapid sequence induction)	
5.2 Regional (Specify which)	
5.3 Combined general and regional (specify)	
5.4 Conscious sedation	
6. Induction	
6.1 Please briefly describe your induction technique	
6.2 Was the patient pre-oxygenated? (if applicable)	
6.3 Was cricoid pressure applied? (If applicable)	
6.4 Were there any problems during induction and how were they managed?	
7. **Airway** (If applicable)	
7.1 Type and size (Eg Endotracheal tube, supraglottic airway device, oro-pharyngeal, facemask oxygen)	
7.2 Was there any difficulty with the airway and how was it managed?	
8. Ventilation	
8.1 Please state mode of ventilation	
8.2 Fio2	
8.3 Ppeak	
8.4 Respiratory rate	
8.5 PEEP	
8.6 Tidal volume	

9. Monitoring and equipment	
Please tick which equipment was used during the procedure	
9.1 Pulse oximetry	
9.2 Capnography	
9.3 ECG	
9.4 Non-invasive blood pressure	
9.5 Arterial line	
9.6 Cardiac output monitor	
9.7 Central Venous Catheter	
9.8 Temperature probe	
9.9 Urinary Catheter	
9.10 Nerve Stimulator	
9.11 Nasogastric tube	
9.12 Forced air warmer	
9.13 Fluid warmer	
9.14 Arterial blood gas	
9.15 Other	
10. Drugs	
Please state which drugs were used: (Name, dose, route , time of administration)	
10.1 Induction	
10.2 Maintenance	
10.3 Emergence	
10.4 Recovery/PACU	
10.5 Drugs used for regional anaesthesia	
10.6 Were there any adverse drug reactions and how were these managed?	

11. Fluids	
11.1 Input: (Type, amount, route)	
11.2 Were there any adverse blood product reactions? (If applicable)	
11.3 Output (Type and volume of each Eg blood, urine, NGT, other)	
12. Postoperative care	
12.1 Please state where patient went after the surgery: Straight to ward, PACU, ICU	
12.2 If ICU was requested but denied, please state reasons for denial.	
12.3 Were there any immediate post-operative complications?	
13. Cardiac arrest (if applicable)	
13.1 Please describe details of the arrest	
13.2 Time of arrest	
13.3 Management of arrest including drugs and doses given	
14. Cause of death	
In your opinion what was the likely cause of the death?	

Appendix 6: Revised PRDN instrument

Item	Score	Comments
1.Demographics (To be repeated on every page)		
1.1 Name of patient		
1.2 Age		
1.3 Sex		
2.Hospital		
2.1 Name of hospital		
2.2 Level of hospital (PHC facility/District/Regional/Tertiary)		
3.Anaesthetist		
3.1 Level of training (Intern/Community Service officer / Medical officer (state with or without Diploma in Anaesthesia/ Registrar/Consultant)		
3.2 Was there an assistant (Doctor or nurse) present during induction? If yes, please specify who.		
3.3 Was there an assistant (Doctor or nurse) present during emergence? If yes please specify who.		
3.4 Was a more senior anaesthetist available in case of emergency? (if yes please state if telephonically or on the premises)		
3.5 Was there a change-over of anaesthetist during the case?		
4.Preoperative assessment		

4.1 Elective or emergency surgery		
4.2 History of presenting problem		
4.3 Relevant co-morbid diseases		
4.4 Relevant previous anaesthetics		
4.5 Allergies		
4.6 Clinical examination		
4.7 Results of relevant special investigations		
4.8 Final clinical assessment and ASA rating (include table of ASA scoring system for those not familiar with it.)		
4.9 Hours since last meal: Specify: Solids and infant formula Breastmilk Clear fluids		
4.10 Pre-operative optimization		
4.11 Pre-medication prescribed		
5.Anaesthetic Technique		
5.1 General (Specify elective sequence or rapid sequence induction)		
5.2 Regional (Specify which)		
5.3 Combined general and regional (specify)		
5.4 Conscious sedation		
6.Induction		
6.1 Were there any problems during induction and how were they managed?		
7. Airway (If applicable)		
7.1 Type and size (Eg Endotracheal tube, supraglottic		

airway device, oro-pharyngeal, facemask oxygen)		
7.2 Was there any difficulty with the airway and how was it managed?		
8. Ventilation		
8.1 Please state mode of ventilation (eg Spontaneous, IPPV, Assist- ventilation)		
8.2 Were there any problems with ventilation of the patient and how were they managed?		
9. Monitoring and equipment		
Please tick which equipment was used during the procedure		
9.1 Pulse oximetry		
9.2 Capnography		
9.3 ECG		
9.4 Non-invasive blood pressure		
9.5 Arterial line		
9.6 Cardiac output monitor		
9.7 Central Venous Catheter		
9.8 Temperature probe		
9.9 Urinary Catheter		
9.10 Nerve Stimulator		
9.11 Nasogastric tube		
9.12 Forced air warmer		
9.13 Fluid warmer		
9.14 Arterial blood gas		
9.15 Other		
9.16 Were there any problems with equipment and monitoring?		

10. Drugs		
Please state which drugs were used for: (Name, dose, route).		
10.1 Induction		
10.2 Muscle relaxants		
10.3 Analgesia		
10.4 Maintenance		
10.5 Emergence		
10.6 Recovery room/PACU		
10.7 Drugs used for regional anaesthesia		
10.8 Were there any adverse drug reactions and how were these managed?		
11. Fluids		
11.1 Fluid input: (Type, amount, route)		
11.2 Blood products: (Type, amount, route)		
11.3 Were there any adverse fluid and blood product reactions?		
11.4 Estimated blood loss (ml)		
11.5 Estimated urine output (ml)		
11.6 Estimated amount (ml) of other losses (Eg NGT, Stoma- please specify)		
12. Postoperative care		
12.1 Please state where and in what condition the patient went after the surgery: Straight to ward, Recovery room, High Care, Intensive care unit (ICU), other		
12.2 Was ICU requested?		

12.3 Were there any immediate post-operative complications?		
13. Cardiac arrest (if present during the arrest)		
13.1 Time of arrest		
13.2 Please describe details of the arrest		
13.3 Management of arrest including drugs and doses given		
14. Cause of death		
In your opinion what was the likely cause of the death?		
15. Other: Please add any other important information relevant to the case:		
16.Demographics of Doctor: 16.1 Doctor name, signature, qualifications, contact details		

Appendix 7: Cumulative binomial distribution

Table 2. Proportion of Experts (Above the Line) Whose Endorsement Is Required to Establish Content Validity Beyond the .05 Level of Significance

Number of Experts	Number of Experts Endorsing Item or Instrument as Content Valid								
	2	3	4	5	6	7	8	9	10
2	1.00								
3	.67	1.00							
4	.50	.75	1.00						
5	.40	.60	.80	1.00					
6	.33	.50	.67	.83	1.00				
7	.29	.43	.57	.71	.86	1.00			
8	.25	.38	.50	.63	.75	.88	1.00		
9	.22	.33	.44	.56	.67	.78	.89	1.00	
10	.20	.30	.40	.50	.60	.70	.80	.90	1.00

Appendix 8: Final PRDN instrument

Item	Score	Comments
1. Demographics (To be repeated on every page)		
1.1 Name of patient		
1.2 Age		
1.3 Sex		
1.4 Hospital number		
2. Hospital		
2.1 Name of hospital		
2.2 Level of hospital (PHC facility/District/Regional/Tertiary/Other-please specify)		
3.Anaesthetist		
3.1 Level of training (Intern/Community Service officer/Medical officer (state with or without Diploma in Anaesthesia)/Registrar/Consultant)		
3.2 Was there an assistant (Doctor or nurse) present during induction? If yes, please specify who.		
3.3 Was there an assistant (Doctor or nurse) present during emergence? If yes please specify who.		
3.4 Was there a change-over of anaesthetist during the case?		

4.Preoperative assessment		
4.1 Elective or emergency surgery		
4.2 History of presenting problem		
4.3 Relevant co-morbid diseases		
4.4 Acute and chronic medication		
4.5 Relevant previous anaesthetics		
4.6 Allergies		
4.7 Clinical examination		
4.8 Results of relevant special investigations (eg CXR, ECG, blood results)		
4.9 Final clinical assessment and ASA rating (include table of ASA scoring system for those not familiar with it.)		
4.10 Hours since last meal: Specify: Solids and infant formula Breastmilk Clear fluids		
4.11 Pre-operative optimisation		
4.12 Pre-medication prescribed		
5.Anaesthetic Technique		
5.1 General (specify elective sequence or rapid sequence induction)		
5.2 Regional (specify which)		
5.3 Combined general and regional (specify)		
5.4 Conscious sedation		
5.5 Other (specify)		

6.Induction		
6.1 Date and time of induction		
6.2 Were there any problems during induction and how were they managed?		
7.Airway (If applicable)		
7.1 Type and size (Eg Endotracheal tube, supraglottic airway device, oro-pharyngeal, facemask oxygen)		
7.2 Was there any difficulty with the airway and how was it managed?		
8.Ventilation		
8.1 Please state mode of ventilation (eg Spontaneous, IPPV, Assist- ventilation)		
8.2 Were there any problems with ventilation of the patient and how were they managed?		
9.Regional Anaesthesia (if applicable)		
9.1 Were there any complications due to the regional technique and how were they managed?		
10.Monitoring and equipment		
Please tick which equipment was used during the procedure		
10.1 Pulse oximetry		
10.2 Capnography		
10.3 ECG		
10.4 Non-invasive blood pressure		
10.5 Arterial line		
10.6 Central Venous Catheter		

10.7 Temperature probe		
10.8 Urinary Catheter		
10.9 Nerve Stimulator		
10.10 Nasogastric tube		
10.11 Forced air warmer		
10.12 Fluid warmer		
10.13 Arterial blood gas		
10.14 Gas analyser		
10.15 Other		
10.16 Were there any problems with equipment and monitoring?		
11.IVI Access		
11.1 What IVI access was available during the case?		
12.Drugs		
Please state which drugs were used for: (Name, dose, route)		
12.1 Induction		
12.2 Muscle relaxants		
12.3 Analgesia		
12.4 Maintenance		
12.5 Emergence		
12.6 Recovery room/PACU		
12.7 Drugs used for regional anaesthesia		
12.8 Please state any other drugs used during the procedure (Name, dose, route)		
12.9 Were there any adverse drug reactions and how were these managed?		

13.Fluids		
13.1 Fluid input: (Type, amount, route)		
13.2 Blood products: (Type, amount, route)		
13.3 Were there any adverse fluid and blood product reactions?		
13.4 Estimated blood loss (ml)		
13.5 Estimated urine output (ml)		
14.Postoperative care		
14.1 Please state where patient went after surgery and in what condition they arrived at their destination: Straight to ward, Recovery room, High Care, Intensive care unit (ICU), other		
14.2 Was ICU requested? If denied please state reasons why.		
14.3 Were there any immediate post-operative complications?		
15. Cardiac arrest (if present during the arrest)		
15.1 Date and time of arrest		
15.2 Please describe details of the arrest		
15.3 Management of arrest, including drugs and doses		
16. Details of Death		
16.1 Date and time of death		
16.2 Exact place of death		
16.3 In your opinion what was the likely cause of death?		
17. Other		

17.1 Please add any other important information relevant to the case:		
18. Demographics of Doctor 18.1 Doctor name, signature, qualifications, contact details		

Appendix 9: GW 7/24 Form

GW 7/24

DEPARTMENT OF NATIONAL HEALTH AND POPULATION DEVELOPMENT

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

INSTRUCTION

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

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

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

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

   Part E—by any other person (e.g. nursing sister).
3. Use additional sheets if space provided is inadequate.
4. It is advisable to keep a copy on the patient's file.

PART A.—GENERAL INFORMATION (IN BLOCK LETTERS)

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

   In charge .....

   Others .....

   .....

   .....

   .....

   .....

   .....

   .....

   Anaesthetist .....

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

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

GW 7/24

PART B.—MEDICAL PARTICULARS OF PATIENT

Name of patient .....

1. History .....

Drug or alcohol addiction .....

Previous anaesthetics .....

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

(b) after admission .....

2. Pre-operative examination:

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

Temperature ..... °C. Septic Foci .....

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

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

Respiratory system .....

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

(mention specially any evidence of excessive mucus).

Uro-genital system .....

..... Urine .....

Other systems .....

3. Diagnosis .....

4. Patient's general condition:

Good	Fair	Poor	Serious	Grave

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

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

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

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

Signed .....

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

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

Name of patient.....

(This excludes the anaesthetic administration)

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

Signed .....

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

PART D.—THE ANAESTHETIC

Name of patient .....

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

1. (b) .....

2. Premedication prescribed .....

Was premedication satisfactory .....

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

4. Agents used:

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

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

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

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

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

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

Complications .....

What was the first alarming sign?.....

.....

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

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

.....

Method of cardiac massage and/or defibrillation .....

.....

Result.....

Resuscitative measures.....

.....

.....

.....

5. Details of drugs used and general condition:

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

6. Account of death and events leading thereto .....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

7. Opinion with regard to cause of death.....

.....

.....

.....

.....

Signed .....

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

GW 7/24

PART E.—OTHER ACCOUNTS OF THE DEATH

Name of patient .....

1. .....

Signed .....

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

2. .....

Signed .....

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