The Development and validation of an instrument for labour epidural analgesia recordkeeping in hospitals in Southern Gauteng

Elizabeth Johanna Jacobs

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, 2015

Declaration

I, Elizabeth Johanna Jacobs, declare that this research report is my own work. It is being submitted for the degree of MMed in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Elizabeth Johanna Jacobs

September 2015.

To my family

ABSTRACT

Adverse events are a potential outcome, no matter how skilled the anaesthetist, or how stringently he/she observes protocol. The medical notes made after regional procedures are poor in comparison with those made for general anaesthesia, and this has come under scrutiny in recent years due to increased patient awareness, medical insurance billing strategies and the presence of regulatory bodies. Currently, different labour epidural anaesthesia records are used in the hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand. There is a need for standardised labour epidural anaesthesia records that comply with the minimum standards of the Health Professions Council of South Africa.

The aim of this study was to develop and validate an instrument for labour epidural analgesia recordkeeping, using local and national experts and following the two stages of instrument validation described by Lynn. In the development stage, the concept instrument, identifying items considered important on anaesthetic records, was developed through literature review. The concept instrument was refined by a peer group discussion with local experts and the items rated with a four point Likert scale. Items were added, removed or changed according to their ratings. The concept instrument became known as the rated instrument and the items on it were again rated with a four point Likert scale, this time by a national expert panel, and items changed or removed according to Content Validity Indices.

The results showed that most of the clinical aspects which are deemed important for labour epidural analgesia recordkeeping by the international anaesthetic community also apply to South Africa. The page layout and presentation of the labour epidural chart is not considered important in a South African context. The information gained from using this instrument in a clinical context can be incorporated into a usable format to facilitate labour epidural analgesia recordkeeping.

Table of contents

List of tables

List of Figures

List of appendices

CHAPTER ONE

OVERVIEW OF THE STUDY

1.1. Introduction

In this chapter an overview of the study is provided. This consists of the background of the study, the problem statement, the aim, the objectives, the research assumptions, the ethical considerations, the research methodology, the significance, reliability and validity of the study and a summary of the chapter.

1.2. Background

Labour is widely acknowledged to be amongst the most painful experiences known and multiple methods have been used for labour analgesia. A balance between optimising foetal and maternal wellbeing and the multidimensional experience of childbirth should be the obstetric anaesthetist's goal in labour anaesthesia. (1) Epidurals encompass most of the characteristics of ideal labour analgesia and so have become the gold standard of pain relief intrapartum. (2)

There is a progressive increase in the use of labour epidural analgesia worldwide. In 2004, two thirds of labouring women in the United States of America (USA) (3) had epidurals, the rate having tripled between 1981 and 2001. Approximately 50% of Canadian women who have a normal vaginal delivery have epidurals, showing the rate varying between provinces from 30-69%. (4) Twenty one percent of women in the United Kingdom (UK) (5) have epidurals prior to delivery, whether they deliver via caesarean section or vaginally (6).

The use of epidurals in developing countries, especially South Africa, is unknown. However, Dyer (7) recently made note of the dynamic changes in the indications for neuraxial anaesthesia in developing countries. It is now feasible or even preferable to perform neuraxial anaesthesia for patients with severe pre-eclampsia and certain heart valve lesions. In South Africa, epidural anaesthesia is recommended for early labour analgesia (8) yet the rate of epidurals done in the Chris Hani Baragwanath Academic Hospital (CHBAH) labour ward is 3%, only 60 of an average of 2000 deliveries per month (9).

A Tygerberg Academic Hospital labour epidural analgesia audit in 2014 showed a labour epidural rate of 2,2%, illustrating the need to increase this service. Most patients were satisfied with their analgesia and the complications secondary to the labour epidurals was comparable to those in the developed world. However, time and staff constraints and specific patient indications for the epidurals (morbid obesity, cardiovascular disease and preeclampsia) limited the scope of the study. (10)

Given that the use of labour epidural analgesia is on the increase in both developed and developing countries and keeping in mind that it is a procedure with risk, this demands a means for documenting each case appropriately. A standardised labour epidural analgesia record would have advantages for both the anaesthetist and the patient and is a recognised vital constituent of anaesthetic care. (11)

Anaesthetists are required to keep comprehensive records as outlined by various professional societies and statuary bodies in guidelines (12, 13). Labour epidural analgesia recordkeeping should be considered as part of the anaesthetists' anaesthetic recordkeeping. However most of the guidelines recommendations are vague, and not specific to labour epidural anaesthesia (11).

Despite the importance of anaesthetic records, there is a plethora of local systems attempting to conform to nationally agreed standards and recommendations. A survey reviewing the structure and content of all anaesthetic record charts in use in the 40 hospitals of Yorkshire in the UK showed that 22 different anaesthetic charts were used by 290 anaesthetists in this region (14).

Following the Royal College of Anaesthetists (15) and the Association of Anaesthetists of Great Britain and Ireland published guidelines on recordkeeping in 1996, a study conducted in North West England in 1997 concluded that no anaesthetic record complied fully with the these guidelines. A subsequent study in Scotland examined the anaesthetic charts of 27 out of 29 National Health Service anaesthetic departments by auditing 202 charts from two district general hospitals against the RCOA guidelines and also found that no chart complied fully with these guidelines. A new chart was therefore developed to facilitate guideline compliance. (16)

In the Western Cape in 2003, James et al (17) randomly audited 284 anaesthetic charts at a local hospital with a broad range of practice without the knowledge of the anaesthetists filling them in. This study showed that only a third of anaesthetic records met the minimum criteria as required by the Health Professions Council of South Africa (HPCSA) (18) (13).

No international or national research could be identified that evaluated if labour epidural anaesthesia records comply with guideline recommendations, but it can be assumed the results will be similar to that of anaesthetic records.

1.3. Problem statement

Adverse events are a possible outcome, no matter how skilled the anaesthetist, or how stringently he/she observes protocol (19). The medical notes made after regional procedures are notoriously poor in comparison with general anaesthesia, and this has come under more scrutiny in recent years due to increased patient awareness, medical insurance billing strategies and the presence of regulatory bodies (20).

A well-defined standard record is necessary to remove the possibility of misinterpretation and data manipulation and to eradicate the risk that events may well have occurred that are not documented (21).

Currently, different labour epidural anaesthesia records are used in the hospitals affiliated with the Department of Anaesthesiology at the University of the Witwatersrand (Wits). There is a need for a standardised labour epidural anaesthesia record that comply with the minimum standards of the HPCSA.

1.4. Aim and objectives

1.4.1 Aim

The aim of this study was to develop an instrument for labour epidural analgesia recordkeeping using local and national experts and following the two stages of instrument validation as described by Lynn (22).

1.4.2 Objectives

The objectives of this study were to:

- develop a concept instrument (Appendix 1) from the literature using Lynn's development stage (domain identification and item generation)
- develop a rated instrument (Appendix 2) using Lynn's development stage (item formation)
- determine content validity of the rated instrument using Lynn's quantification stage.

1.5. Research assumptions

The following definitions were used in this study:

Labour epidural analgesia record: is a record that allows the anaesthetist to record in a concise and reasonable manner, either electronically or by hand, all aspects of epidural management, including the pre and postprocedural management of the patient. Foetal monitoring may be included. This is a tool for auditing the efficacy of the procedure and patient satisfaction, the incidence of complications and the adherence to management protocols as well as a medicolegal document. The labour epidural analgesia record is regarded as part of anaesthetic recordkeeping. (21)

Anaesthesiologist: a medical doctor who has completed post graduate training and examination in the field of anaesthesiology and has become a Fellow of the College of Anaesthetists and registered with the HPCSA as such.

Expert: is an anaesthesiologist in the public or private sector that has a standing in the anaesthesiology community as an authority in the skills and knowledge of what a labour epidural analgesia record requires. An expert may be a Junior or a Senior Consultant.

Lynn's model: this model describes a structured two stage process (development and quantification) of instrument development through literature and expert validation and instrument quantification through expert validation (22).

Instrument:

- **Concept instrument (Appendix 1)** will be the instrument developed by the researcher through comprehensive literature review. Items deemed by the literature to add value to the labour epidural analgesia record will be used to develop the concept instrument.
- **Rated instrument (Appendix 2)** the concept instrument once it has been validated by peer group discussion in the development stage will be referred to the rated instrument.
- **Instrument for labour epidural analgesia recordkeeping or final instrument (Figure 4.4)** the rated instrument once it has been validated by national experts in the quantification stage will be the final instrument.

1.6. Ethical considerations

Approval to conduct the study was obtained from the relevant authorities.

The study was conducted according to the principles of the Declaration of Helsinki (23) and the South African Good Clinical Practice Guidelines (24).

1.7. Research methodology

1.7.1. Research design

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

1.7.2. Study population

The study population consisted of South African anaesthesiologists that are experts in labour epidural analgesia.

1.7.3. Study sample

Sample size: Development stage

Lynn (22) states that there is no consensus on the number of experts that should be included in this process and it depends on the number of accessible and willing persons who agree to participate and not on a population estimation principle. Ten local experts who met the inclusion criteria were invited to participate.

Sample size: Quantification stage

The study sample in this stage consisted of twelve experts. Lynn (22) states that a minimum of three experts should be used and the maximum number has not been established but is unlikely to exceed ten.

Sampling method

Purposive sampling was used in both the developmental and quantification stages of the study.

Inclusion and exclusion criteria for both stages were defined.

1.7.4. Data Collection

The experts were sent invitation letters inviting them to participate in the study in the Development and Quantification stages. The experts who replied to the invitation gave their consent to be included in the study. The ratings that the items on the concept instrument (Appendix 1) and the rated instrument (Appendix 2) received were analysed and used to develop the final instrument for labour epidural analgesia recordkeeping (Figure 4.4).

1.8. Significance of the study

The study is significant in that a standard labour epidural analgesia record that is content valid could be used in all the affiliated hospitals of the Department of Anaesthesiology of Wits. This instrument could be valuable in improving the transmission of anaesthesia related medical

information. It could help in quality improvement, research and be acceptable medico-legal documents.

During the quantification stage, the rated instrument was nationally validated by experts from other academic hospitals to those affiliated with Wits. If these experts deem the instrument to be relevant and significant in their context, it may be applicable nationally.

1.9. Validity of the study

Measures were taken to ensure the validity and the reliability of the study.

1.10. Overview of the study

This study will contain the following:

Chapter 1-Overview of the study

Chapter 2-Literature review

Chapter 3-Research methodology

Chapter 4-Results and discussion

Chapter 5- Study summary, limitations, recommendations and conclusion

1.11. Summary

In this chapter an overview of the study was provided. In the following chapter a review of the literature is discussed.

CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

In this chapter a history of labour epidural analgesia, labour epidural analgesia as the gold standard for pain relief intrapartum and the importance of record keeping to the anaesthetist are discussed. The national and international guidelines regarding recordkeeping, specifically for anaesthesia and parturients is explored. The consequences of non-standardised records and poor record keeping were discussed, highlighting the importance of recordkeeping in anaesthesiology. The proper technique for the epidural procedure is alluded to as well as the clinical variables which the literature suggests should be recorded on a labour epidural analgesia record. Lynn's model is reviewed as it will be used to develop the concept and rated instruments. Manual record design in contrast to automated record keeping is discussed.

Labour epidural analgesia recordkeeping should be considered as part of the anaesthetists' anaesthetic recordkeeping. Some of the principles of anaesthetic record keeping apply to labour epidural analgesia recordkeeping and where appropriate, aspects of anaesthetic recordkeeping are discussed.

2.2. History of labour epidural analgesia

Central neuraxial blockade for labouring parturients was first described by Oskar Kreiss, a Swiss obstetrician in the late 19 th century, a year after the first spinal was performed by August Bier, a German surgeon. They rendered their patients anaesthetised by "cocainization of the spinal cord". (1) The first recorded use of an epidural was in 1885, when New York neurologist J. Leonard Corning injected cocaine into the back of a patient suffering from "spinal weakness and seminal incontinence" (25). Walter Stoeckel, a German obstetrician, reported on his performance of 141 cases of caudal epidural analgesia for labour pain in 1909. He used novocaine (synthesized in 1905) and had a success rate of approximately 50% (1).

The formulation of new equipment and drugs allowed for the rapid progression of this technique during the 20th century. The Tuohy needle facilitated continuous analgesia and the

addition of opioids into the epidural space optimised pain relief. “Patient-controlled epidural analgesia”, described by Gambling et al (1) in 1988, has also enhanced patient safety and satisfaction.

Labour is widely acknowledged to be amongst the most painful experiences known and multiple methods have been used for labour analgesia including chloroform and high doses of morphine, which risk maternal aspiration or respiratory depression of the neonate. A balance between optimising foetal and maternal wellbeing and the multidimensional experience of childbirth should be the obstetric anaesthetist’s goal. (1)

Epidurals encompass most of the characteristics of ideal labour analgesia and have become the gold standard of pain relief intrapartum. (1) They reduce adverse physiologic responses to stress, postoperative cardiac and pulmonary embarrassment (26), and can reduce the incidence of hypercoagulable events, which has a higher probability of occurring in pregnancy. Studies have also shown an improvement in foetal acid-base status on placement of neuraxial analgesia. (2)

2.3. Labour epidural analgesia: the gold standard

As a result of superior analgesia, the foetal and maternal benefits, and greater safety in the parturient, there is a progressive increase in the use of central neuraxial blockade for labour analgesia worldwide. Controversy has existed on whether neuraxial labour analgesia increases the caesarean delivery rate, affects the course of labour or increases the rate of instrumental delivery. (27)

In 2004, two thirds of labouring women in the USA had epidurals, the rate having tripled between 1981 and 2001 (28). Approximately 50% of Canadian women who have a normal vaginal delivery have epidurals, showing the rate varying between provinces from 30 - 69% (29). Twenty one percent of women in the UK have epidurals prior to delivery, whether they deliver via caesarean section or vaginally (6).

The number of epidurals done in the developing world, including South Africa, is unknown. However, Dyer (7) recently made note of the dynamic changes in the indications for neuraxial anaesthesia in developing countries. It is now feasible or even preferable to perform neuraxial anaesthesia for patients with severe pre-eclampsia and certain heart valve lesions (7). In

South Africa, epidural anaesthesia is recommended for early labour analgesia (8) yet the rate of epidurals done in the CHBAH labour ward is 3%, only 60 of an average of 2000 deliveries per month (9) .

A Tygerberg Hospital labour epidural analgesia audit in 2014 showed a labour epidural rate of 2,2%, illustrating a need to increase this service at the institution. Most patients were satisfied with their analgesia and the complications secondary to the labour epidurals was comparable to those in the developed world. However, time and staff constraints and specific patient indications for the epidurals (morbid obesity, cardiovascular disease and preeclampsia) limited the scope of the study (30).

It is important to note that epidural analgesia in labour is not without risk. In the Confidential Enquiries into Maternal and Child Health in the UK, from 2003-2005, six maternal deaths were directly due to the anaesthesia (4.5%) although only one resulted from an epidural (31). This is in contrast with South Africa where 121 maternal deaths were directly due to anaesthesia in the triennium 2008-2010, 2.5% of the total amount of maternal deaths. Seventy three of these were due to spinal anaesthesia and one was due to epidural analgesia (32). Although this initially appears promising, the number of epidurals being done in South Africa is less than those done in the UK (8). The data collected in a rural South African context may also be less reliable than the UK data as South Africa has a larger population, spread across a more divergent socioeconomic context. There may be underreporting of incidences of maternal death, related to anaesthesia or otherwise. (32)

The use of neuraxial anaesthesia is on the increase in both developed and developing countries (7) and it is not a procedure without risk (19). This demands a means for documenting each case appropriately. A standardised labour epidural analgesia record would have significant advantages for both the anaesthetist and the patient and is a recognised vital constituent of anaesthetic care. (33)

2.4. The anaesthetist and recordkeeping

Anaesthetists are required to keep comprehensive records as outlined by various professional societies and statuary bodies in guidelines (34). However most of the guidelines recommendations are vague, this will be illustrated by a brief discussion of selected

guidelines. Anaesthetic record keeping is further complicated in that there are no standardised records and that recordkeeping is poor. These two issues will be discussed briefly.

2.4.1. Guidelines for labour epidural analgesia recordkeeping

International guidelines

The World Federation of Anaesthesia has International Standards about the safe practice of anaesthesia which states that "records of each anaesthetic should be made and preserved with the patient's medical record." It is recommended that these records be accumulated and analysed for increased efficiency and progress in anaesthesia care. (34)

The amended American Society of Anaesthesiologists' guidelines on neuraxial anaesthesia in obstetrics have 10 basic guidelines which need to be followed for quality patient care without a guarantee of a specified outcome. After these 10 guidelines have been followed, it is suggested that different institutions with a varying availability of resources allows for difference in interpreting and establishing their own regulations. There is no guideline as to the type of anaesthetic recordkeeping that is necessary. (35)

The Canadian Anaesthesiologist's Society has an extensive guideline that was revised in 2010. In the 15 pages dedicated to the practice of anaesthesia, only one paragraph is dedicated to anaesthetic recordkeeping. It states that that "all monitored physiological variables should be charted at intervals appropriate to the clinical circumstances." (36)

It mentions that heart rate and blood pressure should be recorded at least every five minutes and that oxygen saturation must be continuously monitored and frequently recorded at set intervals. Any reason for deviation from the above charting guidelines must be recorded on the anaesthetic record itself. Monitors, equipment, techniques, time, dose and route of all drugs and fluids as well as intraoperative care should be recorded. The first determined level of consciousness, heart rate, blood pressure, oxygen saturation and respiratory rate in the recovery room must be included in this record. (36)

The Guidelines for Safety and Quality in Anaesthesia Practice in the European Union by the European Union of Medical Specialists states that all activities in theatre must be systematically documented and that all anaesthetic cases must have an anaesthetic record.

All departments should use the data recorded for quality improvement strategies and use them to identify and manage anaesthetic related adverse incidents. Unfavourable events which are related to the anaesthetic must then be analysed by the department, using the anaesthetic record and what was documented. (37)

In 2015, RCOA and the Association of Anaesthetists of Great Britain and Ireland published guidelines recommending a data set for the anaesthetic record, with the minimum amount of included information being detailed. (15)

The New Zealand and Australian College of Anaesthetists also recognize the importance of the anaesthetic record. Its role in making the anaesthetist accountable for his/her actions and putting him/her in a defensible position cannot be underestimated. These guidelines on anaesthetic recordkeeping were established in 1990, reviewed in 1996 and revised in October 2006. These guidelines have been divided into four main components: basic demographic information, pre anaesthetic consultation, anaesthesia information and post anaesthetic information. (38)

The National Institute for Health Care and Excellence (NICE) have complete guidelines about regional analgesia intrapartum. Recommendations for preprocedural counselling, the patients' fears and expectations and the epidural itself are covered. NICE also has recommendations on epidural anaesthesia for caesarean section and makes note of the common misconception that epidurals increase the risk for a caesarean section. (39)

National guidelines

The HPCSA states that "a health record may be defined as any relevant record made by a health care practitioner at the time of or subsequent to a consultation / examination or the application of health management." There is no specific information about anaesthetic records but basic constituents of a health care record are mentioned and the record should be contemporaneous. Health care record keeping is a compulsory component of the ethical standards of professional conduct as approved by the HPCSA. (4)

The South African Society of Anaesthetists (SASA) (33) Practice Guidelines state that "a record of the details of each anaesthetic should be made and preserved with the patient's medical record. This should include details of the preoperative assessment and the postoperative course. It is recommended that individuals, departments, and regional and national groups

collect cumulative data to facilitate the progressive enhancement of the safety, efficiency, effectiveness, and appropriateness of anaesthesia care". SASA further states that "it is imperative that all practitioners provide and maintain documentation to support the execution of any tasks as set out in these practice guidelines in as much detail as is practical and useful." (33) This would fall upon each individual anaesthetist to determine what he/she feels is appropriate and accurate for complete documentation (20). This makes the documentation subjective.

2.4.2. Non-standardised records

Despite the importance of anaesthetic records, there is a plethora of local systems attempting to conform to nationally agreed standards and recommendations. A survey reviewing the structure and content of all anaesthetic record charts in use in the 40 hospitals of Yorkshire in the UK showed that 22 different anaesthetic charts were used by 290 anaesthetists in this region. Some of the charts were not standard for size (A4) and most were not colour coded. Fourteen of the 22 charts omitted important headings concerned with patient identification and 8 charts were incomplete in documenting the full perioperative period. No survey at the time had yet indicated what anaesthetists would prefer as a chart design. (14)

Following the RCOA's guidelines published in 1996, a study conducted in North West England in 1997 concluded that no anaesthetic record complied fully with these guidelines. A subsequent study in Scotland examined the anaesthetic charts of 27 out of 29 National Health Service anaesthetic departments by auditing 202 charts from 2 district general hospitals against the RCOA guidelines and found that no chart complied fully with the guidelines. A new chart was therefore developed to facilitate guideline compliance. (16)

According to SASA and South African Nursing Council guidelines, it is within the scope of practice of registered nurses and registered midwives in South Africa to monitor epidurals once they are in place. (40) They are also permitted to top up epidurals, provided it is for labour ward analgesia and not for surgical anaesthesia and the orders are well defined and written. The doctor's orders must be written as a prescription on the epidural chart to minimise confusion regarding the nursing instructions and to optimise patient care when several health care practitioners are responsible for the patient simultaneously (41).

2.4.3. Poor recordkeeping

Adverse events are a possible outcome, no matter how skilled the anaesthetist, or how stringently he/she observes protocol (19). The medical notes made after regional procedures are notoriously poor in comparison with general anaesthesia, and this has come under increased scrutiny in recent years due to increased patient awareness, medical insurance billing strategies and the presence of regulatory bodies (11).

A retrospective database analysis of anaesthetic records in Portugal found 20% of anaesthetic charts to be incomplete, but less so in the presence of a resident rather than an anaesthesiologist. This showed inaccurate recording of the data, but may also reflect inadequacies of chart and database design. (42)

In Canada in 2006, Tessler et al (43) noted that even the variable considered most important, which is the airway, was only documented on 84% of the charts. On only 27% of charts were the postoperative vital signs recorded.

The most consistent recurring criticism of anaesthetic records is that they are inaccurate which negates the advantages of using them. These inaccuracies have been investigated and noted to be due to several factors. Poor manual entries by anaesthetists are noted when recording physiological variables as there is a tendency to smooth out physiological fluctuations by understating extreme values. It has been postulated that this is not significant and merely "clinically relevant filtering of physiological artefact". (44) It has also been postulated to be an unconscious defence strategy on the part of the anaesthetist as fewer extreme recordings imply better case management. In New Zealand data manipulation was found to occur regularly and knowingly on the part of the anaesthetist. This was qualified as either being direct omission or purposeful recording of the incorrect information. (11)

In the Western Cape in 2003, James et al (17) randomly audited 284 anaesthetic charts in a local hospital with a wide scope of practice without the knowledge of the anaesthetists filling them in. This study showed that only a third of anaesthetic records met the minimum criteria as required by the HPCSA.

However, it has been proposed that the reason for inaccuracy is the anaesthetist's attitude towards the record's value and a response to inadequacies in its design, rather than a defensive stance against litigation risk. (44)

2.5. The importance of recordkeeping in anaesthesiology

“If you did it, write it down; if you don't write it down it didn't happen.” (45).

The anaesthetic record serves several functions in assisting staff and other anaesthetists with information regarding the patient; to be available throughout the patients hospital stay and to be easily accessible in subsequent visits; to document the components demographic details and physiological variables and to be signed by the anaesthetist. (38)

Chalwa et al (45) identified the following advantages for keeping comprehensive anaesthetic records:

- “provides a common language and aids communication;
- predict patient outcome;
- help evaluate and standardize treatment within the same centre and between centres;
- protocol based management and quality assurance;
- accurate and consistent information;
- help in planning and allocation of resources;
- evaluate and validate new methods, research and epidemiological studies;
- uniformity of patient care, teaching and training standards; and
- key document for medico-legal support.”

Without appropriate documentation, there can be no forewarning to future anaesthetists about previously encountered anaesthetic difficulties. This information may be useful if a life threatening incident occurred previously in aiding the anaesthetist to prepare appropriately for potential problems and avoid adverse outcomes. (17)

“Incomplete or illegible medical record entries create the impression that the care received by the patient was careless, superficial, and substandard”, although in reality, it may have been reasonable (46). The deduction is that poor documentation equates to poor care (47).

An incomplete anaesthetic record could potentially compromise care of the patient which may have multiple and devastating repercussions for all involved (46). Adherence to documentation guidelines protects both the patient and the anaesthetist and the ideal

anaesthetic record should facilitate this by reminding the anaesthetist for perform all relevant tasks. The design of the record must serve as an anaesthetic checklist (45).

In 1986 Lunn (44) observed “the folly of a design which permits mixture of fact with opinion, particularly when subsequent interpretation is anticipated.” A well-defined standard is necessary to remove the possibility of misinterpretation and data manipulation and to eradicate the risk that events may very well have occurred that are not documented (20). Therefore, a complete understanding of epidurals and what they entail is essential as well as the understanding of the importance of good anaesthetic recordkeeping.

2.6. Labour epidural analgesia record

In order to understand which parameters should be included in a labour epidural analgesia record the following aspect will be reviewed in this section:

- the labour epidural analgesia procedure,
- the contra-indications and the complications of epidural analgesia,
- clinical variables identified in the literature that should be included.

2.6.1. Labour epidural procedure

A complete preprocedural anaesthetic assessment is necessary. Resuscitation equipment and a team trained in cardiopulmonary resuscitation must also be available. (35) As with all procedures, the benefits stated above must outweigh the accepted risks. Maternal request for analgesia in labour and the absence of contra-indications can warrant the placement of an epidural catheter (43).

Informed consent for the procedure must be taken prior to commencement, and in the reasonable anaesthetist's view the patient must be able to: "understand the information relevant to the decision; retain that information; use or weigh that information as part of the decision making process; and communicate that decision". The adverse effects of the epidural itself as well as the drugs given and the complications thereof must have been explained to the patient. The patient must sign a consent form for the epidural. (48)

Preparation will include patient positioning which can be either sitting or the lateral decubitus position. An assistant to help support the parturient is preferable for the sitting position, with a chair under the patient's feet in order to open up the spaces between the interspinous processes or lumbar vertebral spaces. The position depends on patient factors and the experience of the anaesthetist but is ultimately a large determinant of the ease of the epidural procedure. (26)

The equipment required must also be prepared prior to the procedure and should be sterile. It is important that the cleaning solution does not contaminate the needle due to the risk of chemical arachnoiditis. Usage of a Tuohy epidural needle (with a blunt point and a 15 – 30 degree curve to prevent accidental dural puncture) is also advocated. Minimum monitoring would include pulse oximetry and blood pressure monitoring. (21) Complete aseptic precautions are imperative, including a surgical scrub, gown, a head covering, mask and sterile gloves. (49)

The approach to an epidural can be median, paramedian, caudal, and modified paramedian (Taylor approach). Usage of these again depends on patient factors and anaesthetic preference. The median approach is most commonly employed. Detection of the epidural space is done with one of three methods: the loss of resistance method (described by Digliotti in 1933), the hanging drop method (not used in our setting) or via ultrasonic detection. (26)

The loss of resistance method to either air or saline is employed at CHBAH. There are two negative points against the loss of resistance method to saline method. They are that the saline cannot be differentiated visually from cerebrospinous fluid and that only finding the liquid positive for protein or glucose on urine Dipstix will confirm placement in the subarachnoid space. The other negative point is that a large volume of saline may dilute the local anaesthetic drugs resulting in a patchy sensory block (26). However, there are multiple causes of a patchy epidural block (catheter migration out of epidural space, catheter coursing laterally within the epidural space, septations within the epidural space causing segmental sparing) which may occur regardless of the loss of resistance method used. (50)

The test dose of 10 - 15 micrograms of adrenaline in combination with 45 milligrams of local anaesthetic is given once the epidural catheter has been placed to ensure that the catheter is not in intravascular or subarachnoid spaces. The value of this has been queried but it is still recommended. The 45 milligrams of local anaesthetic will provide analgesia and motor weakness within five minutes of administration if it is a spinal block. The added adrenalin will cause an increase in heart rate greater than or equal to 10 beats per minute if the epidural catheter is in the intravascular space and the epidural catheter should then be removed. (51) Care should be taken not to administer the adrenaline during a uterine contraction in women in labour as confusion will arise on whether the increase in heart rate is due to the pain or the intravascular adrenaline. (52)

Dosing should be done carefully, with 0.125 - 0.5% bupivacaine. Five millilitre increments can be given every 3 - 5 minutes, checking the patient's response to the drugs. (26)

Comprehensive documentation of the above factors will assist the nursing staff and the anaesthetist monitoring the patient and facilitate good clinical care. (53)

2.6.2. Contra-indications to epidural anaesthesia

Contra-indications to epidural labour analgesia may be absolute or relative and their absence should be noted prior to administering the epidural. Absolute contra-indications are actual or suspected coagulopathy, hypotension, haemodynamic instability, sepsis at the site of epidural needle insertion, a fixed cardiac output state, raised intracranial pressure, a known allergy to local anaesthetic or patient refusal. Relative contra-indications include septicaemia, pre-existing neurology, central nervous system disease, anatomical spinal cord abnormalities and

an unco-operative patient. These contra-indications must be looked for and excluded preprocedurally. (50)

Complications of neuraxial anaesthesia

Complications may occur after any procedure that is performed. Obstetric anaesthetists need to be cognisant of these complications and document them meticulously.

Local complications of lumbar epidurals include backache, a post dural puncture headache, spinal cord injury which may result in paralysis, epidural haematoma formation which may put local pressure on the nerve roots, block failure or a segmental blockade, intravascular injection of local anaesthetic which may result in systemic local anaesthetic toxicity, infection which may result in epidural abscess formation or failure to place the epidural by the anaesthetist. Adverse systemic effects of a lumbar epidural are urinary retention, a high block with resultant respiratory embarrassment, hypotension, which may be accompanied by nausea, vomiting and dizziness, total spinal anaesthesia and cardiac arrest. (50)

2.7. Suggested clinical variables which should be documented

The logbook function of the anaesthetic chart is divided into two categories, one relating to the patient demographics and history and another to specific intraoperative events. This should include any information that may be relevant intraoperatively and should encompass the preoperative evaluation of the patient as well. A preoperative diagnosis, the patient's position, precautions against harm to patient and what surgical procedure was performed must be documented. Complications and their details should also be meticulously recorded. (54)

In 2006 in Canada, Tessler et al (43) reached a consensus amongst anaesthesiologists at four adult hospitals affiliated with McGill University about what should be included on an anaesthetic record. The preoperative variables considered essential were an airway assessment, known allergies, current medications, past medical history, time since last meal, family problems with anaesthesia, exercise tolerance, patient's blood pressure and heart rate, and a history of gastro-oesophageal reflux disease.

Intra-operative variables considered important were:

- name of the anaesthesiologist and surgeon
- starting time of anaesthetic and surgery and type of surgery and anaesthetic
- patient's vital signs
- patient position
- oxygen saturation
- endotracheal tube route
- intravenous drugs given to the patient
- type of local anaesthetic used
- inhalational agents used
- time of giving the medications
- fluids administered
- use of a central line
- postoperative observations. (43)

The use of the anaesthetic record for the progression of clinical management is not to be underestimated. The recording of administered drugs and the times that they were given has clinical relevance for when the patient is transferred to the recovery room and when the patient goes to the ward. It is important to consider intravenous fluids and administered blood products as drugs as well and to document their details. (54)

Plotting the trends not only for the specific patient but also for all the anaesthetics done at an institution has a role in the extrapolation of data into guidelines and protocols. This may help to identify diagnostically useful patterns or recurring problems.(54)

A list of parameters deemed important for recordkeeping in labour epidural analgesia is presented in the concept instrument.

2.8. Lynn's model to determine content validity

In 1986, Lynn created a two stage model for instrument development and validation. This instrument can then be used to collect, analyse and validate data (22). This model has subsequently been used by medical professionals in studies in the UK and the USA as recently as 2010 (55). Lynn's model is strongly based on statistics and her seminal study has been

especially influential. Polit et al found “considerable consistency” for item level CVI’s (as are used in this study.) The item level CVI’s were based on “universal agreement among experts.” Content validity is defined as “the degree to which an instrument has an appropriate sample of items for the construct being measured”, “whether or not the items sampled for inclusion on the tool adequately represent the domain of content addressed by the instrument” and “the extent to which an instrument adequately samples the research domain of interest when attempting to measure phenomena”. It is also agreed that content validity is largely a matter of judgement, based on acceptance that the scale developer carefully conceptualized and analysed the domain (as was done in the literature review and development of the concept instrument) prior to item generation and evaluated the relevance of the scale’s content through expert assessment (as was done in the development and quantification stages.)

Lynn states that prior to use, all instruments should be validated. Validity is the extent to which an instrument measures what it is intended to measure and is a crucial factor in determining how applicable the instrument is (22).

Lynn (22) uses content validity, which involves applying a two-stage development process consisting of a development stage and a quantification stage to the items or elements of an instrument. This two-stage process determines the content representativeness or content relevance of the instrument.

The development stage consists of domain identification, during which the literature is thoroughly reviewed so that the opinions of an array of experts can be used. The important items are then generated through identification of all the dimensions and subdimensions in the literature. Finally, the generated items are assembled into a refined, useable form. (22)

In the quantification stage the items must be reviewed and determined to be valid by a selected number of experts. The whole instrument is then considered to be content valid. (22)

The number of experts depends on the number of identified experts the developer has access to who agree to validate the instrument. A minimum of five experts would provide adequate control for chance agreement. If five experts are not available, three may be used but any less than three experts are not statistically justifiable and increase the risk of a type II error

(acceptance of a false null hypothesis). It is unlikely to find more than ten agreeable experts however a maximum is number is yet to be established. (22)

The experts must be given a structured procedure for evaluating content validity. The most commonly used tool for quantification of content validity is the content validity index (CVI), using cumulative binomial distribution (Appendix 3), which is derived from rating the items on an instrument in terms of content relevance using a four-point rating scale. One connotes an irrelevant item and four an extremely relevant item. The resultant CVI is the proportion of items that received a rating of three or four by the experts. (22)

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. (22)

2.9. Manual record design

Current laws, regulations and association guidelines are unspecified and there is leeway and flexibility on chart design. An informal regional survey in Ontario, Canada showed a significant variability in precision and order of resourceful data entry. Several charts had not been revised for decades. Yet throughout the world the approach to clinical anaesthesia is relatively similar. It would follow that the anaesthetic should be more homogeneously documented in a more equivalently designed chart. Ideally, chart design should be specified to a universal standard and yet retain its function in clinical anaesthesia. If logical chart design criteria are used abidingly, the anaesthetic chart would be clearer which would facilitate the entry of correct information. The standardization of the specific criteria would also smooth the progress of developing a new labour epidural analgesia record. (57)

Criteria to consider when designing a manual labour epidural analgesia record will be discussed however a designed record is beyond the scope of this study.

Paper and Ink

If coloured paper is used it should be a pale or pastel shade in order to contrast with handwriting and printing. A variety of colours can make the epidural chart instantly recognisable and attractive so that staff will want to complete it. (53) The light background will also facilitate photocopying, microfilming or digitalizing the record to an optic disk. Black

ink is least expensive but blue, brown, green or red ink provides a better contrast to the ink used in most commercially available pens used to fill in the record. Blue ink may print poorly with some photocopying and microfilming machines. Using more than one ink colour per page will increase printing costs. (57)

Multi-part carbon copy forms

No-carbon-required forms are convenient for producing multi-part carbon copies. Industry standard pre-collated papers are less expensive than custom collated forms, but usually have white as the top/original sheet's colour. The top/original copy must be retained in the medical record. Copies are held together with glue on two adherent edges of paper or by a tear-off margin. (57)

Margins

A 1.9 cm margin must be allowed on the edge of the form that will be punched with holes in order to mount it in the anaesthetic chart without loss of information. Pre-drilled holes are more efficient. There should be a minimum of 0,6 cm from all the edges of the paper as a printing press may not be able to print closer to the edge of the paper. A margin of less than 0,6 cm may also make it difficult to photocopy or microfilm the document. (59)

Text

It has been shown than people read faster and with the greater comprehension when words and lines of text have distinct, recognisable shapes. Lowercase text has greater shape content than uppercase.Therefore it is recommended that lowercase letters be used throughout the chart. (57)

Typestyle

Too wide a variety of typestyles on one record should be avoided as it may distract the reader. The proportionally-spaced font known as Helvetica is the standard typestyle used on medical forms. Proportional spacing means that the space taken by each letter varies in width. (57)

Abbreviations and short forms

Different institutions have diverse abbreviations and short forms of various words and employ these at different times. A copy of a medical record may be sent to a different institution where the abbreviation and short forms may be misinterpreted or not understood. As

knowledge and technology progress, the trends in abbreviation use may change to the extent that understanding dated records becomes difficult. (57)

Checkboxes

Square shapes equal in height to the tallest letter of the font used in the adjacent text should be used. The bottom edge of each checkbox should align with the baseline of the adjacent text. All text items should be on the right of the applicable checkboxes so that the eye can rapidly read the items that have been checked in a left to right fashion. A single space gap or more should be inserted between each checkbox and the next adjacent item. Other text items on the same line should be separated by at least a 3 - space or 2 - checkbox wide gap. (57) Checkboxes also remove a large part of the risk of data manipulation.

Test Results

Transcription errors may occur when copying laboratory, radiological or other diagnostic tests. This renders the documentation unavoidably incomplete. However, copying the test results to the front of the anaesthetic record gives the anaesthetist immediate access to them when they are required and proves that they were noted at the time of the procedure. (57)

Area reserved for patient identification

The area of the record reserved for the patient identification is typically the top right hand corner. Each institution should have written guidelines for defining the dimensions of this area. The required edges of the paper should be included in these dimensions. (57)

Date and time

Locales use different formats for date and time. It is recommended that the Systeme International (SI) format be used for all dates (YYYY.MM.DD) and times (HH:MM.) (57)

2.10. Automated recordkeeping

For completeness automated recordkeeping will be discussed briefly. There are advantages and disadvantages to this form of recordkeeping which can serve to highlight some of the problems with manual record design.

It is not always easy to have the time to make anaesthetic notes during an eventful anaesthetic. The development of anaesthetic monitors and equipment has made anaesthetic record keeping both easier and more difficult. What has facilitated having two hands available for accurate documentation is the development of airway devices such as laryngeal mask airways and endotracheal tubes and precalibrated vapour specific vaporizers. This is opposed to having to manually open the airway in an anaesthetized patient, or to drip one's own ether or chloroform over a mask. The number of recorded variables in anaesthesia, however, has increased significantly, as well as the threat of litigation. This has made the required parameters to be recorded on the anaesthetic chart much more complex and remembering all the details an arduous task. (57)

Gravestein (54) compared the speed and timing in between critical anaesthetic events in modern and historical anaesthesia and noted how much more time there was to make adequate notes prior to the advent of the rapid sequence induction, the ventilator and intravenous induction agents. It is a concern that there is no ongoing recording of anaesthetic events during the clinically significant or dramatic moments of an anaesthetic because the anaesthetist is busy managing the patient. Thus, at the very moment when it would be most pertinent to record accurately, manual documentation falls far short.

Many versions of automated records have been proposed but all must record physiological variables and a list of the events which transpired (54). The Mayo Clinic has used a computerised anaesthetic recording system for many years. In eight years over 24,000 surgical procedures were recorded with an automated system and the records were consistently found to be more legible, complete and organized than manual records. (58)

The negative aspects of automated data collecting are numerous however, some data must still be put in manually, which leaves room for human error. It may be difficult for users to learn how to use the computer. Sometimes it takes time for the record to be produced and the user interface is not always interactive. The computers are also susceptible to interference and artefacts from other systems. (58)

In a comparative study between eight automated and handwritten variables in the Netherlands, all except two instances of inaccuracy or incompleteness was caused by

handwritten error, which supported that automated anaesthetic record keeping is clinically relevant. (59)

A small study from London on 50 consecutive patients receiving epidural analgesia on switching a labour ward from paper based epidural records to automatic recordkeeping showed an increased availability of paperless records. However, similar data capture was achieved with the respective recordkeeping methods. Follow up data capture improved with electronic records and auditing the epidural records was facilitated. (60)

2.10. Summary

In this chapter the literature review was presented. In the next chapter the methodology will be discussed.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the problem statement, aim and objectives, ethical considerations, the research methodology, data analysis and reliability and validity of the study.

3.2 Problem statement

Adverse events are a possible outcome, no matter how skilled the anaesthetist, or how stringently he/she observes protocol (19). The medical notes made after regional procedures are notoriously poor in comparison with general anaesthesia, and this has come under more scrutiny in recent years due to increased patient awareness, medical insurance billing strategies and the presence of regulatory bodies (12).

A well-defined standard record is necessary to remove the possibility of misinterpretation and data manipulation and to eradicate the risk that events may well have occurred that are not documented (20).

Currently, different labour epidural anaesthesia records are used in the hospitals affiliated to the Department of Anaesthesiology at Wits. There is a need for a standardised labour epidural anaesthesia records that comply with the minimum standards of the HPCSA.

3.3 Aim

The aim of this study was to develop an Instrument for labour epidural analgesia recordkeeping, using local and national experts and following the two stages of instrument validation as described by Lynn (20.)

3.4 Objectives

The objectives of this study were to:

- develop a concept instrument (Appendix 1) from the literature using Lynn's development stage (domain identification and item generation)
- develop a rated instrument (Appendix 2) again using Lynn's development stage (item formation)
- determine content validity of the rated instrument using Lynn's quantification stage.

3.5 Ethical considerations

Approval to conduct the study was obtained from Human Research Ethics Committee (Medical) (Appendix 4) and the Postgraduate Committee of the University of the Witwatersrand (Appendix 5.)

Experts were invited to participate in this study by emailing an information letter to them. The information letter explained the study with entailed developing and quantifying the instrument as individuals in an expert peer group. Separate information letters were given to the participants in the Development stage (Appendix 6) and in the Quantification stage (Appendix 7.) Acceptance of the invitation to participate in each stage implied consent.

Anonymity could not be guaranteed in the development stage as many of the experts knew each other; however participants were asked to maintain confidentiality. Participants were free to withdraw from the study at any time.

In the Quantification stage, anonymity could again not be assured as the participants responded via email but knowledge of the participants' identity was limited to the researcher. The data captured by the researcher contained no identifying information of any participant, thereby ensuring confidentiality. Data will be stored for six years following completion of the study.

The study was conducted according to the principles of the Declaration of Helsinki (23) and the South African Good Clinical Practice Guidelines (24).

3.6 Research methodology

3.6.1 Research design

A prospective, methodological study design was used in this study.

A prospective study is a study in which the variables was measured at the time at which the study takes place (61). This study was prospective because data was collected as the study progressed.

This study was a methodological design as it focused on instrument development. The instrument may be used by others clinically and for research purposes. This investigation will obtain high quality data with valid and reliable outcome measures (62). Specific rules, as proposed by Lynn's (22) model were applied to develop an Instrument for the labour epidural analgesia record.

3.6.2 Study population

The study population consisted of South African anaesthesiologists that are experts in labour epidural analgesia.

3.6.3 Study sample

Sample size: Development stage

Lynn (22) states that there is no consensus on the number of experts that should be included in this process and it depends on the number of accessible and willing persons who agree to participate and not on a population estimation principle. Ten local experts who met the inclusion criteria were invited to participate. This number was chosen as the process is similar to that of a focus group where between six and ten participants have been described as suitable. (22)

Sample size: Quantification stage

The study sample in this stage consisted of 12 experts. Lynn (22) states that a minimum of three experts should be used and the maximum number has not been established but is unlikely to exceed 10. Determining the exact number was arbitrary, depending on how many experts are available. The expertise required by the content/domain of the study will limit the numbers in the study sample. Using less than three experts means that although the content may be valid, it may not be statistically significant.

Sampling method

Purposive sampling was used in both the development and quantification stages of the study. This type of sampling is where the researcher purposefully selects people who are particularly knowledgeable on the topic. (63)

Inclusion and exclusion criteria for both stages were defined:

Development stage

Inclusion criteria in this stage were:

- anaesthesiologists that are experts in labour epidural analgesia
- working in the Department of Anaesthesiology at Wits
- willing to participate in the study.

The exclusion criteria in this stage was any anaesthesiologist working in the Department of anaesthesiology at Wits who had been identified to participate in the quantification stage.

Quantification stage

Inclusion criteria in this stage were:

- national anaesthesiologists that are experts in labour epidural analgesia
- working in the public and private sector
- willing to participate in the study.

The exclusion criterion in this stage was anaesthesiologists who participated in the development stage.

3.6.4 Study methods

A two stage process was used to develop an instrument for labour epidural analgesia recordkeeping. These stages are the development stage and the quantification stage (22).

Development stage

Lynn (22) suggested that the development stage should consist of three steps viz. domain identification, item generation and item formation. The researcher made use of three steps by performing a literature review (domain identification), developing a concept instrument (item generation) and conducting a peer group discussion (item formation) to debate the concept instrument in order to develop a rated instrument.

The concept instrument, with preparation instructions, was emailed in advance to the appointed local experts who agreed to participate in the peer group discussion.

The aim of the peer group discussion was to refine the concept instrument and if necessary, to expand the instrument to ultimately enhance the content validity. During the peer group discussion, the following was expected from the participants:

- To review and grade the instrument according to the following Likert scale (Table 3.1) by determining whether each item is:

Table 3.1: Likert scale score number with rating

Rating	Likert scale score
Irrelevant	1
Relevant but unimportant	2
Relevant and important	3
Relevant and essential	4

- To make recommendation for changes, additions or deletions to the instrument.

The peer group discussion was conducted by the researcher. Each item of the concept instrument was debated until one hundred percent consensus was reached. If the item rates as irrelevant, it was removed from the instrument.

On completion of the peer group discussion, the necessary changes according to the peer group recommendation were made and the concept instrument was prepared for the quantification stage. It then became known as the rated instrument. The rated instrument was then given to two participants of the peer group discussion to verify that the recommended changes had been made.

Data analysis was not necessary for this stage as each item was debated until consensus was reached. Consensus was based on the importance of each item to clinical practice. Any additional recommendations were added and irrelevant items were removed.

Quantification stage

The quantification stage of instrument development has two steps. These steps entailed the assertion by a specific number of experts that the items on the instrument were content valid and that the entire instrument was content valid. (22)

Lynn (22) is of the opinion of the most widely used method for the quantification of content validity is the CVI (content validity index.) The CVI is derived from the rating of the content importance of the items on an instrument using an ordinal rating scale. A four point rating scale known as a Likert scale will be preferable because it does not include the ambivalent middle rating common in odd number rating scales. The same rating scale as used in the development stage was used here.

Each selected participant for the quantification stage was contacted telephonically and asked about their interest in participation in the study. Appropriate selection of the expert panel was ensured by senior assistance with the selection process. The rated instrument was then emailed to each participant with background information, stating the aim of the research and instructions for validating the items.

The data from the rated instrument was entered into a Microsoft Office Excel® spread sheet by the researcher.

3.7 Data analysis

The CVI for each item was determined by the proportion of experts that rated the items as content valid with a rating of three or four on the rating scale. Lynn (22) makes use of cumulative binomial distribution (Appendix 3) to determine the proportion of experts needed to rate an item as valid. The cumulative binomial distribution is published as standard norms. The CVI of the rated instrument is the proportion of total items judged as content valid.

3.8 Validity and reliability

Botma et al (64) defines validity as “the degree to which a measurement represents a true value” and reliability as “the consistency of the measure achieved”.

The validity and reliability of this study was maintained by:

- using a validated model to develop the Instrument
- using an appropriate study design
- giving participants specific instructions for contributing to the study
- having a standardised assessment tool/instrument
- all data entered into the Microsoft Office Excel® spreadsheet was checked for accuracy
- a well described method was followed when doing the CVI

Content validity of the concept instrument was ensured by:

- development of an instrument from validated literature
- the use of a two stage process to determine and quantify content.

Validity in the development phase will be ensured by:

- domain identification by a means of literature review
- generating items from literature review to develop a concept instrument
- having the concept instrument debated by the panel of experts until consensus is reached.

Validity in the quantification stage was ensured by:

- the rating of each item and the Instrument as a whole
- determination of the proportion of experts who rated each item as content valid and the proportion of total items judged content valid.
- the proportions were predetermined by published norms (Appendix 3).

3.9 Summary

In this chapter the problem statement, aim and objectives, ethical considerations, research methodology, data analysis and reliability and validity of the study was discussed. The next chapter will contain the results and discussion of the study.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents the results of the study and the discussion thereof. The objectives were:

- develop a concept instrument from the literature using Lynn's development stage (domain identification and item generation)
- develop a rated instrument using Lynn's development stage (item formation)
- determine content validity of the rated instrument using Lynn's quantification stage

4.2 Approach to data analysis

An approach to data analysis is summarized in Figure 4.1

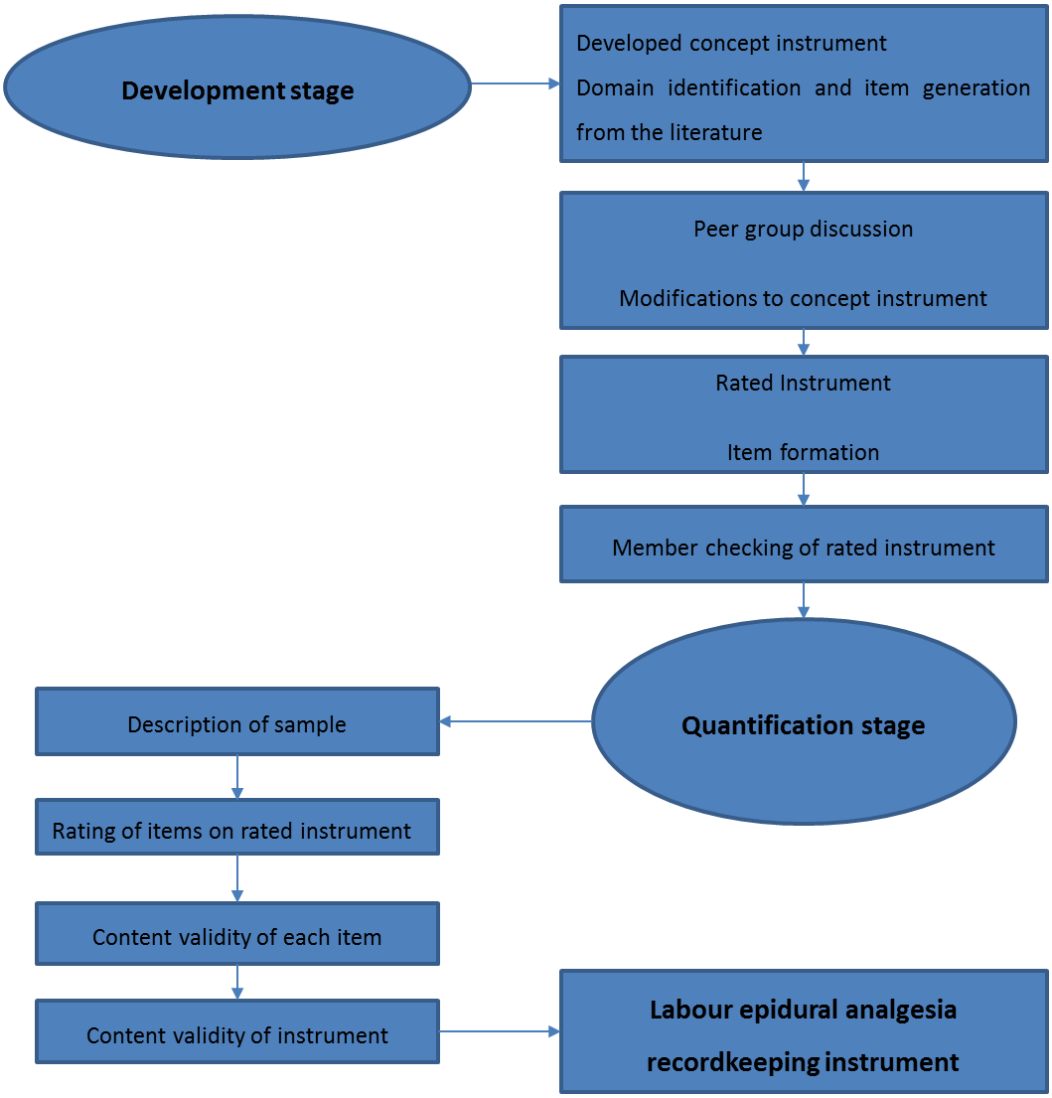

Figure 4.1: Approach to data analysis

4.3 Results

Percentages were rounded off to whole numbers. Data for the quantification stage was analysed using the cumulative binomial distribution in content validity indices (Appendix 3). According to the cumulative binomial distribution, in order for an item to be content valid, ten of the twelve respondents would have to rate an item as a 3 or 4 on the Likert scale. In the graphs showing content validity (Figures 4.3-4.6), a solid line indicates the level at which an item is judged content valid by the respondents. In this study, the line is at the level of 10 respondents.

4.3.1 Development stage

Development of concept instrument: domain identification and item generation

The domain was identified by a thorough review of the literature and the concept instrument was developed by the researcher using the items identified as important for labour epidural analgesia recordkeeping. Sixty eight items were generated.

Development of rated instrument: item formation

The development stage of the study involved the development and validation of the concept instrument through a peer group discussion with 10 local experts. The demographics of the experts are shown in Table 4.1.

Table 4.1: Demographics of the development stage expert panel

Demographic	Number	Percentage
Professional designation		
• grade 3 consultant	1	10%
• grade 2 consultant	1	10%
• grade 1 consultant	8	80%
Gender		
• male	4	40%
• female	6	60%
Hospital where employed		
• CHBAH	3	30%
• CMJAH	6	60%
• RMMCH/HJH	1	10%

The peer group discussion was held on 14 January 2015 after a departmental meeting at a neutral venue in Johannesburg. The discussion lasted for an hour. The experts all knew each other and felt comfortable engaging in an academic discussion with each other. Each item in the concept instrument was rated using the four point Likert scale shown in Table 4.2.

Table 4.2: Likert scale

Rating	Likert scale score
Irrelevant	1
Relevant but unimportant	2
Relevant and important	3
Relevant and essential	4

Each item was discussed until consensus was reached. The concept instrument was then modified in accordance with the recommended changes from 68 to 54 items. The modifications and reasons for the modifications from the concept instrument (Appendix 1) are shown in Table 4.3.

Table 4.3: Modifications to items on concept instrument

No.	Item	Modification	Reason
8	Exercise tolerance	Removed	A patient in the third trimester is extremely unlikely to have no decrease in exercise tolerance.
11	Gastro-oesphageal reflux disease	Removed	If the patient needs a general anaesthetic, a rapid sequence induction will be done, regardless of the presence of gastro-oesophageal reflux disease.
20	Parity	Removed	This was not considered essential information.
21	Presence of friend/partner/relative	Removed	This is not applicable in our setting as partners and relatives are not allowed in the labour wards.
25	Ward of origin	Removed	The postpartum wards will be where the patients will be for follow-up.

No.	Item	Modification	Reason
31	Labelled drugs: document that all the drugs are clearly labelled.	Removed	The peer group felt that this was irrelevant.
32C	Temperature	Removed	The relevance of monitoring this variable has not yet been established in the literature.
33	Foetal heart rate	Removed	An isolated reading has no diagnostic value and therefore should not be documented. An epidural should not be placed in the case of a foetal bradycardia as the foetus is already compromised.
35	Monitors used continuously	Removed	The physiological variables are measured at a set time interval, not continuously.
37	Grade of anaesthetist	Removed	The anaesthetist will have their name and contact details on the record already.
41	Approach: median/paramedian	Removed	The paramedian approach is not used in our setting.
44B	Level of analgesia	Moved	Level of analgesia was moved to the area reserved for the items to be monitored as this should also be monitored at specific time intervals.

No.	Item	Modification	Reason
46	Mode of delivery (instrumental/normal vaginal delivery/caesarean section)	Added	The method of anaesthesia if progresses to caesarean section (general anaesthetic/spinal/top-up) and the name of the anaesthetist who performs it was added.
47	Pain relief	Added	Pain relief and postoperative pain must be quantified with a pain scale.
48	Maternal satisfaction	Removed	Too general a question.
43	'Would you have an epidural again?' Yes/No	Added	For better qualification of experience.
51	Complication: backache	Added	Commonly occurs
52	High care/intensive care unit admission	Removed	This would either be documented on the theatre chart or expanded on in complications.
53	Apgar score	Removed	This will be documented by the midwives/paediatricians.
56	Time interval on grid	Removed	Time interval is chosen and documented by the anaesthetist.
57	Paper and Ink	Removed	This does not influence the quality of the documentation.
58	Multi-carbon copies	Added	Only once off copies are necessary, carbon or otherwise (the possibility of electronic record keeping is discussed further in chapter 3).
59	Typesetting, text and typestyle	Removed	Irrelevant
60	Colour coded	Removed	Irrelevant

No.	Item	Modification	Reason
65	Abbreviations and short forms	Added	Universally recognized abbreviations and short forms may be used on the record.
68	Special Investigations	Edited	This information should be specified in the space reserved for medical history.

4.3.2 Quantification Stage

Rating of items on rated instrument (CVI)

The rated instrument was emailed to experts nationally. They included experts from both the public and private sector. A total of 24 invitations were emailed to experts in the various, but not all, provinces in South Africa. Only 16 responses were received and of those only 12 were usable. Of the unusable responses, an expert from one province responded saying that labour epidural analgesia was not used in the state hospital where the expert works. One uncompleted instrument was returned and two experts did not comply with the instructions in the letter attached. The demographics of the respondents in this stage are shown in Table 4.4.

Table 4.4: Demographics of experts in quantitative stage

Demographic	Number	Percentage
Gender		
• male	8	67%
• female	4	33%
Sector		
• public	10	83%
• private	2	17%

The number of experts emailed, responses received and usable responses per province are shown in Figure 4.2.

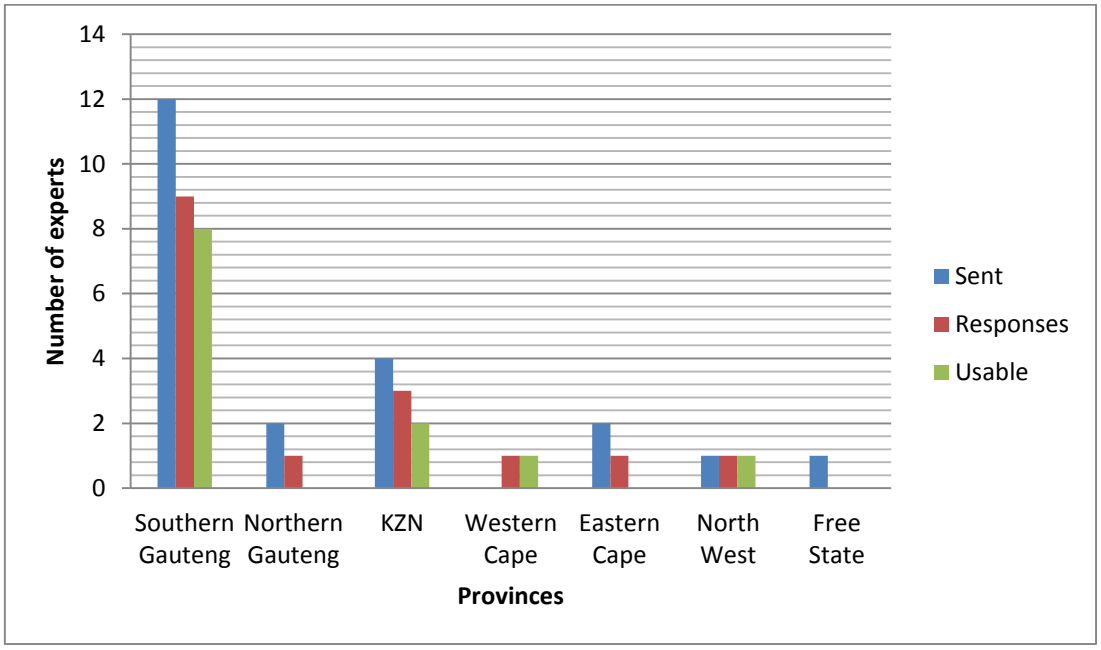

Figure 4.2: The number of study invitaions sent per province, the number of responses per province and the number of usable responses per province

The items in the rated instrument were numbered 1 - 54 and these items were then rated with the four point Likert scale by the 12 experts. The results according to the Likert scale are shown in Appendices 6-9. According to Lynn (22) when doing CVI, items scoring a 1 or 2 on the Likert scale are removed and items scoring a 3 or 4 are retained. To facilitate data presentation, the rated instrument will be presented per section:

- demographic data and preoperative assessment
- intraoperative data set
- follow-up/postoperative details
- layout of chart.

Demographic data and preoperative assessment

Of the 21 items in this section, 3 did not achieve a minimum rating 3 or 4 from at least 10 experts and therefore were removed from the final record. These were items 9 (previous labour epidural), 17 (dilation of the cervix) and 18 (parity).

The CVI for the demographic data and preoperative assessment section is shown in Figure 4.3.

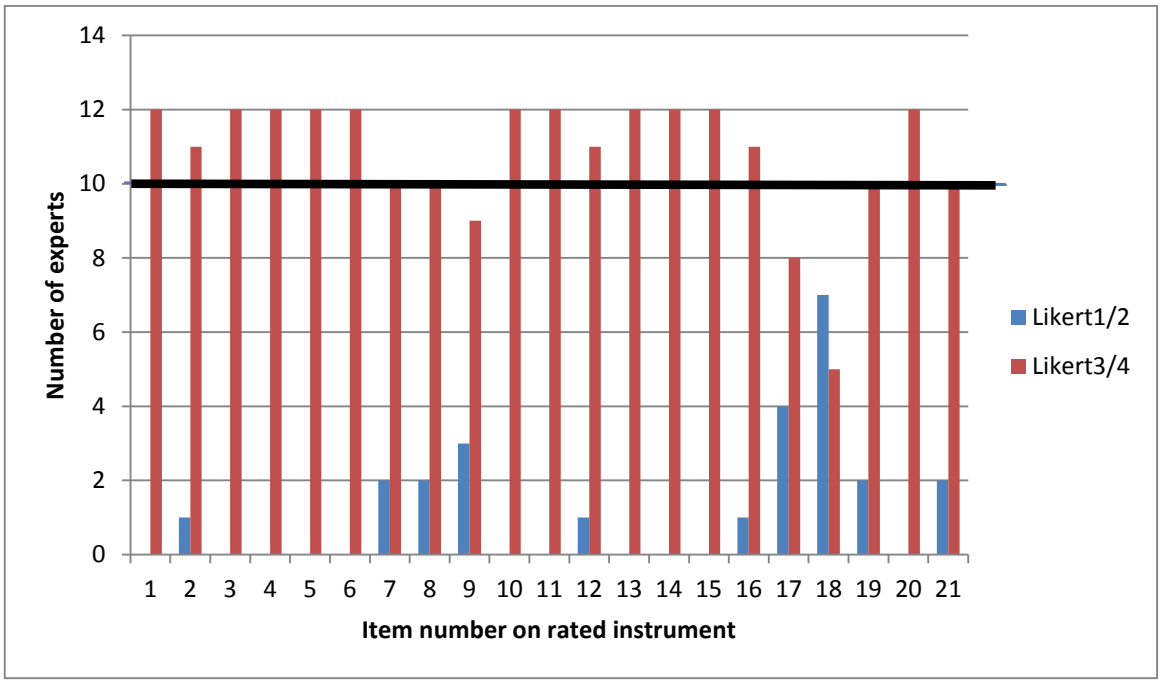

Figure 4.3: CVI for demographic data and preoperative assessment

Intraoperative data set

Of the 17 items in this section, only one item was removed. Item 32 (local given) was removed from the final record as it did not achieve a minimum of 10 experts rating it as important i.e. a 3 or 4 on the Likert scale. The CVI for the intraoperative data set is shown in Figure 4.4.

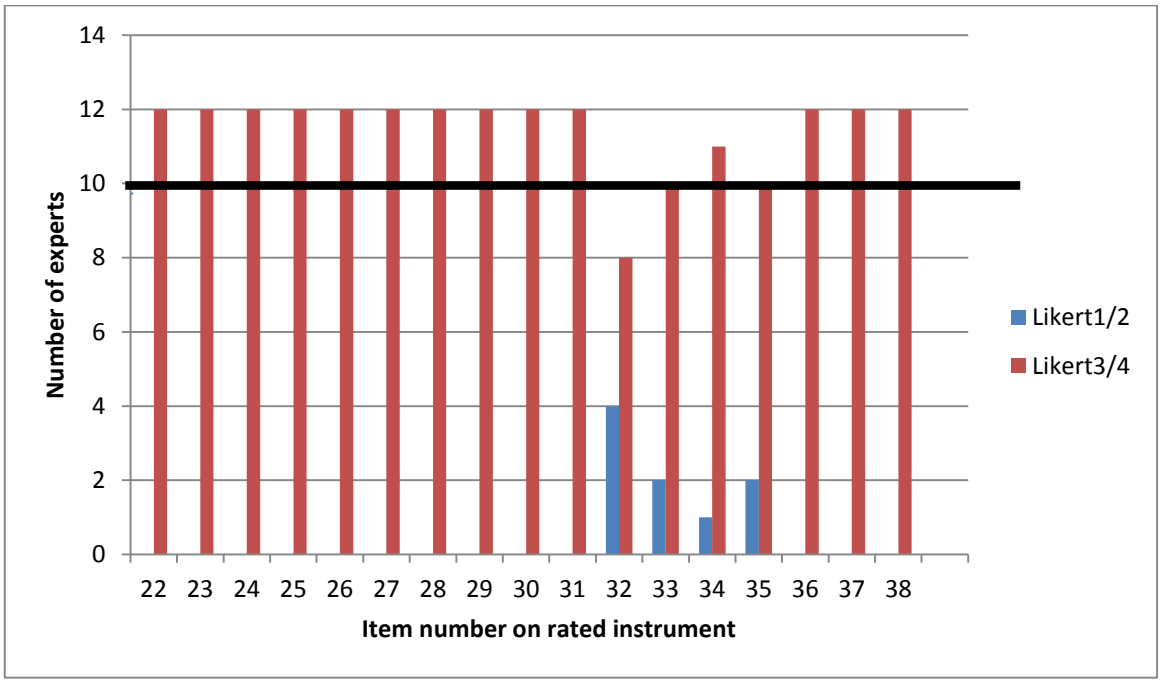

Figure 4.4: CVI for intraoperative data set

Follow up/postoperative details

Of the 8 items in this section the question “Would you have an epidural again?” (item 42) was added during the development stage and then removed during quantification stage. The CVI for follow up/postoperative details is shown in Figure 4.5.

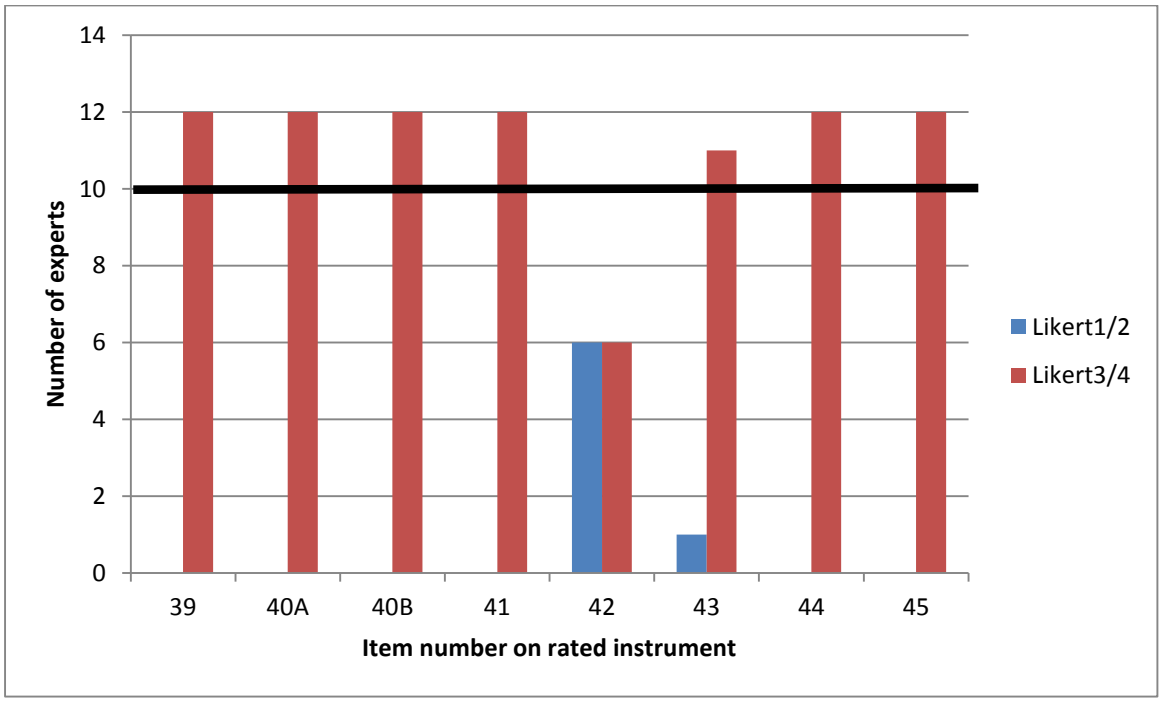

Figure 4.5: CVI for Follow up/postoperative details

Layout of the chart

Of the 9 items in this section, multiple items (items 47, 50, 51, 52, 53) regarding the layout of the chart were removed as they were deemed irrelevant by more than 2 out of 12 experts. This is shown in Figure 4.6.

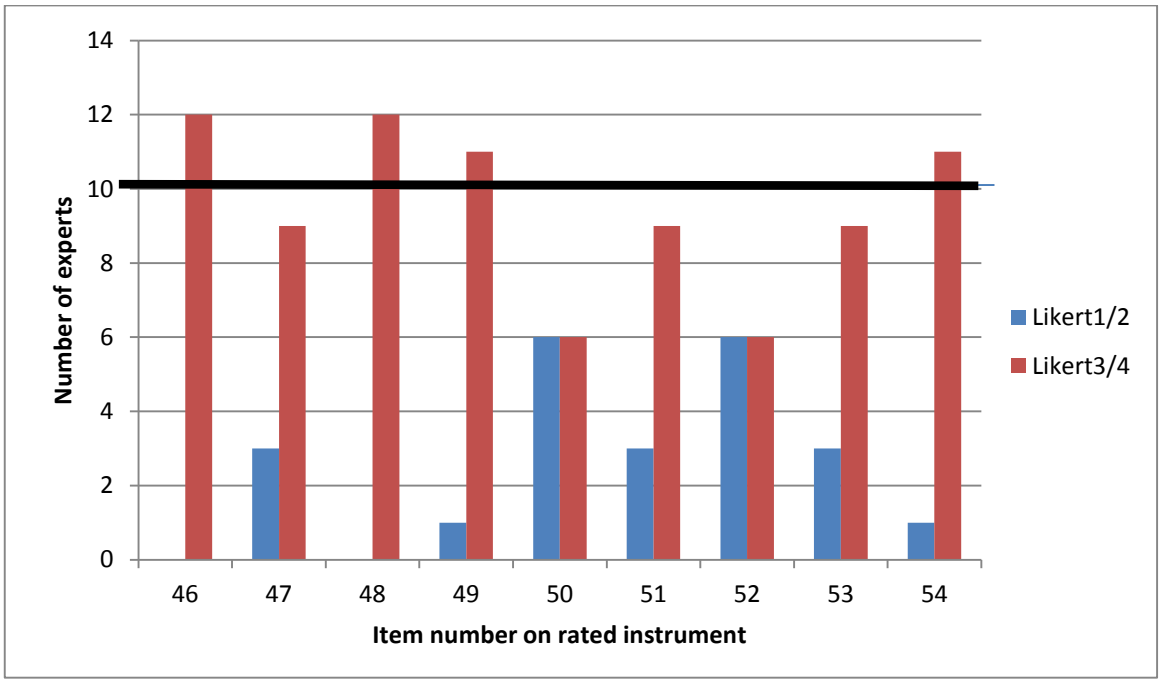

Figure 4.6: CVI for layout of the chart

4.4 Content validity of the instrument as a whole

Grant (55) states that part of the validation process is the examination of content validity. Part of this examination is the use of content experts in the development and rating of the instrument. Errors may occur if the experts are either inappropriately selected or they are not adequately orientated to the systematic process of judgement-quantification. This was ensured in this study by senior assistance in selection of the expert panel. The expert panel was also advised on the expectations of the study telephonically and with an information email.

The content validity of the instrument was also ensured by using an interrater (IR) agreement value of 0.7 to 0.8. The IR agreement is "the number of agreements among content experts (all items rated 1 or 2 by panel members and all items rated 3 or 4 by panel members) divided by the total number of items on the instrument"(65). The IR level is a reflection of the relevance or representativeness of the instrument of the identified domain. (55) It has been

calculated mathematically that an IR level of 0.8 correlates with 10 of 12 experts finding an item valid. In the final instrument developed by this study all the items have an IR value of 0.7 to 0.8, ensuring the content validity of the final instrument as a whole.

The final instrument for labour epidural analgesia recordkeeping is shown in Table 4.5 to Table 4.8.

Table 4.5: Demographic data and preoperative assessment

Number	Items
1	Patient name, date of birth, hospital number
2	Patient height/ weight
3	Past surgical history
4	Past medical history
5	Current medication
6	Allergies
7	Family history
8	Time since last meal/nil by mouth
9	Airway assessment
10	Baseline blood pressure & heart rate
11	Absence of contra-indications
12	Consent-verbal/written
13	Presence of resuscitation equipment
14	Indication
15	Prior analgesia: opioids/hydroxyzine
16	Language translation if necessary
17	Counselled on risks/ complications
18	ASA status

Table 4.6: Intraoperative data set

Number	Item
19	Name of anaesthetist and obstetrician
20	Contact number of anaesthetist & obstetrician (must be available)
21	Date and starting time
22	Intravenous access and fluids given
23	Drugs administered (concentration and volume) and times drugs were given
24	Monitoring of physiological variables
A	Heart rate and blood pressure
B	Saturation/oxygen supplementation given
25	Level of analgesia: L2/L3; L3/L4; L4/L5; L5/S1
26	Complications or untoward events : multiple attempts/bloody tap/dural tap/pain/paraesthesia
27	Frequency of observations
28	Asepsis: gown, glove, mask, skin
29	Loss of resistance: saline/air
30	Needle: type and gauge
31	Site/level of insertion
32	Length of epidural catheter in space: depth of space to skin/total depth of catheter.

Table 4.7: Follow up/postoperative details

Number	Item
38	Mode of delivery: NVD/assisted/ Caesarean
39	If Caesarean: GA/spinal/top-up & name of theatre anaesthetist
40	Pain relief adequate?(pain scale)
A	In labour
B	For delivery
41	Post-operative pain
44	Complications: pruritis; nausea; vomiting; headache; neurological deficits; hypotension; back ache
45	Epidural catheter out & tip visualized

Table 4.8: Layout of chart

Number	Item
46	Time based grid
48	Standardised format for date and time
49	Checkboxes
54	Test results

4.5 Discussion

The initial concept instrument was developed through a literature review. South African literature on what is essential information in labour epidural analgesia records is in limited supply. There was limited information in the SASA guidelines which did not pertain to labour epidural analgesia recordkeeping specifically but to all anaesthetic recordkeeping.

Internationally, the need for a well-defined standard to remove the possibility of inaccuracies within manually compiled anaesthetic records has long been recognized (20) and many systems have been suggested and studied by the anaesthetic community to reduce recording errors. (58) This study focused on the items on an anaesthetic record considered to be important for complete labour epidural analgesia recordkeeping and how to facilitate the recording of these items.

The majority of items that are considered essential information on a labour epidural record internationally are also considered essential in South Africa. In order to adapt the items found in the literature to a South African context a peer group discussion with local experts was held. National experts then made further suggestions. These are briefly outlined in the following paragraphs:

It was suggested by an expert from the quantitative stage expert panel that the word “past” in terms of history should be changed to “current”. This is a logical suggestion. The same expert also suggested the addition of the name and signature of a translator should language translation during the preprocedural counselling and consent process be needed. This could not be reflected in the CVI so is discussed below for completion.

Globalization and the increase of immigration has created a worldwide need for language translators to be available in healthcare practices (66). This is important particularly in South Africa, where there are 11 official languages as well as a multitude of visitors from the rest of Africa and the world. A 2006 study at Hottentots Holland Hospital in the Western Cape concluded that “the effects of the language barrier were considerable and persistent despite an official language policy in the province.” Employment and training of professional language interpreters was recommended. (67) Out of necessity, at CHBAH, this role is often adopted by labour ward staff, although they may not be translators in an official capacity.

Item 9 of the concept instrument i.e. whether the patient had had a previous labour epidural, was not considered essential information by South African experts. This was supported by a Canadian study which showed that "understanding", as rated by a Visual Analogue Score indicating "the ability to understand information" was not affected by previous epidural experience (68).

Parity (item 18 of the concept instrument) was removed by the initial peer group but added again by the two reviewing experts. South Africa has a high birth rate (a crude birth rate of 22,4 live births occurring per 1,000 population in 2014) (69) when compared with Europe (a crude birth rate of 10 live births per 1,000 population) (70) as well as a high rate of still births (71), neonatal deaths , and deaths of children under the age of five (72). In 2009, South Africa was one of eight countries in the world in which the neonatal mortality rate was increasing from the baseline value in 1998 (73). The impact that these realities have for the individual labouring woman should not be underestimated. This may explain why the reviewing experts felt that parity is a contextually significant item to document on labour epidural analgesia record.

In developed countries, such as the USA, parity has also been identified as a factor (along with income and education) contributing to an increased preference for labour epidural analgesia in a study which explored demographic factors related to women's prenatal preferences for using an epidural during labour. The study was taken over a nine month period in 1997 – 1998 in southwest Michigan and women were recruited from prenatal classes. (74) Despite evidence that awareness of a patient's parity is important, it was still not felt to be an essential item for complete documentation of a labour epidural analgesia record. Parity was removed in the quantification stage.

The only item that was not considered essential for the documentation of labour epidural analgesia recordkeeping in the intraoperative data set was whether local anaesthetic was given to skin and subcutaneously prior to the epidural. Although the rated instrument does not specify what type of local anaesthetic should be used it is generally accepted that some form is routinely used. In 1993, Raltson (74) showed that both Eutectic Mixture of Lignocaine and Prilocaine (EMLA) and lignocaine 2% used five minutes prior to the procedure resulted in pain scores of 3 or less on insertion of a 16 gauge Tuohy epidural needle. The use of some

form of local with epidural insertion is regarded as standard practice but it was not considered an essential item to be documented by the South African experts.

The question “Would you have an epidural again?” (item 43 of Appendix 7) was added during the development stage and then also removed during the quantification stage. The expert panel may have felt that because of poor in-hospital recordkeeping and a high likelihood of loss of records that documentation of this item would not be helpful. It is also a difficult question to pose to a parturient who may be physically and emotionally exhausted (48). Although a woman’s ability to give consent intrapartum has been extensively explored in the literature, research on the emotional impact of childbirth and how this could affect maternal responses to questionnaires is recommended. Verbal consent during such a stressful time is of questionable adequacy and ideally written consent should be obtained.

Multiple items (items 48, 51, 52, 53) regarding the layout of the chart were removed during the quantification stage as they were deemed irrelevant. A search of the literature showed no suggestions for chart layout from the developing world. Chart layout and how it can be used to facilitate correct, essential documentation has been extensively researched internationally (75). In South Africa, this may be because an acute pain service is still being established in many public service hospitals, which would provide continuous labour epidural analgesia. Providing this service is a priority, which means that the chart layout may not be. However, a standardised guideline on chart layout would have a valid place in the facilitation of labour epidural analgesia recordkeeping.

Regardless of the variation in individual patients and their specific labour epidural analgesia requirements, “there is a basic core of information which must be documented” (5). This study has identified the information that South African experts in labour epidural analgesia feel will constitute that core.

4.6 Summary

In this chapter the results and the analysis thereof was presented. In the following chapter the study summary, recommendations, limitations and study conclusion is provided.

CHAPTER FIVE

STUDY SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

In this chapter, a summary of study, the limitations and recommendations and conclusion is discussed.

5.2 Study summary

5.2.1 Aim

The aim of this study was to develop an instrument for labour epidural analgesia recordkeeping, using local and national experts and following the two stages of instrument validation as described by Lynn (19).

5.2.2 Objectives

- develop a concept instrument from the literature using Lynn's development stage (domain identification and item generation)
- develop a rated instrument using Lynn's development stage (item formation)
- determine content validity of the rated instrument using Lynn's quantification stage

5.2.3 Summary of methodology

A prospective, methodological study design was used in this study.

Lynn's model, which is a two stage process, consisting of a development stage and a quantification stage was used in this study.

The study population consisted of South African anaesthesiologists that are considered experts in labour epidural analgesia and these experts were purposively sampled.

Ten local experts who met the inclusion criteria were invited to participate. The researcher made use of three steps by performing a literature review (domain identification), developing a concept instrument (item generation) and conducting a peer group discussion (item formation) to debate the concept instrument in order to develop a rated instrument.

The concept instrument, with instructions, was handed out to the appointed experts who agreed to participate in the peer group discussion. The aim of the peer group discussion was to refine the concept instrument and if necessary, to expand the instrument to ultimately enhance the content validity. During the peer group discussion, the concept instrument was reviewed and graded according to a Likert scale. Recommendations for changes, additions or deletions were debated until consensus was reached.

On completion of the peer group discussion, the necessary changes according to the peer group recommendation were made and the concept instrument was prepared for the quantification stage. It then became known as the rated instrument. The rated instrument was then given to two experts from the peer group discussion to verify that the recommended changes had been made.

Quantification stage

The study sample in this stage consisted of twelve national experts who had been selected prior to data collection with assistance of senior consultants in the Department of Anaesthesiology. The rated instrument was emailed to each participant with background information stating the aim of the research and instructions for validating the items.

The data from the rated instrument was entered into a Microsoft Office Excel® spread sheet by the researcher and then analysed with a CVI. The CVI for each item was determined by the proportion of experts that rated the items as content valid with a rating of three or four on the rating scale.

5.2.4 Summary of results

Development stage

Items were removed during the peer group discussion as the experts felt that these items were irrelevant or fall outside of the anaesthetists' scope of practice. There were some modifications to the concept instrument which refined it as an instrument for labour epidural analgesia recordkeeping. The concept instrument, after the peer group discussion was then known as the rated instrument.

Quantification stage

The rated instrument was further refined during the quantification stage and more items were removed. The items that are considered essential and important were consistently rated as such by the experts. No items were added.

5.3 Limitations

This study was limited by a lack of South African literature regarding labour epidural analgesia records. Practice in South Africa is contextually different and most of the literature is from abroad.

A limitation of the development stage was the availability of experts for the peer group discussion. The experts were occupied with clinical responsibilities therefore some junior consultants were approached to assist. This may skew the group dynamic as junior consultants may submit to a senior consultant's opinion.

A limitation of the quantification stage was a low response rate to the invitation email even though many had already agreed telephonically to participate. One expert does not do labour analgesia epidurals at the provincial hospital in his/her province and this was a further limitation to the study. Another limitation was that experts were not identified in every province, therefore not all provinces were represented in this study.

5.4 Recommendations

5.4.1 Clinical practice

The final instrument should be used in a pilot study to see if fellow trainees and consultants find it useful. A workshop could then be held in the Department of Anaesthesiology at Wits so that the instrument can be introduced and its use explained to the members of the department. The final instrument can also be put into a usable format for possible clinical use in hospitals in Southern Gauteng or nationally.

5.4.2 Further research

Compliance with using the instrument can be audited and a database with results of the audit can be developed. This can be used in further studies.

5.5 Conclusion

Many of the items on the instrument were not changed even though the literature focuses on labour epidural analgesia in developed countries where resources and staff are relatively abundant. In a South African context, patients may receive the minimum acceptable standard of care and that which is not seen as completely necessary may be neglected. However, this does not mean that the gold standard of labour analgesia should not be optimised in South Africa. This instrument has been developed by local and national experts for use in the South African context in order to improve the quantity and quality of labour epidural analgesia in this country and reflects that which South African experts in labour epidural analgesia believe to be essential information for acceptable anaesthetic recordkeeping.

REFERENCES:

1. Silva M, Halpern S. Epidural analgesia for labor: Current techniques. 2010. In: Local and regional anaesthesia [Internet]. [143-53.].

2. Cambic C, Wong C. Labour analgesia and obstetric outcomes. British Journal of Anaesthesia. 2010;105(51):50-60.

3. Merry A, Webster C. Multimodal system designed to reduce errors in recording and administarion of drugs in anaesthesia: prospective randomised clinical evaluation. British Medical Journal [Internet]. 2011 06/08/2015 [cited 2011.

4. Rowbotham D CJ, Counsell D, Cox F, Crawford P, Goddard J, et al. Best practice in the management of epidural analgesia in the hospital setting 2010 [Accessed 15/11/2013]. Available from: www.aagbi.org/sites/default/files/epidural_analgesia_2011.pdf.

5. AANA. Documenting the Standard of Care: The Anesthesia Record.: American Association of Nurse Anesthetists.; 2013 [06/08/2015].

6. Buckley S. The hidden risks of epidurals. Mothering. 2005:133.

7. Dyer R. Obsteric Anaethesia: is there anything new under the sun? South African Journal of Anaesthesia and Analgesia. 2013;19(1):29-32.

8. Senekal M. The changing profile of patients presenting for caesarian section in South Africa. South African Journal of Anaesthesia and Analgesia. 2010;16(1):76-8.

9. Wagner J. Statistics from CHBAH labour ward In: EJ J, editor. Johannesburg.2013.

10. Jacobs-Martin G, Burke J. Labour epidural analgesia audit in a tertiary state hospital in South Africa. South African Journal of Anaesthesia and Analgesia. 2014;20(4):174-8.

11. Galletly D, Rowe W, Henderson R. The Anaesthetic Record: a confidential survey on data omission or modification. Anaesthesia and Intensive Care Medicine. 1991;19:74-8.

12. Dickinson P, Berrington J. Informatics / Intensive Care Anaesthetic records: Learning objectives. . Anaesthesia and Intensive Care Medicine 2010;11(12):497-9.

13. HPCSA. Guidelines on the keeping of patient records. Pretoria: HPCSA; 2008.

14. Bembridge M, Bembridge J. A survey of anaesthetic charts. Anaesthesia. 1988 (43):690-3.

15. RCOA. Guidelines for the Provision of Anaesthetic Services 2015 [03/06/2015]. Available from: https://www.rcoa.ac.uk/tags/guidelines.

16. Ulyatt B, Ledingham N, Harrsion E, Burke D. Anaesthetic records-are we up to scratch? European Journal of Anaesthesia. 2005;22(9).

17. Raff M, James M. An audit of anaesthetic record keeping. South African Journal ofAnaesthesia and Analgesia. 2003;9(3):7.

18. HPCSA. Guidelines on the keeping of patient records. Pretoria: 2008.

19. Tsui B, Dryden A, Finucane B. Managing adverse outcomes during regional anesthesia. New York: McGraw-Hill; 2012.

20. Rowe L, Galletly D, Henderson R. Accuracy of text entries within a manually compiled anaesthetic record. . British Journal of Anaesthesia. 1992;68:381-7.

21. Rowbotham D, Cashman J, Counsell D, Cox F, Crawford P, Goddard J. Best practice in the management of epidural analgesia in the hospital setting 2010 2011 [cited 2013 15/11/2013]. Available from: www.aagbi.org/sites/default/files/epidural_analgesia_2011.pdf.

22. Lynn M. Determination and Quantification of Content Validity. Nursing Research. 1986;35(6):382-5.

23. World Medical Association. World Medical Association Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects Brazil: World Medical Association; 2013 [Accessed 15/11/2013]. Available from: http://www.wma.net/en/30publctions/10policies/b3/17c.pdf.

24. Department of Health. Guidelines for Good Practice in the Conduct of Clinical Trails with Human Particiants in South Africa. Pretoria: Government of South Africa; 2006.

25. Loosely A. Corning and cocaine: the advent of spinal anaesthesia United Kingdom2009 [cited 24/04/2015].

26. Deschner B, Allen M, De Leon O. Epidural Blockade. In: Hadzic A, editor. NYSORA Textbook of regional anesthesia and acute pain management New York: McGraw-Hill; 2007.

27. Bucklin B, Hawkins J, Anderson J, Ullrich F. Obstetric anaesthetia workforce survey: Twenty year update. . Anaesthesiology. 2005;103:645-53.

28. Bucklin B, Hawkins J, Anderson J, Ullrich F. Obstetric anaesthetia workforce survey: Twenty year update. Anaesthesiology. 2005;103:645-53.

29. CIHI. Highlights of 2008-2009: Selected indicators describing the birthing process in Canada 2008/2009 [30/10/2013]. Available from: http://www.cihi.ca.

30. Jacobs-Martin GG BJ. Labour epidural analgesia audit in a tertiary state hospital in South africa. SAJAA. 2014;20(4):174-8.

31. Cooper G, McClure J. Anaesthesia chapter from saving mothers' lives; reviewing maternal deaths to make pregnancy safer. British Journal of Anaesthesia. 2008;100(1):17-22.

32. Mlanga, Moodley, Pattinson, Similela, Robinson. Saving Mothers 2008-2010. Department of Health, 2008-2010.

33. Bettings P, Diederiks J, Fourie P, Joubert I, Kluyts H, Lundgren C. South African Society of Anaesthesiologists Practice Guidelines. South African Journal of Anaesthesia and Analgesia. 2013;19(1):S1-42.

34. Merry A, Cooper J, Soyannwo O. International standards for a safe practice of anesthesia. . Canadian Journal of Anesthesia. 2010;57:1027-34.

35. ASA. Guidelines for Neuraxial Anaesthesia in Obstetrics 2012 2012 [26/10/2013]. Available from: http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx.

36. Merchant R, Bosenberg C, Brown K. Guidelines to the Practice of Anaesthesia-Revised Edition 2010. 2010.

37. Mellin-Olsen J, O' Sullivan E, Balogh D. Guidelines for safety and quality in anaesthesia practice in the European Union. European Journal of Anaesthesiology. 2007;24:479-82.

38. ANZCA. The Anaesthesia Record 2006 [10/10/2013]. Available from: http://www.anzca.edu.au/.

39. Kenyon S, Ducker D, Grant S, Gyte G, Jempson J, Markham C. Intrapartum care: Care of healthy women and their babies during childbirth. 2007 [22/11/2013]. Available from: https://www.nice.org.uk.guideance/cg55.

40. Greyer N. Expansions in clinical nursing practice. SA Health Gesondheid. 1997;2(1):22-8.

41. Cox F. Improving epidural safety through new documentation. Nursing Times. 2008;104(12):26-7.

42. Fernanades T, Coelho D, Marantes I, Branca P. Anaesthetic records-analysis of a database European Journal of Anaesthesia. 2003;A.

43. Tessler M, Tsiodras A. Documentation on the anesthetic record: Correlation with clinically important variables. Canadian Journal of Anesthesia. 2006;53(11):1086-91.

44. Cook R, McDonald J, Nunziata E. Differences between handwritten and automatic blood pressure records. Anaesthesiology. 1989;71:385-90.

45. Chawla R, Bhardwaj M. Uniform record keeping in anaesthesia: need of the hour. 45th Annual Conference of Indian Society of Anaesthesiologists Dehli.2006.

46. Gibbs R. The present and future medicolegal importance of record keeping in anesthesia and intensive care: the case for automation. . International Journal of Clinical Monitoring and Computing. 1989;5(4):251-5.

47. Sechzer P. Anaesthesia documnetation and evaluation. . Quality Review Bulletin. 1981;7:28-34.

48. Jackson G, Sensky T, Reide P, Yentis S. The capacity to consent to epidural analgesia in labour. International Journal of Obstetric Anaesthesia. 2011;20(3):269-70.

49. SASA. SASA Guidelines for Infection Control in Anaesthesia in South Africa 2014. SAJAA. 2014;20(3).

50. Butterworth J, Mackey D, Wasnick J. Spinal, Epidural, & Caudal Blocks. In: Butterworth J, Mackey D, Wasnick J, editors. Morgan & Mikhail's Clinical Anesthesiology. 5th ed. ed. New York: McGraw-Hill; 2013.

51. Guay J. The epidural test dose: a review. Anesthesia Analgesia. 2006;102(3):921-9.

52. Hack A. Labour Analgesia. In: Achabahian A GR, editor. The Anaesthesia Guide. New York: McGraw-Hill; 2013.

53. Cox F, Scott K. Improving epidural safety through new documentation. Nursing Times. 2008;104(12):26-7.

54. Gravestein J. The Automated anaesthetic record. International Journal of Clinical Monitoring and Computing. 1986;3:131-4.

55. Grant J, Davis L. Selection and use of content experts for instrument development. Research in Nursing and Health. 1997;20(3):269-74.

56. Lynn M. Determination and quantification of content validity. Nursing Research. 1986;35(6):382-5.

57. Fisher A, Bromberg I, Eien L. On the design of anaesthesia record forms. Canadian Journal of Anaesthesia. 1994;41(10):973-83.

58. Abenstein J, De Vos C, Abel M. Eight year's experience with automated anaesthesia record keeping:lessons learned-new directions taken. International journal of Clinical Monitoring and Computing. 1992;4(1):37-47.

59. Lerou J, Dirksen R, Van Daele M, Nijhis G, Crul J. Automated chrting of physiological variables in anaesthesia: A quantitaive comparisonof automated versus handwritten anaesthesia records. Journal of Clinical Monitoring. 1988;4:37.

60. Gunaratnam G, Reynolds T, Tanqueray T. Electronic epidural analgesia charts on a paperless delivery suite. Three-day course on obstetric anaesthesia; 11-13 November 2013; London2013.

61. Brink H, Van der Walt C, Van Rensburg G. Fundamentals of research methodology for health care professionals. Second edition ed. Cape Town: Juta; 2006.

62. Polit D, Beck C. Sampling in Quantitive Research. 9th edition ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008. 279 p.

63. Brink H, Van der Walt C, Van Rensburg G. Fundamentals of research methodology for health care professionals. 2 ed. Cape Town: Juta; 2006.

64. Botma Y, Greef M, Mulaudzi M, Wright S. Research in Health Sciences. Merrington D, editor. South Africa: Van Schaik; 2010.

65. Martuza V. Applying norm-referenced and criterion-referenced measurement in education. Boston: Allyn and Bacon; 1977.

66. Flores G. Perspective: language barriers in health care in the United States. New England Journal of Medicine. 2006;355(3):229-31.

67. Schlemmmer A, Mash B. The effects of a language barrier in a South African district hospital. South African Medical Journal. 2006;96(10):1084-7.

68. Jackson A, Avery N. Informed consent for labour epidurals: what labouring women want to know. Canadian Journal of Anaesthesia. 2000;47(11):1068-73.

69. Africa SS. Mid-year population estimates. 2014 Contract No.: P0302.

70. Eurostat. Fertility Statistics 2015 [cited 2015 06/08/2015].

71. C. B. Stillbirths-an invisible earthquake. South African Medical Journal. 2011;101(6):364.

72. Nannan N, Dorrington R, Laubscher R. Under-5 mortality statistics in South Africa: shedding some light on the trend and causes 1997-2007. South African Medical Research-Council, 2012.

73. Lloyd L, de Witt T. Neonatal mortality in South Africa: how are we doing and what can we do better? South African Medical Journal [Internet]. 2013; 103(8).

74. Stark M. Exploring Women's Preferences for Labor Epidural Analgesia. Journal of Perinatal Education. 2003;12(2):16-21.

75. NHS. Epidural Record for Labour Analgesia The Queen Elizabeth Hospital King's Lynn2013 [25/11/2013]. Available from: http://www.oaa-anaes.ac.uk/assets/_managed/editor/File/Guidelines/Epidural%20Charts/ANAESTHETIC%20FOLLOW%20UP%20Surendran%20Kings%20Lynn.pdf.

76. Tessler MJ, Tsiodras A, Kardash KJ, Shrier I. Documentation on the anesthetic record: Correlation with clinically important variables. Can J Anaesth. 2006 Nov;53(11):1086-91. PubMed PMID: 17079634. Epub 2006/11/03. eng.

77. Dickinson P, Berrington J. Informatics / Intensive Care Anaesthetic records Learning objectives. Anaesthesia and Intensive Care Medicine. 2010;11(12):497-9.

78. Rowe L, Galletly D, Henderson R. Accuracy of text entries within a manually compiled anaesthetic record. British Journal of Anaesthesia. 1992;68:381-7.

79. Galletly D, Rowe W, Henderson R. The Anaesthetic Record: a confidential survey on data omission or modification. Anaesthesia and Intensive Care 1991;19:74-8.

80. Seed R, Welsh E. Anaesthesia records in Great Britain and Ireland. Anaesthesia 1976;31:1199-210.

81. Anaethetists NZaACo. The Anaesthesia Record 2006. Available from: http://www.anzca.edu.au/.

82. Anaesthesiologists THKCo. Guidelines on Minimal Requirements for an Anaesthetic Record. In: Committee CG, editor.2012. p. 3-6.

83. Saunders T, Schabel J. OB Anesthesia Survival Guide: Department of Anaesthesiology: Stony Brook Medicine; 2013. Available from: http://anesthesia.stonybrook.edu/education/OB.

84. Trust KsLNF. Epidural Record for Labour Analgesia The Queen Elizabeth Hospital [cited 2013]. Available from: http://www.oaa-anaes.ac.uk/assets/_managed/editor/File/Guidelines/Epidural%20Charts/ANAESTHETIC%20FOLLOW%20UP%20Surendran%20Kings%20Lynn.pdf.

85. Fisher A, Bromberg I, Eien L. On the design of anesthesia record forms. Canadian Journal of Anesthesia. 1994;41(10):973-83.

86. ASA. Guidelines for Neuraxial Anaesthesia in Obstetrics 2012 [updated 17/10/201213/11/2013]. Available from: http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx.

87. Trust NHaSC. Epidural analgesia in labour-Guideline for care. In: Keown C, Gordon M, editors. Epidural analgesia in labour-Guideline for care2012.

88. Rowbotham D, Cashman J, Counsell D, Cox F, Crawford P, Goddard J, et al. Best practice in the management of epidural analgesia in the hospital setting 2010 [Accessed 15/11/2013]. Available from: www.aagbi.org/sites/default/files/epidural_analgesia_2011.pdf.

89. Jackson G, Sensky T, Reide P, Yentis S. The capacity to consent to epidural analgesia in labour. International Journal of Obstetric Anaesthesia. 2011;20(3):269-70.

90. Merchant R, Bosenberg C, Brown K. Guidelines to the Practice of Anaesthesia-Revised Edition 2010. Canadian Journal of Anaesthesia. 2010;57:58-87.

91. Bembridge M, Bembridge J. A survey of anaesthetic charts. Anaesthesia. 1988;43:690-3.

92. Wee M, Brown A, Reynolds F. The National Institute of Health Care and Excellence. International Journal of Obstetric Anaesthesia. 2005;34:347-58.

93. Shah A, Shih G. Epidural Analgesia and Maternal Fever: Real or Fiction. Anaesthesiology Clin. 2013;31:559-70.

94. Wagner J. Consultant Anaesthesologist. In: EJ J, editor. statistics from CHBAH labour ward ed. Johannesburg, South Africa2013.

95. Cantwell R, Clutton-Brock T, Cooper G, Dawson A, Drife J, Garrod D. Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom. BJOG. 2011 Mar;118 Suppl 1:1-203. PubMed PMID: 21356004. Epub 2011/03/05. eng.

96. Sechzer P. Anaesthesia documnetation and evaluation. Quality Review Bulletin. 1981;7:28-34.

Appendix 1

Concept Instrument

Demographic data and preoperative assessment

Number	Item	Reference
1	Patient name, date of birth, hospital number	(76-82)
2	Patient height/ weight	(78, 80-84)
3	Past surgical history	(81, 83)
4	Past medical history	(76, 81-83, 85)
5	Current medication	(76-78, 81, 82)
6	Allergies	(76-78, 81, 83, 86)
7	Family history	(76, 77)
8	Exercise tolerance	(76, 77)
9	Time since last meal/nil by mouth	(76, 77, 80, 82)
10	Previous labour epidural	(80-82, 84)
11	Gastro-oesophageal reflux disease	(76, 81, 82)
12	Airway assessment	(76, 77, 81-83)
13	Baseline blood pressure & heart rate	(76)
14	Absence of contra-indications	(50, 87, 88)
15	Consent-verbal/written	(37, 80, 87-92)
16	Presence of resuscitation equipment	(86, 88, 90)
17	Indication	(87)
18	Prior analgesia: opioids/hydroxyzine	(3,9)
19	Dilation of cervix	(83, 84, 87, 92)
20	Parity	(80, 84, 87)

21	Presence of a partner/friend/relative	(7)
22	Language translation if necessary	(7)
23	Counselled on risks/ complications	(3,5,7)(37, 81, 92)
24	ASA status	(77, 82, 86)
25	Ward of origin	(80, 91)

Intraoperative data set

Number	Item	Reference
26	Name of anaesthetist & obstetrician	(76, 80-82)
27	Contact number of anaesthetist & obstetrician (must be available)	(86, 88)
28	Date and starting time	(76, 78, 80-82)
29	Intravenous access & fluids given	(76, 78, 80-82, 85, 86, 90, 92)
30	Drugs administered (concentration and volume) & time given	(76, 77, 80-82, 85, 92)
31	Labelled drugs	(88)
32	Physiological variables:	(76, 80)
A	Heart rate and blood pressure	(86)
B	Saturation/oxygen supplemetation given	
C	Temperature	(93)
33	Foetal heart rate	(83, 86, 92, 94)
34	Complications/untoward events:	(77, 81, 82, 84)
	Multiple attempts/bloody tap/dural tap/pain/paraesthesia	
35	Monitors used continuously	(77, 81, 82, 88, 90)
36	Frequency of observations	(4)
37	Grade of anaesthetist	(81, 88, 95)
38	Local anaesthesia given	(84, 87)
39	Position	(80, 81, 84, 87)
40	Asepsis: gown, glove, mask, skin	(84, 87, 88)
41	Approach: median/paramedian	(84)
42	Loss of resistance: saline/air	(84)
43	Needle: type and gauge	(9,22)

44	Level: L2/L3; L3/L4; L4/L5; L5/S	(83, 84, 95)
A	Site	(9,22)
B	Analgesia	(4)
45	Length of epidural catheter in space	(8,9,22)

Follow up/postoperative details (91)

Number	Item	Reference
46	Mode of delivery: NVD/assisted/caesarean	(84, 92)
47	Pain relief & management if inadequate:	(81, 84, 88, 95)
A	In labour	(81, 84)
B	For delivery	
48	Maternal satisfaction	(84)
49	Post-operative pain	(84)
50	Problems: missed segments/unilateral/delay in pain relief onset	(84)
51	Complications: pruritis; nausea; vomiting; headache; neurological deficits; hypotension	(80, 81, 84, 88)
52	ICU/HC admission	(84)
53	Apgar score	(80, 83)
54	Epidural catheter out & tip visualized	(83, 88)

Layout of chart

Number	Item	Reference
55	Time based grid	(80, 91)
56	Time interval on grid	(86)
57	Paper and ink	(85)
58	Multi-part carbon copy forms	(85)
59	Typesetting, text and typestyle	(85)
60	Colour coded	(53, 80, 91)
61	Standardised format for date and time	(85)
62	Checkboxes	(85)
63	Margins	(85)
64	A4 size	(80, 91, 96)
65	Abbreviated and short forms	(85)
66	Area reserved for patient identification	(85, 91)
67	Test results	(81, 82, 85)
68	Special investigations	(80, 82)

Appendix 2

Rated Instrument

Demographic data and preoperative assessment

Number	Items	References
1	Patient name, date of birth, hospital number	(76-82)
2	Patient height/ weight	(78, 80-84)
3	Past surgical history	(81, 83)
4	Past medical history	(76, 81-83, 85)
5	Current medication	(76-78, 81, 82)
6	Allergies	(76-78, 81, 83, 86)
7	Family history	(76, 77)
8	Time since last meal/nil by mouth	
9	Previous labour epidural	(76, 77, 80, 82)
10	Airway assessment	(4)
11	Baseline blood pressure & heart rate	(76, 77, 81-83)
12	Absence of contra-indications	(76)
13	Consent-verbal/written	(50, 87, 88)
14	Presence of resuscitation equipment	(37, 80, 87-92)
15	Indication	(86, 88, 90)
16	Prior analgesia: opioids/hydroxyzine	(87)
17	Dilation of cervix	(4, 84)
18	Parity	(4)
19	Language translation if necessary	(83, 84, 87, 92)
20	Counselled on risks/ complications	(3,5,6,7,17,19)

21	ASA status	(2,7,11)

Intraoperative data set

Number	Item	Reference
22	Name of anaesthetist and obstetrician	(76, 80-82)
23	Contact number of anaesthetist & obstetrician (must be available)	(86, 88)
24	Date and starting time	(76, 78, 80-82)
25	Intravenous access and fluids given	(76, 78, 80-82, 85, 86, 90, 92)
26	Drugs administered (concentration and volume) and time drugs were given	(76, 77, 80-82, 85, 92)
27	Monitoring of physiological variables	
A	Heart rate and blood pressure	(76, 80)
B	Saturation/oxygen supplemetation given	(86)
28	Level of analgesia: L2/L3; L3/L4; L4/L5; L5/S1	(4)
29	Complications or untoward events : multiple attempts/bloody tap/dural tap/pain/paraesthesia	(77, 81, 82, 84)
30	Frequency of observations	(6,14,22)
31	Local anaesthesia given	(84, 87)
32	Position	(80, 81, 84, 87)
33	Asepsis: gown, glove, mask, skin	(84, 87, 88)
34	Loss of resistance: saline/air	(84)
35	Needle: type and gauge	(84)
36	Site/level of insertion	(9,22)
37	Length of epidural catheter in space	(83, 84, 95)

Follow up/postoperative details (91)

Number	Item	References
38	Mode of delivery: NVD/assisted/ Caesarean	(84, 92)
39	If Caesarean: GA/spinal/top-up & name of theatre anaesthetist	
40	Pain relief adequate?(pain scale)	(81, 84, 88, 95)
A	In labour	
B	For delivery	(81, 84)
41	Post-operative pain	(84)
42	"Epidural again?" Y/N	
43	Problems: missed segments/unilateral/delay in pain relief onset	(84)
44	Complications: pruritis; nausea; vomiting; headache; neurological deficits; hypotension; backache	(80, 81, 84, 88)
45	Epidural catheter out and tip visualized	(83, 88)

Layout of Chart

Number	Item	References
46	Time based grid	(80, 91)
47	Once off copy forms	(85)
48	Standardised format for date and time	(85)
49	Checkboxes	(85)
50	Margins	(85)
51	A4 size	(80, 91, 96)
52	Abbreviated and short forms	(85)
53	Area reserved for patient identification	(85, 91)
54	Test results	(81, 82, 85)

Appendix 3

Cumulative Binomial Distribution

Table illustrating cumulative binomial distribution (reproduced from Lynn's article on determination & quantification of content validity.)

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 4

R14/49 Dr Elizabeth Johanna Jacobs

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140129

NAME: (Principal Investigator)	Dr Elizabeth Johanna Jacobs
DEPARTMENT:	Department of Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Development and Validation of an Instrument for Labour Epidural Analgesia Record Keeping
DATE CONSIDERED:	31/01/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Estie Mostert
APPROVED BY:	Professor Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	12/12/2014

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 5

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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

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

11 March 2015
Person No: 779351
TAA

Dr EJ Jacobs
Unit 2
14 2nd Avenue
Houghton Estate
Houghton
2129
South Africa

Dear Dr Jacobs

Master of Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine** has been approved:

From:	**Development and validation of an instrument for labour epidural analgesia record keeping**
To:	**Development and validation of an instrument for labour epidural analgesia record keeping in hospitals in Southern Gauteng**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 6

Dr Elizabeth Jacobs

Anaesthesiology registrar

University of the Witwatersrand

To: Dr/Professor

Dear Colleague

Hello, my name is Elizabeth Jacobs. I am a registrar in the department of Anaesthesiology, University of the Witwatersrand. I am conducting a research study as part of my MMed degree. This study is called: Development and validation of an instrument for labour epidural analgesia record keeping in the public sector in Southern Gauteng.

This study is motivated by the fact that national and international audits have shown that anaesthetic records are poorly completed. There is no developed instrument with which we can measure if relevant information is recorded on epidural records. I mean to develop a labour epidural analgesic record which will contain all essential information.

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

I hereby invite you as an expert in labour epidural record keeping 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 documentation pertaining to the study prior to the peer group meeting. This will include the provisional instrument with items that I will have developed from reviewing the literature for you to refine and if necessary expand to ultimately enhance content validity. At the peer group meeting, I will ask you to recommend any changes, accompaniments or removals to the provisional labour epidural analgesia record and to rate the items as follows:

- Irrelevant-1
- relevant but unimportant-2
- relevant and important-3
- relevant and essential-4

The decision regarding each item is debatable, and consensus must be reached prior to electing to use the item in the quantification stage.

Consenting to be part of the peer group is voluntary and confidentiality of the debate and discussion is to be maintained. However, I cannot ensure that all members of the peer group will comply with this request.

There will be no remuneration for participation in this study but I hope that the newly developed and validated labour epidural analgesia record will contain information that experts consider relevant and essential. This will be invaluable in improving the transmission of labour epidural analgesia related information, quality assurance, research and protecting the patient and anaesthetist form a medico legal point of view.

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

My e-mail address is lizjacobs25@gmail.com should you have any queries. Alternatively, contact me directly at 0825565033. Professor Cleaton-Jones, the chairman of the HREC can also be reached at 0117171234.

Thank you for your time and please respond within the following two weeks if you wish to participate.

Yours sincerely,

Liz Jacobs

Appendix 7

Dr Elizabeth Jacobs

Anaesthesiology registrar

University of the Witwatersrand

To: Dr/ Professor

Dear Colleague

Hello, my name is Elizabeth Jacobs. I am a registrar in the department of Anaesthesiology, University of the Witwatersrand. I am conducting a research study as part of my MMed degree. This study is called: Development and validation of an instrument for labour epidural analgesia record keeping in the public sector of Southern Gauteng.

This study is motivated by the fact that national and international audits have shown that anaesthetic records are poorly completed. There is no developed instrument with which we can measure if relevant information is recorded on epidural records. I mean to develop a labour epidural analgesic record which will contain all essential information.

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

I hereby invite you as an expert in labour epidural record keeping to be part of the peer group that will participate in the quantification stage of this rated instrument. If you consent, I will send you documentation pertaining to the study. This will include the rated instrument with items that I will have developed from reviewing the literature and a peer group discussion that resulted in the development of the attached rated labour epidural analgesia record instrument. At the peer group meeting, any changes, accompaniments or removals to the concept labour epidural analgesia record were discussed rated as follows:

- Irrelevant-1
- relevant but unimportant-2
- relevant and important-3
- relevant and essential-4

The decision regarding each item was debated, and consensus was reached prior to electing to use the item for use in the instrument. I have attached the original concept instrument and would like you to note the changes made:

Item 8: Exercise tolerance was removed. A patient in the third trimester is extremely unlikely to have no decrease in exercise tolerance.

Item 11: GORD was removed. If the patient needs a general anaesthetic, a rapid sequence induction will be done, regardless of the presence of GORD.

Item 20: Parity was removed. This is not essential information.

Item 21: Presence of friend/partner/relative was removed. This is not applicable in our setting.

Item 25: Ward of origin was removed. The post partum wards will be where the patients will be for follow-up.

Item 31: Labelled drugs was removed.

Item 32C: Temperature was removed. The relevance of monitoring this variable has not yet been established in the literature.

Item 33: Foetal heart rate was removed. An isolated reading has no diagnostic value and therefore should not be documented. An epidural should not be placed in the case of a foetal bradycardia is the foetus is already compromised.

Item 35: Monitors used continuously was removed. The physiological variables are measured at a set time interval, not continuously.

Item 37: Grade of anaesthetist was removed as the anaesthetist will have their name and contact details on the record already.

Item 41: Approach: median/paramedian was removed. The paramedian approach is not used in our setting.

Item 44B: level of analgesia was moved to the area reserved for the items to be monitored as this should also be monitored at specific time intervals.

Item 46: mode of delivery: caesarian was further qualified by adding the method of anaesthesia (GA/spinal/top-up) and the name of the anaesthetist who performs it.

Item 47&49: Pain relief and post operative pain must be quantified with a pain scale.

Item 48: Maternal satisfaction was removed.

The checkbox question, “Would you have an epidural again?” Y/N was added after Item 49.

Item 51: Backache was added as a potential complication.

Item 52: ICU/HC admission was removed as this would either be documented on the theatre chart or expanded on in complications.

Item 53: Apgar score was removed as this will be documented by the midwives/paediatricians.

Item 56 was removed as the time interval is chosen and documented by the anaesthetist.

Item 57 was removed as the paper and ink does not influence the quality of the documentation.

Item 58 was altered: only once off copies are necessary, carbon copied or otherwise (the possibility of electronic record keeping is discussed further in chapter 3.)

Item 59&60 were not deemed relevant in our setting

Item 65: This was qualified as universally recognized abbreviations and short forms may be used on the record.

Item 68: Special investigations was removed as this information should be specified in the space reserved for medical history.

The rated instrument is attached under the heading ‘Rated Instrument’.

Consenting to be part of the peer group is voluntary and confidentiality of the debate and discussion is to be maintained. However, I cannot ensure that all members of the peer group will comply with this request.

There will be no remuneration for participation in this study but I hope that the newly developed and validated labour epidural analgesia record will contain information that experts consider relevant and essential. This will be invaluable in improving the transmission of labour epidural analgesia related information, quality assurance, research and protecting the patient and anaesthetist form a medico legal point of view.

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

My e-mail address is lizjacobs25@gmail.com should you have any queries. Alternatively, contact me directly at 0825565033. Professor Cleaton-Jones, the chairman of the HREC can also be reached at 0117171234.

Thank you for your time and please respond within the following two weeks if you wish to participate.

Yours sincerely,

Liz Jacobs