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Development and validation of an instrument for essential information for anaesthetic records

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DEVELOPMENT AND VALIDATION OF AN INSTRUMENT FOR ESSSENTIAL INFORMATION FOR ANAESTHETIC RECORDS

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

Johannesburg, 2016

DECLARATION

I, Raphael Ntlhane Maja declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

.....[signature of candidate]

15th day of May, 2016

In memory of my uncle, brother and friend

Levy Kgomotso Magagane

1958-2014

ABSTRACT

Introduction

Content validity is a rigorous scientific process that aims to address whether the items on a developed instrument are content valid or not. Content validation is therefore an important process in the development of virtually all instruments.

The aim of this study was to develop an Anaesthetic Record Essential Information Instrument (AR Instrument) that contains the items that South African anaesthetic experts considers are the minimum essential items that should be included in all anaesthetic records. This expert validated contextual AR Instrument has a dual purpose: firstly it can be used as a standard against which existing AR records can be evaluated, secondly, it can be used to develop new anaesthetic records.

Methods and results

A prospective, exploratory and instrumental study design using Lynn's two-stage model of determination and quantification of content validity was followed in this study. The Development Stage, that initially involved a review of the literature by the researcher and followed by a peer group discussion with local experts where every item was debated until consensus was reached, resulted in an instrument with 44 items. This instrument was sent to national experts for validation in the Judgement-Quantification Stage. A four point Likert scale ranging from unimportant to essential information was used to grade each item. Only items deemed important or essential by the experts were retained. This resulted in 41of the 44 items being considered content valid. This entire instrument was quantified using the content validity index (CVI). Lynn suggests that for an instrument to be considered content valid, it should have a CVI of 0.8. The CVI of this AR Instrument is 0.9. This instrument is therefore content valid.

Conclusion

An AR Instrument has been drawn up using a rigorous scientific process to ensure content validity.

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Ke a leboga!

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ABBREVIATIONS

AAGBI: Association of Anaesthesiologists of Great Britain and Ireland

AR Instrument: anaesthetic record essential information instrument

ASA: American Society of Anaesthesiologists

CVI: content validity index

HPCSA: Health Proffesions Council of South Africa

IR: interrater agreement

RCOA: Royal College of Anaesthetists

SA: South Africa

SASA: South African Society of Anaesthesiologists

WFSA: World Federation of Societies of Anaesthesiologists

CHAPTER ONE: OVERVIEW OF THE STUDY

1.1 Introduction

In this chapter an overview of the study is provided. This includes the background of the study, the problem statement, the aim, the objectives, the definitions, the ethical considerations, an overview of the methodology, the significance of the study, the validity and reliability of the study, the validity of the concept instrument and the study outline.

1.2 Background

The anaesthetic record was first used in 1895 at Massachusetts General Hospital. The record's use then expanded to many other hospitals. Initially these records were not standardised and were used only to assess the patient's intra-operative vital signs and therefore the stability of the patient undergoing surgery. (1) Subsequently, these anaesthetic records were standardised in Great Britain in 1965 (1, 2) and their use expanded for various other reasons such as use as medico-legal documents, communication between anaesthetists and other departments, communication between different anaesthetists, administrative uses, teaching, research, accreditation and quality assurance (3, 4).

In 1992 comprehensive anaesthetic record keeping was recommended by the World Federation of Societies of Anaesthesiologists (WFSA) (5) and it is at present also recommended by the South African Society of Anaesthesiologists (SASA) (6). Even though comprehensive record keeping is recommended, no instrument could be identified that ensures that there is documentation of minimum required essential anaesthetic information for the South African (SA) context. This has resulted in anaesthetic records that have differing details as far as the necessary items that should be included in these records are concerned.

Studies (7, 8) done internationally and nationally have proven that, to date, anaesthetic records are still poorly completed. Ulyatt et al (7) in the article: "Anaesthetic records – are we up to scratch?" found that of the 202 completed anaesthetic records in two district general hospitals that the authors audited, none was fully compliant with the Royal College of Anaesthetists (RCOA) guidelines (9). In the two hospitals that they audited, the anaesthetist present was only recorded on 68% of records in one hospital and 85% in the other. The authors concluded that these unacceptable omissions of important information could cause many avoidable problems for future anaesthetics and could make legal cases less defensible and accountable (7).

In a SA audit of anaesthetic records by Raff and James (8), it was found that of the 284 records that were audited, only 85 (29.9%) records were legible and fully completed. Seventy one (25%) records were blank and incomplete. The remainder of the records, 128 (45%) in total, were completed but various aspects of the records were illegible. This audit revealed an unacceptable and poor standard of record keeping.

Given these inconsistencies and the unacceptable standard of record keeping amid the many advantages of keeping the anaesthetic records, it is therefore ideal that an essential record evaluation instrument be developed. The instrument must contain the items that experts regard as the minimum items that must be included in every anaesthetic record. It could also be used as a yardstick to measure the standard of the anaesthetic record and therefore allow objective evaluation of these records (10).

Tessler et al (11), identified the variables that anaesthesiologists at McGill University affiliated adult hospitals regarded as important to document on the peri-operative anaesthetic records. Twelve pre-operative and 23 intra-operative variables were rated as important. The most important pre-operative variables included airway, allergies, medications, diagnosis and past medical history. The most important intra-operative variables included anaesthesiologist's name, vital signs, oxygen saturation, end tidal CO_2 and the medications used. However, a subsequent review of anaesthetic records at these institutions indicated that many of these variables that were regarded as important were recorded inconsistently.

The task of developing the anaesthetic record essential information instrument (AR Instrument) can be undertaken by any of the following: the individual anaesthetists themselves, the professional groups such as SASA, the regulatory body such as the Health Professions Council of South Africa (HPCSA) or by a court or government directive.

Ideally, individual anaesthetists themselves or SASA should take the responsibility of voluntarily developing this instrument. Should this be the case, the developed instrument will have a democratic sense as it will be an instrument that was developed by choice and therefore an intrument which is "of the anaesthetists, by the anaesthetists and for the anaesthetists". An instrument developed following a directive from the courts, government or HPCSA is likely to make anaesthetists uncomfortable as it may feel like a decision that has been forced upon them. (10)

1.3 Problem statement

Intra-operative anaesthetic records are an essential and important part of patient medical records. These medico-legal documents are a communication tool that guides the peri-operative management of anaesthesia and future anaesthetic management of the patient. They are also used for quality assurance basis, for accreditation, teaching and research purposes.

The SASA practice guidelines (6) state that “a full contemporaneous record of the anaesthetic technique, patient responses to anaesthesia, and other pertinent medical information pertaining to the anaesthetic should be made by the practitioner delivering the anaesthetic”.

In SA there is no AR Instrument. The results are that peri-operative records differ in layout, detail required and the way different anaesthetists complete them. There is no legal sanction regarding anaesthetic record keeping until such time as the practitioner falls below the minimum standards (12).

It is against this background that a study was undertaken to develop and validate an AR Instrument that could ensure that minimum essential information is documented on anaesthetic records.

1.4 Aim

The aim of this study was to develop and validate an AR Instrument using Lynn's two stage model (13).

1.5 Objectives

The objectives of this study were to:

- develop a provisional AR Instrument from the literature using Lynn's Development Stage (domain identification and item generation)
- develop a revised AR Instrument using Lynn's Development Stage (item formation)
- determine content validity of the revised AR Instrument using Lynn's Judgement-Quantification Stage.

1.6 Definitions

The following definitions were used in this study:

Anaesthetic record: is a record that allows the anaesthetist to record in a simple and logical manner, either electronically or by hand, all aspects of anaesthetic management, including the pre-, intra- and post-operative management of the patient. This is a medico-legal document, which is also of use for subsequent anaesthesia, management of the patient, quality assurance, accreditation and research purposes. (4, 14)

Anaesthetic record essential information instrument: also referred to as AR Instrument is a document that ensures that minimum mandatory items are recorded on every anaesthetic record.

Expert: is an anaesthetist in public or private practice that has a standing in the anaesthetic community.

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

Lynn's model: this model describes a structured two stage process of instrument development and validation. (13)

1.7 Ethical considerations

Approval to conduct the study was obtained from the relevant authorities. Experts were invited to participate in this study. Consent was implied by accepting the invitation. The study was conducted according to the principles of the Declaration of Helsinki (15) and the South African Good Clinical Practice Guidelines (16).

1.8 Research methodology

1.8.1 Research design

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

1.8.2 Study population

The population for the study consisted of South African anaesthesiology experts.

1.8.3 Study sample and sample method

Stage 1: Development Stage

The sample for the Development Stage consisted of eight local anaesthesiology experts from Johannesburg who were purposively selected.

Stage 2: Judgement-Quantification Stage

The sample for the Judgement-Quantification Stage consisted of 10 national anaesthesiology experts, who were also purposively selected, but excluded those who participated in the first stage.

1.8.4 Study methods

A two stage process was used to develop and validate an AR Instrument. These stages are the Development Stage and the Judgments-Quantification Stage. (13)

Stage1: Development Stage

The Development Stage consisted 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 provisional instrument (item generation) and conducting a peer group discussion (item formation) to debate the provisional instrument in order to develop an AR Instrument.

Local anaesthesiology experts from Johannesburg were identified and invited to a peer group discussion. The peer group discussion was conducted by the researcher. Each item of the concept instrument was debated until 100% consensus was reached. On completion of the peer group discussion, the necessary changes according to the peer group recommendation were made and the instrument was prepared for the Judgement-Quantification Stage.

Data analysis was not necessary for this stage as each item was debated until 100% consensus was reached.

Stage 2: Judgement-Quantification Stage

The Judgement-Quantification Stage of the instrument development consisted of two steps. The first step entailed calculating the level of interrater agreement for relevancy of items (IR) and therefore the number of agreements among the 10 national anaesthesiology experts (all items rated 1 or 2 by the experts and all items rated 3 or 4 by the experts). The second step entailed calculation of content validity across expert scores by determining the proportion of experts who rated items as relevant and therefore content valid with either a 3 or 4 score. The CVI of the entire instrument was then quantified.

1.9 Significance of the study

Comprehensive anaesthetic record keeping is recommended internationally and nationally, however, no instrument could be identified that ensures that there is documentation of minimum required essential anaesthetic information for the South African context. This has resulted in each anaesthetist having a different view on the detail that is necessary for the anaesthetic record (12).

Anaesthetic records that meet the minimum required standards are invaluable. The study is significant in that it provides an instrument that was developed and validated by South African anaesthesiology experts for the South African context. The AR Instrument can be used to evaluate anaesthetic record keeping and identify potential shortcomings, assist with communication, quality assurance, research and ensure that anaesthetic records are acceptable medico-legal documents. Furthermore the AR Instrument can also be used to develop an anaesthetic record.

1.10 Validity and reliability

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

1.11 Outline of the study

This study is presented as follows:

Chapter One:	Overview of the study
Chapter Two:	Literature review
Chapter Three:	Research methodology
Chapter Four:	Results and discussion
Chapter Five:	Summary, limitations, recommendations and conclusion.

1.12 Summary

In this chapter an overview of the study was given. The literature review is presented in Chapter Two.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

In this chapter the literature pertaining to anaesthetic records is reviewed. This includes the history of anaesthetic records, advantages of comprehensive anaesthetic records, consequences of incomplete anaesthetic records, criticisms of anaesthetic records, practice guidelines for anaesthetic records, clinically important variables on the anaesthetic record, manual anaesthetic record design, automated anaesthetic records, and Lynn's model to develop a content validated instrument.

2.2 History of anaesthetic records

The first anaesthetic chart was used in Massachusetts General Hospital in 1895 by two medical students Harvey Cushing and Amory Codman. This was following a tragic unexpected intra-operative death due to aspiration while they were delivering anaesthesia. These charts were initially called "Ether Charts". The first recordings on these charts were that of pulse rate, respiration, depth of anaesthesia and amount of ether given. In 1902, Cushing added blood pressure to these charts. They believed that charting these parameters would lead to safer anaesthesia. These Cushing-Codman Ether Charts became common as they were adopted in other centres (1, 17, 18).

It is also believed that these anaesthetic records may have contributed to the improvement in the status of the anaesthetic profession. Lundy (19) in 1924, stated:

> "In a little over a year there are now more men in Seattle giving nitrous oxide with maximum oxygen and minimum ether and keeping a complete record of blood pressure, pulse rate and respiratory rate, as well as all the procedures in the surgery, than in any other city I know of. These men are depended upon by the surgeon to decide certain questions which, for a long

> time, he himself [the surgeon] has decided, namely: to choose the anaesthetic; to sound the warning to close; to begin anti-shock treatment; to choose that treatment; and to advice some of the measures that are to be employed in the post-operative care".

Even though is believed that the anaesthetic records played an important role in improving the standard of the anaesthetic profession, it seems as though there always have been some pessimism regarding these records. This is reflected in Fischer's (17) article where Lundy (19) is again quoted to have said:

> "At first, those in the surgery felt that I was delaying the work when I took the blood pressure on each patient and demanded the chart before starting the anaesthetic. However, the surgeons politely consented to pamper me".

The general adoption and development of anaesthetic record keeping then became widespread, but few attempts were made to standardise them. It was not until 1965 that the first government intervention was recorded. This government intervention was by the Ministry of Health of Great Britain recommending to the Association of Anaesthesiologists of Great Britain and Ireland (AAGBI) that the anaesthetic records need to be standardised. The AAGBI then set up a subcommittee to standardise these anaesthetic records. The proposed chart was colour coded, had a time based grid for recording vital functions and space for the post operative recovery period notes thus making the immediate post operative period an equally important responsibility of the anaesthetist. (17)

Amid this standardisation, a survey of 22 different charts used by anaesthetics divisions in the Yorkshire Regional Health Authority in 1988,found that, in many cases, the recommendations suggested were not followed (17).Subsequent studies both internationally and locally, also found that there has been little improvement in the standard of documentation and certain important fields are consistently omitted(7, 8, 11, 20).

2.3 Advantages of comprehensive anaesthetic records

The anaesthetic records are presently used as the documents that forms an integral part of the standards of the anaesthetic practice. Gibbs (21) is of the

opinion that the anaesthetic record also provide direct evidence in litigations and therefore poorly completed records will almost invariably provide a "barrier to a successful defence in a malpractice claim".

The advantages of keeping comprehensive anaesthetic records therefore include:

- being key documents for medico-legal evidence;
- assisting in communication amongst anaesthetists and other health care workers;
- provision of protocol based management and quality assurance;
- providing uniformity of care, teaching and training standards; and
- facilitation of epidemiologic studies, evaluation and validation of new methods and research. (10)

It is due to these advantages that many anaesthetic societies, including SASA, recommend that anaesthetists keep comprehensive anaesthetic records. Moreover these advantages are not mutually exclusive but are all interrelated.

Being the key documents for medico-legal evidence (6), these anaesthetic records are a source of credible information for review by expert witnesses, lawyers, magistrates and judges (3).

By providing a common language, the anaesthetic record is an important means of communication between health care workers (10, 22). The recording of the information that the anaesthetists consider important will help other health care personnel who are involved in the management of the patient to be able to have a better understanding of the patient's peri-operative course even in the absence of the anaesthetist who delivered the anaesthesia (3, 8).

Reviewing of the anaesthetic records will also assist in the development of protocol based management, accreditation and quality assurance systems. Discussions around different items on the anaesthetic records can be used for teaching and training purposes. This will also ensure that trainees are taught that meticulous documenting of peri-operative events is an important part of anaesthetic practice (1).

Comprehensive anaesthetic records are an important source of the data for epidemiology studies and research. The data gathered from a properly completed anaesthetic record will help with the identification of the problems in anaesthetic delivery and as a result the measures to address these problems can be undertaken promptly. This will lead to the improvement of the anaesthetic practice.

2.4 Consequences of incomplete anaesthetic records

As a recommendation of good clinical practice, keeping a patient's record is therefore invariably a set standard below which health care workers should not fall (12, 23). The old saying, “if you did it, write it down; if you don’t write it down it did not happen,” is applicable to anaesthetists just as it applies to all other health care providers (10).

It has also been said that “good charting helps, bad charting hurts and no charting hurts worse” (10). This cliché' is becoming more important as litigation against health care workers is increasing. A poor, incomplete anaesthetic record has the potential to create an impression that indeed the care that the patient received was substandard even though they may have received reasonable care.

A well-designed form also serves as a printed checklist for the anaesthetist. It ensures that the anaesthetist asks all relevant questions and it also serves as a reminder that he or she has performed all the necessary tasks. (10)

Complete anaesthetic records may help anaesthetists avoid repeating previous anaesthetic mishaps, because prior "knowledge of any previous difficulties may forewarn a subsequent anaesthetist of potential problems" e.g. problems relating to airway, malignant hyperthermia etc. This will be invaluable in the planning of future anaesthesia for such patients.

Incomplete recording of adverse events therefore, compromises attempts to quantify these adverse events, understand their implications and assess corrective efforts of these events (3, 10, 24).

It would be unrealistic to expect anaesthetists to rely on memory in recalling the details of every anaesthetic that they have previously administered. The only way of ensuring that they remember every little detail of the past anaesthetics, should this be required for future legal or clinical purposes, is to make sure that they made a detailed anaesthetic record of each and every anaesthetic that they previously administered (8).

A deficient anaesthetic record, therefore, may result in serious adverse yet avoidable consequences (12).

2.5 Criticisms of anaesthetic records

Although most anaesthetic groups agree with the international standard guidelines for safe practice of anaesthesia which includes keeping anaesthetic records, there are however, some dissenting views (1, 25).

Zeitlin (1), a critic of anaesthetic records, believes that there is no sense in keeping these anaesthetic records because the routine observation and recording of vital signs every five minutes may lead to the anaesthetist shifting focus from patient care to an anaesthetic record and in the process compromising patient care. The author further argues that anaesthetists are equally qualified to express their observations just like other medical specialists who would usually pay more attention to managing the patient and only later give a literate, intelligent and comprehensible description of the earlier events.

Zeitlin (1) quotes Professor Postner whose research, as to whether an anaesthetic record could act as a defensive shield in the event that anaesthetists become defendant's in a malpractice suit, found that there is no specific role for anaesthetic records as evidence in litigation but instead found that many of the claims revealed multiple problems with the care provided by the anaesthetist and that the anaesthetic records played a minor role in the claim resolution process.

Another confounding factor to anaesthetic records is that audits done on these records revealed that most were incomplete, inconsistent and often illegible to an extent that in some cases, even the anaesthetist who completed the record may

neither be able to decipher his or her own writing nor some of the symbols and abbreviations they themselves used. (3, 26)

Critics of the anaesthetic records argue that the lack of standardisation of these records has resulted in the different institutions developing different versions of these anaesthetic records. They also argue that in very long anaesthetic cases, it is difficult to write more vital signs in the usual small space provided and this has led to anaesthetist sometimes plotting vital signs every ten minutes or more instead of every five minutes as recommended by WFSA. The result of this is a lack of accountability by the anaesthetist of the events that may have occurred during the ten minutes that was not plotted. (3, 27)

2.6 Practice guidelines

According to the HPCSA, the health care profession is a moral and an ethical profession. It is therefore necessary that the members of this profession have a lasting commitment to sound moral and ethical professional practices. This requires that the health care professionals follow guidelines that are aimed at directing their practice e.g. record keeping guidelines. The HPCSA record keeping guidelines advise that the records that contain information about the patients be kept by all health care professionals whenever they are involved in the management of the patients. (23)

An anaesthetic record will provide such guidelines to anaesthetists, their professional societies, hospitals, administrators and governments for improving and maintaining the quality and safety of anaesthesia care. The standards aimed at safe anaesthetic practice were set and adopted by the WFSA on 13 June 1992. These standards were subsequently revised on 5 March 2008 and again on 19 March 2010.

2.6.1 International practice guidelines

Most international professional bodies (2, 4, 14, 28) have formulated anaesthetic practice guidelines and anaesthetic record keeping recommendations that are specific to their context.

By reviewing these practice guidelines and recommendations, it can be seen that most anaesthetic groups worldwide used the American Society of Anaesthesiologists (ASA) recommendations as a template to develop their contextual records. These ASA recommendations are frequently referred to in the literature on anaesthetic record keeping (17, 29).

The peer review recommendations for documentation of anaesthesia care from the ASA are as follows:

“Pre-anesthesia evaluation:

- Patient interview to review medical, anesthesia and medication history.
- Appropriate physical examination.
- Review of objective data (e.g., laboratory, electrocardiogram, x-ray).
- Assignment of the ASA physical status.
- Formulation and discussion of an anesthesia plan with the adult patient and/or responsible adult in case of paediatric patients.

Peri-anesthesia (time-based record of events):

- Immediate review prior to initiation of anaesthetic procedures:
    - Patient re-evaluation.
    - Check of equipment, drugs and gas supply.
- Monitoring the patient.
- Amounts of all drugs and agents used, and times given.
- The type and amounts of all intravenous fluids used including blood and blood products, and times given.
- The technique(s) used.
- Unusual events during the anesthesia period.
    - The status of the patient at the conclusion of the anesthesia.” (28)

It is recognised that due to variations in resources and urgency of anaesthetic delivery there may be deviations from these guidelines and it is therefore incumbent on the responsible anaesthetist that these deviations and the reasons thereof be well documented.

2.6.2 SASA Practice Guidelines

In the 2006 practice guidelines, SASA (6) recommends that: “A full contemporaneous record of the anaesthetic technique, patients responses to anaesthesia, and other pertinent medical information pertaining to anaesthetic should be made by the practitioner delivering an anaesthetic”. In the same document, SASA (6) further recommend the use ASA (28) and RCOA (2) guidelines.

2.7 Clinically important variables on the anaesthetic record

Tessler et al (11) did a survey at four McGill University affiliated teaching hospitals where anaesthesiologists were asked to rank 23 pre-operative and 33 intra-operative variables on a five-point scale: (1 = essential; 2 = important; 3 = useful; 4 = not important; 5 = excessive information). The authors then assessed if all variables that were considered to be essential were actually recorded by these anaesthesiologists on the 60 charts that were randomly selected from each of these four McGill University affiliated teaching hospitals (11).

The pre-operative variables that were considered to be most important were the patient’s airway, known allergies, medications that patients were on, the patient’s diagnosis, past medical history, previous anaesthetic history, time since the last meal, family history of problems with anaesthesia, exercise tolerance, patient’s blood pressure, history of gastroesophageal reflux disease and the heart rate. Of these, the variable that was considered most important, the airway, was charted on only 84% of the charts. (11)

The intra-operative variables that were considered to be most important were the name of the anaesthesiologist, the starting time, the patient’s vital signs, the surgeons name, oxygen saturation, operation finishing time, route of the endotracheal tube, intravenous drugs given to the patient, the type of local anaesthetic used, inhalational agents used, regional anaesthetic technique, arterial line insertion, size of the endotracheal tube, use of supplemental oxygen, intubation technique, the monitors that are used, the time of giving medications, the fluids administered, the patients’ position, use of the central line and vitals of

the patient in the post-operative care unit. Although all these were considered to be important, post-operative vital signs were recorded in only 27% of the charts. (11)

2.8 Manual record design

Some institutions may not have formal anaesthetic records yet. Some may still be using old records that have not been updated in recent years. Fisher et al (17) in the article “on the design of anaesthetic record form” give the following advice on the design of the anaesthetic record:

Paper and ink colours

It is advisable to use a white paper and black ink. If a coloured paper is preferred, it should be a pale or pastel shade as printing and handwriting contrasts better with the lightly coloured background. Forms with lightly coloured backgrounds are also easier to photocopy, microfilm or digitise to optical disk. Although black ink is advisable, blue, brown, green or red ink also provides better contrast to typed or handwritten ink. (17)

Method of duplication

The most convenient format for producing duplicate copies is by making use of no-carbon industry pre-collated papers. Copies can be held together either with a glue along the one edge or by a tear-off margin. The top (original) copy must be retained in the medical record. (17)

Margins

It is advisable to have the printers pre-drilling the holes for filing. Alternatively a 1.9cm margin should be left to the left to allow for filing. (17)

Text

Lowercase text is preferred to uppercase because people read faster and understand better when words and lines of the text have distinct shapes. (17)

Typestyle

A standard typestyle that is commonly used on medical forms is the proportionally spaced font known as Helvetica. Alternatively, any proportionally spaced font may be used because proportional spacing causes less distraction to the reader. (17)

Abbreviations

Abbreviations are not advisable as different places and different institutions use different abbreviations. A copy of a medical record may be sent to a place where some of the abbreviations used may be ambiguous and as a result be misinterpreted. (17)

Area reserved for patient identification

A specific area, usually on the top right or left corner of the anaesthetic record should be reserved for the patients demographics. (17)

Checkboxes

Standardised, square shaped checkboxes are recommended. The size of the checkbox should be equal to the height to the tallest letter of the font used in the anaesthetic record. The bottom edge of each checkbox should be aligned with the baseline of the nearby text. All checkboxes should preferably be positioned to the left of the applicable text items with a single space gap between the checkbox and the text to help the eye to rapidly scan the items that have to be selected. (17)

Medical test results

There must be a specific area on the anaesthetic record for the test results to provide evidence that the test results were noted prior to undertaking the procedure. (17)

The application of this advice on the design of the anaesthetic record will result in a standardised and a uniform anaesthesic record.

2.9 Automated anaesthetic records

Automated anaesthetic records are not the focus of this study. Also, most hospitals in South Africa are not yet using these automated anaesthetic records. However as technology advances these automated records may in the foreseeable future become a popular trend and this therefore warrants their brief discussion.

According to Nickalls (30), the Nargraff machine of 1930 developed by EI McKessons was the first anaesthetic machine capable of generating an automated anaesthetic record. The machine generated a record of inspired oxygen, tidal volume and inspiratory gas pressure.

Further advancements lead to these machines being able to record the arterial and central venous blood pressure, pulse oxymetry, oxygen, carbon dioxide and inhalational anaesthetics concentrations. Presently these machines allow the anaesthetists to also record the names and dosages of the intravenous drugs given, all the events occurring during the anaesthetic and the exact time of these events. (30, 31)

There are many different input systems used to capture the entry. Some allows information to be entered on a keyboard while others allow the anaesthetist to simply speak out loud into a microphone in a headset or suspended from a boom over the anaesthesia machine. (3)

Proponents of automated anaesthetic records are of the opinion that the use of automated records would result more accurate and complete records than manually completed records and also, that using these records would significantly reduce record keeping time and leave more time for the anaesthetist to interpret inta-operative data and therefore take good care of the patient. (30)

Critics on the other hand argues that these systems are complicated, expensive and may even require very sophisticated software. Furthermore, they are of the opinion that allowing these machines to record the vital signs may result in non vigilance by the anaesthetist as he or she is removed from the information feedback loop. (32-35)

2.10 Developing a validated instrument

Validity is the extent to which an instrument measures what it is intended to measure (13, 36). Content validity is the determination of the content representativeness or content relevance of the elements or items of an instrument by the application of a two-stage process involving the Development and the Judgement-Quantification Stages (13).

The Development Stage consists of three steps. The first step is called the domain identification and is accomplished through a thorough review of the literature so as to incorporate the ideas of a variety of experts. The second step result in generation of items for all dimensions and sub dimensions identified in the literature review. In the third step, the items generated are assembled in a usable form, that is, they are refined. (13)

The Judgement-Quantification Stage has two steps. The first of this entail assertion by a specific number of experts that the items are relevant. In the second step, the entire instrument is then quantified to be content valid. (13)

The number of experts often depends on how many accessible and agreeable experts the instrument developer can identify and not on a population estimation principle. A minimum of five experts would provide a sufficient level of control for chance agreement. Should it be difficult for the researcher to locate five experts, a minimum of three can be used as the use of only two experts is statistically unjustifiable and places the instrument developer at great risk of an erroneous conclusion that content validity has not been achieved when it actually was achieved. The maximum number of experts has not been established, but it is unlikely to exceed ten. (13)

Once the number of experts has been determined and the items and the instrument rated, the researcher then uses cumulative binomial distribution published as standard norms (Appendix 6) to calculate the proportion of the number of experts who might agree out of the total number planned for use. These norms are required to establish content validity beyond 0.05 level of significance.

The experts must be given a structured procedure for the evaluation of the content validity. The most widely used quantification of content validity is the content validity index (CVI), which is derived from rating of the content relevance of the items on an instrument using a four-point rating scale, where one connotes an irrelevant item and four an extremely relevant item. A four point rating scale is preferable because it does not include the ambivalent middle rating common in odd number rating scales. The actual CVI is the proportion of items that received a rating of three or four by the experts. (13)

In addition to judging, the experts may add any areas that have been omitted from the instruments. Once the requirements of both stages (Development and Judgement-Quantification) are met, the content validity the instrument may then be asserted. (13)

2.11 Summary

In this chapter a review of literature was provided. The following chapter will address the research methodology used in this study.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter describes the research methodology used in this study. This includes the problem statement, aim and objectives of the objectives, ethical considerations, the research design, study population, the sampling process, study methods, validity of the AR Instrument and validity and reliability of the study.

3.2 Problem statement

Intra-operative anaesthetic records are an essential and important part of patient medical records. These medico-legal documents are a communication tool that guides the peri-operative management of anaesthesia and future anaesthetic management of the patient. They are also used for quality assurance and research purposes.

The SASA practice guidelines (6) state that “a full contemporaneous record of the anaesthetic technique, patient responses to anaesthesia, and other pertinent medical information pertaining to the anaesthetic should be made by the practitioner delivering the anaesthetic”.

In South Africa there is no AR Instrument. The results are that peri-operative records differ in layout, detail required and the way different anaesthetists complete them. There is no legal sanction regarding anaesthetic record keeping until such time as the practitioner falls below the minimum standards (12).

It is against this background that a study was undertaken to develop and validate an AR Instrument that could ensure that minimum essential information is documented on anaesthetic records.

3.3 Aim

The aim of this study was to develop and validate an AR Instrument using Lynn’s two stage model (13).

3.4 Objectives

The objectives of this study were to:

- develop a provisional AR Instrument from the literature using Lynn's Development Stage (domain identification and item generation)
- develop a revised AR Instrument using Lynn's Development Stage (item formation)
- determine content validity of the revised AR Instrument using Lynn's Judgement-Quantification Stage.

3.5 Ethical considerations

Ethics approval was obtained from the Human Research Ethics Committee (Medical) (Appendix 1) and the Postgraduate Committee (Appendix 2) of the University of the Witwatersrand.

Experts were invited to participate in this study. An information letter was mailed to the participants in the Developmental Stage (Appendix 3) and participants in the Judgement-Quantification stage (Appendix 4). Consent was implied by accepting the invitation.

Anonymity could not be ensured in either stage as the researcher made use of a purposive sampling method, however, the data captured by the researcher contained no identifying information of any participant.
Anonymity could further not be guaranteed in stage 1 as many of the experts knew each other; however participants were requested to keep any information divulged during the meeting confidential.
In stage 2, again anonymity could not be guaranteed as the participants responded via e-mail but the researcher and the supervisors were the only people knowing the participants identity. Only the researcher and supervisors had access to the raw data thereby ensuring confidentiality.

The raw data will be securely stored for six years following completion of the study.

The study was conducted according to the principles of the Declaration of Helsinki (15) and the South African Good Clinical Practice Guidelines (16).

3.6 Research design

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

A prospective study is a study in which the variables are measured at the time at which the study takes place (37). This study was prospective because data was collected as the study progressed.

This study was exploratory in nature since it aimed at exploring and describing phenomena. This approach was chosen to generate knowledge on comprehensive anaesthetic record keeping in South Africa, a phenomenon that has not been previously been researched extensively. (36)

This study was instrumental since specific rules, as proposed by Lynn's model (13) were applied to develop a measurement instrument (36).

3.7 Study population

The population for the study consisted of South African anaesthesiology experts.

3.8 Study sample and sample method

3.8.1 Stage 1: Development Stage

The sample for the Development Stage consisted of local experts. According to Lynn (13), an arbitrary number of experts can be used and it will depend on the availability of the experts, but a minimum of five experts would provide a sufficient level of control for chance agreement.

In this study a purposive sampling method was used. Purposive sampling is a type of non probability sampling and according to Burns and Grove (38) "it involves

conscious selection by the researcher of certain subjects or elements to include in a study"**.** The criterion that guided the researcher in the selection of participants was that the participant had to be an anaesthetist in public or private practice that has a standing in the Johannesburg anaesthetic community.

3.8.2 Stage 2: Judgement-Quantification Stage

The same principles of participant selection that was used in the first stage was used in the second stage.The criteria that guided the researcher in the selection of participants was that the participant had to be affiliated to a South African medical school and has a standing in the South African anaesthetic community.

3.9 Study methods

Lynn's two stage model (13) was used to develop and determine content validity of an AR Instrument.

3.9.1 Stage 1: Development Stage

Lynn (13) suggests that the Development Stage should consist of three steps viz. domain identification, item generation and item formation. The researcher made use of three steps, first by performing literature review and therefore identified all dimensions on the topic (domain identification), secondly developing a provisional AR Instrument (item generation) and thirdly, a peer group discussion was conducted (item formation) to debate and refine the provisional AR instrument in order to develop the revised AR Instrument.

Anaesthesiology experts based in Johannesburg were identified and invited to take part in the peer group discussion. An invitation letter to take part in the study and the provisional AR Instrument with preparation instructions was mailed to the experts that were identified.

The peer group discussion was scheduled to follow an anaesthetic workshop that was attended by all the invited experts. As well as refining the provisional AR Instrument, the peer group discussion was also aimed at expanding the instrument to ultimately enhance the content validity. During the peer group discussion, the following were expected from the participants.

- To review and grade the provisional AR Instrument according to the following scale by determining whether each item was:
    - 1 = Not important information
    - 2 = Useful information
    - 3 = Important information
    - 4 = Essential information.
- To make recommendation for changes, additions or deletions to the instrument using set inclusion and exclusion criteria (17) as shown in Table 4.3.

The peer group discussion was conducted by the researcher. Each item of the provisional AR Instrument was debated until 100% consensus is reached.

On completion of the peer group discussion, the necessary changes according to the peer group recommendations were made and the revised AR Instrument was prepared for the Judgemental-Quantification Stage. The revised AR Instrument was given to all participants of the peer group discussion to confirm the changes made.

Data analysis

Data analysis was not necessary for this stage as each item was debated until agreement was reached. Agreement was based on the importance of each item to clinical practice.

3.9.2 Stage 2: Judgement-Quantification Stage

The Judgement-Quantification Stage of instrument development has two steps. These steps entail the assertion (using the same ordinal rating scale for the Development Stage) by a specific number of experts that the items of the instrument are content valid and then quantifying the entire intrument using the CVI. (13, 39)

With background information stating the aim of the research and instructions for validating the instrument, the revised AR Instrument was mailed to each participant. The data was entered into a Microsoft Excel® spread sheet by the researcher.

Data analysis

Firstly, the levels of interrater agreement (IR) for relevancy of items was calculated (all items rated 1 or 2 and items rated 3 or 4 by the experts) divided by the total number of items on the instrument. This is the number of agreements among experts and it therefore facilitates in determining the proportion of items judged relevant. The levels of acceptable IR suggested in the literature ranges from 0.7 to 0.8. For this study 0.8 was chosen as the acceptable level of IR. (39)

Once the IR level was acceptable, a content validity across experts ratings was calculated by determining the proportion of experts who rated the items as content valid with a score of either 3 or 4 out of the total number of experts used, and then setting the standard error of the proportion to identify the cut-off for chance versus real agreement (Appendix 6). Finally the content validity of the entire instrument was quantified using CVI. (13, 39)

3.10 Validity and reliability

3.10.1 Validity and reliability of the study

The following measures were taken to ensure validity and reliability of the study:

- choosing an appropriate study design
- using a well known, frequently used validation process to validate the items on the AR Instrument and the AR Instrument as a whole
- checking every data entry point on the Microsoft Excel® spread sheet to ensure accuracy of capturing.

3.10.2 Validity of the AR Instrument

Lynn (13) states that the use of a two stage process to determine and quantify content validity is fundamental to validation of virtually all instruments, and that the assessment of content validity begins with the development of the instrument. Validity in the Development Stage was ensured by:

- domain identification by a means of a literature review
- generating items from the literature review to develop a provisional AR Instrument

- having the provisional AR Instrument debated by local experts until 100% consensus was reached.

Validity in the Judgement-Quantification Stage was ensured by mailing 10 national experts to validate each item on the four point Likert scale. Content validity of each item and the instrument as a whole was therefore determined by the proportion of items judged relevant and by the proportion of experts who rated each item as content valid.

3.11 Summary

In this chapter the research methodology of the study was described. The next chapter will deal with the results and the discussion.

CHAPTER FOUR: RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents the results according to the objectives and the discussion thereof.

The objectives were to:

- develop a provisional AR Instrument from the literature using Lynn's Development Stage (domain identification and item generation)
- develop a revised AR Instrument using Lynn's Development Stage (item formation)
- determine content validity of the revised AR Instrument using Lynn's Judgement-Quantification Stage.

4.2 Approach to data analysis

An approach to data analysis is summarised in Figure 4.1

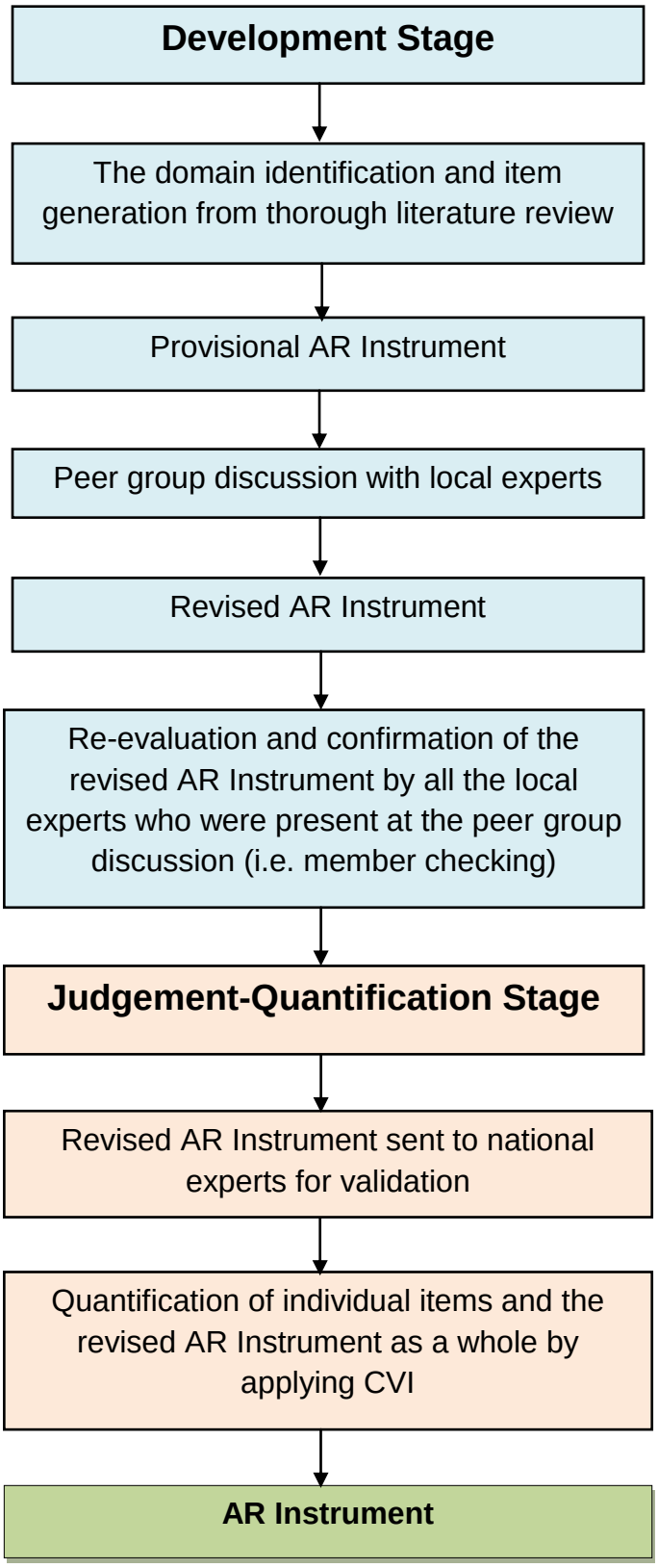

Figure 4.1 Approach to data analysis

4.3 Results

Data for the Judgement-Quantification Stage was analysed by first calculating the level of IR for relevancy of the instrument items. The IR for this study was calculated to be 0.93. This level of IR confirmed the relevancy of the items in the instrument and therefore allowed the investigator to proceed with the rest of the steps in the Judgement-Quantification Stage. Content validity across expert scores was then determined from items that were rated 3 and 4 by these experts. Finally, content validity of the instrument as a whole was quantified using the CVI.

4.3.1 Objective: to develop a provisional AR Instrument from the literature using Lynn's Development Stage (domain identification and item generation)

Domain identification and item generation through a thorough review of the literature identified 11 domains and 50 items which were included in the provisional AR Instrument. This is shown in Table 4.1

Table 4. 1 Domains and items

1. Demographics	9.5 Tourniquet time
1.1 Name	9.6 Surgery time
1.2 Age	9.7 Drugs
1.3 Gender	9.8 Fluids
1.4 Hospital Number	9.9 Monitoring
1.5 Religion	9.10 Blood pressure
2. Anthropometry	9.11 Mean arterial pressure
2.1 Height	9.12 Heart rate
2.2 Weight	9.13 Oxygen saturation
2.3 Body mass index	9.14 End tidal carbon dioxide
3. Name of next of kin	9.15 Temperature
4. Contact details of next of kin	9.16 Minimum alveolar concentration
5.Diagnosis	9.17 Blood loss
6. Proposed operation	9.18 Urine output
7. Pre-operative summary	9.19 Others indicated e.g. invasive pressures
7.1 Mallampati score	9.20 Operation performed
7.2 ASA status	**10. Post-operative (Phase I recovery)**
7.3 Allergies	10.1 Monitoring vital signs
7.4 Plan	10.2 Pain assessment score e.g. Visual Analogue Score
8. Pre-operative assessment	10.3 Discharge score e.g. Aldrete Score
8.1 History	10.4 Post-operative instructions
8.2 Examination	10.5 Destination: phase II recovery
8.3 Investigation	10.6 Anaesthetist discharging the patient
8.4 Pre-operative instructions	**11. Form design criteria**
8.5 Consent for blood transfusion	11.1 Preferably size A4 paper
8.6 Consent for anaesthesia	11.2 Pale or pastel shape paper
9. Intra-operative notes	11.3 No-carbon required forms (industry pre-collated paper)
9.1 Name of anaesthetist	11.4 Pre-drilled holes
9.2 Name of surgeon	11.5 Lowercase text
9.3 Anaesthetic time	11.6 Best contrast ink and paper e.g. black on white
9.4 Positioning of the patient	

4.3.2 Objective: to develop a revised AR Instrument using Lynn's development stage (item formation)

Local experts were identified and invited to a peer group discussion held on Saturday 25 October 2014 at Riverside Sun Resort, Vanderbijlpark, Gauteng following an anaesthesiology workshop. Ten experts, five from the public sector and five from the private sector were invited, of whom eight attended. Prior to the meeting, the provisional AR Instrument was emailed to these experts for perusal. The demographics of these experts is shown in Table 4.2

Table 4. 2 Demographics of local experts

Demographic	Number	Percentage
Gender		
Male	5	62
Female	3	38
Sector		
Public	4	50
Private	4	50
Years of experience		
≥ 10 years	7	88
< 10years	1	12

At the peer group discussion, the experts were given criteria for inclusion and exclusion of the items on the instrument as shown in Table 4.3. These experts were also required to modify the provisional AR Instrument based on their expertise.

Table 4. 3 Criteria for inclusion and exclusion of items

Inclusion criteria	Exclusion criteria
Of clinical importance	Recorded elsewhere in the patient's file
Medico-legal documentation	Specific sub-speciality interest
Events requiring frequent documentation	"Just in case" may be of interest or "nice to have"

Each item on the provisional AR Instrument was debated until 100% consensus was reached. The items that did not reach 100% consensus were removed. Some items were added while others were refined. These modified items are shown in Table 4.4.

Table 4. 4 Modifications to items on provisional AR Instrument

Item no.	Domains and items	Modification	Reason
1	**Demographics**		
1.5	Religion	Removed	Recorded elsewhere
2	**Anthropometry**		
2.3	Body mass index	Removed	"Nice to have"
3	**Name of next of kin**	Removed	Recorded elsewhere
4	**Contact details of next of kin**	Removed	Recorded elsewhere
5	**Diagnosis**	Removed	Recorded elsewhere by the surgeons
7	**Pre-operative summary**		
7.4	Plan	Removed	Recorded elsewhere
8.4	**Pre-operative instructions**		
	Nil Per Os (Solids/clear fluids)	Added	Of clinical importance
9	**Intra-operative notes**		
9.6	Surgery time	Removed	Recorded elsewhere
	Airway	Added	Of clinical importance
	Ventilation	Added	Event requiring frequent documentation
9.9	**Monitoring**	Refined	Main domain not an item
9.11	Mean arterial pressure	Removed	"Nice to have"
9.20	Operation performed	Removed	Recorded elsewhere
10	**Post-operative**		
10.2	Pain assessment score	Removed	"Nice to have"
10.3	Discharge score	Removed	"Nice to have"
10.4	Post-operative instructions	Removed	"Just in case" may be of interest
10.6	Anaesthetist discharging patient	Removed	"Nice to have"

The modified provisional AR Instrument was subsequently emailed back to these experts for member checking. All experts accepted these modifications. The instrument now became known as the revised AR Instrument (Table 4.7).

4.3.3 Objective: to determine content validity of the revised AR Instrument using Lynn's Judgement-Quantification Stage

Twenty national experts affiliated to medical schools in South Africa were identified and invited to be part of the Judgement-Quantification Stage of the AR Instrument's validation. After several emails were sent to remind the experts, 10 responded. All the national experts were anaesthesiologists with more than 10 years' experience. The demographics of these experts are shown in Table 4.5.

Table 4. 5 Demographics of national experts

Demographic	Number	Percentage
Gender		
Male	8	80
Female	2	20
Sector		
Public	8	80
Private	2	20
Province		
Gauteng	8	80
KZN	2	20

The national experts were sent the revised AR Instrument and instructions to rate each item using the Likert Scale shown in Table 4.6

Table 4. 6 Likert scale

Rating	Likert scale score
Not important information	1
Useful information	2
Important information	3
Essential information	4

Table 4. 7 Rating of items by the 10 experts

Domains and items	*	1	2	3	4	CVI
1.Demographics						
1.1 Name					10	1
1.2 Age					10	1
1.3 Gender					10	1
1.4 Hospital number	1		1	2	6	0.8
2. Anthropometry						
2.1 Height			1		9	0.9
2.2 Weight					10	1
3. Proposed operation	5				5	0.5
4. Pre-operative summary						
4.1 Mallampati score				2	8	1
4.2 ASA status					10	1
4.3 Allergies					10	1
5. Pre-operative assessment						
5.1 History				1	9	1
5.2 Examination				2	8	1
5.3 Investigation			1		9	0.9
5.4 Consent for anaesthesia					10	1
5.5 Consent for blood transfusion				1	9	1
6. Pre-operative instructions						
6.1 Nil per os (solids/clear fluids)				1	9	1
7. Intra-operative notes						
7.1 Name of anaesthetist					10	1
7.2 Name of surgeon					10	1
7.3 Anaesthetic time					10	1
7.4 Sequence of events (blank space)			1	2	7	0.9
7.5 IV site			1	3	6	0.9
7.6 Drugs					10	1

Table 4.7 continued

7.7 Fluids					10	1
7.8 Airway				1	9	1
7.9 Ventilation			1		9	0.9
7.10 Positioning of the patient				1	9	1
7.11 Tourniquet time			1	5	4	0.9
8. Monitoring						
8.1 Non-invasive arterial blood pressure					10	1
8.2 Heart rate					10	1
8.3 Oxygen saturation				1	9	1
8.4 End-tidal carbon dioxide				1	9	1
8.5 Temperature				2	8	1
8.6 Minimum alveolar concentration			1		9	0.9
8.7 Blood loss					10	1
8.8 Urine output			1	1	8	0.9
8.9 Blank space for other parameters	1			3	6	0.9
9. Post-operative						
9.1 Phase I recovery				2	8	1
9.1.1 Monitoring (Sats, HR, BP)			1		9	0.9
9.2 Destination: phase II recovery				4	6	1
10. Form design criteria						
10.1 Preferably size A4 paper		1		1	8	0.9
10.2 Pale or pastel shade paper	1	1	1	6	1	0.7
10.3 No-carbon required forms (Industry pre-collated paper)		1	1	4	4	0.8
10.4 Pre-drilled holes		1	3	3	3	0.6
10.5 Lowercase text		1	6	2	1	0.3
10.6 Best contrast ink and paper e.g. black on white		1		2	7	0.9

Note: * refers to items that were not rated.

In order for an item to be regarded as content valid, 8 out of 10 of the national experts in this study are required to rate an item as either 3 or 4. In the Figures 4.2 to 4.9 this is shown by the solid line at 8 experts which is the proportion of experts whose rating of each item per domain determined the content validity.

The experts rating of the domain "Demographics" which had 4 items is shown in Figure 4.2. All the items were rated as content valid

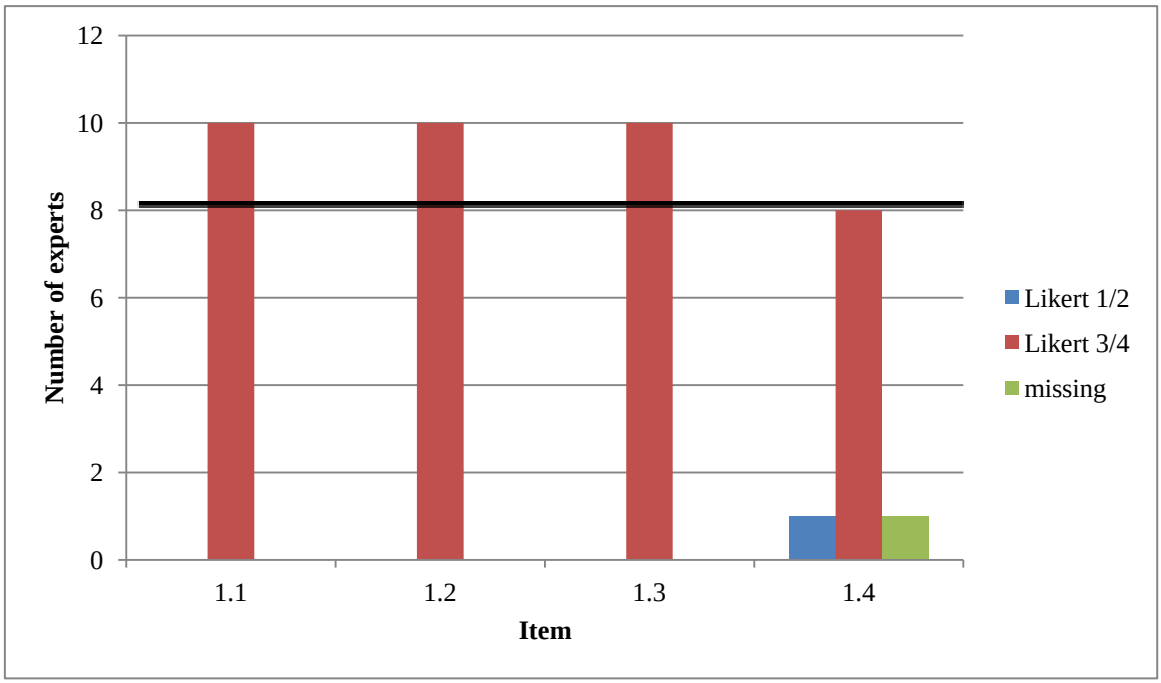

Figure 4.2 Rating of the Demographics items

The experts rating of the domain "Anthropometry" which had 2 items is shown in Figure 4.3. Both the items were rated as content valid

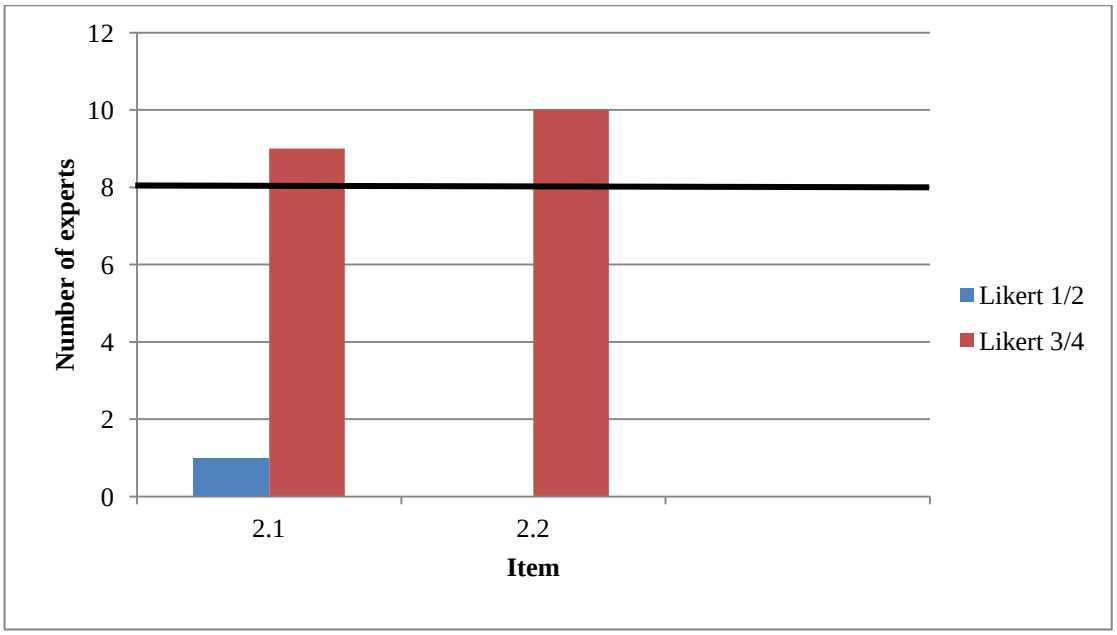

Figure 4.3 Rating of the Anthropometry items

The domain "Proposed operation" was rated by 5 out of 10 experts. All the 5 experts who rated it gave it a rating of 4. It was accepted as content valid.

The experts rating of the domain "Pre-operative summary" which had 3 items is shown in Figure 4.4. All items were rated as content valid.

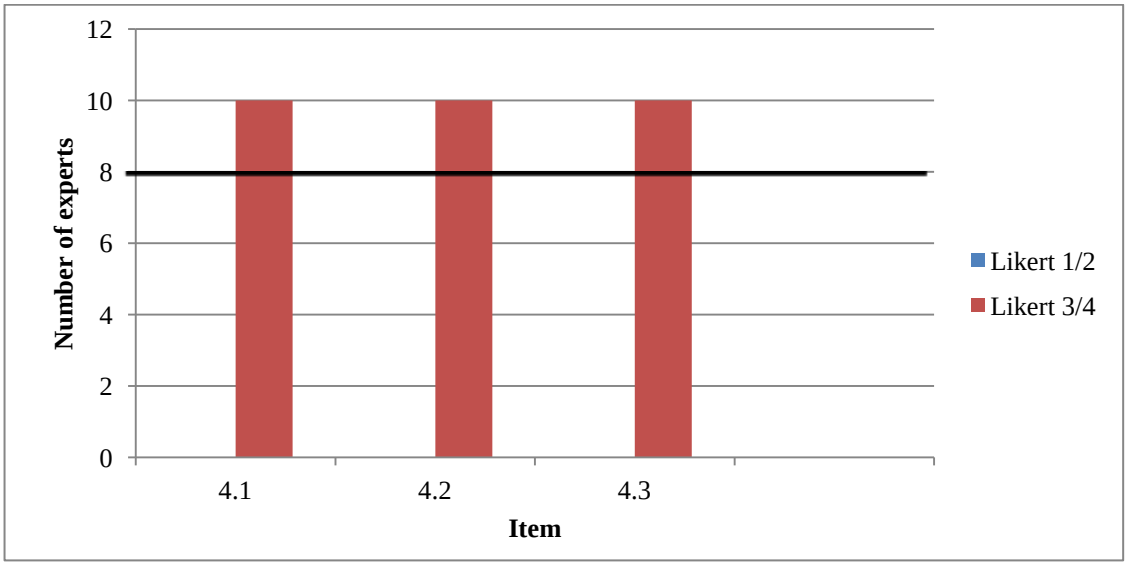

Figure 4.4 Rating of the Pre-operative summary items

The experts rating of the domain "Pre-operative assessment" which had 5 items is shown in Figure 4.5. All the items were rated as content valid.

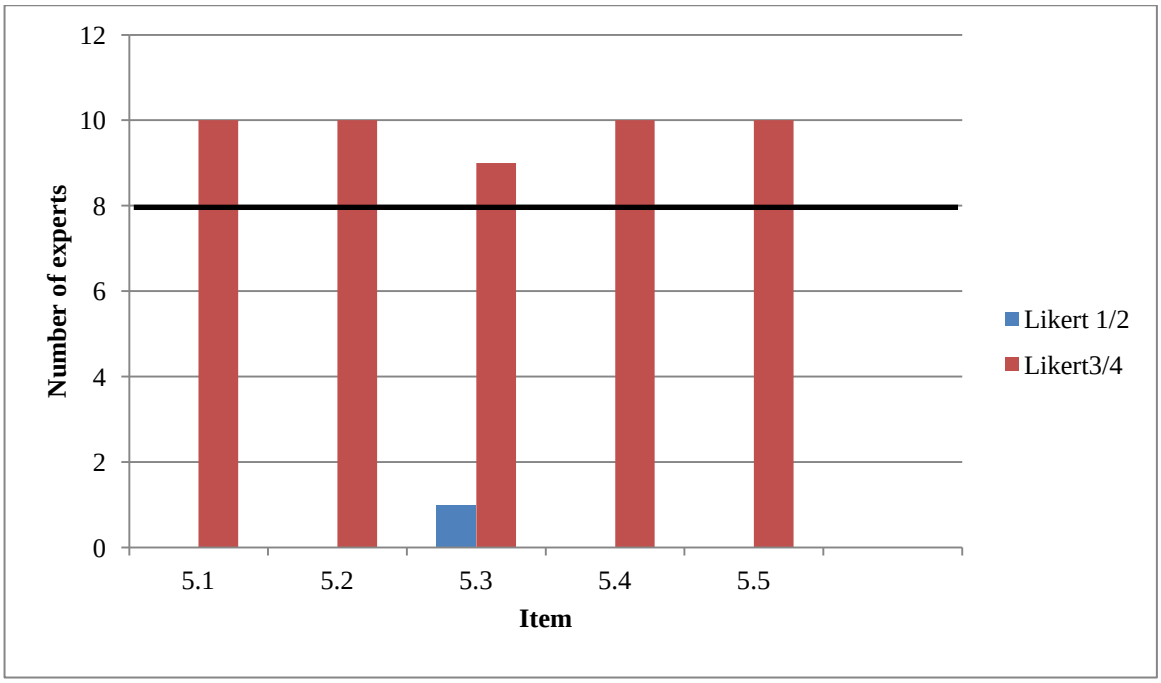

Figure 4.5 Rating of the Pre-operative assessment items

The domain "Pre-operative instructions" only had 1 item (Nil Per Os) which was rated as content valid by all experts. One expert gave it a 3 and nine gave it a 4.

The experts rating of the domain "Intra-operative notes" which had 11 items is shown in Figure 4.6. All items were rated as content valid.

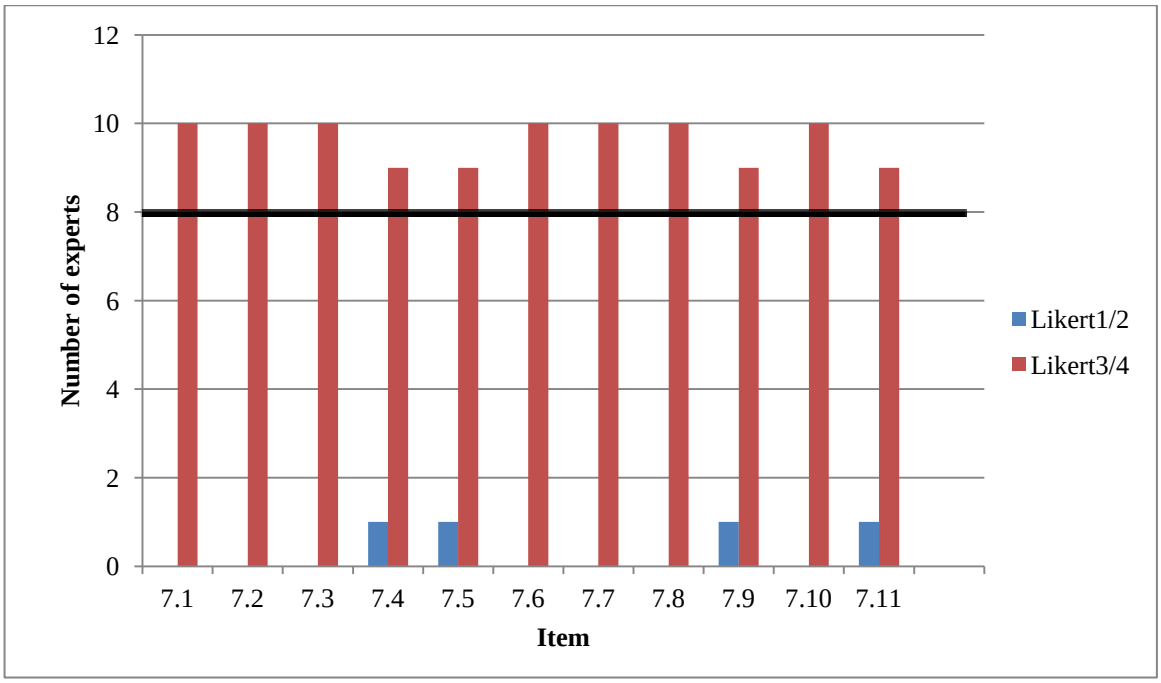

Figure 4.6 Rating of the Intra-operative notes items

The experts rating of "Monitoring" (9 items) is shown in Figure 4.7. All the items were rated as content valid.

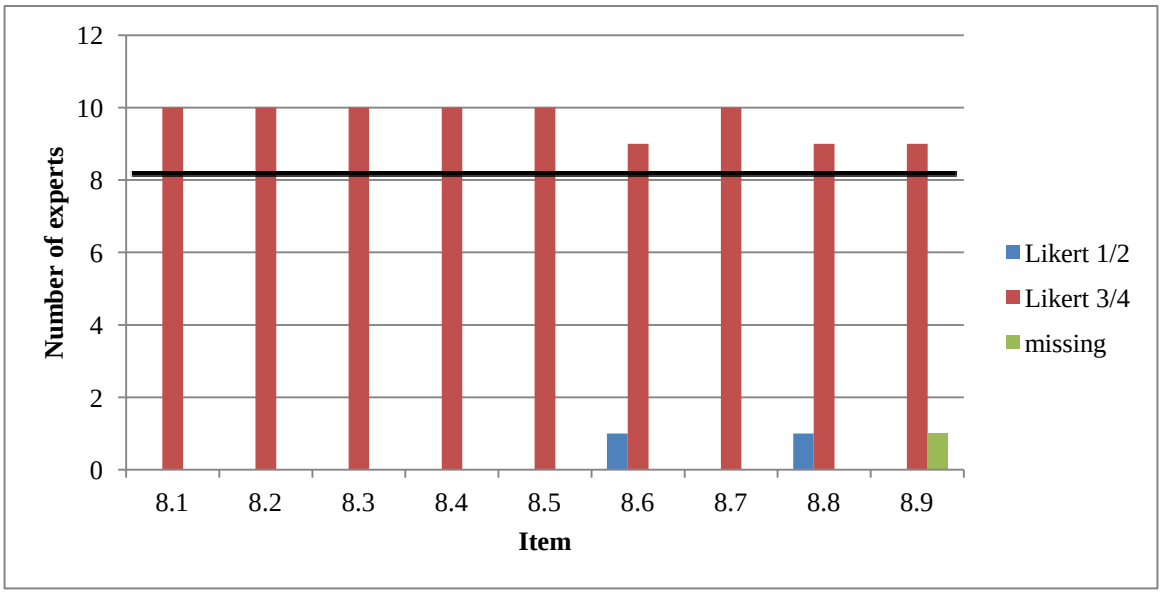

Figure 4.7 Rating of the Monitoring items

The experts rating of the domain "Post-operative" which had 3 items is shown in Figure 4.8. All the items were rated as content valid.

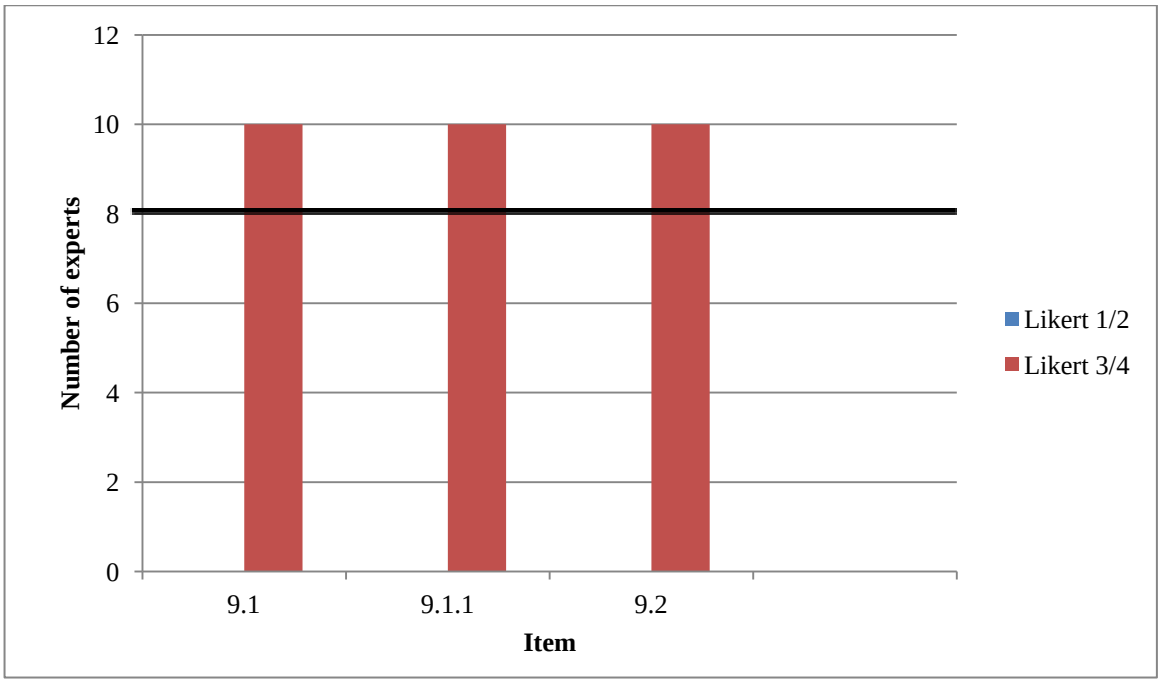

Figure 4.8 Rating of the Post-operative items

The experts rating of the last domain "Form design criteria" which had 6 items is shown in Figure 4.9. Half of these items were rated as content valid.

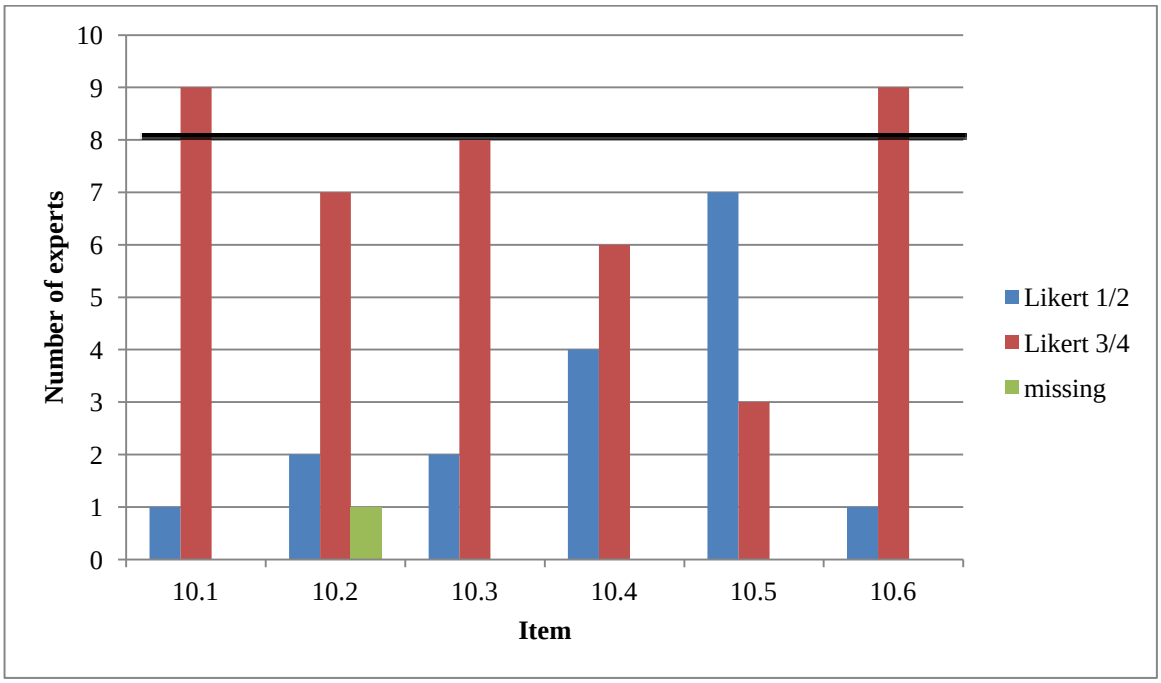

Figure 4.9 Rating of the Form design criteria items

Lastly, the content validity of the of the entire instrument was quantified using CVI. Literature suggests that a new content valid instrument should have a minimum content validity index of 0.8. This index is the percentage of total items judged to be relevant by receiving a rating of 3 or 4. In this study 41 out of 44 (93%) items were judged to be relevant by the experts. The CVI of this entire instrument is therefore 0.9.

4.4 Discussion of results

Professional Associations such as the WFSA (5) and SASA (6) recommend that a "comprehensive and contemporaneous" anaesthetic record be kept by the anaesthetist every time an anaesthetic is being delivered to the patient. Not only is this recommendation a good clinical practice, it is also in the best interest of the patient as it has a number of documented advantages.

SASA Practice Guidelines on the development of such anaesthetic records are however vague and leave much latitude for the content of anaesthetic records. Moreover, audits reveal poor completion of this important document that is widely believed to have raised the status of the anaesthetic profession (19).

There was therefore a need to develop an AR Instrument that would ensure that anaesthetic records contain the minimum essential peri-operative information.

This study used a process of stakeholder involvement to develop the AR Instrument for the SA context following a two stage scientific method - Lynn's model of determination and quantification of content validity of an instrument. The AR Instrument contains items that experts agree are the minimum essential items that should be included in every anaesthetic record.

WFSA recommends that an anaesthetic record should ideally contain relevant information about the patient, pre-anaesthetic evaluation, procedure, anaesthetic technique details, intra-operative events and post-operative instructions of the anaesthetist. WFSA further recognises that due to variability in resources not all the standards can be met in each and every context. It is therefore the duty of respective professional bodies to suggest recommendations that meet their resources and are specific to their context. (5)

The commonly referenced ASA guidelines (28) provide a good template for development of anaesthetic records but they are general and not specific. This study aimed to develop an instrument with clear, concise and specific items for the SA context as this could lead to standardisation of anaesthetic records countrywide.

Tessler et al (11) describes in a more specific way the items that anaesthetists consider important. These items are grouped into pre-operative, intra-operative and post-operative items.

Using ASA template (28) as a guideline, all the items that anaesthetists in Tessler et al's article (11) considered important were assembled and used to generate the provisional instrument that contained 11 domains and 50 items. This provisional AR Instrument was debated upon at the peer group meeting with local experts using Fisher et al's criteria (17) that described what must be included or excluded in anaesthetic records. The resultant revised AR Instrument contained 10 domains and 44 items. It differed slightly from the items in Tessler et al's article (11). The domain "Demographics" which had four items viz. name, age, gender and hospital number was added. Tessler et al (11) specifically mentions intravenous and inhalational and local anaesthetic drugs as the only drugs that anaesthetists found important. In this study the participants decided that the general term "drugs" be used instead as over and above anaesthetic drugs that anaesthetists use, there are many adjuvant drugs that also need to be documented. Also unlike Tessler et al (11) who specifically mentions central venous line and arterial line only, in this study it was decided to list only monitoring that is considered standard but to have a blank space to record additional monitoring that will be dictated upon by a specific case.

Following validation of the AR Instrument by the national experts, a total of 41 out of 44 items were rated as content valid. The domain "Proposed operation" was rated content valid by 5 of the 10 experts. It is possible that the way it was positioned in the questionnaire may have led to it being missed by the other five experts who did not rate it. In hindsight, this important domain should have been made more conspicuous by including items below it or alternatively made to be an item under a closely related domain.

The domain "Form design criteria" had six items. Three (A4 paper, no-carbon required forms and best contrast ink and paper) out of the six items were rated as content valid. The other three (pale/pastel shade paper, pre-drilled holes and lowercase text) were not rated as content valid. It is probable that the experts were more concerned with the content of the anaesthetic record and not concerned with its design. Therefore, of all the items on this AR Instrument, only these three were not rated as content valid. The CVI of this entire instrument was calculated to be 0.9. The AR Instrument is therefore valid.

4.5 Summary

In this chapter the results and discussion were presented. The following chapter contains a summary of the study, the limitations, recommendations and a conclusion.

CHAPTER FIVE: SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

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

5.2 Summary of the study

5.2.1 Aim

The aim of this study was to develop and validate an AR Instrument using Lynn's two stage model (13).

5.2.2 Objectives

The objectives of this study were to:

- develop a provisional AR Instrument from the literature using Lynn's Development Stage (domain identification and item generation)
- develop a revised AR Instrument using Lynn's Development Stage (item formation)
- determine content validity of the revised AR Instrument using Lynn's Judgement-Quantification Stage.

5.2.3 Summary of the methodology and results

Lynn's two stage model of determining and quantifying content validity of an instrument was used to develop and validate this AR Instrument. These stages are the Development Stage and the Judgement-Quantification Stage (13).

The Development Stage consisted of three steps viz. domain identification, item generation and item formation. The researcher made use of three steps by performing literature review (domain identification), developing a provisional instrument that contained 11 domains and 50 items (item generation) and finally at

a peer group discussion, developed a revised instrument that contained 10 domains and 44 items (item formation).

Following the peer group discussion, the necessary modifications according to the peer group recommendations were made and the AR Instrument was emailed back to these same experts for member checking before being emailed to the national experts for validation in the Judgement-Quantification Stage.

The Judgement-Quantification Stage of the instrument development entailed first calculating the level of IR for relevancy of items. Content validity across expert scores was then determined by the proportion of experts who rated items as content valid with either a 3 or 4 score. Finally, the CVI of the entire AR Instrument was calculated to determine the content validity of the AR Instrument.

5.3 Limitations

The following were the limitations of this study:

The AR Instrument developed is contextual for SA and therefore may not be generalised to other countries.

The experts who participated in the study are not representative of all the provinces because experts from other provinces did not respond to numerous reminders requesting them to participate.

5.4 Recommendations

A recommendation for clinical practice is that the AR Instrument should be communicated to SASA because it was validated by SA experts and therefore it can be used to evaluate or develop anaesthetic records countrywide.

The following are recommendations for research:

- audits should be done on anaesthetic records to determine if the essential items are recorded, thus assessing anaesthetic records as adequate or inadequate

- specific sub speciality anaesthetic instruments must be developed for relevant sub specialities.

5.5 Conclusion

In this study an expert validated AR Instrument was developed for the South African context. This contextual AR Instrument can be used to evaluate if all the existing anaesthetic records contain the items that are the minimum essential information that must be included in anaesthetic records. Thus, the instrument could ultimately make it possible to categorise the anaesthetic records as being either “good”, “mediocre” or “poor”.

The AR Instrument can also be used to develop new anaesthetic records. These anaesthetic records are key medico-legal documents which could serve as the anaesthetist friend and key witness should an anaesthetist find himself or herself as a defendant in a law suit. An inadequate record will, in the long term, prove to be his or her worst enemy (21).

The lack of an anaesthetic record with items that experts regard as essential is therefore a "time bomb" for the anaesthetist (12).

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Appendices

Appendix 1: HREC (Medical) clearance certificate



R14/49 Dr Raphael Ntlhane Maja

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130107

NAME: (Principal Investigator)	Dr Raphael Ntlhane Maja
DEPARTMENT:	Department of Anaesthesiology CM Johannesburg Academic Hospital
PROJECT TITLE:	Development and Validation of an Instrument for Essential Information for Anaesthetic for Anaesthetic Records
DATE CONSIDERED:	25/03/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Mrs Juan Scribante
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 19/04/2013

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 30/03/2013

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Post Graduate Committee approval of MMed title

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax:
Tel: 011 7172040

Reference: Ms Mpumi Mnqapu
E-mail: mpumi.mnqapu@wits.ac.za

18 July 2013
Person No: 698967
PAG

Dr RN Maja
PO Box 232
Chuenespoort
0745
South Africa

Dear Dr Maja

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Development and validation of an instrument for essential information for anaesthetic records* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty'shigher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3: Information letter for the experts in the Development Stage

Dr Raphael N. Maja

Anaesthesiology registrar

University of the Witwatersrand

Date

To: Dr/Prof

Dear Colleague

Hello, my name is Raphael Maja. 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. The study is entitled: Development and validation of an instrument for essential information for anaesthetic records.

This study is informed by the fact that audits done internationally and locally have proven that anaesthetic records continue to be poorly filled out. However there is presently no instrument against which we can measure if essential information is recorded on anaesthetic records.

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 anaesthesiology 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 of the literature for you to refine and if necessary expand to ultimately enhance the content validity. At the peer group meeting, I will ask you to make recommendation for changes, additions or deletions to the provisional instrument, and grade the items on a four point scale:

- 1=not important information,
- 2=useful information,
- 3=important information,
- 4=essential information.

We will debate each item and items that reach a 100% consensus will then be prepared for the quantification stage.

Participation in this process is entirely voluntary. Participants will be requested to maintain confidentiality of what is discussed, but I as the researcher, cannot guarantee that this will be adhered to.

I appreciate that you will not benefit from participation in this study, however I hope that the development of an essential information instrument (ARInstrument) will lead to anaesthetic records that contain information that experts consider essential. These will be invaluable in improving the transmission of anaesthesia related information, quality improvement, research and most important, they will be acceptable medico-legal documents.

The study has been approved by the Human Research Ethics Committee (HREC) (number: M130107) and the Post Graduate Committee, University of Witwatersrand.

Should you wish to contact me, or require any further information, my cell number is 0828566365. The chairman of the HREC is Prof Cleaton-Jones (0117171234)

Thank you for taking time to read this information letter.

Yours sincerely,

Raphael Maja

Appendix 4: Information letter for the experts in the Judgement-Quantification Stage

Dr Raphael N. Maja

Anaesthesiology registrar

University of the Witwatersrand

Date

To: Dr/Prof

Dear Colleague

Hello, my name is Raphael Maja. 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. The study is entitled: Development and validation of an instrument for essential information for anaesthetic records.

This study is informed by the fact that audits done internationally and locally have proven that anaesthetic records continue to be poorly filled out. However there is presently no instrument against which we can measure if anaesthetic records contain minimum 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. The development stage was done following a review of the literature and a peer group discussion that resulted in the development the attached provisional essential information instrument (ARInstrument).

I hereby invite you as an expert in anaesthesiology to participate in my study. Should you consent, I would like you to rate each item on this ARInstrument and then the entire instrument on the following four-point scale:

- 1=not important information,
- 2=useful information,
- 3=important information,
- 4=essential information.

Participation in this process is entirely voluntary. I, the researcher, will be the only person knowing your identity and I will capture the data in a way that does not identify information of any participant, thereby ensuring confidentiality.

I appreciate that you will not benefit from participation in this study, however I hope that the development and validation of an ARInstrument will lead to anaesthetic records that contain information that experts consider essential. These will be invaluable in improving the transmission of anaesthesia related information, quality improvement, research and most important, they will be acceptable medico-legal documents.

The study has been approved by the Human Research Ethics Committee (HREC) (number: M130107)and the Post Graduate Committee, University of Witwatersrand.

Should you wish to contact me, or require any further information, my cell number is 0828566365. The chairman of the HREC is Prof Cleaton-Jones (0117171234)

Thank you for taking time to read this information letter.

Yours sincerely,

Raphael Maja

Appendix 5: Consent form for the experts

CONSENT FORM

Development and validation of an instrument for essential information for anaesthetic records

I,_____ (full name), fully understand the contents of the information letter detailing the purpose of the study and how the study will be performed.

I hereby consent to participate in this study.

_____ _____

Participant Signature Date

_____ _____

Researcher Signature Date

Appendix 6: Cumulative binomial distribution

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