ARTERIAL BLOOD GAS: AN EXPERIMENT TO STUDY THE EFFECTS OF TEMPERATURE AND TIME DELAYS ON THE OUTCOME OF A BLOOD GAS RESULT

By

LYNETTE  MARGARET BAKER
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by

LYNETTE MARGARET BAKER

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UNIVERSITY OF SOUTH AFRICA

SUPERVISOR: MRS M. MOLEKI

JOINT SUPERVISOR: DR M.J OOSTHUIZEN

JANUARY 2008
DECLARATION

I declare that: ARTERIAL BLOOD GAS: AN EXPERIMENT TO STUDY THE EFFECTS OF TEMPERATURE AND TIME DELAYS ON THE OUTCOME OF A BLOOD GAS RESULT is my own work and that all sources that I have used or quoted have been indicated and acknowledged by means of correct references.

I declare that permission to undertake the dissertation was granted by the Research Ethics Committee, Groote Schuur Hospital, Observatory, Cape Town and by the Research Ethics Committee of the University of South Africa, Pretoria.

[Signature]  
04.01.2008

SIGNATURE  
DATE

LYNETTE MARGARET BAKER
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Ms M. May, Nursing Unit Manager, Respiratory Unit, Groote Schuur Hospital

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ARTERIAL BLOOD GAS: AN EXPERIMENT TO STUDY THE EFFECTS OF TEMPERATURE AND TIME DELAYS ON THE OUTCOME OF A BLOOD GAS RESULT

STUDENT NUMBER: 0482494-6

STUDENT: LYNETTE MARGARET BAKER

DEGREE: MASTER OF ARTS

SUPERVISOR: MRS M. MOLEKI

JOINT SUPERVISOR: DR M.J. OOSTHUIZEN

ABSTRACT

An arterial blood gas analysis which is conducted in critical care areas contributes to the assessment of a patient’s ventilatory status and acid–base balance.

The purpose of this research was to determine the relationship of time delays and temperature on the result of a blood gas analysis. The objective was to either accept or refute the null hypothesis, that there is no relationship between temperature and time delays and an arterial blood gas result.

Fifteen subjects were randomly selected. The researcher drew three samples of arterial blood from each subject. Ethical principles were observed.

An inferential non-parametric statistic was used. The chi-squared test was used to test the hypothesis and the Friedman and the Wilcoxon signed ranks test were used to test the differences between the means.
The results revealed that there was a relationship between time delays, temperature and the arterial blood gas result. The null hypothesis was rejected.

**KEY TERMS:**

Arterial blood gas analysis; storage temperature; time delays; partial pressure of oxygen; partial pressure of carbon dioxide.
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CHAPTER 1

INTRODUCTION AND OVERVIEW OF THE STUDY

1.1 INTRODUCTION

Arterial blood gas analysis is a test done in Intensive Care units, Emergency and Trauma units and Operating Theatres. They are performed on numerous occasions on a daily basis and play an important role in clinical decision making with regard to a patient's ventilatory status. Allen (2005:42) states the arterial blood gas analysis is a diagnostic tool that allows the objective evaluation of a patient's oxygenation, ventilation and acid-base balance. In many clinical areas nurses are often the first to draw blood for an arterial blood gas, process the sample and the first to interpret the result. The realm of the arterial blood gas analysis is fairly complex and as such an understanding of the significance of the pre-analytical factors involved in preparing an arterial blood gas sample is as important as the interpretation of the results and having the ability to decide when the medical staff need to be informed.

Previous research by Harsten, Berg, Inerot, and Muth, (1988:365) has shown that a delay in processing an arterial blood gas sample can affect the result of an arterial blood gas analysis. If the arterial blood gas sample is not stored on ice (to ensure a temperature of 0 - 4 degrees Celsius) there may be an impact on the outcome of the arterial blood gas analysis.

Nurses are often the first members of the health care team to see arterial blood gas results and are playing a bigger role in the realm of blood gas analysis within the work area, particularly as more analysers are placed in these areas. In some settings nurses are becoming more
autonomous in patient management including ordering and interpreting diagnostic studies, for example arterial blood gas analysis (Fischbach 2002:24). It is therefore of importance that nurse education and training is undertaken as this is the key to ensuring that accuracy and precision is achieved when performing arterial blood gases. Adhering to the correct method of analysis as recommended by the various Committees for Laboratory Standards (Klee 2001:11) will ensure that correct results are received, and patients managed appropriately.

This study was conducted to establish if time and temperature as pre-analytical factors play an important role in impacting on the outcome of an arterial blood gas analysis. Specifically, incorrect temperature storage and time delays in processing an arterial blood gas sample.

1.2 BACKGROUND TO THE STUDY

Against this background the researcher intends to orientate the reader to the rationale and logistics of arterial blood gas analysis in critical care units, for example Intensive Care and Emergency units.

A large number of patients who are admitted to an Intensive Care unit have a respiratory deficit. A quick and easy measurement of a patient's acid-base status, pulmonary function and to determine oxygen delivery in a critically ill patient, apart from assessing the clinical features of a patient, is to measure an arterial blood gas. Shoemaker, Grenvick, Ayres and Holbrook (1996:95) stated that an arterial blood gas analysis can be used in the initial evaluation and workup of patients with unexplained tachypnea, dyspnea, tachycardia and of patients with restlessness, anxiety or mental confusion that is secondary to hypoxemia. Included are patients where it is felt that the condition is deteriorating from a respiratory point of view. Marino (1998:339) states that there is a distinct fondness for arterial blood gases and generally are the most commonly performed
laboratory test in critical care patients, therefore it is likely that blood
gas measurements in days to come will be even more inundating.

The information gleaned from an arterial blood gas result identifies the
acid-base status (pH, base excess and Sodium Bicarbonate) and the
ventilatory status of a patient, more specifically the partial pressure of
oxygen and the partial pressure of carbon dioxide (more detail of these
factors is given in Chapter 2). Haemoglobin, and in the newer
analysers sodium and potassium are also identified. Together with a
clinical evaluation of the patient a plan of action can be formulated on
how best to treat the patient from a ventilation point of view.

The researcher's interest in the preparation of arterial blood gas
samples is rooted in the researcher's area of Intensive Care which for
four years was mainly in the Respiratory unit at a Tertiary level hospital
in Cape Town. In this unit arterial blood gas samples are routinely
drawn on admission and every morning. This enables the nurses to
plan for a patient's treatment for the day (which may include changing
the settings on the ventilator), also when a critically ill patient is thought
to be deteriorating. It was noted that over a period of six months the
total number of arterial blood gas samples drawn between 07h00 and
08h00 was approximately 300. In this unit arterial blood gas samples
taken at other times of the day were not as accurately recorded. The
researcher noted that during this period the preparation of arterial
blood gas samples was not in keeping with recommended practice as
noted in the literature (Fischbach 2002:77).

It is against this background that the researcher planned an experiment
to assess the relationship between the storage of an arterial blood gas
at room air (at a temperature of 19 degrees Celsius) and an arterial
blood gas stored on ice (at a temperature of 0 - 4 degrees Celsius) and
the time delays in analysing the sample and the actual result. The
researcher was interested in two aspects of the arterial blood gas
result, the partial pressure of oxygen and the partial pressure of carbon
dioxide. According to literature these are the two factors which are most affected by storage and time delays (Klee 2001:8).

1.3 PROBLEM STATEMENT

Decisions regarding the ventilatory status and the treatment of critically ill patients in an Intensive Care unit are frequently made based on the results of an arterial blood gas analysis. There appeared to be some discrepancy in the literature with regard to the storage of arterial blood gas samples. Most of the recent studies agree that the optimal time for analysing an arterial blood gas sample is immediately after it has been drawn. The European ad hoc Committee for Clinical Laboratory Standards recommends that samples should be stored for less than two hours on ice and less than fifteen minutes at room air (Klee 2001:11). If arterial blood gas results are faulty because of pre-analytical errors the progress in a patient's condition may be compromised. To address the problem statement the study was guided by the following research question:

What effect does temperature and time delays as pre-analytical factors have on the outcome of an arterial blood gas result and more specifically the partial pressure of oxygen and the partial pressure of carbon dioxide?

1.4 PURPOSE OF THE STUDY

The purpose of the study was to investigate two aspects in the preparation of an arterial blood gas sample which may affect the outcome of the result following analysis. The first was to determine the relationship between the temperature at which a sample is stored and the result of the arterial blood gas,
specifically the partial pressure of oxygen and the partial pressure of carbon dioxide.

The second was to determine the relationship between the time at which an arterial blood gas sample is analysed after it has been drawn and the result of the blood gas analysis, specifically the partial pressure of oxygen and the partial pressure of carbon dioxide.

1.5 SIGNIFICANCE OF THE STUDY

It is envisaged that
➢ the results of the experiment would indicate the most appropriate preparation and handling for an arterial blood gas sample
➢ a protocol and or a flow chart be compiled for all professionals in the preparation and handling of arterial blood gas samples.
➢ a training programme for nurses be developed in the preparation and handling of arterial blood gas samples and the processing thereof.

1.6 HYPOTHESES AND NULL HYPOTHESES

A scientific hypothesis represents the predicted relationship among the variables being investigated and the null hypothesis represents a statement of no relationship among the variables being investigated (Christensen 2004:107). Christensen continues to state that in any study it is the null hypothesis that is always tested, because the scientific hypothesis does not specify the exact amount or type of influence that is expected. To obtain support for the scientific hypothesis evidence must be collected which will enable the researcher to reject the null hypothesis. According to Grinnel (1988:20) a hypothesis should be written in such a way that it can either be
accepted or rejected by valid and reliable data. Grinnel states that the following are applicable to the formulation of the hypothesis:

- it is a tentative preposition
- its validity is unknown
- in most cases it specifies a relationship.

### 1.6.1 Hypotheses

- The arterial blood gas result of a blood sample drawn from a patient in the Respiratory unit which has been stored on slush ice at a temperature of 0 - 4 degrees Celsius after thirty minutes will show a partial pressure of oxygen to be higher and a partial pressure of carbon dioxide to be lower than that stored at room temperature for thirty minutes.

- The arterial blood gas result of a blood sample drawn from a patient in the Respiratory Unit which has been analysed within ten minutes of been drawn will show a partial pressure of oxygen and a partial pressure of carbon dioxide to be the same as that of a blood sample stored on slush ice at a temperature of 0 - 4 degrees Celsius for thirty minutes.

### 1.6.2 Null hypotheses

The null hypothesis aims to demonstrate that there is no relationship between the independent variable and the dependent variable. In this case the independent variables are the temperature at which the arterial blood gas sample is stored and the time delay, from drawing the blood sample to the processing of the sample through a blood gas analyser. The dependent variable is the arterial blood gas result.

The researcher aims to demonstrate by means of an experiment that there is a relationship between the way in which an arterial blood gas sample is stored and the time it takes to process the arterial blood gas
sample and the result following analysis thus refuting the null hypothesis.

\( H_0: \) \text{Null Hypotheses}
- There is no relationship between temperature and time delays on the partial pressure of oxygen (within the arterial blood gas result).
- There is no relationship between temperature and time delays on the partial pressure of carbon dioxide (within the arterial blood gas result).

\( H_1: \) \text{Alternative Hypotheses}
- There is a relationship between the temperature and time delays on the partial pressure of oxygen (within the arterial blood gas result).
- There is a relationship between temperature and time delays on the partial pressure of carbon dioxide (within the arterial blood gas result).

1.7 \text{OBJECTIVE OF THE STUDY}

It was hoped that once the results of the experiment were made available the researcher would be able to fulfil the objective of the study which was to either accept or reject the null hypotheses.

In so doing the researcher would therefore substantiate the assumptions made with regard to the \( H_1 \), alternative hypothesis that there was a relationship between storage of the arterial blood gas sample and the result following analysis and that there was a relationship between time delay (from the time of drawing the blood to analysis) and the result.

1.8 \text{RESEARCH DESIGN AND METHODOLOGY}

Following is a brief description of the concepts in the methodology namely: research design, population and sampling, methods of data
collection, data analysis process and ethical considerations. A detailed
description of the research design and the methods is discussed in
chapter 3 page 30

1.8.1 Research design
The research design is the blueprint or the plan for endeavouring to
answer questions or testing a hypothesis (Polit, Beck and Hungler
This quantitative study adopted an experimental design.

Experimental design involves certain principles, which include
interventions or manipulation by the researcher. The term manipulation
means that the independent or experimental variable is controlled by
the researcher (Nieswiadomy 1993:133). In this research the
researcher manipulated the variables by storing the arterial blood gas
samples at different temperatures and analysing the samples at
different times.

Comparisons are included in this group of principles. Comparisons
allow for easy interpretation of results (Polit, et al 2001:167). The
comparison in this study was to compare different methods of storing
an arterial blood gas sample and to compare the different times after
the arterial blood gas sample was drawn to the time of analysis.

Control is another principle of experimental research (Polit, et al
2001:170) which the researcher incorporated. The researcher had a
control group which was the arterial blood gas sample stored at room
air and processed ten minutes after being drawn.

The most basic experimental design involves random assignment
(Polit, et al 2001:173) that is, each subject has an equal chance of
being assigned to a particular treatment. Clarke (1994:140) states that
random allocation of treatments is basic to experimental design, so that
each sample has the same chance of being exposed to a treatment.
The reason for randomisation is to prevent bias (Brink 1999:102). Sampling bias is affected by the homogeneity of the population and if the population was completely homogenous a single element would be enough for drawing conclusions about the population (Polit, et al 2001:235). For many physical and physiological attributes, for example a blood sample taken from a person’s veins will have a reasonable degree of homogeneity (Polit, et al 2001:235). A single blood sample chosen haphazardly from a patient is adequate for clinical purposes (Polit, et al 2001:235). Therefore, in this study the researcher was able to draw three separate samples of blood from 15 subjects with the knowledge that each blood sample was considered to be reasonably homogenous. The researcher then manipulated the storage of the samples and the time at which the samples were stored.

The research is quantitative because the data was presented numerically using a bi-variate statistical test, the chi-squared test which is a non-parametric procedure used to test hypotheses about the proportion of cases that fall into various categories (Polit, et al 2001:356).

1.8.2 Population

A population is the “aggregate” of all the individuals used in research who have some common characteristics or features (Polit, 2001:40). However, populations are not restricted to human subjects (Polit and Beck 2007:338); a population might consist of all the blood samples taken from clients of a health maintenance organisation. In this study the population consisted of forty five samples of blood taken from fifteen subjects.

1.8.3 Sampling and setting

Sampling is a part of the whole or a percentage of the target group (Brink 1999:133) Statistical sampling includes random or probability
sampling where data items are selected by chance and once the probabilities for selecting the items are known, the individual selecting the sample does not change those probabilities (Groebner and Shannon 1987:7), otherwise any changes can lead to sampling bias. Sampling bias is affected by the homogeneity of the population. If the elements in a population were all identical any sample would be as good as any other. If the population exhibited no variability a single element would be a sufficient sample for drawing conclusions. (Polit, et al 2001:235). Polit continues to state that for many physical or physiologic attributes, it may be safe to assume a reasonable degree of homogeneity, for example, the blood in a person’s veins/arteries is relatively homogenous, a single blood sample from a subject is therefore adequate for clinical purposes.

The researcher in this research used a convenient sampling of fifteen subjects who were treated in the Respiratory unit of a Tertiary level hospital in Cape Town. Three samples of arterial blood were collected from each subject

1.8.3.1 Inclusion criteria

Sampling criteria pertains to all the subjects who meet the set requirement for inclusion. The criteria for inclusion was:
➢ The subjects must be intubated and ventilated
➢ On a Vela ventilator at forty percent oxygen
➢ Each subject had to have an indwelling arterial line from which blood was drawn

1.8.4 Convenient sampling

Convenient sampling entails the use of the most conveniently available people as study subjects (Polit, et al 2001:236) The researcher in this
study selected fifteen subjects who met the inclusion criterion. The convenient sampling was used because the researcher was working in the Respiratory unit at the time of the experiment and because blood gas samples were taken routinely on patients admitted to the unit.

1.8.5 Data collection

There are several data collection techniques. These techniques depend on whether the data to be collected requires face to face interaction for example interviews or questionnaires. Sophisticated physiological measurements and observation are also data collection techniques. The data collection technique used in this study was the collection of arterial blood samples from an arterial line which had been inserted into a subject’s artery.

1.8.6 Data analysis

The researcher used a group of statistics referred to as inferential statistics, which are based on the laws of probability and which provide a means for drawing conclusions about a population, given data from a sample (Polit, et al 2001:343). The researcher, aided by an accredited statistician who recommended the use of a nonparametric procedure to test the hypotheses, this was the chi- squared test. To follow on from this the researcher, also on the recommendation of the statistician used a Friedman test to test if the observed differences were statistically significant. To establish where the significant differences lay a pairwise test was done based on the Wilcoxon signed ranks test. Data analysis is discussed in chapter 3 page 42.

1.8.7. Ethical issues

Individuals with diminished autonomy require protection and in this research context the ventilated patients in the Respiratory unit were
considered as vulnerable persons. Some of these patients were unconscious and those who were awake were compromised by their critical illness. Permission to conduct the research was sought with the Research Ethics Committee in the Tertiary level hospital in Cape Town in order to undertake the research within the hospital setting. This was granted (Annexures A-G). The research was submitted to the Research Ethics Committee of the University of South Africa and permission was granted.

The constitution of the Republic of South Africa (Act 108 of 1998) and the code of the Profession requires that patients are protected (Searle 2000:72-77). The National Health Act 2003. (Act 61 of 2003) Section 68 makes provision for the minister to make regulations relating to tissue, cells, organs, blood, blood products and gametes. Also contained in the National Health Act is a section on Respect for Persons which states that the fundamental ethical principle to be observed in the use of human tissue samples for research is respect for the person.

In this research this was ensured by:

- Provision to the donor of full information about the purposes of the sampling
- The donor's consent to use the sample in the experiment planned
- Provision and maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data.

The World Federation of Critical Care Nurses (WFCCN 2006:2) of which South Africa is a member has also made a position statement on the rights of the critically ill patient incorporating the need for increased vigilance and a requirement to be well informed with regard new technology and experimentation and how this affects human rights. Confidentiality of the subjects was protected as their names were not used.
The subjects and their next of kin were informed of the experiment and an information pamphlet (Annexure G) was given to each one. Consent was obtained from either the patient or their next of kin and a copy of the consent was given to each one (Annexure F).

1.9 DEFINITION OF THE CONCEPTS IN THE STUDY

In this section the following concepts used in the study are defined which will aid in the understanding of the study.

1.9.1 Arterial blood gas analysis (Abg)

This is a test used to assist diagnosis and in the monitoring of patients with respiratory disorders. Arterial blood is analysed to assess the adequacy of oxygenation, ventilation and acid – base status. It furnishes accurate, rapid information about how well the lungs and kidneys are working (Fischbach 2002:150).

1.9.2 Partial pressure of oxygen and the partial pressure of carbon dioxide

The partial pressure of a gas in a mixture is in reality the sum of the force of impact of all the molecules of that particular gas against the surface (Guyton 1971:473). Each gas in a mixture, in this case, oxygen and carbon dioxide, exerts its own pressure in proportion to the concentration of its molecules without affecting other gases, each gas is therefore independent of the other gases in the mixture, which in this case is blood.
1.9.3 The blood gas analyser used in the study

There are numerous models of blood gas analysers. The researcher used a bench top analyser, the Radiometer 520ABL, which was housed in the Respiratory unit and regularly maintained and calibrated by the Respiratory Technologist. This would have helped in excluding any extraneous factors such as poor calibration of the analyser which may have had an influence on the result of the arterial blood gas samples.

1.9.4 Arterial line

An arterial line refers to the catheter inserted into an artery (radial, femoral or dorsalis pedis arteries are the most commonly used). The catheter/line is connected to a transducer for purposes of recording arterial blood pressure. The other advantage of this line is the easy access for blood sampling Clearing of the line prior to drawing blood is important as pure arterial blood is needed for analysis. The researcher drew blood from an arterial blood line so as to prevent any discomfort to the patient (Fischbach 2002:73).

1.9.5 Sodium Heparin

Heparin is an anticoagulant. This was drawn into the syringe prior to drawing blood from the arterial line. The heparin prevents the blood from clotting and clogging the blood gas analyser. The researcher used heparin when preparing syringes for this experiment. The amount used = 0.1millilitre. The amount was also significant for this experiment as too much heparin can alter the blood gas result (Higgins 2007:1). A two millilitre plastic syringe was used to take each sample.
1.9.6 Respiratory unit
This is an eight bedded unit divided into two units with four beds in each unit. The category of patients varies but includes both surgical and medical patients. The criterion for admission is that the patients all suffer respiratory failure in varying degrees. All the patients admitted have an arterial blood gas analysis done on admission and daily as a routine procedure until their condition has stabilized. Not all have an arterial catheter inserted.

1.10 OUTLINE OF THE STUDY

This dissertation is presented in the following chapters:

Chapter 1: Provides an orientation to the study

Chapter 2: Literature review and how the literature guided the researcher

Chapter 3: Research design and methodology

Chapter 4: Analysis and presentation of research findings

Chapter 5: Conclusions, recommendations, future studies and limitations

1.11 CONCLUSION

This chapter describes the background to the research, explores the problem, the objectives and purpose of the research. The concept and research methodology are outlined.

In the following chapter a review of the literature is provided.
CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This Chapter includes an overview of the literature consulted which is relevant to this research.

The researcher conducted a literature review in order to facilitate understanding and to acquire knowledge about other researchers and what has been achieved with regard to

- Arterial blood gas preparation
- Nurses role in the collection and analysis of arterial blood gas samples
- History of arterial blood gas analysis
- Studies conducted with regard to the preparation of arterial blood gas samples

2.2 THE ARTERIAL BLOOD GAS SAMPLE AND ANALYSIS

Arterial blood gases are frequently performed for seriously ill patients. An arterial blood gas may help to ascertain the severity of a particular condition, for example metabolic acidosis, and in establishing the adequacy of ventilation and oxygenation (Royal College of Surgeons 2006:1). Allen (2005:45) states an arterial blood gas is valuable as a diagnostic tool as it enables objective evaluation of a patient’s oxygenation, ventilation and acid – base balance.

Summary of the references of the normal values of arterial blood gas results is presented in Table 2.1 on page 17 (Fischbach 2002:150 and Allen 2005:45).
Table 2.1 Normal arterial blood gas values. The expected test outcomes at sea level, breathing room air.
(Adapted from Fischbach 2002:150 and Allen 2005:45)

<table>
<thead>
<tr>
<th>NORMAL RANGE</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph = 7.35-7.45</td>
<td>Symbol of negative hydrogen ion</td>
</tr>
<tr>
<td>PCO₂ = 4.5-6.0 kPa</td>
<td>Carbon dioxide concentration</td>
</tr>
<tr>
<td>PO₂ = 10-13 kPa</td>
<td>Oxygen concentration</td>
</tr>
<tr>
<td>HCO₃⁻=22-26 kPa</td>
<td>Bicarbonate ion concentration</td>
</tr>
<tr>
<td>Base excess = +2 to -2</td>
<td>Substances which combine with hydrogen ion</td>
</tr>
<tr>
<td>SaO₂ = 95 - 100%</td>
<td>Oxygen saturation</td>
</tr>
<tr>
<td>kPa = kilopascals</td>
<td></td>
</tr>
</tbody>
</table>

The point of interest in this study was the preparation of an arterial blood gas sample and specifically the storage of the sample and the time delays in getting the sample analysed. Two Healthcare services in Australia, St. Andrews Hospital in Adelaide and St. George Hospital in Sydney have identified a number of pre-analytical errors, two of which are delays in analysis and inappropriate sample storage (Cantor 2002:1). They found as a result of these pre-analytical errors inconsistency in test results and also a waste of resources.

2.3 THE NURSES ROLE IN THE COLLECTION OF BLOOD GAS SAMPLES

It is a known fact that the collection of an arterial blood gas sample in Intensive Care units is performed by nurses.
The nurse follows agency protocols for collecting, handling and transporting specimens and observes standard precautions and sterile techniques. Nursing interventions include collecting proper specimen amounts, using appropriate containers and media, processing specimens correctly and storing and transporting specimens within specified time lines (Fischbach 2002:51).

Point-of-care testing (POCT) is performed near the bed and usually by nurses, rather than laboratory trained professionals. A 2001 survey of POCT practices in 584 American hospitals found that 100% were performing POCT glucose testing, 62% offered coagulation tests, 50% blood gas and electrolytes, 36% chemistry assays and 28% haematology testing. There apparently is an expectation in America that POCT will increase between 12-15% per year (Ehrmeyer 2002:1). In the South African context there are no similar statistics. However the researcher’s experience in Intensive Care units is that blood gas analyses are done mostly by nurses.

2.4 HISTORY AND STUDIES IN THE COLLECTION OF BLOOD GAS SAMPLES

Historically the collection of arterial blood gas samples first occurred in 1957 using glass syringes with immediate storage in an ice water slurry (Blonshine 2005:1). Glass is an impermeable barrier to atmospheric gas pressures and minimizes the leucocyte metabolism, thus it provided a negligible change in diffusion between air and blood although there was still a progressive decrease in the partial pressure of oxygen and increase in the partial pressure of carbon dioxide caused by the metabolism of the erythrocytes and leucocytes over time (Blonshine 2005:1).

Practice has changed over the years. The use of plastic syringes is the norm due to cost, safety and convenience. As a result of this change a
number of studies to compare glass and plastic syringes have taken place. This has been essential to identify potential errors in a blood gas analysis. The Clinical and Laboratory Standards Institute which is an international, interdisciplinary, non-profit, standards-developing and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community (D'Archangelo 2007:1), provides specific guidelines and recommendations regarding sample collection, handling, storage and transport. It recommends that arterial blood specimens collected in plastic syringes and left at room temperature be analysed within thirty minutes (Blonshine 2005: 2).

The field of blood gases has a reputation for being confusing, because many different measured and derived quantities are being used. In addition many different personnel including respiratory and critical care practitioners are involved. For this reason the Clinical and Laboratory Standards Institute welcomes input from many professionals involved with blood gas analysis (D'Archangelo 2007:1).

A number of studies over the years have been undertaken:-

One study evaluated the changes in the partial pressure of oxygen. Three different brands of plastic syringe and glass syringes were used. The partial pressure of oxygen measured from the plastic syringes stored at room temperature dropped an average of 1.21 kilopascals / minute for the first ten minutes. When the sample was placed in iced water, the decline decreased to 0.19 kilopascals / minute. The samples collected in glass syringes and stored at room temperature averaged 0.49 kilopascals / minute. This suggested that glass syringes should also be placed on ice (Blonshine 2005:1).

In 1988 a study titled "The Importance of Correct Handling of Samples for the Results of Blood Gas Analysis" was undertaken (Harsten, et al 1988:365). Samples for blood gas analysis were studied in 100 subjects. Sixty minutes storage in iced water lowered the pH by 0.02 pH-units. Storage at room temperature caused considerable changes
in the partial pressure of carbon dioxide and oxygen (0.45 - 1.05 kilopascals). Air bubbles in the syringes increased the partial pressure of oxygen if not expelled within thirty seconds by 1.8 kilopascals and decreased the partial pressure of carbon dioxide by 0.16 kilopascals. The use of plastic syringes induced significant changes in the partial pressure of carbon dioxide and oxygen, the latter by +1.0 kilopascals. The findings of this study highlighted the need for standardization and strict rules in the collection and storage of blood gas samples in order to avoid false results.

Further on from this there are authors that believe samples collected in plastic syringes should be stored on ice to minimize the leucocyte metabolism (Blonshine 2005:1). Klee states (2001:8) it is essential to store the arterial blood samples on ice as the oxygen in the blood continues to diffuse through the plastic syringe thus rendering the partial pressure of oxygen to be lower.

In contrast, studies referred to by Nanji and Whitlow (1984:31:568) found no significant changes in the pH, partial pressure of oxygen and the partial pressure of carbon dioxide in samples kept at room temperature up to two hours. These studies (Nanji and Whitlow 1984:31: 568) found partial pressure of oxygen measurements in samples kept at room temperature to be acceptable only if analysis was performed within thirty minutes of blood drawing. Another study referred to by Nanji and Whitlow (1984:570) showed that the partial pressure of oxygen fell significantly by twenty minutes in samples kept at room temperature whilst pH and the partial pressure of carbon dioxide did not change significantly for up to thirty minutes.

Further Nanji and Whitlow (1984 31:568) evaluated whether arterial blood samples for pH and blood gas analysis need to be transported on ice. Arterial blood samples were obtained from an arterial line in duplicate in heparinized 20 millilitre plastic syringes from 21 subjects in an intensive care unit. One of the samples was stored on crushed ice
at 0 degrees Celsius whilst the other was kept at room temperature, 22 degrees Celsius. Analysis for pH, partial pressure of oxygen and the partial pressure of carbon dioxide was performed on both samples at 0.5, 10, 15, 20, 25, 30 and 60 minutes after obtaining blood. The findings in this study showed that although the changes in pH, partial pressure of oxygen and the partial pressure of carbon dioxide were greater in samples kept at room temperature versus those samples stored on ice, the difference was probably not of clinical significance until the period of time exceeded 20 minutes after blood was drawn. Their recommendations are that blood stored at room temperature be analysed within 20 minutes. They did not state the time period for samples stored on ice.

The researcher noted that the literature dating back to the 1980's showed that nurses were not involved in the analysis of arterial blood gas samples, only in the preparation of the samples. Lynn-Mchale and Carlson (1980:25) provided guidelines for nurses to prepare for the collection of samples for blood gas analysis. They needed the following:

- one 20-25 gauge 1-1½ inch long hypodermic needle
- one 1-5ml syringe with a rubber stopper or cap
- one 1 millilitre ampoule of Sodium Heparin 1:1000 units
- one plastic bag for transport to the laboratory.

(A syringe and needle for withdrawing the heparin into the syringe, a cap to cap the syringe once the blood has been withdrawn and the plastic bag for transporting to the laboratory) There is no mention of ice or what time period the personnel had to get the sample to the laboratory.
The technique of arterial blood gas sampling according to The Respiratory Intensive Care Unit Nursing Manual, Groote Schuur Hospital (Coen (ed), (Sa): 47) is as follows:

The syringe is rolled between the hands to mix the blood and heparin, any air present is expelled and the syringe sealed. The specimen is then labelled and sent on ice to the laboratory with a request form.

From the 1990's to date nurses are more involved in the whole process of arterial blood gas sampling, but still there is discrepancy in the literature on the preparation of the sample as shown in the following information:-

➢ The Bloodgas Handbook suggests the sample be stored at 0 - 4 degrees Celsius for less than thirty minutes in order to slow down metabolism (Radiometer 2001:10).

➢ Szafferski states that if samples are not analysed within 10 minutes then the sample must be stored on ice and not just refrigerated (Klee 2001:8), again there is no storage time stated for the sample stored on ice.

➢ The National Committee for Clinical Laboratory Standards recommended that samples be stored at less than fifteen minutes at room temperature and less than two hours on ice (Klee 2001:11).

➢ Fischbach (2002:154) states that a sample should be analysed within ten minutes and if not the sample should be analysed within one hour. Longer delays can result in changes in oxygen, carbon dioxide and pH levels.

➢ In 2006 the researcher attended a Critical Care Congress at which Radiometer – Copenhagen was represented. A poster was available which stated that pre-heparinized blood samplers with dry heparin be used and analysed within ten minutes. If this is unavoidable the sample is to be cooled to 4 degrees Celsius and analysed within thirty minutes. According to this information liquid heparin can dilute the sample and cause inaccuracies. Pre-
heparinized blood samplers with dry heparin are only available in the private sector at present. The researcher presumes there is a cost factor which is why the state sector still uses the liquid heparin (Radiometer 2004:4).

2.5 PREPARATION FOR AN ARTERIAL BLOOD GAS SAMPLE

Klee (2001:8) referred to an article by Szafirski which emphasises the pre-analytical errors commonly associated with the preparation of an arterial blood gas and of ways to prevent them. Basically the article states:

- there must be no air in the sample
- the sample must be capped to prevent air entering the syringe. Oxygen in room air entering the syringe can influence the partial pressure of oxygen
- Sodium Heparin must not exceed 0.1 millilitre in a 2 millilitre syringe, as too much Sodium Heparin can invalidate an analysis.
- the drawer of the sample must note the inadequate discard volume when drawing from an arterial line.
- instability is associated with storage of the arterial blood gas samples if these are not measured within 10 minutes of being drawn. Instability can contribute to false increases in the partial pressure of carbon dioxide and false decreases in the partial pressure of oxygen
- the samples must be stored on slush ice and not just refrigerated
- leucocyte larceny, (blood containing more than 100,000 white blood cells per millilitre cubed), can occur. The leucocytes in the blood sample can metabolise oxygen and generate carbon dioxide, therefore in patients suffering from leukaemia and leucocytosis it is more critical to process the arterial blood gas sample as quickly as possible or store on ice in order to avoid the false decreases in the partial pressure of oxygen and the false increases in the partial pressure of carbon dioxide (Fischbach 2002:77).
The article by Szafirski to which Klee referred and Klee’s flow chart (Klee 2001:4-12) aided the researcher in setting up for the experiment conducted in this study.

2.5.1 Klee's Flow Chart (Klee 2001:4-12)

Klee (2001:4-12) has reiterated the need for improving the standards of preparing a blood gas sample for analysis, particularly as one of the problems of an arterial blood gas analysis is that its successful result is reliant on human performance. He drew up a flow chart and in each stage he notes that it is a nurse who is generally responsible for the preparation, the drawing of blood and analysing the blood. This flowchart highlights the fact that nurses are therefore responsible for the correct process involved in arterial blood gas analysis. Klee has included eight stages within this chart, each of which highlights the need for training and competence in the realm of arterial blood gas analysis.

Table 2.2 Adapted from Klee’s flowchart (2001:4) follows on page 25

The following is an explanation of Klee’s flowchart:-

2.5.1.1 Stage One - Assessment

The assessment stage refers to the assessment of a patient’s ventilatory status and the timing of drawing an arterial blood gas either by a nurse or clinician.

The performance criteria refers to the competency of the persons involved in the preparation of an arterial blood gas sample which in the researchers experience is always the role of the nurse and occasionally the clinician.
Table 2.2 Klee's flowchart (2001:4)

<table>
<thead>
<tr>
<th>Process block</th>
<th>Responsible person</th>
<th>Performance Criteria</th>
<th>Potential errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assessment</td>
<td>Triage Nurse Clinician</td>
<td>Competency Level of care Response time</td>
<td>Wrong test Wrong entry Wrong time Inapprop. patient</td>
</tr>
<tr>
<td>2. Test Orders</td>
<td>Clinician Nurse Laboratorian</td>
<td>Appropriateness Legibility Accuracy Response Time Time delays</td>
<td>Wrong test Wrong entry Wrong time Inappropriate patient</td>
</tr>
<tr>
<td>3. Specimen Collection</td>
<td>Phlebotomist Nurse</td>
<td>Training Identification Labelling Response Time Anticoagulant Temperature Time delays</td>
<td>Wrong tube Haemolysis Contamination Wrong Patient Wrong Time Wrong Conditions Inadequate Volume</td>
</tr>
<tr>
<td>4. Specimen transport</td>
<td>Phlebotomist Nurse Clerk</td>
<td>Temperature Time delays</td>
<td>Haemolysis Lost stability</td>
</tr>
<tr>
<td>5. Analytical measure</td>
<td>Technologist Nurse Clerk</td>
<td>Training Maintenance Accuracy Precision</td>
<td>Incorrect Procedure Equipment Failure Analytical bias</td>
</tr>
<tr>
<td>6. Report</td>
<td>Technologist Nurse Clerk</td>
<td>Format Error rates Response Time</td>
<td>Transcription error Illegible Delays</td>
</tr>
<tr>
<td>7. Interpretation</td>
<td>Clinician Nurse</td>
<td>Reference data Training Response Time</td>
<td>Wrong reference data Delays Judgement error</td>
</tr>
<tr>
<td>8. Archival</td>
<td>Technologist Clerk</td>
<td>Storage time Storage condition Logging system</td>
<td>Lost specimen Unstable specimen Discarded too soon</td>
</tr>
</tbody>
</table>
Nurses prepare the syringes for drawing blood even when a clinician is involved in drawing blood and in most cases is involved in processing the sample through an analyser. The potential errors involved at this stage involve poor assessment of the patient's condition and poor timing for the need for an arterial blood gas analysis. Improper care plans refers to the fact that oxygen saturation may suffice in planning the ventilation of a patient and an arterial blood gas may not be necessary. An arterial blood gas is a test not to be taken lightly, an incorrect result can often be worse than no result at all (Radiometer 2000:8).

2.5.1.2 Stage Two - Test Orders

Nurses are again involved in this stage. Critical Care nurses can assess a patient's ventilatory status taking into consideration the oxygen saturation and the clinical signs of the patient. Timing of the arterial blood gas is crucial to planning further interventions. If the order to do an arterial blood gas is given then the nurse must ensure that it is the correct patient and the nurse must respond at the correct time approximately 20 minutes after a settings change on the ventilator.

2.5.1.3 Stage Three - Specimen Collection

This is the stage in which the researcher is interested in terms of preparation of an arterial blood gas sample. Klee (2001:4) emphasises the need for training of persons responsible for drawing arterial blood gas samples. The researcher conducted this study in order to highlight the need for the training of nurses involved in drawing blood and its analysis.

There are a few points highlighted which are mandatory for a blood gas analysis. It is the points in the Flow Diagram which the researcher found to be of use in preparing for the experiment in this study:

- correct patient requiring an arterial blood gas analysis
➢ correct labelling of a sample
➢ sufficient anti-coagulant in the syringe
➢ stored at the correct temperature – it is this aspect which the researcher is trying to clarify. How long can a sample be left at room air? Does the nurse place the sample on ice and for how long?
➢ mixing of the sample once blood is drawn is important as the heparin and blood do tend to separate
➢ ensure an adequate volume of blood
➢ training is tabulated which supports the researcher's opinion that this should be an essential aspect of Intensive Care education. Most of the emphasis in the Critical Care Text books is on interpretation of an arterial blood gas.

2.5.1.4 Stage Four – Specimen Transport

Temperature and time delays are the two variables on which the researcher based this study Fischbach (2002:51) states that processing specimens correctly and storing and transporting specimens should be accomplished within fifteen minutes.

2.5.1.5 Stage Five - Analytical Measurement

Most Intensive Care units in the Western Cape have access to a blood gas analyser. The analysers are maintained by Respiratory Technologists who are either employed by the hospital, Private Pathologists or the company supplying the analysers.

Accuracy and precision are important factors in an arterial blood gas analysis. The researcher had to collaborate with the Respiratory Technologist in order to ensure that the analyser that was used for the experiment in this study was calibrated.
Mottram and Blonshine (2006:1) state that published data suggests that the highest rate of error in laboratory testing is not what happens at the bench during analysis but what occurs during the pre-analytical and post-analytical phases of the sample processing cycle.

2.5.1.6 Stage Six - Report

Nurses trained to assess an arterial blood analysis should be able to identify errors within the report. These errors can occur if the sample for example has not been mixed adequately or if there is too much air or heparin in the syringe.

2.5.1.7 Stage Seven - Interpretation

Training is required to interpret the results of an arterial blood gas analysis. Ehrmeyer (2002:1) states that despite sophisticated instrumentation, an accurate and precise result is unlikely unless the operator is familiar with the pre-analytical and post-analytical as well as the analytical phases of the process. It follows therefore that those involved in "Point - of-care" testing be knowledgeable, properly trained and be required to demonstrate ongoing competency.

2.5.1.8 Stage Eight - Archival

Blood gas analysers do have a results printout system. Some do not include the name of the patient unless the name has been entered into the analyser's computer. The nurse must ensure that the result printout is correctly labelled according to the correct patient and placed in the correct patient's file. The nurse must be prudent to await the results before discarding the specimen. The printout on the analyser used in this experiment had no identifying details of the subject thus ensuring confidentiality.
2.6 CONCLUSION

The point of interest was outlined and the nurse's role in the collection of blood gas analysis was highlighted. From the literature reviewed nurses more than ever are becoming involved in "Point-of-Care" testing rather than laboratory trained professionals. It is for this reason that training of nurses in the realm of blood gas analysis has been advocated. The collection of blood gas samples has changed over the years. This was noted in the history of arterial blood gas analysis.

There appears to be discrepancy in the literature with regards to the storage of blood gas samples and the time delay in analysing the samples, it is for this reason that the researcher embarked on this study. The literature made an impact on the researcher which proved to be of use in planning the experiment in this study.

The next chapter will focus on the research design and research methodology which was used to guide this study.
CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

The previous chapter reviewed literature pertaining to arterial blood gas sampling particularly to the method of collection, handling and storage of the sample. This chapter describes the design and the method used by the researcher to collect and analyse the data during the study.

A description of the methods and research process used are important structures within the research as they set guidelines as to the manner in which the study is conducted. The methodological aspects of the study were aimed at describing the purpose of the study which was to determine the relationship between the preparation and handling of the arterial blood gas samples to the analysing of the blood samples and the results.

The objective was to either accept or reject the null hypothesis.

According to Silverman (2000:17) the research methodology refers to the way in which one goes about studying the phenomenon of interest. Henning, van Rensburg and Smith (2004:17) further suggest that research methodology also includes the reasoning strategies that the researcher used. The methodology can then be summed up as a way the researcher argues the stability and utility of the choices of the research process used. These choices depend on the research question to be answered (Speziale and Carpenter 2003:19). This chapter will outline the research design, population and ethical considerations. Following is a detailed discussion of each subheading.
3.2 RESEARCH DESIGN

A research design is the overall plan that a researcher formulates in order to conduct research (Polit, et al 2001:40). Brink (1996:100) states it is the blue print, the pattern or recipe for a study. Research design guides the researcher to choose the methods for the collection of data, the analysis of data and the interpretation of results. Different researchers belong to different categories of design. Mouton (2000:57) states that research designs are tailored to address different kinds of questions or hypotheses. In this study the researcher adopted the quantitative classical/true experimental research design in order to test the hypothesis of cause and effect relationship between the variables. Polit and Hungler (1993:135) are of the opinion that true experimental designs represent a powerful method to test hypotheses of cause and effect relationship between variables. Brink (1999:100) states that experimental nursing research is often the most logically applicable to clinical practice, however, many factors limit the extent to which purely experimental approaches can be used, most notably the fact that the subjects and setting are human. The motivation for the choice of design was based on the researchers keenness to assess the relationship between a dependent variable, in this case the arterial blood gas result, and two independent variables which were the temperature at which an arterial blood gas sample is stored and the time delay from when an arterial blood gas sample is drawn to the time the sample is analysed.

3.3. QUANTITATIVE RESEARCH

Quantitative design is described as the systematic scientific investigation of quantitative properties and phenomenon and their relationship. The process of measurement is central to quantitative research as it provides the fundamental connection between empirical observation and mathematical expression of quantitative relationship
A salient feature of quantitative research is that it emphasises deductive reasoning, through which a researcher can develop hypotheses based on general theoretical principles (Polit and Beck 2004:96).

Quantitative research is most closely allied to the positivist tradition in which the researcher is independent from that which is being researched and is objective (Polit and Beck 2004:14). They state that evidence in the positivist tradition is acquired by deductive processes, it is discrete and there are tight controls over the context, and, furthermore quantitative information is measured including the use of statistical analysis.

Quantitative research focuses on a relatively small number of concepts and it begins with preconceived ideas about how the concepts are interrelated (Brink 1999:13). In this case a blood sample stored at less than ten minutes will be different from that stored at room air for thirty minutes. Objectivity is the essence in collecting data and analysis of the data is done through statistical procedures, in this case inferential statistics (Brink 1999:13). Brink (1999:13) goes on to state that quantitative research incorporates logistical and deductive reasoning. Burns and Grove (2001:19) are of the opinion that quantitative research holds the position that “truth” is absolute and that a single objective reality can be defined by careful measurement.

A quantitative experimental research design was used in this research to determine the relationship of temperature and time delays on the result of an arterial blood gas analysis.

3.4 EXPERIMENTAL RESEARCH

One of the main differences between non-experimental research and
experimental research is that the researcher using an experimental design is an active agent rather than a passive observer (Polit, et al 2001:170). Collection of data is done under controlled conditions.

The advantages and disadvantages of experimental design are:

**Advantages**

Experiments are the most powerful designs for testing hypotheses of cause and effect relationship, particularly because of its special controlling properties. Polit et al state (2001:174) that an experiment offers greater corroboration than any other research approach that the independent variable affects the dependent variable. Experiments have a wide application and can be used in a vast number of situations, biology, industry, medicine and the physical sciences (Clarke 1994:140).

**Disadvantages**

Experimentation in medicine can be difficult as it poses an ethical dilemma. This dilemma arises of having to determine if the potential gain in knowledge from the research outweighs the cost to the research subject. In weighing up the pros and cons the researcher must give primary consideration to the welfare of the participants (Christensen 2004:122). For this reason in some instances manipulation of variables is unethical as it may cause harm to the subjects, either physically or mentally.

The Hawthorne effect, the knowledge that people have of being in a study may change their behaviour (Polit et al 2001:175). In this research the researcher did not have this problem as the researcher was only concerned with blood samples.

In this study a True experiment was conducted. The experiment was conducted in the clinical setting as opposed to a laboratory setting, as this was the most convenient way in which to obtain fresh blood samples from critically ill patients. The Respiratory unit housed a well
maintained, reliable and convenient blood gas analyser, as well as a slush ice machine. All of these were crucial for the experiment.

3.4.1 Manipulation, control and randomization

To qualify as an experiment the research design need possess three properties:

➤ Manipulation, whereby the experimenter does something to the variables in the study (Polit, et al 2001:170), in this case the researcher manipulated the way in which the arterial blood samples were stored and also the length of time that the samples were stored. Nieswiadomy states (1993:133) that the researcher manipulates the independent variable or nursing intervention and the dependent variable or the effects of the nursing intervention are then observed.

➤ Control, the experimenter introduces controls in the study (Polit, et al 2001:170). A control group usually indicates a group in an experimental study that does not receive the experimental treatment (Nieswiadomy 1993:133). Nieswiadomy states in nursing research the withholding of treatment may be considered unethical therefore a comparison group is used rather than a control group that receives no intervention. In this study the researcher used a control group. The arterial blood gas samples which were used as a control were analysed within ten minutes of being drawn. The other samples were analysed at different times and stored differently. This did not pose an ethical problem as the donors of the blood were not in any way affected and consent was obtained before the blood was drawn.
Randomization, the experimenter assigns subjects/variables either to a control group or an experimental group on a random basis (Brink 1999:101). In this case the researcher chose patients in a random fashion and the blood samples drawn were random samples. The blood in a person's arteries is relatively homogeneous, therefore a single sample from a patient was adequate for clinical purposes.

3.5 POPULATION

In order for a researcher to answer the research question or refute or accept the null hypothesis the subjects or objects that can shed light on the phenomenon of interest need to be identified. These subjects are termed the research population.

The population in quantitative research refers to individuals or objects with a common defining characteristic (Polit et al 2001:40). Terminology referring to population includes universal population and accessible population (Burns and Grove 2001: 54). Universal population refers to all the elements with the attributes which the researcher is interested in. The accessible population refers to the portion of the universal population that the researcher has access to. Polit and Beck state (2004:338) that populations are not restricted to human subjects. A population might consist of all the blood samples taken from clients of a health maintenance organization. In this research the researcher chose fifteen subjects who had been admitted to the Respiratory unit of a Tertiary level hospital in Cape Town. The blood samples in this research, three from each of the fifteen subjects, represented the population.
3.6 THE SAMPLE

Fifteen subjects were identified and from each three random samples of arterial blood were drawn. Although this is considered a small number, the fact that this was an experiment and there were tight controls, ensuring a high level of validity and reliability, it was considered an appropriate population.

3.6.1 Sampling process

Sampling is the process of selecting a portion of the population to represent the entire population. A sample is a subset of the population (Polit, et al. 2001: 235).

In this research the researcher chose a group of subjects who were the most accessible. The researcher chose patients who were all ventilated, on forty percent oxygen, critically ill and in the Respiratory unit.

The blood samples had two characteristics of interest for this experiment, the partial pressure of oxygen and the partial pressure of carbon dioxide. Sampling bias is affected by the homogeneity of the population. If the population exhibited no variability a single element would be sufficient for drawing conclusions. (Polit. et al 2001: 235). Polit continues to state that for many physical or physiological attributes it may be safe to assume a reasonable degree of homogeneity, therefore a blood sample is considered to be relatively homogeneous and is adequate for clinical purposes. The researcher chose to take three random samples of arterial blood from fifteen subjects in the Respiratory unit at a Tertiary level hospital in Cape Town.
3.7 DATA COLLECTION

Data collection pertains to the collection of all the facts/figures and information during the research process. Data collection varies depending on the type of research, in this study the researcher chose to collect data by bio-physiological measures. There are two categories of bio-physiological measurements, that is, in vivo measurements which are performed directly in or on living organisms and in vitro measurements which are performed outside the organism’s body, as in the case of measuring serum potassium concentration in the blood (Polit and Beck 2004:441).

Advantages of bio-physiological measures include the following: (Polit and Beck 2004:442):

Bio-physiological measures are accurate and precise compared with psychological measures, they are objective and the bio-physiological instrumentation provides valid measures of the targeted variables. Because the equipment for obtaining bio-physiological measurements is available in hospital settings, the cost of collecting bio-physiologic data may be low.

Disadvantages

The measuring tool may affect the variables it is attempting to measure and the difficulty in choosing bio-physiological measures for nursing studies lies in the selection of appropriate instruments or laboratory analyses with regard to practical, ethical, medical and technical considerations (Polit and Beck 2004 :442).

The researcher undertook an in vitro measurement collecting blood samples from patients and processing the samples through a blood gas analyser.
The researcher collected the data over a period of 1-2 months from December 8 2005 – January 19 2006 and the data collection process took the following steps:

➢ The researcher took the samples of blood herself. This was done in the morning when blood samples are routinely drawn in the Respiratory unit. An arterial blood gas is considered one of the routine bloods on a critically ill patient. The first blood gas drawn was used for the experiment and also as the patient’s blood gas analysis for assessing the patient’s ventilatory status for that particular morning. This was done to avoid any wastage. The other two samples were taken immediately after the first.

➢ Consent was obtained from either a relative (next of kin) of the subject and a copy of the consent was given to the relevant person.
➢ An information sheet was given to the subject or the next of kin.
➢ Blood was drawn into three separate two millilitre syringes all containing 0.1 millilitre of Sodium Heparin and capped.
➢ The first sample was placed on slush ice for thirty minutes and then analysed.
➢ The second sample was kept at room temperature (19 degrees Celsius) for thirty minutes and then analysed.
➢ The third sample was stored at room temperature and analysed within ten minutes.

The sample stored at room air and analysed within ten minutes was used as the control and the other samples as the experimental group.

3.8 VALIDITY AND RELIABILITY OF THE EXPERIMENT

Validity and reliability are of great importance particularly in an experiment where tight controls are required to ensure precision and also because of the small population group.
Accuracy and precision are the hallmarks of biometric, medical and medical technology testing. Precision is used instead of reliability and accuracy in place of validity (Waltz 1991:400).

3.8.1 Validity

Validity is the expression of the degree to which a test is capable of measuring, what it is intended to measure (Beaglehole, Bonita and Kjellstrom 1994:51). Beaglehole et al continue to state that a study is valid if its results correspond to the truth.

Threats to validity are reasons that an inference could be wrong and when researchers can anticipate potential threats to validity and then introduce design features to eliminate or minimize these threats, the validity of the inference is strengthened (Polit and Beck 2004:287). Statistical conclusion validity concerns the validity of inferences that there truly is an empirical relationship, or correlation, between the presumed cause and the effect (Polit and Beck 2004:287). Internal validity is the degree to which the results of an observation are correct (Beaglehole, et al 2004:52). External Validity is the extent to which the results of a study can be applied to other people or measures that are not in the study (Beaglehole, et al 2004:52).

The researcher to ensure accuracy or validity followed a very correct technique in preparing the arterial blood gas samples so that the results were not influenced by extraneous variables.

In the experiment the following precautions were taken:-

➢ a two millilitre plastic syringe was used for each sample.
➢ a 0.1 millilitre of Sodium Heparin (One thousand units per millilitre) was drawn into each syringe before the blood was drawn to prevent clotting. It has been found that using a two millilitre syringe with 0.5
millilitre of Sodium Heparin will cause a 20% dilution resulting in a sixteen percent lowering of the partial pressure of oxygen (Klee 2001:8).

➢ two millilitres of arterial blood was drawn into the two millilitre syringe and air bubbles were removed. Air bubbles can change the level of the partial pressure of oxygen (Klee 2001:8).

➢ each syringe was capped after the blood was drawn. Room air contains twenty kilopascals of oxygen at sea level, so if room air is allowed to enter the syringe the high blood gas levels become lower and the low blood gas levels become higher (Klee 2001:8).

➢ the first few millilitres of blood drawn from an indwelling arterial catheter were mixed with heparinized saline. The researcher had to ensure that the first few millilitres of blood were discarded.

➢ each of these samples was analysed and the data recorded.

➢ in total fifteen subjects gave their consent and three samples from each subject were drawn.

➢ the researcher was the sole person involved in the drawing of blood and in processing the blood through the analyser.

3.8.2 Reliability

Reliability refers to the accuracy and consistency of information obtained in a study, furthermore the term is most often associated with the methods used to measure research variables, that is the instrument used, for example a thermometer (Polit and Beck 2004:196) and in this study the blood gas analyser.

To ensure reliability or precision and to prevent changes in the analytical bias the same blood gas analyser was used, the ABL 520 bench top analyser.
3.9 ETHICAL ISSUES

The ethical issues pertaining to conducting experiments with human tissue and blood products relates to respect for the person (see Chapter 1).

One of the most fundamental ethical principles in research is that of beneficence which encompasses the maxim, above all, do no harm (Polit, et al 2001:75).

Individuals are autonomous which means they have the right to self determination and have the right to decide voluntarily whether or not to participate in a study. Individuals with diminished autonomy require protection. This group includes children, the mentally impaired, the unconscious and institutionalised (Brink 1999:39).

The researcher observed and adopted the following ethical principles and constraints in undertaking this research. The research protocol was submitted to the University of South Africa, Faculty of Health Sciences Ethics Committee and the University of Cape Town, Research Ethics Committee and approved (Annexure B-E).

3.9.1 Informed consent

Informed consent means that participants have adequate information regarding the study, that they comprehend the information and have the power to either consent to the study or decline to participate (Polit, et al 2001:78).

Consent was acquired as follows:

- a letter requesting permission to conduct research in the Tertiary level hospital was sent to the Deputy Director Nursing. Permission was granted on condition that application was made to the Research Ethics Committee in the Hospital (Annexure A).

- a letter together with a Research Proposal requesting permission to conduct the study in the Tertiary level hospital was sent to the Research Ethics Committee at the Health Science Faculty,
University of Cape Town (Annexure E). This was granted on condition that a member of staff was appointed to supervise the research.

- a letter and a copy of the Research Proposal was sent to a medical consultant in the Respiratory unit in the Tertiary level hospital. Permission was granted to conduct the research under his supervision.

- a letter and the Research Proposal was sent to the Chief Professional Nurse in charge of the Respiratory unit.

- a letter and a copy of the Research Proposal was sent to the Respiratory Technologist of the Respiratory unit.

- a consent form was given to each subject on the understanding that the subject or their next of kin could refuse to participate (Annexure F).

- an information sheet detailing the nature of the study and purposes was given to each subject (Annexure G).

3.9.2 Confidentiality

Confidentiality refers to the management of private information regarding the subjects involved in the study. No subject could be linked to this research as the names of the subjects were not included.

3.9.3 Handling of the samples

The arterial blood gas samples were numbered and only handled by the researcher.

3.10 DATA ANALYSIS

Quantitative analysis is always associated with measurement. Whatever exists in some amount can be measured (Polit 1996:337). The most powerful tool available to researchers when
analysing quantitative data is statistics. In this study inferential statistics were used as these help to determine the difference between groups. The inferential statistic used in this study was a bi-variate test. The chi-squared test is a non-parametric procedure used to test hypotheses about the proportion of cases that fall into various categories (Polit 2001:356). The chi-squared test contrasts the observed frequencies within actual data (Polit 1996:194). In this research the data observed was that of the results of the experiment.

3.11 CONCLUSION

This chapter focused on the methods to conduct the research as well as the population, sampling, data collection, validity and reliability. Ethical issues will be discussed including informed consent and confidentiality.

In Chapter 4 analysis and interpretation of the results are discussed.
CHAPTER 4

ANALYSIS AND DISCUSSION OF RESEARCH RESULTS

4.1 INTRODUCTION

The purpose of this research was to determine if there is a relationship between the preparation of an arterial blood gas sample and the result following analysis. An experiment was undertaken and fifteen subjects (n=15) were included in the research study. Three samples of arterial blood were taken from each subject after consent was obtained. The random arterial samples were subjected to manipulation by being stored at different temperatures and for varying lengths of time.

The purpose of the study was to look at two aspects in the preparation of an arterial blood gas sample which may affect the outcome of the result following analysis.

➢ the first was to determine the relationship between the temperature at which an arterial blood gas sample is stored and the result following the analysis.

➢ the second was to determine if there was a relationship in the time from the drawing of the arterial blood gas sample to the result following analysis.

In this research the researcher looked specifically at the partial pressure of oxygen and the partial pressure of carbon dioxide, as it is these two factors which could be most affected by changes in temperature and time delays in analysing the arterial blood gas sample.
4.2. Inferential non parametric chi – squared test

The most frequently used nonparametric test is the chi-square statistic and according to Brink (1999:191) is one of the most widely used in nursing research. This test is designed to make inferences about the existence of the relationship between two or more categorical variables (Polit 1996:193).

4.2.1 The variables in this study

In this research the independent variables were the temperature at which an arterial blood gas sample is stored and the time delay between the drawing of an arterial blood gas sample and processing of the sample through an analyser, the dependent variable was the arterial blood gas result. By manipulating the temperature and storage time of the samples the researcher endeavoured to show the impact and therefore a relationship on the partial pressure of oxygen and the partial pressure of carbon dioxide following analysis. The null hypothesis would endeavour to state that there was no relationship.

4.2.2 The null and alternative hypotheses for the chi- squared test

The null hypothesis for the chi-squared test stipulates the absence of a relationship between the independent and dependent variables.

The researcher formulated the following null and alternative hypothesis.

$H_0$: Null hypotheses:

- there is no relationship between temperature and time delays on the partial pressure of oxygen (within arterial blood gas result).
there is no relationship between temperature and time delays on the partial pressure of carbon dioxide (within the arterial blood gas result).

H₁: Alternative hypotheses:

- there is a relationship between temperature and time delays on the partial pressure of oxygen (within arterial blood gas result).
- there is a relationship between temperature and time delays on the partial pressure of carbon dioxide (within the arterial blood gas result).

Nieswiadomy (1993:291) states that the chi squared test is appropriate for comparing sets of data that are in the form of frequencies or percentages.

The chi-squared test contrasts the observed frequencies in each cell of a contingency table (i.e., the frequencies observed within the actual data) with expected frequencies (Polit 1996:194). The expected frequencies represent the number of cases that would be found in each cell if the null hypothesis were true - that is, if the variables were totally unrelated (Polit 1996:194). In this study, that the manner of storage and the time delays experienced by the arterial blood gas sample have no relationship on the result of the arterial blood gas. If the actual, observed frequencies in a contingency table are identical to the expected frequencies, the value of the chi-squared statistic will equal 0, which is also the population value of chi-squared when the variables are unrelated (Polit 1996:195). The computed value of the chi-squared statistic must be compared to a critical value in a table to determine if the value of the statistic is improbable at a specified level of probability (Polit 1996:195).
## 4.3 The data of the results following an experiment

Table 4.1 Data of the results of the arterial blood gas following analysis = partial pressure of oxygen

<table>
<thead>
<tr>
<th>Number</th>
<th>Analysis after 10 mins-room air</th>
<th>Analysis after 30 mins-room air</th>
<th>Analysis after 30 mins-on slush ice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21.42</td>
<td>21.50</td>
<td>23.53</td>
</tr>
<tr>
<td>2</td>
<td>7.63</td>
<td>7.72</td>
<td>7.88</td>
</tr>
<tr>
<td>3</td>
<td>16.86</td>
<td>16.98</td>
<td>18.28</td>
</tr>
<tr>
<td>4</td>
<td>16.48</td>
<td>16.65</td>
<td>18.78</td>
</tr>
<tr>
<td>5</td>
<td>10.79</td>
<td>11.43</td>
<td>11.33</td>
</tr>
<tr>
<td>6</td>
<td>10.79</td>
<td>15.64</td>
<td>21.62</td>
</tr>
<tr>
<td>7</td>
<td>26.03</td>
<td>22.48</td>
<td>27.73</td>
</tr>
<tr>
<td>8</td>
<td>22.99</td>
<td>20.59</td>
<td>23.64</td>
</tr>
<tr>
<td>9</td>
<td>23.93</td>
<td>21.60</td>
<td>27.52</td>
</tr>
<tr>
<td>10</td>
<td>11.19</td>
<td>10.62</td>
<td>11.73</td>
</tr>
<tr>
<td>11</td>
<td>22.30</td>
<td>20.61</td>
<td>23.21</td>
</tr>
<tr>
<td>12</td>
<td>11.46</td>
<td>11.67</td>
<td>12.12</td>
</tr>
<tr>
<td>13</td>
<td>11.78</td>
<td>11.44</td>
<td>10.67</td>
</tr>
<tr>
<td>14</td>
<td>10.55</td>
<td>11.35</td>
<td>12.80</td>
</tr>
<tr>
<td>15</td>
<td>13.11</td>
<td>12.92</td>
<td>13.68</td>
</tr>
</tbody>
</table>
Table 4.2  Data of the results of the arterial blood gas following analysis
= partial pressure of carbon dioxide

<table>
<thead>
<tr>
<th>Number</th>
<th>Analysis after 10 mins-room air</th>
<th>Analysis after 30 mins-room air</th>
<th>Analysis after 30 mins-on slush ice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4.28</td>
<td>4.43</td>
<td>4.38</td>
</tr>
<tr>
<td>2</td>
<td>9.08</td>
<td>9.24</td>
<td>9.35</td>
</tr>
<tr>
<td>3</td>
<td>3.74</td>
<td>3.83</td>
<td>3.75</td>
</tr>
<tr>
<td>4</td>
<td>4.77</td>
<td>4.89</td>
<td>4.89</td>
</tr>
<tr>
<td>5</td>
<td>4.97</td>
<td>5.06</td>
<td>5.02</td>
</tr>
<tr>
<td>6</td>
<td>5.39</td>
<td>5.51</td>
<td>5.59</td>
</tr>
<tr>
<td>7</td>
<td>4.71</td>
<td>4.75</td>
<td>4.66</td>
</tr>
<tr>
<td>8</td>
<td>5.26</td>
<td>5.35</td>
<td>5.54</td>
</tr>
<tr>
<td>9</td>
<td>5.02</td>
<td>5.27</td>
<td>5.50</td>
</tr>
<tr>
<td>10</td>
<td>5.70</td>
<td>5.76</td>
<td>5.65</td>
</tr>
<tr>
<td>11</td>
<td>5.29</td>
<td>5.32</td>
<td>5.38</td>
</tr>
<tr>
<td>12</td>
<td>7.90</td>
<td>8.06</td>
<td>7.97</td>
</tr>
<tr>
<td>13</td>
<td>4.50</td>
<td>4.44</td>
<td>4.36</td>
</tr>
<tr>
<td>14</td>
<td>4.46</td>
<td>4.30</td>
<td>4.43</td>
</tr>
<tr>
<td>15</td>
<td>4.53</td>
<td>4.68</td>
<td>4.54</td>
</tr>
</tbody>
</table>

There were three samples of arterial blood taken from each subject. The first sample was stored at room air and was analysed within ten minutes after being drawn. The second sample was drawn and stored at room air and analysed within thirty minutes and the third was stored on slush ice and analysed within thirty minutes.
4.4 THE SUMMARY OF RESULTS AS RECOMMENDED BY AN ACCREDITED STATISTICIAN

The chi-squared test, as recommended by an accredited statistician, can be applied to ratio data that have been classified into a small number of groups, furthermore the chi-squared test assumes that the observations are randomly and independently sampled from the population of interest (Polit 1996:196). This was the case in this study.

The calculation of the standard deviation with regard to the partial pressure of oxygen and the partial pressure of carbon dioxide is shown in Table 4.3 and 4.4 on pages 49 and 50 respectively.

Table 4.3  Data following calculation of the standard deviation with regard to the partial pressure of oxygen (PO²)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>MINIMUM</th>
<th>MAXIMUM</th>
<th>MEAN</th>
<th>STANDARD DEVIATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO₂ AT ROOM TEMP WITHIN 10MINS</td>
<td>15</td>
<td>7.63</td>
<td>26.03</td>
<td>15.8207</td>
<td>6.01104</td>
</tr>
<tr>
<td>PO₂ AT ROOM TEMP AT 30 MINS</td>
<td>15</td>
<td>7.7</td>
<td>22.5</td>
<td>15.547</td>
<td>4.8799</td>
</tr>
<tr>
<td>PO₂ ON SLUSH ICE AT 30 MINS</td>
<td>15</td>
<td>7.88</td>
<td>27.73</td>
<td>17.6347</td>
<td>6.58379</td>
</tr>
</tbody>
</table>
Table 4.4 Data following calculation of the standard deviation with regard to the partial pressure of carbon dioxide (PCO₂)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>MINIMUM</th>
<th>MAXIMUM</th>
<th>MEAN</th>
<th>STANDARD DEVIATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO₂</td>
<td>15</td>
<td>3.74</td>
<td>9.08</td>
<td>5.3127</td>
<td>1.39881</td>
</tr>
<tr>
<td>Room Temp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCO₂</td>
<td>15</td>
<td>3.83</td>
<td>9.24</td>
<td>5.3827</td>
<td>1.44115</td>
</tr>
<tr>
<td>Room Temp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCO₂</td>
<td>15</td>
<td>3.75</td>
<td>9.35</td>
<td>5.4007</td>
<td>1.45928</td>
</tr>
<tr>
<td>On ice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.4.1 The standard deviation

With interval or ratio – level data the most widely used measure of variability is the standard deviation which indicates the average amount of deviation values from the mean (Polit and Beck 2004:565).

4.4.1.1 The result of the standard deviation with regard to the partial pressure of oxygen

The mean value in the case of samples held on ice for 30 minutes (17.6347) is larger than the other two means (15.8207 and 15.547). To test whether these observed differences are statistically significant a Friedman test was performed.
4.4.1.2 The result of the standard deviation with regard to the partial pressure of carbon dioxide.

The mean at room temperature at ten minutes (5.3127) is somewhat lower than the other two means (5.3827 and 5.4007). A Friedman test was conducted to test whether these three means are significantly different.

4.4.2 Friedman test

The Friedman test is used when there are three or more correlated groups (Polit 1996:211) or repeated measures situations (Polit and Beck 2004:754). The results of this test are shown in Table 4.5 with regards the partial pressure of oxygen and in Table 4.6 with regards the partial pressure of carbon dioxide.

Table 4.5 The Friedman test – data regarding the partial pressure of oxygen

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CHI-SQUARE</td>
<td>14.533</td>
</tr>
<tr>
<td>Df DEGREE OF FREEDOM</td>
<td>2</td>
</tr>
<tr>
<td>ASYMPTOTIC SIGNIFICANCE</td>
<td>0.001</td>
</tr>
</tbody>
</table>

4.4.2.1 The result of the Friedman test with regards to the partial pressure of oxygen

The asymptotic significance is less than 0.05, which means that there is a significant difference between the three means at the 5% level of
significance. To establish where the significant differences lie, pairwise tests were done based on the Wilcoxon signed ranks test.

Table 4.6 The Friedman test – data regarding the partial pressure of carbon dioxide

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>15</td>
</tr>
<tr>
<td>CHI-SQUARE</td>
<td>5.298</td>
</tr>
<tr>
<td>Df DEGREE OF FREEDOM</td>
<td>2</td>
</tr>
<tr>
<td>ASYMPTOTIC SIGNIFICANCE</td>
<td>0.071</td>
</tr>
</tbody>
</table>

4.4.2.2 The result of the Friedman test with regards to the partial pressure of carbon dioxide

The results revealed that there was a significant difference between the means at the 10% level of significance. To establish where the significant differences lie a pairwise test was done based on the Wilcoxon signed ranks test. The results of the Wilcoxon signed ranks tests are shown in Table 4.7 and 4.8 on pages 53 and 54 respectively.
4.4.3 The Wilcoxon signed ranks test

The Wilcoxon signed ranks test is a nonparametric counterpart of the paired t-test and is used to test for group differences (Polit 1996: 208).

The Wilcoxon signed ranks procedure tests the null hypothesis that the population distributions for the two sets of observations are identical against the alternative hypothesis which states the observations are not identical (Polit 1996:208).

Table 4.7 The Wilcoxon signed ranks test = data regarding the partial pressure of oxygen

<table>
<thead>
<tr>
<th></th>
<th>Z</th>
<th>ASYMPOTOTIC SIGNIFICANCE (2-TAILED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{PO}_2 ) at room temp at 30mins -</td>
<td>-5.68</td>
<td>0.570</td>
</tr>
<tr>
<td>( \text{PO}_2 ) room temp within 10 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \text{PO}_2 ) on ice at 30 mins -</td>
<td>-2.954</td>
<td>0.003</td>
</tr>
<tr>
<td>( \text{PO}_2 ) at room temp within 10 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \text{PO}_2 ) on ice at 30mins -</td>
<td>-3.067</td>
<td>0.002</td>
</tr>
<tr>
<td>( \text{PO}_2 ) at room temp at 30 mins</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.4.3.1 The result of the Wilcoxon signed ranks test with regards to the partial pressure of oxygen

The result of the Wilcoxon signed ranks test (shown on page 53) shows that there is no significant difference between the readings at room temperature, whether tested within ten minutes or at thirty minutes. However the mean value was significantly higher after being kept on ice for thirty minutes. This means that for the partial pressure of oxygen the main factor is temperature and not time.

Table 4.8 The Wilcoxon signed ranks test: = data regarding the partial pressure of carbon dioxide

<table>
<thead>
<tr>
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<th>ASYMPTOTIC SIGNIFICANCE (2 TAILED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCO₂ AT ROOM TEMP - 30 MINS – PCO₂ AT ROOM TEMP WITHIN 10 MINS</td>
<td>-2.171</td>
<td>.030</td>
</tr>
<tr>
<td>PCO₂ ON ICE AT 30 MINS – PCO₂ AT ROOM TEMP WITHIN 10 MINS</td>
<td>-1.761</td>
<td>.078</td>
</tr>
<tr>
<td>PCO₂ ON ICE AT 30 MINS - PCO₂ AT ROOM TEMP AT 30 MINS</td>
<td>-.503</td>
<td>.615</td>
</tr>
</tbody>
</table>
4.4.3.2 The result of the Wilcoxon signed ranks test with regards to the partial pressure of carbon dioxide

At the 10% level of significance the mean of the partial pressure of carbon dioxide at room temperature and analysed within ten minutes differs significantly from the means after thirty minutes with or without ice. Therefore, in the case of the partial pressure of carbon dioxide time is the main factor not temperature. These results are shown on page 54.

4.5 THE NULL HYPOTHESES: THE PARTIAL PRESSURE OF OXYGEN

The Null Hypothesis aims to demonstrate that there was no relationship between the independent and the dependent variable. In this study the results of the experiment show that there was a relationship between the arterial blood gas sample and the result of the arterial blood gas. It was therefore stated that the null hypothesis be rejected in favour of the alternative hypothesis. The researcher expected the partial pressure of oxygen in the arterial blood gas sample stored on slush ice and analysed at thirty minutes to be higher than that stored at room air for thirty minutes. The results of this experiment showed this to be so. However, the researcher also expected the partial pressure of oxygen in the arterial blood gas sample to be the same when stored at room air and analysed within ten minutes as the arterial blood gas sample stored on ice and analysed at thirty minutes after being drawn. This was not the case. The results of the samples on room air analysed within ten minutes and at thirty minutes show no significant difference. The arterial blood gas sample stored on slush ice and analysed at thirty minutes shows means that are much higher than the other two samples. The
relationship highlights the fact that with regards the partial pressure of oxygen, temperature is the main factor and not time.

4.6 THE NULL HYPOTHESES: THE PARTIAL PRESSURE OF CARBON DIOXIDE

The null hypothesis aims to demonstrate that there was no relationship between the independent variable and the dependent variable. The results of the Wilcoxon signed ranks test showed there was an effect on the partial pressure of carbon dioxide within the arterial blood gas result, showing a relationship between storage and the time at which the sample was analysed and the result of the arterial blood gas sample. The researcher expected the partial pressure of carbon dioxide in the arterial blood gas sample stored at room temperature and analysed within ten minutes to be lower than that stored at room temperature for thirty minutes which is what the results show.

The partial pressure of carbon dioxide in the arterial blood gas sample stored at room air and analysed within ten minutes is not the same as that stored on slush ice and room air (and analysed at thirty minutes) as expected. The results indicate that the means are lower than that stored on slush ice and that stored at room air. The researcher has shown that there was a relationship between the independent and dependent variables and can therefore reject the null hypothesis and accept the alternate hypothesis. The relationship highlights the fact that with regards the partial pressure of carbon dioxide, time is the main factor and not temperature.

4.7 CONCLUSION

The researcher looked specifically at two factors contained in arterial blood gas samples, that is the partial pressure of oxygen and the
partial pressure of carbon dioxide in order to highlight the existence of a relationship between the way arterial blood gas samples were stored and the time at which the samples were analysed and the result of the analysis. The researcher set about by using a non parametric test, the chi-squared test as recommended by Professor F. Steffens. A relationship was found and the null hypothesis was rejected in both the case of the partial pressure of oxygen and the partial pressure of carbon dioxide.

Further tests were used to test the significance of the differences, that is, the Friedman test. These showed a significant difference within the result with regard both the partial pressure of oxygen and the partial pressure of carbon dioxide. In order to discover where the significant differences lay; the Wilcoxon signed ranks test was used.

The results with regard to the partial pressure of oxygen showed that there was a significant difference between the readings at room temperature, whether tested within ten minutes or at thirty minutes, and the readings at thirty minutes and stored on slush ice. The partial pressure of carbon dioxide also showed a significant difference and the Wilcoxon signed ranks test revealed that the mean at room temperature and tested within ten minutes differed significantly from the means analysed at thirty minutes whether stored at room air or on slush ice. The researcher was therefore able to accept the alternate hypothesis and reject the null hypothesis.

The next chapter will present the conclusions, limitations and recommendations pertaining to this research.
CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, LIMITATIONS OF THE STUDY

5.1 INTRODUCTION

In Chapter 4 the results of the research were discussed. In this Chapter the researcher is able to present the conclusions of the research, and, furthermore will make recommendations based on the findings for all health professionals involved in patient care in intensive care units, theatre and in the emergency units. Furthermore recommendations for future research and the limitations of this study will be presented.

5.2 THE PURPOSE OF THE STUDY

The purpose of the research was to look at two aspects in the preparation of an arterial blood gas sample which may affect the outcome of the result following analysis:

➢ the first was to determine a relationship between the temperature at which an arterial blood gas sample is stored and the result following analysis of the arterial blood gas sample and specifically the partial pressure of oxygen and the partial pressure of carbon dioxide.
➢ the second was to determine if there is a relationship between the time at which an arterial blood gas is analysed after it has been drawn and the result of an arterial blood gas sample after
analysis and specifically the partial pressure of oxygen and the partial pressure of carbon dioxide.

5.3 OBJECTIVE OF THE STUDY

The objective of the study was to either accept or reject the null hypotheses.

5.4 THE NULL AND ALTERNATIVE HYPOTHESES

The researcher formulated a null hypothesis, that there was no relationship between the independent variable and the dependent variables, whilst the alternative hypothesis was formulated to show that there was a relationship.

\( H_0: \) Null hypotheses:

- there is no relationship between temperature and time delays on the partial pressure of oxygen (within the arterial blood gas result).
- there is no relationship between temperature and time delays on the partial pressure of carbon dioxide (within the arterial blood gas result).

\( H_1: \) Alternative hypotheses

- there is a relationship between temperature and time delays on the partial pressure of oxygen within the result of the analysis
there is a relationship between temperature and time delays on the partial pressure of carbon dioxide within the result of the analysis.

The results revealed that the researcher was able to reject the null hypothesis, which was that there was no relationship between the independent variables, that is, the temperature at which a sample is stored and the time delay from the time a sample is drawn to the analysis and the dependent variable, the arterial blood gas result, in particular the partial pressure of oxygen and the partial pressure of carbon dioxide. The researcher therefore was able to accept the alternative hypothesis, that there is a relationship between the independent variables, temperature and time delays and the dependent variable, the arterial blood gas result.

5.5 A DISCUSSION OF THE CONCLUSIONS

The following discussion was drawn from the statistical data analysis and the researcher has attempted to relate this data to other research on the topic which support the findings of this study.

5.5.1 The partial pressure of oxygen

In this study the partial pressure of oxygen showed no significant difference when stored at room temperature and analysed within ten minutes and at thirty minutes, stored at room temperature. There was however, a significant difference in the partial pressure of oxygen when the arterial blood gas sample was stored on sush ice. The means were significantly higher.
This appears to be in keeping with what Narayanan (2005:3) states that the increase in the partial pressure of oxygen in specimens collected in plastic syringes and stored on ice has been attributed to the influx of exogenous oxygen through the walls of the plastic syringe. This influx of oxygen into the plastic is due to the very high concentrations of oxygen in ice water. In the study by Nanji and Whitlow (1984:569) there was a decrease in the partial pressure of oxygen from twenty minutes onwards when the sample was stored at room temperature. Nanji and Whitelow (1984:570) referred to a study by Madeido et al which found partial pressure of oxygen measurements in samples kept at room air to be acceptable only if analysis was performed within thirty minutes of blood drawing.

In 1992 a German study compared the stability of blood gases, electrolytes and haemoglobin stored in ice water for forty five minutes in six different types of syringes, one glass and five plastic syringes (Blonshine 2005:3). The authors concluded that samples collected in a plastic syringe should be analysed within fifteen minutes or a glass syringe should be used. Wu et al (Blonshine 2005:3) studied the source of errors in the partial pressure of oxygen. They examined the impact of time delays in sample analysis on blood gases, pH and base excess, also on specimens collected in plastic and glass syringes. The authors recommended storage at room air when specimens are collected in plastic syringes and immediate analysis of the specimen. The consistent recommendation (including the findings of this study) is that specimens collected in a plastic syringe be analysed within a fifteen to thirty minute window (Blonshine 2005:3).
5.5.2 The partial pressure of carbon dioxide

In this study the partial pressure of carbon dioxide in the sample being stored at room air and analysed within ten minutes showed a significant difference from the sample stored at room air for thirty minutes and that stored on slush ice for thirty minutes. There was no difference between that stored at room temperature and analysed at thirty minutes and the sample stored on slush ice and analysed at thirty minutes.

The mean (partial pressure of carbon dioxide) of the sample analysed within ten minutes and stored at room temperature is lower than the other two means (stored for thirty minutes at room air and on slush ice). Ishikawa (Nanji and Whitlow 1984:570) found no significant changes in samples kept at room temperature for up to two hours. A study by Harsten et al (1988:366) showed that there were changes in the partial pressure of carbon dioxide, but, only after forty minutes. Biswas et al (Nanji and Whitlow 1984:270) showed that samples kept at room temperature for up to thirty minutes showed no change in the partial pressure of carbon dioxide.

Nanji and Whitlow stated (1988:569) that their study showed an upward trend in the partial pressure of carbon dioxide in specimens stored at room temperature particularly after thirty minutes which is in keeping with this study.

5.6 RECOMMENDATIONS

According to the results of the research done in the Respiratory unit at a Tertiary hospital in Cape Town it would appear that an arterial
blood gas be preferably analysed within ten minutes, however, up to thirty minutes at room temperature is safe and in keeping with this study and with studies such as Nanji and Whitlow (1984:570), Narayanan (2005:1) and the recommendations of the Clinical and Laboratory Standards Institute (Blonshine 2001:1), therefore storage on slush ice is not necessary.

5.6.1 Training and education

Further recommendations are that a training programme be made available to all health professionals involved in arterial blood gas analysis, whether this be the Intensive care units, Emergency and Trauma units or the Operating Theatre, with special attention to the handling and storage of the samples. The Radiometer (2004:2) philosophy states that education is the way to control sample quality and that equipment alone is not enough to ensure sample quality in the pre-analytical phase. Just as important is user knowledge about how to handle the sample and avoid errors that bias the results.

Within the current health care climate patients are becoming sicker. It is therefore not unusual for a nurse to care for patients who require frequent arterial blood tests (Allen, et al 2005:45). As a result of this and the fact that blood gas analysers are being placed in the clinical work place nurses are expected to acquire skills previously the domain of laboratory technicians.

While the immediate availability of test data can be a definite advantage in many situations an inaccurate or incorrect result creates additional problems (Ehrmeyer 2002:1). Personnel competencies particularly for non laboratory staff, is therefore important. This study supports this notion and recommends
competency certification for nurses who are responsible for drawing, analysing and interpreting arterial blood gases.

5.6.2 Nursing practice and blood gas quality control for the future

Published data suggests that the highest rate of error in laboratory testing is not what happens at the bench during analysis but what occurs during the sample processing cycle (Mottram and Blonshine 2005:1). Currently in South Africa there is a trend to quality care according to international standardisation and to risk management. In 2005 Mottram and Blonshine (2005:1) spoke of this and quality models of the future. They felt the need to address all procedures through the path of a workflow system which is aimed at reducing mistakes that increase costs to the institution and to the patient. To improve quality risk management principles can be utilized. Nurses can easily assess risk by first developing a flowchart so that an understanding can be established of what steps need to be followed and identifying which steps could fail and what steps need to be controlled. Figure 5.1 on page 65a is an example of a flowchart which could be adapted to an Intensive care unit setting, Emergency unit or Operating Theatre. A flowchart could also be devised for diagnostic studies such as the arterial blood gas flowchart as shown in Figure 5.2 on page 65b which was compiled by the researcher.
Figure 5.1 - Flowchart as adapted from Mottram and Blonshine (2005:2)

**Patient Identification**

- Arterial blood gas on oxygen
  - Monitor for 20 minutes
  - Is $\text{SaO}_2$ (saturation of oxygen) < 90%? *no*
    - Call MO
    - Does MO want to increase oxygen? *no*
  - Is $\text{SaO}_2$ (saturation of oxygen) < 90%? *yes*
    - Call MO
   - Resume oxygen flow, call MO

- Arterial blood gas on room air
  - Did patient arrive on oxygen? *no*
    - Take patient off oxygen
  - Did patient arrive on oxygen? *yes*
    - Take patient off oxygen
    - Monitor saturation of oxygen
    - Is saturation ≤ 85%? *no*
      - Leave patient on room air for 20 minutes
    - Is saturation ≤ 85%? *yes*
      - Leave patient on room air for 20 minutes

- Select site and draw arterial blood gas
  - Check blood gas result is pH < 7.35, PaO2 < 12 and PCO2 ≥ 6? *yes*
    - MO informed of blood result
  - Check blood gas result is pH < 7.35, PaO2 < 12 and PCO2 ≥ 6? *no*
    - MO informed of blood result

Abg testing is complete
Figure 5.2 An example of a flowchart for an arterial blood gas (Abg) sample

Clinical Assessment of patient

Pre-analysis

Correct Patient

Risk Precautions e.g. gloves
Aseptic technique

Syringe type to withdraw blood

Prepacked 2ml syringe with lithium Heparin (dried)

2ml syringe with sodium Heparin (liquid) Prepared by nurse

Withdraw 2ml blood from patient

Cap syringe after drawing blood

Correct patient check

Label sample
  • Analyse within 10 minutes
  • Store at room temperature
  • Maximum time delay - 30 minutes at room temperature

Analysis

Reliable calibrated blood gas analyser

Probe suction

Inject

Ensure blood is well mixed

Sufficient blood 2ml

No air bubbles in syringe

Correct patient

Correct label

Process through analyser

Post analysis

Correct patient

Check label

Inform medical officer if values are outside the norm

Adjust oxygen delivery to patient according to the Abg clinical assessment and medical officer's prescription

Compiled by the researcher 2007
L.M. Baker
D'Archangelo (2007:1) reiterates the usefulness of a path of workflow in the statement: healthcare services can implement a quality management system, as do many manufacturing and service centres, by understanding and monitoring the path of workflow.

5.7 LIMITATIONS OF THE STUDY

ARTERIAL BLOOD GAS: AN EXPERIMENT TO STUDY THE EFFECTS OF TEMPERATURE AND TIME DELAYS ON THE OUTCOME OF A BLOOD GAS RESULT

Quantitative results often offer the consumer more interpretive opportunities than qualitative ones – in large part, because a quantitative report can summarize much of the study data, furthermore, the researcher has the task not only to interpret the results but also to assess their accuracy and credibility (Polit, et al 2001:407). Evaluation of a particular research should be based on an analysis of evidence both external and internal (Polit, et al 2001: 407). The researcher in this case believes that the results are consistent with prior research (external evidence) which enhances the credibility of the research. However, other research (Nanji and Whitlow 1984:569) used the Student’s paired t test as the statistic for analysis, whereas in this research the chi-squared test was the statistic of choice. The choice of data analysis may have yielded a different result in this case, but, the researcher is confident that because this research is consistent with other studies as stated the results reflect credibility and accuracy.

The size of the sample may have been small, n=15. The researcher feels that because it was an experiment and every effort was made
to ensure validity and reliability it is a credible sample. Nanji and Whitlow (1984:568) used 21 patients for their study.

5.8 RECOMMENDATIONS FOR FUTURE RESEARCH

The first blood gas analysis system was invented in 1957 (Royal College of Surgeons 2006:1) which revolutionized medicine and patient care. From glass syringes to plastic disposable syringes to pre-packaged sampling syringes containing dried heparin, blood gas analysis continues to evolve. Instrumentation will continue to become more sophisticated and systems that use in vivo technology will also advance. Mottram and Blonshine state (2005:3) that in order to ensure accurate results for patients there will continue to be a need for quality control or quality systems models.

The inclusion of electrolytes in the test repertoire excludes the use of sodium heparin in favour of lithium heparin (Higgins 2007:4). This provides another area for future study.

5.9 SUMMARY

A true experiment was conducted in order to reject or accept the null hypotheses. The results showed that there was a relationship between the dependent variable, the arterial blood gas result and the independent variables, the temperature at which an arterial blood gas was drawn and
the time delay from the time the arterial blood gas was drawn to the time of analysis. The alternative hypothesis was therefore accepted.

The main recommendations of this research were discussed and it was felt that an arterial blood gas be analysed within ten minutes and stored at room temperature, however, if there is a delay, then within thirty minutes at room temperature is considered safe. This is also the recommendation of the Clinical and Laboratory Standards Institute (D'Archangelo 2007:1).

Further recommendations are that training and competency programmes be made available to all staff involved in arterial blood gas analyses. The researcher recommends further the implementation of a workflow chart in order to improve the process of arterial blood gas analysis.

The limitations were discussed and it was felt that the sample although small was sufficient for the study. The researcher was also confident that the choice of statistics was suitable and because the results were consistent with other studies it gave this research credibility.
List of References


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LIST OF ANNEXURES

Annexure A:
Permission to conduct research in the Respiratory unit
Deputy Director of Nursing – Groote Schuur Hospital

Annexure B:
Permission to proceed with research in Groote Schuur Hospital – Dr B Patel (for Chief Executive Officer)

Annexure C
Application to conduct research in the Respiratory unit
Groote Schuur Hospital – Mrs L Emjedi

Memorandum to Mrs L Emjedi re Dr Peltret

Annexure D:
Application for ethical approval to conduct medical research – University of Cape Town

Annexure E:
Permission to conduct research – Professor T Zabow,
Health Science Faculty, University Of Cape Town,
Research Ethics Committee

Annexure F:
Patient Consent

Annexure G:
Patient information sheet
ANNEXURE A

PERMISSION TO CONDUCT RESEARCH IN
THE RESPIRATORY UNIT
DEPUTY DIRECTOR OF NURSING – GROOTE
SCHUUR HOSPITAL
Mrs L M Baker
1 Christiaan Street
HOUT BAY
7806

Dear Mrs Baker

RESEARCH PROPOSAL

Your letter undated received on 14 August 2005 refers.

Permission has been granted from the Nursing Division for you to carry out your research in C27 Respiratory nit.

Kindly submit your proposal to Dr Patel as the representative on the Hospital/UCT Ethics Committee for their approval before commencing.

A copy of your results should be forwarded to my office on completion of your research.

Yours sincerely

(MISS) C J THORPE
DEPUTY DIRECTOR: NURSING
GRÖOTE SCHUUR HOSPITAL
for Chief Director
CJT/dr
BAKER.DOC
ANNEXURE B

PERMISSION TO PROCEED WITH RESEARCH IN GROOTE SCHUUR HOSPITAL – DR B. PATEL (FOR CHIEF EXECUTIVE OFFICER)
Dr B Patel
(021) 404-4469
(021) 404-4304
Bpatel@pgwc.gov.za

24 August 2005

Mrs LM Baker
4 Christriaan Street
HCUIT BAY
7806

Dear Mrs Baker

RE: RESEARCH PROPOSAL – PREANALYTICAL ERRORS

Your questionnaire and request to the hospital refers. You are hereby granted permission to proceed with your research.

Please note the following:

a. Your research may not commence before it is formally approved by the Research & Ethics Committee, kindly direct your request to Ms L Emjedi, E53 Rm. 44, Old Main Building, Groote Schuur Hospital Tel. 021-406-6492, Fax No. 021-406-6411. The hospital requires a copy of the approval letter from the Ethics Committee before the research commences.

b. Your research may not interfere with normal patient care.

c. Hospital staff may not be asked to assist in the research.

d. No hospital consumables and stationery may be used.

e. Accurate billing of patients needs to take place.

f. The hospital would like to have a copy of the research results on completion of the project.

I would like to wish you every success with your project.

Yours truly,

[Signature]

DR B PATEL
For CHIEF EXECUTIVE OFFICER

BP/yw
Ref:el-research-ContractBaker
c.c.c. Ms Thorpe – Deputy Director of Nursing
  Prof Zabow - Chair Research Ethics committee

Groote Schuur Hospital
Private Bag,
Observatory, 7935
Telephone: 404-9111

Groote Schuur Hospital
Privaatsak,
Observatory, 7935
Telefoon: 404-9111
ANNEXURE C

- APPLICATION TO CONDUCT RESEARCH IN THE RESPIRATORY UNIT- GROOTE SCHUUR HOSPITAL- MRS I EMJEDI
- MEMORANDUM TO MRS I EMJEDI RE DR PELTRET
2005-10-28

1 Christiaan Street
Hout Bay
Cape Town
7806

Mrs. Lamees Emjedi
E52 Room23
Old Main Building
Groote Schuur Hospital
Observatory
Cape Town

Mrs. Emjedi
RE: Research to be Conducted in Respiratory Unit, Groote Schuur Hospital

I am applying for review of my research proposal by the Ethics and Research Committee.

I am a University of South Africa student, student number 04824946 and am currently enrolled for the degree of Master of Arts (Critical Care Nursing) in the Department of Health Studies.

I am currently working as a Registered Intensive Care Nurse in the various Intensive Care Units at Groote Schuur Hospital.

My Dissertation Title is:
Arterial Blood Gas: An Experiment to Study the Effects of Temperature and Time Delays on the Outcome of a Blood Gas Analysis

My supervisors at the University of South Africa are Mrs M. Moleki and Dr. M.J. Oosthuizen.
Dr. R. Raine and Dr. I Joubert have agreed to supervise me in the Respiratory Unit in Groote Schuur Hospital.

Thanking you
Yours Sincerely

Mrs Lynette Baker
Memorandum

TO: Mrs I. Emjedi

FROM: Mrs. Lynette Baker

SUBJECT: RE: Research Proposal and Confirmation from Dr. Peltret

I contacted Dr. Peltret telephonically on the 6th September 2005 re the budget with regard to my research. He stated that my research project would not impact financially on the University of Cape Town and as far as he was concerned I could go ahead with the research. However, as I shall require hospital supplies for my research I do need to check with the Hospital authorities with regard payment.
ANNEXURE D

APPLICATION FOR ETHICAL APPROVAL TO CONDUCT MEDICAL RESEARCH - UNIVERSITY OF CAPE TOWN
APPLICATION TO CONDUCT MEDICAL RESEARCH

1. All applications must be submitted with a C1 form which the DRC (Departmental Research Committee) Chairperson must sign. Your budget must first be discussed with Dr Peletre (The Business Development Officer) at 406 6730 before Ethics submission.

2. 3 x detailed protocols should accompany the application.

3. The University of Cape Town/Faculty of Medicine/affiliated hospitals actively support research as an essential academic function. It is recommended that all applicants must consult MRC (SA) and international guidelines on good clinical practice (GCP), available for perusal at the Research Ethics Committee, E 45 Room 26 Old Main Building, Groote Schuur Hospital, University of Cape Town.

4. In the case of a drug trial involving an UNREGISTERED MEDICINE, approval must also be obtained from the South African Medicines Control Council. The pharmaceutical firm concerned should assist in this regard.

5. In the case of a drug trial, it is imperative that the Hospital Pharmacy should have a record and control of all pharmaceutical preparations. (Refer to Hospital Notice 41/98)

5.1 Confidentiality must be respected.

5.2 Patients must be informed in the informed consent/document/patient information sheet that their participation in the study is entirely voluntary and that if they refuse to participate or withdraw from participation at any time, there will be no prejudice to the quality of their subsequent clinical management and care.

6. All Medical Investigators must be covered by Professional Liability Insurance.

7. INFORMED CONSENT FORM (S) MUST ACCOMPANY THE PROTOCOL, FOR APPROVAL.

8. Final responsibility for the ethical and effective conduct of the trial lies with the principal investigator.

9. Six- Monthly progress reports must be submitted to the Research Ethics Committee, from date of Formal Ethics Approval.

9.1 Each trial or investigation will be subject to review after 12 months.

9.2 All findings must be reported, at the termination of a study, to the Research Ethics Committee.

9.3 Termination of projects must be reported to the Research Ethics Committee, if projects come to an end before the anticipated end-point is reached.

ALL COMPLETED FORMS, TOGETHER WITH A DETAILED PROTOCOL, TO BE SENT (REGISTERED MAIL) TO:
MRS. LAMEES EMJEDI, RESEARCH ETHICS COMMITTEE
E 52 ROOM 23 OLD MAIN BUILDING, GSH, OBSERVATORY
# Section A - Proposal identification details

1. **Title of the proposal:**
   
   *Arterial Blood Gas: An Experiment to Study the effects of Temperature and Time Delays on the Outcome of a Blood Gas Analysis*

2. Has this protocol been submitted to any other Ethical Review Committee? | Yes | No
---|---|---

2.1 If so, list which institutions and any reference numbers.

   | Dr. B. Patel
   | GSH

2.2 What was/were the outcome/s of these applications?

   | Has given permission

3. Is this proposal being submitted for ethical approval for an amendment to a protocol previously approved by the REC? | Yes | No
---|---|---

3.1 If so, what was the previous REC REF. #?
4. Investigator Details

4.1 Principal Investigator:

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<th>Initials &amp; Last Name</th>
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<tr>
<td>Mv. L. M. BAKER</td>
<td></td>
<td>Critical Care</td>
<td>@0060</td>
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4.2. Details of Professional Registration

4.2.1 Are you currently registered with the HPCSA?  | YES | NO | X | NA |

4.2.2. If so Please provide current registration number:

4.2.3 (If different to 4.1 above) UCT Principal Investigator

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4.3 Co-investigators:

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5. Is the study being undertaken for a higher degree?  

Yes  

If yes,  

5.1 What degree?  

M.A.  

5.2 Student name:  

LYNETTE BAKER  

5.3 Supervisor name:  

Mv. M. M. Moleki (Unisa)  

Bv. M. J. Oosthuizen  

5.4 In what department is the degree?  

Nursing  

Bv. Richard Laine  

Critical Care Dept.
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<tr>
<td>Protocol summary (synopsis)</td>
<td></td>
</tr>
<tr>
<td>32 copies</td>
<td></td>
</tr>
<tr>
<td>Consent form (include translations if indicated)</td>
<td></td>
</tr>
<tr>
<td>32 copies</td>
<td></td>
</tr>
<tr>
<td>Patient/Subject Information sheet (if separate from</td>
<td></td>
</tr>
<tr>
<td>consent form)</td>
<td></td>
</tr>
<tr>
<td>32 copies</td>
<td></td>
</tr>
<tr>
<td>Approval from Departmental Head (signature)</td>
<td></td>
</tr>
<tr>
<td>[Signature]</td>
<td></td>
</tr>
<tr>
<td>Departmental stamp</td>
<td></td>
</tr>
<tr>
<td>Critical Care Dept.</td>
<td></td>
</tr>
<tr>
<td>20.09.05</td>
<td></td>
</tr>
<tr>
<td>Approval from Departmental Research Committee (signature)</td>
<td></td>
</tr>
<tr>
<td>[Signature]</td>
<td></td>
</tr>
</tbody>
</table>
### Section C - Drug Trial information

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Is the product registered with the Medicines Control Council?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.1 If yes, provide registration number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2 If no, is the MCC letter of unregistered medicine attached?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Are results of similar trials available?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8. Estimated number of patients:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Estimated duration of trial:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Is the investigator(s) covered by professional liability insurance?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Does the trial involve hospitalisation of patients?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11.1 If yes, which hospital:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Does the protocol comply with UCT's Intellectual Property Rights Policy (including ownership of the raw data)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>13. Is this a multicentre study?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>13.1 If yes, list the other Centres involved in this study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. If this is a multicentre study, the UCT counterpart/PI undertakes that he or she is fully conversant with the content of the protocol, understands fully the ethical implications of the protocol, and takes full responsibility for the implementation of the protocol meeting ethical standards.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Section D - Information for studies other than Drug Trials

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. Estimated number of participants:</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>16. Estimated duration of study:</td>
<td></td>
<td>1month</td>
</tr>
<tr>
<td>17. Location of study: <strong>Critical Care Department</strong>, <strong>Intensive Care Unit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Does the protocol comply with UCT's Intellectual Property Rights Policy (including ownership of the raw data)?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Section E - Financial and Contractual Information

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>19. Is the study being sponsored or funded?</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>If yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.1 Is the study sponsored/funded by a Pharmaceutical Company?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>19.2 Who is the sponsor/funder of the study?</td>
<td>Researcher: Mrs. Kyenele Baker</td>
<td></td>
</tr>
<tr>
<td>19.3 What is the total budget / sponsorship for the study?</td>
<td>R150.00 - R250.00</td>
<td></td>
</tr>
<tr>
<td>19.3. (a) Is the overall budget inclusive of Ethics Review levy?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>(budget/ sponsorship must be inclusive of this levy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.4 Into what fund is the sponsorship being paid?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>19.5 Are there any restrictions or conditions attached to publication and/or presentation of the study results?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>19.6 Does the contract specifically recognize the independence of the researchers involved?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

(Note that any such restrictions or conditions contained in funding contracts must be made available to the Committee along with the proposal.)

20. Will additional costs be incurred by the hospital?                     | Yes | No |

If yes, specify these costs:

- Blood gas sample: 1 x urine 2ml @ R2.00
- Blood culture 2ml @ R9.00
- Hepatitis 0.1ml serum sample @ R2
- Blood gas analysis: ± R5.00 - R10.00

Total cost estimated R10.42.

No of patients 10
3 samples (1 of which will be a part of vouchre
blood gas done every morning in cc unit)

Total no of samples = 20 @ R10.42 = R217.15c.
Section F - Statement on Conflict of Interest

The researcher is expected to declare to the Committee the presence of any potential or existing conflict of interest that may potentially pose a threat to the scientific integrity and ethical conduct of any research in the Faculty. Such conflicts of interest are detailed in the Faculty Policy on Conflict of Interest in Research. The committee will decide whether such conflicts are sufficient as to warrant consideration of their impact on the ethical conduct of the study.

Disclosure of conflict of interest does not imply that a study will be deemed unethical, as the mere existence of a conflict of interest does not mean that a study cannot be conducted ethically. However, failure to declare to the Committee a conflict of interest known to the researcher at the outset of the study will be deemed to be unethical conduct.

Researchers are therefore expected to sign either of the two declarations below.

a) As the Principal Researcher in this study (name: Lyne Ue Baker),
   I hereby declare that I am not aware of any potential conflict of interest which may influence my ethical conduct of this study.

Signature: Lyne Ue Baker Date: 28.10.2005

b) As the Principal Researcher in this study (name: ________________________),
   I hereby declare that I am aware of potential conflicts of interest which should be considered by the Committee:

Signature: ________________________ Date: ________________________

SECTION G: ETHICAL AND LEGAL ASPECTS
1. Detail of the insurance to be provided
2. The Declaration of Helsinki version 2000 to be included in the references

VERSION 1 2005
ANNEXURE  E

PERMISSION TO CONDUCT RESEARCH – PROFESSOR T ZABOW
HEALTH SCIENCE FACULTY
UNIVERSITY OF CAPE TOWN
RESEARCH ETHICS COMMITTEE
21 November 2005

REC REF: 424/2005

Mrs L Baker
1 Christiaan Street
Hout Bay
Cape Town
7806

Dear Mrs Baker

PROJECT TITLE: ARTERIAL BLOOD GAS: AN EXPERIMENT TO STUDY THE EFFECTS OF TEMPERATURE AND TIME DELAYS ON THE OUTCOME OF A BLOOD GAS ANALYSIS

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has formally approved the above-mentioned study on the 11 November 2005.

Please quote the REC. REF in all your correspondence.

Yours sincerely,

PROFESSOR T. ZABOW
CHAIRPERSON, HSC HUMAN ETHICS
ANNEXURE F

PATIENT CONSENT
Patient Consent

Research Project for Masters Degree
University of South Africa
Department of Health Studies
Supervisors: M. M. Moleki and
Dr. M.J.Oosthuizen

I understand that the researcher will be taking 3 blood samples from a designated line, which would have been inserted by a hospital doctor on admission to the Respiratory Unit as part of the treatment process.

I understand that I/family member shall be randomly chosen and that my name /family member’s name and hospital number will not be used in this research project.

I give permission for the researcher to take my blood/ family member’s blood for the purposes of this research.

I have been given an information sheet detailing the research project and a copy of the consent.

Date

Patient / Next of Kin

Witness

Researcher
ANNEXURE G

PATIENT INFORMATION SHEET
Patient Information

Research Project

Title: Arterial Blood Gas: An Experiment to study the effects of Temperature and Time delays on the outcome of a blood gas result

Researcher: Mrs L M Baker

Masters student - The University of South Africa

Dear Sir / Madame

I shall be undertaking a research project in the Respiratory unit at Groote Schuur Hospital.

I shall be taking 3 blood samples from randomly chosen patients who are being treated in the Respiratory unit.

The reason for this is to assess the preparation of these samples before they are analysed in a machine and to determine if the preparation methods at Groote Schuur Hospital are in line with predetermined standards.

Your name and hospital number will not be used at any stage. You/family member will not experience any pain or discomfort during the taking of blood as the patient will have a designated line (indwelling arterial catheter) from which the blood will be taken by the researcher.

You will be required to sign a consent form on your behalf if you are the patient or on the behalf of your family member. This will give the researcher permission to take blood from yourself or your family member.

You will be given a copy of this information sheet and a copy of the consent form.

This research project has been reviewed and approved by the University of South Africa, Department of Health Studies and by Groote Schuur Hospital.